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BIRAC INNOVATION PROFILES 2021

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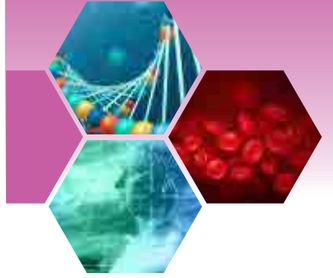
BIO-SCIENCES to BIO-ECONOMY

Contents



Foreword

Biotechnology plays a critical role in the growth of Indian knowledge economy. India is currently undergoing a revolution in the arena of innovation and favourable Government policies and mission programs such as Make in India; Start-up India and the recent initiative of Atma Nirbhar Bharat is helping towards building a self-reliant economy in a large way.

Biotech sector has a direct impact on the well-being of mankind and has the potential to transform as many lives as possible, create opportunities and ensure holistic development for all. Our theme for Global Bio-India, i.e. “Transforming Lives” reflects and echoes this potential and capability of biotech sector touching lives. Global Bio-India is expected to facilitate recognition for India as an emerging Innovation Hub and Bio-manufacturing Hub. As one of the major Bio-event, GBI would showcase India’s biotech strength and opportunities at the global level and would serve as a beacon of interdisciplinary cohesiveness of the different segments of Indian biotech sector, working together to strive towards the larger goal of $150Bn Bioeconomy through Biosciences by 2025.

The first edition of Global Bio-India in 2019 was a huge success that saw participation from over 25 countries, 190 exhibitors, 2500+ delegates, 300+ start-ups, 50+incubators, 60+ Research Institutes, 800+ Bio- partnering meetings and representation from 9 states.

The year 2020 has put a spotlight on the capability, resilience and adaptability of the Indian scientific and innovation ecosystem. I am happy to highlight that the Department of Biotechnology along with BIRAC has been instrumental in delivering innovative solutions during Covid days not just for the country but for the entire world. The efforts made by the scientific community towards dealing with the crisis have been unparalleled. It has helped us build a stronger ecosystem that has paved the way not only to fight COVID but the preparedness will go much beyond.

This compendium is a compilation of the BIRAC supported innovations, products and technologies, new facilities, COVID initiatives and much more. I congratulate the entire team for developing this rich repository that would provide insights into key biotechnological innovations supported and closely mentored by BIRAC and its partners.

The vibrant ecosystem we see today gives us the confidence that our innovators will be recognized globally for developing solutions addressing major societal problems.

We have miles to go and promises to keep. I wish the innovators a successful path ahead!

Dr Renu Swarup
Secretary, Department of Biotechnology
and Chairperson, BIRAC

Preface

Year 2020 was the year of Science & Biotechnology. It was indeed a year of challenges and obstacles but as they say, “Every dark cloud has a silver lining”. One silver lining to this dark cloud was the number of opportunities that the innovators and budding start-ups received. Hon’ble Prime Minister’s clarion call for an Atma Nirbhar Bharat is slowly realizing its true potential. It gives me immense pleasure to share that Department of Biotechnology along with BIRAC has been at the forefront to address the COVID-19 global health crisis.

Biotechnology is recognized as the sunrise sector- a key driver for contributing to India’s USD 5 Trillion economy target by 2024. India has moved up to 48th rank on the Global Innovation Index (GII) this year and Biotech sector has been a major contributor to the pool of innovations coming out of the country.

India is being looked upon as an Innovation hub and the world is looking at India for Make in India innovations that will not only be useful nationally but globally as well. This happens to be the most exciting time to host Global Bio-India 2021, India’s largest biotech event. The Global Bio-India 2019 was a huge success and we definitely aim to be bigger and better. This mega international congregation on digital platform this year would see participation from biotechnology stakeholders including Central and State Ministries, large industries, SMEs, start-ups, bio clusters, research institutes, investors, national and international innovations agencies, experts, mentors, and others supporting the ecosystem.

The compendium 2021 brings to you an insight into the innovative products and technologies supported by BIRAC and how these innovations have come a long way in solving problems in varied sectors. It also details the initiatives taken by the organization in tackling the pandemic. BIRAC innovators have also come up with potential COVID solutions that have been very helpful in the present scenario. The vibrant ecosystem offered by BIRAC has been very helpful in addressing the societal issues.

We will continue to work with entrepreneurs, researchers to strengthen and nurture the innovation ecosystem.

(Anju Bhalla)
Joint Secretary DST and MD BIRAC

About BIRAC

Vision

"Stimulate foster and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly startups and SMEs, for creation of affordable products addressing the needs to the largest section of society."

Mission

Facilitate and mentor the generation and translation of innovative ideas into biotech products and services by the industry, promote academic-industry collaboration, forge international linkages, encourage techno entrepreneurship and enable creation and sustainability of viable bio enterprises.

Focus

Empowering and Enabling the Biotech Innovation Ecosystem for affordable product development

Core Values

- Integrity
- Transparency
- Team work
- Excellence
- Commitment

Set-up in 2012 by Department of Biotechnology, Ministry of Science & Technology, Government of India, to serve as its interface agency to promote industry-academic interface, BIRAC is a Section 8 "Not-for-profit Company" under the Companies Act, 2013. The mandate of BIRAC is to nurture and empower the biotech innovation ecosystem and transform all elements of the nascent biotechnology industry systems. A schedule 'B' Public Sector Undertaking, BIRAC is guided by an independent Board of Directors comprising of senior scientists, academician and policy makers and industrialists.

To serve various dimensions of its mandate, BIRAC operates mainly in 3 verticals. Investment schemes provide funding support to academia, entrepreneurs, start-ups, SMEs and Biotech Companies for all stages of the products development value chain from discovery to proof of concept to early and late stage development to validation and scale up, right upto commercialization. There are also few special development missions. The second vertical is Entrepreneurship, Development which focuses not only on the funding support, but also on making available the right infrastructure, mentoring and other network for technology transfer and licensing, IP and business mentoring including regulatory guidance. Lastly BIRAC's Strategic Partnership group works closely with all partners- national and international which includes Government departments and Ministries both Central and State, industry organisations, international bilateral agencies, philanthropic organisations and corporate sector, to leverage the strength and expertise and mobilize resources and extend the outreach of its activities.

Transforming Lives: Biosciences to Bioeconomy

The recognition of Biotech sector as the sunshine sector reflects its potential to offer technology driven solutions for all spheres of life, be it healthcare, agriculture, nutrition, waste management, clean energy & environment and so on. Biotech products and solutions have the potential to transform billions of lives and at the same time the growth of biotech sector is expected to have cascading multiplier impact on India's economy target of USD 5 Trillion by 2024-25. Today, India is among the top-12 destinations for biotechnology in the world with approximately 3% share in the global Biotechnology industry. India's Bio-economy is valued at approx. $ 70 billion as on date. We are aiming to see Bioeconomy growing to 150 Bn USD by 2024-25.

Last year, India jumped 4 ranks on the Global Innovation Index (GII) and made it to the top 50s. India has become leader in the global supply of DPT, BCG and measles vaccines. The number of start ups in biotech sector are also constantly growing and is expected to exceed 10,000 in next 4 years. In addition, the recent Indian Bioeconomy report estimates that India's BioEconomy can support ~ 10 Mn jobs in 2025 amounting to $100 billion revenue itself. This would also result in placing of over 100 "Made in India" Innovative Biotech products in global markets.

#Biosciences to Bioeconomy, #Power to Transform Lives, #VigyanSeVikas, #AtmanirbharBharat #AyushmanBharat #MadeInIndiaforWorld are the key words driving the growth of Biotech sector. This compendium is a compilation of over 200 innovative products and processes supported by BIRAC, a testimony of undulating support and commitment by the Government towards growth of biotech innovation ecosystem.

BIRAC Innovations: Bio-Sciences to Bio-Economy

The Public Private Partnership (PPP) program was initiated by the Department of Biotechnology in the Year 2007. Small Business Innovation Research Initiative (SBIRI) was the first program launched for providing support to early stage research initiatives by Indian industries. This was followed by the Biotechnology Industry Partnership Program (BIPP) in 2009 for supporting advanced research aimed towards scale-up and large scale validation of products.

Based on the success of these initial schemes, DBT established the Biotechnology Industry Research Assistance Council (BIRAC) in the year 2012 for promoting biotech industries including start-ups in the country. BIRAC is a PSE of GoI. It is successfully implementing programs towards:

- enabling Start-ups in biotech
- promoting academia-industry connect
- attracting industry funding through joint partnership programs
- Make-in India for promoting bio-manufacturing including equity funding

BIRAC operates under the three following verticals:

1. Investment schemes provide funding support to entrepreneurs, start-ups, SMEs and Biotech Companies for all stages of the product development value chain from discovery to proof of concept to early and late stage development to validation and scale up, right upto pre-commercialization. There are also special product development missions.

2. Entrepreneurship Development which focuses not only on the funding support, but also on making available the right infrastructure, mentoring and other networks for technology transfer and licensing, IP and business mentoring including regulatory guidance.

3. Strategic Partnership group works closely with all partners –national and international which includes Government departments and Ministries both Central and State, industry organizations, international bilateral agencies, philanthropic organizations and corporate sector, to leverage the strength and expertise and mobilize resources and extend the outreach of its activities.

The three verticals address the different stages of biotechnology product development, the lateral teams are cross cutting inter disciplinary groups (like healthcare, agriculture, green technology) which focus on a particular product and see it through from discovery to diffusion stage. BIRAC provides support at all levels of the product development chain through its various funding schemes.

- Proof-of-concept studies are supported under Biotechnology Ignition Grant (BIG) and Academic Innovation Research (PACE-AIR)
- Validation studies are supported under Small Business Innovation Research Initiative (SBIRI), Biotechnology Industry Partnership Programme (BIPP) and Contract Research Scheme (PACE-CRS)
- Scale-up of the technology is supported under BIPP and PACE-CRS
- Enabling Product Commercialization through Product Commercialization Program Fund (PCP)
- Promotion of Translational research through Early Translational Accelerators (ETA)
- Apart from the regular schemes, certain niche area programmes are also launched which cater specifically to priority areas (such as Guar Gum, Synthetic Biology, Innovation Clean Technology (jointly with DBT), Anti COVID Botanicals (jointly with DBT), COVID-19 Research Consortium (jointly with DBT), AMR and drug development (jointly with DBT)
- Mission programmes such as Grand Challenges India (GCI) and National Biopharma Mission (NBM), IndCEPI and COVID - Suraksha (jointly with DBT)
- Creating world class Infrastructure and access to incubation support for Startups through the BioNEST programme
- Supporting students and early stage start ups through programs like SITARE and EYUVA
- Equity Funding support through SEED, LEAP and AcE Fund
- Facilitating networking, mentoring, IP, legal support through Make In India Cell

In order to empower and support entrepreneurs and start-ups, BIRAC has supported 59 Bio-incubators under which more than 6 lakh sq. ft. incubation space has been created. In addition to this, 4 Regional Centres have been set up at Venture Centre (Pune), C-CAMP (Bangalore), IKP (Hyderabad) and KIIT (Bhubaneswar) . BIRAC has facilitated access to research resources by establishing dedicated facilities for the following:

1) Cell Line repository for certified cell lines, cell bank characterization and safe storage,
2) Analytical characterization facility for drug substance and drug product characterization,
3) Process Development Lab and GMP manufacturing facility for process development, scale-up and clinical lot manufacturing,
4) Bioprocess facility for large-scale production of microbial antigens and monoclonal antibodies,
5) Scale-up facility for plasma fractionation of clinical grade.
6) National Centre for Immunogenicity Testing (NCIT) to evaluate vaccines in clinical trials

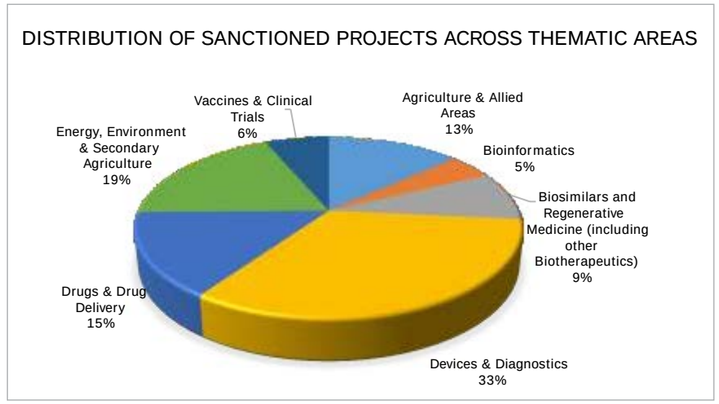
The impact that BIRAC has created in the past 9 years has been remarkable. More than 1000 start-ups and Entrepreneurs have been supported by BIRAC through Rs. 1867 crores worth of funding. This has resulted in the development of 165 products and technologies and 270 new IPs. BIRAC funded projects have generated employment for nearly 10000 people and 200+ Women entrepreneurs have been supported.

The role of BIRAC specifically came to light when COVID-19 was declared as a pandemic by WHO due to the alarming levels of spread and severity. In response to the outbreak, an urgent need to accelerate development of diagnostics, vaccines, novel therapeutics and re-purposing of drugs for this novel coronavirus was realized by BIRAC. As a result of this COVID Consortium was formed by DBT & BIRAC.

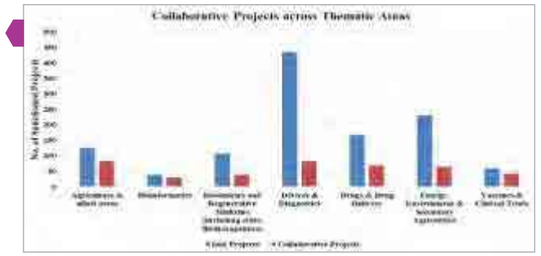
To support the preparedness, readiness and response for COVID-19, project proposals were solicited for developing Diagnostics, Vaccines, Novel Therapeutics, Repurposing of Drugs or any other intervention for control of COVID-19 by Industry/Academia/ Industry-Academia participation. Further follow up call and a focused call on development of anti-Covid botanicals as well as therapeutics were also announced. The details and results of such calls is discussed in detail under subsequent sections of each thematic area.

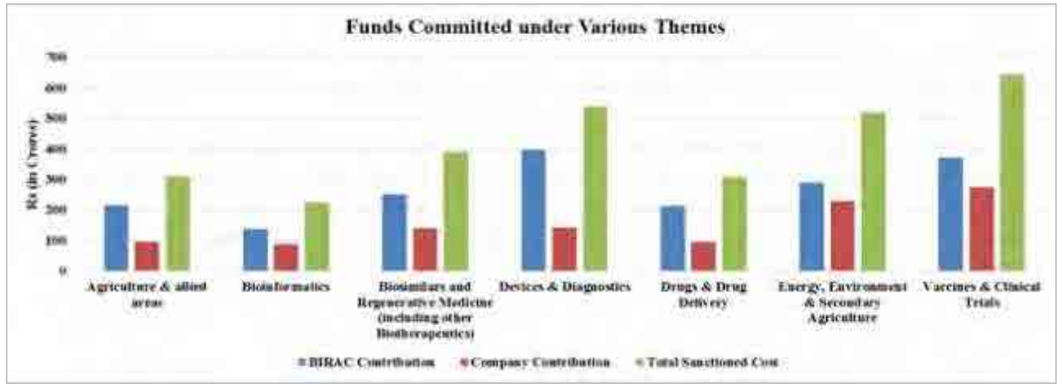
Taking into consideration the emerging trends and practices in the biotechnological sector, BIRAC has also modified its themes to incorporate the dynamics of biotechnology industry. Proposals funded by BIRAC are now categorized under 7 broad thematic areas which include Agriculture and Allied Areas, Bioinformatics, Biosimilars and Regenerative Medicine (including other Biotherapeutics), Devices and Diagnostics, Drugs (including Drug Delivery), Energy, Environment & Secondary Agriculture and Vaccines & Clinical Trials. Agricultural allied areas include Aquaculture and Veterinary Sciences whereas Bioinformatics also include projects focusing on Artificial intelligence, Big Data Analysis, IoT and software development.

Considering the themewise distribution of the sanctioned projects, it is observed that the majority of the projects (33%) falls under the theme Devices and Diagnostics followed by Energy, Environment and Secondary Agriculture (19%), Drugs (15%) and Agriculture (13%). Other thematic areas like Biosimilars and Regenerative Medicine, Vaccines and Clinical Trials and Bioinformatics account for 20% of the total sanctioned projects.

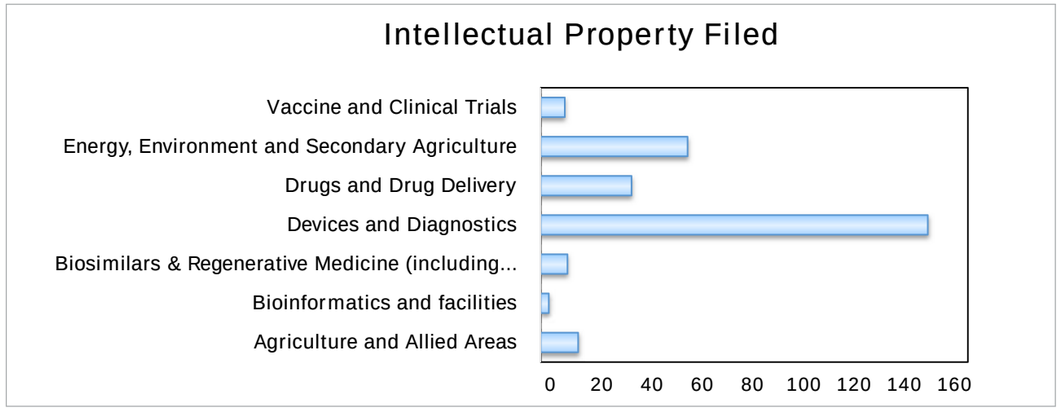


However, a different trend is observed while comparing the funds sanctioned to different thematic areas by BIRAC till date. The projects under "Vaccines and Clinical Trials" correspond to the maximum total cost of the projects followed by "Devices & Diagnostics", "Energy, Environment & Secondary Agriculture" and "Biosimilars and Regenerative Medicine". It is also important to note here that thematic areas "Devices and Diagnostics" and "Energy, Environment & Secondary Agriculture" also have larger number of projects that have been sanctioned by BIRAC.





Another important observation is made when the trend in intellectual property (filed/generated) is compared in different thematic areas. The trend conforms to the number of projects sanctioned under the theme area. The highest number of IP has been filed under Devices and Diagnostics (145) followed by Energy, Environment & Secondary Agriculture (55) and Drugs & Drug Delivery (34). The IP filed/ generated is a good measure of the success of the project and is an important factor that should be considered while assessing the market potential of the product/ technology that have been developed.



BIRAC Innovations: Bio-Sciences to Bio-Economy

BIRAC's foremost mandate is to promote the biotechnology industry in India. Nevertheless, academic institutes and universities have been an integral part in this journey of building and strengthening the biotechnology ecosystem of the country.

To further promote the translational research right from the inception stages, Early Translational Accelerators have been set up by BIRAC across the country. Under this program till date 4 accelerators have been set up and efforts are on to further expand the numbers covering larger landscape of India. The projects sanctioned under first ETA program in the area of healthcare at CCAMP have completed 3 projects which has resulted in 2 IP and all 3 technologies have been transferred to industries.

Other ETAs set up at IIT Chennai, IIT Mumbai and Yenepoya University are working under Industrial Biotechnology, Devices & Diagnostics and Healthcare sector, respectively.

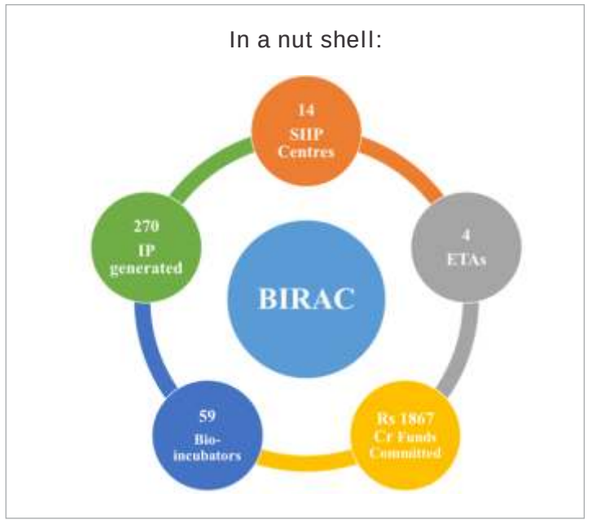
To further deepen the entrepreneurial mindset of young researchers, 14 SIIP (Social Immersion Innovation Programme) centers across the country have been opened. These centres cater to the following areas of biotechnology:

- Maternal and Child Health
- Ageing and Health
- Food and Nutrition
- Waste to Value
- Combating environmental pollution
- Agri-Tech

SIIP is BIRAC's social Innovation fellowship/award program aimed at creating a pool of biotech "Social Innovators" who can identify needs & gaps within communities and then can help bridge the gaps either through an innovative product development or services.

Once the technology/product has been successfully validated (>=TRL 7) and is market ready, there are additional financial requirements for preparing the ground for market launch, test-validation in targeted markets and large scale commercialization, which are not covered under the existing funding programmes. To deal with the situation, BIRAC has launched the Product Commercialization Program Fund (PCP Fund) under the BIRAC Product Commercialization Program (PCP).

Under this scheme 3 projects have been sanctioned under Devices & Diagnostics and Energy, Environment and Secondary Agriculture thematic areas and grant of Rs 7.6 Cr has been committed.



Recognition for BIRAC Startups & SMEs

Several BIRAC supported startups and SMEs have received recognition from other national and international agencies for their products and technologies.

1. Helyxon Healthcare Solutions Pvt Ltd was awarded COVID champion award from Tamil Nadu Chief Minister towards providing innovative solution for managing the COVID in CII Connect-2020, Chennai, between 15-19 September 2020
2. AlgoSurg Pvt Ltd won a grant award of USD 200,000 by winning Global Surgical Training Challenge to develop OpenSurgiSim - An open source training module based on 3D surgery simulation for complex bone deformities.
3. Osind MedTech Pvt Ltd won Best Product Innovation Award by NIITE-KBL MSME Business Excellence Award on December 2019 & Ktech Elevate Fund Grant
4. 4S Medical Devices Pvt Ltd won NBEC 2019 - National Bio Entrepreneurship Competition 2019 award in Digital Health category – cash prize of 5 Lacs INR.
5. Sensivision Health Technologies Pvt Ltd won the Quest grant (Rs. 25L) for Clinical validation, supported by Tata trusts, PATH Labs and Social Alpha.
6. Cutting Edge Medical Devices Pvt. Ltd.: In a small duration of 75 days they were able to install 50 units of the device SCINTIGLO in Small and medium sized pathology labs, Doctor's Clinics and Hospitals in Indore city.
7. Varsha Bioscience and Technology Pvt Ltd bags FTCCI Excellence Award for excellence in Research & Development in Micro & Small Enterprise Category in January 2021.
8. Mallipathra Nutraceutical Pvt Ltd. was selected as Successful Super Achiever Award by DMA (Delhi Management Association) under All India Women Entrepreneurs Award 2020 which was scheduled on 20th of February 2020 at Park Hotel , New Delhi.
9. REVY Environmental Solutions Pvt. Ltd. pronounced as 1st runner up in Grand Finale of FLCTD Accelerator pitching event organised by Sangam Ventures and UNIDO
10. Innaumation Medical Devices Pvt Ltd: AumVoice Prosthesis- a $1 speaking device that helps throat cancer patients to speak once again.
    - won National Start-up Awards, 2020- Start up India
    - won Aarohan Social Innovation Award, 2020- Infosys Foundation
    - won Marico Innovation Awards, 2020 by Marico Foundation
    - won Spirit of Manufacturing Award- 7th edition (Social Impact), 2020- TiE Delhi
    - won Social Alpha Assistive Technologies Grant, 2020- Social Alpha
    - won Nidhi Prayas DERBI Foundation Grant, 2020- DERBI Foundation
11. Trestle Labs Pvt. Ltd. Kibo: Offering a complete Reading Learning suite, making Reading & Learning Inclusive for people with visual impairment and Learning disabilities
    - Top 24 Winners Maharashtra Startup Week by MSInS 2020 Winner
    - Winner on the pitch day under the Leaders in Innovation Fellowship (LIF) program by UK's Royal Academy of Engineering (RAE)
    - Winners of Tata Social Enterprise Challenge 2020
    - Top 100 World Finalists at Entrepreneurship World Cup 2020
12. Kidaura Innovations Pvt. Ltd.ScreenPlay:- a digital-based screening tool that identifies children who may have a potential risk of autism or any other condition in the age group of 3-6 years.

- One of the Winners of NCPEDP-Mphasis Universal Design Awards 2020
- One of the Winners of Innovate for an Accessible India – A NASSCOM Foundation and Microsoft India initiative in partnership with the Department of Science and Technology (DST) and Ministry of Social Justice and Empowerment (MSJE).

BIRAC Innovations: Bio-Sciences to Bio-Economy

13. Thinkerbell Labs Pvt. Ltd.Annie - A device for improving braille literacy in India (both reading and writing skills) Received a grant of INR 30 lakhs by Centre for Augmenting WAR with COVID-19 Health Crisis (CAWACH)-DST.
14. Demosthenes Technologies Pvt. Ltd.Stamurai: A speech therapy app for stammering and for other speech related issues
    - Won 3rd position in Prosus Social Impact Challenge for Accessibility 2020
    - Featured on App Store India's website and was 'App of the Day' on the App Store
15. Tactopus Learning Solutions Pvt. Ltd. Building multi-sensory learning resources to enable children with vision loss to participate in mainstream education
    - Won, ElevateCall2 (March 2020), organized by K-Tech and STARTUP Karnataka
    - One of the Winners of NCPEDP-Mphasis Universal Design Awards 2020
    - Fellow - IIM Calcutta - Social Impact Incubator for Women 2020
    - Runner's-Up - TiE Women Bangalore's 2020 Program
16. Flexmotiv Technologies Pvt. Ltd.Flexmo: All-Terrain Slip Proof Self Standing Crutches
    - One of the Winners of NCPEDP-Mphasis Universal Design Awards 2020
    - India Design Mark Award 2020
    - Leader in Innovation, Royal Academy of Engineering
    - 2020 India Finalists and Fan favorite ASME Innovation Showcase (ISHOW)
17. BeAble Health Pvt. Ltd. ArmAble: A game-based arm rehabilitation deviceAwarded as Startup of the Year - Rehabilitation Technology Category in Nationwide Awards 2020 in Healthcare Awards Category Organized by Business Mint
18. True ConsultancyTurnPlus: Offers easy entry & exit into the front seat of a passenger car, for people with special medical conditions like, arthritis, knee & back issues, etc.
    - Won, ElevateCall2 (March 2020), organized by K-Tech and STARTUP Karnataka
    - One of the Winners of NCPEDP-Mphasis Universal Design Awards 2020
    - Listed as India's top MSME by Economic Times in Medical and Healthcare Industry.
    - One of the Winners of Starable Startup Competition, Nov 2020.
    - Selected as part of ATF (Assistive Tech Foundation) Cohort 3 Acceleration program
19. Raised Lines FoundationDevelopment of affordable tactile graphics to promote K-12 education for visually impaired and provide equal learning opportunities.
    - One of the Winners of of 'Innovate for an Accessible India' (IAI) A NASSCOM Foundation and Microsoft India initiative in partnership with the Department of Science and Technology (DST) and Ministry of Social Justice and Empowerment (MSJE).
    - Won UnLtd India Fellowship 2020.
20. SM Learning Skills Academy for Special Needs Pvt. Ltd. Cogniable: Early screening and behavioural treatment for Autism Spectrum Disorder (ASD) in remote areas
    - Won the Responsible AI for Social Empowerment (RAISE 2020) with a grant prize of INR 20 lakhs.
    - One of the Winners of Pitch event of NTT DATA's Open Innovation Contest (OIC) in Healthcare category
    - Runner's up at Prosus SICA (Social Impact Challenge for Accessibility)
    - Received DBT's grant of INR 1.5 Cr.
    - One of the Winners of Starable Startup Competition, Nov 2020.
    - Selected as part of ATF (Assistive Tech Foundation) Cohort 3 Acceleration program
21. Inceptor Technologies Pvt. Ltd. BrailleMe: In addition to enabling digital braille access for the visually impaired (Blind), it also empowers the deaf blind with digital communication and devices
    - Millenium Alliance Grant Winner - INR 20 Lakhs
    - Winner of SIEMENS Grant for South Asia.

22. Robobionics Pvt Ltd:
    - The company was awarded as Top 15 Start-ups in India StartupToScaleup - Global Acceleration Program, supported by MeitY, Govt. of India organized by The Gain- 29th August, 2020
    - Priyanka Dsa won 3rd Runner Up TiE Women Pitch Competition – Coimbatore, 30th August 2020
    - Mr. Llewellyn Dsa won 2nd Prize in MisFits North II, 22nd October 2020
23. Jeevtronics Pvt Ltd:
    - won grant from PATH Tata Social Alpha
    - included in BIRAC's top 20 Covid related innovations and included in India's top 24 starts by MSIS, Maharashtra
    - won DST CAWACH soft loan to increase manufacturing capacity in response to Covid.
    - accepted in the India Sweden Healthcare innovation Challenge cohort
24. Aspartika Bitoech Pvt Ltd:
    - won Food Technology Innovation Award WHO-ICCIDD & Heal Foundation, September 2020
    - won National Entrepreneurship Award MSDE-GoI, November 2019
    - won Emerging Star of the Year Award, Bangalore Chamber of Industry and Commerce, January 2021
25. KBCols Sciences Pvt. Ltd.
    - Raised seed round of investment in July 2020 led by Chiratae Ventures (Formerly IDG India) and co-participation by Axilor & Derbi Foundation.
    - declared as the winner of the TDB (technology development board) national award 2020 (startup category). The award carries a cash prize of Rs. 15, 00,000
    - selected as the startup of the month by "International sustainable chemistry collaborative Centre, Germany". They interviewed us and published about KBCols work in their newsletter.
26. Aarna Biomedical Products Pvt Ltd:
    - selected in Startup-India-DPIIT for a direct pitch to the honourable PM of India as part of the annual International Summit – Prarambh, Jan 2021
    - covered by Women's Era - a leading magazine articulates a comprehensive journey behind creation of Poorti post mastectomy kit. Also covered by Yourstory - a prestigious magazine, covers the story of the founder and the vision behind Poorti kit., December 2020
    - selected by The Mint as one of the 50 startups on Sarvodaya & The Better India covers the innovation – Sampoorti-Poorti System March, 2020
    - product Sampoorti-Poorti system was selected to be showcased to the Union Minister of Health – Dr. Harshvardhan as part of the Ayushman Bharat Conclave at the Vigyan Bhawan, November 2019

Theme Wise Assessment

Drugs and Drug Delivery

Drug development is one of the challenging fields with low success rates, resource intensive & time-consuming process. The proposals received under this area are generally low as the realization of the product from idea takes minimum 10 years. The drug discovery market worldwide is on the rise. By 2025 the market is expected to be valued at 71 billion U.S. dollars. By 2025 the small molecule drug discovery market will be valued at 48 billion U.S. dollars.

In order to fulfil the gaps BIRAC is continuously trying to increase the investments in discovery and development of new drugs for the diseases of unmet need that have little, or no treatment options for patients.

Drug development programs at BIRAC include new drug discovery (small molecules, NCEs) , repurposing of drugs, novel therapeutics, novel drug delivery platforms, In-vitro and In-vivo screening platforms for potential drugs. Since academic institutions are integral pillars towards creation of novel drugs, BIRAC also supports Indian academic institutions with specific grant programs to support proof of concept and validation through industry partner.

Current drug development efforts for the treatment are hampered by the fact that many preclinical models have been unsuccessful in reproducing human physiology and its response to medications. With a focus on translation, drug screening platforms are important part of drug discovery and BIRAC has supported various in-vitro/in-vivo platforms and target identification technologies for screening of new drugs for various important pathologies i.e. NASH, SARS-CoV-2 etc.

BIRAC has supported a total of 188 projects in the area of Drug and Drug delivery. The analysis shows that total PPP investment (A&B) under this area amounts to Rs. 461 Crores wherein BIRAC has invested Rs. 286 Crores and Industry invested Rs. 175 Crores by supporting 93 projects under BIPP and SBIRI. Collectively, the projects involved >90% Industry followed by few collaborative projects with Industry –Industry and Industry academia projects. BIRAC has invested nearly 140 Crores by supporting 97 projects under Grant programs i.e. PACE, BIG and DBT-BIRACA joint calls (ATGC, AMR Mission).

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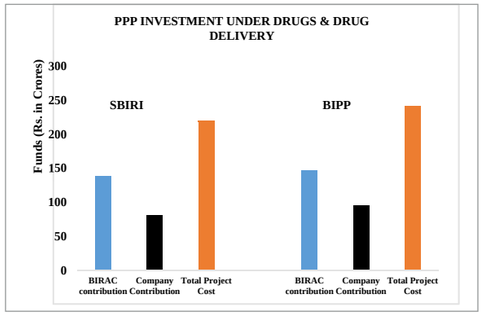

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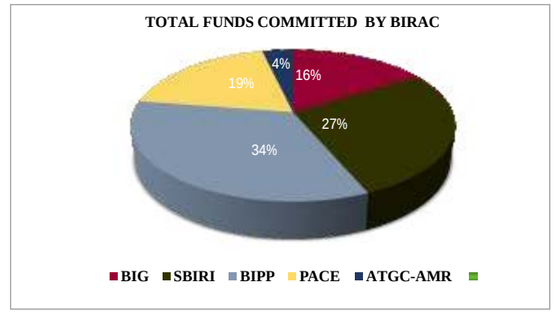

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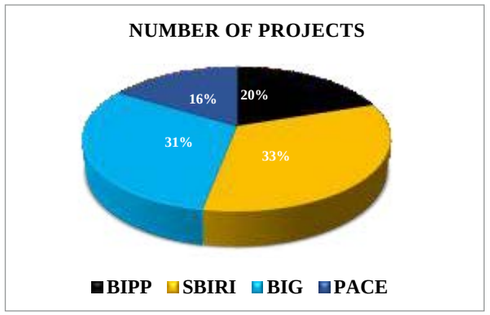

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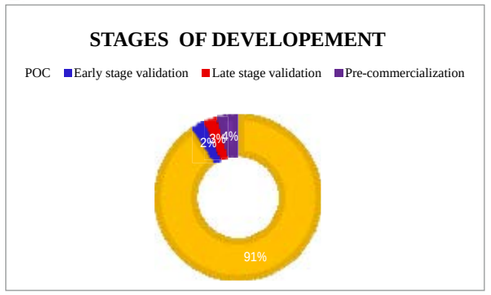

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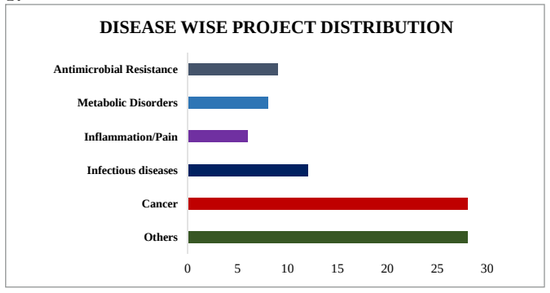


Maximum projects funded under this area are for developing proof of concept followed by preclinical and early-stage validation. Few successful projects in pipeline includes clinical investigation of Galnobax for the treatment of diabetic foot ulcer is in Phase III clinical trials, Diiodothyronine analog for treatment of cardio metabolic risk was supported by BIRAC for Phase II trials and commercialized products from this area include synthesis of drug glucuronides and their deuterium labelled analogs, silk fibroin based wound healing sheets/ powders. A pipeline product to be ready as single innovator product includes generation of clinical grade exosomes which will have commercialization potential in R&D laboratory/clinical areas. A Facility is developed in which 214 phyto chemical reference substances (PRS) from Indian medicinal plants have been isolated & characterized with 95% purity and commercialized nationally and globally.

Many proposals have been supported for preclinical studies such as development of a new molecule for vitiligo, evaluation of efficacy and toxicity for a Non peptide CCK receptor antagonist for inflammatory pain and currently being supported for follow up funding for Phase I clinical trials. Another proposal supported for preclinical studies for the lead compound, ORX-301 for treatment of Niemann-Pick Type C disorder has been licenced outside India.

A product in pipeline has completed validation studies for Insulin receptor auto phosphorylation bioassay using in-house developed engineered cell lines expressing Insulin receptor A and B in CHO cell lines and performance was found to be on par with competitors' products.

The disease wise projection under this theme shows that maximum number of projects are supported for Cancer, infectious diseases, metabolic diseases and other disease areas such as skin & ear disease/ Tissue engineering/ arthritis.

BIRAC is providing much needed support for clinical trials of potentially life-changing treatments for patients with life threatening diseases. To date, the drug products undergoing Clinical trial include Community-Acquired Bacterial Pneumonia CABP in Adults, Muscular Dystrophy, Breast Cancer, Solid tumours, Diabetic foot ulcer and inflammatory pain.

Achievements and products in Pipeline

- Few successful outcomes during last few years are clinical investigation of Galnobax for the treatment of diabetic foot ulcer which is in Phase III clinical trials, Diiodothyronine analog for treatment of cardio metabolic risk was supported by BIRAC for Phase II trials.
- BIRAC has supported the validation studies for Insulin receptor auto phosphorylation bioassay using in-house developed engineered cell lines expressing Insulin receptor A and B in CHO cell lines. They are selling 6 lakhs worth of Phospho Insulin receptor sandwich ELISA kit.
- BIRAC has supported preclinical studies for the lead compound, ORX-301 for treatment of Niemann-Pick Type C disorder. The drug molecule has been licenced outside India.
- Pipeline products to be ready as single innovator product includes generation of clinical grade exosomes which will have commercialization potential in R&D laboratory/clinical areas.

THEME WISE ASSESSMENT

Analysis

- Maximum projects funded under this area are for developing proof of concept followed by preclinical and early-stage validation.
- The disease wise projection under this theme shows that BIRAC has supported maximum projects in the field of Cancer, infectious diseases, metabolic diseases, AMR and other disease areas such as skin & ear disease/ Tissue engineering/ arthritis.

Projects supported for COVID-19

With the joint effort of DBT-BIRAC efforts have been put in the past 10 pandemic months on providing supports for repurposing of drugs, small molecules and new screening platforms to screen candidate drug molecules against COVID-19. BIRAC has supported nearly 5 projects under drugs category and 2 are under consideration which are on different aspects of drug development including drug repurposing, traditional plants extract based prophylactic drug, in-vitro drug screening platforms. The most advanced stage project has completed Phase II clinical trial on Repurposing of Pegylated Interferon alpha-2b to treat COVID-19. The Phase III trial is undergoing.

Initiatives and Future pathway

Two focused programs have been started by DBT-BIRAC on New drug development and antimicrobial resistance. The drug development program is focused on priority disease i.e. TB, COPD, CVD and cancers. AMR mission is focused to seek new innovative approaches that have the potential to transform public health action on a national or global scale by identifying and filling gaps in knowledge on the development of new antibiotics and alternatives to antibiotics to counter AMR. BIRAC is supporting a single proposal under AMR which is focused on preclinical studies on lead compound (PPEF) from the library of bisbenzimidazoles that have shown to inhibit selectively topoisomerase IA enzyme. PPEF, a bis-benzimidazole derivative preferentially targets E. coli topoisomerase IA over Gyrase and human topoisomerase IB.

This is a journey which is well begun and given the pace & the overall role played as a key enabler, BIRAC is on track to be a significant contributor to the overall ecosystem in the years to come.

Biosimilars & Regenerative Medicine (including other Biopharmaceuticals)

Biosimilars and other Biopharmaceuticals

The pharmaceutical industry across the globe, is witnessing a shift from chemical-based drugs to biologics and biosimilars. A biologic drug is a biological product that is very similar to a reference biologic and for which there are no clinically significant differences in terms of its safety, purity, and potency profile. Biologic drugs include a wide variety of products derived from human, animal or microorganisms using biotechnology. The Indian Guidelines mirror the U.S. and European emphasis on detailed structural and functional characterization of the proposed biosimilar in comparison to the reference product. To earn reduced pre-clinical and clinical data requirements, there must be no "significant differences in safety, efficacy and quality studies":

The revised 'Guidelines of Similar Biologics' was released by DBT and Central Drugs Standard Control Organisation (CDSCO) in 2016, to simplify the regulatory pathway and to enable quicker approvals and cGMP manufacturing processes assuring its safety, efficacy and quality. Biosimilars approval process has three stages viz. pre-clinical trial, clinical trial and post clinical trial stages. Pre-clinical studies also includes submission of manufacturing process data which encompasses downstream process development, process development – fermentation, molecular biology considerations and quality based considerations for "similar biologics" such as product characterization and stability. The clinical trial application contains information relating to pharmacokinetic studies, pharmacodynamics studies, multiple dose studies, immunogenicity studies, confirmatory safety, single dose pharmacokinetic studies and efficacy studies. The post-market data/ post clinical trial data consists of post marketing studies (Phase IV Study), pharmacovigilance or drug safety (PV) and reporting of adverse drug reaction (ADR).

The Indian regulatory authorities approved the first biosimilar in 2000. A total of 123 biosimilars have been launched by the Indian pharmaceutical companies and currently have 201 active biosimilars in the pipeline of 52 Indian companies for multiple indications. Most of the targeted diseases were characterized by genetic disorder and/or excessive immune response (including autoimmunity). In addition to niche indications, biologics are of utmost importance for targeting

widespread diseases with an increasingly higher incidence rate and profound implications including cancer. In total, 98 biosimilars have been approved in India, up to September 2019. Some of the major Indian players actively growing in the biosimilars space are Biocon, Glenmark, Torrent, Zydus, Reliance, USV, Dr. Reddy's Laboratories Ltd. etc. A recent report by Associated Chambers of Commerce of India (Assocham) predicts that the global market for biosimilars will have reached $240 billion and the Indian market will be at a booming $35 billion by 2030.

The Indian pharma companies are well placed to chip in into biosimilar sector and take a substantial market share in the next decade. Today there are more than 2,700 biotech start-ups in the country, 600 biotech companies and 100 biotech incubators. These numbers are expected to multiply four to five times in the next five years, says the report. Further to support and nurture this ecosystem, BIRAC supports innovative translational research from ideation to commercialization. Public Private Partnership funding is also encouraged to attract investments from different Industries, Investors and philanthropic agencies. Further with the objective to enhance research and development of biopharmaceuticals, "National Biopharma Mission" a collaborative mission of industry and academia with a corpus of USD 250 Mn has been implemented by BIRAC (initiated by DBT in collaboration with World Bank).

BIRAC has supported a total of 79 projects in the area of different biopharmaceuticals development under its different Schemes (Fig. 1).

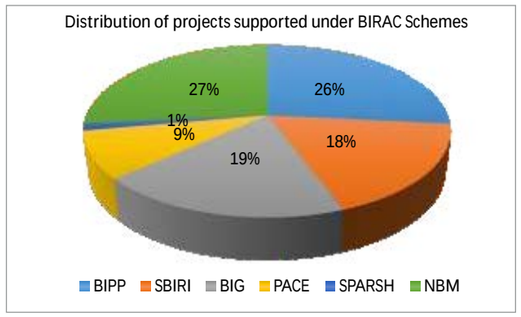


Fig. 1 Distribution of projects supported under different Schemes of BIRAC

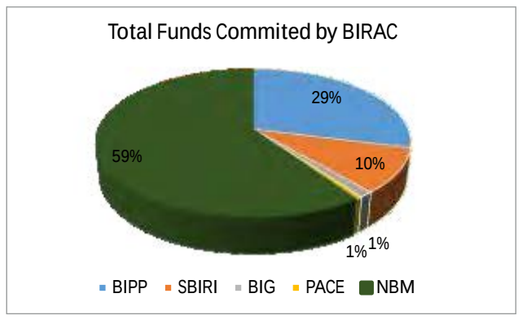


Fig. 2: Distribution of Funds committed under different Schemes of BIRAC

Major percentage of funds for different Biopharmaceuticals development have been committed under NBM Scheme followed by BIPP.

Total PPP investment under this area amounts to more than Rs. 622 Cr wherein BIRAC has invested Rs. 300 Cr and rest being Company's contribution in total, under BIPP, SBIRI and NBM.

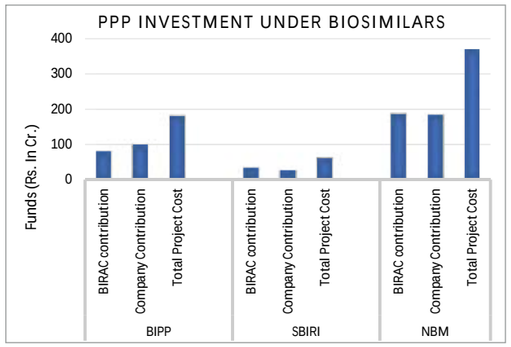


Fig. 3: PPP investment of Funds under different Schemes of BIRAC

Regenerative Medicine

The global regenerative medicine market is expected to reach USD 17.9 billion by 2025 from USD 8.5 billion in 2020, at a CAGR of 15.9%. Market growth is driven by the rising prevalence of chronic diseases, genetic disorders, and cancer; rising investments in regenerative medicine research; and the growing pipeline of regenerative medicine products. The majority of approved regenerative medicines are available in the US, with 19 products available. Rising government investments for cell-based research, the increasing number of GMP-certified production facilities, and the large number of oncology-oriented cell-based therapy clinical trials are the key factors driving the growth of this market.

BIRAC has supported a total of 35 projects in the area of regenerative medicine (including stem cells) with a total fund commitment of Rs. 59.66 Cr. Majority of these projects are towards development of proof of concept or early stage validation of the developed concept.

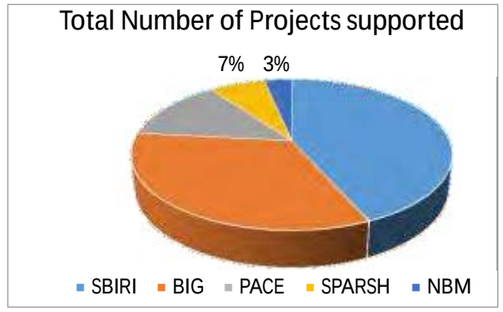


Fig. 5: Number of projects supported under Regenerative Medicine

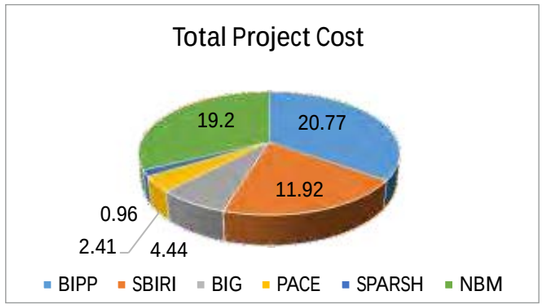


Fig. 6: Total fund distribution across different schemes under Regenerative Medicine

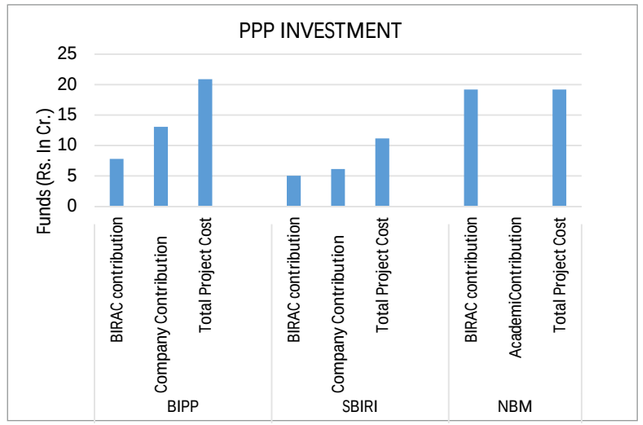


Fig. 7: PPP Investment portfolio for different schemes for Regenerative Medicine

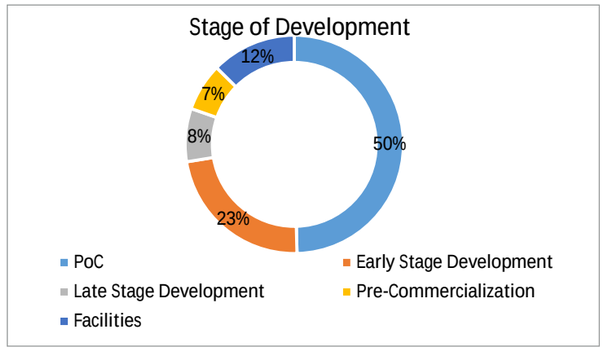


Fig. 7: Stage of different projects under the area of Biosimilars and Regenerative medicine (including other Biopharmaceuticals)

Facilities to support projects under the area of Biosimilars and Regenerative medicine (including other Biopharmaceuticals):

BIRAC has supported different industries to set up facilities for addressing the needs of research, development and manufacture of different biotherapeutics and regenerative medicines. These facilities have been established for fast-forward development of biosimilars from bench to pilot scale and can be used by different start-ups, companies and institutions. Facility support specifically intends to enhance the institutional and organizational capacity needed to successfully translate the early phase development to marketable product and to further offer a full range of GMP and bioanalytical labs. It will also help the manufacturers to test their products at affordable cost and get data as per the regulatory requirements and dossier submissions.

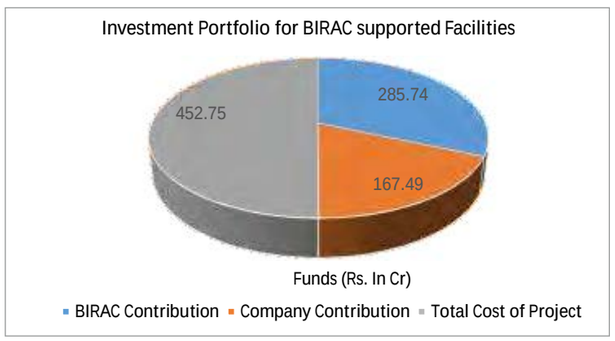


Fig.8: PPP Investment portfolio for different facilities supported under the theme of Biopharmaceuticals including Regenerative Medicines

The supported facilities include: 1) Cell Line repository for certified cell lines, cell bank characterization and safe storage, 2) Analytical characterization facility for drug substance and drug product characterization, 3) Process Development Lab and GMP manufacturing facility for process development, scale-up and clinical lot manufacturing, 4) Bioprocess facility for large-scale production of microbial antigens and monoclonal antibodies, 5) Scale-up facility for plasma fractionation of clinical grade, 6) Snake Venom and Anti-Snake Venom characterization and standardization. A total investment of Rs 452.75 Cr. towards supporting 16 different facilities (including both Industries and Academia) across the Country to support different Biologics development and capacity building, wherein BIRAC's investment is Rs. 285.74 Cr.

THEME WISE ASSESSMENT

Table 1: List of BIRAC supported Facilities:

Sr. No.	Project	Grantee
1	Establishment of Bioprocess Facility for large-scale production of Microbial antigens and Monoclonal antibodies under the conditions Compliant with cGMP	Anthem Biosciences Pvt. Ltd.
2	State of art cGMP production facility meeting regulatory requirement for production of recombinant Bio-therapeutics	Celestial Biologicals Ltd.
3	Creation of a state of art integrated facility for high end structural and functional characterization of protein therapeutics and peptides	Gennova Biopharmaceuticals Ltd.
4	Building a specialized facility to foster innovation, development of technologies culminating into commercial manufacturing of therapeutics made by fermentation processes	Intas Biopharmaceuticals Ltd.
5	Scale-up of Plasma Fractionation Facility for High Value Products	Span Diagnostics Ltd.
6	Center for BioPharma Analysis	Entrepreneurship Development Center
7	Establishment of GLP compliant analytical facility at CSIR-IICT to augment biosimilars characterizations in India	CSIR-Indian Institute of Chemical Technology
8	Establishment of National Repository of GMP Cell Lines for Biopharmaceutical Products NRGCBIO at CSIR-Institute of Microbial	CSIR-Institute of Microbial TechnologyTechnology
9	An Integrated approach to create globally compliant PDL and cGMP manufacturing facilities for mammalian cell line based recombinant	Gennova Biopharmaceuticals therapeuticsLimited
10	Establishment of GMP-compliant National Repository for banking, safe deposit and supply of characterized cells for use in biopharma	National Centre for Cell Science
11	To establish a world class Process Development Lab and a Injectable fill finish facility for Biosimilar development and commercial Manufacturing	M. J. Biopharm Private Limited
12	Development and production of affordable serum-free, chemically defined media and feed supplements for therapeutic proteins	Himedia Laboratories Pvt Ltd
13	Centre for Advanced Protein Studies	Syngene International Limited
14	Setup of a world class, flexible cGMP Biologics Pilot facility cEatering to Clinical Grade Drug Substance and Drug Product requirements of customers for Human Clinical Trials and early commercial batches	Shlipa Medicare Ltd.
15	Establishment of Center of Excellence for Snake Venom Standardization and Supply for Manufacturing	Haffkine Biopharmaceuticals
of Various Antiserum Products		

Achievements:

First recombinant FSH product Foligraf for reproductive technology developed, manufactured and sold by an Indian Company (Bharat Serum & Vaccines). Rasburicase to control Hyperuricemia under trade name TULY is a recombinant Uricase to control hyperuricemia in cancer patients undergoing chemotherapy developed by Virchow Biotech and with number of units sold 27,570. The company is also being funded for clinical grade plasma purified Alpha-1 Antitrypsin and C1- esterase Inhibitor. Affigenix Biosolutions Pvt. Ltd. has developed an immunoassay which enabled drug companies to monitor the clearance of trypsin used in the downstream processing of Biologics and Biosimilars. The kit has been commercially launched as "Trypsin clearance assay kit" and more than 200 kits already sold. Navya (Shilpa Medicare Limited) has developed biosimilar-Aflibercept using in-house high density fermentation process for further RCGM permission towards conduct of preclinical toxicity studies. Under NBM Scheme, the products supported for accelerated development include Trastuzumab, Ustekinumab, Palivizumab, Aflibercept, Ranibizumab, Insulin Glargine, Insulin Lispro,

Liraglutide, rHSA and plasma HSA. Developed by small, medium and large enterprises, industry-academia and academia collaborations, most of these biosimilars are expected to reach the market within the next five years. The Mission is also supporting Biosimilar Clones development for Ramicirumab and Golimumab for cancer.

In the field of regenerative medicine, a multi-centric clinical trial for evaluation of safety and efficacy of UregrowTM (Autologous Adult Live Cultured Buccal Epithelial Cells) implantation for the treatment of urethral strictures has been successfully conducted. Pre-clinical efficacy and toxicology of the developed composite scaffolds (different products on the way - AminoCell, SynCell, CompoCell, ReadyCure) have been demonstrated by Cellugen Biotech. Pvt. Ltd. Cell based screening platform using a human mesenchymal stem cell derived model for novel drug target screening against Alzheimer's disease have been developed and validated by Cuor Stem Cellutions Pvt. Ltd.

Projects supported for Covid-19 treatment:

In search for a promising solution as a therapy against the Covid-19 infection, several projects have been supported by BIRAC under this thematic area. Projects that have been funded from Industries include usage of therapeutic antibodies from convalescent patient blood or Equine sources, generating antibodies using phage-displayed human antibody library, phase I/II clinical trial for safety and efficacy evaluation of convalescent plasma and novel COV-trap therapy to reduce the Covid-19 Infection intensity. Further, with the aim of developing efficient model systems BIRAC is also funding projects for development of in vitro lung organoid model and human ACE2 transgenic mouse for screening of different prophylactic and therapeutic candidates against SARS-CoV-2.

Analysis:

- Industries including Start-ups alone are pursuing maximum number of projects in this area without much of collaborations with Academic Institutions. Such collaborations (either Industry-Industry or Industry -academia) have to be encouraged for successful and timely outputs and to involve more technical expertise in the respective area.
- Maximum number of projects funded are at Proof of Concept stage followed by early stage validation, late stage validation and Pre-commercialization respectively.
- A lot of projects under the Regenerative medicine (including Stem Cells) fail to succeed beyond proof of concept/early stage of development due to lack of awareness of Regulatory mandates.
- BIPP scheme followed by NBM continues to capture maximum share of funds committed due to large scale production units being developed.
- A lot of Industries have initiated their research towards development of Biosimilar Clones for biosimilars that are expected to reach the market within the next five years and further process optimization followed by Clinical Trials
- Several facilities have been funded for strengthening and accelerating the biotherapeutics development as well as development of novel cell lines for the same.

THEME WISE ASSESSMENT

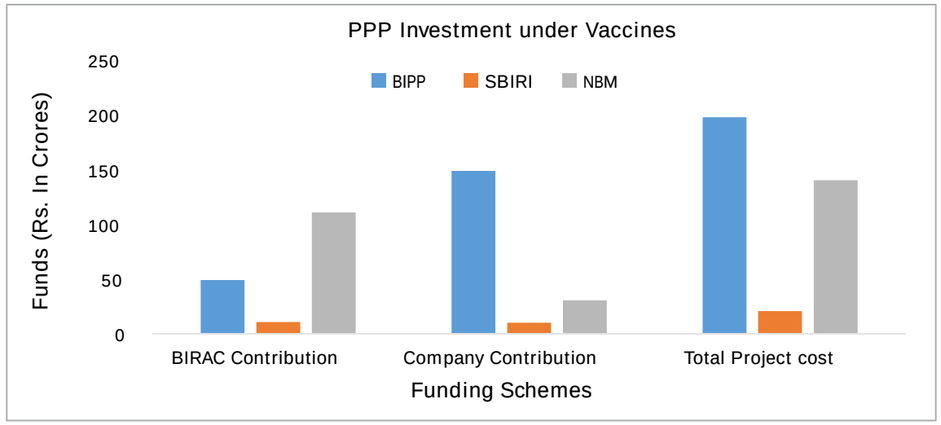
Vaccines and Clinical Trials:

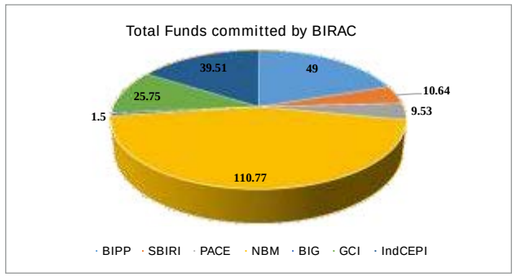
Investing in disease prevention today reaps health, economic, and societal benefits in the future. As a nation, it is critical that we continue to invest in programs that support our children's well being like nutrition, handwashing, sanitation, and immunization. Vaccines are a smart investment, as vaccine-preventable diseases impact so many parts of our lives. Not only does immunization save lives, but it also prevents the devastating costs of hospitalization that may throw families into poverty or exacerbate inequalities.

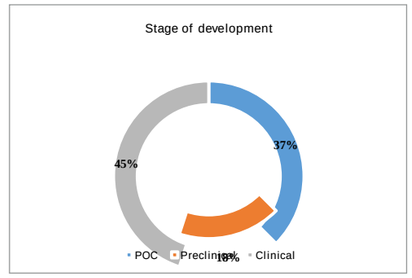
Ideal vaccine is the one that has high protective efficiency with no or less side effects and can be affordable. BIRAC has made concerted efforts in strengthening vaccine research and development since its inception in 2012 through various endeavours.

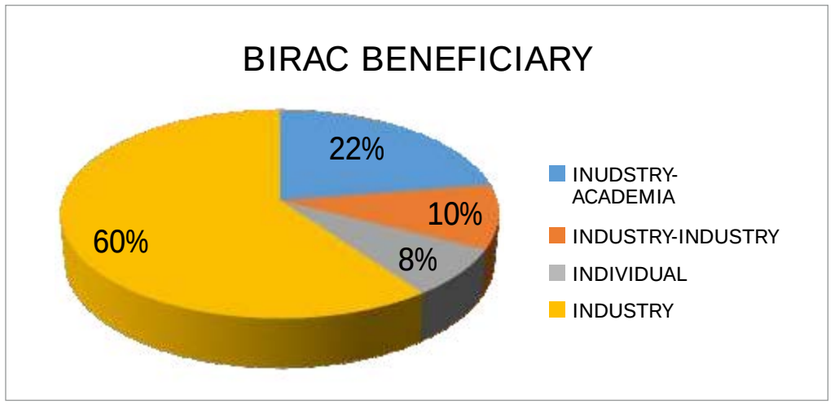
Vaccine development programmes at BIRAC encourages novel and innovative vaccine related discoveries, accelerated development of candidate vaccines for which earlier leads are available, research of basic & applied nature to improvise our current understanding of vaccine science and strengthens the scientific basis for future vaccine design.

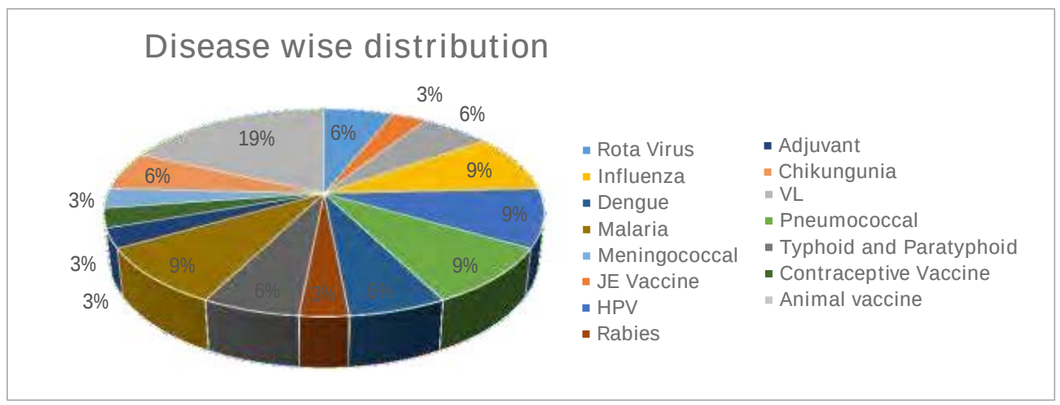
BIRAC has supported a total of 40 projects in the area of Vaccine development. These 40 projects engaged all type of grantees like companies, start-ups, academic institutes, Industry academia collaborative projects and Industry –Industry collaborative projects. Total PPP investment under this area amounts to Rs. total 358.24 Crores wherein BIRAC has invested Rs. 170.41 Crores and Company invested Rs. 189.13 crores.











Achievements:

Support for vaccine development through different schemes of BIRAC have demonstrated major achievements like i) development of low cost Rotavirus vaccine which became part of the universal immunization programme, ii) market license has been obtained for JEEV (Japanese encephalitis vaccine) in India for the age group of >1 year to < 3years and iii) more than a lakh of doses of Pandyflu vaccine (Influenza vaccine) have been supplied to Government of India.

The first indigenous low cost Rotavirus Vaccine from an Indian strain 116E efficacious in preventing severe rotavirus diarrhoea in low-resource settings in India has been introduced in 9 states namely Odisha, Andhra Pradesh, Haryana, Himachal Pradesh, Assam, Tripura, Tamil Nadu, Madhya Pradesh and Rajasthan as a part of India's Universal immunization Programme. The ROTAVAC® was granted WHO prequalification in 2018.

Following technologies have been developed in the area of vaccines:

- New process for the production of thermo stable freeze-dried Brucella abortus strain 19 Vaccine for veterinary use
- A novel technology for producing peste des petits ruminants (PPR) vaccine in suspension culture instead of adherent culture.

THEME WISE ASSESSMENT

- eSAME technology that can be used to produce Virosomes (custom designed non-replicating measles viruses) for vaccines and therapeutic agents.Currently being used for the development of Dengue & Covid-19 Vaccines.

Several other leads in Vaccine Development.

- Malaria Vaccine: Vaccine for Falciparum Malaria is undergoing phase I clinical trial and vaccine for Vivax Malaria has already completed phase I trial.
- Vaccine for Kala-Azar: A live attenuated Centrin gene knock out Leishmania vaccine candidate that protects from all forms of Leishmaniasis in India has been supported. At present the vaccine is undergoing preclinical toxicity analysis. A Multivalenet Leishmania Vaccine candidate has also been supported.
- Pneumococcal vaccine: An affordable, Asia specific 15 valent Pneumococcal Polysaccharide – CRM 197 Protein Conjugate Vaccine has completed Phase II clinical trial and is ready for Phase III clinical trial.
- Dengue Vaccine: The recombinant EDIII- based sub-unit dengue vaccine candidate that protects against all four dengue strains endemic to India has been supported. The team is presently optimizing the production process and are expected to initiate clinical trial in the near future.

Also a Live attenuated Dengue Vaccine candidate licensed from NIH is being supported by BIRAC.

- HPV Vaccine: A VLP based HPV vaccine has been developed and has completed Phase II clinical trial and is ready for Phase III clinical trial.
- Development of Chikungunya, Influenza, Typhoid, Paratyphoid, and Cholera vaccine candidates is also being supported.
- Supported vaccines development for Animal diseases also , Vaccines for Marek disease is ready for commercialization, and filed trials are ongoing for Paratuberculosis, Bovine Herpes virus 1 and canine Paro virus.

Projects supported for Covid-19 Vaccine Development

With the pressing need of the vaccine for Covid-19, BIRAC has floated two subsequent calls for the proposals on vaccine development to fight with this pandemic problem.A total of 14 projects were supported, out of which 8 proposals were for the development of vaccine candidates to be developed through different platforms by small and large industries as well as academia, remaining 6 focus on vaccine related developments which involve development of preclinical assays, production of reagents required for assay development and development of suitable animal models.

One Covid-19 vaccine candidate with this initiative of BIRAC (using DNA vaccine platform) is in Phase III clinical trials.

Analysis:

- Industry Contribution is more than BIRAC contribution under BIPP scheme however BIRAC has contributed a significantly higher amount as compared to Industry for clinical development of vaccines through National Biopharma Mission (NBM) Program.
- Industry prefers to develop vaccines solely without collaborating with any academic institute or other industry. and, collaborations may be encouraged.
- Some projects, which have been funded by BIRAC, are at developing proof of concept and preclinical stage. However certain projects directed towards the development of vaccines for important diseases in India such as Pneumonia, cervical cancer, malaria etc. are undergoing clinical trials.
- A large array of diseases have been covered by industries for the development of vaccines through BIRAC support.
- Rapid response to Covid-19 and fourteen project are being supported.
- All kinds of applicant viz Startups, Large vaccine industries and academic institutes were supported for vaccine development.

Medical Devices and Diagnostics

The Indian healthcare industry has been growing and evolving at tremendous double-digit rate. The various initiatives of Government of India are providing the much needed impetus to the healthcare industry. With the increase of healthcare expenditure from 1.6% of GDP in 2019-2020 to ~ 3% of GDP in 2020-2021, the healthcare spending is expected to increase by 137%.

The medical devices is an integral part of the Indian healthcare industry and is expected to increase at a 35.4% CAGR to reach Rs. 352,450 (US$ 50 billion) in 2025 from Rs. 77,539 crore (US$ 11 billion) in 2020 (Source: India Brand Equity Foundation). The role of medical devices ranges from screening, diagnosis, treatment, restoration and monitoring.

Medical devices comprises of five major segments; 1. Consumables & Disposables which include needles and syringes, etc 2. Diagnostic Imaging includes MRI, X-Ray, Ultrasounds, etc 3. Dental Products include dentures, braces, etc 4. Orthopaedics & Prosthetics include knee implants, artificial joints and 5. Patient Aids which include hearing aids and pacemakers etc.

Apart from the R&D support for the development of innovative products in above mentioned segments, it is important to develop the manufacturing capacity of the nation. India has six medical devices manufacturing “clusters” in the country.

These Clusters have “Medical Device Parks” developing around them. Different states have committed to set-up dedicated industrial parks where efficient domestic manufacturing at lower costs can be performed. In 2019, Andhra Pradesh, Telangana, Tamil Nadu, and Kerala have got in-principle approval from Government of India for new medical devices parks (Source: Invest India).

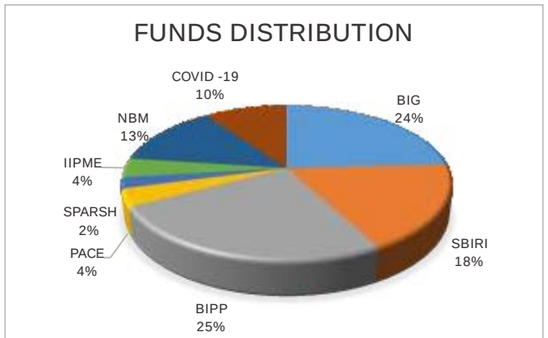


Fig 1: Funds Distribution in various programs of BIRAC

BIRAC’s mandate aligns with the “Aatma Nirbhar Bharat” and “Make in India” initiatives of Government of India. Around INR 482 Crores is pumped into this sector through various programs of BIRAC like BIG, SBIRI, BIPP, PACE, IIPME, SPARSH and NBM. These programs support entrepreneurs and innovators at various stages of product development cycle and help them cross the well-known “Valley of Death”. In year 2020, to fight the pandemic COVID-19, BIRAC made extra efforts to provide the 360 degree facilitation to the diagnostics ecosystem and invested around 52 Crore through its COVID-19 Research Consortium.

615 Individuals, Entrepreneurs, Startups, SMEs and Companies are supported for development of Innovative Products/Technologies by BIRAC through its various programs. Out of these 562 projects are submitted solely by Companies, Academia or Individuals and 53 are collaborative projects. The collaborative projects account for around 9 % of the total projects supported.

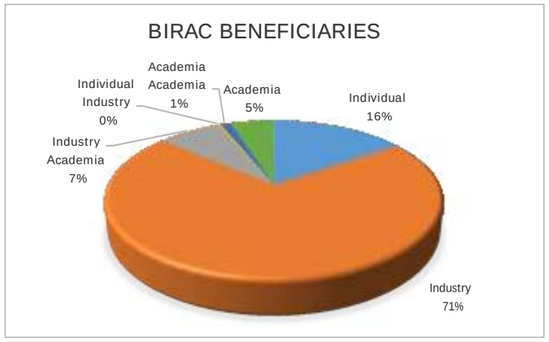


Fig 2: Beneficiaries distribution

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Under the Public Private Partnership Investments, it is witnessed that contribution by applicant in the project is higher than the BIRAC contribution. This highlights the fact that BIRAC is acting as the facilitator along with Company in the product development journey.

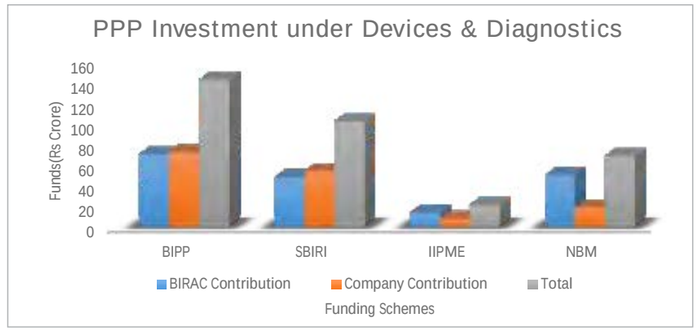

Fig 3: Public Private Partnership Investment

The Oncology, Cardiology and Orthopedic sectors are fetching maximum amount of funds under devices and diagnostics theme at BIRAC. COVID-19 is the recent addition in funding sectors and has received special attention because of pandemic. MCH sector includes projects related to maternal and child health (including neonatal health). Others category includes general projects like hygiene monitoring in public settings, Safety Syringe, easy-to-use stretcher, digital stethoscope, blood bag monitoring solution, Sensors for Connected Health, automated cell counter, Medical Kit for Road Traffic Emergencies, Opto fluidic Microscope and Portable Slide Profiler, Automatic Biochemistry, Urine strip Analysers, and fluorescence correlation spectrometer etc.

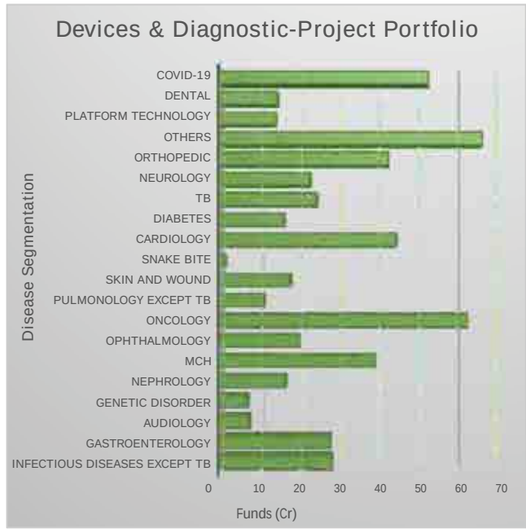

Fig 4: Disease Segmentation

As per the analysis of BIRAC funded projects, maximum interest is observed in the diagnostic imaging/instrument sector. Within diagnostic instruments, connected medical devices which use telemedicine, IoT or digital health as major component is the trend among the young innovators. The future of devices sector is moving towards the artificial intelligence based diagnostic, screening and predictive devices.

BIRAC is increasing its pipeline of projects through various programs like Social innovation Immersion fellowship and BIG. Maximum number of projects are at prototyping stage and as they move towards Pre-commercialisation, the number decreases. It is observed that many companies die out during the product development cycle. Hence, the number of technologies reaching late stage validation and pre-commercialisation stage are very less. BIRAC is working towards increasing the number of products reaching market through various partnerships. It is evident that collaborations with various stakeholders is required to achieve this difficult task. To name a few; BIRAC has partnered with KIHT for testing and standardisation, Government e-Marketplace for public sector procurement facilitation, WISH foundation for last mile validation & connectivity and ICMR for clinical investigation. BIRAC has also instrumental in starting the product commercialisation unit for providing funding support for scale up and manufacturing. Through these efforts BIRAC is successful in facilitating commercialization of 60 products/technologies and generating 114 patents in the medical devices and diagnostics domain.

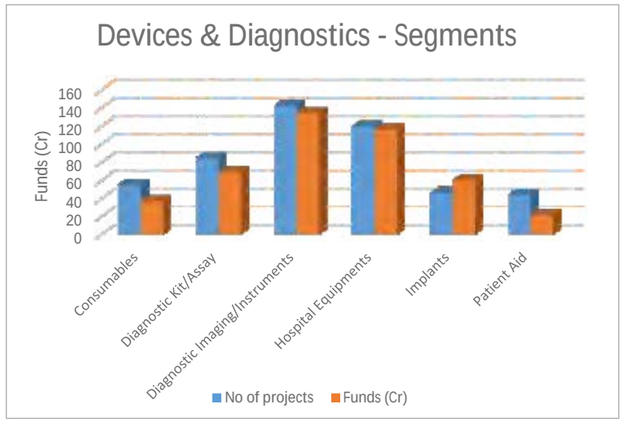

Fig 5: Sector Segmentation

There are 750–800 domestic medical devices manufacturers in India, with an average investment of $2.3–2.7 mn and an average turnover of $6.2-6.9 mn. Around 65% of the manufacturers are mostly domestic players operating in the consumables segment and catering to local consumption with limited exports. Large Multinational Corporations lead the high technology end of the medical devices market with extensive service networks (Source: Invest India).

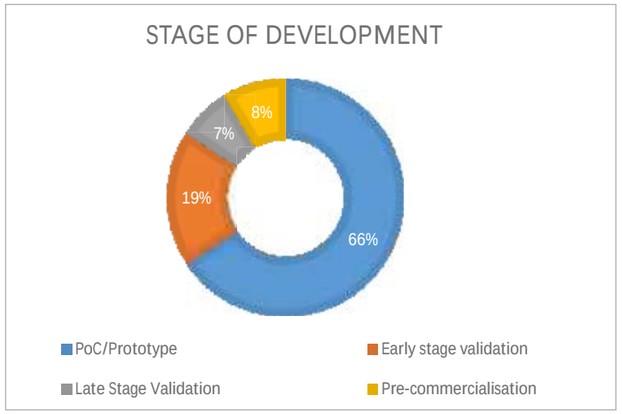

Fig 6: Stage of development

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To facilitate the ecosystem during the COVID-19, DBT and BIRAC initiated the “COVID-19 Research Consortium”. This consortium targets the holistic development of the diagnostic ecosystem of our Country. Under this initiative around 32 projects addressing the different domains of diagnostic development were supported. The project portfolio includes nucleic acid detection kits, antibody detection kits, antigen detection kits and artificial Intelligence based screening platforms. Further, the support was also extended towards development of raw materials like probes, primers, material transport medium, swabs and nucleic acid extraction kits.

BIRAC had supported development of ventilators, RT-PCR and serology based kits manufacturing facility through its COMMAND program with AMTZ. In addition to this to maximise the impact of facilitation, various regulatory workshops were organised and many FIRST HUB sessions were scheduled to address the queries of Innovators.

But with the growing demand for medical devices & diagnostics products, more concentrated efforts are required from various stakeholders and India needs to devise a strong growth model for local manufacturing.

Analysis:

1. The Indian medical devices industry is highly import dependent with 75-80% imports from countries like US, China and Germany. The government may invest in developing the manufacturing capacity in India so that the sector can become self-reliant.
2. With the increase in the medical facilities in the country, due to COVID-19 and increased healthcare expenditure, it is expected that the demand for medical devices will increase in coming years.
3. Manufacturing of innovative prototypes & products in terms of sensor development, fabrication of prototypes, mould creation, 3-D printing, and access to bio-materials require lot of iterations and no Indian company can provide these prototypes in small batch sizes. Indian companies currently do not have the expertise and also cannot compete with Chinese companies in terms of their manufacturing capacities. A large mission mode program to boost manufacturing capabilities of the component level technologies is required so that India can act as “Tools House” of the world.
4. As the 100% FDI is allowed in the medical devices industry in India, high investments are expected in this sector. As per the analysis, it is envisaged that consumables, diagnostic imaging and implants segment will fetch maximum interest of investors.
5. To enhance the exports in this sector the Indian regulator, CDSCO is making significant changes in the regulatory guidelines of medical devices. The New Medical Devices Rules 2017 has brought much awaited clarity in the regulations and is expected to provide the boost to this sector.
6. Some of the challenges associated with this sector include need of testing and calibration facilities, Institutionalized mechanism and guidance for clinical trials, access to Government e-procurement system and connections with mentors/clinicians.
7. BIRAC is successful in facilitating commercialization of 60 products and technologies in the medical devices and diagnostics domain and also facilitated around 114 IP generation.
8. The areas fetching maximum amount of funds at BIRAC under devices and diagnostics are Oncology, Cardiology and Orthopedic.
9. The latest trend is for connected Medical devices with Artificial Intelligence, IoT and telemedicine as an integral component.

Agriculture and Allied Areas

Globally, modern techniques of farming are being adopted to get optimum yield of crops and cereals with minimum effort and least time. The increasing demand for agricultural food products, shift in consumer preferences to higher standards of food safety and quality, unavailability of labour, and climatic changes are some of the driving factors for the Agri-based markets. The global digital agriculture market size is expected to grow from USD 5.6 billion in 2020 to USD 6.2 billion by 2021, recording a CAGR of 9.9% (Reference Research AndMarkets.com's)

Up till now, backed by the Green Revolution, the productivity increase observed has been primarily through improved seeds, fertilizers and pest & disease management. However, exigencies like COVID 19 affecting procurement, labour availability, fall in prices, adverse effects on retail and supply chain, debt and cash flow restraints, takes toll on the overall growth curve. A technology-based approach with modernized techniques of farming, digitization to get optimum yield of crops and cereals with minimum efforts is the need of the hour. According to recent report ', adoption of technology in agriculture is helping in solving several challenges across the spectrum of the traditional agriculture value chain. Indian agri-tech sector can grow to $24.1 billion by 2025 (EY report (2020) 'Agritech – towards transforming Indian agriculture).

In a report by McKinsey and Paine (2015), it was observed that by plotting growth segments vs. risk assessed, the projected 24 hot spots for agribusiness investment could be identified, out of which areas like aquaculture, agriculture machinery, precision agriculture, biopesticides, microbial fertilizers, irrigation, storage infrastructure in emerging markets, information services and diagnostic products for food safety and feed additives, sugar in India have stood out as key areas of common interest.

The scope for technical innovation in agriculture continues to widen with advances in biotechnology. Information and Communications Technology (ICT) and the private sector significantly influence the production, use, and dissemination of knowledge. Reforms directed at agricultural research, education, and services - often considered the centre of innovation in the agricultural sector -have begun to make a difference, despite underinvestment in agricultural research and development.

In totality, a broad range of service providers (the public sector, private sector, farmer organizations, and others) have become relevant to the process of agricultural innovation. The importance of facilitating these services is clear. The challenge is to create sustainable mechanisms that will promote the creation, development, diffusion, application, and overall commercialization of knowledge and technology in a socially inclusive manner.

In the backdrop of the global and Indian Agriculture scenario, BIRAC has been supporting technology intensive projects in agriculture and allied areas like veterinary and aquaculture sciences. Close to 165 projects (Fig 1) have been supported under these three areas. Under Agriculture, the pipeline of projects supported have been grouped under five major

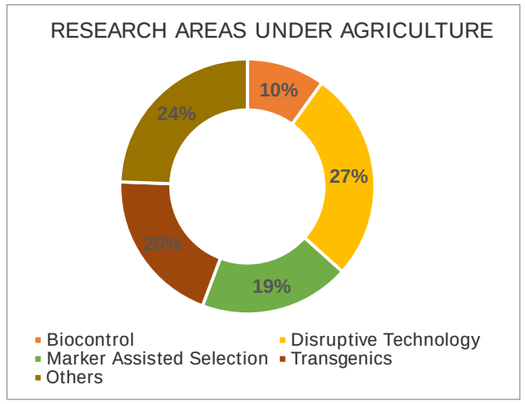

Fig 2 A

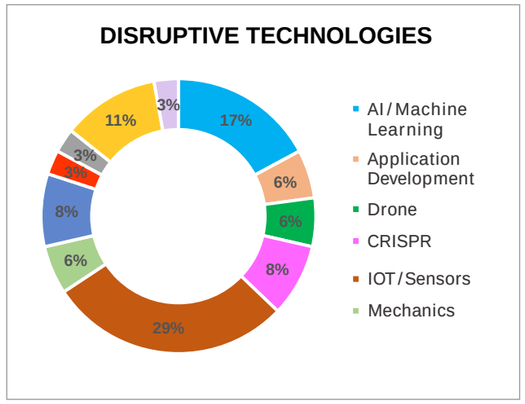

Fig 2 B

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technology areas i..e., Marker assisted selection, transgenics, biocontrol, disruptive technologies. Under aquaculture and marine biotechnology the supported projects mainly deal with disease detection, diagnostics and control. Some of the major projects supported are in the area of WSSV diagnosis and their control for Shrimp. Under veterinary science, some of the research areas supported include livestock disease detection, therapeutics , reproduction and productivity. Some of the major areas of support are devices for artificial insemination, sexed semen, vaccine development for different kinds of animal diseases, etc.

Agriculture

Analysis of the technology portfolio under agriculture suggests that besides the usual Marker Assisted Selection, Transgenics, Biocontrol, and others (including diagnostics, sericulture, tissue culture, tea), major progress has been made under various disruptive technologies which have the ability to transform every link in the food chain. Technologies such as IOT/sensors, AI/machine learning, mechanics, remote sensing, pheromones, food grain storage, drones, nano biofertilizers, genome editing, application development, nanopesticides etc residue testing by Matrix-assisted laser desorption/ionization (MALDI), seed invigoration by magnetopriming, etc. are being encouraged under entrepreneurial ventures to put Indian stakeholders at par with the global players (Fig 2A and 2B).

Some of the technologies/interventions which have reached late-stage validation and shown potential for commercialization under the agriculture area are:

Achievements:

- Control of pests using Specialized Pheromone & Lure Application Technology (SPLAT) (CIB&RC registered and approved)
- Stress (salt) tolerant rice and rice hybrids resistant to Blast and bacterial leaf Blight,
- Development and promotion of local fungal strains of tea ecosystem for the management of tea pathogens and insect pests with special reference to Darjeeling
- Development of an alternative cost effective and faster method for large scale growing of the beneficial nematode, Heterorabdities indica using discarded silkworm pupae as a media for growing the nematodes.These nematodes can be used as a biological control of several insect pests
- A high gingerol containing line developed through somaclonal variations,
- Stable formulation using the active ingredients obtained from the forest tree, Hydnocarpus pentandra, for the management of insect pests like Spodoptera litura and Helicoverpa armigera.
- Genetically engineered Brassica juncea (Male sterility and restorer lines as pollination control mechanism) for heterosis breeding and yield improvement
- BRL-II) trial of Bt Brinjal hybrids containing Cry1Fa1 gene (Event 142) for their efficacy against Leucinodes orbonalis, Helicoverpa armigera, Ezophera Perticella and yield
- Development of Mustard (Brassica juncea) variety Double low NML-100 having low Erucic acid and Low Glucosinolate content i.e. Double low, variety developed (00)
- Use of seaweed for development of a biological product which is useful to improve soil quality and increases plant growth & development

With regard to the projects under the disruptive technologies the trend shows that there has been an overall increase in the number of projects funded under this subarea (46% of the total funded in the last 3 years) due to the efforts put by designing focused calls to encourage innovation and entrepreneurship.

Key Technologies Under Development

- Improvement of line yield per se and efficiency of hybrid seed production in rice using genome editing technologies,

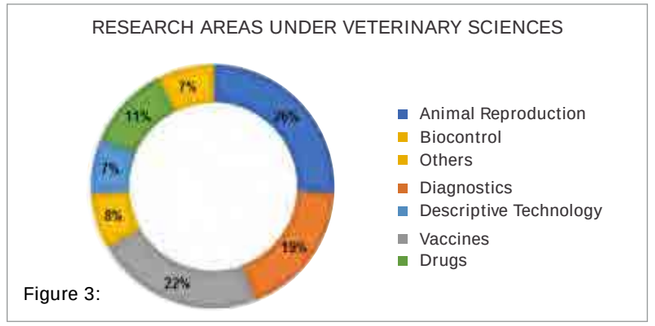


Figure 3:

- RNAi technology has been used to make transgenic Bombyx mori nucleopolyhedrovirus (BmNPV) to carry out multi-locational field trials on transgenic BmNPV resistant silkworm strains to establish their efficacy and generate data for their regulatory approval. Phase I of the project is complete.
- An affordable in-field soil monitoring system which helps the farmers to irrigate their fields by measuring multiple soil parameters like soil moisture, soil temperature, atmospheric temperature and relative humidity.
- Magnetpriming for faster growth of seedlings & enhanced defence
- Decision Support System (DSS) for providing information over farms in real-time etc.
- Development of arsenic detection system using coloured product based methods

Veterinary Sciences:

In this age of reductionist research and the ascension of disciplinary endeavors, veterinary research stands apart because of its breadth and interdisciplinary orientation. The world today is full of unanticipated risks in the form of highly pathogenic CoronaVirus, avian influenza, foreign animal diseases, and transmissible spongiform encephalopathies, to name but a few examples. At the same time, unparalleled opportunities in biomedicine have been afforded by advances in molecular biology, genomics, and other disciplinary sciences. Veterinary research serves as the interface of basic science and animal and human health that is critical to the advancement of our understanding of and response to impending risks and to the exploitation of disciplinary advances in the pursuit of One Medicine.

Entrepreneurship is emerging as one of the potential areas in veterinary science and start-ups are beginning to emerge in this sector.

BIRAC has made concerted efforts in strengthening veterinary research and development since its inception in 2012 through various endeavours. Under veterinary sciences some of the areas supported are livestock disease detection, therapeutics, reproduction and productivity.

Achievements:

Antibody detection ELISA Test kits for Glanders and Equine infectious anemia, Paratuberculosis indirect ELISA Kit, etc are few diagnostics developed with the help of BIRAC support that are already in the market. A specific animal disease diagnostic facility has also been established with BIRAC funds which offers timely diagnosis of infections like Theileria, Bebesia and Trypanosomiasis.

ParvoCure is an enteric protected oral tablet to treat or prevent Parvoviral enteritis in dogs. The tablet contains >100,000 HI units of anti-parvoviral antibodies raised in chicken and formulated in a way that the active ingredient released in intestine are antibodies that neutralize the virus, thereby curing the disease.

Artificial insemination gun : An artificial insemination gun capable of real time imaging of the reproductive tract in a cow and relays image on a smart-phone via Bluetooth. The smartphone has an application where details of the insemination can be entered, stored and retrieved.

Deworming drencjh gun: An efficient and productive tool for deworming/drenching, to overcome the problems of drenching and dosing.

Following technologies have been developed in the area of animal vaccines:

- New process for production of thermo stable freeze-dried Brucella abortus strain 19 Vaccine for veterinary use
- A novel technology for producing peste des petits ruminants (PPR) vaccine in suspension culture instead of adherent culture.

Other leads in Veterinary sciences include:

- Bovine sperms sorting Device
- Sperm cryo-presrvation & transportation medium
- Cryopreservation of Chicken Kadaknath and Aseel Primordial Germ Cells PGCsfor Commercial poultry breeding line development.
- Vaccine for Parovirus , Paratuberculosis.
- gE -deleted BoHV-1 as infectious bovine rhinotracheitis IBR marker vaccine
- Thermostable Combined Sheep Pox, Goat Pox and PPR Vaccine
- Diagnostic kit for BLV infection, Lateral Flow/ELISA Detection Kit for the early diagnosis of theileriosis in Cattle

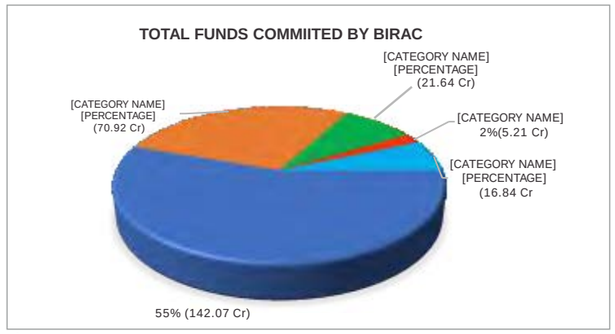


Figure 4:

Aquaculture:

Aquaculture and Marine biotechnology are important sectors in India with a coastline of 7,517 km and widespread freshwater resources, it employs millions of people and contributes to the food security of the country. In view of the above BIRAC identified Aquaculture and Marine Biotechnology as thrust areas to support R&D towards the development of useful products and processes from the fresh water and marine resources.

Acievements:

“Vibrioshield,” a Bacteriophage based control of Vibrio harveyi infection in shrimp. The active ingredients of the product is loaded with high concentrations of potent bacteriophages that can eliminate Vibrios from the culture ensuring higher yield and profitability.

Accusens WSSV,YHV,TSV and IHHNV Detection Kit. It is a single tube nested PCR Kit for the detection of notorious viruses i.e WSSV, IHHNV, TSV and YHV infection in shrimp samples into 3 different levels of infection and uses silica based DNA extraction that ensures quick and efficient purification of DNA. The primer set is specific to the highly conserved VP26 region in the WSSV genome.

Products in Pipeline:

- Nano-formulated dsRNAi to control WSSV infection.
- •? nano-sized formulation of ß-glucan particlesas potent immunity booster for shrimp.
- •? Lateral Flow Immunoassay (LFIA) kit to detect white spot syndrome virus (WSSV) of shrimp.
- •? Some notable technologies /subareas funded under the area of Acquaculture and vetemniary sciences in Fig3

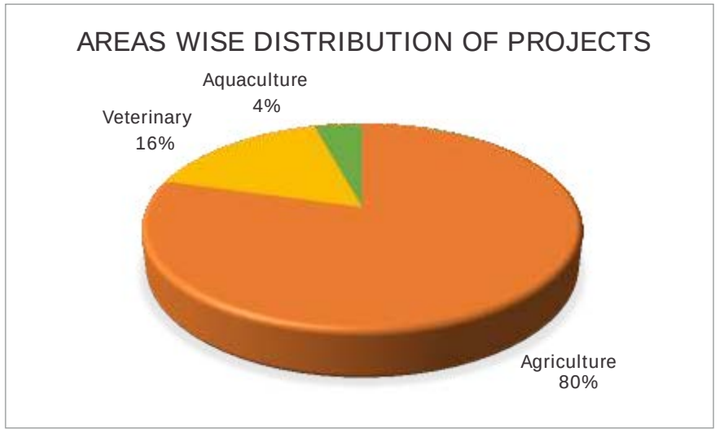
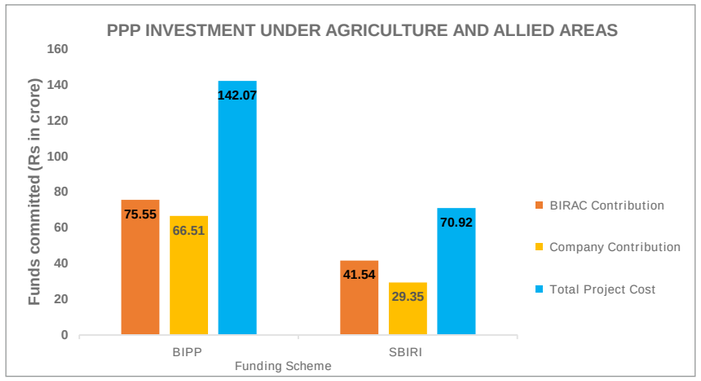


Fig 1

Fig 5



Besides supporting development of products & technologies, BIRAC has also supported/facilitated transfer of technologies through multi-partnered projects:

Under Technology transfer program of BIRAC, a technology transfer and translation for the development of biofortified and disease resistance banana from Queensland University of Technology (QUT), Australia t has taken place to o India. Under this program, technology transfer has been carried out for developing transgenic varieties of Indian banana (Grand Naine and Rasthali) with enhanced micronutrients (iron and pro vitamin A) and disease resistance (Fusarium and BBTV).The program's objectives are being jointly translated by 5 Indian research organizations namely, National Agri-Food Biotechnology Institute (NABI), National Research Centre for Banana (NRCB), Bhabha Atomic Research Centre (BARC), Indian Institute of Horticulture Research (IIHR) and Tamil Nadu Agricultural University (TNAU). Significant progress has been made to develop transgenic plants with enhanced level of Pro Vitamin A (PVA) and the analysis in fruit-pulp of the main crop plants. Biofortified banana (cultivar Grand Naine) lines are present which are showing pro-vitamin A more than the threshold value ($\geqslant$ 20 ìg/gm dry weight) in ripe fruit pulp of main crop plant

BIRAC has also pursued technology transfer initiatives where the translatable leads from the Academic institutions were assigned to the relevant Industries for translation. In this regard three White Rust resistant lines of Oilseed Mustard (Brassica juncea) developed by the Centre for Genetic Manipulation of Crop Plants (CGMCP) Delhi University, South Campus (DUSC) with the financial support of Department of Biotechnology (DBT), Government of India through mapping and marker assisted backcross have been transferred to 7 Indian companies for further translation and eventual commercialization. On similar lines Delhi University has developed two transgenic events of cotton namely Tg2E-13 and TM-2 (using a codon modified, truncated cry1Ac gene against Helicoverpa armigera, a major lepidopteron pest of cotton in India). The technology has been transferredto 2 Indian companies for further translation

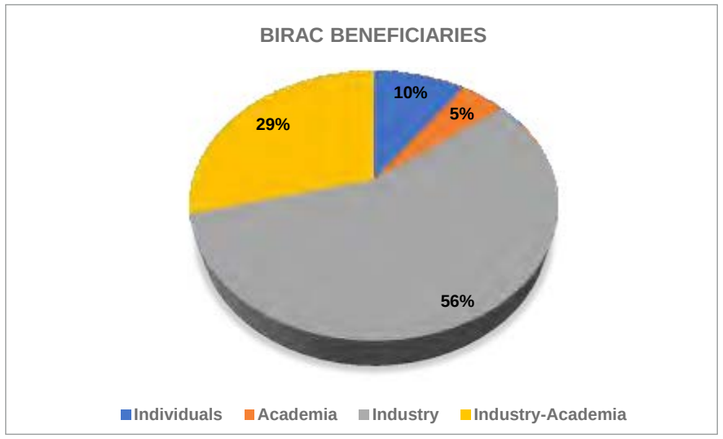
BIRAC in partnership with USAID and Indian Council for Agriculture Research (ICAR) is supporting development of high yielding, heat tolerant wheat cultivars suitable for Indo- Gangetic Plains. These new varieties shall be developed by building upon the available resources and breeding materials by utilizing information from model systems and currently available modern breeding, genetic, genomic, physiological, and biochemical tools. During the course of the study genes/ QTLs controlling heat tolerance will be identified, mapped and tagged; improved insight into physiological, genetic, biochemical, and molecular bases of the trait obtained, and a system will be put in place to utilize the new information in cultivar development.

Overall, for supporting 165 projects in agriculture and allied areas, a total investment of Rs 256.71 crores has been made under various schemes. This includes BIRAC contribution of Rs.160.22 crores. The distribution pattern of funding support under BIPP, SBIRI, PACE, SPARSH and BIG has been provided in Fig. 4. The total BIRAC contribution in agriculture under

public- private partnership (BIPP & SBIRI) is close to 117.0 crores (Fig 5) In agriculture and associated areas, 16 projects are with individuals, 29 projects are with the start ups, 8 had only academic institutions/organizations, and 13 involved academia -Industry, 64 involved industries only and 35 Industry-academia (Fig 6).

So far as the stage of technology development is concerned, maximum projects have been supported for late stage research (72), followed by early stage validation (44), and Proof of concept(21). This was followed by late stage validation (20), pre commercialization (7), commercialization(1). Considering the fact that agricultural projects involve long gestation period relatively fewer projects were funded for late stage validation, pre-commercialization and commercialization (Fig 7).

Fig 6



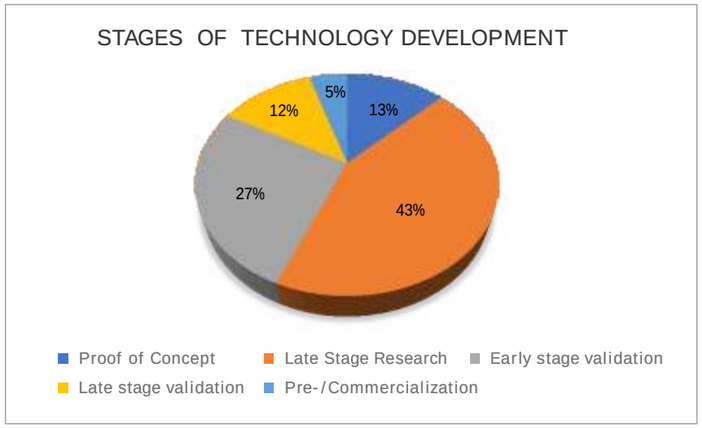
Analysis

- Through its various funding schemes BIRAC has been developing an ecosystem of encouraging disruptive innovation in agriculture and allied areas through its various schemes, focused calls and handholding.
- The technology profiling suggests that under agriculture, BIRAC has supported an array of technologies both regular, as well as new age. The trend shows an increase in number of projects under the Disruptive Technologies in the last few years
- In sync with the current government initiatives BIRAC has also supported projects in the area of soil and plant health, digital agriculture, precision farming, genome editing, drones, IOT, remote sensing and artificial intelligence
- Some other entrepreneurial ventures which BIRAC has supported under agriculture and allied area are: residue testing plant health (grapes), arsenic testing kit for soil health, platform development for precision farming and soil health prediction and monitoring through precision irrigation and remote sensing, etc. Additionally, support has been extended to develop UAV/Drone-based Hyperspectral Remote Sensing & AI for estimation of crop yield, pest infestation, etc
- Other interesting facts regarding agriculture and allied area is a healthy Public Private Partnerships with 8% of technologies developed by academia been taken forward by industry, and 21% of technologies translated by Industry involved academia as the collaborator.
- Regarding stages of development under agriculture and allied area, late-stage research has maximum projects,

followed by early-stage validation, proof of concept, late-stage validation and finally pre commercialization/commercialization. It can be concluded maximum projects under this area are still at the validation/pilot scale and more efforts are needed to take them forward for commercialization

- 11 Patent Applications have been filed out of the total agriculture projects supported. Most are in the field of veterinary sciences and formulations. There are none in Markers, Tissue Culture and Transgenics.
- Some of the products/late stage validations, which have come out in the last year under agriculture are as follows: Using marine resources for plant health, control of pests using Specialized Pheromone & Lure Application Technology (SPLAT), technology assistance software and hardware for preventive protection against pest and disease in crops , estimation of crop yield at farm scale using multi-satellite remote sensing combined with the Big data and physical based modelling , a combination of hardware and software solution that integrates sensor data and satellite imagery to translate data into actionable information for agribusinesses. Further to this some of the technologies were based out of silk worm pupae for EPN biocontrol agent, plant based biocontrol agents and development of novel hybrid orchids using the resource available in India.
- Some of the key regulatory footsteps taken by the government to facilitate product development and validation in agriculture includes making of guidelines for evaluation of nano-based Agri-input and food products in India, consolidation of drone flying rules, UAV flight compliances and genome editing.
- A sturdy Agriculture can enable a stronghold in exigencies like COVID for nations like India. Under the covid consortium an initiative of BIRAC on Anti Covid botanicals indicated that lots of research is needed in bringing the traditional medicinal knowledge forward.

Fig 7



THEME WISE ASSESSMENT

Energy and Environment (including secondary agriculture)

Day to day activities contribute to pollution, environmental deterioration, and global greenhouse emissions and therefore there is a need to protect the environment using the technologies that are clean and energy that is green.

On the other hand, it is important to provide value addition to agricultural products, create facilities for primary processing and stress management in agriculture and add value to the basic agro commodities to allow farmers to get better returns from their harvest.

With this mandate, clean energy and environment (including secondary agriculture) is one of the technical verticals of BIRAC and the mandate is achieved by means of Industrial biotechnology (IB). IB encompass creating new products, modifying or developing new industrial processes or environmental remediation.

Clean energy and environment area at BIRAC involves supporting projects which focus on development of an industrial process, industrial product or a platform technology using biotechnology means.

BIRAC, since its inception has been trying to promote this sector by providing funding, mentoring and training. Total investment under this area amounts to ? 476 crores wherein BIRAC has contributed ? 249 crores for supporting 276 innovative projects. These projects engaged 105 companies, 89 start-ups, 46 entrepreneurs and 51 academic institutes. The major achievements of BIRAC in this area are 53 technologies/product/PoC and 55 intellectual property. One early translation accelerator, 3 SIIP centres and 1 clean energy incubator have also been supported to promote this sector.

The projects that have been supported involves the use of biotechnological platforms and can be categorized in several sub-areas such as bioenergy, speciality chemicals, industrial enzymes, industrial processes, proteins and peptides, environmental remediation, secondary agriculture, infrastructure support and many other fine chemicals. Projects supported by BIRAC in the last one year have had some remarkable achievements in the area of Clean Energy and Environment and Secondary agriculture:

- A technology for bench scale production of snow flake Cordyceps and Cordyceps militaris through solid state and sub-merged fermentation has been developed and commercialized.
- A technology for the production of colors from microbial systems is being developed. Third party validation is going on.
- Water storage containers with Active copper having antibacterial, antiviral and antifungal properties have been developed. These can make the water microbiologically clean within 30 min of storage
- CellBRX single-use bioreactors platform developed for large-scale vaccine production and stem-cell therapy use. It runs on proprietary Dynamic-Bed Reactor (DBR) technology and offers 10X process scalability with 6X production efficiency
- Algae coated fodder with nutritional value for dairy animal called as “Green fodder” has been developed and commercialized
- Technology for the production of organic mushrooms fortified with Vitamin D developed and product commercialized.
- Process validation and development of a highly stabilized Omega-3 fatty acids in liquid matrix.

In the secondary agriculture sub sector, time to time special calls are announced to support the development of techno- strategic interventions. Several successful outcomes such as Industrial scale production of tea catechins, stable

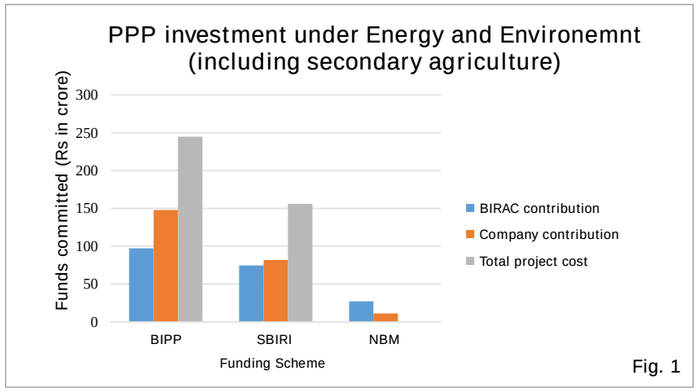


Fig. 1

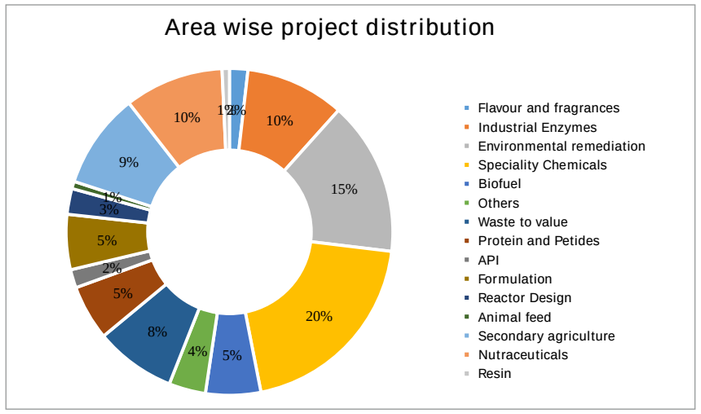


Fig. 2

omega-3 enriched fish oil liquid formulations as emulsion/syrup, supercritical fluid extraction unit for nutraceutical products development are a result of BIRAC's effort to provide adequate funding and mentoring support. Further to promote this area in Northern India, a Network has been supported in Punjab to exploit the resources available at one place. The network in Punjab comprising of 4 partners Punjab State Biotech Corporation (PSBC) along with NABI, CIAB and BioNEST-PU to support food processing industry and promote start-ups in the Agri food sector.

In addition to the PPP programs and collaborative research, several new programs have been initiated to give an impetus to this sector:

- Innovation clean technology - scale up program: A program launched as a part of the 100 days agenda of the Department of Biotechnology under the Swachh Bharat Mission. Few promising technologies in the area of waste management/waste to energy have been taken forward for Scale up/implementation in association with Municipal Corporations/Urban local bodies (ULBs) identified by the companies. Different companies are working to validate the technology in association with municipalities.
- Program on Synthetic biology for development of a bio-based economy: Synthetic biology is in infancy but has enormous capability to promote translational research. Different proposals focussing on development of fragrances, biofuel, nutraceuticals are being monitored for successful concept development.
- Program for guar gum: Program was initiated to promote the use of this marginalized crop in different industrial sectors. Proposals which have been shortlisted focus on biomedical and Industrial applications. They are being mentored and monitored for successful product development
- Department of Biotechnology and BIRAC are working on the development of a Clean Tech Demo Park at the Barapullah Drain site in Delhi. The DBT-BIRAC Clean Tech Demo Park will be used to demonstrate innovative waste-to-value technologies. The park has been inaugurated virtually by Union minister for health and family welfare and earth sciences, Dr Harsh Vardhan in the presence of Delhi Lieutenant Governor Anil Baijal, DBT Secretary Renu Swarup and other officials, scientists and innovators.

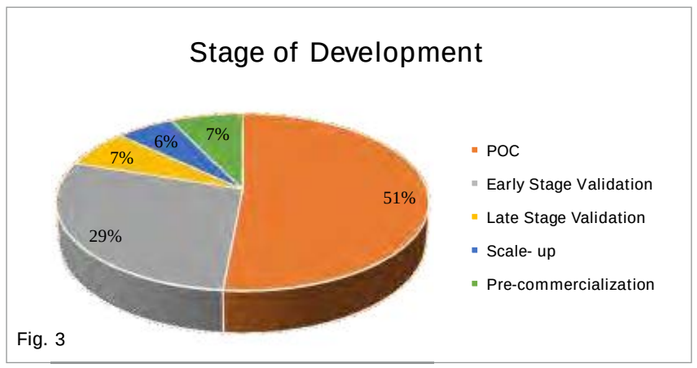


Fig. 3

- For providing translational support, a Clean Energy International Incubation Centre has been established which supports innovative energy technologies. It is a joint initiative of Tata Trusts and Government of India and is supported by DBT, BIRAC, Tata power and Tata Power – DDL. This centre supports innovative energy technologies and mentoring support to the incubatees.
- An Early Translational Centre (ETA) has been established at IIT Madras which focuses on catalyzing transformation of young academic discoveries (publications/ patents) into possible commercially viable ventures and technologies.
- Recently, in the Covid 19 pandemic, a focussed call was also announced for addressing issues related to COVID-19.

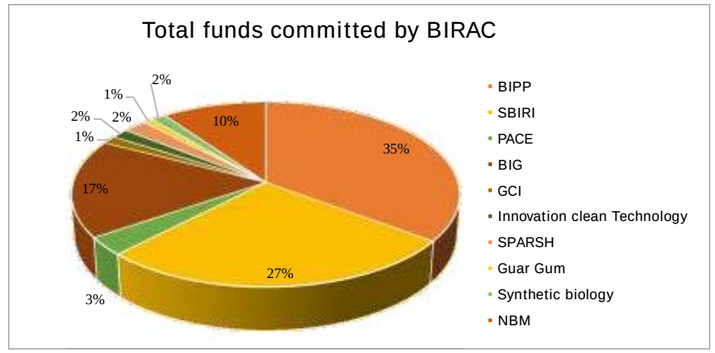
Over the years a number of pilot plants/facilities have also been supported under this sector:

- Pilot scale translational facility for value added chemicals from biomass
- Pilot plant for conversion of methane to single cell protein
- Facility for bulk production of Anaerobic granulated sludge
- Pilot plant for production of lignocellulose ethanol
- Demonstration plant for lignocellulosic ethanol
- pilot-scale Supercritical Fluid Extraction unit for nutraceutical and cosmeceutical products development

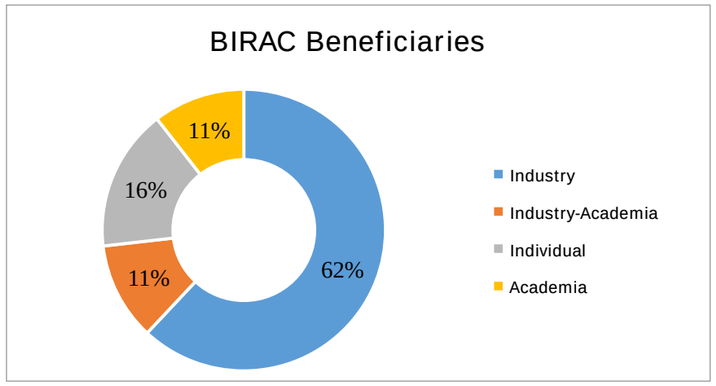
Inspite of all the efforts, challenges such as Investment in early technology development, high cost of setting up the plants, lack of trained manpower and lack of competitiveness of the bio-products compared to "conventional" products still exist. The combination of "technology push" and "market pull" is a very important aspect for promotion of this area. Finally, there is a huge gap between R&D and pre-commercial demonstration and first-of-its-kind production plants which need to be filled if the early stage technologies have to leave a mark.

Nevertheless, some of the grantees in this area have shown remarkable progress and have developed their own production facilities starting their journey from various incubators across the country:

- Aspartika Biotech Pvt Ltd, which was initially incubated, has now established an ISO 9001:2015 & WHO-GMP certified State-of-the Art, Indigenous make Supercritical Fluid Extraction Unit for the extraction of Herbal extracts, Essential oils, Natural colors and Nutraceuticals in Dodballapura Industrial Area, Bangalore through BIPP support.
- String Bio Pvt Ltd, which was initially incubated at Bangalore Bioinnovation Center has set-up a Manufacturing Unit at Nagasandra, Bangalore through BIPP support
- Recently Kbcols Sciences Pvt Ltd., company involved in the production of microbial colorants, inaugurated their new state of the art R&D/pilot facility in 2000 sq.ft. at Bhosari, Pune
- REVY Environmental Solutions Pvt. Ltd. has erected a 20 m3 Pilot UASB Plant and has commissioned it for mass production of Anaerobic Granulated Sludge. Granulated Sludge can be used as a solution for easy start-up as well as help to resolve the washout-associated and shock load related problems of anaerobic digestion



- Another incubatee company Algal R Nutrapharms Pvt Ltd has now its own in-house R&D recognized by Department of Scientific and Industrial Research, Govt. of India and is now capable of supplying 25 MT of DHA and 10 MT of EPA per annum.
- Fermentech GSV Pvt Ltd has set up a bio-processing facility comprising of 500 L working volume bio-reactors, their seed fermenters, Tangential flow filtration systems for purification of enzymes, proteins and vacuum dryers.



Time to time the grantees have received Special recognitions/awards outside BIRAC grant which further highlights the achievements of this sector. Few examples are:

- M/s Mallipathra Nutraceutical Pvt Ltd., was selected as Successful Super Achiever Award by DMA (Delhi Management Association) under All India Women Entrepreneurs Award 2020 which was scheduled on 20th February 2020 at Park Hotel, New Delhi.
- M/s REVY Environmental Solutions Pvt. Ltd. entered Grand Finale of FLCTD Accelerator pitching event organised by Sangam Ventures and UNIDO in January 2021 and were pronounced as 1st runner up in the that event
- Aspartika Bitoech Pvt Ltd won Emerging Star of the Year Award, Bangalore Chamber of Industry and Commerce, January 2021
- KbCols Sciences Pvt Ltd. has raised seed round of investment in July 2020 led by Chiratae Ventures (Formerly IDG India) and co-participation by Axilor & Derbi Foundation.
- At Lakmé Fashion Week's Sustainable Fashion Day (February 2020), Kanpur Flowercycling Pvt Ltd was presented with PETA India's Best Innovation in Vegan Fashion Award for its product Fleather, a biodegradable animal-free leather made from discarded temple flowers, which would otherwise end up in the Ganges

Analysis

- The area seems to be catching the interest of the entrepreneurs as maximum number of projects are being funded under the BIG scheme. However, the maximum funding is being allocated to the BIPP projects considering the scale of operation.
- Speciality chemicals still continue to be the most funded area followed by projects focussing on environmental remediation.
- A technology matrix for all the projects shows that maximum projects and funds continue to be sanctioned for the development of proof of concept and followed by early stage validation projects.
- Collaborative projects continue to be low showing that translation of concepts developed at academic institutes still need more effort.
- The way forward is to integrate people, planet and profit so that sustainability could be attained and environment could benefitted.

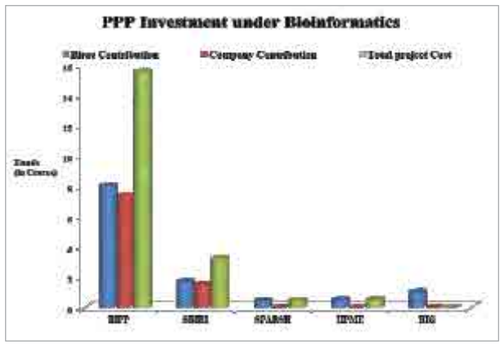
COVID-19

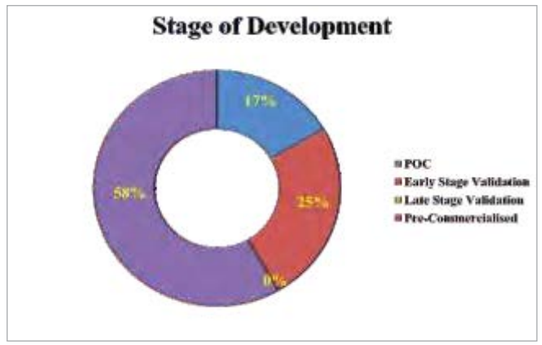
Recently, in the Covid 19 pandemic, efforts were made for creating an innovation ecosystem for a quicker response to this Pandemic. DBT-BIRAC joint calls were announced and funds were given to many start ups and companies for developing sanitizers, face masks, surface coatings, affordable coveralls and gowns. Proposals were also invited for Cost effective production technologies for (microbial route) API needed for treatment of COVID 19 and associated complications

THEME WISE ASSESSMENT

Artificial intelligence, Big Data Analysis, IoT's, software development & Bioinformatics

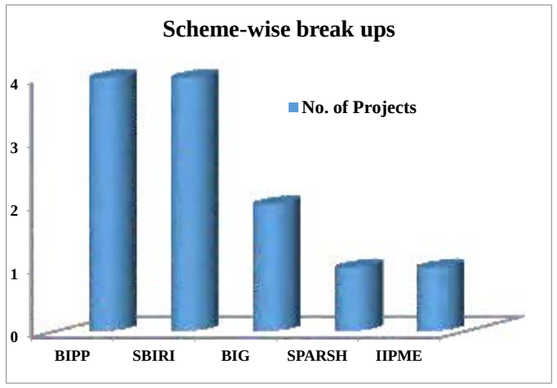
India has achieved remarkable success particularly in the software industry. Over the past decade, the bioinformatics market has significantly evolved across the globe owing to increasing application of genomics in biotech and pharmaceutical research & development. This growth in the global bioinformatics market has positive implications for the Bio-IT industry. The spectacular rise of the commercial Indian genomics industry and the broadening application of genomic techniques in biology and medicine have created a commercial market for Translational bioinformatics. Bioinformatics is growing as an independent discipline and is fundamental to the growth of biotechnology. Bioinformatics is one of the fastest-expanding fields in India's biotechnology sector today and BIRAC is encouraging and focussing on the translational bioinformatics driven projects. Some of the examples of the same are as follows

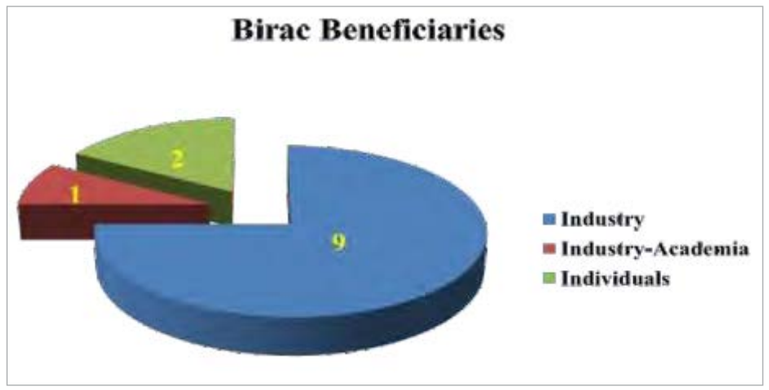




Various technologies developed by BIRAC support:

- In-Silico hepatotoxicity prediction platform to conduct toxicity studies of lead compounds.
- SanGenix named comprehensive NGS data analysis suite that offers a scalable and user friendly solution with predefined or custom workflows for seamless analysis of NGS data. Product is available on (http://www.sangenix.com/Products.html)
- High computing infrastructure set up for NGS data Analysis with more than 16 NGS pipelines & providing 25% discount price to the Indian academics and institutions. Services are available on (http://www.scigenom.com/bipp)
- A kit for the detection of onco mutation for more than 10 type of cancers & computational pipelines for the analysis of NGS data. A NGS based gene panel for the diagnosis of cancer has been developed.
- A system to track and monitor real-time patient data & predict future disease by using big data analysis on cloud through machine learning methods.
- A machine learning based software for the detection of diabetes retinopathy is developed and validated. Software (icheck) has been launched. Currently software has been launched with new Name- ChironEye
- Intelligent health care kiosk for immediate simple healthcare for simple common symptoms is under pipeline. An artificial intelligence based software for the health care kiosk. This medical kiosk will diagnose the vital symptoms and will provide e-prescription and also dispense the drugs.
- A software for improving auditory perception and speech performance of hearing impaired children and adults using their visual cortex.
- A software for improving auditory perception and speech performance of hearing impaired children and adults using their visual cortex
- An integrated immunoassay device for community screening.





Analysis:

- 66% funds are disbursed through BIPP for bioinformatics sector.
- 55% projects have been successfully reached to pre-commercialized stage. Some of the projects are at early and late stage validation.
- Few of the projects from the area involved Industry-academia collaborations though many are pursued by industry alone.
- Artificial intelligence based call has attracted interest among bioinformatics which would be an upcoming field in this thematic area. BIRAC has funded few projects last year in the area of AI.

THEME WISE ASSESSMENT

INNOVATION PROFILES

HEALTHCARE THERAPEUTICS

Ahammune Biosciences Pvt. Ltd.

Title of the Proposal:
Pre-clinical studies of AB1001, a novel drug candidate for debilitating skin disorder, Vitiligo

Brief description:
Ahammune has developed a new drug candidate AB1001, which is a disruptive product that locally restores skin homeostasis and stops vitiligo progression. AB1001 is a topical product that is very safe and effective when applied to animal models for the disease.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Ahammun's new drug candidate specifically targets relevant mechanisms underlying vitiligo pathophysiology and is very safe and effective.

Market Potential:
Vitiligo is a chronic disorder with unpredictable recurrent episodes of trigger and global prevalence of about 1-2 percent. Vitiligo is currently an unattended market and there is tremendous need for a new drug and a huge market potential of over $2.4 billion by 2024.

National/Societal relevance:
The burden of Vitiligo is huge in India, with certain regions like Gujarat having an estimated 8 of population being affected. The fact that depigmentation is more apparent on darker skin tone and the social stigma associated in culture makes vitiligo of extreme relevance to the Indian society. The problem is equally large in other countries, with the disease affecting both personal and professional lives of patients globally as they have to live with the trauma throughout their lives.

Project achievements:

a. **Progress vis-a vis objectives:** Ahammune has submitted an IND application with CDSCO for performing first-in human trials with AB1001.

b. **Technology/Product (to be) developed:** Small molecule as a potential new treatment for vitiligo for which we have filed an IND application with CDSCO for conducting first-in human trials

c. **IP generated/ Potential for IP generation:** Ahammune has filed a patent application for its innovative solution for vitiligo treatment.

d. **Resources Generated:** The Company has recruited research scientist in the biology and chemistry division and is in talks with investors for raising funds to further the R&D efforts.

Plans to take innovation further:
Ahammune will be seeking monetization strategies post Phase II clinical trials with AB1001, including global licensing, regional licensing and/or doing Phase III followed by manufacturing and marketing.

Risks envisaged:
Direct translation of pre-clinical data to humans is a challenging task as it is difficult to predict how a drug will interact with human body. This is particularly true with oral/injectable route of administration. However, being topical application, the probability of AB1001 to have side effects in humans is low.

Project Coordinator:
Parul Ganju

Team Members :
Sudhanand Prasad, Mahesh Kumar Verma, Vinodita Phatak

Contact :
300 NCL Innovation Park
Pashan Pune MAHARASHTRA
India-411008

Aman Aggarwal

Title of the Proposal:
A novel in-vivo drug pre-screening platform for neurodegenerative diseases

Brief description:
To establish an in-vivo drug screening platform for degenerative diseases including neurodegenerative and muscular disorders. This platform should be able to decrease the cost and increase the efficacy of drug discovery, leading to a better probability of technical success for the lead molecules.

Current stage of development:
Validation

Innovative Element(s):
An affordable in-vivo drug screening platform with lower turnaround time and in line with latest CPCSEA guidelines for 3Rs

Market Potential:
This technology is a Make in India platform which would reduce the time and cost in drug discovery process. Thus, this technology has the potential to be utilised globally by various pharmaceutical companies and academic labs.

National/Societal relevance:
Over 30 million people in India suffer from various forms of neurological diseases. This platform can make the drug discovery process more affordable and faster, this could bring down the cost and time involved for the same.

Project achievements:

a. **Progress vis-a vis objectives:** to establish an in-vivo drug screening platform for degenerative diseases

b. **Technology/Product (to be) developed:** A quicker and more affordable in-vivo drug screening platform will be established in next 24 months.

c. **IP generated/ Potential for IP generation:** They plan to work in close collaboration with strategic industrial and academic partners to develop drugs with shared IP

d. **Resources Generated:** Current team consists of 5 members and are now collaborating with NCBS for drug discovery in Parkinson's disease. They plan to register our start-up as well.

Plans to take innovation further:
Strategic partnerships with industrial and academic partners are being developed to extend the platform to be used for drug discovery for diseases other than degenerative diseases.

Risks envisaged:
Drosophila is an invertebrate model system. The neurons in Drosophila are not myelinated, hence can respond differently to the drugs as compared to the mammalian model systems.

Project Coordinator:
Aman Aggarwal

Team Members :
Kuldeep Sachdeva, Konkona Dutta, Ashmita Kumari

Contact :
National Centre for Biological Sciences GKVK Campus Bellary Road Bengaluru 560065

Bharat Biotech International Ltd.

Title of the Proposal:
A Novel Vaccine for Chikungunya Virus Infection

Brief description:
The candidate Chikungunya virus CHIKV vaccine, BBV87, is an inactivated whole virion vaccine developed using the strain CHIK/03/06 derived from an Indian 2006 isolate of the East, Central, South African ECSA genotype and grown on Vero cells. The vaccine is formulated with 0.25 mg of aluminum hydroxide and administered intramuscularly in a volume of 0.5 mL / dose. Extensive pre-clinical studies and phase I clinical trials attest to the safety and immunogenicity of the candidate vaccine.

Current stage of development:
Validation

Innovative Element(s) :
Although developed using time tested inactivated vaccine platform technology, product development was fine tuned to optimally preserve the virus epitopes for enhanced immunogenicity with added safety of any killed virus vaccine.

Market Potential:
First to licensure in India and in three other countries when clinical trials are planned, could help India secure leadership in this segment. Post-licensure, BBIL will consider other markets for exports. WHO prequalification for procurement for Gavi/ UNICEF markets is one of the key objectives of CEPI funded Global Chikungunya Clinical Development Program.

National/Societal relevance:
CHIKV is an alphavirus affecting humans that could cause mild arthralgia to chronic arthritic conditions in some that can persist for months or years. Since 2004, CHIKV has caused millions of cases of disease in the Indian Ocean islands and in the Indian subcontinent, and has emerged in non-endemic areas, including Europe and the Americas.

Project achievements:

a. **Progress vis-a vis objectives:** BBIL is awaiting NOC from DCGI after SEC recommended clinical phase II/III protocol for trials in India. Clinical batches have been certified for batch release by CDL, Kasauli.

b. **Technology/Product (to be) developed:** The vaccine will be advanced shortly into phase II clinical trials in India and three other CHIKV endemic countries.

c. **IP generated/ Potential for IP generation:** BBIL has secured two pioneering patents on development of CHIKV vaccine, which has been granted in more than 20 countries including India, USA and China.

d. **Resources Generated:** While existing manufacturing facilities have been used, the key resource generated is manpower who are trained in novel vaccine product development and in aligning clinical trials across four countries. This is the invaluable resource created in the Company because of the CHIKV vaccine projects. Expertise obtained from the Scientific Advisory Committee of NBM, BIRAC and from CEPI have been invaluable in fine tuning product development and in synchronizing clinical trials across different countries. CHIKV vaccine project is a fine example of multi-institutional cooperation in vaccine development.

Plans to take innovation further:
BBIL has secured CEPI funding that is administered through the IndCEPI program of BIRAC. Comprehensive BIRAC funding will help align the diverse objectives of different programs for wider reach of the vaccine.

Risks envisaged:
As CHIKV does not cause life threatening disease, one of the major risks perceived is vaccine hesitancy that can be expected particularly in large scale immunization in the non-epidemic periods.

Project Coordinator:
Sumathy Kandaswamy

Team Members :
Vijay Dharam, Kiran Kumar, Harsh Jogdand, Rajeshri Manikyam, Siddharth Reddy, Kusuma Rosers, Kiran Kumar

Contact :
Genome Valley Shameerpet
Turkapally Hyderabad
TELANGANA India-500078

Bharat Immunological and Biological Corporation Ltd.

Collaborator Name: Translational Health Science and Technology Institute (THSTI)

Title of the Proposal:

Production of safe and effective oral cholera vaccine of global GMP standards in India through Industry Academia partnership to meet Indias supply needs

Brief description:
The technology has been sourced from International Vaccine Institute Korea which is a proven technology, as has been successfully transferred to many institutions. The product oral cholera vaccine based on this technology has been licensed and WHO pre qualified for procurement by UNICEF

Current stage of development:
Discovery

Innovative Element(s):
The project is for setting up of GMP facility for production of oral cholera vaccine in the country for prevention of cholera in Indian population. Currently only one manufacturer is manufacturing the product and the capacity is low and has commitment to supply to UNICEF.

Market Potential:
The product is likely to be included in the National Immunization Program and this will increase the demand for the product and BIBCOL will be first to manufacture and supply to the needs of the country.

National/Societal relevance:
There are huge cholera cases in the country and introduction of cholera vaccine shall be instrumental in prevention of the cases and thus save human lives and treatment cost due to hospitalization.

Project achievements:

a. **Progress vis-a vis objectives:** The R&D scale facility is ready and the trail to begin in the March 2021 and thus shall meet the objectives and timelines

b. **Technology/Product (to be) developed:** The product shall be manufactured in GMP facility and licensed in the FY 2022-23

c. **IP generated/ Potential for IP generation :** The in house R&D lab shall be used for achieving higher yield and thus the process can be patented

d. **Resources Generated:** At current level 10 scientists have been recruited and are being trained in bacterial vaccine production and testing. The pilot scale shall employ additional 20 to 30 people and thus generate huge employment to local and educated youth.

Plans to take innovation further:
After production at R&D scale the pilot scale facility under GMP condition is being set up for licensing and commercialization of vaccine in the Indian Market

Risks envisaged:
The risk is minimal as technology is proven and licensed. Any delay in inclusion in National Immunization Program shall delay in achieving commercial potential.

Project Coordinator:
S. A. Ansari

Team Members :
Arup Banerjee, Arup Banerjee, C B Benjwal, Amit Kumar, R K Shukla, S K Singh, Ankit Gupta

Contact :
Village Chola Bulandshahr
UTTAR PRADESH India-203203

Biological E Ltd.

Title of the Proposal:
To develop a safe, immunogenic & stable vaccine for all populations against the novel coronavirus COVID-19 which is affordable and accessible for all countries.

Brief description:
The antigen derived from the Receptor Binding Domain RBD of the Spike Protein S on the surface of SARS-CoV-2 used as a vaccine candidate. Bio E has employed classical, proven vaccine technology by formulating purified protein RBD with known adjuvants Alum and CpG .

The RBD of S1 subunit binds to the Angiotensin Converting Enzyme-2 i.e. ACE2 receptor on host cell membrane and facilitates virus entry. RBD protein expression is in yeast Pichia pastoris. Phase I/II study enrolments are completed for all 4 cohorts 3 DSMBs for Phase I safety study are completed serology IgG & nAb assays ongoing.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Bio E's COVID-19 vaccine on classical vaccine technology of a protein antigen, RBD, adsorbed to adjuvant Alum with another approved adjuvant CpG1018, elicited a highly synergistic, balanced immune response in the mouse model. Usage of two co-adjuvants including Alhydrogel and CpG1018 is the novel and innovative approach in this vaccine design!

Market Potential:
Global vaccine demand depends on how long immunity lasts, the effectiveness of the vaccine & the number of doses per vaccine course. As per UNICEF estimation Yr-2021 Global annual demand will be 5.4 billion, for high risk group, by end of 2022 the Global annual demand will be 15.8 billion.

National/Societal relevance:
To be a part of Atmanirbhar Bharat Abhiyaan or Self-reliant India campaign the vision of new India, Bio E developed its adjuvanted RBD platform COVID-19 vaccine and currently it is in Phase II Clinical Trial. The current vaccine can be available as per routine immunization program and no special training required for immunization staff. Further, as the technology is highly scalable Bio E is aiming to produce 1 billion doses per annum and supply at affordable cost.

Project achievements:

a. **Progress vis-a vis objectives:** Objective 1: Receiving P. pastoris strains from MIT & BCM - Completed

   Objective 2: Pre-clinical toxicology PCT study completion - Completed

   Objective 3: Clinical material manufacturing & clinical studies - Completed

b. **Technology/Product (to be) developed:** The RBD of the S1 subunit binds to ACE2 receptor on host cell. Recombinant RBD, glycosylated & non-glycosylated, elicits neutralizing antibodies linked to protective immunity enhanced by various adjuvant systems.

c. **IP generated/ Potential for IP generation:** NA

d. **Resources Generated:** BioE's Covid-19 program and expansion initiatives in Genome Valley is in advance stage, additional employment opportunity for around 1,000 people is in progress

Plans to take innovation further:
The vaccine is licensed from Baylor College of Medicine. BioE has raised funding from BMGF, CEPI and BIRAC for development & clinical trials. They have partnered with Dynavax to procure CpG1018 adjuvant.

Risks envisaged:
Process establishment risk addressed, process established for 3500L. Protocol design and scientific validity risk addressed Review & approval by drug Controller General of India DCGI. Product affordability risk, working to Ensure infrastructure is geared up to manufacture 1 Billion doses of vaccine to make it more affordable for global requirements.

Project Coordinator:
Vikram Paradkar

Team Members :
Martin Reers, Martin Reers, Srinivas Kosaraju, Subhash Thuluva, Sairam Mustoori, Manish kumar, Eswar Reddy K

Contact :
18/1 & 3, Azamabad
HYDERABAD TELANGANA
India-500020

Cadila Healthcare Ltd.

Title of the Proposal:
Multivalenet Leishmania Vaccine Development

Brief description:
Leishmaniasis was declared as one of the world's most neglected diseases at the 60th WHO Assembly 2007. Leishmaniasis can be manifested as a wide range of clinical etiologies including visceral, mucocutaneous, diffuse, and cutaneous leishmaniasis CL . Visceral leishmanasis VL, the most severe form of the disease, can be fatal if left untreated. To date there is no effective vaccine against human leishmaniasis. Several attempts to develop candidate vaccines against leishmaniasis were inconclusive or gave negative results, and very few candidates progressed beyond the experimental phase in model animals. They believe that the natural infection cycle of Leishmania should be taken into account in order to generate a vaccine with the potential to efficiently block vector transmission and infection of the human host. Hence, approach is based on the use of a protein LJL143 present in the sand fly saliva, together with two other Leishmania antigens : Kinetoplastid membrane protein-11 KMP-11 and VID 105 mixed with Virosomal formulation to prepare trivalent Leishmania Vaccine.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Vaccine is likely to establish two lines of protection against natural infection with Leishmania. Additionally, because recombinant proteins alone, as well as peptides, generally induce only weak T cell responses, to facilitate antigen-presentation to immune cells and, therefore, to enhance the immunological response against the target antigens, recombinant proteins are formulated using viral antigen based on the proven Virosome technology.

Market Potential:
The Leishmania disease burden in India and abroad has been reduced in recent time. It is difficult to predict the market potential as no market shaping done due to non availability of Leishmania Vaccine.

National/Societal relevance:
Since Leishmaniasis is a neglected disease ,a vaccine developed against this may have social and national relevance particularly for poor nations.

Project achievements:

a. **Progress vis-a vis objectives:** All objectives of the project has been completed successfully

b. **Technology/Product (to be) developed :** Proof of concept studies have been completed

c. **IP generated/ Potential for IP generation:** NA

d. **Resources Generated:** NA

Plans to take innovation further:
Proof of Concept has been established for this project and no further activities have been planned in the project

Risks envisaged:
Proof of Concept has been established for this project.

Project Coordinator:
Vinay Kumar

Team Members :
Vinay Kumar, Puneet Gupta, Ankita Arora; Suman, Atul Singh, Anurag, Ankit

Contact :
Zydus Biotech Park Opp Ramdev Masala, Sarkhej-Bavla, N.H 8A
Changodar Ahmedabad GUJARAT
India-382213

Cadila Healthcare Ltd.

Title Of The Proposal:
Development of DNA Vaccine against novel Coronavirus SARS-CoV-2

Broad Area:
Vaccines

Brief Description:
Cadila Healthcare developed DNA vaccine candidate ZyCoV-D, comprising of a DNA plasmid vector carrying the gene encoding the spike S protein of the SARS-CoV-2 virus. Once the plasmid construct with S gene is injected in human it will enter host cell, and using the host cell's metabolic machinery, it expresses the Spike protein in the body and induces humoral immune response along with cellular immune response, which is vital in viral clearance and offer protection from COVID-19. The vaccine has successfully completed, Phase I/II clinical study demonstrating good safety and immunogenicity. The vaccine has entered into phase-3 clinical trial for evaluating efficacy in Indian population.

Current Stage of Development
Validation

Innovative Element(s)
1. Non-replicating and non-integrating plasmid carrying the gene of interest making it very safe
2. No vector response
3. Absence of any infectious agent.
4. Improved vaccine stability and lower cold chain requirements.
5. Easley scalable to large scale production.
6. Adaptability of technology to rapidly move to new vaccine design in case of antigenic drift.

Market Potential (with India & abroad):
Considering global pandemic situation, the vaccine has huge market potential for mass immunization in India and abroad.

National/Societal Relevance:
Zydus Covid-19 vaccine has advantage of being stable at room temperature for short time and in common refrigerator for long time. Due to robust stability, it will ease out vaccine distribution in Indian climatic conditions and can be transported easily to remote part of country.

Project Achievements:
a. **Progress vis-a vis objectives:** All the objective assigned in the project have been completed successfully.

b. **Technology/Product (to be) developed:** The ZyCoV-D vaccine is currently in Phase III clinical trial stage. We intend to enter the market by 2Q 2021

c. **IP generated/ Potential for IP generation:** Not Applicable

d. **Resources Generated:** Not Applicable

Plans to take innovation further:
They are evaluating various options of scaling up the manufacturing through partnership in India and abroad and also looking for Technology transfer of the product.

Risks Envisaged:
Phase III Clinical trial is in progress and data is awaited

Project Coordinator:
Kapil Maithal

Team Members :
Sanjeev Kumar, Arun Singh, Ravindra Mittal, Sanjay Bandyopadhyay, Harish Chandra, Ayan Dey

Contact :
Zydus Biotech Park Opp Ramdev Masala, Sarkhej-Bavla, N.H 8A Changodar Ahmedabad GUJARAT India-382213

CSIR-National Chemical Laboratory, Pune

Title of the Proposal:
CHO cell engineering for modulating N-glycosylation in recombinant proteins

Brief description:
The proposal aims to enable modulation of glycosylation of recombinant glycoproteins. They are working on genetically engineering a recombinant CHO cell line to test the ability of the modified cell line to predictably target N-glycosylation profiles of overexpressed recombinant proteins such as antibodies. For this, they propose to use a novel strategy of combinatorial knock-out of enzymes involved in glycosylation using the CRISPR/Cas9 method.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Current approaches mostly use empirical evaluation of medium supplementation strategies to modulate glycosylation. Genetic engineering strategies mostly allow a binary outcome, e.g. complete loss of fucosylation by deleting genes involved in fucosylation. With this strategy, they are exploring the ability to predictable achieve desired glycoform.

Market Potential:
Glycoproteins including monoclonal antibodies (Mab) form a large part of the biopharmaceutical therapeutics in the market and under development. Glycoform of the expressed antibody can affect its efficacy so successful modulation of glycosylation is expected to be of high commercial importance.

National/Societal relevance:
Monoclonal antibodies form a large part of the biosimilar drugs being manufactured, and expected to be manufactured, in India. Manufacturers of such biogeneric drugs need to establish similarity of the MAb to the innovator molecule, which includes similarity to the target glycoform profile of the innovator.

Project achievements:
a. **Progress vis-a vis objectives:** Started

b. **Technology/Product (to be) developed:** Proof-of-concept (PoC) on the ability to genetically engineer CHO cells to predictably modulate glycosylation profile

g. **IP generated/ Potential for IP generation:** No IP generated yet

Resources Generated:
2 Post-doctoral research associates are currently employed.

Plans to take innovation further:
Will depend on the outcome of the project

Risks envisaged:
None at present, as this is a PoC study

Project Coordinator:
Mugdha Gadgil

Team Members :
Dhanasekaran Shanmugam

Contact :
Dr. Homi Bhabha Road Polyolefin lab Pashan Pune MAHARASHTRA India-411008

C N Ramchand

Title of the Proposal:
Development and Pre-clinical Evaluation of a Novel Anti-VEGF Biologic molecule to treat Diabetic Retinopathy

Brief description:
A novel anti VEGF Fab molecule has been developed towards the treatment of Diabetic Retinopathy. The molecule has unique aminoacid sequence capable of binding with VEGF isoforms. The product is developed using a high throughput phage display platform followed by Site directed mutagenesis.

Current stage of development:
Validation

Innovative Element(s):
The unique characteristics of the molecule includes significantly lower size due to higher hydrophobicity, better affinity because of differential epitope binding as compared to competitor drugs and commendable stability at 25 and 37 degrees.

Market Potential :
The current drugs exhibit disadvantages including side effects, higher non responders, being not readily available and affordable. The molecule having unique characteristics could be produced with lesser production cost and could reach common man at affordable cost of around U$100 as compared to U$400 for existing drugs in market.

National/Societal relevance: India is set to emerge as the Diabetic capital of the world. According to the WHO, 31.7 million people were affected by diabetes mellitus DM in India in the year 2000. This figure is estimated to rise to 79.4 million by 2030. Almost two-thirds of all Type 2 and almost all Type 1 diabetics are expected to develop diabetic retinopathy. Diabetic Retinopathy is one of the foremost frequent causes of blindness worldwide.

Project achievements:

a. **Progress vis-a vis objectives:** Non GLP in-vivo studies are ongoing. Biochemical, biophysical characterization, Analytical Method Development and Validation, cell-based assays, consistent batch generation are to be initiated.

b. **Technology/Product (to be) developed:** The product is a novel Anti-VEGF biologic drug.

c. **IP generated/ Potential for IP generation:** The molecule having the unique sequence has been protected.

d. **Resources Generated:** Employed manpower including doctorates and postgraduates and experienced team of scientists, Infrastructure has been developed including 50 L fermenters, associated utilities, Homogenizers and AKTA systems

Plans to take innovation further:
Potential biopharmaceutical companies would be approached for out licensing the molecule for subsequent Clinical Studies.

Risks envisaged:
a. Unexpected outcomes in Phase 1 CT is the main risk in the study.

b. Challenges exist during regulatory approvals with RCGM and CDSCO

Project Coordinator:
C N Ramchand

Team Members :
Ravikant Harit, Sreepriya, Merlin, Rajkumar Paul, Gokuul Thyagarajan, Ankit, Udayabhanu, Dr Shakambari

Contact :
2nd floor, R.K.Electro Biotechnologies Research Centre, No.153, 1st Main Road, Industrial Estate, Perungudi Perungudi Chennai TAMIL NADU India-600096

Datt Mediproducts Pvt. Ltd.

Title of the Proposal:
A study for safety and efficacy of VELGRAFT containing Human Bone marrow derived Mesenchymal Stem Cell and Mesenchymal stem cell differentiated adipocytes as a skin substitute on wounds of Diabetic Foot Ulcers

Brief description:
VELGRAFT is ready to use biodegradable and biocompatible artificial skin substitute that incorporates the use of biopolymers and mesenchymal stem cells MSCs for rapid and scar free wound healing in case of burn injuries, diabetic foot ulcers and deep wound.

Current stage of development:
Validation

Innovative Element(s):
The unique innovative aspects of VELGRAFT technology relies on the combination of Human Bone Marrow derived Mesenchymal Stem Cells BM-MSCs and BM-MSCs differentiated adipocytes embedded in a biodegradable and biocompatible matrix made up of gelatin and chitosan.

Market Potential:
Increasing prevalence of chronic diseases such as diabetes and obesity, rise in geriatric population, technological advancements and problems associated with traditional wound healing methods fuel the growth of advance wound care product.

National/Societal relevance:
In a developing countries awareness and availability of these skin substitutes is not adequate considering the volume of cases that require this modality of treatment and cost of their use may be much higher. Considering all these facts and challenges, the proposed technology aims to bridge the gap between the conventional management of acute and chronic wounds through development of bioengineered skin substitute Velgraft.

Project achievements:

a. **Progress vis-a vis objectives:** The Dossier has been submitted to DCGI office, Trial sites have been identified and Principle Investigator has been already assigned to these sites. Clinical trial agreement has been signed and budget of each site has been allotted and finalized.

b. **Technology/Product (to be) developed:** Technology has already been developed and Initiation of Clinical trials for safety and efficacy studies is in process

c. **IP generated/ Potential for IP generation:** Three US patents have been granted for Velgraft technology in the year 2018. Besides, Velgraft patent has also been filed in Indian, European and Israel.

d. **Resources Generated:** Two manpower has been under this project

Plans to take innovation further:
Application has been submitted to CDSCO for approval of Phase I & Phase II clinical trials. Clinical Studies have been initiated in USA with Ayu Incorporation, Paraxel & CBCC. Currently, in process of initiating Velgraft clinical trials in European continent particularly in Ireland.

Risks envisaged:
Lengthy developmental timelines and Navigating the regulatory environment

Project Coordinator:
Siddharth Pandey

Team Members :
Pankaj Bablani, Poonam Meena, Anupama Kakkar

Contact :
56, community center, East of Kailash, New Delhi

Enzene Biosciences Ltd.

Title of the Proposal:
Clone Development for Biosimilar Ramucirumab

Brief description:
Enzene has developed a novel cloning platform and a fully connected continuous process to have a very high product yield per batch. This technology is being tried for development of biosimilar Ramucirumab. The continuous process allows them to make a kilogram of protein per batch with a reduced footprint area, leading to make product at a very cheap rate.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Cloning platform and a fully connected continuous process

Market Potential:
Ramucirumab is used for treatment of digestive system cancers. The current therapy cost is approximately INR19,00,000 per patients. Making Ramucirumab with Enzene technology the product cost reduced at least 50 percent cost to INR 10,00,000 per patient.

National/Societal relevance:
As per Cancer statistics, the incidence reported in the year 2020 was approximately 3,00,000 which is 1 in 39 patients get affected with digestive system cancer. Patients in India cannot afford a therapy at a cost of INR 19,00,000 hence, affordable and safe medicine is not accessible. Enzene technology will allow making this therapy cost effective so that a larger population can be treated.

Project achievements:

a. **Progress vis-a vis objectives:** Clone development completed. Analytical and bioanalytical methods developed. Process development started

b. **Technology/Product (to be) developed:** The process consistency shall be established by Feb 2022 and the expected product commercialization is planned for Q2 2026

c. **IP generated/ Potential for IP generation:** IP from the cloning platform establishment is expected

d. **Resources Generated:** Enhanced their capabilities of screening clones and media at shake flask level by including additional CO2 incubator shaker. The cell analysis is being under establishment using flow cytometer purchased through this grant. The employees deputed for this project got trained in the molecular biology, cell line engineering, process science and analytical science techniques at industrial level.

Plans to take innovation further:
After the establishment of process consistency, would be requiring funding support from BIRAC to continue clinical trial development to fasten the product development.

Risks envisaged:
The price competition from the innovator company.

Project Coordinator:
Hatim Motiwala

Team Members :
Arindam Chakraborty, Abijar Bhori, Shilpa Gadgil, Veerendra Reddy, Harish Shandilya

Contact :
Plot No 165-1-26 Block T Bhosari MIDC Bhosari Pune, Maharashtra, India-411026.

Foundation for Neglected Disease Research

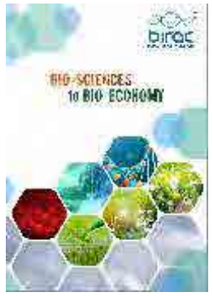
Title of the Proposal:
Development of novel quinolines for the treatment of tuberculosis

Brief description:
Despite the availability of potent drugs that can kill the causative agent of TB , 16 per cent of the people diagnosed with TB died in 2017 [Global tuberculosis report 2018, WHO]. Among the major challenges in treating TB is the emergence of antimicrobial resistance [AMR] and the long duration of the treatment. The AMR strains make it impossible to treat TB with approved drugs and long treatment duration results in extensive lung damage in the patients before complete eradication of the pathogen. Therefore, new drugs with a novel mechanism of action can help fight AMR and shorten the treatment duration. FNDR has identified a novel hit-series which exhibits excellent in vitro activity on lab strains and drug-resistant clinical isolates of Mtb and in vivo efficacy.

Current stage of development:
Discovery

Innovative Element(s):
The FNDR-20081-series works by a mechanism distinct form from first-line TB drug as evidenced by its activity on drug resistant clinical isolates. The growth inhibition activity for rifampicin-, isoniazid, kanamycin-, moxifloxacin and d-cycloserine resistant strains are similar to that for sensitive strains. They have also ruled out that FNDR-20081 targets decaprenylphosphoryl-B-D-ribose 2-epimerase [DprE1]. DprE1, is the target of many TB drugs currently in development.

Market Potential:
The total global market size of TB per year is around 1 billion USD attributable relatively large number of incidences and long treatment duration, despite of active efforts of international organizations such as Unitaid, WHO, UNICEF, and TB Alliance to bring the TB therapy affordable [Tuberculosis market research report].



National/Societal relevance:
Huge social relevance

Project achievements:

a. **Progress vis-a vis objectives:** Synthesis of lead candidates- 55 candidates have been synthesized so far out of 60. Evaluation of the lead candidates synthesized- Ongoing

In vivo efficacy testing in mouse model of TB- yet to achieve

b. **Technology/Product (to be) developed:** Lead drug candidate for tuberculosis from the novel quinoline series. Since the project is in the discovery phase, it will take a few years to enter the market.

c. **IP generated/ Potential for IP generation:** In process of filling a patent.

d. **Resources Generated - Manpower employed:** 3 (1 RA1 and 1 SRF through applicant's contribution and 1 RA1 through SIBRI contribution)

Plans to take innovation further:
plan is to develop a lead drug candidate, funds for further development will be requested through grants along with any foreseeable partnership opportunities.

Risks envisaged:
They may not get any candidate with the desired target product profile by the end of the study. The mitigation strategy is the best candidate FNDR-20081 will be developed further to be used in a combinational regimen to treat drug resistant TB and shorten the duration of TB.

Project Coordinator:
Shridhar Narayanan

Team Members :
Chandra Sekhar G, Siva Shanmugham, C N Naveen

Contact :
Sir M. Visvesvaraya Institute of Technology, Bengaluru KARNATAKA India-562157

GeNext Genomics Pvt. Ltd.

Title of the Proposal:
Development and Characterization of Golimumab biosimilar clone.

Brief description:
Developed a platform to produce structural and functionally active protein. GNG is developing the clone of Golimumab SIMPONI, currently marketed by Jansen & Jansen and will compare the efficacy with its innovator molecule and identify the best clone for taking it to Biosimilar development. GNG also has antibody library platform from which it is working on several novel targets and discovering efficacious binders. One such binders GNG is working on has neutralizing efficacy in SARS-CoV 2.

Current stage of development:
Discovery

Innovative Element(s):
Methods are employed to get higher yield with a platform expression system.

Market Potential:
Currently Golimumab has the market of $ 1.2 Billion and considering its vast indication, the market is growing. There are two competitor presently for Biosimilar molecule of Golimumab, GNG will be sharing its market from amongst the need and competition.

National/Societal relevance:
Golimumab Biosimilar, made indigenously would not only decrease the cost but will also increase the availability to t e Indian population.

Project achievements:

a. **Progress vis-a vis objectives:** Currently at the stage of high yield clone expansion.

b. **Technology/Product (to be) developed**: Currently at the stage of high yield clone expansion.

c. **IP generated/ Potential for IP generation:** Yet to be

d. **Resources Generated:** Looking for fund mobilization from other sources.

Plans to take innovation further:
Conducting Pre-clinical studies, followed by Out-licensing the Golimumab clone for clinical studies

Risks envisaged:

a. Breach of any license terms & termination of license agreement.
b. Irregularity in procurement.
c. IP conflict regarding use of technology.

Project Coordinator:
Supriya Kashikar

Team Members :
Chinmay Umbarkar, Shriya Sapre, Prachi Tiwari, Akash Nehare,

Contact :
103, Abhyankar Nagar
Nagpur, Maharashtra,
India-440010

Gennova Biopharmaceuticals Ltd.

Title of the Proposal:
Next-generation mRNA vaccine against COVID-19 to provide long-term protection to the population within its national/international territories

Brief description:
Gennovas COVID-19 vaccine candidate - HGCO19, is a novel mRNA-based vaccine, using spike protein of the virus, reported to interact with host cells receptor, and lipid inorganic nanoparticle -LION used as a delivery system that has demonstrated safety, immunogenicity, neutralization antibody activity in the rodent and non-human primate models. Gennovas mRNA vaccine is based on a self-replicating mRNA platform, giving a dose-sparing advantage. This pandemic ready mRNA platform technology offers a rapid development path that will empower the nation to comb future pandemic outbreaks or any mutant form of the SARS-CoV-2 virus.

Current stage of development:
Validation

Innovative Element(s):
HGCO19 uses the most prominent mutant of spike protein D614G. Self-amplifying mRNA platform, which gives the advantage of a low dosing regimen. The mRNA is attached on the surface of the nano-lipid carrier that increases the bioavailability of the mRNA HGCO19 is stable at 2-8Â°C.

Market Potential:
Morgan Stanleys report estimates a $47 billion market for this vaccine for both pandemic and endemic phases. Considering other competitors, Gennova conservatively estimates to gross annual revenue of $8 - $10 billion - 20 of the global market.

National/Societal relevance:
Establishment of mRNA based technology platform. Novel vaccine development can take anywhere between 10 -15 years. Considering the immediate need for a vaccine against COVID 19, the vaccines developmental time must be reduced. mRNA-based vaccines are thus the ideal choice because of their rapid developmental timeline.

This is a first of its kind platform technology can be used for the production of other viral vaccines like influenza, zika, rabies etc.

Project achievements:

a. **Progress vis-a vis objectives:** HGCO19 has demonstrated safety, immunogenicity, neutralization antibody activity in the rodent and non-human primate models. Gennova will soon start the Phase I/II CT, subject to Indian regulatory approvals.

b. **Technology/Product (to be) developed:** After demonstration of correlation of protection from Phase-I/II CT, Gennova might launch the vaccine under emergency use authorization by July 2021, while it conducts Phase-III CT.

c. **IP generated/ Potential for IP generation:** Process and Product patents have either been filed or are in the process of being filed.

d. **Resources Generated:** More than 30 people are involved in developing this novel mRNA based vaccine in Gennovas Process Development Laboratory, PDL. 11 people with various levels of experience have been hired in the last 6 Months for different PDL roles. The PDL has been augmented with new analytical instruments for its QC and equipment for mRNA production and estimation.

Plans to take innovation further:
Gennova is in conversation with various partners from foreign countries exploring commercial agreements to export the vaccine after it caters to the national requirement and subject to Governments approval.

Risks envisaged:
In addition to the competition from other vaccine manufacturers, particularly the mRNA-vaccine producers, a clear understanding of the regulatory and clinical path in various geographical regions poses a barrier to enter different markets. Securing the supply chain of raw materials for vaccine manufacturing could potentially be a challenge to commercialize.

Project Coordinator:
Ajay Singh

Team Members :
Swarnendu Kaviraj, Amit Saraf, Praveen Agarwal, Durgesh Kumar, Arjun Singh Raghuwanshi, Rajesh Kumar Singh, Tathagata Mukherjee

Contact :
I.T.-B.T. Park P1 MIDC,
Hinjwadi Pune MAHARASHTRA
India-411507

HiMedia Laboratories Pvt. Ltd.

Collaborator Name: Institute of Chemical Technology

Title of the Proposal:
Designing & commercialization of affordable chemically defined serum free media & feed for high value Biosimilars manufacture

Brief description:
Because of lack of indigenous media manufacturers, most of the biopharmaceutical companies are forced to import these media components at the astronomical prices which eventually results in high cost of life- saving drug products. There is an urgent need for India to look for alternatives for these expensive media components and come with a suitable commercial solution for the same. A very affordable chemically defined Serum Free Media of incredible quality have been developed for biosimilar manufacture specially Herceptin & Avastin

Current stage of development:
Validation

Innovative Element(s):
1. Only Indian company that manufactures CD-SFM for biosimilars & other therapeutics; 2. Use of Cryomill & ultra-rapid mixer for blending 100s of components to form perfect media blend in a highly soluble & bioavailable form; 3. Granulation using the Roll Compaction Granulator technology for the best distribution of ingredients

Market Potential:
The CHO cell culture SFM market is expected to represent the highest absolute opportunity of US$ 23.8 Mn in 2019 over 2020 @ a CAGR of 7.3 with 19.6 market share in FY 2019-20.

National/Societal relevance:
The rising incidences of cancer and other deadly & debilitating diseases Rheumatoid arthritis, autoimmune diseases, hyper-tension, and diabetes , expensive treatments and the economic status of the society suggests that, e.g. cancer-chemotherapy is not affordable even for the middle class society. Media is one of the key factor contributing to production cost of such products. All these factors necessitate that CD-SFM media as well as indigenously designed mAb and protein producing clones be made available at affordable costs to the industry to tackle this treatment cost and disease burden in India

Project achievements:

a. **Progress vis-a vis objectives:** Media & feed validation of Avastin & Herceptin clone completed, Scale up at 10L bioreactor scale both clones - completed

b. **Technology/Product (to be) developed:** Clone specific serum-free, animal component free, protein free, chemically defined media for production of Herceptin i.e. Trastuzumab and Avastin i.e. Bevacizumab.

c. **IP generated/ Potential for IP generation:** Not applicable

d. **Resources Generated:** Facility: Upstream BioProduction facility Up to 10L Volume established; Manpower: 2 Fermentation technologist recruited

Plans to take innovation further:
NBM has funded further for development of facility for manufacture of CD-SFM for certified and validated commercial clones.

Risks envisaged:
Non-sharing of industrial CHO clones by Indian biopharma; Established brands of SFM already being used for mAb production; Industries are reluctant to switch over to another media; Multiple sampling required for performance validation. Development process delays due to this; multiple raw materials involved & difficult to control their cost

Project Coordinator:
Vishal G. Warke

Team Members :
Priti V. Warke, Ratnesh Jain, Gauri Page, Shraddha Mane, Mausami Bhattacharya, Soni Shukla

Contact :
23 Vadhani Industrial Estate. LBS Marg. Opposite Shreyas Cinema Ghatkopar Mumbai Maharashtra India-400086

Indian Immunologicals Ltd.

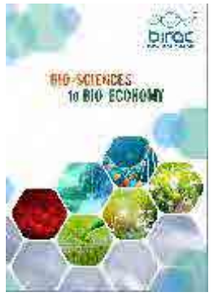
Title of The Proposal:
Live attenuated Tetravalent Dengue Vaccine Development

Brief Description:
Indian Immunologicals Limited has licensed the Live attenuated Dengue vaccine strains for the Serotypes Type1, Type2, Type 3 and Type 4 for the development of Tetravalent Dengue vaccine from NIH, USA. NIH has conducted several clinical trials using the same Live attenuated vaccine strains and found to be safe and elicit balanced immune response against all serotypes Type1, Type 2, Type 3 & Type 4 in over 90 of the vaccines, which is very much important in case of Dengue vaccine. Our Live attenuated vaccine recombinant Dengue Tetravalent Vaccine is a single dose administration by sub-cutaneous route which is more economical as compared to other inactivated / attenuated / sub unit vaccines. It elicits a balanced immune response against all four dengue serotypes. After licensing the strains from NIH, we have successfully optimized the production process in bioreactor and developed a stable freeze dried formulation.

Current Stage of Development:
Discovery

Innovative Element(s):
Successfully scaled up the process in bioreactor for production of DS for all the four serotypes. Developed a stable freeze dried vaccine formulation

Market Potential:
The incidence of dengue has grown dramatically around the world in recent decades. An estimated 3.9 billion people, in 128 countries, are at risk of infection with dengue viruses. Currently, there is no vaccine available for Dengue infections in India. The currently available vaccine Dengvaxia is not effective in Dengue naive population.



National/Societal Relevance:
The vaccine can be made available to the Public health programs which will effectively bring down the Dengue infections in the coming years at an affordable price.

Project Achievements:

a. **Progress vis-a vis objectives:** Production process developed for the manufacture of Drug Substance for each of the Dengue Serotypes - Type 1, Type 2, Type 3 and Type 4. A stable tetravalent vaccine formulation developed and Pre-clinical Toxicology studies completed. Obtained RCGM and GEAC approvals for proceed to clinical trials. GMP clincial batches manufactured and anticipate to initiate the Phase I clinical trials by Q1, 2021.

b. **Technology/Product (to be) developed:** The product has entered the clinical phase. They anticipate to launch the product by Q3, 2023

c. **IP generated/ Potential for IP generation:** The I.P is owned by NIH and Indian Immunologicals Limited has licensed the technology in specified territories.

d. **Resources Generated :** They have created pilot scale GMP freeze drying facility. As a part of the project, we recruited new man power in the areas of Bioprocess, Clinical Immunology and Analytical virology. People have been trained in scale up of the process using bioreactor.

Plans to take innovation further:
They have proposed for Stage 2 funding i.e conduct of Phase I clinical trials, Process validation at commercial scale.

Risks Envisaged
No specific risks identified. NIH has licensed the same vaccine strains to other vaccine manufacturers in India and abroad. Safety and serological response is already established in both naive and previously exposed population to dengue virus. Need to establish large scale safety and efficacy data in Indian population.

Project Coordinator:
Rajendra Lingala

Team Members :
K.R.Gurukumar, Vibhu Kanchan, N.V.Sridevi, P. Satheesh, K.J.L.Narayana Murthy, G.P. Vishnu Vardhan, Y. Venugopal

Contact :
Road no : 44 Jubliee hills Hyderabad ANDHRA PRADESH India-500033

Indian Immunologicals Ltd.

Title of the Proposal:
Development of Recombinant Human anti Rabies Monoclonals for Post exposure Prophylaxis of Rabies

Brief description:
A stable CHO cell lines expressing two human monoclonal antibodies RVC58 and RVC20 and develop a stable mixture of the two antibodies for effective post exposure prophylaxis of rabies bites.

Current stage of development:
Discovery

Innovative Element(s):
The proposed mixture of antibodies have a broad neutralizing spectrum

Market Potential:
The neutralization spectra of the currently available antibody is not effective against some of the Rabies isolates & mutants. So the present proposed combination of antibodies have broader neutralization spectrum than the currently available antibodies.

National/Societal relevance:
The product will be made available to the National mission programmes. The proposed cocktail of antibodies will be made available at an affordable price meeting the country's demand.

Project achievements:

a. **Progress vis-a vis objectives:** To develop a stable cell lines expressing the set of antibodies. Develop an affordable production process by maximizing the yields and finally to develop a stable and potent cocktail formulation.

b. **Technology/Product (to be) developed:** Expected commercial launch of the product Q4,2024

c. **IP generated/ Potential for IP generation:** IP owned by collaborator

d. **Resources Generated:** Manpower recruited in the area of Bioprocess for scale up studies. Facility is gearing for high throughput expression screening system.

Plans to take innovation further:
Propose to develop a thermostable formulation

Risks envisaged:
None

Project Coordinator:
Rajendra Lingala

Team Members :
N.V.Sridevi, P. Santha Kumar, P. Sathhesh, Y.Venugopal, A.Praveen, Shukra Madhaha, Satheesh Varma

Contact :
Road no : 44 Jubliee hills
hyderabad ANDHRA PRADESH
India-500033

Indian Institute of Technology, delhi

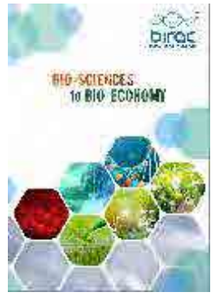
Title of the Proposal:
Production of affordable biopharmaceuticals: Ranibizumab as a case study

Brief description:
to establish upstream and downstream manufacturing process for Ranibizumab. A batch manufacturing process will be initially developed followed by its intensification by implementation of continuous technologies like coiled flow inversion reactor, inline concentrator, multicolumn chromatography and membrane chromatography. The major outcomes will be in the form of creation of a scalable continuous processing platform for Fab therapeutics and a state of the art facility that is capable of developing continuous manufacturing processes harvest to formulation for production of biotech therapeutics.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
An integrated continuous manufacturing platform for Fab therapeutics expressed in E.coli as inclusion bodies- Ranibizumab as a case study, has been developed. A novel clone for efficient expression of Ranibizumab has been developed at DBT-COE-CBT IITD.

Market Potential:
Currently, there is only one manufacturer in India selling Ranibizumab biosimilar. Thus, there is an under-utilized market potential for new manufacturers to extend their customer base. Moreover, with the advancements in continuous manufacturing, the cost of Ranibizumab can be brought down improving its accessibility.



National/Societal relevance:
The proposal is intended to position India as a key player in manufacturing of biotech therapeutics and thereby make a significant contribution to the Make in India campaign for the biotechnology sector. The project envisions the manufacturing process for biotech therapeutic Ranibizumab, an antigen-binding fragment Fab expressed in bacterial cells E.coli. The upstream and downstream manufacturing process and the required analytical methods will be established at DBT-COE-CBT IITD.

Project achievements:

a. **Progress vis-a vis objectives:** Upstream Process development followed by Downstream Process development at 5L scale and analytical method development Analytical and functional assay development.

b. **Technology/Product (to be) developed:**

Product: Microbial based FaB therapeutic Ranibizumab.

Technology: Integrated continuous purification process platform for manufacturing of Ranibizumab.

c. **IP generated/ Potential for IP generation -** Potential for IP exists for integrated continuous purification platform for Ranibizumab.

d. **Resources Generated:** Research Associate- 3, Senior Research Fellow-3, Project Assistant- 1, AKTA purifier-1

Homogenizer-1

Plans to take innovation further:
Upon completion of proof of concept, conversations for technology transfer licensing will be initiated with interested manufacturers.

Risks envisaged:
None

Project Coordinator:
Anurag.
S. Rathore

Team Members :
Priyanka Dalal, Pradnya Meshram, Sharad Narnarware, Anamika Tiwari, Surbhi Gupta

Contact :
Department of Chemical Engineering IIT-Delhi Hauz Khas New Delhi DELHI India-110016

Indian Institute of Technology Indore

Collaborator Name: NCCS Pune

Title Of The Proposal:
Production of pseudotyped SARS-CoV-2 in BSL-2 setting using vesicular stomatitis virus VSV platform for candidate vaccine development and biomedical research use

Brief Description:
This proposal aims to generate a replication-deficient pseudovirus containing SARS-CoV2 virus spike protein for developing candidate vaccine and other biomedical research use. The proposed VSV glycoprotein deleted VSV?G platform containing immunodominant SARS-CoV-2 S protein aims to elicit an adequate humoral immune response in the murine host. Although our initial plan is to develop this reagent to use it as a candidate vaccine in human as well in animal hosts, the same will be available for other biomedical research use like i study-virus entry, ii neutralizing antibody response, iii diagnostic use in antigen coating in ELISA plate development, iv monoclonal antibody development, and v drug discovery and screening purpose, etc.

Current Stage of Development:
Validation

Innovative Element(s):
Modified the Spike protein so that the packaging of virion will be efficient. And higher titer stock can be produced. It is well established that for virion packaging, certain domains of the envelope protein interact with other proteins

Market Potential :
Currently few companies including Bharat Biotech International limited, INTAS, Oncoseek Bio have expressed interest in their platform for vaccine efficacy screening

National/Societal Relevance:
In the COVID era, our reagent fulfils and replaces largely the requirement of wild-type SARS-CoV2 their requires BSL-2 conditions. However, ours approach is BSL-2 method and it can be used for i study-virus entry, ii screening neutralizing antibody response, iii diagnostic use in antigen coating in ELISA plate development, iv monoclonal antibody development, and v drug discovery and screening purpose etc

Project Achievements:

a. **Progress vis-a vis objectives:** We are on path to complete said objectives in the stipulated time.

b. **Technology/Product (to be) developed:** The product need be scaled up. Further animal-challenge study is required before going for human clinical trials.

c. **IP generated/ Potential for IP generation:** They are in the process of filing IP. Already invention disclosure statement is communicated to BIRAC.

d. **Resources Generated:** Not yet

Plans to take innovation further:
In talk for Technology transfer to a potential costumer.

Risks Envisaged:
They anticipate competition from early adopters and entrants

Project Coordinator:
Debasis Nayak and
Akansha Chaturvedi

Team Members :
Anurag Mishra,
Ritudhwaj Tiwari

Contact :
Simrol Campus Khandwa Road
INDORE MADHYA
PRADESH India-452553

Intas Pharmaceuticals Ltd.

Title of the Proposal:
Development of recombinant adeno-associated virus [rAAV] based genetic vaccine for COVID-19

Brief description:
10 of the total COVID-19 infections are reported from India. Recently approved, all the first-generation vaccines have some concerns related to its supply logistics meeting supply and demand, reliance on 1 injection and thermostability and long-term safety and efficacy reactogenicity, durability of immune responses, and efficacy in immunocompromised, elderly, obese and pregnant populations . Additionally, little is known about important factors expenses and reliability of scale-up manufacturing critical in assessing the feasibility of using any vaccine in global vaccine campaigns. Therefore, development of rAAV-based highly safe and efficacious single dose second-generation vaccine is important to overcome some of the above limitations.

Current stage of development:
Innovative Element(s) Our rAAV-COVID vaccine has been cleared by Intas IP-team against any IP protection in India and expected to cost ~1000Rs/-. Hence, vaccine is intellectually and commercially viable in India. Another AAV based vaccine, AAVCOVID, is granted $2.1million from the Bill & Melinda Gates Foundation to set up human trials.

Market Potential:
COVID-19 is a global pandemic and causes infection irrespective to the geography, ethnicity and age across the globe. Whole eight billion population of risk of getting infection. One vaccine or one supplier could not meet the demand. Therefore, there is huge market to cover.

National/Societal relevance:
Despite significant development, India continues to remain resource limited country mainly attributed to its large population. Even today, despite being largest producers of vaccine only ~44 children are getting complete vaccinations. Vaccine supply even fell short for the area restricted endemic infections like JE. Other than this, there is no or efjective vaccine against several endemic infections like HEV, nipah virus, KFDV, chikungunya, and many more. Our rAAV-technology could be purposed in two ways i gene therapy for hereditary disorders and ii novel vaccine development for endemic as well as re- emerging infections. Development of a novel intellectually and commercially viable tailored-universal vaccine platform, will enable us to overcome these limitations. Additionally, the process can be quickly adapted and scaled for any new emerging strain w/o much effort.

Project achievements:

i. **Progress vis-a vis objectives:** Generated six rAAV-based COVID vaccine candidates and selected one candidate based on in-vivo pre-POC studies and currently scaling the process for RCGM readiness and PCT study

j. **Technology/Product (to be) developed:** Expect another 12-18 months to enter the Market

k. **IP generated/ Potential for IP generation:** There is a possibility to generate IP. However, instructed by our IP team that considering COVID as global pandemic it is not advisable

l. **Resources Generated:** Intas is additionally investing 451 lac for this project. We have put 21 FTE for this program. cGMP facility for the production of clinical grade facility is under construction.

Plans to take innovation further:
Once the PCT is completed, we would like to approach funding agencies for the setting up a AAV based COVID manufacturing facility and for conduct of Phase I/II clinical trials

Risks envisaged:
Currently, we are developing rAAV9-based genetic vaccine against SARS-CoV-2. However, seroprevalence of rAAV9 is not known is India and could be a limiting factor during clinical trails. We believe this will not be a major challenge. However, to overcome the limitation, we are working on development of rAAVpo1-based vaccine development. We are also working on the development of Ides enzyme as add on therapy to rAAV-treatment

Project Coordinator:
Lakshmikanth
Gandikota

Team Members :
Niraj Mishra, Varun Lahoti,
Deepak Kanjwani, Siva
Sankar Bingi

Contact :
Corporate House, Nr. Sola
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Ahmedabad, GUJARAT
India-380054

IGY Immunologix India Pvt. Ltd.

Title of the Proposal:
Novel Interleukin-1 receptor-associated kinase 4 IRAK4 inhibitor for the treatment / prevention of sepsis shock

Brief description:
IgY Immunologix is working on active IRAK4 inhibitor molecule for septic shock. With the promising profile of IRAK4 20nM compound with highly selectivity over more than 40 kinases on different pathways, series of compounds showed promising profile in biochemical, cell-based assays and animal model. With good ADME and pharmacokinetic profile compounds has shown excellent in vivo efficacy model of septic shock.

Current stage of development:
Discovery

Innovative Element(s):
With selective profile over kinases pool has given an edge over existing IRAK4 inhibitor molecules. Good ADME and pharmacokinetic profile compounds have shown promising small molecule clinical candidate for septic shock.

Market Potential:
Existing clinical candidate can be further developing with regulatory studies for Investigational New Drug Application and further development is clinics. They are exploring to add value addition of novel molecule for selected clinical candidate for better market potential. The progress of IRAK4 inhibitor 20nM compound as clinical candidate is remarkable

National/Societal relevance:
Novel IRAK4 inhibitor clinical candidate molecule will be further developed for septic shock as well as it will be explored for rheumatoid arthritis. At present, few clinical candidates are coming in clinics and this molecule series has differentiation from other competitor molecules. The molecule is well poised for further development as candidate for clinical trials for septic shock and rheumatoid arthritis.

Project achievements:

a. **Progress vis-a vis objectives:** The team has developed selective and good pharmacokinetics and in vivo efficacious molecule for sepsis

b. **Technology/Product (to be) developed:** They plan to explore the utility of these IRAK4 inhibitors as IND candidate for sepsis as well as further explored for rheumatoid arthritis.

c. **IP generated/ Potential for IP generation -**

d. **Resources Generated:** Developed novel IRAK4 inhibitor series of compounds is patentable, we have submitted for provisional patent.

Plans to take innovation further:
Developed IP will help us to develop better market opportunities in future.

Risks envisaged:
licensing opportunities for developed novel IRAK4 inhibitor.

Project Coordinator:
Lavleen Kumar Gupta

Team Member:
Deepali Srivastava, Dikshita Panwar, V. V. Vaidyanathan, M.R. Harsha

Contact :
2903, LH17, Lanco Hills Manikonda HYDERABAD ANDHRA PRADESH India-500089

Iheal Innovations LLP

Title of the Proposal:
Electrically Active Anti-Microbial Bandage for Wound Healing

Brief description:
Microbes attach to the wound surface and proliferate to form a thin but robust layer of mucilage called Biofilm. These complex structures are resistant to defence mechanisms of the body and even to antibiotics leading to treatment failure and infection recurrence.

Current stage of development:
Validation

Innovative Element(s):
Bacteria rely on electrostatic interactions for adhesion to surfaces and inter-bacterial communication, an important aspect of pathogenesis of biofilm. Inducing a physiologically safe current weak electric fields is one possible strategy for altering bacterial movement, thereby providing enough and strong evidence of anti-biofilm strategies. This is achieved through our innovative technology of using electrically active bandage supplied with a microampere current.

Market Potential:
The global wound dressing market generated $11.4 billion revenue in 2017 and is projected to witness a CAGR of 7.2 during 2018-2023. Being a new and a disruptive innovation in wound care, this product will bring differentiated performance to the market place. The competitive advantage over the competitors is the cost advantage through patented electrically active bandage. It will drastically reduce the cost and time of wound healing.

National/Societal relevance:
The India wound care products are expected to cater to the demand and provide the quality healthcare facilities needed by and beyond 2020. This novel technology can be a boon to developing countries like India and a path for stronger commercial perspective in developed countries.

Project achievements:

a. **Progress vis-a vis objectives:** A microcircuit that supply microampere current 1400ÂµA has been designed which have been successfully connected to the bandage and its in-vitro efficacy has been tested.

b. **Technology/Product (to be) developed:** Electrically active bandage generating microampere current which shows anti-microbial property as well as pro-wound healing effect. The expected time to enter market is projected at 24 months. Bandage is for external use with least potential of toxicity and it would be easy to get regulatory approval.

c. **IP generated/ Potential for IP generation:** SYSTEM AND METHOD FOR PREVENTING BIOFILM FORMATION - 201811034718 A

d. **Resources Generated:** 1 Manpower, 3 Equipments purchased through the project Laminar Hood, Autoclave, Refrigerated Shaker Incubator

Plans to take innovation further:
With the further data generated from clinical trials, iHeal may work on partnering with firms working in the field of wound healing or may license the technology and know-how.

Risks envisaged:
A major challenge that this bandage will face is price sensitivity. Also, bringing out this disruptive technology to the current market could be an associated risk factor provided they are able to prove it with human trial.

Project Coordinator:
Madhusudan Bhat

Team Member:
A. K. Dinda, Dinesh Kumar, Sarita Mohapatra, Maneesh Singhal, Shiwangi Gupta

Contact :
IHeal Innovations LLP A 39, Fourth Floor, FIEE Complex Okhla Phase-II New Delhi South Delhi DL NEW DELHI South Delhi 110020

Innule Biosciences Pvt. Ltd.

Title of the Proposal:
Development of small molecule TNF-alpha inhibitors as anti-Rheumatoid arthritis drug candidates: Safe and cheaper alternatives to existing biologicals therapy

Brief description:
The project concept is aimed at developing safer and sustainable clinical candidates for inflammatory related auto-immune and rheumatoid arthritis diseases. The approach for this is the de-trimerization of Tumor Necrosis Factor alpha TNF-alpha protein, a proinflammatory cytokine that has been fundamentally implicated in rheumatoid arthritis. Use of biologicals/biosimilars like Enbrel and Humira is the only available clinical option that is practiced in clinic now. Reports suggest the clinical complications on the chronic use of these existing biologicals. They have novel small molecule candidates that simply targets endogenous soluble TNF-alpha and neutralizes its function through reversible inhibition and de-trimerization mechanism.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
They are small molecule Reversible Inhibitors of TNF-alpha RITA , exclusively de-trimerizes TNF-alpha assembly and inhibits its function. They are Safe and non-toxic drug molecules.

Market Potential:
$ 40 Billion/year global market for anti-rheumatoid agents

National/Societal relevance:
Historically, the biotech/pharmaceutical industry effectively utilized recombinant derived biologicals and the associated analogues to advance drug discovery and development programs in varied disease therapy ranging from cancer, autoimmune disease, diabetes management and infectious diseases.

Project achievements:

a. **Progress vis-a vis objectives:** Starting from ligand library in-vitro screening to pre-clinical/Phase-I stage development of reversible inhibitors of TNF-alpha RITA .

b. **Technology/Product (to be) developed:** Small molecule reversible Inhibitors of TNF-alpha RITA as safer clinical alternative to existing biologicals therapy

c. **IP generated/ Potential for IP generation:** Patent filing is initiated and is in progress

d. **Resources Generated - Manpower:** Four employees with Masters Degree in Biotechnology and one PhD in biochemistry/bioorganic/drug discovery.

Plans to take innovation further:
Licensing out the product and technology at the end of 24 months.

Risks envisaged:
Safety data outcome from animal/pre-clinical studies have a relevance to the progress or direction of the project.

Project Coordinator:
KOTEPPA PARI

Team Member:
Ramya G R, Deekshitha H S, Shrilaxmi Bhat, Suchitra Krishna Prasad

Contact :
I-112, Ittina Mahaveer, Neeladri Road, Electronic City Phase I
BENGALURU 560100

Jamia Hamdard, New Delhi

Collaborator Name: National Institute of Pathology, New Delhi

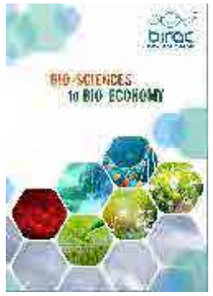
Title of the Proposal:
Preclinical evaluation of Centrin knockout live attenuated Leishmania clinical grade parasite vaccine against visceral leishmaniasis

Brief description:
Hira Nakhasi's group at the CBER/USFDA, USA in collaboration with Poonam Salotra at the Inst. Of Pathology, ICMR, New Delhi, India under the Indo-US Vaccine Action Program developed a L. donovani strain with centrin1 LdCen1 gene double knockout. Deletion of LdCen1 arrested the growth of only the intracellular stage of the parasite. This attenuated parasite was later found to be safe vaccine and provided mice and hamster protection against virulent challenge. This set our further goal to pre-clinically test this parasite for its toxicity in the animals and subsequently as vaccine in humans

Current stage of development:
Validation

Innovative Element(s):
Past DNA or Protein based vaccine candidates did not yield till now a vaccine against the parasitic fatal disease visceral leishmaniasis VL. Hence through a unique approach they have developed and are validating here the preclinical aspects of a gene deleted live attenuated Leishmania parasite as vaccine candidate

Market Potential:
Based on prevailing epidemiological estimates, considering on an average 10 sub-clinical infection per case, around 90,000 people will be the potential customers of this vaccine in the first phase. The total market size in South East Asia is about 300 million with 100 million in India alone.



National/Societal relevance:
Leishmaniasis, caused by protozoan parasite Leishmania, ranges from self-healing cutaneous leishmaniasis CL , mucocutaneous leishmaniasis MCL to fatal visceral leishmaniasis VL . As of March 2016 about 200-400 thousand of new cases of VL have been reported to occur worldwide and about 90, 000 of them occur in Bangladesh, Brazil, Ethiopia, India and Sudan [http://www.who.int/mediacentre/factsheets/fs375/en/]. In India, VL is endemic in the states of Bihar, Jharkhand, West Bengal and Uttar Pradesh, with more than 65,000 of cases in Bihar alone.

Project achievements:

a. **Progress vis-a vis objectives:** Currently the preclinical evaluation of the vaccine candidate for toxicity is in progress

b. **Technology/Product (to be) developed:** After completion of the successful preclinical evaluation, the we intend to use the product for clinical trials. If everything proceeds as intended, in 3-5 years from now the materials should enter the market.

c. **IP generated/ Potential for IP generation:** 1. LIVE ATTENUATED LEISHMANIA VACCINES. :
US patent number: WO 2005/021030.
2. LIVE ATTENUATED LEISHMANIA VACCINES. India patent number: 243725
3. International application No. PCT/US2004/028008 filled 2004

d. **Resources Generated:** Sufficient intellectual input and manpower are in place among the collaborating partners to take the vaccine candidate forward which includes manufacturing cGMP grade parasites, test immune responses and the toxicity aspects towards both preclinical as well as clinical studies.

Plans to take innovation further:
In progress

Risks envisaged:
No risk particularly envisaged at the moment

Project Coordinator:
Angamuthu Selvapandiyan

Team Member:
Hira Nakhasi, A. Selvapandiyan, Poonam Salotra, Sanjay Singh

Contact :
Jamia Hamdard, New Delhi, India,

Jawaharlal Nehru Centre for Advanced Scientific Research

Title of the Proposal:
A high throughput assay to find small molecules modulators to break HIV master transcription circuit

Brief description:
Transcriptional silence of HIV-1 offers a formidable challenge for functional cure. The immune system, vaccines, drugs, and other intervention strategies fail to eradicate HIV as the virus establishes a silent infection. Therefore, breaking viral latency is of paramount importance for efficient disease management. Through the BIRAC-supported project, a novel high throughput screening HTS assay have been developed to find small molecule inhibitors targeting the master transcription regulation circuit of HIV-1 against which currently no drugs are available.

Current stage of development:
Validation

Innovative Element(s):
The mammalian cell-based HTS assay exploits a variant HIV-1 promoter of a novel class of HIV-1 strains emerging in India. The variant viral promoter R2N3-LTR is highly resistant to latency reversal compared to the canonical viral promoter RN3-LTR. The R2N3-LTR generates significantly low transcriptional noise, offering an advantage of discrimination between false and genuine hits in the HTS assay.

Market Potential:
The search for latency-reversing agents LRA is of high priority worldwide for the functional cure of HIV-1. Several academic and industrial laboratories have active programs to identify LRA. The assay in its optimized form will have a market given the merit of low screening noise.

National/Societal relevance:
The emergence of viral strains containing variant promoters highly resistant to latency reversal is unique to HIV-1C, therefore, to countries such as India and South Africa where HIV-1C strains dominate the epidemic. Nevertheless, any LRAs identified must have universal application for latency reversal regardless of genetic variations of HIV-1 families.

Project achievements:

a. **Progress vis-a vis objectives:** Optimized an HTS assay and screened two chemical libraries for potential HIV-1 latency-reversing agents as a proof-of-concept. The HTS will be applied to screen more extensive libraries

b. **Technology/Product (to be) developed:** The HTS assay has been optimized and is ready for use or licensing.

c. **IP generated/ Potential for IP generation:** Filed a patent application on 14-Feb-2020| PCT Application No.: PCT/IN2020/050148| Title: Recombinant vector comprising HIV-LTR promoter, and associated high throughput screening method

d. **Resources Generated:** A Ph.D. student and three R&D assistants have been trained

Plans to take innovation further:
In talks with a few companies to license the HTS assay.

Risks envisaged:
May face difficulties on two different counts. First, the stringency of the assay. The selected viral promoter for the assay is too stringent that latency reversal requires the presence of multiple cell activators, each at a high concentration. The stringency of the assay is an advantage to reduce the background noise but also can be a limitation to find potential hits. Second, viral transcriptional silence is a highly complicated process regulated at multiple levels. A cocktail of latency reversing agent may be required for efficient reversal of HIV latency.

Project Coordinator:
Udaykumar Ranga

Team Member:
Ravi Manjithaya, Chhavi Saini, Yuvrajsinh Gohil, Kaushik V Iyer, T Gokul Sriman

Contact :
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Karnataka, India-560064
India-500089

Lazuline Biotech Pvt. Ltd.

Title of the Proposal:
Process development and commercialization of Recombinant Human Albumin

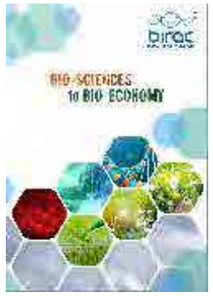
Brief Description :
Our Recombinant Human Albumin, rAlblaz is a safe and reliable alternative to blood derived albumin developed to overcome the inherent challenges associated with the traditional sourcing of Albumin. It is animal origin free and will be available at highest purity, thus eliminating risks of contamination and infections to the patients.

rAlblaz is developed and manufactured using Pichia Pastoris as expression system, a result of experienced team of scientists with deep knowledge about different protein isolation methods. They have established consistent batch production with purification methods comprising of different chromatography steps and tested as per the pharmacopeial methods.

Current Stage of Development:
Validation

Innovative Element(s):
They will be the first company to enter therapeutic Recombinant Albumin space in India. Secondly, entire process manufacturing protocols are developed in house using innovative approaches.

Market Potential (with India & abroad):
The current demand for human albumin in India is 125 MT per Annum, growing at 9 annually. There is still a shortage of about 30 MT per annum. Hence, an opportunity for filling the supply gap and also will reduce dependence on imports in the long run.



National/Societal Relevance:
On a National or societal level, the demand-supply gap is almost 30 % for therapeutic usage in India. This resulting in non-availability of Albumin to patients in emergency need. Our rAlblaz can augment the supplies and reduce the gap, providing access to the patients. It can help patients with advanced therapies as a result of reliable supply of Recombinant Albumin. It can further add to societal significance in a cost effective manner.

Project Achievements:

a **Progress vis-a vis objectives:** Fully operational cGMP facility with supply readiness for the clinical grade product for non-therapeutic usage. Completed preclinical toxicology studies. Submitted clinical trials protocol for approval from DCGA. Planning to initiate CT by May 2021.

b. **Technology/Product (to be) developed:** rAlblaz is developed using rDNA technology. Scale up process completed to 5000 Lts fermenter capacity. Product test runs completed and achieved batch to batch consistency.

c. **IP generated/ Potential for IP generation:** They will file for process patents in the future.

e. **Resources Generated:** 85 employees and about 50 contractors. Created world class cGMP manufacturing facility. R&D facility and a testing lab are fully functional with an investment of about Rs.1250 Million.

They are in the process of establishing strategic partnerships for forward integration to cell therapy. They are also planning for multifold capacity expansion.

Risks Envisaged Envisaged
Product is ready, cGMP plant is commissioned, established at commercial scale, they have to complete clinical trials, we don't see any issues with completing clinical trials successfully. However, there is a possible risk of timelines for completing clinical due to covid related delays at hospitals and with regulators.

Project Coordinator:
B.Ramesh

Team Member:
Prasad Kandimalla, Giri Raghava Raju, Indrapal Reddy, Venkata Narasaiahupta

Contact :
34A, Road No. 12, Huda Heights, Banjara Hills, Hyderabad, Telangana 500034

Levim Biotech LLP

Title of the Proposal:
Phase III Clinical Trial - Comparative Study to Test the non-inferiority of Biosimilar Liraglutide manufactured by Levim Biotech with Victoza manufactured by Novo Nordisk in Patients with Type 2 Diabetes Mellitus

Brief description:
Levim is developing Liraglutide biosimilar due to its superior benefits in management of Type-2 Diabetes Mellitus (T2DM). Levim has developed a highly efficient process and has patented its methodologies for manufacturing Liraglutide.

Current stage of development:
Validation

Innovative Element(s):
Enhanced process efficiency for conversion of Liraglutide precursor to Acylated Liraglutide with a facile process against that reported in literature. With this process, Levim has circumvented the yield & quality bottleneck at the crucial final step of the product.

Market Potential:
Global diabetes prevalence is projected to increase by 51 to 700 Mn by 2045.Mn [IDF 2019]. Liraglutide has shown substantial benefit in diabetes & the innovator had sales of $4 billion albeit with low penetration in developing countries. With liraglutide biosimilar at discounted pricing and even at 5 penetration, the potential is estimated to be $400 Mn globally.

National/Societal relevance:
In Indian market, the high drug cost of Liraglutide [MRP INR 5324/-], is a huge hindrance to its widespread usage and to becoming the preferred choice by clinicians. With no available generic alternatives to Victoza, there is no choice for the clinicians and the patients. Further, being a daily dosing drug with high pricing sensitivity in the Indian market, positioning the biosimilar Liraglutide as a cost-effective alternate to other injectables will greatly help in penetrating the market.

Project achievements:

a. **Progress vis-a vis objectives:** Completed process validation and analytical biosimilarity was established. A comparator Pharmacokinetic study has been successfully completed in healthy human subjects.

b. **Technology/Product (to be) developed:** In the process of conducting the Ph-III clinical studies and plans to launch the product in India in 2022

c. **IP generated/ Potential for IP generation:** None

d. **Resources Generated:** Manpower- 1 Clinical project coordinator, and 2 Executives for Quality Assurance and Regulatory Affairs activities have been inducted and trained Levim with the support of NBM-BIRAC has been able to augment itself with various equipment required for scale up and improving manufacturing efficiency. These include the preparative HPLC system, DAC prep-HPLC column and Rotavapor.

Plans to take innovation further:
In the process of associating with a Pen device manufacturer and register as medical device as per regulations. Marketing tie-ups are also under exploration.

Risks envisaged:
Risk of higher dropout that may arise due to unanticipated circumstance that the pandemic may pose in future, including regulatory delays. Further, there are market penetration risks posed due to new generation molecules being launched.

Project Coordinator:
Kadalmani Krishnan

Team Member:
Jatin Vimal, Srikar Raman, Siddarthan Gopalakrishnan, Arthi R, Suneetha D, Nitin Vimal

Contact :
TICEL Bio Park, Phase II CSIR Road Taramani Chennai Tamilnadu India-600113

Lupin Ltd.

Title of the Proposal:
Development of biosimilar Aflibercept

Brief description:
Aflibercept is a recombinant fusion dimeric glycoprotein consisting of two identical polypeptide chains. The aflibercept was cloned using CHO cell line. The upstream process consists of cell bank revival followed by seed generation at bioreactor and final production. The production phase consists of less than two weeks of fed batch process using chemically defined media and feed. The cell culture harvest is purified using series of chromatography and UF/DF unit operation affinity, low pH treatment, ion exchange and hydrophobic interaction chromatography and virus filtration. The virus filtered product is buffer exchanged against in-house formulation provisional patent filed

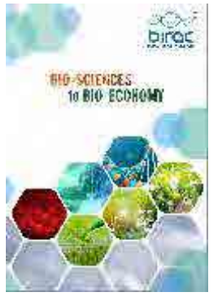
Current stage of development:
Preclinical Toxicity evaluation

Innovative Element(s):
1. Use of a defined additive during cell culture to control post translational modifications.
2. PAT driven accurate control of isoforms by unique design of chromatography gradient system.

3. In-house formulation provisional patent filed

Market Potential:
With a very conservative approach of 10 market share of the Biosimilar market, Lupin is expecting a market potential by 10th year of sales ~ 100 crore sales and USD 100 to 250 mn in annual topline sales at Peak sales from markets outside of India.

National/Societal relevance:
The current cost of therapy is very high and almost not affordable to the larger population. The current development is looking at making a cheaper version of a drug that has proven to benefit patients with AMD and DME at affordable cost â€“ there by enabling the patient to have access to better medicines and improve their quality of life and vision. The biosimilar is expected to be in the price range of 60 of the current innovator prices there by bringing in a huge benefit to the patients cost for treatment. This also going to help with access to these high quality medicines to many more patients around India.



Project achievements:

a. **Progress vis-a vis objectives:** Toxicity report submission and approval by RCGM on toxicity study - on track
Complete scale up material preparation for Phase III and Biosimilarity assessment - on track
Complete patient recruitment & Final report submission - on track

b. **Technology/Product to be developed:** Consistency batches at developmental scale completed and Pre-clinical toxicity studies ongoing. Currently the process is being scaled for clinical material generation. The material from the said scale up batches also would be utilized for stability studies, product characterization and DP manufacturing.

The expected time to enter the market would be around 2024-25.

c. **IP generated/Potential for IP generation:** A provisional patent application has been filed for the formulation composition. Process is being evaluated for patentability.

d. **Resources Generated:** Project has enabled training of at least 50 cross functional manpower across domain areas of research, manufacturing and quality. The project has also necessitated manufacturing scale state of art facility for production of complex biologics.

Plans to take innovation further:
Lupin plans to take this development up to market authorization. However, Lupin is open for milestones specific partnership.

Risks envisaged:
Unplanned activities due to ever evolving regulatory guidelines/practices likely to impact timelines

Project Coordinator:
Sanjay Tiwari

Team Member:
Rishank Goel, Kalyan Sundaram, Ashok Mishra, Bhaskar Jyoti Prasad, Ankit Srivastava, Vaibhav Deokara

Contact :
3rd Floor, Kalpatraru Inspire off. Western Expressway, Santacruz East, MUMBAI, Maharashtra 400055

Luxmatrainnovations Pvt. Ltd.

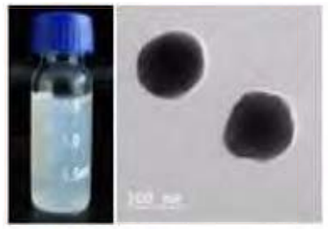
Title of the Proposal:
Engineered nano-immuno platform for Cancer Immunotherpay

Brief description:
They have engineered a biodegradable, biocompatible nanoparticle-adjuvant which has been designed to achieve a 3-pronged immunotherapeutic effect comprising of: i targeted activation of the innate immune system n-IM-S against cancer, ii augment efficacy of currently approved immune check-point inhibitors n-IM-ICI and iii Enhancing humoral and T cell activation during the infectious disease vaccination. Having demonstrated the proof of concept data in vivo tumor models, primary objective of this project is to optimize a nano-immunotherapeutic composition n-IM-S that can activate innate immune system as stand-alone immune-activator without the use of any antigen

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The most important novelty of n-IM-S platform is its ability to co-activate of both innate DC and macrophages and adaptive immune T cells systems, optimized by nano-engineering of composition. This novel nano-adjuvant showed promising immune response in cancer models and infectious disease models including COVID19 vaccine

Market Potentia:
The global immunotherapy Cancer as well as infectious disease market size was valued at USD 100 billion in 2019. With COVID19 pandemic and the whole world looking for vaccine as the only options, the world market for vaccines and adjuvants will cross 500billion by 2025. In this context, aim to develop an affordable and efficient nano-adjuvant vaccine technology for next generation vaccine. focus is on high efficiency without compromising safety as most of the current vaccines suffer from these two aspects



National/Societal relevance:
In case of cancer, the greatest shortcoming of immunotherapy for Indian patient is the exuberant cost A primary reason for such exuberant costs is the lack of indigenous technology at the national level. We need to address this challenge by making indigenous nano-vaccines for cancer in India.

In case of infectious disease vaccines, learning from the current COVID19 scenario, most of the conventional vaccines being distributed in INDIA registered efficiency not more than 70, whereas mRNA vaccines and Sputnik vaccine by USA or Russia respectively showed 90 efficiency. Hence our focus will be to enhance the efficiency of peptide and DNA vaccines to 90 using nano-adjuvant technology.

Project achievements:

a. **Progress vis-a vis objectives:** Developed and Patented nano-adjuvant technology, demonstrated proof of concept in animals models for cancer and COVID19 vaccine

b. **Technology/Product (to be) developed:** Nano-adjuvant vaccine have been successfully tested in liver cancer model. In next 12 months they will be testing in metastatic melanoma model, proceed to regulatory safety and cGMP scale-up.

c. **IP generated/ Potential for IP generation:** Three patents have been filed. New divisional application will be filed after completing the ongoing melanoma and Covid19 studies'd.Resources Generated: 04 scientific staff and 03 principal investigators working. Private funding from US investors obtained

Plans to take innovation further:
After completing cGMP process optimization in SBIRI project, they plan for IND filing within next two years. This will be done with the help of BIPP scheme and private funding.

Risks envisaged:
Product is an immune activator, the main risk they envisage is adverse immune response in patients. This will be managed by optimizing the compositions by conducting safety studies in primate models

Project Coordinator:
Manzoor Koyakutty

Team Member:
Vijay Harish Somasundaram,
Anusha Ashokan,
Girish CM,
Anjana Ramkumar

Contact :
6/1005-N, 13A, Sunny Sands,
Classic Apartments Thrikkakara PO
Thrikkakara PO Ernakulam KERALA
India-682021

Lini Basil

Title of the Proposal:
Antimicrobial moisturizing oral bio-patch - A novel intervention for rehabilitation of dry mouth/ Xerostomia patients

Brief description:
The hydrating patch is made of bio materials which have inherent ability to absorb and release water. Along with this, the materials used have natural moisturizing and antimicrobial effects too. The patch can be sticked on to the oral mucosa and used during the day time. The patch will absorb the drinking water that the patient takes in and slowly releases it and thereby gives all time moisturisation to the oral cavity

Current stage of development:
Proof-of-Concept

Innovative Element(s) :
They have used unique combination of bio materials which resulted in inherent capacity of the oral patch to moisturize the oral cavity using a novel water based technology. The patch is bio compatible and environmentally safe and the value they propose is ease of use and affordability for end users.

Market Potential:
It is estimated that more than 30 million people who are above 65 yrs. suffer from Xerostomia. In India,30 percent of all cancers are H&N cancers . Over 2, 00,000 new cases are reported every year. Globally,77 million suffer from Sjogrens syndrome and more affected are females. In 2019, the global Dry Mouth Relief market size was USD 4297.3 million and it is expected to reach USD 5508.5 million by the end of 2026, with a CAGR of 3.6 during 2021-2026.

National/Societal relevance:
In India, around 30-40 % of all cancers are Head and Neck cancers. The radiation treatment for HNC s is one of major cause for dry mouth in patients. Geriatric population in Ind ia is also rising, so as the poly drug therapy among them. India being a developing country, the products for dry mouth are imported through Gsk, Colgate etc. The effectiveness of such existing costly products is for a very less time which makes the dry mouth issue an unmet need among patients. The affordability to patients of all socioeconomic strata is questionable. This results in the need of sustainable and affordable indigenous product in India.

Project achievements:

a. **Progress vis-a vis objectives:** Ideation is over. Validation of materials done. Patient and market research has been done. Proof of concept is obtained. Animal trials for bio compatibility tests going on. Will do the final prototype after obtaining the results.

b. **Technology/Product (to be) developed:** Proof of concept is obtained and Validation of materials done. Patient and market research has been done. Animal trials for bio compatibility tests going on. Will do the final prototype after obtaining the results.

c. **IP generated/ Potential for IP generation:** Applied for Patent in India with application no: No. 201941033017 and PCT application done with application no: PCT/IN2020/050714

d. **Resources Generated:** Employed a project assistant. Training given under Co investigator Dr Senthil Kumar.
Incubated at SCTIMST TIMed, Facility for laboratory work and office created
Established ByLin Medtech private limited on 18/11/2020
Along with BIG , Nidhi prayas was obtained through SCTIMST TIMed

Plans to take innovation further:
Fund raising for clinical trials and scaling up. Will do a collaboration for marketing. Licensing is also considered as an option

Risks envisaged:
They hope to enter into the market which is owned by huge companies like GsK, Colgate, Sunstar, Sanofi etc. Our team need regulatory clearance mentoring, marketing and commercialization expert advice and mentoring. The funding and investor connect for scaling up is also needed.

Project Coordinator:
Dr Lini Basil

Team Member:
SenthilKumar M,
Alexander K A,
Asha V Nath, Malu Mohan,

Contact :
4-E Swan Hills, Favorite
Homes Gandhipuram,
Sreekaryam
Trivandrum 695017

Losjovenes Clinilogic Pvt. Ltd.

Title of the Proposal:
Matricaria chamomilla L. Chamomile nanospheres in the treatment of Skin Hyperpigmentation- a novel approach with stem cell extracts

Brief description:
They envision to develop an innovative, nano-sphere encapsulated novel phytostem cell extract for treatment of skin hyperpigmentation. Plant Stem Cell Extracts known for their regenerative powers on the skin and boost the health of the skin. The applicant has tested that the chamomile stem cells extracts have shown to downregulate melanin synthesising genes. Due to their high concentration of antioxidants, stem cells can offer respite against skin pigmentation. Chamomile stem cell extracts are novel sources which will be coated with lecithin based nanosphere and incorporated into water based serum. These novel nanocarriers have advantages of enhanced skin penetration, controlled and sustained drug release, higher stability, site-specific targeting, and high entrapment efficiency.

Current stage of development:
Validation

Innovative Element(s):
Nano sphere encapsulated plant stem cell extracts from Matricaria chamomilla L &. In order to enhance the efficacy of the stem cells extract the applicant will incorporate it in nanospheres before creating the water-based serum. This would enhance the stability of the active extracts and better skin penetration.

Market Potential:
Globally, the pigmentation disorders treatment market was valued at approximately USD 5.2 million in 2017 and is expected to reach USD 8.4 million by 2024.As mentioned above about 80 percent of the Indian population is affected with skin hyperpigmentation and no concrete solution is available in the Indian market.

National/Societal relevance:
Skin hyperpigmentation is a common presentation in diabetic patients, patients on chemotherapy, with endocrine diseases, patients suffering from chronic kidney disease and on dialysis. In India, about 80 population is affected by pigmentation disorders. The most common among them include lentigines, post-inflammatory hyperpigmentation, dark eye circles, and melasma.

Project achievements:

a. **Progress vis-a vis objectives:** Currently at the stage of initiation of callus culture, suspension culture, preparation of stem cell extract as per the objectives.

b. **Technology/Product (to be) developed:** They propose to regenerate the stem cells of Matricaria chamomilla, followed by extraction and encapsulating them with lecithin based nanospheres. These nanospheres would be used for serum formulation, which will be ultimately used for hyperpigmentation treatments.

c. **IP generated/ Potential for IP generation:** They have filed a provisional patent (Patent Application No: 202031036835)

d. **Resources Generated:** Employed Manpower-2. Established laboratory facility.

Plans to take innovation further:
The applicant is currently working with regulatory agencies to help support our application to CDSCO to help licensing of the product. They are planning to raise next round of funding for product launch and also, in discussion with companies to help support bulk manufacturing partners.

Risks envisaged:
Raising funds for further activities.

Project Coordinator:
Lita Mohapatra

Team Member:
Gopal Chowdhary, Sanchari Dutta, Pamela Chanda Roy, Mama Behera and Vishal Sidhpuria

Contact :
Losjovenes Clinilogic Private Limited, shop 3, first floor galaxy mall, near mani tribhuvan apartment, nandan kanan road patia, Bhubaneswar -751024

Mazumdar Shaw Medical Foundation

Title of the Proposal:
Novel COV-trap Therapy to reduce the intensity of Covid-19 infection

Brief description:
A recombinant fusion protein between ectopic domain of human ACE2 receptor and the Fc portion of human IgG

Current stage of development:
Discovery stage

Innovative Element(s):
A recombinant fusion protein to trap SARS-Cov2 virus in airway or blood circulation and prevent it from entering the cells

Market Potential:
World wide

National/Societal relevance:
To address the Covid pandemic

Project achievements:

a. **Progress vis-a vis objectives**
Objective1 and 3 is almost complete
Objective 1: In vitro Efficacy Study with SolAce
Objective 2: In vivo Efficacy in Golden Syrian Hamster
Objective 3: In vivo safety profile

b. **Technology/Product to be developed:** A recombinant fusion protein to trap SARS-Cov2 virus in airway or blood circulation and prevent it from entering the cells

c. **IP generated/Potential for IP generation:** Provisional patent filed

d. **Resources Generated:** Not Yet

Plans to take innovation further:
Industry partners will be contacted post in vivo validation

Risks envisaged:
Failure of in vivo studies

Project Coordinator:
Manjula Das

Team Member:
Manjula Das, Radha Shendil

Contact :
Hosur Road, Anekal, Taluk, Bommasandra Industrial Area, Bengaluru, Karnataka 560099

MYNVAX Pvt. Ltd.

Title of the Proposal:
Development of recombinant influenza vaccine

Brief description:
Mynvax has developed a recombinant quadrivalent influenza vaccine formulation using components of the head and stem regions of hemagglutinin, a surface protein of the human influenza virus. Two products are being developed, one a seasonal influenza vaccine based on WHO recommendation and an improved vaccine using stem HA components added to the seasonal vaccine for protection against antigenic drift and shift. The vaccine formulations are currently in pre-clinical development

Current stage of development:
Validation

Innovative Element(s) :
Two products under development. One is a seasonal influenza vaccine that has modified hemagglutinin molecules for the 4 WHO recommended strains. The other is an improvement which incorporates stem components of the HA that have been developed and patented by IISc, Bangalore which enhances protection to a wide variety of influenza strains

Market Potential :
Global influenza market size is estimated to be about US$5 Billion in 2020. There are no manufacturers of recombinant influenza vaccines in India and currently all vaccines available in India are imported. The Indian market size was estimated to be about Rs.250 Crores in 2017-18 and this has been steadily increasing in view of the awareness of the damage caused by respiratory viruses and that vaccination is important and life-saving for senior citizens and individuals with co-morbidities.

National/Societal relevance:
With the recent experience of COVID19, there is an urgent need to enhance local R&D, manufacturing of vaccines that cater to requirements of India. Influenza is a known respiratory virus with pandemic potential. Therefore, it is very important to have the ability to rapidly design and manufacture vaccines for potential pandemic requirement. In addition to being a development platform for pandemic preparedness, vaccine formulations when approved will make available low-cost and highly efficacious and improved influenza vaccines to Indians. Since the production technology is not based on production of viruses, either in eggs or in cell-culture, and is rapidly scalable, program has the ability to rapidly react and produce vaccines for any future pandemic outbreaks

Project achievements:

a. **Progress vis-a vis objectives:** Mynflu001, novel seasonal influenza vaccine is being produced in bioreactors for GLP Safety Toxicity studies. Mynflu002, improved influenza vaccines is being tested in ferrets for efficacy

b. **Technology/Product (to be) developed:** They expect that our seasonal influenza vaccine would be in human clinical testing in 2022 and 2023 after which we will apply for marketing authorization approvals

c. **IP generated/ Potential for IP generation:** Both Mynflu001 and Mynflu002 have novel molecular designs. PCT patent applications will be initiated shortly

d. **Resources Generated:** The program has employed 8 scientists 4 with PhDs, 3 M.Sc. and 1 M.Tech . Mynvax has also been able to attract investments and grant funding for its vaccine design and development program from private investors and venture funds.

Plans to take innovation further:
Mynvax will be raising Series A investment for the clinical development and commercialization of the vaccine

Risks envisaged
The further development of the vaccine formulation is based on acceptable results from safety toxicity studies followed by acceptable immunogenicity and safety data in human clinical trials.

Project Coordinator:
Raghavan Varadarajan

Team Member:
Gautham Nadig, Suman Pandey, Nupur Agarwal, Randhir Singh, Poorvi M. Reddy, Nidhi Girish, Aditya Upadhyaya, Madhuraj Bhat

Contact :
399, 17th Main Road, 36th Cross Road 4th T Block, Jayanagar Bangalore KARNATAKA India-560041

National Institute of Immunology, New Delhi

Title of the Proposal:
A novel vaccine evaluation platform to support SARS-CoV-2 vaccine development in resource-limiting settings

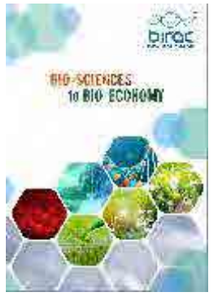
Brief description:
The aim is to provide the human ACE2 expressing animal model for pre-clinical vaccine evaluation and to develop the T-cell and B-cell based assays that would test the immunogenicity, quality and stability of protective immune response to a SARS-CoV-2 vaccine candidate. Moreover, SARS-CoV-2 Pseudotyped virus has been developed for vaccine evaluation in BSL-2 settings.

Current stage of development:
Discovery

Innovative Element(s):
The human ACE-2 expressing transgenic mouse model will be superior over wild type mouse model to test the immunogenicity and efficacy of SARS-CoV-2 vaccine. The SARS-CoV-2 Pseudotyped virus has been developed on the VSV virus backbone that has very high yield in a mammalian expression system. The MHCII-peptide tetramer with novel Tfh-epitope of SARS-CoV-2 Spike RBD domain will be helpful for testing the long-term efficacy of a vaccine.

Market Potential:
The animal model, process and benchmark parameters of vaccine evaluation to facilitate the critical evaluation of vaccines. The MHCII-peptide tetramer with novel T-cell epitope of SARS-CoV-2 Spike RBD domain will be commercialized

National/Societal relevance:
The proposed platform with cutting-edge immunology setup is futuristic to speed the vaccine development by rigorous evaluation of a candidate in early phase. The comprehensive immunological evaluation in early phase of vaccine development during pre-clinical to phase 1 clinical trial will allow modifying the vaccine preparation to achieve optimal efficacy before it reaches to the advanced human trials. Thus, in addition to support the current efforts the platform will have enormous potential in vaccine preparedness against any future pandemic



Project achievements:

a. **Progress vis-a vis objectives:** The human ACE2 expressing mouse model is available for vaccine evaluation.

   The SARS-CoV-2 spike expressing VSV-based Pseudovirus is available for measuring the neutralization potential of vaccine-induced antibodies.

   The development of T-cell tetramer targeting SARS-CoV-2- RBD is in process.

b. **Technology/Product (to be) developed:** The marketable technology will reach to the proof-of-concept within one year

c. **IP generated/ Potential for IP generation:** T-cell tetramer targeting SARS-CoV-2- RBD has the potential for IP

d. **Resources Generated:** 3 Research Associate 1 Junior Research Fellow. Facility for pseudovirus generation, animal model characterization and infrastructure for T-cell and B-cell based vaccine evaluation assays.

Plans to take innovation further:
A vaccine evaluation platform will be developed for comprehensive immunological evaluation and measuring the efficacy of a vaccine in human trials. Particularly, cutting-edge T-cell based assays will be adapted for vaccine evaluation in Phase 1 human trials.

Risks envisaged:
The usage of tetramer may be limited to one pathogen. However, the patented process could be applied to generate the T-cell tetramers for a variety of pathogens

Project Coordinator:
Nimesh Gupta

Team Member:
Devinder Sehgal, Santiswarup Singha

Contact :
Aruna Asaf Ali Marg, DELHI, India-110067

National Centre for Antarctic and Ocean Research

Collaborator Name: Foundation for Neglected Disease Research and Anthem Biosciences Pvt. Ltd.

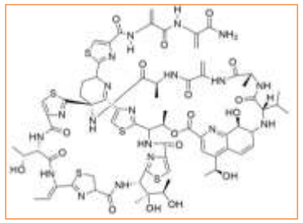
Title of the Proposal:
Development of PM181108 as an anti-tubercular agent

Brief description:
PM181108A is a novel, first in class, anti-tubercular peptide antibiotic. It is a natural product derived from Streptomyces species from Antarctica. It is a protein synthesis inhibitor with a novel mechanism of action. It has highly bactericidal with excellent in vitro and in vivo activity in tuberculosis infection models, including promising results against MDR-TB clinical isolates. PM81108A works in combination with first and second line TB drugs suggesting its fitment for developing novel combinations. The compound has been scaled up to gram scale. It is being developed in partnership with Foundation for Neglected Disease Research and Anthem Biosciences Pvt Ltd.

Current stage of development:
Discovery

Innovative Element(s):
PM181108A kills TB through a novel mechanism of action MOA by inhibiting ribosome associated GTPase activity blocking protein translation. Since new drugs with novel MOA are required for developing new TB combination regimens, it has significant potential for treatment of MDR-TB, shortening duration of therapy and sterilization.

Market Potential:
Tuberculosis is a deadly disease with more than 2.6 million cases in India alone out of which 130,000 have MDR/XDR-TB. Global TB incidence is around 10 million cases. New medications with novel mechanisms of action will be required as anti-microbial resistance grows and more patients get MDR/XDR-TB.



National/Societal relevance:
India represents an estimated 25 of the global tuberculosis burden with a total TB incidence of approximately 2.7 million cases and 450,000 deaths per year WHO, 2018. India has approximately 130,000 cases of MDR/XDR TB with treatment success rate of 48 MDR TB, 30 XDR TB. TB causes immense pain and suffering to patients in India and new treatments are required to reduce treatment times.

Project achievements:

a. **Progress vis-a vis objectives:** The development of PM181108A is on track vis-a-vis the project objectives.

b. **Technology/Product (to be) developed:** PM181108A is a novel, first in class, anti-tubercular peptide antibiotic.

c. **IP generated/ Potential for IP generation:** PM181108A has been patented both as an isolated entity in India and several other leading geographies including the US, EU and Japan. IP is jointly held by NCPOR and FNDR.

d. **Resources Generated:** The project partners have utilized and trained manpower to be able to carry out the project.

Plans to take innovation further:
Partnership and fund raising.

Risks envisaged:
There is a long road for PM181108A from preclinical development to market and multiple traditional risks which are associated with drug discovery are present.

Project Coordinator:
Rahul Mohan

Team Member:
Shridhar Narayanan, Prasad Shivarudraiah, R K Shandil, Parvinder Kaur, C N Naveen, and Siva Shanmugham

Contact :
Headland Sada. Vasco-da-Gama GOA India-403804

NMAM Institute of Technology

Title of the Proposal:
To develop adjunct anti-venom therapy for snake venom from the pharmaceuticals obtained from Coix lacrymajobi root extract

Brief description:
The adjunct anti-venom product developed by us is made up of 100 w/v ethanolic extract or 100 w/v aqueous extract of root of Coix lacrymajobi. Both products showed 100% survival in mice on administration of product orally after intramuscular administration of LD100 dose of Russel viper venom. Both products were stable in the environmental temperature even after 1 year and showed the same results in mice administered with LD100 dose of Russel viper venom. Both the products do not have any adverse toxic effects in mice that survived venom challenge. Since it is orally administered, it can be done by a common person in the villages where snake bites are high.

Current stage of development:
Validation

Innovative Element(s):
Compared to commercially available horse anti-venom, it is cheaper, orally administered, does not need refrigeration, easily transportable and has longer shelf-life in the environmental temperature and when administered will not induce anaphylactic reaction.

Market Potential:
In the current perspective, since there is no similar product in the market, the product has tremendous market and business potential because of its salient features like orally administrable, easily transportable, environmentally stable, and non-sophisticated and can be administered by a lay person to the victim as a first aid measure.

National/Societal relevance:
In India, annually 50,000 snake bites are reported and nearly 70 of them die due to non-availability of medical assistance and anti-venom. The product developed by us is orally administrable, easily transportable, environmentally stable, non-sophisticated and can be administered by a lay person to the victim as a first aid measure. Since it does not require refrigeration, it can be made available at home in places where snake bite incidence is high.

Project achievements:

a. **Progress vis-a vis objectives:** The objective of the project was to develop adjunct therapy for snake venom, which has been achieved through animal experimental studies.

b. **Technology/Product (to be) developed**: Orally administrable antidote for snake venom.

c. **IP generated/ Potential for IP generation:** Appl. No. 201641020142 and Appl. No. 201641020143 have gone through FER and FER has been submitted

d. **Resources Generated:** 2.5 Lit capacity lyophilizer unit

Plans to take innovation further:
To carry out field trials under the supervision of doctor with medical ethical clearance and get it licensed from AYUSH

Risks envisaged:
There is no risk as such because the product is safe and does not cause anaphylactic reaction like the conventional antivenom and does not show toxicity post treatment. There is no such product in the market, hence there is tremendous opportunity to popularize the product and save lives of snake bite victims.

Project Coordinator:
C. Vaman Rao

Team Member:
Two

Contact :
Dept of CSE NMAM IT, Nitte Karkala, UDUPI, KARNATAKA India-574110

HEALTHCARE - THERAPEUTICS

NBM

Oncosimis Biotech Pvt. Ltd.

Title of the Proposal:
Cell line development for Pembrolizumab Biosimilar using AcceTT Technology Platform

Brief description:
Oncosimis Biotech is a research and clinical stage biopharmaceutical company focused on identifying, developing, manufacturing and commercialising therapeutic relevant proteins including mAbs, recombinant proteins. Oncosimis Biotech leverages AcceTTÂ® platform to produce high-quality mAb and recombinant proteins from CHO cells and BacSceÂ® platform to produce endotoxin-free recombinant protein and Fab from E .coli in an efficient and cost-effective manner. Oncosimis proprietary technologies have tremendous potential to reduce the production costs of biologic drugs while increasing yield significantly.

Current stage of development:
Validation

Innovative Element(s):
AcceTT facilitates rapid and high yield production of biologics couple with robust cell growth. AcceTT is a fully integrated technology platform that comprise of vectors, media toolbox and cell line to establish ultra-high producing cells in short period of time.

Market Potential:
The Biopharmaceutical market, the largest growing segment currently at about 20% of the entire pharma markets with a CAGR of 13.8. The Asia Pacific Region is expected to show the highest growth with a CAGR of 17.2 from 2018 to 2025. India is expected to capture 5 of the global Biopharma markets from 16 Billion business opportunity

National/Societal relevance:
In the context of an emergent economy countries including India, with an ever-increasing need for targeted therapy for various cancers, the demand for next generation drugs at affordable cost in health industry remains high. This also engenders a need for developing and testing novel technologies such the one proposed, for their production by novel process of fermentation that can be adapted by biopharma industry throughout world. Being an Indian company, Oncosimis Biotech enjoys a lower cost of the facility, human resource and development costs, than its peers in the developed countries, apart from helping an immense multitude of our domestic patients with affordable targeted bio-pharmacotherapy

Project achievements:

a. **Progress vis-a vis objectives:** So far, they have developed cell line that produces the Pembrolizumab mAb and characterized its function by various biochemical and biophysical analytical assays.

b. **Technology/Product to be developed:** AcceTT platform has been developed and ready for commercialization

c: **IP generated/Potential for IP generation:** One Patent has been granted on proposed technology and two more under preparation

d. **Resources Generated:** The current team size is 12 including the founders, a Ph.D. student from JNTU Hyderabad and one research assistant and one laboratory assistant PhD, Masters /Bachelors Degree .

Plans to take innovation further:
Discussions are ongoing/advance stage for out licensing of AcceTT platform

Risks envisaged:
Radical disruption by some currently unknown stealth technologies Research and Development is an extremely esoteric and equally discreet specialty. The best way to mitigate this risk is to accelerate go-to-market deadlines for both technologies.

Project Coordinator:
Dr. Sridhar Kunchala

Team Member:
Sudarshan Reddy, Ramya Goparaju, Pratyusha Ranga, Yakub Gogu, Sri Krishna Kona, Rajesh Nanipati, Channa Kesavulu

Contact :
CCMB Annexe II, CRTDH, Opp Genpact, Uppal Road, Hyderabad, Telangana 500007

HEALTHCARE - THERAPEUTICS

SBIRI

Protein Design Pvt Ltd

Title of the Proposal:
A novel universal strategy for delivering antigens to dendritic cells using DEC 205 specific single chain fragment variables

Broad Area:
Healthcare-Vaccines and Clinical Trials

Brief description:
Delivery of antigens directly to the dendritic cells results in a robust and sustained immune response to very small quantities of antigens. The technology developed by PDPL comprises of high affinity Single chain Fragment variables ScFv specific for a receptor present on the dendritic cell receptor DEC205 genetically linked to a core streptavidin fragment and can deliver any biotin tagged antigen to the dendritic cells. We are in the process of purifying these ScFvs for commercial development. This technology is potentially useful for developing the vaccines, particularly for animal vaccines. A patent covering this technology has been under consideration.

Current stage of development:
Validation

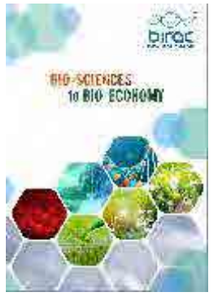
Innovative Element(s):
The DEC205 ScFvs that are being developed by PDPL can deliver any antigen directly to the dendritic cells and leads to long term immune response to very small quantities of antigens. This technology is useful for development of vaccines, particularly, the animal vaccines.

Market Potential:
This technology is particularly useful for developing animal vaccines for which the antigens are in short supply and repeated immunisations are required for sustenance of the immune response

National/Societal relevance:
we envisage that the usage of this technology will allow us to develop vaccines which require repeated immunisations with precious antigens that are in short supply, particularly the animal vaccines. Earlier work has shown that ScFvs developed by the company can deliver gonadotropins, the principal regulators of mammalian reproduction, to the dendritic cells resulting in immunoneutralization of endogenous hormones leading to disruption of the gonadal function and consequently, infertility. This is a safe, single shot, non-surgical method of controlling fertility of stray dogs that are a major menace.to the society. The same strategy can be useful for controlling fertility of animal populations that need to be controlled.

We are exploring the possibility of using this technology for the Foot and Mouth disease vaccine increasing immune response and reducing repeated immunisation.

A patent covering the technology has been filed and is under consideration.



Project achievements:

a. **Progress vis-a vis objectives:** The objectives includes purification and characterization of DEC205 specific ScFvs that are useful in delivering antigens to the dendritic cells. Purification of the ScFvs has been achieved and are being tested for their ability to delver antigens.

b. **Technology/Product (to be) developed:** The product of the project is purified ScFvs specific for dendritic cell receptor DEC205.

c. **IP generated/ Potential for IP generation:** Claiming Priority Application No. : 201741038286

Title :
DENDRITIC CELLS-TARGETING VACCINE

International Application No:
PCT/IN2018/050692 International Filing Date : 26-Oct-2018

Applicants:
INDIAN INSTITUTE OF SCIENCE L&S Ref No. : PD026847EP-NP

d. **Resources Generated:** A research technician has been trained.

We have a fully functional Protein expression and purification laboratory

Plans to take innovation further:

We have received a grant from the ELEVATE program of the Karnataka Government for using the technology for FMD vaccine

Risks envisaged:

The major challenge is large-scale purification of ScFvs

Project Coordinator:
Dr. Deepti Saini

Team Member:
Prof. Rajan Dighe

Contact :
Protein Design Pvt Ltd Anriya Dwellington, Apt 5302 RMV Stage II Lottegollahalli Bangalore KARNATAKA India-560094

Pijush Giri

Title of the Proposal:
Highly Biocompatible and Injectable hydrogel for prevention of post-surgical adhesions

Brief description:
Post-operative adhesion of the tissue with the other tissue or organ because of the injury or cut made by the medical procedure to the patients. The adhesion not only cause body complication as well as increment therapeutic costs. The applicant have built up a hydrogel to prevent adhesion. With time the surgical wounds heal and the hydrogel degrades reducing the possibilities of any post toxic effects. Presently multi-day laparoscopic medical procedure is favoured rather than the regular medical procedure strategy. The essential preferred standpoint of our item is that it is good with both laparoscopic just as an ordinary medical procedure.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The product is consists of a protein and cross linker. Both are biocompatible and degradable material. The hydrogel can work as an anti-adhesive barrier and can also seize the scar tissue formation as it has tissue adhesive property. With time the wound heals and the hydrogel degrades. The rate of degradation is compatible with the rate of wound healing.

Market Potential:
According to a report 232 million surgeries were done in the year 2013 and a study shows that 85 out of 90 patients suffer from adhesion i.e. the chances of getting adhesion after surgery is 94 percent. This shows how severe is the problem. Many a time patients complain about abdominal pain after a month of abdominal surgery and the surgeon will know the reason behind it but can do nothing due to the lack of an effective solution. Application of the anti-adhesion barrier not only ensures the reduction of the pain of the patients but also saves the reputation of surgeons.

National/Societal relevance:
The incidence of adhesions following surgery is very high some estimate an incidence as high as 80. The prevention of adhesions has the potential to save the healthcare market billions of dollars and improve the lives of hundreds of thousands of patients.

Project achievements:
a. **Progress vis-a vis objectives:** The project is progressing well as per the objectives.

b. **Technology/Product (to be) developed:** A hydrogel to prevent adhesion.

c. **IP generated/ Potential for IP generation:** Not filed yet.

d. **Resources Generated:** Employed Manpower- 02

Plans to take innovation further:
Carrying out in-vivo trials, clinical trials, and eventually, commercialization through international partners.

Risks envisaged:
The major challenging part of this project is to make the applicator. Because during making the applicator there are so many things that need to be considered. The outlet force of the applicator should not be such that it spread more to the site of surgery.

Project Coordinator:
Pijush Giri

Team Member:
Devendra Verma and Debasish Pattnaik.

Contact :
Rourkela, Odisha-769008

Rethi Madathil

Title of the Proposal:
Bio-inspired Small Molecule Mimetics of Host Defense Peptide to Treat Acute Bacterial Skin and Skin Structure Infections ABSSSI

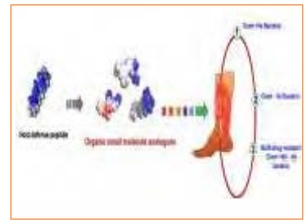
Brief description:
The applicant is developing advance care antimicrobial drug for serious wound infections. Current treatment for complicated wound infection only address MRSA & Gram-positive pathogens. There is a huge unmet need to develop first-in-class broad spectrum antibiotics to treat complicated wound infections associated with accidents, surgery and burns. Apart from Gram positive, such acute wounds are colonised with Gram negative, WHO critical & high priority pathogens including superbugs for which there is critical shortage of drugs.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Despite being the best candidate for the treatment drug resistant infection and Antimicrobial resistant problem, host defence peptides development as antibiotic is hampered by their toxicity, cost and unstable nature. They decided to try to identify organic small molecules that function similarly as Host Defence Peptides. Following the principal of similarity i.e. compounds with similarity in shape & structure exhibiting similar function, we designed & synthetically created an in-house library that contain thirty eighty number of New Chemical Entities that has high probability to destroy bacterial membrane rapidly. As anticipated, the antimicrobial assaying identified lead molecules from the library with potent broad-spectrum activities.

Market Potential:

Customers for this product include patients with wound infections related to accidental, surgical wounds, burns, bites and diabetic ulcers that require prolonged care. Currently no antimicrobial drug available in the market to treat serious wound infections that are colonised with multi-drug resistant bacterial pathogens, especially which belong to gram negative group.



National/Societal relevance:
Multi-drug resistant and superbugs infection are becoming highly prevalent globally and millions of people are dying without getting proper treatment. Majority of antibiotic under discovery or approval are variance of existing antibiotics. This makes them highly prone to microbial resistance within a short time, after introduction into the market. Currently our country, India is in the verge of reaching endemic nature in infectious diseases that caused by multi-drug resistant bacterial pathogens. In India more than 50 percent cases of blood, urinary-tract, intra-abdominal, skin structure infections wound, surgical, burn and bacterial pneumonia are infected with drug-resistant pathogens. The proposed technology have high chances to become an affordable antibiotic for chronic wounds & other related infections.

Project achievements:
a. **Progress vis-a vis objectives:** Antimicrobial susceptibility assaying of host defense peptides mimetic small molecules is on progress.

b. **Technology/Product (to be) developedL:** A first-in-class drug to treat serious & complicated wound infections.

c. **IP generated/ Potential for IP generation:** Nil

d. **Resources Generated** - Incorporated biotech start-up Biosia-Innvation private Ltd. Trained a post doc and project assistant and also research intern in biological assays related to antimicrobial drug discovery.

Plans to take innovation further:
Exploring further fund raising such as SBIRI.

Risks envisaged:
Nil

Project Coordinator:
Rethi Madathil

Team Member:
Sadananda Chaudhury, and Swati Panda

Contact :
SA-03, Institute of Microbial Technology, Chandigarh -160036

Sastra University

Title of the Proposal:
Generation, Characterization and Pre-clinical Evaluation of Chicken Egg Yolk sourced Anti-Snake Venom IgY against venoms of Cobra, Krait, Russells Viper and Saw-scaled Viper

Brief description:
Chicken IgY has been explored as a promising alternative to mammalian antibodies due to its low cost and high yield. Hence, this study is aimed to generate chicken egg-yolk sourced ASV against venoms of Big four snakes Cobra, Krait, Russells viper and Saw Scaled Viper.

Current stage of development:
Preclinical Toxicity evaluation

Innovative Element(s):
Snake envenomation is a common life-threatening medical emergency in the tropics, particularly in rural areas. At present, the administration of animal sourced ASV is the only remedial therapy. Indeed, the potency, hypersensitivity, production & supply are the major concern with the currently available ASV. The prime focus of the current study is to prepare polyvalent ASV at low cost by engaging IgY technology. Besides, this study aims to evaluate the anti-inflammatory effect of chicken egg yolk sourced ASV to resolve venom mediated pathophysiological effect. Since, the production of animal sourced monovalent ASV is cost-intensive the feasibility of monovalent ASV-IgY production would also be assessed in this study.

Market Potential:
Use of polyvalent antisera of equine origin has been existing as a proven treatment against snake envenomation in India. The impact of the proposed study is to decrease the production cost for formulating a polyvalent ASV using egg laying chicken as source of immunoglobulin generation. The present investigation will result in a significant assessment of chicken sourced ASV as a promising alternative to currently available antivenom leading to a ray of hope for commercialization with appropriate pre-clinical assessments and requisite regulatory approvals.

National/Societal relevance:
Snake bite has been a consistent health concern nationwide, especially in rural populations. In India, snake envenomation takes a heavy toll of human lives with the highest number of snake bites 81,000 and deaths 11,000 per year.

Project achievements:

a **Progress vis-a vis objectives:** Objective 1: Construction of a poultry shed at SASTRA at their own cost and immunization of chicken by SASTRA Cobra and Krait venom and PSGCAS Russells Viper and Saw-scaled viper has been completed. Objective 2: To purify IgY of sufficient purity as per the standard protocol has been completed. Objective 3: In-Vitro & In-Vivo evaluation of purified chicken sourced monovalent Anti-Venom-IgY for their efficacy in neutralization and anti-inflammatory properties on par with Equine-Anti-Venom, is under progress.

b. **Technology/Product (to be) Developed:** Under development

c. **IPGenerated/ Scope of IP :** Not Yet

d. **Resources generated :** Manpower employed: A M.Tech. graduate is working as Senior Research Fellow SRF in the applicant institution.

Plans to take innovation further:

- Validation of Chicken sourced ASV-IgY in Central Research Institute CRI , Kasauli
- Applying for IP with established Proof of Concept PoC
- Identifying a suitable Industrial Partner for Validation, Scaling up and Commercialization

Risks envisaged:

The complexity of snake venoms, and the consequent wide spectrum of pathological and pathophysiological manifestations of envenoming due to the concerted actions of several toxin types, represents a great challenge for the evaluation of the efficacy of antivenoms, as a prior condition to the clinical evaluation of their safety and efficacy.

Project Coordinator:
Senthil Ambi Visaga

Team Member:
T. Diraviyam, Key Investigator II, Michael Antonysamy, Gayathri G, Ankit Kumar, Umamaheshwari

Contact :
Trichy-Tanjore Road, Thanjavur, TAMIL NADU-613401

Shivakalyani Adepu

Title of the Proposal:
Herbal antimicrobial pantyliners for the prevention and mitigation of vulvovaginal candidiasis and bacterial vaginosis

Brief description:
1 out of every 3 women of menstruating age suffers from vaginal candidiasis. In pregnant women it is more prevent and they are not recommended to use oral antifungals for a longer duration.

Current stage of development:
Proof of concept

Innovative Element(s):
The synergistic combination of essential oils and the formulation

Market Potential:
Currently, the panty liners market is highly fragmented with several players. While the current penetration is likely low, there is a rapidly growing sense of hygiene especially amongst the urban females.

National/Societal relevance:
Once the product proves its efficacy and non-toxicity, it could be greatly helpful to all women if it is introduced into the FMCG category of products and made available in store. Thus any woman who is suffering from vaginal infection or would like to prevent infection can easily buy it from provisional store and maintain a hygienic life.

The formulation could also be made in to an anti-fungal spray and transdermal patches for treating other cutaneous fungal infections in both men and women

Project achievements:

a. **Progress vis-a vis objectives:** Project is going on

b. **Technology/Product (to be) developed:** Under process

c. **IP generated/ Potential for IP generation:** Patent Number: IP 201841034939

d. **Resources Generated:** Facilities created: 1 lab, Manpower employed: Research associate (1)

Plans to take innovation further:
We are rigorously trying for technology transfer. Once the biocompatibility and efficacy data is established, it will be done.

Risks envisaged:
Endogen toxicity, Mucosal irritation with eugenol – under examination

Project Coordinator:
Dr. Shivakalyani Adepu

Team Members :
Dr. Shivakalyani Adepu, Dr. Mudrika Khandelwal

Contact :
C-602, i-TIC, Academic Block C, IIT Hyderabad, Kandi, Sangaredy, Telangana-502285

Stelis Biopharma Pvt. Ltd.

Title of the Proposal:
Product development of in-house developed insulin Glargine towards commercialisation

Brief description:
The process for Insulin glargine has been developed completely inhouse emphasizing on cost reduction with respect to raw materials, switching to commercial grade material. A robust process has been developed aiding in scaling up the process to 1000 L from 50 L scale without compromising on the product quality and yield.

Current stage of development:
late stage validation

Innovative Element(s) :
Process development with low cost raw material making the process economically viable, development of high cell density fermentation process scalable to commercial scale 50 L to 1000 L Scale.

Market Potential :
According to a study published in the Lancet Diabetes & Endocrinology journal, nearly 98 mn people are expected to have type 2 diabetes by 2030 and at the current rate of access levels, the insulin will be beyond the reach for about half of the diabetes population.

Global sales:
USD 11 billion, India sales· USD 66.5 million, Asia-Pacific sales · USD 786 million by 2024

National/Societal relevance :
Aiming at production of the molecule that was fully developed indigenously in house by significant reduction of RM cost and making in economically viable and market the drug product at much affordable price for treatment of diabetic patients. Product launch of the indigenously developed Glargine in Indian market and regulated markets will drive significant growth and economy boost for the country.

Project achievements:

a. **Progress vis-a vis objectives:** Approval from RCGM on Toxicity study report has been obtained, Phase I Protocol submission to DCGI, Technology Transfer from R & D to manufacturing site at 50 L Scale, Working cell bank preparation and characterization, Feasibility batches at 1KL stage, Initiated Phase I clinical trials

b. **Technology/Product (to be) developed:** The process for indigenously producing Insulin glargine emphasizing on cost reduction with respect to raw materials, switching to commercial grade material

c. **IP generated/ Potential for IP generation:** None

d. **Resources Generated:** 4 employees have been inducted

Risks envisaged:
With many products in the market for Insulin Glargine, the key challenge is to be competitive in terms of the pricing offered for the product and the device

Project Coordinator:
K A Hariharan

Team Member:
Baba Saheb Abhishek Sharma, Shyam KSG, Prathap Kumar, Kamal Preet, Atul Prakash, Revansidappa Gupta

Contact :
293, Bommasandra Jigani Link Road, Jigani Industrial Area Anekal Taluk BANGALORE KARNATAKA India·560105

Sun Pharmaceutical Industries Ltd.

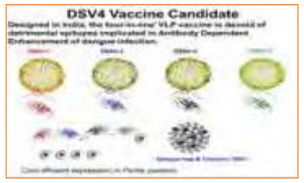
Title of the Proposal:
Four-in-one subunit dengue vaccine development program

Brief description:
Sun Pharma is developing safe, effective and affordable recombinant Dengue Subunit Tetravalent vaccine DSV4 , whose design eliminates disease-enhancing responses that are associated with whole virus based dengue vaccine. DSV4 is composed of Envelope domain III EDIII of all four dengue viruses genetically fused to the Hepatitis B surface antigen S DS . The DS in turn is co-expressed with four copies of S antigen in P. pastoris and assembled as nanoparticles displaying EDIIIs of all four DENV serotypes in cost-effective manner. In early proof-of-concept studies DSV4 has been shown to elicit balanced, neutralizing, serotype-specific, non-enhancing immune response against all four DENVs.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Development of dengue vaccine has been difficult, since predominant immune response in humans to the four-dengue virus serotypes is serotype cross-reactive and cross enhancing but not cross protective. The innovative DSV4 vaccine is designed to elicit protective immune response against all four dengue viruses without the induction of disease-enhancing response

Market Potential:
Estimates indicate 390 million dengue infections per year with 3.9 billion people at risk globally. Published capacities of the licensed and late-stage vaccines is expected to address only a small fraction of this demand. A vaccine like DSV4, offering superior safety profile with cost-effective manufacturing, will address significant gaps in dengue vaccination.



National/Societal relevance:
India contributes 34% of the dengue virus infections estimated to have occurred globally. With population growth, rapid urbanisation, globalisation, climate change, and ineffective mosquito control exacerbating the problem, India is urgently looking to introduce dengue vaccines. However, availability of safe and effective vaccines is a huge barrier. The DSV4 vaccine, designed, developed and manufactured in India offers promising option to address the needs of dengue vaccination in India

Project achievements:

a. **Progress vis-a vis objectives-** Process development, its scale up as well as assay development is complete. Preclinical toxicology studies and Phase I clinical material manufacturing ongoing.

b. **Technology/Product (to be) developed:** Tetravalent Vaccine against Dengue fever

c. **IP generated/ Potential for IP generation:** Indian Patent Application: 2478/DEL/2014

d. **Resources Generated:** Manpower employed: Facility created: Candidate-specific analytical laboratory, GMP manufacturing facility. Reagents and Standards: Candidate specific reference standards

Plans to take innovation further:
Sun is open to partnerships at all stages of development and is actively working with key stakeholders with the aim to synergistically accelerate development and availability of DSV4 vaccine globally

Risks envisaged:
Preliminary studies demonstrate good safety and efficacy in animal models, clinical results regarding safety or efficacy will be the key factors to determine the further course of action in the development of this vaccine candidate

Project Coordinator:
Sachin Kale

Team Member:
Rustom Mody, Altaf Lal Sanjay Mandhane Satish Panchal, BSaif Ismail Upasana Arora, Sharad Kamble

Contact :
Sun house, cts no 201 B1 Western Express Highway, Goregaon · East Mumbai MAHARASHTRA India·400063

Tergene Biotech Pvt. Ltd.

Title of the Proposal:
Development of an Affordable, Asia specific 15 valent Pneumococcal Polysaccharide - CRM197 Protein Conjugate Vaccine

Brief description:
Tergenes, Asia specific 15 valent Pneumococcal Polysaccharide - CRM 197 Protein Conjugate Vaccine candidate is powered by its twin USPs - being the only 15 valent vaccine in the national pipeline with broader coverage and a more Asia specific Target Product Profile TPP, and greater cost effectiveness from indigenous technology developed for manufacturing of CRM 197 carrier protein.

Current stage of development:
Validation

Innovative Element(s):
The Pneumococcal Conjugate Vaccine, 15 valent PCV-15 under development at Tergene Biotech relates to a vaccine composition that includes polysaccharide antigens isolated from 15 different serotypes of S.pneumonia, individually conjugated to a carrier protein, CRM-197. This is the only 15-valent PCV being developed with two specific serotypes that are prevalent in the Asian region.

Market Potential:
Potential demand was forecasted at approximately 50 million doses, increasing to nearly 160 million doses by 2020, and peaking at just over 200 million doses by 2030. Assuming pneumococcal vaccines prevent 7 deaths per 1000 children vaccinated the impact observed in the Gambia trial, the 2005 demand forecast projects that approximately 5.3 million deaths can be averted between 2010 and 2030.

National/Societal relevance:
Increasing incidence of streptococcal infection in the young and elderly and wide spread antimicrobial resistance AMR and diversity in the serotype distribution necessitate the need for the development of an Asia specific, indigenous and cost effective vaccine for S.Pneumoniae. According to WHO, Pneumonia is the leading cause of death in children worldwide. Pneumonia kills an estimated 1.6 million children every year worldwide, 25 in India alone more than AIDS, malaria and tuberculosis combined. India is witnessing the highest number of pneumonia-related child deaths in the world

Project achievements:

a. **Progress vis-a vis objectives:** Phase II Clinical trial in 140 healthy toddlers was completed with encouraging safety and immunogenicity results

b. **Technology/Product (to be) developed:** Product under development: Pneumococcal Polysaccharide Conjugate Vaccine - 15 valent. Expected Launch date: Mid 2022

c. **IP generated/ Potential for IP generation:** Indian Patent application was filed prior to the project

d. **Resources Generated - Manpower trained:** 30

Plans to take innovation further:
1. To conduct Phase III clinical trials
2. Obtain market approval for India
3. To obtain WHO PQ and supply to UNICEF

Risks envisaged:
Conduct and outcome of Clinical Trials

Project Coordinator:
M. Kuppusamy

Team Member:
Sathyan Kuppusamy, Arani Chatterjee, Sundar Srinivasan, Kapil, Mr. Antony Joseph Rio Madhan

Contact :
Suite 121 and 122, Building 450
Genome Valley, Turkapally Village,
Shamirpet Mandal, RR Dist Hyderabad
TELANGANA India-500078

Tranalab Pvt. Ltd.

Title of the Proposal:
BioBetter Therapeutic for a Genetic Disorder

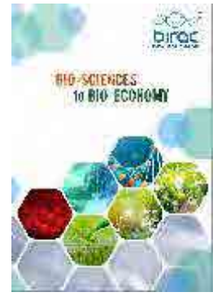
Brief description:
To create affordable Biobetter to treat a genetic disease, whose treatment currently costs INR 40 Lakhs per annum and lifelong treatment required. The Biobetter will help reduce the dose and/or frequency of administration, whilst at 1/10 th the cost of the current marketed biotherapeutic

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The Biobetter would be a designed novel molecule, compared to the currently available Biotherapeutic.

Market Potential:
The current annual global market for the Biotherapeutic is INR 9000 Cr. The addressable market is INR 800 Cr., considering India patients estimate of 20,000 and 1/10th the current cost

National/Societal relevance:
India has estimated 20,000 patients for this genetic disease, of which 2 percent only are currently being treated due to the prohibitive cost of the Biotherapeutic. No treatment leads to very poor quality of life and death. The aim is to bring the annual cost to the patient below INR 5 Lakhs Ayushman Bharat scheme limit, which can allow for far more patients to be treated.



Project achievements:

a. **Progress vis-a vis objectives:** Computational design of a set of potential candidate Biobetters has been carried out. Experimental shortlisting for improved characteristics, compared to the currently marketed Biotherapeutic, would be carried out.

b. **Technology/Product (to be) developed:** A Biobetter to treat a genetic disease and to disruptively reduce the cost to 1/10 th of the current Biotherpeutic. Market entry is expected 2025

c. **IP generated/ Potential for IP generation:** Potential for IP generation is very high for Biobetters, as they are being designed and not exist earlier. Compared to a BioSimilar, a Biobetter opens up the possibility to enter the global market

d. **Resources Generated:** 5 Manpower employed

Plans to take innovation further:
Partnership with established Biopharma is a potential way forward. Will seek further investments to take forward the innovation.

Risks envisaged:
None

Project Coordinator:
Chandramowli Ganesh

Team Member:
Alzu Manocha Kapoor, Vaishnavo Pai, Nitin S Deshpande, C. Ganesh

Contact :
205 Anandanilaya, NSY No 11/1 &12/1, AECS Layout A Block, 9th Cross Chinnappanahalli, Bangalore

Translational Health Science and Technology Institute (THSTI)

Title of the Proposal:
Development, characterization and evaluation of protective efficacy of self amplifying mRNA vaccine candidates against the Severe acute respiratory syndrome coronavirus 2 (SARS CoV2)

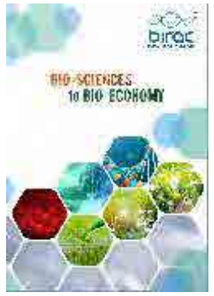
Brief description:
Propose to evaluate the efficacy of self-amplifying mRNA SAM technology to develop a potent vaccine against the SARS-CoV-2. Our approach involves production of vaccine antigen inside the host by delivering a self-amplifying mRNA that encodes the antigen of interest. S protein of SARS-CoV-2 is being used as the vaccine antigen.

Current stage of development:
Discovery

Innovative Element(s):
use of self amplifying RNA instead of mRNA. parallel testing of multiple antigens to select the best

Market Potential:
The current supply of Covid-19 vaccine is unable to cover the entire demand of vaccine shots. Moreover, the technology is different than the existing vaccines. Hence, there is a possibility of obtaining superior efficacy than the currently used vaccines. There is a demand for more vaccines against the COVID-19.

National/Societal relevance:
There is an urgent requirement of COVID-19 vaccines in India and other countries. Their vaccine will be easier to produce and supply. Hence it will be ideal for use in our country. Moreover, once the technology is optimised, vaccines can be produced against India-specific strains, mutant viruses, at short notice



Project achievements:

a. **Progress vis-a vis objectives:** Vaccine antigen has been produced and its expression has been validated

b. **Technology/Product (to be) developed:** Protective efficacy of the vaccine antigen will be evaluated in a small animal model challenge study in next 3 months.

c. **IP generated/ Potential for IP generation:** The vaccine formulation will be patented

d. **Resources Generated:** none.

Plans to take innovation further:
nnovation will be carried forward after generating the proof of concept.

Risks envisaged:
Efficacy of delivery could be a potential issue.

Project Coordinator:
Milan Surjit

Team Member:
Tripti Shrivastava,
Shailendra Mani,
Shubbir Ahmad,
Sankar Bhattacharyya,
Oinam Sing

Contact :
Faridabad NCR Biotech Science Cluster Gurgaon Faridabad Highway New DELHI India-121001

Vellore Institute of Technology

Title of the Proposal:
Clone Development for Biosimilar factor VIII

Brief description:
Factor F VIII, is an essential blood coagulation factor which plays a key role in the pathology of Hemophilia A. Currently, plasma concentrates of FVIII or recombinant r FVIII replacement is done to counter hemophilia A, both of which involves expensive processes for production, and they are imported. The propriety products such as ReFacto-rFVIII whose patent has expired provides a tremendous opportunity to develop a biosimilar product. Our project focuses on generating cGMP certified cell line for high yields of ReFacto-rFVIII, safer and cost-efficient recovery of the product by a patented technology which eventually be scaled up in industry for commercialization.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The project aims to develop a cGMP certified cell line development for the bioproduction ReFacto rFVIII followed by efficient purification of rFVIII in simple steps to obtain viral free product and formulate the product efficiently for the treatment of Hemophilia A at affordable prices.

Market Potential:
Global market value for rFVIII products: $11.00 billion USD. Expected to grow at 2.4 CGAR by 2024. All FVIII products are imported to India. No company in India is manufacturing it and there is a big demand for the product at affordable prices.

National/Societal relevance:
India has one of the highest numbers of reported Hemophilia A in the world. Currently, only 30% of patients have been diagnosed and only 25% of patients receive partial treatments due to the very expensive nature of the FVIII treatment which costs Rs.9.0-15.0 lakhs per year direct costs for replacement therapy. This suggests only a very few patients have been able to receive treatment in India. There is a clear and urgent need for developing FVIII products in India at affordable prices to treat patients.

Project achievements:

a. **Progress vis-a vis objectives:** Industrial partner Amthera has identified cGMP certified identified potential high yielding cell lines. VIT is carrying out downstream processing with patented purification technology.

b. **Technology/Product (to be) developed:** 1.cGMP certified cell line producing high yields of ReFacto rFVIII, 2. Simple and cost-efficient recovery of ReFacto rFVIII with patented chromatography technology which can be scalable both at preparative and pilot-scale, 3.Formulation of the product integrated during the purification steps which saves an additional step in obtaining the product for treatment.

c. **IP generated/ Potential for IP generation:** VIT team has been EU patent awarded for the efficient recovery of FVIII and its fragment from various sources

d. **Resources Generated:** Manpower recruited

Plans to take innovation further:
Upon successful completion of cell line development, Amthera will establish a research cell bank. VIT will collaborate with Amthera for the establishment of the pilot-scale downstream processing platform for the production of the ReFacto product. Funding from Government organizations or venture capital institutions will be sought for preclinical and clinical studies and finally for commercialization

Risks envisaged:
The complexity of developing any FVIII products poses both technological and economic challenges for commercialization. We are implementing novel strategies during clone and process development upstream and downstream for producing a biosimilar product ReFacto-FVIII which will pave way for the mitigation of risks due to high costs of production and commercialization.

Project Coordinator:
Prof. Krishnan Venkataraman VIT Vellore

Team Member:
Susobhan Das,
MA Vijayalakshmi

Contact :
VIT, Vellore Campus,
Tiruvalam Road, Katpadi,
Vellore, Tamil Nadu-632014

Wockhardt Ltd.

Title of the Proposal:
A Phase III, Randomised, Multicentre, Double-Blind, Comparative Study to Determine the Efficacy and Safety of Oral Nafithromycin WCK 4873 versus Oral Moxifloxacin in the Treatment of Community-Acquired Bacterial Pneumonia CABP in Adults

Brief description:
WCK 4873 INN: Nafithromycin, Molecular formula: C42H62N6O11S is novel antibiotic from lactone-ketolide class of antibacterial. It has been developed to meet the unmet need of effective short duration empiric therapy against bacterial community respiratory infections (RTI).

Current stage of development:
Phase -III clinical trail

Innovative Element(s):
Unlike other macrolides 11, 12 carbamate core, nafithromycin is developed on novel basic core 11, 12 lactone ketolide. The double bond amidoxime core, absence of fluoro in core, ring chiral centre, chiral methyl, domain II interacting side chain with flexible linker and absence of fluoro substitution helps nafithromycin demonstrate a superior oral bioavailability, hepatic safety, remarkable lung concentrations and lack of CYP inhibitory/induction activity. These attributes makes nafithromycin as an effective short duration 3 day therapy against CABP caused by antibiotic resistant bacteria.

Market Potential:
The total community respiratory infection market in India, as per the 2018 IMS data is 6337 million units which translates into $665M sales. Based on the superior therapeutic profile, nafithromycin is expected to achieve peak sales volume of INR 250-500 Cr.

National/Societal relevance:
UNICEF has estimated that annual paediatric mortality in India is 4, 100, 00 Indian Paediatrics 2007 44: 491-496. Despite vaccination, S. pneumoniae continues to be major cause of mortality and morbidity in paediatric population.

Project achievements:

a. **Progress vis-a vis objectives:** CDSCO have approved Phase 3 study protocol. The recruitment of subjects in Phase 3 study has been initiated.

b. **Technology/Product (to be) developed:** To Determine the Efficacy and Safety of Oral Nafithromycin WCK 4873 versus Oral Moxifloxacin in the Treatment of Community-Acquired Bacterial Pneumonia CABP in Adults

c. **IP generated/ Potential for IP generation:** Nafithromycin is the propriety drug of Wockhardt with support of following Granted Patents: Indian Patent No 300868 Application. No. 3352/MUM/2010 and USA Patent No 9,175,031 Application. No. 13/991,762 have been granted.

d. **Resources Generated:** Nil

Plans to take innovation further:
Efforts will be undertaken to introduce this antibiotic in countries with high antibiotic resistance rates in community respiratory pathogens.

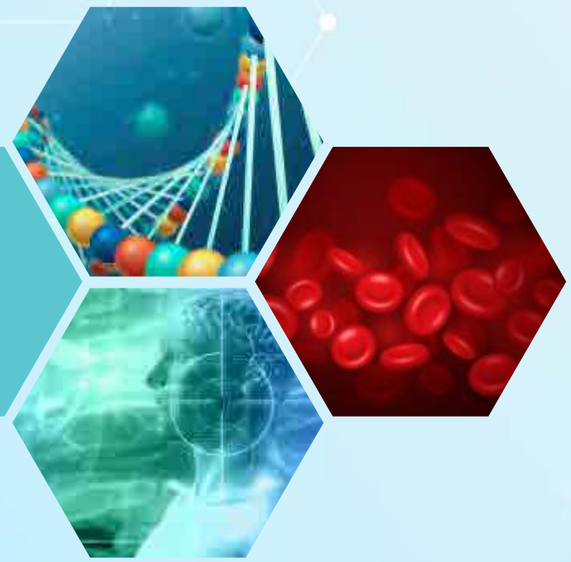
Risks envisaged:
The only potential risk factor could be the time required for recruiting the target number of 500 patients and challenges in institutional ethics committees approval in timely manner for smooth conduct of Phase 3 study.

Project Coordinator:
Ashima Bhatia

Team Member:
Manish Kumar Shah, Kedar Pawar, Snehal Chalke, Mushtaque Mastim, Neha Bhatia, and Rajvinder Gog.

Contact :
Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai MAHARASHTRA India-400051

INNOVATION PROFILES



HEALTHCARE DEVICES & DIAGNOSTICS

4S Medical Research Pvt Ltd

Title of the Proposal:
See Sound Live - A smart phone based, novel speech visualization tool to help improve speech performance and communication skills of a deaf and dumb person, currently relying only on sign language.

Brief description:
See Sound Live is an assistive technology that empowers a deaf person develop speech. In the absence of auditory feedback, See Sound Live gives the deaf person, visual feedback of his speech efforts. This allows the deaf person to modulate his speech efforts and over time with practice, learn speaking small sounds and later by joining them, bigger sounds and then words.

Current stage of development:
Validation

Innovative Element(s):
Developing speech using visual feedback of their speech efforts is akin to hearing with their eyes. This has never been done before anywhere in the world.

Market Potential:
There are about 51 Million deaf people in the world who rely only on sign language. 14 Million live in India. See Sound Live has the potential to empower them with speech allowing them to better integrate with the hearing community thus improving their quality of life and productivity, both social and economic.

National/Societal relevance:
See Sound Live demonstrates the Make in India objective of our nation and will help the deaf in India and the world alike. It will be Indias gift to the world in the field of innovation and technology.

Project achievements:

a. **Progress vis-a vis objectives:** See Sound Live has been developed and validated in users in India over the last two years. The product is now nearly ready for commercialisation worldwide.

b. **Technology/Product (to be) developed:** Technology is ready for deployment.

c. **IP generated/ Potential for IP generation:** Patent for See Sound Live as a Speaking Aid for the deaf device and method has been completed in India including Patent cooperation Treaty. Patent has also been applied to include North America and Europe.

d. **Resources Generated - Manpower:** Sales and Marketing Team and Product Development Team. Speech therapists and Teachers of the Deaf have been trained on the use of See Sound Live that empowers them to get more out of their skills in training a deaf child.

Plans to take innovation further:
See Sound Live is on the verge of world wide marketing and distribution. Distributors in North America, Europe and Middle East and Far East areas are being explored. Research Partnerships are being forged with Universities in Europe and USA.

Risks envisaged:
Novel technologies can take time for adoption. Initial skepticism has to be countered. The deaf so far have never hoped to speak since such a technology did not exist. As such, although the need is huge, the markets have to be developed.

Project Coordinator:
Shomeshwar Singh

Team Members :
Sirisha Singh, Arti Sinha & Hardarshan Singh Nirankari

Contact :
A-7, Neeti Bagh , New Delhi

Aarna Biomedical Products Pvt Ltd

Title of the Proposal:
Deployment of physical trial based Sampoorti-Poorti System for post-surgical prosthetic rehabilitation of mastectomees pan-India

Brief description:
Aarna Biomedical Products – A nascent innovation led Social Enterprise passionately convert aspirations around a unmet/underserved social healthcare need into a holistic solution & create dignified income opportunities through dissemination of the developed solutions

Current stage of development:
Commercialized in the name of Sampoorti Breast Prosthesis Trial System and Poorti Post Mastectomy Kit

Date of commercial Launch:
1 January 2018 (pilot launch) and then 1 January 2020
Number of units sold: > 2850
Number of end users: > 2700

Innovative Element(s):
Created a single holistic platform aimed at delivering prosthetic needs of breast cancer patients following surgical intervention (modified radical mastectomy and radical mastectomy) by creating two solutions: "Sampoorti" – An institution-centric product named as Sampoorti which is a mobile and concise suitcase comprising of prosthesis of different sizes and pocketed bras & "Poorti" – a user-centric post mastectomy kit

Market Potential:
Breast cancer is the top most common cancer affecting women all over the world which translates to a very high market potential.

National/Societal relevance:
Unmet/underserved need of affordable and holistic non-invasive solution for the post-surgical prosthetic rehabilitation of mastectomees pan-India and beyond.

Project achievements:

a. **Progress vis-a vis objectives:**
- Development of a manufacturing set-up and warehouse space – Completed.
- Creation of a marketing/awareness team on ground – Due to Covid, the option of digital presence on social media platforms is being developed.
- Deployment of Sampoorti for physical trial across various cities in India – "By-women-for-women-social-enterpreneurship network" and presence in all cancer hospitals

b. **Technology/Product (to be) developed:** Sampoorti-Poorti System has been developed after user feedback trials through a patented manufacturing process and in-house manufacturing set-up.

c. **IP generated/ Potential for IP generation:** Indian patent granted for manufacturing of breast prosthesis

d. **Resources Generated:** Enterprise created in March 2017, facility created in February 2019, presence created in 63 cities across 17 states leading to 8 direct employments and numerous (>50) indirect employments. Support from BIRAC, Social Alpha (Tata Trusts), IIT-Kanpur (Villgro), THSTI-DBT, IIT-Delhi (FITT) and Venture Center-Pune.

Plans to take innovation further:
Creation of "By-Women-For-Women-Social-Entrepreneurships-Network" pan-India and beyond. Women in different cities would be searched, equipped and trained to offer a sympathetic physical trial to the patients and earn a value in return.

Risks envisaged:
Risk from price fluctuations and supply of the raw materials used in our product, as India doesn't manufacture Silicone gel and it is imported from overseas.

Project Coordinator:
Pawan Mehrotra

Team Members :
P.V.M. Rao, Kshama Kothari, Kausalya Santhanam, Vinod. K. Mehrotra, Divas Gupta, Bhanu Singh, Pranav Kumar, Ravinder Negi, Vicky Sharma, Siddharth Jain

Contact :
A-43, Sector-7, NOIDA-201301, U.P., India

Abhishek Rai

Title of the Proposal:
A portable, and modular robotic physical rehabilitation device which assists in mobility and strength recovery of knee, elbow and wrist using strength feedback and gamification, for use in space constrained physiotherapy settings.

Brief description Product is a portable robotic and virtual physical rehabilitation solution, which equips space constrained physiotherapy setups with the prowess to treat the patients with evidence based robotic systems and can be used for training multiple joints of both upper and lower limb by swapping attachments on a portable device

Current stage of development:
Validation

Innovative Element(s):
This solution is portable and occupies 2 sq ft of floor space. Both upper and lower limbs can be treated with more than 20 different exercises

Market Potential:
Global robotic rehabilitation market is about 641 Million USD with 1,00,000+ outpatient clinics and 2000+ inpatient rehabilitation centers in US & India. 5 million people per year survive stroke globally and undergo rehabilitation for at least 3 to 6 months.

National/Societal relevance:
With the limited practising physiotherapists, rehabilitation devices aid and assist the physiotherapists to handle more patients with better efficiency

Project achievements:

a. **Progress vis-a vis objectives:** Prototypes were tested at various centres to develop the current prototype which is being used in 3 private physiotherapy clinics.

b. **Technology/Product (to be) developed:** Solution needs to be clinically validated and refined for manufacturing at scale and also for regulatory approvals. 12 to 18 months will be required to enter the market

c. **IP generated/ Potential for IP generation:** Indian patent has been filed and PCT application has also been filed

d. **Resources Generated:** 5 interns were trained and have secured jobs or are pursuing higher studies

Plans to take innovation further:
To commercialise innovation, fund raising will be done through various initiatives of Govt of India, through Incubators and also through Angel Investors.

Risks envisaged:
Getting the design for manufacturing ready, deciding the right go to market strategy and setting up the logistics chain for providing quick and hassle free delivery

Project Coordinator: Chirag Shah

Team Members : Abhishek Rai, Abhishek Kansara, Hrishikesh Thakker

Contact : B-305, building no. 44,Tilak Nagar Chembur Mumbai 400089

Adil Khan Yusufzai

Title of the Proposal:
Indigenous Production of Novel Personal Protective Equipment for Healthcare Personnel

Brief description:
A full-body suit that can provide full-body protection and also has the following features like safe and easy doffing, good vision without fogging, better communication, and comfortable breathability with minimized sweating

Current stage of development:
Validation

Innovative Element(s):
Its one full-body suit with all the components integrated and usage of the Protection and Ventilation PAV System. This PPE facilitates easy donning and safe doffing. The PAV system facilitates by providing filtered and safe ventilation and great comfort

Market Potential:
Even though COVID-19 cases are declining, the product can be used in treating patients with HIV or other bloodborne pathogens. The market in places like the USA and the west looks immense

National/Societal relevance:
The product can make our country better prepared for future pandemics and infection outbreaks this technology will provide healthcare professionals with safer PPE to fight COVID. With high temperatures in summer, this technology will prevent sweating and a comfortable environment.

Project achievements:

e. **Progress vis-a vis objectives:** Final prototyping of PPE suit and PAV system done. PPE has been successfully tested in SITRA. The PAV system will be tested by BIS or any other Government lab.

f. **Technology/Product (to be) developed:** The novel design of the PPE with an integrated PAV system that provides safety and comfortability to HCP while treating patients. After the certifications, the product will be launched within 2 months

g. **IP generated/ Potential for IP generation:** A provisional patent has already been filed for this technology. With the requirement of safety, while treating patients increasing multifold, the scope of the technology is huge

h. **Resources Generated :** Yes

Plans to take innovation further:
The technology developed will be the third party licensed to an entity who is established in the market and has the commitment to serve the healthcare system

Risks envisaged:
Highly competitive market

Project Coordinator: Adil Khan Yusuf Zai

Team Members : Arun TR, Balamurugan S, Naveen KT, Sandeep Singh, Rakesh Lodha, Ramesh Agarwal, Praveen Gulati

Contact : C-204,Taj Enclave, Geeta Colony New Delhi-110031 New Delhi

Affigenix Biosolutions Pvt Ltd

Title of the Proposal:
COVID-19 Immuonogenicty ELISA for Community Surveillance

Brief description:
Our ELISA kit can diagnose large number of samples within a very short duration ~30mins for 90 samples . The immunogenicity test for COVID-19 is a bridge ELISA method to quantitatively determine the total anti-covid immunoglobulin IgG, IgA, IgM, IgE and IgD response in the samples without revealing the stage of infections as recent exposure to COVID 19 or later stage of infections. By using cocktail of viral antigen as capture and detection to quantitatively determine the anti-COVID antibody in the serum, our approach offer a major advantage to overcome any present or future mutations in strain or isolation, and help generate a robust diagnostic assay for use in low resource testing as well as in highly established labs

Current stage of development:
Validation

Innovative Element(s):
The ELISA kit has been developed on the principle of specific interaction of antigen and antibody to monitor the presence or absence of antibodies against SARS-CoV-2. The unique multi antigenic approach can also be used as a single use stand-alone kit to quantitatively determine the anti-covid 19 antibodies. It is relatively easy to convert the assay to determine the stage of infection as early or late, by swapping the detection reagent gold conjugated triple antigen with anti-human IgM or IgG. As the virus isolates or the strain undergoes mutation, our cocktail of surface proteins coated on the plate ensures the sensitivity of the assay.

Market Potential:
The late and post infection status in the community/area wise for surveillance and monitoring can be done by diagnosing the suspected patients by serological testing using immunoassay platform techniques such as ELISA. We anticpate the demand for our immunogenicity kit will be very high nationally and internationally and with correct marketing and pricing strategy even if we could capture 2 market share it will be in several crores.

National/Societal relevance:
The developed rapid screening method easily scalable, enable high throughput screening, affordable, specific, sensitive, user friendly, robust, almost equipment free and can be used by any trained lab technician. All the critical reagents can be indigenously prepared and assembled and need not import material enabling continuous and reliably supply of diagnostic reagents.

Project achievements:

a. **Progress vis-a vis objectives:** In-house Immunogenicity/Screening ELISA assay developed and tested successfully and test batch kits manufactured for clinical validation under a CDSCO manufacturing license. The 3 batch test kits have been submitted to ICMR -NIV Pune.

b. **Technology/Product (to be) developed:** The immunogenicity test for COVID-19 is a bridge ELISA method to quantitatively determine the total anti-covid immunoglobulin IgG, IgA, IgM, IgE and IgD response in the samples without revealing the stage of infections as recent exposure to COVID 19 or later stage of infections.

c. **IP generated/ Potential for IP generation:** To the best of our knowledge there is no publication or patent for screening and detection of COVID 19 using multi antigenic approach and hence we plan to file a patent at least in India as we have made modification in the assay to obviate the obviousness.

d. **Resources Generated:** We have hired 4 scientist in the last 8 months to develop COVID 19 related diagnostic kits. We are in the process of obtaining our ISC13485 certification to comply with GMP manufacturing of the IVD kits. We are recipients of 3 COVID related grants from BIRAC, IKP-ICO fund and Millennium Alliance.

Plans to take innovation further:
We plan to partner with marketing team to take our IVD products nationally and Internationally

Risks envisaged:
Price erosion due to competition from imported kits as well as from local manufacturers. Ban on exports and allowing imports are a big concern for Indian IVD manufacturers

Project Coordinator:
Arumugam Muruganandam

Team Members :
Bindu Mahesh, N.Durkeshwaran, Sathiya V, Vinothkumar

Contact :
265/1F, KSSIDC Industrial area Bommasandra, Anekal Taluk Bangalore Distt, Karnataka-560099 India

All India Institute of Medical Sciences, Delhi

Title of the Proposal:
Minimally invasive nano enabled targeted technology for Sentinel Lymph Node (SLN) detection

Brief description:
The nanoparticle is designed for use as per the Sentinel lymph node (SLN) detection technique wherein peri-tumoral injected nanoparticles may migrate along lymphatic channels and identify metastatically involved lymph nodes versus the uninvolved nodes

Current stage of development:
Validation

Innovative Element(s):
Detecting the metastatic cells housing within the lymph node. The products currently available in the market non-specifically stains the sentinel lymph nodes which are removed surgically even if they do not house any metastatic cells

Market Potential:
The current technology is a single step minimally invasive technique for detection of sentinel lymph node with potential high sensitivity and specificity for detection of involved lymph nodes. There is no other similar product available

National/Societal relevance:
Oral Cancer is now the commonest cancer in males in India. As per the recent reports, India accounts for 60 of head and neck cancer cases, owing to high tobacco consumption by a large population Hindustan Times, June 2018.

Project achievements:

a. **Progress vis-a vis objectives:** Anti-Cytokeratin tagged 99mTc labeled collagen nanoparticles have been successful fabricated and stability of the product over 6 months time is being assessed. Currently, the nanoparticles have been submitted for GLP toxicity assessment.

b. **Technology/Product (to be) developed:** The current technology is a single step detection of sentinel lymph node with higher sensitivity, specificity as well as minimal invasive method. The innovation involves the targeted imaging system using antibody conjugated radiotracer tagged nanoparticles.

c. **IP generated/ Potential for IP generation:** IP filed entitled "Tagged proteinaceous nanoparticles and methods of preparation thereof"

d. **Resources Generated:** 1 Manpower employed

Plans to take innovation further:
The technology and know-how would be licensed prior market entry.

Risks envisaged:
Price sensitivity

Project Coordinator:
Alok Thakar

Team Members :
A. K. Dinda, Rakesh Kumar, Reeta Chaudhary, Geetanjali Arora, Madhusudan Bhat

Contact :
All India Institute of Medical Sciences Ansari Nagar Ansari nagar New Delhi

Amit Kumar Singh

Title of the Proposal:
Smart system for contactless mass screening of COVID-19 for moving subjects by every smart mobile user

Brief description
Contactless thermal scanning is done with the help of a contactless thermopile-based sensor and ultrasonic sensors to monitor distant moving objects. The developed system is attached to smart mobile via USB protocol and this system uses the power, display, and processing of the data of the user smart mobile. So, the community spread of this disastrous disease can be reduced with the help of our developed device and smartphone users, as it is faster, smarter, affordable, lightweight, user friendly.

Current stage of development:
Validation

Innovative Element(s):
The developed accessory for the smart mobile is accurate, affordable, lightweight, and user friendly. Uses a smart mobile camera and a contactless thermal sensor to accurately screen the body temperature of the moving subject from safe distance.

Market Potential:
The COVID-19 pandemic is still increasing and monitoring is still required at many public places. So the expected business is around 100 billion dollar world market

National/Societal relevance:
The developed system can help in mass screening the COVID-19 suspect at public places as well as offices.

Project achievements:

a. **Progress vis-a vis objectives:** A phase-3 clinical trial of the developed system is completed along with the commercial design, smart mobile app, and the system is at TRL6 plus.

b. **Technology/Product (to be) developed:** The developed system is an accessory for the smart mobile. Used to screen the temperature of the moving subject from a safer distance using a smart-mobile camera and IR sensor

c. IP generated/ Potential for IP generation: An Indian patent is filed.

d. **Resources Generated:** Two manpower has been employed and trained for the different processes of the system developed

Plans to take innovation further:
In the future, we can do the partnership as well as fundraising from different government and private schemes for the commercialization and phase four clinical trials of the developed product.

Risks envisaged:
No risk is involved in commercializing

Project Coordinator:
Amit Kumar Singh

Team Members :
Manoj Kumar

Contact :
61/3 Janta Nagar Garh Road
Meerut UTTAR PRADESH India-250001

A. R. Poongothai

Title of the Proposal:
Non-Invasive Point of Care Diagnostics For Sickle Cell Disease

Brief description:
To come up with a Non-Invasive device for Point of Care testing which could be more affordable and accessible. This technology makes use of measurement of blood parameters non-invasively, specially, the sickle cell. The Point of Care (POC) screening or testing shortens the time for clinical decision-making about additional testing or therapy, as transport and preparation of clinical samples no longer causes delays as the test results are available at the point of care rapidly. Hence, we are coming up with a NON-INVASIVE POINT OF CARE DIAGNOSTICS FOR SICKLE CELL DISEASE. Overall POC screening may improve medical outcome and lower costs. Keeping this in view, the POC for Sickle cell disease is being designed and developed.

Current stage of development:
Validation stage

Innovative Element(s):
Peltier, Sensor

Market Potential:
Sickle cell disease(SCD) is highly prevalent in the parts of central and southern India and is more common amongst the tribal population which constitutes 8.6% of the total population of India, Though SCD is a global issue , we intend to first reach the domestic market i.e., the Indian market.

National/Societal relevance:
A screening device for hematological disease more particularly for sickle cell disease at POINT OF CARE

Project achievements:

a. **Progress vis-a vis objectives:** To come up with a cost effective screening device for sickle cell disease and our achievements are we are now in the final device validation of the final prototype and soon would initiate the clinical validation in order to finalize on the working of the device on the patients.

b. **Technology/Product (to be) developed:** A sensor based technology which is a screening device for sickle cell disease at Point of care.

c. **IP generated/ Potential for IP generation:** The patent application has already reached an FER stage and presently preparing the documents to address the queries raised.

d. **Resources Generated:** At various points we have seeked and involved the expertise and technical know-how of the persons skilled in the art for the development of the device. So far we have been using the funds raised from BIRAC-BIG for the development of the device.

Plans to take innovation further:
We plan to take the innovation further for scaling up and commercialization of the product under development

Risks envisaged: Being a NON-INVASIVE POINT OF CARE SCREENING DEVICE very little /no risk is foreseen . In fact we use a Heating and a cooling mechanism namely the Peltier even while using a heating element to increase the temperature to just 400C.

Project Coordinator:
A. R. Poongothai

Team Members :
M.Venkateswara Rao,
Suman Jain

Contact :
501 Block IV Smr Vinay
Acropolis White Fields Kondapur
Hyderabad

Aumeesh Tech Pvt. Ltd

Title of the Proposal:
Mechanically Activated Stance Controlled Knee Ankle Foot Orthosis

Brief description:
Mechanical Actuated Stance Control Knee Ankle Foot Orthosis which focuses on providing a better alternative to the existing orthotic calipers by automatic locking and unlocking of the knee joint according to the stance and swing phase of the user to provide lower limb stability, mechanical stability, comfortable to wear for day to day life chores.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
It is a simple mechanism when the heel strikes the ground, the mechanism in the Knee locks the movement its only moving in an anticlockwise direction when the body facing the right-hand side up to 135 degrees of the angle at the standing position so its help in sitting. And when its in the swing stage the mechanism automatically unlock due to removed pressure in the heel.

Market Potential:
More than 2 million people in India and more than 100 million abroad Suffering from locomotor Disability

National/Societal relevance:
There are more than 2 million people in India and more than 100 million who suffer from a loco-motor disability like polio, cerebral palsy, spinal cord, multiple sclerosis, stroke, movement disability, etc.

Project achievements:

a. **Progress vis-a vis objectives:** The second milestone work is in progress.

b. **Technology/Product (to be) developed:** The Launch our Product is expected in the DEC 2022

c. **IP generated/ Potential for IP generation:** Indian IP - 341/DEL/2015

d. **Resources Generated:** Win awards like NCPEDP, MPHASIS award, Infosys Social Innovation Aarohan Award Silver Category, IITK -Techkriti and BIG ideas summit award

Plans to take innovation further:
Fundraise from winning Silver Prize in Aarohan award Organized by Infosys, RNCT NGO, MOBILITY India Foundation, MGM hospital, UMID foundation, FOD foundation and NINA Foundation

Risks envisaged:
The existing market players in orthotic and Prosthetic domain

Project Coordinator:
Aneesh Karma

Team Members :
Aaliya Baig, Aakash Singh , Neha Kumari, Jaykishan

Contact :
SINE,3rd Floor, Bombay, Center of Studies in Resources Engineering Y P Road, Academic Section, IIT Area Powai Mumbai

Ayati Devices Pvt. Ltd

Title of the Proposal:
Portable Diabetic Foot Screening Device

Brief description
NEUMU Neuropathic Measurement Unit to screen diabetic foot patients at an early stage to prevent foot amputations.

Current stage of development:
Validation

Innovative Element(s):
The major novelty of the device is in removing the subjectivity and automating the whole screening process. The invention is in designing a single probe which is the integration of multiple actuators and sensors. The probe can apply three different kinds of stimuli - pressure, vibration, and temperature

Market Potential:
5 Billion USD worldwide market including 10M+ GPs. The Serviceable Addressable Market for NEUMU in India is approximately USD 1.5 Billion.

National/Societal relevance:
One in every six persons with diabetes is from India. India is home to more than 70 million diabetic patients and is likely to grow to 123 million by 2040. Diabetes comes with a lot of complications. One of the complications which are important and neglected is diabetic foot.

Project achievements:

a. **Progress vis-a vis objectives:** Entered the market with MVP, called VIBRASENSE in January 2021. With VIBRASENSE, They will study the market, understand the customer behavior, do the market segmentation and get traction for NEUMU.

b. **Technology/Product (to be) developed:** The functional prototype is ready. We are now working on Design for manufacturing, testing, and Industrial designing for the product

c. **IP generated/ Potential for IP generation:** 2 patents filed

d. **Resources Generated:** Yes

Plans to take innovation further:
looking for fund-raising around INR 3 Crores

Risks envisaged:
The major challenge is awareness among the people. 90 percent of the subjects do not have the symptoms and end up with neuropathy. But this challenge can be overcome by equipping clinicians with the right technology, conducting more screening camps, and marketing campaigns.

Project Coordinator:
Nishant Kathpal

Team Members :
Rupesh Ghyar, Shumeel Momin, Adarsh Lodhi, Rajesh Jat

Contact :
507 C, ECSTASY BUSINESS PARK, City of Joy, ACC Road, Mulund West Mumbai Mumbai 400076

Bagmo Private Limited

Title of the Proposal:
To pilot a novel smart blood bag monitoring solution for safe and reliable blood transfusion

Brief description:
Blood availability in rural areas should be increased and in this regard, we developed a blood bag monitoring solution

Current stage of development:
Validation

Innovative Element(s):
The device is able to tell the temperature of each blood bag in an innovative way. The proposed product is bringing a process innovation in the way of blood transportation which will help the health workers to concentrate on healthcare delivery more efficient. The product also consisting of software as a service which is bringing innovation in the field of end to end documentation for the blood bag supply chain

Market Potential:
Every year 1 to 3% of the population require blood bags in a country. Using our solution we can monitor these many blood components and ensure quality and availability in the blood supply chain.

National/Societal relevance:
Nearly 30% of the maternal health associated with no availability blood. We enable healthcare facilities to reduce blood wastage and increase blood availability

Project achievements:

a. **Progress vis-a vis objectives:** The project objective is to complete the pilot studies in 10 blood storage centres and we have completed 50% of this objective.

b. **Technology/Product (to be) developed:** The product is market-ready and the beta product is deployed in both government and private hospitals.

c. **IP generated/ Potential for IP generation:** One patent is filed. Another one will be filed in this year.

d. **Resources Generated:** 5 freshers have worked and able to join multinational companies

Plans to take innovation further:
Looking forward to grants for productisation.

Risks envisaged:
Long period in converting interest to sales & Government level installation is time-consuming and expensive

Project Coordinator:
Ashfaq Ashraf

Team Members :
Anas Dalintakam, Dilghas Ommer, Vyshakh

Contact :
12/332, anjoom vadakara nadakkuthazhe kozhikode KERALA India-673104

BeAble Health Pvt Ltd

Title of the Proposal:
ArmAble: Gamified Upper Limb Rehabilitation - Extensive validation & Software Optimization

Brief description:
ArmAble is an Interactive game-based, arm training rehabilitative device. The product is aimed towards assisting Physiotherapists in the neuro-rehabilitation of stroke victims and motor rehabilitation of victims with an upper motor deficit due to conditions such as Cerebral Palsy, Multiple Sclerosis, Traumatic Brain Injury, Fracture, Frozen shoulder, etc

Current stage of development:
Validation

Innovative Element(s):
Biomimetics: The movement trajectories adapted by the device are biomimetic pathways that represent inter-joint coordinations & Virtual Reality: The device is coupled with an interactive gaming environment to keep the target user motivated.

Market Potential:
Targeted customers are more than 6000 hospitals and rehabilitation centres. The market size is estimated to be more than Rs. 200 Crores

National/Societal relevance:
The use of arm function contributes a lot to the lives of people and holds significant national and social importance.

Project achievements:

a. **Progress vis-a vis objectives:** Manufacturing of 3 devices for clinical study completed. Clinical Study initiated.

b. **Technology/Product (to be) developed:** Under validation

c. **IP generated/ Potential for IP generation:** Under process

d. **Resources Generated:** 2 Full-time employees employed

Plans to take innovation further:
Raising funds to scale up operations and sales

Risks envisaged:
Post-Covid Market scenario

Project Coordinator:
Habib Ali

Team Members :
Sreehari KG, Sravan Udutha, Jatin Goel

Contact :
223 - 2nd Floor, Center for Healthcare Entrepreneurship, IIT-H Kandi, Sangareddy Hyderabad

Biomoneta Research Pvt Ltd

Title of the Proposal:
Field validation of Z-Box: A device to reduce the spread of infection in Healthcare Environments

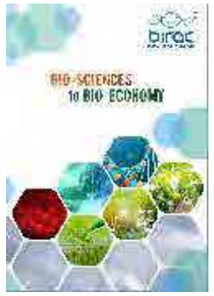
Brief description:
ZeBox Technology powered devices use air as a carrier medium to extract microbes from air and nearby surfaces and use a proprietary kill mechanism to eliminate viruses, bacteria, fungi and spores with very high efficiency. The devices are capable of eradicating billions of microbes in less than 10 minutes under test conditions

Current stage of development:
Commercialization

Name of the commercialized Product/Technology:

ZeBox-Mid ZeBox-Mini
Date of commercial launch- 2019-11-22
Number of units sold- 30
Number of end users- 300

Innovative Element(s):
The technology combines a novel surface that is potentiated in the presence of a designed electric field, and smart air-flow geometry to trap and kill microbes from free flowing air.



Market Potential:
The size of the global air disinfection market was USD2,484 million in 2018. The Indian market size was USD49 million with a projected CAGR of over 28 percent

National/Societal relevance:
The World Health Organization states that Healthcare associated infections, HAIs, are the most frequent adverse event in healthcare delivery worldwide

Project achievements:

a. **Progress vis-a vis objectives:** Successfully demonstrated the technologys capability in reducing environmental microbial load in healthcare setting. Future studies will be undertaken to show its efficiency in reducing infection rate.

b. **Technology/Product (to be) developed:** ZeBox Technology: An air-decontamination technology

c. **IP generated/ Potential for IP generation:** Filed (International Application No.: PCT/IN2018/050296)

d. **Resources Generated:** 8 manpower employed

Plans to take innovation further:
Commercialization and licensing of ZeBox Technology

Risks envisaged:
Primary risk is in differentiating the product and helping customers gain confidence in the claims

Project Coordinator:
Janani Venkatraman

Team Members :
Arindam Ghatak,
Ramanujan K.S

Contact :
8, Prestige Regent Place,
28/2, Thubarahalli Village,
Varthur Bangalore
KARNATAKA India-600066

Bionic Hope Pvt. Ltd.

Title of the Proposal:
User Validation and Certification for Affordable Upper Limb Prosthesis

Brief description:
We at Robo Bionics have Developed Grippy. India's own NABL Lab Safety Tested and Certified, 3D printed Prosthetic hand with a sense of touch and multi-grip control. Designed, engineered, and proudly made in India, Grippy is a lightweight and affordable, battery-powered prosthesis now available in the Indian market for people with below elbow amputation age 15 years and above welcome to the future where we have made Bionics as simple as switching on a light bulb.

Current stage of development:
commercialization

Commercialized in the name of (Product/Technology Name): Grippy

Date of commercial Launch: 2021-04-01

Number of end users: 15

Innovative Element(s):
Grippy focuses on achieving Grip control and Shape Adaptation mechanically instead of traditional devices that do the same electronically. Grippy also is the only device that can tell the user if the object they are picking is a soft or a hard one without the need for the user to look at it. All of this aids in a faster training of a Single day and ensures ease of use.

Market Potential:
Around 5 Million amputees worldwide and 1.6 Million amputees in India with some form of hand amputation can benefit from this technology.

National/Societal relevance:
India relies solely on import devices to obtain similar functionality, Grippy is an Indigenous product that can replace these import devices.

Project achievements:

a. **Progress vis-a vis objectives:** Product ready to Launch in the Market

b. **Technology/Product (to be) developed:** NA

c. **IP generated/ Potential for IP generation:** The IP generated for Grippy can be implemented into other domains as well

d. **Resources Generated:** Manufacturing Facility Created. 3 Personnel Trained. Investments from IC IITP and SINE IITB

Plans to take innovation further:
Partner with at least 1 Limb fitting Centre / Hospital in each State in India to gain wide-spread reach. Raise Funding to scale-up Manufacturing as well as make Grippy an export Product for International Markets

Risks envisaged:
Changing Regulatory Requirements

Project Coordinator:
Llewellyn Dsa

Team Members :
Anil Nair

Contact :
Bionic Hope Pvt. Ltd. Incubation Centre, 06/415, Incubatee Office 1, Block 6, IIT Patna,
Bihta Kanpa Road Bihta Patna
BIHAR India-801103

BioSensika Labs LLP

Collaborator: Labcare Diagnostics Pvt. Ltd

Title of the Proposal:
Lateral flow based testing kit for Covid-19: Combined Antigen and Serological CAS detection

Brief description:
The objective of the testing kit is to check early/ ongoing/ post-infection conditions by measuring IgG, IgM and viral antigen so that necessary measures can be taken. The specific detection of viral antigens and antibodies are detected onto the designed sensors which are asses by fabricated readout. The developed test is ideally suited for hospitals, clinics and test laboratories.

Current stage of development:
Validation

Innovative Element(s):
Sensor design, Nanomaterial synthesis, Assay methodology

Market Potential:
The global COVID-19 diagnostics market size is estimated at USD 84.4 billion in 2020 and is expected to expand at a compound annual growth rate CAGR of 3.1 from 2021 to 2027. The market is driven by the rising government initiatives targeted toward the implementation of mass testing.

National/Societal relevance:
Our technology can act as a quick and one-stop solution to the current crisis of COVID pandemic for screening.

Project achievements:

a. **Progress vis-a vis objectives:** (1). development of point of care electrochemical test for COVID-19 antibodies. (2). development of point of care electrochemical test for COVID-19 antigens. (3). development of point of care electrochemical test for COVID-19 RNA.

b. **Technology/Product (to be) developed:** It uses electro chemistry principles using screen printed electrodes for detection of analytes.

c. **IP generated/ Potential for IP generation:** We are in process of drafting Indian patent on the design of sensors and the assay methodology

d. **Resources Generated:** Project fellow is hired under the project. Interns are being trained on the electrochemical workstation which is procured under the project.

Plans to take innovation further:
We are planning to integrate our sensors for other infectious diseases. We need to raise aggregate 4-5 Crore funding over the next 2-3 years to develop the entire regime of infectious disease diagnostic solution. For this purpose, we continue to explore funding from angel investors and Govt. funding schemes

Risks envisaged:
Market is flooded with conventional kits mainly lateral flow assays and the gold standard PCR. Will be challenging for a new technology to intrude the market.

Project Coordinator:
Dr. Priyanka Sabherwal

Team Members :
Kishor Kumar

Contact :
BioSensika 1003, Julian Alps J4, B Wing, Bhakti Park Wadala East Mumbai MAHARASHTRA India-400037

BKL Walawalkar Hospital Diagnostic Research

Title of the Proposal:
Menstruation Prediction Kit during luteal phase of menstrual cycle

Brief description:
Indian women face anxiety about menses onset when socializing or in a professional setting. Premenstrual period lingers for almost two weeks. Its accurate prediction will help in planning events. This will help pre-menopausal women. The kit is very easy to carry and simple to use.

Current stage of development:
Validation

Innovative Element(s):
Currently no such point of care device is available which is easy to carry and operate. The test is based on saliva sample and not on blood and urine which needs separate, private place.

Market Potential:
Government of India has started partnering- Reproductive and Child Health Program, Eco Femme and My Pad. On account of these factors, IMARC Group estimates the market value of sanitary pads to reach US$ 992.8 Million by 2024, at a projected CAGR of around 12 during 2019-2024.

National/Societal relevance:
Despite advances in technology and education India is still predominantly rural where women folks are expected to carry family traditions and rituals. In urban India substantial number of women commute for their jobs, participating sports activities etc. All these practices might get hampered by sudden onset of menses. So an accurate predication will help women to reorganize these activities.

Project achievements:

a. **Progress vis-a vis objectives:** Prototype is in validation stage. We tested total 100 women from three different age groups for blood and salivary progesterone. In addition, we also tested one third of these for one complete menstrual cycle for salivary progesterone

b. **Technology/Product (to be) developed:** Technology under validation. We have a prototype manufacturing agreement with a LFIA manufacturer.

c. **IP generated/ Potential for IP generation:** We have applied for Indian Patent. Provisional Patent No.:201921024182 A

d. **Resources Generated:** Two lab technicians, 1 medical officer and 1 social worker were hired for execution of this project. We were able to setup an ELISA testing laboratory in the hospital from the funds provided by BIRAC.

Plans to take innovation further:
We are exploring partnership for contract manufacturing of LFIA kits and marketing agreements with organizations having presence in the pharmaceutical and womens health care market.

Risks envisaged:
Women health and women menstruation cycle is important but neglected issue in India. Thus there might be some social taboo attached to the purchasing of the kit. Inclusion of kit together with sanitary pad will lead to increase in cost

Project Coordinator:
Dr Suvarna Netaji Patil

Team Members :
Rohini Shinde, Miss Shraddha Desai, Miss Pradnya Pawar, Mrs Megha Pise

Contact :
Post Sawarde Taluka Chiplun, District Ratnagiri Sawarde Chiplun MAHARASHTRA India-415606

Centre for Human Genetics

Title of the Proposal:
Affordable technologies for diagnosis of rare skin genetic disease - Epidermolysis Bullosa

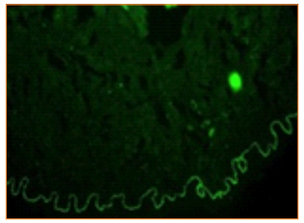
Brief description:
Epidermolysis bullosa (EB) is a rare genetic disorder characterized by blistering of the skin and mucosal surfaces. The severity and prognosis of the disease depend on the type of (EB). The diagnosis of (EB) subtypes is based on clinical manifestations, immunofluorescence mapping (IFM) of skin biopsy, electron microscopy and genetic testing. (IFM) is the standard diagnostic tool followed worldwide. An earlier study involving 85 Indian EB patients and found IFM useful in sub typing, particularly in the early infantile period.

Immunofluorescence mapping and subtyping of EB: We propose to develop antibodies to map the proteins affected in EB simplex, junctional and dystrophic conditions.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The unique antigenic regions are used to generate antibody for skin proteins. IFM of skin disease for IFM would help to find molecular pathology in the heterogenous genetic condition for better outcome /prognosis. Clinical diagnosis and NGS are also employed who have their merits, however the skin pathology identifies how the mutations skin condition pan out in case of allelic heterogeneity.

Market Potential:
The antibody validation for skin pathology holds promise for diagnostic kit for subtyping EB on a skin biopsy. The product is expected be available by June 2021.



National/Societal relevance:
This disease is reported pan India however the prevalence is not clear due to poor registry data. Presently the project is aimed at serving the unmet national need for the EB community by providing the affordable accessible antibody panel

Project achievements:

a. **Progress vis-a vis objectives:** Generation of Specific antibody against proteins involved in genetic disease and visualization on normal skin sections: (i) Design and generation of epitopes specific to target proteins, KRT14, Laminin Alpha, Laminin Beta, Laminin Gamma, Collagen 4a and Collagen7a. (ii) Expression of recombinant protein, immunization of the animals and analyzing immune response KRT5 KRT5 , KRT14, Laminin Alpha, Laminin Beta, Laminin Gamma, Collagen 4a and Collagen 7a. (iii) Generation of cell fusions mabs' screening and validation

   For deriving skin sections, due approvals were obtained from human ethics

   Immunofluorescence on skin sections Krt5 Krt14, laminin beta collagen 7a are accomplished.

b. **Technology/Product (to be) developed:** Development of multi channel imaging of Biopsy using EB antibody panel.

c. **IP generated/ Potential for IP generation:** The EB specific antibodies with unique Compliment Determinant Region CDR

d. **Resources Generated:** A complete pipe line for mapping of the antigenic regions, generation of antibodies and validation under one roof at Centre for Human Genetics, Bengaluru

Plans to take innovation further:
We are scaling up production using roller bottles. We would seek funding sources in public and private agencies.

Risks envisaged:
We do have limited understanding about deploying in market. We are looking forward to take this product by non exclusive licence.

Project Coordinator:
Gurudatta Baraka

Team Members :
Ravi Hiremagalore, Anjali Karande, Asha Kubba, Mala R, Sheetal Desai

Contact :
Biotech Park Electronics city phase 1 Electronics city phase 1 Bangalore KARNATAKA India-560100

Cutting Edge Medical Devices Pvt. Ltd.

Title of the Proposal:
Scintiglo-a portable urine protein analyzer device for Mass Healthcare

Brief description:
SCINTIGLO is a smart Point of care diagnostic device for early detection of kidney disease in patients with diabetes and hypertension and also identify high-risk pregnancies by a simple urine test at point of care with lab like accuracy instantly at a fraction of cost.

Current stage of development:
commercialization

Commercialized in the name of (Product/Technology Name):
SCINTIGLO - A digital Microalbuminuria estimation Device SCINTIGLO MINI

Date of commercial Launch: 2020-11-18

Number of units sold: 56

Number of end users: 56

Innovative Element(s):
1. Liquid biochemistry based. 2. Not a dipstick based device unlike others. 3. Affordable. 4. Data collection capabilities. 5. Smart capabilities and works with Android/iOS smartphone applications.

Market Potential:
10,00,000 Customers including small and medium size pathology labs, Individual/poly clinics and hospitals in India. Ideal for Primary Healthcare centers and Heath and wellness centers in public healthcare system.

National/Societal relevance:
Ideal device for early detection of Chronic Kidney disease (CKD) in patients very early for a proper management of disease and help reduce the burden of CKD in our Country.

Identification of high-risk pregnancies very early, for Pre-eclampsia by a simple urine test and have a better outcome of pregnancies an reduce Maternal Mortality.

Project achievements:

a. **Progress vis-a vis objectives:** We have the all the required Quality and regulatory approvals from Government of India and have the product in the market since Nov 2020.

b. **Technology/Product (to be) developed:** Home Healthcare version of the device is under development

c. **IP generated/ Potential for IP generation:** Patent pending

d. **Resources Generated:** DIPP recognised startup, 10 Employees, 22 Trainees trained. Taking the product to Mexico very soon, signing agreement with one of the large medical device distributor in Mexico

Plans to take innovation further:
MOU with AIIMS Rishikesh , Oncosurgery department for product development.

Risks envisaged:
We are looking to raise funds and are finding it difficult to reach out to the right investors

Project Coordinator:
Pankaj Parashar

Team Members :
Ankita Parashar, Rishi Sharma, Pooja Sharma, Mithilesh Pal, Pankaj Vyas

Contact :
Sector 2406 Sudama Nagar Indore MADHYA PRADESH India-452009

Devjani Ghosh Shrestha

Title of the Proposal:
Patient Stratification for Transoral Robotic Surgery in Oropharyngeal Cancers through development of a Non-invasive HPV Detection Panel

Brief description:
Proposed solution: Development of a non-invasive, salivary and serum E6/E7 exosomal mRNA HPV Diagnostic Panel. It will address the following unmet needs in the treatment of Human Papilloma Virus positive oral and pharyngeal cancers: Unmet Need: (1) No routine screening HPV test for oral cancers (2) Lack of risk assessment and determination of prognosis in HPV positive oral cancers (3) Lack of comprehensive, simple, non-invasive, cost-effective, biomarker protocol for follow up. USP: Comprehensive HPV Diagnostic and Therapy Follow-up panel (1) Non-invasive (2) Cost-effective

Current stage of development:
Validation

Innovative Element(s):
Gold-standard for diagnosing HPV status is detection of HPV E6/E7 mRNA. Our technology is based on detection of HPV E6/E7 mRNA in exosomes of body fluids. This detects transcriptionally active virus and hence active infection. Since the test is non-invasive, simple and cost effective, it will act as a screening, diagnostic and follow up biomarker protocol for HPV positive cancers.

Market Potential:
The market for HPV Diagnostics has grown exponentially in the last few years from 267 million in 2009 to 617 million in 2015 - Indian market is predicted to be one-third & Southern Asian market half of the worldâ ™s market. All the HPV diagnostics available in the market are validated in cervical cancers and are biopsy or PAP smear based. This head neck cancer validated non-invasive diagnostic and follow up panel promises to have immense potential in the Indian and world market.

National/Societal relevance:
Head and neck squamous cell carcinoma is the sixth most common cancer worldwide and fifth most common cancer in Southeast Asia region. Hence it is of very high social relevance.

Project achievements:

a. **Progress vis-a vis objectives:** We will complete development of the prototype i.e. establishment of a protocol for exosomal detection of HPV E6/E7 in body fluids.

b. **Technology/Product (to be) developed:** We plan to enter Late validation stage in 2021 and further strengthen the panel with additional markers, on completion of BIG Project, followed by Regulatory Clearance in 2022. We expect to hit the market latest by 2023.

c. **IP generated/ Potential for IP generation:** Indian and PCT Filing completed
Indian Patent Application no. 201931019425. International Application No: PCT/IN2020/050717. Applicants: DEVJANI GHOSH SHRESTHA. Title: “METHODS FOR DIAGNOSIS AND IN VITRO RISK STRATIFICATION FOR HEAD AND NECK CANCER BASED ON EXOSOMAL MRNAS”. Patent applied for: Process patent and patent of the HPV E6/E7 Primers

d. **Resources Generated -** We have employed our Junior Scientist and Senior Scientist for the team with the grant funds.

Plans to take innovation further:
(1) Collaboration with Apollo Hospitals, for project execution and future commercialization. (2) In conversation with Investors in the Cambridge Ecosystem for partnerships for International Validation of the Panel .

Risks envisaged:
(1) Further strengthen the panel with additional markers to make it a comprehensive screening, diagnostic and follow up tool. (2) Recruitment of patients is a challenge in this COVID-19 Pandemic period which needs to be addressed.

Project Coordinator:
Devjani Ghosh Shrestha, Consultant ENT and Head-Neck Surgeon

Team Members :
Sreekanth Patnam, G. Praveen, Sasidhar Manda

Contact :
Devjani Ghosh Shrestha Apollo Gleneagles Hospitals 58, Canal Circular Road Kadapara Kolkata 700054

Dzeal Private Limited

Title of the Proposal:
Clinical validation of BIG file

Brief description:
BIG file is a patented India rotary endodontic file in basket shape that is Conservative, Failsafe and easy to master technology.

Current stage of development:
Licencing out the technology for manufacturing and marketing

Innovative Element(s):
Innovation lies in the design of the file and the change it will bring of doing root canal treatment. This innovation is an attempt to merge these efficient ways, where we want removing organic tissue by efficient circulation of sodium hypochlorite with minimal removal of hard dentine.

Market Potential:
Global Market of rotary endodontic file system is about 200 Million USD.

National/Societal relevance:
(1). Reduce incidence of file separation will help in providing the optimum root canal services to patients. (2). As more teeth would be saved with this treatment, it will help to decrease the morbidity and poor quality of life due to missing teeth. (3). Reduced incidence of file separation and complete removal of broken file will boost the confidence of dentist.

Project achievements:

a. **Progress vis-a vis objectives:** An ex vivo study on extracted teeth has shown that the file has enough cutting efficiency to be used as a single file system for endodontic treatment.

b. **Technology/Product (to be) developed:** Product is ready to be manufactured and marketed.

c. **IP generated/ Potential for IP generation:** Indian Patent has been granted.

d. **Resources Generated - Manpower:** 4 engineers has worked on developing the manufacturing process of file.

Plans to take innovation further:
Fund raising for manufacturing and marketing.

Risks envisaged:
Manufacturing setup and marketing need substantial amount of funds.

Project Coordinator:
Lavkesh Bansal

Team Members :
Vishal Shendge, Meet Patel, Shilpi Bansal, Mangesh Patankar, Dr. K S Banga

Contact :
FLAT NO. 102, BLDG. NO. D/05, PLOT NO.38 SAGAR DARSHAN CHS, SECTOR 18 PALM BEACH ROAD NERUL / THANE MAHARASHTRA India-400706

FastSense Diagnostics Pvt Ltd

Collaborator: Revy Environmental Solutions

Title of the Proposal:
Point of care detection to trace COVID-19 sources with wastewater-based Epidemiology.

Brief description:
We proposed a LAMP based detection kit as a surveillance tool for screening of waste-water samples of communities based on wastewater-based epidemiology WBE. Our proposed point of care LAMP based detection kit can trace covid-19 genetic material in wastewater of communities for identification of asymptomatic patients.

Current stage of development:
Validation

Innovative Element(s):
At present most of the diagnostic assays are detecting Covid-19 from nasal swab and mostly symptomatic patients are being tested. With our proposed surveillance tool, we can detect covid-19 traces in water samples from community and asymptomatic patients can be identified. Our technology is based on RT-LAMP and we are developing an assay that can be deployed point of care and to the best of our knowledge no waste water based method is available on the same concept.

Market Potential:
In an estimate, concentrations of 0.15 to 141.5 million viral genomes per liter of wastewater generated in North America and Europe per infectious person/day. As covid-19 outbreak is a short time opportunity & WBE based surveillance tool has potential to serve as an additional screening method to identify infected asymptomatic patients at community level in a rapid and point of care manner in lesser cost.

National/Societal relevance:
Our proposed WBE based surveillance tool can provide an efficient screening tool at community level and being point of care any remote location/ villages or in urban societies by monitoring the covid-19 traces in wastewater, asymptomatic patients can be identified and preventative measures be applied accordingly. Our detection kit can be deployed as an effective monitoring tool in many locations to get data about infected personals.

Project achievements:

a. **Progress vis-a vis objectives:** Water processing protocols have been optimized and we have optimized RNA extraction and spiking volume. In-house detection assay has been developed and tested with real samples for sensitivity and specificity.

b. **Technology/Product (to be) developed:** There are two vertical in this proposal: development of in-house assay for covid -19 and we have attained this milestone while other vertical is point of care WBE surveillance tool and we are optimizing the strategy to develop an easily handled on the spot water processing and monitoring assay for Covid-19 screening.

c. **IP generated/ Potential for IP generation:** We have filed one patent before the start of the project IN 202021015198 and now would file another once we completed the process optimization and real sample testing in wastewater samples.

d. **Resources Generated:** We have an established infrastructure for mol bio assays also. We are recipient of Seed fund. We have increased our team strength and have given employment to three more people in our company. Its a collaborative project with Revy Environmental Solutions based on their expertise in water processing.

Plans to take innovation further:
Once the POC would be ready with validations, we would like to take it further either by raising funds for large scale manufacturing or jointly in partnership with established market players for better reach.

Risks envisaged:
Covid-19 was a sudden outbreak and still studies are going on about its pathogenicity, spread and presence. So in this scenario a quick product development is the key of market entry. Due to unpredictability of many aspects associated with Corona, the major risk is any delay in product development.

Project Coordinator:
Preeti Nigam Joshi

Team Members :
Mamta Gandhi, Azima Khan, Saurabh Srivastava, Sweena Chaudhary, Vanita Prasad, Kishore Sonwane

Contact :
Flat No. A 701, Bhagwati Aashiyana, S.No.114 Pashan Pune Pune MAHARASHTRA India-411021

Gavaskar Jayakanthan

Title of the Proposal:
Shelf life enhancement of perishable horticulture produce using biomolecules

Brief description:
The proposed innovation is a biomolecular formulation in portable forms of spray and coating on biodegradable materials. It supresses ethylene using blend of specific antagonists such as chitosan, salicylic acid and gibberellic acid is the underlying principal of the proposed product.

Current stage of development:

- Various blends of Chitosan, salicylic acid and gibberlic acid in different concentrations are being developed and shelf life studies on fruits and vegetables with different blends are currently undertaken.
- Simultaneously bags, papers and other accessory materials to coat the blend and cover the fruits and vegetables is also in progress
- Optimized blend formulation and supporting materials will be developed into a product in this project.
- Further, microbial origin ethylene deaminase extract is processed through fermentation process to limit the ethylene –climacteric peak thus extension of shelf life. The process is under standardization and will complete earliest.

Innovative Element(s):
It is a unique technology of biomolecule blend that suppresses ethylene biochemical function in fruits, vegetables and cut flowers extending the shelf life. The product has three prototype – (1) biodegradable sheet coated with blend of Gibberlic acid, chitosan and salycilic acid (GCS) to wrap produce at harvest (2) liquid spray to use in pre/postharvest (3) cotton/jute bag coated with GCS formulation to carry the produce

Market Potential:
Preliminary work done has extended the shelf life of produce by inhibiting ethylene release the underlying chemistry for extended shelf is also understood and published in reputed journals. In banana 5 days and in papaya 7 days additional shelf life has been achieved.

National/Societal relevance.
This technology sustainably addresses the issues of postharvest losses for farmers and exporters and directly adds to their income. The technology is safe and ensures quality life for consumers and farmers by ensures supply and consumption of fresh quality produce with high nutritional and aesthetic value. The technology also has potential environmental impact by reducing usage of plastic covers.

Project achievements:

a. **Progress vis-a vis objectives:** Antagonists such as chitosan, salicylic acid and gibberellic acid optimum concentrations will be standardized and various blend combinations will be worked out for development of product for enhanced shelf life of the fruits and vegetables

b. **Technology/Product (to be) developed:** The product has three prototype – (1) biodegrabale sheet coated with blend of Gibberlic acid, chitosan and salycilic acid (GCS) to wrap produce at harvest (2) liquid spray to use in pre/postharvest (3) cotton/jute bag coated with GCS formulation to carry the produce

c. **IP generated/ Potential for IP generation:** Quick prior art search says good scope for patenting. Patent will be filed soon

Plans to take innovation further:
Talks are going on with few companies and expressed their interest for validating once the final product with data is developed. Once the final field validation data is obtained the technology can be completely commercialized. Also planning to collaborate with companies which can help in commercializing the technology as channel partners.

Risks envisaged:
1. Un expected failure of crop due to environmental factor or diseases
2. Reaching out to grass root level

Project Coordinator:
Gavaskar Jayakanthan

Team Members :
Manjunath, Vishnuvardhan, Vasudev

Contact :
11204, Tiara Block, Prestige Monte Carlo, Ananathapura gate, Yelahanka new town, Bangalore 560064

Gowsiya Shaik

Title of the Proposal:
Aeroponic technology for the Coleus forskohlii and Vetivera zizanoides for improved production of roots containing active principles.

Brief description:
Vetivera is being cultivated for essential oil production from its roots. And Coleus is an important medicinal plant cultivated for forskohlin which is derived from its roots. We propose a novel aeroponic technology platform for the cultivation of these plants and their roots with multiple harvests to achieve high yields of the active components.

Current stage of development:
POC

Innovative Element(s):
Technology and Process

Market Potential
Huge

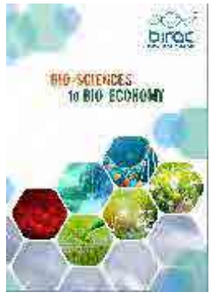
National/Societal relevance:
End product has both national and global relevance.

Project achievements:

a. **Progress vis-a vis objectives:** All envisages objectives are being reflected through the progress of the project.

b. **Technology/Product (to be) developed:** Commercial aeroponic platform for the improved root growth and active principles in vetivera

c. **Resources Generated:** (in terms of Manpower employed/trained, Facility Created, Enterprise Created, Fund Mobilization from other sources etc) Manpower-3 members



Plans to take innovation further:
Planning for partnership

Risks envisaged:
NA

Project Coordinator:
Gowsiya Shaik

Team Members :
Appanna V. Koppad, Kiranmai Kurnool, Shashibhushan, Yeshwanth, Asifa Shaik, Krishnappa

Contact :
12/107, Ramabhadrappa building, Thindlu, Bengaluru-560097

Healthcare Technology Innovation Center, IIT Madras

Collaborator Name: Mitra Medical Services

Title of the Proposal:
SmartEye - Technology platform for endoscopy

Brief description:
SmartEye is a comprehensive technology platform for endoscopy including all hardware and software components, and two flexible endoscopy products. The goal of the project is to indigenise the flexible endoscopy technology, develop, deploy, clinical validate and market, the following products- a. Flexible Video Endoscope, b. Advanced Multispectral Flexible Video Endoscope

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Typical endoscopy systems available in market come with passive scope which can only be used with a specific video processor. The primary differentiator of the SmartEye platform is the intelligent USB interface scope feature which provides scope agnostic functionality for the SE video processor. In addition, in contrast to the typical FPGA heavy processing units available on the video processors from other manufacturers the SE video processors runs on a CPU-GPU architecture.

Market Potential:
The targeted price point half of other competitors and state of the art image quality should be able to provide a good market advantage in India, South East Asian, Latin America and African countries.

National/Societal relevance:
The primary objective of the project is to indigenize the flexible endoscopy technology in India thereby making it possible to bring down the cost to half of the competitors price at the same quality. In addition, capabilities like advance multispectral imaging techniques are supposed to help even clinicians with minimal experience in decision making. Thus, the cost and lack of expertise issues in India are expected to be addressed with this solution

Project achievements:

a. **Progress vis-a vis objectives:** The goal of the project is to develop, deploy, clinical validate and market two variants.They are currently in prototype stage.

b. **Technology/Product (to be) developed:** Product 1 SE +V1 clinical validation is expected to be completed aby early 2022 and will go it manufacturing immediately after that. Product 2 SE +V2 will be available in Q4 2023.

c. **IP generated/ Potential for IP generation:** Potential:
   1. Combined AGC/ALC/AEC for endoscopic imaging systems
   2. Multispectral systems with LED at the tip for flexible endoscopy

d. **Resources Generated:** A team of 15 employees for development and 4 students 3 MS and 1 PhD for research.

Plans to take innovation further:
We are in the process of platformatising CPU-GPU architecture for imaging applications involving miniature cameras. This will mean short development time for similar systems like bronchoscopy, ureteroscopy, laparoscopy and laryngoscopy.

Risks envisaged:
Miniature lens design is outsourced to facilities in Switzerland and Japan due to the lack of availability of micro-optics fabrication facilities in India. Lead time and cost per unit is absolutely in their control.

Project Coordinator:
Mohanasankar Sivaprakasam

Team Members :
Preejith S P, AMALAN S, Gurrala Ajay Kumar, Ananth Raj V, Shubham sharma, K. Yesurathnam, A.Maheswari

Contact :
Room No: 215, Periyar Tbi, Periyar Maniammai Univeristy, Periyar Nagar Vallam Thanjavur Tamil Nadu India-613403

Heamac Healthcare Pvt. Ltd

Title of the Proposal:
nLite 360 – An intelligent phototherapy device to treat jaundice neonates

Brief description:
We intend to solve the need for a dedicated device to treat all the severities of jaundice providing customized and optimum treatment. So, we developed and validated the ideas i.e., nLight360 – an intelligent Phototherapy system to provide dynamic treatment to neonatal jaundice ensuring customized and uninterrupted treatment and Zero separation between the mother and the child.

Current stage of development:
Minimum Viable Product (MVP) development and Pre-Compliance Testing

Innovative Element(s):
The innovative elements of nLite 360 are
1. MULTI SURFACE MODE in Heamac Phototherapy System. 2. MODULAR DESIGN with battery backup. 3. COMPATIBLE with Neonatal ICU products. 4. MULTI BABY MODE. 5. SMART IRRADIANCE MODE: Our device adjusts the intensity of therapy as per the inputs of Baby Serum Bilirubin Levels, Weight and Gestational age.

Market Potential:
There is no phototherapy device in the market which can treat severe jaundice cases. We are focusing on the demand of 50,000 devices per annum. We have potential clinical partners to conduct trials and MoU with the Manufacturer to produce the Marketable product. We have validated our product design and included safety alarms after discussion with the medical device manufacturer.

National/Societal relevance:
The existing product providers are not able to address these sectors of the population where 80% of the deliveries happen and lead to high Neonatal Mortality Rate (NMR) . The major issue is product maintenance and servicing. We are addressing both issues with our design innovations and customized business model. This will reduce 40% of the neonatal mortality and morbidity rate and also save the babies from lifetime disabilities.

Our vision is to provide solutions to the neglected needs in the field of neonatal and maternal health by ensuring Zero Separation between the child and mother.

Project achievements:
Secured the Nidhi Prayas grant by Derbi Foundation

a. **Progress vis-a vis objectives:** We have developed the Minimum Viable Product (MVP) of our concept. We are currently working on the Pre compliance testing of the device
b. **Technology/Product (to be) developed:** Heamac developed the product "nLite-360", which is an intelligent phototherapy device for neonatal jaundice conditions. The device is AI powered and can detect the condition of the baby on its own.
c. **IP generated/ Potential for IP generation:** We have a patent filed for our innovation and the details of the patent are
Title of Patent: Phototherapy System, Apparatus, and Kit (Patent Number: 201841024663(Indian Patent Office)
Patent Status: Non provisional Filed (Examination Pending)
Patent Number: PCT/IN2019/050493 (Jurisdictions filed in THE INTERNATIONAL BUREAU OF WIPO)
d. **Resources Generated:** We have four founding team members and ten employees. The source of funding into the company was all from grants and funds. We received incubation support from IIT Hyderabad and IIM, Calcutta.

Plans to take innovation further:
We have our manufacturing and distributing partner, Nice Neotech Medical Systems from Chennai. We have our clinical advisors from Niloufer Hospital, Khamineni Hospitals, MNR Hospital and Mallareddy Hospitals.
We also have our US Partner BiliTool who will support us in expanding our product deployment to the US markets.
We have already received LoI's from Hospitals in Dubai to launch our product into their hospitals after completing the clinical trials of our product.

Risks envisaged:
Change in the design post clinical trial will include additional costs from iterative tests. The current pandemic will require additional safety and sanitation measures. This might make our trials more difficult. But On the other hand, we can make our device more robust for use and sensitive for user safety.

Project Coordinator:
Subbrahmanyam Prasad Muddam

Team Members :
Akitha Kolloju, Karthikeyan Harikesavan, Renu John, Morarji Peesay, Prashanth Babu

Contact :
H. No: 1-11-254/11, Motilal Nagar, Behind ICICI Bank, Begumpet - 500016

Huwel Lifesciences Pvt. Ltd.

Collaborator Name: National Institute of Animal Biotechnology

Title Of The Proposal:
Complete solution for molecular diagnosis of COVID 19 multiplex assay along with screening for other related respiratory diseases

Brief description:
We aim at optimizing and establish manufacturing of all the reagents required to perform real time PCR assay which includes sample collection, extraction and amplification.

At present Huwel is manufacturing Enzymes and mixes. Although high quality enzymes and optimized mixes are main requirement for manufacturing of molecular assays, good quality primer and probes are required to achieve good sensitivity and stability.

In India we realize that 95 of fluorescence probes are synthesised outside country and at the time of crisis it becomes bottle neck to procure sufficient quantity of probes. Moreover since most of the primers and probes are to imported, the supply to the researcher would take more than a month for simple probes.

Next technology which is lacking in the country is nucleic acid extraction kits. In this case again we are dependent only on international suppliers. Molecular transport medium not only allows to transport intact Nucleic acid at room temperature but also inactivates the virus. For Countries like India, where containment facilities are not in abundance molecular sample transport medium becomes of utmost importance.

Here we propose to develop molecular transport medium, establish manufacturing of different fluorescent probes, and development of silica coated magnetic beads which can be produced in bulk easily and automated easily for efficient extraction avoiding cross contamination. Detection Panel will include multiplex assay for COVID-19, as well as other related and symptomatically similar respiratory diseases.

Current stage of development:
Commercialization

Commercialized in the name of:
Huwel MTM, Huwel nucleic acid extraction kit

Date of commercial Launch: 2020-07-02

Number of units sold: 17 lakh of extraction units, 8lakh 0f Huwel MTM

Number of end users: 45 customers

Innovative Element(s):
Transport medium which stabilises DNA and RNA at room temperature. Multiplex kit with inhouse generated primers and probes

Market Potential:
Currently Indian market is more than 200-250 Cr Indian market , Global market is more than 200 milllion USD.

National/Societal relevance:
Huwel is the only company which manufactures all the components inhouse, this make COVID kit to priced lowest in the market. Hence, screening for mass is possible. Screening the best way to curtail transmission of COVID.

Project achievements:
a. Progress vis-a vis objectives- Establishing synthesis of primers and fluorescent probes and kit validation
b. Technology/Product (to be) developed – Extraction kit and molecular transport medium already in the market.
c. IP generated/ Potential for IP generation - Potential: Molecular transport medium can be explored for patenting
d. Resources Generated - Oligo synthesis facility created

Plans to take innovation further:
Fund raising for bulk production

Risks envisaged:
Already in the market

Project Coordinator:
Rachana Tripathi

Team Members :
Rachana Tripathi, Munpally shesheer Kumar, B.Ravi, Shibashish sahoo, Sheema Rameeza

Contact :
House No. 3-14/2, Narsingi First Floor, Rajendra Nagar, Hyderabad-500075

Huwel Lifesciences Pvt. Ltd.

Title of the Proposal:
Development and manufacturing of end to end room temperature stable molecular diagnostic reagents.

Brief description:
Product is ready to use lyophilised DNA and RNA real time PCR amplification reagent for HBV and Dengue. Product does not require dry ice transportation and -20 storage. This will allow usage of assay in resource limited setting and drastic reduction in transportation cost.

Current stage of development:
Validation

Innovative Element(s):
Stability at room temperature.

Market Potential:
As product does not require dry-ice shipment, it can be transported to different parts of country or internationally without hassel of monitoring temperature and maintaining dry ice. long distance dry-ice transport at times costs more than cost of kits, making it expensive and restricts the distribution of kits to different countries.

National/Societal relevance:
COVID season has taught us that reach of real time PCR testing to each and every corner of country is important. and present innovation would allow its reach and application in every part of country.

Project achievements:

a. **Progress vis-a vis objectives:** Establishing lyophilization of Amplification mixes in ready to use vials at lab scale- done, Amplification mix preparation on production scale-done, Generation of thermostable reverse transcriptase enzyme-done

b. **Technology/Product (to be) developed:** Lyophilsed or dry down product of multiplex asasy is developed as platform technology . In view of family approach for amplification in dry down form two assays were developed one for DNA virus and other for RNA virus amplification.

c. **IP generated/ Potential for IP generation:** Potential: Novel formulation used for increased stability can be patented.

d. **Resources Generated:** Manpower recruited are training in protein purification, formulation , quality control and lyophilisation.

Plans to take innovation further:
Currenlty planning to export products to neighbouring countries. We are collaborating with various institute for development of various assays.

Risks envisaged:

1. Improper storage after partial usage of kit can cause degradation if it contacts moisture
2. Temperature above 45^{0}C can cause product instability.

Project Coordinator:
Dr Rachana Tripathi

Team Members :
Rachana Tripathi, Munpally shesheer Kumar, Chakravarty Vajhala, Ravi Kumar

Contact :
House No. 3-14/2, Narsingi First Floor, Rajendra Nagar, Hyderabad-500075

Icaltech Innovations Pvt. Ltd.

Title of the Proposal:
Diagnosing and Managing treatment Monitoring of COPD / Asthma diseases for Elderly

Brief description:
Pulmonary Function Device Model: Antlia is used to diagnose pulmonary diseases such as Asthma, COPD, ILD, Emphysema, Bronchitis. Currently spirometers are used for this purpose - here the patient has to breathe very hard. This causes great inconvenience for children geriatric patients. Our innovation solves this problem by using FOT Technology - here the patient has to breath normally for lung measurements. This is also known as tidal breathing.

Current stage of development:
Commercialization

Commercialized in the name of:
PFT Device

Date of commercial Launch: 2021-01-15

Number of units sold: 20

Number of end users: 20

Innovative Element(s):
1. We have developed oscillometry based solution for breath diagnosis. 2. Our AI based algorithms aid clinicians in diagnosing lung function abnormalities.

Market Potential:
Chronic Obstructive Pulmonary Disease is second largest cause for death in India and third worldwide. Our customer segments include pulmonologists chest physicians, General Physicians and Pediatricians. The target market segment is over 10 lakh units in India alone.

National/Societal relevance:
COPD cases in India has increased to 55.3 million in 2016 from 28.1 million in 1990.Asthma cases increased to 37.9 million from 22.9 million in the same time. Prevalence rates were usually higher in the rural areas compared to urban areas. Our device with remote diagnosing capabilities would help rural patients to get better and quicker access to medication.

Project achievements:

a. **Progress vis-a vis objectives:** We have completed regulatory compliance testing and clinical validation successfully as per the plan.

b. **Technology/Product (to be) developed:** We have launched the product in 3 states as part of soft market launch plan.

c. **IP generated/ Potential for IP generation:** We have applied for 1 patent in India.

d. **Resources Generated:** 20 engineers are currently working on our firm with offices in Bangalore and Pune. We are planning to add another 50 resources as we scale up our operations during 2021-22.

Plans to take innovation further:
We are working on product variants to cater to export market. Discussions are on with VCs for fund raising.

Risks envisaged:
Slow adaptation of technology. Although Doctors are seeing great benefits, its usage is slow. We are addressing this issue by forming a network of Key Opinion Leaders for education, report interpretation, clinical case discussions and so on.

Project Coordinator:
Jayavanth Kamath

Team Members :
Mandar Natu, Roopashree, Shubhangi Tidke, Nishil Shetty, Omkar Sathe, Gopalakrishna, Nitin Vanjare

Contact :
14th Main Road, Indiranagar HAL II Stage, Bangalore-560008

IIT Delhi

Collaborator Name: Vanguard diagnostics Pvt limited

Title of the Proposal:
Development and evaluation of aptamer based lateral flow assay kit for detection of SARS-CoV2 detection.

Brief description:
A lateral flow assay kit was developed for SARS-CoV2 antigen detection in nasal swab samples. Specific aptamers were employed as recognition agents for detection of virus in samples. Internal validation was completed. External ICMR validation is under process.

Current stage of development:
Validation

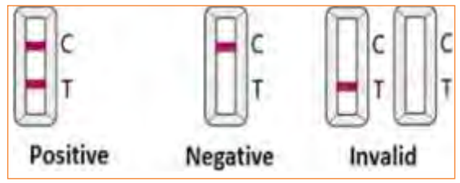
Innovative Element(s):
Aptamers were employed as recognition agents.

Market Potential:
As antigen testing is still underway for curtailment of the COVID situation, we still have room to be a contributor to the existing demand.

National/Societal relevance:
As we have walked the path of development, we are now equipped to produce similar kits for detection of viruses. Our products might address the future outbreak challenges in a timely manner.

Project achievements:

a. **Progress vis-a vis objectives-**
   1. Developed aptamers
   2. Used them for detection of virus
   3. Conducted evaluation studies
   4. Made way to market through commercial partner vanguard.



b. **Technology/Product (to be) developed:** Aptamer based lateral flow assay kit

c. **IP generated/ Potential for IP generation:** Sequences are patentable, and it is in process

d. **Resources Generated:** Trained Manpower, Facility created

Plans to take innovation further:
Market entry through partner

Risks envisaged:
if we clear through ICMR validation, our market entry doors will open

Project Coordinator:
Ashok Kumar Patel

Team Members :
Siva Raghavendhar B, Mohit Bhardwaj, Pushpraj

Contact :
Kusuma school of biological sciences Hauz Khas DELHI-110016 India

IIT Guwahati

Collaborator Name: 1) IIT Jammu 2) ICMR-National Institute of Cholera and Enteric Diseases

Title of the Proposal:
CRISPER based diagnosis of Covid-19 using paper microfluidics

Brief description:
We are aiming to offer one solution for COVID testing with the help of paper-based microfluidics sample analysis using lab-based and clinical trials, IoT or smartphone-based image processing recording/sharing for further analysis.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The concept for this proposal is to develop paper-based microfluidic system to detect the nucleic acid employing RT-LAMP assay amplification for diagnosing COVID-19. The paper-based diagnostic tools have been widely applied for a variety of biochemical analysis and immune assays, attributed primarily to the low cost, ease of use, and fast detection.

Market Potential:
After the development of the prototype and conducting the initial test and IPR filings Provisional patent the PIs will contact companies for their expression of interests EoI for their feedback and the technology commercialization. A company has already shown interest in this project from marketing perspective.

National/Societal relevance:
In this proposal, we aim to detect SARS-CoV-2 RNA sequences through a CRISPR-Cas12 based diagnostic tool using paper-based capillary flow microfluidic device. The test is expected to be rapid, affordable, and precise. The CRISPR-Cas12 is crucial in resource limited settings like in India, where the number of patients may increase, considering its large population.

Project achievements:

a. **Progress vis-a vis objectives:** Procurement of equipment, chemical and reagents, recruitment of staffs has started.

b. **Technology/Product (to be) developed:** Proof-of-concept for individual module of the proposed setup, that is, fabrication of point-of-care microfluidic device, sample preparation, sample transportation, sample analysis.

c. **IP generated/ Potential for IP generation:** Potential: In India, We found that there is no IP granted or published within 18 months period related to the CRISPR-Cas12a system.

d. **Resources Generated:** recruitment of staffs has started, equipment procurement has started

Plans to take innovation further:
We will engage the company based on the merit of the potential licensee during the project on exclusive/non-exclusive basis. The engaged company will eventually arrange for obtaining the required license for the final product and its commercialization well before the successful completion of the project.

Risks envisaged:
There is no risk/cost involvement while developing the product by the company on our part.

Project Coordinator:
Pranab Kumar Mondal

Team Members :
Ravi Kumar Arun, Aloke Kumar Chakraborty

Contact :
Mechanical Engineering Department Guwahati Guwahati ASSAM India-781039

IMGENEX India Pvt. Ltd.

Collaborator Name: Regional Medical Research Centre

Title of the Proposal:
Large Scale Production of SARS CoV2/COVID-19 Proteins and Development of Antibodies for Serological Tests.

Brief description:
Validated serologic assays are crucial for patient contact tracing, identifying the viral reservoir hosts, epidemiological studies, evaluation of results of vaccine trials and development of therapeutic antibodies. Hence, a steady supply chain of the high quality reagents are essential for developing diagnostic kits, research on therapeutics and vaccine development.

Here, we propose to produce S and N two major antigens of SARS-CoV2 in amounts that will help to develop at least two million diagnostic kits per antigen per month for supplying to Indian manufactures of diagnostic kits apart from developing monoclonal antibodies against structural proteins of SARS-CoV2.

Current stage of development:
Validation

Innovative Element(s):
Recombinant proteins and antibodies required for diagnostic tests are made in India to cater the need of the diagnostic kit manufacturers.

Market Potential:
In the initial days with spiraling infection rate of COVID-19 it was predicted that the testing kit business will reach 8-10 billion USD by the end of 2026. Though there is a sharp decline in the infectivity, new mutations of the virus may lead to production of more testing kits.

National/Societal relevance:
India ranks 2nd in the world after the USA in the number of infection and death. Quick, reliable and inexpensive tests are important to test the large number of people in India. We do not have to rely on expensive imported antigen and antibody for tests.

Project achievements:

a. **Progress vis-a vis objectives:** Antigens to be produced in bacteria are completed. Transient production of certain antigens in Mammalian cells are also produced. Monoclonal and polyclonal antibodies against S1, RBD and Nucleocapsid proteins are developed and characterized.

b. **Technology/Product (to be) developed:**
   1. COVID-19 IgG ELISA and LFA: Market launch 4 months.
   2. Large scale production of Nucleocapsid antigen and antibodies are already achieved and are already marketed..

c. **IP generated/ Potential for IP generation:** None

d. **Resources Generated:**
   1. Experienced senior scientist has been hired to develop LFA kits.
   2. Clean room has been set up to develop LFA kits.
   3. Bioreactor for large scale bacterial culture and equipment for downstream processing have been procured.
   4. Equipment for development of LFA kits have been procured.

Plans to take innovation further:
The products will be sold directly as well as through channel partners. We are looking to raise money by out-licensing the technology.

Risks envisaged:
With less number of patients demand for testing has gone down indicating that the market has shrunken. It may be assumed that there is some risk in antigen production business with low volume of market.

Project Coordinator:
Sujay Singh

Team Members :
Jabed Akhtar, K. Gopinath Achary, Shreenath Nayak, Purushottam Ojha, Sangamitra Pati, Ira Praharaj, Jyotirmayee Turuk

Contact :
Technology Corridor, InfocityChandrasekharpur, Bhupaneswar. Odisha-751024

Incredible Devices Pvt. Ltd.

Title of the Proposal:
Automatic Reprocessing System ARS to reprocess medical devices like ventilator circuits and expiration parts, catheters, balloons and other various medical devices to meet the demands in healthcare and at the same time ensure patient-staff safety.

Brief description:
ARS Advanced Reprocessing System is a revolutionary device which safely reprocesses essential medical devices like ventilator expiratory parts used on COVID Patients to ensure doctor & patient safety. COVID-19 patients need to be put on life supporting system such as Ventilators. There are multiple reusable/Single Use items required to operate a ventilator which need to be reprocessed. ARS resolves all challenges related with manual reprocessing. It is a computer aided fully automatic machine which works on a patented technique that comprises of 5 phases which cleans the essential medical devices with accuracy and precision. It eliminates human errors and is the cost-effective way to meet the demand of medical supplies amid COVID-19.

Current stage of development:
Validation

Innovative Element(s):
Currently, there are no automatic systems in the world to clean and reprocess ventilator expiratory parts and hence they are cleaned manually. ARS automates this process. It works on a patented technique that comprises of 5 phases: 1. Water jet cleaning 2. Enzymatic cleaning 3. Chemical Rinsing 4. Disinfection 5. Drying, which cleans the essential medical devices with accuracy and precision which ensures patient staff safety amid the pandemic.

Market Potential:
With huge COVID patient load within India and abroad, ARS has a huge market potential in both Private and Government Sector. ARS will not only ensure no cross contamination between staff and patients but also help in reducing the hazardous biomedical waste generation.

National/Societal relevance:
Yes

Project achievements:

a. **Progress vis-a vis objectives:**
   1. Prototype Development – Completed
   2. Product Validation – Ongoing
   3. Commercialization - To be started

b. **Technology/Product (to be) developed:** ARS is currently in validation stage

c. **IP generated/ Potential for IP generation:** ARS is the optimized version of our existing product in the ma Reprocessing System and is hence based on its patented parent technology. Incredible Devices will apply for the Design Patent for ARS.

d. **Resources Generated:** (1) Manpower - Incredible Devices has generated manpower for 5 people for the development of ARS. (2). Funds - Incredible Devices has won BIRAC COVID Grant and Maharashtra State Innovation Grant for the development and deployment of ARS at high load COVID sites.

Plans to take innovation further:
Incredible Devices plans to commercialize ARS in India post the validation stage and import the system to countries highly impacted by COVID in the second stage of expansion.

Risks envisaged:
There are no automatic reprocessing units available in the world to clean & reprocess ventilator parts hence there is no entry barrier for ARS.

Project Coordinator:
Vikram Goel

Team Members :
Rajwinder Kaur, Paritosh Tariyal, Anurag Dua, Amit Sharma, Nitin Kumar, Vijay Pal Goyal

Contact :
D-77, Sector 80, Phase 2
Sector 80 Noida Noida
UTTAR PRADESH
India-160071

Innnaumation Medical Devices Pvt. Ltd.

Title of the Proposal:
Aum Voice Prosthesis

Brief description:
The Aum Voice Prosthesis is an affordable voice prosthesis for throat cancer patients. It is a one size fits all device that allows the patient to speak even in the absence of a larynx. The partial shutter relatively opens when the air is exhaled from the lungs and allows the air to pass through from the second end to the first end of the cylinder.

Current stage of development:
Commercialized in the name: Aum Voice Prosthesis
Date of commercial Launch: March 2020
Number of units sold: 100
Number of end users: 500

Innovative Element(s):
One size fits all device. The partial shutter relatively opens when the air is exhaled from the lungs and allows the air to pass through from the second end to the first end of the cylinder. The presence of rings in the voice prosthesis helps in preventing the piston effect thus increasing the life span

Market Potential:
Globally there are more than 5 Lakh patients who need voice prosthesis. With throat cancer prevalent in more than 180 countries, company is classifying them to Least Developed Countries (LDC's), Low Middle Income Countries (LMIC's) and Organisation for Economic Cooperation and Development (OECD) and work out a pricing structure based on their Purchase Power Parity.

National/Societal relevance:
Aum Foundation has helped more than 400 patients speak again some of them have spoken after more than 5-8 years of silence. Actively pursuing the issuance of disability certificates and helping the patients get all the benefits under the Rights for Persons with Disabilities Act.

Project achievements:

a. **Progress vis-a vis objectives:** Completed clean room works and we are in the process of setting up the machinery for manufacturing the voice prosthesis and allied accessories. Already procured and commissioned the Sealing machine for medical grade paper and blister and the ETO Sterilization machine

b. **Technology/Product (to be) developed:** Developing the a hands free version of the device

c. **IP generated/ Potential for IP generation:** Patent awarded for a trochar with Cannula

d. **Resources Generated:** Manpower-15

Plans to take innovation further:
In the backdrop of COVID 19 they are currently developing the hands free version of the device, where the patient needn't apply pressure on the prosthesis using the thumb. Going forward we are planning to launch the Konttho Clubbs (earlier known as Lary clubs) in hospitals.

Risks envisaged:
Reaching expected sales for the next two years

Project Coordinator:
Vishal U S Rao

Team Members :
Shashank Mahesh, Prasanna Hegde, Madhukar S M, Vishwas U S Rao, Asif Ahamed

Contact :
#B26, 2nd Main Road, Peenya 2nd stage, Peenya Industrial area, Bengaluru, 560058

Institute of Chemical Technology, Mumbai

Collaborator Name: Tvasta Bio-Science Pvt. Ltd.

Title of the Proposal:
Bioprinting of 3D skin in a microfluidic device for pre-clinical investigations

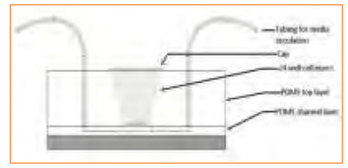
Brief description:
The project will focus on building Proof of Concept models of the technologies that are aimed to be developed. A prototype Bio-printer will be developed during the course of this project. This prototype printer will be used for printing skin tissues using skin-on-a-chip technology. The end result of the project will be PoC versions of the technologies a software-controlled extrusion Bioprinter and a skin-on-a-chip tissue for preclinical research that will be prototyped and scaled up in further efforts that will be undertaken.

Current stage of development:
Validation

Innovative Element(s):
3D bioprinted skin-on-a-chip model will provide all the advantages of 3D culture while also allowing for automation. This will improve precision and reproducibility and the resultant improvement in cell-cell and cell-extracellular matrix ECM interactions provide physiologically relevant tissue models.

Market Potential:
A new Bioprinter will be developed for the sake of this project with unique features.The skin tissue that will be printed using the Bioprinter can be commercialized separately. This skin tissue can be used by cosmetic companies for testing their cosmetics products. The microfluidic chip can also be commercialized

National/Societal relevance:
The proposed project is aimed to fabricate software controlled 3D extrusion based bio-printer equipped with temperature control system and achieve POC organotypic skin culture. It will serve as the first-of-its kind platform at a global level by providing the dual advantages of accelerated and precisely controlled process of tissue development 3D bioprinting and highly relevant and perfusive skin model skin-on-a-chip for preclinical research.



Project achievements:

a. **Progress vis-a vis objectives:** Development of 3D printer, temperature control system, and microfluidic device has been completed. Characterization of 3D skin in the device is pending.

b. **Technology/Product (to be) developed:** 3D bioprinter Tvasta Origin Plus Bioprinter with a temperature control system has been developed. Skin-on-a-chip model to be developed in 1-2 months.

c. **IP generated/ Potential for IP generation:** The novel process of 3D culture on the microfluidic device has the potential for patentability. Other innovations related to the bioprinting process are also potentially patentable

d. **Resources Generated:** 1 Junior research fellow employed by the primary applicant ICT Mumbai, 3 employees maintained by the partner company Tvasta

Plans to take innovation further: ICT Mumbai will license out technology to various organizations interested to build products using this technology. Tvasta will be commercializing the Origin Plus Bioprinter and the related technologies including bioinks.

Risks envisaged:
The optimization of the process of bioprinter operation for culture development in the microfluidic device is challenging. Also, delays caused by the COVID-19 pandemic, competition from startups in the Bioprinting area represent the risks envisaged.

Project Coordinator:
Dr Prajakta Dandekar Jain

Team Members :
Advait Bhagwat, Yuvaraj V, Vikas MR, Manish Amin

Contact :
Nathalal Parekh Margh
Matunga Mumbai
MAHARASHTRA India-400019

Indian Institute of Technology (IIT), Mumbai

Title Of The Proposal:
Pilot clinical investigation for alveolar ridge augmentation using 3-D scaffold matrix

Brief Description:
3-D scaffold matrix bone graft with unique combination of n-HA/gel/CMCh provides ionic interaction among ingredients which results in highly porous 3-D network with visco-elasticity and high structural stability cum integrity. Consequently, an optimal nanostructured mechano-sensory environment was developed to enhance cell adhesion, proliferation, network formation for effective osteoblastic activity and faster mineralization. Thus, developed a 3-D scaffold will enhance bone regeneration and eliminate the use of autograft, which require a second surgical site, membrane for closure and maintains the stability at the site.

Current Stage of Development:
Validation

Innovative Element(s)
1. Completely resorbable. 2.Spongy elastic in nature. 3. Hemostatic in nature. 4. Nanostructured mimicking ECM. 5. Micro porous 6. 3D structure

Market Potential:
Potential buyers include Ambulatory Surgical Centre, patients and Clinic, hospital administration in government and private setting from dentistry and orthopedics domain.

National/Societal Relevance:
This product will bring down the cost of treatment and reduce healing time for patients by faster bone regeneration at competitive price.

Project Achievements:

a. **Progress vis-a vis objectives:** The device is currently under pilot clinical investigation at AIIMS, New Delhi on 20 patients for alveolar ridge augmentation application

b. **Technology/Product (to be) developed:** It is a bone regeneration solution and is used for the treatment of fractures, defects from infection, osteonecrosis, trauma, injuries, benign tumours and cysts, spinal fusion, and joint problems.

c. **IP generated/ Potential for IP generation:** IN3221/Mum/2012.A method for preparing a composite scaffold comprising nanocrystalline hydroxyapatite, gelatin and carboxymethyl chitin Granted

d. **Resources Generated**: 1. GMP Manufacturing facility. 2. Expertise on lab development to clinical validation. 3. Trained manpower on GMP manufacturing and clinical evaluation

Plans to take innovation further:
We plan to form a start-up company and raise funds from BIRAC and other investors, currently we compiling the report on business plan, financial projections, presentation and background.

Risks Envisaged:
There are many challenges to enter into market Regulatory clearance and time, Long Gestation period, Establishing manufacturing facility, Conduction of pivotal investigation under pandemic, Raising of large funds and Acquiring licenses and permit

Project Coordinator:
Jayesh Bellare, Kunal Khanna

Team Members :
Ajoy Roychoudhury, Rohan Mane, Sudhakar Bangera, G S Bhuvneshwar, Sunil Mehta

Contact :
Department of Chemical Engineering Mumbai
MAHARASHTRA
India-4000761

Irillic Pvt. Ltd.

Collaborator Name: CMR University

Title of the Proposal:
Front end acquisition hardware and signal conditioning technology solutions for Minimally Invasive Fusion Imaging Endoscopy for Laparoscopic surgeries and other spin-offs

Brief description:
Irillic has developed the core technology around Fluorescence Imaging for Open Surgery and we have received very positive feedback from surgeons. This solution and therefore the modality has been clinically validated across 2000+ surgical/screening procedures within India.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Irillic has developed the core technology around Fluorescence Imaging for Open Surgery and it is widely used by surgeons. One patent around Laser multiplexing has been filed. Solution has multiple innovative features such as multiple spectral imaging modes, pulsating fluorescence, integrating recording and so on.

Market Potential:
As per IBEF Survey in 2017, the number of hospitals in India were 1,96,312. Assuming 10 of them would have advanced surgery, implies 19,631 hospitals. At 10 market share for FGS in next 5 years, implies 1,963 hospitals. Total India Opportunity Size @Rs. 45Lacs/unit is Rs. 88,000 Lakhs.

National/Societal relevance:
As per published reports, Cancer is emerging as a major public health concern in India. Further, studies show many patients have to travel to Metros for related surgery. Among the various applications of the system, use of Open or Endoscopic Fusion imaging system obviates the need for depending on nuclear medicine. More importantly, it enables oncology surgeries to be done Pan-India even in Tier-2/Tier-3 locations improving the accessibility of cancer treatment across the population.

Project achievements:

a. **Progress vis-a vis objectives:**
1. Objective 1 at a high level is completed - a few tasks are remaining. 2. Objective 2 is in progress. 3.1 Patent is filed in India PTO and 1 more is in progress. 4. Clinical Partner Gunasheela Hosptial identified in principle.

b. **Technology/Product (to be) developed:**
1. An Engineering Prototype of a 4K White Light Imaging System for minimally invasive surgeries planned for commercial launch in Q2 FY21-22
2. An Engineering Prototype of a 4K Fluorescence Fusion Imaging System White Light + NIR for minimally invasive surgeries planned for commercial launch in Q1 FY22-23.

c. **IP generated/ Potential for IP generation:** Patent Filing at India PTO is complete.

d. **Resources Generated:** 7 people employed under the BIRAC project grant
Plans to take innovation further:
Product s will be tested for EMI, EMC, Safety as per relevant medical device standards before launch. CE certification process will follow subsequently.

Risks envisaged:
The rigid laparoscope IR-optimized optical module which is inserted into human anatomy during surgery is currently planned as a item to be purchased from 3rd party. There are challenges on sourcing such a module at this time.

Project Coordinator:
B D Vijaya

Team Members :
B D Vijaya, C D Anant, B R Viswanath, Saish Kamat, Navaneeth Mohan Prashanth Koundinya

Contact :
76, 10th Cross Rd, Jeewan Sathi Colony, 1st Phase, J. P. Nagar, Bengaluru, Karnataka 560078

Janitri Innovations Pvt. Ltd.

Title of the Proposal:
KEYAR - An affordable, easy to use and wearable fetal heart rate and uterine contraction monitoring device which communicates with DAKSH - An Intrapartum monitoring mobile application

Brief description:
KEYAR is an wearable, portable and wireless intrapartum fetal heart rate, uterine contraction and maternal heart rate monitoring device which also communicates with DAKSH intrapartum monitoring mobile application for intelligent alerts and remote/central monitoring

Current stage of development:
Validation

Innovative Element(s) :
1. No need for location identification for fetal heart rate and uterine contraction monitoring. 2. Patient Mobility. 3. Automated WHO Partograph. 4. Remote/central monitoring

Market Potential:
Global fetal monitoring market was valued at $2,206 million in 2015, and is expected to reach $3,584 million in 2022.

National/Societal relevance:
During intra-partum period, delay in diagnosis of fetal distress leads to neonatal morbidity & mortality. An affordable & easy to use labor monitoring device for early detection of fetal distress for low resources healthcare settings has a potential to prevent neonatal mortality & morbidity. In low resources healthcare settings where cesarean facility is not available, the early detection of fetal distress will help low skilled health workers in early decision for referral to higher health facility.

Project achievements:

a. **Progress vis-a vis objectives:** Developed product which is ready to Commercialise

b. **Technology/Product (to be) developed:** In pre-sales activities

c. **IP generated/ Potential for IP generation:** Patents filed. 2 have been granted

d. **Resources Generated:** 1. 20 full time employee employed 50+ people in last 4 years . 2. Full fledge office in Bangalore. 3. Raised grants and seed funding

Plans to take innovation further:
In a phase of pre-sales activities and next fund raising for scaling up

Risks envisaged:
Regulatory, Product localization

Project Coordinator:
Arun Agarwal

Team Members :
Mukund Pipalav, Kautilya Hari, Aravind, Tejas, Parishmita, Priyanka

Contact :
207, APEX Tower Lalkothi
Jaipur RAJASTHAN
India-302015

JC OrthoHeal Pvt. Ltd.

Title of the Proposal:
Clinical Investigation of FlexiOH as definitive cast for immobilization of fore-arm fractures in emergency settings

Brief description:
FlexiOH is NextGeneration Orthopedic immobilization which is more skin hygienic, comfortable, and easy to use unlike conventional casts.

Current stage of development:
Commercialization

Innovative Element(s):
FlexiOH is breathable, Washable hence more skin hygienic and comfortable as Immobilization therapy for Musculoskeletal injuries.

Market Potential:
With FlexiOH we are targeting Total market of ~$3B globally, while team had aimed to obtain ~10 of market by end of 2025.

National/Societal relevance:
Through FlexiOH we have generated 30 Direct employment as well as 100 indirect employments. apart from that as on today we have exported FlexiOH 30 countries across globe.

Project achievements:

a. **Progress vis-a vis objectives:** Under BIRAC-NBM project, we are doing multicentric randomized clinical trial to Investigate FlexiOH as definitive cast immobilization

b. **Technology/Product (to be) developed:** Launched FlexiOH product in December 2019, since then we are continuously adding more variants of FlexiOH to cover maximum possible fracture treatments.

c. **IP generated/ Potential for IP generation:** Licenced FlexiOH technology from DBT- GoI, and filed national phase applications

d. **Resources Generated:** Generated 30 full time employment while 15 temporary or contractual employment and 100 indirect employment through vendors.

Plans to take innovation further:
Team is ooking for Series A funding to scale up manufacturing as well as marketing team to increase presence in India as well as Globally.

Risks envisaged:
Price sensitivity, Team scale up, Timely availability of funding for marketing expansion.

Project Coordinator:
Pankajkumar Chhatrala

Team Members :
Nidhi Chhatrala, Subrat Kumar, Manisha Pawar, Heena Prajapati, Kirti Poriya, Devang Solanki

Contact :
GF 33 34 Classic Towers
Near Akota Garden Akota
Vadodara GUJARAT
India-390020

Kranti Kiran Reddy Ealla

Title of the Proposal:
BacNo Gel: Antibacterial and Osteoinductive, Drug induced hydro-gel formulation for Post tooth extraction Regenerative Wound Management

Brief description:
We propose to develop a novel silk based hydrogel system for drug delivery tailored for antimicrobials and regenerative potential. With initial prototype in hand, we wish to further optimize the gel for clinical use in case of post extraction wound.

Current stage of development:
Hydrogel Optimization and Drug release profile studies being undertaken

Innovative Element(s):
Silk Fibroin based local drug delivery for post tooth extraction wound management

Market Potential:
Antibiotic resistance is a serious problem globally. New antibiotics to tackle resistant bacteria are urgently needed however, a recent report from the European Center for Disease Prevention and Control and the European Medicines Agency EMA warns of an almost empty pipeline, leaving patients vulnerable to dangerous infections

National/Societal relevance:
Unique concept for Anti-microbial Resistance and reducing the load

More than 90 percent of Indian population undergoes extraction of teeth once in a lifetime. And most of the cases do not require antibiotics as body immune mechanism takes care of wound healing and chances of secondary infection are low. Hence there is an unmet clinical need to develop a localized antibiotic delivery system to avoid systemic exposure of antibiotic wherever it can be avoided.

Project achievements:
Incubation at AIC CCMB Hyderabad BIRAC BIG Grant

a. **Progress vis-a vis objectives:** Objective1: Recruitment of people and procurement of instruments
Objective2: Optimization and characterization of BacNo Gel (In Progress)
b. **Technology/Product (to be) developed:** BacNo Gel : Antibacterial and Osteoinductive, Drug induced hydro-gel formulation for Post tooth extraction Regenerative Wound Management
c. **IP generated/ Potential for IP generation:** NA
d. **Resources Generated:** NA

Plans to take innovation further:
Commercialization:

Market entry strategy:
Our plan is to develop the product and build a successful venture. We have a well-established clinical facility Malla Reddy Institute of Dental Sciences. Once the clinicians validate our product, we will go for regulatory compliances and clinical trials. We will raise further funding to manufacture, scale up and also collaborate with pharmaceutical company.

Risks envisaged:
Working in close association with CCMB Hyderabad will help in easy access to technological input to develop the prototype. The team has a good experience of biomaterial, nano-medicine drug delivery concept and its development which will add to the success factor. Dentists, oral surgeons and oral pathologists are in board of scientific advisors, that will help to resolve the clinical problem.

Project Coordinator:
AIC-CCMB

Team Members :
Kranti Kiran Reddy E, Ira Bhatnagar, Sri Durga Chandra, Srinivas CN

Contact :
H.No:7-51, Flat No - 202, Devi Homes, Bapuji Nagar, Nacharam, Hyderabad

Lumisoft Technologies Pvt. Ltd.

Title of the Proposal:
Affordable portable digital slit lamp

Brief description:
Lumisoft, Bangalore, is developing technician friendly ophthalmic screening devices. Our ideas bridge the gap of worldwide shortage of ophthalmologists by utilising the services of technicians and GPs to remotely assess the eyes. Now, the trend is to use affordable medical devices which can be used in multiple scenarios.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
3D rendering of images captured

Market Potential:
Potential for slitlamps: 60000 in India and 400000 around the world. Aim for capturing 5 of potential.

National/Societal relevance:
Addresses the shortage of eye specialists in rural areas.

Project achievements:
a. **Progress vis-a vis objectives:** Proof of concept is ready
b. **Technology/Product (to be) developed:** Need industrial production and clinical trials
c. **IP generated/ Potential for IP generation:** An Apparatus for Ophthalmic Diagnosis Complete Indian patent filing 1901001IN-CA filed on 27/1/2020 PCT and Convention Filing Docket No. 1901001WO
d. **Resources Generated:** 4 manpower created a 3d printing service, flat bed printer acquired

Plans to take innovation further:
Licensing

Risks envisaged:
Tough competition from established players

Project Coordinator:
H V Srinivas

Team Members :
Sreevatsa

Contact :
244, 7th Cross, 6th Block, 3rd Phase, Banashankari 3rd stage BANGALORE KARNATAKA India-560085

MagGenome Technologies Pvt. Ltd.;

Collaborators: Sri Ramachandra Institute of Higher Education and Research, Porur, Chennai and Central University of Kerala

Title of the Proposal:
Development of a diagnostic kit comprising sample collection buffer and RNA extraction kit for real time RT PCR based detection of SARS CoV-2

Brief description:
A reliable and quick extraction kit which yields significantly high quantity and quality of RNA is a major requirement for any RT PCR based detection system for COVID 19. The developed RNA extraction kit will be a solution to the issues associated with the quality and quantity of RNA extracted from patient samples. The Company has also developed a unique formulation of sample collection solution which can ensure the proper storage of viral RNA in the sample for several days even at room temperature. The collection method proposed is especially unique as it can be self-collected with appropriate instructions reducing the risk of exposure to healthcare workers at the time of sample collection. The sample collection solution is suitable for storing nasal and throat swabs and saliva samples.

Current stage of development:
Validation

Innovative Element(s):
SARS CoV 2 Viral RNA extraction from Saliva

Market Potential:

The Company planning to commercialize this product in India and expects that the saliva based kits can replace the swab based kits.

National/Societal relevance:

Development of rapid and extremely sensitive diagnostic methods which can ensure early detection of the newly identified SARS-CoV-2 virus is the need of the hour.

Project achievements:

a. **Progress vis-a vis objectives:** Completed development of sample collection solution MTM, Development of viral RNA extraction kit for swab and saliva is ongoing and the final product which comprises the MTM, RNA extraction kit and RT PCR kit is to be completed

b. **Technology/Product (to be) developed:** Molecular Transport Medium MTM , Viral RNA extraction kit, RT-PCR kit

c. **IP generated/ Potential for IP generation:** IP for the project is owned by MagGenome patent filed

d. **Resources Generated:** Facility established and one Junior research staff hired and trained.

Plans to take innovation further:

MagGenome will commercialize the product after taking ICMR and CDSCO approval.

Risks envisaged:

Approval from ICMR for saliva based Viral RNA extraction for SARS CoV 2 might be challenging since the currently approved RNA extraction kits are all swab based.

Project Coordinator: Tessy Iype

Team Members : CN Ramchand, Aniruddha Bhati and Gayathri R

Contact : Plot No.43A SDF 3rd Floor, CSEZ Kakkanad Kochi Cochin KERALA India-682037

Manali Datta

Title of the Proposal:
Non Invasive chronic kidney disease nanosensor for point-of-care diagnosis

Brief description:
Our aim is to design and validate non-invasive, rapid, ultra-sensitive point-of- care diagnostics for early stage detection of CKD in human enabling delivery of timely medical care. Biomarker based detection is more specific and lacks the blindspot associated with the current biomarker, creatinine. The diagnostic platform does not require sophisticated instruments, and its point of care test [POCT] detection has its distinct advantages

Current stage of development:
Standardization of the synthesis for the CKD specific diagnostic platform has been done

Innovative Element(s):
Our platform encompass following innovations:-
1. First sensor platform proposed for chronic kidney disease
2. No Trained manpower required.
3. Non invasive sample used for detection
4. Detection of stage 1 and stage 2 kidney disease

May be used to monitor the baseline correct functioning of the kidney

Market Potential:
The global market for chronic kidney disease is very high

National/Societal relevance:
In India, diabetes and hypertension today account for 40% to 60% cases of CKD. The healthcare infrastructure is considerably limited to large towns. Thus, to add to woes, the lack of availability of professional medical service, the patients get detected with CKD at very late stages. Thus a financially safe solution to prognosis of the CKD would be to curb its progression at initial stages

Project achievements:

a. **Progress vis-a vis objectives:**
Our proposal aimed at preliminary testing of the designed platform for detection of chronic kidney disease as a part of first milestone. We replicated the platform we had designed and tested with various biophysical [FTIR and SEM] and electrochemical methods [DPV and CV]. Concurrently, the standardized platform is now been actively used for generating data from clinically relevant samples. Testing in progress

b. **Technology/Product (to be) developed:** Development of standalone device [Cystatinometer] akin to glucometer for assessing kidney malfunction

c. **IP generated/ Potential for IP generation:** As this is the first of kind proposed sensor for CKD, there will be patent filed with respect to design of the sensor platform

d. **Resources Generated:** MANPOWER. Within the grant period, three personnel have been trained in designing and standardization of the sensor platform. They are additionally equipped to handle collection of samples with their biochemical as well electrochromic analysis and correlate it with the severity of the disease.

FACILITY: We have developed a biosensor development and testing facility where we can in-house generate sensor platforms and test the working of the designed platform

Plans to take innovation further:
We are in talks with two industries who have shown interest in the product post clinical validation. Once the clinical validation of the designed platform is done, we will get involved in development of the standalone "Cystatinometer" for CKD detection.

Risks envisaged:
In addition to the stringent competition, development of the validated diagnostic platform would be the first step to develop a standalone CysC sensor something akin to glucometer which will require its own standardization period

Project Coordinator: Manali Datta

Team Members : Desh Deepak Singh, Dignya Desai, Ms Hemangi Ranade, Abhishek SIngodia

Contact : Amity University Rajasthan, Jaipur

Manipal Academy of Higher Education, Manipal University

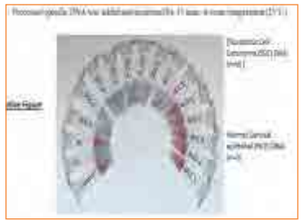
Title of the Proposal:
Translation of CpG-Methylation Biosignatures of Genes for Rapid and Sensitive Diagnostic and Prognostic Applications during Cervical Cancer Progression

Brief description:
Current cervical cancer screening methods have several disadvantages and there is a need for alternative methods to identify and detect early precursor lesions and cervical cancer. MAHE has validated the clinical utility of CpG methylation biosignatures using exfoliate cytology samples in large number of specimens and developed a simple, sensitive, low cost, robust, non-invasive and nanoparticle based visual/photometry based detection system.

Current stage of development:
Discovery

Innovative Element(s):
A panel of 11 genes with specific CpG epigenetic signatures that represent various stages of cervical cancer progression have been developed. The process to test these are developed and streamlined. These are compatible with the sample processing and amenable for deployment in laboratory or field settings.

Market Potential:
The global cervical cancer diagnostics market is expected from $8.02 billion in 2019 to $8.62 billion in 2023 at a CAGR of 6.04. Breaking the stigma associated with cervical testing in India is being overcome through education, and the testing is expected to follow as per the global trends.



National/Societal relevance:
Since testing for HPV and cytology based screening are presented with several disadvantages there is a need for an alternative method with high sensitivity and specificity to identify, detect and prognosis of early precursor lesions and cervical cancer. Towards this direction, the grantee has been working on these aspects to translate effective biosignatures with societal relevance.

Project achievements:

a. **Progress vis-a vis objectives:** The group has validated clinically relevant CpG specific DNA methylation signatures for diagnosis, prognosis and for therapeutic purposes by developing simple, rapid, sensitive, cost-effective diagnostic method for cervical cancer. This is also amenable for large scale screening.

b. **Technology/Product (to be) developed:** Cervical Cancer detection method

c. **IP generated/ Potential for IP generation:** An Indian IP has been filed. A separate process IP is being filed to Indian patent office.

d. **Resources Generated:** Trained four personnel, created, infrastructure to perform the same, a startup has been Registered under a Bioincubator. Fund mobilization is in the process.

Plans to take innovation further:
Keen to pursue viable models including partnership, licensing and fund raising activities.

Risks envisaged:
The risk involved include failed business strategy. Risk involved also include acceptance and implementation in clinical practice widely due inability to overcome the traditional practice. Risk is involved if anticipating a short term gain.

Project Coordinator:
K. Satyamoorthy

Team Members :
Pralhad Kushtagi, Krishna Saran, Deeksha Pandey and Shama Prasad K.

Contact :
Manipal Academy of Higher Education, Manipal University
MADHAV NAGAR KMC QUATRES
179 MANIPAL KARNATAKA
India-576104

MicroGO LLP

Title of the Proposal:
Prevention of nCoV spread via Hands in pubic health settings

Brief description:
GOassure is India`s first and only smart hand hygiene platform that assures Good Hand Hygiene Practices, Provides Sustainability and Real time monitoring. The IoT enabled platform provides real time SOP monitoring and assuring hand hygiene compliance

Current stage of development:
Commercial launch in August, 2020, 500 units sold with 50 lakh end users.

Innovative Element(s):
Assuring Good Hand Hygiene Practices as per WHO recommendation - 6 steps and 20 secs, Provides sustainability and Ensures real time monitoring

Market Potential:
The hand hygiene market in India and globally is poised to grow by USD 405.31 million and 1.96 billion during 2020-2024.

National/Societal relevance:
Any nation worldwide especially India - Preventive technologies for hygiene are considered as expense since the problem causing agents like bacteria and viruses are invisible to the naked eye. Products and Technologies provided by MicroGO not only assures highest standard of hygiene but are an investment for the customers. They provides sustainability and increases their cash flow.

Project achievements:

a. **Progress vis-a vis objectives:** GOassure MAX and GOassure LITE are successfully commercialised.

b. **Technology/Product (to be) developed:** Hand sanitization solution

c. **IP generated/ Potential for IP generation:** Patent pending

d. **Resources Generated:** Manpower, Facility and Funds: BIRAC COVID, DST CAWACH, IKP-ICO, ACT Grants

Plans to take innovation further:
Distribution network via Channel Partners are in progress.

Risks envisaged:
None

Project Coordinator:
Rachna Dave

Team Members :
Deepa P, Deepti Subbaraya, Sanjay Singh, Lingaperumal P and Sujitha Balu

Contact :
7, Golden Jubilee Biotech Park for Women Society Inside SIPCOT-IT PARK, 4th Main Road, 2nd Cross Road Siruseri Chennai TAMIL NADU India-603103

MicroGO LLP

Title of the Proposal:
Portable, on-the-go Steriliser

Brief description:
Portable on-the-go sterilizer is developed to sterilize reusable surgical instruments. Chlorine dioxide is used as gas sterililant for sterilization. The most unique feature is in the delivery of chlorine dioxide for sterilization in a portable manner without the need of water and continuous use of power. Tubelet, is the only platform in India that releases surgical sterilant chlorine dioxide gas in portable form without the need of elaborative setup.

Current stage of development:
Validation

Innovative Element(s):
It is portable, can perform sterilization on-the-go without the need of continuous source of power and does not require water.

Market Potential:
The sterilization market is constantly increasing and post COVID the Indian Disinfection Market is expected to be 10 billion USD by 2025.

National/Societal relevance:
All around the world including India, the market is looking for technologies which are sustainable and dependable. While autoclaving is very dependable technology for sterilization of surgical instruments but it is bulky and required continuous source of power and compulsory water. Both pre-requisites are limiting in low resource settings.

Project achievements:

a. **Progress vis-a vis objectives:** Third party validation study is completed in PHCs. Stage 1 audit is completed for ISO 13485:2016. QMS implementation will be completed by July 2021 and product shall complete third party performance studies followed by pre-commercialization.

b. **Technology/Product (to be) developed:** Portable sterilizer that shall be launched by September, 2021

c. **IP generated/ Potential for IP generation:** Indian Patent Granted. PCT Applied

d. **Resources Generated:** ISO 13485: 2016 certified manufacturing facility in progress

Plans to take innovation further:
The current distributors/channel partners have been sensitised with GOsteri.

Risks envisaged:
Market reluctance to shift from steam sterilization to gas sterilization and bringing awarenenss on importance of sterilization in limited resource settings.

Project Coordinator:
Rachna Dave

Team Members :
Sujitha Balu, Murali N, Murali Kumar and Deepthi Subbaraya

Contact :
MicroGO LLP 7, Golden Jubilee Biotech Park for Women Society Inside SIPCOT-IT PARK, 4th Main Road, 2nd Cross Road Siruseri Chennai TAMIL NADU India-603103

Mimyk Medical Simulations Pvt Ltd

Title of the Proposal:
An Immersive Endoscopy Simulation Platform

Brief description:
The Company is building a VR and haptic-based robotic platform for training in endoscopy skills. The proposed endoscopy simulator named EndoMimyk enables the trainee to train for complex manoeuvres and hand-eye co-ordination in a safe virtual world. It offers realistic visual, haptic feedback and auditory guidance for immersive learning in a safe virtual environment. It also provides assessment, tracking, and training in advanced GI diagnostic and therapeutic procedures.

Current stage of development:
Validation

Innovative Element(s):
Haptics, physics-based simulation, and product design are the key distinguishing features of EndoMimyk. As a result of these key technologies, the simulation platform engages the user in multimodal interaction for an immersive experience and imparts best practices in endoscopy training.

Market Potential:
In Indian market, the Company expects to sell 2-4 EndoMimyk simulators in every quarter. They are also looking at ways of monetizing the simulation engine separately. Globally, simulation is projected to be a USD 5 Billion market.

National/Societal relevance:
Endoscopy simulator developed in India and made available for trainee doctors will have a large social impact by creating better access to healthcare. It also improves patient outcomes and safety.

Project achievements:

a. **Progress vis-a vis objectives:** During the SBIRI project, the initial proof-of-concept prototype has been developed into an advanced prototype for commercialisation activities.

b. **Technology/Product (to be) developed:** Haptics and Real-time simulation are the key technologies being developed for endoscopy simulator. The product is ready for launch and initial trials and demonstrations are underway.

c. **IP generated/ Potential for IP generation:** The Company has two patent applications filed in Indian from their prior work and have also filed for a US patent.

   An additional PCT and Indian patent has been filed during the project.

d. **Resources Generated:** The Company has built a multidisciplinary team of about 10-12 engineers, designers, and artists. They work with research teams at the Indian Institute of Science, Bangalore and closely collaborate with leading hospitals.

Plans to take innovation further:
The Company plans to raise seed funding to take the innovation forward. They are also in talks to enterprises for co-development and co-selling.

Risks envisaged:
Scaling from a start-up to a large production facility, while maintaining high-quality control of the finished product is one challenge. The complexity in selling to institutions and training centres is the other challenge.

Project Coordinator:
Shanthanu Chakravarthy

Team Members :
Nithin Shivashankar and Raghu Menon

Contact :
Mimyk Medical Simulations Pvt Ltd No 29, Kanasu 16th Cross Jakkur Layout Bangalore KARNATAKA India-560012

Module Innovations Pvt. Ltd.

Title of the Proposal:

To Validate USenseTM: Platform based Low cost, Rapid and POC diagnosis of specific Uropathogens causing UTI, helping reduce AMR

Brief description:
Urinary Tract Infections (UTI), the second highest infections in the human body, affect 150 million people worldwide. Lack of a point of care diagnostic indicating bacterial presence and its class make clinicians prescribe a broad spectrum empirical antibiotic, leading to treatment failures and consumption of ineffective antibiotics leading to Anti Microbial Resistance AMR . USENSe a 15 minute, point of care test indicates presence of bacteria in urine, also differentiating if its gram positive or negative aiding clinicians at all levels of healthcare take an informed antibiotic decision.

Current stage of development:
Validation

Innovative Element(s):
Detects the bacteria directly and not by its products, is rapid with time to result just 15 minutes and is easy to use and can be used at doctors clinic or a PHC

Market Potential:
UTI global diagnostic market is pegged at 47 Billion USD. There are more than 10 million cases of UTI every year making Urine testing for bacteria a lucrative market. USENSe will not only empower the clinicians but also labs to process more samples in a day.

National/Societal relevance:
In a country such as India, where doctors to patient ratio is skewed, rapid and point of care test are the need of hour. UTI are one of the most common diseases that require antibiotic prescription. In the absence of such test, the empirical antibiotic treatment has made India one of the largest contributor to AMR.

Project achievements:

a. **Progress vis-a vis objectives:** Successfully validated USENSe on 250 patient samples with hospitals in Pune.

b. **Technology/Product (to be) developed:** USENSe is now under large scale validations across 3 states in India. Once that is completed successfully, USENSe would be translated to manufacturing and is expected to enter the market is Q4 of 2021

c. **IP generated/ Potential for IP generation:** None

d. **Resources Generated:** 4 people employed and a pilot lab scale manufacturing was created. Rs 135 lacs raised to perform next stages of development

Plans to take innovation further:
Performing large scale validations. Module is talking to Japanese and US multinationals for distribution and sales partnerships

Risks envisaged:
Scale up of raw materials has been a challenge. Perception of a rapid test for UTI has several levels of responses in India, however it has been welcomed in US and UK.

Project Coordinator:
Sachin Dubey

Team Members :
Usman Khan, Rahul Chaudhari, Maya KV, Shruti Kulkarni and Komal Shamnani

Contact :
100, NcI Innovation Park Dr.
Homi Bhabha road Pashan
PUNE, MAHARASHTRA
India-411008

Monitra Healthcare Pvt. Ltd.

Title of the Proposal:
Compliance of the Smart MCT platform with IEC safety & radio-frequency standards.

Brief description:
India`s first advanced 24x7 continuous biosensing platform for capturing cardiac events anytime anywhere. The product, upBeat, is redefining 24x7 patient monitoring. Granted patent in India.

Current stage of development:
Commercialized in the name upbeat. 800 units sold

Innovative Element(s):
Quality of signal tracings with minimal noise & clinically relevant reports, Real-time data transmission and cloud based data analytics and Complete stack Biosensing patches & Cloud analytics.

Market Potential:
15+ million patients in India and 50+ million patients worldwide
Addressable market is USD 10B globally & USD 1B in India for the above conditions

Home Healthcare & other adjacent markets is USD 100B+.

National/Societal relevance:
This technology enables early diagnosis of heart rhythm disorder ailments, which allow the disorders to be treated before they become chronic where treatment options are limited. The product facilitates remote monitoring and can scale quickly to the remotest towns and villages.

Project achievements:

a. **Progress vis-a vis objectives:** Completed

b. **Technology/Product (to be) developed:** upbeat. Full Market Release in FY21-22.

c. **IP generated/ Potential for IP generation:** "WIRE-FREE CARDIAC ELECTRODE", Publication Number 21/2017, Publication Date 26/05/2017, Publication Type INA Application Number 2418/CHE/2015

d. **Resources Generated:** Funds raised from Indian Angel Network

Plans to take innovation further:
Full Market Release in FY21-22.

Risks envisaged:
Ability to raise funds prior to full market release

Project Coordinator:
Ravi Bhogu

Team Members :
Aparna B, Archana G and Sashank B

Contact :
202 Mani Niketan, Plot 496
Defence Colony Hyderabad
TELANGANA India-500094

Nageswara Rao Pulipati

Title of the Proposal:
Laboratory Scale Process for Pegloticase Biosimilar

Brief description:
Pegloticase is a PEGylated uricase indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Uricase catalyzes the first step of the conversion of uric acid (UA) into the highly water-soluble end-stage metabolite allantoin, which is eliminated by renal excretion. Pegloticase is produced as a recombinant enzyme in E.coli. Pegloticase is very expensive drug and not sold in India. Biosimilar produced in India will be affordable.

Current stage of development:
Clone development and shake flask studies were completed

Innovative Element(s):
The aim is to produce the biosimilar in affordable cost

Market Potential:
Rs 50 – 100 cr annual sales

National/Societal relevance:
Unmet medical need and affordability

Project achievements:

a. **Progress vis-a vis objectives:** Objective 1: Clone development: Cloning & Expression- Completed

   Objective 2: Optimization of expression & yield- Completed

b. **Technology/Product (to be) developed:** Biosimilar to Krystexxa (Pegloticase)

c. **IP generated/ Potential for IP generation:** NA

d. **Resources Generated:** Employees hired: 2

Plans to take innovation further:
Not yet

Risks envisaged:
Issues may arise during scale-up in fermentation and purification

Project Coordinator:
Nageswara Rao Pulipati

Team Members :
Chandresh Kumar, Gnanadeepthi

Contact :
Plot No 197, Mathrusree Nagar, Miyapur, Hyderabad 500049

NextGen In-Vitro Diagnostics Private Limited

Title of the Proposal:
Research trial for developing a rapid biomarker-based non-sputum-based test for detecting TB

Brief description:
RU- 1 is a Rapid biomarker-based non-sputum-based test for the detection of Tuberculosis on a Point of Care Platform. RU-1 is joint efforts of NGIVD and Appgenex, a University of California Davis UCD spinoff. Panel of 8-12 M. tuberculosis antigens, detecting corresponding antibodies were identified for diagnostic applications.

Current stage of development:
Validation

Innovative Element(s):
Developing a Serology based non-sputum test which has a sensitivity of 98% for smear-positive culture-positive pulmonary TB, and 68% for smear-negative culture-positive pulmonary TB in adults, meeting the WHO norms for Performance characterization. The test is a Point-of-Care platform which can be operated with minimal training at primary health care centre.

Market Potential:
In India, there are about 23% of the total TB patients across the world. WHO report of a consensus meeting has recommended need of non-sputum based point of care diagnosis of Tuberculosis. RU-1 can be implemented in future for identifying paediatric and extra pulmonary TB.

National/Societal relevance:
Till date, there is no simple, rapid and efficient diagnostic test available for identifying TB, leading to continued transmission of infection in the community. Therefore, early detection and successful treatment of patients with TB is the cornerstone of TB control programmes. In high TB burden countries like India healthcare system will substantially benefit from rapid, accurate, and cost-effective blood tests for TB screening. Importantly, such a screening system should be high throughput and amenable to automation.

Project achievements:

a. **Progress vis-a vis objectives:** The cut-off determination with 11 plex and 3 new antigens multiplex kit is completed, new kit configuration showed Sensitivity and specificity of 85 and 90 percent, respectively.

b. **Technology/Product (to be) developed:** RU-1-Rapid biomarker-based non-sputum-based test for the detection of Tuberculosis

c. **IP generated/ Potential for IP generation:** Patent granted file no 201641006487 dated 24/02/16; System and Method for Active tuberculosis detection by multiplexing serology using mycobacterium tuberculosis antigens

d. **Resources Generated:** Manpower get trained for this technology at multiple sites.

Plans to take innovation further:
Partnering for commercialization is in discussion.

Risks envisaged:
The cost of the kit and sensitivity and specificity of the test when compared to culture, which is currently the gold standard for tuberculosis diagnosis.

Contact: NextGen In-Vitro Diagnostics Private Limited

Project Coordinator:
Vivek Chandra

Team Members :
Suresh Thakur, Prabhakar M, Priyanka Bhardwaj, Anjali Singh and Jaskiran Kaur

Contact :
C - 1/59 Safdarjung Development Area DELHI, India-110016

Nikky Kumar Jha

Title of the Proposal:
Development of a retrofittable device for rapid urine testing

Brief description:
The solution is a plug-and-play device that can be fitted onto any type of urinals and toilets and people can get their health records on their email by paying a small one-off-cost. The device is fitted with various kinds of sensors capable of measuring physical, chemical, and biological properties of urine. The device also senses large protein molecules and biomarkers for chronic kidney diseases. It also provides an entire array of options like visiting nearby local health clinics/pharmacies/pathology labs to increase the early diagnosis of lifestyle diseases. The service is an all-encompassing platform for metabolic health.

Current stage of development:
Validation

Innovative Element(s):
The Rapid Urine Test is reusable, self-cleaning at every flush with no consumables and provides real-time data.
Urinalytics seeks to bring healthcare directly to the mass public through a solution that fits onto toilets and urinals even at workplace and gyms.

The service offering is an accessible email that does not require any other upfront data or payment and gives you a choice to pay for a full health report at your convenience.

Market Potential:
The primary target market is developing countries like India and then immediately rolling out to Developed Nations, with a focus on people with limited time to invest in physically visiting healthcare professionals and limited willingness to buy health insurance.

National/Societal relevance:
In a country like India, the innovative solution would create awareness about preventive healthcare and promote hygiene and sanitation. The solution would help in the early detection of life-threatening ailments.

Project achievements:

a. **Progress vis-a vis objectives:** The solution has been developed and is under validation

b. Technology/Product (to be) developed: The product allows real-time evaluation of Chronic Kidney Disease related biomarkers in human urine. The electrochemical sensors test and compare the urine biomarkers with their healthy concentrations, giving an estimate of the build-up of possible chronic ailments. The rapid urine technology does not use any consumables and is the first green solution in the market.

c. **IP generated/ Potential for IP generation:** Applied for a Patent and design patents.

d. **Resources Generated:** The Company was selected on a global platform by Young Sustainable Impact, Norway and is the winners of the SMC Master Class, IIT Patna. The start-up has been identified by Google Cloud Platform and Google had extended its support in the form of services and subscription for a year.

Plans to take innovation further:
Looking for potential investors and collaborators for pilots to test the product at larger scales. The product would be licensed in the future for more expansion and better reach.

Risks envisaged:
Market acceptability

Project Coordinator:
Nikky Kumar Jha

Team Members :
Vipasha Bhardwaj, Garry Christopher, Deeksha Yadav, Shivani Jha, Animesh Sharma and Vaishnavi Manikam

Contact :
Naya Tola Dudhelaaya Tola Dudhela, Po-Mirzapur, Via-Champanagar, Dist- Bhagalpur Bhagalpur 812004

Nuverse Health Solutions Private Limited

Collaborator: PinkTech Design Pvt Ltd

Title of the Proposal:
Contactless Digital Sanitation Assurance Entry Exit System

Brief description:
The Nuverse Contactless Digital Sanitation Assurance Entry Exit System (DSAS) provides hand sanitisation, temperature checks and regular user sanitation ratings.

Current stage of development:
Validation

Innovative Element(s):
Use of IOT and AI neural network provides a detailed report of user behaviour.
Market Potential: The device has the potential to replace the existing access systems and is designed as per the new post COVID norms.

National/Societal relevance:
In a vast country like India, personal hygiene is of utmost importance to prevent the spread of any disease. The device can be installed at all places, including Govt. and private offices, schools, gardens, etc.

Project achievements:

a. **Progress vis-a vis objectives:** Having accomplished all objectives successfully, the DSAS is in the final stage of validation.

b. **Technology/Product (to be) developed:** Contactless Digital Sanitation Assurance Entry Exit System

c. **IP generated/ Potential for IP generation:** In process

d. **Resources Generated:** IOT and Software engineers

Plans to take innovation further:
Applied for BIRAC PCP funding

Risks envisaged:
None

Project Coordinator:
Richa Vashisht

Team Members :
Kanav Kahol and Mukesh Mhatre

Contact :
Nuverse Health Solutions Private Limited,

Orthocrafts Innovations Pvt. Ltd.

Title of the Proposal:
Manufacture and commercialization of polylactic acid based indigenous bioabsorbable implants

Brief description:
Traditionally metal implants are used for the fixation of soft tissues such as tendons, ligaments etc. If remained inside the body metal implants pose issues such as stress shielding, implant movement, metal ion leaching. The bioabsorbable implants that will perform equal to the metal implants and dissolve inside the body over the period of time is the choice solution amongst medical practioners. Orthocrafts Innovations has developed proprietary know-how for the synthesis of biomedical grade polymers and implants using the same in affordable manner.

Current stage of development:
Validation

Innovative Element(s):
There is no Indian manufacturer of bioresorbable implants despite clear need. India imports all its bioresorbable implants. The PLA required to make implants is available at premium prices in international markets. In this context, Orthocrafts has developed the proprietary knowhow to make biomedical grade PLA and implants using same.

Market Potential:
More than a million surgical procedures are performed every year across the globe for the fixation of torn tissues in knees and shoulder. The market is pegged at USD 5 billion and its growing at a CAGR of 7 annually according to reports published by various market research agencies.

National/Societal relevance:
Bioabsorbable implants are choice solutions amongst surgeons over metallic implants. By developing safe to use implants, Orthocrafts will create a strong option for bioabsorbable implants in domestic market adhering to Make in India initiative.

Project achievements:

a. **Progress vis-a vis objectives:** Orthocrafts has successfully demonstrated its ability to synthesize bioabsorbable polymers at a kg scale. The Company has established a GMP compliant facility capable of producing bioabsorbable polymers.

b. **Technology/Product (to be) developed:** Orthocrafts has established facility to produce biomedical grade polymers and has the capability of making implants using the same.

c. **IP generated/ Potential for IP generation:** Orthocrafts has secured trademarks for proposed products. Further, they envisage IP to be generated through new implant designs, material compositions and instrumentation designs.

d. **Resources Generated:** Orthocrafts has established the GMP compliant facility to produce biomedical grade polymers. Resources such GPC for polymer molecular weight analysis, clean rooms suitable for medical device manufacturing and packaging have been created. 3- 5 new jobs have been generated.

Plans to take innovation further:
Orthocrafts plans to commercialise its products by obtaining CDSCO approvals in Indian market. They are open to discuss the new product development opportunities with other industry players.

Risks envisaged:
The early adoption of products by medical practioners as against the international brands is envisaged one of the greatest hurdle. Partnering with appropriate marketing and distribution agencies without compromising on affordability of products would be another challenge.

Project Coordinator:
Piyush Joshi

Team Members :
Piyush Joshi, Sameer Huprikar, Waheed Rahman, Ashish Lele and V Premnath

Contact :
Flat No B/12, Montvert S. No. 140/a Pashan Sus Road, Pune MAHARASHTRA India-411021

Orthocrafts Innovations Private Limited

Title of the Proposal:
Bioabsorbable implants based on polylactic acid (SBIRI)

Brief description:
Traditionally metal implants are used for the fixation of soft tissues such as tendons, ligaments etc. If remained inside the body metal implants pose issues such as stress shielding, implant movement, metal ion leaching. The bioabsorbable implants that will perform equal to the metal implants and dissolve inside the body over the period of time is the choice solution amongst medical practioners. Orthocrafts Innovations has developed proprietary know-how for the synthesis of biomedical grade polymers and implants using the same in affordable manner.

Current stage of development:
Validation

Innovative Element(s):
There is no Indian manufacturer of bioresorbable implants despite clear need. India imports all its bioresorbable implants. The PLA required to make implants is available at premium prices in international markets. In this context, Orthocrafts has developed the proprietary knowhow to make biomedical grade PLA and implants using same.

Market Potential:
More than a million surgical procedures are performed every year across the globe for the fixation of torn tissues in knees and shoulder. The market is pegged at USD 5 billion and its growing at a CAGR of 7 annually according to reports published by various market research agencies.

National/Societal relevance:
Bioabsorbable implants are choice solutions amongst surgeons over metallic implants. By developing safe to use implants, Orthocrafts will create a strong option for bioabsorbable implants in domestic market adhering to Make in India initiative.

Project achievements:

a. **Progress vis-a vis objectives:** The Company will manufacture the implants in the GMP compliant facility.

b. **Technology/Product (to be) developed:** Orthocrafts has established facility to produce biomedical grade polymers and has the capability of making implants using the same.

c. **IP generated/ Potential for IP generation:** Orthocrafts has secured trademarks for proposed products. Further, they envisage IP to be generated through new implant designs, material compositions and instrumentation designs.

d. **Resources Generated:** Orthocrafts has established the GMP compliant facility to produce biomedical grade polymers. Resources such GPC for polymer molecular weight analysis, clean rooms suitable for medical device manufacturing and packaging have been created. 3- 5 new jobs have been generated.

Plans to take innovation further:
Orthocrafts plans to commercialise its products by obtaining CDSCO approvals in Indian market. They are open to discuss the new product development opportunities with other industry players.

Risks envisaged:
The early adoption of products by medical practioners as against the international brands is envisaged one of the greatest hurdle. Partnering with appropriate marketing and distribution agencies without compromising on affordability of products would be another challenge.

Project Coordinator:
Piyush Joshi

Team Members :
Sameer Huprikar, Waheed Rahman, Ashish Lele and V Premnath

Contact :
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Osind Meditech Pvt. Ltd.

Title of the Proposal:
A hand in need - a self driven rehabilitation device for stroke and neuromuscular deficit patients - extensive validation

Brief description:
A Self-Driven Hand Rehabilitation device for patients with neuromuscular deficit of the hand which consists of two gloves. The patient can use his / her healthy hand wearing a Sensor glove to mirror similar movement on the affected hand wearing a Motorized glove. This allows the patient to do functional exercises with independent movement of each finger and the gloves provide good visual feedback. The device can also support Passive Mobilization Therapy.
Current stage of development: Validation

Innovative Element(s):
It is self-driven, allowing smooth, realistic movements and real-time mirroring for better visual feedback than currently used passive mobilization therapy. It is Automatic, Highly Portable, Customizable, Compact & Wearable all in one unit. It uses Remote Monitoring & Control for increased patient compliance

Market Potential:
India has more than 100,000 New patients per year who suffer from neuromuscular deficit. The device also has a huge potential abroad to offer cost-effective rehabilitation for patients. Current hand rehabilitation devices are very Expensive and exclusively available in High End Rehabilitation Clinics and Hospitals which is not affordable for everyone.

National/Societal relevance:
More than 2.5 Million people suffer from neuromuscular deficit in India. These patients need long term rehabilitation which is expensive and time consuming. Frequent visits to the hospital are a financial and social burden on the family.

Project achievements:

a. **Progress vis-a vis objectives:** Extensive Validation in 2020. Early Market Adoption in 2021.

b. **Technology/Product (to be) developed:** The Android Application for the widespread adoption and reusability of the device and Web Dashboard system to allow Multiple products under one Ecosystem of HAND IN MOTION.

c. **IP generated/ Potential for IP generation:** IP has been generated with BIRAC- PATH support for the mechanism of the self driven rehabilitation system

d. **Resources Generated:** A Team of 5 including 2 Biomedical Engineers, 1 Electronics Engineer, 1 Fashion Designer, 1 Operations Manager has been employed full time and 2 Interns part time. Trained several Engineering and Management Graduates in the process. Also provided jobs for Local Tailors for development of gloves.

Plans to take innovation further:
Exploring collaborations to commercialize the device with early adopters such as Hospitals, Therapy Centers and Therapists.

Risks envisaged:
Implementation of the New Therapy device in current clinical practice will need exposure on a National Scale, digital training and time. Several Clinical Studies may need to be conducted to show efficacy in different environments and situations.

Project Coordinator:
Mohammad Samheel

Team Members :
V S Venkatesan, Issac B Jacob, Mohammad Anies, Neha Sheikh, Mohammed Tameem Ahmed, Suprith Kunder, Yunus Tonse

Contact :
202 A , Innovation Centre
MIT MANIPAL Manipal
Udupi KARNATAKA
India-576104

Plasmaart Resto Pvt. Ltd.

Title of the Proposal:
Lyophilised Platelet Lysate In Wound Care Management "A Low Cost Remedy From Human Unused Platelet Concentrate"

Brief description:
IPlatelets embedded within blood clots have a main role in the physiological process of wound healing, not only as haemostatic agents but also as regulators of inflammation, angiogenesis, cell migration, and proliferation. Hence we have formulated a powder that has cocktail of human natural growth factors derived from unused blood bank platelets and also to extend the shelf life. These platelet products including our homologous lyophilised platelet lysate is sourced from approved blood banks with all safety features established.

Current stage of development:
We have got form 29 test licence FDA Maharashtra state - TL 201517316 Dt 1/1/19 for animal testing.

Innovative Element(s):
At present only recombinant growth factors like becaplermin, which is available in Indian market has single tailored growth factor that is not sufficient for ulcer healing. Also there is a warning that repeated applications of the same will cause cancer. Hence we have formulated a powder that has cocktail of human natural growth factors derived from unused blood bank platelets and also to extend the shelf life. At present similar products are available for veterinary applications only and that too not in India

National/Societal relevance:
In India, DFUs affect 15% of diabetics during their lifetime. Evidence from published literature showed 100,000 leg amputations/ year due to diabetes-related problems and an expense of approximately $1,960 for complete treatment of DFUs. Out of 62 million diabetics in India, 25% develop DFUs, of which 50% become infected, requiring hospitalization while 20% need amputation. DFUs contribute to approximately 80% of all non-traumatic amputations in India, annually. Patients with a history of DFU have 40% higher 10-year death-rate, than those without. Average time required for healing of DFUs is 28 weeks (range 12-62 weeks). Moreover, 50% of DFU patients who get amputated once, suffer another amputation within next 2 years. In order to bring out a new therapeutic modality out of unused blood bank product that is being discarded at present can be made in medical wealth.

Project achievements:

a. **Progress vis-a vis objectives:** Phase 1 of the objective is being achieved i.e., Preparation of Biological – lyophilised platelet lysate (LPL, PLYCEL M) from unused platelet concentrates (expired >5days only) from approved blood banks. Phase 2 stability study and characterization is in process

b. **Technology/Product (to be) developed:** The prototype of the major product is made and diabetic wound model in animal has to be made to test the efficacy and safety of the product.

c. **IP generated/ Potential for IP generation:** Prior Art search is in progress and writing up of patent preliminary application is being done.

d. **Resources Generated:** Two existing employees were assigned in this project and the two new women entrepreneur is being employed under this BIG scheme project.

GLP & GMP training is being made to the employees

Plans to take innovation further:
Our Target audience are Physicians dealing & Patients with Diabetic foot ulcer.
a. Educate them on regenerative medicine & biological based approach towards wound healing
b. Demo for application
Plasmaart Resto has contacted few pharma companies for the next level of product development. MMC pharma, Chennai is ready to take up the product & fund partially for clinical trial once the products safety is proved in animal trials

Risks envisaged:
Availability of unused platelet concentrate was found during the spread of dengue that was overcome by approaching many number of blood banks inter districts.

Project Coordinator:
Dr. Avinash Gandi Ph.D.

Team Members :
Dr V R Ravi MS (Ortho), Dr Avinash Gandi D, Mrs Shree Vaishnavi R, Mrs Shinu SM

Contact :
44A, I Floor, Vishranthi Suriya Cplx. Vayalur Road, MGR Nagar, Puthur, Trichy – 620017, Tamilnadu

Pooja Goswami

Title of the Proposal:
A novel device to detect gram- negative bacterial infection and antibiotic resistance in patients with Acute Leukemia

Brief description:
Infection is a critical issue, especially in the ICU where almost 60-80 patient develop the dangerous infections, such as catheter-related bloodstream infections, ventilator-associated pneumonia and catheter-associated urinary tract infections. Because of the high infection rates, 100 of all patients are tested in the ICU. It is cost effective in compare to all existing testing methods like culture, PCR as it reduces the cost on infrastructure up-to 95 and almost 80 reduction in staff. It is cost effective in compare to all existing testing methods like culture, PCR as it reduces the cost on infrastructure up-to 95 and almost 80 reduction in staff.

Current stage of development:
Validation

Innovative Element(s):
First paper-based nanosensor to detect species-specific infection and antibiotic resistance in 90 minutes

Market Potential:
For all over the worldwide 150 million people get affected with UTI infection.The healthcare market can increase three-fold to Rs 8.6 trillion US$ 133.44 billion by 2022. RAMJA Genosensor is providing a rapid, easy and cost effective solution: a novel paper based device to detect microbial infection and antimicrobial resistance in less than 2 hours. Define market size & your customer base. Among the whole population, 35 population, almost 47 crore people do develop UTI in India every year.

National/Societal relevance:
This technique will help Indian heath care system, not in term of time, which lead to high mortality due to prophylactic antibiotics, because this device will give immediate direction to physician , to prescribe result oriented antibiotics to the patients. Existing tests cost patients almost Rs. 1000-16000 rupees and hospitals invest almost 2-3 crore rupees to pay for highly trained microbiologist staff to manage these tests.

Project achievements:

a. **Progress vis-a vis objectives:** E.coli infection detection sensor developed
CTX-M antibiotic resistance gene-based sensor developed
Clinical trial for the validation A.I.I.M.S. Delhi going on

b. **Technology/Product (to be) developed:** Unique technology for species-specific Infection and gene-specific antimicrobial resistance detection in 90 minutes, developed

c. **IP generated/ Potential for IP generation:** 3 Indian Patents and one PCT filed

d. **Resources Generated:** NEXUS graduate Award in 2020 from American Center at Delhi.

Plans to take innovation further:
To apply for the ATGC program otherwise, plan to Launch the product after the regulatory clarification.

Risks envisaged:
Filled patent, so it will benefiting us into entering market, the only risk is, to deal with existing time taking set up, we need to habbituate for our technology.

Project Coordinator:
Pooja Goswami

Team Members :
Rajrani Goswami,
Raghavendra Giri,
Jasdeep Singh, Annapurna,
Inderjeet Singh

Contact :
Department of
Gastroenterology and HNU,
AIIMS, New Delhi

Pooja K Jha

Title of the Proposal:
A portable Biophysically stimulated Therapeutic device for persons with knee osteoarthritis.

Brief description:
Swayogya is designing and developing a non invasive Therapeutic device for persons who have osteoarthritis at knee joint. The device consists of a hand held electronic system with which probes from the knee orthosis is connected. The device functions on pulsed electromagnetic field technology which provides chondroprotective effect at the knee joint.

Current stage of development:
Validation

Innovative Element(s):
The device claims its uniqueness in providing non -invasive, portable technology for slowing down cartilage degeneration and also real time monitoring of the same in case of persons who have osteoarthritis at knee joint

Market Potential:
In terms of market potential, the proposed orthosis can be categorized in orthopaedic medical device class B healthcare industries. According to 2019 Indian Medical Devices report, it was estimated that, orthopaedic device market is valued at over USD 450 Million, and growing 30 per year.

National/Societal relevance:
Musculoskeletal diseases are now the second greatest cause of disability in all regions of the world, with osteoarthritis OA showing the greatest increase in the last 20 years. A recent WHO report on the worldwide burden of disease indicates that knee OA alone is likely to become the 4th most important cause of disability in women and the 8th in men.

Project achievements:

a. Progress vis-a vis objectives: After validating the multiple iterated designs of prototype through clinical trials we will apply for required certification followed by market launch

b. **Technology/Product (to be) developed:** The final product will combine both therapeutic and diagnostic features and team members are expecting to hit the market in two years from now

c. **IP generated/ Potential for IP generation:** The PEMF technology when Amalgated with vibroarthrography claimed to be novel technology and patent has already been published with this idea.

d. **Resources Generated:** Created Enterprise

Plans to take innovation further:
in process of collaborating with major stakeholder for better dissemination of technology into market.

Risks envisaged:
The core challenge will be raising funds to carry out manufacturing.

Project Coordinator:
Pooja Kumari Jha

Team Members :
Vikas Kumar,
Sanyal Kumar

Contact :
RZF 762/36, Raj Nagar Part
2, Palam Colony,
South West Delhi, DELHI,
India

Prameela Rao

Title of the Proposal:
Eco-friendly adult diapers with antimicrobial properties and disease indicators based on natural fibers and hydrogels

Brief description:
According to studies one in three women and one in eight men suffer from the problem of urinary incontinence or loss of urinary bladder control. Many with urinary incontinence problem are forced to stay indoors and thus suffer from depression, loss of confidence. Adult diapers available in the market contain plastics making them harmful to both environment and to patients. Unlike conventional incontinence pads and diapers, this Banana fiber incontinence solution is biodegradable, elderly-friendly and affordable. The product with antimicrobial properties and disease indicators is first of its kind an early, self-detection tool for common diseases.

Current stage of development:
Validation

Innovative Element(s):
Unlike available adult diapers, banana fiber diaper with disease indicators is the first indigenous product. The pads have anti-microbial properties. Besides effective management of urinary incontinence problem, natural fibers in direct contact with skin prevents itching and rashes on skin. The goal is to set up a low-cost sanitary diapers manufacturing unit in rural areas and stop migration of youth

Market Potential:
According to a study, more than 400 million people worldwide and 50 million people in India suffer from Urinary incontinence. One out of 10 people above 60 years suffer from the problem of incontinence. There are many elderly people who due to some disability cannot visit toilet. The market value in 2018 was estimated around US$ 8,000 million. With cloth adult diapers being the trend, there is a huge market in Europe and South Asia.

National/Societal relevance :
- In using waste as a resource, it may increase income of farmer.
- With indigenous product being affordable, care of bedridden elderly people will no longer be a burden for middle class families
- Due to the self-detection tool for common diseases, patients can be rushed to hospitals within golden hour
- Banana plant consumes less water than cotton and is biodegradable in a landfill six months
- The goal is to set up a low-cost sanitary diapers manufacturing units in villages and stop migration of youth.

Project achievements:

a. **Progress vis-a vis objectives:** Successfully fabricated paper analytical device, which has to be incorporated into adult diaper. Demonstrated a feasibility to detect pH and Urea. Raw banana and coconut fibre chemically processed in different ways and fibre sheets produced. Antibacterial hydrogel synthesis and optimization are underway.

b. **Technology/Product (to be) developed:** Development of natural fibre. Thus it make two more years for the product to hit market

c. **IP generated/ Potential for IP generation:** As the market is set to grow, IP has a huge potential. When the product inches closer to the stages of clinical validation, IP application will be submitted.

d. **Resources Generated:** A state-of-the art facility has been set up at the Incubation laboratory in Yenepoya Research Centre YRC to ensure quality results. As work on the product is still in initial stages, no manpower has been employed or funds mobilised for expansion and other works.

Plans to take innovation further:
In next three to four years, plans are afoot to launch an independent company with or without collaboration with existing companies.

Risks envisaged:
Marketing such an indigenous product is the biggest challenge. The product will first take the path of e-commerce before going for commercialisation.

Project Coordinator:
Prameela Rao

Team Members :
Asim Syed Sheeraz, Prabha Adhikari, Renjith P Johnson, Sudhakar Prasad

Contact :
Mathrushree,
Soujanya Lane, Bikarnakatte,
Mangalore-5

Prem Nandhini Satgunam

Title of the Proposal:
Pediatric Perimeter: A device to measure visual fields

Brief description:
Visual field is the extent of side vision a person has when looking straight ahead. Measuring visual fields reflects the health of the visual pathway, which are structures all the way from the eyeball to the brain. Perimeters are devices used to measure the visual field.

Current stage of development:
Validation

Innovative Element(s):
Team has built a dome in which the baby is placed. Light appears on the dome. Team monitors the baby with a camera. An eye/head movement to the light is a surrogate measure of detection and is marked as their visual field extent.

Market Potential:
The device can be used to screen these babies. Eventually the device can be used to screen every baby born.

National/Societal relevance:
Early detection of disease can lead to early intervention which will result in appropriate treatment or rehabilitation for children. The number of disability/blind years are more for children than for an adult who develops a vision problem later in life.

Project achievements:

a. **Progress vis-a vis objectives:** Operational prototypes have been deployed in one eye institute and in one children's hospital. Over 500 babies have been tested with this device till date.

b. **Technology/Product (to be) developed:** Pediatric Perimeter device has been developed as an operational prototype now. It can enter the market within a year or two.

c. **IP generated/ Potential for IP generation:** Indian patent application number: 4341/CHE/2015
US Patent No.: US 10,517,475 B2 [granted]
CIP Patent Pub. No.: US 2020/0085291 A1 [applied]

d. **Resources Generated:** Clinical human resources trained: 8
Humanpower employed: 3 clinicians + 3 engineers
Facility created: Visual field testing room at a children's hospital and at an eye institute
Training protocols for conducting the test and analyzing the results have been developed

Plans to take innovation further:
Industrial partnerships are explored for manufacturing and commercializing. Grant applications have been sent for testing babies with vision problems.

Risks envisaged:
There are no competing devices to compare to. Thus the main challenge is to create a new market

Project Coordinator:
PremNandhini Satgunam

Team Members :
Sourav Datta, Monika Thakur, Eashwar Sudheer, Ashish Kumar Singh, Jagadesh Rao, Ashutosh Richhariya & Gaddam Manoj Kumar

Contact :
Road 2, Banjara Hills,
L V Prasad Marg,
Hyderabad

Rajesh Thangavel Yadav

Title of the Proposal:
Duo-Vent: AI-enabled smart ventilation system to provide independently controlled ventilation for each lung.

Brief description:
Duo-Vent is the worlds first AI-enabled smart ventilation system that can provide lung isolation and independently controlled ventilation to each lung for unilateral lung consolidation or in conditions like ARDS where one lung is infected more than the other.

Current stage of development:
POC

Innovative Element(s):
The invention provides apparatuses and methods for independently controlled synchronous delivery of ventilation to each of a patient's lungs. It also provides an automated smart mechanical ventilation system for respiratory failure patients, which can provide independently controlled ventilation to each lung. The invention also provides pressure and volume controlled sensor system for controlling the air supply in the respiratory illness patient, who is suffering from respiratory diseases that involve consolidation formation inside the alveoli of the lungs.

Market Potential:
Enhanced treatment of the patient using our device will result in decreased hospitalization time and it will reduce the cost burden on the middle and low-income patients of developing countries. Our main aim is to make mechanical ventilation affordable for low-income groups so that they don't have to worry about the cost.

National/Societal relevance:
ICU is the most expensive and resource-demanding unit when compared to all the other units in the hospital, they alone utilize about 20 of all hospital costs. Among the total ICU hospitalization costs charged by the patient, around 45-55 percent is charged only for Mechanical ventilators. The daily total cost for a non-ventilated patient was Rs. 6585 ± 932 for medicines etc., whereas that for a ventilated patient is Rs. 12,429 ± 9720.

Project achievements:

a. **Progress vis-a vis objectives:** Developed the Proof of concept for the device and now we are in the process of developing a Minimal Viable product.

b. **Technology/Product (to be) developed:** The tablet-based User interface with Bluetooth and wifi feature has been developed and currently in process of validation by doctors

c. **IP generated/ Potential for IP generation:**

Patent Number: 201941046449, Title of Patent: Apparatuses and Methods for Assisted Ventilation, Applicant: Foundation of Cfhe, IIT Hyderabad

d. **Resources Generated:** The initial RnD inputs on Duo-Vent helped us to develop our second device Jeevan Lite a low-cost IoT-enabled ventilator for ICU patients. Team has expanded our team from 2 to 10 full-time employees, 6 interns.

Plans to take innovation further:
To raise funds to manage the animal study and pilot study on patients.

Risks envisaged:
Device is very new to the market, we might have to train the medical students and practitioners to explain the advantage of our device over existing devices in the market. This might delay our market entry timeline. Hence we plan to bring in more hospital heads in the project and use key influencers to help us get the device into the market.

Project Coordinator:
Rajesh Thangavel Yadav

Team Members :
Rajesh Yadav,
Cyril Antony

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Periyar Maniammai Univeristy,
Periyar Nagar Vallam Thanjavur
Tamil Nadu India-613403

Reinste Nano Ventures Pvt. Ltd.

Title of the Proposal:
Early Validation/ Testing and Certification of Long acting Virus Propagation inhibition Coatings for Various Surfaces

Brief description:
Coatings for all surfaces like metals, plastics, wood, textiles, leather, stone, glass, paper etc. which are long lasting, cost effective, human safe, easy to use, very esthetic also which provide Self sanitization of surfaces by curbing the viral and microbial propagation through surfaces and thus making them need of hour.

Current stage of development:
Commercialization

Innovative Element(s):
Current methods evolve use of acid, alcohol, bleach which causes surface decay on which they are applied, Warrior Coatings are totally free from any agents which corrode or degrades the surface on which they are applied.

Current Technology is limited to a very small period on any surface few minutes to few hrs and require frequent re-application where as Warrior Coatings can last up to year with out any recoating .

Market Potential:
Nano Based Antimicrobial/antiviral coating has a great potential in the Indian as well as the international market. As market needs an economically viable and technologically advanced product and we are in position to cater both the needs.

National/Societal relevance:
The microbes propagation and growth can be significantly curbed by Warrior Antiviral and Antimicrobial Coatings and thus significantly reducing the Hospital Borne infections .

Project achievements:

a. **Progress vis-a vis objectives:** Some Coatings are ready for commercialization and rest after successful development are under evaluation stage.

b. **Technology/Product (to be) developed:** The need for a very broad spectrum, cost effective, easy to use, environmentally and human safe, Antiviral and Antimicrobial Coatings for long term effective sanitization of surfaces is the goal.

c. **IP generated/ Potential for IP generation:** Has tremendous potential for generating new IP in both process, Product and application areas

d. **Resources Generated:**
Manpower employed : 5
Facility Created : Lab and Materials

Plans to take innovation further:
MOU Signed:1, Distributorships Signed: 3, Enquiries received: 10.

Risks envisaged:
Awareness, High Marketing Cost.

Project Coordinator:
Puneet Mehrotra

Team Members :
Archana Mehrotra, Tanya,
Mansi, Sanjeev, Siddharth,
Mamchand

Contact :
TBIU, Unit-12, DBEB, Indian
Institute of Technology Delhi,
NEW DELHI 110016

Rmmedi Innovations Pvt. Ltd.

Title of the Proposal:
Development of Reusable and Portable Negative Pressure Wound therapy device

Brief description:
Development of Advanced, Affordable, Reusable and Portable Negative Pressure Wound therapy device.

Current stage of development:
Validation

Innovative Element(s):
High suction capacity in a compact sized device with high degree of reliability. Protection against fortuitous vacuum failure

Market Potential:
As per the study, there is an increasing incidence of surgical site infections and chronic wounds amongst the masses worldwide.

National/Societal relevance:
Currently, India is a premium consumer of Wound Healing Technology. Negative Pressure Wound Therapy devices used in Indian healthcare system is mostly imported from USA and EU countries. So, developing a nation by developing a competent technology is challenging and promising to the nation. The challenges facing during the development is procuring the accessories, parts and other materials.

Project achievements:

a. **Progress vis-a vis objectives:** 1. The system is re-engineered by incorporating the technological advancements. 2. Clinical trial of the product has started

b. **Technology/Product (to be) developed:** The product is under development PEQUE, Negative Pressure Wound Therapy device . Expected time needed to enter the market is 6 months

c. **IP generated/ Potential for IP generation:** The design of the product is unique. The reliability enhancement technology of our product is planning for patent process.

d. **Resources Generated:** One more person has joined in the company as Hardware Engineer

Manufacturing facility is under development. Developing other variant of NPWT device named HUG

Plans to take innovation further:
The procedures are initiated for obtaining ISO13485 certification

Risks envisaged:
The project has delayed by 12 months due to current COVID-19 pandemic.

Project Coordinator:
Joseph Thomas

Team Members :
Stephen George, Ashif S

Contact :
Rmmedi Innovations Private Limited DOOR NO 319A15, MADUKKAKUZHI H PARATHODU PO , KANJIRAPALLY Parathode Kottayam KERALA India-686512

Salcit Technologies Pvt Ltd

Title of the Proposal:
DIGITAL HEALTH ADVISORY SYSTEM FOR CHRONIC RESPIRATORY DISEASES

Brief description:
Salcit technologies has developed a patented Swaasa, AI platform, which is a Point-of-care technology to assess users' respiratory condition. The platform analyzes cough signals along with a subset of symptoms from SGRQ St Georges Respiratory Questionnaire and provides an assessment. Using proprietary machine learning and artificial intelligence algorithms, the platform identifies underlying respiratory condition (yes/no), the pattern obstructive, restrictive, mixed or normal and its severity.

Current stage of development:
commercialization
Commercialized in the name of: Swaasa - Revolutionizing Respiratory Healthcare
Date of commercial Launch: 2020-05-07
Number of units sold: More than 70000 assessments using the platform
Number of end users: 70000+

Innovative Element(s):
A patented ML model that brings the functionality of spirometry unbounded by time, space, specialized equipment and trained professionals. This core ability allows the solution to be rapidly deployed at scale to screen, diagnose and monitor approximately 500m people suffering from the Big Five respiratory diseases.

Market Potential:
TAM In India 2 Billion Dollar. TAM outside India 5 Billion Dollar

National/Societal relevance:
Our technology by its very nature, erases the rural-urban gap and helps deliver location independent, superior care across the board. Swaasa enables frequent, inexpensive, widespread screening, diagnosis and monitoring of patients with respiratory conditions. This changes the healthcare paradigm from being reactive to proactive from treatment to prevention. Early Screening helps in arresting the disease and further prevention. Screening/Monitoring can be facilitated at Public Health Centers PHCs and Community Health Centers CHCs as well using our tool.

Project achievements:

A. **Progress vis-a vis objectives:** Completed one clinical validation.

b. **Technology/Product (to be) developed:** We are already deployed in market.

c. **IP generated/ Potential for IP generation:** 1. India Patent, Granted No. 308156 - A system for analyzing risk associated with cough sounds.
2. US Patent Application No. 16/ 768872 - Method and system for analyzing risk associated with respiratory sounds.
3. US Continuation-in-Part Patent Applied - No. 17/ 081149 - A method and system for health risk of a user.
4. Canada Patent Application - No. 308363 - Method and system for analyzing risk associated with respiratory sounds

d. **Resources Generated**: 6 full time employees. More than 20 Internships. 2 Consultancy projects. 1 PhD Scholar.

Plans to take innovation further:
Actively looking for partners who can see value in our technology. Essentially interested in strategic alliances. Though we are making revenues, to scale up and have bigger impact we are looking for investments.

Risks envisaged:
Acceptability by wider audience / customer segments taking longer than expected times. There is a notion that AI/ML based solutions need to be validated on millions of subjects. A right mind set is needed in balancing gains with short term limitations. Consider AI based predictions as an aid and amplifier of medical knowledge.

Project Coordinator:
Narayana Rao Sripada

Team Members :
Venkay Yechuri, Manmohan Jain, Shuba Deepti, Bawarj Mamidji, Gowrisree R, Charisma

Contact :
Salcit Technologies Pvt Ltd P405, VJHUB, Bachupally Hyderabad - 500090, Telangana, India Hyderabad Hyderabad 500090

S. Vishnuvardhan Reddy

Title of the Proposal:
Biosynthesis of Ectoine: An important pharmaceutical ingredient

Brief description:
Ectoine is an important ingredient in large number of pharmaceutical formulations, which is mostly produced through chemical synthesis, which is costly and complex. However, biological route of Ectoine synthesis is an economical alternative method that can be used for large scale production, which is absent at present in the country

Current stage of development:
Proof of Concept

Innovative Element(s):
The use of unique wild type bacterium which also secretes most of the Ectoine produced, without any process manipulation requirement, thus simplifying the downstream process and the overall cost of production.

Market Potential:
An estimated 15K tons demand was found in 2015, which is expected to increase 3 fold by 2025, because of the novel applications of this versatile compound. Average market price is 1500 USD per Kg, which is up trending due to the increase in demand and limited production in the country, where no known manufacturers through biological route are reported.

National/Societal relevance:
Most of the requirement at present is met through import, though there are few chemical manufacturers in the country. However, there are no known biological route producers in the country, which is an actual efficient economical method of ectoine production

Project achievements:

a. **Progress vis-a vis objectives:**
- Three novel wild type strains have been identified which have high potential for Ectoine production;
- Upstream and downstream processes optimization at small flask level has been completed for all these bacteria.
- 5L fermentor scale upstream process as well as, similar volume downstream process is under optimization at present.
- Plan to complete the physicochemical as well as, toxicity – stability studies within the next 12 months.

b. **Technology/Product (to be) developed:** Process for biologically synthesized Ectoine is to be developed

c. **IP generated/ Potential for IP generation:** Process that been already filed for India Patent

d. **Resources Generated:** Two M.Sc. personnel employed, small Microbiology laboratory created (instruments like HPLC, Lab fermentor have been bought from BIG funds, a limited company has been incorporated - "Microbztech Labs Pvt. Ltd.", at present actively searching for investors.

Plans to take innovation further:
Upscale optimization in 50L and 100L capacities before the genuine commercialization of the product as a JV or through licensing.

Risks envisaged:
Behavioral issues of the wild type strains during scale-up.

Project Coordinator:
S. Vishnuvardhan Reddy

Team Members :
M. Srikanth Reddy,
A. Srinivas

Contact :
Plot No. 102, Phase 1, Sri Sai Dwarakapuri Colony, Cherlapally, Nalgonda-508001, Telangana

SCMS Institute of Bioscience and Biotechnology Research and Development - Pratap Foundation for Education and Training

Collaborator: Malabar Cancer Centre

Title of the Proposal:
LAMP based, point of care POC rapid and low cost diagnostic test for COVID-19

Brief description:
This invention is a LAMP Loop activated isothermal amplification based method to diagnose the COVID-19 virus. A rapid, point of care, low cost method that does not require highly skilled personnel, but offers same sensitivity as the current RT PCR method.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
This LAMP based COVID test detects the SARS-COV2 virus within one hour time, can be performed at the point of care, and does not require expensive infrastructure or skilled scientists. The test result is a visible colour change and sensitivity at par with real-time PCR. Price per test 500 INR.

Market Potential:
Cost of the LAMP equipment is 2L INR and hence affordable for the healthcare centres. Currently there are only 2400 COVID diagnostic labs in India, more than one lakh clinical labs in India could be the clientele for this test. Precision and affordability makes the test exportable to other countries.

National/Societal relevance:
Specific Indian Challenges addressed by this technology: (1) Affordability of the test for a vast majority of our people. (2) Infrastructure: This test does not need expensive infrastructure. (3) Trained personnel: This test is relatively simple does not need specially trained molecular biologists, but lab technicians and nurses can be easily accustomed to perform the test. (4) Scarcity of the testing centres (5) More number of tests can be done which is important in epidemiological and public health point of view.

Project achievements:

a. **Progress vis-a vis objectives:** In line with the objective the LAMP amplification of synthetic Spike gene segment amplification is done and being validated with Real time PCR and clinical samples.

b. **Technology/Product (to be) developed:** Our product is the LAMP based COVID 19 detection system and it is expected to take 4-6 months to reach the market

c. **IP generated/ Potential for IP generation:** This LAMP based COVID 19 detection system uses LAMP amplification of spike region of SARS COV2 virus, under conditions. Our test system is unique and patentable.

d. **Resources Generated:** Employed two JRFs at SIBB R&D and two JRFs at MCC Collaborator

Plans to take innovation further:
Currently associating with a start up company named ZyGene Biotechnologies Pvt Ltd, Kochi. Will take the innovation ahead with appropriate interested companies

Risks envisaged:
Bio safety facilities exactly like in the sample collection kiosks have to be followed while doing the test in the point of care. This needs utmost care and adhesion to COVID 19 guidelines.

Project Coordinator:
Sethulekshmy Nair C.

Team Members :
Harish M, Madona Paul, Devaki Suresh, Parthiban Rudrapathi, Saravanan Murugan

Contact :
SCMS Institute of Bioscience & Biotechnology Research & Development Management House South Kalamassery KERALA India-692033

Seragen Biotherapeutics Pvt. Ltd.

Title of the Proposal
A Novel sperm transportation medium using a thermoreversible gelation polymer, N-isopropylacrylamide-based copolymer: SeraGel®

Brief description:
Seragen Biotherapeutics Private Limited (hereafter referred to as Seragen) is a fertility only biotech venture using Regenerative medicine based therapy engaged in the discovery, development and clinical validation and implementation of novel therapeutics designed to treat unmet infertility conditions.

Current stage of development:
Proof of concept

Innovative Element(s):
Our solution will help patients/donors/diagnostic centres or IVF clinics to collect semen sample and ship it overnight to a sperm bank or diagnostic centre or an IVF clinic at room temperature without cold chain logistics while preserving the semen quality parameters intact

Market Potential:
Male Infertility Market was valued at $216 million, and is expected to reach $301.5 million by 2020, supported by a CAGR of 5. Technavios analysts forecast the global sperm bank market to grow at a CAGR of 4.12 during the period 2017-2021

National/Societal relevance:
Since the quality of fresh human semen deteriorates rapidly, patients are often required to physically come to the diagnostic labs and deliver fresh semen samples for analysis. For patients living in remote or far areas it becomes difficult. This logistic encumbrance can be overcome by developing a reliable product that can preserve the sample for longer time without harming the quality of the sample. Thus the sample can be shipped to centralized, accredited, diagnostic laboratory having the facilities and expertise for evaluating and storing the sample.

Thus our solution will help patients/donors/diagnostic centres or IVF clinics to collect semen sample and ship it overnight to a sperm bank or diagnostic centre or an IVF clinic at room temperature without cold chain logistics while preserving the semen quality parameters intact

Project achievements:

a. **Progress vis-a vis objectives:** Completed first objective :Standardisation of polymer preparation-quantity, stability and solubility

b. **Technology/Product (to be) developed:** "Room temperature stable sperm transportation medium". Expected time to enter the market: 18 months

c. **IP generated/ Potential for IP generation:** Methods For Improving Sperm Functionality And Applications Thereof 2018 E-2/1197/2020/CHE

d. **Resources Generated:** (in terms of Manpower employed/trained, Facility Created, Enterprise Created, Fund Mobilization from other sources etc)

Man power employed: 3

Plans to take innovation further:
Partnership and Fund raising

Risks envisaged:
Clinical Validation and Regulatory approvals

Project Coordinator:
Vasanthi Palanivel

Team Members :
Ajith Kumar, Mathiyarasu, Karthick, Vasundhara

Contact :
Seragen Biotherapeutics Private Limited (Regd office: No. 677,13th Cross Road, 27th Main road, HSR Layout, Bengaluru - 560102)

Shankaranarayana Life Sciences LLP

Title of the Proposal:
SN-RAMP device: A low-cost isothermal close tube colorimetric platform for rapid and reliable pen side diagnosis of COVID-19 from non-invasive clinical samples

Brief description:
SARS CoV-2 a highly infectious coronavirus that has never been found in humans before. RT-PCR tests require well-equipped laboratories and skilled personnel. Since many COVID-19 infected individuals are reported negative in the commonly used RT-PCR test. we are addressing the need for a rapid, reliable, point-of-care molecular diagnostics with higher sensitivity assay: Closed-Tube SN-RAMP Assay Device for detection of SARS CoV-2. The assay will be used in the hospitals, clinics and at ports of entry and even at patient home because this would require minimally trained personnel without a need for sophisticated equipment.

Current stage of development:
Validation

Innovative Element(s):
Low-cost isothermal close tube RAMP colorimetric platform. Heat block device integrated with spectrophotometer for RAMP assay amplification

Market Potential:
WHO declared COVID-19 as pandemic throughout the world. Only way to decrease the disease burden is testing and isolation of individuals. Low-cost bed side SN-RAMP detection device can replace available recommended diagnostic platforms, thereby having assured market potential in India and abroad.

National/Societal relevance:
Though all countries are having adequate testing facility but is not economical and accessible to maximum number of populations. In consideration, the proposed SN-RAMP device can be provided to any hospitals, clinical laboratory and port of entry, it would be reliably diagnosing patients within an hour or even a shorter time thereby initiating highly effective response mechanisms to check the spread of disease, which is very useful in country like India and throughout the world to encounter the present crisis

Project achievements:

a. **Progress vis-a vis objectives:** The sensitivity and the specificity of the SN-RAMP assay platform has been optimized. Development of heat block device integrated with spectrophotometer is nearing completion.

b. **Technology/Product (to be) developed:** SN-RAMP device: Colorimetric isothermal platform for bed side detection of SARS CoV-2

c. **IP generated/ Potential for IP generation:** RT-RAMP reverse transcription recombinase loop-mediated isothermal amplification primer sets and kit for detecting SARS CoV-2 and application thereof Submitted for filing

d. **Resources Generated:** Manpower-4

Plans to take innovation further:
The platform will be validated by ICMR, and will seek approval from CDSCO for manufacturing license

Risks envisaged:
Bulk reagents manufacturing facility for RAMP assay commercialization. Generation of market potential and awareness.

Project Coordinator:
Bhairab Mondal

Team Members :
Vinay Kumar, Puneet Gupta, Ankita Arora, Suman, Atul Singh, Anurag, Ankit

Contact :
144-C/1, Kirloskar Road, Bommasandra Industrial Estate, Hebbagodi BANGALORE KARNATAKA India-560099

Sruthi Babu

Title of the Proposal:
A smart locomotory device with a novel mechanism for defecation assistance

Brief description:
The product Sahayatha, a convertible wheelchair cum bed with inbuilt defecation assistance for the mobility-impaired population.

Current stage of development:
Validation

Innovative Element(s):
The product converts into a bed to chair and vice versa and helps in defecation collecting, cleansing, and packing mechanism.

Market Potential:
Market Analysis: Ageing Population is projected to increase to 7 in 2020. More demand for products that cater to their health care needs such as the proposed idea. The proposed product will fall under the Patient Aids category under Medical Devices segmentation in India.

National/Societal relevance:
The proposed project can be incorporated into Swachh Bharat Mission SBM as it has a clean and hygienic way of defecation system for the mobility impaired population. The expected impact of the project is (1) Improving the quality of life. (2) Improve in social and economic wellbeing. (3) Decreased dependency. (4) Easier and hygiene defecation process. (5) Reduce in fall rate of immobile patients during transfer.

Project achievements:

a. **Progress vis-a vis objectives:** Have completed, PoC, Prototype, MVP development for clinical pilot study which is in process to know the impact of the product Sahayatha

b. **Technology/Product (to be) developed:** Currently, we are on the TRL- 6, We will be ready to launch into the market in 6 months.

c. **IP generated/ Potential for IP generation:** We have filed a non-provisional product Indian patent our application number is 201941015140. We have also filed a WIPO application number is PCT/IN2020/050352.

d. **Resources Generated - Have created a startup:** Dhanvantri Biomedical Private Limited with in house R & D laboratory and employed manpower of 5 numbers.

Plans to take innovation further:
Have raised EDII-IVP voucher B grant of Rs.3.75Lakhs.

Risks envisaged:
(1) As a medical device innovation for an unmet clinical need, this product would require to be promoted by providing sufficient awareness to the target customers. (2) Large Scale manufacturing and licensing: On a larger scale, product manufacturing may require significant investments. The option of licensing can be considered based on product demand.

Project Coordinator:
Sruthi Babu

Team Members :
K.K.Babu, Gokul, Gokuleswaran, Vignesh

Contact :
Door.no.7, Parkwood apartments, 85 Bharathiyar road, P.N.Palayam, Coimbatore 23, V.G.P. Layout P.N.Palayam, Coimbatore 641037

Stanome Solutions Pvt. Ltd.

Title of the Proposal:
Enterprise Cloud-Based Genomics Applications Platform

Brief description:
Genomics is a big data management problem that requires solutions from four data pillars: storage, security, analysis, and provenance. Stanome is developing a cloud-based genomics data management platform. This one-stop solution addresses all four data pillar problems that enable innovation in diagnostics, therapeutics, food-safety, and agrigenomics. The platform is available as Software as a Service or Bioinformatics as a Service mode to boost operational efficiency of Next Generation Sequencing labs.

Current stage of development:
Validation

Innovative Element(s):
Stanome's unique features are focused on genomics application development rather than providing an analytical tool. The cloud-optimized solution addresses all the genomics data problems under one roof, unlike the competitors.

Market Potential:
The current market size of genomics data analytics is approximately 10 billion USD and growing 15% annually for the next five years. Expected growth rates are similar across different segments Research Use Only RNA-seq, Exome, whole genome in geographical regions North America, Europe, and Asia.

National/Societal relevance:
As molecular biology research is progressing into large-scale genomics studies, the Stanome platform is ready to handle the massive amounts of data and drive the fundamental research and accelerate innovation. This can be easily extended to other research genomics areas such as COVID sequencing and annotation.

Project achievements:

a. **Progress vis-a vis objectives:** The prototype product is ready and currently under validation with early adopters.

b. **Technology/Product (to be) developed:** The platform would be ready in six months for beta customers in early access mode.

c. **IP generated/ Potential for IP generation**: Smart Infrastructure Selector and machine learning based dynamic workflow manager have a high potential for IP.

d. **Resources Generated:** Hired three full-time employees.

Plans to take innovation further:
The initial product under test with a multi-national genomics and molecular diagnostics company. Another partnership is brewing with an animal vaccines organization.

Risks envisaged:
Need to develop the product quickly and platform should comprise of a multitude of solutions to stay ahead in competition. Requires lots of resources for marketing and sales

Project Coordinator:
Kshama Goyal

Team Members :
Srujana Karavadi, Kapila Jain, Lakshmi Nallabilli

Contact :
VG505, Hima Sai lake view Towers, Nallagandla, Hyderabad-500019

Startoon Labs Pvt. Ltd

Title of the Proposal:
Pheezee – An Intelligent device for Physiotherapy Monitoring

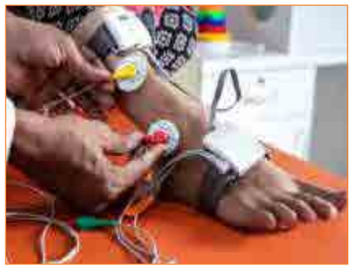
Brief description:
Physiotherapy is done in a subjective way and this leads to lack of standards and non-evidence based treatment methods. Our product - Pheezee generates scientific evidence based reports that quantify the recovery of patients and aims to revolutionize the assessment and monitoring methods in physiotherapy and rehabilitation.

Current stage of development:
Mass Manufacturing, Ready to Launch

Innovative Element(s):
The innovative elements include portability and in a wearable formfactor, without loss of accuracy or performance, onboard novel and proprietary algorithms for signal analysis, unique and well researched downloadable reports and remote monitoring, assessment and consultation using Pheezee's IoT capabilities.

Market Potential:
Currently, there is no biofeedback device to quantify the recovery of patients undergoing physiotherapy and rehabilitation post neurological and musculo-skeletal disorders (joint replacement surgeries, stroke, spinal cord injuries etc).

National/Societal relevance:
Pheezee has multiple roles to play considering the national and socio-economic status of the Country. Pheezee, being an indigenously designed and manufactured product adds to the medical technological capabilities of the Country. Lots of patients who undergo physiotherapy in India lack assessment and monitoring of their recovery progress, which unfortunately leads to improper treatment in the long term.



Project achievements:
Pheezee has won numerous awards since the beginning for its novelty and usefulness in the area of physiotherapy and rehabilitation. Some of the recognitions were from Medicall, Cahotech, IIM Calcutta & DST, IIT Kharagpur, IIT Madras, IKP, THIT – Apollo & Samsung

a. **Progress vis-a vis objectives:**
   1. Develop the first version of hardware and algorithms and test it on 40 healthy volunteers
   2. Fine tune the product and algorithms (academic study at hospitals with 60 patients – KIMS & MNR Hospitals)
   3. Clinical investigation with 600 patients at partnered hospital- MNR

b. **Technology/Product (to be) developed:** Pheezee is a wearable product which the patient wears during physiotherapy, that shows in real time how accurately the exercises are being done with live audio and visual biofeedback.

c. **IP generated/ Potential for IP generation:** Pheezee is backed by two filed Indian patents with the application numbers being 201741013399 (filed and published, awaiting final examination) & 201941038532 (filed)

d. **Resources Generated:** Since inception, we have employed three fulltime engineers for hardware, firmware and software design and development. Almost 20 interns have interned with us at various stages of the startup.

Plans to take innovation further:

Pheezee is now at pre-commercialization stage. It has already undergone the safety certifications and a clinical study is completed. We are currently working towards raising funds to manufacture, market and sell 1000 units of Pheezee in the FY21-22.

Risks envisaged:

Physiotherapy being a niche market, and Startoonlabs still on the way of building its brand value, one of the challenges will be to educate the customers and convince them to buy the product, as there is no predicate to this device, in similar fields.

Project Coordinator:
Mythreyi Kondapi

Team Members :
Suresh Susurla

Contact :
Startoon Labs Private Limited, Plot No. 10, First Floor, Beside Strawberry Hotel, Sardar Patel Road, Secunderabad, TELANGANA – 500003

Steward Gracian

Title of the Proposal:
Assistive Oral Care Device for long term bedridden elderly

Brief description:
Assistive Oral Care Device is a novel and patent pending mouthpiece based oral hygiene device to redefine oral care for dependent individuals. It clears the oral biofilms by a combination of pressurized air and pulsating liquid that is delivered on the surface of the teeth with the help of a portable external controller unit and a specially designed mouthpiece.

Current stage of development:
Validation

Innovative Element(s):
a) Mouthpiece based inclusive design, b) Functioning and efficiency of the device is not completely dependent on caregivers support. It is different from the current solutions because it is a tailor made oral hygiene device for dependent individuals.

Market Potential:
The Target Market is 1.5 million Stroke patients and 2000-3000 Quadriplegics per year in India and other non-disabled individuals with high risk of gum infection. CAGR is 5.5 for 2019-2026

National/Societal relevance:
Oral Health inequity is a common problem that exists in developing countries like India. Unfortunately, majority of the rural and vulnerable population lack access to quality and affordable dental health care services. Action on oral health is mandatory for achieving the 2030 SDGs and its NCD-related targets.

Project achievements:
a. **Progress vis-a vis objectives-**
   - Proof of concept established & Alpha prototype developed
   - First functional prototype built
   - Final functional Prototype iterations started
   - Plans to incorporate Start up and incubate

b. **Technology/Product (to be) developed:** Assistive Oral Care Device consists of a) Specially Designed Mouthpiece Universal Sized or Customized b) Integrated Multi-Chamber Pump Unit + Modular Suction Unit + Smart Controller c) Necessary tubing, valves, and control interface. The mouthpiece is fabricated using the latest 3D printing technology..

c **IP generated/ Potential for IP generation:** Final Patent Published in Indian Patent office

d **Resources Generated:** One full time electronics engineer and one part time consultant product designer.

Plans to take innovation further:
Planning to complete the pilot and pivotal clinical validation of the product in 12-15 months for market launch. Technology presented to various spinal injury associations, Chennai, Association of People with Disability, Bangalore, PMR department in CMC Vellore and to the R2D2 Labs of IIT. Once done with the basic validations, these organizations may support in some possible ways

Risks envisaged:
Finding the right materials/components which offers optimum ergonomics, functioning, aesthetics and affordability, limited oral hygiene awareness in India and finding the early adopters, investors and collaborators post COVID season.

Project Coordinator:
Steward Gracian

Team Members :
Rohan Hanagi, Shivendu Jauhari

Contact :
Campus 11, KIIT University Bhubaneswar, Odisha-751024

Thirumurthy Velpandian

Title of the Proposal:
Development and Validation of TransReCon Technique for Sterile Pharmaceutical Preparations

Brief description:
TransReCon innovation demonstrates a patent protected novel packaging solution for the sterile solid pharmaceutical agents especially those which have poor stability in aqueous media that allows instant, on site, sterile preparation of an aqueous solution/suspension of the active ingredient without the additional need of any skilled personnel. This enables Pharma companies to make prescribed drug formulations available for self-preparation and administration as eye drops/ injectables/oral liquids which cannot otherwise be made available due to pharmaceutical instability in aqueous solutions. Concept can also be used for heat sensitive vaccines for remote places and injectable drugs in emergency situations.

Current stage of development:
Validation

Innovative Element(s):
A patient friendly unique packaging utility for sterile, instant and safe reconstitution of formulations having unstable active pharmaceutical ingredients / off label drugs.

Market Potential:
This sterile package solution enables the pharmaceutical marketing of drugs which are unstable for commercialization especially for the use as drops nasal, eye & ear drops. The easiness of this packaging solution enables self-preparation by the patient even in the remote area.

National/Societal relevance:
This product is expected to increase the range of antimicrobial and other agents required while handling drug resistant eye infections which are resistant to existing agents and other therapeutic agents in the commercial area.

Project achievements:

a. **Progress vis-a vis objectives:** At the stage of validation of the device for enabling its possibility to be used in the approved yet not commercially available pharmaceutical agents for their topical use as eye drops.

b. **Technology/Product (to be) developed:** TransReCon is expected to be ready in 6 months' time before 2021 Dec

c. **IP generated/ Potential for IP generation:** Patent filed including USA, India and China Utility via PCT. Design has been applied and keep adding more in near future too.

d. **Resources Generated:** Facility created for 3D scanning and printing, two manpower being trained

Plans to take innovation further:
Expected to go ahead with licensing in the due course of time

Risks envisaged:
Market size of the product for the catering sector

Project Coordinator:
Thirumurthy Velpandian

Team Members :
Nabanita Halder, Jayaram, Shifali Barua, Tapas Roy

Contact :
Ocular Pharmacology and Pharmacy Division, Dr. RPCentre for Ophthalmic Sciences AIIMS, New Delhi-29 New Delhi 110029

Transform SciTech

Title of the Proposal:
Easy to apply lifesaving drug injection patch

Brief description:
If a life-saving drug is administered during the Golden hour, the patient may be rescued by prolonging his survival until he reaches a hospital. This project addresses this problem by designing an easy to apply patch that delivers requisite dose of life saving drug as a part of first-aid. The objective is to evolve an easy to use method of delivering rescue medications directly into blood circulation by self or with help from fellow personnel present on the spot of emergency event.

Current stage of development:
Prototype development

Innovative Element(s):
The novelty of the current proposal is on application of microArrays to small molecules used in emergency rescue medication. MicroNeedles patch will allow for the rescue drug to be applied in the location of patient presence so that the immediacy of the drug is made available. This does not require trained medical staff as a patch can be administered by self or by people around like a plaster on an open skin region. The benefit of this method, is evident for several situations.

Market Potential:
Global emergency market valued at ~ USD 20 billion

National/Societal relevance:
Reach and access to remote areas of critical care becomes available through this product. Difficult situations such as non-cooperating patients, unconscious patients, can be treated by administering their drug with ease. For Armed defence forces front line usage, DMN can be a life saving system. Example Pain killers like Morphine, Fentanyl etc.

Project achievements:

a. **Progress vis-a vis objectives:** The project kick started in September 2020 and it is currently in prototype development in progress

b. **Technology/Product (to be) developed:** An Easy to apply dissolving microneedle patch for administration during critical care conditions

c. **IP generated/ Potential for IP generation:** There is scope for design and composition patents linked to specific case of utilization

d. **Resources Generated:** A company Transform SciTech Private limited is registered under Companies act 2013.

Plans to take innovation further:
Looking for Funds to advance in TRL levels. Looking for partners to collaborate and evolve the technology.

Risks envisaged:
The following are identified as critical challenges which has to be resolved for business success of this technology.

- A critical aspect of this technology is scalability of manufacturing method.
- There is a need to have high initial capital to set up manufacturing facility. Hence appropriate venture capitalists VCs or agency funding need to be identified post PoC Proof of Concept stage

Project Coordinator:
Badri Viswanathan

Team Members :
Major Activities are outsourced

Contact :
Flat no 402, Block 3, SMR Vinay city, Narenn's estates, Miyapur – 500049, Hyderabad, Telangana

Truspectra India Pvt. Ltd.

Title of the Proposal:
Robotic UVC hospital room disinfection system with sensor navigation with Robotic chemical cleaning system for human body fluids tissues in OT/ICU/Isolation room.

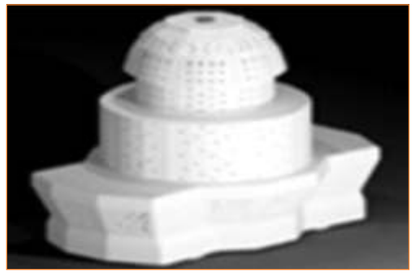
Brief description:
AI based Surveillance, Detection and Autonomous Robotic UV Disinfection Systems.

Autonomous robotic UV disinfection device is designed for large space / room Disinfection with an option for affordable UV disinfection system for LMICs. The UVC disinfection device shall achieve 4LOG within 35min for room size of 27m3

Current stage of development:
Proof-of-Concept

Innovative Element(s):
AI based UV dose Algorithms, Autonomous AI driven Robotic AGV, Unique Polygonal Prism Design with specially designed multi angle Narrow Beam Optics, etc. The UV System is AI enabled and can be integrated with AI based Hospital surveillance, detection and prediction system to provide enhanced value preposition for customers

Market Potential:
TruSpectra aims to be CE certification and primarily enter Nordic countries with AI and Autonomous Robotic UV disinfection systems. In India, the focus shall be on affordable UV disinfection system. TruSpectra is also heavily focused on developing AI based detection Image, prediction and surveillance solutions



National/Societal relevance:
The solutions are equally important for large populous, resource constraint country like India, where value preposition, affordability, cost and quality becomes important parameter for success. The applications scans beyond biotech/health space. The AI Detection, prediction and surveillance systems are being developed for both medical HAI, Images and Disease detection & prediction and non-medical space crime detection, prediction and surveillance.

Project achievements:

a. **Progress vis-a vis objectives:** Mechanical Design completed, with system under fabrication, assembly and development. PLC Automation Algorithms and web based HMI programming under development. Robotic ROS Algorithms under progress. AI Algorithms path planning, ROS, object and face detection complete integration with ROS under progress. Electrical schematics and development under progress.

b. **Technology/Product (to be) developed:** Autonomous Robotic and AI based system 10 months

c. **IP generated/ Potential for IP generation:** Preliminary patent filed, final specification to be filed

d. **Resources Generated:** More than 10 employees employed and trained on various aspects of mechanical product design, Circuit and PCB engineering, etc.

Plans to take innovation further:
Fund Raising and Licensing

Risks envisaged:
Supply chain Risks, Customer price risks, acceptability risk in India

Project Coordinator:
Sheetal Katyayani

Team Members :
Sonal Katyayani, Akash Shinde, Vrushubh Jinde, Meet Patel, Ramesh Aldar

Contact :
902, Amaro, Nyati Eternity, NIBM Annex Undri PUNE 411060

TTK Healthcare Ltd.

Title of the Proposal:
Pilot Clinical Investigation of Rigid Tilting disc TTK Chitra-Titanium Heart Valve Model TC2 - the next version of the highly successful TTK-Chitra Heart Valve, Model TC1

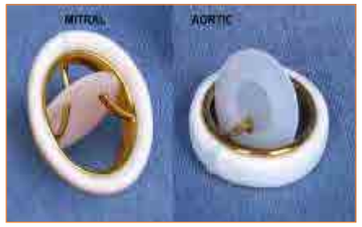
Brief description:
The TTK Chitra Titanium Heart Valve Model TC2 is a Rigid Tilting Disc Heart Valve Substitute, intended for use as a replacement valve in patients with a diseased, damaged or malfunctioning aortic or mitral heart valve.

Current stage of development:
Validation

Innovative Element(s):
The current Model TC2 is a product of extensive research including design optimisation that could improve the performance of the existing Model TC1. Current model highlights are (a) Improved design (b) Improved MRI compatibility and (c) Improved thrombo-resistance.

Market Potential:
TTK will be able to sell the next generation mechanical heart valve at an affordable cost thereby continuing to meet a sizeable portion of the Indian market demand as existing.

National/Societal relevance:
In 2015, 13.17 million cases has been reported in India due to Rheumatic Heart Disease (RHD) and 1,19,000 RHD deaths occur every year. Hence the demand for artificial heart valves is high in developing countries like India. A large scale manufacturing program based on porcine valves or bovine pericardium is not realistic. Hence mechanical valve is a suitable model for Indian market.



Project achievements:

a. **Progress vis-a vis objectives:** Regulatory Approvals: Obtained Clinical Investigation Permission and Test Manufacturing License.
Manufacturing of Clinical Investigation Devices: In progress
Clinical Study: Site initiation done

b. **Technology/Product (to be) developed**: The device has completed all the preclinical studies and currently is in the Single Centre Clinical Investigation stage. This will be followed by multicenter pivotal study and the product is expected to be in the market within next 5 years

c. **IP generated/ Potential for IP generation:** No IP is generated for TTK Chitra-Titanium Heart Valve Model TC2

d. **Resources Generated:** The new project has resulted in the generation of employment in the manufacturing as well as in the clinical site. In this phase of the project, we were able to provide eight numbers of direct employment in our manufacturing sector. An equal number of indirect employment is also generated during this phase.

Plans to take innovation further:
Once the pilot study is completed successfully, a pivotal study is planned during which about 400 devices will be implanted across the country in designated hospitals. After successful completion of the Pivotal study the device will be launched commercially after obtaining required regulatory approvals.

Risks envisaged:
The risk related to technology and manufacturing are very low. The surgical team at the clinical site are well trained in similar procedures and are also part of the development team.

Project Coordinator:
Anupama V Raj

Team Members :
K Sunil, Rajiv K Nair, D K S Kumar, Indu V Nair, Nayana Asokan, G S Bhuvaneswar, Padman R Bijoy

Contact :
Plot A-28, KINFRA Apparel Park
St.Xaviers College P.O. Thumba
Thiruvananthapuram KERALA
India-695586

Ubiqare Health Pvt Ltd

Title of the Proposal:
Specialty mobility healthcare platform with Clinical Intervention support

Brief description:
The Ubiqare platform is a digital and mobility healthcare technology platform that supports a distributed network of clinicians for delivering the last-mile interventions. This is designed to be used by a care team of specialists, doctors, and nurses, in a hospital or in their own independent practices.

Current stage of development:
Commercialization

Commercialized in the name of (Product/Technology Name): Specialty Medical Care at Home Services and m-HaaS platform
Date of commercial Launch: 2018-07-01
Number of units sold: 314 apps downloaded from 2 cloud-hosted platforms

Number of end users: 314 patients and 15 clinicians

Innovative Element(s):
Ubiqare is unique in its hybrid care platform, for complex care with physical touch, and in extending the care of the healthcare organisation. Ubiqare stands out with its doctor-driven care and specialist extension services. Its collaborative business model empowers and leverages the ecosystem to deliver affordable care to remote patients.

Market Potential:
In the initial stages we target Urban segment. For the targeted illnesses and income group, the TAM is 3 M cases/year. The SAM is 1.37M/ year, for Metros, Tier I, II. At an estimated spend of 600$ to 1000$/person/year, this is more than 1B$ market.

National/Societal relevance:
Our product and collaboration model together create a new pathway for delivering specialised healthcare to remote patients.

Project achievements:

a. **Progress vis-a vis objectives:** Bed-days capacity added per year - 3900. Average Length of stay - 64 days. Prevented 90 of readmissions/ revisits. Adoption by 25 specialists across 7 hospitals. Enabled 1 major hospital in Bangalore.

b. **Technology/Product (to be) developed:** Specialty Care platform is in market for 2+ years. m-HaaS for COVID has recently been deployed. Digital Care Workflow assets and AI/ML based anticipatory care features are planned

c. **IP generated/ Potential for IP generation:** We plan to develop a Techno-clinical IPs for modelling the disease trajectories b immersive remote clinical examination technology and c Anticipatory Care episode predictions using precision illness trajectory models.

d. **Resources Generated:** We have enabled 25 specialists to extend their care to their patients at home. We have trained 10 nurses and 5 doctors to manage interventions at home.

Plans to take innovation further:
Supply chain partnerships with independent specialists and nursing service providers to grow our capability. Technology partners for the back-end and front-end development capacity. Partnerships with Hospital for techno-clinical innovations.

Risks envisaged:
Quality of nursing staff available in market is an issue. Scaling the business through B2B2C/ B2C may take very long. B2B enablement promises faster growth. B2C mode of acquiring patients will need creative low-cost solutions. B2B mode of enablement can incentivise the specialists to extend their care to home.

Project Coordinator:
Sridhar Pillalamarri

Team Members :
Sundararajan Srinivasan, Prasanna Limaye, Sanjeeth KG, Sanjeev Kumar, Dr Sultan Mohammed, Dr Pratyush M

Contact :
First Floor of House No 5 14th Main, 15th Cross 4th Sector, HSR Layout Bengaluru KARNATAKA India-560102

Unicita Consulting Pvt. Ltd.

Title of the Proposal:
Radiolucent Carbon Fiber Truss for X Ray machines

Brief description:
Manufacture X Ray system patient table support structures that are radiolucent

Current stage of development:
Validation

Innovative Element(s):
The innovative element is the novel carbon truss and panel structure that utilizes the least amount of material, lightweight and that passes X Rays with the least attenuation

Market Potential:
This product can be exported to all X Ray system manufacturers.

National/Societal relevance:
This is an import substitute. This will help in reducing the cases of false positives in X Ray diagnosis in India as the number of artefacts will be reduced.

Project achievements:

a. **Progress vis-a vis objectives:** Manufactured the Radiolucent Carbon Fiber Truss for X Ray machines and have successfully supplied samples/product to two customers at the end of the project

b. **Technology/Product (to be) developed:** Technology is focused on creating a low mass structure with the least X Ray attenuation property

c. **IP generated/ Potential for IP generation:** Filed a patent on Carbon fiber X Ray patient table top

d. **Resources Generated:** Employed people for the project and look forward to mass manufacturing

Plans to take innovation further:
Plans to supply to Indian customers, followed by contract manufacturing to foreign firms.

Risks envisaged:
Primary risk is the existence of artefacts, which can be eliminated by maintaining non contaminating conditions in the factory.

Project Coordinator:
Gosakan Aravamudan

Team Members :
Praveen M

Contact :
No. 44/1, 1st Floor Sriram Mandir Road, Basavanagudi, Bengaluru KARNATAKA India-560004

HEALTHCARE - DEVICES & DIAGNOSTICS

NBM

Univlabs Technologies Pvt. Ltd.

Title of the Proposal:
4k CMOS Optical & IR Imaging techniques & medical grade camera demonstrated for endoscopy

Brief description:
UnivLabs is developing 4k Surgical camera UL-UHDClearView capable of operating in visible as well as Near Infrared range. The uniqueness of the surgical camera is that it shall be made in two parts Camera Head and Camera control unit for dexterity. Camera Head contains an imaging Sensor and shall have to be as small a form factor as possible, while camera control unit process the image for clarity, runs algorithms to display images in various forms to optimally identify organs, tissues, vessels, etc.

Current stage of development:
Validation

Innovative Element(s): NIR Imaging and proprietary algorithm to look through smoke during electrosurgery.

Market Potential:
IGlobally Endoscope and related equipment market is valued at more than INR 700 Billion.

National/Societal relevance:
With indigenous development and manufacturing of operating room capitals surgical instruments like Endoscope Tower, UnivLabs aims to make India self-reliant in a critical technology that is required in almost every operating room for minimally invasive surgeries.

Project achievements:

a. **Progress vis-a vis objectives:** All objectives are met. UnivLabs is planning clinical evaluation in the second quarter of 2021

b. **Technology/Product (to be) developed:** 4K Surgical Camera capable of Visible Spectrum and NIR Imaging.

c. **IP generated/ Potential for IP generation:** Two IPs generated.

d. **Resources Generated:** UnivLabs has a strong team of twenty people which consists of thirteen engineers, three graduates, two diplomas, and two manufacturing support staff. UnivLabs design, development, and manufacturing facility have been accredited with ISO 9001-2015 Certification for Quality Management System and ISO 13485- 2016 Certification for Medical Device Quality Management System.

Plans to take innovation further:
UnivLabs is actively working towards commercializing products by the third quarter to 2021. UnivLabs is reaching out to various VC firms for raising equity/ debt investment. UnivLabs has received incubation in a French healthcare incubator and would be using the same to further improve products and run European operations.

Risks envisaged:
Competitors have a lot of historical data on which they have improved the product. UnivLabs selling point will be affordability and extensive features.

Project Coordinator:
Sunil Kumar Singh

Team Members :
Dr Anil Mandhani, Dr Khurram Saghir, Prabhat, Sanjeev Shrivastava, Shivanand Gautam, Neeraj Kumar

Contact :
Plot 66 1st Floor Udyog Vihar Phase 6 Sector 37 GURGAON HARYANA India-122001

HEALTHCARE - DEVICES & DIAGNOSTICS

BIG

Urumeditech LLP

Title of the Proposal:
Sutureless Chemoport with flexible flanges

Brief description:
Long term venous access in a cancer patient to transfuse multiple chemotherapy & blood transfusions

Current stage of development:
Mould making is in progress

Innovative Element(s):
First of its kind sutureless chemoport-patented

Market Potential:
Number of cancer patients rising in India & abroad. Approx 70% to 80% of the patients requires chemptherapy .Therefore the market is huge.

National/Societal relevance:
Made in India, A step towards Atmanirbhar Bharat and affordable device

Project achievements:

a. **Progress vis-a vis objectives:** Mould making is in progress so that clinical trials can start in phase 2

b. **Technology/Product (to be) developed:** Sutureless chemoport ,a medical device as a product

c. **IP generated/ Potential for IP generation:** Already done

d. **Resources Generated:** 6 employees (part time and full time on work basis)

Plans to take innovation further:
After launching the product it will be planned in future.

Risks envisaged:
Clinical trials will be help us to reduce the risk

Project Coordinator:
Vikash kumar Agarwal

Team Members :
Vikash Kumar Agarwal, Vibha Agarwal, Sanjeev Kayal, Ritabrata Mukherjee, Kuldeep

Contact :
120,Swami Swarupanand Sarani,Abasika Apartment, Ground Floor

Vasmed Health Sciences Pvt. Ltd.

Title of the Proposal:
Application for commercialisation of Vision FFR System with 0.014 pressure/IBP wire

Brief description:
Vasmed Vision FFR Fractional Flow Reserve Console and Vision IBP Pressurewire is intended to be used for identification of clinically significant lesion during Coronary Angiography and Angioplasty. The device consists 0.014 Guidewire 350 micron Outer diameter with a 150 x 150 micron SOI based MEMs pressure sensor mounted at the tip, a wireless dongle with PCBA for communicating with the sensor, a console for integrating the pressurewire to the display module and for measuring Aortic pressure, a portable display module, IEC 62304 compliant software including firmware and application software with multiple algorithm for hemodynamic computations.

Current stage of development:
Validation

Innovative Element(s):
Ultra miniature MEMs pressure sensor of dimension 150 x 150 x 1500 micron with inbuild temperature compensation developed in association with Centre for Nano Sciences CeNSE IISc, Bangalore - with joint patent. Unique guidewire design Patent applied, with sensor and microwire integration for invasive pressure measurement.

Market Potential:
Vasmed device is positioned as a cost effective alternative to imported devices with equivalent effectiveness.

National/Societal relevance:
With a cost effective tool, the amount of stents can be limited to clinically significant lesions, giving a valuable tool to end-user.

Import Substitution: With a cost effective locally available FFR wire, there can be substantial import substitution.

Project achievements:

a. **Progress vis-a vis objectives:** MEMs pressure sensor release – completed. Guidewire Release - in progress. External testing & Certification – Planned. Clinical evaluation - Planned

b. **Technology/Product (to be) developed:** All the technology for the device is developed and is under testing.

c. **IP generated/ Potential for IP generation:** Patent Application No. 201941010987 Title: "A unique guidewire design for measurement of one or more physiological variable in a human body" in the name of Vasmed. Patent Application no. 202041015485 : For ultra miniature pressure sensor, joint application by IISc and Vasmed.

d. **Resources Generated:** Vasmed has established a custom build factory of 25,500 Sq. Ft. in Bangalore for manufacture of multiple Medical devices, currently the team strength including production team is 45 nos. with team expected to grow over this year

Plans to take innovation further:
Application of the miniature pressure sensor & new delivery systems to be expanded to wider hemodynamic monitoring. Under discussion for set up of volume scale manufacturing of the sensors in India.

Risks envisaged:
New technologies of non-invasive CT angiograms are expected in a horizon of 10 years, reducing window for the specific product, but risk can be mitigated with more wider application of the technology.

Project Coordinator:
Anoop Varghese

Team Members :
Takashi Sato, Vijesh K, Venkatesh H, Sourav Kumar Pany, Chandana K V, Namitha K M, Sujai N S

Contact :
Plot No. 160, 161 KIADB Obedanahalli Industrial Area, Doddaballapura 3rd Phase, Devanahalli Taluk, Bengaluru, Karnataka, India-561205

Venkatesh Chelvam

Title of the Proposal:
Indigenous Targeted Radiopharmaceuticals for Detection and Therapy of Prostate Malignancy

Brief description:
A special biomarker called prostate-specific membrane antigen PSMA highly over-expressed during prostate malignancy is a suitable target for early diagnosis and treatment of Prostrate Cancer (PCa). Several new, indigenous, small molecule radiopharmaceuticals will be evaluated by targeting PSMA protein to detect and treat primary, metastatic and recurrent stages of PCa. The PSMA ligands will be conjugated to prosthetic groups or chelating linkers to introduce radioisotopes such as 18F, 99mTc, 68Ga or 177Lu. These new radiopharmaceuticals after in vitro and in vivo animal studies will be translated for human clinical trials to detect and treat PCa.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
New inhibitors or ligands are developed for PCa radiopharmaceuticals. This is an indigenous technology and the molecules are developed in our country.

Market Potential:
50% national and 10% international market for diagnostics and therapeutics will fetch approximately INR 67 crores and 2000 crores respectively due to original IPR.

National/Societal relevance:
The FDA approved imaging agents are very expensive, requires special facilities. The proposed diagnostics in this idea are indigenous, cost-effective estimated to INR 5000, specific to PCa malignancy, short serum clearance time and few scanning sessions

Project achievements:

a. **Progress vis-a vis objectives:** New small molecule inhibitors or ligands have been designed, synthesized, evaluated in vitro and found to be highly effective in nanomolar concentration

b. **Technology/Product (to be) developed:** The product or technology is currently under development and it will take 3-yeras after preclinical trial to reach the market

c. **IP generated/ Potential for IP generation:** Indian as well as USA patents

d. **Resources Generated:** Two Research Associates Auditor, Biosafety and cell culture lab, Enterprise RONCOV Diagnostics and Therapeutics Pvt. Ltd. incorporated

Plans to take innovation further:
Looking for venture capital

Risks envisaged:
Procuring 99mTc radioisotopes from Board of Radiation and Isotope Technology, BARC which are sometimes delayed. 99mTc from private players are expensive

Project Coordinator:
Venkatesh Chelvam

Team Members :
Philip S. Low, Kavita Shah, Kamalakannan, Anupam Mathur, Ravi Seshan, Amit Pandit, Mena Asha Krishnan

Contact :
Khandwa Road, Simrol
Simrol Indore 453552

Vikas Sahu

Title of the Proposal:
Handheld smart dental instrument to visualize "dental pulp chamber and canal orifice" for root canal treatment.

Brief description:
The visibility of root canal orifice in posterior teeth is one of the major problems a dentist faces while doing a root canal treatment. Majority have to only rely on the basic dental mirror and experience to visualize the prepared endodontic cavity to see pulp chamber and canal orifice which can be easily missed while doing the root canal treatment.

Current stage of development:
We have developed the prototype and currently doing the clincal validation studies with dentists in real time clincal scenario

Innovative Element(s):
The root canal visualizer RCV is specifically designed to solve the problem of visualization of pulp chamber and root canal orifice using simple optical principles and device design consideration. The image can be projected in the LCD screen future mobile screen so there will be no need to straining eyes as with microscope and loups and limited vision with dental mirror indirect vision

Market Potential:
Dentists being the end user and end customer as 95% of dentists practice in their individual clinical setting, the key buyer of the product are dentists. Around 2.7 lakhs dentists practice in India and around 7 lakhs dentists worldwide who are potential customers.

National/Societal relevance:
Portable device and AI based solution to give a predictive analysis of canal orifice will help dentist to do root canal treatment and gain confidence and improve treatment efficiency in lower resource setting establishments also.

Project achievements:

a. **Progress vis-a vis objectives:** Prototype ready

b. **Technology/Product (to be) developed:** Under process

c. **IP generated/ Potential for IP generation:** 1 Patent filed

d. **Resources Generated:** Few manpower hired

Plans to take innovation further:
Looking for venture capital

Risks envisaged:

Competitor

Project Coordinator:
Vikas Sahu

Team Members :
Nibedit Dey,
Priyabrata Rautray

Contact :
Dept of Oral Pathology, Malla Reddy Institute of Dental Sciences, Suraram X Road, Hyderabad -55

VMP Ortho Innovations LLP

•**Title of the Proposal:**
Navigation in Orthopaedic and Trauma surgery

Brief description:
The system is a trackerless navigation system in Orthopaedic and Trauma surgery which is able to predict and visually display the future position of guide wires and implants. This helps to eliminate trial and error, revision and re-positioning. This navigation system can do so by showing virtual images of future positions of implants on the surface and inside of bone in 2D as well as 3D. Moreover, this happens intraoperatively in real time.

Current stage of development:
Validation

Innovative Element(s):
A navigation system without invasive tracking sensors. 3D bone image representation is obtained with only 2 shots from Anteroposterior view and Lateral view. as opposed to 3D C-arm systems of multiple more than 100 shots. Universality - the system can be used on any bone fracture, with any implant from any manufacturer and on any C arm system unlike other navigation systems

Market Potential:
The global orthopedic navigation systems market size was valued at USD 122.95 million in 2016 and was expected to grow at a CAGR of 10.6. Huge number of potential users is possible with even a small share of this market

National/Societal relevance:
It is well established that probability of cancer risk increases with increase in radiation exposure. Radiation to OT staff over a period of years can be significant. Use of this system will significantly reduce the radiation thereby reducing the risk of cancer and other medical issues. This tests results have shown up to 80% reduction in radiation

Project achievements:

a. **Progress vis-a vis objectives:** Development of all modules for various bones, productization for software and hardware systems and initial clinical validation were achieved during the project duration

b. **Technology/Product (to be) developed**: Regulatory approvals are required for intraoperative use and this process may take about six months.

c. **IP generated/ Potential for IP generation:** Indian patent granted: System for accurate guide wire positioning; US patent granted: System for accurate guide wire positioning; Indian patent filed: An improved system for accurate guidewire positioning

d. **Resources Generated - Direct employment:** 2; Indirect Employment generated : 11; Software development team: 3

Plans to take innovation further:
Plans to take this further by partnering with software development firms for licensing and commercialization

Risks envisaged:
The navigation system will have to undergo the process of regulatory approvals. Further studies will have to be planned if required by DCGI

Project Coordinator:
Vijay Panchanadikar

Team Members :
Rucha jog, Prasad Samgiskar, Kedar Panchanadikar

Contact :
42/3, Marunji, Sidhar Sovereign, C1 Building, Flat No 904, PUNE MAHARASHTRA India-411057

Voxelgrids Innovations Pvt. Ltd.

Title of the Proposal:
Compact, lightweight, high field, next generation magnetic resonance imaging scanners

Brief description:
Voxelgrids has recently built Indias first indigenous MRI scanner prototype that is the lightest 1.5 Tesla MRI scanner in the world. It also is the first full body scanner that does not contain any liquid helium. Finally, it also contains physics software that can accelerate MRI scans by factors of 3-4 more than any other scanner in the world. Going forward, planning to develop a custom designed vehicle on which the scanner will be installed, thus demonstrating the world's first high field full body mobile MRI scanner

Current stage of development:
Commercialization

Innovative Element(s):
Lightweight, compact, liquid helium, low power consumption MRI scanners

Market Potential:
Total market potential of INR 300 Crores within three years of launch expected

National/Societal relevance:
The obvious benefit of indigenous medical devices development as import substitution

Project achievements:

a. **Progress vis-a vis objectives:** On track with our milestones

b. **Technology/Product (to be) developed:** Mobile platform for MRI scanner is pending

c. **IP generated/ Potential for IP generation:** At least one patent application in the pipeline

d. **Resources Generated:** Total employment - eighteen.

Plans to take innovation further:
Commercialization in partnership with established MRI vendors is the fastest way to reach the market.

Risks envisaged:
Absence of a brand presence and general hesitation in buying locally built medical devices.

Project Coordinator:
Arjun Arunachalam

Team Members :
Shankar Udupa, Sairamesh Raghuraman, Swathy Padarthi, Kamaraj S, Pooja Murthy, Srinivasa Rao

Contact :
FISE "Social Alpha" No. 3, 14th Main, Sector 5, HSR Layout
Bengaluru KARNATAKA
India-560102

Vphore labs Private Limited

Title of the Proposal:
Video Laryngoscope for use in Emergency Rooms, Operation Theaters and Surgeries

Brief description:
Vphore Labs has developed a video laryngoscope product. This product offers support for adult as well as pediatric and neonatal subjects offering an effective tool to clinicians in managing critical care. The solution offers a way to intubate patients without having to manipulate the injured area. It will also facilitate swift intubation reducing the pressure on the clinician.

Current stage of development:
Validation

Innovative Element(s):
The solution offers a real time imaging of the laryngeal area during the procedure. A channeled design ensures that the ET tube is guided straight into the wind pipe. A compact design ensures that the solution is usable on adults as well as neonates.

Market Potential:
With the unique feature combination which our product offers we would be able to offer a significantly improved solution to the clinicians. This device would find its use in every district hospital where surgeries are done, every ambulance for emergency intubations and every emergency, trauma centers and operation theaters.

National/Societal relevance:
Quicker time to medication especially in trauma cases, improved success rate, less trauma for patients, lesser efforts from the clinician. The economic loss in terms of the loss of time, stress on clinicians, secondary trauma will be greatly reduced.

Project achievements:

a. **Progress vis-a vis objectives:** Design improvements for reduced EMI / EMC performance. Mechanical tooling is under progress and is expected to finish in coming weeks.

b. **Technology/Product (to be) developed:** A video laryngoscope for use in emergency settings.

c. **IP generated/ Potential for IP generation:** None for this project or product. The endoscopic platform solution which has been indigenous development by Vphore Labs. It is expected to be useful in many more medical use cases.

d. **Resources Generated:** The initial R&D was partially funded by Government of Karnataka apart from internal resources.

Plans to take innovation further:
Going forward, the plan is to ready the innovation for market. Towards this we plan to explore options for marketing partnerships across geographies. We are also open towards licensing to a suitable entity

Risks envisaged:
Delays due to regulatory approvals, setting up a good manufacturing process, forging the right partnerships to enter market

Project Coordinator:
Priyank

Team Members :
Hemanth, Gunjan, Sujith, Vijay

Contact :
Vphore labs Private Limited A001, CHARTERED CORONET, 102-1, AREKERE BANNERGHATTA ROAD
BANGALORE KARNATAKA
India-560076

Wills Pallara Janardhanan

Title of the Proposal:
An ELISA based immunological detection of tiger moth Asota spp. disease

Brief description:
Mystery fever epidemics occur in India every year and majority of the cases are detected negative for infectious diseases especially dengue and chikungunya. Intriguingly, these fever outbreaks are co-integrated with the emergence of adult tiger moths which mimic the hallmark symptoms of infectious fevers make diagnosis difficult for clinicians. Proposing to develop tiger moth specific IgE detection kit on ELISA platforms which are reliable, quick with high sensitivity and specificity. Timely and accurate diagnosis will help to ensure proper treatment is chosen and will reduce morbidity and mortality due to tiger moth toxins.

Current stage of development:
Validation

Innovative Element(s):
The diagnosis is designed to provide routine, non-invasive and effective detection of novel tiger moth allergens from fever patients' blood sera

Market Potential:
In the year 2018, the country recorded ~120 million fever cases with majority of negative or suspected cases for infectious viral fevers and is classified as mystery fevers. There is a definite opportunity to introduce tiger moth disease detection among these mystery fever cases for differential diagnosis in the country or abroad.

National/Societal relevance:
Tiger moths Genus Asota are distributed globally and they carry deadly toxins that can be definite threat to human. Tiger moths Asota caricae are highly migratory and explode their population in different regions at different seasons in India. For example, in Kerala, millions of adult tiger moths explode from June to August correlates with devastating fever outbreaks every year. Fever outbreaks subside when tiger moth population decline in September and migrate to northern parts of the country. In this context, the ELISA based diagnosis of tiger moth disease would provide differential diagnosis, timely and precise clinical treatment for the fever patients and avert large number of deaths

Project achievements:

a. **Progress vis-a vis objectives:** Synthesized tiger moth specific recombinant antigens for immobilizing ELISA wells and raising monoclonal antibodies. Presently, chemical characterization of antigens is being carried out.

b. **Technology/Product (to be) developed:** Currently validating the prototype and clinical validation of the final prototype would be completed by March 2022. The product will undergo mandatory pilot study and clinical performance testing and is expected to be launched by September 2022.

c. **IP generated/ Potential for IP generation:** The product is patentable since we are targeting novel tiger moth allergens.

d. **Resources Generated:** 2 Manpower, Project Coordinator and Research Scientist employed. Toxicology expert facility created. New enterprise created- Zetlon Biotech Pvt. Ltd. incorporated

Plans to take innovation further:
Focus on transfer the technology to leading in vitro diagnostics manufacturing companies for commercialization of tiger moth disease detection kit

Risks envisaged:
WHO or ICMR must consider tiger moth disease as serious and include tiger moth disease detection for differential diagnosis.

Project Coordinator:
Wills Janardhanan

Team Members :
Anjana Mohan, Shahzad Ubaidulla, Madhusudhana Murthy

Contact :
Wills Pallara Janardhanan
Edayileparambil H Mylapra
Town P O Pathanamthitta
Pathanamthitta 689678

Yaathum Biotech Pvt. Ltd.

Title of the Proposal:
Development and validation a real-time RT-PCR test for detection of SARS-CoV-2 virus for COVID-19 diagnosis, RNA extraction and RT kits, Automated sample prep and RNA extraction system, Affordable Battery operated qPCR platform

Brief description:
An indigenous multiplex real-time RT-PCR based molecular diagnostic test to detect SARS-CoV-2 virus in respiratory specimens naso/oropharyngeal swabs of COVID-19 suspected individuals in 2 hours and at a fraction of current costs, at Rs.100 per test. It targets 3 different regions E, N, orf1ab in SARS-CoV-2 genome and RNAse-P internal positive control within the same reaction through multiplexing qPCR. Positive control also included. Our kit performance has been validated and approved by ICMR

Current stage of development:
Validation completed approved by ICMR DCGI license in process

Innovative Element(s):
An indigenous multiplex real-time RT-PCR based diagnostic test to detect SARS-CoV-2 virus in respiratory specimens naso/oropharyngeal swabs of COVID-19 suspected individuals even those with new strain in 2 hours and at a fraction of current costs, at Rs.100 per test. It targets 3 different regions E, N, orf1ab in SARS-CoV-2 and RNAse-P internal positive control within the same reaction through multiplexing. All kit components including enzymes/master mixes are developed and produced indigenously.

Market Potential:
The global COVID-19 diagnostics market size estimated at USD 84.4 billion in 2020. It is expected to grow at a CAGR of 3.1 from 2021 to 2027 to reach USD 104.7 billion by 2027 and molecular PCR testing projected to dominate the market with a revenue share of over 60.0 which is considered as the most accurate technique for detection of COVID-19.

National/Societal relevance:
In India, number of COVID-19 cases has crossed 10M with over 100 thousand deaths. Also the demand for testing is around 5 lakh tests per day. Aggressive testing, contact tracing and focus on high-risk target groups e.g. above 75 years of age extensive testing in hotspots and high-risk occupational groups and isolating the infected individuals is the main way for control of its spread. Ramp up in indigenous development/production of test kits is key for pandemic preparedness now and in future since there is a huge demand for supply of RT-PCR tests gold-standard confirmatory and allied components like RNA extraction kits/ RT enzyme mixes required for testing that can be met through our kits.

Project achievements:

a. **Progress vis-a vis objectives:** (1). Indigenous development of affordable real-time RT-PCR based diagnostic test for COVID-19 SARS Co-V-2 including validation/IVD approval - product development completed and kit approved by ICMR NIIRNCD. (2). Immediate deployment of the test kits in authorized testing labs in India at a fraction of the current cost of testing - kit priced at Rs.100 per test DCGI license/approval in process currently and expect to hit the market by end of March 2021

b. **Technology/Product (to be) developed:** An indigenous multiplex real-time RT-PCR test for confirmatory diagnosis of COVID-19 in 2 hours and at a fraction of current costs of testing.

c. **IP generated/ Potential for IP generation:** IP to be filed for the kit.

d. **Resources Generated:** Employment generated - 9 in the process of raising additional funds for scale-up

Plans to take innovation further:
Raising funds for scale-up in production and commercialization.

Risks envisaged:
Potential delays in regulatory approvals /processes.

Project Coordinator:
Anitha Rajagopal

Team Members :
Arivan.T, Puneet Garg, Imran Hussain, Preethi.R, Hanna.J, Nayeem Basha

Contact :
03-G2 Third Floor, IIT Madras Research Park, Kanagam Road, Taramani, Chennai, Tamil Nadu 600113

Yostra Labs Pvt. Ltd.

Title of the Proposal:
Clinical validation of "Kadam", a novel device for treatment of Diabetic Foot Ulcers using warm oxygen therapy

Brief description:
Kadam is a medical device developed for the treatment of Diabetic Foot Ulcers. The medical equipment in the proposed therapy involves exposing the patients foot with diabetes to a constant stream of warm oxygen inside a disposable therapy bag. The foot with the diabetic ulcer is placed in a bath of warm oxygen inside the therapy chamber. The temperature of oxygen inside the therapy chamber is maintained at a constant temperature of 39 - 41^{0}C. This procedure dilates the capillaries in the ulcer tissues resulting in better oxygen systemic and antibiotic delivery to the ulcer thence faster healing

Current stage of development:
Validation

Innovative Element(s):
KADAM therapy equipment is compact - hence the therapy is focused only on the affected area, thereby eliminating the need for huge and costly equipment. The treatment can be given in outpatient and resource poor settings

Market Potential:
Foot Ulcers affect approximately 64 million diabetic patients the world over, while it affects 11 million in India and approximately 5.7 million patients in the US. The chronic wound care device market is dominated by products based on Hyperbaric Oxygen Therapy and Vacuum Assisted Closure/Negative Pressure Wound Therapy with a combine market size of approximately USD 6.5 billion.

National/Societal relevance:
With 70% of its population in rural areas in India is facing great difficulties in managing diabetes. This population is at high risk of developing foot ulcers due to unhygienic living conditions, poverty, barefoot gait, low income, smoking and cultural practices. In India, the prevalence of foot ulcer among diabetic patients is around 3 – 14%

Project achievements:

a. **Progress vis-a vis objectives:** Pilot clinical validation has been completed and extended clinical validations are currently in progress

b. **Technology/Product (to be) developed:** KADAM will be introduced in the Indian market in the second quarter of 2021.

c. **IP generated/ Potential for IP generation:** KADAM has been patented in India, and have applied for IP protection in the US and Europe

d. **Resources Generated:** The project has generated a direct employment for 5 individuals and indirect employment for 6. Company has been able to mobilize additional funding of INR 25 Lacs for the project.

Plans to take innovation further:
By end of 2021, plan is to sell 100 units of KADAM in India, post which will target the South East Asian market.

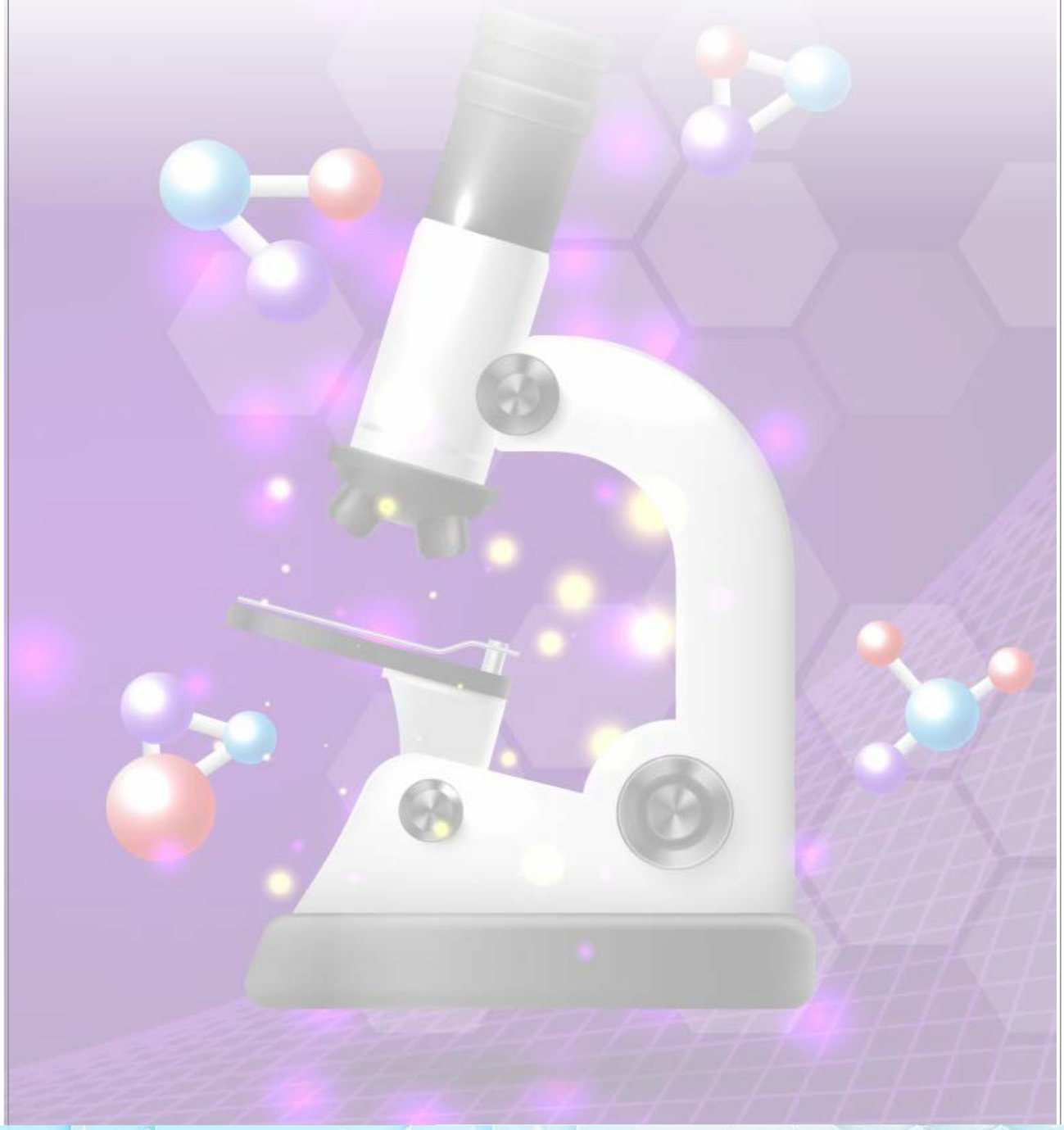
Risks envisaged:
Challenge of slow adoption of the product. Country specific regulatory approvals will pose a significant challenge for market entry.

Project Coordinator:
Vinayak Nandalike

Team Members :
Maruthy K.N, Sanjay Sharma

Contact :
200, 2nd Cross, 1st Block,
Koramangala Bangalore
KARNATAKA India-560034

HEALTHCARE - DEVICES & DIAGNOSTICS SBIRI birac Ignite Innovate Incubate



INNOVATION PROFILES

AGRICULTURE

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SBIRI

Acsen Hyveg Pvt. Ltd.

Collaborator Name: ICAR-IARI Regional Station, Katrain, Kullu, HP

Title of the Proposal
Development of high yielding DH lines of broccoli using microspore culture, their conversion into CMS lines using MABC and utilization in hybrid breeding

Brief description:
Donor growth is major factor for DH development and has been optimized for broccoli. Only nutritional rich entries have been taken for protocol development. Significantly improved protocol for embryo development from microspores has been standardized for DH development followed by efficient regeneration and hardening also. Conversion of haploid into doubled haploids will get confirmed at the time of flowering.

Current stage of development:
Proof of concept

Innovative Element(s):
All entries showed response for embryogenesis. Average 340 embryos per 90 mm petri dish have been produced whereas in literature it was maximum 140 embryos, therefore its a significant improvement followed by regeneration

Market Potential:
This DH protocol will be used to develop DH lines, which will further convert into CMS background and finally for hybrid development of broccoli. Hybrid having good producibility and rich in nutritional qualities, completely developed in India, will be 1st time and will be major breakthrough.

National/Societal relevance:
All hybrids of broccoli in India are imported. After the company's hybrids , the prices of seeds will be much lesser for farmers, producibility will not be lesser than imported, nutritionally better and will support economy by converting import into export of broccoli seeds

Project achievements:

a. Progress vis-a vis objectives: Absolutely on time with planned objectives as predicted and planned till now.

b. **Technology/Product (to be) developed:** DH protocol development using microspores for nutritionally rich broccoli.

c. **IP generated/ Potential for IP generation:** In future, the company will try for IP generation for nutritional rich broccoli DH lines and also for technology used.

d. **Resources Generated:** 3 people are under training and will get trained completely to use this technology independently.

Plans to take innovation further:
Company will apply for CMS conversion of DH lines and hybrid development from BIRAC.

Risks envisaged:
Minute change at any step of protocol can lead to major changes in results.

Project Coordinator:
Arun Agarwal

Team Members :
Chanderprakash IARI,
Sandeep Dhatwalia IARI,
Rohit Kumar ,Sharma Acsen Hyveg, Kajal Rana,
Rohit Negi, Khekram

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Nunhera Village, Near Toll Plaza,
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HARYANA India-122103

AGRICULTURE

PACE-AIR

Andhra Pradesh State Sericulture R and D Institute

Title of the Proposal:
Popularization of silkworm sex-limited foundation cross SLFC27 for cocoon colour with Pure Mysore PM race in the production of cross breed for Industrial seed production.

Brief description:
Presently the Pure Mysore Female parent and SLFC27 Male parent and silkworm eggs were distributed among the Registered Seed Producers under Seed Act for silkworm rearing in a large scale and filed trials were carried out.

Current stage of development:
Commercialization

Innovative Element(s):
Introducing of sex-limited foundation crosses for cocoon colour will be the better choice for the production of commercial cross breed. The added advantages of sex-limited foundation crosses are easy to multiply at farmers level with improved fecundity and reduce the labour cost, as the yellow cocoons can be sent for reeling and 100 males can be utilized successfully for the preparation of cross breed

Market Potential:
Since, the new hybrid PM x SLFC27 is a Cross Breed and it performs well under high temperature and low humid conditions. Hence, the new silkworm hybrid eggs has huge demand among the farmers of South India and also other tropical belts of the country

National/Societal relevance:
Introducing of sex limited foundation crosses for cocoon colour will be the better choice for the production of commercial cross breed.

Project achievements:

a. **Progress vis-a vis objectives:** Maintenance of newly developed silkworm sex-limited breeds and their foundation crosses under Race maintenance system has been completed, commercialization of newly developed silkworm Cross Breed with sex-limited foundation cross as a male parent PM x SLFC27 at field level has been completed and performance evaluation of PM x SLFC27 in comparison with the existing hybrid including reeling parameters and silk fabric properties shows that the hybrid performed better than the control.

b. **Technology/Product (to be) developed:** The technology New Cross Breed, Pm x SLFC27 has been developed and commercialization is under progress.

c. **IP generated/ Potential for IP generation:** The technology will be patented with NRDC, Visakhapatnam, Andhra Pradesh

d. **Resources Generated:** Manpower: Employed 03 persons under the project.

Plans to take innovation further:
The parents of the new hybrid, PM x SLFC27 especially the male component will be maintained as breeders stock at APSSRDI adherent to Race maintenance rearing will be conducted with the Registered Seed Cocoon producers RSP and the P1 cocoons will be transported to Govt. F1 grainages for commercial seed production.

Popularization of this hybrid in the cross breed belt of the country for authorization by Central Silk Board, Govt. of India.

Risks envisaged:
There is absolutely no risk involved in popularizing the technology. The developed technology new hybrid, PM x SLFC27 has been initiated for commercialization among the sericulture farmers.

Project Coordinator:
P.J.Raju

Team Members :
Seetharamulu

Contact :
R and D Institute Road No - 72
Prashasan Nagar Jubilee Hills
Hyderabad TELANGANA
India-500096

Anitha Peter

Title of the Proposal:
Development of biosensor for the detection of papaya ringspot virus infecting Carica papaya

Brief description:
Papaya Carica papaya L. is one of the most widely grown fruits in the tropics and subtropics. The production of this economically important fruit crop is being limited because of the destructive disease caused by papaya ringspot virus PRSV . Early detection of the disease is the best preventive strategy to overcome the economic loss of yield. This can be achieved by the immuno-diagnosis of infection. The recombinant coat protein CP of the PRSV was expressed in the prokaryotic expression system and polyclonal antibodies were raised against it. These were used as capture antibodies in an electrochemical biosensor for the early detection of PRSV in laboratory and field conditions. This is a model system and can be used as a platform technology in pathogen detection, food industry, environmental pollution monitoring and other applications.

Current stage of development: Proof-of-Concept

Innovative Element(s):
An hand-held electrochemical biosensor for the detection of PRSV

Market Potential:
The gadget developed is a platform technology which can be extended to the detection of single and multiple plant pathogens, animal and human pathogens like Covid-19 and hence it has a huge market potential .

National/Societal relevance:
Early detection of pathogens helps in providing disease free planting material like seeds, saplings and tissue cultures plantlets to the farmer thereby curtailing crop loss and improving the socio-economic status of the farmer. A device like biosensor can help towards this and also for pathogen monitoring and multiple pathogen detection over the presently available detection devices like lateral strips.

Project achievements:

a. **Progress vis-a vis objectives:** The CP gene of an isolate of PRSV was amplified through RT-PCR, expressed in a bacterial host, PURIFIED and polyclonal antibodies produced against the recombinant CP . A prototype of an electrochemical hand-held biosensor was developed for the detection of PRSV. The gadget was validated for field collected PRSV samples from Karnataka, Kerala and Tamil Nadu.

b. **Technology/Product (to be) developed:** The gadget has to be improvised for background noise reduction, better sensitivity and miniaturization

c. **IP generated/ Potential for IP generation:** Attempts are being made for a provisional patent

d. **Resources Generated:** Manpower employed: One SRF, One JRF, an administrative assistant and a contract labour were employed during the project

Facility created:
Two cooling centrifuges and a 37 degree centigrade shaking water bath were added to the existing equipments of the lab

Fund mobilization:
A fund of Rs. 2 lakhs was raised from the University of Agricultural Sciences, Bangalore for miniaturization of the gadget and field evaluation

Plans to take innovation further:
The team requires collaboration with a specialist in biosensors using antibodies for further improvisation and commercialization of the product

Risks envisaged:
The gadget has to be modified and hence the risk and cost factor has to be assessed to bring it below the cost of a lateral strip.

Project Coordinator:
Anitha Peter

Team Members :
Vinay J Nagaraj, Nirmala Arun, Rohini Bhat, Soumya Bhat, Roshni M, Ramachandra Anantapur

Contact :
Anitha Peter Dept Plant Biotechnology UAS B GKVK Bangalore KARNATAKA India-560065

Anurag Gupta & Team

Title of the Proposal:
Development of a Thermostable Combined Sheep Pox, Goat Pox and PPR Vaccine

Brief description:
In general veterinary vaccines suffer serious deterioration in vaccination campaigns due to the difficulty in maintaining cold-chain during the storage and transport of vaccine in far reaching areas, which inevitably result in loss of vaccine potency in tropical and subtropical environments. This is one of the major constraints in control of the diseases. Thermostable vaccines are therefore considered more suitable under tropical field situations wherein the viability of the vaccine viruses will be ensured. Therefore, in proposed development program The PI is working towards such combination vaccines those are highly effective and thermostable, will provide a One-Shot cost-effective solution to immunize and protect Small Ruminants against these diseases

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Cell culture based combined, thermostable Sheep Pox, Goat Pox & PPR vaccine that would provide a One Shot cost effective solution to protect Small Ruminants against these three diseases. A single shot combination vaccine would be effective, cost saving and would lead to successful immunization considering logistics difficulties

Market Potential:
Estimated requirement of 1.0 to 1.5 billion doses globally in first five years of introduction. In India alone millions doses of PPR, Goat Pox and Sheep Pox Vaccine are procured for Immunization programs at State Level and under Central Government.

National/Societal relevance:
Combination Vaccine are required worldwide to prevent these diseases and save poor farmers livelihood. currently no combination vaccine for these three diseases together is available. Early delivery of combination vaccine will give a big boost in the immunization program

Project achievements:

a. **Progress vis-a vis objectives:** Generation of Cell Bank & Virus seed banks for all three virus strains, Process development & Formulation development and Optimization, Analytical /Bio analytical method establishment has been completed. Stability studies of Drug Substance & Drug Product are ongoing and Safety and immunogenicity study in Small Animal are to be carried out.

b. **Technology/Product (to be) developed:** A trivalent Combination Vaccine against Sheep Pox, Goat Pox and PPR disease in small ruminants

c. **IP generated/ Potential for IP generation:** Based on development result PI are in the process of filing a patent application on a Thermostable Combined Sheep Pox, Goat Pox and PPR Vaccine

d. **Resources Generated:** A new technology is being generated

Plans to take innovation further:
The PI will explore all the three options such as Partnership, Fund Raising and Licensing of the Technology for commercialisation

Risks envisaged:
None

Project Coordinator:
Anurag Gupta

Team Members :
Utsav Ghosh

Contact :
528 FF , Sector 37, Faridabad 121003

R. Aswati Nair

Title of the Proposal:
Development of endophyte-based biopesticides for pre- and post-harvest soft-rot disease management

Brief description:
Soft rot disease caused by Pythium species is of serious concern especially in ginger, an export oriented spice crop wherein resistant cultivars are non-existent. Beings oil-borne, disease management is difficult with Pythium-induced decay jeopardizing productivity in various ginger-producing regions resulting incomplete crop devastation and reduction in marketable yields. Present formulation contains molecules/metabolites of endophytic and plant origin that prevents Pythium infestation through rhizome in soil. Being an export commodity, organic practices are essential for ginger and the formulation developed offers a sustainable alternative with minimal impact on health and environment

Current stage of development:
Validation

Innovative Element(s):
Present formulation of benefit to ginger farmers in practicing organic agriculture considering non-availability of biopesticides for control of Pythium ,2. Cost-effective formulation, easy to apply and safe 3. Solution to one of the most pressing problems affecting ginger productivity

Market Potential:
Area under ginger cultivation in India is 164.85 thousand ha in 2016-17 [Spices Board.Currently Trichoderma based biopesticides for Pythium infestation control in many crops cost around Rs. 100 per acre. Thus the market size of the segment is INR 4,000 crores with a huge opportunity for new formulations

National/Societal relevance:
Global ginger market revenue amounted to $5.3B in 2018 with approximately 3.3MT of ginger produced worldwide with India being the leading producer. Ginger production is seriously affected by soft rot caused by Pythium species resulting in absolute production loss, the severity of which is reported every year. Present innovation offers an environment friendly solution to control soft rot disease in ginger

Project achievements:

a. **Progress vis-a vis objectives:** Developed a biopesticide formulation for effective control of soft rot disease caused by Pythiummyriotylum, a necrotrophic posing major problem in productivity of ginger, aspice of significant commercial value

b. **Technology/Product (to be) developed:** Film like formulation containing metabolites that provides protection from Pythium ingress froms oil.

c. **IP generated/ Potential for IP generation:** Provisional patent Application No. 202041011053

d. **Resources Generated:** Trained three students

Plans to take innovation further:
Partnership through technology transfer effected by licensing agreement to take the technology to market considering its significant potential.

Risks envisaged:
Regulatory approvals Finding partners for commercialization of product.

Project Coordinator:
R. Aswati Nair

Team Members :
Kavya K,
Harsha K,
Harshitha K

Contact :
R. Aswati Nair Departmentof Biochemistry and Molecular Biology Central University of Kerala Periye Kasaragod 671316

BAIF Development Research Foundation

Title of the Proposal:
Development of high biomass, drought and salinity tolerant mutant lines in Lucerne Medicago sativa

Brief description:
Lucerne Medicago sativa is an important legume fodder as a major source of protein and calcium for animals. Drought and salinity are limiting factors in cultivation and sustainable production of perennial types. Development of a variety/ies tolerant to drought and salinity is need of day. TILLING Targeting Induced Local Lesions IN Genome , a non-GM technology is the possible alternative. A candidate gene SPL8 from Medicago truncatula has been identified as an excellent candidate for generating high biomass, drought and salt tolerance Gou et al., 2018 . TILLING of this particular locus will be carried out to develop mutants from selected germplasm.

Current stage of development:
Proof of concept

Innovative Element(s):
TILLING combines traditional chemical mutagenesis with sensitive molecular screenings to discover induced point mutations in genes controlling important traits. It is non-GMO without genetic modification-based approach and no regulatory hurdles as like GM.

Market Potential:
Mutant lines further will be utilized for development of variety/ies suitable to drought and salinity conditions.

National/Societal relevance:
At present in India salinity and drought affected area is ~ 27 and 510 lakh ha respectively. This area will be brought under cultivation of newly developed high biomass, drought and salinity tolerant variety/ies of Lucerne which will increase total green fodder production at national level. This will help in reducing the shortage of legume green fodder at national level and balancing the animal diet.

Project achievements:

a. **Progress vis-a vis objectives:** Generation of M2 population and Phenotyping for high fodder biomass: 1182 M2 plant families were generated and established 9282 plants are being phenotyped in the field

b. **.Technology/Product (to be) developed:** Ten potential mutants with high fodder biomass. After advancement for 4 to 5 generations high biomass variety es will be developed in 5-6 years

c. **IP generated/ Potential for IP generation:** There is a potential to register the mutant lines with high fodder biomass under PVP act and non GMO variety of Lucerne

d. **Resources Generated:** Two Senior Research Fellows were employed under the project. Facilities for establishment of mutant Lucerne plants, their phenotyping and DNA extraction from M2 plants were created.

Plans to take innovation further:
Backcrossing of mutant line s with parental line for cleaning of undesirable background mutations and variety development. Screening of same TILLING population for other candidate genes e.g. miR 156, MtSGR, MsSPSA

Risks envisaged:
The mutant lines necessarily to be developed in to variety/ies and further tested under ICAR AICRPFC programme for notification and release. Unless the variety is notified by ICAR it may not come under seed multiplication chain.

Project Coordinator:
Mr. P. S. Takawale

Team Members :
Dr. R .A . Bahulikar, Mr .S . S. Jade, Ms. S. P. Jadhav, Mr. V. N. Gaikwad

Contact :
BAIF Development Research Foundation Kamdhenu Nagar Urulikanchan Urulikanchan Pune MAHARASHTRA India-412202

Beej Sheetal Research Pvt. Ltd. (Bejo Sheetal Seeds Pvt. Ltd.)

Title of the Proposal:
Development of disease resistant double haploid line in Cucumber

Brief description:
Powdery mildew is one of major pathogen in cucumber production specially in kharif season or in polyhouse. Conventional back cross breeding delivers nearly genetic homozygosity. However, to develop elite powdery mildew PM resistant with genetic homozygocity double haploid DH technology has been used. PM resistant heterozygous lines have been identified using artificial inoculation of disease, selected lines crossed with cultivars & segregating BC2 population used to develop DH lines. Elite highly PM tolerant or resistant lines have been selected as in bred line to develop promising F1 hybrids in cucumber.

Current stage of development:
Validation

Innovative Element(s):
Doubled haploids in cucumber is cumbersome and gametic response to tissue culture is poor. Hence novel gamma radiated pollens used to induce haploids and doubling of chromosome is done using chemical treatment. Reproducible protocol has been developed and validated.

Market Potential:
Global cucumber seed requirement is costing to the tune of 1342.3 million USD, India consumes seeds costing about 26 of the global demand. Mostly cucumber seeds are imported for cultivation in India. Hence to reduce the import, newly technology based F1 varieties will replace import.

National/Societal relevance:
Cucumber is consumed all over world including India. Indian varieties are having limited productivity 6.34 tonnes/ha whereas worlds productivity is 30.23 tonnes/ha. Hence there is big scope for increasing productivity for this local genetics with traits in homozygous conditions will have better scope. To replace/reduce import of seeds, indigenous gyanoceious F1 hybrids with quality traits are need of the day.

Project achievements:

a. **Progress vis-a vis objectives:** Doubled haploid cucumber production technology has been developed using novel approach & validated for routine production. Powdery mildew resistant lines have been identified & BC2 population developed using quality trait cultivar. Elite doubled haploid lines developed, screened & selected

b. **.Technology/Product (to be) developed:** Doubled haploid based newly developed elite PM resistant/tolerant lines are being used to develop promising F1 hybrids. It needs critical evaluation and multi-location trials for trait performance as well as suitable for the agro climatic zones. To bring the product three to five timeline is required.

c. **IP generated/ Potential for IP generation:** NA

d. **Resources Generated:** Two manpower is trained for implementation of this technology, three plant growth chambers have been installed for DH production.

Plans to take innovation further:
Own funds will be used to take this technology to market

Risks envisaged:
Generated Although the technology is developed, validated in one location, the other location pathogen strains may vary & PM resistance to be checked for all those strains

Project Coordinator:
Nandkumar S. Kunchge

Team Members :
Sameer S. Agrawal, Prashant Firke, Sachin Bodkhe, Pravin Naphade, Shripad Joshi, Vaibhav Chindhe

Contact :
P. Box. No. 77, Beejsheetal Corner, Mantha Road Jalna Jalna MAHARASHTRA India-431203

Daftari Agrobiotech Pvt. Ltd

Collaborator Name: ICAR - National Rice Research Institute

Title of the Proposal:
Double haploid breeding in development of Rice varieties for enhancing resilience against biotic and abiotic stresses

Brief description:
Present proposal aim to develop biotic and a biotic stress tolerant high yielding rice variety with the basic research done at National Rice Research Institute Cuttack and Daftari Agro biotech Pvt. Ltd. Wardha.

Current stage of development:
Proof of concept

Innovative Element(s):
Rice yield loss due to BLB, and drought is the major challenges in India for which development of a high yielding rice variety with all these traits is the need of the hour without compromising of yield.

Market Potential:
The tremendous growth of human population worldwide has increased the demand for rice production, however in a situation of deficient rainfall, severe attacks by pests it is now critical for farmers to sustain with existing rice varieties and thus farmers advocating for new varieties with traits like drought tolerance and BLB resistance which can cope up with the biotic and abiotic stress. Thus development of varieties with drought tolerance and BLB resistance will definitely increase its demand in market which positively influences its market potential

National/Societal relevance:
Rice Oryza sativa is the world most important crop and a staple food for more than half of the world population, thus it is an important target to provide food security and livelihood for millions. Increasing frequency of climate extremes such as water deficit stress, high temperature and altered soil properties along with higher incidence of pests BLB, is posing a serious threat to rice farming. On the other hand, due to water and labor scarcity and energy intensive condition rice crop is become less profitable therefore development of BLB, and drought resistant rice varieties is an alternative and economical option and thereby ensuring long-term Sustainability

Project achievements:

a. **Progress vis-a vis objectives:** 702 SSR markers were screened out of which 71 markers showed parental polymorphism.F1s and recurrent parental lines Daftarri-1008 were sown in net house for validation of target traits. The androgenic protocol has already been standardized for different F1s which will be utilized in development of DHs from the BC1F1s

b. **Technology/Product (to be) developed:** Rice varieties pyramided with BLB, and Drought traits will be developed using haploid breeding however this product is under development and it will take around 24 months to enter market

c. **IP generated/ Potential for IP generation:** No IP generated

d. **Resources Generated:** Scientific Manpower generated through this project for company as well as collaborator. Infrastructure and instruments procured through project. capacity building as well as as infrastructure development has been done for company and collaborator.

Plans to take innovation further:
Hybrids and varieties developed though this project will be registered at PPVFRA , NEW DELHI . these hybrids will be commercialize all over India in paddy growing area to generate profit for company as well as for farmer

Risks envisaged:
Incorporation of Three BLB,and drought traits simultaneously is difficult due to involvement of multiple gene/alleles/QTLs. Hence, large number of crossing population will need to be generated to find suitable number of lines with all three trait combinations. The crossing program will need to be standardized to achieve a high degree of success

Project Coordinator:
Madhukar Jaipurkar

Team Members :
Sanghamitra Samantaray, Parameswaran C, Devanna, Ramlakhan Verma, Madhukar Jaipurkar, Pratibha pote, Shivshankar Kale

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Division of Veterinary Biotechnology, Indian Veterinary Research Institute

Collaborator: Genomix CARL Pvt. Ltd.

Title of the Proposal:
A venture towards translating the Indigenous diagnostic kits for economically important poultry viral diseases from lab to land

Brief description:
The present proposal aims at development of ELISA kits for three economically important poultry viral diseases namely Newcastle disease, Infectious bursal disease and avian infectious bronchitis infection in birds using recombinant antigens to replace inactivated antigens which are traditionally used in ELISA kits available in the country.

Current stage of development:
Validation

Innovative Element(s):
Indigenously developed diagnostics for veterinary use are not vogue in this country. The diagnostics which are being used in the country are either being imported thereby causing huge loss to the country's exchequer or are being produced using whole inactivated viruses as coating antigen.

Market Potential:
Poultry industry is a multibillion-dollar organized sector in India.

National/Societal relevance:
Cheaper diagnostic assay kits are the need of the hour for the Indian poultry health care system. The changing global climate, demography, ecology, socio-economic conditions, global tourism are mainly responsible for the changing epidemiology of these infectious diseases. Hence, the newer generation diagnostics like the recombinant antigen-based test kits will help to understand the current scenario in India.

Project achievements:

a. **Progress vis-a vis objectives-:** The three-candidate diagnostic recombinant antigens against NDV, IBDV & IBV and reagents were bulk produced and characterized. The recombinant proteins as developed and the sera panel were transferred to the collaborator. The reagents are being used by the collaborator to develop the kit.

b. **Technology/Product (to be) developed:** Three recombinant antigen-based kits namely NDV, IBD and IB ELISA kits

c. **IP generated/ Potential for IP generation:** IN277404: Recombinant antigen based rapid sero-diagnosis of Infectious bursal disease IBD, IN325899: Recombinant antigen based sero-diagnosis of Newcastle disease

d. **Resources Generated:** One Research Associate and one high skilled labour has been engaged at ICAR-IVRI. One Research Associate has been recruited at Genomix.

Plans to take innovation further:
The three kits will be released in the market once the products are validated by third party.

Risks envisaged:
None

Project Coordinator:
Sohini Dey

Team Members :
C.Madhan Mohan,
P. V. Janardhan Reddy,
Rathnagiri Polavarapu

Contact :
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Dtronics Technology Pvt. Ltd.

Title of the Proposal:
Proof of Concept on development of field portable Arsenic testing kit

Brief description:
Uniform illumination based image processing technology has been applied for detection of arsenic in ground water.

Current stage of development:
Validation

Innovative Element(s):
Generally arsenic testing kit is used for onsite detection of arsenic in ground water. In these kits, developed colour is supposed to be matched with the colour strip provided with the kits. But this process is inaccurate as through naked eyes, it is almost impossible to match the colour with the colour strip. So company has developed uniform illumination based image capturing device for easy and quick onsite detection of arsenic percentage in ground water.

Market Potential:
Uniform illumination-based image analysis technology for detection of colour due to presence of Arsenic is accurate, repeatable, easy and quick method. So this artificial technology based process has huge market potential not only for arsenic detection in ground water but also for pathological laboratories where colour is required to be matched with reference colour for analysis.

National/Societal relevance:
These kits produce a significant number of false positives/ negatives due to human errors in matching the detection test-strip colors to the reference color chart.

Project achievements:

a. **Progress vis-a vis objectives:** Detection of arsenic in water using biotechnology-based receptor, arsenic in water using chemical receptor and development of uniform illumination and prototype system

b. **Technology/Product (to be) developed:** Uniform illumination-based image processing technology has been applied for detection of arsenic in ground water.

IP generated/ Potential for IP generation: Will apply for IP after making a commercial product.

c. **Resources Generated:** Three manpower were involved for twenty-one months for development two products.

Plans to take innovation further:
Company have applied in BIRAC for grant in aid for making these prototype systems into a commercial system.

Risks envisaged:
As this technology i.e., uniform illumination-based image capturing technique has huge market potential not only for arsenic detection in ground water but also for pathological laboratories where colour is required to be matched with reference colour for analysis, they can easily penetrate into market.

Project Coordinator:
Chinmay Sarkar

Team Members :
Souvik Pal, Mrittika Ray Goswami, Chinmay Sarkar, Atanu Barui, Amit Sarkar, Paramesh Das, Subrata Sarkar

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Filo Lifesciences Pvt. Ltd.

Title of the Proposal:
Validation studies of Precision specific nutrition using NMPS colloidal mineral and PUFA for Poultry and Aqua

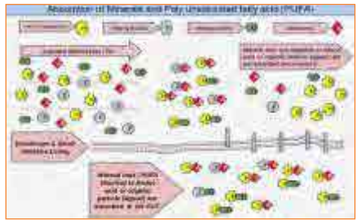
Brief description:
Nano meter particle size NMPS colloidal Minerals and Polyunsaturated Fatty acids PUFA are bio-assimilable nano particle a precise nano nutrition feed supplements in Poultry, Aquaculture and Veterinary.

NMPS Minerals:
Stabilized colloidal minerals embedded in matrices of amino acids reduced to nanometer size particles, encapsulated with a food grade polymer. Form: Colloidal solution Particle size: 50 to 250 nm

NMPS PUFA:
Stabilized emulsion of poly unsaturated fatty acid PUFA embedded in matrices of amino acids and reduced to nanometer size particles, encapsulated using a food grade polymer. Form: Colloidal solution Particle size: 100 to 350 nm

Current stage of development:
Validation

Innovative Element(s):
High purity, Nano particle size 50 -250 nm colloidal solution, Covers exponentially high surface area and Bio-assimilable form helps for near 100 percent absorption, assimilation and metabolism of nano nutrition.



Market Potential:
Business potential as feed supplement in a Indian-Desi and commercial poultry birds Export oriented Prawns farming and Fresh water fish farming done in agriculture field ponds. Feed manufactures can use NMPS nutrients in the feed formulations for poultry and Aqua

National/Societal relevance:
Present challenges in poultry and Aqua is increase in quality, quantity and antibiotic - residue free produce. Irrational use of growth oriented chemicals and antibiotics resulting in produce with antibiotics and residues a threat to consumer and cannot be exported. NMPS nutrition can address this problem by improving the quality, quantity with residue free produce.

Project achievements:

a. **Progress vis-a vis objectives:** Efficacy study in poultry "Increase in Livability by 23 percent, Weight gain by 27 percent and Residue free produce. No toxicity in Preclinical laboratory animals' study-High safety profile

b. **.Technology/Product (to be) developed:** NMPS minerals, Multimineral formula and PUFA is developed. Already initiated placement in poultry and Aqua feed supplement market.

c. **IP generated/ Potential for IP generation:** IP is not generated

d. **Resources Generated:** Initiated development of feed manufacturing using NMPS nutrition through FPOs and Rural feed manufacturers.

Plans to take innovation further:
Further New development: NMPS colloidal solution minerals and PUFA conjugate and conversion of colloidal products in to feed concentrate supplements in granule / powder form.

Risks envisaged:
NMPS is and innovative technology and a novel concept. Establishing new concept in the industry is a challenge.

Project Coordinator:
Heramb Rahalkar

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Flic Farm Pvt. Ltd.

Title of the Proposal:
Autonomous Mobile Robots for weed and pest detection in dry row crops

Brief description:
The flagship product X100 performs every farm operation beginning with seeding till harvesting with the help of various smart attachments. It is designed ground up to be crop agnostic and to suit both small and large farms alike. The intelligent AI driven attachments take precise care of each individual plant as required by fusing data points from several on-board sensors in-order to achieve optimum yields. X100 not only allows for agriculture to be done the way it should but also solves the pressing labor shortage problems in Agri industry.

Current stage of development:
Validation

Innovative Element(s):
The fusion of Robotics technologies, Computer Vision, Artificial Intelligence and on-board sensors to take precise timely actions at the ground level resulting in the optimal yields of the plant with no damage to ecology is the primary innovation of this product. On top of the product benefits, its versatility to perform multiple operations in multiple dry crops at various stages of crop life cycle makes it a unique product.

Market Potential:
This product is being marketed to Vegetable growers within India as well as small scale organic vegetable growers in European markets.

National/Societal relevance:
The primary motivation behind this product is to completely eliminate the chemical residues from vegetables. Due to the increase in labor charges caused due to worker shortages, Indian farmers are being forced to adopt chemical alternatives such as herbicides. The utilization of chemicals not only pollutes the soil and groundwater bodies but also seeps into the vegetables that we consume on a daily basis which affects the health of its consumers. They believe that by bringing advanced technologies at an affordable price into Indian farming eco-system will drastically drive down the inclination to use chemicals for growing food and potentially eradicate it in the coming future.

Project achievements:

a. **Progress vis-a vis objectives:** Successfully developed the Computer Vision and Machine Learning algorithms as well as the smart attachments required to perform weed control and pest control in vegetable crops.

b. **Technology/Product (to be) developed:** By the end of this project an autonomous mobile robot along with intelligent AI driven weed control and pest control attachments are to be developed. This product is going to be launched in 2022.

c. **IP generated/ Potential for IP generation:** Provisional patent has been filed for this product so far.

d. **Resources Generated:** So far they have raised Rs. 68 Lakhs and employed 4 engineers.

Plans to take innovation further:
The company is going to raise substantial amount of funds to commercialize this product for both Indian & International markets.

Risks envisaged:
The biggest hurdle to achieve market penetration for this product at a pace they intend is to the cost of the product itself which is a result of high cost of Research & Development as well as the inherent costs of computing components. Due to which during the first 3 years Governments help will be required in order to subsidize the product cost. However, they can foresee a future in which this product could be extremely affordable to a typical Indian farmer.

Project Coordinator:
Trivikram Kumar
Dogga

Team Members :
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Kwaklei and Khonggunmelei Orchids Pvt. Ltd.

Title of the Proposal:
Commercial orchid breeding and production of clones of elite hybrids

Brief description:
Utilization of the rich orchid resource of India can be achieved through breeding of the potential species either for pot plant or cut flower. The company has been focusing mainly on synthesis of new hybrid orchids using potential parents available in India, particularly in the northeastern states. Elite genotypes of the already synthesized hybrids have been selected and propagated clonally since the BIG program in 2014. Further breeding work is being carried out with the SBIRI grant. So far, more than 100 primary as well as secondary orchid hybrids are being developed.

Current stage of development:
Validation

Innovative Element(s):
Most of the orchids being cultivated in India are those imported ones. This project focuses on development of novel hybrid orchids using the resource available in India. This breeding effort shall result in production of hybrid orchids suitable for commercial cultivation in different parts of India.

Market Potential:
Orchids are very sought after horticultural items worldwide. India, which is a late entrant in orchid business, has been importing from other heavyweight orchid producing countries. So, there is high market potential both at domestic and international. The new hybrid orchids developed by K&K Orchids will provide foundation for a booming orchid industry in India.

National/Societal relevance:
Despite having rich orchid resources India has been importing orchids from other orchid producing countries in SE Asia for commercial purposes. One of the reasons is lack of elite commercial orchid breeds developed in India. Those orchids developed in tropical Asia may not perform well in sub-tropical or temperate climates. Hence, there is the need for development of specific commercial breeds for providing to the growers in different climatic regimes in India.

Project achievements:

a. **Progress vis-a vis objectives:** Approximately 100 primary as well as secondary hybrids are maintained in the laboratory and greenhouse. Clonal propagation of some of the elite hybrids is done. Some of the acclimatized plants have matured and flowered and are ready for registration.

b. **Technology/Product (to be) developed:** Newly synthesized hybrid orchids are the product of this project and at present there are approximately 100 new hybrid orchids being raised.

c. **IP generated/ Potential for IP generation:** Clones of elite hybrids are yet to be registered under Plant Variety Protection Act.

d. **Resources Generated:** One project fellow and one field assistant were appointed. Equipment including a laminar flow cabinet, an autoclave and a pH meter were purchased.

Plans to take innovation further:
The venture is at TRL 6 and moving to TRL 7. The company is looking for parternership ventures as well as for investments.

Risks envisaged:
Long gestation period for the orchid plants to become marketable is the main challenge in this breeding program. They usually take 3 or more years to mature and flower. Without flowers the plants are not in a position to advertise for market.

Project Coordinator:
Dr Rajkumar Kishor

Team Members :
Mr. Laishram Lenin Singh;
Ms. K. Madhuri Devi

Contact :
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MANIPUR India-795001

Maharashtra Animal and Fishery Sciences University

Collaborator Name: 1) Genext Genomics Pvt. Ltd.

Title of The Proposal:
Development of Lateral Flow/ELISA Detection Kit for the early diagnosis of theileriosis in Cattle.

Brief Description:
Bovine Tropical Theileriosis caused by Theileria annulata is a tick borne apicomplexian protozoa affecting cattle & buffaloes in India and other tropical countries. Diagnosis of Theileriosis observing the clinical symptoms by field veterinarians as well as observations of piroplasms in RBCs and Koch Blue Bodies in the lymphocytes in the laboratory are mostly misleading. PCR is the most accurate tool available for diagnosis but not affordable and limitations for field veterinarians.

Current Stage of Development:
Validation

Innovative Element(s):
Few articles mentioned an ELISA using TaSP and TamS1 antigens of Theilleria annulata for theileriosis detection. But none of the product in the market. We targeted the TACP and made monoclonal and polyclonal antibodies. Our sandwich ELISA observations are promising for to develop lateral flow assay.

Market Potential (with India & abroad):
The number of cattle, cows and buffaloes are around 180 million with an yearly increase of 6.75 percent in India. Currently around 30 Million cattle are at risk of the disease across India which means 1 Million Death/year. Indian market require quick and on field assays. Tropical countries at international level would be the high potential market for the lateral flow assay.

National/Societal Relevance:
A Theileriosis increases the animal mortality rate as well as decrease in milk production.The lateral flow assay is important for White Revolution of India. Quick, reliable and on-field assays are the need of the hour.

Project Achievements:

a. **Progress vis-a vis objectives:** The reagents in the form of antigen and antibodies are ready for the lateral flow assay development. At least 12 MAbs to be validated for the best assay.

b. **Technology/Product (to be) developed:** Products for assay development and know-how of technology is ready. 6-9 months with funding require for the final product.

c. **IP generated/ Potential for IP generation:** Indian patents has been filed which is under review.

d. **Resources Generated:** GNG has expert and trained man power as well as in collaboration for development of such assays.

Plans to take innovation further:
GNG is ready to take further with partnership as far as funding for the final technology development is available.

Risks Envisaged:
MAFSU and its veterinarian scientist know the severity of the disease. Market through government supplies as well as private veterinary practitioners is high potential.

Project Coordinator:
Vinod B. Agarkar

Team Members :
Vinod B. Agarkar,
Supriya A. Kashikar

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Jalna MAHARASHTRA India-431203

Maharashtra Hybrid Seeds Company Ltd.

Title Of The Proposal:
Improvement of line yield per se and efficiency of hybrid seed production in rice using genome editing technologies.

Brief Description:
To overcome existing bottlenecks, genome editing techniques are used for the improvement of line yield and also for increasing the efficiency of hybrid seed production in the parental lines of rice hybrids. Finally, stacking of edited yield and floral anatomy genes together in indica rice background will benefit farmers by having access to superior products.

Current Stage of Development:
Validation

Innovative Element(s):
Genome editing techniques are used in developing enhanced rice hybrids.

Market Potential (with India & abroad):
The global rice production has stagnated, and is hovering around 490 million tonnes for the past few years. Interestingly, hybrid rice yields 15-20 per cent more compared to traditional varieties.Taking advantage of this, high yielding rice hybrids can be introduced into global rice farming to assure the global food security through genome editing.

National/Societal Relevance:
The scope for increasing the area under rice production is limited, therefore increasing the productivity of Rice is the only path forward. While several technologies exist for increasing Rice production, genome editing technologies offer a promising approach to improving yield and to enhance production potential.

Project Achievements:

a. **Progress vis-a vis objectives:** The project is in the final phase of evaluation in the validation phase. Stacking of edited genes is in progress along with stack evaluation.

b. **Technology/Product (to be) developed:** Hybrid rice with enhanced yield. Documented grain yield increased by 17-30 per cent. Expected to enter market by 2024 subject to regulations, if any.

c. **IP generated/ Potential for IP generation:** NA

d. **Resources Generated:** Genome editing expertise developed in-house.

Plans to take innovation further:
The products coming from this project will be commercialised subject to regulations on the technology.

Risks Envisaged:
Regulatory guidelines are not in place.

Project Coordinator:
Bharat Char

Team Members :
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Vilas Parkhi

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India-431203

Manoj Kumar R

Title of The Proposal:
Novel trap and kairomone to control fruit flies damage in horticulture crops

Brief Description:
Fruit flies are among the most destructive agricultural pests in the world, destructing acres of fruit and vegetable crops at an alarming rate, thus forcing food and agriculture agencies to spend hundreds of crores towards control and management measures. There is increasing demand for eco-friendly methods to control fruit flies as residue free produce is the key requirement for food processing industries to increase export volumes. All these issues being faced by farmers can be overcome by use of NaturActiv+ female cum male fruit fly trap with prolonged release.

Current Stage of Development:
Validation

Innovative Element(s):
The product is world's first female cum male fruit fly trap, no need to replace lure in one full season. Lure works for one season without replacement. This is different from current products as there are only male fruit fly traps in market.

Market Potential (with India & abroad):
Huge potnetial in market as there are only male fruit fly traps in India & Abroad. Male traps are not effective as they are polygamous, and one male fly can mate with many females and multiply faster. This can substitute import of female traps and protein baits & male fruit fly traps.

National/Societal Relevance:
Increases exports of fruits as currently exports of fruits infested by fruit fly is quarantined. Reduced pesticide residues on fruits. Its able to increase quality fruit yield, decrease labour for pest crontrol, reduces cost of cultivation increasing profitability. Supports fruit processing industry to increase exports by meeting demand for residue free fruits.

Project Achievements:

a. **Progress vis-a vis objectives:** As committed in the project successfully identified useful kairomones for control of female and male fruit flies. A blend of female male fruit fly trap is formulated and evaluated sucssefully and patented. A slow release model trap was designed succesfully and could produce is succesfully during pilot trials and validated in field conditions.

b. **Technology/Product (to be) developed:** Product ready to enter market now.

c. **IP generated/ Potential for IP generation:** Two indian patents & two international patents were filed for slow release design of trap and female cum male lure.

d. **Resources Generated:** Five technical people were trained in the project. Product final commercial mould is prepared. Pilot scale production and testing facility is created. Company formation is under process. Trained about 200 farmers on use of the traps during validation. Data is generated on the efficiency of trap under field conditions.

Plans to take innovation further:
Working currently on strategic partnerships with biological control companies for marketing the product. Technology is ready for licensing in India and aborad.

Risks Envisaged:
There are several male fruit fly trap mannufacturing companies. Hence planning to enter into tieups with those companies that have good market coverage that can easily make the product reach to maximum number of farmers. There are not many risks, mainly climatic factors would be expected to be some risk. There are no risks associated to production related aspects.

Project Coordinator:
Manoj Kumar R

Team Members :
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BENGALURU 560064

Mohan Babu Appaiahgari

Title of the Proposal:
Development of a live, attenuated Fowl Adenovirus 4-based candidate poultry vaccine against Hepatitis-Hydropericardium Syndrome

Brief description:
The proposal aims at generating POC data and currently we are in the process of conducting immunogenicity studies in experimentally immunosuppressed birds. Soon, we are also initiating vaccine efficacy studies against a pathogenic strain of FAdV4 in the challenge experiments.

Current stage of development:
PoC

Innovative Element(s):
The vaccine virus is a naturally avirulent strain of FAdV4 and the proposed vaccine, unlike the currently available inactivated vaccine, is based on a live virus. The proposed isolate has several novel genetic features compared to other known FAdV4 reported till date. We also proposed to demonstrate the efficacy of the vaccine virus under simulated field conditions.

Market Potential:
Poultry industry in India alone is worth > Rs. 53,000 crores and India is among the top 5 poultry meat exporters in the world market.

National/Societal relevance:
Due to higher cost of vaccination and lack of effective prophylactic/therapeutic interventions, poultry farmers are adopting unethical practices like the use of antibiotic-supplemented feed to reduce disease burden in their farms. Such practices are adulterating the poultry meat with large amounts of antibiotics and consumption of this meat is contributing to the development of multi-drug resistant (MDR) strains of pathogenic bacteria.

Project Achievements:

a. **Progress vis-a vis objectives:** Project is going on

b. **Technology/Product (to be) developed:** They proposed to develop a live vaccine for HHS using a naturally avirulent strain of FAdV4

c. **IP generated/ Potential for IP generation:** They are yet to submit an IP application. However, they have outsourced the prior art search activity to IKP's IP cell and the same is now available with us. Based on the prior art search, the team at IKP's IP cell opined that the invention has potential to generate novel IPR both in India and abroad.

d. **Resources Generated:** They recruited an experienced researcher having years of experience in poultry nutrition and bird handling.

Plans to take innovation further:

They are currently awaiting completion of our immunogenicity and efficacy studies. Next, They have plans to carryout field efficacy studies in endemic regions for HHS through funding support from BIRAC and/or from suitable industry collaborators.

Risks envisaged:

Trials

Project Coordinator:
Dr. Mohan Babu Appaiahgari

Team Members :
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SHC Shine biotech Pvt. Ltd.

Title of the Proposal:
Development of highly sensitive & specific, rapid, point-of-care, low-resource-requiring and cost-effective diagnostic kit for bovine leukemia virus BLV infection in dairy cattle

Brief Description:
Bovine Leukemia Virus, BLV, is one of the most common infectious viruses of cattle and endemic in many herds. The prevalence of BLV in India is reported to be highly variable 0-75 percent among different herds and states.

Current Stage of Development:
Validation

Innovative Element(s):
Faster amplification of target coupled with colorimetric detection potentially facilitating improved sensitivity/early-diagnosis compared to PCR and antibody-based assays

Market Potential:
An assessment of BLV infection in USA dairy operations in 2007 showed that 83.9 percent of them were seropositive for BLV. A more recent survey from cattle presented at slaughter in USA in the period 2014 & 2015 resulted in 38.6 percent BLV seropositive samples, with significantly higher infection rates for dairy compared to beef cattle. Besides, BLV-infection was observed to increase overtime in US indicating increasing market size for the proposed test. It is estimated to causes annual economic losses of ~$285 million for producers and $240 million for consumers. However no organized market survey is yet available for India.

National/Societal Relevance:
BLV not only raises economic and animal welfare concerns but public health also. Stability & sustainability of dairy industry is crucial for human food security. But recently, consumption of BLV-infected milk has been reported to be associated with human leukemia and breast cancer. Besides, drinking milk collected from a cancer patient cattle could be considered in-humane. Todate, only limited efforts have been made, specifically in India, to establish the prevalence of BLV-infection among dairy cattle and its impact on public health. This is primarily because 1. the disease typically remains silent/asymptomatic, and 2. todate, there is no highly sensitive & specific, rapid, POC and cost-effective test available for diagnosing BLV-infection.

Therefore, we are working to develop quality, rapid and cost-effective diagnostics for BLV-infection.

Project Achievements:

a. **Progress vis-a vis objectives**
   1. Production of diagnostic reagent and optimization of LAMP assay- Completed
   2. Optimization of protocol for rapid and cost-effective DNA isolation from needle-prick whole blood- ongoing

b. **Technology/Product (to be) developed:** Point of care LAMP-based equipment-free BLV-diagnostic test is under development and validation. The product will meet the market, hopefully by the end of the year.

c. **IP generated/ Potential for IP generation:** We plan to file IP for membrane-based DNA extraction device.

d. **Resources Generated:** We have 3 manpower for this project and currently are incubated in the BBB bio-incubator.

Plans to take innovation further:
We aim to generate fund for multisite clinical validation of the product and commercialize the product as the earliest possible.

Risks Envisaged:
Availability of limited number of well-characterized BLV positive or negative samples as no accurate or confirmative diagnostics is used in the field while defining the samples

Project Coordinator:
Priyanka Maurya

Team Members :
Vidhika Goel, Surender Fagna

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Proximal Soilsens Technologies Pvt. Ltd.

Title of The Proposal:
An affordable soil monitoring system for precise irrigation

Brief Description:
Soilsens station is solar-powered and measures soil moisture, soil temperature, ambient humidity, and ambient temperature. It is modular and its height is adjustable. Data can be recorded as per the customer requirement. This system can be used in open farms, polyhouses, greenhouses, mushroom farming to monitor environmental parameters in real-time.

The farmer gets the advisory on his mobile about
1. When to irrigate
2. How much to irrigate
3. Any probable occurrence of disease Based on the data available
4. With this system, farmers can improve yield, save water, reduce crop loss due to disease and pests.

Current Stage of Development:
Commercialization:
a. Commercialized in the name of :SoilSens Station
b. Date of commercial Launch:2020-01-01
c. Number of units sold:20
d. Number of end users:10

Innovative Element(s):
We have an indigenously developed moisture sensor that forms the part of the system. Apart from that, we have kept the complexity to a minimum by integrating only the required sensors which will be useful for disease prediction and controlled irrigation.

Market Potential:
The global soil moisture sensor market size was valued at USD 173.6 million in 2018 and is expected to grow at a compound annual growth rate CAGR of 14.0 from 2019 to 2025.

National/Societal Relevance:
Water use efficiency in agriculture is very low. Govt is planning to reduce subsidies on water. By using such technology, Govt can regulate water usage based on the crop water requirement.

Project Achievements:

a. **Progress vis-a vis objectives:** Developed and validated SoilSens station and Automatic Weather Station.

b. **Technology/Product (to be) developed:** Technology developed.

c. **IP generated/ Potential for IP generation:** NA

d. **Resources Generated:** Multiple people are trained and employed. Set up a manufacturing and assembling facility. Generated funds through revenue and grants.

Plans to take innovation further:
We are seeking funds and are looking for business partners and investors. We are also adding features to existing technology.

Risks Envisaged:
Generating Market and Raising Funds.

Project Coordinator:
Rajul Patkar

Team Members :
Rajul Patkar, Mangesh Gurav, Vinay Palaparthy, Jobish John, V Ramgopal Rao,Maryam S Baghini

Contact :
D 203, Marvel Citrine, Near Gulmohar Society, Rakshak Nagar, Kharadi Pune MAHARASHTRA India-411014

Seragen Biotherapeutics Pvt. Ltd.

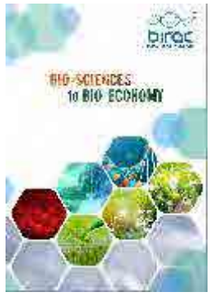
Title of the Proposal:
A Novel sperm transportation medium using a thermoreversible gelation polymer, N-isopropylacrylamide-based copolymer: SeraGel

Brief description:
Seragen Biotherapeutics Private Limited hereafter referred to as Seragen is a fertility only biotech venture using Regenerative medicine based therapy engaged in the discovery, development and clinical validation and implementation of novel therapeutics designed to treat unmet infertility conditions. The most advanced programs at the company are focused on the development of autologous stem cell based therapy for male infertility.. The field of RM is advancing rapidly than ever before and many regenerative products are in clinical trials and which would be beneficial to the general population years ahead.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The solution will help patients/donors/diagnostic centres or IVF clinics to collect semen sample and ship it overnight to a sperm bank or diagnostic centre or an IVF clinic at room temperature without cold chain logistics while preserving the semen quality parameters intact

Market Potential:
Male Infertility Market was valued at $216 million, and is expected to reach $301.5 million by 2020, supported by a CAGR of 5. Technavios analysts forecast the global sperm bank market to grow at a CAGR of 4.12 during the period 2017-2021.y



National/Societal relevance:
The product will prove useful to those patients who cannot come to IVF centers or sperm bank facilities as they can collect semen sample in the privacy of their home and ship it for analysis or storage. Thus the solution will help patients/donors/diagnostic centres or IVF clinics to collect semen sample and ship it overnight to a sperm bank or diagnostic centre or an IVF clinic at room temperature without cold chain logistics while preserving the semen quality parameters intact.

Project achievements:

a. **Progress vis-a vis objectives:** Completed first objective :Standardization of polymer preparation-quantity, stability and solubility.

b. **Technology/Product (to be) developed:** 18 months

c. **IP generated/ Potential for IP generation:** METHODS FOR IMPROVING SPERM FUNCTIONALITY AND APPLICATIONS THEREOF 2018 E-2/1197/2020/CHE

d. **Resources Generated:** Man power employed: 3

Plans to take innovation further:
Partnership and Fund raising

Risks envisaged:
Clinical Validation and Regulatory approvals

Project Coordinator:
Vasanthi Palanivel

Team Members :
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Contact :
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Shradha Jamwal

Title of The Proposal:
Recombinant Buffalo Leukemia Inhibitory Factor rBuLIF in the treatment of iatrogenic infertility in bovine

Brief Description:
This project is focused on the production of recombinant bovine Leukemia Inhibitory Factor rBuLIF using fermentation technology for treating iatrogenic infertility in bovine. We propose that the recombinant protein rBuLIF will enhance the pregnancy rate in bovine when administrated via intravenous/intrauterine route by reducing early embryonic mortality. rBuLIF is a cytokine which is expressed copiously in endometrium and plays a significant role in embryonic attachment during early phases of pregnancy in human, bovine, and mouse. It has been recommended clinically to treat many cases of unexplained infertility in humans with success.

Current Stage of Development:
Discovery

Innovative Element(s):
rBuLIF will improve the uterine environment which is important for successful implantation. rBuLIF is not available in the market. The dose of rBuLIF and doses regimen will be unique to treat infertility cases. To date, hormonal therapy is recommended to prevent pregnancy failure which is ineffective to treat implantation failure.

Market Potential:
There are 300 million cattle in India with many cases of early embryonic mortality. There is immense scope of its commercialization by administering rBuLIF during the early phase of conception. rBuLIF is also an essential factor that is used in stem cell research to maintainin pluripotency. Therefore this molecule has a global market value.

National/Societal Relevance:
Infertility in cattle leads to major economic losses in dairy farming.

Project Achievements:

a. **Progress vis-a vis objectives:** We have successfully cloned and purified the biologically active rBuLIF in small scale.

   Administration of recombinant protein is yet to be given to herd to study the effect on pregnancy rate.

b. **Technology/Product (to be) developed:** The purified biologically active rBuLIF has been developed and the dose regimen to treat infertility is under process. The expected time to enter the market is 4 years.

c. **IP generated/ Potential for IP generation:** rBuLIF protein, the process of large scale production, purification of rBuLIF, Therapeutic dose, and regimen of rBuLIF in the management of infertility in bovine will be protected as IP

d. **Resources Generated:** we have developed suitable lab infrastructure

Plans to take innovation further:
We are in touch with the potential startups and potential stakeholders who are eagerly waiting for the tested product for use in field conditions.

Risks Envisaged
There is no risk with the product however the early and accurate diagnosis associated with the early embryonic mortality is challenging.

Project Coordinator:
Shradha Jamwal

Team Members :
Sudarshan Kumar,
Ashok Kumar Mohanty,
Rubina Baithalu, S.S. Lathwal

Contact :
Shradha Jamwal Animal Biotechnology Centre NDRI karnal Karnal 132001

Thomas Biotech and Cytobacts Centre for Biosciences OPC Pvt. Ltd.

Title of the Proposal:
Feasibility of Long-term Micropropagation of Papaya [Carica papaya L.] and the Prospects of Commercial Level Scaling Up

Brief description:
The Company has come out with the novel technology for tissue-culture TC -medicated rapid multiplication of papaya, coupled with two elite clonal selections of papaya, namely, Dawn Delight and Thomas Delight.

The company has just launched the supply of TC papaya plants across the country.

Current stage of development:
Commercialization

Innovative Element(s):
Commercial Production of Elite Tissue Culture Papaya

Papaya is conventionally propagated through seeds with the segregation of seedlings to different-sex forms. The country relies on the import of seeds of Red Lady papaya for commercial cultivation. The company makes quality planting material in the country and thus supports the farmers.

Market Potential:
There is a great demand for elite papaya types and quality planting material in papaya. Current requirements are met largely through the import of seeds of the elite papaya Red Lady from Taiwan. Elite papaya lines with similar or better fruit qualities and yields have great market potential throughout the country with the currently estimated area of 1,00,000 ha under cultivation.

National/Societal relevance:
This is perhaps the first time in India/ overseas successful commercial micropropagation of papaya is accomplished. Therefore, there is a great market potential for the elite lines which are clonally propagated through biotechnological intervention.

Project achievements:

a. **Progress vis-a vis objectives:** All the projected objectives have been accomplished with the validation of the micropropagation technique for papaya from the protocol stage to a commercially viable option

b. **Technology/Product (to be) developed:** Demonstrating the feasibility of micropropagation of papaya and taking the same to commercial scale

c. **IP generated/ Potential for IP generation:** A patent application entitled: TISSUE CULTURE BASED METHOD OF PROPAGATION OF CARICA PAPAYA PLANT was filed on 31 Aug. 2020 at Chennai

d. **Resources Generated:** Current man/womanpower: 10 nos Previously employed or trained during the last 2 years: 16 nos

Facility Created: Tissue Culture production, hardening, Research facilities of Tissue Culture and basic microbiology

Plans to take innovation further:
Collaboration for secondary hardening and/or marketing of TC papaya in different parts of the country from interested parties Technology transfer to overseas companies

Risks envisaged:
High microbial interference during papaya tissue culture
Difficulty with the hardening phase for papaya
Field Constraints due to various virus diseases.

Project Coordinator:
Pious Thomas

Team Members :
T. P. Rajendran, Patron,
Anita Mariet Thomas,
Advisor

Contact :
No. 318, SERENITY,
Ist Main, Thalacauvery
Layout Amruthahalli
Bangalore 560092

Transpacks Technologies Pvt. Ltd.

Title of the Proposal:
Preventing counterfeiting in seeds, pesticides, medicines and medical implements and farmer and consumer education using augmented/virtual reality technology

Brief description:
Transpacks has developed the world's first copy proof labels which can be scanned by a 4MP camera even when the communication network becomes unavailable. The three-dimensional Checko tag is a unique identifier based on the mathematical concept of physically unclonable functions and cannot be reproduced. The uniqueness of the solution lies in the fact that they can authenticate, even when the communication network is unavailable or in offline mode.

Current stage of development:
Commercialization

Innovative Element(s):
Checko is non-clonable, low cost, user friendly, for both B2B & B2B2C markets.

Market Potential:
Global anti-counterfeiting market-$1.7 trillion,Indian Market- $25 billion

National/Societal relevance:
Counterfeiting is a serious threat to health and life in critical sectors such as pharmaceuticals, medical devices, agro products and agro-inputs. Whereas counterfeiting is prevalent in all sectors of the economy, the sectors listed here are particularly vulnerable, because of the consequences of either the ingestion of fake medicines or the devastation caused to a marginal farmer from the fake seeds, pesticides, for which spoilage of a crop has life and death consequences. The human cost of counterfeiting, resulting from fake medicines and nutritional products, has been highlighted above. In addition, counterfeiting has a significant societal impact in terms of economic losses, job losses, loss of revenue to the Government.

Project Achievements:

a. **Progress vis-a vis objectives-:** 1-Demonstration on a mobile phone, to distinguish between a 3D tag and its 2D look alike, Develop a user-friendly app-less method for farmers and users of agro and medical products for authenticating a PUF/tag and play AR/VR videos, Printing 3D tag on the roll-to-roll machine.

b. **Technology/Product (to be) developed:** Company has developed a 3D detection algorithm based on a classical image processing approach that is more than 90 accurate. In the current process, when a flash image is taken, the shadows at the edges make a 3D tag appear slightly different from its copied 2D clone. These differences will be trained into a small deep learning network, implementable on a smartphone

c. **IP generated/ Potential for IP generation:** NA

d. **Resources Generated:** 6 people employed

Plans to take innovation further:
The company envisage the next step to be technology development & licensing to manufacture the anti-counterfeiting PUFs on laminate & other substrates.

Risks envisaged:
Availability of specialized resources as image processing & machine learning engineers.

Project Coordinator:
Deepak Gupta

Team Members :
Sudhanshu Bahadur,
Pranav Asthana,
Satish Chandra

Contact :
National Center for
Flexible Electronics IIT Kanpur
Kanpur 208016

Vaseeharan

Title of The Proposal:
Development of marine polysaccharides mediated nanoproducts for shrimp disease management

Brief Description:
BIONAN-COMPO is a feed supplement gel contains natural polysaccharides-based nanoparticles exclusively made for shrimp and fish culture. This product can be mixed with different ranges of feed before feeding to the animal.

Current Stage of Development:
Proof-of-Concept

Innovative Element(s):
• Free from harmful chemicals and antibiotics • Made purely of natural ingredient and ecofriendly • Excellent immune enhancer to protect against harmful diseases • Plays multipotential role by enhancing growth, development and immunity • Act as a complete range of solution for shrimp and fish culture

Market Potential:
Aquaculture medicine is the major sector of shrimp culture Industry and it is occupied approximately 10-15 of the production costs.

National/Societal Relevance:
At this point, BIONAN COMPO pays a way to combat the adverse effects of existing therapeutics. This would help to explore a novel mechanism of nanocomposite using marine polysaccharides from marine sources for enhancing the disease resistance in fishes and shrimps. BIONAN COMPO would bring a new insight in aquaculture and pharmaceutical industry.

Project Achievements:

a. **Progress vis-a vis objectives**
- Seaweeds were collected from different geographical locations and dried. Bioactive compounds were extracted and processed
- Polysaccharides were isolated and purified. Polysaccharides were characterized using UV, FTIR and NMR analysis
- Polysaccharide based zinc oxide nanoparticles were synthesized, characterized and confirmed using UV, FTIR, Zeta potential and TEM analysis.
- The growth performance of shrimp were assessed after field trail
- Disease resistance in shrimp against Vibrio Sp, APHND and WSSV were assessed
- The accumulation of zinc in feed, sediment, water and shrimp muscle were examined using ICPMS analysis. Toxicological assessment were evaluated in Artemia, Daphnia and Fish as a model organism and mortality rates were also recorded.

b. **Technology/Product (to be) developed:** Novel multipotent BIONAN COMPO for the benefits of aqua farmers.

c. **IP generated/ Potential for IP generation:** New IP filled

d. **Resources Generated:** 3 Manpower hired

Plans to take innovation further.
Field trial of BIONAN compo will be conducted.

Risks Envisaged:
Field trial of BIONAN COMPO.

Project Coordinator:
B. Vaseeharan

Team Members :
R. Jayakumar, G. Kumerasan,
C. Shanthini, A.M. Sibiya,
D. Karthick Rajan

Contact :
Department of Animal Health
& Management, Alagappa
University

AGRICULTURE

SBIRI

Visargha Agri Sciences Pvt. Ltd.

Title of The Proposal
Development of an accelerated and precision breeding system for trait integration in plants

Brief Description
The company has developed a direct DNA delivery in plants with high transformation efficiencies both for invitro and inplanta methodologies and in this project its efficacy for trait integration is being validated by developing anthocyanin rich tomatoes and submergence tolerant rice by precise modification of DNA through gene targeting and homologous recombination

Current Stage of Development:
Validation

Innovative Element(s):
Our unique transformation system aids in high transformation efficiencies and is well adapted for inplanta transformation leading to easier and accelerated development of gene edited plants. This can be exploited for testing and correlating the genotype/phenotype, varietal background effects and deployment of novel traits.

Market Potential:
The principal mode of commercialization would be in form of research service and contract research

National/Societal Relevance:
Ushering in second green revolution for national food security and increasing the farmers income is the need of the hour. Accelerated and precision breeding can play a significant part in this by decreasing the timelines and input costs.Aided by our novel DNA delivery technology this can rapidly advance testing, development and deployment of novel crop varieties

Project Achievements:

a **Progress vis-a vis objectives:** Gene edited rice and tomato plants for Sub1A and Ant1 gene imparting submergence tolerance and high anthocyanin content were sucessfully devloped and are being evelauated at the molecular level over generations

b. **Technology/Product (to be) developed:** A DNA transfection kit, services for trait testing and integration

c. **IP generated/ Potential for IP generation:** Patentability is taken and will apply at the end of the project

d. **Resources Generated:** Three people at research associate and assistant level were employed and trained

Plans to take innovation further:
The principal mode of commercialization would be in form of research service and contract research

Project Coordinator:
Phanindra Mullapudi

Team Members :
Rajashree Pattnayak,
|Godinda Bindhani

Contact :
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University Patia Bhubaneswar
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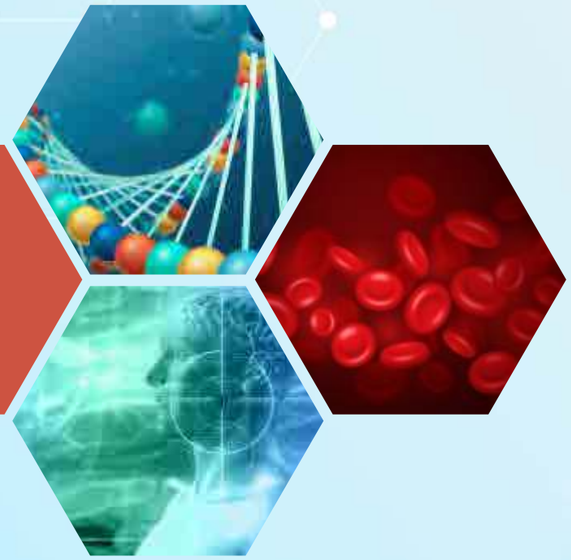
INNOVATION PROFILES



ENERGY AND ENVIRONMENT

A. Michael

Title of the Proposal:
Developing highly purified, cost effective chicken egg yolk IgY antibodies that enables improvement in food nutrition and healthcare in humans and animals

Brief description:
Passive immunization using avian egg antibodies IgY has been found to be effective in providing protection against several pathogens affecting animals and humans namely Helicobacter pylori and Streptococcus mutans. Current study describes the potential immunotherapeutic applications of purified IgY antibodies for the prevention and treatment of oral and enteric diseases of humans.

Current stage of development:
Proof of Concept

Innovative Element(s):
Chickens possess numerous advantages over mammals to be used as hosts for immunization, especially their phylogenetic distance, modes of immune diversification and the means by which IgY immunoglobulin is deposited in the egg yolk and showing remarkable high affinity, avidity and highly neutralizing abilities for an infectious pathogen. Mammalian sera contains many classes of antibodies after immune stimulation with single antigen whereas egg yolk consist of only single class of antibody i.e., IgY, thus facilitating ease of purification using monolithic columns and ultra filtration processes using TFF systems.

Market Potential:
The IgY therapeutic applications are highly encouraging and further work would pave into the market entry of novel commercial nutraceutical or health supplements based on the utility of mono-specific or mixed IgY formulations. Consumer preferences for natural resources to lessen health issues, medicinal costs and the recent move ahead in drug delivery systems and combinational therapeutic regimens, likely the usage and applications of IgY may swing from functional food category towards development of novel pharmaceuticals in the near future

National/Societal relevance
high

Project achievements:

a. **Progress vis-a vis objectives:** ongoing as per the GLA

b. **Technology/Product (to be) developed:** Highly purified IgY antibodies for application in human and animal health

c. **IP generated/ Potential for IP generation:** Patent No: 355278 entitled "Method for Detection of Staphylococcus Enterotoxin B and its application thereof" Venkataramana. M, Shivakaran S, Naveen S, Kadiravelu K, Michael A

d. **Resources Generated - Manpower employed/trained:** 1 Ph. D graduate and 2 Post graduates were employed. Facility Created – Currently working as incubatee in BioNest, PSG STEP. 1500 sq. ft facility is being created. MoU with Pasteur Institute of India. Planning to register company by April, 2021.

Plans to take innovation further:
Proposal to collaborate with Theragen Molecular Innovation, Chennai and ProdIgY, USA Proposal to collaborate with SKM egg products, Erode and INZPERA, Mumbai.

Risks envisaged:
None. It is put forward that the current proposal will certainly have a positive outcome

Project Coordinator:
A. Michael

Team Members :
S. Rajeshwari; K.V. Ashok Raj; S. Dhivya; J. M. Malliga

Contact :
Associate Professor and Head, Department of Microbiology, PSG College of Arts & Science, Coimbatore

Arboreal Bioinnovations Pvt. Ltd.

Title of the Proposal:
Development of a Commercial Process Scheme for Manufacturing of Enzymatically Modified Stevia Extracts

Brief description:
Certain higher glycosides like Reb D and Reb M in the Stevia extract mix perform better at higher concentrations without the after taste issue. Arboreal proposes to develop a bioprocess involving the treatment of Steviol glycosides with naturally occurring enzymes as biocatalysts that could achieve the biotransformation of lower glycosides like Stevioside and Reb A into higher glycosides like Reb D, Reb M in a cost-effective way.

Current stage of development:
Proof of concept

Innovative Element(s):
Arboreals aims at developing a bioconversion process that uses only naturally occurring and non-GMO enzymes and substrates. Arboreals process also uses naturally existing Steviol Glycosides for deriving Reb D and Reb M based products which requires production of Stevia leaf by Indian farmers instead of completely synthetic pathways that do not require any farming.

Market Potential:
It is estimated that Stevia will substitute about 10% of the global sugar demand in the next 10 years, which will represent a 10 Billion USD market opportunity.

National/Societal relevance:
People suffering from Diabetes lead severely limiting lives and commercialisation of Stevia in India can enable better quality of life for millions of Indian consumers. The current market for Stevia extracts in India is over 60MT, that is currently imported from China. At 2000MT Stevia extract production capacity, Arboreal will benefit over 5000 smallholder farmer families. Stevia is cultivated on sandy loam Soil and requires 1/10th the amount of land and 1/30th the amount of water to produce the same volume of sweetness as Sugarcane. As such, it is an environment friendly cash crop, that can free up land for other food crops.

Project achievements:

a. **Progress vis-a vis objectives:** Identified the right combination of naturally occurring enzymes and glucose donors that is leading to the bioconversion of more than 90% of the Steviol glycosides used in the process into higher glycosides.

b. **Technology/Product (to be) developed:** The technical feasibility of the bioconversion process on a lab scale has been established. Currently working on optimising the process parameters to improve the yield

c. **IP generated/ Potential for IP generation:** Identified a unique combination of naturally occurring enzymes to catalyse the process that will be looking to get patented.

d. **Resources Generated:** setup a small scale lab that can be used to conduct other bioconversion experiments in future too.

Plans to take innovation further:
Once the process parameters are optimised and the feasibility on pilot scale is established, process will be scaled up and commercial production will be started and marketing of EMS extracts in and outside India.

Risks envisaged:
While EMS extracts are being used as a sweetener in food and beverage products in many other countries including US, Japan, Korea etc. for the past many years, FSSAI still has not given its approval.

Project Coordinator:
Swati Pandey

Team Members :
Manish Chauhan; D. C. Jain; Tejas Tanmay; Suresh Chander; Amit Pratush

Contact :
Biotech Park Sector G, Jankipuram Kursi Road Lucknow 226021

Aspartika Biotech Pvt. Ltd.

Title of the Proposal:
Production and Commercialization of Omega 3 Fatty Acids based products and nutraceuticals using Supercritical Fluid Extraction Technology

Brief description:
The company has developed a novel supercritical fluid extraction technology of producing omega 3 fatty acid from silkworm pupae discarded from silk reeling industries. The omega 3 fatty acid has been used to develop poultry feed supplement for the egg layer industries to produce Nutritive or Designer Eggs. The leftover cake after extraction is a rich source of silk protein which has been used to develop growth promoters for poultry and aqua industries.

Current stage of development:
Commercialization

a) Commercialized in the name of (Product/Technology Name): Silkworm pupa oil (Omega 3 Fatty Acids, YeggMore Omega, Growthmin Aqua & Asprogrow)

b) Date of commercial Launch: 2018

c) Number of units sold: 10

d) Number of end users: 125

Innovative Element(s):
Indigenous made technology which is chemical free & odourless. Novel source of omega 3 fatty acid which is 50% cheaper and 10% richer in omega 3 fatty acid content compared to the common marine sources. The process used for extraction is a complete clean and green technology focused on waste reclamation, where, even the left over cake after extraction is used further to develop products

National/Societal relevance:
India is the second largest producer of silk with an annual raw silk production of 33,000 MT per annum. Sericulture is practiced in 52,360 villages in India and provides employment opportunity to about 7.6 million people in India. Silkworm pupae accounts for 80% of the total raw silk produced. This silkworm pupa is cheaply discarded (due to its bad odor) and becomes an environmental hazard. If this waste is effectively utilized it can completely meet the Omega-3-fatty acid requirement (RDA) of 78 lakh children or 26 lakhs pregnant women/lactating mothers

Project achievements:

a. **Progress vis-a vis objectives:** Commercialization Strategy for Close to Market Products. Inputs on GMP manufacturing to scale up production. Establish commercial/strategic partnerships & Assistance in achieving long term financial milestones

b. **Technology/Product (to be) developed:** Supercritical fluid extract of Silkworm pupa oil comprising min 40% Omega 3 Fatty Acids, purified form, No chemicals and odorless; De-oiled Protein rich cake: Poultry & aqua feed supplement for growth promotion. Novel Products developed: YeggMore Omega; Asprogrow and Growthmin Aqua: Silk Protein enriched aqua feed supplement

c. **IP generated/ Potential for IP generation:** Patents applied: 3965/CHE/2015

d. **Resources Generated:** Facility created: R&D facility: DSIR-SIRO certified; Production facility: WHO-GMP, ISO 9001:2015, AYUSH-GMP and KSPCB-CFO approved; Manpower: Indirect: 154 farmers trained on hygienic processing of silkworm pupae; Other manpower: 06

Plans to take innovation further:
Strategic partnership for export marketing and commercialization of Omega 3 Fatty Acids and YeggMore Omega

Risks envisaged:
None

Project Coordinator:
Srinivas B V

Team Members :
Priyanka R; Amish Noah

Contact :
Dodballapura Integrated Textile Park Ltd, SW-51, Dodballapura Industrial Area, Apparel Park, Bangalore-561203

CFTRI, Mysore

Title of the Proposal:
Sustainable and cost effective production of stable anthocyanin in Saccharomyces cerevisiae by synthetic biology approach

Brief description:
Anthocyanin is a natural colorant which also imparts health benefits. They are increasingly used in the food and beverage industry as natural alternative to artificial colorants. The production of anthocyanin in yeast is attractive alternative to plants to avoid seasonal fluctuations and degradation of the compounds due to presence of other phenolic compounds.
Current stage of development: Proof-of-Concept

Innovative Element(s):
The project has focused on using specific plants anthocyanin genes which has been optimized for rapid conversion of precursors for production of anthocyanin in yeast

Market Potential:
Anthocyanin Market size was worth USD 318 million in 2019 and is expected to grow at a compound annual rate of 4.6%, to reach USD 388 million in 2024. Due to consumer awareness its use in food and cosmetic industries has increased.

National/Societal relevance:
Production of anthocyanins by microbial cell cultures has been suggested as a feasible technology that has attracted considerable industrial and academic interest in the last two decades. This if established will definitely have an impact on national and as well in the global market. And, most importantly, as it is an eco-friendly method of production of ACNs would result in huge social and environmental impact

Project achievements:

a. **Progress vis-a vis objectives:** Multi-gene expression system of anthocyanin biosynthetic in yeast has been carried out and three important genes from plants has been transformed in yeast. Production of precursors and anthocyanin has been done however stabilization by addition of one more gene needs to be carried out. Bioreactor studies for production of anthocyanin will be initiated soon.

b. **Technology/Product (to be) developed:** Development of constructs in yeast for production of anthocyanin

c. **IP generated/ Potential for IP generation:** The knowledge on development of yeast model which can produce anthocyanin can be patented

d. **Resources Generated:** One Research Associate and one project assistant was trained in the project.

Plans to take innovation further:
Joint project with industry for scale up studies

Risks envisaged:
The stability of anthocyanin in yeast could challenge due to yeast enzymes and also could be considered as GMO

Project Coordinator:
Nandini Prasad Shetty

Team Members :
Poornima Priyadarshini; Bijesh

Contact :
CFTRI, Mysore, Plant cell biotechnology MYSORE KARNATAKA India-5700020

Chemlife Innovations Pvt. Ltd.

Title of the Proposal:
Unconventional fermentation of grain byproducts to produce natural mould inhibitors

Brief Description:
Unhygienic and improper storage conditions result in mould infestation in animal feed ingredients which manifests in mycotoxin contamination. Mycotoxins like T-2 toxin, aflatoxin, ochratoxin etc affect growth and health of the animal, farm produce and the consumer. The novel product under development is made from agricultural by-products like wheat bran, rice bran etc through a proprietory ANBioT technology which involves pre-treatment in NADES medium followed by saccharification and fermentation, for effectively controlling mould formation and growth. The use also ensures feed safety and hygiene along with positive impact on animal health and minimisation of feed wastage.

Current Stage of Development:
Proof-of-Concept

Innovative Element(s): Use of Eutectic solvent containing for pre-treatment and as a medium with reduced water content for subsequent steps of hydrolysis and fermentation. The resulting product provides twin use of mould inhibition and liver stimulation activities for mycotoxin detoxification.

Market Potential:
Market potential India: INR 200 Crores; Market potential Global: INR 1400 crores. Kemin, Cargill, Alltech, Borregaard, Adisseao are the competitors.

National/Societal Relevance: Feed hygiene, Mold growth and Mycotoxin contamination and Farm produce quality are specific challenges that we are addressing from India point of view.

Project Achievements:

a. **Progress vis-a vis objectives:** Composition of NADES is finalized, pre-treatment work is completed and at present working on hydrolysis phase. Once this stage is standardized, They will move to final stage of fermentation.

b. **Technology/Product (to be) developed:** Mold inhibitor product focussing on Feed hygiene, Time to enter the market: 2 years

c. **IP generated/ Potential for IP generation:** Applied for provisional patent

d. **Resources Generated:** They have hired two research associates for the project and trained on various biotechnological & analytical skills. Have created dedicated bench space & equipment to carry out the project work.

Plans to take innovation further: Scale up:
Utilisation Outsourced manufacturing facility; Sales Marketing : Wish to do co-branding in partnership with feed additive manufacturing companies.

Risks Envisaged:
Quantitative conversions of all carbohydrates present in wheat bran into required organic acids may not happen. The effort is towards maximizing the bio-transformation.

Project Coordinator:
Sharadamma K C

Team Members :
Sharadamma K C;
Radhakrishna P M;
Nayana B; Megha G D;
Balaji R; Ajay Kumar

Contact :
25, DITPL, Apparel Park,
KIADB Industrial Area
Doddaballapur Bangalore Rural
KARNATAKA India-561203

Clensta International Pvt. Ltd.

Title of The Proposal:
Biosurfactant Based Toothpaste Safe to Swallow

Brief Description:
To address the oral hygiene accessibility for people with limited or lack of access to water, a toothpaste is being prepared that can be used without water. Importantly, the product would be free of synthetic surfactant, alcohol, fluoride, and other harmful preservatives.

Current Stage of Development:
Commercialization

Date of commercial Launch:
2021-03-31

Innovative Element(s):
Composed of biosurfactant, safe to swallow, safe for long term usage, safe for kids, clinically tested for oral hygiene safety without water

Market Potential:
Growing awareness among people regarding oral hygiene and the increasing incidence of dental caries has led to the high growth of the market. The global oral care market is anticipated to reach USD 40.92 billion by 2025, according to a new report by Grand View Research, Inc.

National/Societal Relevance:
The Clensta Toothpaste would not only provide the oral hygiene to everyone and everywhere but also save the water. The beauty of the toothpaste would be that people can clean and maintain the oral hygiene without any use of water. The product would be safe for pregnant women and child. Because, periodontal disease is actually a risk factor for giving birth to preterm, low-weight babies. Also, dental caries is still a major oral health problem in most industrialized countries, affecting 60-90[0] of schoolchildren and the vast majority of adults and elders.

Project Achievements

a. **Progress vis-a vis objectives:** Achieved all the milestones

b. **Technology/Product (to be) developed:** Hygiene product

c. **IP generated/ Potential for IP generation:** None

d. **Resources Generated:** Several employees will be generated in the future

Plans to take innovation further:
B2B & B2C Platforms

Risks Envisaged:
The risk factors of the company include the patent infringement. If the ingredients are used beyond this range, the product will not provide the desired efficacy and stability. Also, the technology being new and innovative, people are unaware of the technology but with proper branding and marketing, this challenge can be overcome.

Project Coordinator:
Vinay Kumar

Team Members :
Vinay Kumar; Puneet Gupta;
Ankita Arora; Suman;
Atul Singh; Anurag; Ankit

Contact :
TBIU, Unit-12, DBEB, Indian
Institute of Technology Delhi,
NEW DELHI 110016

Coimbatore Institute of Technology

Title of The Proposal:
Novel design of a one pot reactor for biodiesel production bypassing lipid extraction by complete utilisation of sericulture waste

Brief Description:
The primary objective of this project is to employ sericulture waste as feedstock for biodiesel production. An exclusively designed one-pot reactor along with the application of activated feedstock as catalyst will help contract the complexity of the process.

Current Stage of Development:
Validation

Innovative Element(s):
Mineral content in the chrysalis mainly consists of potassium, magnesium and phosphorous. This can be activated and used as self-catalyst for transesterification process. An exclusive one-pot reactor that simplifies multi-stage biodiesel production process into a single stage is designed, to be operated by unskilled labours at reeling units.

Market Potential:
The idea of using a self-catalyst and the reactor designed can be patented generating an indirect revenue. The products of this process, namely, biodiesel, glycerol and biofertilizer produced with the marc can be marketed. Consultancy partnerships with the spin-off companies can help generate indirect revenue.

National/Societal Relevance:
Viewing the existing production of biodiesel and the projected biodiesel production quantity, various feedstock for biodiesel production is to be explored. This project introduces desilked silkworm pupae waste as a potential feedstock for biofuel production and also methodizes a single-stage process for easier biodiesel production.

Project Achievements:

a. **Progress vis-a vis objectives:** The first milestone of the project, namely, cost analysis of biodiesel production from silkworm pupae using conventional catalyst is under progress. It will be achieved by the end of March 2021.

b. **Technology/Product (to be) developed:** An exclusive one-pot reactor for biodiesel production from sericulture waste with ease of operation, use of self-catalyst and efficient down-streaming process will be fabricated. This, with its process optimization, will be completed by September 2021.

c. **IP generated/ Potential for IP generation:** An IP can be applied for the following claims:

   1. Use of the desilked silkworm waste as a feedstock for biodiesel production

   2. Wherein, part of the waste, namely, chrysalis can be activated to be used as a catalyst

   3. Wherein, the feedstock is to be processed in a single step one-pot reactor designed in particular for this purpose.

d. **Resources Generated:** Two project assistants have been recruited under this project, and they have been carrying out research since January 2021The reactor proposed has been designed, and prototype fabrication is under progress.

Plans to take innovation further:
Partnerships ventures with Central or State Silk Boards and subsequent spin-offs with private reeling units may be carried out in the future.

Risks Envisaged:
A factor of concern associated with this project is the promotion of this idea and creating awareness on the use of biodiesel among the producers and consumers.

Project Coordinator:
M. Thirumarimurugan

Team Members :
Dhivya Priya N., Yuvaraj M; Nivedhithalakshmi V; Vijayakumar V.

Contact :
Civil Aerodome Post, Avinashi Road Coimbatore TAMIL NADU India-641014

College of Temperate Sericulture

Collaborator Name: Aspartika Biotech Pvt Ltd, Bengaluru

Title of the Proposal:
Conversion of the silkworm, Bombyx mori droppings into value added products in Jammu and Kashmir.

Brief Description:
The major aim of the project is to utilize the silkworm excreta discarded in the silkworm rearing houses of Jammu and Kashmir and to produce value added products. Through this project, they propose an alternative approach of developing high value products enriched with the bioactives from the excreta through supercritical fluid extraction.

Current Stage of Development:
Proof-of-Concept

Innovative Element(s):
Extraction of high-value active ingredients like 1 DNJ, GABA, Phytosterols etc using supercritical CO2 extraction has never been explored in the prior art Remnants after extraction to be used for agricultural applications.

Market Potential:
Few companies at a national and international level are producing Green Tea comprising of 1 DNJ and GABA from organically grown Mulberry leaves for nutraceutical applications 1 DNJ is being produced through expensive methods like Fermentation of Bacillus subtilis etc. the yield obtained through such techniques are minuscule compared the abundantly available silkworm litter.

National/Societal Relevance:
In Jammu and Kashmir around 22000 farmers are dependent on sericulture as their only source of livelihood and 4 lakh man-days are dedicated to this industry. The process of silkworm rearing produces excreta on a daily basis in large quantities as 60 per cent of the ingested food is excreted by the worms.

Project Achievements:

a. **Progress vis-a vis objectives:** The initial objective was to obtain the sterile silkworm litter which is completed and further process of extraction is ongoing to extract the bioactive components.

b. **Technology/Product (to be) developed:** Extraction of bioactive from the waste discarded silkworm litter using a novel technology of Supercritical fluid extraction unit. These bioactive have applications in human health care. Utilization of the residue after extraction in various fields as source of nitrogen.

c. **IP generated/ Potential for IP generation:** Indian patent has been filed with industry partner Aspartika Biotech Pvt Ltd

d. **Resources Generated:** 2 direct employment has been generated and approximately 100 sericulture farmers are indirectly employed in the project. The institute was capable to create the facility to obtain the sterile silkworm litter to the collaborating institute to extract the bioactives.

Plans to take innovation further :
To establish a similar facility available with the collaborator in Jammu and Kashmir and utilize the available by-products from sericulture industry for extracting bioactive components.

Risks Envisaged:
Currently, there are no risks. In future challenges would be with competitors.

Project Coordinator:
Aabid Khaliq Tantray

Team Members :
M F Baqual, K A Sahaf, Z H Rufaie

Contact :
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CSIR-National Institute for interdisciplinary Science

Title of The Proposal:
Valorization of spent turmeric/amla: Process development for antioxidant dietary fibre enriched products as metabolic enhancers

Brief Description:
The study focus on process optimization of extraction of resistant starch and bioactives, chemical/biochemical finger printing in comparison to fresh turmeric and in vitro & in vivo metabolic enhancing activities and prebiotic properties.

Current Stage of Development:
Validation

Innovative Element(s):
Prebiotic dietary fibre from spent turmeric

Market Potential (with India & abroad):
Agri/food/Spice/Nutraceutical industries generate a large volume of spent materials which are often rich source of bioactive phytochemicals and dietary fibre. Valorization of spent materials/byproducts for food and feed applications are gaining lot of attention in the past few decades. Industrialists are now aware of the benefits of deriving potentially marketable high value components such as proteins, polysaccharides, fibers, flavor compounds, and phytochemicals present in foods wastes and co-products Laufenberg et al. 2003 . National/Societal Relevance: Metabolic syndromes, represents a cluster of risk factors identifying subjects at a high risk of developing obesity, type 2 diabetes and cardiovascular problems. It is estimated that by 2020, diabetes and CVD will be the largest cause of disability and death in India. Globally, India ranks second after China in the incidence of Diabetes.

Project Achievements:

a. **Progress vis-a vis objectives:** Comparison studies of bioactives using LC-MS/MS completed which indicated consistency of key components from various batches. In vitro cell culture studies on various marker and signalling pathways and acute toxicity study is completed. The product is non toxic for 2000mg/kg. Antidiabetic study started with a dosage of 500 mg/kg in rats. First level in vivo studies completed, analysis are ongoing. Ethical clearance for the second level in vivo studies obtained

b. **Technology/Product (to be) developed:** Process for dietary fibre enriched products as metabolic enhancers for addressing metabolic syndrome by dietary intervention

c. **IP generated/ Potential for IP generation:** Process for dietary fibre enriched products as metabolic enhancers for addressing metabolic syndrome by dietary intervention

d. **Resources Generated:** Two projects assistants were involved in the project

Plans to take innovation further:
Scale up the process in collaboration with industry

Risks Envisaged:
The existing competition in the market.

Project Coordinator:
P Nisha

Team Members :
Merina Benny

Contact :
Industrial Estate
Pappanamcode CSIR- NIIST
Trivandrum KERALA
India-695019

Devlina Das

Title of the Proposal:
Flocco- An Organic Flocculation System

Brief description:
Flocco' is an organic flocculant formulation made of chitosan and plant gum which is used for the remediation of wastewater or drinking water. Being 100% organic in nature, it has been developed to be a suitable alternative to polyacrylamide which is a neurotoxin, yet being pursued as a water treatment agent.

Current stage of development:
Validation

Innovative Element(s):
Chitosan has been uniquely designed with plant gum and marine clay as a water treatment and fortification agent. The uniqueness lies in the multiple forms in which this formulation can be used.

Market Potential:
The Fortification strips though has a potential in India, especially targeting the low income groups. Chitosan flocculant has a huge market potential as a water treatment agent in Europe and Britain.

National/Societal relevance:
Pure water free from pollutants is important, as there is a strong correlation between the immunity developed and the pollutants in water. This demands to use a water treatment system free of synthetic polymers. Chitosan based flocculant or tablet can have a national and societal relevance specially if it can be tested on the virus removal efficiency.

Project achievements:

a. **Progress vis-a vis objectives:** A flocculant formulation comprising of, plant gum was developed and successfully applied on sewage wastewater unit in Coimbatore. Montmorillonite was discovered as a surface active agent to accelerate the flocculation process, together resulting the trademark B-Clay technology. The formulation worked best in STP, but was also tested for grease contaminated wastewater from watch manufacturing units like Titan. Pilot scale testing of flocculant was conducted up to 100 L in Salem district on Arsenic contaminated wastewater. For specific treatment of drinking water, a product Purvital Minis was developed which comprised of a B-Clay biopolymer tablet (works on the principle of adsorption), which had a biopolymer casein shell around it, fortified with vitamins.

b. **Technology/Product (to be) developed:** The product was developed as Flocculant Powder and Water Treatment and Fortification System

c. **IP generated/ Potential for IP generation:** Three patents have been filed. Flocculant for Sewage Water Treatment Application No. 201841016111; Ferric Activated Arsenic Filter Application No. 201841028681; Water purification tablets with Biopolymer Shell Application No. 201941035086

d. **Resources Generated - Number of people employed:** 2; Trained in biopolymer and colloid chemistry. Funding received from European Union for studying flocculation mechanism on microplastic remediation from ocean

Plans to take innovation further:
Planning for developing the flocculation system as a sensor towards microplastic remediation. The product Purvital minis (developed using flocco and trademarked as a B-Clay technology) would be communicated to different food sectors for a technology transfer

Risks envisaged:
The current market of flocculants in India is such that polyacrylamide is the major key player. Chitosan is disruptive but cost is the major factor for replacing it. Hence the best formulation is still under research, which could beat the synthetic polymer in price and availability both

Project Coordinator:
Devlina Das

Team Members :
V. Ramamurthy

Contact :
Department of Biotechnology,
PSG College of Technology
Coimbatore, 9600483644

Fermentech GSV Private Limited

Title of the proposal:
De-regulated expression of CodY controlled proteins in Lactococcus lactis for enhancing nisin production using CRISPR/Cas9 genome editing

Brief Description:
GSV 234 is a potent anti-bacterial and produced by natural fermentation activity of lantibiotics producing lactic acid bacteria. Food industries can use it with the possibility of getting clean labelling and natural tag for extending shelf life of many milk products, beverages like processed coconut water and Indian specialties like Kolkata Rasagulla etc.

Current Stage of Development:
Proof-of-Concept

Innovative Element(s):
The project has used food grade synthetic biology methods to enhance the specific productivity of nisin.

Market Potential:
The market for preservatives in India and abroad is poised towards natural molecules. Currently, the market in India is dominated by brands like Amul, Go cheese and new processed natural beverages like coconut water, neera water etc

National/Societal Relevance:
Food processing in India has ambitious targets. From Cold Chain to preservation, we need to have domestic products and technologies. GSV 234 will certainly fill the gap in natural food preservatives.

Project Achievements

a. **Progress vis-a vis objectives:** Strain and bio-process development is successfully carried out and pilot testing in industrial settings is next step

b. **Technology/Product (to be) developed:** GSV 234, Nisin ferment

c. **IP generated/ Potential for IP generation:** Patents in drafting stage

d. **Resources Generated:** Two resources were trained in bio-process development

Plans to take innovation further:
Pilot testing planned in commercial facility, IIFPT has invited for collaboration in applications of nisin, especially in Nerra water

Risks Envisaged:
Nisin Imports from china and very cheap nature of sodium benzoate

Project Coordinator:
G. R. Gopi

Team Members :
P. Sathyavrathan;
Swathy Meera; R. Premkumar;
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Flycatcher Technologies LLP

Title of the Proposal:
Zero Landfill Community with the Rhino Digester System

Brief Description:
Rhino Digester System converts food waste into immediately usable fuel gas and organic fertilizer. It is compact, easy to use, odor and pest free and operated by kitchen staff. Users enjoy an easy to use method to dispose their bio-degradable waste in compliance with the Solid Waste Management Rules 2016.

Current Stage of Development:
Commercialization; Date of commercial Launch 2017-05-01

Innovative Element(s):
Patented method for circulation and gas generation measurement. This eliminates expensive and high maintenance components and minimizes chances of a breakdown

Market Potential:
The number of potential users in the restaurant and hotel industry is estimated to be 500,000 with a market size of about ?5,000 crore in India. The technology can be extended for use in residential, canteens, temples, food processing and agricultural sectors and hence a conservative estimated market size is of 20,000 crore in India.

National/Societal Relevance:
Processing bio-degradable waste is a significant global challenge and one of the primary objectives of the Swatchh Bharat Mission. Our current practice of dumping waste in landfill is causing serious environmental damage and is also a breading grounds for infectious diseases such as the plague and cholera.

Project Achievements:

a. **Progress vis-a vis objectives:** Manufacturing and installation of Rhino Digesters is in line with objectives.

b. **Technology/Product (to be) developed:** Technology platform

c. **IP generated/ Potential for IP generation:** Patent Number: 295520 Application Number: 201721007670 Title: System and method for liquid circulation and gas generation measurement

d. **Resources Generated:** Production facility with 5 nos. technicians Engineering design and development; Technical service and installation capabilities; Administration and business development

Plans to take innovation further:
Franchisee model

Risks Envisaged:
Policy changes that facilitate dumping of waste

Project Coordinator:
Kabir J. Udeshi

Team Members :
Richard Dias;
Pravin Nizama;
Archana Totekar; Rudresh
Satarkar; Pravin Parmar

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Fuma Labs Pvt. Ltd.

Title of The Proposal:
To demonstrate proof of concept for improvised structural and economic performance of crop residue driven engineered wood particle boards, MDF etc. using a formaldehyde free adhesive

Brief Description:
500 million tonnes of crop waste is generated in India every year.16% of this is being burnt which releases millions of tonnes of CO2 into the atmosphere. This waste is being used to create value-added products for furniture applications.

Current Stage of Development:
Validation

Innovative Element(s):
One of the major issues in the engineered boards industry is the usage of formaldehyde which is carcinogenic. The board being prepared is formaldehyde-free and has superior properties as compared to the existing commercial boards in India.

Market Potential (with India & abroad):
90 percent of India's 4 Billion USD market is plywood and the rest is particle boards and MDF Boards. This is in contrast to the world's average of 80% market share of particle boards and MDF Boards. The trends in India are also changing with increased environmental awareness. Increase in urbanization and infrastructure growth will lead to the high demand for these boards for construction and furniture applications.

National/Societal Relevance:
This products tackle the issue of crop burning by converting the waste into value added products. India is a timber deficit country and usage of crop waste for furniture will boost the local economy, help the farmers and also reduce the dependence on imports.

Project Achievements:

a. **Progress vis-a vis objectives:** Patent Pending blending technology, Grade 2 Particle Board Certified by NABL lab

b. **Technology/Product (to be) developed:** Grade 1 Particle Board under progress

c. **IP generated/ Potential for IP generation:** Patent has been filled.

d. **Resources Generated:** Team of 7 people. The lab is at Venture Center Pune.

Plans to take innovation further:
Setup 10,000 CBM facility and partnering with furniture companies.

Project Coordinator:
Shubham Singh

Team Members :
Himansha Singh; Amol B Ichake; Onkar Siddheswar; Pratik Kokil; Abhishek Dhobe

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Gennova Biopharmaceuticals Ltd.

Title of the Proposal:
Development of recombinant E. coli L-asparaginase and a lyophilised formulation of polyethylene glycol-conjugated recombinant E. coli L-asparaginase for the treatment of acute lymphoblastic leukemia, ALL, in Indian patients.

Brief Description:

The aim is to provide a cost-effective, sustainable, quality-assured access to the essential biotherapeutic in the treatment of ALL. Gennova has completed the developmental and scale-up work and has started the preclinical toxicity studies for both the products. After completing the clinical trials, this made in India product will cater to the need of the Indian population and have the potential to generate FOREX with global exports.

Current Stage of Development:
Validation

Innovative Element(s):
Recombinant asparaginase is heterologously expressed in a proprietary novel cell-line, created by deleting endogenous asparaginase, such that there is no contamination of endogenous asparaginase in the final product. Additionally, Gennova has developed a novel formulation of the long-acting version to suit the Indian weather conditions.

Market Potential:
Market research reports an ever-growing market for asparaginase. One of the reports mentioned that the market for asparaginase is nearly $390 million in 2018 and will reach $420 million by 2025. Approximately 300,000 cases of leukemia are diagnosed worldwide. This epidemiology is pretty lucrative and sustainable for an orphan drug.

National/Societal Relevance:
Approximately 25,000 acute lymphoblastic leukemia-ALL cases are diagnosed in India every year, of which 15,000 are in those below 15 years of age.

Project Achievements:

a. **Progress vis-a vis objectives:** Gennova is near completion of process development to produce recombinant asparaginase and its long-acting version at 5L scale and is currently conducting the products preclinical toxicity studies.

b. **Technology/Product (to be) developed:** Upon completion of preclinical toxicity studies, Gennova will start clinical trials of both the products in 2021. It is estimated to commercialize recombinant asparaginase in 2022 and launch the long-acting version in 2023.

c. **IP generated/ Potential for IP generation:** Process and product patents have either been filed or are in the process of being filed

d. **Resources Generated:** Gennovas analytical development laboratory was augmented with HPLC with MS detector. A couple of MSc students were trained during their masters project and later employed at Gennova to continue work on this project.

Plans to take innovation further.(for e.g Partnership):
Gennova has no plans to license out the technology. Gennova, however, is ready to enter into a supply agreement with local marketing partners in various geographies to market these two indigenous products.

Risks Envisaged:
In addition to the competition from Servier the innovator, a clear understanding of the regulatory and clinical path in various geographical regions poses a barrier to enter different markets.

Project Coordinator:
Tathagata Mukherjee

Team Members :
Praveen Agarwal; Swarnendu Kaviraj; Amit Saraf;Arjun Singh Raghuwanshi; Laxman Savargave; Ritu Singh;

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I.T.-B.T. Park (P1) MIDC,
Hinjwadi Pune MAHARASHTRA
India-411507

GPS Renewables Pvt. Ltd.

Title of the Proposal:
High rate biomethanation of 2 tonnes per day installed capacity processing organic fraction of municipal solid waste to generate power

Brief description:
BioUrja, has enabled setting up and running a biogas plant in 1/3rd the area, by using 1/10th the water and improving economic returns by generating almost double the biogas as compared to traditional biogas plants. All this, with ease of operations and maintenance has led to easier adoption by clients. Its remote monitoring system and automated biohealth check process, has enabled clients with no technical background too, to operate a biogas plant with ease.

Current stage of development:
Commercialization

Innovative Element(s):
Complete supervision of the health including acidity and alkalinity via automatic health measurement device. Automated heating system to maintain temperature of the digester in the range 38-41°C. Proprietary gas management system enables monitoring of quantity of biogas generated, reduced area requirement for storage and good cooking experience due to optimum pressure.

Market Potential
Based on the technology and product we can address both small scale i.e. 100KPD as well as centralized large scale units. Besides that given the international focus on carbon neutrality, biomethanation technology has high potential across the globe.

National/Societal relevance:
Urban India due to the dense population and limited space availability, is grappling with waste management problems. The technology will provide a compact, minimal land and resource foot print solution which is financially viable and environmentally beneficial. The SATAT scheme and Swachh Bharat Abhiyaan initiative, further highlight the need of having a huge focus on the biogas technology and waste management.

Project achievements:

a. **Progress vis-a vis objectives:** The project is under installation which is expected to be completed by end of February. After this the project inoculation would be done and the feeding of OFMSW will be started.

b. **Technology/Product (to be) developed:** BioUrja is an existing product, thus no new product will be developed as part of this scale-up project.

c. **IP generated/ Potential for IP generation:** No new IP is expected to be generated in the project

d. **Resources Generated:** A 2TPD Biogas plant based on Organic fraction of MSW as a feedstock will be setup. The project will employ two labour. The project will generate about 300 units of power per day at peak loading.

Plans to take innovation further:
GPS is in the process of raising series B round, forming strategic partnerships with ULB & leading waste management companies.

Risks envisaged:
The SWM Rules need to be implemented stringently.

Project Coordinator:
Swati Aggarwal

Team Members :
Rakesh Menon, Praveen S

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Old Airport Road Domlur
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India-560008

Hi Tech Biosciences India Ltd.

Collaborator Name: Indian Institute of Science, Banglore

Title of the Proposal:
Engineering of a microbial host for biocatalytic synthesis of a steroid drug intermediate

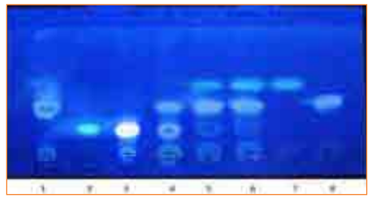
Brief Description:
This project is built on the on-going collaborative effort to produce progesterone from phytosterol using specifically modified enzymes. The specific goal of this project is the identification of a suitable host that is sufficiently robust for efficient biotransformation at high substrate and solvent concentrations at the commercial scale.

Current Stage of Development:
Proof of concept

Innovative Element(s):
This project is built on HTBLs experience in developing biotransformation processes, and expertise in B. Gopal's laboratory in the field of protein engineering/structural biology and handling the Mycobacterial systems.

Market Potential:
Global market for steroid drugs is US $10 billion annually. India supplies 20 percent of global generic medicines market exports, in terms of volume, making country the largest provider of generic medicines globally and expected to expand even further in coming years.

National/Societal Relevance:
Indian steroid industry currently uses semi-synthetic process for the production of steroids. This involves chemical conversion of a steroidal sapogenin called diosgenin which is extracted from the tubers of the plant called Dioscorea.



Project Achievements:

a. **Progress vis-a vis objectives:** Co-expression of AlkL gene: All objectives of the current phase were acheived with no deviations from the approved work-plan.

b. **Technology/Product (to be) developed:** Microbial host for bioconversion of phytosterol to pregnenolone.

c. **IP generated/ Potential for IP generation:** None

d. **Resources Generated:** Two personnel are employed in the project at the site of the academic and industry partner.

Plans to take innovation further:
Have been in contact with a leading bulk steroid manufacturer to take this technology to the next level.

Risks Envisaged:
This can be estimated after the current phase scale up progresses to the bulk manufacture level.

Project Coordinator:
Raghavendra P.
Gaikaiwari

Team Members :
B. Gopal, Vaishali Subhedar-
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Kurhade, Nishank Reddy;,
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MAHARASHTRA India-411038

Himedia Laboratories Pvt. Ltd.

Title of the Proposal:
Development of cost effective production technology for production of microbial hydrocolloids for biotechnology application

Brief description:
After establishing the PoC using mutants of Sphingomonas trueperi a yield of 17-25g/L native gellan-gum through multiple batches of 10L bioreactor-level was demonstrated. One strain yielded high acylated Gellan-gum and another, the low acylated and were effectively extracted and purified through optimization of downstream-processing ways.

Current stage of development:
Validation

Innovative Element(s):
First in India to consider indigenous manufacture and commercialization of Gellan-gum, first to report gellan-gum from Sphingomonas trueperi, developed DSP for extracting both acylated and less acylated gellan-gum in significant amounts.

Market Potential:
Currently, Gellan gum is solely dependent on Imports. C.P. Kelco, DSM, H, and A Canada, Zhengzhou Cinogel Biotech are key global manufacturers.

The global market for gellan-gum was US$ 171.5 million in 2019, which is likely to increase at 11.8 CAGR to reach US$ 416 million by 2027.

National/Societal relevance:
The development of indigenous technology of gellan gum production using novel strain had a major impact on Import substitution and revenue generation.

-Being a microbial fermentation product, it is a uniform, independent substitute for solidifying agents and traditional agar which otherwise has a negative impact on marine habitat.

Project achievements:

a. **Progress vis-a vis objectives:** 1. Established 10L level fermentation process for two mutants of Sphingomonas sp. yielding HA & LA gellan-gum ~25g/L.

   2. Established downstream process for isolation and purification. Completely characterized the gellan gum

b. **Technology/Product (to be) developed:** Developed upstream and down-stream processes for the production of HA & LA Gellan gum from 2 Sphingomonas strains to pre-pilot level

c. **IP generated/ Potential for IP generation:** New process patent filed

   for viscous polysaccharide production from Microorganisms

d. **Resources Generated-** An upstream and downstream facility established for 10L level bioreactors, 2 manpower employed, Upstream down-stream facility has been made available for training/visit for PG and UG students on a request basis.

Plans to take innovation further:
Plant to set up pilot scale at 100-500 L at Ambernath facility followed by commercial set-up through soft-loans from DBT and in-house funding.

Risks envisaged:
Stability of mutants at pilot level, Scale-up need more optimization studies, heavy capital investment.

Project Coordinator:
Rahul G Warke

Team Members :
Girish B Mahajan, Tanuja A Patil, Rachana C Dalvi, Milan R Satardekar, Manoj J Dev

Contact :
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Indian Institute of Technology, Roorkee

Title of the Proposal:
Development of ready to go culture strips for fermented dairy products

Brief description:
The present proposal involves an integration of the lactic acid bacteria in a food grade edible strip a thin layered structures of biopolymer composition to develop the desired fermented dairy products. The edible strip will be used as a carrier for the delivery of several bioactive compounds e.g. vitamins, antioxidants and Lactobacillus strains in to the target food system.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The proposed strip offers advantage that the there is no step involving freezing and thawing of cells. Therefore the strip offers higher viable count. The strip can be easily packed and used directly by inoculating in milk.

Market Potential:
The global starter cultures market size is estimated to be valued at USD 1.0 billion in 2020 and is projected to reach USD 1.3 billion by 2025, recording a CAGR of 5.3%, in terms of value. Most of these starter cultures are commercially sold by dairy giants such as Chr. Hansen.

National/Societal relevance:
The development of this product carries huge national importance as curd is an indigenous product prepared in every home in our country. Around 7% of market milk is converted to curd for domestic usage but has no defined microflora.

Project achievements:

a. **Progress vis-a vis objectives:** Prepared and optimized edible culture strip loaded with lactic acid bacteria. Characterized the films in terms of stability of lactic acid bacteria and shelf life etc.

b. **Technology/Product (to be) developed:** Edible strips with various starter culture bacteria for easy and reproducible fermented milk products like Dahi, Lassi and yogurt formation.

c. **IP generated/ Potential for IP generation:** NA

d. **Resources Generated:** Training of one MSc Student, one project staff. Procurement of a K-control coater for making films in the department.

Plans to take innovation further:
In discussions with one company based in Maharashtra for use of edible strip formulation as animal feed additives.

Risks envisaged:
product shall have to compete with established dairy giants like Chris-Henson etc.

Project Coordinator:
Naveen Kumar Navani

Team Members :
Anupama Semwal, Arun Beniwal, Shahnawaz A Baba

Contact :
Indian Institute of Technology Roorkee IIT Roorkee UTTARANCHAL India-247667

Indian Rubber Manufacturers Research Association

Title of the Proposal:
Novel application of guar gum based sealant for leak proofing structures

Brief description:
The synthetic petroleum based sealants are toxic to environment and treatment with these products does not last for long time. The proposed guar gum based leak fixation solution is natural and will consists of guar gum, natural latex, one or more natural oil, minerals, natural gum, starch and fibers from agro biomass.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The sealant for tyre puncture is already developed. The area of application for leak proofing is being explored.

Market Potential:
Different types of sealants are commercially available in the market. However, the problem with them is non-renewable source of raw material, toxicity like skin burns to the ecosystem. The applicant has developed eco-friendly, environmentally sustainable material based on the guar gum and other naturally available ingredients.

National/Societal relevance:
There is a huge demand for the development of bio-based sealants as an alternative to the petroleum based synthesized currently used sealants to maintain the eco-system and environmental sustainability. A large amount of guar gum is used as a binder, thickener and fixing agent for enamels, porcelain in ceramic industry which triggers the invention to use this bio-material for this application. So, diversification of guar gum based products application will create a lot of opportunities for development guar growers farmers, guar gum manufacturers in India.

Project achievements:

a. **Progress vis-a vis objectives:** Project Fellow Recruitment, material and instruments arrangement has already been done. Some small scale trial is started to obtain the modified guar gum with required viscosity for sealant application.

b. **Technology/Product (to be) developed:** We will start the product development in small and large scale after receiving the materials and instrument. The probable time needed to introduce our technology/ product in the market is 8-10 months minimum.

c. **IP generated/ Potential for IP generation:** Not initiated

d. **Resources Generated:** One project fellow has been taken for this project from November, 2020. All materials and instrument has ordered from different source.

Plans to take innovation further:
Partnership with different industry for technology transfer and commercialization of the biobased product.

Risks envisaged:
High viscosity of natural guar gums.

Project Coordinator:
Bharat Kapgate

Team Members :
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Debdipta Basu,
Soumen Sardar

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Institute of Microbial Technology

Collaborator: Mynvax Private Limited

Title of the Proposal:
Development of a novel, robust, industrial scale recombinant protein manufacturing yeast using an improved strain of Kluyveromyces marxianus

Brief description:
The ongoing work is a step forward in the direction of made in India initiative for developing first of its kind indigenous K. marxianus based expression system. The expression system will have huge value to produce proteins and enzymes for therapeutics as well as industrial applications.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The developed strain has maximum auxotrophic markers in the same strain engineered for improve homologous recombination efficiency by knockout NHEJ pathway gene. Applicant have also developed expression vectors having novel constitutive and inducible promoters with novel terminators.

Market Potential:
Global biologics market size US $ 250 Bn and its continuously growing. The developed strain can be used to produce these biosimilars.

National/Societal relevance:
The ongoing project is of huge national importance as the proposed technology will be the first of its kind indigenous expression platform technology.

Project achievements:

a. **Progress vis-a vis objectives:** identified strong promoter and terminator. Engineered K. marxianus strains with various auxotrophic markers.

b. **Technology/Product (to be) developed:** First of its kind indigenous K. marxianus based expression kit for the production of biosimilars. The product is expected to enter in the market in 2-3 years of time frame.

c. **IP generated/ Potential for IP generation:** Patent filed ("Vector for high-expression of proteins in yeast" and "Novel inducible promoter for high-expression of proteins in Kluyveromyces marxianus")

d. **Resources Generated:** One Ph.D. is submitted and two manpower are undergoing training. A collaborative project have been funded.

Plans to take innovation further:
Further improvement for glycosylation pattern and protein expression will be attempted.

Risks envisaged:
Protein glycosylation pattern might need optimization.

Project Coordinator:
Deepak Kumar Sharma

Team Members :
Debendera Kumar Sahoo,
Pradeep Kumar, Laxmi
Swami, Anubhav Singh
Nahar, Abhishek Sharma

Contact :
Sector 39-A,
Sector 39-A, CHANDIGARH
India-160036

Invoviron Industries Trading Pvt. Ltd.

Title of the Proposal:
Protein-based bioplastics and biocomposites made from upcycled poultry waste from a processing perspective

Brief description:
The company is working to develop 100 compostable polymer resin to replace a few single-use plastic applications. The product being developed is compatible with the existing infrastructure and the landing cost of the material is economical as compared to existing materials available with similar standards.

Current stage of development:
Validation

Innovative Element(s):
Use of waste chicken feathers to extract protein and developing the technology which will make the end product compatible with existing processing machinery.

Market Potential India:
150 Million USD, Worldwide: 2.2 Billion USD.

National/Societal relevance:
Will provide alternate material to curb single-use plastic pollution, which is presently the biggest problem of the century.

Project achievements:

a. **Progress vis-a vis objectives:** Compostable Polymer Resins Achieved, Injection Molded Product Working, Blow Film is completed.

b. **Technology/Product (to be) developed:** Compostable Egg Trays and Compostable Packaging Film

c. **IP generated/ Potential for IP generation:** Extraction of Keratin: Improving the existing process to develop an IP, Polymerization of Keratin: Patent Applied and published

d. **Resources Generated:** Keratin Extraction Setup has been Created, 2 trained and 4 untrained manpower have been employed, funds raised: NIDHI Prayas 6 lakhs, BIG 49.3 Lakhs.

Plans to take innovation further:
After successful validation of the product and technology, will look for Industry Partners to help take the technology forward.

Risks envisaged:
Acceptability and Adaptability by the general public.

Project Coordinator:
Sarthak Gupta

Team Members :
Mohd. Shahid Jamal,
Sunil Singhal,
Vivek Verma

Contact :
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Rampuram Shyam Nagar
Kanpur 208013

Jananom Pvt. Ltd.

Collaborator: IBAB

Title of the Proposal:
Commercial production of rose oxide by fermentation

Brief description:
High cost and limited availability of natural rose oxide restricts its pervasive application in high-value perfumes. Jananom, in collaboration with IBAB, have successfully demonstrated early POC to produce cis-rose-oxide precursors using synthetic biology, for greener & sustainable production of rose oxide by fermentation.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
First in the world effort for De novo microbial production of rose oxide using microbial hosts using biomolecular engineering of entire pathway will offer a convenient, safe and scalable cost effective method to produce the high value fragrance compound.

Market Potential:
High-quality rose oil is priced around 6000 USD per kg. The harvest is labour-intensive, it takes 1.25 million handpicked flowers and about 800 worker hours to produce 1 kg of rose oil. The fermentation based production would bring down the final cost by a fraction.

National/Societal relevance:
In the case of rose fragrances, the price, limitation in natural source and sustainability are the main criteria driving the switch to a fermentation-based production route. India is expanding capacities for production of aromatic chemicals due to the growing demand of such chemicals within the Indian market.

Project achievements:

a. **Progress vis-a vis objectives:** Completed genome integration and pathway assembly to produce rose oxide precursors in the chosen microbial host.

b. **Technology/Product (to be) developed:** Once the strain is fully engineered, it requires optimization by process development experts to scale for commercial requirement.

c. **IP generated/ Potential for IP generation:** Patents would be filed on the final microbial host successfully producing rose oxide

d. **Resources Generated:** It has enabled imparting advanced synthetic biology skills to several budding molecular biologists as well.

Plans to take innovation further:
Post scaleup the product would be partnered with a large commercial player to maximize its market potential.

Risks envisaged:
Product toxicity as rate limiting function will be checked during scalability to mitigate process risks.

Project Coordinator:
Sathish Kumar

Team Members :
Sanjay Ghosh

Contact :
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Tower 1 Cessna Business Park
Sarjapur ORR Bengaluru
KARNATAKA India-560103

Jananom Pvt. Ltd.

Title of the Proposal:
CCD matrix for High value apo-carotenoid isomers

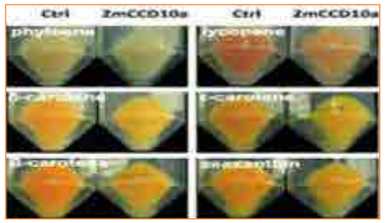
Brief description:
Jananom has recently established POC on its CCD matrix enzyme platform and developed metabolic tools for engineering non-conventional yeasts such as Yarrowia lipolytica which can utilize wide range of substrates and tolerate harsh conditions, and optimize the process for utilising carotenoid rich substrates such as floral, crab shell and palm oil effluent POME for generating high value products.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Cell surface yeast expression of unique CCDs and conversion of carotenoids into high value apo carotenoids.

Market Potential:
The project is aimed at taking atleast double digit market share post commercialization, out of the 500 M USD market for value added carotenoids.

National/Societal relevance:
Indian players have successfully added R&D to their repertoire of strengths, and are now able to develop and manufacture products which are high quality, scientifically evidenced, globally accepted and competitively priced. Given India's natural advantages in these segments, the industry is expected to grow at a healthy rate and high-quality Indian players to outgrow most of their global peers. Given the fact that the nutraceutical industry is still based primarily in the developed markets and 80% of India's production is exported, it is very critical to have a strong research and development machinery to come up with globally acceptable and efficacious products to scale up in this space.



Project achievements:

a. **Progress vis-a vis objectives:** Optimization of CCD enzyme for apocarotenoids using carotenoid rich substrates completed. Characterized CCD enzymes for high value saffron intermediate Croctein and Retinol

b. **Technology/Product (to be) developed**: Process to convert carotenoid rich substrates into high value products such as crocetin and retinol using CCD enzyme matrix.

c. **IP generated/ Potential for IP generation:** IP to be filed on the potential applications of CCD matrix

d. **Resources Generated:** Besides training of technically skilled synthetic biologists, processes for analysing carotenoid metabolites from cells, tools & vectors, enzyme repositories are are being developed as part of the project.

Plans to take innovation further:
Several potential partners have expressed interest from Japan and Europe for production after the initial process optimization step is complete.

Risks envisaged:
Optimization of final organoleptics for the chosen formulation & field of application will mitigate the risk of commercialization.

Project Coordinator:
Sathish Kumar

Team Members :
Nalini

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KARNATAKA India-560103

KBCOLS Sciences Pvt. Ltd.

Title of the Proposal:
Microbial Pigments: A sustainable alternative to existing natural pigments

Brief Description:
KBCols is exploring microbes as an inexhaustible feedstock of natural colors, as they represent one of the cheapest, most abundant & unexplored biological feedstock available in large quantities. These natural colors can find applications in food, pharmaceuticals, textiles and cosmetics.

Current Stage of Development:
Validation

Innovative Element(s):
Water soluble bio-pigments eco-friendly to environment and Non-GMO product more global consumer acceptance and less regulatory hurdles. Further, sustainable natural bio-colors which are the need of the future. Less energy intensive process with savings on effluent treatment cost. Some of the bio-pigments show excellent dye uptake and can be used in dyeing of all fabric types.

Market Potential (with India & abroad):
In recent times the market landscape has changed dynamically with respect to natural colors. KBCols has recently signed multiple paid pilots with leading European Luxury Brands, Japanese and Indian luxury brands for testing, manufacturing & launching luxury products with our natural colors in the apparel industry. The potential of the technology is far outreaching and with support of Industrial partners KBCols envisions building a world class product/technology for the future.

National/Societal Relevance:
Most of the workers in textiles are unskilled labourers who work with these chemical colors. These chemical colors constituting amines & heavy metals can cause a lot of health concerns like skin diseases and in some cases even cancer. The present work would produce safe colors which would be non-hazardous to the unskilled labourers working with them. Making the product and process of production as environmentally friendly as possible. Thereby leading to reduction in cost of treating effluents and reducing environmental load.

Project Achievements:

a. **Progress vis-a vis objectives:** Checking safety profile of KBCols Bio-colors achieved; Scale up process to 20 L pilot scale Achieved; Signed multiple paid pilots for evaluating performance of KBCols Bio-colors Achieved

b. **Technology/Product (to be) developed:** KBCols technology of natural colors has been developed till Lab pilot scale. The product is now being tested with various Industrial partners with the objective of launching products with KBCols natural bio-colors.

c. **IP generated/ Potential for IP generation:** Tremendous IP potential in terms of new isolates, production processes and completely new pigments product patent.

d. **Resources Generated:** KBCols recently created its own 2000 sq. ft. state of the art R&D/pilot facility. KBCols also recently raised its seed round from India's leading VC firm Chiratae Ventures Formerly IDG India. The fund is being utilized for expansion of team and scale up.

Plans to take innovation further:
KBCols is actively looking for collaborating with Industrial partners in domains of textiles, cosmetics, foods etc. KBCols is also actively fund raising for its pre-series A/Series A round to have on board like minded partners who can help to accelerate the growth.

Risks Envisaged:
Technical Challenges: Scale up of technology and Integration of product in existing manufacturing line.

Project Coordinator:
Vaishali Kulkarni

Team Members :
Arjun Singh Bajwa

Contact :
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Vishnu nagar Dombivli
MAHARASHTRA India-421202

JSP Enviro Pvt. Ltd.

Title of the Proposal:
Development of an energy efficient Bionano-electrochemical system for textile effluent treatment

Brief description:
Microbial fuel cells can treat the textile effluent thus making the water suitable for reuse in industries. MFCs can also produce electricity in the process of treating the water. Thus, MFCs reduce the need for exerting external energy required for wastewater treatment and the technology is sustainable. MFCs contain bacteria under anaerobic conditions at the anode that can utilize the organics in the wastewater and transferring electrons to the anode which are captured as current. The cathode of the MFC can be operated with microorganisms or enzymes that reduce the oxygen to water thus completing the circuit. A single chamber MFC known as SMFC is a type of MFC that contains the anode chamber and an air-breathing cathode. This design significantly reduces the amount of energy that would otherwise have been needed to aerate the MFC.

Current stage of development:
Validation and piloting

Innovative Element(s):
The electrodes used for the development of MFC biofilm; Nanomaterial for the development of CDI; Bioreactor design

Market Potential (with India & abroad):
Indian market of 100 million USD and global market of 400 million USD

National/Societal relevance :
A new bio-nanotechnological system will be integrated to reduce the cost of the existing energy intensive systems in place. The current system is aimed to be an energy positive and carbon neutral process. The MFC unit of the system is aimed at producing energy sufficient for the self-sustenance of the system. Zero-liquid discharge ZLD policy is currently adopted by the government against the discharge of the effluent into the natural water body. These ZLDs are energy intensive and expensive to adopt for small and medium scale industries (SMEs). Our technology is aimed at providing low-cost solutions for SMEs. The target market includes India and south-Asian countries where textile industry is concentrated

Project achievements:

a. **Progress vis-a vis objectives:** Reduction in COD and increased power output achieved. The retention time of the effluent is decreased to 8 hours compared to 18-20 hours initially. Progress in development of capacitive deionization (CDI) technology. Design of novel bioreactor and circuit design for treatment of water and capturing electricity.

b. **Technology/Product (to be) developed:** MFC-CDI integrated bioreactor for effluent treatment from 10-100 KLD capacity

c. **IP generated/ Potential for IP generation:** In process.

d. **Resources Generated:** Employed one research scientist – Two manpower employed and trained; Establishment of electrochemical workstations; Set-up a comprehensive water analysis unit. Work in progress for scaling up and implementation of the product in an industry

Plans to take innovation further:
Fashion for good (FFG) platform for international ventures. Tie-up with textile and dyeing industries.

Risks envisaged:
The major risk involved is the adoption of similar technology by other competitors. Building of the team with right expertise is essential as the technology involves multi-disciplinary aspects. If the product is not subsidized by the government, the initial installation may seem expensive for the customers. The benefits will be in long-term through low OPEX, maintenance and carbon-credits with ROI of 5 years.

Project Coordinator:
Priyadharshini Mani

Team Members :
V T Fidal; Suresh Paul Jones

Contact :
3/2, 2nd Sterling road,
Nungambakkam, Chennai

Mallipathra Nutraceutical Pvt. Ltd.

Collaborator: Sir M Visvesvaraya Institute of Technology

Title of the Proposal:
Bench scale production of snow flake Cordyceps and Cordyceps militaris through solid-state and sub-merged fermentation respectively for nutraceutical application

Brief description:
A novel technology to grow Cordyceps mushrooms on non-vegetarian and vegetarian substrate within 60 days, as opposed to 365 days in nature. It is also known as Bhu-Sanjeevani as it is known to have a cure for every ailment and also called as the Himayan Viagra due to its aphrodisiac properties.

Current stage of development:
Commercialization (Mallis Cordyceps)

Innovative Element(s):
Developed novel technique to grow Cordyceps mushrooms on non-vegetarian and vegetarian within 60 days, as opposed to 365 days in nature. Enhancement of bioactive like Cordycepin, Cordycepic acid by utilizing novel vegetarian and non-vegetarian substrates.

Market Potential:
There is huge demand for good quality Cordycep in the international B2B market. According to Want China Times the price of Natural Cordycep sp. skyrocketed from 6,000 yuan USD2,571 per kilogram in 2003 to 888,000 yuan USD142,680 per kilogram in 2012 when SARS hit China.

National/Societal relevance:
Rare: As it grows on only specific high altitude areas; Seasonal: It grows once a year July-September; Expensive: It is highly expensive due to the non-availability and huge demand; Inconsistent Host: Grows on un-identified hosts and hence highly inconsistent in the quality; Over Exploitation: Due to its high value and increasing demand has led to over exploitation of the natural resources and this mushroom have made it endangered species.

Project achievements:

a. **Progress vis-a vis objectives:** Optimization of culture conditions for solid state snowflake Cordyceps and sub-merged fermentation of Cordyceps militaris at Bench Scale, Batch wise quality assurance of the Products, Standardization and validation of scale up to 25 kg

b. **Technology/Product (to be) developed:** The technology for the growing of Cordyceps in an artificial environment both for vegetarian and non-vegetarian and submerged fermentation have been standardized. Developed the products like fruiting body, Mycelium powder, Capsules etc. under the brand name Mallia Cordyceps.

c. **IP generated/ Potential for IP generation:** 1 patent

d. **Resources Generated:** Created artificial environmental condition for Bench scale production of Cordyceps with all required instruments, with suitable conditions for the growth and maintenance of Cordyceps cultures.

e. Trained about 4 personnel and the company has hired them to handle the project efficiently.

Plans to take innovation further:
Scaling up the technology and develop Products for national interest. Looking for commercialization of products to Indian and international markets.

Risks envisaged:
Nil.

Project Coordinator:
Mousumi Mondal

Team Members :
P. Sathyavrathan,
Swathy Meera,
R. Premkumar E. Praksh
Modiya, J. Krishna Kumar

Contact :
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Mathru Layout, GKVK Post
Yelahanka Bangalore
KARNATAKA India-560065

National Institute of Immunology, New Delhi

Title of the Proposal:
Developing Mycobacterium smegmatis for metabolic engineering of delta-decanolactone/ or/ delta-dodecanolactone.

Brief description:
Acyl lactones are lipid derived aroma compounds with high commercial relevance. Study focusses on engineering Mycobacterium smegmatis to produce these compounds utilizing the secondary metabolite pathway of the bacteria. Applicant has engineered the large secondary metabolite synthesizing protein polyketide synthase to produce delta acyl lactones.

Current stage of development:
Discovery

Innovative Element(s):
Method aims at utilizing the secondary metabolic pathway of bacteria to produce these molecules naturally.

Market Potential:
These molecules are high value products that is used in food and aroma industry.

National/Societal relevance:
Decalactones are used as flavoring agents in food and fragrance industry. The study aims at producing these molecules using Synthetic Biology toolkit.

Project achievements:

a. **Progress vis-a vis objectives:** Able to produce these metabolites using novel multifunctional enzymes. Endeavor is to produce in large amounts

b. **Technology/Product (to be) developed:** engineer polyketide synthase to produce delta acyl lactone in vitro. Has genetically engineer this pathway in M. smegmatis. Currently working on redirecting the flux to produce these molecule in vivo.

c. **IP generated/ Potential for IP generation:** NA

d. **Resources Generated:** Trained a post doctoral fellow in the synthetic biology lab.

Plans to take innovation further:
Partnership with suitable people to forward this innovation.

Risks envisaged:
Need to reroute metabolite precursors for large scale production.

Project Coordinator:
Rajesh S. Gokhale

Team Members :
Vinay K. Nandicoori,
Sonali Srivastava

Contact :
Aruna Asaf Ali Marg,
New Delhi
India-110067

Nuevo Polymers Pvt. Ltd.

Title of The Proposal:
Ultra Low Viscosity Clear Guar

Brief Description:
The native Guar Gum has limited applications due to its extremely high viscosity.

Current Stage of Development:
Proof-of-Concept

Innovative Element(s):
This method of product development will be by using enzyme, filtration, purification and drying. Product will be clear. Available methods are by Irradiation process on guar gum, Filtration and purification will be by freezing, not sure product produce will be clear or not and can be use in food or not.

Market Potential (with India & abroad):
This product can be labelled as Partially Hydrolyzed Guar Gum and will be use in: Nutraceuticals items as dietary fiber; Fruits and Vegetables juice; Bakery products; Pharmaceuticals; Health products

National/Societal Relevance:
Guar Gum is extracted out of Guar seed which is produced is India, especially in desert area of Rajasthan where nothing else can be produced. Any new application or use of Guar Gum will give extra income to poor farmer of Guar growing areas.

Project Achievements:

a. **Progress vis-a vis objectives:** Achieved first objective involving production of Ultra low viscosity guar gum of 10 solution with a viscosity range of 20-200 cps. Work is in progress to achieve second objective Production of clear solution of Ultra low viscosity guar gum.

b. **Technology/Product (to be) developed:** The company is aiming to develop low viscosity clear guar gum

c. **IP generated/ Potential for IP generation:** None

d. **Resources Generated:** Manpower; 2 Chemist; 1 Lab assistant

Plans to take innovation further:
Not applicable at this stage

Risks Envisaged:
Guar Gum is a natural Product. It is a new product so it will require special effort and funds to introduce in the market

Project Coordinator:
A.P. Dadoo

Team Members :
Anurag Dadoo, Vikram Prajapati, Adarsh Singh, Krishan Kumar

Contact :
W6/13, DLF PHASE-3
GURGAON HARYANA India-
122002

Rajkumar Halder

Title of the Proposal:
Writable-erasable coatings on articles and usage thereafter with high positive social impact

Brief description:
The company has developed an indigenous writable-erasable coating that can be applied on any surface, write with a whiteboard marker, Pencil, Sketch Pen and Chalk and erase thereafter without leaving any ghost images and the cycle can be continued unlimited time. The product can be used as a slate, wallboard in the classroom, 360-degree classroom, corporate offices and more.

Current stage of development:
Validation

Innovative Element(s):
Competitor products are organic solvent-based which are not good for health and needs high temperature for functional whereas current product can work for a minimum of 10 years and it is completely water-based and can be applied on any surface at any temperature from -10C to 50C.

Market Potential:
There is a huge market potential for this indigenous economical writable-erasable coating that can be sold as a state for learning purposes, 360-degree classrooms in every academic institute School, Collage, Universities and can be exported to other countries for education and office purposes

National/Societal relevance:
The product can be used in every school for fearless learning and there is no need for extra board once this indigenous writable-erasable coating has been applied on the wall or any other surfaces. Students can use a pencil, chalk, markers and sketch pen for learning and discussion purposes.

Project achievements:

a. **Progress vis-a vis objectives:** The product is ready for deployment. The main objective is to get assistant from government agencies to promote the indigenous writable-erasable product.

b. **Technology/Product (to be) developed:** The technology of indigenous writable-erasable coating/paint has been developed and patented. The large scale process has also been developed for mass production and fulfill national needs.

c. **IP generated/ Potential for IP generation:** The technology has been patented. Filing number 202011041588

d. **Resources Generated:** The R&D centre has been created, trained more than 10 people who are also working in the company, Individual investment has been created.

Plans to take innovation further:
Working to make further development on the product. Looking for a partner who can buy the technology and/or like to invest to deploy the product in the market.

Risks envisaged:
There are polythene based low categories of writable-erasable films available in the market that are toxic to health and the environment. This is an eco-friendly and easy to use with whiteboard markers, pencil, Sketch pen and Chalk.

Project Coordinator:
Rajkumar Halder

Team Members :
Himadri Shekar Samantha, Ramesh Karri, Ranjeet Kumar Sah, Sarita Devi, Mridula Bharti, Naman Garg, Krishana Mohan Halder

Contact :
Plot-123,Pocket-2,
Jasola Vihar, New Delhi

R Narasimha Vydyanath

Title of the Proposal:
Development of a Novel Pentadentate chelator PDC Resin for Purification of Histidine-tagged Recombinant Protein.

Brief description:
We aimed at large scale production of Immobilized metal affinity chromatography resin using high density of Pentadentate metal chelating ligands immobilized onto cross linked agarose beads. The proposed matrix is well suited for efficient single step extraction of recombinant proteins with a poly histidine tag. A cost efficient method for the production of the said chromatography matrix will help the biotech manufacturers to avail the advantage of superior purity and ease of handling as well as shorted product development cycles.

Current stage of development:
Proof of concept

Innovative Element(s):
Novel resin for purification of His-tagged protein.

Market Potential (with India & abroad):
25 millon $ in India, 5,580 millon $ per year in Global

National/Societal relevance:
Generate revenue in India. No need to import from other country. Resin can be made in India

Project achievements:

a. **Progress vis-a vis objectives:** Concept was proved at 10 ml and 100 ml scale

b. **Technology/Product (to be) developed:** New technology developed and proven at lab scale

c. **IP generated/ Potential for IP generation:** Potential for filing IP.

d. **Resources Generated-** Employed one research scientist – Employed one research scientist and project assistant; Trained two internship students from Vignan University, Guntur.

Plans to take innovation further:
Present focus is to reach 1000 ml scale, we are ready for partnership if any one interest

Risks envisaged:
Establishment of Industrial scale manufacturing unit

Project Coordinator:
R Narasimha Vydyanath

Team Members :
K. Githa Vani, V Narayana Swamy, Raja Ram Mohan Roy, Venkat Reddy Yelma

Contact :
1-100/38/1/2/3, Gopanpally, Gachibowli, Hyderbad, Telangana

Ruby Gupta

Title of the Proposal:
Tamarind hydrocolloid: A critical import substitute for pectin

Brief description:
The value proposition and key activities of Duosis includes utilization of agro-industrial spin-offs as a novel, cost-effective & sustainable source of potential hydrocolloid Jellnex

Current stage of development:
Proof of concept

Innovative Element(s):
Production of Jellnex affordable and indigenous import substitute for pectin

Market Potential:
The demand for pectin is further expected to reach a volume of around 144 Thousand Tons by 2022, growing at a CAGR of 5.7 during 2017-2022.

National/Societal relevance:
Duosis will train & assist all stakeholders to enhance their competence and efficiency at each level through establishing simple post-harvest technologies for collection & processing of forest produce. As of now large chunk of forest produce in Jharkhand is moving out of the forest villages in raw form and traded without any value addition. Therefore, this initiative will provide an alternative livelihood option and will eventually enhance the socio-economic status of local communities.

Project achievements:

a. **Progress vis-a vis objectives:** Working on the isolation and characterization of Jellnex and also pilot study

b. **Technology/Product (to be) developed:** one year

c. **IP generated/ Potential for IP generation:** not yet.

d. **Resources Generated:** Employed 03 manpower, received BIRAC-TiE WiNER award

Plans to take innovation further:
Licensing and fund raising

Risks envisaged:
Scalability and acceptability

Project Coordinator:
Ruby Gupta

Team Members :
Pummi Pradeep,
Y M Joshi, Neyaz Ahmed,
Truptee V Gharat,
Amresh Chakra

Contact :
Janta Market, Near Bank of India, Chhota Govindpur, Jamshedpur 831015

S. Vishnuvardhan Reddy

Title of the Proposal:
Biosynthesis of Ectoine: An important pharmaceutical ingredient

Brief description:
Ectoine is an important ingredient in large number of pharmaceutical formulations, which is mostly produced through chemical synthesis, which is costly and complex. However, biological route of Ectoine synthesis is an economical alternative method that can be used for large scale production, which is absent at present in the country.

Current stage of development:
Proof of Concept

Innovative Element(s) :
The use of unique wild type bacterium which also secretes most of the Ectoine produced, without any process manipulation requirement, thus simplifying the downstream process and the overall cost of production.

Market Potential (with India & abroad):
An estimated 15K tons demand was found in 2015, which is expected to increase 3 fold by 2025, because of the novel applications of this versatile compound. Average market price is 1500 USD per Kg, which is up trending due to the increase in demand and limited production in the country, where no known manufacturers through biological route are reported

National/Societal relevance:
Most of the requirement at present is met through import, though there are few chemical manufacturers in the country. However, there are no known biological route producers in the country, which is an actual efficient economical method of ectoine production

Project achievements:

a. **Progress vis-a vis objectives:** Three novel wild type strains have been identified which have high potential for Ectoine production; Upstream and downstream processes optimization at small flask level has been completed for all these bacteria.5L fermentor scale upstream process as well as, similar volume downstream process is under optimization at present.

b. **Technology/Product (to be) developed:** Process for biologically synthesized Ectoine is to be developed

c. **IP generated/ Potential for IP generation:** Process that been already filed for India Patent.

d. **Resources Generated:** Employed one research scientist – Two M.Sc. personnel employed, small Microbiology laboratory created (instruments like HPLC, Lab fermentor have been bought from BIG funds, a limited company has been incorporated - "Microbztech Labs Pvt. Ltd.", at present actively searching for investors

Plans to take innovation further:
Upscale optimization in 50L and 100L capacities before the genuine commercialization of the product as a JV or through licensing.

Risks envisaged:
Behavioural issues of the wild type strains during scale-up.

Project Coordinator:
S. Vishnuvardhan Reddy

Team Members :
M. Srikanth Reddy,
A. Srinivas

Contact :
25, DITPL, Apparel Park, KIADB Industrial Area Doddaballapur Bangalore Rural KARNATAKA India-561203

Sathyabama Institute of Science and Technology

Title of the Proposal:
Production, characterization and scaling-up of earthworm coelomic fluid based serum-free cell culture medium for animal cell culture

Brief description:
Fetal bovine serum (FBS) is a ubiquitously used supplement in cell and tissue culture protocols. The search for alternatives to FBS has drawn global attention for more than two decades due to a number of ethical, scientific and supply challenges in the utilization of FBS. Coelomic fluid (CF) of the earthworm has shown to be a better alternative for FBS in animal culture. Advantages such lack of unintended antibody interactions, presence of macro and micronutrients, reduced or no cellular cytotoxicity, simple extraction and availability render them an enticing alternative to FBS

Current stage of development:
Validation

Innovative Element(s):
Heat inactivated CF (HI CF) is used as the FBS replacement in the culture of animal cells. The earthworms are not sacrificed, but applying a 5V-10V electrical shock for less than 2 minutes, coelomic fluid extrudes from the dorsal surface and is collected and processed.

Market Potential:
The HI-CF for suspension culture and HI-CF supplement with fibronectin for adherent cells have a large potential to be used as an alternative to FBS for animal tissue culture. It can support a wide variety of cell lines and has an immense market value for replacing FBS

National/Societal relevance:
The cost of animal cell culturing would be significantly reduced with this product. This benefits research laboratories and scientists working in the animal cell culture. It will enhance the financial position of farmers who is following vermicomposting and cultivating earthworms thus, a financial bridge will be built between farmers and industries. Heat Inactivated CF comes under green products so, it helps to eliminate the ethical concern associated with FBS.

Project achievements:

a. **Progress vis-a vis objectives:** Sterility testing, chemical characterization and trace element profiling of the coelomic fluid have been performed.

b. **Technology/Product (to be) developed:** The HI-CF for suspension culture and HI-CF supplement with fibronectin for adherent cells may enter into the commercial market within next 18 months.

c. **IP generated/ Potential for IP generation:** Alternative supplement for serum in animal cell culture medium. IPR Registration details: 201941009691 dated on 11/12/2019. Status: Filed.

d. **Resources Generated:** Two Junior Research Fellows were appointed for the execution of the project.

Plans to take innovation further:
Planning in Partnering with global companies such as Hi-media, Thermo fisher, Cell clone, Gibco for HI-CF for product commercialization.

Risks envisaged:
Whether it supports versatile cell lines needs to be checked. The amount of CF collected per earthworm was quite lower, which may hinder the scaling up processes.

Project Coordinator:
S. Johnson Retnaraj Samuel and
S. Jackson Durairaj

Team Members :
R. Melinda Grace,
S. Ravichandran

Contact :
Jeppiaar Nagar, Rajiv Gandhi Salai Chennai TAMIL NADU India-600119

Sengathali Biofiber Pvt. Ltd.

Title of the Proposal:
Novel process & device to extract banana sap and centre core dietary fiber

Brief description:
After harvesting the banana bunch, the remaining portion of the tree becomes agriculture waste. This waste contains valuable silk grade banana fiber and banana dietary fiber and banana sap. The innovative project is developing a device to extract the banana sap and banana dietary fiber from the banana stem.

Current stage of development:
Proof of concept

Innovative Element(s):
The device is highly innovative and unique in the world to extract banana dietary fiber and banana sap

Market Potential:
This product is a natural product. So it has very good market potential in local and international market

National/Societal relevance:
India is basically agriculture based country. The innovative project is helping the farmers income double. So the project and technology is national importance one.

Project achievements:

a. **Progress vis-a vis objectives:** They have completed successfully the banana dietary fiber extraction device and another one is banana sap extraction system. Both the devices are demonstrated in front of the expert team and successfully completed.

b. **Technology/Product (to be) developed:** The extraction process and device and technology is readily available for the market. This system and technology also scalable upto any level. So it is readily suitable for the market

c. **IP generated/ Potential for IP generation:** Will be done soon.

d. **Resources Generated:** They have given employment opportunities more than 25 families in terms of machining work, rural work, transport work, fabrication work and process work.

Plans to take innovation further:
The innovation soon will come to the market with full force and create big impact in the rural economy.

Risks envisaged:
The product and device will easily copied by others.

Project Coordinator:
Murugan Kottaisamy

Team Members :
Lalithamurugan;
Arulprakash

Contact :
29A/1, Bryant Nagar,
8th Street Thoothukudi
TAMIL NADU India-628008

Shivakumar H N

Title of the Proposal:
Guar gum based Dermal Bio-adhesive for Biomedical Patch Applications

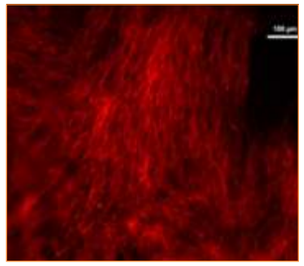
Brief description:
The presently available bioadhesives are synthetic and are only imported from US and European companies. There are absolutely no medical grade bioadhesive manufacturers in India who can offer eco-friendly, economical, indigenously developed, biocompatible, safe and stable bioadhesives.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The currently available synthetic bioadhesives do not allow development of patches incorporated with polar therapeutic agents, causes allergies, not eco friendly, expensive, occlusive, and flammable. Moreover, most of these medical grade adhesives have to be imported as they are not readily available in India making Guar gum as an one of the natural adhesives of choice to many of pharmaceutical companies in India.

Market Potential:
The proposed Guar Gum Adhesives Patches have high commercial viability as there are no hydrogel bioadhesives available except a few kaolin based adhesives and would be a great alternative to currently available synthetic adhesives. It would be first of its kind, the product will not infringe on any patents or existing technologies.

National/Societal relevance:
The development of guar gum based skin bioadhesives will lead to a new paradigm of products that would be highly affordable and would be useful for the treatment of chronic disorders in pediatric and geriatric patients. The skin bioadhesive is of natural origin and non-sensitizing, economical, ecofriendly and will offer unique advantages in terms of scope of drugs that could be incorporated in the mediated bandages and transdermal patches.



Project achievements:

a. **Progress vis-a vis objectives:** Objective1 is Completed. Physicochemical characterization has been performed. The protocol to assess the skin sensitivity as per OECD guidelines in rabbits is approved. The model water soluble drug lidocaine hydrochloride is incorporated into the bioadhesive. The work has been initiated. Analytical methods have been developed.

b. **Technology/Product (to be) developed:** Guar gum based skin bioadhesives would be a potential alternative to currently available synthetic adhesives and it would be first of its kind.

c. **IP generated/ Potential for IP generation:** In conversation with attorney team in filling the patent for the proposed product idea.

d. **Resources Generated:** A Co-PI and a Research scientist is working on the project. Will procure the equipment soon.

Plans to take innovation further:
Partner or out license the product once product is patented.

Risks envisaged:
Incorporation of lipophilic molecules, formulation is amenable to microbial contamination.

Project Coordinator:
Shivakumar H N

Team Members :
Paranjothy Kanni,
Sarasija Suresh,
Anusha Echanur

Contact :
West of Chord Road, 2nd stage,
Mahalaxmipuram Opp to post
office Bangalore KARNATAKA
India-560086

Shubhankar Takle

Title of the Proposal:
A universal method to manufacture edible scaffolds from mycelium for the lab-grown meat industry

Brief description:
A tissue engineering scaffold that is targeted toward the newly emerging cell-based meat industry

Current stage of development:
Proof-of-Concept

Innovative Element(s):
The novel biomaterial is edible, vegan and scalable. This is unlike most of the materials available for tissue engineering on the market that are either expensive/non-scalable due to the use of biofunctionalized polysaccharides or animal derived ECM proteins

Market Potential:
The clean meat industry eventually aims to replace the livestock factory farming industry that will reach a market size of $7.3 Trillion by 2025 if left undisrupted. In the short term, there are roughly two dozen clean meat companies around the world that are working on a variety of meat, many of which will come to market within the next five year.

National/Societal relevance:
The sourcing and production of meat using industrial livestock farming methods is responsible for 18% of all anthropogenic greenhouse gas emissions. It also occupies significant usable land because 26 Earth's ice-free surface is used for livestock farming. This represents 70% of all agricultural land. It strains the water resources as well since 27-29% of humanity's freshwater footprint is used for the production of animal products. Â industrial livestock farming also exacerbates desertification, deforestation, water pollution and land degradation.

Project achievements:

a. **Progress vis-a vis objectives:** 2D proliferation of mouse muscle cells on the scaffolds has been achieved and documented

b. **Technology/Product (to be) developed:** The scaffold will initially be sold as a bench-top lab-grade cellular scaffold kit and later will be sold as a bulk manufacturing B2B product

c. **IP generated/ Potential for IP generation:** under filing.

d. **Resources Generated:** Formed a company and have a fully functioning lab at the SINE IIT-Bombay

Plans to take innovation further:
Plan to market the current bench-top lab-grade cell culture scaffold internationally to raise market awareness about the product and company as well as generate some revenue

Risks envisaged:
Cellular Agriculture as a field of research is in its nascency, thus it will take some more gestation time for the company to be its most successful version

Project Coordinator:
Shubhankar Takle

Team Members :
Nihal Singh,
Ankita Srivastava

Contact :
5 Krishnaratna,
New Pandit Col. Sharanpur
Road, Nashik 422002

Sir MVIT (Sir M. Vishveshwarayya Institute of Technology)

Title of the Proposal:
Evaluation of a non-antibiotic feed supplement towards enhancement of immune response against mycoplasma infection in poultry to prevent the occurrence of Complicated chronic respiratory disease

Brief description:
Chronic Respiratory Disease (CRD) is one of the major respiratory diseases in poultry and leads to huge economic loss in terms of bird weight reduction, mortality, reduced egg production etc. The use of antibiotics leads to antimicrobial resistance. The developed technology is a combination of Preventive/Prophylactic approach (Synbiotic formulation which comprises of unique combination of probiotic strains with prebiotics) and Curative approach (herbal expectorant formulation which comprises of extracts of expectorant and antitussive herbs).

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Existing solutions against CRD are Antibiotics and vaccines. These result in antimicrobial resistance, are expensive and effective only in parent flocks. The current technology is a novel combination of Preventive & Curative approach which increases the immune response against CRD, reduces respiratory distress, enhances overall bird performance, reduces mortality & other CRD associated loss.

Market Potential:
Poultry Probiotic market to exceed USD 1.8 billion by 2024. Probiotics are used by 70-80% of poultry producers in the US market. Lactobacilli based poultry probiotics market size should generate over USD 1 billion in sales by 2024. Bifidobacterium may witness gains at over 5% by 2024

National/Societal relevance:
CRD is a Respiratory disease caused by Mycoplasma gallisepticum. This respiratory infection occurs in every poultry farms and it spreads vertically from the parents breeders to chicks through egg and horizontally between birds through fomites. Occurrence of CRD has resulted in a global economic loss of 780 million USD and loss of 250 million USD in the India scenario. Due to the drastic weight loss and reduction in FCR, the poultry farmer has to bear an additional cost of Rs. 7 per bird upon the occurrence of CRD. The antibiotics which are used for the treatment of CRD are also commonly used for the treatment of various human diseases and have a withdrawal period of 14 days. Since the birds fed with antibiotics and are lifted for consumption much before the withdrawal period, it has led to its confirmed presence in the meat and egg that we consume.

Project achievements:

a. **Progress vis-a vis objectives:** Development of the optimal combination of Symbiotic, low cost agricultural substrates, herbs, non-antibiotic growth promoters etc has been done. Evaluation of the effect of formulation on immune response in broilers, breeders and egg layers and Scale up of developed formulation is ongoing.

b. **Technology/Product (to be) developed:** The PoC for 2 products established at laboratory scale.

c. **IP generated/ Potential for IP generation:** Patents filed on the technology developed

d. **Resources Generated:** 8 graduate/post graduate student projects; 1 MTech, 3 BE and 2 MSc were trained. The BE and Government school students trained Won prize in Anveshana, A Science and Engineering Fair.

Plans to take innovation further:
Technology to be validated at industrial scale and will be licensed to industry partners for commercialization

Risks envisaged:
none

Project Coordinator:
H G Nagendra

Team Members :
Ashwathy S Das I,
Deepa H N

Contact :
Krishnadevaraya nagar,
Hunasemaranahalli, via,
Yelahanka, Bangalore
KARNATAKA India-562157

SRM Institute of Science and Technology

Title of the Proposal:
Metabolic pathway engineering of Clostridium acetobutylicum for homobutanol production through strategic manipulation of solvent production pathways

Brief description:
C. acetobutylicum is a mesophilic, non-pathogenic, and anaerobic bacteria, widely used in the industrial fermentation of ABE (acetone, ethanol, and butanol). The butanol production is diverted due to the production of acetone and ethanol resulting in the reduction of acetyl CoA availability. The acetyl CoA availability could be increased by knocking out genes responsible for acetone and ethanol production (acetoacetate decarboxylase & aldehyde dehydrogenase) and by overexpression of pyruvate decarboxylase and acetaldehyde dehydrogenase.

Current stage of development:
Proof-of-Concept

Innovative Element(s):
Earlier studies were focused on a single pathway manipulation approach for enhancing butanol production. The current proposal implies both knockout and knock-in approach to enhance homobutanol production. A combination of approaches to channel the solvent pathway is the novel step towards homobutanol fermentation.

Market Potential:
The domestic consumption of butanol is going to increase significantly as it is now seen as an alternative to gasoline. Very few companies are involved in butanol production in India. Hence, there is always growing demand for butanol.

National/Societal relevance:
The domestic demand for n-butanol is usually met through imports and the international market has a direct influence on domestic prices. The consumption of the chemical is expected to increase as it is now seen as an alternative fuel to replace gasoline, and above all, it will increase the amount of energy derived from biomass in comparison to ethanol. It is also used as a solvent for the extraction of essential oils, paints, natural and synthetic resins, dyes, alkaloids, and camphor. The current technology will overcome the challenges that exist.

Project achievements:

a. **Progress vis-a vis objectives:** Construction of double knockout strain of C. acetobutylicum and double expression vector is completed. Confirmation of recombinants and fermentation analysis of recombinant C. acetobutylicum is ongoing.

b. **Technology/Product (to be) developed:** Homobutanol producing C. acetobutylicum strain. The expected time it takes to enter the market is 1 year.

c. **IP generated/ Potential for IP generation:** Homobutanol producing strain of C. acetobutylicum.

d. **Resources Generated - Manpower employed:** Junior Research Fellow and few M Tech Students; Facility Created: Anaerobic chamber, Fermenter, Freezer, Electroporation facility.

Plans to take innovation further:
The engineered strain will be further evaluated and tested for scale-up using large scale fermentation collaborating with industry

Risks envisaged:
Genetic stability confirmation and redox requirement

Project Coordinator:
M. Ramya

Team Members :
N. S. Raja,
R. Srinivasan

Contact :
Department of Genetic Engineering, SRM Institute of Science and Technology
Kattankulathur, Kancheepuram,
TAMIL NADU India-603203

T. Sree Latha

Title of the Proposal:
Dual Ligand Affinity Matrix for Purification of Alpha-1-antitrypsin (AAT) from Human Plasma

Brief description:
Development of a novel process for a single step efficient extraction of alpha-1-antitrypsin from human plasma is the objective of this proposal. This involves establishment of an affinity chromatography-based purification strategy that offers the advantages of easy scale-up, enhanced recovery and improved product quality.

Current stage of development:
Proof of concept

Innovative Element(s):
Novel and high binding resin for purification of alpha-1-antitrypsin protein

Market Potential:
Global Market for AAT - $500M/year

National/Societal relevance:
Generate revenue in India. No need to import from other country. Resin can made in India

Project achievements:

e. **Progress vis-a vis objectives:** Technology developed and proved at 3 Liters scale

f. **Technology/Product (to be) developed**: Technology developed and proved at 3 Liters scale.

g. **IP generated/ Potential for IP generation:** Filed provisional patent. Complete filing is in process.

h. **Resources Generated:** Employed one research scientist - Trained five internship students from Vignan University, Guntur

Plans to take innovation further:
Resin need to develop at industrial scale to enter into market

Risks envisaged:
Regulatory Issues for supply of AAT protein; Raw material is expired blood. Getting raw material is envisaged

Project Coordinator:
T. Sree Latha

Team Members :
T. Shiva Prasad,
Pallu Reddanna,
Venkat Reddy Yelma

Contact :
Department of Animal Biology,
University of Hyderabad,
Telangana-500046

Vivekanand Arts, Sardar Dalip Singh Commerce & Science College, Aurangabad

Title of the Proposal:
Pilot scale studies of Electronic Waste Management using Economical and Eco friendly Method

Brief description:
Project focuses on pilot scale studies of biological metal removal from waste printed circuit boards (PCBs). No stringent regulations from CPCB, since process in eco-friendly. Minimum processing cost due to the type of bacteria using and the unique mechanism involved. Safer process- Even though the bacteria released into the environment no hazards.

Current stage of development:
Validation

Innovative Element(s):
Using a sequence of steps for selective removal of metal from e-waste using bacteria assisted leaching.

Market Potential:
E-waste management market to expand at a CAGR of 5.7 between 2018 and 2026.

National/Societal relevance:
E-waste is a growing concern. More particularly management of waste PCBs is troublesome due to its heterogeneity. Lack of sufficient method to extract metals from waste PCBs results into heavy metal contamination of landfills. Traditional physical or chemical method leads to pollution. In this context, the developed process not only solves such issues but also helps to boost economy.

Project achievements:

a. **Progress vis-a vis objectives:** Demonstration at 100L scale is achieved

b. **Technology/Product (to be) developed:** Process has been demonstrated at 100L scale and is now ready for commercialization.

c. **IP generated/ Potential for IP generation:** Potential is there.

d. **Resources Generated:** 5 Bioreactors having capacity 10 L each. Complete Process Demonstration at 100L scale. Two Project Assistants are working.

Plans to take innovation further:
Ready to license the tech-know how preferably on non exclusive basis. Partnership would be done with some NGOs, social groups for creating the awareness of e-waste management. Partnership would also be done with waste pickers association/companies.

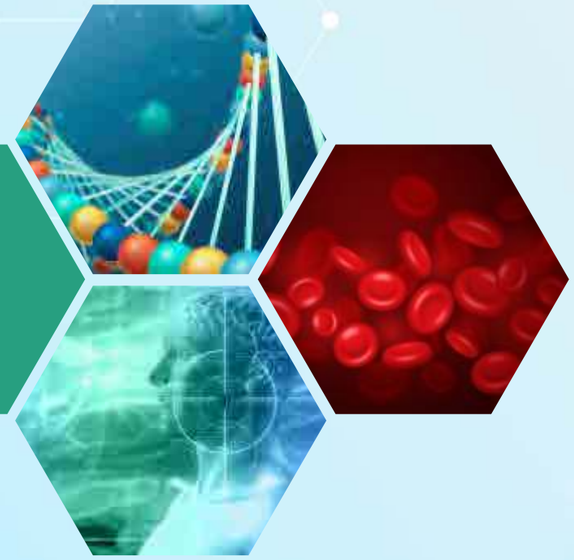
Risks envisaged:
Since e-waste included in hazardous waste category, the safety precautions need to be taken during process. Restricting the traditional pollution causing methods of metal extraction from waste PCBs is a challenge

Project Coordinator:
Adhapure Nitin Narhari

Team Members :

Contact :
Aurangabad Samarth Nagar,
Behind That Baat Restaurant
Aurangabad Maharashtra
India-431001

NATIONAL BIOPHARMA MISSION
innovate in India for inclusiveness (i3)



SHARED INFRASTRUCTURE

KIMS, Rajya Vokkaligara Sangha

Name of Facility:
NATIONAL CENTRE FOR PNEUMOCOCCAL VACCINE IMMUNOGENICITY EVALUATION

Broad area:
Shared Facility

Brief description of facility:
National centre for pneumococcal vaccine immunogenicity evaluation at CRL, KIMS is a dedicated facility for Serotype specific ELISA and MOPA tests. These tests measure reactogenic and functional antibody levels in the clinical specimen before and after vaccination. Presently, Indian vaccine manufacturers and researchers are dependent on the facilities situated outside the country, resulting in delay and high cost. The NABL, GCLP and GFGP accredited facility at CRL, KIMS established with support of National Biopharma Mission BIRAC and Services and support are provided as per NABL and GCLP standards. Standards for reference strains, serum, reagents and consumables are under development and evaluation for indigenization. The laboratory is beings established with technical support from WHO referral laboratory.

Types of Services offered:
Identification & AST on automated platform
Serotyping by Quellung test & Sequential PCR
Quantitative Multiplex real time PCR for ID and typing
Vaccine immunogenicity testing by ELISA & MOPA
Bacterial whole genome seqeuncing

Project achievements:

a. **Infrastructure available**

BSL-3 facility with Molecular biology, Microbiology, Immunology, Cell culture & Bioinformatics sections.

Microarray, Flow cytometer, Automated ELISA, Luminex connected to LIMS.

b. **Types of products developed/ tested**

Vaccine immunogenicity testing with ELISA and OPA for pneumococcal vaccine evaluation

c. **Accreditation of facility:** (ISO 13485, NABL, etc.)
NABL, GCLP, GFGP

Current stage of facility readiness:
Services being offered: Serotyping, qPCR, AST
Services ready for offering: ELISA and OPA assay for vaccine immunogenicity evaluation

Differential pricing offered:
Services are offered on fee for service model and differential pricing structure.
Indian manufacturers will be supported with subsidized, competitive costing.
Concessional and discounted pricing is extended for researchers and academia.

Website for services:
www.crlkims.com (Under development)

Project Coordinator:
K.L. Ravikumar

Team Members :
13

Contact :
K.L. Ravikumar
Phone no: 09880229905
Email: klravikumar@gmail.com,
crlkimsb@gmail.com

IRSHA, Bharati Vidyapeeth University

Name of Facility:
National Immunogenicity and Biologics Evaluation Center (NIBEC)

Broad area:
Shared Facitlity

Brief description of facility:
National Immunogenicity and Biologics Evaluation Center, NIBEC, was established in the year 2019, jointly by Interactive Research School for Health Affairs IRSHA , Bharati Vidyapeeth University, Pune and the Department of Biotechnology, Government of India under ·National Biopharma Mission, BIRAC. The primary mandate of the center is to standardize, validate and get accredited the front line tests to evaluate immunogenicity of dengue and chikungunya vaccines in clinical trial. A State of art facility is established having 1 BSL· 3 lab and 4 BSL·2 laboratories. Various tests for dengue, chikungunya and SARS·CoV·2 have been accredited by NABL under ISO 17025. GCLP quality system is established and services to many vaccine manufacturers are being provided.

Types of Services offered:
Analysis of samples for immunogenicity and antiviral testing

Project achievements:

a. **Infrastructure available:**

BSL1, BSL2 and BSL3 laboratories. High end equipment like flowcytometer, real time PCR machine, plaque cum ELIspot counter, NSF certified Biosafety cabinets, etc. Separate air handling system for laboratories, effluent treat plant, building management system, etc. Laboratory information management system under development.

b. **Types of products developed/ tested :**

Dengue PRNT, Chikungunya PRNT, SARS·CoV·2 PRNT, Dengue NS1 ELISA, Dengue IgM ELISA, Chikungunya IgG ELISA (Qualitative and quantitative), Dengue viremia, Dengue virus serotyping, Dengue virus quantification by real time PCR, Influenza A and B hemagglutination inhibition test.

c. **Accreditation of facility:** NABL

Current stage of facility readiness:
Services are being offered.

Differential pricing offered:
Discount is offered to start·up, academia and projects approved by BIRAC (NBM).

Website for services:
https://irsha.bharatividyapeeth.edu/index.php/ncia/467·ncia·home

Project Coordinator:
A.C. Mishra

Team Members :
10

Contact :
91·020·24366920,
acm1750@gmail.com

CSIR-IMTECH

Name of Facility:
National Repository of GMP-Compliant Microbial Cell Banks for Biopharmaceutical Products (NRGCBIO)

Broad area:
Biorepository

Brief description of facility:
The Biopharmaceutical industries are one of the most rapidly growing sectors in the Indian Biotechnology space. The growing pipeline of biologics has resulted in a continuous increase in the demand for different types of cell substrates/lines in the nation. This is to emphasize that the availability of GMP compliant and quality cell banks and cell bank characterization is one of the major challenges and bottleneck in Biopharmaceutical/Biomolecule development in India. In general, the majority of Cell banks are imported from outside of India. Getting a cell bank in India suffers from various limitations like very high cost, licensing and royalties' charges, uncertainty in identity and purity shipping costs, delays in delivery, import and customs duty payment etc. Furthermore, the characterization of cell bank as per international regulatory guidelines (e.g. FDA-ICH) is also a major challenge in India. In the current scenario where a number of small industries, startups, MSME, and research organizations are emerging and getting engaged in the development of various Biopharmaceuticals and biomolecules of national importance. It is imperative to have a facility with the availability of a GMP/quality cell bank for R&D, QC, and production from indigenous sources, cell bank characterization as per regulatory guideliens, and safe storage of cell bank in India.

Taking into consideration the above gap and scope, CSIR-IMTECH, Chandigarh is setting up a national facility under the project entitled 'Establishment of a National Repository of GMP cell lines for Bio-Pharmaceutical products (NRGCBIO). The programme is supported by National Biopharma Mission-Biotechnology Industry Research Assistance Council (NBM-BIRAC), under the Government of India's mission "Innovate in India (I3)-Empowering Biotech Entrepreneurs & Accelerating Inclusive Innovation in the country. This facility is to be accredited by Drug Controller General of India (DCGI) for GMP compliance.

Types of Services offered:

cGMP Cell Banking, Cell Bank Characterization as per FDA-ICH guidelines and Storage.

Project achievements:

a. **Infrastructure available** (Integrated Facility equipped with Fermentation, downstream and Analytical lab to be used for cGMP grade cell bank production, their storage and characterization as per international regulatory guidelines.

b. **Types of products developed/ tested** Microbial cell banks and expression systems used for development and production of Biopharmaceutical products.

c. **Accreditation of facility:** (ISO 13485, NABL, etc.): DCGI

Current stage of facility readiness:
Facility setup ongoing, expected to be ready by next 6 months.

Differential pricing offered:

A differential pricing for startup, MSME, Entrepreneurs, Industries, not-for-profit organizations and academics to be implemented for the products and services as per set guidelines of the institute.

Website for services:
In process

Project Coordinator:
Ravi P.N. Mishra

Team Members :
3

Contact :
Tel. No: +91 7702455188, 0172-6665314, 2690223 (Off.),
E-mail:
ravi.mishra@imtech.res.in

National Centre for Cell Science

Name of Facility:
National Repository for GMP Compliant Mammalian Cell Banks for use in biopharma

Broad area:
Biorepository

Brief description of facility:
Under the aegis of the National Biopharma Mission, NCCS has been entrusted with responsibility to establish a state-of-the-art National cGMP-compliant mammalian cell line repository. The ease of access to well-characterized, high quality and validated cell lines is one of the requirements for development of robust biopharma industry. While Indian biopharma industry can access international repositories, often the costs are prohibitive and overcoming regulatory/legal hurdles takes long time. The proposed National cGMP-compliant facility would function to acquire, characterize and provide mammalian cell cultures for use in biopharma to users in India. It would facilitate safe deposit for secured storage of production and other proprietary mammalian cell lines from biopharmaceutical industry. Furthermore, cell line characterization services would also be provided. The proposed repository would be established in par with international cell repositories using global benchmarks, stringent quality control parameters in GMP/GLP and as per national and international regulatory requirements.

Types of Services offered:
We are in the process of setting-up the proposed National cGMP-compliant facility. After the facility is established the following services would be offered to the users in India.

1. Mammalian cell lines acquired under third-party license agreement would be characterized, banked and supplied to biopharma and scientific community in India.
2. Safe-deposit cell line storage service to Indian biopharma industry.
3. Cell line characterization services.

Project achievements:

a. **Infrastructure available** We are in the process of setting-up the proposed National cGMP-compliant facility. The proposed facility would to be established in the existing building of NCCS at Jidnyasa, Kothrud, Pune which has a plot area of the site is 16807 sq ft. The building is basement plus 3 floors with a total built-up area of 9300 sq ft. The facility would be designed in order to meet both national and global regulatory requirements and equipped with state-of-the-art equipment to provide value-added services to the users.

b. **Types of products developed/ tested** (broad categories e.g., Microfluidics medical devices, analytical characterization of small molecules/ biosimilars/ cell extracts, IVD kits for certain diseases, vaccine immunogenicity using XYZ parameters)

The services of the facility would be commenced after establishment of the proposed facility.

c. **Accreditation of facility:** (ISO 13485, NABL, etc.)
DCGI

Current stage of facility readiness:
We are in the process of setting-up the proposed National cGMP-compliant facility wherein the activity towards designing and construction has been initiated. The services of the facility would be initiated in 18-24 months.

Differential pricing offered:
Differential pricing for start-up, MSME Industries, not-for-profit organisation will be in place.

Website for services:
(Website would be developed after the services are initiated

Project Coordinator:
Manoj Kumar Bhat,
Director, NCCS

Team Members :
04

Contact :
91-20-25708121
director@nccs.res.in

Gennova Biopharmaceuticals Ltd.

Name of Facility:

1) **Facility 1:** Process Development Laboratory (PDL) / Gennova's Vaccine Formulation and Research Center
2) **Facility 2:** Mammalian Production Facility/PROFESSOR KRISHNA TEWARI BUILDING/The Next-Generation Mammalian Multi-Product Bio-Manufacturing Facility
3) **Facility 3:** Fill & Finish Facility/Sterile Parenteral Division

Broad area:

Biosimilars and Novel biologics (Mammalian cell-line based recombinant biotherapeutics)

Brief description of facility:

This project aims to create an integrated regulatory compliant PDL – cGMP manufacturing facility to enable Indian innovations to reach the clinic by providing access to the biopharma developers to quality infrastructure and facilities. This facility would empower users from both industry and academia and Gennova to take their product from development stage to commercialization.

Types of Services offered:

- Research cell bank preparation, and maintenance of cell banks
- Process development of recombinant biotherapeutics till pilot scale including purification and formulation development followed by complete analytical characterization for drug substance and drug product, analytical development, qualifications and validations, in-process quality control and product release. Generation of preclinical material and assistance in regulatory filing.
- Manufacturing capability for production as well as phase III clinical trial material generation from seed to filled vial for mammalian products up to 1000 L scale
- Technology for suspension-perfusion or packed bed perfusion mammalian upstream processes. Fill finish capabilities for liquid and lyophilized products can be filled in vials and pre-filled syringes
- Regulatory support for national and international filings for clinical trials and market authorizations. Technology transfer to clients for ready to use processes from PDL or cGMP facilities.

Project achievements:

- **Infrastructure available**

  The process development laboratory (PDL) at Gennova has molecular biology, upstream process development, downstream process development, analytical development, and formulation development laboratories for making clinical-grade biologics for therapeutic purposes. All these labs are equipped with routinely used as well as high end equipments to support product development.
- Types of products developed/ tested
- Process Development Laboratory (PDL) works on end-to-end product development of biologics of both mammalian and microbial origin
- Mammalian Production Facility, once built, will cater to the cGMP production of Mammalian cell-line based recombinant biotherapeutics for clinical and commercial purposes.
- Accreditation of facility:
- DSIR affiliation and Manufacturing license to produce cGMP clinical grade material for phase I and II studies. Mammalian Production Facility, once built, will have accreditation from CDSCO, Govt. of India and WHO GMP

Current stage of facility readiness:

The PDL facility is ready to execute whie Mammalian Production Facility should be operational in 2 years' time frame.

Differential pricing offered:

- For non-academics – Actual cost + 22 % service charge
- For academics – Actual cost + 10 % service charge

Actual cost will include - fixed cost, consumables, logistics, external consultancy etc.

All the calculated charges can be audited by independent chartered accountants/ firms or by auditors recommended by the NBM/BIRAC.

Website for services:

- Main website - www.gennova.bio
- Service website
  - For the Process Development - https://gennova.bio/pdl2/

Project Coordinator:
Tathagata Mukherjee

Team Members :
25

Contact :
Office - +91 20 39166300
Mobile - +91 84110 20033
E-mail - tathagata.mukherjee@gennova.co.in

M. J. Biopharm Pvt Ltd.

Name of Facility:
100 L cGMP Microbial facility and fill finish facility (Dosage form: Vials)

Broad area:
Biosimilars and novel biologics

- Biopharmaceuticals and Biotherapeutic product Process Development and manufacturing of Microbial based products.
- Recombinant vaccine manufacturing from early phase development to large scale production.
- cGMP offering for Cell Bank Preparation (Bacterial and Mammalian Cell Culture)
- Manufacturing of finished dosage form in Vials from clinical to commercial. This includes Insulins, Mab's, and Vaccines.

Brief description of facility:

- Process development on microbial platform up 100 L and cGMP manufacturing facility upto 5 kL

Types of Services offered:
Cell bank preparation and storage

- Preclinical, Clinical and commercial manufacturing on Microbial platform
- Process Developmental services
- Clinical and commercial manufacturing of finished product in vials

Project achievements:

a. Infrastructure available

List of Proposed / Approved Major Equipment's

1. HPHV Steam Sterilizer
2. Biosafety Cabinets
3. Shaker Incubator
4. 5 L Seed Fermenter
5. 100 L Production Fermenter
6. High Pressure Homogenizer System
7. High Speed Continuous Centrifugation System
8. Chromatography Skid (Low and High Pressure Combination)
9. Tangential Flow Filtration system (TFF)
10. Lyophilizer System
11. Depyrogenation system (DHS)
12. Process Vessels -20L,75L,200L, 300L
13. Vial filling machine
14. Packaging and inspection line
15. 1000L compounding vessels

b. Types of products developed/ tested (broad categories e.g., Microfluidics medical devices, analytical characterization of small molecules/ biosimilars/ cell extracts, IVD kits for certain diseases, vaccine immunogenicity using XYZ parameters)

Proposed Products developed /under development in Microbial facility

1. Recombinant Human Insulin
2. Recombinant Insulin Lispro
3. Recombinant Insulin Glargine
4. Recombinant Insulin Detemir manufacturing
5. Recombinant Insulin Degludec
6. Recombinant Insulin Aspart
7. Monoclonal Antibodies
8. Blood Plasma Fractionation
9. Vaccine Development and

Sr. No	Finished Dosage forms	Name of the Biosimilar Product
1	Monoclonal antibodies	Becavzimumab, Rituximab, AbixiRel, Denosumab, Abaxicimab, Panitumumab, Human anti-rabies mAb, Rituximab, Ranibizumab, Etanercept, Nimotuzumab
2	Insulins	Human Insulin and analogs
3	Vaccine	Covid19 vaccines

c. Accreditation of facility: (ISO 13485, NABL, etc.)
Target for WHO, PICS, EU approval

Current stage of facility readiness:
Microbial production related services from 15L ready and 100L from Oct2021 and Fill finish in vials from April 2022.

Differential pricing offered:
Competitive prices to support launch product, get market penetration.

Website for services:
www.mjgroup.co.in

Project Coordinator:
Principle Investigator:
G. Krishna Prasad

Team Members :
12 for Microbial facility
100plus for fill finish facility

Contact :
Email ID:
Krishna.prasad@mjbiopharm.com
+91-7350008692

Shilpa Biologicals Pvt. Ltd.

Name of Facility:
Shilpa Biologicals Pvt Ltd, Plot 532A, Belur Industrial Area, Dharwad 580011, Karnataka, INDIA

Broad area:
Biosimilars and stem cells / vaccines

Brief description of facility:
Integrated R&D, MSAT cum commercial manufacturing center for biologics, recombinant and adenoviral/AAV vaccines with production capacities of 50L, 200L and 1000L and associated downstream, with following services –

- Clone development/screening, characterization, Fermentation and downstream process development, protein characterization, formulation development and stability studies, Container closure studies, freeze-thaw studies
- Scaleup studies in non-GMP and GMP environment upto 50L in SUBs
- Master and Working cell bank development and characterization, storage services
- Pilot and Commercial GMP production of biologics in 200L and 1000L bioreactors (with/without perfusion option) for drug substance
- Pilot and commercial GMP production of drug products (PFS, Vials (Liquid) and Vials (Lyophilised products))
- GMP stability studies, degradation studies of biologics

Project achievements:

a. Infrastructure available (Names of infrastructure and special equipment/ set up available with the facility)

- Sartorius SU STR Bioreactors (50/200/1000L two trains expandable to 16KL)
- Associated AKTA chromatography units – AKTA Pilots, AKTA modular, AKTA ILC-Hydrids
- Fully automated filtration skids
- · Automated media preparation units
- Automated filling units to cater to PFS, Vial fills for liquids, Vial fills for Lyophilised products (60u/min)
- R&D facility with high end molecular biology facility
- Clone screening with AMBR microbioreactors
- 2/10/50/100L bioreactors and fermentation units
- Lab scale TFF and automated chromatography units
- Lab scale Freeze-Thaw units
- High end, high through put biologics analytical platform including HPLC/UPLCs with UV/PDA/Fluorescence/RI/mass detectors, DLS, DSC, CD Spectrometer, Fluorescence Spectrometer, UV Spectrophotometers, BLI – High and low throughput, Q-ToF, Multimode readers, Automated Kjeldahl apparatus, GCs etc

b. Types of products developed/ tested (broad categories eg. Microfluidics medical devices, analytical characterization of small molecules/ biosimilars/ cell extracts, IVD kits for certain diseases, vaccine immunogenicity)

Types of products developed/tested – Mabs, fusion proteins, glycoproteins, Blood proteins, Adenoviral vectors

c. Accreditation of facility: (ISO 13485, NABL, etc.) –

- GMP facility with Form 29 for clinical batches and test batches

Current stage of facility readiness:
Fully ready and services already being offered as above

Differential pricing offered:
For BIRAC/DBT funded startups and institutions, we have a differential pricing which is Cost price plus 10%

Website for services:
www.shilpabio.com (upcoming)

Project Coordinator:
Rajyashri KR

Team Members :
Vinay Konaje

Contact :
Plot no. 531, 532A Belur Industrial Area, Karnataka-580011

Entrepreneurship Development Center (Venture Center)

Name of Facility:
Center for Biopharma Analysis (CBA)

Broad area:
Biosimilars and stem cells

Brief description of facility:
Center for BioPharma Analysis (https://www.venturecenter.co.in/biopharma/) is an open access, aspiring to be GLP compliant, one-stop destination for high quality in vitro characterization of biopharmaceuticals, which is hosting dedicated high-end instrumentation and providing hand holding and advisory support to biopharma researchers and technology developers. This facility is hosted at Venture Center and has been supported by the National Biopharma Mission of the Government of India as well as BIRAC. CBA is addressing the gap of open access, single facility for comprehensive analytical characterization of Biotherapeutics in India. The facility aims to cater all academic, small to Medium size biosimilar developers through-out the India and the world. At CBA, we are following GLP like workflows and will be soon applying for GLP Certification.

Types of Services offered:
Analytical characterization of Biomolecules

List of Services:

1. Protein Intact Mass Analysis using HRMS
2. Peptide Mapping using HRMS
3. Post Translational Modifications Analysis using HRMS
4. Host Cell Protein Impurity Identification using HRMS
5. Host Cell Protein Impurity Profiling using SDS-PAGE
6. Secondary Structure Analysis using far-UV CD Spectroscopy
7. Tertiary Structure Analysis using near-UV CD Spectroscopy
8. Tertiary Structure Analysis using Fluorescence Spectroscopy be announced)
9. Higher Order Structure Analysis using Fluorescence Spectroscopy (To be announced)
10. Secondary Structure Analysis using FTIR Spectroscopy
11. Higher Order Structure Analysis using DSC
12. Aggregate/Multimers Analysis using SEC-MALS
13. Protein N-Glycan Analysis by LC-MS
14. Amino Acid Composition Analysis using UHPLC (To be announced)
15. Protein N-Glycan Analysis using UHPLC (To be announced)
16. Protein Charge Variant Analysis using cIEF (To be announced)
17. Binding Kinetic Analysis (To
18. ADCC Assay and CDC Assay

Project achievements:

a. **Infrastructure available:** Details of major equipment at CBA are as below.
   Major Equipment Set Up at CBA
   1. **High Resolution Mass Spectrometer (HRMS):**
      i. **Mass Spectrometer (MS):**
         Make: ThermoFisher Scientific
         Model: Q Exactive Plus Biopharma Orbitrap Mass Spectrometer
      ii. **Liquid Chromatography (LC):**
         Make: ThermoFisher Scientific
         Model: Ultimate 3000
      iii. **Nano-LC:**
         Make: ThermoFisher Scientific
         Model: Easy-nLC
   2. **Circular Dichroism Spectrometer (CD):**
   3. **Fluorescence Spectrometer (FLD):**
   4. **Differential Scanning Calorimeter (DSC):**
   5. **Size Exclusion Chromatography – Multi Angle Light Scattering (SEC-MALS):**
   6. **Surface Plasmon Resonance System (SPR):**

b. **Types of products developed/ tested :** Analytical characterization of Therapeutic proteins & Monoclonal antibodies

c. **Accreditation of facility:** CBA is GLP compliant facility (We plan to apply for GLP certification soon)

Current stage of facility readiness:
Services offered by CBA are listed above in section 6.

Differential pricing offered:

Sr. No.	Category	Differential Pricing offered
1	Industry (National)	20% Discount on GLP-Like Services
2	Registered Startups	30% Discount on GLP-Like Services
3	BIRAC Grantees	40% Discount on GLP-Like Services
4	Strategic Partners	30% Discount on GLP-Like Services
5	Non-Profit Organizations	30% Discount on GLP-Like Services

Website for services:
https://www.venturecenter.co.in/biopharma/services/
Link for the Brochure: https://online.fliphtml5.com/laonc/jyhf/

Project Coordinator:
Smita Kale; Co-PI-
Manisha Premnath

Team Members :
12

Contact :
9923147592,
smita@venturecenter.co.in

CSIR-IICT

Name of Facility:
GLP compliant analytical facility at CSIR-IICT, Hyderabad to augment biosimilars characterization in India

Broad area:
Analytical Characterizations of Biologics including Biosimilars

Brief description of facility:
The overall objective is to establish GLP compliant analytical facility for Biosimilars characterization at CSIR-IICT, Hyderabad to serve the Pharma and Biotech Industry to augment biosimilars product development.

The specific objectives include,

a. Augmentation of existing analytical facility at CSIR-IICT
b. GLP accreditation of augmented analytical facility
c. Service from GLP accredited analytical facility

The established facility is expected to provide comprehensive analytical solutions to Pharma and Biotech Industry to support their Biosimilars product development as per ICH Q6B guidelines.

Types of Services offered:
The established facility will offer testing/ analysis of candidate biosimilars with innovator reference biologics for

- Physicochemical and structural characterization using different analytical techniques under GLP compliance laboratory
- Primary structure
  - o Intact mass,
  - o peptide mapping,
  - o glycan profiling,
  - o disulfide linkage mapping
- Secondary structure prediction
- High order structure prediction
- The purity, impurity and charge variant analysis studies

Project achievements:

a. **Infrastructure available**

Capillary Electrophoresis	NMR
Plate Reader (MMR)	Mass Spectrometer
Circular Dichroism	HPLC and UHPLC

b. **Types of products developed/ tested** (broad categories e.g., Microfluidics medical devices, analytical characterization of small molecules/biosimilars/cell extracts, IVD kits for certain diseases, vaccine immunogenicity using XYZ parameters)

Analytical characterization of biosimilars in GLP certified facility

c. **Accreditation of facility:**
Certification by NGCMA, GOI for GLP compliance as per OECD principles for the established facility (In process)

Current stage of facility readiness

- The establishment of GLP compliant analytical facility is in progress
- The protocols optimization to do comparative analytical characterizations to establish biologics as Biosimilars to Innovator reference molecules
- Expected to be ready by September 2021

Differential pricing offered:
The pricing details will be finalized after facility is ready to work in GLP compliance situation

Website for services:
http://www.iict.res.in

Project Coordinator:
Mohana Krishna Reddy Mudiam, FTAS

Team Members :
A total of 20 staff including permanent and contractual

Contact :
Mobile: 8418048736
Email id: mmudiam@iict.res.in

Syngene International Ltd.

Name of Facility:
Syngene International limited, Biocon SEZ Unit, Bommasandra – Jigani link road, Bangalore 560099

Broad area:
Biosimilars and stem cells/ Medical devices and diagnostics/ Vaccines and clinical trials/ Biorepository

Brief description of facility:
This is a national facility called "Center for Advanced Protein Studies", a BIRAC project with a broad objective of partnering with startup companies and academia to fulfil their analytical need using high end analytical technologies.

Types of Services offered:
Analytical method developments/sample analysis/ collaborating for research projects/support during regulatory filings.

Project achievements:

a. **Infrastructure available** Advanced Analyticals facility equipped with two QToF mass spectrometers, SEC MALS, CE, iCE, AUC, Biacore T200 and many other Instruments. In addition to this, Bioanalytical lab with Triple Quad MS instrumentation to support GLP Bioanalytical studies. To be accredited by National GLP Compliance Monitoring Authority.

b. **Types of products developed/ tested**

Analytical characterization of large molecules/ biosimilars/ cell extracts, IVD kits for certain diseases, vaccine immunogenicity

c. **Accreditation of facility:** To be accredited by NABL& GLP Compliance Monitoring Authority

Current stage of facility readiness:

Advance Analytical studies already started functioning and services are being offered for innovative research projects. Bioanalytical Lab will be soon ready with NABL accreditation to offer service for large molecule quantification in Blood, plasma, serum samples. Also services would be available to support for Biomarker discovery.

Differential pricing offered:
At the rate of only service charges

Website for services:
https://caps.syngeneintl.com

Project Coordinator:
Nithyakalyani Sri Rangan

Team Members :
Kalaiyarasi Duraisamy, Thummala Praveen, Priti Prakash, Jitendrakumar Singh, Thejaswi and Ajay Pakalapati

Contact :
Nithyakalayni Sri Rangan, 9980015360.
nithyakalyani.101@synegeneintl.com

Centre for Cellular and Molecular Platforms

Name and address of Facility:
NBM Medtech Rapid Prototyping Facility for Microfluidic Diagnostic Devices, Centre for Cellular and Molecular Platforms, NCBS-TIFR campus, UAS-GKVK post, Bangalore 560065

Broad area:
Medical devices and diagnostics (Rapid Prototyping Facility)

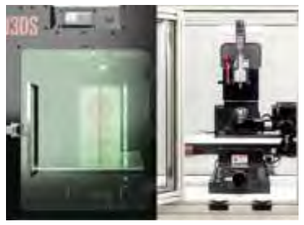
Brief description of facility:
This facility is envisaged to be a national one-stop facility with capabilities for design to pilot scale which will reduce start-ups' dependence on foreign vendors and vendor management. The vision is to establish an enabling facility which would become the core for microfluidic medtech development in the country and nurture innovation in medical technology by entrepreneurs and academia. The objectives of the project are 1) to augment the existing facility to a fully functional microfluidic diagnostics prototyping unit, 2) to establish the Service model along with implementation of Quality Management System, and 3) facility certification, training of personnel for start-ups and researchers, as well as the completion of microfluidic medical device prototyping projects.

The pilot scale production is to be ISO13485 certified, and we aim to have under one month turnaround time for all processes. We also offer microscopy and fluid flow QA/QC testing in house for devices produced here as well as elsewhere.

Types of Services offered:
Design for manufacture, PDMS device fabrication, Plastics (COC, PMMA, PS) microfluidic device fabrication, Lateral flow device fabrication, Microfluidic device prototyping, pilot scale manufacture of plastic devices, Fluid flow testing, Device QA/QC testing

Project achievements:

a. **Infrastructure available**
   CLASS10000 cleanroom
   Dassault Solidworks Design Suite Full
   PDMS fabrication equipment
   Laser Cutter
   3D printer
   Minitech 3-axis CNC minimill (Ordered. Awaiting installation.)
   Automated Inverted Fluorescence Microscope and Upright Fluorescence microscope
   Piezoelectric peristaltic pump system and Syringe pump system
   Dektak Surface Profiling system
   NI LabVIEW DAQ and automation systems



b. **Types of products developed/ tested**
   Microfluidic flow devices and Microfluidic diagnostic devices
   Design for medical devices and Design for microfluidic devices
   Testing platform for microfluidic and other devices/imaging

c. **Accreditation of facility:**
   Working towards ISO 13485

Current stage of facility readiness:
Design capabilities and PDMS fabrication capabilities available. Plastic device fabrication available from 01 April 2021. Pilot scale fabrication available from 01 June 2021. Device testing (electronics) available. Device testing (fluid flow) available from 01 March 2021. Microscopic device testing and profilometry available from 01 June 2021.

Differential pricing offered:
Academic users charged at cost. Startups charged at subsidized rates, and established companies and individuals charged at full rates.

Website for services:
https://www.ccamp.res.in/tps/

Project Coordinator:
Taslimarif Saiyed &
Feroz M.H. Musthafa

Team Members :
Anusha Keloth,
Nasir Ashraf, Subhash K.M.,
& Krishna Kumar

Contact :
ferozm@ccamp.res.in,
9791728876

IIT Kanpur

Name of Facility:
MedTech facility, Near Media center lab, IIT Kanpur, Kanpur – 208016, UP, India.

Broad area:
Medical devices and diagnostics (Rapid Prototyping Facility)

Brief description of facility:

The facility is being develop to provide a center for design and manufacturing of cost effective, viable medial products and solutions under quality-controlled environment. Along with in-campus solutions in fabrication, facility will also serve and support local businesses those who are lacking in access to a state of the art manufacturing facility. The long term goal for this facility is to stimulate medical devices industries in north India by providing technical and financial support to both entrepreneurs and small and medium size industries.

Following objectives are laid to execute the project

a. Augmenting the existing facility to a fully functional prototyping unit

b. Establish the Service model along with implementation of Quality management system

c. Providing Services in ISO 13485 certified facility

Types of Services offered:
Designing, prototyping, testing of medical devices

Project achievements:

a. **Infrastructure available:** Infrastructure include dedicated facility of Additive manufacturing, Post processing, Tool room, Inspection and sterilization, Electronics fabrication).

b. **Types of products developed/ tested:** Non-invasive medical devices

c. **Accreditation of facility:** ISO 13485

Current stage of facility readiness: Facility is operational for design and prototyping of medical devices
ISO certification is in process.

Differential pricing offered:
State of the art design and development facility include Reverse engineering, Design analysis and Additive fabrication under single roof.

Website for services:
www.medtechiitk.in

Project Coordinator:
A.C. Mishra

Team Members :
10

Contact :
91-020-24366920,
acm1750@gmail.com

Netra Accelerator Foundation

Name of Facility:

Marathwada Medtech Lab, M-CIP Building, Gate No. 6, MIT Group of Academic and Research Institutes, Beed Bypass Road, Aurangabad. 431010 M.S.

Broad area:
Medical devices and diagnostics (Rapid Prototyping Facility)

Brief description of facility:

Marathwada Medtech Lab is set up to provide rapid prototyping facility for start-ups, researchers and industry engaged in developing medical devices. Local industry has set up a brown field electronics manufacturing cluster for supporting manufacturing. There was a gap in terms of rapid prototyping facility. Marathwada Medtech Lab fulfills the need.

Marathwada Medtech Lab has industry grade thermoplastic 3 D printing machines with capability to print 13 different materials including biocompatible material, antistatic material for electronic assembly, chemical resistant, high temperature withstanding materials along with general purpose materials like ABS, and ASA. The product build size is 16"x14"x16" with +/- 0.0015 mm/mm to +/-0.127 mm/mm accuracy range. The slice thickness is ranging from 0.127 mm to 0.330 mm. It will soon be equipped with 3 D scanner.

The metal machining facility has 5 axis VMC for machining complex geometrical shapes within +/- 10 microns and CNC Lathe with 800 mm ABC and 350 mm chuck.

Our facility also has PCB prototyping machines and SMD devices mounting and soldering facility for wearable devices and all types of electronics parts.

The facility will have ISO 13485 accreditation for meeting regulatory compliance.

Types of Services offered:

Prototyping manufacturing

Project achievements:

a. **Infrastructure available** 3 D printer - Startasys make 450 MC, 5 Axis VMC BFW Xtron 1100 and CNC Lathe of BFW BHT2570 already installed, commissioned and in operation. PCB making machine, Laser cutter and 3 D scanner will be commissioned by end of Feb 21.

b. **Types of products developed/ tested** Patient care and delivery auto guided robotic trolley, Automatic sanitizer dispenser, Preoperative skull model for surgeons, prototype of BLDC motor and various molds for injection molding.

c. **Accreditation of facility:** ISO 13485 in process.

Current stage of facility readiness:

We are ready to offer services for RPT with range of thermo plastics, metal and electronics PCB.

Differential pricing offered:

Details of differential pricing available for users

Machine	Start-ups /researchers for Medical devices	Industry
5 Axis VMC	Rs. 300/ Hr	Rs. 450 /Hr
CNC Lathe	Rs. 175/Hr	Rs. 250/Hr
3 D printing (as per job and material used)	Material cost +Power consumption per hour	Material+Power+30%

Website for services:

Project Coordinator:
Vishwas Kurundkar

Team Members :
Sanjay Deshmukh,
Sanjay Gadkari,
Ajay Bankar

Contact :
0240-2375337, 9834149934,
vishwas.kurundkar@mit.asia,
rpt@mit.asia

Yenepoya (Deemed to be University)

Name of Facility:
Yenepoya (Deemed to be University), University Road, Derelakatte, Mangalore 575018.

Broad area:
Medical devices and diagnostics (Rapid Prototyping Facility)

Brief description of facility:
The MedTech Design and Rapid Prototyping facility at Yenepoya has been setup to help serve the growing MedTech community by providing state-of-the-art rapid prototyping and product validation infrastructure. This facility would serve as a platform for transformation of ideas into scalable prototypes and also to encourage commercialisation of the research and the patents. This facility is located within Yenepoya (Deemed to be University) and has access to infrastructure and expertise from Medical, Dental, Public Health, Hospital and Life Sciences and Biomedical Research domains. The facility will attract MedTech startups and innovators by offering wide array of services which includes Medical Need Validation and Clinical Validation of Medical Devices.

Types of Services offered:
Prototyping and Clinical Validation of Medical Devices

Project achievements:

a. **Infrastructure available:** The MedTech Design and Rapid Prototyping facility houses high end instruments for 3D Printing, CNC Machining, Bioprinting, PCB Fabrication and Automated Assembly, Injection Moulding, etc. The 3D printers available at the facility will include FDM, SLA, SLS and DMLS (Metal), along with high-end 3D scanners. The facility offers wide array of services which includes, Clinical Need Validation, Industrial Product Design, fabrication of thermoplastic, polymer and metal-based parts/products, Bioprinting/Tissue Engineering, PCB fabrication, Electronics Prototyping, Application Development and Product Validation.

b. **Types of products developed/ tested:** (broad categories eg. Microfluidics medical devices, analytical characterization of small molecules/ biosimilars/ cell extracts, IVD kits for certain diseases, vaccine immunogenicity using XYZ parameters).

Medical Devices, Surgical Guides, Medical Training Models, Microfluidics.

c. **Accreditation of facility:** ISO 13485 accreditation in process

Current stage of facility readiness:
The facility is functional and is offering services

Differential pricing offered:
The facility has a differential pricing model to ensure affordability for different user/client groups such as students, researchers, startups and SMEs.

Website for services:
https://ytincubator.com/

Project Coordinator:
Akhter Husain

Team Members :
Asim Syed Sheeraz,
Arun AB, Rekha PD

Contact :
Mobile - +91 9845084266
Email - drakhter@yahoo.com

IIT Kanpur

Name of Facility:
EMI/EMC & Electrical Safety Testing Facility at IIT Kanpur

Broad area:
EMI/EMC and Electrical Safety Testing of Medical Devices

Brief description of facility:
The main aim is to establish a world-class EMI/EMC (Electromagnetic Interference and Compatibility) test facility at the Indian Institute of Technology Kanpur, where the major focus would be to test the EMC compliance of modern electronic instruments and gadgets presently used in the medical industry. It is to be noted that most of the modern electronic instruments are high-speed digital devices, and the major challenge with the usage of these digital electronic gadgets is the mitigation of electromagnetic interference (EMI) as they continuously generate broadband undesired electromagnetic (EM) fields. The EMI/EMC issue is more challenging for the electronic instruments used in the medical field because of the human health risk involved in addition to the compliance with the regulatory EMC standard prevalent in the country. The EMC testing of medical instruments is presently not given due consideration in the country primarily due to non-availability of EMI/EMC testing facility at an affordable price, and lack of awareness of the EMI/EMC issue among the medical professionals and the product developers. The EMI/EMC testing facility would provide extensive compliance tests of all types of electronic and communication devices with special emphasis on medical instruments starting from low frequency to RF range, which would especially be quite helpful to start-ups developing new electronic and medical instruments.

Types of Services offered:
Testing

The EMI/EMC testing facility would conduct the electromagnetic interference and electrical safety tests required for various medical instruments as per the IEC 60601-1-2, IEC 61010 and CISPR 11 standards.

Major Test Services:
The facility would conduct the pre-compliance and full compliance testing:
Radiated and Conducted Emission Testing,
Radiated and Conducted Susceptibility Testing,
Electrical Safety Testing

The facility would be compliant to CISPR 16 standard including the provision for automated test setup for performing EMI/EMC measurements. At a later stage, it the facility would be made fully compliant to the ISO 17025 standards, and accreditation by NABL would be obtained.

Project achievements:
a. **Infrastructure available:** Facility Development is underway

b. **Types of products tested:** Medical Devices

c. **Accreditation of facility:** NABL accreditation to be completed

Current stage of facility readiness:
Facility preparation is underway

Differential pricing offered:
Subsidized testing will available to academia and SME

Website for services:
Website is currently being prepared

Project Coordinator:
M. Jaleel Akhtar

Team Members :
A. R. Harish, Nandini Gupta, Seema Awasthi, Rakesh Roshan, Nilesh kumar tiwari, Hitesh Chaubisa.

Contact :
M. Jaleel Akhtar, email:mjakhtar@iiitk.ac.in / Seema Awasthi, email: seemaaw@iitk.ac.in, Mob:9793602999

Society for Applied Microwave Electronics Engineering & Research (SAMEER)

Name of Facility:
SAMEER-EMC Centre, Sector 7, Rain tree marg, CBD Belapur, Navi Mumbai – 400614. India

4. Broad area:
EMI/EMC, Electrical Safety & Environmental compliance testing of Medical devices

Brief description of facility:
The facility will address the compliance testing needs as per international standard IEC 60601-1 & IEC 60601-1-2 for the Medical devices manufactured in the country or imported from other countries before putting them in services. As of now, there are very few facilities available within the country which would support the kind of services the proposed facility intends to provide for Indian manufacturers and users. Also the trained manpower required for the compliance testing is very small for catering to the needs of the country. The proposed facility would also create trained manpower for running similar facilities created in future. Thus the medical devices manufactured within the country would also be acceptable in the global market. The turnaround time for establishing such accredited facility is expected to be 30-36 months.

Types of Services offered:
EMI/EMC, Electrical Safety & Environmental Compliance testing of Medical devices manufactured within the country / Imported from other countries before putting them in service of the patients.

Project achievements:

a. Infrastructure available:
EMI/EMC, Electrical Safety & Environmental test facility.

b. **Types of products developed/ tested:**
Clinical instruments and medical devices required for diagnosing patients.

c. **Accreditation of facility:**
NABL accreditation as per ISO/IEC 17025:2017 is available

Current stage of facility readiness:
Available services: EMI/EMC related test and Consultancy services, Environmental test services

Services being established: Electrical Safety testing

Differential pricing offered:
A discount of 20% is available to all SSI units

Website for services:
http://www.sameer.gov.in,
Email – emcdivision@sameer.gov.in

Project Coordinator:
Milind Y Joshi, Scientist F & Head (EMI/EMC division) & Gautam S Shende, Scientist D

Team Members :
Ramesh G Pawar, Scientist - D

Contact :
Phone no – 022-2759 3115, 022-2759 3132, 022-2759 3121
Email – milind@sameer.gov.in, gautam@sameer.gov.in, emcdivision@sameer.gov.in

Palamur Biosciences Pvt. Ltd

Name of Facility:
Palamur Biosciences Pvt. Ltd., Madigatla Village, Bhoothpur Mandal, Mahabubnagar, Telangana State -509382

Broad area:
Medical Devices and Diagnostics (Swine facility for medical device testing)

Brief description of facility:
Palamur Biosciences established a state of art large animal Medtech facility branded as MRIDA (Medical Research Institute of Devices Assessment) under the aegis of NBM /BIRAC to support the medical device eco system for Biological and Preclinical Testing Facility For Medical Implants, Devices and Drug Device combinations).

- The objective of the facility is to provide high end medical devices safety testing's using large animals such as Beagle Dog, Swine and Sheep.

Palamur is developing a global standard testing facility by adding a swine facility so that it can cover the entire gambit of the medical device industry. This world class testing facility will cater to various devices relating to Intervention Cardiology, Orthopaedics, Nephrology, Neurology and Urology.

Besides the above, Palamur will provide training facility for the cardiologist and technicians at the national levels to improve as well as horn their skill sets . We believe the above requirements are met with through our facility

Types of Services offered:
Palamur offers the following services:

- Biocompatibility study (full battery of tests for medical devices)
- Preclinical safety and Performance evaluation studies for medical devices

Project achievements:

a. Infrastructure available
The following state of art of the facilities are available:

1. Dedicated Cath lab for implantation and scanning of implants (AERB approved)5.High end Necropsy Rooms
2. Separate Operation Theater with class 10000
3. Animal Preparation Room
4. Post Animal Observation Rooms
6. High end Pathology Room
7. High end Clinical Pathology Rooms

Equipment's:

1. Intravascular Radiography
2. Ultrasonography Machine
3. Inhalation Anesthesia Machine
4. Bone implant drilling
5. Optical coherence tomography machine
6. Intravascular ultrasonography machine
7. Heart lung machine
8. Electro suction
9. Defibrillator

b. Types of products developed/ tested:
The following types of medical devices are tested at our facility

1. ECMO Pump
2. Coronary stents
3. Peripheral stents
4. Hemostatic Devices
5. Dilatation balloons
6. Cell based and Herbal wound Dressings

c. Accreditation of facility:
Palamur is having NABL ISO 17025, CDSCO and GLP Accreditations

Current stage of facility readiness:
Facility is already started the service offerings to medical device manufacturers

Differential pricing offered:
Discounted service charges are offered to BIRAC grantees

Website for services:
https://www.pbsmrida.com

Project Coordinator:
D. C. Sharma

Team Members :
Anoop, Sachin Bansal, Tharun

Contact :
Ph. No.: 7821047012,
E-mail:
dcsharma@palamurbio.com

Huwel Lifesciences Pvt. Ltd.

Name of Facility:
Huwel lifesciences pvt. ltd., 4th floor, M N Capital, kokapet, Hyderabad

Broad area:
Medical devices and diagnostics - Manufacturing of IVDs

Brief description of facility:
Facility is equipped to manufacture:

a) Enzymes and mixes required for manufacturing of molecular diagnostic kits, i.e. Taq polymerase, reverse transcriptase, Bst polymerase.

b) Molecular diagnostic kits with segregated area for positive control manufacturing, buffer manufacturing area, automated labelling and filling.

c) Primer probe manufacturing and HPLC purification

d) Extraction column and reagent manufacturing

e) Reagents and plastic ware manufacturing for magnetic bead extraction

f) Sample collection and nucleic acid stabilization media manufacturing

Types of Services offered:
Product development, Manufacturing, probe primer synthesis and purification

Project achievements:
probe, primer manufacturing and purification. Molecular Transport Medium and Nuclic Acid extraction Kit Manufacturing

a. Infrastructure available:
ISO 7/8 facility, oligo synthesizer, oven, -20, fume hood, refrigerator, analytical HPLC, preparatory HPLC, concentrator.

b. Types of products developed/ tested: Primers desalted, Primers HPLC purified, taqman Probes, FAM-BHQ, Hex-BHQ, Cy5-BHQ.

c. Accreditation of facility: ISO 9001-2016, IVD 13485-2016, CE certification for product development, manufacturing.

Current stage of facility readiness:
commercial services have been initiated for unlabeled and fluorescent-labled primers and probes

Differential pricing offered:
we offer 10% less to government organizations compared to least price offered to private organizations.

Website for services:
We are in the process to create a dedicated website.
Enquiry at Email: oligo@huwellifesciences.in.

Project Coordinator:
Rachana Tripathi

Team Members :
Rachana Tripathi, Shesheer Kumar, Shibashish sahoo, Ritu Saxena, Ravi, sreenivas

Contact :
9704567313,
rachana@huwellifesciences.in

Andhra Prdesh MedTech Zone

Name of Facility:
DBT – AMTZ Covid Medtech Manufacturing & Development (COMManD) Strategy

Broad area:
Medical Devices and Diagnostics – Manufacturing of medical devices and diagnostics.

Brief description of facility:
AMTZ is an established medical equipment manufacturing ecosystem. DBT is supporting Andhra Pradesh MedTech Zone (AMTZ) which is Asia's first medical equipment manufacturing ecosystem, uniquely dedicated for MedTech.

Many medical device manufacturers have the potential to make critical equipment like ventilators and diagnostic kits, thermal scanners or medical textiles, which is much needed in COVID context as well post-COVID period. However, to rapidly scale up the manufacturing, it would require a huge investment in plant and machinery, without which such scale-up will not be possible. DBT, therefore, is supporting AMTZ to invest in the plant and machinery in these companies which are situated within AMTZ campus in Visakhapatnam so that their rapid scale-up of infrastructure and production capabilities could be achieved.

To increase the production capacity and to meet the demand of the current pandemic scenario, there is a need to increase production, automate assembly process, develop quality management systems and many other sophisticated methodologies. This demands for Lyophilization units, Cold rooms, Liquid filling and Labelling machines, Spectroscopic Equipment, Bio-luminescence readers, High throughput laser welding and ultrasonic welding machines and the necessary support facility for production of cartridge plates as well as sample preparation devices. All these P&M that were installed with the support from DBT-AMTZ partnership increases the production capacity to make the cartridges, sample preparation, extraction techniques to process the infectious samples without contaminating the testing environment. A MedTech Park of this capacity housing multiple laser welding and ultrasonic welding lines with 50000 square feet of clean rooms, testing labs, sterilization units, EMI-EMC facility would facilitate to increase the production manifold and fight the COVID-19 battle.

Types of Services offered:
Prototyping, Manufacturing and Testing of IVDs, Ventilators, IR Thermometers, IR Thermal Scanners, Pulse oximeters, N95 Masks, PPE Kits

Project achievements:

a. **Infrastructure available:** Plant and Machinery for scale up of production of ventilators, N95 masks, PPEs, IR thermometers

b. **Types of Products Developed / tested:** Molecular diagnostic kits, antigen detection rapid test kits, antibody detection rapid test kits, ELISA kits, nucleic acid extraction kits, Viral transport medium, Ventilators, pulse oximeters, IR thermometers

c. **Accreditation of facility:** A2LA, NABL accredited EMI- EMC Testing Facility, BIS Recognized Biomaterial testing facility (BIOME), IS Recognized Medical Textile Lab (Textura)

Current stage of facility readiness:
Facility is fully operational and services are being offered

Differential pricing offered:
Subsidised rates for testing and manufacturing are applicable to all SMEs.

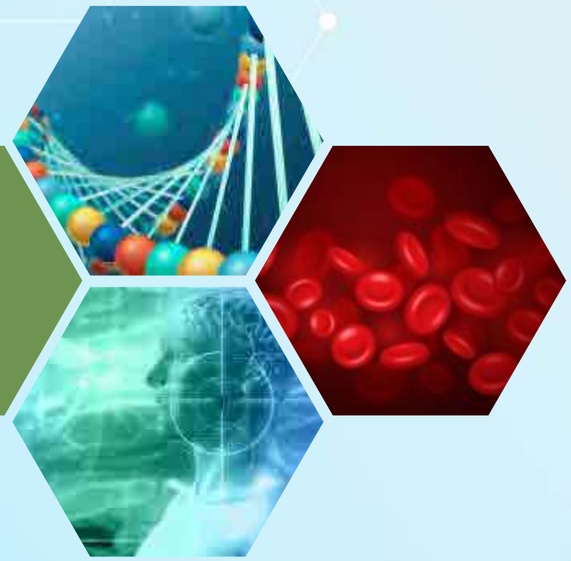
Website for services:
www.amtz.in

Project Coordinator:
Jitendra Sharma

Team Members :
Dilip Kumar, Santosh Baliwada, Krishna Kanth, Syed Junaid Ahmed

Contact :
Andhra Prdesh MedTech Zone
Pragati Maidan
VM Steel Project S.O
Visakhapatnam, Andhra Pradesh 530031

Grand Challenges India



GRAND CHALLENGES INDIA

Grand Challenges India

Grand Challenges India (GCI) is the Indian arm of Global Grand Challenges, launched in 2012 and is the flagship program managed by the GCI at BIRAC and is collaboratively funded by Department of Biotechnology (DBT), Bill & Melinda Gates Foundation (BMGF), and the Wellcome Trust.

The main aim was to address some of the daunting challenges that we face today and tackle them by encouraging Indian innovation and research to develop affordable and sustainable solutions in order to improve health and well-being in India and then across the globe.

GCI is committed to seeking and rewarding established researchers, young entrepreneurs, and innovators from both academia and industry. GCI aims to help innovators expand the pipeline of ideas for developing new preventive and curative therapies, piloting new technologies, and exploring new ideas.

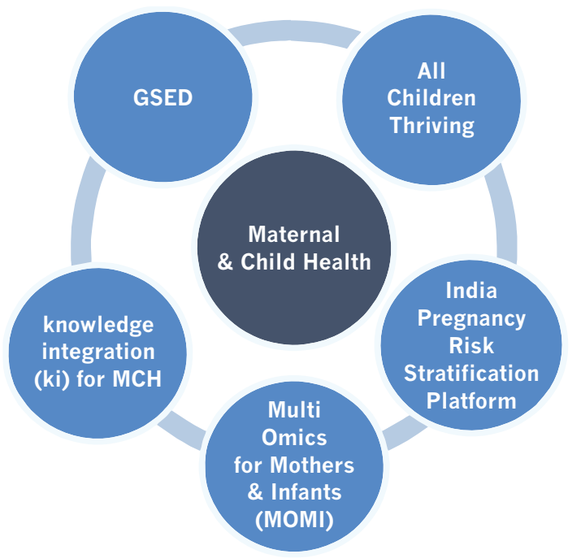
Over the years, GCI has grown both as an idea and as a partnership covering varied themes from maternal and child health to agriculture, nutrition, infectious diseases etc. in order to respond to the ever-changing needs of research in public health in India.

Presently, GCI supports a range of research and development activities. We have supported basic research, translational research, intervention trials, clinical trials, data integration and analysis, product and technology development. GCI also funds projects at various stages in their lifecycle; from basic science research in laboratories, to proof-of-concept projects and potentially to scale-up to innovation projects. GCI is currently working to expand the funding arenas and mechanisms.

Grand Challenges India works across 4 major themes; Maternal and Child Health, Infectious disease, Agriculture & Nutrition and Medtech development and entrepreneurship support. There is also a suite of cross-thematic programs. Programs in these areas are funded through the open call as well as specialised programs mechanism.

Maternal and Child Health

To tackle the huge challenge of maternal and child health, especially in developing countries, GCI has made maternal and child health an important vertical to direct investments. The MCH programs under GCI are aimed at ensuring not only the survival of mothers and their children but also ensuring that they lead a healthy and productive life.



GRAND CHALLENGES INDIA

All Children Thriving

All Children Thriving (ACT) was launched as the third thematic call under GCI with the aim to investigate novel cost-effective measurement tools and mechanisms to combat unhealthy birth, growth and development. The call was launched with intend to promote maternal nutrition status, reduce the incidence of low birth weight, reduce child stunting or wasting, reduce nutritional deficiency and improve overall development (including cognitive) in children.

There are seven projects supported under ACT initiative (1 full grant and 6 seed grant). All the projects are aimed at exploring a unique element with special emphasis on innovative, impactful research on maternal and child health and development. There is also a sub-study supported under the full grant.

Of six seed grants, three are aimed at developing simple low-cost biomarkers that can be applied early in life for adverse outcomes among mother and children. Two projects were intended to validate/ develop intervention for improvement in maternal and child health. By providing access to repertoire of specimens a well characterized information on environmental, clinical, social and epidemiological determinants at different time points in pregnancy, the **Biorepository project** is aimed at developing an important health system intervention, algorithms and predictive models to address multiple strategic priorities in preterm birth, discovery and development.

One of the main grants supported under ACT call is study entitled **"Linear Growth Study"** also known as **Women and Infants Integrated Growth Study; (WINGS trial).** The project aims to achieve optimal growth and development in infants and children living in low resource settings in India, through integrated delivery of a package of evidence-based interventions endorsed in our national programs and by the World Health Organization. The study is an individually randomised, factorial design trial that is assessing the impact of an integrated package of interventions, including nutrition, WASH, medical treatment of disorders affecting growth, and psychosocial care in 13,500 women. The interventions are delivered according to a factorial randomization scheme throughout the pre- and peri-conception period, pregnancy and first 2 years of life to establish the maximum growth and developmental potential of their infants and children living in low resource settings in India.

Nutrition interventions to Improve Linear Growth during Infancy in India (IMPRINT Trial)

One of the sub-studies supported under the WINGS trial is IMPRINT Trial. The study aims to answer relevant scientific questions on the role of improving maternal dietary intake in promoting linear growth during the first 6 months of life, and the benefits of increasing protein quantity and quality in complementary foods to improve linear growth in the second 6 months of life in a population with high rates of stunting. The trial includes two sub-studies. The first aims to promote nutritional adequacy of lactating mothers through use of nutrition supplement(s) and assess its impact on linear growth in the first 6 months after birth. The second sub-study intends to address the effect of nutrition supplement(s) with varying amount of protein and high-quality protein, together with adequate energy and micronutrients, for 6–12-month-old infants on their linear growth.

Use of the Global Scale for Early Development within the Women and Infants Integrated Growth

The available evidence strongly supports that the first 1000 days (conception through age 24 months) and the period to the end of the third year of life, are foundational for brain development. Keeping in view the same, Global Scale for Early Development (GSED) study is following children of WINGS trial up to 24 months of age to assess their linear growth, with secondary outcomes i.e. neurodevelopment scores and developmental milestones. Although the importance of early development has been well recognized globally, universal measures designed to quantify early child development are lacking. In light of existing knowledge gap, a new tool termed as "The GSED" has been developed, with the overall intent is to create a harmonized scale to measure child development in children under three years of age. The GSED tools are currently being validated in a cohort of children against available psychometric tools through a rigorous and standardized exercise in six countries that are diverse in terms of geography, language, culture and income i.e., Bangladesh, Pakistan, Tanzania, Brazil, Ivory Coast, and The Netherlands. However, it will still be unknown how the GSED tools perform in an intervention trial setting, specifically in terms of their ability to detect intervention effects on developmental outcomes. The proposed study aims to use the ongoing WINGS trial as a platform to test the GSED tools for their ability to detect effects of intervention on neurodevelopmental outcomes in children aged (6, 12 and 24 months of age). The integration of the GSED tools within the ongoing WINGS trial to help answer relevant question. The study will also provide an opportunity to understand the responsiveness of GSED tools (sensitivity) and validate it against standardized psychometric tools) (Ages and Stages

Questionnaire 3rd Edition and Bayley Scales of Infant and Toddler Development- 3rd Edition while detecting its intervention effects on neurodevelopmental outcomes.

Knowledge Integration (ki) Data Challenge

Data Science Challenge was the sixth call under GCI, launched with a goal to foster new approaches in data-driven decisions designed to answer critical scientific questions related to maternal and child health and development outcomes, using innovative data analytics and modelling approaches applied to ki India or to other relevant data sets that applicants can access. The call was synergized with the Grand Challenges calls from Brazil and later with Africa.

The program received 119 applications and each application underwent three-tier screening process and 10 projects were shortlisted for funding support. However, 3 grantees whose due-diligence processes were done and based on the approval of the Competent Authority were sent the funding agreements declined to accept funding for their proposal due to the COVID-19 pandemic.

The seven supported teams are using specialized skills and valuable experience that will help interpret conclusive results through additional analyses that may help predict pregnancy outcomes, birth outcomes and childhood health and development patterns.

In 2018-2019, a global kick-off meeting was conducted in New Delhi, India with the GC India, Brazil teams that were selected to synergise and collaborate teams with similar research interests and share experiences.

The Summary of the shortlisted projects is as below:

1. **Preterm birth risk in pregnant women – prediction using machine learning models, Translational Health Science and Technology Institute; Collaborator: Indian Institute of Technology, Madras**

   The study proposes on pregnant women (Garbh-ini) cohort, a multidimensional longitudinal dataset purposely designed to study preterm birth. The study will apply data-driven machine learning approaches to develop an accurate and clinically useful model to predict the risk of preterm births.

2. **A data science approach to develop growth cut-offs for graded care of malnutrition;**

   St. John's Research Institute, Bangalore; Collaborator: Society for Applied Studies

   The study aims to calculate cut-offs using data provided by HBGDki and datasets with SAS, SJRI where weight, height, and age are available for children below five years in combination with other outcomes such as death, morbidity or hospitalization.

3. **Child undernutrition in India: Exploration of the nutritional gap based on distal and proximal factors,**

   St. John's Research Institute, Bangalore

   Intends to adopt unconventional data analytical techniques to explore the multiple dimensions of child undernutrition in India, utilizing existing national surveys and the HBGDki database.

4. **Developing district-level forecasts of vaccine coverage and inferring vaccine confidence across India using large public health datasets;**

   IIT Delhi; Collaborator(s): INCLEN Trust, JNU & Imperial College, UK

   The study aims to explore regional trends and variations in vaccine uptake, uncover relationships to other socioeconomic, demographic, and public health indicators, and develop a predictive model of the state of vaccine confidence in different parts of India. The main goal of the study is to develop a prototype coverage monitoring and forecasting system across districts by using Gaussian process methods.

5. **Size matters: Predicting personalized risk of SGA, National Chemical Laboratory, Pune**

   The project aims to solve the problem of a large number of low-weight births in the Indian population and the inability to predict the risk reliably in the antenatal period.

6. **Understanding the effects of initiation of complementary feeding at four months compared to six months on growth and infection among Indian children,**

Christian Medical College and Hospital

The study may describe the breastfeeding patterns in individual studies using a survival analysis approach and overall, through a meta-analytic approach.

7. **Exploring risk factors of adverse maternal and child health outcomes using machine learning and other advanced data analytical approaches, Department of Humanities and Social Sciences, IITD**

   Combining multiple data sets from HBGDKi using ML tools for prediction, classification and topic discovery may yield new insights for adverse birth outcomes and intermediate outcomes of interest.

Multi-Omics for Mothers and Infants (MOMI) Consortium

A hospital-based cohort of pregnant women, **GARBH-Ini** (*interdisciplinary Group on Advanced Research on BirtH outcome - DBT INdia Initiative)* has been established at the civil hospital at Gurugram, Haryana, India by **Translational Health Science and Technology Institute (THSTI)** with the hypothesis that risk stratification of pregnant women using time series multidimensional data on clinical, epidemiological, genetic, proteomic, metabolomic and ultrasonographic attributes will facilitate the development of an effective algorithm for early prediction and timing of intervention of PTB with support from the **Dept. of Biotechnology, Govt. of India.**

The cohort is being supported with the additional funding from the Grand Challenges India - All Children Thriving program, which supports the electronic clinical record repository with a related imaging bank of ultrasound images, and a biospecimen repository.

The GARBH-Ini Cohort has been invited to join the Multi-Omics for Mothers and Infants (MOMI) Consortium, which is an international group of leading experts on maternal, newborn, and child health, and innovative 'omics' technologies working together to accelerate solutions for adverse pregnancy outcomes and optimize health for mothers and infants in low-and-middle-income countries.

The specific objective is to carry out extensive **omics assays (genetics, metabolome, proteome etc.)** on samples collected in different studies across low and middle-income countries (AMANHI cohorts in South East Asia and Africa and GAPPS cohort in Africa) to look in-depth at the clinical and biological risk factors and predictors in preterm birth, stillbirth, preeclampsia and IUGR. The Consortium's Guiding Principles were prepared by the MOMI Consortium Members which sets forth the terms and conditions governing the relationship between BMGF, the MOMI Consortium and the MOMI Consortium Members.

MOMI is bringing together the 17 large cohorts with well characterised clinical phenotypes across geographies, robust analytics approaches and exceptional investigators from diverse disciplines and geographies who have collaborated deeply and equitably to answer fundamental questions about the pathophysiology of pregnancy complications and thereby to improve outcomes.

The India PRS platform – the parent study

The establishment of a Pregnancy Risk Stratification platform is being supported to CMC Vellore by the Gates Foundation, as a surveillance and trial platform at 2 sites in India-Palwal, Haryana and Makunda (Bazaricherra), Assam.

The Makunda Christian Leprosy and General Hospital (MCLGH) in Bazaricherra, Silchar District, Assam and the Community Health Centre (CHC) in Hodal, Palwal District, Haryana have been identified as community-based sites with high morbidity and high rates of infant and maternal mortality. The PRS team is conducting periodic surveillance in the catchment areas of MCLGH and CHC Hodal to generate population-based information in the proposed study area that includes key risk factors resulting in adverse pregnancy outcomes, maternal mortality ratio and the burden of morbidity and mortality in new-borns and children.

The major-specific objectives will be achieved in multiple phases across 4 years in ongoing IPRS study:

i. Build on the establishment of the community-based pregnancy risk stratification platform to harmonise data and sample collection strategies with the global Antenatal/Postnatal Research Collective and with the Garbhini study in India

ii Establish data sharing through the ki initiative

iii. Conduct pilot sampling through the India pregnancy risk stratification platform at Makunda paralleling those processed from Garbhini for the MOMI study

iv. Validate epidemiological, clinical, ultrasound and socio-demographic risk factors identified by Garbhini in the community-based cohorts

v. Build towards validation of biomarkers identified by Garbhini in the community-based cohorts.

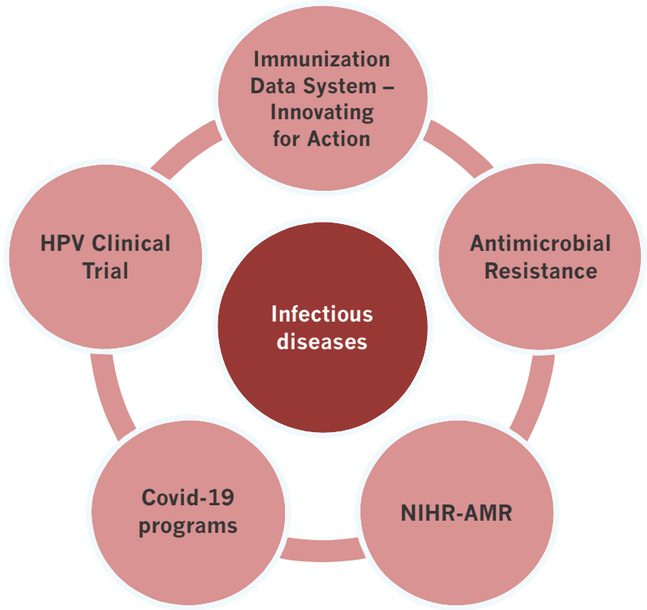
GCI is supporting with the **goal** of Garbhini India Pregnancy Risk Stratification Platform Alignment (GIPA) is to align and validate the findings from the DBT supported Garbhini platform in a subset of the India Pregnancy Risk Stratification (PRS) Platform.

Key Objective(s) under GCI-BIRAC governance for GIPA study are as follows:

1. Build on the establishment of the community-based pregnancy risk stratification platform to harmonise data and sample collection strategies with the global Antenatal/Postnatal Research Collective and with the Garbhini study in India.
2. Data sharing through the ki initiative and the PRS/ARC platform. A document will be prepared in alignment with the Garbhini-MOMI data sharing agreement which is in process.
3. Conduct pilot sample collection through the India pregnancy risk stratification platform at Makunda paralleling those processed from Garbhini for the MOMI study.
4. Validate epidemiological, clinical, ultrasound and socio-demographic risk factors identified by Garbhini in the community-based cohorts. Garbhini has yielded and will continue to yield interesting insights and develop tools for risk prediction.
5. Build towards validation of biomarkers identified by Garbhini in the community-based cohorts.

Infectious diseases:

Recognising the importance of innovation and research in the space of infectious diseases, the partners of Grand Challenges India (GCI) have kept Infectious diseases as an important vertical where innovations/projects are funded.



Immunization Data: Innovating for Action (GCI-IDIA)

The Grand Challenges India fourth open thematic call was announced on 15th November, 2017 on 'Improving Immunization Data Systems' for 60 days with funding support from Department of Biotechnology, GoI and the Bill & Melinda Gates Foundation to support the set of projects aligned to the Indian strategy requirement.

The call was open for 60 days with funding support from the Department of Biotechnology, GoI, and the Bill & Melinda Gates Foundation to support the set of projects aligned to the Indian strategy requirement and in technical partnership with the Ministry of Health and Family Welfare, Government of India, the Department of Health Research (DHR) and the Indian Council of Medical Research (ICMR), who will be providing their valuable technical and practical inputs in selecting and reviewing projects.

The overall goal is to seek ideas that should be potentially translatable to practical interventions in India's immunization program and at addressing challenges faced in collecting, analyzing, and using data on immunization and health.

The program was planned in phases:

Phase I - Grant for developing proof of concept (12-18 months): Funded at a maximum of $200,000 per project, these awards for a maximum of 10 projects required preliminary data and are meant to provide an opportunity to develop, refine, and rigorously test approaches that have previously shown promise in controlled or limited settings.

Phase II - Grant for validating impact (18-24 months): This grant is envisaged for follow funding to scale the most successful and impactful projects from Phase I, with the ultimate aim being integration into the government program.

Phase I:

The supported nine project teams are testing a blend of innovative technologies involving blockchain technologies, data warehousing, mobile applications and development of health monitors for distinct health officials. In FY 19-20 all the projects undertook their specific activities, supported by mentors and the GCI teams, as well as the state immunization officers and health authorities.

Details of GCI -IDIA Phase I projects:

1. **HealthChain: an accelerator for immunization data integration, analysis, and use in India**

   Avalon Information Systems Pvt. Ltd., New Delhi

   The projects aims to reconcile coverage (from ANMOL / CAS) and consumption data (from eVIN) using **blockchain technology** to create a robust, scalable, real-time tracking and triangulation system on immunization data in India. This solution will integrate the immunization data of the Mother and Child Tracking System (MCTS) with IndiaStack to offer a public health solution for immunization based on India's unique identity project Aadhar.

2. **Image recognition based data entry processes to ensure immunization completeness and auditing of reported data**

   OnionDev Technologies Pvt. Ltd., New Delhi

   The proposed solution aims to develop an application for optical scanning of the Mother and Child Protection (MCP) card immunization record for use by frontline workers equipped with a mobile smartphone. Real-time point-of-service data entry will leapfrog the existing MCTS/ RCH approach based on data entry at the Primary Health Centre (PHC) to improve data accuracy, timeliness and completeness.

3. **App for Tracking and triangulating Coverage and Vaccine Consumption on a GIS Platform to Assess Immunization Program Dynamics in India through Reliable and Timely Analytics and Visualisation of** *DataML Infomap Pvt. Ltd., Delhi*

   The proposed solution aims to access, interface/integrate population coverage (HMIS/ANMOL) data and vaccination consumption (eVIN) data on a GIS server platform and to track and triangulate the datasets in near real time and enable quantitative analysis of these data sets and visualize the relevant KPI (Key Performance Indicators) through dynamic dashboards and active maps

4. **Improving Immunization Data Quality for Action: Biometry Beneficiary Linkage and Data Convergence for Monitoring**
   The INCLEN Trust International, Delhi

   This proof of concept proposal aims at improving the immunization data quality (accuracy, validity, consistency, completeness and timeliness) through four approaches: **(1) Aadhar (biometry/QR scan)** and **mobile number linkages of beneficiaries;** (2) bridging ANMOL and eVIN platforms for data convergence; (3) user-friendly monitoring dashboards to empower the program managers for tracking and improving performance; and (4) generating timely and appropriate data inputs for HMIS.

5. **Immunization Blockchain: Transforming Immunization Data Storage using Blockchain Technology**

   NEERMAN, Mumbai

   The initial pilot seeks to create data connectors that will translate MCTS and E-Vin data into a common format and store it onto the blockchain. A **blockchain database** will be the secure, decentralized, common backbone for recording data from disparate sources like MCTS and e-VIN to allow the tracking of vaccinations from the factory to the beneficiary level by using Aadhaar/UPI.

6. **IMMUNOCHAIN: A traceability solution for vaccines in immunization programs**

   IIITM-K, Trivandrum

   IMMUNOCHAIN, is to build a big data and **blockchain technologies powered, mobile/web** enabled vaccine traceability solution for immunization programs in India. It is proposed to be vendor neutral, scalable, replicable and reusable across different immunization programs in any geographical context. The goal of the Immunochain is to address the problem of traceability of immunization vaccines from manufacturing facility, through the distribution mechanisms in cold storage network and the vaccine handling/administration facilities, till the end consumer.

7. **Mobile Application For Immunization Data In India (MAIDI),** Indian Council of Medical Research Hq., Delhi

   The solution proposes to develop, pilot and assess the feasibility of an **integrated mobile-based application tool** to improve knowledge on India's Universal Immunization Programme, uptake of routine immunization services, and data access targeting beneficiaries/care-givers, health care providers and the health system.

8. **Nagarik Rog Pratirakshak: Unified Smart Immunization Coverage Monitoring And Analysis (UNISICMA)**

   Indian Institute of Information Technology, Una in collaboration with, SSN College of Engineering

   The project is working on an infrastructure that embraces cloud and fog computing and involves a novel platform with machine-to-machine (MM) messaging, seamless data management, and the use of data fusion and decision fusion to facilitate immunization data coverage.

   An mobile application is being developed, with natural language interfaces and edge analytics, performing big data analytics by using deep learning and federated stream mining techniques that supports Online Analytical Processing (OLAP) of real-time data UniSICMA NITT – SSNCE 3 and deploying immunization real-time data analysis as Analytics As A Service (AaaS) to promote ease of accessibility and interoperability.

Antimicrobial resistance call

Antimicrobial resistance (AMR) has become a major healthcare threat in recent times due to excessive use of antimicrobials, especially antibiotics, leading to dramatic rise in resistance. There are greater levels of AMR resistance reported from India and comparable geographies as compared to developed countries.

Given the increasing importance of tackling AMR in these developing geographies, GCI launched an open call specific to AMR with the purpose of transforming public health action on a regional or global scale by identifying and filling gaps in knowledge on AMR burden. AMR call was launched as a joint call where Grand Challenges partners from Brazil, South Africa, Africa and India have come together and announced a call for proposals. Each partner country has run the call in their specific geographies with the understanding that there could be opportunities for cross-country collaborations during the course of the program.

The call solicited proposals that were exploratory in nature or seek to develop proof of concept in three specific categories: solutions for better use of surveillance data to achieve actionable results; innovations in products and technologies to break infection cycles in healthcare settings; and to remove antibiotics from effluents.

The program call received an overwhelming response and of responsive applications 10 projects were recommended for funding support.

1. **A blood-based host biomarker for discriminating viral and bacterial infections: A clinical decision support tool, Indian Institute of Science Bangalore.**

   The project proposes to develop a biomarker-based blood test to rapidly discriminate between viral and bacterial infections. The test will aid in stewardship efforts by reducing the indiscriminate use of antibiotics for all suspected infections in the clinical setup.

2. **High Resolution Genome Based Tracing of Antimicrobial Resistant Escherichia coli in Pork production chain to identify the Critical Control Points: A One Health Systems Study, ICAR-NEH in collaboration with 4 institutes.** The Project will quantitatively assess the dynamics of antimicrobial resistant E.coli across the pork-value-chain in three different states, Tamil Nadu, Karnataka and Meghalaya to identify critical control points of entry and exit of E.coli to design a relevant Hazard Analysis and Critical Control Points plans (HACCP).

3. **Low cost Ferroelectric Material based technology to combat microbial resistance and prevention; Indian Institute of Technology- Mandi:** The project proposes to develop new low cost technology based on ferroelectric materials bulk, powder coating/thick film to impair the life of microbial cells commonly found in drinking tap water, water storage tanks and nosocomial infections.

4. **Biomarkers for bacteremia, antimicrobial resistance and hospital acquired infections by NMR and Mass Spectrometry among febrile neutropenic patients, All India Institute of Medical Sciences (AIIMS, Delhi):** The project aims to discover biomarkers to differentiate viral and bacterial infections using metabolomics including high throughput NMR spectroscopy and LC-MS mass spectrometry in febrile neutropenic cancer patients.

5. **Development of low cost Sericin coated industrial capacity filters to remove antibiotics and associated chemicals from effluents, Indian Institute of Technology- Guwahati:** The project proposes the development of a low-cost sericin coated filters for the removal of antibiotics from effluents. In first phase, large capacity sericin coated UF membrane will be developed with the collaboration of industrial partners. The second phase of the project will be focusing on optimal design of filtration system and field trial of the developed UF membrane across India.

6. **Development of Raman spectroscopy as a surveillance technology for antimicrobial resistance, Indian Institute of Science, IISC Bengaluru:** The project proposes creating a Raman database by collecting and recording Raman spectra at every step of various bacterial strains that are sensitive, intermediate or resistant to antimicrobial agents. The focus is to understand the progression/emergence of AMR to work as a supportive surveillance technology. The spectral database will also aid in prediction of possible resistance in bacterial strains.

7. **Harmonized One health Trans-species and community Surveillance for Tackling Antibacterial Resistance in India HOT-STAR-India, The INCLEN Trust International, New Delhi**

   The study intends to implement an ecological multi-host surveillance to document the bacterial infections and antibacterial resistance (ABR) among humans, animals, birds and fishes sharing the environment and linkage with antibiotics and disinfectant exposures at individual, household/habitation and community levels from different sources. A multi-host and multi-species approach shall improve understanding on pattern and spread of bacterial infection and resistance considering the "One Health" perspective.

8. **Understanding the transmission of antibiotic resistance between hospitals and the environment, National Centre for Cell Science (NCCS), Pune**

   The proposal aims at monitoring AMR at metagenomic level by focusing on unique microbial antibiotic resistance genes (ARG) signatures and tracking the resistance from the "source" to the "sink". The approach intends to provide direct information about AMR and its implications on vulnerable populations. This information is lacking in Indian context and a reliable catalogue would help in proper visualization of the network involved in AMR and to develop strategies to mitigate it.

9. **Community and Hospital Acquired Invasive Carbepenem Resistant Enterobacteriaceae: Longitudinal Study of the Gut Microbiome in Infected and Non-Infected Children and their families, Christian Medical College (CMC) Vellore**

   The project, by collecting stool samples from children admitted to the ICU aims to identify invasive MDR Enterobacteriaceae. Serial sampling of these children and subsequently their family members in the community will allow for longitudinal study of the microbiome and the presence of carbapenemase bacterial genes in their fecal samples. This will allow assessment of the risk of secondary transmission of hospital acquired resistant strains to household contacts.

10. **Impact of AMR burden on the health Index of poultry farm workers, CSIR-Institute of Microbial Technology (IMTech), Chandigarh**

    The project intends to study transmission dynamics of resistance in poultry farm workers to estimate the possibility of zoonotic transfer of pathogens. In addition, the team will also analyse humans, animals, air and water for microbial diversity and molecular signatures indicative of antibiotic resistance to gauge the potential for spread of AMR due to use of antibiotics in poultry rearing.

Establishment of National Institute of Health Research - Global Health Research India Unit for Genomic Surveillance of Antimicrobial Resistance at Central Research Laboratory (CRL), Kempegowda Institute of Medical Sciences (KIMS) Hospital and Research Centre, Bangalore

The increasing prevalence of antimicrobial resistance (AMR) threatens to affect healthcare at every level, and is now a major threat to public health. The reasons for limited concerted response against AMR are, lack of expertise and infrastructure in microbial genomics, inadequate focus of microbial genomics to resolve the issue of AMR and lack of country wide network to address the challenge. The use of whole genome sequencing (WGS) of bacterial pathogens promises to transform our ability to understand epidemic dynamics. It allows identification of genetic changes responsible for resistance and virulence and to compare the genomes of isolates from different individuals and locations and infer likely routes of spread.

In line with its work, the Sanger Institute through funding support of UK National Institute of Health Research (NIHR) has partner with National/sentinel laboratories at four strategically important location across the globe i.e. India [Central research Laboratory (CRL), Kempegowda Institute of Medical Sciences (KIMS), The Philippines [Research Institute of Tropical Medicine (RITM)], Colombia in South America [Colombia (Agrosavia)] and Africa [Nigeria (Ibadan University)] to create country specific Global Health Research Unit (GHRU) to strengthen intelligent surveillance network hub for early warning of emerging pathogen and resistance threats.

Building on the existing expertise of GCI that is already implementing and managing programs on AMR, the present proposal on genomic surveillance of AMR is brought under the ambit of GCI. The GCI besides serving as the implementing organization on behalf of the partners is also coordinating and managing this program in India.

The UK-NIHR funded GHRU at CRL, KIMS, Bangalore, is aimed at providing intelligent global surveillance of bacterial pathogens by focusing on the WHO listed 10 key priority pathogens. The team intends to sequence 10,000 genomes of pathogens through appropriate sampling (from 50 centres PAN India) and analysis. The initiative will help enhance local capacity of each of the aforementioned sentinel laboratories and equip them to undertake WGS and generate actionable data that will enable policy makers and public health programs to make informed decisions to respond to AMR in most efficient manner.

qHPV clinical development

Cervical Cancer, the leading cause of female cancer mortality worldwide, affects women in low and middle-income countries. India has the highest burden of cervical cancer. Although there are two vaccines for cervical cancer viz., Gardasil and Cervarix, both licensed in India, very limited vaccination have occurred in India due to the high cost of vaccines.

Papilloma Virus (HPV) vaccine development initiated in 2011 that was funded by DBT and was inherited by BIRAC. India contributes to 25.4% and 26.5% of the global burden of cancer cervix cases and mortality, respectively. Cervical cancer is the second most prevalent cancer among females aged 15 to 44 years. Human papillomavirus prevalence among cervical cancer patients in India varied from 87.8% to 96.67%. The project main focus to reduce the burden of cervical cancer in India. Serum Institute of India completed Preclinical and phase 1and 2 clinical trial in India and Phase 3 clinical trial is ongoing.

GCI – COVID -19 Activities

Recognizing the most pressing global threat of the current **COVID-19 pandemic,** GCI has launched and is supporting programs on **Sewage Surveillance, Mobile Diagnostics Labs, Sero-surveillance** etc. to find solutions to the challenges posed by the pandemic.

Covid-19 Sewage Surveillance

The monitoring of wastewater for viral RNA will help public health officials and administrators to be aware of trends in the cases of the disease in the area from where the sewage is collected. Wastewater surveillance would be a complementary approach to measure the presence and prevalence of Covid-19. There are two projects being proposed in this program. One project which has been funded to CMC Vellore with the overarching goal of Development of sewage and sludge sampling and processing protocols and assay to identify COVID-19 viral RNA fragments and transfer to initiate community sewage surveillance by different partners across India. The second proposal is working on wastewater-based epidemiology and screening for Covid19 which is under BITS Pilani.

Mobile Diagnostic Labs:

The DBT and Gates Foundation through the Grand Challenges India mechanism has considered to support and fund the four Mobile Diagnostics labs. The shared investment will support to the 4 buses in 2 investments to establish proof of concept of Mobile Diagnostics Labs. and to consider infrastructure to set up 4 mobile labs, supported by BMGF and DBT.

The first investment has supported the private labs models, one is of the labs Pvt Ltd. supported by DBT, which is functional at THSTI and another is that of Kawach, which is being developed by a private company based in Mumbai, SciencebyDesign Labsystems (I) Pvt. Ltd., has been sanctioned funds for the fabrication of the mobile testing lab. The fabrication of the mobile testing lab is underway and will be ready to be launched shortly. The mobile lab is planed to be deployed at ILS, Bhubaneshwar.

The second investment is supporting the Defence Research and Development Organisation (DRDO) model, of which 2 vans will be supported, which will be developed in Chennai through a private vendor. These two mobile labs will be deployed at IITM, Chennai and IIT Guwahati each.

Covid-19 Serosurveillance

The Sero-surveillance program is being proposed for active case finding, testing, and contact tracing as reports indicate that SARS-CoV-2 causes asymptomatic infection. The population-based sero-epidemiological studies will help to determine the burden of COVID 19 infection at the community level, to monitor the trends in the transmission of SARS-CoV-2 infection and help generate evidence on role of asymptomatic and mild infections in transmission. The outcomes will help in designing and implementing suitable Coronavirus containment measures. The sero-surveillance platform data would serve as a base to determine the sero-prevalence of SARS-CoV-2 infection in the local communities, and further would help monitor the trends of sero-prevalence for SARS-CoV-2 infection in the general population and high burden cities, determine the socio-demographic risk factors for SARS-CoV-2 infection, and delineate the geographical spread of the infection in the general population and hotspot cities. The program is supporting one site (01)- KEM Vadu, of the 5 sites in this program that are being managed by the National Biopharma Mission. GCI will be providing operational and administrative support for the grant and the scientific and technical purview for the study is with the SAG and TAG constituted by the NBM to run the full program. The second investment in this space is for THSTI and TIFR for neutralization assays to be conducted on a sub-set of samples collected during the round 2 of a NITI Aayog commissioned sero-surveillance study in Mumbai.

Agriculture and Nutrition

Agriculture and nutrition are one of the cores and underlying themes that GCI has been working on since its inception and we support work on both nutrition-specific as well as nutrition- sensitive interventions, very often within the same program or project. One of the first programs launched by GCI, which is now a graduated program, was on Achieving healthy growth through agriculture and nutrition.

Nutrition-Sensitive Agriculture program

The project entitled ***'Food-based nutritional security for malnourished rural households through capacity building and establishment of Nutri-gardens'*** is being implemented by M. S. Swaminathan Research Foundation in collaboration with four State Agriculture Universities (Chandra Shekhar Azad University of Agriculture and Technology, Kanpur Dehat, UP; Dr. Balasaheb Sawant Konkan Krishi Vidyapeeth, Dapoli, Maharashtra; Orissa University of Agriculture and Technology, Bhubaneswar, Odisha; Tamil Nadu Agricultural University, Coimbatore, Tamil Nadu) and Krishi Vigyan Kendras (KVKs) at Palghar, Maharashtra; Thirur, Tamil Nadu; Kanpur Dehat, Uttar Pradesh; Jeypore Campus of MSSRF, Odisha.

This program is being supported for the purpose of advocacy as a specialized initiative under the Agriculture Development and Nutrition portfolio, to showcase the vibrancy and the impact that GCI supported programmes are creating in communities across the country- improving lives through improved food & nutrition, livelihoods, farm productivity for larger public health goals.

The National Nutrition Strategy by NITI Aayog, Government of India, in its vision 2022 is committed to ensuring that every child, adolescent girl, and woman attains optimal nutritional status- especially those from the most vulnerable communities, focussing to prevent and reduce undernutrition across the life cycle, especially in the first three years of life, since the first few years of life are the foundation for ensuring optimum physical growth, development, cognition and cumulative lifelong learning.

The overall impact of the project will be an improvement in Diet Diversity Score of the undernourished farm households' up to 60% from base level and appropriate awareness through training at the grassroots level (farmers and malnourished sections of the society) and other stakeholders including policymakers to come out with enabling policies that will eradicate malnutrition.

Current Progress Updates:

The program has completed two years of its implementation and has been reviewed by the Scientific Advisory Group constituted for this program.

The program has achieved the following during the reporting period.

- Completion of the landscaping of 4 gardens on respective sites on the basis of nutrition themes. More than 50 species of the plants have been collected for germplasm at each site.
- Establishment and maintenance of mother nursery - The establishment of mother nursery has also been completed at all four sites
- Planting of nutri-rich plants: Specific area has been allotted, for each nutrient section, nested plots were developed to accommodate herbs, annuals and perennial crop/plant. The information board in each section provided issues related to the deficiency of nutrition and its manifestation in human health vs. the plants that provide specific nutrition.
- In each of the sites, 25 small and marginal farmers from 10 villages were selected to form 10 Farmers Self Help Groups (FSHGs) who will participate in horticultural training and to make their farms enriched with nutri-rich plants.

GRAND CHALLENGES INDIA

- Training of master trainers and members of Farmer Self Help Groups and Community Hunger Fighters to disseminate knowledge through nutrition literacy programmes.

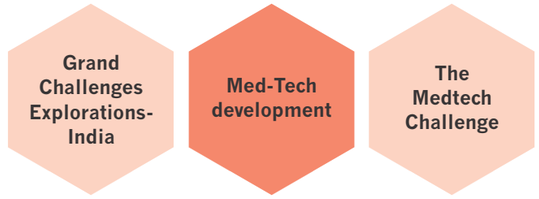
Project activities at KVK, Kanpur Dehat

Nutrition Gorden | Land preparation | Land preparation | Land preparation

Germplanm collection | Germplammultiplcation | Brochure for the Nutri-rich Garden | Media Report

Medtech development and entrepreneurship support

GCI supports this theme with two unique programs in this space.



Grand Challenges Exploration (GCE)-India

Grand Challenges Exploration (GCE)-India is one of the initiatives under GCI ambit that has been launched with the aim of identifying health care innovation that will enable the goal of equitable health care in India and beyond. GCE-India intends to provide seed funding to highly innovative ideas at the pre-proof concept stage in an effort to develop a sustainable mechanism for supporting health and development innovations in the exploratory domain of India. The initiative basically seeks to validate ideas from talented and motivated individuals that lend themselves to be incubated in start-ups with the aim to encourage entrepreneurship.

Being managed and administered by GCI team at BIRAC, the program is implemented by IKP Knowledge Park, Hyderabad. The ultimate goal for the program is a quest for new medical technology devices, drug delivery systems, diagnostics, and technology enabled service models that can potentially be made available to people from all socio-economic strata. In view of the important public health goals, the call mandates are explicitly drawn from the domain of maternal and child health, wearables, diagnostics and devices, cervical cancer, antimicrobial resistance (AMR), agriculture and nutrition, geriatric care, and water sanitation & Hygiene (WASH).

Since inception five calls have been launched under the GCE-India platform, and a total of 1958 applications have been received under 58 grand challenges mandates that were defined across global health priorities. Total 35 awards have been made so far with the majority of awardees working on areas such as Maternal Child Health, Geriatric Care, Infectious Diseases, AMR followed by Nutrition, Water and Sanitation etc.

Total number of awardees developing Medical diagnostics are 15, Devices 10, Medical technologies 5, Nutrition 3, and Sanitation 2 respectively. GCE-India awardees are located across 14 states in India with majority of them from Karnataka, New Delhi and Maharashtra. 20 candidates have their own ventures while remaining 13 are from Academia and 2 from NGOs. The supported projects are progressing as per their intended timelines. Of supported projects, few are ready to deploy their products.

The GCI team ensures that besides granting funding assistance, the investigators also receive access to technical and regulatory advisors along with a network of market entry/business development professionals to help refine the proposed solutions proposed and take the ideas to the next stage of realization. Besides, leveraging the mentorship, resources, successful projects also have the opportunity to apply for follow-on funds from BIRAC.

The Medtech Challenge: Market Acceleration Training & Award Program

The MedTech Challenge: Market Acceleration Training & Award program is designed around the needs of Indian innovators and entrepreneurs working in the areas of developing medical technologies for public health who have a validated proof-of-concept for their technology and are in the process of taking their product to the market.

The program aims to fill the gap in the development and delivery of affordable medical technologies in India and plans to address the low movement of affordable technologies through the development pipeline. It will therefore select and mentor Indian entrepreneurs to further develop their medical technology innovations, which will already have strong proof-of-concept data.

The funded projects will also be mentored from a business-readiness perspective to deliver affordable medical technologies which would have maximum access through public and private markets and fulfil a strong unmet medical need.

An international technical facilitator VentureWell provided the technical assessment as well as curate and deliver the workshop to the selected applicants.

The initial submissions and interviews for assessment were completed in Jan/Feb 2020. The Joint Triage Committee had it meeting to select the applicants for the workshop was held via video conferencing on 2nd March 2020 and after due approvals, the selected applicants were informed of their selection via email on 6th March 2020.

There was a total of 22 submissions for the challenge. All applicants were assessed, and the Joint Triage Committee recommended that all 22 applicants be selected for the workshop.

The MedTech workshop was due to be held from 21-25th March in Delhi. However, due to the Covid-19 pandemic, several international restrictions were put into place at the time. Therefore, it was decided to postpone the workshop.

The partners then decided that the workshop would be held over a 5-week period starting 1st September 2020, through a virtual mode, with simultaneous mentorship. The workshop ended on 12th October 2020, which was followed by 4 weeks of mentorship till 9th November 2020.

The MedTech Accelerator grant application was opened on the BIRAC portal on 13th October 2020 and closed, 45 days on 26th November 2020, at 1700hrs.

At the close of the deadline, 20 applications were received on the BIRAC portal.

Virtual Workshop

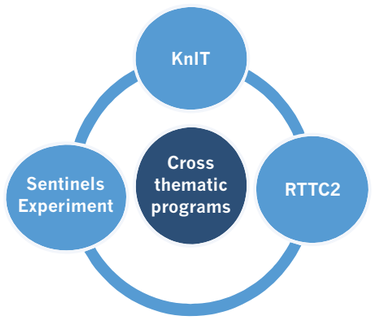
To accommodate time zones and manage online meeting fatigue, the weekly plan for the conduction of the workshop was planned such that Mondays focused on presentations and introduction of key topics, Wednesdays on networked learning, where teams participate in group discussions and attend breakouts with mentors and instructors to discuss lecture topics, customer discovery interviews, and activities in the workbook and Friday focused on 'individual check-ins" between teams and mentors to receive feedback on their work and how it applies to their ventures.

The workshop was inaugurated on 1st August 2020 and the 5-week workshop period came to an end on 12th October 2020 and then mentorship period continued for another 4 weeks where innovators had individual check in times with their assigned and other mentors.

The reception of the workshop was very positive with all the innovators who appreciated the content, design and delivery of the workshop.

Cross-thematic programs

Some programs under the GCI umbrella, fall under multiple themes, often such as maternal and child health and nutrition, or sanitation, which has direct and indirect effects on nutrition, infectious disease and maternal and child health.



Knowledge Integration and Translational Platform

KnIT is a unique knowledge synthesis platform that has been launched with the aim to bridge the gap between research and policy and facilitate evidence-based policy making in public health.

KnIT was designed to address a particular set of challenges that the states in India face today, with respect to designing evidence- based policy for public health.

The first of these challenges is that while there is a large quantum of research studies and demographic data being carried out and collected across the country, there is no formal and scientifically rigorous mechanism that collaboratively assesses existing relevant information to inform states and provide them with actionable interventions to address their particular challenges.

Second, given India's population, unique demographics and the particular problems that we face in public health, it is important that this information comes from Indian data, or data from comparable geographies.

Third, there is no mechanism that packages data and information for policymakers such that they receive the pertinent details that will enable them to compare interventions to choose the most relevant to their context.

The design and mandate of KnIT is to address these challenges, in the detailed and scientifically rigorous manner to ensure scientific credibility.

The platform

KnIT as a platform is responsible for collating and analyzing available evidence within India, to inform bureaucrats and health authorities and aid in the development of evidence-based policy to address the inequalities in the health outcomes in our country.

This platform specifically targets Indian policymakers as the end users of the knowledge synthesized, specifically at the State level, in keeping with the current health policy structure, where health is a state subject. This is to ensure that the data and evidence collection is done with the overarching goal of developing and implementing cost-effective, sustainable interventions or packages of multi-sectoral health interventions that are appropriate to the context of different states.

The platform identifies gaps in our knowledge and policy, and synthesizes currently available evidence to improve our understanding of current or new interventions or packages of interventions to address the major health issues in our country.

The platform works by conducting extensive systematic reviews and conducts workshops and other meetings to widely share the findings of these studies.

Domain Centers

Domain centers are the units that work on specific areas of public health, as decided by the KnIT platform and the Scientific Advisory Committee.

Currently, KnIT focuses on two tracks, maternal and child health issues and nutrition and has two Domain centers working in these areas.

The Society for Applied Studies, New Delhi is the Nutrition Domain Center. The International AIDS Vaccine Initiative, New Delhi is the maternal and child health domain center.

The Nutrition Domain Center

The Nutrition track examines public health and medical interventions to mitigate stunting, wasting, severe malnutrition, low birth weight, optimal body composition and metabolic unfitness or obesity. The nutrition track has worked on areas where there are important questions to be addressed such as low-birth weight babies, anaemia, complementary feeding and diarrhea among others.

The nutrition track works primarily in the secondary data analysis space, using national survey data, or by conducting systematic reviews to present the current state of knowledge as well as identify gaps in research.

The center also conducts consultative meetings as a part of its methodology to understand and reach consensus regarding issues.

The Nutrition track examines public health and medical interventions to mitigate stunting, wasting, severe malnutrition, low birth weight, optimal body composition and metabolic unfitness or obesity. The nutrition track is previously worked on four areas where there are important questions to be addressed; low-birth weight babies, anaemia, complementary feeding and diarrhea. They are now focusing on weight gain in pregnancy and growth in early life. This domain center is also working on analysing the factors that contribute to different outcomes in states with the Covid-19 disease.

The Maternal and Child Health Domain Center

MCH focuses on identifying the health system challenges that are barriers to effective, equitable, impactful delivery of health services and identifies strategies how to overcome them. It also focuses on designing delivery strategies based on evidence, and piloting and evaluating programs aimed at improving program delivery, directing implementation research to optimize primary and secondary level healthcare, and generating evidence-based, human resource linked strategies relevant to MCH.

The MCH team is currently focusing on the care of sick and small newborns in the SNCUs, to assess the state of treatment and the demand-supply gap in this space.

Although, KnIT was primarily designed with the purpose of conducting secondary data collection/analysis on the questions that were selected however, due to paucity of data on certain issues, this domain center has gone into primary data collection in the form of surveys conducted in Himachal Pradesh.

Some of the research questions were addressed through systematic reviews (this incorporates cross-sectional, observation, randomized controlled and non-randomized controlled trials) that was supplemented by secondary data analysis (essentially from HMIS). The variation in quality of newborn care provided in the district facilities, was studied through a facility survey (in Himachal Pradesh). The association between quality of care provided and outcomes was derived from survey and secondary data analysis. The surveys were conducted in operational SNCUs of district hospitals of two identified districts of Himachal Pradesh.

The findings from the qualitative and quantitative surveys (including facility assessments) would be triangulated to provide recommendation of care of small and sick babies in the district and are in the process of being disseminated through the state of Himachal Pradesh.

The MCH team are now exploring assessment of interventions for Respiratory Syncytial Virus in children and an exemplar study on managing stunting across states in India. The results of these studies is expected in 2021-2022.

Sentinels Initiative

The Gates Foundation launched 'Sentinels Experiment in India' as an open initiative to support explicit innovation practitioners, new partners, new ideas, and new opportunities that can either solve gaps in existing strategies or create completely new opportunities and pathways to the outcomes sought on the broader global health challenges.

The Sentinels initiative intends to source innovation in India, by working with sentinels for excellence and innovation, who can help identify new ideas and scientists in their institutions, networks, and regions. The experiment used special administrative mechanisms to provide awards of INR 50.00 lakhs to each innovative project to generate proofs-of-concept.

The initiative engaged with seven innovation practitioners for new ideas that are focused on exploring, the unique aspect of the health issues with special emphasis on innovative, impactful research of new innovations.

The seven supported projects aiming to solve a wide range of problems are enlisted below vis-à-vis piloting and testing varied concepts -

- Two projects are exploring the nutrition predictive metrics and nutrient uptake and metabolism coordinates, one, through protein synthesis dynamics in the brain, in rat models and later is studying the Environmental Enteric Dysfunction (EED) in Drosophila Melanogaster (vinegar fly) a low-cost animal model.
- The other two projects are studying Mycobacterium tuberculosis, likely to identify the potential 'anti-latency' lead molecule(s) and the other is trying develop a novel mycobacterium OMV coated nanoparticle (OMV-particles) for efficient vaccine delivery system.

- One team plans to test a technique to establish a gene drive method and engineer into the carrier of Flaviviral infections, Aedes aegypti population without disturbing the ecological niche.
- A Pune based company, Module Innovations plans to establish proof of concept for a novel system to determine antibiotic resistance profile of 4 major uropathogens against a panel of 8 antibiotics used in current clinical practice, these 4 bacteria include E. coli, Klebsiella, P. aeruginosa and Enterococci spp.
- Lastly, Sea6 Energy Private Limited, Bangalore aims to improve upon the prototype product by conducting extensive field trials, and developing next-generation products by blending the active ingredients of existing products with the potential active ingredients from other red seaweed species.

Reinvent the Toilet Challenge Phase II (RTTC 2)

''Reinvent the Toilet Challenge - India'', is one of the program that is directed at addressing the problems in sanitation and especially in the rural and urban areas. A major chunk of the population of the country are still struggling as to how to capture and store their waste, with no sustainable way to handle it once their on-site storage—such as a septic tank or latrine pit—fills up. Sustainable solutions supporting the entire value chain of sanitation from collection to treatment is the need of the hour.

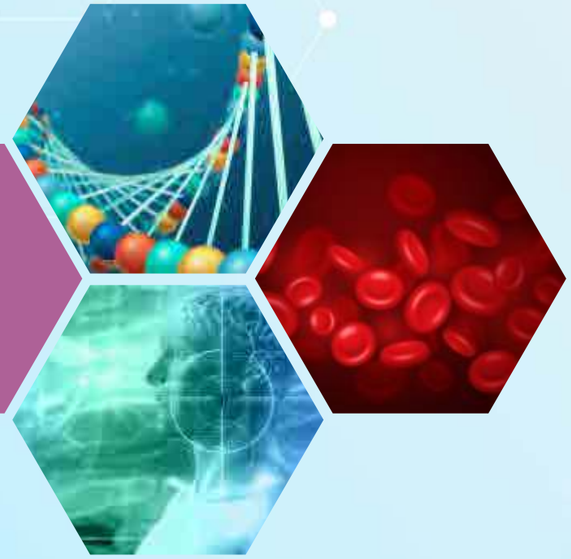
Our ultimate goal is to help ensure clean cities in India with universal access to hygienic toilets as well as local solutions to contain, treat, and safely dispose of human waste. According to the World Health Organization (WHO) and UNICEF, sanitation rated as "safe for people" has increased by only three percent worldwide over the last five years.

The objective of "Reinvent the Toilet Challenge – India" is to develop a portfolio of Indian-led pilot projects that seek to contribute innovations which can be incorporated into a next- generation toilet that will reduce the burden of excreta-related disease and improve the lives. The aim is to expand the use of toilet and sanitation technologies that do not connect to a sewer, as this is by far the most common approach used by the poor. The first round of the RTTC program was launched in 2013 and six projects were funded under GCI. Out of six projects two technologies had successfully demonstrated proof of concept at a laboratory scale with experimental data. The developed technologies have been installed in some parts of Delhi for demonstration and greater visibility.

The two technologies that are simple, cost-effective, reliable and culturally acceptable have been supported under innovation-to-scale Phase II of the RTTC program. Decentralization of wastewater treatment is a sustainable solution to address these problems that locally treats the sewage and also reuses as well as recycles. One of the technologies such as the electrochemical reactor that works on a novel electrochemical process in which the water to be treated is subjected to extremes of pH to kill the coliform and Helminth's.

The second technology is the completely solar powered eToilet which is connected to the NEW Generator thus creating a unique model of sanitation recovery with a perfect back-end processing through which resource generation and recovery is made possible. The NEW generator harvests nutrient fertilizers (Nitrogen, Phosphorous, and Potassium), energy through biogas, and clean water from human wastes. The machine achieves a high level of waste treatment through the use of anaerobic membrane bioreactor technology (AnMBR). A high level of pathogen destruction is performed to ensure safe sanitation.

With the improvements in coverage and access to sanitation in the country, there is now more need than ever for innovations in the sanitation space, and this continues to remain and important area of work for GCI.



NATIONAL BIOPHARMA MISSION

INNOVATE IN INDIA FOR INCLUSIVENESS (i3)

National Biopharma Mission

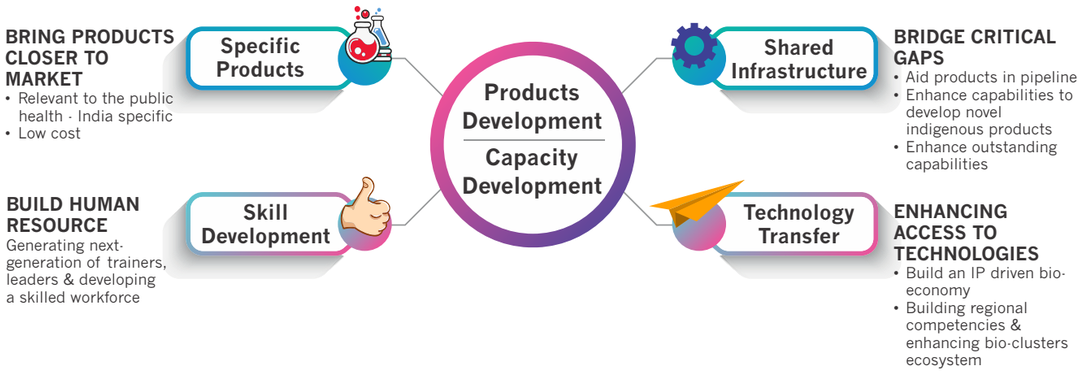
Introduction:

The Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals of the Department of Biotechnology (DBT), Govt of India was approved by the Cabinet for a total cost of INR 1500 Cr and 50% co-funded by the World Bank. The program referred to as National Biopharma Mission (NBM), is being implemented by Biotechnology Research Assistance Council (BIRAC) and this program is aligned with the national mission of Make-in-India.

Vision: *To enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals to a level that will be globally competitive over the next decade, and transform the health standards of India's population through affordable product development.*

Key Components:

- Development of product leads that are at advanced stages of the product development lifecycle and relevant to the public health need in vaccine, biosimilar and medical devices & diagnostics.
- Establishing and strengthening shared infrastructure facilities for product development and validation.
- Developing human capital by providing specific trainings to address the critical skills gap across the product development value chain.
- Creating and enhancing technology transfer and intellectual property management capacities and capabilities.



Major initiatives taken:

NBM published about 16 Requests for Proposals in this year to solicit pan-India applications from academia and industry across different thematic areas like Vaccines, Biotherapeutics, Indigenous Development of Technologies for Affordable Biomanufacturing, Medical Devices and Diagnostics, Translational Research Consortia for Malaria, Hepatitis E (HEV) and Respiratory Syncytial Virus (RSV), Clinical Trial Network and the COVID-19 Research Consortium. To strengthen the technology transfer capacity in the country, five (05) Technology Transfer Offices were established with NBM support. Under the various initiatives of the Mission in the skill-development domain; a large number of candidates with a high female representation were trained. The Mission also engages three consultants for various domains: CDSA, Faridabad was engaged for Clinical Trial Regulatory Advisory & Data Safety Consultancy; Sathguru Management Consultants for Enabling and Training Personnel at Technology Transfer Offices while International AIDS Vaccine Initiative (IAVI) was taken on-board as the Technical Knowledge Partner.

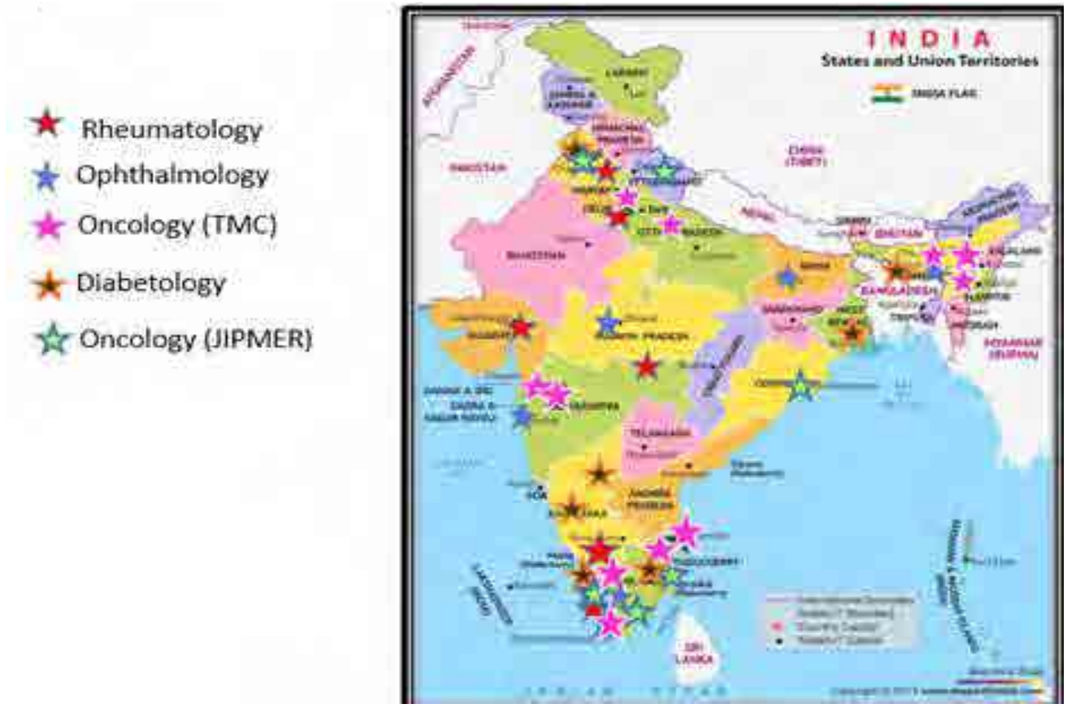
Clinical Trial Network

- Studies on serosurviellance will be conducted at four field sites.
- All hospital sites will be trained on GCP.
- Training on different aspects of Biotherapeutics, Devices and diagnostics and Vaccines will be undertaken
- COVID 19 vaccine candidates will be followed up for conduct of clinical trials.

Hospital Based Clinical Trial Networks (CTNs)

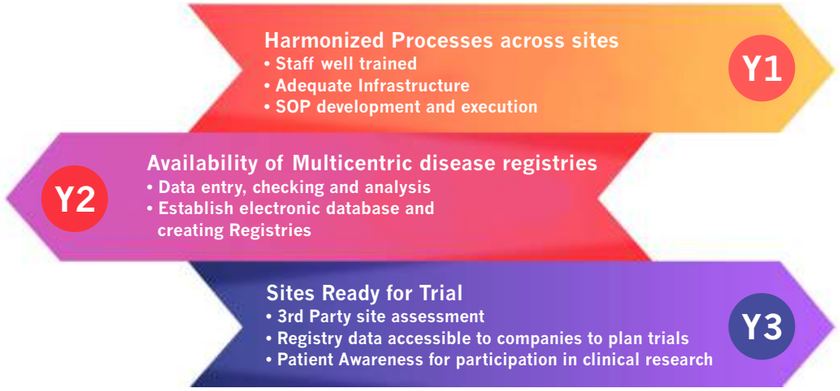
Clinical trial is an important step in the product development path. Indian Biotech companies face numerous challenges in identifying trial sites which have the required infrastructure, capacity, trained manpower, harmonized processes and background data on disease incidence at institutional, local, regional/state, and national levels. The delay in conduct of clinical trials can impact the development timelines of biologics and drugs, thereby delaying the launch of affordable biosimilars for Indian population.

To address this gap, a National Biopharma Mission's initiative, Consortia of Hospitals in the areas of Oncology, Ophthalmology, Rheumatology and Diabetology – CHOORD aims to strengthen the capacity to conduct clinical trials in India



for products developed in these areas. It comprises of 5 networks of 36 organizations – public and private hospitals, clinics, reputed academic institutions – spread across 18 states of India.

Each specialty network comprises of at least 6 hospital-based investigational sites (public and private hospital sites) across



CHOORD- Consortia of Hospitals in the areas of Oncology, Ophthalmology, Rheumatology and Diabetology

Oncology

TMC- Tata Memorial Centre
ACTREC- Advanced Centre for Tretment, Research and Education in Cancer
BBCI- Dr. Bhubaneswar Borooah Cente Institute
BBCH- Homi Bhabba Cancer Hospital Varnasi
CI- The Cancer Institute
MCC- Malabar Cancer Centre
NEIGRIHMS- Northeastern Indira Gandhi Regional Institute of Health and Medical Sciences
RCC- Regional Cancer Centre, Thiruvananthapuram
CMC- Christian Medical Colletge, Vellore Association
CCHS- Cachar Cancer Hospital Society

Oncology

JIPMER- Jawaharlal Institute of Postgraduate Medical Education and Research
IMS&SUM- Institute of Medical Sciences and Sum Hospital
AIMS- All India Institute of Medical Sciences
MMHRC- Meenakshi Mission Hospital and Research Centre
ACHS- Amala Cancer Hospital Society

Dlabetology

GEF- Gokula Education Foundation
VH&BMCRI- Victoria Hospital, Bangalore Medical College and Research Institute
IPGMER- Institute of Post Graduate Medical Education and Resarach (SSKM)
SGRDUHS- Sri Guru Ram Das University of Health Sciences
SIMS- SRM Institutes for Medical Science

Ophtalmology

AIMS- Amrita Institute of Medical Sciences
RIO- Regional Institute of Ophthalmology
SDN- Sankara Deva Nethralay
SSST- Shri Sadguru Seva Sangh Trust
AEH- Adityajyot Eye Hospital Private Limited

Rheumatology

MIER- Medanta Institute of Education and Research
MGIMS- Mahatama Gandhi Institute of Medical Sciences
CARE- Centre for Arthritis & Rheumatism Excellence
St'JNAHS- St Johns National Academy of Health Science
KDH- Kusum Dhirajlal Hospital
PGIMER- Post Graduate Institute of Medical Education & Research

NBM-BIRAC envisions that these networks will be the sites with unique combination of tertiary medical facilities, clinical research expertise, patient pool and regulatory compliant and ethically sound ecosystem for conduct of hospital-based trials.:

- All network sites will be encouraged to conduct trials in collaboration with industry and will be assessed for readiness as per protocol and study requirements
- The geographical distribution of sites across the country ensures that trials conducted by networks have strong validity (the trial results will be broadly representative of real-world practice)
- The Registries from the networks will reduce the gap that exists between the publication of research on treatment of ailments of respective specialty and in clinical practice.

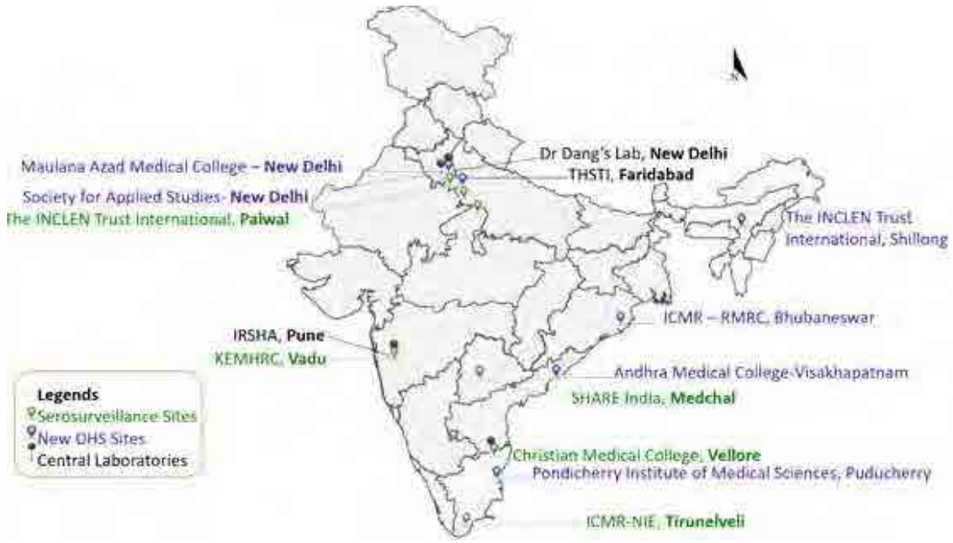
Clinical Trial Network – Field Sites

DBT's Resource of Indian Vaccine Epidemiology Network (DRIVEN)

Lack of access to healthy population cohorts for clinical trials in the community, trained manpower (Good Clinical Practice) and well-equipped clinical trial sites have been some of the bottlenecks which lead to delay in the clinical development of vaccines. To overcome these hurdles and fill these gaps, DBT's National Biopharma Mission is supporting the establishment of Clinical Trial Networks (CTN) and Strengthening Clinical Trial Capacity in the country. Efforts are directed towards strengthening already existing Health and Demographic Surveillance Systems (HDSS) and establishing new HDSS sites at different locations in the country. In view, of the COVID-19 pandemic, these efforts are steered to address the current crisis, at hand.

Support is provided to establish population-based geographical cohorts towards having Demographic and Health Surveillance (DHS) sites. The size of each cohort to be equivalent to or higher than 01 Block or 50,000 population. The focus is to have adequate human resource and training of personnel for conduct of GCP compliant trials, engage the community in advance, collect information on co-morbidities for preparing the sites that meet internationally accepted clinical and ethical standards.

Geographical Representation of DRIVEN Clinical Trail Sites



Establishment of new Demographic, Development and Environmental Surveillance sites: 06 field sites in different geographical locations across India have initiated establishing new demographic, development and environmental surveillance sites which are being supported by the National Biopharma Mission for collecting demographic data electronically for future studies through a common protocol with the objective to establish a population-based cohorts. The personnel at these sites are also being prepared for Good Clinical Practices and Good Documentation Practices through online trainings and focuses on Training of Trainers program that was conducted from 28th Oct to 2nd Nov 2020 at Faridabad. Considering their experience, the training led by The INCLEN Trust International and CDSA, harmonizing the processes to be followed to bring in uniformity in the methodology and steps to be followed in carrying out the study which eventually will reflect in the quality of data collected and preparedness of all these sites for future clinical trials. A total of 150 participants attended this training program both in-person and virtually. These sites are;

1. CHRD Society for Applied Studies (SAS), New Delhi
2. Maulana Azad Medical College, New Delhi
3. Andhra Medical College, Vishakhapatnam
4. ICMR- Regional Medical Research Centre, Bhubaneshwar
5. Pondicherry Institute of Medical Science, Pondicherry
6. The INCLEN Trust International, Shillong, Meghalaya

Establishing serial sero-surveillance to monitor the trend of SARS-CoV-2, Dengue and Chikungunya infection transmission in the general population, India

05 field sites in different geographical locations across India have established healthy cohorts and are being supported for initiating serial sero-surveillance COVID-19 studies through a common protocol. In order to realize the preparedness of these sites, the following efforts are underway:

Sero-surveillance studies: The study protocol, Informed consent documents (ICD), Subject Information Sheets (SIS), Case Record Forms (CRFs), Blood sample management and testing manual; and training manuals are being developed. The protocol has planned 5000 subjects to be enrolled and followed up prospectively at each site for the first serology sampling.

Preparation for conduct trials as per Good Clinical Practices Guidelines (GCP): This includes, access to Ethics Committee, approvals from District Health authorities, trained manpower, participant recruitment strategy, SOP's for inventory management, SAE's and Informed Consent processes and details of other infrastructure including power supply. Amongst this network of sites, KEMHRC, Vadu is being supported through the Grand Challenges India program and the remaining four, under the National Biopharma Mission. All these 05 sites have access to existing cohort of around 100,000+ healthy interested subjects. These sites are;

1. The INCLEN Trust International, Palwal
2. Christian Medical College, Vellore
3. SHARE India, Medchal, Hyderabad
4. ICMR – National Institute of Epidemiology, Chennai
5. KEMHRC (VRHP), Vadu, Pune

Central Lab for Immunogenicity: The National Immunogenicity Biologics Evaluation Center (NIBEC) at the Interactive Research School for Health Affairs (IRSHA), Bharati Vidyapeeth, Pune and THSTI, Faridabad supported by the National Biopharma Mission are the GCLP facilities for viral neutralization assays, acting as the central laboratories.

Identification of Central Biorepository: This biorepository is being established at THSTI, Faridabad.

Training of Trainers programs: For successful implementation of the project, The INCLEN Trust International has been identified as a coordinator for training these network sites on a paperless electronic data management interface (SOMAARTH-3) for harmonizing the processes in establishing the serial sero-surveillance to monitor the trend of SARS-CoV-2, Dengue and Chikungunya infection transmission in the general population; laboratories protocol to follow for collection, labelling, storage, shipment and understanding and testing of processes, validations and algorithms in site establishment; and for development of implementation, monitoring and data management mechanism of the sites acting as central laboratories for serological investigations for glycated Hb, ELISA and neutralisation assays for COVID, Dengue and Chikungunya over a period of 1 year.

Electronic data management (SOMAARTH platform)

The INCLEN Trust International, New Delhi has developed an electronic data management platform namely SOMAARTH-1 and SOMAARTH-3 for collecting data, reporting, analysis and archival of community-based demographic, development and environmental surveillance sites and associated studies.

National / Societal relevance: This network sites are being sought to bring harmonization in the process and the uniformity in the methodology and steps to be followed in carrying out the study which eventually would reflect in the quality of data collected from all the sites and preparedness of all these sites for future clinical trials. In view, of the COVID-19 pandemic, these efforts are steered to address the current crisis, at hand and also to prepare the country for such unforeseen circumstances.

Translational Research Consortium

TRC-Dengue:

The program entitled 'The Translational Research Consortium for Establishing Platform Technologies to Support Prophylactic and Therapeutic Strategies for Dengue - Discovery to Proof-of-Concept' is led by Dr. Anmol Chandele, Group Leader at the International Center for Genetic Engineering Biotechnology (ICGEB), New Delhi. Alongside consortia partners the Translational Health Science and Technology Institute (THSTI), All India Institute of Medical Sciences (AIIMS), National Institute of Immunology (NII), Indian Institute of Technology (IIT), Christian Medical College (CMC), Manipal Academy of Higher Education (MAHE) and Clinical Development Services Agency (CDSA), the programme delivers unique interdisciplinary, complementary and synergistic expertise to tackle dengue (Figure 1). The expected deliverables of the project are in Figure 2.

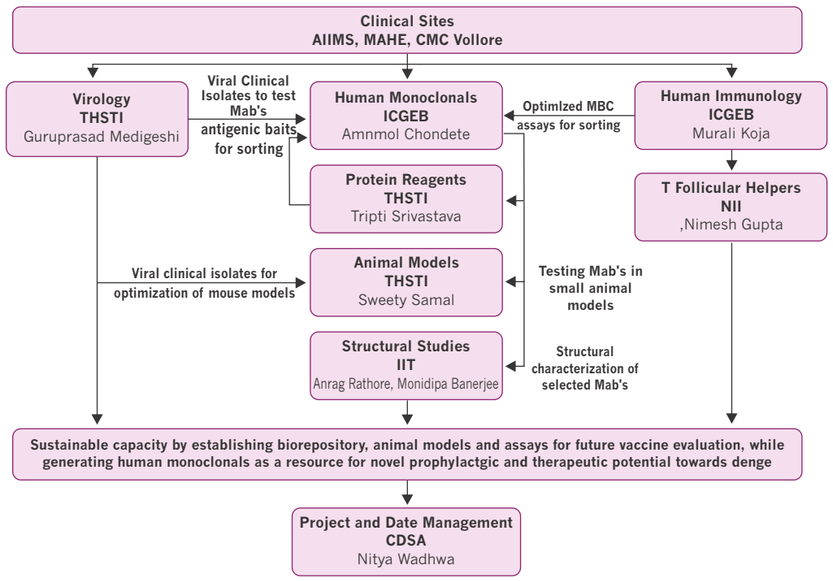


Figure 1

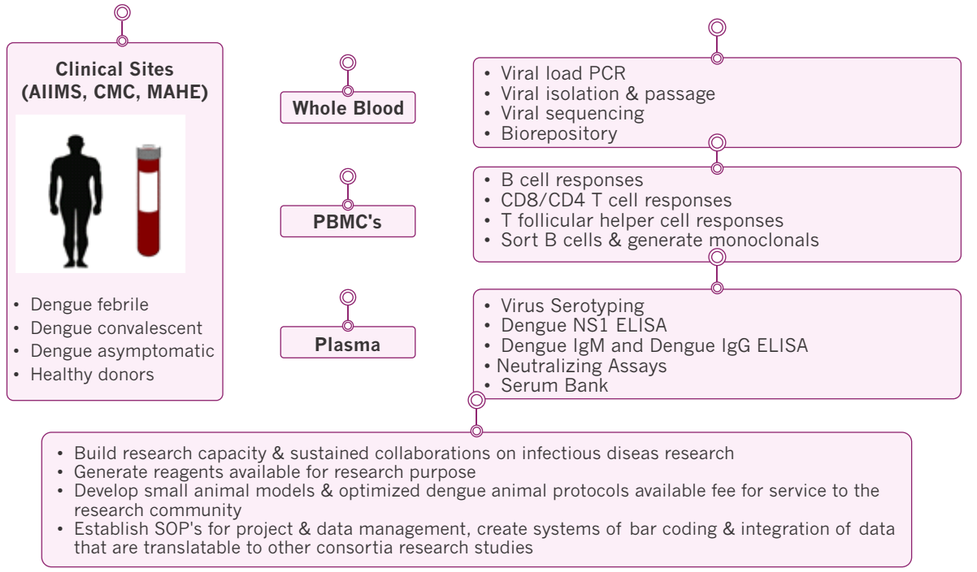


Figure 2

TRC for Chikungunya Virus

The Translational Research Consortium for Chikungunya Virus (CHKV) was formed with advanced medical and research institutions, led by Manipal Academy of Higher Education (MAHE). Along with TRC partners namely, International Centre for Genetic Engineering and Biotechnology (ICGEB), Institute of Life Sciences (ILS), Topiwala National Medical College & B. Y. L. Nair Charitable Hospital (TNMC), Mumbai, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, All India Institute of Medical Sciences (AIIMS), Bhubaneswar, the consortium aims to deliver a unique, interdisciplinary and synergistic expertise to tackle Chikungunya.

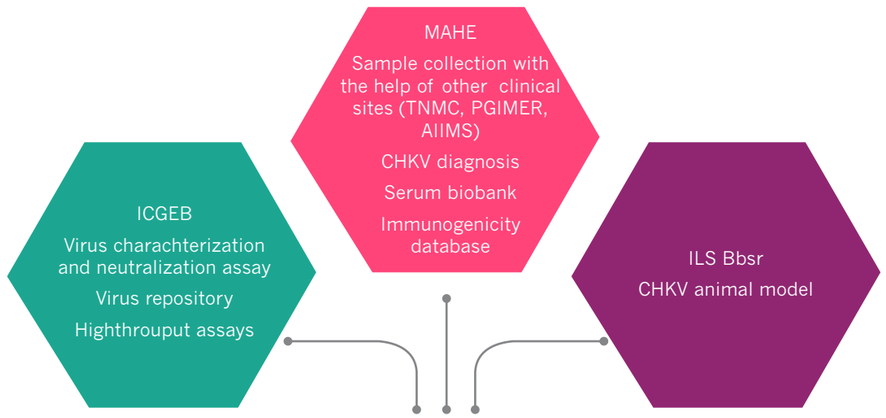


Figure. Chikungunya Translation Research Consortium

With clinical sites at MAHE, TNMC, PGIMER & AIIMS, the consortia will establish the serum biobank for CHKV clinical samples which will be accessible to researchers as a fee for service. App based data collection tool implementation is conducted by coherent efforts made by MAHE wherein acute and convalescent serum samples of Chikungunya positive cases are recorded. The data will be updated on public domain quarterly to create a database. ICGEB is putting in efforts to create a virus repository of well characterized Chikungunya strains which will also be accessible to researchers on a fee for service basis. Based on clinical sample cohorts collected by medical partners from different geographical locations, ICGEB will conduct whole genome sequencing and will develop high throughput assays for Chikungunya virus. The other TRC partner, ILS has developed and characterized mice model (C57BC/J) for acute Chikungunya infection. These models will also be available to academic researchers and industry partners on a fee for service basis. These coherent efforts made for Chikungunya will establish high throughput virological and immunological assays to facilitate Chikungunya vaccine testing and further evaluation.

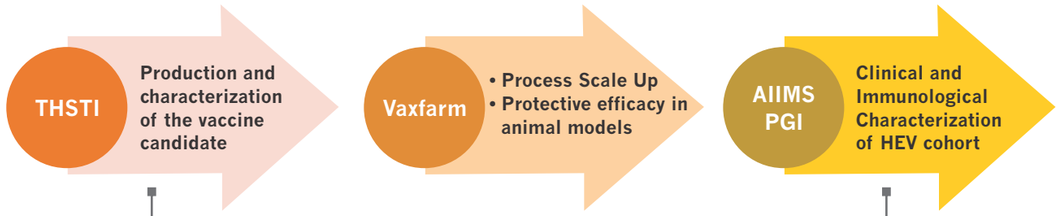
Hepatitis E-Translational Research Consortium

The National Biopharma Mission (NBM) initiated a program to support collaborative proposals that combine complementary and synergistic research strengths for establishment of Translational Research Consortium (TRC) for Hepatitis E virus. The purpose of this TRC is to stimulate discovery, and/or early translational research to enable and accelerate the development of novel HEV vaccine candidates. India is hyperendemic for HEV, with the disease presenting both as outbreaks and as cases of acute sporadic viral hepatitis. The collaboration will enable cross-fertilization of ideas among clinicians, immunologists, molecular and cell biologists, protein chemists, bioinformaticians capable of big data

analytics, structural biologists and other domain experts leading to rapid development of vaccines. Two consortia with industry academia collaborations were approved for development of novel HEV vaccines. The TRC will accelerate the development of effective vaccines against Hepatitis, identifying early markers of vaccine efficacy, defining correlates of protection and analysing mechanisms of long lasting protective immune response.

THSTI-HEV TRC:

The proposal entitled "Development of a recombinant vaccine against the Hepatitis E virus and immunological characterization of Hepatitis E immune cohort and potential vaccine recipient" led by Dr. Milan Surjit group leader at the Translational Health Science and Technology (THSTI), New Delhi. Consortia partners include Vaxfarm, All India Institute of Medical Sciences (AIIMS), New Delhi, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh, Regional Centre for Biotechnology (RCB), Faridabad. The objective of the consortia is to develop a novel vaccine against the Hepatitis E virus, establishment of immune cohort and clinical and immunological characterization of the cohort.



The lead applicant THSTI will be involved in production and characterization of the 112-608 ORF2 VLP vaccine candidates, identification of additional epitopes and assessment of immunogenicity, safety and protective efficacy in animal models. The industry partner Vaxfarm will develop and process the scale up of the DS/DP antigen for evaluation of protective efficacy of vaccine formulation in NHP model of HEV. The clinical sites AIIMS and PGIMER will conduct serological screening and identify the immune cohort and potential vaccine recipient cohort for establishing future vaccine recipient group. Additionally, THSTI will develop high throughput immunological and virological assays to facilitate future hepatitis vaccine testing and evaluation.

Malaria TRC

The nation-wide growing malaria burden was identified as a major health challenge by the National Biopharma Mission and formation of a Translational research consortia, to work towards solutions was envisioned. A multi-institute, multi-expertise, multi-disciplinary approach was adopted towards tackling the unmet need of effective anti-malarial vaccines. The consortium aimed at identifying novel candidates and formulations for development of vaccine.

The Malaria Translational Research Consortium was established between Regional Medical Research Center, Bhubaneswar; National Institute of Immunology, New Delhi; ICMR- National Institute of Malaria Research, New Delhi and Multi Vaccines Development Program, New Delhi. A novel combination of antigens will be evaluated as potential vaccine candidates. The antigens will target different stages of the malarial parasite Plasmodium falciparum such as the sexual stage and pre-erythrocytic stage to try to generate effective anti-malarial efficacy. The evaluation will be done in small animal models, transgenic parasites and validated using complex assays which include SMFA. Epidemiological findings from high endemicity areas will provide additional information in support of the antigenic candidates under consideration.

Technology Transfer Officers

Technology Transfer Capabilities in India: Establishment and Strengthening for Sustainable Development Goals

Technology Transfer Offices (TTOs) facilitate translation of publicly funded research results into products and their delivery to markets by licensing innovation to enterprises and also bridge the gap between industry and academia to trigger collaborative or contract research and license institutional IP assets to such enterprises. Technology transfer strengthening is a long-time commitment and National Biopharma Mission has committed significant resources for creation of technology transfer office network and strengthening technology transfer professionals for the advancement of publicly funded research.

The National Biopharma Mission has supported establishment and strengthening of Technology Transfer Offices that are a vitally needed requirement of academic research bodies and innovation clusters to build institutional capacity in Innovation management and technology transfer. The vision and the commensurate investment in creating and nurturing the Regional Technology Transfer Offices (RTTOs) initiative is unprecedented in its scale.

05 TTO's have been established under the National Biopharma mission and spread geographically across the country. The goal is to establish/ expand chosen entities designated as Regional Technology Transfer Offices (RTTOs) to function as strategic drivers of innovation within the host institution and vitally engage with number of affiliate and non-affiliate institutions within a geographical region to bring in transformative approach to recognition of the value of academic research results and their translation to markets. These RTTOs will undertake activities such as technology mapping, linkages with industries and academic institutions, facilitating sponsored research, conducting IP awareness workshops and developing human resources trained in technology transfers processes. The RTTOs have necessary digital tools for patent analysis and management, licensing transactions management and post-license monitoring. The RTTOs will bring under their fold several other institutions that need professional support for advancing their research results to markets.

These are located at:

- IKP Prime at IKP Knowledge Park, Hyderabad
- Office of Technology Transfer at Centre for Cellular and Molecular Platforms (C-CAMP), Bengaluru
- KIIT - TBI Technology Transfer Office at KIIT Technology Business incubator, Bhubaneswar
- Innovation Technology Transfer Office at Foundation for Innovation and Technology Transfer (FITT), New Delhi
- Tech Ex.in at Entrepreneurship Development Center (EDC), Pune

In partnership with Society for Technology Management (STEM), NBM supported a series of basic to intermediate courses in Intellectual property management and Technology Transfer and also an advanced training program in order to strengthen the core foundation of applied and multi-disciplinary skills needed for accelerating technology commercialization. In this effort, 15 candidates from the courses have secured their Registered Technology Transfer Professional (RTTP) certification due to NBM support. STEM continues to build capacity for further cohorts while the TTOs are functional with complete strength of professional staff.

The RTTOs established with NBM support have already started to conduct regular online trainings on different aspects of technology transfer and IP activities. They have signed MoU with national and international bodies and some technologies have been identified for transfer to industry.

The TTOs identified have been provided access to capacity building and professional mentoring support by Sathguru Management Consultants, the technology management enterprise recognized globally for spearheading academic innovations to enterprises. Technology Transfer is an area of applied skill sharpened through practice. The experts from Sathguru are engaged intensively in RTTOs adopting contemporary technology transfer practices while enhancing the professional depth of RTTOs.

Skill Development:

The Mission supports trainings and workshops in various domains as per its mandate. Workshops in the areas of clinical research, regulatory compliances, technology transfer, biopharmaceuticals and medical devices have been majorly supported. 1749 candidates have been trained under Mission supported trainings with about 36.7% female participation up till now; 987 candidates trained with ~42.85% female representation in the current year.

A year which did not allow physical meetings was not a deterrent to continue the trainings and webinars. The need for trained clinical research professionals with knowledge on Good Clinical Practice (GCP) and Good Clinical Lab Practice (GCLP) and bioethics has never been felt more than in these COVID times. Conduct of clinical trials and generation of robust clinical data is a critical need for development of any new biomedical solution. Hence National Biopharma Mission conducted trainings on 'GCP, 'GLCP" and "Bioethics" in collaboration with CDSA, Faridabad. These were some of the prominent programs that benefitted the stakeholders associated with clinical research in the country. The 'Training of Trainers' (ToT) programs held at Faridabad and Hyderabad were a step further in the direction to have trained manpower at clinical trial sites. All these programs were very well received.

Additionally, a series of 4 webinars on Ethics in Clinical Research in collaboration with Department of Bioethics, U.S. National Institutes of Health Clinical Center (NIH) for promoting Clinical Research Ethics capacity in India and a series of 6 webinars on 'Environment, Health and Safety' to sensitize and create awareness about environment management and sustainability amongst the stakeholders of biopharmaceutical sector, were some of the major highlights. These webinars received wide participation from 4007 attendees with ~47% female representation.

SEPTEMBER 24	WEBINAR 1|4-6 PM IST Scientific and Ethical Standards of Clinical Research in Public Health Emergencies
OCTOBER 08	WEBINAR 2|4-6 PM IST Navigating Ethical Issues in Large Community-based Vaccine Field Trials
OCTOBER 01	WEBINAR 1|3-5 PM IST Regulatory Framework for Environment Protection in India: Biopharma Sector Perspective
NOVEMBER 19	WEBINAR 5|3-5 PM IST Adopting Green and Sustainable Practices in Biopharma Sector
NOVEMBER 12	WEBINAR 4|3-5 PM IST Building a Safe and Resource-Efficient Laboratory
OCTOBER 22	WEBINAR 3|4-6 PM IST Challenges in Conducting Human Challenge Studies: Policy Perspectives from India and United States
NOVEMBER 05	WEBINAR 4|4-6 PM IST Ethical Perspectives in Planning and Conducting Clinical Trials
OCTOBER 29	WEBINAR 3|3-5 PM IST Waste Management in Biopharmaceutical Sector: An Integrated Approach
OCTOBER 15	WEBINAR 2|3-5 PM IST Biosafety and Biocontainment Requirements for Biopharma Research and Manufacturing
NOVEMBER 26	WEBINAR 6|3-5 PM IST Developing Skills & Career as EHS Professional in India

NATIONAL BIOPHARMA MISSION

Glimpses from training programs

RFP's Published:
Since August 2019, the Mission has published 16 requests for proposals (RFP's) under various calls for Vaccines, Biotherapeutics, Medical devices and diagnostics, Clinical trial network etc.

S.No.	Title
1	To establish Clinical Trial Networks (CTNs) for hospital-based trial in specialties of Diabetology, Ophthalmology, Rheumatology and Oncology
2	To study epidemiology of Dengue & Chikungunya in different age-groups at existing DSS/DHS/DDESS* site(s) and to further prepare the sites for conduct of GCP compliant field-based clinical trials
3	Establish new DSS/DHS/DDESS* sites within the country to have complete geographical representation of potential trial sites and to study epidemiology of Dengue & Chikungunya in different age-groups at these sites
4	To Establish data management platform: An IT platform for community-based data collection, analysis and reporting
5	Medical Devices and Diagnostics in Categories of Wound Management, Trauma & Emergency Medicine, Surgical Tools and implants
6	Development of affordable serum-free, chemically defined media (SFCDM) and feed supplements for biopharmaceuticals
7	Development of affordable chromatography resin for protein purification
8	Development of filtration systems, process accessories and/or storage devices for affordable biomanufacturing
9	Develop IT platforms for quality management system in biopharmaceutical Industry
10	Development of Bio-betters and Biotherapeutics
11	Development of Antibody Drug Conjugates (ADCs)
12	Development of CAR-T therapies
13	Clinical Development of novel/new/next-generation vaccine candidate(s)
14	Translational Research Consortia (TRC) for Malaria, Hep E and RSV
15	COVID-19 Research Consortium
16	COVID-19 Research Consortium-Follow up

Proposed Activities:

- The grantees funded in 2018-2020 will continue to be monitored through a rigorous Project Review Monitoring process and evaluated for their technical milestones and fund utilization. All the four Scientific Advisory groups: Sag-BIO, SAG-Vaccines, SAG D&D, SAG-Clinical trials will meet at least twice a year to evaluate all the funded proposals.
- Grant-in-Aid letter agreements will be signed with all to approved projects.
- Two new Consortiums for HEV and Malaria will be initiated.
- Five additional facilities will be inaugurated.
- Two additional Technology Transfer offices will be established. Effectiveness of the TTOs will be evaluated through twice a year meeting with review committee.
- The field sites selected will be connected to Indian Vaccine manufacturers for conduct of clinical trials.

NATIONAL BIOPHARMA MISSION

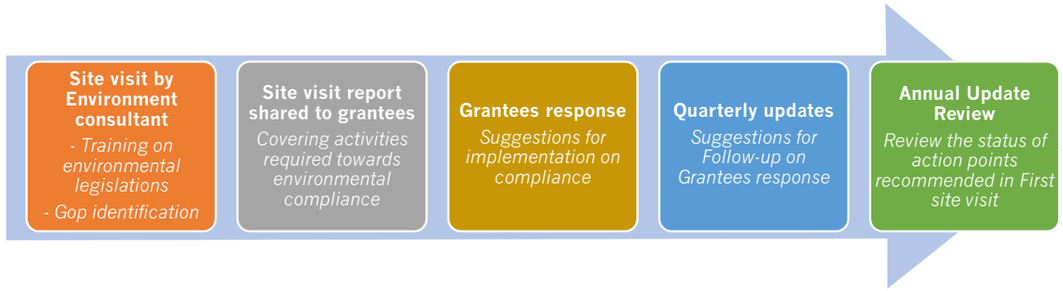
Environment & Safety monitoring activity for NBM projects:

1. Brief description:

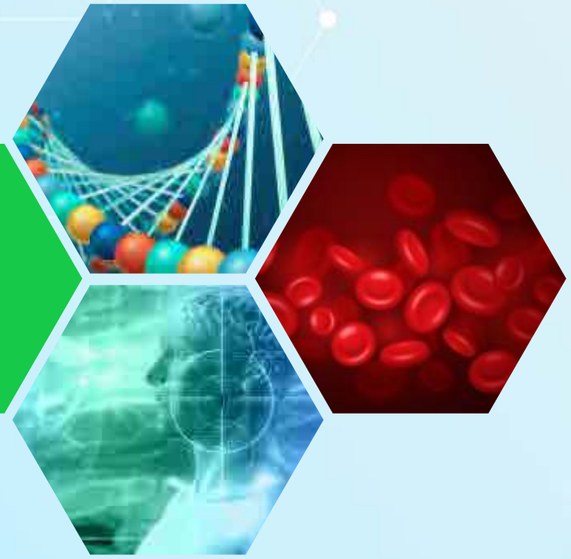
Environment occupational health and safety management framework (EMF) developed for i3 program in consultation with world bank. Based on the Programme objectives, the relevant Environmental, Occupational Health, and Safety aspects have been collated and can be found at https://birac.nic.in/nbm/uploads/2019/08/emf.pdf

In accordance with the EMF document, environmental due-diligence of all the projects funded under NBM is carried out. NBM conducts training, monitoring and consultancy for the grantees to ensure projects operates in environmentally friendly manner as per the EMF.

The overall environment & safety monitoring process is carried out as below:



IND-CEPI



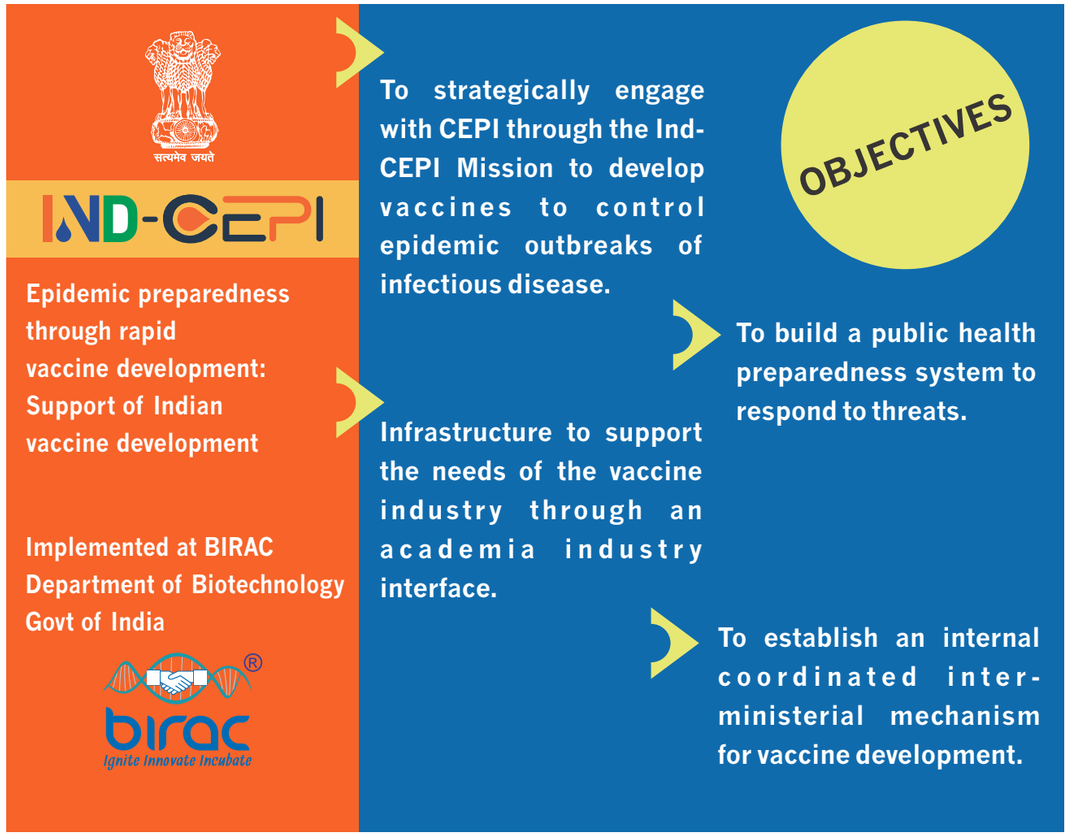
Ind-CEPI MISSION

India-Coalition for Epidemic Preparedness Innovations

Ind-CEPI MISSION

Introduction:

The Ind-CEPI Mission is an India centric collaborative mission of Department of Biotechnology (DBT), Govt. of India, aligned to the global initiatives of CEPI (Coalition of Epidemic Preparedness Innovations). The mission will facilitate pathways for vaccine development and assessment, developed in consultation with CEPI. The Mission aims to strengthen the development of vaccines for the diseases of epidemic potential in India as well as build coordinated preparedness in the Indian public health system and vaccine industry to address existing and emergent infectious threats in India. DBT is supporting the implementation of the Ind-CEPIs mission "Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the Coalition for Epidemic Preparedness Innovations (CEPI)", through a dedicated Program Management Unit (PMU) at Biotechnology Industry Research Assistance Council (BIRAC). The Ind-CEPI Mission was approved on 27th March 2019 with a total cost INR 312.92 crore.



Ind-CEPI MISSION

IND-CEPI

Supporting Vaccine Development:

Mission Ind-CEPI is taking decisive steps towards development of key vaccine candidates and supporting the same through clinical trials. In the endeavor to provide effective vaccines, mission Ind-CEPI has supported the mRNA vaccine candidate by Gennova Biopharmaceuticals Ltd. The supported mRNA vaccine candidate is the only of its kind being developed in India. To make the last mile delivery of the vaccine candidate more effective, vaccine candidate is designed to be thermo tolerable and can be transported at 4-8 . Apart from the response to the COVID-19 pandemic, mission Ind-CEPI is also supporting the development of Chikungunya vaccine candidate by Bharat Biotech international Ltd. An efficacious vaccine candidate against Chikungunya has been a long-standing need to immunize millions throughout the world especially in the developing countries. By the supportive action of the mission Ind-CEPI along with CEPI, our country is stepping towards delivering yet another vaccine needed by the global community. Details of both the vaccines currently being supported under mission Ind-CEPI are mentioned below.

Disease Area	Platform	Title	Grantee	Duration	Endpoint
SARS-CoV-2	mRNA vaccine	**"Next-generation mRNA vaccine against COVID-19 to provide long-term protection to the population within its national/ international territories"**	Gennova Biopharmaceuticals Limited, Pune	18 months	Manufacturing of vaccine candidate, and safety and immunogenicity in Phase I/II clinical trial.
Chikungunya	Inactivated virus	**"Global Chikungunya Vaccine Clinical Development program" (GCCDP)**	Bharat Biotech International Ltd (BBIL)	24 months	GMP manufacturing of the vaccine in India and subsequent manufacture of clinical trial materials.

Skill Development:

The Mission is making concerted efforts to promote capacity building, skill development and regional coordination. In this direction, an e-course series entitled “Strengthening Clinical Trial Research Capacity in Neighbouring Countries” was launched in collaboration with CDSA, Faridabad. The series was very well received by the neighbouring countries and proved to be an important diplomacy initiative for regional networking and coordination. An orientation session to e-course series “Strengthening Clinical Trial Research Capacity in Neighbouring Countries” was conducted on 22nd Sep 2020 through online platform. This training imparted a comprehensive coverage of Good Clinical Practice, Ethical considerations in clinical research, Good Clinical Laboratory Practice and Novel vaccine development and immunization policy in a pandemic. This 4-Programs 10 sessions series were conducted via online platform with total engagement of 771 participants from neighbouring countries like Afghanistan, Bangladesh, Bhutan, Maldives, Mauritius, Nepal and Srilanka.

Program 1-Good Clinical Practice (GCP):

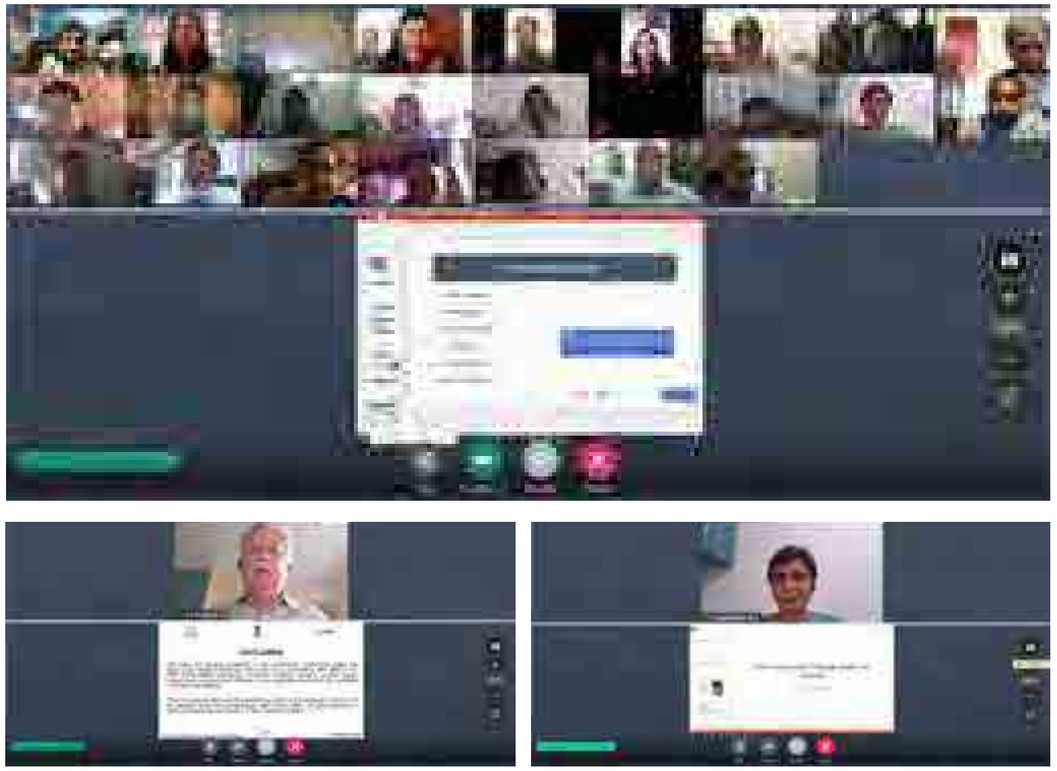
4 sessions were held on 9th, 16th, 23rd, 29th Oct 2020 that covered various aspects of GCP by esteemed faculty and key opinion leaders from renowned intuitions from industry and academia. These 4 sessions observed a participation from 75, 90, 60 and 88 participants respectively from neighbouring countries. Major topics covered included GCP & ICH Guidelines, importance & essential components of protocol, investigational brochure, Informed consent, roles and responsibilities of sponsors, investigators and ethics committee, recruitment methods and retaining strategies, types of adverse events, quality assurance, audits and inspections and adoption of Technologies in Clinical Trials, clinical trials of medicinal products in health emergencies, consequences of GCP non-compliance: case studies, research misconduct and assessment.

Glimpses from the Sessions on GCP

Ind-CEPI MISSION

Program 2-Ethical Considerations in Clinical Research:

2 sessions were held on 6th and 13th Nov 2020 that were attended by 116 and 88 participants respectively. Major topics covered included introduction to research ethics, challenges ahead for the ethics committees, ethics and human challenge studies for vaccines and ethics in population-based vaccine trials, ethical issues in international collaborative research, composition, competence, functioning and decision making of ethics committee, informed consent process overview: relevance, requirements, and documentation and informed consent process challenges vulnerable population, interventional studies, etc.



Glimpses from the Session on Ethical Considerations in Clinical Research e-Course

Program 3-Good Clinical Laboratory Practice (GCLP):

2 sessions were held on 20th and 27th Nov 2020 that were attended by 73 and 68 participants respectively. Major topics covered included Laboratory Quality Management System (LQMS), GCLP principles and guidelines, infrastructure, equipment, reagents & consumables, sample management: the cradle to grave journey, pre-examination, examination and post-examination procedure, sample acceptance/rejection, discussion on writing SOPs, sample storage & disposal, internal quality control, external quality assessment/ proficiency testing, internal audit, quality indicators, safety in laboratories, ethical considerations, risk management and data management.

Glimpses from the Sessions on GCLP

Program 4-Novel vaccine development and immunization policy in a pandemic:

2 sessions were held on 4th and 11th Dec 2020; attended by 69 and 44 participants respectively. Major topics covered included introduction to vaccine development, epidemiology and fundamentals on immunology in relation to vaccine development, vaccine pre-clinical development and manufacturing, novel vaccine development: overview with emphasis on Phase III vaccine trials, Good Participatory Practice (GPP): participant screening, eligibility, consent, retention in population-based studies, adverse event following immunization during clinical trials and after licensure, challenges of delivering vaccine trials during a pandemic and public and stakeholder engagement during clinical development and policy impact post-licensure.

Glimpses from the Sessions on Novel vaccine development and immunization policy in a pandemic

EOI's Published: An expression of interest (EOI) for establishing Quality Management System (QMS) For Immunogenicity laboratories and animal challenge study facilities under Mission Ind-CEPI has been announced. This EOI aims at providing accreditation to laboratories and animal facilities being strengthened under Mission COVID Suraksha. Call open till 16th Feb 2021.

Mission Ind-CEPI
and
Biotechnology Industry Research Assistance Council (BIRAC)

ANNOUNCE

Request for Expression of Interest
On
Quality Management System
Immunogenicity Laboratories and Animal Facilities

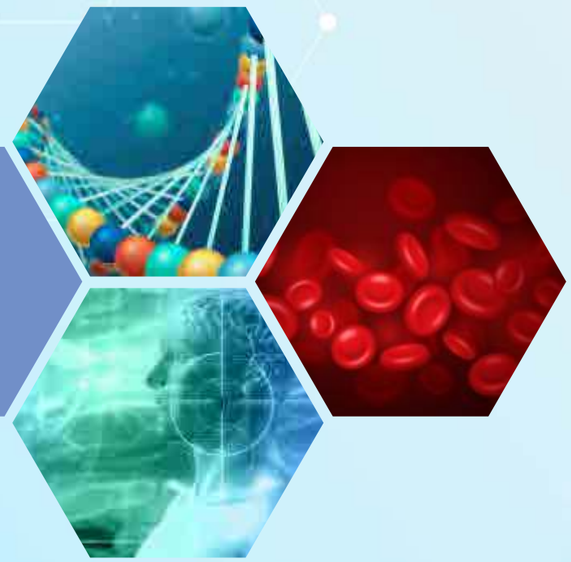
REOI: Quality Management System (QMS)

Call opens on : 26.01.2021
Call closes on : 16.02.2021 (5 PM)

for additional information and queries please contact:
Dr. Sreejata Chatterjeet, Email: user-040@birac.nic.in
Dr. Md. Iftikar Hussain, Email: user-042@birac.nic.in

Proposed Activities:

- Planning activities in convergence with the National Biopharma Mission
- Rolling out EOI/RFP
- Selection of Grantees
- Diplomacy and cooperation activities for capacity building and skill development



MISSION COVID SURAKSHA

Mission COVID Suraksha

As part of the Government of India's response to the COVID 19 Pandemic, the Department of Biotechnology, Ministry of Science and Technology, has been working with all stakeholders to address the urgent need of COVID 19 Vaccine. One of the key intervention is the launch of "The Indian COVID-19 Vaccine Development Mission- Mission COVID SURAKSHA" under Atma Nirbhar Bharat package 3.0., in November 2020, for a period of 12 months at a cost of 900.00 Cr.

Mission COVID Suraksha

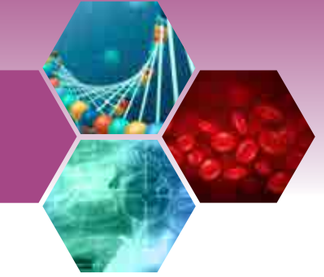
The Mission will address the need for accelerated development of COVID-19 vaccine by consolidating and streamlining the available resources. Mission COVID Suraksha aims to bring to the citizens of the country safe, efficacious, affordable, and accessible COVID vaccine at the earliest with a focus on Atma Nirbhar Bharat and fulfil our commitment of serving not just the country but the entire globe.

The Mission is engaged in supporting the development of vaccines with preferred characteristics applicable for India and that is proposed to be achieved by strengthening the following functional domains.

- Accelerating the production of clinical trial material, and clinical development for licensure of COVID-19 vaccine candidates.
- Establishing clinical trial sites, immunoassay laboratories, central labs and suitable facilities for animal challenge studies, other testing facilities to support COVID-19 vaccine development.

It is expected that the consolidated enabling ecosystem of clinical trial sites, immunoassay lab, animal challenge study facilities will strengthen the ability of product developers for a rapid response for any future pandemic.

So far following Request For Expressions have been published under Mission COVID Suraksha



Way Forward

During its eight years of existence, BIRAC has made a special effort to reach out to all its stakeholders and launch special initiatives which cater to the needs of the growing enterprise and build and strengthen the Innovation Research Ecosystem. BIRAC's key strategies are aligned in a manner that the attention stays focused on "Innovation for development of globally competent affordable product development to address unmet need".

As we move on BIRAC's endeavour would be to consolidate what it has created so far and pick on those critical components which need to be built upon. #Atamnirbhar Bharat, #Biosciences to Bioeconomy, #Power to Transform Lives, #VigyanSeVikas, sustaining innovation and facilitating the Startup Biotech Ecosystem towards commercialization of products, technologies would be a high priority.