birac
Ignite Innovate Incubate

7th ANNUAL REPORT
2018-19

Biotechnology Industry Research Assistance Council
(A Govt. of India Enterprise)

AWARDS

The World Academy of Sciences (TWAS) Regional Award for Science Diplomacy awarded to Dr. Renu Swarup, Secretary DBT & Chairperson BIRAC

Dr. Renu Swarup receiving TWAS Regional Award

Dr. Mohd. Aslam, MD, BIRAC was awarded "CEO with HR Orientation" by ETNOW during 27th Edition of World HR Congress at Taj Lands End, Mumbai.

The award was received by Ms. Nameeta Khare, Chief Manager & Head, HR& Admin, BIRAC

BIRAC awarded with "IP Excellence in India 2018" awarded by the Questel - Orbit - Indian IP Awads 2018

The award was received by Dr. Vinita Jindal, Sr. Manager, IP&TT

ANNUAL REPORT
2018-19

Biotechnology Industry Research Assistance Council

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 of 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 academia – 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

Key Strategies

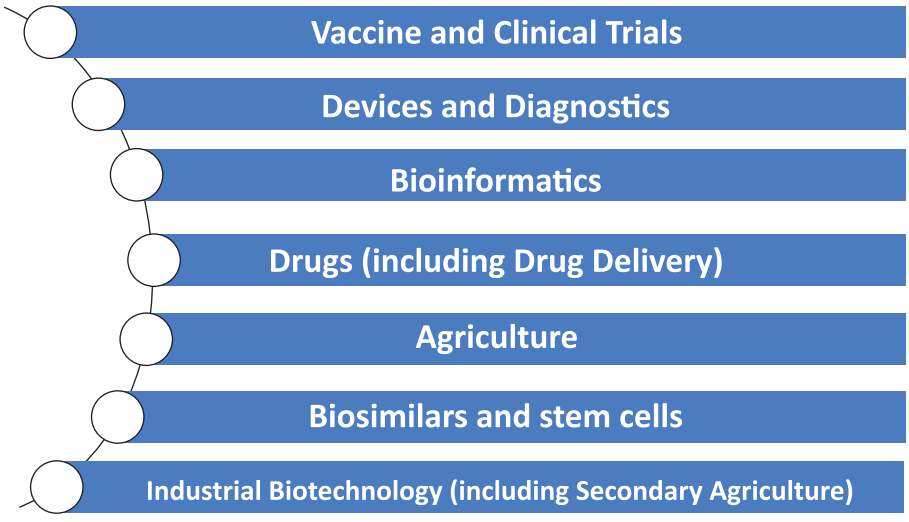
- Foster innovation and entrepreneurship in all places of research
- Promote affordable innovation in key social sectors
- Higher focus on startups & small and medium enterprises
- Contribute through partners for capacity enhancement
- Encourage diffusion of innovation through partners
- Enable commercialisation of discovery
- Ensure global competitiveness of Indian enterprises

Board of Directors

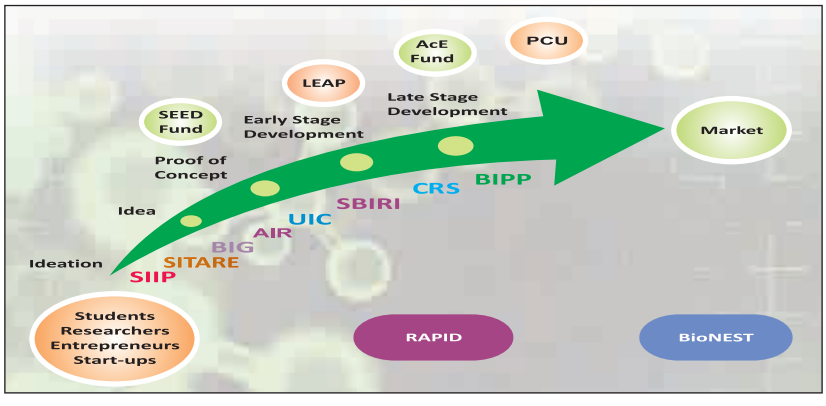
L to R : Dr. Mohd. Aslam, Shri Naresh Dayal, Prof. Pankaj Chandra, Dr. Renu Swarup,
Prof. Akhilesh Tyagi and Prof. Ashok Jhunjhunwala

Executive Summary

BIRAC's vision is to '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 of the largest section of society'. For the last 7 years, BIRAC's focus has been to act as a 'Development Agency' promoting the biotech ecosystem in the country. The support provided at BIRAC extends across all themes of biotechnology.



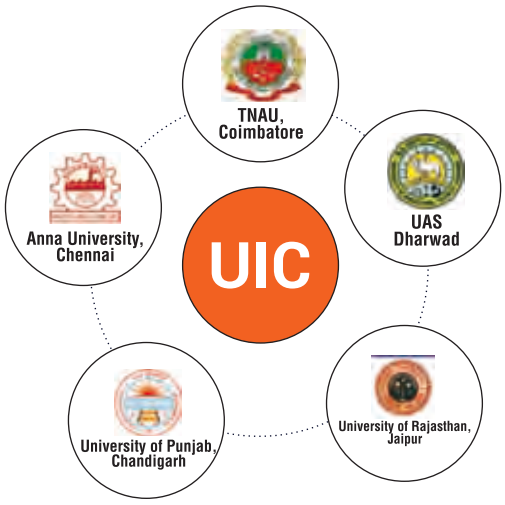
Covering the entire span of biotech arena right from pre-proof of concept till commercialization BIRAC has been supporting the innovation arena through its pioneering schemes.



To create pathways for 'Entrepreneurial Journeys', BIRAC has initiated the engagement with innovators right at the Foundational Level by launching programmes for early stage funding.

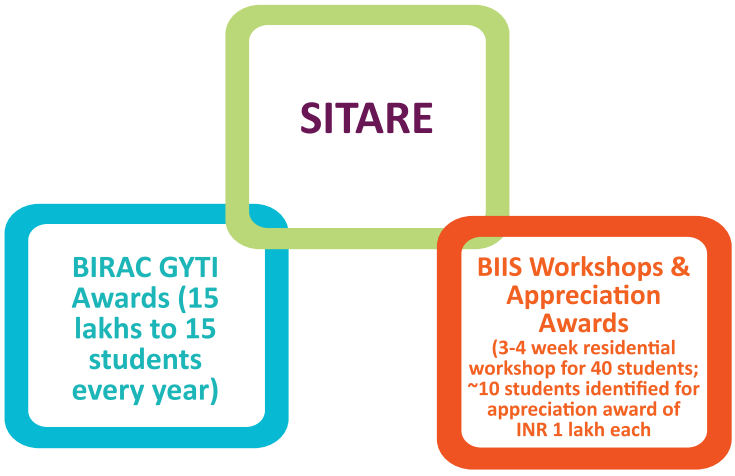
eYUVA (Encouraging Youth for Undertaking Innovative Research through Vibrant Acceleration)-University Innovation Clusters (UICs)

UICs are mandated to foster a culture of innovation and techno-entrepreneurship at University / Institution level. 5 UICs benefitted 23 students (Post-Graduate & Post-Doctoral level) so far. The scheme is now being expanded to benefit undergraduate level students. New UICs will also be identified in the coming year.



SITARE (Students Innovations for Advancement of Research Explorations)

- 60 SITARE Awardees
- 150+ Appreciation Awardees
- 4 BIIS Workshops



Social Innovation Immersion Program (SIIP)

- Provides fellowships to "Social Innovators" for identifying and addressing specific needs and gaps in social sector and promote social entrepreneurship.
- SIIP partners provide the rural and clinical immersion to the innovators
- Since inception, 35 SIIP fellows have been enrolled who have worked on finding solutions for society's most pressing problems in the area of Ageing and Health, Maternal and Child Health and Waste to value.

For promoting the development and commercialisation of cutting edge and affordable biotech products BIRAC has launched several transformational programs

Biotechnology Ignition Grant (BIG)

BIRAC's flagship funding scheme that supports early-stage funding for biotech startups and entrepreneurial individuals to support ideation and propel it towards proof-of-concept for ideas with translational potential.

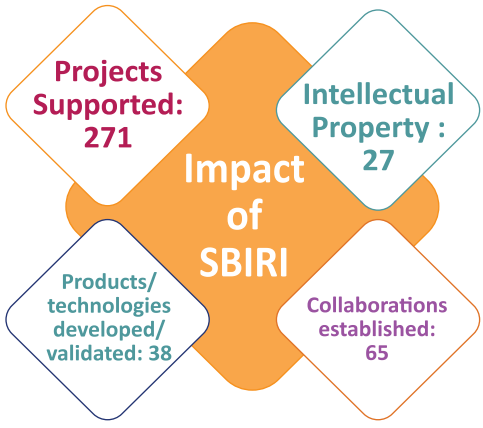
Funding support of up to INR 50 lakhs (as grant-in-aid)

Highlights of the scheme:

- ~400 Projects supported (including 112 new projects during FY 18-19)
- INR 148 Cr Released so far (including INR 42 Cr. in FY 18-19)
- 110+ New Startups created
- 100+ IPs filed
- 750+ Manpower supported for high end skills
- 4 BIG Conclaves (4th conclave at Venture Centre, Pune in July 2018)
- 5 BIG Grantees attended IGNITE programme at JBS, Cambridge (Total of 29 fellows trained so far)

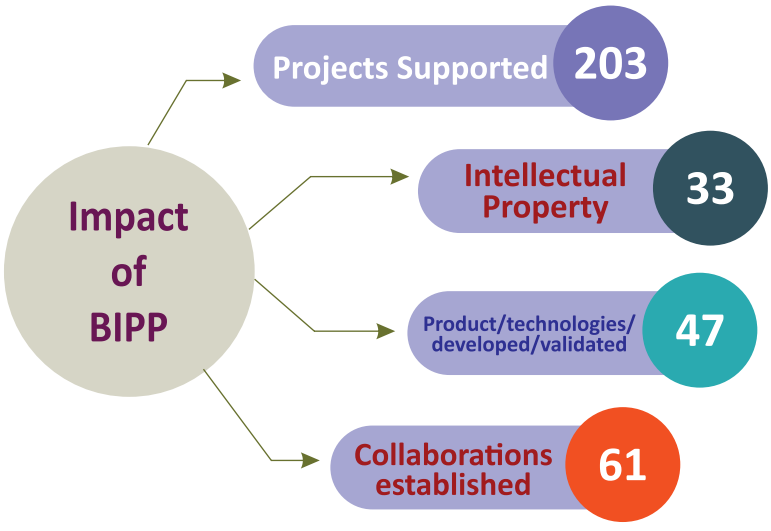
Small Business Innovation Research Initiative (SBIRI)

SBIRI was launched to promote and facilitate companies to take their established proof of concepts towards early stage validation. The Scheme has played a vital role in fostering public private partnership



Biotechnology Industry Partnership Programme (BIPP)

- Promotes innovative research for development of transformational technologies/processes in Biotech Sector.
- Serves as a launch pad for scaling and commercializing high risk innovations through cost sharing between BIRAC and the industry.



Social Innovation Programme for Products: Affordable & Relevant to Societal Health (SPARSH)

- The Social Innovation Programme of BIRAC is aimed at promoting the development of innovative solutions to society's most pressing social problems through biotechnological approaches.
- Different themes supported such as :
  - Reducing child mortality and improving maternal health
  - Ageing and Health
  - Innovative Diagnostic tools for Soil and Plant Health
  - Soil & Plant Health and Human Health
  - Waste to Value
  - Livestock health and improvement
  - New and improved agricultural tools
  - Reducing post-harvest losses
  - Combating environmental pollution

Projects supported: 46

Products/technologies developed/ validated: 13

Promoting Academic Research Conversion to Enterprise (PACE)

Encourages/supports academia to develop technology / product (up to PoC stage) of societal / national importance and its subsequent validation by an industrial partner Promoting Academic Research Conversion to Enterprise (PACE)

Academic Innovation Research (AIR)

- Promotes development of PoC
- Industry partner not mandatory
- Projects with well-established proof-of-principle supported
- Basic / exploratory research not supported
- IP rights may be with academia alone, or jointly shared

Contract Research Scheme (CRS)

- Validation of a process of prototype (developed by an academia) Industry partner mandatory
- Academia must have an established Proof-of-Concept
- The industry partner has first right of refusal for commercial exploitation of the New IP

Projects supported: 71

Collaborations established: 31

Intellectual property generated: 2

Products/ technologies developed/ validated: 7

Promoting Incubation, Translation and Scaling- BioNEST

Biotech startups face an uphill task for commercialisation. The access to infrastructure and lab space always remains a critical hurdle. In this regard, BioNEST (Bioincubators Nurturing Enterprises for Scaling Technologies) serves as a nesting ground for big take-offs and provides:

- Incubation space to start-ups and entrepreneurs
- Access to world class infrastructure and high end equipment facilities
- Connect between industry and academia enabling efficient exchange of knowledge and facilitating technical and business mentorship

Enabling services and required mentorship for IP and Technology Management, legal contracts, resource mobilisation and networking platform

41 Incubators supported (Including 10 new incubators during FY 18-19)

- INR 270 Cr+ sanctioned
- INR 180 Cr+ disbursed

Cumulative area of 4, 41,349 sq. ft. created

800+ Jobs created

BIRAC's Initiative **Sustainable Entrepreneurship and Enterprises Development Fund (SEED Fund)** aims at providing financial equity based support to the start- ups and enterprises through bio incubators for scaling enterprises.

Biotechnology Innovation Fund – Accelerating Entrepreneurs (AcE) Fund

BIRAC has set up Early Translation Accelerator (ETA) to pull academic discoveries towards translation.

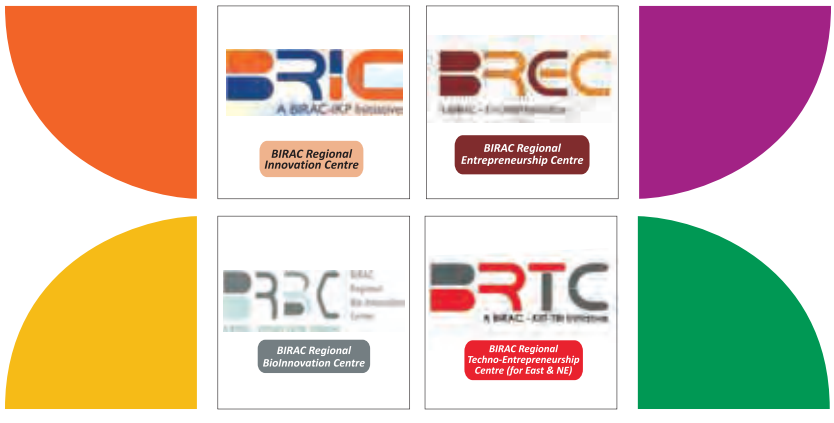
PATH to Commercialization

BIRAC operates BIRAC-PATH (Patenting and Technology Transfer for Harnessing Innovations) that extends support to protect the intellectual property which emerges out from the innovative projects funded by BIRAC and facilitate technology transfer.

A Product Commercialization Program has been launched to hasten the product commercialization process by providing support to projects that have completed early stage validation.

Engaging with Regional Communities to map innovations and support entrepreneurs

BIRAC Regional Centres



BIRAC Regional Innovation Centre (BRIC)

Mandate of BRIC:

- Mapping Regional Innovation Ecosystems to understand the current status of innovation and identify the gaps
- Build IP awareness and provide IP & Technology Management support to start-ups & innovators
- Promote Entrepreneurship development in academia and R&D institutes

BRIC Impact (2013-2019)

- **Pan India 22 clusters covered**
- **750+ Innovators engaged**
- **200+ Key Opinion Leaders (KOLs) connected**
- **55+ workshops and networking meetings on IP, funding opportunities, regulatory guidance and capacity building through Incubation in Tier II and III cities**

BIRAC Regional Entrepreneurship Centre (BREC)

- National Life Science Entrepreneurship Awareness Programme
- Entrepreneurship Development Workshops
- Meet the Investors Series (Dragon's Den)
- National Bio-Entrepreneurship Boot Camp
- National Bio Entrepreneurship Competition

BREC Impact (2017-2019)

90+ Start-ups mentored for business development strategy, pitching and fund-raising

200+ One-on-one meets between start-ups and investors

200+ Bio-entrepreneurs and Innovators provided specialised domain knowledge

700+ Students participated in awareness programmes about entrepreneurship as career

2000+ Innovators registered for National Bio Entrepreneurship Competition (NBEC) and 11 Industry partners supported NBEC as grand prize sponsor, investment partner and mentorship partner

BIRAC Regional BioInnovation Centre (BRBC)

- Venture Mentoring Services
- Venture Base Camps
- Regulatory Information and Facilitation Center
- BioIncubation Practice School for western regions

BRBC Impact (2018-2019)

120+ entrepreneurs connected with mentors

50+ one to one follow up meetings

50+ participants provided domain knowledge through Venture Base Camps

15+ incubation managers trained

100+ students/entrepreneurs provided insights into essentials of scientific entrepreneurship

50+ start-ups assisted for solving regulatory queries

BIRAC Regional Techno-Entrepreneurship Centre (BRTC) (for East & NE)- New Centre

BRTC shall undertake following activities:

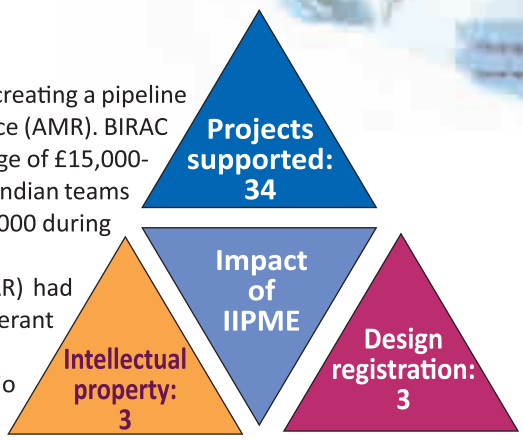
- Mining and assessment of Techno-commercial resource pool in East & NE regional

Human Resource Development Programmes

- Road shows
- Workshops /trainings
- Design workshops
- NE Immersion Program
- NE Showcase Event
- Hands-on training for rural women
- Incubation Practice School for NE

Spreading wings through National & International Partnerships

- Indo-French agency CEFIPRA, BPI France and Wellcome Trust
- Partnership with USAID and IKP in the realm of TB Diagnostics
- BIRAC has collaborated with NESTA a UK based innovation foundation, for creating a pipeline of innovators for the Longitude Prize, in the area of Anti-microbial Resistance (AMR). BIRAC has supported 9 teams with BIRAC- Discovery Award Fund (DAF) in the range of £15,000-20.000 each during FY 16-17 and 17-18. To further enhance the chances of Indian teams winning Longitude Prize, BIRAC announced Boost Grant of upto INR 90,00,000 during the FY 18-19. Three teams were awarded BIRAC Boost Grant Award.
- BIRAC in partnership with USAID and Indian Council for Agriculture (ICAR) had initiated a five year long project for development of high-yielding, heat-tolerant wheat cultivars appropriate for the Indo-Gangetic Plains.
- BIRAC has supported a technology development and transfer program for bio fortified and disease resistance banana from Queensland University of Technology (QUT), Australia with an overall aim to address food and nutritional security through bio-fortification.



- Ministry of Electronics and Information Technology, Government of India (MeitY) - Industry Innovation Programme on Medical Electronics (IIPME). A collaborative project between the Ministry of Electronics and Information Technology, Government of India and BIRAC. Initiated in February 2015 to help address the challenges of the medical electronics fraternity
- BIRAC has partnered with Lords Education and Health Society (LEHS) through its Wadhwani Initiative for Sustainable Healthcare (WISH) for accelerating innovations and enterprise scale up for sustainable healthcare delivery systems in primary health care centres through State Governments. Under this Partnership with WISH, annually four (4) BIRAC supported innovations would be validated
- BIRAC has a partnership TiE-Delhi NCR under which a woman specific award has been constituted, named as WInER Award (Women In Entrepreneurial Research). 2nd Edition of WInER was launched during the year 18-19 and15 women were selected for an award of INR 5 lakhs each. These awardees would now undergo an intensive one week long accelerator programme and 3 out of these 15 would receive further funding of INR 25 lakhs each.

Secondary Agriculture Entrepreneurial Network

- Jointly set up by Punjab State Council for Science & Technology (PSCST) and Panjab University to develop agricultural technologies with an aim to enhance farmers' income and promote crop diversification.

Aims at promoting new enterprises and supporting existing industry in the secondary agriculture sector

The initiative will develop technologies such as value-added products from tomatoes and anthocyanin-rich wheat (anti-oxidants).

After laboratory success and validation, the technologies will be transferred to the industry for commercial exploitation.

Network jointly launched by Dr. Renu Swarup, Secretary, Dept. of Biotechnology, Govt. of India and Sh. Karan Avtar Singh, IAS, Chief Secretary, Govt. of Punjab

SoCH:

BIRAC had launched an Innovation Challenge Award, SoCH i.e. Solutions for Community Health in September 2017, wherein Innovative ideas from individual entrepreneurs, academia and companies were sought under two themes (Platform technologies for reducing disease burden and Sanitation & Waste recycling) aimed at developing viable solutions to address certain challenges in the Community Health Sector.

In FY 2018-19, BIRAC announced the two final winners (1 from each theme) of SoCH, and were awarded a sum of INR 50 lakhs each along with technical & business mentoring through one of the BIRAC's BioNEST-incubators.

- The 7th Innovator's Conclave of BIRAC was held at Heritage Village, Manesar on 19th-20th September 2018 and focused on 'VIGYAN SE VIKAS. The Innovators' Conclave witnessed a confluence of around 300 Scientists, Entrepreneurs, Academicians, and Industry Experts.
- The 7th Foundation Day of BIRAC was celebrated at Hotel Pullman, Aerocity on 19th-20th March, 2019, with a theme 'Nurturing Innovations: Empowering India'. An exhibition demonstrating the products/technologies developed by BIRAC funded projects was also organized during the 7th foundation Day of BIRAC.
- During the year 2018-19, BIRAC participated actively in events including BIO Boston, BIO-KOREA, BioAsia and Bengaluru Tech Summit
- BIRAC also organized awareness workshops for students under BIRAC-TiE partnership. These workshops were conducted in Tier 2 cities, namely Jammu, Patna, Jaipur, Shimla, Indore, Dehradun.

Training and Workshops

Genetic tools and techniques for synthetic biology

- Organized in collaboration with IIT Madras Research Park, Chennai
- Number of participants: 26

Biopharmaceutical Technology Course

- Organized in collaboration with IIT Delhi
- Number of participants: 95

Biosimilar Characterization

- Funded by BIRAC and TEQIP III (Technical Education Quality Improvement Program) III and organised by Institute of Chemical Technology, Mumbai
- Number of participants: 73

Down Stream Bioprocessing Course

- Jointly organized by Centre for Cellular and Molecular Platforms (C-CAMP) and GE Healthcare
- Number of participants: 12

Genome Engineering of Fungal and Yeast Strains for Biomolecule Production

- Organized in association with ICGEB
- Number of participants: 24

Regulatory Workshops

- Organized at ICGEB (attended by 100 participants)
- Organized at Venture Centre (Attended by 96 participants)

IP and Technology Management workshops

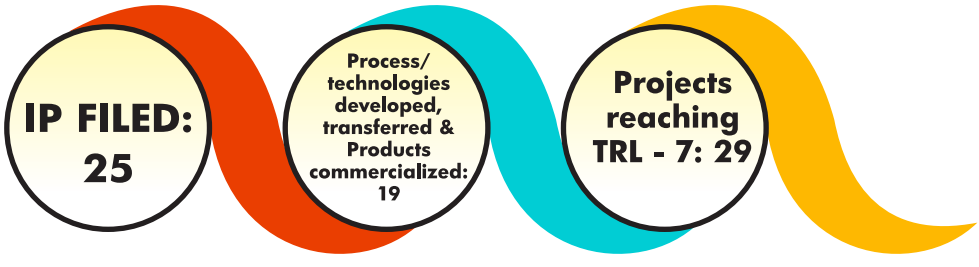
- Organized at KIIT Bhubaneswar (Attended by 45 participants)
- Organized at C-CAMP, Bangalore(Attended by 50 participants)
- Organized at IIT, Kanpur (Attended by 55 participants)
- Organized at IKP and University of Hyderabad, Hyderabad (Attended by 50 participants)

Awareness workshops for students under BIRAC-TiE partnership

- Workshops were conducted in Tier 2 cities, namely Jammu, Patna, Jaipur, Shimla, Indore, Dehradun

National Biopharma Mission (NBM)

- Approved by the Cabinet in May 2017 at a total cost of US$250 million for five years with 50% funding through World Bank loan.
- A dedicated Project Management Unit (PMU) established at BIRAC for implementation
- RFP published focussing on development of
  - (I) Vaccines
  - (ii) Biosimilars
  - (iii) Medical devices and diagnostics
  - (iv) Facilities to support development of Biologicals
  - (v) Testing and prototyping facilities for Devices and diagnostics
  - (vi) Facility for clinical immunogenicity of vaccines (GCLP labs)
  - (vii) Establishing Translational Research Consortia for Dengue and Chikungunya
  - (viii) Novel cell line.



CONTENTS

Biotechnology Industry Research Assistance Council

CIN: U73100DL2012NPL233152

Regd office: 1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi-110003

Website: www.birac.nic.in • Email: birac.dbt@nic.in • Tel: 011-24389600 Fax: 011-24389611

NOTICE

Notice is hereby given that the **Seventh Annual General Meeting** of the Company will be held on:

Day and Date: Monday, September, 23, 2019 **Time:** 10.15 a.m.

Venue: Department of Biotechnology, 2, CGO Complex, 7th Floor, Lodhi Road, New Delhi _ 110003.

for transacting the following business:

Ordinary Business:

1. To receive, consider and adopt the Audited Financial Statements of the Company as on March 31, 2019 together with the Reports of the Directors and Auditor thereon and comments of the Comptroller & Auditor General of India in terms of Section 143(6)(b) of the Companies Act, 2013

2. To fix the remuneration of the Statutory Auditor for the financial year 2019-20, in terms of provisions of Section 139(5) read with Section 142 of the Companies Act, 2013.

NOTES:

1. MEMBERS ENTITLED TO ATTEND AND VOTE MAY APPOINT ONE OR MORE PROXIES TO ATTEND AND VOTE INSTEAD OF THEMSELVES. PROXIES TO BE VALID MUST BE RECEIVED AT THE REGISTERED OFFICE OF THE COMPANY NOT LESS THAN FORTY-EIGHT HOURS BEFORE THE APPOINTED TIME OF THE MEETING

2. Only bonafide members of the Company whose names appear in the Register of Members in possession of valid attendance slips duly filed and signed will be permitted to attend the meeting. The Company reserves its right to take all steps as may be deemed necessary to restrict non-members from attending the meeting.

3. It will be appreciated that queries, if any, on accounts and operations of the Company are sent to the registered office of the Company ten days in advance of the meeting so that the information may be made readily available.

By Order of the Board

Kavita Anandani
Company Secretary

Registered Office:
1st floor, MTNL Building, 9, CGO Complex,
Lodhi Road, New Delhi _ 110 003,

Date: August 21, 2019

Our Chairperson's Message

Dr. Renu Swarup
Secretary DBT &
Chairperson, BIRAC

As I reflect on our progress this past year, I would first like to thank the BIRAC board, the BIRAC team, all our experts, partners and grantees for their commitment to nurturing innovations in the biotech ecosystem.

One of the greatest privileges I have had as Secretary of the Department of Biotechnology and Chairperson BIRAC, and previously as Managing Director, BIRAC is seeing the incredible impact that our technologies have had on people and organizations across India. Our ecosystem touches the lives of millions of people every single day, creating new opportunities for our grantees and partners and positively impacting the entire Biotech economy in India. We are living at a crucial time in history where the impact of technology on every part of our daily life, work, our society and economy is more acute than ever before.

Our mission is to empower start-ups, innovators, industries, and academia in India to achieve more. I'm proud of what we have accomplished together as we innovate and help grantees to navigate their transformation, and I am even more optimistic about the opportunities ahead.

BIRAC can be thought of having two major activities in its mandate to support innovators and entrepreneurs in the biotech space.

One, of course, is providing funding to absorb some of the risk that innovators and entrepreneurs face along their development pipeline, especially for high-risk high-reward challenges. In FY 2018-2019 BIRAC committed/disbursed INR 161.80 crore for programs and projects.

The other is handholding and mentoring of our projects and innovators, to help them navigate the often obstacle-filled path to taking their products to the market. In this regard, BIRAC launched new programs and initiatives that are specifically aimed at filling this gap. These include the LEAP Fund, the Product Commercialization Unit and the FIRST Hub programs.

The LEAP Fund (Launching Entrepreneurial Driven Affordable Products) was launched to enable potential start-ups to pilot/commercialize their products/Technologies. LEAP fund is aimed at providing next level funding support of up to Rs. 1 Cr for investing in potential start-ups against equity and equity-linked instruments by implementing incubators/partners. The proposed funding support is positioned to act as a catalyst in bringing technologies/products forward towards piloting/commercialization and reducing their gestation to commercialization.

The Product Commercialization was created to play a catalytic role in commercializing BIRAC funded projects and assists with regulatory, intellectual property, policy, funding and other aspects of taking products to the market, which is usually a difficult prospect for fledgling start-ups. It has also become a fully functional unit within BIRAC to provide funding for those innovators who are navigating the path to commercialization.

The FIRST Hub program is a first of its kind platform created by BIRAC where innovators and regulators are brought together to discuss the regulatory challenges that innovators are facing in their product development. The program has been well received by both innovators as well as regulators.

In secondary agriculture sector, the SAEN (Secondary Agriculture Entrepreneurial Network) was also launched in 2018, aiming to promote new enterprises and to support the existing industry in the secondary agriculture sector. The last financial year also saw the first technology transfer in secondary agriculture from academia to companies.

BIRAC remains committed to supporting and encouraging women entrepreneurship. After the success of the 1st edition, BIRAC launched the 2nd edition, the BIRAC-TiE Women In Entrepreneurial Research (WInER). The award is focused on supporting women entrepreneurs in the biotech sector that provides a seed fund of 15 winners. A weeklong accelerator program for the awardees led to the selection of 3 for Rs.25 lakh award. BIRAC's contribution to the Government's national programs such as "Make in India (MII)" and "Start-up India" is an an important aspect of the organisation's work. The MII Facilitation Cell within BIRAC continues to interact with other agencies to frame policies and track achievements of our commitment to the MII and Startup India plans.

BIRAC's collaborations, both national and international have been an important vertical of our work. Our partnerships with the Bill & Melinda Gates and Wellcome Trust as well as the World Bank have been strengthened through the Grand Challenges India program and the National Biopharma Mission. Our partnerships with CEPIFRA, Tekes, TiE, the Indian Council of Medical Research, Indian Angel Network, WISH and USAID remain critical in delivering important programs. These partnerships allow both partners to leveraging the core competencies each other which helps us align and achieve the target of developing India's innovation ecosystem.

BIRAC has received an 'Excellent' rating on compliance with the Guidelines on Corporate Governance Guidelines for CPSEs for the year 2018-19, as announced by the Department of Public Enterprises (DPE)

BIRAC's last financial year saw many positive outcomes, and we will continue to create opportunity, growth, and impact in start-ups, academia and industry in the biotech space. We will continue to invest in the most significant growth opportunities and innovate boldly to serve our nation. BIRAC remains committed to support the biotechnology industry in India to making this a $ 100 billion economy by 2025.

Dr. Renu Swarup
Secretary DBT & Chairperson, BIRAC

Managing Director's Message

Dr. Mohd. Aslam
Managing Director,
BIRAC

BIRAC's 7th Annual Report showcases the activities BIRAC has conducted over the last year against its mandate to help build the nation's biotech innovation ecosystem by nurturing, enabling, catalyzing and empowering biotech entrepreneurs, startups and SMEs alike with innovative ideas for novel biotech products and processes.

The challenge, however, is that Biotech R&D is expensive, which is a particular problem when the products are intended for cost-effective solutions. Therefore, BIRAC has worked with start-ups to help to overcome the risk and uncertainty, either by providing a partial or full grant for product development through our early stage programs such as the Biotechnology Ignition Grant (BIG), which is the largest early-stage biotech funding program in the country. Some of our flagship programs, such as SBIRI, BIPP, PACE, SPARSH, and IIPME, have transformed the biotech start-up landscape in the country. Today BIRAC has supported around 1000 Start-ups, entrepreneurs and SMEs across the country and looks forward to working with and supporting many more.

BIRAC has in the last year worked aggressively on expanding the programs and projects that we fund across a variety of themes. Staying true to our mandate to support innovation, through both funding and as well as mentoring and handholding of grantees, BIRAC has implemented technology transfer initiatives as well as mechanisms that allow innovators to address their regulatory, IP and commercialization queries etc.

BIRAC has aggressively pursued technology transfer initiatives where the translatable leads from academic institutions are assigned to the relevant industries. In this regard in the agricultural technologies' commercialization space for the first time, three White Rust resistant lines of Oilseed Mustard (*Brassica juncea*) were 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. These lines which were developed through mapping and marker-assisted backcross have been transferred to 7 Indian companies for further translation and eventual commercialization.

The Product Commercialization program announced last year has now become an active unit within BIRAC. This unit was created to play a catalytic role in commercializing BIRAC funded projects and assists with regulatory, intellectual property, policy, funding and other aspects of taking products to the market, which is usually a difficult prospect for fledgling start-ups. In the last financial year the operational plans for the working of the fund were developed. An extensive review process was conducted through the year to identify the possible beneficiaries of the fund.

BIRAC, further in its endeavor to handhold innovators, launched the Biotech FIRST (Facilitation of Innovation & Regulation for start-ups and Innovators) HUB having representation from regulatory bodies such as the CDSCO, ICMR, DBT, BIS, NIB, as well as BIRAC. This facilitation unit addresses clarifications and provide advice to start-ups, entrepreneurs, researchers, academicians, incubation centers, SMEs, on regulation, funding opportunities, mentorship, investment opportunities, market access, Industry-academia partnerships, and intellectual property matters.

To provide adequate infrastructural support to innovators across the country, BIRAC has also established 41 Bio-incubators through BioNEST scheme with an incubation space of 3,91,849 sq. ft. till date. The 1st Clean Energy international incubator has been set up under mission innovation by DBT & BIRAC. A new regional center, BIRAC Regional Techno-Enterpreneurship Centre (BRTC) was also established at KIIT-BioNEST, Bhubaneswar.

BIRAC continues to establish deeper engagements with several national & international partners to foster the biotech entrepreneurial ecosystem in India. Organisations such as TDB (Technology Development Board, Department of Science & Technology), ALEAP (Association of Lady Entrepreneurs of India), TiE (The Indus Entrepreneur) Delhi-NCR, WISH Foundation, Bill & Melinda Gates Foundation (BMGF), Welcome Trust, Nesta UK, HIA Australia, CARBX, USAID, Business Finland, World Bank, BioCuba Farma and Vinnova have partnered with BIRAC.

BIRAC's contribution to the Government's national programs such as "Make in India (MII)" and "Start-up India" have also grown.

The support that we have extended to over 1000 entrepreneurs and startups over the last 6 years has now started translating into development of more than 130 novel products and technologies.

As we work achieve our goals for the future, we are excited and motivated to improve and innovate to continue delivering impact.

Dr. Mohd. Aslam
Managing Director, BIRAC

BOARD OF DIRECTORS

Dr. Renu Swarup	:	Chairperson
Dr. Mohd. Aslam	:	Managing Director and Government Nominee Director

Non-Executive Independent Directors

Prof. Ashok Jhunjhunwala	:	Director
Prof. Akhilesh Tyagi	:	Director
Shri. Naresh Dayal	:	Director
Prof. Pankaj Chandra	:	Director

Dr. Renu Swarup

Dr Renu Swarup is presently Secretary, Department of Biotechnology (DBT), Government of India. Having served in Department of Biotechnology for over 29 years, she also holds the position of Chairperson, Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Company incorporated by the Government to nurture and promote innovation research in the Biotech Enterprise with special focus on Start ups and SMEs.

A PhD in Genetics and Plant Breeding, Dr.Renu Swarup completed her Post Doctoral at The John Innes Centre, Norwich UK, under Commonwealth Scholarship and returned to India to take up the assignment of a Science Manager in the Department of Biotechnology, Ministry of Science and Technology, GoI, in 1989. As a Science Manager issues related to policy planning and implementation were a part of her assignment. She was actively engaged as the convenor in formulation of National Biotechnology Vision and Strategy in 2001, 2007 and 2015.

She has been closely involved in Programmes related to Bioresource development and utilization, Energy Sciences and Women & Science. She was also a member of the Task Force on Women in Science constituted by the Scientific Advisory Committee to the Prime Minister. Dr. Renu Swarup has been instrumental in the planning and implementation of some major National programmes such as Spatial Characterization of Biodiversity, Second Generation Bioethanol, Drugs from Microbes, National Biopharma Mission.

A Fellow of the National Academy of Sciences (NASI) India, A Life Member of Trust for Advancement of Agricultural Sciences (TAAS) and a Member of the Organization for Women in Science for the Developing World (OWSD), she was awarded the "BioSpectrum Person of the Year Award" in 2012. "National Entrepreneurship Awards 2017", TiE WomENABLER Award 2018 "Dr. P. Sheel Memorial Lecture Award" 2018 by NASI and the TWAS Regional Office Prize on Science Diplomacy in 2018. She has been awarded the Agriculture Research Leadership Award 2019.

Dr. Mohd. Aslam

Dr. Mohd. Aslam, Advisor (Scientist 'G') in the Department of Biotechnology (DBT) is currently holding additional charge as Managing Director, BIRAC. He is involved in planning, coordination and monitoring of various R&D programmes related to Bioresources Development and Utilization including Translational Research in Products and Processed from Medicinal & Aromatic Plants, Technology Development in Silk and Biotech-KISAN. He is Head of International Cooperation and Member Secretary of DBT Apex Board. He is also working as the Coordinator in DBT for three autonomous institutions _ National Agrifood Biotechnology Institute (NABI), Mohali, Central Institute of Applied Bioprocessing (CIAB), Mohali and Institute of Bioresources and Sustainable Development (IBSD), Imphal, Manipur. He is also Liaison Officer for International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi.

Profile of Non Official Independent Directors

Prof. Ashok Jhunjhunwala

Prof. Ashok Jhunjhunwala is an Institute Professor at Indian Institute of Technology, Madras at Chennai, India. He did B.Tech from IITK, MS and Ph.D. from the University of Maine and was a faculty at Washington State University from 1979 to 1981, before joining IIT Madras in 1981. Dr. Jhunjhunwala is considered the pioneer in nurturing Industry - Academia interaction in India towards R & D, Innovation and Product Development. His group (TENET) at IIT Madras has innovated, designed, developed and commercialized a large number of technologies in the area of Telecom, IT, Banking and Energy sectors, especially in solar rooftop and electric vehicles. He conceived and built the first Research Park (IIT Madras Research Park) in India which houses over 90 R & D companies and 200 incubated companies. He has set-up and currently drives technology innovation and entrepreneurship through IITM Incubator. Dr. Jhunjhunwala has been Chairman and member of various government committees and has been on boards of several education institutions in the country. At the same time, he has been on the boards of a number of public and private companies and has driven comprehensive changes, especially in the area of technology, in the companies. He was a Director on the board of State Bank of India, Bharat Electronics, HTL, NRDC, IDRBT, VSNL and BSNL. He has also been a board member in Tata Communications, Mahindra Rewa, Sasken, Tejas Networks, TTML, Intellect and Exicom. He is currently also on the board of BIRAC and Chairman of Technology Advisory Group of SEBI. Dr. Jhunjhunwala was conferred Padma Shri in 2002, Shanti - Swarup Bhatnagar award, Vikram Sarabhai Research award, H. K. Firodia award, Silicon India Leadership award, Millenium Medal at Indian Science Congress, UGC Hari Om Ashram award, IETE's Ram Lala Wadhwa Gold Medal, JC Bose fellowship and Bernard Low Humanitarian award. TiE conferred on him the title of "Dronacharya" for his contributions to the cause of entrepreneurship. He is fellow of IEEE, INSA, NAS, IAS, INAE and WWRF. He has also been conferred Honorary Doctorate by University of Maine and Blekinge Institute of Technology, Sweden.

From November 2016 to August 2018, he took leave from IITM and worked with Government of India as Principal Advisor to Shri Piyush Goyal, Minister of Power and MNRE and Railways, Delhi, he is now back at IIT Madras.

Prof. Akhilesh Tyagi

Working in the area of Plant Genomics and Biotechnology, Professor Tyagi led first successful Indian initiatives on genome-wide sequencing in rice, tomato and desi chickpea. This has heralded the era of high throughput genomics in India. Pioneering contributions were made to the area of neo- and sub-functionalization of regulatory gene families in plants during evolution. A transcriptome atlas of water-deficit response and grain development in rice has been generated. Novel genes/ alleles were characterized with a view to gain and protect yield. Overall, >250 publications of international repute have been generated. This research is largely an outcome of investigations of national/international collaborators and >120 Post-Doctoral, Doctoral, Master, Fellow and Trainee researchers, carried out under the auspices of several projects executed in his leadership. He has delivered over 300 invited lectures and chaired over 50 sessions in national (~50 cities) and international (~15 countries) meetings. In addition, he is serving on Editorial Boards of Transgenic Research, Molecular Genetics & Genomics, Rice, and others.

At the University of Delhi, Professor Tyagi has served as Head, Department of Plant Molecular Biology, Chairman, Board of Interdisciplinary and Applied Sciences and Director, Interdisciplinary Centre for Plant Genomics. Professor Tyagi has also provided leadership to the National Institute of Plant Genome Research as Director. In his leadership as President, the National Academy of Sciences, India and its chapters reached about 20000 people, including children, women and those from rural areas, under its science and society program during 2015-16. He served as Chairman of DBT-UGC Task Force on Human Resource Development and Program Advisory Committee on Plant Sciences, DST, Government of India, and on Governing Boards of more than ten institutions. He has been given JC Bose National Fellowship Award, National Bioscience Award, NASI-Reliance Industries Platinum Jubilee Award in Biological Sciences, Bhasin Award for Science and Technology, Birbal Sahni Medal of IBS, BP Pal Memorial Award of ISCA, and FC Steward Lecture Award of PTCA(I), among others. He is Fellow of the National Academy of Sciences, India, the Indian National Science Academy, the Indian Academy of Sciences, the National Academy of Agricultural Sciences and The World Academy of Sciences.

Shri. Naresh Dayal

Shri. Naresh Dayal, IAS, has worked with the Government of India for 37 years in various positions at the state and national levels. As Secretary, Ministry of Health and Family Welfare, He has been responsible, among other things, for all policies and programs in Public Health, supervising National Health Authorities, assessing and devising the policies for the country's manpower requirements in health. He holds a Masters degree in Arts from University of Delhi and also in Professional Studies, Agriculture, from University of Cornell, USA. Shri Naresh Dayal is also the Chairman of the Expert Appraisal Committee for Coastal Regulation Zone and Infrastructure Projects for Environment and CRZ clearances by the Ministry of Environment, Government of India. He was a Director of State Trading Corporation of India Limited. He has been Non-Executive -Director at Balrampur Chini Mills Limited since November 15, 2016. He has been an Independent Director of GlaxoSmithKline Consumer Healthcare Limited since April 23, 2010. He served as an Independent Director of The State Trading Corporation of India Ltd. from July 10, 2011 to July 9, 2014.

Prof. Pankaj Chandra

Professor Pankaj Chandra is the Vice Chancellor of Ahmedabad University. He was the Director of the Indian Institute of Management Bangalore (2007-2013) and Professor of Operations & Technology Management at IIM Ahmedabad and IIM Bangalore before joining Ahmedabad University. He has also held tenured appointment at McGill University in Montreal and has been a Visiting Professor at the University of Geneva, International University of Japan, Cornell University, and Renmin University, Beijing. He was the Chairperson of the Doctoral Programme at IIM Ahmedabad and the first Associate Dean (Academic) at ISB, Hyderabad. He was part of the founding team at the Centre for Innovation, Incubation and Entrepreneurship at IIMA and its first Chairperson. He holds a Bachelor of Technology degree from Banaras Hindu University and a PhD from The Wharton School, University of Pennsylvania.

Professor Chandra was a member of the Government of India Committee on Rejuvenation of Higher Education (Yashpal Committee) that relooked at the Indian Higher Education system as well as the Committee on the Autonomy of Central Institutions. He has been a member of the Telecom Regulatory Authority of India (TRAI).

Professor Chandra's research and teaching interests include manufacturing management, supply chain coordination, building technological capabilities, higher education policy, and hi-tech entrepreneurship. His recent book titled 'Building Universities that Matter' studies issues of Governance, Change & Institution Building in Indian Universities. He serves on boards of several firms and institutions and has been involved with startups.

CORPORATE INFORMATION

REGISTERED OFFICE	:	1st floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi _ 110 003 CIN: U73100DL2012NPL233152 Website: www.birac.nic.in Email: birac.dbt@nic.in Tel: +91-11-24389600 Fax: +91-11-24389611 Twitter handle: @BIRAC_2012
STATUTORY AUDITORS	:	**RMA & ASSOCIATES** Chartered Accountants A-13, Ground Floor, Lajpat Nagar-III, New Delhi _ 110024 Tel: 011-49097836 Email:ca.jamit@gmail.com Website: www.rma-ca.com
BANKERS	:	**Corporation Bank** Block 11, CGO Complex Lodi Road, New Delhi -110003.
	:	**State Bank of India** Core 6, SCOPE Complex, Lodi Road, New Delhi -110003.
COMPANY SECRETARY	:	Ms. Kavita Anandani

DIRECTORS' REPORT

DIRECTORS' REPORT

To the Members,

1. ABOUT BIRAC

Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Section 8 company incorporated under the Companies Act, 2013 and a Schedule B, Public Sector Enterprise, set up by Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India as an interface agency to strengthen and empower the emerging biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

BIRAC is an industry-academia interface and implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring innovation excellence to the biotech firms and make them globally competitive. In its seven years of existence, BIRAC has initiated several schemes, networks and platforms that help to bridge the existing gaps in the industry-academia Innovation research and facilitate novel, high quality affordable products development through cutting edge technologies. BIRAC has initiated partnerships with several national and global partners to collaborate and deliver the salient features of its mandate.

2. OUR PHILOSOPHY & ACHIEVEMENTS

BIRAC's vision aims to 'Stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly start-ups and SMEs, for creation of affordable products addressing the needs of the largest section of society'. BIRAC's philosophy is rooted in its mission to 'trigger, transform and tend biotech start-ups to convert innovative research in public & private sector into viable and competitive products and enterprises'.

Since its inception in 2012, BIRAC has acted as a 'Development Agency' to lay the foundation of a biotech ecosystem in the country. The vision of the organisation clearly defines its core philosophy to create societal impact through cutting edge products that are affordable as well as exemplified in the statement 'affordable products addressing the needs of the largest section of society'. This foundation has been built on the premise that for India to grow to become a knowledge driven economy it is essential that biotechnology plays a significant role in this endeavour.

BIRAC aims to achieve the vision and mission, which have been enshrined in its charter, through various mechanisms that call for strategy involving multitudes of aligned partnerships such that bio-innovation takes root in start-ups, SMEs as well as in research institutes and academia.

Over the last 7 years, BIRAC has been instrumental in creating and expanding the Biotech Startup ecosystem in the country. This ecosystem requires careful handholding and constant need identification to expedite the growth. BIRAC known for its agility and strategic initiatives, has revised existing schemes, operationalized a few new schemes and expanded the partnership network to bring new value added opportunities for Biotech Startups and Entrepreneurs. This includes advanced stage funding under Biotechnology Innovation Fund _ AcE Fund of Funds, Product Commercialization Program, LEAP (Launching Entrepreneurial Driven Affordable Products); expansion of incubator base under BioNEST to 41 and creation of 6 clusters; adding 4th Regional Centre _ BRTC; expansion of BIG footprints taking total beneficiaries count to 400+; new partnerships with Sweden (Vinnova-BIRAC for Incubator connect), European Union for Incubator connect, Finland (Business Finland), Indo-Cuba for Startups exchange, others; CARB-X for AMR; rolled out BIRAC NESTA Boost grants for Indian Startups and 2nd Edition of BIRAC-TiE WInER Awards _ Women Entrepreneurship, among others. BIRAC continues to stay engaged with the whole community of Biotech Startups, Entrepreneurs and aspirants through Social Media. Our twitter followership base has crossed 10,000+ mark.

Engagement at the Foundational Level: Students, Entrepreneurs and Start-ups: Building New Pathways for exciting 'Entrepreneurial Journeys' through early stage funding, incubation, product commercialization support and equity funding

It is essential to recognise that to build and transform an industry, one has to begin at triggering positive changes in the foundation. BIRAC's programmes under the umbrella of **SITARE** and **eYUVA** are stimulating a forward change in the biotechnology entrepreneurial drive. These programmes capture the entrepreneurial energies of students and nudge them towards greater creativity and innovation. For example, through **BIRAC-SITARE GYTI** awards, we provide INR 15 lakhs to student teams in academic institutions to take forward their research ideas under the guidance of an academic mentor (49 such ideas have so far been awarded). We also provide INR 1 lakh to students pursuing validation of grassroot ideas (more than 150 such ideas have been facilitated). BIRAC & SRISTI also organize 3-4 weeks residential hands on training programme for UG/ PG students in the area of grassroot innovations.

We have also focused on deepening our engagement with universities pro-actively through **University Innovation Cluster** (UIC) wherein we have supported 5 universities across the country through Innovation Fellowships and Pre-Incubation space. 23 Innovation fellows are currently working in different UICs across the country. The scheme is now being expanded at national level to engage with students at undergraduate level through challenge programs.

Social innovation is gaining traction as innovators try to find novel solutions to societal challenges such as public health, ageing, maternal & child health and sanitation. The **SPARSH** programme, launched in 2013, has focused on building the social innovation potential in India through biotech tools and products. Within SPARSH, BIRAC has designed an immersion programme called SIIP that allows young fellows to immerse in various communities and hospitals and identify gaps that can be bridged by innovative solutions. 20 SIIP fellows are currently working diligently to identify societal needs in the area of Ageing and Health and Waste to value. Noticeably, many of the SIIP fellows have been able to transition into enterprise mode with follow on funding under BIG and other non-BIRAC schemes.

BIRAC's **Biotechnology Ignition Grant (BIG** as it is popularly known) is a pioneering early stage idea to proof-of-concept funding scheme and it is India's largest early stage program in the biotech space. Through BIG, BIRAC has supported 400+ entrepreneurial ideas which have successfully translated into 30+ market deployed products/ technologies while another 15-20 are in validation stages. In 2018-19, 13th and 14th BIG calls were announced. More than 1100 proposals were received under these two calls indicating an exponential rise in the interest for creating Biotech Start-ups. It is interesting to note that BIG has catalysed setting up of more than 110 new start-ups wherein individual BIG grantees have incorporated their Biotech Enterprises. These start-ups are intellectual wealth for their cutting edge technologies as indicated by 150+ IP filed by BIG grantees.

Biotech start-ups face an uphill task for commercialisation, as access to infrastructure remains a critical hurdle. The need for biotech incubator is greater than ever and BIRAC in 2012 initiated the Biotech Incubator Support Scheme (BISS) which is now appropriately called as **BioNEST**. Through this program, BIRAC has been able to provide support to 41 bioincubators across the country. These bioincubators together provide more than 4,50,000 sq. ft. of incubation space, access to common instrument facilities besides office space for nascent start-ups to grow. BioNEST provided incubation support to more than 355 biotech start-ups and entrepreneurs during FY 18-19.

BIRAC's Initiative **Sustainable Entrepreneurship and Enterprises Development Fund** (SEED Fund) provides financial equity based support to the start-ups and enterprises through bio incubators for scaling enterprises. A total support of INR 26 Crores has been provided to 14 BioNEST Incubators SEED fund partners for investing up to INR 30 lakh per start up against equity.

LEAP **(Launching Entrepreneurial Driven Affordable Products)** is also an equity linked funding scheme newly launched in 2018-19. LEAP fund is aimed at enabling potential biotech startups to pilot/commercialize their products/technologies. Under this, a startup can be provided up to INR 1 Crore. BIRAC has deployed this funding opportunity through 5 BioNEST incubators recognizing those as LEAP fund partners.

Biotechnology Innovation Fund - **Accelerating Entrepreneurs** (AcE) Fund is a Fund of Funds that will be managed professionally by AIF Fund Managers. AcE daughter Funds are SEBI registered private funds to invest equity in start-ups for providing the risk capital to undertake innovation, research and product development. During the FY 18-19, INR 82 Crores have been committed in 6 AcE Daughter Funds for investment upto INR 7 Cr/ startup. AcE fund partner will invest 2X of BIRAC total committed amount into Biotech startups. The number of AcE partners will be expanded further next year.

A Product Commercialization Program has been launched in the 2017-18 to hasten the product commercialization process by providing support to projects that have completed early stage validation. Through this program pressing challenges faced for commercialization of products/technologies by start-ups were identified through regional one-to-one meetings. A Product Commercialization Program Fund (PCP Fund) was initiated in 2018-19 for funding start-ups with matured products/technologies for meeting the challenges towards large scale commercialization. Few start-ups have been shortlisted from first round of selection for PCP Fund.

Engagement at SME level for Product Development: Catalysing Commercialisation of cutting edge and affordable biotech products for the nation and the world through transformational PPP models, industry-academia partnerships and focused approaches through Early Translation Accelerators.

Supporting translation of ideas until its commercialisation is one of the core mandates of BIRAC and in this regard many of our flagship programmes such as SBIRI and BIPP provide impetus for pulling the idea past POC and taking it further along the innovation chain especially validation and scale. A wide gamut of cutting edge projects were supported via the two programmes covering areas such as drugs, bio-similars, stem cells, agriculture, industrial biotechnology and device and diagnostics.

SBIRI and BIPP were the pioneering industry focused programs which were initiated by the Department of Biotechnology (DBT) in 2006 and 2009 respectively. These programs over the years, have helped several products reach the market and impact people's lives positively.

SBIRI provides support to pull a POC to early stage validation and in 2018-19, three calls were announced which supported project in various areas of Biotechnology. While two of these were regular calls, one of the calls was a challenge based call targeting specific area for each theme. Over the years, SBIRI has supported 271 projects that have resulted in development of 38 product/technologies.

BIPP, another truly pioneering PPP program, was launched in 2009. This program provides support from validation to scale and eventual commercialisation and remains our flagship 'late stage funding' instrument. Over the years, BIPP has supported 203 projects involving 142 sole companies and 61 collaborative projects. A total of 47 products/technologies have been developed till date and 31 new IPs have been generated. During 2018-19, 59 projects were supported including 10 new projects.

A concerted effort by BIRAC to bring together academia and industry and collaborate is through **Academic Innovation Research (AIR)** and the **Contract Research Scheme (CRS)**. Through CRS, academic leads could be tested via an industry partner. So far 71 projects have been supported under this program including 61 academia and 31 companies.

SPARSH is the Social Innovation Program of BIRAC which addresses the need of finding innovative solutions to society's most pressing social problems. 46 projects have so far been supported and 13 products/ prototypes/technologies have been developed.

Similarly, BIRAC has set up **Early Translation Accelerator (ETA)** to pull academic discoveries towards translation. An ETA focused on "Healthcare" has been established at C-CAMP and the second one in industrial biotech/bio processing has been established at IIT Madras. C-CAMP ETA has successfully completed the first set of three projects. Four projects are ongoing at IIT-Madras ETA.

BIRAC Regional Centres: Engaging with Regional Communities to map innovations and support entrepreneurs

BIRAC now has 4 regional centres: BRIC at IKP, Hyderabad; BREC at CCAMP, Bangalore, BRBC at Venture Centre, Pune and BRTC (for East & NE) at KIIT-TBI.

BIRAC Regional Innovation Centre (BRIC) has generated a consolidated report on mapping regional innovation ecosystems covering 10 clusters across the country. Next 12 clusters are being mapped. So far, BRIC has conducted >55 workshops and networking meetings on IP, funding opportunities, regulatory guidance and capacity building requirements in Tier II & Tier III cities engaging innovators and connected >200 Key Opinion Leaders.

BIRAC Regional Entrepreneurship Centre (BREC) conducted various awareness events, workshops, national level entrepreneurial challenges, boot camps etc. with a view to boost entrepreneurship in the Indian biotech sector. In two years of existence, BREC reached out to 700+ students, mentored 300+ startups, facilitated more than 200 one-on-one meetings between startups and investors and mobilized participation of 2000+ startups for NBEC.

BIRAC Regional Bioinnovation Centre (BRBC) provided training to 15+ incubation managers and assisted 50+ startups for regulatory queries, provided mentor match service to 120+ entrepreneurs, facilitated 50+ one on one meetings with specialized experts.

BIRAC Regional Techno-Entrepreneurship Centre for East & North East (BRTC-E&NE) is a new centre set up at KIIT-TBI with a mandate to perform mining & assessment of Techno-commercial resource pool in East & NE and human resource development programmes such as Design Workshops, NE Immersion Program, Showcase Events, training for rural women, incubation practice school etc. This centre has been mandated to stimulate Social Entrepreneurship and promote Women entrepreneurs in East and North East region. About 70% activities will be focused in North East region and 30% in East region.

BIRAC working towards fulfilment of the goals of the National Mission Programs: Make in India &Start-up India

The Make in India Cell at BIRAC ensures wider dissemination of the Government programmes and other information relevant to the establishment and growth of startups, SMEs and Companies. After the successful completion of Make in India 1.0, the facilitation cell at BIRAC under the guidance of DBT has formulated the Make in India Action Plan 2.0. The progress of this action plan is reviewed by DPITT.

It also contributes under the Start-up India action plan integrating through BIRAC's facilitating funding and incubation support to start-ups. BIRAC's commitment to Start-up India is to build 50 biotech incubators, 5 regional centres and supporting 2000 start-ups by 2020. Policy level suggestions, initiatives, identifying and creating opportunities at national and international forums are supported by this cell.

Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals - "Innovate in India for Inclusiveness (i3)

The program named Innovate in India (i3) is an industry- academia collaborative mission of Department of Biotechnology (DBT) in collaboration with World Bank for accelerating discovery research to early development of Biopharmaceuticals and is being implemented by BIRAC. The program was approved by the Cabinet for implementation in May, 2017 with a total cost US$ 250 million which is 50% co-funded by World Bank. Requests for proposals were published and applications solicited pan India. The calls announced have been for the GCLP Lab for Vaccine Clinical Immunogenicity Evaluation and Translational Research Consortia for Dengue and Chikungunya that ended on 31st August 2018. The second call was pertaining to Medical Devices and Diagnostics and MedTech Facility (Testing: Electrical safety testing, Medical laser safety testing and Medical device testing in large animals and Prototyping facility (Metal, Plastics, electronics and biocompatible material) that ended ended on 30th December, 2018. The next call was for Biosimilars Development, Shared Facilities Development of Biotherapeutics and Novel Cell Line Development. Under the shared facilities the following three RFP's were advertised: Cell Line Repository, process development lab and GMP manufacturing (CMC facility) and GLP compliant analytical facility. Till date about 332 applications have been received against the various calls under the mission, about 50 proposal have been recommended for receiving funding support.A GLP Bioanlaytical lab to provide analytical testing of biologicals was inaugurated under NBM in April, 2019 by Secretary DBT.

National & International Partnerships to Amplify our Mandate

BIRAC is cognisant of the fact that transformation of an idea to product would need joint efforts from other organisations. It is with this aim, BIRAC has expanded its partnerships and alliances with both Indian and international agencies. Some of the partnerships provide funding while others open networks and knowledge for India's start-up and SME community.

Our partnership with **Ministry of Electronics and IT (MeitY)** in the area of medical electronics (Industry Innovation Programme on Medical Electronics) focuses on boosting innovation capabilities in electronics, software, algorithms and hardware in a range of areas such as imaging and navigation to technologies for chronic. A total of 36 projects were funded in three rounds of selection during 2016-18.Most of the funded projects from first two rounds of funding have successfully been completed. One of the funded product has reached commercialization stage. There are seven more products which are at pre-commercialization phase.

Access to primary and secondary care healthcare facilities remains a challenge for many of our start-ups who are developing cutting edge medtech products. Our partnerships with **WISH Foundation** attempts to provide access to these facilities such that the products being developed can be validated in 'field settings'. Four technologies/year will be validated through field testing in PHCs, low resource setting or tertiary care centres under this partnership. Validation studies for 3 technologies from Biotech Startups are under way.

BIRAC has joined hands with **Tata Institute Social Sciences (TISS)**, **Mumbai** to help our social innovators.

BIRAC has partnered with **TiE-Delhi NCR** for mentoring biotech start-ups and providing continuous platform for BIRAC supported start-ups to interface with funders and investors. Second edition of BIRAC-TiE WInER Award (Women In Entrepreneurial Research) was launched this year and 15 women entrepreneurs awarded. Six awareness workshops for university/college students were also conducted in tier 2 cities under BIRAC-TiE partnership umbrella.

BIRAC has also signed a MoU with **Indian Angel Network (IAN)**, to bring the biotechnology start-ups closer to angel investors. Mentoring from an Investor's perspective to technology driven founders of Biotech Startups prepares them for refining Go to market strategy, fund raising.

Another MoU was signed between BIRAC and Association of Lady Entrepreneurs of India (ALEAP), Hyderabad with an aim to promote women entrepreneurship in the area of life sciences and to extend support for integrating efforts in India. Through South Asian Women Development Forum (SAWDF), ALEAP there is an effort for a possible extension of BIRAC ecosystem outreach in BIMSTEC nations.

On the 7th Foundation Day, BIRAC has signed a tripartite agreement with UDSC and five Indian companies namely Metahelix Life Sciences Limited, Hytech Seed India Pvt. Ltd., Tierra Agrotech India Pvt. Ltd., Rasi Seeds (P) Ltd. and Ganga Kaveri Seeds for transfer of UDSC technology on non-exclusive and non-transferable basis for use withing India. On the day, BIRAC also signed an MoU with CARB-X, a global non-profit partnership, led by Boston University, dedicated to accelerating antibacterial research to tackle the global rising threat of drug-resistant bacteria. Nine product launch from biotech startups was also done at this national platform in the presence of Niti Ayog's Vice Chairperson.

BIRAC has strengthened its partnerships with the Indo-French agency CEFIPRA, Bpifrance and Wellcome Trust. BIRAC had a partnership with USAID and IKP in the realm of TB Diagnostics and successfully completed three projects funded in two phases.

NESTA UK has launched a global Longitude Prize aiming to find several solutions to AMR. BIRAC's partnership with NESTA is aimed at supporting innovators working for innovative diagnostics for anti-microbial resistance (AMR). This year, BIRAC and NESTA organized a 3 days residential accelerator programme for the discovery award winners and awarded BOOST GRANT support of up to GBP 100,000 each to three winners after the accelerator programme. The Boost Grant will further help these innovators compete for the Longitude Prize.

Our continuing partnership with the Judge Business School, **University of Cambridge, UK** is engaged in connecting our BIG innovators with the deep innovation ecosystem of Cambridge and beyond. In 2018-19 we sent **five BIG grantees** to Cambridge to train in business and technical aspects of their enterprises in the flagship Ignite workshop. The partnership with Business Finland is for connecting Finnish innovation ecosystem with India. In December 2018, three BIRAC supported start-ups participated in the Global start-ups event SLUSH, which provided them the platform to interact with international investors, participate in various talks, interviews, panels and pitches.

This year, a letter of Intent was signed between BioCuba Farma, BIRAC and KIHT with a focus on exchange of technologies, products & innovations and transfer of technologies and commercialization of innovative healthcare products of interest to both the countries.

The Grand Challenges India (GCI) is a unique initiative that is borne out of joint partnership between Department of Biotechnology (DBT), Ministry of Science and Technology (MOST), Government of India (GoI), and Bill & Melinda Gates Foundation (BMGF). The Wellcome Trust has also partnered/joined with GCI for essentially supporting clinical and translational research in India.

BIRAC's partnership with the **Bill & Melinda Gates Foundation** through the **Grand Challenges India program** was further strengthened. In this financial year three grand challenges programs in different fields as well as several specialised programs have been launched within the larger theme of improving public health in India. The Immunization Data: Innovating for Action", "Antimicrobial Resistance" and "ki data Challenge for Maternal and Child health", were launched with both national and international partners. The Nutrition Sensitive Agriculture program with MS Swaminathan Research Foundation is an important program in the area of agriculture which was also launched this year. The HPV Clinical Trial was also approved. The Sentinels Experiment was also launched in the southern part of the country to encourage basic research.

Platforms: Bringing the evolving Community together for Collaborations

BIRAC pro-actively nurtures emerging start-ups and SMEs through seminars, workshops and other platforms. In 2018-19 several Roadshows, Grant writing, IP, regulatory and hands-on training, business mentoring workshops were organised. Several seminars and workshops were also conducted through our programme (BIG, BRIC and SIIP) Partners.

We have created platforms such **as Innovators Meet** (the 7th Innovator Meet was held in September 2018), **Foundation Day** (7th Foundation Day was organised in March, 2019) for networking/collaborations and providing a national level outreach platform for Startups and Entrepreneurs. The flagship platform for BIG startups, the 4th annual BIG Conclave was organised in July, 2018 with the intention of bringing together biotech startups to one platform. Cumulatively, we connect close to 1500 stakeholders each year and along with our partners this number increases beyond 2500. Together, these platforms have allowed innovators to meet, share information and best practices, catalyse partnerships and networking. BIRAC representation also actively participated in BIO 2018. A BIRAC powered industry 4.0 session and 5 Startup awards were supported at BIO Asia 2018.

BIRAC announced the final two awardees of SoCH (Solutions for Community Health) an innovation challenge Award, announced last year through an open discussion on MyGov Portal.

3i Portal

3i Portal has been providing a user friendly and convenient solution for effective management of various funding schemes of BIRAC. New features are added to the portal on regular basis in order to enhance the ease of use for all types of users. The portal is now being expanded to manage loan recoveries under BIPP and SBIRI. In addition, data mining and analysis has been made easier through number of newly added reports. The portal has assisted in conducting surveys and generating reports based on the same. New features to be implemented in near future include advanced search options (such as single click view of all information related to a project) and development of mobile application.

In addition, it is also envisaged to develop a networking portal as a platform to connect the biotech community (at national level as the first step and subsequently at global level). The networking portal shall provide information about products and services offered by various companies, key areas of active research being undertaken by companies/academic institutes/entrepreneurs, technologies available for licensing/sale etc.

A technology portal was launched on the 6th Foundation Day which provides information about the technologies and products emerged out of BIRAC funding which are launched in the market or ready to enter the market. There are around 120 technologies/products on the portal for technology seekers to connect with the innovators.

Recognition for BIRAC Startups & SMEs

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

1. Dr Vanita Prasad, Founder & Director **REVY Environmental Solutions Pvt. Ltd** has won the following awards:
   - REVY Environmental Solutions Pvt. Ltd has received "Smart Fifty Award" conferred by Department of Science and Technology, Government of India and IIM Calcutta Innovation Park for the development of innovative solution in waste water treatment space.
   - An award for "Iconic Women Creating A Better World Award" conferred to Dr. Vanita Prasad during Annual International Women Economic Forum 2018 held from April 26th to 1st May, 2018 at New Delhi on the theme of "The Economics of Goodness: Empowering Potential, Engineering Change"
2. **Oraxion Therapeutics**, a spin-off from BIRAC supported **Aten Porus Lifesciences** has entered into an "option to license" agreement for US $125 million with a US-based biopharma company to licence its drug ORX-301 for the treatment of rare diseases.
3. **AIndra Systems** won the RICH Cancer Innovation Challenge conducted by the Telangana Government in August 2018.
4. **Cutting Edge Medical Devices Pvt Ltd.** received following awards:
   - INVENT MP - an investment of Rs. 35,00,000/- on convertible notes a program by CIIE - IIMA, Tata Trust, Rajasthan Industries Corporation - RICO and Startup Oasis
   - 3rd Prize: Pitch Day - Leaders in Innovation Fellowship Program by Royal Academy of Engineering, London, UK among more than 60 participants across 5 countries.
5. **Janitri Innovations Private Ltd.** has received following awards and recognitions:
   - Supported by Bill and Melinda Gates Foundation (GCE) (100,000 USD)
   - Got selected for Qualcomm Design India Challenge 2018 (Total 15 Startups)
   - Got selected for Techemerge Brazil (total 30 healthcare companies from across the globe), An Initiative by IFC (World Bank Group)
   - Published on yourstory and factordaily
   - 28th December 2018 "Startup showcases device to ensure safe delivery" Covered by Deccan Herald News Paper
   - One among Top 15 in Qualcomm Design in India Challenge 2018
   - The 10 Most Prominent Healthcare Companies in 2018- Prime View Article- January 2019
6. Prof.M.Manivannan (**Merkel Haptic Systems Pvt Ltd**) was awarded "Fellow of IMSA" by the International Medical Sciences Academy at the Royal College of Physicians and Surgeons, Glasgow, UK on 25th August, 2018, for developing affordable next generation Medical Training systems using Virtual Reality and Haptic technologies.
7. **Periwinkle Technologies Pvt. Ltd**. received following awards and recognition:
   - Invited by the Duke of York to represent India at the Pitch@Palace Commonwealth - Apr 2018
   - Recognition in media - several newspapers, social media (YourStory, VCCircle etc) and TV channels such as CNBC, eTV
8. **Sensivision Health Technologies Pvt Ltd** received the following recognitions
   - Top 50 finalists of India Innovation Growth Program (IIGP) 2.0 conducted by DST, Lockeed Martin and Tata Trusts.
   - Got selected for Karnataka Govt Startup Elevate100 during this time-frame. We got a grant for Rs.15L and additionally mentoring and resource support
   - Selected to be funded (Rs.25 Lakh) and mentored by PATH - Tata Trust "Quest" program specifically focused on Clinical Trial/Validation.
9. **Jeevtronics Pvt Ltd.** was among the finalists at Pune International Center's NSCI conference
10. **Aarna Biomedical Products Ltd** (Product: Poorti) won the India Innovation Growth Programme (IIGP 2.0) - 2018 in social innovations category.
11. **Dr. Shalini Gupta (NanoDx)** won the Nesta Longitude prize UK with an award money of 25000 GBP.
12. **Prantae Solutions** (Dr. Sumona Karjee) - Received award as 40 under40 from The New Indian Express Group

13. **CyCa Oncosolutions Pvt Ltd** (Dr. Nusrat) - Won the National Award for development of Technology having Commercialization Potential Winner of Best innovative product -Rubicon's Award, Ireland
14. Milind Chaudhari, **Weinnovate Biosolutions Pvt. Ltd.** won AABI torch award for Internationalization from Asian association of Business Incubators, Shanghai, China.
15. Sachin Dubey, **Module Innovations Pvt Ltd** won "Design: Impact Awards for Social Change" in collaboration with Tata Trusts
16. **Innaumation Medical Devices LLP AUM** voice prosthesis Dr. Vishal Rao featured in Harvard Business Review as 3 Entrepreneurs Who Made It Their Mission to Lower Health Care Costs
17. **Helyxon Healthcare Solutions Pvt. Ltd** - On 31st March, 2019, Dr Kanchana, a PG- Neonatology student from Institute of Child Health (ICH) , Chennai presented a paper on her findings about Helyxon Feverwatch in a conference on NeoCore, held at JIPMER Pondicherry and was awarded the best paper presented.
18. **Robobionics Pvt. Ltd.** was Awarded 1st Place at Startup Masterclass Select IIT Patna in December, 2018

Key achievements

During the year BIRAC supported projects in all major areas of biotechnology sector i.e. Healthcare, Agriculture, Industrial biotechnology and Bioinformatics/Infrastructure as part of meeting its objective of promoting affordable innovation in key social sectors. Healthcare covers the areas of Drugs (including drug delivery), Bio-similars (including regenerative medicine), Vaccines/Clinical trials & Devices/diagnostics, whereas Agriculture covers Marker assisted selection (MAS), RNAi, Transgenics & soil health management and Veterinary & Aquaculture and Industrial biotechnology includes Industrial products/processes and secondary agriculture.

During the year, **16** BIRAC supported grantees got funding from agencies other than DBT which is a reflection of the quality of innovation/ enterprise which has been created with BIRAC's support. The average decision making time to support a project for funding was **161 days** during the financial year 2018-19.

During the year, 29 projects out of the identified 50 projects achieved Technology Readiness Level -7 (TRL-7) amounting to **58%** of the total number of projects which had been identified for achieving TRL-7. The projects which have reached TRL-7 are ready to move into demonstration/ late stage validation and would be a pipeline for the product commercialization. In addition, **19** new products/ processes/ technologies have been developed with support from BIRAC

419 beneficiaries were supported by BIRAC under its various schemes during 2018-19. Two regulatory workshops and five Hands on training workshops, apart from trainings provided by BIRAC incubators, were conducted during the year, benefitting **426 participants**. **359 incubatees** have been incubated in the bio-incubation system of BIRAC during the year 2018-19.

The total amount mobilized from sources other than the Department of Biotechnology (DBT), which is the Administrative Ministry was **25%** of the annual allocation from DBT. During the financial year 2018-19, **92%** of the total funds mobilized by the organization were disbursed towards fulfilling the mandate of BIRAC. There was **119%** increase in Royalty received over previous year.

Over the 7 years, BIRAC has been able to nurture and grow the biotech ecosystem in the country through a combinatorial approach that involves instruments such as funding for product development, advice and mentor startups in a range of technical, IP and business issues, create and operationalise networks for knowledge sharing as well as build effective partnerships. The cumulative strategy is to take the Indian biotech industry to become a global innovation destination in R&D and manufacturing such that our academia, translational centres, incubators and industry become hubs for ideation and development of cutting edge products that can bring positive social impact to communities and help India achieve her goal of being a US$100Billion economy by 2025.

3. AUDIT COMMITTEE

BIRAC is a Schedule B CPSE under the Department of Biotechnology, Ministry of Science and Technology registered as a Section 8 Not-for-profit Company under the Companies Act, 2013. The constitution of the Audit Committee is a requirement under the Corporate Governance Guidelines issued by the Department of Public

Enterprises (DPE). The Audit Committee has four directors, three of them being non-official Independent Directors viz. Prof. Akhilesh Tyagi as Chairman and Prof. Ashok Jhunjhunwala, Prof. Pankaj Chandra and Dr. Mohd. Aslam as members.

4. FINANCIAL STATEMENT

The financial statement is made on accrual method of accounting under the historical cost convention, in accordance with the accounting standards issued by the Institute of Chartered Accountants of India.

5. EXTRACT OF THE ANNUAL RETURN

In accordance with Section 134(3)(a) of the Companies Act, 2013, an extract of the Annual Return in the prescribed format is appended as Annexure 1 to the Directors' Report.

6. NUMBER OF MEETINGS OF THE BOARD

The Board met 6 times during the financial year, the details of which are given in the Corporate Governance Report, which forms a part of the Annual Report. The intervening gap between any two meetings was as prescribed under the Companies Act, 2013.

7. PARTICULARS OF CONTRACTS OR ARRANGEMENTS MADE WITH RELATED PARTIES

BIRAC has not entered into any contracts or arrangements with related parties as per the provisions of Section 188(1) of the Companies Act, 2013.

8. RTI

BIRAC follows all the necessary procedures and processes in accordance with the Right to Information Act, 2005, as amended from time to time and Government Guidelines. It has appointed a Central Public Information Officer (CPIO) and an Appellate Authority. The details are available on its website (www.birac.nic.in)

9. RISK MANAGEMENT POLICY

BIRAC has a Risk Management Policy in place approved by the Board. The mandate of BIRAC is to nurture innovation by mentoring and funding high risk, highly innovative projects by itself or with multiple partners throughout the innovation value chain, namely, early stage innovation research, product development, product validation and commercialization. BIRAC, being a Government organization, the need for Risk Management is reflected in its commitment to ensure transparency and public accountability of its partnerships, activities and schemes. The schemes, activities, workshops and partnerships are monitored by Standard applications, formats, MoUs and funding agreement which have inbuilt controls and accountability mechanisms at every stage.

There is a proper technical evaluation of projects by a Committee of experts and an in-house legal drafting and vetting process, financial due diligence and screening of projects is undertaken, internal controls and audit protocols are in place with the Comptroller & Auditor General of India (C&AG) conducting supplementary audit.

Risk Management monitoring process in the organization is based on compliance reporting in the Risk calendar which is circulated to all the Department Heads with comprehensive parameters drawn from the Risk Register for managing schemes, activities and providing funding support. The Board ensures the integration and alignment of the risk management system with the corporate and operational objectives and also ascertains that risk management is undertaken as a part of normal business practice and not as a separate task at set times.

An Internal Process Review Committee reviews the process vis-à-vis the Standard Operating Procedures and records the deviations, if any and implements suggestions to make the processes better.

10. DISCLOSURE UNDER THE SEXUAL HARASSMENT OF WOMEN AT WORKPLACE (PREVENTION, PROHIBITION AND REDRESSAL) ACT, 2013

BIRAC has in place an Internal Complaints Committee under the Prevention of Sexual Harassment of Women at the Workplace (Prevention, Prohibition and Redressal) Act, 2013 and the rules notified thereunder with the terms of reference as required under the CSS (Conduct) Rules and the Guidelines laid down by the Hon'ble Supreme Court in Vishaka and others vs. State of Rajasthan. The mandate of the Internal Complaints Committee is to redress the complaints, if any, received regarding sexual harassment as defined in the said Act.

All employees of BIRAC including regular employees, contractual, part time, daily wage earners, either employed directly or through an agent or contractor, whether for remuneration or not, trainees, apprentices, those working on a voluntary basis, directors and experts on various committee are covered under this policy.

The Internal Complaints Committee met on February 1, 2019. The organisation has not received any grievances under this Act, during the financial year 2018-19.

During the year 2018-19, a workshop was conducted on 'Gender Sensitization & Sexual Harassment at Workplace' to sensitise the employees on Gender issues and educate them on the various aspects of the Act.

11. MEMORANDUM OF UNDERSTANDING (MOU)

BIRAC had entered into the fifth Memorandum of Understanding (MoU) for the financial year 2018-19 with the Administrative Ministry, the Department of Biotechnology (DBT), Ministry of Science and Technology on May 8, 2018, as per the Guidelines issued by the Department of Public Enterprises.

BIRAC was also awarded 'Very Good' grading for its achievements against the targets set out in the MoU for the year 2017-18 by the Department of Public Enterprises (DPE).

12. PROCUREMENT FROM MICRO AND SMALL ENTERPRISES (MSEs)

The total annual procurement for the financial year 2018-19 was Rs.3.05 crore, out of whcih the procurement from MSEs was Rs.1.46 crore amounting to 48% of the total procurement and the procurement from MSEs owned by women was Rs.0.15 crore amounting to 10% of the total procurement from MSEs.The expected annual procurement from MSEs for the financial year 2019-20 is Rs.1.18 crore.

13. DIRECTOR'S RESPONSIBILITY STATEMENT

In accordance with the provisions of Section 134(5) of the Companies Act, 2013, the Directors' state that:

- in the preparation of the annual accounts, the applicable accounting standards had been followed along with proper explanation relating to material departures;
- the directors had selected such accounting policies and applied them consistently and made judgements and estimates that are reasonable and prudent so as to give a true and fair view of the state of affairs of the company at the end of the financial year and of the profit and loss of the company for that period;
- the directors had taken proper and sufficient care for the maintenance of adequate accounting records in accordance with the provisions of this Act or safeguarding the assets of the Company and for preventing and detecting fraud and other irregularities;
- the directors has prepared the annual accounts on a going concern basis; and
- the directors had devised proper systems to ensure compliance with the provisions of all applicable laws and that such systems were adequate and operating effectively.

14. CORPORATE GOVERNANCE

A separate report on Corporate Governance is annexed with this report

15. AUDITORS' REPORT

M/s. RMA & Associates, Chartered Accountants are the Statutory Auditors of the Company appointed by the Comptroller and Auditor General of India for the period under review (Financial year 2018-19). The Auditors' report and CAG report are appended to the financial statements and are self-explanatory and suitably explained in the various Notes to the accounts.

16. BANKERS

The Bankers of the organisation are:

- Corporation Bank, Block 11, CGO Complex, Lodhi Road, New Delhi _ 110003.
- State Bank of India, Core 6, SCOPE Complex, Lodhi Road, New Delhi _ 110003.

17. ABOUT DIRECTORS

BIRAC is guided by a Board comprising of senior professionals, academicians, policy makers and eminent professionals from the industry. Dr. Renu Swarup, who was the Senior Adviser, DBT and holding additional charge of Managing Director, BIRAC, was appointed as Secretary, DBT and thereby Chairperson of BIRAC with effect from April 10, 2018. Dr. Mohd. Aslam, who is the Government Nominee Director on the Board of BIRAC is holding additional charge as Managing Director, BIRAC.

In addition to Dr. Renu Swarup, Secretary DBT and Chairperson, BIRAC and Dr. Mohd. Aslam, Scientist 'G', Department of Biotechnology who is the Managing Director and Government Nominee Director, the Board comprises of four independent directors i.e. Prof. Ashok Jhunjhunwala, Professor, IIT Chennai, Prof. Akhilesh Tyagi, Professor of Plant Molecular Biology, South Campus, Delhi University, Prof. Pankaj Chandra, Vice Chancellor and Chairman, Board of Management of Ahmedabad University and Shri. Naresh Dayal, IAS and Retd. Secretary, Ministry of Health and Family Welfare.

18. CONSERVATION OF ENERGY, TECHNOLOGY ABSORPTION AND FOREIGN EXCHANGE EARNINGS AND OUTGO

The information pertaining to conservation of energy, technology absorption, foreign exchange earnings and outgo as required under Section 134(3)(m) of the Companies Act, 2013 read with Rule 8(3) of the Companies (Accounts) Rules, 2014 is as follows:

A. Conservation of Energy

Disclosure regarding conservation of energy is not applicable to our Company.

B. Technology Absorption, Adoption and Innovation

Particulars required under Rule 8(3)(B) of the Companies (Accounts) Rules, 2014 have not been given since the company has no direct Research and Development activity. However, the main function of BIRAC is to facilitate and provide financial support for generation and translation of innovative ideas into biotech products/technologies, foster innovation in all places of research and to encourage diffusion of innovation through partners. The details are provided in the Management Discussion and Analysis Report.

C. Foreign Exchange Earnings & Outgo

The foreign exchange earnings and outgo during the year are given below:

Grant received in foreign exchange to the extent utilized (in Rs.)	27,94,85,783
Foreign Exchange outflow (in Rs.)	
A. Technology Transfer	61,77,266
B. Books, journals and database subscriptions	10,55,680
C. Entrepreneurial Development	42,71,356
D. Advertisement, Publicity, Publication	55,88,002
E. Foreign travel & Meeting	18,80,496
CIF Value of Import	**Nil**

ACKNOWLEDGMENT

The Directors wish to place on record their appreciation for the valuable guidance and co-operation extended by the Auditors, Banks and various Government agencies. The Directors also wish to place on record their appreciation for the sincere efforts put in by the executives and staff of the Company.

For and on behalf of Board
Dr. Renu Swarup
Chairperson

Place: New Delhi
Date: August, 21, 2019

EXTRACT OF ANNUAL RETURN

as on the financial year ended on March 31, 2019

[Pursuant to section 92(3) of the Companies Act, 2013 and rule 12(1) of the Companies (Management and Administration) Rules, 2014]

I. REGISTRATION AND OTHER DETAILS:

i) CIN: **U73100DL2012NPL233152**

ii) Registration Date: **March 20, 2012**

iii) Name of the Company: **Biotechnology Industry Research Assistance Council**

iv) Category / Sub-Category of the Company: Section 8 Private Limited Company limited by shares (Government Company)

v) Address of the Registered office and contact details: 1st floor, MTNL Building, 9, CGO Complex, New Delhi _ 110003. Website: www.birac.nic.in Email: birac.dbt@nic.in Tel: +91-11-24389600

vi) Whether listed company Yes / No: No

vii) Name, Address and Contact details of Registrar and Transfer Agent, if any:
Skykine Financial Services Pvt. Ltd., D-153 A, 1st Floor, Okhla Industrial Area, Phase - I, New Delhi _ 110020 Contact Person: Shri Virender Rana

II. PRINCIPAL BUSINESS ACTIVITIES OF THE COMPANY

All the business activities contributing 10% or more of the total turnover of the company shall be stated:-

Sl. No.	Name and Description ofmain products/ services	NIC Code of the Product/ service	% to total turnover of the company
1	Research and experimental development on natural sciences and engineering (NSE)	73100	100%

III. PARTICULARS OF HOLDING, SUBSIDIARY AND ASSOCIATE COMPANIES -

S. NO	NAME AND ADDRESS OF THE COMPANY	CIN/GLN	HOLDING/ SUBSIDIARY/ ASSOCIATE	% of shares held	Applicable Section
1	N.A.	N.A.	N. A	N. A	N.A

IV. SHARE HOLDING PATTERN (Equity Share Capital Breakup as percentage of Total Equity)

i) Category-wise Share Holding

Category of Shareholders	No. of Shares held at the beginning of the year				No. of Shares held at the end of the year				% Change during the year
	Demat	Physical	Total	% of Total Shares	Demat	Physical	Total	% of Total Shares	
A.Promoters									
(1) Indian									
i) Individual/ HUF	-	-	-	-	-	-	-	-	-
ii) Central Govt.	**10000**	**N.A.**	**10000**	**100**	**10000**	**N.A.**	**10000**	**100**	**NIL**
iii) State Govt. (s)	-	-	-	-	-	-	-	-	-
iv) Bodies Corp.	-	-	-	-	-	-	-	-	-
v) Banks/FI	-	-	-	-	-	-	-	-	-
vi) Any Other	-	-	-	-	-	-	-	-	-
Sub-total (A) (1):-	**10000**	**N.A.**	**10000**	**100**	**10000**	**N.A.**	**10000**	**100**	**NIL**
(2) Foreign									
a) NRIs - Individuals	-	-	-	-	-	-	-	-	-
b) Other - Individuals	-	-	-	-	-	-	-	-	-
c) Bodies Corp.	-	-	-	-	-	-	-	-	-
d) Banks / FI	-	-	-	-	-	-	-	-	-
e) Any Other....	-	-	-	-	-	-	-	-	-
Sub-total (A) (2):-	-	-	-	-	-	-	-	-	-
Total shareholding of Promoter (A) = (A)(1)+(A)(2)	**10000**	**N.A.**	**10000**	**100**	**10000**	**N.A.**	**10000**	**100**	**NIL**
B. Public Shareholding									
1. Institutions									
a) Mutual Funds	-	-	-	-	-	-	-	-	-
b) Banks/FI	-	-	-	-	-	-	-	-	-
c) Central Govt.	-	-	-	-	-	-	-	-	-
d) State Govt.(s)	-	-	-	-	-	-	-	-	-
e) Venture Capital Funds	-	-	-	-	-	-	-	-	-
f) Insurance Companies	-	-	-	-	-	-	-	-	-
g) FIIs									
h)Foreign Venture Capital Funds									
i) Others (specify)	-	-	-	-	-	-	-	-	-
Sub-total (B)(1):-	-	-	-	-	-	-	-	-	-
2.Non-Institutions									
a) Bodies Corp.									
i) Indian	-	-	-	-	-	-	-	-	-
ii) Overseas	-	-	-	-	-	-	-	-	-
b) Individuals									

i) Individual shareholders holding nominal share capital upto Rs. 1 lakh	-	-	-	-	-	-	-	-	-
ii) Individual shareholders holding nominal share capital in excess of Rs 1 lakh	-	-	-	-	-	-	-	-	-
c) Others (specify)	-	-	-	-	-	-	-	-	-
Sub-total (B)(2):-	-	-	-	-	-	-	-	-	-
Total Public Shareholding (B) = (B)(1) + (B)(2)	-	-	-	-	-	-	-	-	-
C. Shares held by Custodian for GDRs & ADRs									
Grand Total (A+B+C)	**10000**	**N.A.**	**10000**	**100**	**10000**	**N.A.**	**10000**	**100**	**NIL**

(ii) Shareholding of Promoters

Sl. No.	Shareholder's Name	Shareholding at the beginning of the year			Shareholding at the end of the year			
		No. of Shares	% of total Shares of the company	%of Shares Pledged/ encum-bered to total shares	No. of Shares	% of total Shares of the com-pany	%of Shares Pledged/ encum-bered to total shares	% change in Share holding during the year
1	President of India	9000	90%	Nil	9000	90%	Nil	Nil
2	Dr. Renu Swarup, Secretary, DBT and Chairperson, BIRAC (on behalf of the President of India)	900	9%	Nil	900	9%	Nil	Nil
3	Dr. Mohd. Aslam, MD, BIRAC (on behalf of the President of India)	100	1%	Nil	100	1%	Nil	Nil
	Total	**10000**	**100%**	**Nil**	**10000**	**100%**	**Nil**	**Nil**

(iii) Change in Promoters' Shareholding (please specify, if there is no change)

Sl. No.		Shareholding at the beginning of the year		Cumulative Shareholding during the year	
		No. of shares	% of total shares of the company	No. of shares	% of total shares of the company
	At the beginning of the year				
1.	Dr. Renu Swarup (held on behalf of the President of India)	100	1	900	9
2.	Prof. Ashutosh Sharma (held on behalf of the President of India)	900	9	0	0

	Date wise Increase/ Decrease in Promoters Shareholding during the year specifying the reasons for increase/decrease (e.g. allotment/transfer/bonus/ sweat equity etc.)				
1.	Dr. Renu Swarup (on account of being appointed as Secretary, DBT w.e.f. April 10, 2018 and ceasing to hold additional charge as MD, BIRAC) (held on behalf of the President of India)	100	1	900	9
2.	Prof. Ashutosh Sharma (on account of ending of his tenure as Secretary, DBT w.e.f. April 9, 2018) (held on behalf of the President of India)	900	9	0	0
3.	Dr. Mohd. Aslam (on being given additional charge as MD BIRAC w.e.f. April 10, 2018) (held on behalf of the President of India)	0	0	100	1
	At the End of the year				
1.	Dr. Renu Swarup, Secretary DBT (held on behalf of the President of India)	100	1	900	9
2.	Dr. Mohd. Aslam, Managing Director, BIRAC (held on behalf of the President of India)	0	0	100	1

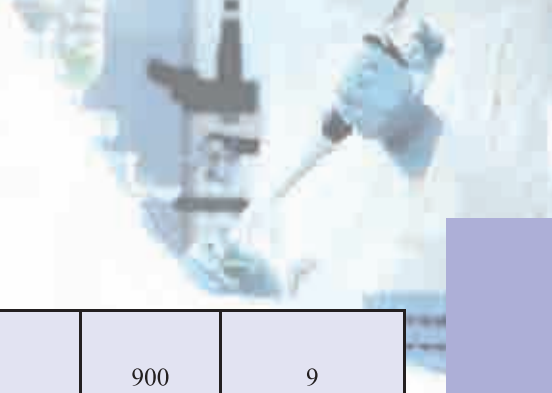
(iv) Shareholding pattern of top ten Shareholders (other than Directors, Promoters and Holders of GDRs and ADRs):

Sl. No.		Shareholding at the beginning of the year		Cumulative Shareholding during the year	
	For Each of the Top 10 Shareholders	No. of shares	% of total shares of the company	No. of shares	% of total shares of the company
	At the beginning of the year	NIL	Nil	Nil	Nil
	Date wise Increase/Decrease in Shareholding during the year specifying the reasons for increase/decrease (e.g. allotment/ transfer/ bonus/sweat equity etc.)	NIL	Nil	Nil	Nil
	At the End of the year (or on the date of separation, if separated during the year)	NIL	Nil	Nil	Nil

(v) Shareholding of Directors and Key Managerial Personnel

(A) Dr. Renu Swarup, Chairperson (on behalf of the President of India)

Sl. No.		Shareholding at the beginning of the year		Cumulative Shareholding during the year	
	For Each of the Directors and KMP	No. of shares	% of total shares of the company	No. of shares	% of total shares of the company
	At the beginning of the year	100	1	900	9
	Date wise Increase / Decrease in Shareholding during the year specifying the reasons for increase / decrease (e.g. allotment / transfer / bonus/ sweat equity etc)				



	On account of being appointed as Secretary, DBT and Chairperson BIRAC and ceasing to hold additional charge as MD, BIRAC w.e.f. April 10, 2018	100	1	900	9
	At the End of the year	100	1	900	9

(B) Dr Mohd. Aslam, Managing Director (on behalf of the President of India)

Sl. No.		Shareholding at the beginning of the year		Cumulative Shareholding during the year	
	For Each of the Directors and KMP	No. of shares	% of total shares of the company	No. of shares	% of total shares of the company
	At the beginning of the year	0	0	100	1
	Date wise Increase / Decrease in Shareholding during the year specifying the reasons for increase / decrease (e.g. allotment / transfer / bonus/ sweat equity etc)				
	On account of holding additional charge as Managing Director, BIRAC w.e.f. April 10, 2018	0	0	100	1
	At the End of the year	100	1	100	1

V. INDEBTEDNESS:

	Secured Loans excluding deposits	Unsecured Loans	Deposits	Total Indebtedness
Indebtedness at the beginning of the financial year i) Principal Amount ii) Interest due but not paid iii) Interest accrued but not due	Nil	Nil	Nil	Nil
Total (i+ii+iii)	**Nil**	**Nil**	**Nil**	**Nil**
Change in Indebtedness during the financial year • Addition • Reduction	NA	NA	NA	NA
Net Change	**Nil**	**Nil**	**Nil**	**Nil**

Indebtedness at the end of the financial year i) Principal Amount ii) Interest due but not paid iii) Interest accrued but not due	Nil	Nil	Nil	Nil
Total (i+ii+iii)	**Nil**	**Nil**	**Nil**	**Nil**

VI. REMUNERATION OF DIRECTORS AND KEY MANAGERIAL PERSONNEL

A. Remuneration to Managing Director, Whole-time Directors and/or Manager:

Sl. no.	Particulars of Remuneration	Name of MD/WTD/ Manager				Total Amount
		Dr. Mohd. Aslam, Managing Director	--	--	--	
1.	Gross salary (a) Salary as per provisions contained in section 17(1) of the Income-tax Act, 1961 (b) Value of perquisites u/s 17(2) Income-tax Act, 1961 (c) Profits in lieu of salary under section 17(3) Income- tax Act, 1961	N.A as he is holding Additional Charge as Managing Director of BIRAC	-	-	-	-
2.	Stock Option	-	-	-	-	-
3.	Sweat Equity	-	-	-	-	-
4.	Commission - as % of profit - others, specify...	-	-	-	-	-
5.	Others, please specify	-	-	-	-	-
	Total (A)	-	-	-	-	-
	Ceiling as per the Act	-	-	-		-

B. Remuneration to other directors

Sl. no.	Particulars of Remuneration	Name of Directors				Total Amount
		Prof. Ashok Jhunjhunwala	Prof. Pankaj Chandra	Prof. Akhilesh Tyagi	Shri. Naresh Dayal	
1.	Independent Directors					
	• Fee for attending Board committee meetings (6 Meetings)	50,000	40,000	60,000	30,000	1,80,000
	• Commission	--	--	--	--	--
	• Others, please specify	--	--	--	--	--
	• Audit Committee (5 Meetings)	50,000	30,000	50,000	--	1,30,000
	Remuneration Committee	10,000	10,000	--	--	20,000
	Total (1)	**1,10,000**	**80,000**	**1,10,000**	**30,000**	**3,30,000**
2.	Other Non-Executive Directors	**Dr. Mohd. Aslam (Government Nominee)**	--	--	--	--
	• Fee for attending Board committee meetings	NIL	--	--	--	--
	• Commission	--	--	--	--	--
	• Others, please specify	--	--	--	--	--
	Total (2)	**-**	**-**	**-**	**-**	**-**
	Total (B) = (1 + 2)	**1,10,000**	**80,000**	**1,10,000**	**30,000**	**3,30,000**
	Total Managerial Remuneration	**1,10,000**	**80,000**	**1,10,000**	**30,000**	**3,30,000**
	Overall Ceiling as per the Act	**N.A.**	**N.A.**	**N.A.**	**N.A.**	**N.A.**

C. REMUNERATION TO KEY MANAGERIAL PERSONNEL OTHER THAN MD/MANAGER/WTD Exempted from disclosure as BIRAC is a government company.

Sl. No.	Particulars of Remuneration	Key Managerial Personnel			
		CEO	Company Secretary	CFO	Total
1.	Gross salary (a) Salary as per provisions contained in section 17(1) of the Income-tax Act, 1961 (b) Value of perquisites u/s 17(2) Income-tax Act, 1961 (c) Profits in lieu of salary under Section 17(3) Income-tax Act, 1961	- - -	- - -	- - -	- - -
2.	Stock Option	-	-	-	-
3.	Sweat Equity	-	-	-	-
4.	Commission - as % of profit - others, specify...	-	-	-	-
5.	Others, please specify	-	-	-	-
	Total	-	-	-	-

VII. PENALTIES/PUNISHMENT/COMPOUNDING OF OFFENCES:

Type		Brief Description	Details of Penalty/ Punishment/ Compounding fees imposed	Authority [RD/ NCLT/COURT]	Appeal made, if any (give Details)
A. Company					
Penalty		Nil	Nil	Nil	Nil
Punishment		Nil	Nil	Nil	Nil
Compounding		Nil	Nil	Nil	Nil
B. Directors					
Penalty		Nil	Nil	Nil	Nil
Punishment		Nil	Nil	Nil	Nil
Compounding		Nil	Nil	Nil	Nil
C. Other officers in default					
Penalty		Nil	Nil	Nil	Nil
Punishment		Nil	Nil	Nil	Nil
Compounding		Nil	Nil	Nil	Nil

MANAGEMENT DISCUSSION AND ANALYSIS REPORT

MANAGEMENT DISCUSSION AND ANALYSIS REPORT

(Forming Part of the Directors' Report for 2018-19)

INDUSTRIAL STRUCTURE AND DEVELOPMENT

India has grown exponentially in the field of Science and Technology in the last four years and the Research and development work has addressed many of the problems the society has been facing. Science is now considered as one of the most powerful tools for growth and development. At present India is ranked 6th globally in the number of scientific publications and 9th in the number of patents filed.

Biotechnology plays a pivotal role in the scientific innovation ecosystem of the country. Government's initiatives and role in harnessing the biotechnology potential of the country has been critical for strengthening the roots of innovations and research and development. BIRAC has launched several programmes that align to Government of India's national missions such as Swachh Bharat, Swasth Bharat, Startup India, Make in India, Doubling farmer's income etc.

According to Able's 2018 report on Bioeconomy, India is presently growing at 6.8% and is valued at USD 44.47 Billion. The industry continues to be dominated by the Biopharma segment. It alone contributes to 54.67% share of the total Bioeconomy. It is also reported that half of the bioeconomy is through diagnostics and medical devices. Vaccines contributed to 30% while therapeutics contributed for the rest. Bioagri is the second largest contributor to the country with 23.17 % percent share.

During 7 years of its existence, BIRAC has made a significant contribution in developing and strengthening biotech ecosystem in the country through its various flagship programmes such as BIG, BIPP, SBIRI, PACE, BioNEST, SITARE, eYUVA, UIC, etc. Besides various funding programs that have spurred the growth of start-ups in the field of biotechnology, BIRAC has made serious efforts to make early stage capital/ seed money accessible to the start-ups. Under BIRAC's BioNEST programme, 41 bioincubation facilities have been established across the country. In 2018-19, BIRAC has launched Product Commercialisation Program Fund to facilitate the process of product commercialization and de-risk the challenges faced by start-ups. BIRAC has been instrumental in connecting its beneficiaries with venture capitalists, biotech/healthcare accelerators and early stage funders.

The Indian Biotechnology sector has always been the flag bearer for showcasing the country's strength and advancement in the modern technology arena. The onus now is to handhold, mentor and harness the innovations that can contribute towards the economic and scientific development of the nation by catering to the basic needs of food and nutrition and healthcare of the masses. It is with this objective and focus that BIRAC has to step up its efforts to deliver on the priority areas.

STRENGTH AND WEAKNESSES

BIRAC's vision and mission directly aligns with the National Biotechnology Development Strategy (NBDS), formulated by DBT in 2015. It is also contributing to entrepreneurship and innovation ecosystem in the field of biotechnology under Atal Innovation Mission, Ministry of Skill Development & Entrepreneurship, MeitY, ICMR, through its own programmes or in partnership with agencies sharing common goals. BIRAC actively contributed to Make in India Biotech Strategy and Start up India. All these national missions mention BIRAC as the go-to partner in the realm of biotechnology.

While the infrastructure (both human resources and facilities) and the overall environment that facilitates entrepreneurship and innovation has improved significantly in the recent past, there still exists a gap between industry and academia in translating gains of academic research into products and processes for societal benefit. In order to catalyse translational research, over the years, BIRAC has strengthened its partnership with academic institutes by establishing Early Translation Accelerators (ETAs), bioincubators, UICs and supporting industry-academia collaborative projects.

Regulatory landscape will be one of the key factors that would determine the future growth of the Indian biotechnology sector. Aligning with government policy of Ease of Doing Business, BIRAC aims to provide key inputs to regulatory agencies in building a transparent evidence based regulatory landscape in India in the field of biosimilars, stem cells, medical technology, clinical trials and bio-agri products.

RISK AND GOVERNANCE

The biotechnology innovation pathway involves long gestation period. This generates enormous pressure on start-up enterprises that are attempting to build novel, high quality and affordable products in India. For building an excellent bioeconomy funded on innovation, the industry needs an aligned strategy that integrates all aspects of biotechnology innovation- science, translational research, industry-academia partnerships, academic curricula, entrepreneurship & vibrant startup and SMEs, incubators, early stage funding, Angel funding, late stage VC funding, routes to IPO, ease of doing business, financial and technical regulation. All these elements need to come together.

One of the gaps in Indian biotech startup is lack of extensive 'Angel Funding' especially in the range of INR 1.5 crores to INR 5 crores. This funding is crucial for startups to cross the valley of death. For this, BIRAC has launched the AcE (Accelerating Entrepreneurs) fund. BIRAC has also initiated four regional centers, BIRAC Regional Entrepreneurship Centre (BREC), BIRAC Regional Innovation Centre (BRIC), Biotechnology Regional Bioinnovation Center (BRBC) and Biotechnology Regional Techno-Entrepreneurship Centre (BRTC) that conduct multitudes of programs which help start-ups to understand and refine their business models, regulators, connect them to investors for follow on funding and so on.

One of the risks is the global economy and its health which is influenced by numerous factors as well as understanding the emerging paths of global biotech industries. This would need pro-actively connecting to the leading centres across the world- be it in the US, UK, Germany, Finland, Singapore or Japan. BIRAC's partners bring the knowledge of growth of biotech industry in other countries. BIRAC proactively seeks partnerships with other S&T knowledge agencies across the world such as Tekes, Nesta, UKTI, BIO-US to name a few, learning about the best practices in other geographies and leveraging our partnership to bring value for Indian companies

OUR WORK

I. Investments

1. Biotechnology Ignition Grant (BIG)

The Biotechnology Ignition Grant (BIG) is BIRAC's flagship funding scheme that nurtures Biotech entrepreneurship in individuals and promotes early stage start-ups in the country. It provides early-stage funding for biotech start-ups and entrepreneurial individuals to support ideation and progression to proof-of-concept for ideas that have potential for commercialization. BIG is targeted towards researchers, scientists, clinicians, engineers, medical and non-medical graduates, experienced industry/ corporate entrepreneurs who could be from research institutes, academia and startups.

BIG works with four major mandates:

- Foster generation of ideas having commercialization potential
- Validate proof of concepts
- Encourage researchers to take technology closer to market through start-ups
- Promote biotech enterprise formation

The scheme is implemented through six BIG Partners to spread awareness who work closely with BIRAC for creating BIG outreach across the country, selection of BIG Innovators, disbursement of funds to grantees, providing technical mentoring and hand-holding for activities related to mobilizing resources, IP management, legal contracts and other business development related activities.

BIRAC's BIG Partners are also supported through BIRAC's BioNEST scheme.

- Centre for Cellular and Molecular Platforms (C-CAMP), Bangalore
- Foundation for Innovation and Technology Transfer (FITT), New Delhi
- IKP Knowledge Park, Hyderabad
- KIIT-BioNEST, Bhubaneswar
- Venture Center, NCL, Pune
- SIDBI Innovation & Incubation Centre (SIIC), IIT Kanpur

In FY 2018_2019, two new calls: BIG 13 and BIG 14 were launched on 1st July 2018 and 1st January 2019 respectively.

The 12th call of BIG identified 51 proposals for support out of a total of 587 proposals received and BIG 13th call supported 61 projects out of 506 proposals received. In total 112 new projects were supported in FY2018-19.

As of FY 2018-19, a total of 115 projects were active. A total of INR 42 crores was released to BIG partners to be disbursed to new and ongoing awardees.

BIG IMPACT

So far, BIG has received more than 4000 proposals, out of which, approx 400 have been supported. These 400 projects under BIG have yielded filing of 100+ Patents; development of 50 products/technologies and development of 750+ high calibre workforce. The scheme has also catalyzed setting up of 110+ new startups and promoted women entrepreneurship by supporting more than 60 women entrepreneurs. Notably, more than 60 of these 400 projects have also received follow on funding through other sources including from other schemes of BIRAC, state government funding schemes, trusts/foundations, angel investors and venture capitalists.

Some of the BIG Grantees who raised follow on funding from private investors during the FY 18-19 are as follows:

S. No.	Awardee (Company/Individual)	Investor
1	Smartify Health Pvt Ltd	Angel Investor
2	Synthera Biomedical Pvt Ltd	1 crowd (an early stage investor)
3	CyCa Oncosolutions	a) SOSV Funding (Ireland Accelerator) b) BPCL (Start Up Fund)
4	Bugworks	UTEC, a Tokyo-based early-stage VC
5	Prantae Solutions	BPCL (Start Up Fund)
6	Adit Biosciences Pvt Ltd	BPCL (Start Up Fund)
7	Omix Labs	Menterra Ventures and Artha Lesing
8	Adiuvo Diagnostics	Menterra Ventures
9	Inaummation	NUS Enterprise & DBS Foundation
10	Predible	Unitus Ventures and
11	Docturnal	Mumbai Angels
12	Microgo LLP	Angel Investor
13	Innotech Interventions Pvt. Ltd.	Oil India Corporation Limited
14	Evelabs Technologies Pvt Ltd	Angel Investor

Products developed with suport from BIG

4th BIG Conclave

The 4th BIG Conclave was organized at Venture Center Pune, on 26-27 July, 2018

The conclave witnessed a confluence of experts from industry, academia, law firms and BIRAC BIG Entrepreneurs. The conclave was a platform for the BIG Grantees to showcase their journey as innovators and entrepreneurs, reflecting the aspects of starting small, scaling up, USPs of the technology, business models, investment pitch, scouting for and building the team, patenting and licensing strategies, regulatory challenges, and incubation and mentoring. Entrepreneurs and experts shared their entrepreneurial journey, experiences and knowledge about the innovation ecosystem in the country which benefitted the audiences immensely.

Around 120 participants attended the conclave to make and expand their networks for collaborative opportunities.

Inaugural session at the 4th BIG Conclave

2. Small Business Innovation Research Initiative (SBIRI)

SBIRI was launched to promote and facilitate companies to take their established proof of concepts (PoC) towards early stage validation, thus fulfilling a major gap in the product development cycle. However, the

scheme has been instrumental in nurturing not only established companies, but also Start-ups and SMEs who are now availing this grant after completing the PoC studies in the BIG or other schemes of BIRAC.

Ever since its inception, 271 projects involving 206 sole companies and 65 collaborative projects have been supported through SBIRI with a commitment of Rs. 264.59 crore. 27 Intellectual property has been generated through these projects and 38 products/technologies have been developed/ validated; some of which have already been commercialized. Many promising research leads are getting ready to hit the market.

In the last financial year, three calls for proposals were processed. The 37th and 38th call were regular calls targeting the major thematic research areas of BIRAC such as Vaccines and Clinical trials, Drugs, Biosimilar and Stem cells, Agriculture, Device and Diagnostics, Bioinformatics and Industrial Biotechnology. The 39th call was a challenge based call targeting specific research area for each theme.

Under the 37th and 38th calls (as well as the 36th call that got closed on 31st March, 2018), 211 proposals were received out of which 40 proposals have been recommended for financial support. The 39th Call for proposals, which closed on 31st March, 2019 received 69 proposals which are under further consideration.

Of all the recommended projects, 18 projects from BIG scheme, 3 projects from IIPME scheme and 1 project from SPARSH scheme matured to secure a follow on SBIRI funding. These focus on development of a minimally-invasive device to treat symptomatic uterine fibroids; development of a Virtual Reality (VR)-based haptic endoscopy simulator for training doctors in GI endoscopy; a novel therapeutic device based on warm oxygen therapy for the treatment of diabetic foot ulcers; a novel fungus assisted fermentation-distillation pipeline for enhanced production of fragrant Assam agarwood oil; Clinical validation of endodentic files for root canal treatment, to name a few.

The ongoing projects under the various thematic areas were mentored and monitored through "Project Monitoring Committee" site visits, online evaluations or presentations before Technical Evaluation Committee. In 2018-19, 74 unique beneficiaries were supported. Out of these, 65 beneficiaries were companies (SMEs and start-ups) and 9 were academic collaborators. A total of 14 projects got completed. Some of the products/ technologies developed during the financial year are:

- "VoDCA" device developed by Vivira Process Technologies, Pune has been commercialized for industrial waste water applications.
- A Syphilis antibody detection rapid test platform and HCV rapid test kit has been commercialized by Dhiti Life Science Pvt Ltd. These indigenously developed kits displayed same level of sensitivity and specificity as that of imported commercial antigens.
- A technology developed by Porus Lifesciences Pvt Ltd for Niemann-Pick Type C Disorder has been licenced to US based company, Oraxion Therapeutics, Inc., a spin-off from Aten Porus Lifesciences.
- VAPCare, an intelligent secretion and oral hygiene management system to reduce chances of aspiration pneumonia in the patients who are on the ventilator, has been developed by Coeo labs Pvt Ltd.
- Nasoclean, a Nano-Respiratory Nasal Filter, has been developed by Nanoclean Global Private Limited which saves daily commuters from the harmful effect of microbial infections and tiny suspended particles in air. The device is under large-scale production.
- Z-Box, a nanofiber based bedside device, acts at the source of infection to protect vulnerable patients from a range of microbes, from viruses to fungi. The device has been developed by Biomoneta Research Pvt. Ltd and is under late stage validation.
- A technology for conversion of methane to single cell protein has been developed by String Bio Pvt Ltd. The technology has been validated at 60 L with complete downstream processing. Scale up is in process.

VAPCare: An intelligent secretion and oral hygiene management system to reduce risk of acquiring ventilator associated pneumonia

VoDCa (Vortex Diode Cavitation) device for industrial waste water treatment

Nasoclean – Nasal filters

Syphilis kit

Z-box - a nanofiber based bedside device

One project funded to String Bio Private Limited, under the SBIRI scheme was also awarded the BIRAC Innovator award during the year.

3. Biotechnology Industry Partnership Programme (BIPP)

The Biotechnology Industry Partnership Programme (BIPP), a public-private partnership scheme, promotes innovative research for development of transformational technologies/ processes in Biotech Sector. The Scheme serves as a launch pad for scaling and commercializing high risk innovations through cost sharing between BIRAC and the industry.

Proposals funded in BIPP are categorized under 7 thematic areas namely Drugs including **drug delivery**, Vaccines, Biosimilars & **Stem cells**, Devices & Diagnostics, Agriculture, Industrial Biotechnology including Secondary Agriculture and Bioinformatics.

Ever since its inception, 203 projects involving 142 sole companies and 61 collaborative projects have been supported under BIPP. A total of 47 products/technologies have been developed till date. While some of these have already been commercialized, others are at the pre-commercialisation stage. In addition, 8 facilities have been created as research resources and 31 new IPs have been generated.

During **2018-2019**, a total of 59 projects, including 10 new ones were supported. 17 projects got successfully completed during this period. Three new calls (44th, 45th and 46th) for proposals were announced, out of which 44th and 45th were regular calls targeting major thematic areas. The 46th call was a challenge based call on identified priority areas. Under 44th Call, 50 proposals were received out of which 11 proposals were recommended for support. Under 45th Call, 32 proposals were received out of which 3 proposals were recommended for financial support. In the 46th Call for proposals (which closed on 31st March, 2019), 50 proposals have been received which are under various stages of technical evaluation.

In the financial year 2018-2019, the key achievements of the projects supported under BIPP are as below:

- "3netra neo", a compact, portable and easy to use mydriatic digital wide field imaging system, developed by Forus Health Pvt. Ltd. has been commercialized
- "Upgraded version of Mobile-Lab" has been commercialized by Accuster Technologies Pvt. Ltd.
- anuPath or "Lab on a Palm", a multi analyte diagnostic device, has been commercialized by PathShodh Healthcare Pvt. Ltd.
- "Growth-Min Aqua" and "YeggMore", animal nutritional products were introduced in the market by Aspartika Biotech Pvt Ltd.
- Inhouse purified DHA has been sold by AlgalR NutraPharms Private Limited.
- Technology for production of rare sugars i.e. Isomaltulose, Trehalulose (50-100 Kg/day) and D-Psicose (l0-50 Kg/day) has been demonstrated by Nagarjuna Fertilizers & Chemicals Ltd.
- Novel SPLAT technology for integrated pest management through mating disruption has been developed and multi-location field trials performed by ATGC Biotech Pvt. Ltd.

3netra neo: Compact, portable and easy to use mydriatic digital wide field digital imaging system

anuPath: Point-of-care multi analyte diagnostic device

SPLAT Technology for Mating Disruption in Pests

Encapsulated DHA Powder

Omega 3 fatty acid enriched with silkworm pupa oil and de-oiled cake

Upgraded version of Mobile-Lab

4. Promoting Academia Research Conversion to Enterprise (PACE)

The PACE scheme was launched to promote translation research within the country by the academia. This scheme encourages and supports academia to develop technology/product (up to PoC stage) of societal/ national importance and its subsequent validation by an industrial partner. The scheme has two components (a) Academic Innovation Research (AIR) and (b) Contract Research Scheme (CRS). The objective of AIR is to promote development of Proof-of-concept (PoC) for a process/product by academia with or without the involvement of industry. The CRS component aims at bridging the industry-academia gap through validation of a process or prototype (developed by the academia) by an industrial partner.

Since inception of the scheme, 17 calls have been launched and 71 projects have been supported involving 61 academic institutions and 31 companies. A total of 7 technologies/products have been developed under the scheme that have achieved TRL7 and 2 IPs have been generated.

In financial year 2018-19, a total of 52 projects were supported (52 academic institutions and 31 collaborators). During the year, three calls for proposals were announced and processed. The 15th and 16th call were regular calls targeting the major thematic research areas of BIRAC. The 17th call was a challenge call targeting specific area for each theme.

Under the 15th and 16th calls (as well as the 14th call that got closed on 31st March, 2018), 359 proposals were received out of which 47 proposals have been recommended for financial support. The 17th call for proposals, which closed on 31st March, 2019 received 123 proposals which are under various stages of technical evaluation.

Progress of projects with regard to the development of new technologies/products for moving towards commercialization was carefully monitored through PMC visits, thematic reviews, and online evaluation in accordance to the scheme guidelines. Successful outcomes of the projects supported under PACE during 2018-19 includes:

- TRA and Varsha Biosciences Pvt. Ltd have done *in vivo* multi location/ ecological zones trials of the formulations developed from 20L fermenters. Required data for CIB registration is being generated.
- CRRI and Xcelris Pvt. Ltd completed their studies for identification of QTLs/genes associated with grain yield reproductive stage drought stress. Validation of marker_ trait association mapping populations (RILs) for use in the MAS breeding programs. The project attained TRL-7.

Reproductive stage drought stress

Reproductive stage non-stress-Irrigated

5. Social Innovation Programme for Products: Affordable & Relevant to Societal Health (SPARSH)

SPARSH is the Social Innovation Programme of BIRAC aimed at promoting the development of innovative solutions to society's most pressing social problems through biotechnological approaches. Since its inception, the program has been investing in high impact ideas and innovations that could address neglected unmet needs and challenges. Till date, eight calls for proposals have been launched under the program which focus on varied themes like *"Reducing child mortality and improving maternal health", "Ageing and Health", "Innovative Diagnostic tools for Soil and Plant Health", "Soil & Plant Health and Human Health" and "Waste to Value, Livestock health and improvement, New and improved agricultural tools, Reducing post-harvest losses and Combating environmental pollution".*

Under the Scheme, 46 projects have so far been supported and 13 products/prototypes/technologies have been developed. Some of the major product/technologies developed during the year are:

- "NeuroTouch", a point of care diagnostic device for Diabetic Peripheral Neuropathy, has been developed by Yostra Labs. It is a portable diagnostic device that helps the clinicians to perform basic screening tests for Diabetic Peripheral Neuropathy.

- "Saans", a device to address the respiratory distress syndrome for babies in resource constrained settings by the application of Continuous Positive Airway Pressure (CPAP) has been developed by Coeo Labs' Pvt. Ltd..

Virtual Reality (VR) Goggles have been developed by Lattice Innovations to treat those affected with balance disorders. Patients are immersed in a VR environment that covers cityscapes, motorways and boat rides. Games are graded to provide successively higher levels of challenge. The app logs time for completion or each activity, and the number of falls, to generate scorecard for each session. These results can then be exported from the app, used to devise a treatment plan, and most importantly - track progress. Lattice's system is among the first to utilize emerging consumer technologies to develop a VR application for clinical use.

Social Innovation Immersion Program (SIIP)

SPARSH through its Social Innovation Immersion Program (SIIP) provides fellowships to "Social Innovators" for identifying and addressing specific needs and gaps in social sector and promote social entrepreneurship.

The SIIP partners provide the rural and clinical immersion to the innovators. The innovators are also mentored for systematic clinical & community observation, need assessment, refinement and affordable technology development. On completion, the Social innovators reach a point when they could submit an advanced proposal with some preliminary results suitable for seed funding.

BIRAC for "Maternal and Child Health" (MCH) partnered with four SIIP partners (i) Venture Center, Pune (ii) THSTI, Faridabad (iii) KIIT, Bhubaneswar and (iv) Villgro, Chennai. The Immersion program on MCH had

supported 14 social innovators who had developed solutions for most pressing problems of society under MCH.

Venture Centre has been implementating Immersion program for thematic area "Waste to Value" under which four SIIP fellows were undergoing immersion. In the financial year 2018 - 19, the following achievements were made by the SIIP fellows:

Shubham Singh: Formed FuMa Labs through SIIP Developed a crop residue derived straw panel board for use in construction, furniture and packaging industry.

Aishwarya Nair: Raised follow on BIG Grant for a platform to measure and monitor disinfection levels of surfaces in public settings.

Pramod Bhurji: Formed Fudokame Pvt Ltd. Raised follow on Prayas Grant for Hybrid solar-biomass dryer for processing agriculture produces to reduce wastage.

Under the theme "Ageing and Health" four SIIP Implementation partners namely, Venture Centre, CCAMP, KIIT and SC-TIMED were added. 16 SIIP fellows are inducted in the program who are working towards finding solutions related to problems faced by senior citizens.

Pre – Pilot Workshop -SCTIMST - TIMED

Tata Institute of Social Sciences (TISS) has been engaged as SIIP knowledge partner to train, mentor, and monitor the performance of SIIP fellows.

Venture Design Workshop, Venture Centre

6. Affordable Products and Technologies developed through Investment schemes

BIRAC has an inherent system of grading the projects into 7 theme areas for project monitoring and promoting innovation in that sector. The Healthcare sector has been categorized into 4 thematic areas namely, Drugs (including drug delivery), Biosimilars and Regenerative Medicine, Vaccines, Devices and Diagnostics. The other theme areas for which BIRAC provides funding are Agriculture (including Aqua culture and Veterinary Sciences), Industrial Biotechnology (covering Industrial Processes, Industrial Products and Secondary Agriculture), Bioinformatics and Facilities.

BIRAC emphasizes that projects supported through its various funding schemes on conclusion yield the targeted outcome in the form of products, technology development, IPR, etc. Towards this end, BIRAC supported projects under various schemes are regularly mentored and rigorously monitored for their Technological Readiness Level (TRL) on a scale of TRL 1 to TRL 9. This monitoring is achieved through visits of Project Monitoring Committee (PMC) experts to the project implementation site, presentation of progress of the work by the Project Coordinators before the Technical Expert Committee (TEC) and online evaluation of milestone completion reports by the subject matter experts associated with a particular project.

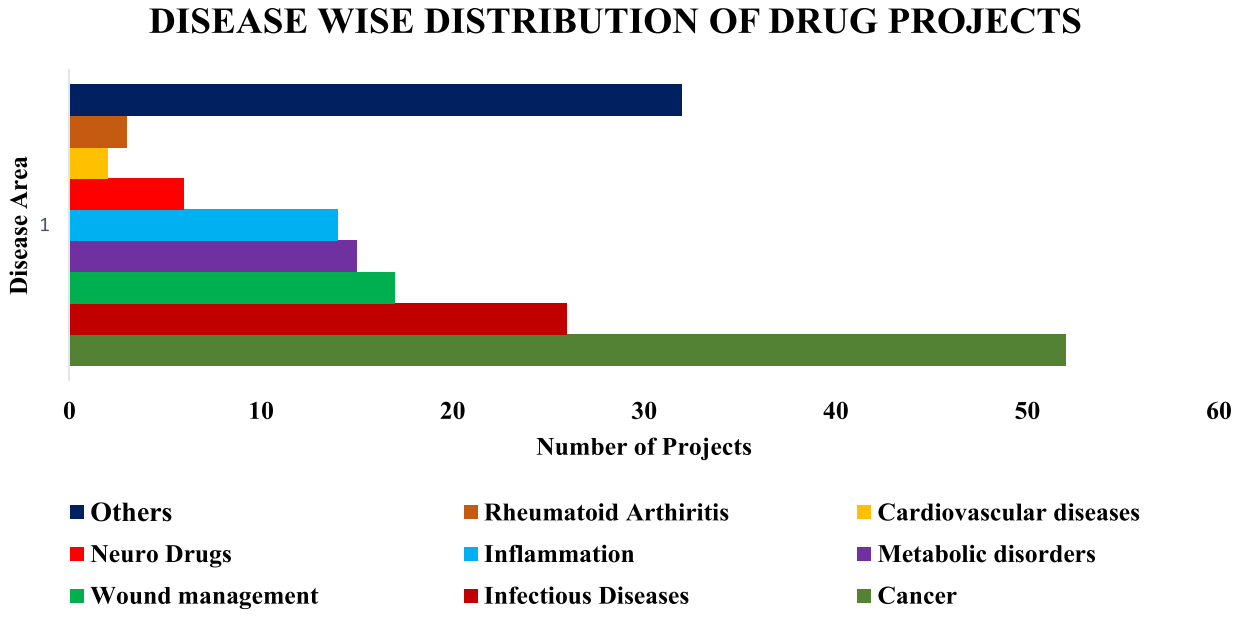
There is always an effort on part of BIRAC to enable/assist the beneficiaries so that the product/process under development could be commercialized at the earliest. To this end, BIRAC has initiated a Product Commercialization Program (PCP) to address the challenges faced by innovators towards commercial launching of their product and market expansion.

The initiatives undertaken by BIRAC have resulted in successful completion of targeted milestones of many projects from different sectors, and development of many early/late stage technologies and affordable products. During the year 2018-19, 29 projects completed Early Stage Validation and 19 projects reached commercialization stage

1. Sector-wise
i. Healthcare
a. Drugs

BIRAC supported projects for drug development, drug delivery and for the development of platform technologies in this sector. BIRAC's funding to drugs sector focuses on development and validation of affordable technologies and products with a view to reduce their cost and increase their availability and

accessibility to the society. The projects supported mainly focus on establishment of proof of concept, preclinical studies of leads and clinical trials (Phase II and Phase III). Many of the projects accomplished the objectives successfully and are ready to go to the next stage. Disease wise distribution (depicted below) of projects revealed maximum funding for drug development in cancer followed by infectious diseases, wound management.



Following Products/Technologies have completed technology out-licensing or early stage technology Validation in 2018-19.

1. **First-in-Class Therapeutics for Niemann-Pick Type C Disorder (Aten Porus Life Sciences Pvt Ltd)**

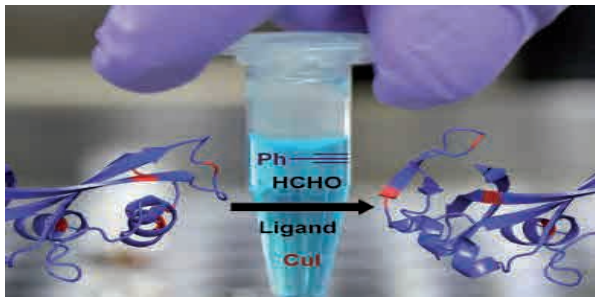
   Synthesized and characterized polymeric pro drug ORX-301 for Niemann-Pick Type C Disorder. The molecule was found to be safe and efficacious in NPC knockdown mice. The technology has been licenced to US based company by Oraxion Therapeutics, Inc., a spin-off from Aten Porus Lifesciences. The total aggregate payments under the agreement have the potential to reach upwards of $125 million as well as typical royalties and associated sales milestone payments.

2. **Novel technology to generate stable transgenic systems (Viravecs Labs LLP)**

   Successfully validated the simplified method for the targeted insertion of a foreign gene into genome and developed the technology to harness the power of CRISPR-Cas9 based genome editing. Validated process for cell line development assessed in 6 cell lines, including primary cells.

3. **Protein labelling technologies through Linchpin directed modification (Dr. Vishal Rai)**

   Generated 30 analytically pure reagents through Linchpin directed modification (LDM) platform. They have performed LDM platform for labelling of structurally diverse 12 proteins. All the labelled proteins were completely characterized. Technology is ready for B2B services and is undergoing further testing and validation with a few industrial and academic users.



b. Biosimilars and Regenerative Medicine

BIRAC has supported projects for development of different biosimilars & regenerative medicines and for the process development of existing products in this area for increasing the present market share/output in the country. In general, the projects funded under this category are for development of proof of concept followed by technology/process/product development along with their validation.

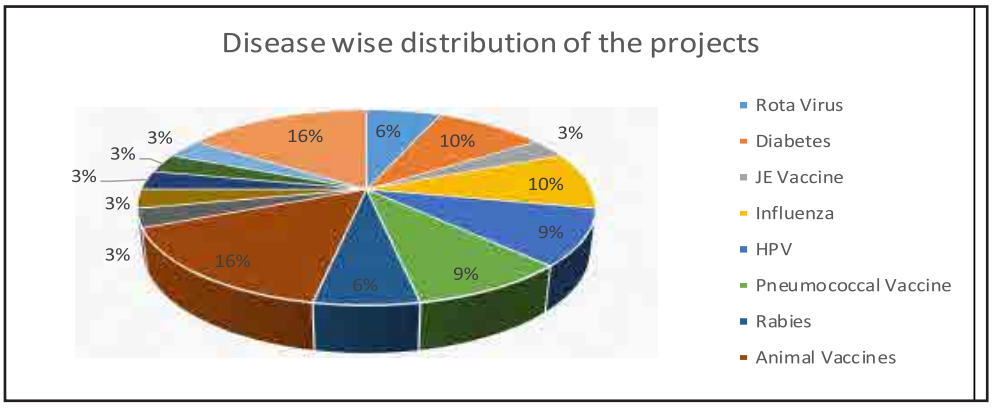
The projects supported under the biosimilar area addressed different diseases like Cancer, Diabetes, Inflammatory diseases, Alzheimer's. Further funds were also provided for development and validation of different platform technologies for producing affordable monoclonal antibodies. The bio therapeutics under focus included Foligraf, Rasburicase, Trastuzumab, Aflibercept, Sinapultide-A, Bevacizumab, Trastuzumab etc.

The projects under the thematic area of regenerative medicine included device development for stem cells isolation and usage of different types of stem cells for indications like Periodontal Tissue repair, urethral strictures, urinary incontinence etc. Along with supporting clinical trial in the field of regenerative therapy, preparation of Stem cells Bank has also been funded by BIRAC.

Among BIRAC supported projects under the above theme, maximum number of projects are supported for development of Proof of Concept (POC) or Early Stage Validation of a POC. Further, to nurture indigenous innovation, the program named Innovate in India (I3), an industry- academia collaborative mission of Department of Biotechnology (DBT) in collaboration with World Bank for accelerating discovery research to early development of Biopharmaceuticals has been implemented by BIRAC with a specific focus on the development of bio-therapeutics.

c. Vaccines

Vaccine development has played an important role in combating infectious diseases. BIRAC has supported 27 projects under this theme. The projects supported in this area addresses diseases like Diarrhoea (Rotavirus), Japanese Encephalitis (JE), Influenza, Cervical Cancer (HPV), and Dengue . BIRAC supported projects to combat bacterial infections like Pneumococcal and Meningitis, Parasitic infections like Malaria and Leishmaniasis. Vaccines for Cattle and Rabies were also supported by BIRAC. Disease-wise breakups of projects supported so far is represented below:



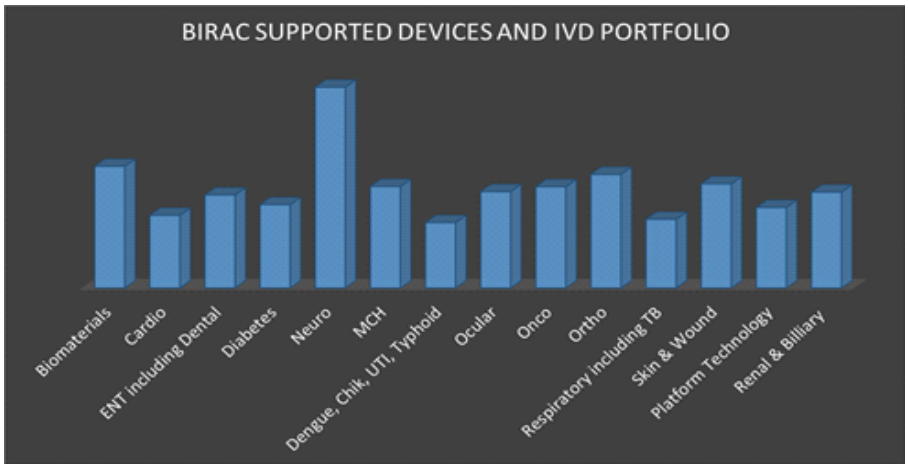
For making India a hub for design and development of novel, affordable and effective biopharmaceutical products and solutions, BIRAC launched National Biopharma Mission (A collaborative mission of DBT and World Bank) in the year 2018 for the development of Biopharmaceuticals. So far under National Biopharma mission program BIRAC supported 6 projects for the development of different vaccines for infectious diseases like, Dengue, Chikungunya, Influenza, cholera and pneumococcal vaccine.

d. Devices and Diagnostics

BIRAC along with Country has witnessed a positive wave of developments in the devices and diagnostics sector over the year. Lot of young individuals have ventured into the sector and started their entrepreneurship journey. BIRAC also promoted the "Make in India" "Start Up India" and Invested around INR 235 Cr in Devices and Diagnostics through its flagship schemes.

BIRAC is successful in supporting innovators and helping them to achieve TRL _ 9 from Devices and Diagnostics sector i.e. 40 products have been commercialized. The devices and diagnostics sector has seen maximum number of patent filing i.e 76 patents are filed by various companies for innovative technologies.

BIRAC supported technologies ranging from handheld PoC devices to high end diagnostic imaging devices and surgical Instruments. Neurology, Biomaterials, Skin & wounds, Ortho, Oncology, ophthalmology and Maternal and Child Health has witnessed maximum number of projects. Orthopedics, Biomaterials, Implants and hospital consumables are few latest attractions which are high on market demand.



List of commercialized Products and Technologies:-

1. 3Nethra Neo - PoC system for screening Retinopathy of Prematurity (ROP) in Children (Forus Health Pvt. Ltd.)

The 3nethra neo is a compact, portable and easy-to-use mydriatic wide-field digital imaging camera used for the photo documentation of ocular diseases that manifest in human eyes. The ergonomically designed, light weight hand piece allows for single-handed operation, and captures 120-degree high resolution images of the posterior and anterior segments of the eye.

2. VAPCare: An intelligent secretion and oral hygiene management systems (Coeo Labs Pvt. Ltd.)

Coeo labs have developed VAPCare, an intelligent secretions and oral hygiene management systems to reduce chances of aspiration pneumonia in the patients who are on the ventilator for more than 48 hours. It is a holistic system that provides targeted suctioning of the secretions in order to reduce the risk factors for VAP in ICU patients. Secretion management by doing automatic suctioning from three location oral, oropharyngeal and subglottic regions. The device has been pilot level validated on 20 patients and they are planning for a Pivotal study to prove the Ventilator Associated Pneumonia prevention property at multiple centres. Product has been launched as oral secretion management system and is under demo at many hospitals in India, both private and public, who are interested in its procurement. Large scale Clinical validation is planned at three sites for VAP care prevention efficacy with BIRAC support, which is awaiting regulatory approval.

3. AnuPath- Multi-analyte Device (Pathshod Healthcare Pvt. Ltd)

PathShodh healthcare has developed a novel indigenous point-of-care device for management of diabetes and early detection of complications thereof. The device is capable of measuring eight paramaters - HbA1c, Hb, Glycated Albumin, Human serum albumin, blood glucose, Urine creatinine, Microalbuminuria and Urine ACR utilizing test strips. The test strips are based on dry chemistry and all the test utilize separate test strips. Planning to take CE and applied for manufacturing license from CDSCO.

4. Upgraded version of Mobile-Lab (Accuster Technologies Pvt. Ltd.)

Accukine or Mobile Lab is a Compact Portable Clinical Laboratory with an open system in a suitcase. The product is USFDA approved. The mobile lab is very rugged and maintenance free. It can easily work

at temperatures ranging from 2-50°C and has a power backup of 4 hours extendable to 24 hours. A total of 36 tests can be performed on the Mobile Lab (extendable to 68 tests) which includes Sugar Profile, Haematology, Kidney Function Test, Liver Function Test, Lipid Profile and Electrolytes.

5. Dozee- Non-invasive vital and sleep monitoring device (Turtle Shell Technologies Pvt. Ltd)

Dozee is a contactless health monitoring device that silently tracks the sleep patterns, heart, respiration and stress levels. Dozee app, managed by health experts, gives detailed insights that help to manage stress and sleep better.

6. Poorti Kit/Sampoorti- Affordable breast prosthesis and mastectomy bras for breast cancer patients (Aarna Biomedical Products Pvt. Ltd)

Aarna has developed Poorti- Post-Mastectomy Kit and Sampoori- A display suitcase for breast prosthesis and accessories for hospitals. The kit comprises of one external pre-made silicone (medical grade CE certified material) breast prosthesis (available in different sizes and shapes as per the choice of patient), two pocketed brassieres (available in different sizes and two colours), two prosthesis covers, one prosthesis holder, information and usage manual and an outer waterproof kit which accommodates all the aforementioned components discreetly. Validation study were conducted through Army R&R hospital in Delhi, Pune and Lucknow, through collaboration with Indian Cancer Society, by involving patients from various city. Over a 1000 Poorti Kits have been sold and Sampoorti display kit is present at over 40-50 hospitals all over India.

7. SAANS_ A neonatal CPAP device (Coeo Labs Pvt. Ltd.)

Coeo Labs has designed Continuous Positive Airway Pressure (CPAP) as a solution to address Respiratory distress syndrome in resource constrained settings. Saans has completed a clinical evaluation on 50 neonates and achieved success in delivering CPAP from this device and has recently been launched by InnAccel. Features of the product are:

a. Multi-Power mode including manual
b. Minimum skill Needed, only 1 attendant
c. Aligned with various transport mode in the India
d. User determined Oxygen + Air mixture
e. Passive humidification

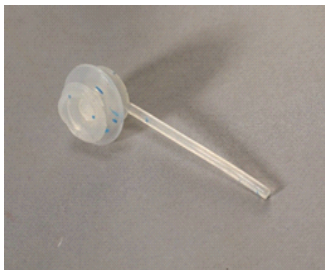
8. FlexiOH: Breathable, Washable and Lightweight cast immobilization for fractured bone (JC OrthoHeal Pvt Ltd)

JC Ortho has developed a breathable and washable cast immobilization and splint, FlexiOH. FlexiOH has an innovative design of immobilization cast with completely washable material. The design has holes through the surface providing air circulation to skin. FlexiOH is less than 300 grams and has a zipper system for hassle free application and easy removal. FlexiOH is based on Liquid silicon rubber, which is currently imported. For casting purpose a photo curable resin is used. The kit includes the rubber based immobilization cast, light curable resin and a curing light (410 nm). The product has been market launched and is undergoing post-market validation at many hospitals.

9. AYU Lynk Digital Stethoscope (Ayudevices Pvt. Ltd)

AyuLynk converts conventional stethoscope into Smart stethoscope. Product name is AyuLynk (Wired version) and AyuSynk (Wireless version). The device is modular, hence it can be attached to existing stethoscope to convert it to Smart stethoscope. AyuLynk provides amplification, filtering, recording, sharing and analysis of heart and lung sounds through a mobile or computer. It is used by doctors for enhanced auscultation and better diagnosis in clinical practice, medical students for learning auscultation and digital health companies for telemedicine applications. Device was launched on 18th of April, 2018. So far more than 200 units of AyuLynk have been sold.

10. AUM- Affordable voice prosthesis (Innaumation Medical Devices LLP)



Aum voice prosthesis is an affordable tracheo-esophageal voice prosthesis for laryngectomy patients who have lost their voice box to speak again. Current western devices in market cost anywhere between 25,000/- to 45,000/- rupees. This device (AUM) is made using platinum cured silicon medical grade comes nearly at cost of Rs. 50. Innaumation medical devices LLP has developed this voice prosthesis device, which is implanted in patients undergoing laryngectomy enabling the patient to speak after surgery. The voice prosthesis device comprises a cylinder that includes a first end and a second end. The device further includes an outer washer, an inner washer, a partial shutter, a shutter guard and adjustable rings. Innaumation has completed tests with more than 100 patients with very successful results and have launched the device during BIRAC 7th Foundation day.

List of Products and Technologies completed Early Stage Validation:-

1. Portable Hand Held Dermascope (Adiuvo Diagnostics Pvt. Ltd)

Wound assessment and management is very crucial with the rise in Skin and soft tissue Infections SSTI. Company is developing a portable non-invasive device, Skinscope, that can non-invasively detect and monitor any SSTI ranging from diabetic foot ulcer, burns, Pressure ulcers, surgical sites infections etc. within 2 minutes, aiding doctors by providing information on colonizing pathogen, pathogenic load and wound closure rate. They have developed a prototype capable of detecting few clinically relevant pathogens and likely to enter pilot studies.

2. Nano-Respiratory Nasal Filter (Nanoclean Global Pvt. Ltd)

Nanoclean Global Private Limited has developed a ground breaking filter technology to save daily commuters from the harmful effect of bacteria, viral infections and tiny suspended particles emitted from vehicles, coal-burning power plants or factories and hence avoid respiratory disease, heart problem and lung cancer, especially keeping in mind 2.5pm concentration in Delhi as well as pollen allergies. They have developed a simple use and throw, disposable nasal filter, which sticks to the user's nasal orifice unlike traditional surgical masks which covers the half of the face and produces discomfort while wearing.

3. Foetal Movement Monitor (Empathy Design labs Pvt. Ltd.)

Empathy Design Labs has developed a wearable and non-invasive screening "KRIYA" patch for rapid pregnancy monitoring by expecting parents and clinical Obstetricians. Early alerts and timely actions can save the lives of millions of babies who are stillborn due to delays in reaching care providers. As a non-invasive IOT device it alerts parents24-hours prior to a pregnancy turning into a stillbirth. With such a notification there is an opportunity to intervene and save a pregnancy.

4. Neurotouch- Affordable diagnostic device for screening Diabetic Peripheral Neuropathy (Yostra Labs Pvt. Ltd)

A Point of Care diagnostic device for Diabetic Peripheral Neuropathy. It is a portable device that helps the clinician to perform basic screening tests for Diabetic Peripheral Neuropathy. The tests include Graduated Monofilament Test, Vibration Perception Test, Hot and Cold Perception Test and Infrared Thermometry for Skin Temperature Measurement. The diagnostic test data is transferred over Bluetooth to a webserver that generates an AI based test report.

5. Smartscope- Transvaginal Digital Colposcope ((Periwinkle Technologies Pvt. Ltd)

The SmartScope is a portable trans-vaginal digital colposcope with smartphone interface for Single-Visit Cervix Cancer Screening in Low Resource Settings. As a part of the validation study, the device was used to screen 600+ patients (across 4 centers including Tata

Memorial Center) qualified as per criteria of age, sexual activity, pregnancy status, surgical status. Test Performance Comparison Data suggests that against a standard Colposcope there is 130% better SCJ Visualization, against Pap Smear test there is 1.5X more sensitivity and specificity and against naked eye VIA/VILI test there is 2X more sensitivity and specificity when the developed Smart Scope is used.

6. A smart blood bag monitoring device for safe and reliable blood transfusion in rural India (Bagmo Pvt. Ltd.)

Bagmo has developed a blood bag monitoring device which can tell the temperature of each blood bag while it is transported and stored. The device will be able to reduce wastage at blood storage centres. The device will also reduce effort in logistics and communication issues. This is a hardware product with connectivity to cloud. The same technology can be used in other sectors like Food, Pharma etc.

7. X-ray based Patient Specific Instrumentation for Knee Replacement Surgery (Algosurg Pvt. Ltd)

Algosurg Pvt. Ltd has developed an X-ray based patient specific instrument (XPSI) for the resection of knee joint bones, required by knee replacement surgeons. An accurate bone resection (perpendicular to its mechanical axis) leads to accurate positioning of knee implants and hence better patient outcome. The principle of XPSI is to use the unique 3D shape of the knee joint bones (femur and tibia) of a patient to design a 3D printable surgical guide (XPSI) for accurate bone cuts for the same patient. The key benefit here is that the 3D bone model will be reconstructed from 2D X-ray images, using the BIRAC supported algorithm Tabplan-XrayTo3D. Through BIRAC support XPSI were designed, 3D printed and used in total knee replacement surgery of 60 cases in a clinical validation study at Hinduja Hospital, Mumbai with successful outcomes.

8. Z-Box: Electrodynamic Ablation of Pathogens from Healthcare Environments (Biomoneta Research Pvt. Ltd)

Biomoneta's nanofiber based technology is a bedside device, Z-Box that acts at the source of infection to protect vulnerable patients from a range of microbes, from viruses to fungi. Biomoneta's Z-Box technology synergistically combines a three-dimensional, microbicidal nanofiber material with a trapping innovation that potentiates the effect of the material. The three dimensional architecture of the nanofiber greatly enhances its trapping ability along with the unique air flow design to maximize the impact of microbes on the material while eliminating issues like clogging, traditionally seen in the filtration based techniques. The device is currently validated and positioned to provide clean environments for laboratory conditions, like animal cell culture rooms. Z-box is undergoing validation at hospital ICU settings for testing its efficiency in providing microbe free environment to prevent hospital acquired infection in ICU patients.

9. Compact Mobile Digital X-ray (Iatome Electric India Pvt Ltd)

The portable handheld X-ray system (AlerioXR) is a totally wireless dental intra oral X-ray system. The key features of the product are

- Light Weight & Compact _ Handheld operation.
- Battery Operated. On full charge of battery, 150 dental X-rays can be done. The battery retains charged for >30days if not used. Battery is charged from mains using a AC/DC adapter provided with the unit. A discharged battery can be fully charged in 1 hour.
- Gun Type Design for Easy Handling and Use.
- X-Ray Leakage on the Surface is 7 Times Lower than AERB Limits.

The device is BIS certified and AERB approvals have been obtained. The upgraded version of the product (Alerio Neo) having improved ergonomics functions and safety, is also ready for commercialization.

10. A Point-of-sample-collection screening tool for Cervical Cancer (Aindra Systems Pvt. Ltd)

Aindra systems has developed CervAstra system (Autostainer, VisionX, AI Algorithm) where a field ready Autostainer IntelliStain has been developed and third party validated at multiple centres at clinical settings. The Whole slide Image Acquisition system, Vision X along with the AI software has been developed and is undergoing inhouse verification testing using real patient slides for improving the sensitivity and specificity. Aindra is an ISO13485 company and IntelliStain is ready for commercialization.

11. On the GO, Powerless, Steamless Surgical Sterilizer for Resource Limited Settings (MicroGo LLP)

Development of a portable sterilizer, which has quality to deliver the chlorine dioxide for sterilization of surgical instruments in a portable manner without the need of water and continuous use of power. Tubelet, releases the surgical sterilant chlorine dioxide gas in portable form without the need of elaborative setup.

ii. Agriculture

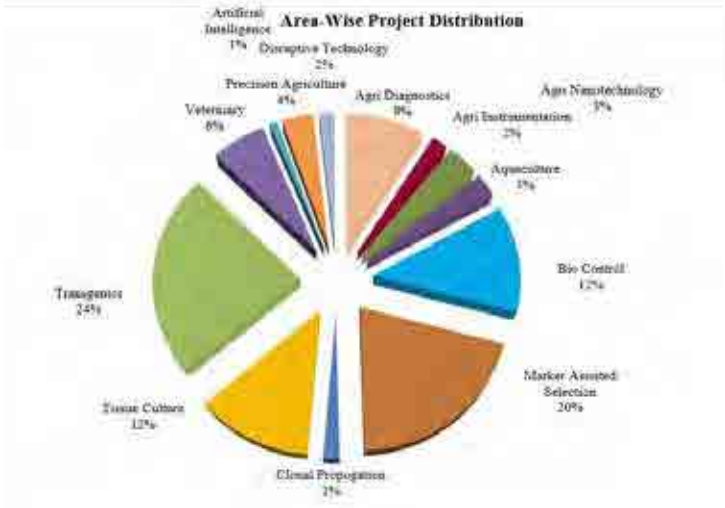
Agriculture is a potent resource for promoting sustainable development and reducing poverty in the 21st century. However, it requires a widening and perpetually changing array of knowledge and innovation to meet the diverse needs of the world's growing population and to resist or mitigate the effects of climate change. The forces that generate knowledge and drive innovation in agriculture will also continue to change. Agricultural development is now driven less by production and more by the forces of markets, urbanization, globalization, and shifting patterns of consumption, competition, and trade rules. 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.

Over the years, BIRAC has supported projects in the field of agriculture and allied areas. Recombinant DNA technology, marker assisted selection, and tissue culture are some of the key technologies wherein a sizable number of projects have been supported. Besides funding research studies involving high technological merit in the field of Agri-nanotechnology, and Agri-diagnostics, several projects related to Agri-instrumentation, and development of environmentally benign biopesticides and biofertilizers have also been supported. In addition to this, some interesting proposals in the field of Precision Agriculture were funded under a special call of SPARSH.

To further strengthen the innovation chain, BIRAC has supported few platform technologies which are expected to push forward the agriculture ecosystem further. This includes:

1. Pest Management through mating disruption using patented SPLAT formulation.
2. Gene editing using CRISPR/Cas9 technology
3. Seed invigoration using magneto priming techniques
4. Efficient delivery of pesticides using nano-biotechnology

BIRAC has also been supporting research studies in the field of aquaculture and veterinary sciences. Some of the prominent ones include, development of improved B-glucan based natural immunity booster for aqua culture with enhanced absorption and potency and fat measuring device for small dairy farmers.

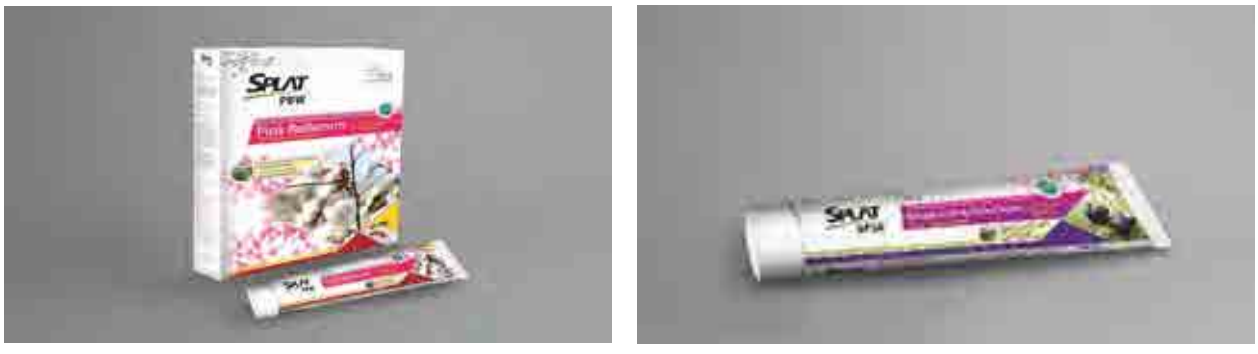


List of commercialized Products and Technologies

1. **Control of pests using Specialized Pheromone & Lure Application Technology (SPLAT) ATGC Biotech Pvt. Ltd.**

   The technology aimed at developing a revolutionary tool for the control of pests with use of Specialized Pheromone & Lure Application Technology (SPLAT) through mating disruption/ Autoconfusion/ Atract& Kill and MAT in males. Large scale implementation of mating disruption projects has yielded significant reductions in pesticide use while maintaining acceptably low crop damage levels. The technology developed has controlled release of pheromone formulations for manipulating insect behaviour by sending false female signals to males, creating auto-confusion and disrupt mating.

   In some of the SPLAT treated fields, where the farmers income got doubled along with quality produce with minimal to no chemical pesticide application and the highest damage yield loss was below 5-8 %. Whereas, in untreated control fields the damage yield loss among these 4 different crops was ranging from 30-80 % with multiple insecticide spray. The study also shows increase in farm productivity and farm income significantly.



Product Pictures for Pink bollworm for cotton and Brinjal shoot and fruit borer

2. Pocket Spectrophotometer for small dairy farmers (ShubhamRathore, TestRight Systems Pvt. Ltd.)

TestRight, an IIT Delhi start-up supported by BIRAC, has developed the country's first pocket spectrophotometer, Prizm+ for measurement of fat in the milk. It is an easy to use device which can help to assess the quality of the biological liquid material. Currently, the company is providing the device to the educational institutes and disseminating the commercial applications of the Prizm+ in water and soil testing, diagnostics, and food testing.

Prizm uses an optical train to fold the optics into a tiny pack. It is the first device of its kind to have smartphone connectivity for quick display and sharing of data and need no other battery source or power supply.

Products / Technologies completed early stage validation

3. Development of improved b-glucan based natural immunity booster for aquaculture with enhanced absorption and potency. (Theevanam Additives and Nutraceuticals Pvt. Ltd.)

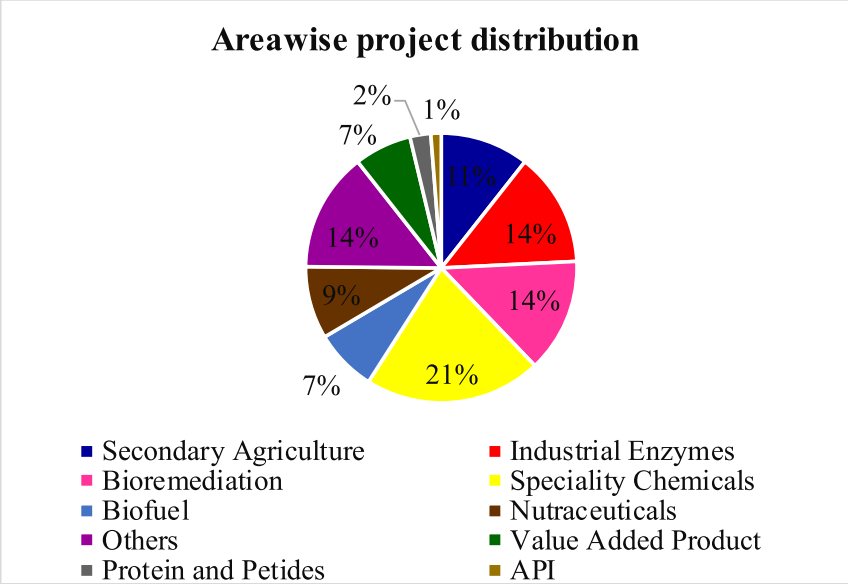
The project involved large scale screening of various yeasts and primitive fungi for B - 1,3/1,6-glucan. Post screening, the Glucan was extracted from cell wall components and was nano precipitated as an alkali-soluble glucan fraction. Physico chemical characterization of nano-glucan particles was carried out and lab trials on shrimps were done for enhanced growth and immunity. Finally challenge studies against viral infection and field trials showed enhanced growth and immunity in shrimp.

iii. Industrial Biotechnology including secondary agriculture

Industrial biotechnology (including secondary Agriculture) encompass the area which consists of development of technologies focussing on creation of new products useful to the industry, modifying or developing processes using enzymes, finding alternative technologies to replace petroleum based products and environmental remediation. This area has the potential to develop processes with reduced water and energy consumption.

In the last financial year, a large number of projects have moved on for follow on funding for scale-up or late stage validation. These include technologies for the production of rare sugars, recombinant streptokinase, Supercritical Fluid Extraction, Production of rare mushroom species, Docosahexaenoic acid and immobilized lipases, to name a few.

Area wise project distribution is shown below:



List of commercialized Products and Technologies and established facilities:-

1. **A stand-alone compact digester for decentralized waste processing (Flycatcher Technologies):** The Rhino Digester System is completely sealed, compact odor free and easy to use. The waste is feed into the system through an integrated crusher mounted below a sink that pulverizes and injects waste into the system. The small quantity of water required is readily available in the faucet mounted on the sink. The prototype has been developed and installed at few places.

2. **An innovative device (VoDCa) for enhancing biogas yield of distillery spent wash or reducing COD in effluents (Vivira Process Technologies):** VodCa is uniquely designed to generate hydrodynamic cavitation by utilizing rotational flow rather than the conventional axial flows. The novel design can precisely control the nature of cavities. It does not have any moving components, offers better performance and is far more durable. The device has been validated and installed at several places.

3. **A technology for pilot scale production of docosahexaenoic acid from microalgae (Algal R Nutraceuticals Pvt Ltd):** A new technology to produce DHA from microalgae has been developed. The company has demonstrated the process in 7500 L bioreactor and commercialized the product. They have formulated the powder and granules and tested the stability up to 6 months by addition of tocopherol and astaxanthin. Algal DHA oil and free flowing Algal DHA powder has been produced.

4. **Establishment of pilot-scale supercritical fluid extraction unit for nutraceutical and cosmeceutical products development (Aspartika Biotech Pvt Ltd.):** A technology for the complete utilisation of Silkworm Pupae waste generated in the silk reeling industries and it's conversion to high value nutraceutical like Omega 3 Fatty Acid and Silk protein has been developed. Wide range of products (Poultry and Aqua feed supplement) have been formulated by the Company. The facility has been set-up at the Textile Park, Dodhballapur and the production has been started (1000 litres of oil per month).

5. Pilot scale translational facility for value added chemicals from biomass (Privi biotechnologies Pvt. Ltd.)

The project was to set-up a pilot plant for demonstrating the technology of Biorefinery from biomass at a commercial scale. Under this they have developed a sustainable method for fractionation of corn bran to xylose and ferulic acid at 500 kg scale followed by conversion of ferulic acid into vanillin. In addition, conversion of xylose to xylitol was one of the major objectives. The DBT-ICT Centre for Energy Biosciences has developed a platform technology for cost competitive conversion of lignocellulosic biomass to its mono-sugar components and lignin. This technology achieves a sugar production yields 90% that would at commercial scale cost less than Rs 15kg, a good Rs.10 cheaper than sugar from any other source. The plant design includes novel solid handling equipment especially suited for handling biomass intermediates at all stages of processing. Production of these chemicals using cheaper bio-based raw materials available from novel bio refinery concept can make breakthrough in market prices. Eventually, a pilot scale plant scale plant was set up and demonstrated for successful implementation of the technology.

Dr. Renu Swarup, Secretary DBT and Chairperson BIRAC inaugurated the pilot plant set up at Privi Biotechnologies, Mumbai

6. Facility for development of technologies culminating into commercial manufacturing of therapeutics made by fermentation processes (Anthem Biosciences Private Limited, Bangalore)

BIRAC has supported a specialized facility to foster innovation, development of technologies culminating into commercial manufacturing of therapeutics made by fermentation processes to Anthem Biosciences, Bangalore.

The multipurpose facility, is housed at Bangalore, and is meant to nurture development as well as manufacturing of global quality therapeutics. The facility would be used for the in-house development programs as well as for commercial manufacturing. Anthem intends to facilitate indigenous and innovative technology development, by encouraging Government authorized public and private institutions and companies to judiciously make use of the facility for their respective applications of national importance. The facility consists of a microbial fermentation unit having 75 L scale of fermentor& a cell culture facility of about 200 L scale of fermentor. The facility will be GMP

certified. The facility was inaugurated by Dr. Renu Swarup, Secretary DBT and Chairperson BIRAC in April this year.

List of Products/Processes/Technologies completed Early Stage Validation

1. **A technology for conversion of methane to single cell protein (String Bio)**

A technology to convert methane to single cell protein has been established and validated at 60 L with complete downstream processing. The product "String Pro" has Protein profile similar to fishmeal. It is a Non-GMO product and is Environment friendly and sustainable. Scale up studies are going on.

2. **Pilot demo plant based on conversion of faecel waste to fertilizer (Bactreat Environmental Technologies LLP)**

The project objective was to produce Terra Preta (TP) compost from fecal sludge through a two stage process involving lactic acid fermentation and vermicomposting. The technology was demonstrated for waste collected from one septic tank per day (8m3) at Baina Sewage Treatment Plant (Goa). Cost of production of compost was approx. Rs 9/kg.

3. **A green technology of solvent free extraction for purification of catechin from tea leaves (Baijnath Pharmaceuticals Pvt. Ltd.)**

The proposal aimed at industrial scale production of tea catechins (100 kg batch). The technology involves a solvent-free method for purification and extraction of tea catechins. The technology of catechin production from tea leaves has been transferred from the CSIR-Institute of Himalayan Bioresource Technology (CSIR-IHBT). Process optimization for purification of catechins at 100 Kg fresh tea leaves per batch (3 batches) at industrial partner's site was successfully completed replicating the process parameters established at CSIR-IHBT campus with 20 Kg.

4. **Anaerobic co-digestion developed for treating septage and leachate (Dr. Sankar Ganesh)**

A technology for co-treatment of domestic septage and municipal solid waste landfill leachate using dry-thermophilic anaerobic digestion for the production of bioenergy and biofertilizer has been demonstrated at 100 L. The reactor developed has Intelligent mixing and online monitoring mechanism.

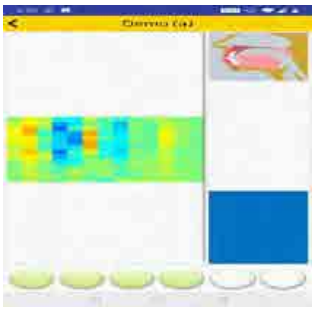
iv. Bioinformatics

BIRAC had supported seven proposals based on quality & final deliverables. Maximum fund is mobilized through the BIPP scheme, even though, number of projects are same in SBIRI & BIPP scheme implying Funded projects equally belong to both categories i.e. early stage development & product development. 5 IP's have been generated (3 Patents & 2 Trademarks). Currently 5 Projects are ongoing 78% funds are disbursed through the BIPP for bioinformatics sector. 58% projects have been successfully completed late stage validation. Rest of them are at early and late stage validation technologies.

Following are few bioinformatics technologies developed through BIRAC support:

1. **See Sound- A novel speech visualization tool for improving auditory perception and speech performance of hearing impaired children and adults using their visual cortex (4S Medical Research Private Limited)**

Development of See sound Live App, it is a novel speech visualization tool to improve speech performance and communication skills of a deaf and dumb person, currently relying only on sign language. See Sound Live uses its advantage, computing skills of a smart phone, to create a Visual Equivalent of the sound spoken. The brain is then trained to use this visual equivalent as a feedback of its efforts to speak.



2. Cloud based platform for creation of 3d printed Surgical Guides online (Osteo3d Pvt. Ltd)

A cloud based software platform for generation of patient specific 3d printed surgical guides for mandibular reconstruction. The platform enables efficient, affordable and accurate design and creation of patient specific guides for use by surgeons for fibula based reconstruction for patients suffering from Oral Cancer.

v. Technology upgradation

The technical group along with experts take the responsibility of continuously monitoring and mentoring the supported projects to meet their objectives. Technical group assigns nodal officers for each thematic area (to have overall understanding of projects from that theme) and technical officers for each project (to closely monitor the progress of the project). Further, they take the responsibility of achieving the goals for their respective projects. This close monitoring and mentoring has resulted in development of several process, technologies, commercialization of products/technologies, technology maturation of projects to Technology Readiness Level-7 (TRL-7) and filing of IPRs. Table below provides the number of details of the development of process, technologies & products facilitated, number of projects that reached TRL-7 and number of IP filed through BIRAC funding in the year 2018-19.

S.No	Category	Accomplished
1	Process/technologies developed, technology transferred & Products commercialized	19
2	Number of projects that have achieved Technology Readiness Level (TRL) of 7	29
3	IP filed	25

IP Filed:

The following Indian Patent applications were filed during 2018-2019:

4. Method, System and Monitoring Device for Managing Storage of Blood Bags in Blood Cold Chain (IN201841012703)
5. A Polymeric scaffold and implementations thereof (IN201831014946)
6. Development of snakebite detection kit and its use thereof (IN201841003902)
7. Process for the production of in vitro entomopathogenic nematode (EPN) and composition thereof (IN201841028784)
8. Articulating Guide to facilitate access in small anatomical areas (IN201841015921)
9. A system to allow compression and alignment of Tissue using balloons (IN201841015924)
10. Flocculant for sewage wastewater treatment (IN201841016111)
11. Ferric activated adsorbent for removal of arsenic (IN201841028681)
12. Coated Mesh for Hernia Repair (IN201811026236)
13. A Digital Device Facilitating Body Cavity Screening and Diagnosis (IN201823028816)
14. A Novel Process for production of recombinant peptides in prokaryotic expression system (IN201841034585)

15. Mass Multiplication of EPN (IN 201841046489)
16. Pattern Recognition by Convolutional Neural Networks (IN201831008797)
17. Speaking aid for hearing impaired (IN20181105125)
18. Nano-Fibrous Polyelectrolyte complex for rapid control of haemorrhage (IN201831026577)
19. An economical process of treatment of organic pollutants and heavy metals in industrial effluents using anaerobic microorganisms. (TEMP/E-1/2451/2019-MUM)
20. Live Attenuated Universal Influenza Virus Vaccines, Methods And Uses Thereof (201941008237)
21. System for renal puncturing assistance (IN201841043103)
22. Toxins targeted specific novel antisnake venom (IN201831038837)
23. System for detection of volatile organic compounds (VOC) in exhaled breath for health monitoring (IN201821016758)
24. Integrated process for biochemicals production from agro-industrial waste (TEMP/E-1/29862/2018-KOL)
25. A system for diagnosis and planning treatment for spinal deformities (IN201841020060)
26. A portable Slit Lamp (IN201941003637)
27. A system and method for the ablation of uterine fibroids (IN 201841028351)
28. Production Of L-2-Aminobutyrate From Pyruvate/Citramalate/Citraconate By Biotransformation And Cell Free System (IN201841037493)

II Entrepreneurship Development

1. Bioincubators Nurturing Enterprises for Scaling Technologies (BioNEST)

BIRAC is aware of the needs of the biotech start-ups in the country and our portfolio for entrepreneurship development includes not just funding but also support for bioincubation-a crucial determinant for developing a holistic ecosystem for biotech enterprises. Through the Flagship BioNEST scheme, BIRAC has extended funding support to 41 bioincubators across the nation. Each of these bioincubators have been selected based on an assessment matrix that evaluates their capabilities in supporting biotech ventures as well as ability to provide nesting grounds for the budding biotech start-ups. This is in line with the key strategies of BIRAC that are to foster innovation and entrepreneurship in all places of research, to promote affordable innovation in key social sectors with higher focus on start-ups and SMEs.

Each of the bioincubator is also creating building blocks of a bio-innovation ecosystem which will add value and foster the growth of biotech start-ups. Over the years BioNEST has been able to create the world class infrastructure and high end equipment facilities to bring global competitiveness in the Indian Biotech enterprises.

BIRAC under the BioNEST Scheme:

- Provides incubation space to start-ups and entrepreneurs
- Provides access to world class infrastructure and high end equipment facilities
- Connects industry and academia and enables interactions for efficient exchange of knowledge as well as facilitate technical and business mentorship
- Provides enabling services and required mentorship for IP and Technology Management, legal contracts, resource mobilisation and networking platform
- *BIRAC has supported 41 bio incubators creating a cumulative area of 4,41,349 sq. feet for budding entrepreneurs and created 6 Bio-Clusters.*

Impact created by BIRAC's BioNEST Programme

Over the years, BioNEST has been able to create a nurturing ecosystem for the budding biotech sector entrepreneurs and start-ups. Till now INR 272.26 crores of funds have been sanctioned and INR 182.97 crores has been disbursed under BioNEST. BIRAC has approved 41 bio incubators creating a cumulative area of 4, 41,349 sq. ft. for budding entrepreneurs. The incubators sanctioned during the FY 2018-19 are as follows: Foundation for Innovation and Social Entrepreneurship (FISE)- Delhi, TIDES- IIT Roorkee, SPMVV _ Women Biotech Incubation Facility Tirupati, Andhra Pradesh Med Tech Zone (AMTZ)- Vizag, Crescent Innovation & Incubation Council- Chennai, Institute of Advanced Study in Science and Technology (IASST)- Guwahati,

National Institute of Pharmaceutical Education & Research (NIPER)- Guwahati, Shanmugha Arts, Science, Technology & Research Academy (SASTRA)-Tamil Nadu, Mazumdar Shaw Medical Foundation (MSMF)- Bangalore, DPSRU Innovation & Incubator Foundation (DIIF)- New Delhi, Mizoram University- Aizawl.

S.No.	List of Bio-incubators supported under BioNEST
1.	Punjab University
2.	Foundation for Innovation And Technology Transfer, IIT Delhi
3.	Zonal Technology Management & Business Planning and Development Unit (ZTM-BPD), IARI, Delhi
4.	Birla Institute of Technology & Science, Pilani, Goa Campus
5.	B. V. Patel Pharmaceutical Education and Research Development Centre (PERD), Ahmedabad
6.	Ahmedabad University
7.	SRISTI Innovations, Ahmedabad
8.	Gujarat State Biotechnology Mission, Savli
9.	Regional Centre for Biotechnology, Faridabad
10.	C-CAMP, Bengaluru
11.	Bangalore Bioinnovation Centre, Bengaluru
12.	Indian Institute of Horticultural Research (IIHR), Bengaluru
13.	IKP Eden, Bengaluru
14.	Venture Center, NCL, Pune
15.	Society for Innovation and Entrepreneurship, IIT Bombay
16.	RiiDL (Research Innovation Incubation Design laboratory Foundation), SomaiyaVidyavihar, Mumbai
17.	KIIT-TBI, Bhubaneswar
18.	IIT Madras Research Park, IIT Madras
19.	Healthcare Technology Innovation Centre - IIT Madras
20.	Golden jubilee Biotech Park for Women Society, Chennai
21.	PSG-STEP, Coimbatore
22.	VIT-TBI, Vellore
23.	IKP Knowledge Park, Hyderabad
24.	SBTIC, Hyderabad
25.	a-IDEA, NAARM-TBI, Rajendra Nagar, Hyderabad
26.	University of Hyderabad

27.	ICRISAT, Hyderabad
28.	L.V. Prasad Eye Institute, Hyderabad
29.	IIIT Hyderabad
30.	SIDBI Innovation & Incubation Center, IIT Kanpur
31.	Foundation for Innovation and Social Entrepreneurship (FISE), Delhi
32	TIDES , IIT Roorkee
33	SPMVV _ Women Biotech Incubation Facility, Triupati
34.	Andhra Pradesh Med Tech Zone (AMTZ), Vizag
35.	Crescent Innovation & Incubation Council, Chennai
36.	Institute of Advanced Study in Science and Technology (IASST), Guwahati
37.	National Institute of Pharmaceutical Education & Research (NIPER), Guwahati
38.	Shanmugha Arts, Science, Technology & Research Academy (SASTRA), Tamil Nadu
39.	Mazumdar Shaw Medical Foundation (MSMF), Bangalore
40.	DPSRU Innovation & Incubator Foundation (DIIF), New Delhi
41.	Mizoram University , Aizawl

2. Sustainable Entrepreneurship and Enterprise Development Fund (SEED Fund)

Through Bioincubators BIRAC is able to support the "space, services and knowledge" requirements of start- ups, however there are wide gaps that exist in financial support required by a technology driven start-up in the initial phases. BIRAC's SEED Fund primarily aims to address these needs through BIRAC's BioNEST bioincubators.

The basic idea of SEED Fund is to provide capital assistance to start-ups with new and meritorious ideas, innovations and technologies. This would enable some of these start-ups to graduate to a level where they will be able to raise investments from angels/venture capitalists or they will reach a position to seek loans from commercial banks/financial institutions. The SEED fund support is positioned to act as a bridge between promoters' investment and Venture/Angel investment. Financial equity based support is provided to the start-ups and enterprises through bio incubators for scaling enterprises. Under the SEED fund programme:

- The SEED Fund Partner (Bioincubator) can invest INR 15 _ 30 lakhs per start-up against a small equity/equity linked instruments. Upon exit 50% of net returns will be retained by SEED Fund partner Incubator and 50% will be shared with BIRAC for it to plough back in the ecosystem.
- 13 BioNEST incubators have been provided upto INR 200 Lakhs for investing in Biotech Startups.
- Total Sanctioned Amount under the programme is INR 26.00 Cr., out of which INR 17.50 Cr. has been disbursed.

3. Biotechnology Innovation AcE Fund

BIRAC is implementing AcE fund on behalf of DBT. AcE (Accelerating Entrepreneurs) Fund operates as "Fund of Funds", which is mandated to foster R&D and innovation in Biotechnology domains (including areas such as healthcare, pharma, medical devices, agriculture, sanitation, clean energy etc.). Through AcE Fund, BIRAC partners and co-invests with SEBI-registered Alternate Investment funds (i.e. Venture Funds and Angel Funds) that are professionally managed to nudge them for investment in biotech sector. The main role of AcE Fund is to plug the gap of the "Valley of Death" encountered by the Biotech start-ups during their product development cycle and growth phase. AcE Fund will enable creation of an ecosystem that will provide risk capital to young enterprises to undertake research and development in high priority technology areas.

The Daughter Funds are committed to invest 2X amount of BIRAC's investment in biotech start-ups. The Daughter Funds supported by the AcE Fund will support start-ups at an early and growth stage that may be ready to receive pre-Series-A or Series-A funding with a minimum commitment towards start-ups in the biotech space. The Fund can make a maximum capital commitment of up to INR 30 crore or up to 30 per cent of the total aggregate capital commitment amount (i.e. fund corpus) in each daughter fund.

Under BIRAC's mandate, a daughter fund can invest up to INR 7 crore in a start-up against equity held by the Partner.

Under the AcE Fund initiative, INR 150 Cr has been sanctioned. BIRAC has identified 6 AcE fund partners and committed INR 82 Cr with the following distribution:

- Bharat Innovation Fund - INR 25 Cr
- IAN (Indian Angel Network): INR 20 Cr
- GVFL Ltd - INR 8 Cr
- Stake boat Capital - INR 5 Cr
- KITVEN Fund - INR 4 Cr

There has been a change in the status of the 6th partner identified therefore it has not been mentioned here. Expansion of AcE daughter funds is in progress.

4. Encouraging Youth for Undertaking Innovative Research through Vibrant Acceleration (eYUVA)

University Innovation Clusters (UIC) is an initiative of BIRAC to promote applied and need-oriented innovative research among young students. UICs are mandated to foster a culture of innovation and techno-entrepreneurship at University/Institution level. Five University Innovation Clusters have been set up as mentioned below :

1. **Anna University, Chennai**
2. **Panjab University, Chandigarh**
3. **Tamil Nadu Agricultural University, Coimbatore**
4. **University of Rajasthan, Jaipur**
5. **University of Agricultural Sciences, Dharwad**

Each UIC provides a pre-incubation space of 2000-3000 sq.ft. to selected fellows for conducting translational R&D. These fellows are at postgraduate/postdoctoral level and UICs provide mentorship and guidance to the fellows for setting up their ventures. 23 Innovation fellows have benefited through the UIC scheme. Major achievements are mentioned below :

- 8 Fellows incorporated start ups.
- 6 Fellows applied for BIG funding and 2 could secure the same.
- 5 Fellows have filed patent applications.
- Cluster forming efforts initiated at Anna University, Chennai (TN BioEconomy Cluster), TNAU, Coimbatore and Panjab University.
- UIC_Punjab University graduated and has added a Bioincubator supported by BioNEST scheme. Other UICs actively trying to expand to a full Bioincubator.
- UIC-Rajasthan University and UAS, Dharwad could secure State Government support by virtue of their being a UIC.

UIC Scheme is now being extended to support Undergraduate student teams for inculcating a culture of Biotech innovation research and development at UG level.

5. Students Innovations for Advancement of Research Explorations (SITARE)

Students Innovations for Translation & Advancement of Research Explorations (SITARE) Scheme is aimed at supporting innovative student (upto PhD) projects in the area of Biotechnology. The scheme is mandated to expand and populate innovation funnel especially early stage innovations for meeting unmet societal needs through frugal and sustainable approaches. The scheme is operated by BIRAC in partnership with Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI) and may be expanded to include other partners in future.

There are two components of the scheme as mentioned below :

- **BIRAC-SITARE Gandhian Young Technological Innovation (GYTI) Awards :** Under this component, 15 innovative projects, led by a student are awarded INR 15 lakhs each. This award is given for carrying out research work on an innovative idea for a period of 18 to 24 months.
- **BIRAC-SITARE Appreciation Awards:** About 30-40 students are awarded up to INR 1 lakh each for

carrying out research work in the area of grass root innovations. These awardees are identified through residential workshops of upto 4 weeks each conducted by SRISTI. This residential workshop programme is called as Biotech Innovation Ignition School (BIIS).

BIIS Workshop for Female students at SITARE, Ahmedabad

We now have more than 50 innovators supported under SITARE GYTI awards covering areas such as development of new antimicrobials, devices and diagnostics for resource poor settings, maternal and child health care, wastewater treatment etc.

During the BIIS Workshop, students are provided hands on training in various basic techniques of biochemistry, microbiology, phytochemistry etc. in collaboration with large institutions. One such workshop dedicated only for female students was organized at Ahmadabad during FY 18-19.

The partnership with SRISTI for GYTI Awards and Appreciation awards is now being converted to a scheme mode.

6. BIRAC Regional Innovation Centre (BRIC)

The BIRAC Regional Innovation Centre was established in partnership with BIRAC's BioNEST incubator IKP in 2013 and undertook the following activities in 2 Phases over the last 5 years:

- RIS Mapping for ten clusters
- Engaging with academia and start-ups on IPR through its IP and Technology Transfer Cell
- Entrepreneurial Capacity Building

During the initial 3-year period (2013-2016), BRIC focused on four life sciences clusters in southern India: Hyderabad, Bengaluru, Chennai and Thiruvananthapuram. With the successful completion of Phase I, a report on mapping the four innovation ecosystems was released. A similar exercise was taken up as part of Phase II of the study in six clusters in Central India: Ahmedabad, Mumbai, Pune, Bhopal-Indore, Bhubaneshwar and Vishakhapatnam. The Phase II initiative was a continuation of Phase I with the above mentioned objectives that were spread over 13 months (Dec., 2016 to Feb., 2018). A consolidated report on mapping of the ten clusters along with a set of policy recommendations to improve and enhance the performance of the clusters was released in October, 2017.

Based on the learning derived from the above studies and the effectiveness of such work in policy making, BRIC Phase III was initiated in 2018 to cover entire country by expanding the study to twelve additional clusters covering North and Eastern India and also two clusters in the West and South not covered in the earlier Phases. The Phase III study, along with the earlier reports, would provide a national level perspective of the status of life science innovation as well as variations in innovation capacity and maturity across clusters. The outcome of the study would provide insights along with recommendations that can be helpful for BIRAC in designing targeted programmes at the cluster level. The activities proposed in Phase III are:

- Mapping 12 established and emerging life science clusters mainly in North and East India. The clusters include Pilani-Jaipur, Mohali-Chandigarh, Shimla-Palampur-Solan, Delhi-NCR, Karnal-Rohtak, Dehradun-Roorkee, Lucknow-Kanpur, Allahabad-Varanasi, Kolkata-Kalyani-Kharagpur, Guwahati-Shillong-Tezpurand, Panaji-Goa and Mangalore-Manipal (that were not covered in the earlier Phase). This together with the earlier studies will provide a fairly comprehensive map of the Life Science Innovation Hotspots across India.

- Undertake a suite of entrepreneurship development activities that are specifically tailored towards the emerging clusters of innovation.
- Provide services around Intellectual Property and Technology Transfer to entrepreneurs and innovators.

BRIC Stakeholder Meeting at IKMC, Hyderabad

Open Dialogue

7. BIRAC Regional Entrepreneurship Centre (BREC)

The BIRAC Regional Entrepreneurship Centre (BREC) was set up in partnership with BIRAC's BioNEST incubator C-CAMP in the year 2016. The mandate is to create awareness and inculcate a spirit of bio-entrepreneurship, facilitate and catalyze the journey of biotech ideas of bio-entrepreneurs towards commercialization, enable and empower bio-entrepreneurs through business and technology advice and mentorship covering aspects of raising investments, legal, IP and market understanding.

In FY 2018-19, BREC conducted various awareness events, workshops, national level entrepreneurial challenges, boot camps etc. with a view to boost entrepreneurship in the Indian biotech sector.

Major activities conducted under BREC are as follows:

a. **National Life Science Entrepreneurship Awareness Programme for students:** Four awareness programs were conducted at following locations:

- Atal Incubation Centre, Banasthali Vidyapith
- IMA House, Kochi
- Institute of Science, Banaras Hindu University, Varanasi
- School of Life Sciences, NEHU, Shillong

Through these programmes, BREC reached out to over 700 undergraduate and post graduate students to excite them about bio-entrepreneurship as a positive career choice.

National Life Science Awareness Workshop at Varanasi

b. **BIRAC _ C-CAMP National Life Science Entrepreneurship Challenge (NBEC)-2nd Edition:** 2nd Edition of NBEC _a Nation-wide call for inviting innovative ideas across the country was launched on August 16, 2018. The call received over 2000 registrations from across the country. 180 applicants out of these were selected for regional qualifiers held at Bangalore, Delhi, Mumbai, Kolkata, Hyderabad and Chennai. Out of these, 42 finalists were shortlisted for 2 day entrepreneurship development and mentoring session at Bangalore. This session culminated into the final pitching by 15 selected participants. 11 industry partners were associated with NBEC in various capacities such as grand prize sponsor, investment partner, and mentorship partner. Cash prize and investment opportunity of upto INR 2.25 crores was made available to the winners.

Grand Finale of NBEC 2.0

c. **Entrepreneurship Development Boot camp Programme:** BREC organized a 4-day National Bio-Entrepreneurship Boot Camp from 5-8 September in Bangalore. Participants learnt to think strategically in selecting and managing projects, understand requirements of stakeholders and oversee the essential components of the commercialization process. Designed and delivered by eminent international faculty from the United Kingdom along with 14 domain experts from the country, the 2018 edition of National Bio Entrepreneurship Boot Camp was attended by 56 founders and co-founders of life science start-ups from across the country.

National Entrepreneurship Boot Camp

d. **Meet the Investor Series-Dragon's Den:** This programme includes a quarterly series of one on one meetings between investors and start up bio-entrepreneurs. The objective of this series is to initiate and catalyse interactions between start-ups and investors by providing them a common platform. BREC organized 4 such meetings during the year through which over 200 one-on-one meetings between start-ups and investors were set up.

Investors Meet

e. **Entrepreneurship Development Workshops:** BREC organized 5 such workshops on different topics during the FY 18-19 at the following locations:

- Value-Added Agriculture, Bangalore
- Understanding Investor Term Sheets, Chennai
- Demystifying the Cost, Value & Price Triad of Biotech Products & Services, Bangalore
- ESOPs, Founder's & Employment Agreement & More, Pune
- How to Develop and Deliver an Effective Pitch, Bangalore

Through these workshops, BREC provided valuable domain specific knowledge to more than 200 start-ups and entrepreneurs across the country.

Entrepreneurship Development Workshop

8. BIRAC Regional Bio-Innovation Centre (BRBC)

BIRAC Regional Bioinnovation Centre (BRBC) at Venture Centre, Pune is mandated to be a high quality national resource center to support and promote Entrepreneurship in Life Sciences.

The centre conducted following activities during FY 18-19:

- **Venture Mentoring Service:** This activity is aimed at creation of high level mentor pool for networking and match making with prospective and experienced entrepreneurs. During the year 18-19, BRBC organized 6 mentor match mixers reaching out to 150+ beneficiaries and engaged 50 mentors. As a follow up of the mentor mixers, more than 100 one on one clinics with mentors were organized.
- **Venture Base Camps:** BRBC conducted 3 base camps during the year on following topics:
  - Intellectual property and licensing strategy
  - Regulatory processes and certifications
  - Raising money for your startup

The camps benefitted 100 entrepreneurs/start ups.

4 Day Venture Base Camp on Fund Raising at Venture Center, Pune

- **Regulatory Information and Facilitation Center (RIFC)**: Through RIFC, BRBC facilitates a seamless, personalized approach for entrepreneurs in understanding the regulatory approval process for biotech products in India. During the year 18-19, 4 Regulatory clinics and 1 international workshop were conducted. More than 170 entrepreneurs and start-ups benefitted through the clinics and workshop.

Dr. Arvind Savargaonkar, Founder & CEO at Streben Healthcare Private Limited addressing participants about grouping, safety and performance of medical devices

Dr. Rubina Bose, Deputy Drugs Controller (I), CDSCO (West Zone), Mumbai interacting with a participant

- **BioIncubation Practice School for western regions**: Incubation Managers from 11 incubators including recently approved and newly formed BioNEST incubators were trained with good practices for bioincubation during the year 18-19. The immersion programme focused on following topics:
  - Relation between Incubator and host institution

- Drawing a roadmap based on inputs, outputs, outcomes, activities and resources
- Formats of incubation: physical vs. virtual vs. associate
- Creating a pipeline of incubatees
- Types of incubatees to focus on: competencies leveraged, industry focused, market focused, customer focused, women centri.
- Sustaining the incubator

Day 1 of Incubation Practice School

Incubation Manager receiving certificate on successful completion of Incubation Practice School

- **City Camps:** 2 City Camps were organized providing an overview of the essentials of scientific entrepreneurship. The camps were held at PSG-STEP, Coimbatore and PERD, Ahmadabad. The city Camps were attended by more than 100 entrepreneurs/start ups focused on topics such as Fund raising, company formation, IP, Legal, Regulatory Requirements, Business Strategies etc.

City Camp on "Essentials of Scientific Entrepreneurship" at PSG-STEP, Coimbatore

9. BIRAC Regional Techno-Entrepreneurship Centre for East & North East_ BRTC (for E & NE)

BIRAC's 4th Regional Centre in partnership with BIRAC's BioNEST incubator KIIT-TBI was rolled out in March 2019. This center is mandated to boost biotech entrepreneurship in North East and East region of the country. A focused effort would also include promoting Women Entrepreneurship and Social Entrepreneurship in the region. Activities to be undertaken by BRTC include:

- Mining and assessment of Techno-commercial resource pool in East & NE regional
- Human Resource Development Programmes
  - Road shows
  - Workshops training
  - Design workshops

- o NE Immersion Program
- o NE Showcase Event
- o Hands-on training for rural women
- o Incubation Practice School for NE

The launch of BRTC was announced during 7th Foundation Day of BIRAC.

Launch of BRTC: Dr. Mrutyunjay Suar, CEO, KIIT-BioNEST & Head, BRTC talking about BRTC mandate during BIRAC's 7th Foundation Day

III Affordable Product Development

1. Early Translation Accelerator (ETA)

BIRAC is supporting Early Translation Accelerators (ETAs) to focus on catalyzing transformation of young academic discoveries (publications/patents) with possible commercial and societal impact into economically viable ventures and technologies. The aim of the ETA is to add translational component to establish proof-of-concept/validation and to attract industry to take these validated technologies further in terms of development and is expected to collaborate with academic investigators, engage industry and to leverage international translation ecosystems. Although commercialization of early stage technologies is a difficult task, adding this translational component to establish proof-of-concept/ validation is a big step towards attracting industry to take these validated technologies further in terms of development.

The ETA is being created to act as an interface between academia and industry, with the main objective of identifying academic ideas with commercial potential and finding a suitable industrial partner for technology transfer and commercialization. The ETA will not only act as an interface, but also play an active role in further developing lab-scale ideas and tailoring them to suit industrial requirements. The network developed by the ETA with academia and industry and the modalities developed for translational research and technology transfer will make the ETA as an attractive proposition to be leveraged by academia as well as industry. The key goal is to develop and showcase this platform at a bioincubator which can be replicated at other places and lead to a strong nexus between academia and industry.

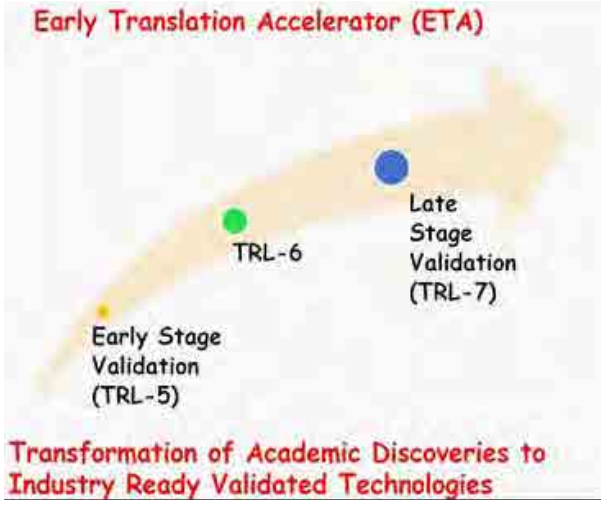
Towards achieving this BIRAC has already supported healthcare ETA at C-CAMP and Industrial Biotechnology ETA (ETA-IB) at IIT-Madras.

A total of three projects were selected and supported under the health care ETA at C-CAMP. These are as follows:

1. Platform for improved erythropoietin (EPO)
2. Validation of novel compounds in neuro-degenerative diseases
3. Validation of novel Self-assembled short peptide based nanomaterials for Glioblastoma therapy.

All the project under ETA _ healthcare at C-CAMP has been completed. A process and product patent filed in the first project at C-CAMP i.e. Lentiviral Vector Platform for improved Erythropoietin expression concomitant with shRNA mediated host cell elastase down regulation has been completed. The technology has been taken by Sekkei Bio Private Ltd. Patent filling for the other two projects are underway.

The second ETA for Industrial Biotechnology (IB) has been established at IIT-Madras in 2017-18. The ETA-IB involved the development of a structure for translational research, and technology development for production of industrially important proteins and metabolites, from natural and recombinant systems. There were total four projects supported under this areas.



2. Research Alliance for Product Innovation and Development (RAPID)

i. BIRAC - USAID _ ICAR _ Development of climate resilient wheat cultivars

BIRAC in the year 2016-17 in partnership with USAID and Indian Council for Agriculture Research (ICAR) had initiated a five year long project for development of high-yielding, heat-tolerant wheat cultivars appropriate for the Indo-Gangetic Plains. These new varieties were proposed to be developed by building upon the available resources and breeding materials by utilizing data from model systems and currently available modern breeding, genetic, genomic, physiological, and biochemical tools.

The specific objectives of the project include a) Optimizing marker assisted background selection (MABS) at the partner institutions and transfer of already available and newly discovered QTLs for heat tolerance to popular, elite wheat cultivars grown in the Indo-Gangetic Plains, b) Identifying and developing user-friendly DNA markers for the heat tolerance by evaluating wheat germplasm, c) Pyramiding various individually introgressed genes and QTLs controlling complementary modes of heat tolerance by doubled-haploid approach to further increase the heat tolerance of the cultivars d) Understanding physiological basis of heat tolerance and e) Establishing an objective-oriented and targeted approach to train graduate students and junior scientists.

In Washington State University, the selected lines have been evaluated for drought stress tolerance and double haploid populations have been developed. These have been evaluated for heat tolerance under the controlled condition screening. Screening of three more populations under controlled condition is being planned. The protocol has now been shared with the Indian partners who have controlled condition facility to use it to screen their respective BC1 populations.

Drought tolerant wheat lines

ii BIRAC-QUT, Australia _ Bio-fortification and disease resistance in Banana

BIRAC has supported a technology development and transfer program for bio fortified and disease resistance banana from Queensland University of Technology (QUT), Australia with overall aim to address food and nutritional security through bio-fortification.

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 (FOC) and Banana bunchy top virus (BBTV)).

The program's objectives are being jointly translated by 5 Indian research organisations namely, National Agri-Food Biotechnology Institute (NABI), National Research Centre for Banana (NRCB), Bhabha Atomic Research Centre (BARC), Indian Institute of Horticultural 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. Evaluation and initial results of agronomic & yield performance of main crop plants and distinctness, uniformity and stability (DUS) testing for PVA are have shown promising results. The ongoing work on FOC and BBTV too is quite encouraging.

Provitamin A expressing transgenic Banana at NRCB net house

iii. Secondary Agriculture

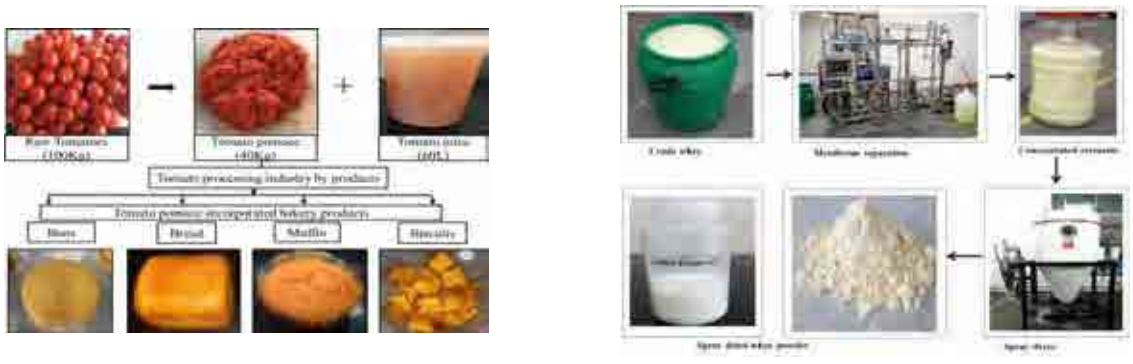
The Punjab State Council for Science & Technology (PSCST) and Panjab University have joined hands with three premier Central agencies to develop agricultural technologies with an aim to enhance farmers' income and promote crop diversification Biotechnology Industry Research Assistance Council (BIRAC) would help the state in setting up the secondary agriculture entrepreneurial network for early translation from primary to secondary agriculture under the secondary agriculture entrepreneurial network. The Network was jointly launched by Dr. Renu Swarup, Secretary, Dept. of Biotechnology (DBT), Govt. of India and Sh. Karan Avtar Singh, IAS, Chief Secretary, Govt. of Punjab . The project aims at promoting new enterprises and to support existing industry in the secondary agriculture sector.

The initiative will develop technologies such as value-added products from tomatoes and anthocyanin-rich wheat (anti-oxidants). It will also lead to development of technologies for enhancing shelf life of fruits and curbing stubble burning. After laboratory success and validation, the technologies will be transferred to the industry for commercial exploitation. The strategic initiative is to support the food processing industry and promote start-ups in the Agri food sector.

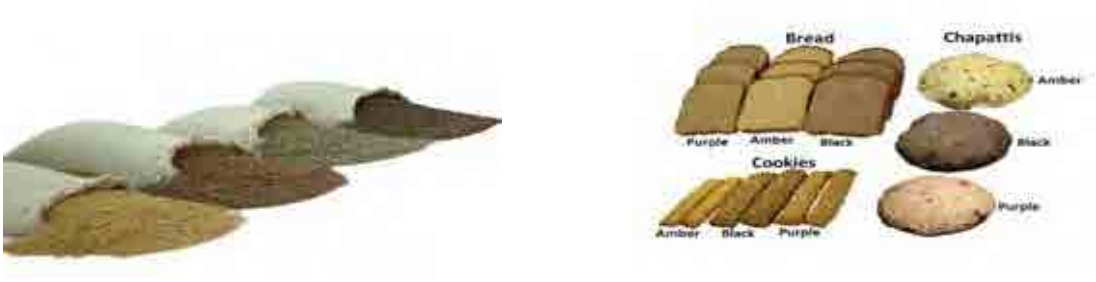
The project will also assess the unmet needs of the Agri-food industry and develop technological solutions for the agricultural sector. The project will validate technology and provide support for its commercialisation.

The multi-agency efforts are led by PSCST. Other partners are National Agri Food Biotechnology Institution (NABI), Centre for Innovative and Applied Bioprocessing (CIAB) and BioNest_Panjab University as the partner institutions. A special call was launched to invite proposals under secondary agriculture.

Few of the technologies supported are shown in the below figures.

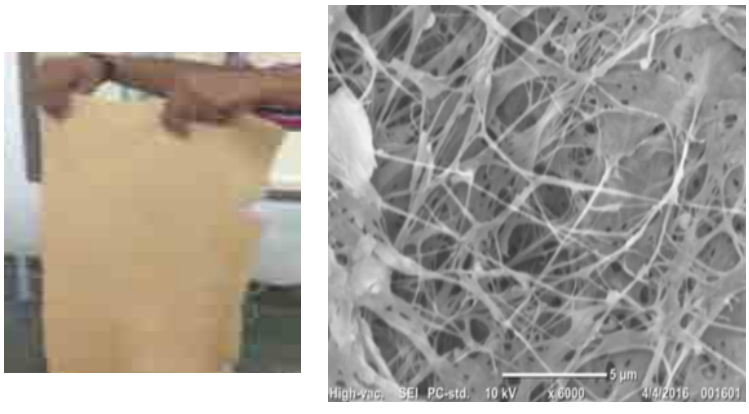


By-products of tomato processing industry and illustration of ultra-filtration membrane reactor at CIAB



Chapatti and Biscuits and bread prepared from Purple, Black and white wheat

Up-scale production of L-Arabinose Isomerase in a 14 L bioreactor. SDS-PAGE of Ni-NTA purified recombinant L-arabinose Isomerase protein.



Bacterial cellulose obtained from liquid whey and SEM image of obtained bacterial cellulose.

iv. Waste to Energy Mission

BIRAC with core competency as a knowledge provider can bring about a transformational change in the sanitation condition of the country by fostering and nurturing innovative technologies for Waste treatment, disposal and conversion to value added products. BIRAC can institutionalize a major role in identifying appropriate intervention themes including:

1. Facilitating the development of technologies that could be commercialized or scaled up within a specified time frame.
2. Formation of commercially viable model for waste management services.

To take this program forward, BIRAC had announced a call for proposals on Waste to Value under the 8th Call of SPARSH. Proposals are at the stage of short listing.

v. Program on synthetic Biology

The area of Synthetic Biology today requires special attention in view of the enormous applicable potential. Since synthetic biology is an emerging technology, BIRAC has supported a program on "Synthetic Biology for transition towards a bio-based economy". The main aim of the program is to generate joint research, development and commercialization activities.

7 proposals have been recommended for funding and first release has been made for 5 projects. Second call for proposals has been announced.

IV. Partnerships

a. Co-funding Partnerships

A. International

a). Wellcome trust

BIRAC has collaborated with the Wellcome Trust, a global charity based in the United Kingdom, to scout and support innovations in translational medicine in the domain of diagnostics for infectious diseases. The objective of this initiative is to fund translational research projects to deliver safe and effective healthcare products for India at affordable costs through collaborative research. Two proposals have been funded from the first call. The proposal on 'High Sensitivity Multiplex point-of-care assay systems for the detection of blood borne infections in emergency setting' is pursued by THSTI-Designinnova-University of Turku-Kaviogen whereas the second proposal on 'A Bench side molecular assay for detection of carbapenem resistant gram negative bacteria' is pursued by VITAS Pharma. VITAS proposal, has been completed and focused on developing a molecular diagnostic assay, based on Loop-mediated isothermal amplification (LAMP), for the detection of Carbapenem resistant Gram negative bacteria (CRGNB). LAMP based assays were found to be sensitive enough to detect the resistance in patients samples and they have performed multicentric trials (approx. 1800 isolates). The other proposal from THSTI focuses on developing a multiplex point-of-care assay system for the detection of blood borne infections with high sensitivity such as HIV, HCV, HBsAg and HCV core antigen. These projects are regularly monitored. BIRAC is planning to announce a call in collaboration with the Wellcome Trust in 2019-2020

b) CEFIPRA and Bpifrance

BIRAC has joined hands with CEFIPRA _ the Indo-French Centre for Promotion of Advanced Research in India to support high quality bilateral research, encourage and enable Indo-French collaboration between public, private research groups, industry, clinicians and end-users. Under this initiative, BIRAC has implemented two partnership programs, one with the French Embassy (2014-2015) and another with Bpifrance financement (2015-2016). The two calls have been launched till date under two joint partnerships under the collaboration i.e. BIRAC CEFIPRA FRENCH EMBASSY and BIRAC CEFIPRA Bpi France program

The first call in collaboration with French Embassy was announced during 2014 and two projects were selected for funding in the areas of molecular diagnostics for cardiovascular diseases. One project has been completed from first call and has developed mAbs against oxidized ApoA1 which could recognize the human, mice and rabbit atherosclerotic plaques. These monoclonal antibodies were developed for the screening validation of CVD patient sera, atherosclerotic plaques of CVD patients.

The second call with French Embassy was launched in the areas of Molecular diagnostic for prediction of Alzheimer's & other dementia, new assisting technologies for mobility of physically challenged (incl. prosthesis and robotics applications) and biomaterials & cell engineering for health applications. One

project has been recommended and awarded in 2016-17 which is working on designing an electrochemical immunosensor for the detection of Amyloid Beta in Biological Fluids of Alzheimer's Patients. This project is going to complete in June 2019. All these projects are continuously monitored.

Bpi-France financement is a public investment bank which finances businesses from the seed phase to transfer to stock exchange listing through loans, guarantees and equity and provides support to innovation projects. The call for proposals has been launched in the area of digital health & individualized medicine and one project has been recommended for funding in 2016-17 which will be monitored in 2017-2018. The ongoing proposal is working on developing a simple telemedicine tool that can be used by patients and their family and professionals which allows to connect examination devices: blood pressure cuff / sphygmomanometer, thermometer etc.

BIRAC will launch the third calls in each partnership in 2019-2020 after deciding upon the scope of future calls and themes aiming to promote interaction between potential French and Indian participants.

C) USAID IKP-TB

BIRAC is supporting new diagnostics for TB in collaboration with IKP/USAID. IKP has entered into an agreement with USAID and secured a grant to support "Innovations in tuberculosis (TB) control in India" at a 1:1 leverage with funds raised by IKP from other sources. The first call for proposals from IKP focussed on addressing the problem of treatment adherence in collaboration with BMGF.

Six proposals have been selected for funding in the first phase of the program i.e. in 2015-16 and funds were released to IKP. The projects that are funded in the first phase are in the areas of novel methods for MTB sample collection, detection of infection by X-ray scattering, real time detection by Smart Genie, diagnosis using biomarker signatures and non-invasive & biomarker based triage test for TB. The phase I is complete and as per the review of the progress of the projects three projects have been selected for the second phase of the program. They are a) A filter paper based method of MTB sample collection, transportation and storage at room temperature b) NextGen Real time MTB LAMP detection by Smart Genie and c) Biomarker-based triage test for TB.

The three phase II projects are complete wherein project A and B have successfully reached TRL 5 and project C was able to reach TRL 3 and a follow on funding under BIPP scheme.

d) Nesta

BIRAC has collaborated with NESTA, a UK based innovation foundation, for creating a pipeline of innovators for the Longitude Prize, in the area of Anti-microbial Resistance (AMR). Longitude Prize is a £10 million prize fund to be awarded for creating an affordable, accurate and rapid point of care test that will allow health professionals worldwide in decision making for the use of right antibiotics at the right time. Under the ambit of BIRAC-Nesta partnership, 2 calls were announced for BIRAC- Discovery Award Fund (DAF) during FY 16-17 and 17-18. Nine teams were identified through the two calls and awarded £15,000-20.000 each. These teams are amongst a total of 78 teams from 14 countries competing for Nesta's Longitude Prize.

To further enhance the chances of Indian teams winning Longitude Prize, BIRAC in F.Y. 18-19 announced BIRAC Boost Grant of upto £ 100,000. All Indian teams competing for Longitude Prize were invited to participate in a two day long residential accelerator programme at Society for Innovation and Entrepreneurship (SINE), IIT Bombay. The programme was conducted with involvement of international faculty and provided necessary guidance for technical, business, regulatory and clinical aspects and tips for overcoming hurdles in the development of their diagnostic tests. The teams pitched in front of a jury and 3 start-ups were selected for BIRAC BOOST GRANT Award.

The winning teams included:

- Module Innovations, Pune - Usense™ developed by Module Innovations is a credit card size test, which detects four major uropathogens in a single test. The results are seen in 30 minutes and the test can be done at the point of care itself, with results visible to naked eye.
- NanoDx, Delhi and Hyderbad- The team is creating a point of care test called Septiflo that can detect and stratify the Gram status of bacterial infections in a drop of human plasma in under 10 minutes. Results are visible to the naked eye and semi-quantified using a color score chart.
- OmiX and Spotsense, Bengaluru -The collaborative teams are creating a non-invasive diagnostic test using salivary markers of infection as the basis for diagnostics. The assay goes from sample to result (currently) in 60 minutes. Detection is through digital camera readout of a colorimetric signal.

BIRAC Boost Grant Winners

B. National Partnerships

a. Ministry of Electronics and Information Technology, Government of India (MeitY)- Industry Innovation Programme on Medical Electronics (IIPME)

Industry Innovation Programme on Medical Electronics (IIPME) is a collaborative project between the Ministry of Electronics and Information Technology, Government of India and Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology, Ministry of Science and Technology, Government of India. The project is mandated with funding a portfolio of Indian led projects that target innovations in the multi-disciplinary areas comprising of electronics, engineering, medical devices, healthcare, software, algorithms and information technology.

IIPME was initiated in February, 2015 to help address the challenges of the medical electronics fraternity and to bring in fast-paced research and development in this hitherto untouched area. The call for proposals was announced in the following areas:

- Imaging and navigation
- Technologies for chronic diseases
- Convergence of medical device and bioinformatics
- Increasing the outreach through Medical electronics

There were two calls announced in 2015 and 2016 and a total of 288 proposals were received. Through three rounds of evaluation between 2015 and 2017, 34 projects were supported under three categories a) Seed fund b) Early Transition c) Transition to Scale. Twelve projects have been successfully completed and seven more projects are nearing completion. Many of the supported projects have reached technology maturation and achieved success in generating early stage technology/prototype, completing clinical validation and even market launching. There were few new IP generated from supported technologies during the project period in the form of patent or design registration. Some of the successful projects from the IIPME scheme have received recognitions and awards at many national and international platforms as promising technologies. Few successful outcomes from the projects supported under IIPME are listed below:

1. **Smartscope- Transvaginal Digital Colposcope (Periwinkle Technologies Pvt. Ltd)**

Transvaginal Digital Colposcope, Smart Scope®, along with the image analysis software Net4Medix has been developed after iterative version design & verification. Smart Scope was used to screen 600+ patients qualified as per criteria of age, sexual activity, pregnancy status, surgical status at Tata Memorial Center Mumbai, Deenanath Mangeshkar Hospital & Research Center, Pune and Lavale RHTC by BVDU Medical College and the device has been proven to have over 90% sensitivity compared to conventional methods. Periwinkle technologies has obtained ISO

13485 for manufacturing of Smartscope. Trademarks Smart Scope ® and Net4Medix® and one Indian patents have been granted during the project and two more patents have been filed on the technology. Product was launched at 7th BIRAC Foundation day by Dr. Rajeev Kumar, Hon. Vice-Chairman, Niti Ayog, Government of India.

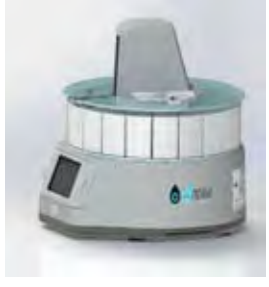
2. **Fever Watch with Respiratory rate monitoring for NICUs (Helyxon Healthcare Pvt. Ltd)**

HELYXON has developed FEVERWATCH FW device which continuously monitors temperature of a baby through a small form factor wireless device for home and hospital scenarios at affordable price. Through IIPME support FEVERWATCH was added with further advanced features like continuous wireless monitoring of respiratory rate and easy usability by the combination of thermistor and 3D accelerometer sensors with on-chip algorithms. Such a device will be first-of-its-kind in the market and address an existing social & economical market needs like improving IMR Infant Mortality Rate. A supporting mobile app was also developed to manage the sensor and provides the interface between the user and the cloud. The developed device was validated in a pilot clinical study at NICU at hospitals in Chennai.

3. **Compact Mobile Digital X-ray (Iatome Electric India Pvt Ltd)**

Iatome has developed a highly mobile X-ray unit for diagnostic radiography. It is lightweight and easy to move and convenient for bedside x-ray such as those needed at emergency room or ICU. The product will be a secondary or standby unit for large hospitals with fixed regular units. The differentiator is the use of engineering to make the typical components smaller and thus reduction in overall size of unit. Internal validation is done by in-house team. Regulatory approvals are in place from BIS and AERB and few units are placed at hospitals and clinics for feedbacks.

4. **AutoPAP Stainer & Whole Slide Imager system(Aindra Systems Pvt. Ltd)**



Aindra systems has developed CervAstra system (Autostainer, VisionX, AI Algorithm) where a field ready Autostainer IntelliStain has been developed and third part validated at multiple centres at clinical settings. The Whole slide Image Acquisition system, Vision X along with the AI software has been developed and is undergoing inhouse verification testing using real patient slides for improving the sensitivity and specificity. Aindra is an ISO13485 company and IntelliStain is ready for commercialization.

5. **KEYAR-Wearable Uterine Contraction and Fetal Heart Rate monitor (Janitri Innovations Pvt. Ltd)**Janitri Innovation has developed KEYAR- a wearable Uterine Contraction and FHR monitoring device along with associated algorithms for digitalizing the intrapartum monitoring process in primary health settings. Through IIPME the company has completely developed the Uterine Contraction device and compared the Uterine EMG signals obtained against cardiotocography signals from studies on pregnant cases. They have optimized the design of the abdominal sensor patch along with the arrangements of sensors. Currently the device has been validated for intrapartum monitoring at more than three hospitals in Karnataka and Kerala to achieve over 93% sensitivity and over 85% accuracy. Janitri has filed Indian patents on the technology and Sensor patch design has been registered.

Based on the success of IIPME phase 1, BIRAC with support from MeitY is proposing to launch a Phase II of IIPME scheme during FY 2019-20.

b. Bio-toilets in North Eastern India

Given the central importance of sanitation and hygiene in India and in light of the Swachh Bharat Abhiyan, it is important to explore sanitation solutions from different sources. The Department of Biotechnology funded a program from The Energy and Resources Institute (TERI) North Eastern Regional Centre, Guwahati to install 100 toilets in schools in North Eastern India, and BIRAC is mandated with the implementation, management and coordination of the entire project.

Biotoilet in a school in Manipur

The proposal aimed at phase wise installation of 100 toilets and exploring the scale-up option for indigenously available technologies such as bio-digestor technology.

All the 100 toilets have been installed. The state wise break-up for the installed units is as follows: Assam: 35; Tripura: 15; Mizoram: 10; Manipur: 10; Nagaland: 5; Sikkim: 5; Arunachal Pradesh: 5; Meghalaya: 15 Data generation and analysis is ongoing.

b. Networks, Platforms and Market Access

i. WISH

BIRAC has partnered with Lords Education and Health Society (LEHS) through its Wadhwani Initiative for Sustainable Healthcare (WISH) for accelerating innovations and enterprise scale up for sustainable healthcare delivery systems in primary health care centres through State Governments. The main objectives of this partnership are to:

- Identify and assess need based, high potential innovations and demonstrate their technical worthiness for scale up
- Conduct field test beds for demonstration of innovations within public health service delivery system
- Build effective partnerships to identify and nurture innovations
- Facilitate introduction and connect of innovators with public procurement initiatives
- Build an innovation ecosystem to accelerate scale-up of innovations

Taking this partnership forward,4 innovations were given to WISH Foundation for the validation purposes in the field test beds of Primary Healthcare Centres. These centres would help to create a pipeline for the state governments to systematically induct promising and high impact innovations on continuous basis.

Four technologies undergoing field validation studies are as follows:

1. **Accurate Tele-ECG On Mobile (ATOM), Cardea Biomedical Technologies Pvt. Ltd.:** The device generates a report of simultaneously recorded medical grade 12-lead ECG signal in a pdf format which can be shared to a doctor.
2. **Sohum, Sohum Labs:** Detection of hearing impairment in neonates to avoid a preventable disability. It is based on Brainstem Evoked Response Audiometry (BERA) and eliminates the use of sedatives during the procedure.
3. **Aina, Jana Care:** A low powered device to measure glycosylated haemoglobin, blood sugar, lipid and creatinine from a drop of blood and applied to a single-use test strip. It works in conjunction with smartphones.
4. **Pathsodh:** A point-of-care device for Diabetes management.

Launch at Jaipur, Rajasthan

Signing of Agreement

ii. BIRAC-ICMR

BIRAC and ICMR has signed a MoU, wherein, both the parties decide to establish a collaborative framework under which both can carry out activities related to the exchange of best practices and setting up of coordinated support measures to foster technology and knowledge transfer and cooperation for validation studies.

BIRAC and ICMR together has formulated a model whereby BIRAC supported start-ups can validate their innovations by leveraging ICMR's labs, research facilities and associated resources. The proposed model will enable BIRAC supported startups and SMEs to use ICMR's resources.

It was agreed that Clinical validation studies for BIRAC supported products/technologies can be performed through ICMR clinical trial network.

BIRAC has sent a list of 19 projects which have reached at least TRL6/7 and are ready for human clinical investigations. As informed by ICMR, they will take forward 5-6 projects in Phase-I for clinical validation/ trials. In order to review the data available for these technologies, an advisory committee meeting was organised at ICMR, which was chaired by Dr Balram Bhargava.

Out of the five discussed technologies, two were shortlisted for clinical validation at ICMR centres. Axxonet has submitted a proposal for multi-centric trials to BIRAC. Four centres have been identified and PIs are shortlisted for the trial. The clinical trial will commence in next few months.

iii Business Finland

BIRAC - DBT have entered into a tripartite partnership with Finnish Innovation Agency _ Business Finland for leveraging the expertise and ecosystem in Finland to boost the capacity and network of the Indian Start- ups. In December 2018, BIRAC participated in the 10th edition of SLUSH series at Helsinki, Finland. Two BIRAC supported start-ups along with BIRAC representative participated in the event, which provided them a platform to meet numerous international investors, participate in various talks, interviews, panels etc.

Signing of MoU between DBT, BIRAC and Business Finland

On 3rd December there were pre- SLUSH side events which included Founders day workshop, roundtable meeting with investors. The workshop was conducted by reputed firms like techstarts and business mentors which were from around the global firms. The workshop gave understanding to founders, how to study & read the potential customers and market before introducing and scaling the product in the market.

BIRAC start-ups also attended networking dinner hosted by Hon'ble Ambassador of to India. This opportunity gave them to meet various Industry leaders from India as well as from the Finland ecosystem.

SLUSH gave good international exposure to BIRAC supported start-up to meet and interact with various parts of world & discuss issues that are common to others.

iv. The Indus Entreprenuers (TiE - Delhi NCR)

BIRAC has partnered with TiE-Delhi NCR to leverage each other's strengths for mentoring biotech startups and providing continuous platform for BIRAC supported startups to interface with funders and investors.

Under the umbrella of this partnership, BIRAC and TiE jointly organized two sets of activities during the FY 2018-19 as mentioned below :

- **BIRAC _TiE WInER Award**: BIRAC and TiE launched an award focused at rewarding the women entrepreneurs in biotechnology. The award is named as **WInER** Award **(Women In Entrepreneurial Research)**. 15 women entrepreneurs were selected and awarded with 5 lakhs each on the BIRAC's 7th Foundation Day. The awards were conferred upon by Dr. Rajiv Kumar, Vice Chairman, NITI Aayog, Govt. of India, Dr. Renu Swarup, Secretary, DBT & Chairperson, BIRAC and Dr. Mohd. Aslam, Advisor, DBT & MD, BIRAC. The awardees would also receive access to a residential accelerator programme for regulatory, IP, licensing, fund raising, mentoring; additionally a chance for top 3 women entrepreneurs to win final award of INR 25 lakhs each.

15 WInER awardees with Dr. Ted Bianco, Dr. Renu Swarup, Dr. Mohd. Aslam, Dr. Rajiv Kumar, Dr. Chris Karp & Dr. Manish Diwan

- **BIRAC-TiE Entrepreneurship awareness workshops** : Six workshops for students were organized in different tier 2 cities: Jammu, Patna, Jaipur, Shimla, Indore, Dehradun. The workshops witnessed an attendance of over 400 students and were highly appreciated.

BIRAC-TiE Entrepreneurship Awareness Workshop at Shimla

v. PerkinElmer Inc.

BIRAC partnered with PerkinElmer, Inc., USA with the intention to promote the portfolio of 'Indian led revenue based innovations/start ups' in multidisciplinary areas comprising medical devices, point of care, algorithms and information technology/software in thrust areas including maternal health, new born health and food, to support innovators for funding, mentorship and incubation space. With close association of PerkinElmer, industry partner from an early stage, the innovators would gain from business mentorship and validation of the product/ technologies to enhance global competitiveness. A change in leadership at Perkin Elmer's US and India offices has affected implementation of intended activities.

c. BIRAC Innovation Challenge Award

BIRAC launched an Innovation Challenge Award, SoCH i.e., Solutions for Community Health on 22nd September, 2017. Innovative ideas from individual entrepreneurs, academia and companies were sought under two themes aimed at developing viable solutions to address certain challenges in the Community Health Sector. The following two themes were identified for the SoCH award through an open discussion on MyGov Portal:

1. Platform technologies for reducing disease burden (Communicable & Non-Communicable Diseases).
2. Sanitation and Waste recycling.

Proposals were received from all over the country under both the themes. Best 49 proposals were shortlisted for Hackathon and Ideathon to identify Top 10. These 10 early winners were awarded Rs. 15 lakhs each. They also received Incubation opportunity for a period of 6 months to develop Minimal Viable Prototype (MVP) in BIRAC's BioNEST-incubators along with access to high end instrumentation facilities, technical, legal, IP and business mentorship.

In FY 2018-19, BIRAC announced the 2 final winners (1 from each theme) of SoCH. The award included a sum of Rs 50 lakhs to each winner and technical & business mentorship opportunity at one of the BIRAC's BioNEST-incubators. The winners were felicitated on the 7th Foundation Day of BIRAC and their names are as follows:

1. Bodhisattwa Sanghapriya, developing a Smartphone Based Low Cost Point of Care Device for Early Screening of Breast Cancer.
2. Ajinkya Dhariya, developing an Eco-Sanitary Pad Disposer.

SoCH awardees with Dr. Mohd. Aslam, Dr. Renu Swarup, Dr. Rajiv Kumar, Dr Ted Bianco,Dr. Chris Karp & Dr. Manish Diwan

V. Extramural Project Management Units

i. Program Management Unit at BIRAC - a partnership of the Department of Biotechnology, the Bill & Melinda Gates Foundation, the Wellcome Trust.

Grand Challenges India (GCI), managed by the Program Management Unit at BIRAC is a partnership of the Department of Biotechnology, the Bill & Melinda Gates Foundation and the Wellcome Trust.

Launched in 2012, GCI aims to direct funding and research to address some of the most daunting health and development challenges we face today. It does this by fostering Indian-led innovation to develop affordable and sustainable solutions to these challenges, both in the country and across the globe.

The ambit of GCI is intentionally diverse to include a wide range of research areas that have direct or indirect impacts on public health and development. GCI also supports projects at various stages in their lifecycle; from basic science research in laboratories, to proof-of-concept projects in the field and potentially larger scale-up efforts of successful innovations.

The Program Management Unit at BIRAC (PMU-BIRAC) executes, manages and provides technical and financial oversight of GCI and also manages specialised programs on behalf of one or more of the partners.

Currently, GCI manages programs in the areas of agriculture and nutrition, sanitation, maternal and child health, immunizations and infectious disease, data integration, and analysis, knowledge dissemination among others. GCI run open calls as well as specialised programs or initiatives on behalf of the partners.

I. Open Calls:

GCI runs open calls or calls that are open to the public to apply under various themes. Open calls are typically run as time-bound programs that provide a specific amount of funding for a particular period of time. Most open calls are theme-based, i.e. each call is based around a 'Grand Challenge' with a specific mandate.

1. Grand Challenges Exploration-India:

The Grand Challenges Exploration-India (GCE-India) is aimed at identifying health care innovations that will enable the goal of equitable health care in India and beyond. The program is implemented by IKP Knowledge Park, Hyderabad and supported by DBT and BMGF and managed by GCI.

The ultimate goal is the quest for new medical technologies, drug delivery systems, diagnostics, and technology-enabled service models that enhances the health and development of the people from all socio-economic strata. Since inception five calls have been launched under this program.

The last four calls have altogether supported 19 innovative ideas.

This fast-track program is aimed at identifying, nurturing and encouraging innovative ideas to create novel, indigenous technologies to improve the public health situation in India. Although, GCE-India mirrors the global GCE program of the Bill & Melinda Gates Foundation (BMGF) in its mandates, being India-centric, it also addresses challenges that are specific to the Indian health ecosystem.

As grantees are supported for 18 months to the tune of $100,000 to test their idea and generate initial evidence, the calls for application only requires a two-page proposal based on which ideas are chosen.

The award is open for all the spheres of the scientific community, ranging from academia (faculty, postdocs/researchers in colleges/ universities/government laboratories/ institutions) to industry (large corporates, small-medium enterprises, start-ups), non-governmental organizations as well as non-profit organization, and Individual researchers. The two-page proposals are evaluated for novelty, societal impact, alignment with the goals of the partners, affordability to end users, sustainability and execution capabilities.

The unique feature of this bi-annual call is that it solicits proposals across a range of mandates, typically 13-14 different mandates under the broader field of public health. Some of these mandates mirror those of the Global Grand Challenges Explorations call if they are considered relevant to the Indian context. The other mandates are specifically designed based on the needs and contexts of public health in India.

The Selection Committee Meeting of the 4th GCE- India call

2. **All Children Thriving (ACT)**

The program intends to investigate novel cost-effective measurement tools and mechanisms to combat unhealthy birth, growth, and development of babies. The overall goal of the program is to ensure that not only all children survive, but also remain on the trajectory of healthy and productive lives and try to adequately alleviate the burden of congenital disabilities, adverse pregnancy, outcomes and developmental disabilities in children.

The following seven projects funded under this program (1 full grant and six seed grant) explores a unique element with special emphasis on innovative, impactful research on maternal and child health development.

A. **Improving linear growth of children in low-income settings through integrated nutritional, environmental WASH and care interventions in pregnancy and early childhood a randomized controlled trial from the Society for Applied Studies, New Delhi** has now been provided the abbreviated name as "WINGS" study - Women and Infants Integrated Growth Study. This trial aims to establish the maximum growth and developmental potential of infants and children living in poor households through an integrated package of interventions. The study plans to enroll a big cohort of approx. 12500 peri-conceptional married females from slum areas of South Delhi. Around 9000, women have been enrolled in study, and out of these about 2500 women have become pregnant, and approx. 1000 reported live births. The study is progressing well, and all interventions are being delivered as per the standard protocols. This community-based trial is very critical for understanding vertically and horizontally linked delivery of interventions to provide continuity of care from Pre-pregnancy through early childhood; learnings that could aid in determining future design of health systems. Furthermore, the evidence drawn from the study could address critical questions, and the answers to these may also form the basis of ideas for National Nutrition Mission (NNM) in India. The TAG for this trial was conducted in January 2019, which provided strategic guidance to the study.

B. **Stress outcomes on pregnancy, fetal growth, and birth weight. Development of methods to identify mothers at risk of preterm birth and intrauterine growth restriction resulting from maternal stress from National Institute of Biomedical Genomics, West Bengal:** plans to develop biological markers of stress during pregnancy that correlate with enhanced risk of adverse outcomes in mothers and their babies. Till date, all the study participants have been enrolled. A-Z stress test has been performed on all subjects, and stress score cut-offs decided based on the scores tabulation in each range of stress scores. Cortisol estimation in hair shaft samples has been performed for all women falling under each category of stress. Telomere length shortening by Real-Time PCR has been performed on the required number of DNA samples. Project is nearing completion and will soon have analyses in place to answer the question of the extent to which maternal stress impacts the pregnancy outcomes.

C. **An intergenerational prebiotic approach to establishment of a healthy colonic microbiome in infants from SRM Institute of Medical Sciences (SIMS), Chennai, Tamil Nadu** will evaluate the effect of orally administered prebiotic starches on fecal microbiota composition and metabolic capacity, and breast milk microbiota

composition and breast milk immune function, in lactating women of childbearing age in a semi-urban setting in India. Completed sample collection. Samples all transported from the two field sites under cold chain conditions to the PI's laboratory in Chennai. Completion of fecal DNA extraction and QC. Short chain fatty acid analysis on fecal samples by GC-MS and Quantitative analysis of pathogens by PCR have completed.

D. **Creation of a Biorepository and Imaging Data Bank for Accelerating Evidence Generation to Facilitate Children to Thrive from Translational Health Science and Technology Institute:** To estimate the factors/predictors of preterm birth and to gain mechanistic insights into disease progression, we require a plethora of high quality homogenously collected biospecimens (like maternal serum, plasma, saliva, urine, high vaginal swab, faeces, cord blood, neonatal heel prick venous blood, placental punches, ultrasound images etc) at different time points of pregnancy with well characterised standardized clinical and environmental information. Keeping in view the same, the current project has established biorepository in an area of 2572 sq.feet. The biorepository has approximately~ 6,20,000 serial biospecimens and 3,25,672 ultrasound images collected across pregnancy, delivery and post delivery from a large cohort of pregnant females (n=5000) who are less than 20 weeks of gestation. The women are followed-up for facilitating the development of predictive biomarkers and a practical algorithm for early prediction and timing of intervention of PTB in low middle-income countries like ours.

E. **The simple absolute neutrophil count as a measure of mucosal inflammation and as a predictor of linear growth in Indian infants from the Translational Health Science and Technology Institute:** It has been hypothesized that infants residing in settings with poor sanitation conditions and exorbitant inflammation of the gut, subsequently have weak absorptions of nutrients and loss of supplements that eventually leads to stunting. The neutrophils are drawn to sites of microbial colonization or are exhausted during the clearing of microbes from circulation. The study is trying to establish the low absolute neutrophil count as a measure of mucosal inflammation and as a predictor of linear growth in Indian infants. The study collected blood samples (cord blood and venous blood at 6-14 weeks and 24 weeks of life) as well as stool samples (meconium and stool collected at 1,2,4,6,10,14 and 24 weeks of life) from 200 infants to identify markers of mucosal inflammation.

F. **Low-cost salivary progesterone testing for detecting the risk of preterm births in rural community settings of India from the Mamta Health Institute for Mother and Child, New Delhi and Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra:** Currently, there is no simple test/ biomarker available to screen women at risk of PTB in resource-constrained settings. The present study aims to evaluate the accuracy and feasibility of salivary progesterone testing to predict PTB. This simple, non-invasive test permits estimation of progesterone in saliva and its association with PTB. The study has recruited 2000 pregnant women in the first trimester of their pregnancy from Panna and Satna districts of Madhya Pradesh with a high crude birth rate of 31.7 and 28.8 respectively and high rate of prematurity (24% of births occurring < 37 weeks), and collected saliva samples from these females between 24-28 weeks of gestation.

G. **Tamil Nadu Rice model: Enhancing nutritional security of pregnant women, infants and young children in rural households of Tamil Nadu, India through agricultural intervention, by Tamil Nadu Agricultural University, Coimbatore, India** in collaboration with Home Science College and Research Institute, Madurai, India and University of California Davis, California, USA. The study is aiming at the development of nutrient-rich genotypes in rice possessing the key nutraceuticals, and therapeutic clues through which required nutrients such as iron and zinc for pregnant women and infants of rural households will be supplemented sustainably. Improved line of rice will be compared with the traditional parents and other popularly eaten white rice varieties for its nutritional content and therapeutic values. The improved lines of rice having nutritive, anti-diabetic, and curative characters will be registered. Maker assisted selection of Recombinant inbred lines population of CO50, and Kavuni resulted in the identification of 65 photo-insensitive lines. Grains of CO50 and Kavuni and the other two selected RILs are under Glycemic index analysis/estimation. Research activities are underway to tag genes controlling the accumulation of essential therapeutic compounds through Bulk Segregate Analysis method. Attempts to channelize the carotenoid accumulation towards b carotene in rice grains through genome editing is in progress.

IMPRINT trial (Improving Linear Growth in Infants from Low Resource Setting in India: A sub-study under the Linear Growth Study trial called as the IMPRINT trial has also been supported. This trial started in Jan 2018 for a period of 2 years and total study subjects around 2000. It has two components:

Sub-study 1: This trial aims to test the hypothesis that ensuring adequate nutrition in lactating mothers

by the provision of additional requirements of micronutrients and macronutrients through balanced food supplements will improve linear growth in their infants at six months of age. Study plans to enroll 680 mother-infant dyads from JJ clusters of South Delhi, of which 50% enrollment has been completed. Maternal food supplements are through snacks, specifically prepared and procured and micronutrients are being covered through a tablet of micronutrient supplements. Outcomes under study are the breastmilk composition, maternal health measures, as well as infant anthropometric measures, and microbiome composition.

Sub-study 2: This trial aims to test the hypothesis that food supplements were given daily for six months, starting from 6 months of infant age, that provide balanced energy, protein, fat, and essential micronutrients will improve length for age Z scores (LAZ) at 12 months of age in comparison to standard care. Total subjects estimated for this study is 1290 infants who will be fed a variety of Infant milk-cereal mixes with appropriate micronutrients. Till date, around 600 subjects have been enrolled in the study and started on interventions.

The findings of these two studies will help in answering one of the significant nutritional supplementation questions and may inform the ongoing Linear Growth Study (LGS), as well as help, interpret the findings of the LGS trial.

This trial was sanctioned in January 2018, and the first Technical Advisory Group Meeting was conducted in January, 2019.

The Technical Advisory Group Meeting of the IMPRINT Trial

3. Immunization Data: Innovating for Action (GCI-IDIA):

The fourth thematic call was announced on 15th November, 2017 on 'Improving Immunization Data Systems', a program directed at addressing challenges faced in collecting, analyzing, and using data on immunization and health. 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), which will be providing their valuable technical and practical inputs in selecting and reviewing projects.

The program explicitly sought solutions that focus specifically on conceptualizing and demonstrating innovations in data systems for immunization to aid in real-time visibility of correlation between consumption and coverage of immunizations and should have the potential to be scaled up in multiple settings. The overall goal is to seek ideas that should be potentially translatable to practical interventions in India's immunization program.

The Phase 1 funding support in the form of grant at a maximum of $200,000 per project is for developing

a proof of concept in 12-18 months, for a maximum of 10 projects. Phase 1 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.

The Phase 2 funding support in the form of grant is for validating impact in 18-24 months for the following funding to scale the most successful and impactful projects from Phase I, with the ultimate aim being integrated into the government program.

The call closed on 15th January, 2018 at 11:59:59 PM and accepted 70 applications that were submitted online only. The screening was done on the 70 applications internally, which assessed initial eligibility of proposals which reviewed the scope of the scheme as per the mandate pre-defined in the call RFP and did the due diligence of submitted documents. Thirty-Six applicants were selected for presentation to TAG, where 9 applications were shortlisted for funding support. These projects were all signed in FY 2018-2019.

A. **Health Chain: an accelerator for immunization data integration, analysis, and use in India, Avalon Information Systems Pvt. Ltd., New Delhi.** The projects aim 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 India Stack to offer a public health solution for immunization based on India's unique identity project Aadhaar.

B. **Image recognition based data entry processes on ensuring 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.

C. **eVaccination: Immunization in the last mile, Operation ASHA, New Delhi**

eVaccination app to ensure each newborn's vaccination through trained semi-literate local people as incentivized Community Health Workers (CHWs) to find, counsel, and accompany new mothers to public hospitals for immunization. This process will be verified by finger scans of the CHW and the mother. If a vaccine is missed, the app will send SMSs to the CHW and the mother, to retrieve her immediately.

D. **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 Data, ML 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.

E. **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) Aadhaar (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.

F. **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 standard 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.

G. **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 Immunostain 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.

H. **Mobile Application For Immunization Data In India (MAIDI), Indian Council of Medical Research, 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/caregivers, health care providers and the health system.

I **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 proposes 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 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.

4. **Grand Challenges India: Antimicrobial Resistance (GCI-AMR)**

The fifth Grand Challenges India call on Antimicrobial Resistance was launched on 11th April, 2018 as a program directed at addressing challenges that are being faced in tackling antimicrobial resistance in India and in comparable geographies.

This call is part of a global call on antimicrobial resistance, 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 program.

This program aims at encouraging innovation in tackling AMR under 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.

With the increased awareness on the threat of antimicrobial resistance in the last few years, this call was designed specifically to focus on certain areas that are particularly important for India or have had less research and funding.

Under the mandate of surveillance, the call focused on innovations in new data sources, analytical methods and new biomarkers for surveillance, given that the Government of India is heavily supporting the setting of traditional surveillance networks and systems through the Indian Council of Medical Research. There is a need to explore new data sources, analytical techniques and biomarkers that may allow us to gather better and more accurate data about how resistance develops and moves in the community. This kind of data will be particularly useful for establishing algorithms that can predict trends in resistance development and its associated factors so that appropriate interventions could be planned.

Another area where research is particularly important, especially for India, given its high rates of infectious disease, is innovative low-cost products and technologies that can be used to break the cycle of infections especially in healthcare settings. Since the drug development pipeline takes a very long time, another alternative to tackle resistance is to break the chain of transmission of these resistant microbes.

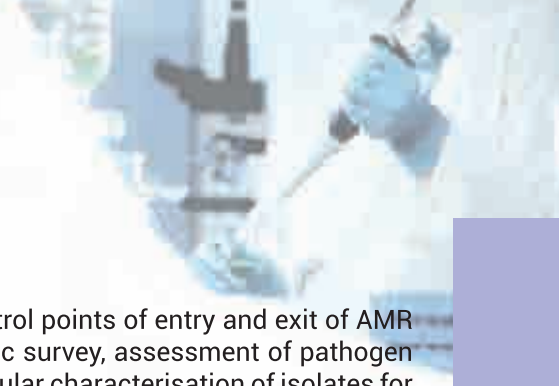
The effect of antibiotics in the environment is still not well understood, but what is known is that there is a large outflow of antibiotics/antimicrobials from various sources such as industries that produce APIs for antimicrobials, the community, farms, industrial agricultural set ups among others. It is therefore important to arrest this flow of antibiotics into the environment through new technologies and products.

This call closed on 25th May, 2018 and received a total of 293 applications. The review process was conducted and the Technical Advisory Group selected 10 projects for funding. These were in the process of finalising and signing the agreements in FY 2018-2019.

A **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.

B. **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** will quantitatively assess the dynamics of antimicrobial-resistant AMR 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 AMR E.coli to design a relevant HACCP. Three aspects: rapid ethnographic survey, assessment of pathogen levels at different points of production, through phenotypic and molecular characterisation of isolates for presence or absence of AMR genes.

C. **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.

D. **Biomarkers for bacteremia, antimicrobial resistance and hospital acquired infections by NMR and Mass Spectrometry among febrile neutropenic patients, All India Institute of Medical Sciences:** 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.

E. **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.

F. **Development of Raman spectroscopy as a surveillance technology for antimicrobial resistance, Indian Institute of Science Bangalore**: 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 the prediction of possible resistance in bacterial strains.

G. **Harmonized One health Trans-species and community Surveillance for Tackling Antibacterial Resistance in India HOT-STAR-India, The INCLEN Trust International:**

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. The application of geospatial epidemiology technology shall allow integrating data from multiple sources. The evidence base generated shall address the gap to transform the public health action across sectors and trigger advanced molecular and genetic epidemiology.

H. **Understanding the transmission of antibiotic resistance between hospitals and the environment, National Centre for Cell Science, 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 the Indian context and a reliable catalogue would help in proper visualization of the network involved in AMR and to develop strategies to mitigate it.

I. **Community and Hospital Acquired Invasive Carbepenem Resistant Enterobacteriaceae: Longitudinal Study of the Gut Microbiome in Infected and Non-Infected Children and Their Families, 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.

J. **Impact of AMR burden on the health Index of poultry farm workers, CSIR-Institute of Microbial Technology:**

The project focuses on the transmission dynamics of resistance in poultry farm workers to estimate the possibility of zoonotic transfer of pathogens. Will be looking at humans, animals, air and water as well.

The Technical Advisory Group meeting of the GCI-AMR program

5. Ki Data Challenge: knowledge integration (ki) Data Challenge

The 'knowledge integration' (ki) Data Challenge, sixth call under GCI was launched on 3rd July, 2018 for 45 days 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 modeling approaches applied to HBGDki India or to other relevant data sets that applicants can access.

The program was directed at addressing challenges that we face in improving the health of mother and child in comparable geographies through data science approaches. The purpose of the ki data challenge call is to have innovative data analytics solutions by analyzing existing data arising from multiple sources in India, results from which shall be used to inform policy decisions related to maternal and child health as well as design subsequent related challenges.

Robust outreach was done through various digital, social, and print mediums. The ki team did outreach at premier institutes like IITD, IIT Madras, NCL Pune, ISI Kolkata, NIRRH Mumbai with a very unique mandate and different landscape of researchers as the idea behind this call was to develop strong collaborations between data scientists/modelers and Clinical researchers, thus enabling development of data analytics capacity in India with respect to MCH domain.

The application process was open until 17th August, 2018, and the program received a good response with 116 submissions of applications.

The TAG meeting held on 1st & 2nd November, 2018 shortlisted ten applications for support and nine were waitlisted in case of availability of funds. The applications are in the process of agreement execution.

In 2018-2019, a global kick off meeting was conducted in New Delhi, India with the GC India, Brazil teams that were selected.

II. Specialised programs/initiatives

Specialised programs or initiatives are programs that are run by the PMU-BIRAC across a variety of themes and support a specific research program.

1. Healthy Birth, Growth and Development knowledge integration (HBGDki) India

This initiative aims to create a knowledge compendium that will allow researchers and others to access a variety of data from different parts of the world, to allow them to obtain a much clearer picture of global trends and analyses on factors that affect childbirth and subsequent development. The three major areas of focus for this initiative are Preterm birth, physical growth faltering, and impaired neurocognitive development. Eleven collaborators signed an agreement to share 24 datasets, 23 datasets have been curated and uploaded on GHAP Platform. Last year, two webinars were conducted online, as an effort towards growing the current HBGDki-India community and leveraging the aggregated HBGDki-India data for greater utilization by Indian scientists:

i) An online webinar entitled: "Exploring aggregated HBGDki-India data: descriptive epidemiology of stunting and wasting" provided a detailed composite view of all of the Indian study data. This analysis looked across the entire body of aggregated HBGDki-India data to characterize the epidemiology of moderate and severe wasting and stunting among Indian children from birth until age 24 months.

ii) webinar entitled: "Epidemiology of Stunting" aimed at identifying the child, maternal, and household level characteristics associated with growth velocity, incident stunting, and recovery as well as the nutritional interventions that impact the prevalence of and recovery from stunting.

2. Knowledge Integration and Translational Platform (KnIT):

The Knowledge Integration and Translational Platform (KnIT) was launched in 2016 and are a unique knowledge synthesis platform that aims to bridge the gap between research and policy and facilitate evidence-based policy making for public health in India.

KnIT was set up as a response to the challenges discussed previously and specifically targets Indian policymakers as the end users of the knowledge synthesized, explicitly at the State level, in keeping with the current health policy structure, where the mandate of healthcare lies with the state. 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 in the country.

KnIT currently has two parallel streams of work.

The first, knowledge synthesis, is the responsibility of domain centers which work in specific themes in public health and seek to answer the most pressing questions in these areas through extensive analysis of currently available data in the Indian and comparable contexts.

The second, knowledge translation, is under the purview of the State Implementation Unit (SIU), a specialized unit that works with individual states to translate the synthesized knowledge and to package it for policymakers.

Currently, KnIT knowledge synthesis focuses on two tracks, maternal and child health issues and nutrition. 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 tracking is currently working on four areas where there are essential questions to be addressed; low-birth-weight babies, Anemia, complementary feeding, and diarrhea. This track has lead to the publishing of a total of 15 peer-reviewed articles in leading national and international journals on the topics of domain center, and in 2018-2019, ten articles were published.

MCH focuses on identifying the health system challenges that are barriers to effective, equitable, impactful delivery of health services, and identifies strategies on 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. The team has conducted a quantitative and qualitative survey in Himachal Pradesh to collect data from SNCUs and NBSUs and has also undertaken in-community follow-ups to assess the care that the babies are receiving. In FY 2018-2019, the data collection was conducted across three districts in Himachal Pradesh.

The State Interaction Unit has worked with the states of Haryana, Rajasthan, and others to provide evidence-based recommendations.

3. 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. Two vaccines for cervical cancer, Gardasil, and Cervarix are available. Although both vaccines are licensed in India, very limited vaccination has occurred in India due to the high cost of vaccines.

The Executive Committee (EC) provided in principle approval for qHPV Vaccine Phase II/III Clinical Development. International Agency for Research on Cancer (WHO-IARC) will act as an advisory partner.

The Investigators Meet

4. **Food-based nutritional security for malnourished rural households through capacity building and establishment of nutri-gardens:**

The GCI partnership is supporting a program focusing on a food-based approach to eradicate malnutrition and bringing nutrition focus to farming systems to the MS Swaminathan Research Foundation.

The program is focused on developing and demonstrating location specific several common and rare nutrient-rich plants garden at local Krishi Vigyan Kendras (KVKs) to enrich the farming systems and enhance human nutrition in four different agro-ecosystems (KVK Palghar District, Maharashtra; KVK Kanpur Dehat, Uttar Pradesh; KVK Thiruvallur District, Tamil Nadu; BPMPGRC, MSSRF Jeypore, Odisha) along with State Agricultural Universities. The selected districts are highly malnourished or vulnerable districts.

The project is supporting the implementation of the approaches of 'diversification of the diet' and 'Biofortification' in the Farming System for Nutrition (FSN) model for developing nutrition responsive agriculture among 2000 small-holders (500 farmers in each location) by providing quality planting material of nutrient-rich plants with related actions for adoption in the farming systems and on behavioural changes communication through nutrition education for practice by Community Hunger Fighters (CHFs). The Nutri gardens would also provide an opportunity for landless families and smallholders to access different, nutrient-rich foods. The program intends to improve Diet Diversity Score of the undernourished farm household's up to 60% from the base level.

Launch of the Food based nutritional security for malnourished rural households through capacity building and establishment of nutri-gardens program at the M S Swaminathan Research Foundation

The Inception Meeting for the project on 'Food based nutritional security for malnourished rural households through capacity building and establishment of nutri-gardens' program being implemented by the MS Swaminathan Research Foundation a specialized initiative under the Grand Challenges India program was held on 23rd January, 2019 at IGNOU Hall, at the MSSRF Headquarters in Chennai.

The meeting was attended by the representatives from Krishi Vigyan Kendras from the four zones involved in the program and State Agriculture Universities. Dr. Shirshendu Mukherjee, Mission-Director, PMU-BIRAC and Ms. Arshi Mehboob, Manager (Programmes) also attended the meeting.

Prof. M. S. Swaminathan, in his address spoke about the Indian food current scenario, on how food and nutrition deficiency impacts the cognitive capacity of school children. He stressed on the importance to address not only protein and calorie deficiencies but that micronutrient deficiencies along with sanitation and Primary Health facilities are important components that should be integrated as interventions to address the problem in totality.

Dr. Purvi Mehta, Head_Asia, Agriculture at the Bill & Melinda Gates Foundation, India Country Office opined that the country has been focussing on enhancing the productivity of staple food and it's time to focus on the nutritional perspective of both the staple food like rice/ wheat/ tubers and to widen the varietal diversity in our diets.

She stressed on three aspects of scalability, monitoring and evaluation and diversification angle, to develop a consortia of partners through ICAR and learn from each centre challenges. She also emphasized the need for diversifying the crop/ varieties along with the livestock system to achieve a complete food based approach to eradicate hidden hunger and malnutrition.

The project team with Dr. M S Swaminathan, Dr. Shirshendu Mukherjee and Dr. Purvi Mehta, at the launch of the program.

5. The Sentinels Experiment:

The 'Sentinels Experiment' intended to source innovations in India to address global health challenges by working with sentinels for excellence and innovations, who can identify new ideas and scientists in their institutions, networks, and regions.

The initiative engages with explicit innovation practitioners, new partners, new ideas and new opportunities focused on creating and fostering the delivery of more appropriate (affordable, deliverable and scalable) versions of existing interventions; the contribution could be by way of a new product, service or process.

Towards this, a series of meetings were held at Centers of Excellence namely, IISc, NCBS Bangalore and CMC Vellore in April, 2018 to socialize the "Sentinels" experiment and find people who ideally are not working on global health problems but have relevant skills, technologies, and a potential passion.

Twenty four two pager proposals were received from a closed list of innovators/companies, academicians from the key institution like IISc, NCBS and other Institutes in Bangalore which were reviewed by international experts. Five applications were shortlisted for the award, which is in the process of agreement execution.

The Sentinels Experiment Exploratory Meeting

III. Programs Under Development:

1. The Med-Tech Challenge:

The DBT-GoI, BMGF & Wellcome together plan to launch a challenge under the Grand Challenges, focused on funding some of the most compelling and unfinished medical technologies and tools through a competitive grant process, through a portfolio approach. The theme of the call will be compelling medical technologies and tools and the innovators of the technologies specifically those in the translational space would be selected from the current pool of DBT, BIRAC, GCI, Wellcome and other programs that are currently being run by the partners. This program is designed as a call by nomination, where each of the funding partners will nominate applicants that fit into the inclusion criteria. The call will also have a Technical Facilitator who will be assessing and providing the training to the selected participants and will also be part of the review process.

The Med-Tech Challenge: Innovation to Impact 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 reliable 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 substantial unmet medical need.

The current proposal aims to support medical technology innovations where the successful innovator will be supported through a series of training workshops and mentoring to augment their skill set to improve the probability of translation and speed up time to the market.

This program has been designed for entrepreneurs who are far along enough in the development pipeline to develop their market strategy. This program, through the workshop and mentoring components, will aid these entrepreneurs in developing a realistic business development plan. They will be provided with the training and tools required for them to build their customized business model that is targeted towards their specific medical technology or device. In FY 2018-2019, the tripartite agreement was worked on as was the call design and process.

2. Achieving Healthy Growth through Agriculture and Nutrition (Transition to Scale Activities planned for 2019 _ 2024)

Funded projects were in the pilot phase and tested a wide range of concepts. Three successful interventions exhibit the breadth of efforts that were undertaken by researchers.

The Technical Advisory Group held in October, 2017, reviewed all five projects that were completed and agreed for consideration of a Transition to Scale Grant, for three interventions (Integrated Farming System, Solar Conduction Dryer, Zinc bio fortification) while adding more clusters to bring out a significant social impact.

TAG noted that the duration of the studies was concise of producing reliable results in terms of behaviour change and deriving health impacts with diet diversities. The Executive Committee has agreed in agreed principle to support the three interventions.

'Integrated Farming System (IFS) for the enhancement of household diet diversity and livelihoods of small-holder women farmers' tested the viability of an alternative farming system on productivity, economic return and women empowerment. The domestic solar conduction dryer project tested a new technology to assess its impact on diet diversity of the participants and economic returns. Finally, the zinc bio-fortification project tested an agricultural intervention that used a foliar application of zinc on rice and wheat crops to potentially address micronutrient deficiency through supplementation of food crops.

3. Reinvent the Toilet Challenge (Transition to Scale Activities planned for 2019 _ 2024 Phase 2)

The two technologies that are simple, cost-effective, reliable, and culturally acceptable would be supporting under innovation-to-scale. Decentralization of wastewater treatment is a sustainable solution to address this problem that locally treats the sewage and also reuses/recycle. 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 Helminths.

The second technology is the completely solar powered eToilet connected to the NEWGenerator this creating a unique model of sanitation recovery with a perfect back-end processing through which resource generation/recovery is made possible. The NEWGenerator 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.

IV Graduated Programs

These are programs whose projects have been completed and whose successful projects are under active consideration for next steps.

A. Achieving Healthy Growth through Agriculture and Nutrition:

The Grand Challenges India (GCI) partnership announced the first program titled 'Achieving Healthy Growth through Agriculture and Nutrition' in August, 2013, supported by the DBT, Bill & Melinda Gates Foundation, and USAID. The overall goal of the program was to target the linkage and relationship between agriculture, nutrition, and health.

The program sought proposals in the areas of agricultural/nutrition/social innovation, with thrust to develop interventions to improve the nutritional and economic outcomes of women farmers; understanding the causes, determinants and developing interventions to address low birth weight, stunting and wasting; and identifying and designing tools to improve communication around nutrition and agriculture especially among women farmers.

The supported five Indian led pilot studies or pilot models provided diet diversity to underprivileged women and children from varied sources to improve their nutrition thereby bringing about a positive change in their health and nutritional needs, leveraged local micro-entrepreneurial motivations and processes to solve smallholder farmers' poverty through a distribution network of digitally-trained entrepreneurs and strengthen and engage women's groups to address MIYCN, produce and disseminate a series of nutrition-specific participatory videos to address nutrition-specific behaviours. All the projects under this call, stand completed at their respective sites.

B. Reinvent the Toilet Challenge:

"Reinvent the Toilet Challenge - India", a program directed at addressing the problems in sanitation and especially needed in the rural and urban areas, where billions of people are only capturing and storing 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 and UNICEF, sanitation rated as "safe for people" 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 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 launched in 2013 and six projects 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 installed in some parts of Delhi for demonstration and greater visibility.

Inauguration of the e-toilets at the Barapullah Sundial Park

V Convenings

A. Executive Committee (EC) Meeting (2018)

The 7th and 8th Executive Committee meetings were held in FY 2018-2019. The Executive Committee of Grand Challenges India is the apex governing the body of the Grand Challenges India partnership and is chaired by the representatives of both the original funding partners, the Department of Biotechnology, Government of India and the Bill & Melinda Gates Foundation. In 2018-2019, Dr. Renu Swarup, Secretary DBT and Dr. Nachiket Mor, Country Director, India Office, Bill & Melinda Gates Foundation were the Co-chairs of the EC. The other members include the members of the Joint Steering Committee (JSC), who are representatives from DBT, BMGF, as well as the Wellcome Trust.

In FY 2018-2019, two convenings were held, one via circulation and one in person meeting on 30th July 2018. The EC meetings took reviews of all the current and old programs of the Grand Challenges India partnership and provided in principle approval of the new programs.

The Executive Committee Meeting with Special Invitees

B. Grand Challenges Annual Meeting 2019 Berlin, Germany

The 2018 Grand Challenges Annual Meeting was held from October 14 to 18, at Estrel Congress Center, Berlin, Germany. Bill & Melinda Gates Foundation hosted the meeting in collaboration with Wellcome, German Federal Ministry of Health, and the German Federal Ministry of Education & Research.

The meeting had representation from Global Grand Challenges (GC) Network Partners; Government units/councils; prominent academic institutes; research organizations; and development innovation organization that are corroborating breakthrough research and innovation.

Secretary, DBT, Dr. Renu Swarup, led the DBT, BIRAC and Grand Challenges India delegation at the meeting and was accompanied by Dr. Sundeep Sarin, Advisor DBT, Dr. Shirshendu Mukherjee, Mission Director, Dr. Richa Vashishtha and Anjana Seshadri from Grand Challenges India. In addition to attending the various sessions, including the by-invitation Funders Forum meeting, there were several side meetings with old and new partners to deepen and explore new opportunities to work together.

C. Grand Challenges Learning & Evaluation (L&E) Meeting 2019:

The 2019 Grand Challenges Learning and Evaluation Meeting was hosted in New Delhi by the Grand Challenges India team, on behalf of the funding partners, the Department of Biotechnology, Government of India, BIRAC, and the Bill & Melinda Gates Foundation. Dr. Renu Swarup, DBT, Secretary and Dr. Chris Karp, Director, Global Health Discovery & Translational science inaugurated the meeting.

The annual Grand Challenges Learning and Evaluation Meeting provide an opportunity for Grand Challenges program leads from around the world to come together to learn and leverage each other's experiences and learn from the opportunities and challenges that each team faces in their geographies. These meetings also allow the program leads to the explore the future of Grand Challenges as part of the broader innovation ecosystem.

This year's L&E was hosted by Grand Challenges India in New Delhi and saw the participation of over 80 participants from all over the globe.

The L&E 2019 Group

The dignitaries lighting the lamp

D. Knowledge Integration Grand Challenges (Ki GC) partners: Data Science Approaches to Improve Maternal, and Child Health in India, Brazil, and Africa, New Delhi:

The first ever global convening was a three-day event of the Knowledge Integration Grand Challenges (Ki GC) partners: Data Science Approaches to Improve Maternal, and Child Health in India, Brazil, and Africa was held in New Delhi India from 14-16th March, 2019.

The meeting introduced the Grand Challenges (GC) and Knowledge Integration (Ki) teams that initiated the MNCH data-focused Grand Challenge programs, orient ki GC grantees towards successful delivery on their grant proposals _ in particular, begin a dialogue with key stakeholders in India and Brazil, who will be the ultimate consumers of the data products.

The meeting also provided tools and training to grow a community of public health data scientists from India, Brazil, and Africa and also offer a day of ClinEpiDB HBGD data resource training and office hours to the grantees.

The meeting also provided a common platform for ki GC teams to collaborate across Ki GC teams and work together, share their outcomes (when they are ready), and contribute to the high visibility of the Ki GC initiative within Brazil, India, and Africa.

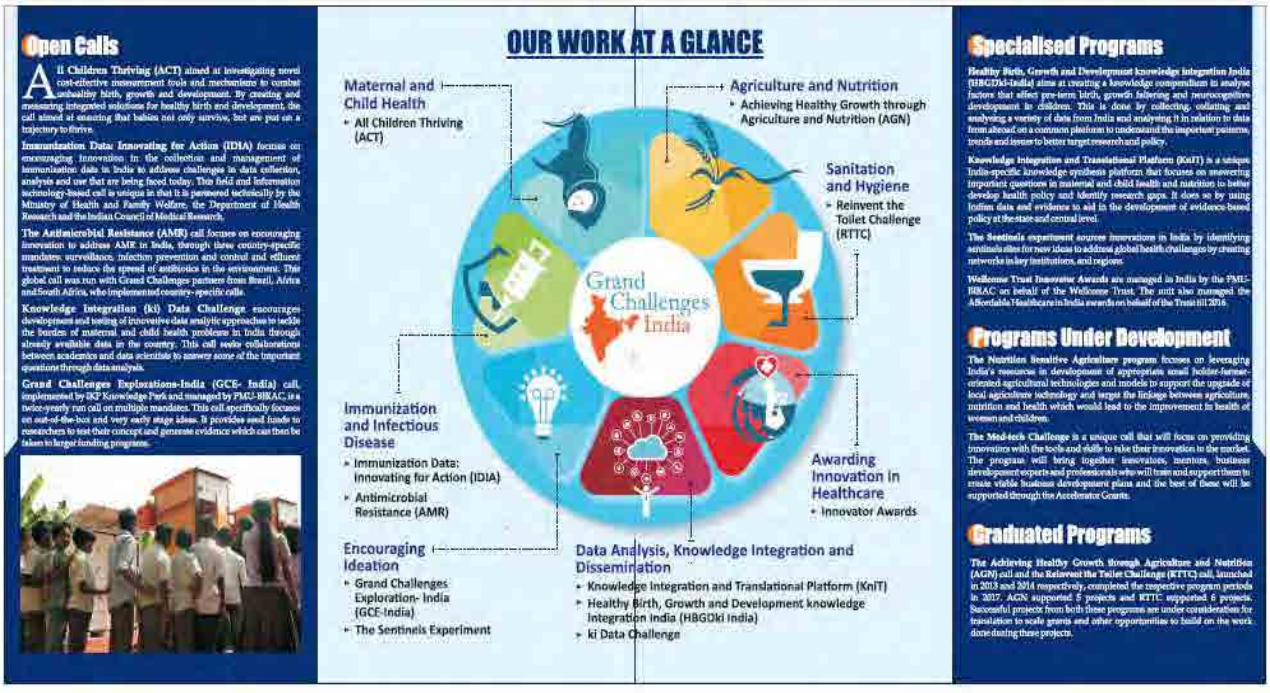
The ki Data Challenge goal is to harness the power of massive datasets through advanced modeling and scientific collaboration to discover and deliver interventions that matter at the individual and population level. If successful, this approach will accelerate progress towards solving global health challenges. An important aim of this convening was also to brainstorm on India-specific datasets through HBGDki platform consortia.

Knowledge Integration Grand Challenges (Ki GC) partners: Data Science Approaches to Improve Maternal, and Child Health in India, Brazil, and Africa Meeting participants

VI. Communications

Apart from event-based communications, the GCI Communications team maintains and manages the GCI microsite, hosted on the BIRAC website.

Each year the team also develops a brochure for the year, which is disseminated at meetings and events as well as on the GCI website.



GCI Brochure 2018

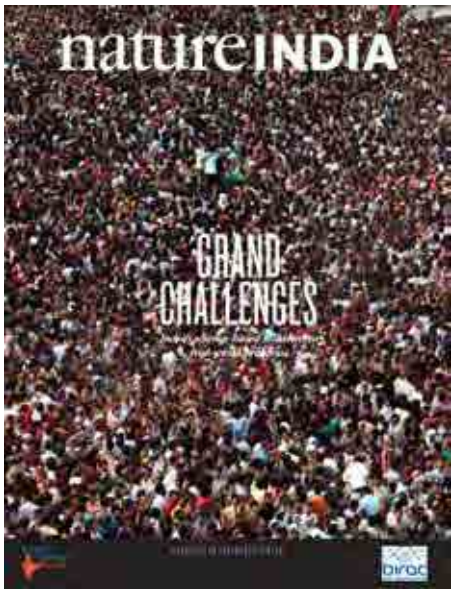
Along with the Communications Partners, Global Health Strategies, the Communications team also works on developing content for GCI, BIRAC, and DBT for various media platforms.

The team also provides communications support for all the calls that are launched.

A. Nature India Grand Challenges India Special Issue launch:

The Grand Challenges India team collaborated with Nature India to publish a Special Issue on Grand Challenges India, as a part of the 10th Nature India Anniversary. The cover page of the issue was launched at the BIRAC 6th Foundation Day, and the issue itself was launched at the Nature India 10th Anniversary Event, in April 2018.

This issue was dedicated to the work of the Grand Challenges India partnership and had articles by eminent scientists, leaders and experts from the field of public health who discussed the grand challenges that we still face in India.



Launch of the Nature India Special Issue on Grand Challenges, unveiled by Secretary DST, Prof. Ashutosh Sharma

VII. Special Activities

A. Scientific Sub-Committee of National Technical Board on Nutrition (SSC-NTBN)

The Ministry of Women and Child Development, Government of India, has set up the 'National Technical Board on Nutrition (NTBN)' under the Chairmanship of Dr. Vinod Paul, Member, NITI Aayog to make technical recommendations on policy-relevant issues on Nutrition, in September, 2017.

The Scientific Sub-Committee of National Technical Board on Nutrition (SSC-NTBN) was constituted to make technical recommendations to the National Technical Board on Nutrition on the issues referred to the SSC-NTBN

A Secretariat financially supported by Department of Biotechnology, Ministry of Science and Technology, Government of India, has been set up for four years, i.e., March, 2022 to coordinate and manage the activities of the SSC-NTBN and provide support in its functioning.

The Secretariat for SSC-NTBN will be located at BIRAC. The Secretariat will be responsible for the organization of meetings, liaising with stakeholders, obtaining relevant data and publications, and supporting the SSC group for synthesis and presentation to the SSC-NTBN. The Secretariat will also hold and convene priority area identification meetings in consultation with SSC-NTBN.

The PMU-BIRAC will act as a primary fiduciary agency and will be responsible for the execution and management of the various strategic programs which have been mutually agreed by SSC-NTBN.

ii. Industry-Academia Collaborative Mission for Accelerating Discovery Research To Early Development For Biopharmaceuticals - "Innovate in India for Inclusiveness" (i3)

The National Biopharma Mission was approved by the Cabinet in May, 2017 at a total cost of US$250 million for five years with 50% funding through World Bank loan. The loan agreement between the World Bank and Department of Economic Affairs for flexible financing arrangements for this Mission of DBT was executed on April 24, 2018 and the project agreement between World Bank and BIRAC was also executed in April 2018. PMU NBM evaluated the proposals submitted in response to the first round of Request for Proposals (RFPs) under the Mission in alignment with its objectives soliciting proposals from academia and industry focusing on development of (i) Vaccines for Pneumococcus, Dengue, HPV and candidates for other diseases of high burden in India (ii) Biosimilars for cancer, diabetics and rheumatoid arthritis and (iii) Medical devices and diagnostics (iv) Process Development Laboratory; GMP Manufacturing Units and GLP analytical characterization facility for Bio therapeutics. The Scientific Advisory Group and Technical Advisory groups were created for assessment and shortlisting of proposals for receiving financial support.

Overall activities under the National Biopharma Mission

PRODUCTS

Vaccines

The National Biopharma Mission supports the development of vaccine candidates at various stages including proof-of-concept, optimization, toxicity studies and clinical trials. From the call for proposals launched in December, 2017, six proposals for vaccine development have been approved by the Technical Advisory Group (TAG) in July, 2018 for funding support worth about Rs. 54 crores. The vaccine development program is expected to help reduce the dependence of India on other countries for vaccine supplies.

A 15-valent Pneumococcal vaccine has been supported for phase II-III clinical trials and should be available for commercial use in the Indian market by mid-2021. Two novel vaccines for Dengue (a subunit vaccine and a live, attenuated vaccine) have been supported for pre-clinical and clinical trials. Two vaccine candidates were selected as there is no effective commercial vaccine available against this important public-health menace and the two candidates utilize very different approaches towards vaccine development. If successful, they should be available in the market in 2026 and 2023 respectively. GMP-grade scale-up process and toxicity studies have also been supported for a cholera vaccine. A universal Influenza vaccine candidate has been supported for early stage development. A vaccine for Chikungunya though recommended for support for phase II clinical trials in India is yet to initiate the clinical trial.

Biosimilars

Applications were invited in December, 2018, for development of Biosimilars (monoclonal antibodies and other therapeutic proteins) based on patent expiry of original biotherapeutic between 2015-2020 (US/EU) and beyond or not patent protected in India. Applications were also invited under a separate RFP for development of Biosimilar expressing clones and with patent expiry between 2020-2025. The proposals will be evaluated and as per recommendation of the Scientific and Technical Advisory group be funded for support in 2019-20.

Medical Devices and Diagnostics

India is the 4th largest market for medical devices in Asia, and finds a place in the top 20 markets worldwide. There are a large number of medical devices companies in India, but they are either start-up companies or engaged in trade, rather than manufacture. Due to this, India has a heavy dependency on imported medical devices, which account for almost 75% of the market. Some segments, such as MRI, show 100% dependency on imported products.

With a view to reduce import dependency, improve affordability and increase the innovation quotient of Indian medical devices and diagnostics products manufacturers, a call for proposals was launched in December, 2017. Five proposals from this call were approved by the Technical Advisory Group (TAG) for funding in July 2018 for a total worth of Rs.15.8 crores. These included development of subcomponents of a CT scanner, pumps for hemodialysis machines to make the product completely indigenous, process scale up for manufacture of bone implant raw material, development of room temperature-stable molecular diagnostics kits for infectious diseases and development of next generation endoscopes. A second call for development of critical medical devices was launched in November, 2018 and proposals are being considered by the Technical Advisory group for funding to be released in 2019-2020.

SHARED FACILITIES

GCLP Labs

Over the last decade, India is being recognised as the epicentre for vaccine manufacturing in the world. Vaccine development requires extensive pre-clinical and clinical evaluation to prove their safety and efficacy. Availability of validated serological assays for bacterial and viral vaccines in GCLP compliant laboratories can fill in a critical gap in vaccine development. The availability of well characterized and reproducible assays would permit rapid assessment of immunogenicity of products and the use of qualified methods following GCLP practices would assure that all data generated is useful to support product licensure.

With this in mind, a call for proposals was launched in June, 2018 to establish national service facility(s) that

will provide services to vaccine developers in evaluating the immune responses in biological fluids samples collected from subjects enrolled in a clinical trial.The focus of the call was on Pneumococcal, Dengue, Chikungunya and Influenza vaccine evaluation to supplement the vaccine development programs supported under the mission. Two facilities were recommended by the TAG in November, 2018 for funding under this call _ one for Pneumococcal assays and another for serological assays for viral diseases (Dengue and Chikungunya). These facilities would provide testing facilities at par with WHO reference labs, and the data generated can be utilized for regulatory submissions. The Pneumococcal assay laboratory is collaborating with University of Alabama, a WHO reference lab, for transfer of knowledge for the required assays.

GLP Analytical facility

Regulatory approval of complex biological molecules involves extensive and advanced analytics including assessment of physiochemical characteristics, efficacy, immunogenicity (antidrug antibody), contamination, strength and more. All these tests need to be performed in a GLP compliant analytical facility. Availability of appropriate certified facilities at affordable costs is a challenge that the start-ups, SMEs/MMEs and the academia in India, have to often face. Centre for Advanced Protein Studies (CAPS) funded under the National Biopharma Mission at Syngene campus near Biocon in Bengaluru, is ready and functional for providing affordable analytical services which will be big boost in advancing biopharma research and product development in India.

CAPS facility at Syngene International, Bengaluru

cGMP manufacturing facility-Shilpa Medicare Ltd.

Biosimilars & Biologics are likely to be the therapies of choice over the next decade for a majority of Indian patients provided they are available in a cost effective manner. Most independent commercial or academic R&D laboratories do not have access to high quality cGMP CMC facilities to produce clinical grade biologics to help progress their products through Human Clinical Trial.

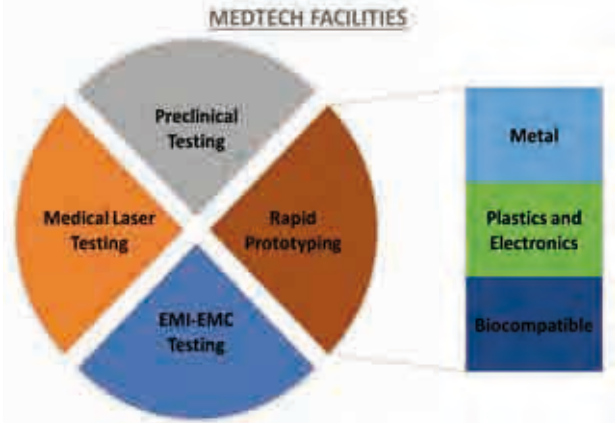
National Biopharma mission funded Shilpa Medicare Ltd. Biologics unit at Dharwad, Karnataka, is a world class contract mammalian cell culture-based Biologics CMC facility including fill-finish facility for generation & supply of clinical grade drug substance and Drug product to conduct human clinical studies. The facility has 1x200L disposable mammalian bioreactors with option to run perfusion process along with one downstream facility that ensures optimum capacity utilization. Fill & Finish facility that can handle both, PFS and vials. Both these facilities commit to provide affordable services to start-ups, SMEs and academia.

cGMP manufacturing facility at Shilpa Medicare Ltd., Dharwad

MedTech Facilities

A major area identified during the proposal evaluation process of the two call for proposals was a shortage of facilities for early-stage prototyping of medical devices and the eventual testing of the devices for regulatory compliance. This is a bottleneck area for many small companies as multiple design iterations and testing charges add to the total cost of product development. As more and more medical devices are coming under regulation, the cost of bringing a product from lab to market is bound to increase many times. Subsidizing the cost in these important areas for the developers will lead to affordability of products to the consumer also.

Considering these points, the call for proposals in November 2018 included call for establishment of facilities. Four types of facilities for prototyping and testing were identified as major requirements under this call: Facilities for EMI/EMC & Electrical safety testing of medical devices, a large animal facility for biological & pre-clinical testing of medical devices, a test facility for medical lasers and rapid prototyping of medical devices. These facilities will also be evaluated for providing support under the mission in 2019-20 so that they are operational in the next two years and will provide testing services at subsidized rates to start-ups/ SMEs along with training the next generation of technology users.



Types of Medtech facilities

SCIENTIFIC RESEARCH

Novel Cell Line

A key factor in reducing the production costs of biopharmaceuticals is the development of cell lines that produce a high yield of product with the desired critical quality attributes. Selecting the right cell line early in

the production process enables significant time and cost savings in later stages of development. A call for development of such cell lines in bacterial (E. coli) and eukaryotic (CHO cell line) systems was launched in December, 2018 and are currently under evaluation. These cell lines, to be developed using vector engineering, cell line engineering or strain development, are required to be made available as a platform technology to Indian companies on negotiable licensing/ royalty terms.

Translational Research Consortia (TRC)

A call to establish a Translational Research Consortium was published in June, 2018. This call requested proposals with an aim to establish multi-disciplinary research partnerships that would focus on development of translational ecosystem for supporting the ongoing vaccine development efforts. It also aimed at advancing existing discovery to late-stage pre-clinical or early clinical development of vaccines and therapeutic monoclonal antibodies for specific diseases. The emphasis of the research activities was on generating better understanding of virus and circulating viral diversity, developing novel and high-throughput assays for transfer to GCLP labs and development of animal models of diseases in the country.

Dengue

The Translational Research Consortium for Establishing Platform Technologies to Support Prophylactic and Therapeutic Strategies for Dengue _ Discovery to Proof-of-Concept has been recommended for funding and will receive the grant in 2019-20 for a duration of 04 years. The program will be lead by International Centre for Genetic Engineering Biotechnology (ICGEB), New Delhi. And the consortia partners are: 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 is expected to deliver unique interdisciplinary, complementary and synergistic expertise to tackle dengue. With clinical sites at AIIMS, CMC, and MAHE, the consortia is expected to establish a biorepository of whole genome sequenced primary dengue viruses isolates for research work. It is also expected to establish the dengue mouse model of infection with WHO reference virus strains and circulating strains that will be available to researchers as a fee for service. The researchers will also generate a bio-bank of well-characterized human sera that shall also be publicly available as reference controls for dengue neutralization assays.

Chikungunya

A proposal for a partnership for Chikungunya research was recommended for funding and will receive the grants in 2019-20. This proposed consortium consisted of four hospitals and three premier research institutes across the county, led by Manipal Academy of Higher Education. Research areas included collection and follow-up of Chikungunya positive patients for characterization of the immune response profiles in the Indian population along with isolation of the viruses from these samples to understand the epidemiological distribution of the virus subtypes. A sero-conversion serum bank of positive samples and a viral repository of approximately 500 Indian Chikungunya viral isolates for use on a fee-for-service model is expected to be established from the samples collected in the course of this study. The study would also lead to development of high-throughput assays for the virus and animal models in mice for acute and chronic Chikungunya infection. These research tools are expected to benefit the vaccine development efforts ongoing in the country and around the world.

Components of Translational Research Consortia

CONSULTANCY

To achieve its aims and objectives, the mission has already identified a consultancy partner and is in the process of identifying another partner. The International AIDS Vaccine Initiative, New Delhi (IAVI) was selected as the Technical Knowledge Partner (TKP) for NBM in September, 2018. It will act as a centralized knowledge hub that links with the NBM and provides inputs to the Advisory groups of NBM (SAG and TAG). It will facilitate shared learning and good practices to reduce isolation of the biopharma mission and increase its credibility by increased access to knowledge, experience, resources and connections. It will provide well-researched, thoroughly analyzed structured evidence including market opportunity, industry analytics and competitive intelligence for strategic decision-making.

Invitations have been invited to provide consultancy as a Clinical Trial Regulatory Advisory and Data Safety Consultancy. The consultancy firm will support the PMU in fulfilling the expectation of monitoring/auditing of clinical trial conduct and will cover all the five basic processes of clinical trial planning, initiation, execution, monitoring and data analysis & reporting. It will help ensure suitability of trial sites, review the essential documents during the trial and provide independent analysis of the trial data.

Environment, Occupational Health and Safety Management Framework (EMF) Activities

DBT/BIRAC with the mission to promote innovation and self-sufficiency in the biotechnology sector, strives to reduce any social and environmental risks in its activities. As the Product developments and related components for creation of robust innovation ecosystem in the biotech sector is the primary focus of I-3 Program, the following elements become inevitable such as compliance to corresponding legislations, good practices in research and development methods and enhanced awareness on social and environmental risk management procedures.

In order to enhance awareness on social and environmental risk management procedures, an extensive monitoring of the project activities to ensure environmental compliance and training of manpower at the grantee site has been initiated. An environmental expert is doing the due-diligence and provide necessary feedbacks, training and guidance for complete compliance to corresponding legislations.

Started in December, 2018, eight grantee-sites have been visited till March, 2019. A strong framework is established for regular site-visits, feedback reports to grantee and receiving quarterly updates from grantee for environmental compliance.

DISCUSSION FORUMS/ MEETINGS/TRAININGS CONDUCTED DURING APRIL 2018-MARCH 2019

- Training program on 'Principles and Practice of Clinical Research India 2018' held from 16 April to 21 April, 2018 at Hyderabad
- 'Understanding the Need, Existing capabilities and the Gaps of GCLP lab(s) and Clinical Trial Network for

Vaccine evaluation in India' at BIRAC office on 01 June, 2018

- INDO-US Vaccine Action Program; Meeting of the Candidate Vaccine Advisory Committee (CVAC) at The Claridges, New Delhi on 15th January, 2019
- INDO-US Vaccine Action Program; Meeting of CVAC Steering Group On Epidemiological Preparation for Flavivirus Vaccine Trials at The Claridges, New Delhi on 16th January 2019
- Discussion Forum: 27th March with Industry and Academia entitled: "Adopting Modern Production Technologies for Biologicals by Indian Companies"

OVERALL IMPACT

- Enhance the product development portfolio: Funds were released for proposals recommended for financial support under the Request for Proposal (RFPs) of biologicals facilities, vaccines, biosimilars and devices and diagnostics.
- Supported 2 trainings and 1 workshop with about 100 manpower trained
- 01 industry academia partnership programmes being supported
- New funded facilities started functioning

VI. Specialized services

1. IP&TT

BIRAC in-house IP & Technology Management cell provides support to start-ups, academia and SMEs on various aspects of IP & Technology Management such as Patent searches, (Patentability Search, Freedom-to-operate, landscaping, Validity/invalidity search), patent drafting, filing, Technology evaluation and assessment.

BIRAC conducts an extensive IP evaluation for grant proposals that it receives for its flagship funding programmes such as BIPP, PACE, SBIRI, IIPME, SPARSH, BMGF, Wellcome Trust, National Bio-Pharma Mission and BIG. In addition to this, the cell also provides clarity on many of the IP and licensing issues in collaborative research projects including the international projects.

BIRAC operates BIRAC-PATH (Patenting and Technology Transfer for Harnessing Innovations) that extends support to protect the intellectual property emerge out from the innovative projects funded by BIRAC and facilitate technology transfer. The BIRAC-PATH program was launched in 2013 and under the scheme; eleven (11) Start-ups and SMEs have been supported so far.

BIRAC intends to closely work with Bio-incubators and Regional Centres to provide the whole gamut of IP & Technology Management services to the local ecosystem. To begin with, IP & Technology Management Cell initiated "IP Clinic" for its beneficiaries. The mandate of IP Clinic is to provide a platform to BIRAC supported innovators to have one-to-one interaction and solution based approach on IP & Technology Transfer related matters. In 2018-2019, 4 such IP Clinics were conducted in association with Bio-NEST and BIG partners at Bangalore, Bhubaneswar, New Delhi and Hyderabad.

Apart from the various IP & Technology Management offerings, the BIRAC IP & Technology Management cell also organizes several IP & Technology Management awareness and capacity building workshops for Start-ups, SMEs and academicians. In 2018-2019, four such workshops were organized at different locations such as Bhubaneswar, Bangalore, Hyderabad and Kanpur. Details of the workshops conducted at different places are provided below:

S. No.	Workshop Partners	Number of Participants attended
1.	KIIT, Bhubaneswar	45
2.	C-CAMP, Bangalore	50
3.	IIT, Kanpur	55
4.	IKP and University of Hyderabad, Hyderabad	50

Patent & Technology Transfer for Harnessing Innovations (PATH)

- To facilitate the protection of entrepreneur's, industries and SMEs Intellectual Property, BIRAC has initiated a Patenting & Technology transfer for Harnessing Innovations (PATH) scheme, to encourage the technological innovation in the country.

- To implement the scheme, BIRAC has also empanelled technically competent and experienced IP & Technology Transfer (TT) firms who could provide assistance for Patent search, filing, drafting and commercialization of such technologies if required. BIRAC had supported projects under BIG, SBIRI and BIPP and had provided assistance in supporting IP generated in the funded program. A total of 11 patents have been supported through the PATH. In 2018-2019, a total of 7 start-ups were supported for patent drafting and filing nationally and internationally and 1 technology has been transferred to the Indian companies through the empanelled technology transfer firm.

S. No.	Name of Company & Scheme	Project	Jurisdictions supported
1.	Cleanergis Biosciences Private Limited (BIG)	A process for bioremediation of industrial effluent	Complete filing in India & PCT filing
2.	Windmill Health (BIG)	Foot Pedal	India, US & EU
3.	Pentavalent Biosciences Pvt Ltd (BIG)	Live Attenuated Universal Influenza virus vaccines, methods and uses thereof	Provisional Filing in India
4.	Swasti Agro (SBIRI)	Chitosan derivative formulations for plant growth, and building disease resistance	India & ARIPO
5.	TestRight Nanosystems Private Limited (BIG)	Spectrometer and method for measuring the spectral characteristics thereof	EU, India & US
6.	Synthera Biomedical Private Limited (SBIRI)	Manufacture of porous glass and glass-ceramic particulate structures by gel-casting	US & India
7.	Osind (IIPME)	A Self Driven Rehabilitation Device for Stroke and Neuro-Muscular Deficit Patients	Provisional Filing in India

- Patent filing support has been extended for Provisional and Complete Indian filing, PCT filing and national phase entries in different countries such as ARIPO, US, EU, Australia, UK and India. These patent applications are filed mainly in the area of secondary agriculture, agriculture and healthcare.

IP & Technology Management Workshop

IP Clinic

VII. Mentoring and capacity building

1. BIRAC-University of Cambridge Entrepreneurship Education Programme - IGNITE

BIRAC partnered with CfEL, Judge Business School (JBS) at University of Cambridge in 2013 for IGNITE programme with an aim to provide the bioentrepreneurs international mentoring opportunity to transform their innovative idea to a successful business venture.

In FY 2018-19, five BIG Grantees were awarded the IGNITE fellowship to attend the training programme

at JBS.

IGNITE structured training programme of one week includes lecture series by renowned and qualified mentors covering various areas of entrepreneurship such as Value Proposition, Preparation of Business Models, Team building, defining Marketing Strategy, Finance and Business Negotiations etc. After the program, a customized second week was specially created for 5 BIRAC sponsored Startups to facilitate networking meeting. It included meeting start-ups from Cam Bioscience, Accelerator Cambridge for exchange of knowledge and experience among themselves; visits to Swift Molecular Diagnostics, PharmEnable, Astra Zeneca, Spirea. Site visits were followed by workshops for BIRAC Innovators on "company structure", "how to pitch", "branding of your products".

The regular one week programme provided a great platform for the Start-ups to make international collaborations, networking and pitching with investors and polish their business idea. BIRAC plans to continue its participation in the IGNITE one week program.

BIRAC BIG Ignite fellows, 2018 at Judge Business School, University of Cambridge, UK

2. Hands-on training for skill development and Regulatory workshops

Hands-on Trainings

Realizing the importance of conducting hands-on training workshops for upgrading the technical skills of the start-ups and industry personal, BIRAC organizes hands on training workshop regularly. The following five hands on training workshops were organized during 2018-19

1. Synthetic Biology Workshop, IIT Madras Research Park, Chennai (26-28th July, 2018)

The three-day workshop Genetic tools and techniques for synthetic biology was attended by 26 participants and the sessions covered topics like Genetic tools and techniques for synthetic biology, Rational engineering of synthetic enzymes for Biotechnology, Big data technology for designing of highly stable biobricks for synthetic biology, iGEM: Role in synthetic biology advancement etc. The practical session coverd synthetic promoter construction and evaluation of the promoters using fluorescent promoters/basic genetic engineering techniques, big data technology, rational engineering of synthetic enzymes, designing pathway engineering for adipic acid production in E. coli, designing pathway engineering for hyaluronic acid production in L. lactis etc.

2. Centre of Excellence "Biopharmaceutical Technology Course" Series, IIT Delhi (12-14th December 2018)

The course event was attended by academia, professionals from different pharma companies, government research institutes and regulatory bodies. The event was marked by the presence of Dr. MK Bhan, Ex-Secretary, DBT, Prof. V. Ramgopal Rao, Director, IIT-Delhi and Dr. S. Eswara Reddy, DCGI. During the workshop importance of different aspects of biopharmaceutical technology was discussed with the special emphasis on regulatory pathway required to realize the commercial potential of the technology. A critical aspect of similar biologics development is having comprehensive regulatory guidelines. The three-day course aimed at strengthening the regulators and the industry on the various aspects of the Guidelines: process and analytical development, preclinical and clinical development, and regulatory and Good Manufacturing Practices (GMP) issues that relate to development and manufacturing of biopharmaceutical products. The lectures were delivered by eminent scientists and academicians from respective fields.

Total 95 individuals registered for the course series to attend following sessions:

- Elucidating the Guidelines on Similar Biologics for India
- Process Optimization and Scale-Up with Single-Use Bioreactors
- Multivariate Data Analysis for Bioprocessing Data
- Proteomics for Characterization of Biotherapeutics
- Continuous Processing for production of Biopharmaceuticals
- Formulation and Stability of Biotherapeutic Product
- Design of Experiments

3. C-CAMP-GE Collaboration "Down Stream Bioprocessing Course" C-CAMP, Bengaluru (November 13-16, 2018)

This course was jointly organized by Centre for Cellular and Molecular Platforms (C-CAMP) and GE Healthcare, in collaboration with BIRAC. The principle aim of this course was to provide basic hands-on training in 'Downstream Bio-Processing' to individuals from academia and industry. Along with providing a thorough understanding of basic purification techniques and strategies to the participants, this course also included a primer on bio-molecular interaction kinetics. The first three days of the course were held at C-CAMP and were focussed on the basic design and execution of chromatography experiments, with emphasis on gel filtration, ion-exchange chromatography, affinity chromatography, hydrophobic interaction chromatography, & reverse phase chromatography. The course covered the hardware (ÄKTA) and the software (UNICORN 7) aspects of the instruments involved. The technical aspects of the course included purification procedures related to sample preparation, column packing, optimization, scale up and fine tuning, columns, resin maintenance etc. The last day of the course was dedicated to the basics and use of Biacore in exploring bio-molecular interaction kinetics, and was carried out at JFWTC, GE campus. Total 12 registered participants attended the course.

4. Hands on training workshop on Biosimilar Characterization, Institute of Chemical Technology, Mumbai (Nov 29- Dec 1, 2018)

This Biosimilar Workshop 2018 was funded by BIRAC and TEQIP III (Technical Education Quality Improvement Program) III and was organised by Institute of Chemical Technology, from Nov 29-Dec 1, 2018. The first two days of the event provided hands-on-training on biosimilars/biologics characterization and the third day was dedicated to Entrepreneurship talks and Leadership Conclave.

Applications for participation in workshop were screened based on the relevance of the workshop to their immediate research efforts and a total of 73 participants from different enterprises were selected for the Workshop. The two-days intensive training program, involved brainstorming lectures by esteemed keynote speakers from Biocon, Syngene International Pvt Ltd, Wockhardt, Ipca Laboratories, Adello, ACRNS Technologies, Intas as well as academic research institutes such as CSIR-IGIB, CSIR-NCL, IIT-B and subject experts from industry and academia. Participants of the workshop also involved a diverse population of candidates from academic institutes and industries, as well as students, which provided an excellent opportunity for interdisciplinary interactions and collaborations.

Hands-on training on Dynamic Light Scattering (DLS) and Analytical Ultracentrifugation (AUC), the primary bio-analytical techniques used for the determination of Higher Order Structures (HOS) was provided to the workshop participants in association with Beckman Coulter. Associates and sponsors for the workshop from US Pharmacopeia gave practical sessions on Glycan Analysis. Team from Eppendorf was instrumental in providing support and expertise in conducting hands on training in the area of Upstream Bioprocessing to the participants. Along with hands-on-training in sample preparation, analysis and data interpretation, the workshop organizers also provided practical manuals and handouts relevant to the course for benefit of the trainees.

4. BIRAC-ICGEB workshop on "Genome Engineering of Fungal and Yeast Strains for Biomolecule Production"

BIRAC organized a three-day hands on training workshop on "Genome Engineering of Fungal and Yeast Strains for Biomolecule Production" in association with ICGEB, New Delhi. This training workshop was organized as part of Industry mentoring of BIRAC. The total number of participants in the workshop was 24 from different industries and academic institutions. The workshop involved theory and practical sessions on Fungal platform for enzyme production and Yeast platform for biomolecule production. This included synthetic biology application in metabolic pathway engineering for C5 utilization and fatty acid ethyl ester production, genome annotation and identification of targets for genome engineering, Selection of appropriate vector and transformation tools and CRISPR-Cas9 and its application for biomolecule synthesis. A booklet containing all the background information and methods to perform these experiments and do data analysis was distributed to all the participants.

Regulatory Workshops

As per the one of the recommendations of the inter-ministerial meeting at Niti Ayog, BIRAC has worked with Department of Biotechnology (DBT) and Central Drugs Standard Control Organisation (CDSCO) and Clinical Development Services Agency (CDSA); to organise a series of six "National workshops on regulatory compliance for accelerating innovations".

First workshop of this series was organized on December, 10th 2018 at ICGEB, New Delhi. The workshop was attended by senior representatives from Government organizations, academia, medical device industry, IVDs, new drugs, biopharma, phytopharma representing from various start-ups, hospitals, and International organizations from India. 100 participants representing 57 institutions attended this one day program at New Delhi.

The second workshop of the series was held in Venture Centre on February, 2019. There were total 96 participants representing 67 institutes who attended this interactive meet.

Next four regulatory workshops of the series are planned to be held in Bangalore, Hyderabad, Guwahati and Vadodara.

3. New initiatives

i. FIRST HUB

The FIRST HUB was launched on 10th August, 2018 and within a short time has received huge response from Innovators across Country. The FIRST HUB is a platform to solve the queries of Innovators through Face to Face meetings, Telecon or E-mail response. FIRST HUB provides the platform wherein queries related to various governmental organisations can be discussed. The FIRST HUB has representation from CDSCO, ICMR, DBT, BIS, NIB and BIRAC along with KIHT. The participants are encouraged to book their slots in advance to avoid any delay. The queries can be submitted through FIRST HUB portal available at BIRAC website. Queries are solved on the FIRST CUM FIRST SERVE basis. BIRAC is committed to develop the start-up ecosystem in India and facilitate the innovators in their product development journey.

The 1st meeting of the FIRST HUB which is a Facilitation Cell to address the queries of Start _ups,

Entrepreneurs, Researchers, Academicians, Incubation Centres, SMEs was conducted on 7th Sep 2018 at BIRAC. The representatives from Niti Aayog, CDSCO, ICMR, NIB, DBT and BIRAC addressed the queries of innovators.

Seven monthly meetings were conducted during 2018 _ 19 and close to 140 queries were resolved.

ii. BIRAC Regulatory Affairs Cell

Regulatory Affairs Cell was created in November, 2018 at BIRAC with a mandate "To facilitate the process of interpreting the rules and regulations and fostering innovation through helping entrepreneurs pass through regulatory hurdles"

Two meetings of Regulatory Advisory Committee were organized on December, 2018 and March, 2019 respectively. Total number of 54 and 42 proposals respectively were discussed for identifying probable regulatory issues in the area of Bio-similars, Vaccines, Agriculture, Secondary Agriculture, Industrial Biotechnology, Medical Devices and Diagnostics.

Regulatory Advisory Cell's Advisory Committee has members from all the above mentioned areas and help in identifying regulatory requirements for the proposals shortlisted for Apex consideration in the SBIRI, BIPP, SPARSH and NBM programs of BIRAC.

iii. Product Commercialization Program (PCP)

BIRAC is promoting product/technology development in different fields of biotechnology through various funding schemes such as BIG, BIPP, SBIRI, PACE, IIPME and SPARSH. On successful project completion, the technologies developed with BIRAC support attain certain level of maturity, which is measured on a TRL (Technology Readiness Level) scale of 1 to 9. When the technology/product has been successfully validated (TRL 7 and above) and is moving towards commercialization, then besides technical and funding support, the start-ups also requires guidance and support on various other issues such as IP, technology transfer, regulatory, business plan, market conditions, networking, etc.

The main objectives of PCU are:

- To hasten the product commercialization processes by providing all necessary support to the projects which have performed well under the ongoing funding programs of BIRAC and have high commercial potential.
- To become a Product Development Partner of such technologies by providing required support including financial grant, mentoring, connecting with Investors, regulatory facilitation, market access, etc.

Irrespective of the funding program, all ongoing BIRAC funded projects would be monitored for their TRL. A BIRAC internal Committee would meet on a monthly basis to identify those projects that have attained TRL 7 or higher TRL and have the potential to get commercialized. Projects short-listed by the BIRAC internal Committee would then be placed for the consideration of SCPC committee which would identify the specific needs of the project and accordingly decide on the required support (technical, financial, etc.)

The Program was approved by the BIRAC Board of Directors in December, 2017. The operational guidelines and implementation strategy for the Program has been worked out. A Market Readiness Assessment (MRA) form was finalized uploaded online for receiving the support required by Start-ups under various category for further technology advancement and product development. It has been communicated to

those projects that have achieved TRL-7 or above for past two years during FY 2016-2018.

Two regional One-to One Product Commercialization Meetings were conducted in FY 2018-19 to identify potential challenges faced by BIRAC supported start-ups towards commercialization of their technologies. The first meeting was held at SINE incubator, IIT-Bomaby on 14th April, 2018 eight short-listed start-ups from the Western India presented their challenges before Dr. Renu Swarup, Secretary, DBT and BIRAC PCU committee. The second meeting was held on 4th June, 2018, at C-CAMP, Bengaluru where 11 start-ups from Southern region presented their challenges before BIRAC PCU committee. Challenges presented by individual start-ups were addressed separately and common challenges were included within the scope of PCP for addressing them through the program. Few potential start-ups from these meetings were invited for submitting proposals to BIRAC PCP.

BIRAC Start-ups from Western India region with Dr. Renu Swarup, Secretary, DBT and BIRAC PCU committee during PCU regional one-to-one product commercialization meetings at SINE incubator, IIT-Bombay on 14th April, 2018.

BIRAC Start-ups from South India region with BIRAC PCU committee during PCU regional one-to-one product commercialization meetings at C-CAMP, Bengaluru on 4th June, 2018

The MRA forms and other Expression of Interest to BIRAC PCU for PCP Fund during FY 2018-19 was considered by internal PCU committee and the finally shortlisted applicants were invited for full proposal submission. The full proposals submitted by were evaluated by the Screening Committee for Product Commercialization (SCPC) and those recommended for funding are being taken forward.

1st SCPC meeting held at BIRAC on 8th February, 2019.

VIII Supporting National Programs

Biotechnology has emerged as an integral part of the Indian bio-economy. The estimated value of biotechnology sector was USD 44.47 billion in 2017 with a recorded growth of 6.8% from 2016. The projected target for the government is to reach the market size value of USD 100 billion by 2025. Currently, Indian biotech industry holds 3% of the global market share and is 3rd largest in Asia-Pacific region.

BIRAC along with Department of Biotechnology (DBT) is playing a crucial role in the implementation and delivery of the flagship programs of the Indian Government, such as 'Make in India' and 'Startup India'. BIRAC recognizes the necessity for entrepreneurship development among the youth in the country

and hence has taken initiatives to build, support and promote Indian Biotech Ecosystem in Healthcare, Agriculture and Industrial Biotechnology.

1. Make in India

Make in India (MII) Facilitation Cell for Biotechnology at BIRAC is spearheading MII, the flagship program of Government of India through multiple initiatives for supporting the Biotech innovation ecosystem, developing the manufacturing sector and promoting foreign direct investments.

Focus of Make in India Facilitation Cell at BIRAC

Objectives:

- Contribute to Make in India growth through identifying and promoting new areas in Biotechnology
- Coordinate activities of Make in India with Department for Promotion of Industry and Internal Trade, Government of India
- Catalyse the growth of manufacturing industry by mapping incentives and opportunities provided by Central and State Governments
- Facilitate Startups, SMEs and companies by communicating policies and incentives extended by the Government for the programme
- Support the Make in India programme by addressing queries received from various stakeholders

Major activities of Make in India:

1. Identifying and promoting new areas in Biotechnology

   SAEN (Secondary Agriculture Entrepreneurial Network) was launched in 2018 which is led by the Punjab State Council &Technology (PSCST) and other partners, such as, National Agri Food Biotechnology Institution (NABI), Centre for Innovative and Applied Bioprocessing (CIAB) and BIRAC's BioNEST _ Panjab University (BioNEST-PU). The project aims at promoting new enterprises and to support existing industry in the secondary agriculture sector.

Launch of SAEN

2. Monitoring of DBT/ BIRAC Programmes

The Facilitation Cell plays a critical role in monitoring the progress of various programmes of DBT and BIRAC specifically related to Startups, Entrepreneurs and companies and also helps in linking these programmes to the Major National Initiatives.

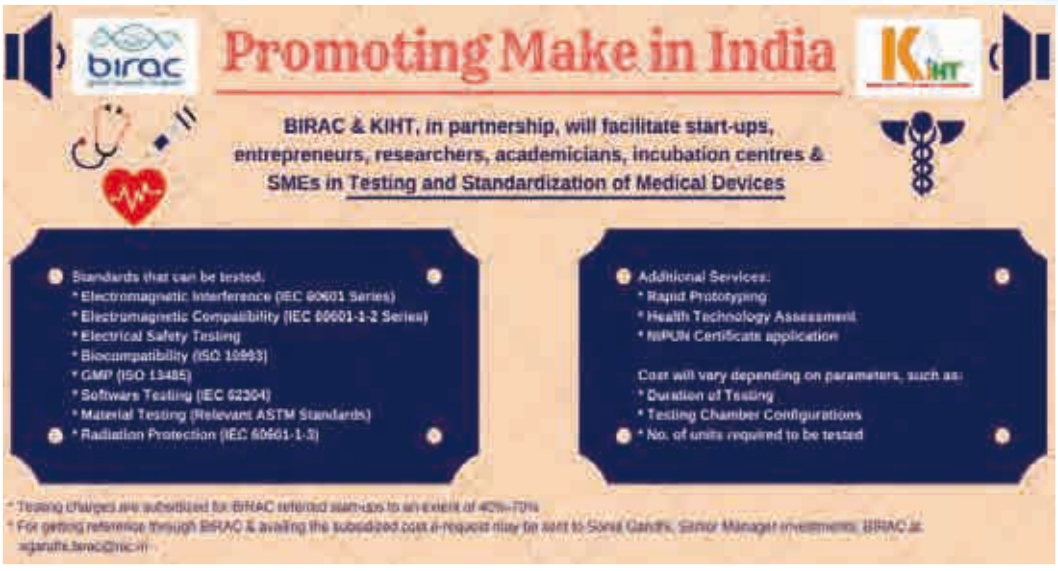
The Cell monitors specifically Startup India and Make in India Action Plan mandated activities and prompts the respective scheme coordinators regarding the progress of some of the important initiatives of DBT & BIRAC such as:

- BioNEST-Till now 41 Bioincubators have been established and the target is 50 by 2020.
- BIRAC Regional Centers- 4 regional centres have been established and the target is 5 by 2020
- Equity Funding Schemes- Track the utilization of funds sanctioned and update the same to DPIIT.

The Cell handles critical feedback from DPIIT and other departments which further helps in refinement of various initiatives. DBT & BIRAC have leveraged from these interactions. The facilitation cell provides the platform to showcase the performance of Department of Biotechnology and BIRAC at National level and to other Ministries.

3. Regulatory Facilitation to Startups/ Entrepreneurs & SMEs

- **FIRST (Facilitation of Innovation and Regulations for Start-ups and Innovators) HUB** is created at BIRAC to recognise the queries of Start _ups, Entrepreneurs, Researchers, Academicians, Incubation Centres, SMEs etc. The FIRST HUB has representation from CDSCO, ICMR, DBT, BIS, NIB and BIRAC along with KIHT. It brings stakeholders at a single F2F platform.
- With an aim to promote Make in India, BIRAC & KIHT (Kalam Institute of Health Technology) have partnered to facilitate start-ups, entrepreneurs, researchers, academicians, incubation centres & SMEs in the area of Testing & Standardization of Medical Devices. BIRAC supported start-ups can avail 40-70% differential service charges for HTA (Health Technology Assessment).



4. Communicating policies and incentives extended by the Government for the programme

- The Make in India Cell ensures wider dissemination of the Government programmes and other information relevant to the establishment and growth of startups, SMEs and Companies. A dedicated website has been developed for information dissemination and handholding of startups and companies (http://birac.nic.in/mii/)

5. Role in strategic decisions and policy making

- MII Facilitation Cell provides key inputs for articulating major policy recommendations for the Biotechnology Sector both to the Department of Biotechnology and BIRAC. The research and analysis team of the Cell seeks and collates information required for designing new programmes and initiatives at BIRAC.
- Strategy Meets and Stakeholder discussions are organized by the Cell to discuss and formulate the roadmap and strategies for DBT & BIRAC. The recommendations of such meetings are instrumental in evaluating existing and creating new programmes.

  Certain examples of need identification and leading to new initiatives by BIRAC include:

  - ✓ Creation of Regulatory Facilitation Cell at BIRAC
  - ✓ Product commercialization program
  - ✓ Facilitation of seamless transition of proposals across different schemes of BIRAC such as from BIG to SBIRI.
  - ✓ Updated BIRAC website with a dynamic dashboard
  - ✓ Field validation for scaling of new technologies
- Make in India Facilitation Cell at BIRAC organized a Strategy Meet in July, 2018 to discuss the road map for achieving $100 Billion bio-economy of India by 2025. Follow on work is in progress for implementing the recommendations.

Strategy Meet organised by Biotechnology Industry Facilitation Cell for Make in India

6. Resolving Queries related to Startup India and Make in India

The Facilitation Cell acts as a single window for resolving the queries of startups, entrepreneurs and companies. More than 80 such queries have been handled till now. The Cell connects them to the relevant departments and endeavours that queries are addressed.

7. Providing visibility to BIRAC supported Startups/ Entrepreneurs & SMEs

National level:

- **National level Product launch platform provided to Startups**: 9 Products supported by BIRAC were launched by Niti Ayog's Vice Chairperson _ Dr. Rajiv Kumar on 19th March at BIRAC's 7th Foundation Day. The names of Innovators and their products are as follows:
  - **"Poorti Kit"** -a Post-mastectomy rehabilitation kit by Dr. Pawan Mehrotra from Aarna Biomedical Products Pvt. Ltd., Delhi.
  - **"ArmAble"** -a Gamified Arm Rehabilitation Device by Mr. Habib Ali from BeAble Health Pvt. Ltd, Hyderabad
  - A mouth-dissolving, **thin-film platform** by Mr.Vishal Kataria from BonAyu Life Sciences Pvt. Ltd., Bhubneswar
  - Voice prosthesis named **"AUM"** by Mr. Amitha & Madhukar from Innaumation Medical Devices LLP, Bangalore
  - **Mush D+**, Mushrooms with enhanced Vitamin D by Dr. Priyangshu Manab Sarma from Innotech Interventions Private Limited, Guwahati
  - **GOsterion**-the-go surgical sterilization solution by Dr. Rachna Dave from MicroGO LLP, Hyderbad
  - **"PurVital Minis"**, a miniaturized water treatment and fortification system by Dr. Devlina Das from N-Science Sustainable Solutions Pvt. Ltd., Bhubneswar
  - **Smart Scope®**: a device for doctors to perform routine cervical health checkups in women by Ms. Veena Moktali from Periwinkle Technologies Pvt. Ltd., Pune
  - Microcrystalline cellulose **(RICEL)** and Silica gel **(RISIL)** by Mr. Mohammad Gulebahar from Pro Biokem Pvt. Ltd., Bhubneswar
- **Lab To Market Booklet**- This booklet released on the 7th foundation Day of BIRAC features representative 32 innovative products that have reached to market. Description about the product/ technology USP, Value proposition, Pricing, Target Customer, units sold, contact information of the Startup were included in this booklet (online version available on BIRAC's website).

- **Lab To Market Pitching to Stakeholders**_12 Startups pitched at the 7th Foundation Day. 9 of these received commitment of handholding by the participating stakeholders who included representative from Hospital, Med Tech Industry, Investors.
- **CII HealthTech India**- The 2nd Edition of Health Tech India 2019 was held from 3_5 February, 2019 at Pragati Maidan, New Delhi, India. During the 3 day long exhibition, more than 75 exhibitors displayed their technology/ innovations. BIRAC displayed its various funding schemes, international collaborations and impact created so far.

BIRAC representative and supported startups at CII HealthTech Summit

BIRAC booth at CII HealthTech Summit

BIRAC supported 3 Startups to showcase their innovative technologies, namely - JC Orthoched, Turtshell and Niramai who received an encouraging traction including market connects.

International level

- **MEDinISAREL**- MEDinISRAEL 2019 was organised from 25-28th March, 2019 in Tel Aviv, Israel for the Israeli and global (Digital) Health ecosystem to come together and leverage each other's experience. 3 BIRAC supported MedTech startups were given opportunity to participate and network with the Israeli Startup Ecosystem.

BIRAC representative and supported startups at MedinIsrael, 2019

- **Global Bio-India 2019**

  BIRAC along with DBT will be organising Global Bio-India from 21-23 November, 2019 in New Delhi. This event will be a congregation of about 3500 international and national delegates representing Industry, Scientific Research bodies, Academia, Ministries, Organizations, Agencies, Startups, Incubators, Investors, States and other stakeholders to showcase the strength of Indian biotech ecosystem. This major activity will be co-steered through Make in India Facilitation Cell at BIRAC.

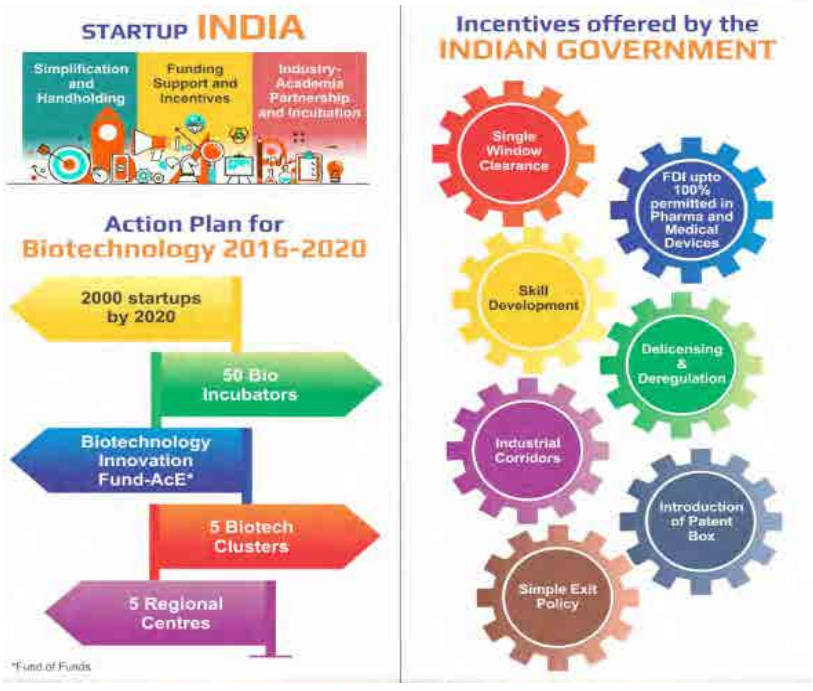
2. Startup India

Startup India is a flagship initiative of the Government of India, intended to build a strong eco-system for nurturing innovation and Startups in the country that will drive sustainable economic growth and generate large scale employment opportunities. The Government through this initiative aims to empower startups to grow through innovation and design. The Prime Minister of India formally launched the initiative on January 16, 2016.

To further strengthen and empower the emerging biotech startup ecosystem, DBT along with BIRAC has drafted a detailed action plan with a mandate of promoting and nurturing the innovation research ecosystem in the country with special focus on startups and SMEs. BIRAC's activities are aligned with the deliverables of StartUp India mission.

Objectives

To foster and facilitate bio-entrepreneurship.



Status:

- Scale up the number of startups in the biotech sector to reach around 2,000 by 2020 - *target likely to be achieved*. India will cross 2000+ biotech startups before 2020
- 41 Bioincubators established by BIRAC
- Ace Fund of Funds has been operationalized
- 4 BioClusters created
- 4 Regional centres created

IX Facilitating Industry Academic Interaction

1. Innovators' Meet

The 7th Innovator's Conclave of BIRAC was held at Heritage Village, Manesar on 19th-20th September, 2018. The theme for this event was 'VIGYAN SE VIKAS'. The Innovator's Conclave witnessed the confluence of around 300 Scientists, Entrepreneurs, Academicians and Industry Experts. The event was inaugurated by Dr Renu Swarup, Secretary DBT, Ministry of Science & Technology and Chairperson BIRAC; Dr Mohd Aslam, MD BIRAC & Advisor Scientist 'G', DBT; Dr Anand Anand Kumar, Co-Founder and CEO, Bugworks Research; and Dr Anuradha Acharya, Founder & CEO, Mapmygenome.

Lamp lighting ceremony

Dr Mohd Aslam, Dr. Anuradha Acharya, Dr. Renu Swarup & Dr. Anand Anand Kumar releasing BIRAC Publications

The inaugural session also witnessed the announcement of the BIRAC Innovators Awards:

1. Best Innovation in Healthcare (Devices & Diagnostics) was awarded to Forus Health Private Limited, Bengaluru in collaboration with Healthcare Technology Innovation Center, Chennai and Narayana Nethralaya Foundation, Bengaluru for their significant contribution to innovative research on "Shishunethra - Preventing blindness in Infants".

2. Best Innovation in Agriculture was awarded to Jiva Science Private Limited, Bengaluru for their significant contribution to innovative research on "Development of Microfluidic Laser Based Sperm Sorting (MLBSS) chip for Bovine sperm sorting".

3. Best Innovation in Healthcare (Therapeutics) was awarded to Regrow Biosciences Private Limited, Mumbai for their significant contribution to innovative research on "A Prospective, Open-label, Multi-centric Study to Assess the Safety and Efficacy of Autologous Adult Live Cultured Buccal Epithelial Cells Uregrow® in Subjects with Urethral Stricture".

4. Best Innovation in Industrial Biotechnology was awarded to String Bio Private Limited, Bengaluru for their significant contribution to innovative research on "Nanobubble technology for economical gas fermentation".

5. Best Innovation in Healthcare (Devices & Diagnostics) was awarded to PathShodh Healthcare Private Limited, Bengaluru for their significant contribution to innovative research on "Diabetes Management Device and Strips: Scale up, Quality Control and Deployment".

BIRAC Innovator Awardees

The Poster session was also organised and inaugurated by Dr Mohd Aslam, MD, BIRAC & Scientist 'G', DBT.


Glimpses from Poster Session

Make in India cell sponsored awards for the Winners of the Poster Session:

1st Prize-(INR 25,000)-BmNPV Resistant Transgenic Silkworm (APSSRDI& CDFD).

2nd Prize-(INR 15,000)-USENSE™ (Module Innovations Pvt Ltd).

3rd Prize-(INR 10,000)-Refining of Biogas (DCM Shriram Daurala Sugar Works).

4th Prize-(INR 5,000)-Cocoons to Tissue (Biolmed Innovations Pvt Ltd).

5th Prize--(INR 5,000)-Orthoscrew, Osteoanchor, PromaTack (Orthocrafts Innovations Pvt. Ltd.).

2. Foundation Day

The 7th Foundation Day of BIRAC was celebrated at Hotel Pullman, Aerocity on 19th-20th March, 2019. The theme for this event was 'Nurturing Innovations: Empowering India'. The event witnessed a confluence of around 300 Scientists, Entrepreneurs, Academicians, Hospitals, Industry and National & International experts.

The event was inaugurated by Dr. Rajiv Kumar, Vice Chairman, NITI Aayog, Govt. of India and attended by Dr. Chris Karp, Director, Discovery & Translational Sciences, BMGF; Dr Ted Bianco, Former Director, Wellcome Trust, UK; Dr. Renu Swarup, Secretary, DBT & Chairperson, BIRAC and Dr. Mohd. Aslam, Advisor, DBT & MD, BIRAC.

Lamp lighting ceremony

A special session on Women Entrepreneurship **"Biotech powered Women entrepreneurs creating Regional and Global solutions:** Vigyan Se Vikas" was attended by South Asian countries including Nepal, Bhutan, Maldives, Sri Lanka, Afghanistan and Bangladesh representative promoting Women Entrepreneurship in their countries. BIRAC can facilitate as a knowledge partner to nurture Startup ecosystem in these countries.

South Asian Women Development Forum representatives along with other dignitaries

Another special session, **Lab 2 Market: Pitching to Stakeholders**, on outcome-oriented interaction between Stakeholders and BIRAC supported commercialized Startups to facilitate their next level engagement was conducted on Day 2 of the Foundation Day event on 20th March, 2019. During this session, 12 BIRAC grantees with projects under the category of medical devices and diagnostics presented their innovative products to the panelists.

3. Outreach Initiatives

A. Communications

The communications team in BIRAC, working with the various teams and verticals, is charged with externally communicating the work that the organisation is undertaking to a diverse range of audiences, which includes innovators, scientists, academics, policy makers, investors among many others. The Communications Team is also responsible for promoting the brand presence of BIRAC through a variety of digital, print and social media.

The communications team, with the various departments within BIRAC, develops content for collaterals such as brochures, flyers, and other publications. The team also develops collaterals for the official BIRAC twitter handle and manages the account. The team also developed the Friday Feature _ Vigyan se Vikas _ which showcases innovations supported by BIRAC as a regular twitter update every week.

The team is also responsible for the newsletters which are quarterly publication of BIRAC which feature cover stories, expert opinions, innovator opinions, BIRAC events and program updates.

Hunnarbaaz 2018- BIRAC is partnering with the Hunnarbaaz Cinema Vision team to develop a series of short videos that will be showcased on DD National. These will showcase BIRAC innovators from across the country.

The BIRAC Communications team also assisted with the Ministry of Science and Technology, Government of India Communications Campaign in June 2018 that coincided with the launch of the Ministry's 4-year Achievement Report.

B. BIRAC Representation at BIO KOREA 2018

Bio Korea 2018 held in Seoul from 9 to 11 May, 2018, South Korea was organized by Korea Health Industry Development Institute, KHIDI, a government (Ministry of Health and Welfare) affiliated organization in Health Technology (HT) R&D to strengthen the global competitiveness in various sectors of Korean health industry. BIRAC was represented by Dr. Manish Diwan, Head, SPED, BIRAC and Mr. Utkarsh Mathur, BD Manager, BIRAC. Few Indian Startups and companies also participated in this event. The delegates interacted with potential companies, health technology transfer centers, Bio Hubs, Business & Science Accelerators & various centers involved in commercialization of the cutting edge medical products innovations. The Bio Korea 2018 & Medical Korea was inaugurated by Honorable President of South Korea - Mr. Lee Nak _ Yeaon along with a group of Ministers.

The Bio- Korea 2018, featured more than 1500 exhibitors including more than 15 international, regional & province pavilions. The participants included leading biotech and pharma companies, CROs, Academic Institutions, Government Agencies, patent advocacy firms and Venture Philanthropy Organizations. In addition, the event witnessed more than 1000 partnering meetings.

Dr. Manish Diwan & Mr. Utkarsh Mathur at BIO Korea 2018

C. BIRAC's presence at BIO International Convention 2018

The annual BIO International Convention, hosted by the Biotechnology International Organization was held from 4th-7th, 2018 June at Boston Convention and Exhibition Centre (BCEC), Boston. BIO Boston 2018 gathered over 18,000 attendees from 67 countries. BIO also hosted nearly 47,000 BIO One-on-One Partnering between more than 7,900 delegates from 3,900 companies.

Team INDIA at BIO 2018 was represented by 27 teams from the Government of India and States of Karnataka and Telangana along with 21 companies who represented the dynamic Innovation ecosystem in the Indian Life Sciences space. The Ministry of Science & Technology, Government of India was represented by Department of Biotechnology, BIRAC and Council of Scientific & Industrial Research (CSIR). The India delegation was led by Mr. C. P. Goyal, JS (Adm.), DBT along with Kiran M Shaw, CMD, Biocon Ltd.

BIRAC participated in BIO 2018 by putting up an exhibit in the India Pavilion. Ms. Jaya Sitaram, Senior Manager - Corporate Affairs and Ms. Shipy Kochar, Manager, Enterprenuership Development represented BIRAC at Bio Boston 2018. BIRAC booth witnessed an excellent response and attracted several visitors from different countries. The visitors included :

- Officials from Technology Transfer Offices
- Biotech Clusters willing to help Indian startups in setting up their units in other parts of the world and raising funds for the same
- NRIs/OCIs willing to set up their companies in India and
- Technology providers willing to set up their manufacturing units in India

One on one partnering sessions were conducted with likeminded organizations across the globe and possibility of collaboration with them was explored. BIRAC also created awareness about the funding schemes, other support services, Start Up India, Make In India schemes of the GoI amongst the potential community. The visitors appreciated BIRAC's efforts and expressed astonishing views regarding the impact made by BIRAC over last 6 years.


BIRAC's participation at BIO Boston

D. Visit of Indian Delegation to Sweden

A high level Indian delegation led by Dr. Renu Swarup, Secretary Department of Biotechnology, and Chairperson, BIRAC visited Sweden during 20-22 August, 2018 to explore collaboration opportunities between the two countries in the area of biotechnology. The meetings included Face to Face discussions on Sweden-India Innovation Partnership at G2G level, interactions with implementing agencies to understand their policy, Triple Helix model of Innovation and site visits to Innovation Clusters and Test Beds. The 3-day agenda included visits to Ministry of Enterprise and Innovation, Ministry of Education and Research, Swedish Research Council, Nobel Media, Vinnova, Uppsala Innovation Center (UIC), Uppsala University Bio Cluster, KTH Royal Institute of Technology and Karolinksa Institute Innovation Centers.

During visits to Vinnova, Uppsala Innovation Center (UIC), Uppsala University Bio Cluster, KTH Royal Institute of Technology and Karolinksa Institute Innovation Centers, their core activities and policies were discussed to explore possible areas of collaborations.

A MoU of extension of existing partnership was also signed between DBT & Vinnova and BIRAC as an implementing agency under the umbrella MoU. New initiatives were discussed to leverage the DBT/BIRAC - Vinnova partnership such as exchange programme of Indian & Swedish Startups, Market access to startups, Networking events and access to Test Beds.

Indian delegates also attended the launch of Testa Center (GE Healthcare, Sweden) by Mr. Mikael Damberg, Minister of Enterprise & Innovation, Sweden. The Testa Center is a test bed for production of biological products.

Dr. Renu Swarup, Secretary DBT Chairperson, BIRAC along with BIRAC representatives at Vinnova, Sweden

Meeting between Indian Delegates and Vinnova, Sweden for discussion on future activities

E. BIRAC's presence in Bengaluru TECH Summit 2018

21st edition of Karnataka State flagship Information Technology and Biotechnology event, Bengaluru Tech Summit was held from 29th November to 1st December, 2018 with the theme: "Innovation & Impact". The event was inaugurated by Hon'ble Chief Minister of Karnataka, Shri HD Kumaraswamy at the Bengaluru Palace. The conference attracted over 10,000 visitors, 200+ visionary speakers, 200+ startups and global leaders from 11 countries. The event focused on convergence of technologies such as artificial intelligence, IoT, Blockchain etc which help provide solutions for the challenges faced in health, agriculture, energy etc.

Inauguration of Bengaluru Tech Summit 2018 by Hon'ble Chief Minister of Karnataka

F. BioAsia 2019: "Life Sciences 4.0 _ Disrupt the Disruption" (25th February to 27th February, 2019)

With the intent to strengthen a robust ecosystem for Life Sciences, Biotech and Healthcare enterprises, Telangana State Governor, Mr. E. S. L. Narasimhan inaugurated the three-day event 16th Edition of BioAsia 2019 _ Asia's largest biotechnology and life-sciences forum bearing the theme "Life Sciences 4.0 _ Disrupt the Disruption". The event over the years has emerged as the most prominent technology and bio-business convention in Asia for life sciences, pharmaceuticals and healthcare. More than 1,700 delegates from industry, governmental authorities, academia and start-ups representing over 50 countries with around 100 high-profile speakers and 700 corporates participated in the event.

BIRAC powered session at BioAsia, 2019

BioAsia also organized a BIRAC powered session 'Life Sciences 4.0: Challenges and strategic opportunities for healthcare in India' chaired by Dr. Renu Swarup, Secretary DBT & Chairperson BIRAC.

The Governor inaugurated the International Exhibition & Startup Stage wherein a huge number of corporates and 75 start-ups participated. Many BIRAC supported start-ups such as Beable Health, Predible, Janitri, Oncosimis, NemoCare, OmniBRx were among the exhibitors in the summit. The event concluded with a valedictory Session where top five Startups were presented "BIRAC Start-ups Awards" sponsored by BIRAC.

OUR FUTURE PLANS

- Given the importance of primary health care in India, it is proposed to launch a call seeking solutions for improving primary healthcare in India. The program will provide an opportunity to take into account newer health issues in India, such as the burden of non-communicable disease, and to specifically strengthen the primary healthcare system with a focus on improving health outcomes.
- India has made significant strides in improving the health of its nation. However, variances are observed in health across sector of the population. The behaviour change communication (BCC) strategies when employed in these scenarios intends to generate demand for the uptake of health products and services to improve health outcomes among the populations. Keeping in view the same a competitive program on Behavior Change Communication is being proposed to address identified evidence gaps on what interventions would work to improve frontline workers (FLW)/ community health workers (CHW) performance in India.
- The Ki, knowledge integration challenge launched under GCI umbrella gives researchers access to a huge trove of integrated data and the tools to analyze it in powerful ways that generate new insights quickly. On similar lines, it has been proposed to launch a knowledge integration (ki) Data Challenge (ki 2.0) to further develop and validate data analytic approaches to foster Maternal, Newborn and Child Health (MNCH) challenges.
- Keeping in view the success of first phase of Grand Challenges Explorations (GCE) _ India initiative that was aimed at identifying pool of innovations to create novel, indigenous technologies to improve the public health situation in India, it is being proposed to launch second phase of GCE-India to identify health care innovations that will enable the goal of equitable health care in India and beyond.
- The agriculture and nutrition (AGN) investment under GCI ambit was meant to encourage innovation and research in the areas of agriculture, nutrition and social empowerment, which would lead to the larger goal of improvement in health of women and children. As supported pilot studies met their milestones and brought together a multi-disciplinary consortium of interventions to evaluate an innovation at the nexus of agriculture, nutrition, and health it is proposed to Scale-up AGN innovations and interventions.
- Establishment of SPARSH (Social Innovation programme for Products: Affordable & Relevant to Societal Health) centres for Social Innovation Immersion.
- To announce a call in the area of Guar Gum.
- To launch a program and set up a facility in the area of nutraceuticals.
- **Setting up of the 5th Regional Centre**

  BIRAC is spreading the ecosystem reach and expanding the inclusion throughout the country. So far it has strategically created 4 Regional Centres_BREC (Bangalore), BRIC (Hyderabad), BRBC (Pune) and BRTC (Bhubaneswar). It would be expanding the number of Regional Centres to a total of 5 by 2020.
- **Democratize Entrepreneurship reaching to North East Region (NER)**

  Special call for North East under BIG.

  Create 100 Social Entrepreneurs and Women entrepreneurs in NER.
- **Women Entrepreneur Network in NE**

  Roll out Special Award for Women Entrepreneurs from North East_BIRAC TiE WiNER Award.
- **Resource Mobilization**

  BIRAC as Implementing/ Knowledge partner to co-promote Entrepreneurial & Startup activities with Ministries/ States/ Corporates (CSR).
- **Upscale initiative of Field validation on patients/ subjects to facilitate traction of products/ technologies**

  From current 4/year to 15/year; expanding partners and activity spectrum from medical devices to other products and technologies. For example Assistive technologies.

- **AcE fund** - expansion of AcE fund partners from current 5 to 10. Attempt to expand the corpus for AcE fund.
- **Global Bio-India 2019**

  This 3 day international mega event will be led by DBT and co-steered by BIRAC through Make In India Facilitation Cell. About 3000+ delegates including Industry, Research Institutes, Policy Makers, Regulatory Agencies, Ministries, States, Departments, Startups, Investors and Biotechnology sector related stakeholders would be targeted.

SUPPORTING SERVICES

a. Legal

The Legal Cell of BIRAC provides a wide array of advisory and support services including drafting, reviewing, executing and modifying contracts, agreements and internal policies and ensuring that they are in compliance with all the statutory and legal requirements.

The services of the Legal Cell also includes providing legal guidance for the on-going and new funding programs, providing legal protection and risk management advice to management, managing the legal due diligence process pertaining to the various funding schemes, advising the management on the modalities of national and international co-funding initiatives facilitating technology acquisition, implementation of the National Biopharma Mission, promoting alternative dispute resolution etc.

b. Internal control system and their adequacy

The Company has established systems providing adequate internal controls, commensurate with the size and nature of the business. Such systems have been appropriately documented. There is a very clear policy to maintain confidentiality and ensure No-Conflict of Interest.

c. Human resources

The HR & Administration Department in BIRAC is an essential component which is primarily focused on maximizing employee productivity in line with Company's objectives. It plays an essential role in developing a company's strategy as well as handling the employee-centered activities of an organization.

The HR & Administration Department with its diverse mix of skill sets and its unique perspective on business operations, is positioned to add strategic value on critical issues across the employee life span from recruiting and on boarding to talent development and retention.

HR Department is constantly in the endeavour to induct right people at the right time to meet organizational needs. The department has put concerted efforts in talent management and succession planning practices, strong performance management and training initiatives to ensure that it consistently develops inspiring, strong and credible leadership. BIRAC is a growing organisation and succession planning is an integral part of the strategic planning process to connect with the long term goals and objectives of the Company and to help mitigate risk associated with attrition. A holistic succession plan has been implemented across the organization and an integrated, systematic approach has been adopted for identifying, developing, and retaining capable and skilled employees in line with current and projected organisational objectives.

HR Department reviews the performance of employees in a systematic way and takes it as a developmental tool for all round development of the employee and the organization. Online submission of Annual Performance Appraisal Reports (APAR) in respect of all executives (E1 and above) is activated in the beginning of the financial year and closes in April _ May of the following year with end year appraisal and review. Based on the performance ratings, the contracts of employees are renewed and promotions are awarded. DPC is convened twice a year and assesses the suitability of employees for contract renewals and promotions.

HR & Administration Department with IT team took an initiative to develop and implement HRMS integrated with Finance which has been firmed up and covers the full spectrum of tasks associated with Human Resources department including tracking & improving process efficiency, managing organizational hierarchy, and simplifying financial transactions of all types. The HRMS software is being updated regularly to make it more effective for the organisation.

Training and development activities have played a key role to upgrade the workforce to adopt new

technologies, systems and practices and make the workforce ready to face the future challenges. BIRAC is focussed on enhancing skill development of its employees by organizing in-house trainings and identifying domain specific training in reputed training institutes. In 2018-19 more than 200 man-days training have been imparted to BIRAC Employees including domain specific trainings and soft skill trainings.

Online quarterly vigilance clearance is updated for Senior Executives (Level -4 and above) as per the DPE norms.

World HRD Congress has awarded Dr. Mohd. Aslam as CEO with HR Orientation.

Human Resource & Administration Department in BIRAC strives on implementing employee engagement activities through which employees feels a strong emotional and personal connection to their workplace which in turn reduces staff turnover, improve productivity and efficiency. National events such as Vigilance Awareness Week, Swachhata Pakhwada, Hindi Divas, Anti-terrorism day, Women's Day etc. are also observed in BIRAC with fervour and zeal.

Swachhata Pakhwada

Swachhata Pakhwada was observed in BIRAC from 1st May to 15th May, 2018. Swachhata pledge was administered by MD, BIRAC to all employees. All employees have taken a pledge to devote 100 hours in a year as 'Shramadaan' to ensure cleanliness of the work area & surroundings.

As an initiative to promote green environment and clean environment under Swachhata Abhiyan, BIRAC employees planted saplings in the presence of Dr. Renu Swarup, Secretary DBT, Govt. of India & Chairperson BIRAC and Dr. Mohd. Aslam, Advisor (Scientist 'G') DBT, Govt. of India & MD, BIRAC.

A series of other activities like cleaning drive, technical forum and various competitions like best innovative idea to keep our environment clean, quiz and poster making competition were organised as part of Swachhata Pakhwada in which all employees actively participated and contributed towards the mission.

Anti _ Terrorism Day

The staff observed Anti-Terrorism Day by pledging for promoting peace on 21st May, 2018. The pledge was administered with the objective to wean away the youth from terrorism and the cult of violence by highlighting the sufferings of the common people. The Day is observed to generate awareness in the country among all sections of people, about the menace of terrorism and violence and its effect on the people, society and the country as a whole.

Vigilance Awareness Week

Vigilance Awareness week was observed in BIRAC from 29th October to 3rd November, 2018. The observance of the Vigilance Awareness Week commenced with the Integrity Pledge taken by all employees of to encourage all employees to collectively participate in the prevention of corruption and fight against. The basic motto of this week is to create a corruption free society.

National Unity Day

BIRAC celebrated Rashriya Ekta Diwas by administering a pledge as part of Birth Anniversary Celebration of Sardar Valabhbhai Patel on 31st October, 2018.

Hindi Diwas

This year BIRAC observed Hindi Maha from 14th September to 14th October, 2018 to promote and propagate the use of our national language. During this period, competitions like Hindi Varnmala, Hindi Lekhan Pratiyogita and Hindi Shabdkosh were organized in BIRAC, where all employees participated with zeal.

Swachhata Hi Seva Campaign

BIRAC carried out various activities under Swachhata Hi Seva - 2018 campaign during 15th September, 2018

to 2nd October, 2018 as a part of the 150th Birth year Celebration of Mahatma Gandhi. A cleanliness activity to clean the area near by electrical installations, stairs and glass doors was organized at the office premises. During the programme, all the Employees of BIRAC performed "Shramdaan" and carried out a cleanliness drive by cleaning terrace at office building and collected the waste material for onward disposal.

Women's Day

International Women's Day is observed on March 8 every year celebrating the social, economic, cultural and political achievements of women. BIRAC also celebrated Women's Day where Dr. Renu Swarup, Secretary DBT & Chairperson BIRAC and Dr. Mohd. Aslam, Advisor (Scientist 'G') DBT & MD BIRAC addressed employees.

BIRAC celebrated exceptional work done by Indian women by remembering how Indian Women have broken gender barriers and worked hard for their rights and made progress in the field of politics, arts, science, law etc.

Employees of BIRAC also actively participated in the event by singing inspirational songs and Poems.

With regular communication and sustained efforts HR and Admin Department is ensuring that employees are aligned on achieving BIRAC's strategic mission, while keeping employees engaged and motivated. It strongly believes in fostering a culture of trust and mutual respect in all its employees and seeks to ensure that BIRAC's core values and principles are understood by all.

REPORT ON CORPORATE GOVERNANCE

REPORT ON CORPORATE GOVERNANCE

1. BIRAC Philosophy on Guidelines on Corporate Governance

Corporate Governance refers to a set of systems, principles and processes by which a company is governed. They provide the guidelines as to how a company can be directed or be controlled such that it can fulfil its goals and objectives in a manner that adds to the value of the company and is also beneficial for all the stakeholders in the long term. Stakeholders in this case would include everyone ranging from the board of directors, management, shareholders to customers, employees and society. BIRAC is committed to sound principles of Corporate Governance with respect to all its policies, practices and procedures. The Company's policies clearly reflect its values of transparency, professionalism and accountability. BIRAC consistently strives to uphold these values so as to generate long term economic value to all the stakeholders.

2. Board of Directors

The Board of Directors currently consists of 6 Directors viz. an Executive Chairperson, an Executive Managing Director and Government Nominee Director and 4 independent directors.

Six Board meetings of the Company were held on the following dates: May 16, 2018, July 3, 2018, August 24, 2018, September 25, 2018, November 15, 2018 and February 20, 2019

The details of the Directors and the Board meetings attended are as follows:

Name of the Director	Category	Directorships in other companies	Member/ Chairman of Committees in other companies		Board Meetings Attended (Nos.)	Attendance at last AGM
			Member	Chairman		
Dr. Renu Swarup*	Chairperson (Executive)	Nil	Nil	Nil	6	Yes
Dr. Mohd. Aslam**	Managing Director (Executive) and Government Nominee Director	2	Nil	Nil	6	Yes
Prof. Ashok Jhunjhunwala	Independent Director	3	Nil	Nil	5	Yes
Prof. Pankaj Chandra	Independent Director	Nil	Nil	Nil	4	Yes
Prof. Akhilesh Tyagi	Independent Director	1	Nil	Nil	6	Yes
Shri. Naresh Dayal	Independent Director	2	Nil	Nil	3	Yes
Prof. Ashutosh Sharma#	Chairman	Nil	Nil	Nil	Nil	NA

* Managing Director upto April 9, 2018 and subsequently appointed as Secretary DBT and Chairperson BIRAC with effect from April 10, 2018

** Appointed as Managing Director (additional charge) w.e.f. April 10, 2018 in addition to being the Government Nominee Director

\# Was Chairman, BIRAC for the period from February 3, 2018 to April 9, 2018

None of the Directors are members of more than 10 Committees and/ or act as Chairman of more than 5 Committees as prescribed under the Guidelines on Corporate Governance for Central Public Sector Enterprises (CPSEs) issued by the Department of Public Enterprises (DPE).

There are no pecuniary relationships or transactions of the non-executive directors of the Company.

3. Audit Committee

The Audit Committee consists of four Directors viz. Prof. Akhilesh Tyagi, Independent Director as Chairman, Prof. Pankaj Chandra, Independent Director, Prof. Ashok Jhunjhunwala, Independent Director and Dr. Mohd. Aslam, Managing Director as members. The Audit Committee was reconstituted on May 16, 2018, where Dr. Renu Swarup, by virtue of being appointed as the Secretary, DBT ceased to be a member of the Audit Committee and Dr. Mohd. Aslam who was the Government nominee director and was given additional charge as Managing Director, BIRAC, was inducted into the Audit Committee by virtue of being the Managing Director, BIRAC.

Five Audit Committee meetings were held on the following dates: July 3, 2018, August 24, 2018, September 25, 2018, November 15, 2018 and February 20, 2019

The details of attendance of the directors at the Audit Committee meeting are as follows:

Name of the Director	No. of Audit committee meetings attended
Prof. Akhikesh Tyagi	5
Prof. Ashok Jhunjhunwala	5
Prof. Pankaj Chandra	3
Dr. Mohd. Aslam*	5

*Was inducted as a member on May 16, 2018

#Dr Renu Swarup Secretary DBT was a member till Dr Mohd. Aslam was appointed MD on 10th April, 2019

4. REMUNERATION COMMITTEE

The Remuneration Committee of BIRAC was constituted on August 24, 2018 to decide on the annual variable pay pool and the policy for its payout within the prescribed time. Prof. Pankaj Chandra, Independent Director was appointed as the Chairman of the Committee and Prof. Ashok Jhunjhunwala, Independent Director and Dr. Mohd. Aslam, Managing Director, BIRAC were the members of the Committee.

The first meeting of the remuneration meeting was held on September 25, 2018 to decide on the annual variable pay pool for payment of the Performance Related Pay (PRP).

5. BOARD PROCEDURE

The meetings of the Board are generally held at the Company's registered office at New Delhi. The Company complies with the statutory requirements for holding board meetings. Apart from the statutory matters requiring Board's approval, all major decisions including key financial ratios, actual operations, feedback reports and minutes of meetings are regularly placed before the Board.

6. SHAREHOLDER INFORMATION AS ON MARCH 31, 2019

Category Code	Category of shareholders	Total number of shares	Total value of shares (in Rs.)	Total shareholding as a percentage of total number of shares
Shareholding of Promoter and promoter category	President of India	9000	90,00,000	90
	Dr. Renu Swarup (held on behalf of the President of India)	900	9,00,000	9
	Dr. Mohd. Aslam (held on behalf of the President of India)	100	1,00,000	1
	GRAND TOTAL	**10000**	**1,00,00,000**	**100**

The Company had received its International Securities Identification Number (ISIN) under the Depository system.

6. GENERAL BODY MEETINGS

The details of general body meetings are as follows:

Period ended on	Venue	Date	Time
31.03.17	MTNL Building, 1st floor, 9, CGO Complex, Lodhi Road, New Delhi _ 110 003	12.09.17	4.30 p.m.
31.03.18	MTNL Building, 1st floor, 9, CGO Complex, Lodhi Road, New Delhi _ 110 003	25.09.18	12.30 p.m.
31.03.19	Department of Biotechnology, 2, CGO Complex, 7th Floor, Lodhi Road, New Delhi-110003	23.09.19	10.15 a.m.

7. DISCLOSURES (AS PER DPE GUIDELINES)

1. The Company has not entered into any material, financial or commercial transaction with the Directors or the management or their relatives in which they are either directly or through their relatives interested as directors and/or partners.
2. The Company has complied with applicable rules and regulations and no penalties or strictures were imposed on the Company by any statutory authority during the last two years.
3. The Company has complied with the applicable provisions of the guidelines of Corporate Governance.
4. Department of Public Enterprises vide its OM dated 29.07.2010, advised all CPSEs to submit an annual compliance report on implementation of policies and guidelines issued by DPE by 30th June every year. In compliance of the directives of DPE, BIRAC submitted its compliance report to the Department of Biotechnology for onward transmission to DPE.
5. No item of expenditure was debited in the books of accounts which was not for the purpose of the organisation.
6. No expenses of a personal nature of the Members of the Board of Directors were incurred out of the funds of the Company.

8. MEANS OF COMMUNICATION

Members/ shareholders are apprised about the performance of the Company at each Annual General Meeting. The Company is an unlisted, private limited Section 8 Company and therefore, the need to communicate its quarterly or half-yearly results does not arise.

9. COMPLIANCE CERTIFICATE

In terms of Clause 8.2 of the DPE Guidelines on Corporate Governance, a certificate from a practising Company Secretary, M/s. P.N. Gupta & Associates, New Delhi confirming the compliance of the provisions of Corporate Governance forms a part of the report on Corporate Governance.

10. CODE of CONDUCT

BIRAC is committed to conduct business in accordance with the highest standards of business ethics and compliance with the applicable laws, rules and regulations. A Code of Business Conduct and Ethics in accordance with the DPE Guidelines has been laid down for all Board members and senior management.

All the members of the Board and senior management personnel have affirmed compliance with the same for the financial year 2018-19. The Code of Business Conduct and Ethics has also been put up on the website of the Company (www.birac.nic.in)

Declaration as required under the DPE Guidelines on Corporate Governance

"All the members of the Board and Senior Management Personnel have affirmed compliance of the **Code of Business Conduct & Ethics for Board Members and Senior Management** for the financial year ended on March 31, 2019"

Sd/-
Dr. Mohd. Aslam
Managing Director

CERTIFICATE OF COMPLIANCE OF CORPORATE GOVERNANCE AS PER THE GUIDELINES OF DEPARTMENT OF PUBLIC ENTERPRISES (DPE) BY A COMPANY SECRETARY IN WHOLE TIME PRACTICE.

To the Members of Biotechnology Industry Research Assistance Council (BIRAC)

We have examined the compliance of conditions of Corporate Governance by Biotechnology Industry Research Assistance Council ("hereinafter referred the Company"), for the year ended on March 31, 2019 as stipulated in the Guidelines of Corporate Governance for Central Public Sector Enterprises (CPSEs) issued by Department of Public Enterprises (DPE) vide its order dated May 14,2010.

The compliance of conditions of Corporate Governance is the responsibility of the management. We have examined the relevant records of the Company in accordance with the provisions of the guidelines of DPE and limited to a review of the procedures and implementation thereof, adopted by the company, for ensuring compliance with the conditions of Corporate Governance. It is neither an audit nor an expression of opinion on the financial statements of the Company.

In our opinion and to the best of our information and according to the explanations given to us and the representations made by the management, we certify that the Company has complied with the conditions of Corporate Governance as stipulated in the Guidelines of DPE.

We further state that such compliance is neither an assurance as to the future viability of the Company nor of the efficiency or effectiveness with which the management has conducted the affairs of the Company.

(P.N.Gupta)
Practicing Company Secretary
C.P. No. 6778

Place: New Delhi
Date: 02 August 2019

AUDITORS' REPORT
&
ANNUAL ACCOUNTS

RMA & ASSOCIATES LLP
Chartered Accountants
LLPIN : AAI-9419 (ISO 9001:2015)

Address : Plot No. A-13, Ground Floor,
Lajpat Nagar-III, New Delhi-110024
Phone : 011-49097836
Email : ca.jamit@gmail.com
Website : www.rma-ca.com

INDEPENDENT AUDITOR'S REPORT

To the Members of
Biotechnology Industry Research Assistance Council
Report on the Financial Statements

Opinion

We have audited the accompanying financial statements of **Biotechnology Industry Research Assistance Council** ("the Company") which comprises the Balance Sheet as at March 31, 2019, the Statement of income & expenditure and statement of cash flows for the year ended, and notes to the financial statements, including a summary of significant accounting policies and other explanatory information.

In our opinion and to the best of our information and according to the explanations given to us, the aforesaid financial statements give the information required by the Act in the manner so required and give a true and fair view in conformity with the accounting principles generally accepted in India, of the state of affairs of the Company as at March 31, 2019, and income and expenditure for the year ended on that date.

Basis for Opinion

We conducted our audit in accordance with the Standards on Auditing (SAs) specified under section 143(10) of the Companies Act, 2013. Our responsibilities under those Standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the Company in accordance with the Code of Ethics issued by the Institute of Chartered Accountants of India together with the ethical requirements that are relevant to our audit of the financial statements under the provisions of the Companies Act, 2013 and the Rules there under, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the Code of Ethics. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibility of Management for the Financial Statements

The Company's Board of Directors is responsible for the matters stated in section 134(5) of the Companies Act, 2013 with respect to the preparation of these financial statements that give a true and fair view of the financial position, financial performance, and cash flows of the Company in accordance with the accounting principles generally accepted in India, including the accounting Standards specified under section 133 of the Act. This responsibility also includes maintenance of adequate accounting records in accordance with the provisions of the Act for safeguarding of the assets of the Company and for preventing and detecting frauds and other irregularities; selection and application of appropriate implementation and maintenance of accounting policies; making judgments and estimates that are reasonable and prudent; and design, implementation and maintenance of adequate internal financial controls, that were operating effectively for ensuring the accuracy and completeness of the accounting records, relevant to the preparation and presentation of the financial statement that give a true and fair view and are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Those Board of Directors are also responsible for overseeing the company's financial reporting process.

Auditor's Responsibility for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with SAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

RMA & ASSOCIATES LLP
Chartered Accountants
LLPIN : AAI-9419 (ISO 9001:2015)

Address : Plot No. A-13, Ground Floor,
Lajpat Nagar-III, New Delhi-110024
Phone : 011-49097836
Email : ca.jamit@gmail.com
Website : www.rma-ca.com

Report on Other Legal and Regulatory Requirements

As required by the Companies (Auditor's Report) Order, 2016 ("the Order"), issued by the Central Government of India in terms of sub-section (11) of section 143 of the Companies Act, 2013, we give in the Annexure a statement on the matters specified in paragraphs 3 and 4 of the Order, to the extent applicable.

As required by Section 143(3) of the Act, we report that:

We have sought and obtained all the information and explanations which to the best of our knowledge and belief were necessary for the purposes of our audit.

a. In our opinion, proper books of account as required by law have been kept by the Company so far as it appears from our examination of those books.
b. The Balance Sheet, the Statement of Income & expenditure and the cash flow statement dealt with by this Report are in agreement with the books of account
c. In our opinion, the aforesaid financial statements comply with the Accounting Standards specified under Section 133 of the Act, read with Rule 7 of the Companies (Accounts) Rules, 2014.
d. On the basis of the written representations received from the directors as on 31st March, 2019 taken on record by the Board of Directors, none of the directors is disqualified as on 31st March, 2019 from being appointed as a director in terms of Section 164 (2) of the Act.
e. With respect to the adequacy of the internal financial controls over financial reporting of the Company and the operating effectiveness of such controls, refer to our separate Report in "Annexure A".
f. With respect to the other matters to be included in the Auditor's Report in accordance with Rule 11 of the Companies (Audit and Auditors) Rules, 2014, in our opinion and to the best of our information and according to the explanations given to us:
    1. The Company has disclosed the impact of pending litigations on its financial position in its financial statements.
    2. The Company has made provision, as required under the applicable law or accounting standards, for material foreseeable losses, if any, on long-term contracts including derivative contract.
    3. There were no amounts which were required to be transferred to the Investor Education and Protection Fund by the Company.

Further as per the direction of comptroller and Auditor General of India, We are reporting on the points as asked u/s 143(5) as given below:

S. No.	Direction u/s 143(5)	Reply
1.	**Whether the company has system in place to process all the accounting transactions through IT system? If yes, the implications of processing of accounting transactions outside IT system on the integrity of the accounts along with the financial implications, if any, may be stated.**	**Yes**
2.	**Whether there is any restructuring of an existing loan or cases of waiver/write off of debts /loans/interest etc. made by a lender to the company due to the company's inability to repay the loan? If yes, the financial impact may be stated.**	**Nil**
3.	**Whether funds received/receivable for specific schemes from central/ state agencies were properly accounted for/ utilized as per its term and conditions? List the cases of deviation.**	**Nil**

For **RMA & Associates LLP**
Chartered Accountants
Firm Registration No. 000978N / N500062

Rahul Vashishtha
Partner
M. No. 097881

Place: New Delhi
Date: 12.06.2019

Annexure 'A'

Report on Internal Financial Controls over Financial Reporting

Report on the Internal Financial Controls under Clause (i) of Sub-section 3 of Section 143 of the Companies Act, 2013 ("the Act")

We have audited the internal financial controls over financial reporting of **Biotechnology Industry Research Assistance Council** ("the Company") as of March 31, 2019 in conjunction with our audit of the financial statements of the Company for the year ended on that date.

Management's Responsibility for Internal Financial Controls

The Company's management is responsible for establishing and maintaining internal financial controls based on the internal control over financial reporting criteria established by the Company considering the essential components of internal control stated in the Guidance Note on Audit of Internal Financial Controls over Financial Reporting issued by the Institute of Chartered Accountants of India. These responsibilities include the design, implementation and maintenance of adequate internal financial controls that were operating effectively for ensuring the orderly and efficient conduct of its business, including adherence to company's policies, the safeguarding of its assets, the prevention and detection of frauds and errors, the accuracy and completeness of the accounting records, and the timely preparation of reliable financial information, as required under the Companies Act, 2013.

Auditors' Responsibility

Our responsibility is to express an opinion on the Company's internal financial controls over financial reporting based on our audit. We conducted our audit in accordance with the Guidance Note on Audit of Internal Financial Controls Over Financial Reporting (the "Guidance Note") and the Standards on Auditing, issued by ICAI and deemed to be prescribed under section 143(10) of the Companies Act, 2013, to the extent applicable to an audit of internal financial controls, both applicable to an audit of Internal Financial Controls and, both issued by the Institute of Chartered Accountants of India. Those Standards and the Guidance Note require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether adequate internal financial controls over financial reporting was established and maintained and if such controls operated effectively in all material respects.

Our audit involves performing procedures to obtain audit evidence about the adequacy of the internal financial controls system over financial reporting and their operating effectiveness. Our audit of internal financial controls over financial reporting included obtaining an understanding of internal financial controls over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion on the Company's internal financial controls system over financial reporting.

Meaning of Internal Financial Controls over Financial Reporting

A company's internal financial control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal financial control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Inherent Limitations of Internal Financial Controls over Financial Reporting

Because of the inherent limitations of internal financial controls over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may occur and not be detected. Also, projections of any evaluation of the internal financial controls over financial reporting to future periods are subject to the risk that the internal financial control over financial reporting may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Opinion

In our opinion, the Company has, in all material respects, an adequate internal financial controls system over financial reporting and such internal financial controls over financial reporting were operating effectively as at March 31, 2019, based on the internal control over financial reporting criteria established by the Company considering the essential components of internal control stated in the Guidance Note on Audit of Internal Financial Controls Over Financial Reporting issued by the Institute of Chartered Accountants of India.

For RMA & Associates LLP
Chartered Accountants
Firm Registration No. 000978N / N500062

Rahul Vashishtha
Partner
M. No. 097881

Place : New Delhi
Date : 12.06.2015

Biotechnology Industry Research Assistance Council (BIRAC)

BALANCE SHEET AS AT 31st March 2019

CIN U73100DL2012NPL233152

(Amount in Rs.)

Particulars	Note No.	As at 31.03.2019	As at 31.03.2018
I EQUITY AND LIABILITIES			
(1) Shareholder's Funds			
(a) Share Capital	1	1,00,00,000	1,00,00,000
(b) Reserves and Surplus	2	98,24,31,682	92,43,26,051
(2) Deferred Government Grant	3	85,67,288	-
(3) Non Current Liabilities	4	84,02,24,048	89,57,87,216
(4) Current Liabilities	5	2,54,14,07,314	92,44,26,484
TOTAL		**4,38,26,30,333**	**2,75,45,39,751**
II ASSETS			
(1) Non-Current Assets			
(a) Fixed Assets			
(i) Tangible Assets	6	85,39,180	1,02,23,661
(ii) Intangible Assets	6	28,108	3,642
(b) Non-Current Investments	7	6,60,60,717	-
(c) Long-Term Loans and Advances	8	47,61,98,733	1,00,36,45,034
(2) Current Assets			
(a) Cash and Cash Equivalents	9	2,83,11,71,319	94,65,06,431
(b) Other Current Assets	10	1,00,06,32,275	79,41,60,983
TOTAL		**4,38,26,30,333**	**2,75,45,39,751**
Significant Accounting Policies and the accompanying Notes to Accounts.	16 & 17		

The notes referred to above form integral part of Financial Statements.

For and on behalf of Board of Directors

Sd/-
Kavita Anandani
(Company Secretary)

Sd/-
Mohd. Aslam
(Managing Director)
DIN 06786302

Sd/-
Renu Swarup
(Chairperson)
DIN 01264943

Auditor Report
As per our report of even date attached
For RMA & Associates LLP
Chartered Accountants
Firm Reg. No. 000978N / N500062

Sd/-
CA Rahul Vashishtha
(Partner)
Membership No. 097881
Place : New Delhi
Date : 12.06.2019

Biotechnology Industry Research Assistance Council (BIRAC)
Statement Of Income & Expenditure for the Period Ended 31st March 2019
CIN U73100DL2012NPL233152

(Amount in Rs.)

Particulars	Note No.	For the Period ended 31.03.2019	For the Period ended 31.03.2018
(1) INCOME			
Grants Received as Utilised	11	1,74,54,27,149	1,67,79,41,513
Extra-Mural Grants Received as Utilised	13A-F	99,60,29,904	25,06,37,613
Other Income	12	5,38,14,398	2,97,86,524
Total Revenue		**2,79,52,71,451**	**1,95,83,65,650**
(2) EXPENDITURE			
Programme Expenditure	13	1,62,87,10,442	1,56,68,17,041
Extra-Mural Programme Expenditure	13A-F	99,60,29,904	25,06,37,613
Employee Benefit Expenses	14	8,26,98,629	5,14,60,171
Depreciation & Amortisation Expenses	6	28,08,111	40,57,035
Other Expenses	15	6,96,11,287	7,01,55,081
Total Expenses		**2,77,98,58,372**	**1,94,31,26,942**
(3) Surplus of Income over Expenditure before exceptional and extraordinary items		**1,54,13,079**	**1,52,38,709**
Add/(Less): Prior Period Income/(Expenditure) (net)		-	-
(4) Surplus before extraordinary items		**1,54,13,079**	**1,52,38,709**
Add/(Less): Extraordinary Items		-	-
(5) Income before tax		**1,54,13,079**	**1,52,38,709**
Less: Provision for Income Tax		-	-
Surplus Carried Forward to Reserve & Surplus A/c		**1,54,13,079**	**1,52,38,709**
Earning per equity share:			
(1) Basic		1,541	1,524
(2) Diluted		1,541	1,524
Significant Accounting Policies and the accompanying Notes to Accounts.	16 & 17		

The notes referred to above form integral part of Financial Statements.

For and on behalf of Board of Directors

Sd/-	Sd/-	Sd/-
Kavita Anandani	**Mohd. Aslam**	**Renu Swarup**
(Company Secretary)	(Managing Director)	(Chairperson)
	DIN 06786302	DIN 01264943

Auditor Report
As per our report of even date attached
For RMA & Associates LLP
Chartered Accountants
Firm Reg. No. 000978N / N500062

Sd/-
CA Rahul Vashishtha
(Partner)
Membership No. 097881
Place : New Delhi
Date : 12.06.2019

Biotechnology Industry Research Assistance Council (BIRAC)
Cash Flow Statement for the Period Ended 31st March 2019
CIN U73100DL2012NPL233152

(Amount in Rs.)

Particulars		For the Period ended 31.03.2019	For the Period ended 31.03.2018
Cash Flow from Operating Activities:			
Net Surplus as per Income & Expenditure Account		1,54,13,079	1,52,38,709
Adjustments for :			
Depreciation		28,08,111	40,57,035
Management Expenses		(7,16,495)	(7,16,495)
Foreign Exchange Fluctuation		1,93,725	69,138
Interest Income		(4,66,55,603)	(2,46,75,233)
Operating Profit before Working Capital changes		**(4,43,70,262)**	**(2,12,65,555)**
Increase/(Decrease) in Provisions & Payables		13,85,32,977	38,44,23,479
Increase/(Decrease) in Grant Utilisation		1,54,26,40,878	40,88,86,527
Increase/(Decrease) In Capital Reserve/Deffered Income		(16,60,015)	3,16,755
Fund Utilisation Towards PPP Activities (Net)		(26,43,312)	(83,57,22,163)
Provision for Sub-Standard & Doubtful Assets		-	(18,54,09,997)
(Increase)/ Decrease in Other Current Assets		(5,51,99,489)	90,13,832
(Increase)/Decrease in Advances PPP Activities (Net)		24,64,43,525	30,81,10,745
		1,86,81,14,564	8,96,19,178
Cash Generated from / (used in) Operations		1,83,91,57,381	8,35,92,331
Income Tax Refund / (Paid)		-	-
Net Cash from (Used in) Operating Activities	(A)	**1,83,91,57,381**	**8,35,92,331**
Cash Flow From/ (Used In) Investing Activities:			
Purchase of Fixed Assets		(11,48,096)	(3,16,755)
Net Cash from/(Used in) Investing Activities	(B)	**(11,48,096)**	**(3,16,755)**
Cash Flow From/ (Used In) Financing Activities:			
Interest Income		4,66,55,603	2,46,75,233
Net Cash from/(Used in) Financing Activities	(C)	**4,66,55,603**	**2,46,75,233**
Net Increase in Cash and Cash Equivalents	D=(A+B+C)	1,88,46,64,888	10,79,50,809
Cash and Cash Equivalent at beginning of the year	(E)	94,65,06,431	84,26,12,657
Cash and Cash Equivalent at end of the year (Refer Note 17.15)	**F=(D+E)**	**2,83,11,71,319**	**95,05,63,466**

For and on behalf of Board of Directors

Sd/-	Sd/-	Sd/-
Kavita Anandani	**Mohd. Aslam**	**Renu Swarup**
(Company Secretary)	(Managing Director)	(Chairperson)
	DIN 06786302	DIN 01264943

Auditor Report
As per our report of even date attached
For RMA & Associates LLP
Chartered Accountants
Firm Reg. No. 000978N / N500062

Sd/-
CA Rahul Vashishtha
(Partner)
Membership No. 097881
Place : New Delhi
Date : 12.06.2019

Biotechnology Industry Research Assistance Council (BIRAC)		
NOTES TO FINANCIAL STATEMENTS		
1. Share Capital		**(Amount in Rs.)**
Particulars	**As at 31.03.2019**	**As at 31.03.2018**
A. Authorised		
10,000 (10,000) Equity shares of Rs 1000/-each	**1,00,00,000**	**1,00,00,000**
B. Issued, Subscribed & Fully paid		
10,000 (10,000) Equity shares of Rs 1000/-Each fully paid up	1,00,00,000	1,00,00,000
Subscribed but not fully paid	Nil	Nil
TOTAL	**1,00,00,000**	**1,00,00,000**

C. Reconciliation of Number of Shares

Particulars	**As at 31.03.2019**	**As at 31.03.2018**
	No of shares	No of shares
Number of equity shares at the beginning	10,000	10,000
Add: Equity shares issued during the period	-	-
Number of equity shares at the end (closing balance)	10,000	10,000

D. Details of Shareholders holding more than 5% in equity of the company.

Name of Shareholder	**As at 31.03.2019**		**As at 31.03.2018**	
	No. of fully paid up shares	% of shares held	No. of fully paid up shares	% of shares held
President of India	9,000	90%	9,000	90%
Prof. Ashutosh Sharma (held on behalf of President of India)	-	-	900	9%
Dr. Renu Swarup (held on behalf of President of India)	900	9%	-	-

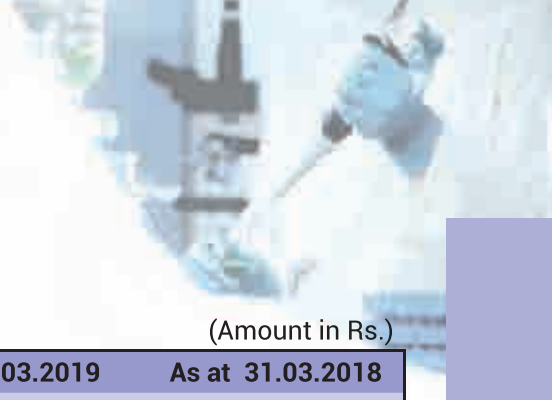
E. Other details and Rights

The company has only one class of equity shares issued at par value of Rs.1000 each.
Each equity shareholder has right to one vote per share.
The shares do not have dividend rights.
Shares carry no distribution right in the event of liquidation.

2. Reserves and Surplus (Amount in Rs.)

Particulars		As at 31.03.2019	As at 31.03.2018
I. Capital Reserve			
BIRAC Fund (Non Recurring)			
Opening Balance		1,02,27,303	1,39,67,583
Add: On Account of Capital Expenditure during the period		-	3,16,755
		1,02,27,303	1,42,84,338
Less: Depreciation on Capital Expenditure (Refer Note 6)		-	40,57,035
		1,02,27,303	**1,02,27,303**
Less: Transferred to Deferred Income (Refer Note 16.2.4A & Note 17.16)		(1,02,27,303)	-
	(A)	**-**	**1,02,27,303**
II. Other Reserve			
Funds Utilised for Loans under PPP Activities after 31/03/2014(#)		67,06,74,654	85,45,31,106
Less: Provision for Sub-Standard & Doubtful Assets (Refer Note 17.3)		(53,49,938)	-
Post BIRAC Realised		24,21,26,246	-
	(B)	**90,74,50,962**	**85,45,31,106**
III. General Reserve			
Surplus			
Opening Balance		5,95,67,641	4,43,28,933
Appropriation :			
Less: Fund utilised during the previous year		-	-
Add: Transfer from Statement of Income & Expenditure		1,54,13,079	1,52,38,708
	(C)	**7,49,80,720**	**5,95,67,641**
TOTAL	**(A+B+C)**	**98,24,31,682**	**92,43,26,051**

Include interest not yet realisable amounting to Rs. 14,41,22,007/- (Previous year Rs. 14,32,19,156/-).



3. Deferred Government Grant #

(Amount in Rs.)

Particulars	As at 31.03.2019	As at 31.03.2018
Opening Balance	-	-
Deferred Government Grant Transferred from Capital Reserve (Refer Note 16.2.4A)	1,02,27,303	-
Add: On Account of Capital Expenditure during the Period	11,48,096	-
Less: On Account of Depreciation on Fixed Assets during the Period	(28,08,111)	-
TOTAL	**85,67,288**	**-**

Refer Note 16.2.4A & Note 17.16

4. Non Current Liabilities

(Amount in Rs.)

Particulars		As at 31.03.2019	As at 31.03.2018
Pre-BIRAC Unrealised Portfolio			
Pre-BIRAC Unrealised Portfolio		1,20,28,18,642	1,26,54,05,716
Less: Provision for Sub-Standard & Doubtful Assets (Refer Note 17.3)		42,86,55,311	36,96,18,500
	(A)	**77,41,63,331**	**89,57,87,216**
ACE Funding (Refer Note 17.18.1)	**(B)**	6,60,60,717	-
TOTAL	**(A+B)**	**84,02,24,048**	**89,57,87,216**

5. Current Liabilities (Amount in Rs.)

Particulars		As at 31.03.2019	As at 31.03.2018
Unutilised Grant (Refer Note 17.12)			
Unutilised Grant (BIRAC)		-	-
Unutilised Grant (PPP Activities)		-	1,22,24,591
Unutilised Grant (DBT-BMGF-WT PMU) #		66,18,23,417	42,70,96,482
Unutilised Grant (Make in India Facilitation Cell)		62,20,460	4,50,770
Unutilised Grant (Bio-toilets in schools from North East Region)		4,44,505	1,24,12,762
Unutilised Grant (National Biopharma Mission - I3)		87,79,84,456	3,77,92,702
Unutilised Grant (MeitY)		53,51,299	-
Unutilised Grant (SSC NTBN)		78,17,000	-
	(A)	**1,55,96,41,137**	**48,99,77,307**
DBT AcE Fund (Refer Note 17.12)			
Unutilised AcE Fund	**(B)**	**68,77,24,686**	**21,47,47,638**
Trade Payables			
Trade payables dues to micro and small enterprises (Refer Note 17.14)		37,39,803	27,37,895
Trade payables other than due to micro and small enterprises		2,36,54,734	1,51,53,762
	(C)	**2,73,94,537**	**1,78,91,657**
Other Payables			
Pre-BIRAC Realised Portfolio		25,81,47,857	91,74,15,521
Less: Refunded to DBT		-	72,04,66,688
	(D)	**25,81,47,857**	**19,69,48,833**
Statutory Liabilities		46,73,839	39,75,245
Provision for Gratuity & Leave Encashment		38,25,258	8,85,804
	(E)	**29,40,41,491**	**21,97,01,539**
TOTAL	**(A+B+C+D+E)**	**2,54,14,07,314**	**92,44,26,484**

Unutilised Grant under DBT-BMGF-WT PMU is to be utilised over a period of three years.

6. Schedule of Fixed Assets

(Amount in Rs.)

Particulars	Gross Block				Depreciation				Net Block	
	As at	Addition	Sales/ Adjustments	As at	As at	For the Period	Adjustments	As at	WDV as at	WDV as at
	1-Apr-2018	2018-19	2018-19	31-Mar-19	1-Apr-2018	2018-19	2018-19	31-Mar-19	31-Mar-19	31-Mar-2018
Tangible Assets										
Furniture & Fixtures	2,65,77,824	-	-	**2,65,77,824**	1,69,75,142	24,88,385	-	**1,94,63,527**	71,14,297	96,02,682
Office Equipment	2,98,733	64,900	-	**3,63,633**	2,30,232	40,185	-	**2,70,417**	93,216	68,501
Computers	44,52,271	10,55,829	-	**55,08,100**	38,99,793	2,76,640	-	**41,76,433**	13,31,667	5,52,478
Total Tangible Assets	**3,13,28,828**	**11,20,729**	-	**3,24,49,557**	2,11,05,167	**28,05,210**	-	**2,39,10,377**	85,39,180	1,02,23,661
Intangible Assets	7,40,419	27,367	-	**7,67,786**	7,36,777	2,901	-	**7,39,678**	28,108	3,642
Total Intangible Assets	**7,40,419**	**27,367**	-	**7,67,786**	**7,36,777**	**2,901**	-	**7,39,678**	28,108	3,642
Total	**3,20,69,247**	**11,48,096**	**-**	**3,32,17,343**	**2,18,41,944**	**28,08,111**	**-**	**2,46,50,055**	**85,67,288**	**1,02,27,303**
Previous Year Figures	3,17,52,492	3,16,755	-	3,20,69,247	1,77,84,909	40,57,035	-	2,18,41,944	1,02,27,303	1,39,67,583

7. Non-Current Investments (Amount in Rs.)

Particulars	As at 31.03.2019	As at 31.03.2018
Others (held on behalf of DBT)		
AcE Funding (Refer Note 17.18.1)	6,60,60,717	-
	6,60,60,717	**-**

8. Long Term Loans & Advances (Amount in Rs.)

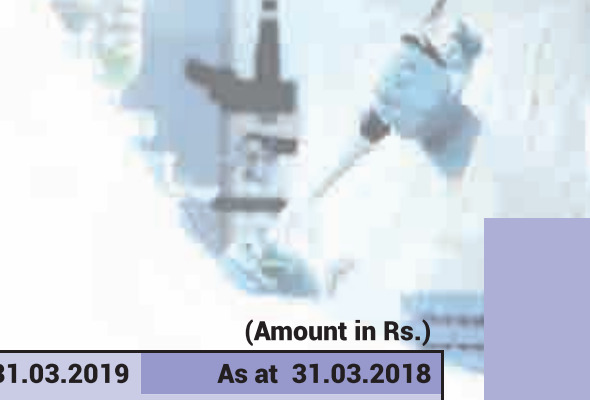
Particulars	As at 31.03.2019	As at 31.03.2018
Security Deposit		
Security Deposit - MTNL Premises	1,05,39,969	94,08,300
Security Deposit - BCIL	-	18,956
	1,05,39,969	**94,27,256**
Long Term Loans and Advances		
*(Secured against Bank Guarantee/ Hypothecation/ Personal Guarantee)**		
Loans Portfolio *(Including Interest on Loan Accounts PPP Activities)- Not yet realisable) #"*	1,87,34,93,295	2,11,99,36,820
Less: Current maturities of Long Term Loans & advances reflected under Current assets ($)	97,38,29,281	75,61,00,542
Less: Provision for Doubtful Assets (Refer Note 17.3)	39,17,28,981	33,71,49,132
Less: Provision for Sub-Standard Assets (Refer Note 17.3)	4,22,76,269	3,24,69,367
	46,56,58,764	**99,42,17,778**
TOTAL	**47,61,98,733**	**1,00,36,45,034**
* Refer 17.3 & 17.4.		

Interest not yet realisable amounting to Rs. 14,41,22,007/- upto 31.03.19 (Previous year Rs. 14,32,19,156/-).

($)The current maturities of Long term Loans & Advances of Rs.97,38,29,281/- (Previous year Rs. 75,61,00,542/-) includes the overdues as per Note no. 17.4 of Notes to Accounts.

9. Cash & Cash Equivalents (Amount in Rs.)

Particulars	As at 31.03.2019	As at 31.03.2018
Cash in Hand	12,207	28,923
Balances with Banks: (Refer Note 17.15)		
In Current Accounts	2,78,381	1,79,468
In Saving Accounts	1,43,85,40,597	67,26,97,540
In Fixed Deposits	1,39,23,40,135	27,36,00,500
TOTAL	**2,83,11,71,319**	**94,65,06,431**



10. Other Current Assets **(Amount in Rs.)**

Particulars	As at 31.03.2019	As at 31.03.2018
Current maturities of Long Term Loans and Advances:(*)	97,38,29,281	75,61,00,542
(Secured against Bank Guarantee/Hypothecation/ Personal Guarantee)		
Other Assets		
Recoverable from MeitY (IIPME)	-	2,22,60,450
Accrued Interest-FD & Saving Account (PPP, DBT / WT)	61,60,421	32,11,102
Recoverable from Government Agencies (Tax Credit)	1,58,04,311	80,61,566
Prepaid Expenses	23,35,066	36,14,635
Other Recoverable	25,03,196	9,12,687
TOTAL	**1,00,06,32,275**	**79,41,60,983**

* Refer 17.3 & 17.4

11. Income **(Amount in Rs.)**

Grants Received as Utilised	For the Period ended 31.03.2019	For the Period ended 31.03.2018
PPP Activities	1,43,62,26,139	1,37,62,09,785
BIRAC Activities	30,92,01,010	30,17,31,728
TOTAL	**1,74,54,27,149**	**1,67,79,41,513**

12. Other Income **(Amount in Rs.)**

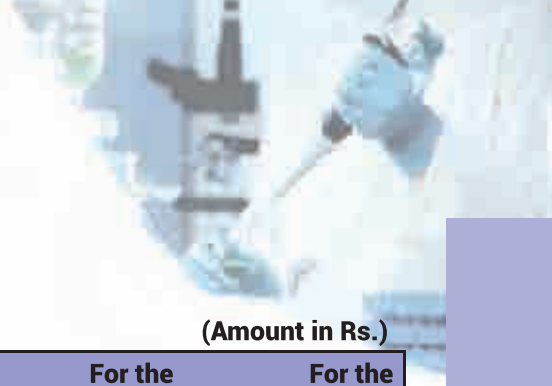
Particulars	For the Period ended 31.03.2019	For the Period ended 31.03.2018
Interest Received - Bank Accounts	4,66,55,603	2,46,75,233
Management Fee - BMGF	7,16,495	7,16,495
Additional Interest	9,14,124	2,36,294
Amortisied Deferred Government Grant	28,08,111	40,57,035
Miscellaneous Income	27,20,066	1,01,467
TOTAL	**5,38,14,398**	**2,97,86,524**

13. Programme Expenditure **(Amount in Rs.)**

Particulars	For the Period ended 31.03.2019	For the Period ended 31.03.2018
Grants Disbursed		
PPP Activities	1,42,12,19,799	1,34,13,98,572
BIRAC Activities	16,49,45,976	19,06,07,257
Programme Expenditure		
PPP Activities *(Operational expenditure on Advertisement, Meeting and PMC)*	4,25,44,667	3,48,11,213
Total	**1,62,87,10,442**	**1,56,68,17,041**

13A. Programme Management Unit DBT & BMGF **(Amount in Rs.)**

Particulars		For the Period ended 31.03.2019	For the Period ended 31.03.2018
Programme Expenditure (GCI)		27,69,39,212	11,42,62,794
Operational Expenditure		5,02,42,740	6,12,33,006
Operational Non Recurring Expenditure		-	-
	(A)	**32,71,81,952**	**17,54,95,800**
Less:			
Programme Funds from DBT (GCI)		4,30,33,046	5,26,70,095
Programme Funds from BMGF (GCI)		23,38,50,911	5,90,60,931
Programme Funds from US AID (GCI)		55,255	25,31,768
	(B)	**27,69,39,212**	**11,42,62,794**
Less:			
Operational Fund from DBT		46,63,123	40,64,141
Operational Non Recurring Fund from DBT		-	5,15,265
Operational Fund from BMGF		3,87,85,079	5,12,55,936
Operational Non Recurring Fund from BMGF		-	-
Operational Recurring Fund from WT		67,94,538	53,97,664
	(C)	**5,02,42,740**	**6,12,33,006**
(Refer to Note : 17.13.3)	**(A-B-C)**	-	-



13B. Extra-Mural Programme - MeitY **(Amount in Rs.)**

Particulars		For the Period ended 31.03.2019	For the Period ended 31.03.2018
Programme Expenditure		2,02,40,183	4,47,66,812
Operational Expenditure		2,44,227	7,23,802
	(A)	2,04,84,410	4,54,90,614
Less:			
Programme Funds from MeitY		2,02,40,183	4,47,66,812
	(B)	2,02,40,183	4,47,66,812
Less:			
Operational Fund from MeitY		2,44,227	7,23,802
	(C)	2,44,227	7,23,802
(Refer to Note : 17.13.5)	**(A-B-C)**	-	-

13C. Extra-Mural Programme - Make In India **(Amount in Rs.)**

Particulars		For the Period ended 31.03.2019	For the Period ended 31.03.2018
Programme Expenditure		-	-
Operational Expenditure		49,10,330	33,97,083
	(A)	49,10,330	33,97,083
Less:			
Programme Funds from Make in India		-	-
	(B)	-	-
Less:			
Operational Fund from Make in India		49,10,330	33,97,083
	(C)	49,10,330	33,97,083
(Refer to Note : 17.13.6)	**(A-B-C)**	-	-

13D. Extra-Mural Programme - Biotoilets in Schools from NER **(Amount in Rs.)**

Particulars		For the Period ended 31.03.2019	For the Period ended 31.03.2018
Programme Expenditure		1,20,20,000	80,20,000
Operational Expenditure		1,36,349	11,22,470
	(A)	**1,21,56,349**	**91,42,470**
Less:			
Programme Funds from Biotoilets in NER School		1,20,20,000	80,20,000
	(B)	**1,20,20,000**	**80,20,000**
Less:			
Operational Fund from Biotoilets in NER School		1,36,349	11,22,470
	(C)	**1,36,349**	**11,22,470**
(Refer to Note : 17.13.7)	**(A-B-C)**	-	-

13E. Extra-Mural Programme - National Biopharma Mission (Innovate in India) **(Amount in Rs.)**

Particulars		For the Period ended 31.03.2019	For the Period ended 31.03.2018
Programme Expenditure		57,25,61,084	-
Operational Expenditure		5,75,12,552	1,22,07,298
	(A)	**63,00,73,636**	**1,22,07,298**
Less:			
Programme Funds from National Biopharma Mission (I3)		57,25,61,084	-
	(B)	**57,25,61,084**	**-**
Less:			
Operational Fund from National Biopharma Mission (I3)		5,75,12,552	1,22,07,298
	(C)	**5,75,12,552**	**1,22,07,298**
(Refer to Note : 17.13.8)	**(A-B-C)**	**-**	**-**

13F. Extra-Mural Programme - AcE Fund **(Amount in Rs.)**

Particulars		For the Period ended 31.03.2019	For the Period ended 31.03.2018
Operational Expenditure		12,23,227	49,04,348
	(A)	12,23,227	49,04,348
Less:			
Operational Fund from AcE Fund		12,23,227	49,04,348
	(B)	12,23,227	49,04,348
(Refer to Note : 17.13.9)	**(A-B)**	**-**	**-**

14. Employees Benefit Expenses **(Amount in Rs.)**

Particulars	For the Period ended 31.03.2019	For the Period ended 31.03.2018
Salary & Allowances to Staff	7,18,05,826	4,42,04,916
Employer's Contribution to Provident Fund & Other Funds	1,08,92,803	72,55,255
TOTAL	**8,26,98,629**	**5,14,60,171**

15. Other Expenses **(Amount in Rs.)**

Particulars	For the Period ended 31.03.2019	For the Period ended 31.03.2018
(A) Rent	3,52,93,480	4,12,69,867
(B) Advertisement & Publication	25,49,255	34,60,506
(C) Journal & Subscription	25,53,812	7,85,797
(D) Meetings:		
Meetings & Conferences	45,42,605	54,44,170
Sitting Fees & TA and DA	4,74,929	4,13,498
(E) Office and Administration Expenditure:		
Travel	31,57,201	33,54,414
Office Expenses	85,25,281	48,40,486
AMC Computer	11,93,372	9,45,051
Legal & Professional	66,740	3,89,291
Postage & Telephone Expenses	6,87,658	6,42,316
Power & Electricity	23,54,358	18,60,858
Printing & Stationery	6,32,581	3,38,778
Internet Expenses	17,07,313	16,63,906
(F) Training Expenses	7,01,608	2,50,300
(G) Consultancy Fee	47,99,722	42,40,187
(H) Statutory Audit Fees	1,77,000	1,59,300
(I) Miscellaneous Expenses	647	27,218
(J) Foreign Exchange Fluctuation	1,93,725	69,138
TOTAL	**6,96,11,287**	**7,01,55,081**

Refer Notes: 17.20 List of Abbreviations used in Financial Statement:

16. Significant Accounting Policies

1. Corporate Information

Biotechnology Industry Research Assistance Council (BIRAC) "the Company" is a Section 8 "Not-for-Profit Company" under the provisions of the Companies Act 2013, having CIN U73100DL2012NPL233152. BIRAC is also registered under Section 12A of the Income Tax Act 1961.The Company is engaged in nurturing, promoting and mentoring Research and Development in Biotech Sector.

2. Basis of Preparation of Financial Statements

The Financial Statements of the Company are prepared in accordance with Generally Accepted Accounting Principles in India (Indian GAAP). These are in compliance, in all material respects, with the Accounting Standards notified under the Companies (Accounting Standards) Amendment Rules, 2016, (as amended) and the relevant provisions of the Companies Act 2013. The Financial Statements are prepared on accrual basis and under the historical cost convention.

Preparation of Financial Statement requires the Management to make estimates and assumptions in regard to the reported amount of assets, liabilities, expenses and income of the reporting period. The estimates used in preparation of the Financial Statement are prudent and reasonable. The difference between the actual results and estimates, if any, are recognised in the reporting period in which the results are known and / or materialised.

2.1 Revenue Recognition

i) Interest:

a) Interest on loan granted is recognised on a time proportion basis taking into account the amount outstanding and applicable rate of interest. Interest Accrued, not yet realisable during the year on loans under various schemes are shown under other Reserves. Additional interest on the delayed payment is recognised on receipt basis.

b) Interest against time deposits with banks are accounted on accrual basis.

ii) Royalty is recognised on accrual basis on acknowledgement of amount due by the beneficiary.

iii) Management Fee is recognised on accrual basis in accordance with the terms of the relevant agreement.

2.2 Grants-in-Aid

Income by way of grants-in-aid has been recognised under Matching Principle of Accounting. All expenditure incurred out of the grants-in-aid, comprising of grants disbursed and other programmatic expenditure are matched with equal amount of income and adjusted against the grants- in -aid. Unspent balance of Grants- in -aid are carried forward as liability to be utilised in subsequent years.

The application of funds for disbursement of loans under different schemes is shown as Loans and Advances under Non-Current Assets. Loans disbursed during the year under different scheme are shown under other reserves as per Matching Principle of Accounting.

2.3 Expenditure

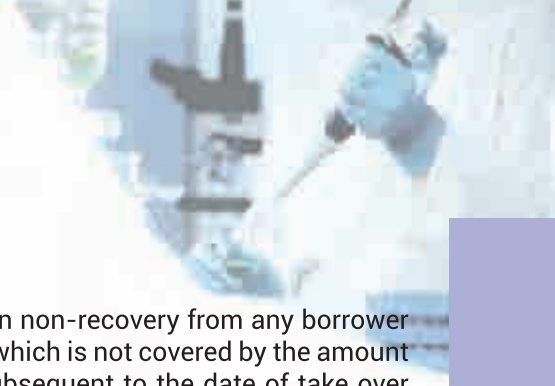
All expenses are accounted for on accrual basis.

Funds released as grants-in-aid are treated as expenditure in the Income & Expenditure Account. Further, amount unutilised as per the Utilisation Certificates received on completion of the projects are accounted as Income.

2.4 Reserve & Surplus

a) Grant-in-aid used for acquiring depreciable assets set up as Deferred Government Grant and recognised in the Statement of Income & Expenditure on a systematic basis over the useful life of the asset.

b) DBT portfolio taken in account by BIRAC from BCIL as on 31.3.2014 vide DBT transfer Order dated 25th September, 2012 and approved by Board dated 17th December, 2013 was classified as Other Reserves. Consequent to the direction by DBT vide Order dated 8.11.2017, the pre BIRAC Realised Portfolio is to be refunded back to DBT. In accordance to the Order, outstanding unrealised portfolio has been transferred from Other Reserves to Non-Current Liabilities and pre -BIRAC Realised Portfolio has been transferred from Other Reserves to Current Liabilities. Funds utilized for Loans subsequent to the date of take over along with accrued interest (not yet realisable) during the financial year is continued to be held as Other Reserves.



Provision for any substandard / doubtful / Bad debt that may arise on non-recovery from any borrower would be adjusted against the taken over amount first. Any write-off which is not covered by the amount taken over would be subsequently adjusted against Fund utilized subsequent to the date of take over held under "Other Reserves".

2.4A Deferred Government Grant

Grant-in-aid used for acquiring depreciable assets set up as Deferred Government Grant and recognised in the Statement of Income & Expenditure on a systematic basis over the useful life of the asset.

2.5 Fixed Assets

Fixed Assets are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Gains or losses arising from disposal of fixed assets are measured as the difference between the net disposal proceeds and the carrying amount of the assets disposed of.

2.6 Depreciation and Amortisation

Depreciation on assets is provided on useful life basis on written down value method as prescribed under Schedule II to the Companies Act, 2013.

Depreciation on fixed assets added/disposed of during the year/period is provided on pro-rata basis with reference to the date of addition/disposal.

2.7 Intangible Assets

Intangible assets acquired are measured separately at cost. Intangible assets are carried at cost less accumulated amortization and accumulated impairment losses, if any. Internally, generated intangible assets are not capitalized and expensed off in the Statement of Income and Expenditure in the year in which the expenditure is incurred.

Intangible assets are amortized over a period of five years as per Accounting Standard - 26 as no useful life provided in Schedule II to the Companies Act, 2013.

2.8 Investments

Current investments are carried at lower of cost and quoted/fair value, computed category-wise. Long-term investments are stated at cost. Provision for diminution in the value of long-term investments is made only if such a decline is other than temporary.

2.9 Foreign Exchange Transactions/Translation

Foreign currency transactions and balances: Foreign Currency Transfer is made as per the approved Government guidelines. For any contribution being received from foreign entities, the necessary approval is obtained under the Foreign Contribution (Regulation) Act, 2010.

(i) Initial Recognition: Foreign currency transactions are recorded in the reporting currency by applying the exchange rate between the reporting currency and the foreign currency at the date of the transaction.

(ii) Conversion: Foreign Currency monetary items are retranslated using the exchange rate prevailing at the reporting date.

(iii) Exchange Difference: Exchange differences arising on long-term foreign currency monetary items related to acquisition of a fixed asset are capitalized and depreciated over the remaining useful life of the asset. The exchange differences on other foreign currency monetary items are accumulated in 'Foreign Currency Monetary Item Translation Difference Account' and amortized over the remaining life of the concerned monetary item.

All other exchange differences are recognized as income or as expenses in the period in which they arise.

2.10 Employees Benefits

a) All the employees of the Company are on contractual basis. Provision of Employer's contribution is made as per the provisions of Employees Provident Fund Act, 1952.

b) The Company makes annual contributions under the Employees Gratuity scheme to a fund administered by Trustees covering all eligible employees. The plan provides for lump sum payments to employees whose right to receive gratuity had vested at the time of resignation, retirement, death while in employment or on termination of employment of an amount equivalent to 15 days salary for each completed year of service or part thereof in excess of six months. Vesting occurs upon completion of five years of service except in case of death.

The plan assets are maintained with SBI Life Insurance Company Ltd. Employee Gratuity Scheme. The details of Investments maintained by SBI Life Insurance Company Ltd are not made available and have therefore not been disclosed.

c) Company's liability towards employee benefits such as leave encashment is provided on the basis of actuarial valuation.

2.11 Operating Leases

Lease payments for assets taken on operating lease are recognised as an expense in the Statement of Income & Expenditure as per terms of lease agreement.

2.12 Provisions & Contingent Liabilities

a) Funds sanctioned and yet to be released till the reporting period due to timing difference of milestone are not taken as liability, these are accounted as expenses on actual release of payment.

b) Provisioning on substandard Asset has been provided as per the approved classification of asset based on recoverability.

c) A provision is recognized when the company has present obligations as a result of past event. It is probable that an outflow of resources embodying economic benefits will be required to settle the obligations and reliable estimate can be made of amount of the obligation. Provisions are not discounted at their present value and are determined based on the best estimate required to settle the obligation at the reporting date. These estimates are reviewed at each reporting date and adjusted to reflect the current best estimates.

2.13 Earning Per Share

The company is a section 8 "Not for Profit Company". It does not generate any income/ revenue from its activities. It does not distribute any dividend to its shareholders. However for the compliance of AS -20 the company has computed EPS as under :

a) Basic earnings per share are calculated by dividing the net income or loss for the period attributable to equity shareholders by weighted average number of equity shares outstanding during the period.

b) For the purpose of calculating diluted earnings per share, the net profit or loss for the period attributable to equity shareholders and the weighted average number of shares outstanding during the period are adjusted for the effects of all diluting potential equity shares.

17. **Notes to Accounts for the period ended 31st March, 2019.**

17.1 Biotechnology Industry Research Assistance Council (BIRAC) receives funds from Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India by way of grant-in-aid for its operation.

17.2 The disbursement were made in tranches as per the milestones determined for the activities. Contingent liability on account of sanctioned grants but not disbursed due to the timing difference of milestone based payments are not accounted.

During the current reporting period BIRAC disbursed the following amounts under different Schemes.

(Amount in Rs.)

Particulars	Disbursement For the year 2018-19	Disbursement For the year 2017-18
PPP Activities		
Biotechnology Industry Partnership Programme (BIPP)	24,32,29,341	24,58,40,888
Small Business Innovation Research Initiatives (SBIRI)	6,58,27,702	6,53,50,605
Bio- Incubators support Scheme (BISS)	24,74,46,540	49,37,31,051
Biotech Ignition Grant (BIG)	42,09,00,000	34,29,00,000
University Innovation Cluster (UIC)	1,19,90,000	78,00,000
Translation Accelerator (TA)	89,00,037	2,08,57,180
Contract Research Scheme (CRS)	9,05,22,741	11,58,81,738
Social Innovation programme for Products: Affordable & Relevant to Societal Health (SPARSH)	6,42,80,438	5,49,52,515
Seed Funding for Incubators	10,50,00,000	4,00,00,000
Leap Funding	19,50,00,000	-
Total	**1,45,30,96,799**	**1,38,73,13,977**
BIRAC Activities		
Partnership Program	3,46,03,544	8,30,93,047
Capacity Building & Awareness	1,08,84,304	89,40,287
Technology Transfer / Acquisition	83,49,488	2,13,09,512
IP Services	95,04,124	58,65,076
Entrepreneurial Development / Regional Centres	9,47,94,878	7,13,99,335
Communication Strategy Campaign	68,09,638	-
Total	**16,49,45,976**	**19,06,07,257**

17.3 Loan and instalment due from borrowers shown under Long term Loans & Advances and other Current Assets respectively are secured wholly or partly by way of bank Guarantee/Hypothecation of asset/ personal guarantee.

BIRAC has classified the loan assets based on aging of overdue under standard asset, standard asset _ Rescheduled, sub-standard asset, and doubtful assets as under:

Standard Asset	Loan accounts not rescheduled and not classified as substandard or doubtful.
Standard Asset - Rescheduled	Loan accounts which, on account of reschedulement, are not classified as substandard or doubtful assets.
Substandard Asset	Loan accounts, other than Standard Asset- Rescheduled, in which payment of instalment is due for more than one year.
Doubtful Asset	Loan accounts certified as doubtful assets by Internal Recovery Committee of BIRAC.

On Classification of an asset from standard to sub-standard or doubtful, interest has been derecognised and requisite provisioning are made for the substandard asset and Doubtful assets. The details of standard, standard- rescheduled, substandard and doubtful assets and the provisions made are given below;

(Amount in Rs.)

Particulars		**As on 31.3.2019**	**As on 31.3.2018**
Standard Asset	A	1,08,12,57,225	1,33,45,04,464
Standard Asset _ Rescheduled	B	13,27,22,103	23,30,20,409
Sub Standard Assets	C	15,67,13,615	12,06,74,509
Doubtful Assets	D	50,28,00,355	43,17,37,439
Total Assets	E (A+B+C+D)	**1,87,34,93,298**	**2,11,99,36,821**
Provision on Substandard Assets	F	4,22,76,269	8,71,541
Provision on Doubtful Assets	G	39,17,28,981	24,09,727
Total Provision	**H(F+G)**	**43,40,05,249**	**32,81,268**
Interest derecognised	I	30,34,631	2,26,02,327

17.4 The current maturities of the loan & advances amounting to Rs. 97,38,29,281/- (Previous Year Rs. 75,61,00,542/-) includes overdue amount as per Table below and are disclosed under other current assets (Refer to notes to financial statement 8)

(Amount in Rs.)

Age Wise Overdue Position		**As on 31.03.2019**	**As on 31.3.2018**
Upto one year	(A)	4,60,49,447	58,62,554
More than one year accumulated	(B)	58,27,88,541	32,83,62,766
	Total (A+B)	**62,88,37,988**	**33,42,25,321**

17.5 Suit Filed Accounts:

17.5.1 Suits filed by the company: 2

	As on 31.03.2019		**As on 31.03.2018**	
	Number of accounts	Total Amount*	Number of accounts	Total Amount
Suit filed accounts	2	10,98,33,667.95	2	10,98,33,667.95

* The Suit filed account as above are classified as doubtful assets and 100% provision has been made.

17.5.2 Suits filed against the company: Nil

17.6 **Programme Management Unit _ DBT and BMGF**

Department of Biotechnology (DBT) and Bill Melinda Gates Foundation (BMGF) have signed an MOU for supporting priority areas of research. BIRAC has been entrusted the responsibility to be the "Technical Management Unit". In this regard, BIRAC established a Programme Management Unit to administer programmes, of affordable product development in the area of Health Care and Agriculture. **Refer Note 17.13.3.**

17.7 **BIRAC _ Extra Mural Programme**

(a) **MeitY(IIPME):** Industry innovation programme on Medical electronics has been initiated by BIRAC in collaboration with Ministry of Electronics and Information Technology, Government of India. **Refer Note 17.13.5.**

(b) **Make in India Facilitation Cell:** BIRAC has established a programme management unit for Biotechnology Industry Facilitation _ Make in India Cell to channelize investment in India. **Refer Note 17.13.6.**

(c) **Bio-toilets in schools from North East Region:** BIRAC is undertaking a programme on Bio toilets in schools from North East Region for benchtop demonstration of anaerobic digester for biogas generation and its utilization. **Refer Note 17.13.7.**

(d) **National BioPharma Mission (I3)** : The program named Innovate in India (I3) is an industry-academia collaborative mission of Department of Biotechnology (DBT) in collaboration with World Bank for accelerating discovery research to early development of Biopharmaceuticals and to be implemented by Biotechnology Industry Research Assistance Council (BIRAC). **Refer Note 17.13.8.**

(e) **AcE Fund:** BIRAC is implementing the Biotechnology Innovation Fund - AcE Fund initiated by Department of Biotechnology, Govt of India for providing risk capital to Biotech startups for product development cycle and growth phase. **Refer Note 17.13.9.**

17.8 **Prior Period Adjustment**

The prior period items are accounted in accordance with Accounting Standard - 5.
The previous year figures are reclassified and regrouped in accordance with the requirements applicable in the current financial year.

17.9 **Related Party Disclosure:**

The provisions of Accounting Standard-18 are not applicable as there is no transaction between a reporting enterprise and its related parties.

17.1 **Provision for Tax:**

No Provision for Income Tax has been made in the current reporting period since the company has been registered as a charitable entity u/s 12A of Income Tax Act, 1961 vide order No. 2974 dated 12th May, 2014.

17.11 **Foreign Exchange Transactions:**

During the current reporting period the following income/expenditure has been incurred.

A. Income: Grant received in foreign exchange to the extent utilised Rs. 27,94,85,783 (Previous Year Rs. 11,82,46,299)

B. Expenditure:

S. No.	Particulars	For the Period ended 31.03.2019	For the Period ended 31.03.2018
(i)	Technology Transfer	61,77,266	8,57,941
(ii)	Books, Journal and Database Subscriptions	10,55,680	53,39,046
(iii)	Entrepreneurship Development	42,71,356	13,49,720
(iv)	Advertisement/Publicity/Publication	55,88,002	23,94,520
(v)	Foreign Travel and Meetings	18,80,496	3,98,749

C. CIF Value of import is Nil for the current reporting period.

17.12 **Details of Grant Utilisation** **(Amount in Rs.)**

S. No.	Particulars	Fund Available	Fund Utilised	Balance
1	BIRAC	31,03,49,106	31,84,03,987.60	(80,54,882)
2	PPP Activities	1,46,81,03,139	1,49,56,41,466.08	(2,75,38,327)
3	PMU - DBT/BMGF:			
	(i) **Operational**	**20,05,58,464**	**5,02,42,739.61**	**15,03,15,724**
	BMGF	18,07,32,379	3,87,85,078.61	14,19,47,300
	DBT Operational	85,91,069	46,63,123.00	39,27,946
	DBT - Non Recurring	-	-	-
	WT Operational	1,12,35,016	67,94,538.00	44,40,478
	(ii) **Projects**	**78,84,46,905**	**27,69,39,212.00**	**51,15,07,693**
	BMGF	55,43,32,780	23,38,50,911.00	32,04,81,869
	DBT	22,04,67,146	4,30,33,046.00	17,74,34,100
	USAID	1,36,46,980	55,255.00	1,35,91,725
	Total	**98,90,05,369**	**32,71,81,951.61**	**66,18,23,417**
4	MeitY(IIPME)	2,58,35,709	2,04,84,410.00	53,51,299
5	Make in India Facilitation Cell	1,11,30,790	49,10,329.60	62,20,460
6	Bio-toilets in schools from NER	1,26,00,854	1,21,56,349.00	4,44,505
7	National BioPharma Mission (I3)	1,50,80,58,092	63,00,73,636.45	87,79,84,456
8	AcE Fund	75,50,08,630	12,23,227.00	75,37,85,403

17.13 **Supplementary Schedule on Scheme Balances as on 31.03.2019**

17.13.1 **PPP Activities Funds** **(Amount in Rs.)**

Particulars			AS ON 31.03.19	AS ON 31.03.18
	Opening Balance		1,22,24,591	41,52,403
Add:	Funds received from DBT	1,44,02,85,000		1,41,00,00,000
Add:	Interest Income	45,69,819		82,75,838
Add:	Recoveries from unspent grant	1,10,23,729	1,45,58,78,548	1,19,21,540
			1,46,81,03,139	1,43,43,49,781
Less:	**Amount disbursed during the year :**			
	Grants Disbursed	1,42,12,19,799		1,34,13,98,572
	Loans Disbursed	3,18,77,000		4,59,15,405
	Programme Expenses	4,25,44,667	1,49,56,41,466	3,48,11,213
			(2,75,38,327)	1,22,24,591
Add :	Surplus Redeployed towards Expenses		2,75,38,327	
	Unutilised Balance Carried Forward		-	**1,22,24,591**

17.13.2 **BIRAC Funds** (Amount in Rs.)

Particulars			AS ON 31.03.19	AS ON 31.03.18
	Opening Balance		-	-
Add:	Received from DBT		30,98,80,000	30,00,00,000
Add:	Interest Income		4,69,106	20,48,483
			31,03,49,106	30,20,48,483
Less:	**Amount disbursed for Grants**			
	Partnership Programmes	3,46,03,544		8,30,93,047
	Technology Transfer & Acquisition	83,49,488		2,13,09,512
	Intellectual Property	95,04,124		58,65,076
	Entrepreneurial Development	9,47,94,878		7,13,99,335
	Capacity Building & Awarness	1,08,84,304		89,40,287
	Communication Strategy Campaign	68,09,638	16,49,45,976	-
			14,54,03,130	11,14,41,226
Less:	**Utilisation towards:**			
	Manpower Expenses	8,26,98,629		5,57,00,358
	Non-Recurring Expenses	11,48,096		3,16,755
	Recurring Expenses	6,96,11,827	15,34,58,012	6,58,45,756
			(80,54,882)	(1,04,21,643)
Add :	Surplus Redeployed towards Expenses		80,54,882	1,04,21,643
	Unutilised Balance Carried Forward		-	-

17.13.3 **BMGF PMU** (Amount in Rs.)

Particulars			AS ON 31.03.19	AS ON 31.03.18
	Opening Balance			
	Operations Fund	12,66,92,499		11,37,96,876
	Project Fund	30,04,03,983	42,70,96,482	12,07,87,962
Add:	Received From BMGF - Project	29,82,04,192		19,90,35,985
	Received From BMGF - Operations	3,42,19,115		4,65,97,732
	Received From DBT - Project	18,78,12,144		9,30,33,000
	Received From DBT - Operations	83,69,625		1,62,86,000
	Received From WT - Operations	1,09,11,225	53,95,16,301	-
Add::	Bank Interest & Unspent Grant	2,23,92,586	2,23,92,586	1,30,54,728
			98,90,05,369	60,25,92,282
Less:	**Project Disbursement**			
	GCI: AgNu	3,73,347		18,16,000
	GCI: ACT	7,33,06,634		7,88,62,367
	GCI: IKP	4,80,00,000		2,52,00,000
	GCI: IDIA	2,54,28,084		10,84,517
	GCI: HPV	10,00,06,250		-
	GCI: AMR	1,00,42,624		-
	GCI: Ki Data Challenge	1,32,303		-

	GCI: Sentinels	3,99,970		-
	GCI: MSSFR	1,80,00,000		
	GCI: RTTC	12,50,000	27,69,39,212	72,99,910
Less:	**Activities Expenditure**			
	HBGDki	10,57,000		73,37,135
	KSTIP (KnIT	1,18,27,000		67,50,258
	Communication Support	18,52,177	1,47,36,177	92,28,825
Less:	**Operational Expenditure**			
	Manpower Expense	85,85,514		74,59,633
	Meeting Expenses	78,35,898		66,14,385
	Expenses for Space	1,02,58,920		1,01,93,715
	Administrative Expenses	13,15,198		70,19,631
	Equipment Expenses	-		5,15,265
	Wellcome Trust- Manpower	54,81,419		51,57,418
	Wellcome Trust- Travel	13,13,119		2,40,246
	Management Expenses	7,16,495	3,55,06,563	7,16,495
	Balance Fund			
	BMGF - Projects	32,04,81,869		25,60,72,247
	DBT - Projects	17,74,34,100		3,12,24,739
	USAID - Projects	1,35,91,725		1,31,06,998
	BMGF - Operations	14,19,47,300		12,61,47,264
	DBT - Operations	39,27,946		2,21,444
	WT- Operation	44,40,478	66,18,23,417	3,23,791
			66,18,23,417	**42,70,96,482**

* Details of Equipment Expenses: **(Amount in Rs.)**

Particulars	**AS ON 31.03.19**	**AS ON 31.03.18**
Office Equipment	-	5,15,265
Computers	-	-
Intangible Assets	-	-
Total	-	5,15,265

17.13.4 **DBT- Wellcome Trust Programme** **(Amount in Rs.)**

Particulars		**AS ON 31.03.19**	**AS ON 31.03.18**
	Opening Balance	-	2,80,70,953
Add::	FDR & Saving A/c Interest	-	5,24,731
	Total	-	2,85,95,684
Less:	Unspent Grant Returned	-	2,85,95,684
	Unutilised Balance Carried Forward	-	-

17.13.5 **MeitY(IIPME)** **(Amount in Rs.)**

Particulars		AS ON 31.03.19	AS ON 31.03.18
	Opening Balance	(2,22,60,450)	32,30,164
	Received during the period	4,80,80,000	2,00,00,000
		2,58,19,550	2,32,30,164
Add:	Bank Interest	16,159	-
		2,58,35,709	2,32,30,164
Less :	Programme Expenditure*	2,02,40,183	4,47,66,812
	Operational Expenditure	2,44,227	7,23,802
	Unutilised Balance Carried Forward	**53,51,299**	**(2,22,60,450)**

* The programme Expenditure includes loan disbursed amounting to Rs. 10,00,000/- (Previous Year Rs. 22,00,000) having the total outstanding of Rs. 61,02,172 (including accrued interest) (Previous Year Rs. 50,03,818).

17.13.6 **Make in India Facilitation Cell** **(Amount in Rs.)**

Particulars		AS ON 31.03.19	AS ON 31.03.18
	Opening Balance	4,50,770	69,634
	Received during the period	1,05,65,000	37,07,956
		1,10,15,770	37,77,590
Add:	Bank Interest	1,15,020	70,263
		1,11,30,790	38,47,853
Less :	Operational Expenditure	49,10,330	33,97,083
	Unutilised Balance Carried Forward	**62,20,460**	**4,50,770**

17.13.7 **Bio-toilets in schools from North East Region** **(Amount in Rs.)**

Particulars		AS ON 31.03.19	AS ON 31.03.18
	Opening Balance	1,24,12,762	34,69,977
	Received during the period	-	1,78,76,000
		1,24,12,762	2,13,45,977
Add:	Bank Interest	1,88,092	2,09,255
		1,26,00,854	2,15,55,232
Less :	Programme Expenditure	1,20,20,000	-
	Operational Expenditure	1,36,349	91,42,470
	Unutilised Balance Carried Forward	**4,44,505**	**1,24,12,762**

17.13.8 **National Biopharma Mission (Innovate in India)** **(Amount in Rs.)**

	Particulars	AS ON 31.03.19	AS ON 31.03.18
	Opening Balance	3,77,92,702	-
	Received during the period	1,45,00,00,000	5,00,00,000
		1,48,77,92,702	5,00,00,000
Add:	Bank Interest	2,02,65,390	-
		1,50,80,58,092	5,00,00,000
Less :	Programme Expenditure	57,25,61,084	-
	Operational Expenditure	5,75,12,552	1,22,07,298
	Unutilised Balance Carried Forward	**87,79,84,456**	**3,77,92,702**

17.13.9 **AcE Fund** **(Amount in Rs.)**

Particulars		AS ON 31.03.19	AS ON 31.03.18
	Opening Balance	21,47,47,638	-
	Received during the period	52,29,00,000	21,77,51,612
		73,76,47,638	21,77,51,612
Add:	Bank Interest	1,73,60,992	19,00,374
		75,50,08,630	21,96,51,986
Less :	Ace Funding	6,60,60,717	-
	Operational Expenditure	12,23,227	49,04,348
	Unutilised Balance Carried Forward	**68,77,24,686**	**21,47,47,638**

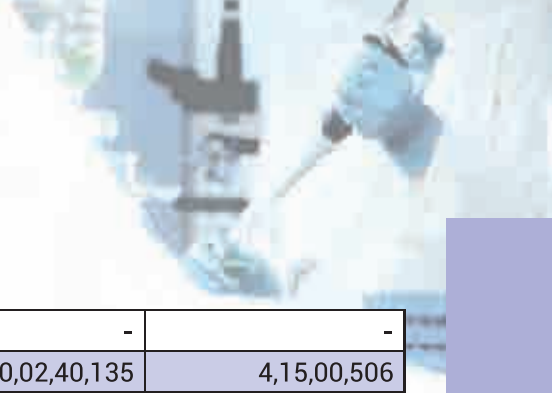
17.14 Disclosures required under Section 22 of Micro, Small and Medium Enterprise (MSME) Development Act, 2006 **(Amount in Rs.)**

S. No.	Particulars	AS ON 31.03.19	AS ON 31.03.18
(i)	Principal amount remaining unpaid to MSME suppliers as at the end of the reporting period.	37,39,803	27,37,895
(ii)	Interest due thereon remaining unpaid to MSME suppliers as at the end of the reporting period.	-	-
(iii)	The amount of interest paid along with the amounts of the payment made to the supplier beyond the appointed day.	-	-
(iv)	The amount of interest due and payable for the period.	-	-
(v)	The amount of interest accrued and remaining unpaid at the end of the reporting period.	-	-
(vi)	The amount of further interest due and payable even in the succeeding year, until such date when the interest dues as above are actually paid.	-	-
	Total	**37,39,803**	**27,37,895**

The above information regarding dues to Micro and Small Enterprises has been determined to the extent such parties have been identified on the basis of information collected with the Company.

17.15 Details of Balances with Banks **(Amount in Rs.)**

Particulars	31-Mar-19	31-Mar-18
In Current Accounts		
Corporation Bank (DBT-BMGF PMU)	2,78,381	1,79,468
In Saving Accounts		
Corporation Bank (BIRAC/Make In India/Bio-Toilets/MeitY)	23,36,85,956	4,60,04,704
State Bank of India (PPP Activities/AcE,NBM)	67,02,51,122	26,20,53,001
State Bank of India (DBT-NBM PMU)	4,47,28,984	2,58,692
State Bank of India (DBT-BMGF PMU)	48,98,74,535	36,43,81,143
	1,43,85,40,597	**67,26,97,540**
In Fixed Deposits		
Corporation Bank -FD		
(BIRAC/Make In India/Bio-Toilets/MeitY)		



- Maturity More than 12 Months	-	-
- Others	40,02,40,135	4,15,00,506
Yes Bank - FD		
(AcE Fund/ PPP Activities/Portfolio Realised)		
- Maturity More than 12 Months	-	-
- Others	30,00,00,000	-
State Bank of India - FD		
(PPP Activities/Portfolio Realised)		
- Maturity More than 12 Months	-	-
- Others	69,21,00,000	23,20,99,994
	1,39,23,40,135	**27,36,00,500**

Cash and Cash Equivalents include deposits maintained by the Company with banks, which can be withdrawn by the Company at any point of time without prior notice or penalty on the principal in accordance of the terms & conditions of the creation of the deposits.

17.16 Consequent to the amendment made in significant accounting policy as per 15.2.4 & 15.2.4A & 15.2.8 & 15.2.10, the financial impact on the amendment is as under:

S.No	Particulars	Impact
1	Reserves & Surplus	Capital Reserve amounting to Rs. 1,02,27,303/- has been transferred to Deffered Government Grant Account as on 30th September, 2018.
2	Deferred Government Grant	Deffered Government Grant amounting to Rs. 1,02,27,303/- has been transferred from Capital Reserve Account as on 30th September, 2018.
3	Income and Expenditure Account	Grant-in-aid used for acquiring depreciable assets set up as Deferred Government Grant and recognised in the Statement of Income & Expenditure on a systematic basis over the useful life of the asset. Rs. 13,98,880/- has been amortised in the Income & Expenditure Account for the current reporting period.
4	Investments	Current investments are carried at lower of cost and quoted/fair value, computed category-wise. Long-term investments are stated at cost. Provision for diminution in the value of long-term investments is made only if such a decline is other than temporary.
5	Leave Encashment	Company's liability towards employee benefits such as leave encashment is provided on the basis of actuarial valuation.

17.17 **Disclosure pursuant to Accounting Standard (AS) 15 Revised "Employee Benefits" :**

i) **Defined Benefit Plans (Gratuity):**

a) The amounts recognised in Balance Sheet are as follows: Para 120(n) of AS 15

(Amount in Rs.)

Particulars	Financial Year ending	
	2018-19	2017-18
Present Value of Defined Benefit Obligations at the end	87,35,999	57,98,777
Fair Value of Plan Assets at the end	68,26,041	49,12,973
Funded Status - Deficit / (Surplus)	19,09,958	8,85,804
Unrecognized Past Service Cost	-	-
Effects of Asset Ceiling	-	-
Net Liability / (Asset) at the end of the period	**19,09,958**	**8,85,804**

b) The amount recognised in profit and loss account are as follows:

(Amount in Rs.)

Particulars	Financial Year ending	
	2018-19	2017-18
Expenses to be recognised in Profit & Loss accounts	**24,59,452**	**28,60,921**

(Amount in Rs.)

Particulars	Financial Year ending	
	AS ON 31.03.19	AS ON 31.03.18
(Gain) / Loss on Plan Liabilities	73,289	11,40,451.00
% of Opening Plan Liabilities	1.26%	41.62%
Gain / (Loss) on Plan Assets	47,027	8,757
% of Opening Plan Assets	0.96%	0.00%

ii) The Company's required Contribution during the next year is INR 19,09,958/- or one months salary of the employees covered under the scheme, which ever is lower.

iii) **Valuation Results**

The valuation results for the defined benefit gratuity plan as at 31/03/2019 are produced in the tables below:

a) The changes in the present value of defined benefit obligation representing reconciliation of opening and closing balance thereof are as follows: Para 120 (c)of AS 15

(Amount in Rs.)

Particulars	Financial Year ending	
	AS ON 31.03.19	AS ON 31.03.18
Defined Benefit Obligation at the beginning	**57,98,777**	**27,40,475**
Add :-Current Service Cost	22,13,390	16,98,613
Add :- Interest Cost	4,63,902	2,19,238
Add :- Prior Service Cost _ Vested benefit	-	-
Add :- Prior Service Cost _ Non Vested benefit	-	-
Add :-Curtailments	-	-
Less :-Benefits Paid directly by the Company	-	-
Less :-Benefits Paid from Fund	-	-
Add/Less :-Net transfer in/(out) (including the effect of any business combinations/divestitures)	-	-
Add/Less :- Actuarial Loss / (Gain) on Obligation	2,59,930	11,40,451
Defined Benefit Obligation at the end	**87,35,999**	**57,98,777**

b) Changes in the fair value of plan assets representing reconciliation of the opening and closing balances thereof are as follows:

(Amount in Rs.)

Particulars	Financial Year ending	
	AS ON 31.03.19	AS ON 31.03.18
Opening balance of the fair value of the plan assets	49,12,973	-
Add: Adjustment to Opening balance	-	-
Add: Expected Return on plan assets	4,30,743	1,88,624
Add: Contributions by Employer	14,35,298	47,15,592
Add: Contributions by Employer	-	-
Add: Assets Distributed on Settlements	-	-
Add: Assets Acquired on acquisition/(Distributed on Divestiture)	-	-
Add: Exchange Difference on Foreign Plans	-	-
Add/(less): Actuarial gains/(losses)	47,027	8,757
Less: Benefits Paid	-	-
Closing balance of the plan assets	**68,26,041**	**49,12,973**

c) **Fair value of plan assets** **(Amount in Rs.)**

Particulars	Financial Year ending	
	AS ON 31.03.2019	AS ON 31.03.2018
Opening balance of the fair value of the plan assets	49,12,973	-
Add: Adjustment to Opening balance	-	-
Add: Actual Return on plan assets	4,77,827	1,97,381
Add: Contributions by Employer	14,35,298	47,15,592
Add: Contributions by Employer	-	-
Add: Assets Distributed on Settlements	-	-
Add: Assets Acquired on acquisition/(Distributed on Divestiture)	-	-
Add: Exchange Difference on Foreign Plans	-	-
Add/(less): Actuarial gains/(losses)	-	-
Less: Benefits Paid	-	-
Fair value of the plan assets at the end	**68,26,098**	**49,12,973**
Excess of Actual over estimatedd return on Plan Assets	47,027	8,757

d) **Expenses Recognised in the Profit & Loss Account** **(Amount in Rs.)**

Particulars	Financial Year ending	
	AS ON 31.03.2019	AS ON 31.03.2018
Current Service Cost	22,13,390	16,98,613
Interest Cost on Obligation	4,63,902	2,19,238
Past Service Cost	-	-
Expected return on Plan Assets	-4,30,743	-1,88,624
Amortization of Prior service cost	-	-
Net acturial (Gain)/Loss to be recognised	2,12,903	11,31,694
Transfer In/Out	-	-
Curtailment (Gain)/Loss recognized	-	-
Settlement (Gain)/Lossrecognised	-	-
Expense recognised in Profit & Loss account	**24,59,452**	**28,60,921**

e) Amount for the current period **(Amount in Rs.)**

Particulars	Financial Year ending	
	AS ON 31.03.2019	AS ON 31.03.2018
Actuarial Loss / (Gain) for the current period - Obligation	2,59,930	11,40,451
Actuarial Loss / (Gain) for the current period - Plan Assets	-47,027	-8,757
Total Actuarial Loss / (Gain) for the current period	**2,12,903**	**11,31,694**
Actuarial Loss / (Gain) loss recognized in the current period	**2,12,903**	**11,31,694**

f) Movement in Liability recognized in the Balance Sheet **(Amount in Rs.)**

Particulars	Financial Year ending	
	AS ON 31.03.19	AS ON 31.03.18
Present Value of Obligations as at the beginning	57,98,777	27,40,475
Expenses Recognized in P & L Statement	24,59,452	28,60,921
Benefits Paid	-	-
Actual Return on Plan Assets	4,77,827	1,97,381
Acquisition Adjustment	-	-
Present Value of Obligations as at the end	**87,36,056**	**57,98,777**

g) Major categories of Plan Assets (as percentage of Total Plan Assets) **(Amount in Rs.)**

Particulars	Financial Year ending	
	AS ON 31.03.19	AS ON 31.03.18
Equities	-	-
Gilts	-	-
Bonds	-	-
Insurance Policies	100%	100%
Total	-	-

h) Bifurcation of Present Value of Obligation at the end of the current period as per revise Schedule III of the Companies Act, 2013 **(Amount in Rs.)**

Particulars	Financial Year Ending	
	AS ON 31.03.19	AS ON 31.03.18
Current Liability (Short Term)	8,20,845	4,98,430
Non-Current Liability (Long Term)	79,15,211	53,00,347
Present Value of Obligation as at the end	**87,36,056**	**57,98,777**

The principal assumptions used in determinning gratuity obligation for the company's plan is shown below:-

Particulars	Financial Year Ending	
	AS ON 31.03.2019	AS ON 31.03.2018
Discount Rate (Per Annum)	8.00%	8.00%
Salary Growth Rate (Per Annum)	10.00%	10.00%
Expected Rate of Return on Plan Assets (Per Annum)	8.00%	8.00%

The estimates of future salary increases, considered in acturial valuation, take account of inflation, seniority, promotions and other relevant factors, such as supply and demand in the employment market.

17.18.1 Other Non-Current Investment **(Amount in Rs.)**

S. No.	Particulars	Financial Year Ending	
		AS ON 31.03.2019	AS ON 31.03.2018
1	**Other Non-Current Investment (unqouted)**		
a)	GVFL Startup Fund	2,87,00,000	-
b)	IAN Fund	3,36,60,000	-
c)	StakeboatCapital Fund	37,00,717	-
		6,60,60,717	**-**

Note:

1. BIRAC is implementing the Biotechnology Innovation Fund - AcE Fund initiated by Department of Biotechnology, Govt of India for providing risk capital to Biotech startups for product development cycle and growth phase.
2. The value of the investments are stated at cost. Provision for diminution in the value of long-term investments is made only if such a decline is other than temporary.
3. BIRAC undertakes Management and operation of AcE fund in the area of Biotechnology and life sciences and holds all investrnents made out of the AcE Fund in a fiduciary capacity for DBT.

17.18.2 **Contingent liability**

With respect to AcE fund draw down request as per the contribution agreement is yet to be received amounting to Rs. 26.39 crores.

17.19 The previous year's figures are reclassified and regrouped in accordance with the requirements applicable in the current financial year to make items comparable.

17.20 List of Abbreviations used in Financial Statement:

S. No.	Abbreviation	Description
1	BIRAC	Biotechnology Industry Research Assistance Council
2	AcE Fund	Accelerating Entrepreneurs Fund
3	ACT	All Children Thriving
4	AgNu	Agriculture-Nutrition Projects
5	AMR	Antimicrobial Resistance
6	BCIL	Biotech Consortium India Limited
7	BIG	Biotechnology Ignition Grant
8	BIPP	Biotechnology Industry Partnership Programme
9	BISS	Bio Incubator Support Scheme
10	BMGF	Bill Melinda Gates Foundation
11	CRS	Contract Research Scheme
12	DBT	Department of Biotechnology, Ministry of Science & Technology, Government of India
13	ETA	Early Translational Accelerator
14	FD	Fixed Deposit
15	GCI	Grand Challenges of India
16	HBGDKi	Healthy Birth Growth Development Knowledge Integration
17	I&M	Industry and Manufacturing
18	IDIA	Immunization Data for Innovating Action
19	IIPME	Industry Innovation Programme on Medical Electronics
20	IMPRINT	Improving Growth in Infant Trail
21	IP	Intellectual Property
22	Ki	Knowledge Integration Data Challenge Programme
23	KSTIP(KnIT)	Knowledge Integration and Translation Platform (Knowledge Integration)
24	MeitY	Ministry of Electronics and Information Technology
25	Misc.	Miscellaneous
26	MTNL	Mahanagar Telephone Nigam Limited
27	NBM (I3)	National Biopharma Mission (Innovate in India)
28	PMC	Projects Monitoring committee
29	PMU	Programme Management Unit
30	PPP Activities	"Public-Private Partnership Activities (Earlier termed as Industry and Manufacturing (I&M) Sector.)"
31	RTTC	Reinvent the Toilet Challenge
32	SBI	State Bank of India
33	SBIRI	Small Business Innovation Research Initiative
34	SPARSH	Social Innovation programme for Products: Affordable & Relevant to Societal Health
35	SSC-NTBN	Secretariat for Scientific sub-committee under the National Technical Board on Nutrition.
36	TA & DA	Travel Allowance & Diem Allowance
37	UIC	University Innovation Cluster
38	WT	Wellcome Trust

COMMENTS OF THE COMPTROLLER AND AUDITOR GENERAL OF INDIA UNDER SECTION 143(6)(b) OF THE COMPANIES ACT, 2013 ON THE FINANCIAL STATEMENTS OF BIOTECHNOLOGY INDUSTRY RESEARCH ASSISTANCE COUNCIL FOR THE YEAR ENDED 31 MARCH 2019

The preparation of financial statements of Biotechnology Industry Research Assistance Council for the year ended 31 March 2019 in accordance with the financial reporting framework prescribed under the Companies Act, 2013 (Act) is the responsibility of the management of the company. The statutory auditor appointed by the Comptroller and Auditor General of India under Section 139(5) of the Act is responsible for expressing opinion on the financial statements under section 143 of the Act based on independent audit in accordance with the standards on auditing prescribed under section 143(10) of the Act. This 1s stated to have been done by them vide their Audit Report dated 12 June 2019.

I, on behalf of the Comptroller and Auditor General of India, have decided not to conduct the supplementary audit of the financial statements of Biotechnology Industry Research Assistance Council for the year ended 31 March 2019 under section 143(6)(a) of the Act.

For and on behalf of the
Comptroller and Auditor General of India

Place: New Delhi
Dated: 17.07.2019

(राजदीप सिंह)
प्रधान निदेशक वाणिज्यिक लेखापरीक्षा
एवं पदेन सदस्य, लेखापरीक्षा बोर्ड–IV

Regd. Office: 1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi-110003
Website: www.birac.nic.in E-mail: birac.dbt@nic.in Tel: 011-24389600 Fax: 011-24389611
CIN NO: U73100DL2012NPL233152

Attendance Slip

Name of the Member/proxy (In Block Letters)	
Address of Member /Proxy:	
Folio No. :	
No. of Shares Held	

I certify that I am a member /proxy for the member of the Company.

I hereby record my presence at the 7th Annual General Meeting of the Company held on Monday, 23rd September 2019 at 10:15 a.m. at Department of Biotechnology, 2, CGO Complex, 7th floor, Lodhi Road, New Delhi – 110003.

.....

Member's /Proxy's Signature

Regd. Office: 1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi-110003
Website: www.birac.nic.in E-mail: birac.dbt@nic.in Tel: 011-24389600 Fax: 011-24389611
CIN NO: U73100DL2012NPL233152

PROXY FORM

[Pursuant to section 105(6) of the Companies Act, 2013 and rule 19 (3) of the Companies (Management and Administration) Rules, 2014]

Name of the Member(s):		*E-mail ID:*
Registered Address:		*Folio No. :*

I/We, being the member(s) of ..... shares of the above named Company, hereby appoint:

(1) Name: .....
Address: .....
E-mail Id: .....
Signature: ..... or failing him/her;

as my/our proxy to attend and vote (on a poll) for me/us and on my/our behalf at the **7th Annual General Meeting of the Company, to be held on Monday, 23rd September, 2019 at 10:15 a.m.** at Department of Biotechnology, 2, CGO Complex, 7th floor, Lodhi Road, New Delhi – 110003 and at any adjournment thereof in respect of such resolutions as are indicated below:

S.No	Resolutions	For	Against
1	***Ordinary Business*** *To receive, consider and adopt the Audited Financial Statement of the company as on March 31, 2019 together with the Reports of the Directors and Auditors, thereon and comments of the Comptroller & Auditor General of India in terms of Section 143(6)(b) of the Companies Act 2013*		
2	*To fix the remuneration, of the New Statutory Auditor for the Financial year 2019-20, in terms of provisions of Section 139 of the Companies Act 2013.*		

Signed this..... day of..... 2019. Signature of the Shareholder

....

Signature of first proxy holder Signature of Second proxy holder

Affix Revenue Stamp

* Applicable for investors holding shares in electronic form.

Notes:

1. MEMBERS ENTITLED TO ATTEND AND VOTE MAY APPOINT ONE OR MORE PROXIES TO ATTEND AND VOTE INSTEAD OF THEMSELVES. PROXIES TO BE VALID MUST BE RECEIVED AT THE REGISTERED OFFICE OF THE COMPANY NOT LESS THAN FORTY-EIGHT HOURS BEFORE THE APPOINTED TIME OF THE MEETING
2. Only bonafide members of the Company whose names appear on the Register of Members in possession of valid attendance slips duly filed and signed will be permitted to attend the meeting. The company reserves its right to take all steps as may be deemed necessary to restrict non-members from attending the meeting.

birac
Ignite Innovate Incubate

Impact

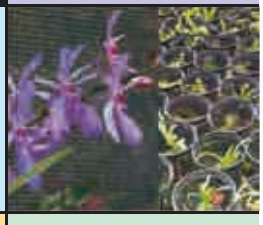
1000+
Beneficiaries supported

41
Bio-Incubators supported

4
Regional & Entrepreneurship Development Centres

Funding support by BIRAC -
INR 978 Cr.

Industry Commitment -
INR 937 Cr.



150+
Academic institutes Supported

Ignite Innovate Incubate

INR 150 Cr+
Partnered funding raised by Start-ups

10,000+
Manpower supported for high end skills

4,50,000 sq. ft.
of Incubation space created

INR 300 Cr+
Committed through Equity fund

600
Companies supported

14
Bio-incubators supported under Equity based SEED Fund

175+
IPs filed

130+
Products & Technologies developed

500+
Start-ups and Entrepreneurs supported

Biotechnology Industry Research Assistance Council

(A Govt. of India Enterprise)

CIN NO: U73100DL2012NPL233152

1st Floor, MTNL Building, 9 CGO Complex, Lodhi Road, New Delhi-110003

Email : birac.dbt@nic.in, Website : www.birac.nic.in, Twitter handle @birac_2012

Goldmine 2019