

**IGNITE • INNOVATE • INCUBATE** 

# Enabling Transformations



**Biotechnology Industry Research Assistance Council** 

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## chief editor's take



tis a matter of great delight that BIRAC completes two years of its successful existence on 20<sup>th</sup> March 2014. From day one, BIRAC's thrust has been on creating an Innovation ecosystem that is conducive to the needs of young entrepreneurs and start ups and networking them in such a manner that their ideas and discoveries stand up to their full potential through the rigors of the product development pipeline. In the institutional space, BIRAC strives to leverage national and international expertise through strategic partnerships to help Indian biotech enterprise become globally competitive.

Given the urgency of requirements of SMEs in the biotech sector, BIRAC launched unique models of innovation funding and ecosystem development. In a short span of time BIRAC has notched up impressive results. It has reached out to more than 250 companies, mainly start ups and SMEs, and has also supported more than 50 young entrepreneurs through seed funding.

Additionally, BIRAC has provided incubation space, and mentoring for IP & technology management and business development to more than 100 companies.

It is now well recognized that S&T agencies of the country need to establish a sustained dialogue not only with their direct stakeholders but also with the society at large, to create a constituency of support for S&T and to draw in fresh talent to take pursuit of science forward. As a step towards realising its outreach mandate we are pleased to present the first issue of **DIFQC23**, the quarterly newsletter of BIRAC. We are sure that **DIFQC23** will help us connect with BIRAC's stakeholders and soon emerge as a platform for the biotech innovation research community to interact with BIRAC, and with each other.

I, and my colleagues in this endeavor, bank on your valuable feedback to make brocks directly relevant to our needs in the times to come.

Renu Swarup

Managing Director, BIRAC & Adviser, DBT

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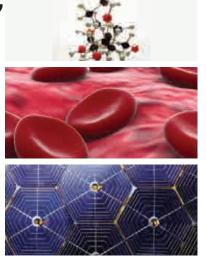
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## Biotechnology for Socio-Economic Transformation of India



'ndia is going through an extraordinary phase in its history, akin only to the challenges it faced at Lindependence. Today, as in 1947, there is a renewed attempt to use knowledge and science as a component of social and economic change. In one perspective, India is full of problems. Health, agriculture, nutrition, sanitation, energy, infrastructure, manufacturing, the eco-system, are all major areas that need to be urgently addressed. In another perspective, India's continued investment over the past six decades in science and technology has been paying off in ways which position it to address the post complex of challenges. In this context, the key question that BIRAC faces is as simple as the answer is complex: How can BIRAC, with its modest resources, catalyse the biotech industry and entrepreneurial space into being socially and economically transformative? The answer to this question is what we grapple with at BIRAC constantly.

The foundations of our ventures lie in understanding and using the best in science and technology. From these foundations we reach out in every way to scientists, entrepreneurs, industry and science agencies in India and the world over. BIRAC's structure and its purpose to connect knowledge for public-good make its position and mandate unique. Just two years old, we have a lot to learn, but we have a preternatural ability to deal with complex

problems. This has come about only because of the early nurturing by our partners. These are the Department of Biotechnology, various ministries in the Government of India and our extraordinary national and international collaborators.

Because of our accelerated growth, BIRAC has taken on many tasks in catalysing innovation in several biotechnology sectors. The canvas of urgent problems in India is huge. On one hand BIRAC will find it difficult to neglect any part of this canvas and on the other it does not currently have the wherewithal to deal with all of it. As we meet in our second year, we hope to solve such conundrums through partnerships. The shared commitment that we share with all our partners is what makes us confident that we will paint the broad canvas well for India and the planet's future.

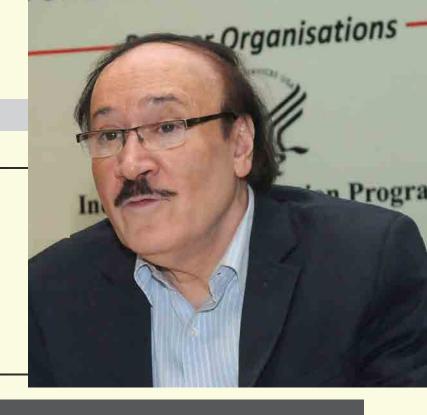
I would like to use this opportunity to reiterate BIRAC's commitment to do everything to work together with our community and our partners in the coming years and to congratulate all of BIRAC's staff in their extraordinary zeal and motivation.

**K VijayRaghavan** Secretary DBT & Chairman BIRAC

## through the prism

Dr. M.K. Bhan

# No resting on the oars



Dr. Maharaj Kishan Bhan served as Secretary, Department of Biotechnology, Government of India from March, 2004 to November, 2012. Dr. M K Bhan was the driving force behind the thinking that led to setting up of several institutions, including BIRAC.

Dr. Bhan is widely respected not only as a scientist but also for his vision about how the S&T ecosystem in India can be strengthened at an institutional and policy level in order to encourage young people to take to pursuit of science and also to allow this young talent achieve the best of natural skills and acquired knowledge. Dr. Bhan took time off to speak to biracza about past and future of BIRAC as he sees, and envisions.

Can you throw some light on the thought process that prompted the setting of BIRAC with its given institutional arrangement? Why a Section 25 company and not another division of DBT? How does that make it unique?

**Dr. M K Bhan (MKB):** Public policy is an inclusive process in which government ministries, with engagement with multiple stakeholders, determine priorities for deployment of public funds, keeping constitutional provisions and societal aspirations in view. Implementing a policy requires two things. One is strategy, second is execution. If you can't execute brilliantly and efficiently, even a good policy loses its relevance. Executional brilliance is difficult to achieve through ministries. There may always be an odd department headed by an individual having nature gifted skills and attitude, but it does not represent a lasting sustainable system. Real progress is when excellence of an executing mechanism outlives natural variations in human leadership. Another important requirement is that executing mechanisms should

operate in a competitive space. Competition should not be between policies and ministries, but between execution structures. Say DBT runs 20 schemes and each scheme has 3 or 4 execution structures that compete with each other to serve stakeholders. When you create competition, performance improves.

BIRAC represents an arrangement that can translate the will of the DBT in the biotech sector into practice. National Biotechnology Strategy sets the goals for that practice by saying we must support start-ups & small companies, promote public private partnership in diverse forms and direct this energy towards public good. For this, our execution mechanisms must be bench marked to best of industry efficiency levels. The efficiency of people who work for profit must also be directed to serve public good. In this backdrop the decision was that BIRAC's structure should be of a not for profit company. I also felt that all BIRAC schemes should have multiple vending nodes. This creates

internal competition and exerts pressure on various nodes to improve relative performance. In line with this thinking we set up the DBT Welcome Trust alliance as a competition for BIRAC so that no one becomes sleepy. This sense of pressure for sustained excellence comes from internal systems, accountability frameworks and challenging but supportive & caring boards. Like in politics, even in service delivery there should be a feeling that if you do not serve the people well, others will take over in the race of serving the human society.

Biotechnology is a dynamic multi-disciplinary domain. In this complexity, which are the low hanging fruits that BIRAC should aim to capture in the short and medium terms, to quickly mark its effect as an organization?

MKB: BIRAC started with a value proposition to fulfill entitlement of the most vulnerable and creative sections of biotech industry that take risks, but are small. All over the world biotech innovation occurs in small companies while production and marketing is done by big players. BIRAC shouldn't see itself as a fund disbursement agency but the one that seeks to empower by engaging in transactions where it sweats with a small company or a public institution in a product development project. BIRAC has started doing more and more work of this type. They became the government non-money participant in the rotavirus vaccine project. While in earlier phase they supported the project, now the investigator is funding them to play this role. Slowly the relationship for entitlement fulfillment according to government's policies is being supplemented with efforts aimed at empowerment like being a pressure point for efficient regulatory system, being an advocate for favorable government policies for small enterprises and innovation. It is not a small role but a much bigger role. In the biotech sector it is the small fries that account for much of innovation. They need empowerment, as much as funding, if not more.

It is often noted that the stakeholder base of agencies set up to promote S&T is narrow and overlaps with larger institutions accounting for bulk of resources. What in your view can be done that S&T funding is most inclusive and broad based?

**MKB:** BIRAC has succeeded in democratization of the merit based funding to a degree that no science agency has. Their biggest strength is derived out of their systemic transparency and executional efficiency. I believe that if we empower institutions and individuals and not just fund and monitor them, many others will come upto standard. As a nation we value experience of seniors, but we are not great nurturers of young people. But it's slowly changing with more and more

young people coming to the fore. If we develop schemes to nurture young people, say like INSPIRE, there will be talented people in all kinds of places.

An unaimed arrow never misses. What in your view should be BIRACs shape after 10 years from now?

MKB: I would like to see BIRAC as an organization that learns how to do and manage product development projects of great public value by not just funding and monitoring, but by becoming a partner. Identify a bright bunch of people, do the needed filtration, design a project and join as a partner. That's how rotavirus vaccine was developed. Everybody just got in. Monitoring and partnering are two sides of the coin. Even though BIRAC started as a funding agency it should strive to become a "development agency" or an "innovation promotion agency". Every young person who starts a startup company or any innovator in a public institution should know that they could just walk over to BIRAC.

What are the pitfalls that BIRAC should be very cautiously avoiding in its journey over the year ahead?

**MKB:** BIRAC will do well to develop a measurement weighted matrix for different achievements. One is to say we have supported 5000 projects so far, another is to say though we supported just 200 projects but out of these 20 delivered a public good. It's breadth vs depth. People remember you for the impact you create, not for the running around you do.

Another way is to see how your stakeholders rate you for empowerment, efficiency, transparency, lack of corruption, values etc. Did they learn and became stronger because of BIRAC? Is the flow of IP, tech transfer, knowledge sharing etc enhanced because BIRAC is creating young innovators in this country who know what BIRAC does that can be of help to them? You can create a large number of models to measure user satisfaction measuring things like number of new drugs, affordable technologies, quality start ups that are there, for having survived the valley of death because of BIRAC. You have to imaginatively create evaluation matrices for evaluating entitlement as well as empowerment services. I will feel proud if 10 people in BIRAC in 10 years time come to be considered as authorities on development of vaccines, drugs, agricultural technologies, environmental technologies, devices etc. where they are seen to be the most valuable experienced based resource in the country. I repeat not merely "knowledgeable" but also "experienced".

It is not just about making industry powerful but having an impact on the society, making industries collaborate even in the competitive space, creating quality research services that

## through the prism

are widely accessible, smoothening knowledge flows between academia and industry and reverse. This is what BIRAC should measure itself for.

What would you like to say about BIRAC's international partnerships and its emerging role as a development agency?

MKB: In a very short period of time BIRAC has earned a name that makes everyone envious. Be it NIH, WHO, Bill and Melinda Gates Foundation..., everybody wants a partnership with BIRAC. Gates Foundation has established a management unit with BIRAC. Wellcome Trust has decided that in the INDIA DBT Health Technology Alliance, projects will be handled through them, and so on. This is government as an empowerer. We brought international partnerships not to run the race on their own but to let

government created instruments drive it further. For all our suspicions about everyone who comes to India, we have never created a system where we take the responsibility and they contribute. They now run to BIRAC whereas earlier they used to run away from the ministries. This is because BIRAC has the efficiency and openness that is critical for innovation, and is not suspicious and low risk taking as government ministries. Government ministries often tend to be. And sometimes you realize that may be ministries are meant to be like that.

Our policies have never been a problem, our execution has always been. So my recommendation is that every ministry should create a BIRAC, create ten for each different job and you will see the difference.

# BIRAC Strategy Meet Mapping the terrain

BIRAC in its short history of two years as a not-forprofit public enterprise has delivered several pioneering programmes that have catalysed the transformation of the Indian biotechnology landscape and spurring innovation to bring affordable and high quality products to the market.

BIRAC's Strategy Meet was convened on 4th and 5th February 2014 to reflect and deliberate on BIRAC's business model as it steps into the future. A high level group representing stakeholders from the government, industry and academia, BIRAC's senior leadership including Board Members as well as BIRAC resource persons met over two days to deliberate on the evolving role of BIRAC. The deliberations were directed at the following themes such as identifying challenges and issues that would impinge upon the innovation ecosystem and how BIRAC should strategise to address those issues, new focus areas that BIRAC could explore and identifying sustainable model for BIRAC to grow.

During the deliberations BIRAC programmes were analysed to make them efficient. The meeting provided BIRAC strategies to both deepen existing programmes and expand its



reach through partnerships both national and international. Further it was deliberated on BIRAC's strategies to focus on new areas of platform technologies, personalised medicine and diagnostics and biomanufacturing. It was also suggested that BIRAC devises ways to engage with other venture funding agencies, play a significant hand-holding role for startups and SMEs especially in establishing a mentorship programme, play a positive role in influencing and advocating an optimal regulatory landscape and renew its efforts to engage with the wider public through science communication especially in making the public understand the benefits that the society accrues from cutting edge biotech research and how BIRAC is playing a significant role in the ecosystem.



## BIRAC Innovators Meet

## Expanding the horizons

BIRAC organized its second Innovators Meet on 23-24 September 2013 at the Heritage Village Resort, Manesar, Haryana. The theme of the Innovators Meet 2013 – *Catalysing the Growth of an Innovation Driven Biotech Enterprise* – focused on policy changes and pathways to drive the Indian bio-economy to reach the level of USD 100 Bn by 2025. More than 200 stakeholders including policy makers, industry leaders, entrepreneurs and academic researchers attended the meet.

The Innovators Meet 2013 was inaugurated by Prof. K. VijayRaghavan, Secretary, Department of Biotechnology (DBT), Govt. of India & Chairman BIRAC. Prof. G Padmanaban, Senior Scientist and Innovation Advisor to BIRAC, delivered the Keynote Address focusing on the preparedness of the country to achieve the USD 100 Bn mark and areas of opportunities in the biotechnology that India could leverage upon in its pursuit of the same.

To mark the occasion a compendium of BIRAC funded schemes and innovative projects titled "BIRAC Innovators: Creating an Impact" was officially released.

The amalgamation of thoughts from industry and academia highlighted various issues that are considered critical for growth of biotech sector in India and measures that need to be adopted in order to address them. The two day long meet witnessed deliberations on several relevant issues that impinge upon the growth of the biotechnology enterprise. These included funding opportunities and institutional/

regulatory gaps that biotech-entrepreneurs need to negotiate. Strategies to foster innovation through bio-enterprises were also a subject of discussion that specifically focused on the needs of start-ups and SMEs, they being the engines of bio-innovation.

#### BIRAC INNOVATORS AWARD

The Innovators Meet was also an occasion to announce the winners of *BIRAC Innovators Award* instituted to honor outstanding biotech innovators. Through these awards, five best innovations by the industry, in various domains of biotech sector, leading to cutting edge innovative products were recgonised.

#### Agriculture

**Aristogene Biosciences Pvt. Ltd., Bangalore** for the development of improved PCR Kits with internal control for shrimp viruses.

#### Healthcare

**Tergene Biotech Pvt. Ltd., Secunderabad** for the development of an indigenous India specific 15 valent *pneumococcal* conjugate vaccine.

#### Biomedical Devices, Implants and Diagnostics

**Vinvish Technologies Pvt. Ltd., Trivandrum** for the development of an indigenous PDT Lase system.

#### **Industrial Processes and Green Technology**

**Thermax Ltd., Pune** for the development of Anaerobic Membrane Bioreactor for waste to energy solutions, and,

## update

**Millenium Exports, Chennai** for the development of pet animal food, fish leather and other marine biotechnology products from fish waste.

#### PITCHING IN

The Innovators Meet also provided a platform for start-ups to pitch their ideas to the distinguished audience and also display their innovative projects in the poster session. While evaluating the business pitches, the Jury Panel considered presentation clarity, value proposition, project concept, business plan, stage of product development and presenters ability to address concerns of jury members about the project. Two pitches adjudged as best were:

**Achira Labs, Bangalore** for microfluidics-based platform for multiplexed point-of-care immunoassays.

Mr. Jayant S. Karve, Stanford India Biodesign for intra osseous access device.

#### POST IT

Poster session at the Innovator's Meet received as many as 24 entries. They were evaluated on level of innovation related to the project, quality of presentation and progress/outcome of the project. Three posters adjudged as outstanding were presented by:

**Kaveri Seed Co. Ltd.** on development of biotic stress resistance rice through conjunct use of bio and hybrid technolo-

gies marker-assisted dissection of genetic basis of yield and improving yield potential under drought stress in maize.

**Oriental Aquamarine** on design modification and commercialization of nitrifying bioreactor technology for establishment of organic recirculation prawn seed production system.

**Praj Industries** on lignocellulosic biomass to ethanol technology: simultaneous saccharification and fermentation.

On the agenda of the Innovators Meet was to deliberate and discuss the issues pertaining to the various facets of Indian biotechnology. To achieve this, several plenary sessions and focused roundtables were organized in various areas of the biotechnology landscape of the country. Targeted roundtables focused on mapping granular challenges that various segments of the biotech sector face and provided useful recommendations on steps that can help diverse biotech domains to contribute to the larger goal of achieving USD 100 Bn by year 2025.

The meet concluded with several recommendations for fostering the innovation in Indian bio-economy and creating an environment that is conducive for the commercialization of socially relevant and responsive innovations.

#### PLENARY SESSIONS

The three plenary sessions organised during the Innovator's Meet drew very enthusiastic participation. The sessions



## BIRAC Innovators Meet

were designed to focus on key challenges faced by the Indian biotech sector. The main themes were:

## Catalyzing the growth of an Innovation Driven Biotech Enterprise

**Focus :** Specific issues and action required to achieve USD 100 Bn dollar industry by 2025 and create a vibrant bio-economy.

## Accessing & Harnessing Smart Funds for Innovation Driven Biotech Enterprises

**Focus**: Current situation in India for biotech/medtech firms to access capital including policy action points needed to bridge existing gaps and how biotech firms can harness different funding sources & mechanisms to grow the biotech enterprise.

## How can Start-ups unleash the power of Innovation driven Biotech Enterprise

**Focus**: How startups can be fostered to drive an innovation driven biotech enterprise, status of innovation driven entrepreneurial climate in the country, India specific challenges for start-ups, technology access, availability of mentors and networks and challenges faced by start-ups in different domains.

#### ROUNDTABLES

**Bio Pharma Roundtable** focused on current needs of the country in biopharma especially in biosimilars, vaccines, stem cells and devices, new technologies and platforms required for biopharma R&D and ways to overcome challenges in discovery, manufacturing and access to technology.

Bio Agri Roundtable deliberated on how the bioagri sector can strategise to be one of the biggest contributors of Indian bioeconomy by 2025 and on current needs of the country in bioagri especially in food productivity & security, strategies to make India a hub for cutting edge bioagri R&D. The session also deliberated upon technological infrastructure that India should invest in and how gaps in this sector can be bridged to make India a global bioeconomy.

**Bio Industrial Roundtable** discussed the current needs of the Indian bioindustrial sector, initiatives required in bioindustrial R&D especially in industrial enzymes and green chemistry. New technologies and infrastructure that India should be investing in were also a major point of deliberations.

**Bio Services Roundtable** focused on the current status and challenges in the bioservices sector in India. The panelists discussed how India can become a hub for contract research,



clinical research and manufacturing, capability building in novel drug discovery. Platforms and technologies where investment needs to be done were also highlighted.

**BioInformatics Roundtable** aimed at addressing the challenges faced by Indian bioinformatics sector. The roundtable discussed that how can bioinformatics contribute to drug discovery, agri biotechnology and industrial biotechnology, steps to make India a potential destination for R&D in predictive biology, and new technologies and platform to invest in.

## Session on Systems and Synthetic Biology-New Frontiers in Life Sciences: Opportunities for the Indian Biotech

There was a focused session dedicated to synthetic biology, whereby the talks focused on global scenario and early technological indicators in the arena of Systems & Synthetic Biology. The talks highlighted the opportunities that exist and can help India to be ahead of the curve in these cutting edge fields. The panel discussed the present scenario in India including technology bottlenecks, regulatory and ethical issues, and the impact of synthetic biology on healthcare, agriculture and industrial biotechnology sector.

During the course of the event, industry delegates got an opportunity to interact with senior biotechnologists including Prof. K. VijayRaghavan and Dr. M. K. Bhan and discuss with them the policy challenges faced by the Indian Biotech sector. BIRAC is thankful to all the stakeholders who participated in the meet and gave their value inputs for achieving the set goal of USD 100 Bn bio-economy. BIRAC has taken the note of every recommendation for promoting and fostering the innovation driven bio-enterprise system in India. BIRAC is committed towards the accomplishment and implementation of the recommendations to the best possible extent.

## BIRAC's innovators

# Pushing the envelope

Small steps make for a long journey. BIRAC is proud of its partnerships with enterprising and committed biopreneurs across the country by way of providing them support, mentoring and handholding in their quest to develop new products and services that can enhance the welfare of the common man and bring societal good. Here we showcase some of the notable outcomes of bio-innovation efforts supported by BIRAC.



Vishwas Joshi

Seagull BioSolutions Founded by Dr. Vishwas Joshi to develop new healthcare technologies that benefit the common man in India, Seagull BioSolutions (SBPL) has made a debut with a versatile platform useful for expression of recombinant proteins, RNA molecules & viruses. Called "eSAME system" and developed with support from DSIR it makes it possible to use the enzyme "RNA dependent RNA polymerase" for large-scale protein production. SBPL will soon offer reagent kits & services for production of rec. proteins, viruses & gene therapy agents using this technology. Seagull BioSolutions has also used eSAME technology to synthesize innovative products like a novel nontoxic cancer therapeutic virus similar to Oncovex from Amgen, Virosome platform for development of Dengue Vaccine & gene therapy applications and secretable Dengue Virus Like Particles.

BIRAC has helped SBPL in a multiplicity of ways. In addition to financial support, BIRAC also supported Dr. Vishwas Joshi, founder of SBPL to attend the IGNITE programme at Univ. of Cambridge, UK and to undertake the national phase of the PCT/IN2012/000405 effectively. Moreover, SBPL is being incubated at the Venture Center, Pune, a BIRAC supported bioincubator facility. The mentorship received has helped SBPL to compete successfully in the Grand Challenges Explorations of the BMGF and also attract financial support from ICICI Bank.



**Tuhin Bhowmick** 

Pandorum Technologies Pandorum was co-founded by Dr. Tuhin Bhowmick& Mr. Arun Chandru at IISc. With support from BIRAC, Pandorum Technologies is working on development of novel bio-mimetic elastomeric protein-based hydrogels, which can have important applications in drug delivery and wound management. Pandorum has developed programmable 'advanced' materials for tissue engineering and drug delivery. Biomimetic Modular Elastomeric Platform (MODELAS) targets a tunable viscoelastic hydrogel that mimics the properties of extra cellular matrix of our body. The properties of these materials can be tuned for a variety of functions with possibilities of fabrication through bio-printing. It has applications in joint (facet) resurfacing, inter-vertebral disc (nucleus pulposus) reconstitution and corneal graft. Stimuli Responsive Delivery Platform (TransOrb) is a biopolymer-composite that encapsulates 'cargo' molecules that is released after sensing disease specific stimuli. This has applications in non-invasive, medical imaging systems for disease marker profiling/detection, and target specific drug delivery.

The area of impact of activities of Pandorum covers tissue regeneration & healing, personalized molecular profiling of cancer, alleviating side effects of toxic drugs and improving efficacy through precise delivery.

## BIRAC Innovators



Dhananjaya Dendukuri

Achira

Labs

Achira Labs, a Bangalore-based start-up that is building a microfluidic platform for point-of-care medical diagnostics, was co-founded by Dr. Dhananjaya Dendukuri in 2009. With support from BIRAC, it is devoting its efforts to development of an aptamer-based platform to detect novel tuberculosis markers in human serum.

Achira has developed two platform technologies for point-of-care testing. The first uses a plastic, microfluidic device to perform rapid and multiplexed immunoassays with a small volume of blood or serum. The second is a novel fabric-based platform that we have developed to perform ultra low-cost testing. Silk yarn that has been pre-coated with different reagents is woven into a patch of fabric. Strips of this fabric can then be cut out to perform simple, capillary flow based tests. Achira Labs has been recognized as an innovative start-up company in the biotechnology space in India at multiple different forums including BIRAC Innovation Meet, EmTech India, Gates Foundation, Grand Challenges Canada and several others. It is also the recipient of grants and funding from Grand Challenges Canada, BIRAC-Govt. of India and angel investment from Nadathur Holdings. It has 7 patent applications filed, including 2 granted US patents.



Dinesh Bindiganavale

Pradin

**Technologies** 

Alarming statistics on stillbirths, infant and maternal mortality rates in India indicate the absence of an affordable solution to alert caregivers. Conventional cardiotocographs are expensive, complex to use, non-ambulatory, mains operated and need the presence of a care giver at all times. The legacy systems are good for a spot non-stress test but continuous monitoring costs are prohibitive.

The proposed product wearable transducerless maternal-fetal monitoring device is a simple to use, midwife friendly, wearable, battery powered device that comes at 1/5th the price of a conventional system. The device allows pregnant women to be ambulatory and is tailored for continuous monitoring for extended periods of time in case of high & medium risk pregnancies. Abdominal ECG is acquired from pregnant woman anytime between 25 weeks gestation till the time she goes into labor. There are no conventional transducers used to acquire fetal heart rate or uterine contractions. The embedded fetal components within the maternal ECG are separated by digital signal processing and a real time trend chart of fetal heart rate versus uterine activity is plotted to provide valuable information in case of fetal or maternal distress.

Advancements in digital signal processing, research and concept validation in global academic institutions and Pradin's own experience with conventional systems has aided this novel design. Alpha prototype is ready for acquiring abdominal ECG data. Beta prototype is work in progress. A list of novelty claims is ready for provisional filing in India patent office.



Sidhant Jena

Janacare

Diabetes Management is costly and complicated. 40% of patients don't adhere to drugs within first six months. Janacare, founded by Mr. Sidhant Jena, is leveraging its experience in the emerging markets, medical device design and mobile technology to bring revolutionary products and services to serve diabetic patients. Janacare has built an integrated biochemistry sensor for six basic blood tests and an interactive video based diabetes coaching program on the mobile phone, which reduces testing costs (by 10x), improves drug adherence (by nearly 30%) and significantly improves health outcomes.

Clinical partners of Janacare in these efforts are the AIIMS, New Delhi, Narayana Health Hospitals, Public Health Foundation of India and Dr. Mohan's Diabetes Specialities Center.

The sensor has received approval for use in India and it expects to receive the European CE mark and US FDA approvals in 2014. The product has gained fast acceptance with Narayana Health (14 hospitals) as one of the prominent customers. Janacare is in negotiations with more deals in this context.

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Rajyashri Ramakrishna
Navya
Biologicals

Navyawas founded by Dr. Rajyashri K.R and Mr. Vinay Konaje. Navya's unique YeXtreme™ platform is the result of an idea stage project that was part funded by BIRAC under its SBIRI initiative. The project involved manipulation/modulation of key regulatory genes in the folding and secretion pathway of the yeast cell line leading to generation of a cell line that is a hyper expressor of complex proteins with large number of disulphide bridges. The cell line has thus far been validated with 2 proteins - recombinant human Albumin (NavAlbumin) that meets all physico-chemical guidelines of rHSA in USP-NF and, third generation modified tPA, presently being developed as an NBE at Navya. It has been able to engineer the YeXtreme™ cell line to produce a protein with simple, low cost chemically defined media. The final recovery is in excess of 55%. Navya expects to achieve 10g/lt productivity in the coming months and is in the process of setting up a manufacturing unit that meets all cGMP guidelines and is expected to go on-stream in 2016.

Navya's ContiMAb mammalian expression along with continuous process platform in development at Navya is part funded by BIRAC's BIPP initiative. Navya is now in the process of combining its mammalian expression/media platform with a novel continuous process platform that is under validation. The goal is to bring down the cost of production of MAbs by atleast 50%. Initial results with 2 molecules, a fusion protein and a MAb, have shown extremely promising results with yields in excess of 7g/lt of working volume, expected to reach 12-15g/lt within the next 12 months. A pilot showcase low cost manufacturing facility based on ContiMAb<sup>TM</sup> is planned by 2016-17.



Dinesh Kumar

DesignInnova

DesignInnova was founded by Dr. Dinesh Kumar. The design and development of solid-state, portable, affordable 'Fluorescence Reader Device for Lateral Flow' (LF) assays utilizes up-converting phosphor (UCP) reporter technology. This platform allows porting conventional bio-assay like Lateral Flow for improved high sensitivity & speed in point-of-care diagnostics.

The innovative element in this technology is use of a novel UCP reporter technique as a detection system that removes the sensitivity limitations of conventional bioassays using colloidal gold. It works on the principle of excitation of UCP nano-particle bound to a bio-molecule by low energy infrared laser, resulting in fluorescence in visible region, which is analyzed by highly sensitive fluorescence reading instrumentation. The design of this instrument ensures no degradation and zero fluorescence from biological samples, ensuring very high signal-to-noise ratios resulting in higher test sensitivity. UCP reporters have core-shell structures with surface functional groups suitable for standard bio-conjugations. Also up-converting phosphor particles do not bleach and allow permanent excitation with simultaneous signal integration allowing porting of conventional bioassays to this enhanced platform.

This point-of-care UCP technology platform has the potential to provide multiple diagnostic options in the future. It is suitable for various point-of-care diagnostic tests using standard lateral flow cassette format and adaptable to various common diagnostic formats, and it allows porting the exiting bioassay to this platform ensuring an optimum design that is affordable & portable. This can be adapted for inexpensive tests for detection of HIV, HCV, HBV, Syphilis and other infectious diseases and will help to detect multiple infections simultaneously in remote settings giving it an immense potential and social value for the point-of-care diagnostic applications, both in the developing and developed nations.

## **BIRAC Innovators**



Nitin Kale
NanoSniff
Technologies

Myocardial infarction is difficult to detect in the early stages as it often confused with general gastric problems. It also often does not show on an ECG. Delayed diagnosis makes physicians often miss the "golden hour" i.e. commencement of necrosis. Confirmatory tests are often out of reach for people living in remote locations in rural/semi-urban areas. What is required to deal with the situation is a smart and inexpensive point-of-care sensor that can rapidly detect myocardial infarction. The idea behind the project undertaken by NanoSniff was to develop sensors that can detect cardiac markers released in the blood during and after a myocardial infarction event using a micro-cantilever based bio sensing system.

Microcantilevers translate molecular recognition into a nanomechanical motion as they measure the quasi-static deflection of miniature medical device, caused by target biomolecules binding to functional groups of biomolecules. The project aimed at building a microcantilever based sensing system to detect a cardiac marker such H-FABP. This was achieved by integrating microcantilevers with a fluid handling system and electronic instrumentation, coat them with antibodies designed with targeted proteins and experiment with spiked serum to demonstrate proof of concept. A single test may cost as little as Rs. 500.



Optra Systems

Radiology went digital at a phenomenal speed and now it is the need of the hour for pathology to follow suit. Digital pathology is the process of converting entire glass slides into high resolution, whole-slide digital images that can be viewed, managed, analysed and interpreted as by a pathologist with the aid of a computer instead of a microscope; using a digital pathology work flow management system. OncoScan is built innovatively to achieve all these aspects from end to end.

OncoScan is an automated, affordable and compact whole slide scanner that aims to be a holistic digital pathology solution which empowers the pathologist and revolutionizes the process of pathology reporting in India. OncoScan has multiple game-changing benefits over the conventional microscope. OncoScan scans entire glass slides to produce high resolution digital images. The innovative and extremely complex step in this instrument for process optimization is that a single X-Y stage is used for auto-loading of the slides as well as for high speed scanning. This stage behaves like a robotic arm to pick up the selected slide from the slide holding basket that moves along the Z axis. The prototype has been successfully tested with a large number of slides under laboratory conditions, and the next challenge would be mass validation.



Ashwini Nangia Crystalin Research

Crystalin Research was founded by Dr. Ashwini Nangia, an academic entrepreneur from University of Hyderabad. Crystalin has developed India's first pharma co-crystal (Temozolomide) in pre-clinical investigation for anticancer drug that has improved physic-chemical property and clinical efficacy for drug translation.

The co-crystal of Temozolomide (TMZ) has shown good PK-PD bioavailability and has the ability to cross the blood-brain barrier. The bioavailability and PK-PD parameters of test co-crystal of TMZ-Succinic Acid (Succinic Acid) are comparable to the reference drug in 100-100% range. Long term stability comparision of TMZ and TMZ-SA in accelerated ICH for 6 month indicate that the product stability for at least 2 years in normal ambient conditions of India. This project was funded by BIRAC's BIPP.

The co-crystal has important national and societal relevance as being hydrolytically stable it will be very relevant in tropical countries such as India and other geographies such as Asia and South America.

Crystalin has established collaborations with University of Hyderabad, National Institute of Nutrition and IKP Knowledge Park thus highlighting a success story of academic-industry chemistry to clinic drug translation in a PPP model.

## International Collaborations

# Spreading Wings

Partnerships are a key differentiator during the innovation process especially when the policy goal is to build an Indian bioeconomy of US\$100 Bn by 2025. BIRAC's intention is to join hands with global agencies, that are similarly aligned, and co-create programmes that aim to alleviate the hurdles and close the gaps in the biotechnology innovation ecosystem. These partnerships promote excellence through collaborations between national and international entrepreneurial talents, enable osmosis of best practices and create platforms for mobility of researchers and exchange of ideas.

#### WORKING TOGETHER WITH GATES FOUNDATION

The Bill & Melinda Gates Foundation (www.gatesfoundation.org) works to help all people lead healthy, productive lives. In developing countries, it focuses on improving people's health and giving them the chance to lift themselves out of hunger and extreme poverty. DBT and Gates Foundation have signed an MoU for supporting priority areas of research. BIRAC has been entrusted the responsibility to be the "Technical Management unit" for the joint partnership.

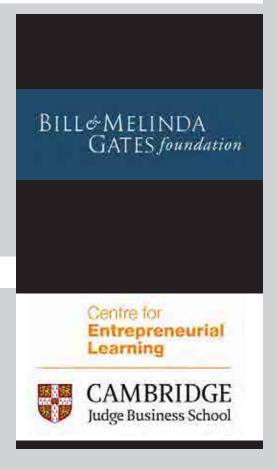
In this regard, BIRAC has established a Programme Management Cell to administer the programmes, which are in the area of health care and agriculture and focus on affordable product development. Under the aegis of Grand Challenges programme, BIRAC has come out with call for proposals in the areas of:

- Health, Agriculture and Nutrition
- Sanitation Reinvent the Toilet Challenge

### CREATING TOEHOLDS FOR ENTREPRENEURS

The Centre for Entrepreneurial Learning (www.cfel.jbs.cam.ac.uk) has mission of a mission to "spread the spirit of enterprise" by providing educational activities to inspire and build skills in the practice of entrepreneurship. CfEL's programmes range from elective modules in University of Cambridge undergraduate and postgraduate programmes to open programmes for aspiring entrepreneurs such as Enterprise Tuesday, Ignite and Enterprisers.

BIRAC and CfEL have initiated a partnership that would enable five BIRAC supported applicants to take part in CfEL's flagship intensive entrepreneurial boot-camp programme called "IGNITE", which is aimed at providing academics



## International Collaborations

(PhDs, post-docs and scientists) entrepreneurial opportunities to explore their innovative ideas and transform them into a business project. CfEL provides one week intense mentorship and training to the BIRAC supported candidates and for another week expose them to Cambridge's entrepreneurial cluster.

The first batch of 5 BIRAC supported IGNITE candidates selected from the pool of its Ignition Grant awardees and Stanford India Biodesign (SIB) fellows visited Cambridge in July 2013.

#### JOINING HANDS WITH CEFIPRA

Indo-French Centre for the Promotion of Advanced Research (CEFIPRA) is an organization committed to promoting bilateral cooperation in science and technology between India and France. BIRAC and CEFIPRA (www. cefipra.org) have signed an MoU to support Indian and French biotech start-ups and SMEs for promoting the innovation ecosystem in both the countries. The partnership aims to improve the competitiveness of both Indian and French biotech industries.

As a part of this collaboration, BIRAC will support Indian industries, whereas CEFIPRA will mobilise support for French industries. The initial focus of the collaboration will be on interventions in red and green biotechnology.

## PARTNERING WITH TEKES

Tekes (www.tekes.fi) is one of the most prominent publicly funded expert organisation for financing research, development and innovation in Finland. Tekes promotes a broad-based view on innovation, besides funding technological breakthroughs, while emphasizing the significance of service-related, design, business, and social innovations.

BIRAC has partnered with Tekes to promote joint cross border resource mobility, which is aimed to enhance the collaborations in the field of technology and innovations and enable the development of affordable technologies and products for the common challenges faced by both the countries.

## IN TANDEM WITH THE WELLCOME TRUST

The vision of the Welcome Trust is to achieve extraordinary improvements in human and animal health. In pursuit of this, it supports the brightest minds in biomedical research and the medical humanities. It focuses on three key areas of activity: a) supporting talented researchers, b) promoting application for research and c), embed biomedical science in the historical and cultural landscape, so that it is valued and there is mutual trust between researchers and the wider public.

BIRAC has collaborated with the Wellcome Trust to announce a joint call on "Affordable Health Care Technologies" with a budget of up to £ 1 million to be contributed by each side for the first call. The deliberations and discussion are currently underway for operationalization of the first call at the earliest.





# BIOTECHNOLOGY INDUSTRY RESEARCH ASSISTANCE COUNCIL

Empowering and Enabling the Biotech Innovation Ecosystem for Affordable Product Development

BIRAC is a 'Not-for-Profit Company' set up by Dept. of Biotechnology, Govt. of India as its interface agency to serve emerging biotech industries. BIRAC is guided by an independent Board of Directors comprising of senior professionals, academicians, policy makers and industrialists. BIRAC operates a variety of schemes to serve various dimensions of its mandate.

## **BIPP**

Biotechnology Industry Partnership Programme (BIPP) seeks to provide support for early to late stage high risk biotech R&D by industry and/or accelerate commercialization of new indigenous technologies.

## **CRS**

Contract Research and Services (CRS) scheme supports academic institutes across the country to take forward research leads through a validation and translation cycle by the industry. Funding is in the form of grant given to both the academic as well as the industrial partner. While the industry performs its role as a validation partner and engages on a contractual basis, the IP rights reside solely with the academic partner.

## BIG

Biotechnology Ignition Grant (BIG) is available to scientist entrepreneurs from research institutes, academia and start ups. It is designed to stimulate commercialization of research discoveries by providing very early stage grants to help bridge the gap between discovery and invention. The BIG Innovators receive mentoring and networking help from five BIG Partners (C-CAMP Bangalore, IKP Hyderabad, FITT IIT Delhi, NCL Venture Center Pune and KIIT-TBI, Bhubaneswar).

## **SBIRI**

Small Business Industry Research Initiative (SBIRI) is the first of its kind, early stage, innovation focussed PPP initiative to support incremental R&D in the area of Biotechnology to facilitate innovation and risk taking by SMEs. SBIRI support is in the form of a mix of soft loans and grants.

## SPARSH

SPARSH combines social innovation and biotechnology for the well-being of the society by helping identify and support cutting edge innovations towards affordable product development with potentially significant social impact. SPARSH provides support in the form of impact funding and fellowships.

## DBT-BMGF

BIRAC manages the DBT-Bill and Melinda Gates Foundation project to support collaborative scientific and technological research to alleviate some of the world's most critical global health and development issues.

## UIC

The University Innovation Cluster Initiative (UIC) focuses on Universities, where conducive environment for biotechnology collaboration and innovation thereof exists and where all stakeholders including industry can be brought together in synergy with each other. UIC initiative seeks to create an entrepreneurial culture in the Universities and help students to take their novel ideas to proof of concept.

For further information please visit www.BIRAC.nic.in or contact:

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