

Annual Report 2020-21











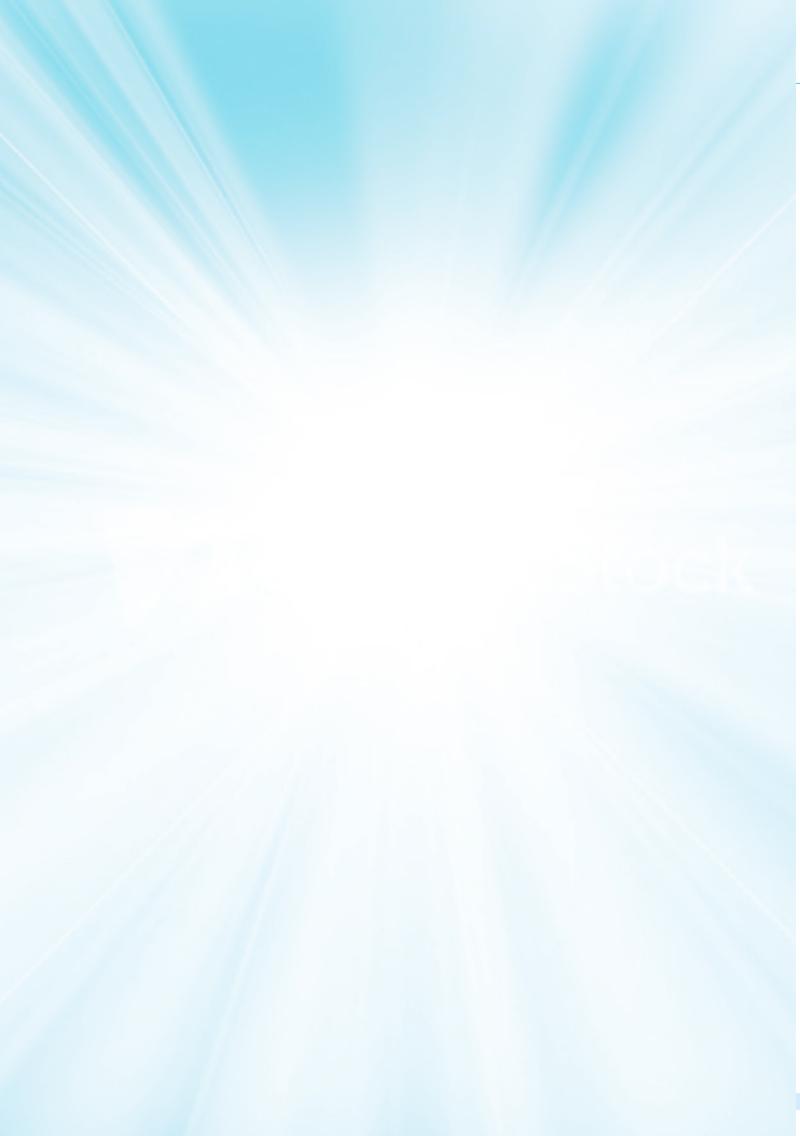


9th ANNUAL REPORT 2020-21



Biotechnology Industry Research Assistance Council

A Government of India Enterprise, Under Department of Biotechnology, Ministry of Science & Technology, Government of India





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











KEY STRATEGIES

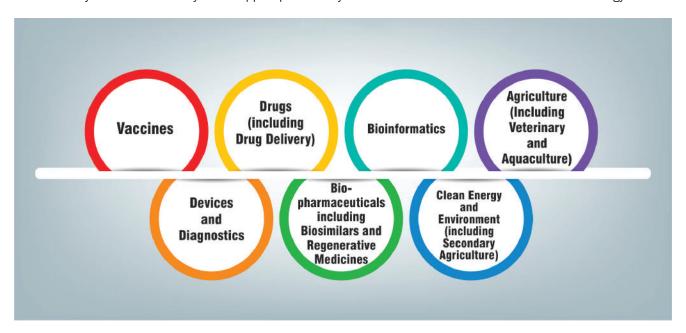
- Foster innovation and entrepreneurship in all places of research
- · Promote affordable innovation in key social sectors
- · Higher focus on startups & small and medium enterprises
- · Contribute through partners for capacity enhancement
- Encourage diffusion of innovation through partners
- · Enable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



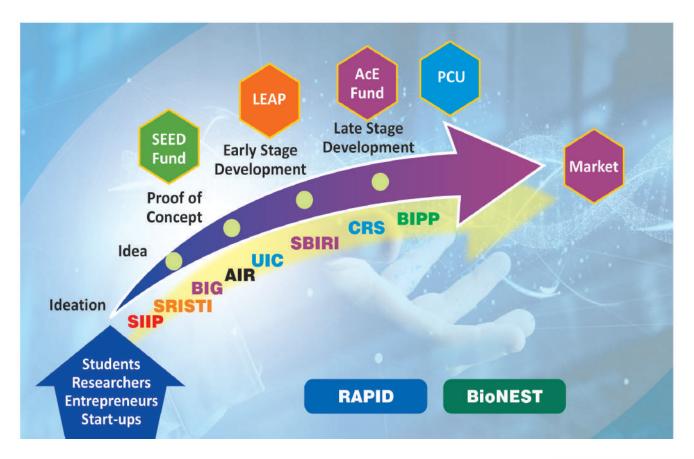


EXECUTIVE SUMMARY

BIRAC 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'. Since the last 9 years, BIRAC's focus has been to act as a 'Development Agency' promoting the biotech ecosystem in the country. The support provided by BIRAC extends across all themes of biotechnology.



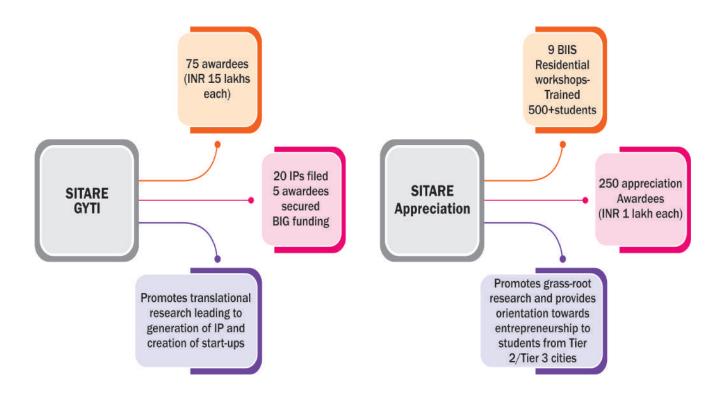
Covering the entire span of biotech arena right from pre-proof of concept till commercialization, BIRAC has been supporting innovations through its pioneering schemes.





SITARE (Students Innovations for Translation & Advancement of Research Explorations)

SITARE scheme is aimed at supporting innovative student projects in the area of biotechnology. The scheme has two components-SITARE GYTI and SITARE-Appreciation. The scheme is implemented in partnership with SRISTI, Ahmedabad



E-YUVA (Encouraging Youth for Undertaking Innovative Research through Vibrant Acceleration) scheme (earlier UIC)

EYUVA is mandated to promote a culture of applied research and need-oriented (societal or industry) entrepreneurial innovation among young students and researchers. The scheme provides funding support through fellowship and research grant technical and business mentoring, exposure to bio incubation model, orientation to entrepreneurial culture etc. to students at various levels including undergraduates, post-graduates and post-doctoral. The scheme is implemented through E-YUVA Centres (EYCs) housed within the University/Institute set up and mentored by a BIRAC BioNEST supported bio-incubator (EYUVA Knowledge Partner).

Till now there are 5 E-YUVA Centres and 5 new EYUVA Centres were selected and identified in the FY 20-21

30 Innovation Fellows	8 Start Ups	14 BIG Applications (5 SuvvessFul)	9 IPs
TN Bioeconomy	Panjab University	Rajasthan & Dharwad-	Other EYCs trying to
Cluster	BioNEST Bioincubator	State Support	mature to BioNEST

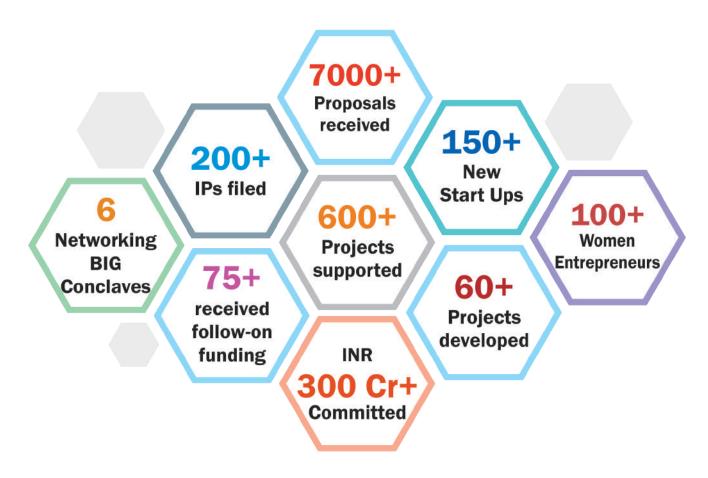
Biotechnology Ignition Grant (BIG)

BIRAC's flagship funding scheme provides the right admixture of fuel and mentoring support to young start-ups and entrepreneurial individuals to establish proof-of-concept for ideas with translational potential.

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

The scheme is implemented through 8 BIG Partners selected out of BIRAC's 50 BioNEST incubators. BIG Partners provide an end to end hand holding to applicants/ grantees and are also responsible for outreach and evangelization.





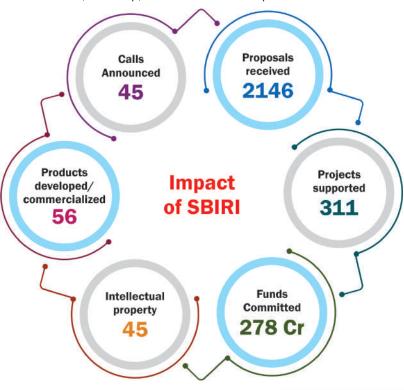
i4 program (Intensifying the Impact of Industrial Innovation)

The i4 program (Intensifying the Impact of Industrial Innovation) of BIRAC supports biotechnological product/technology development by strengthening the R&D capabilities of start-ups/companies/LLPs. It provides impetus for pulling the translational ideas and taking them forward for validation, scale-up, demonstration and pre-commercialization of

products and technologies. The programme is operated through two schemes based on the Technology Readiness Level (TRL).

Small Business Innovation Research Initiative (SBIRI): The end point of the research study is TRL 6 and below.

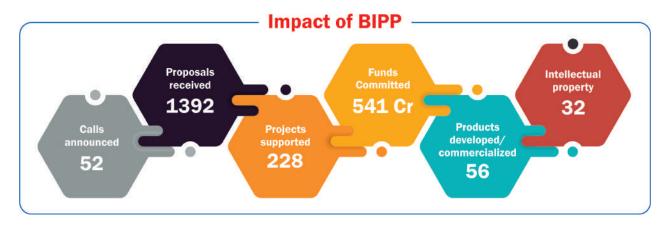
Launched in 2005, the SBIRI scheme was first of its kind early stage, innovation focused effort to boost Public-Private Partnership (PPP) efforts in the country. SBIRI has consistently prioritized early stage funding for high risk innovative research for development of products and processes which have high societal relevance. Over the years, SBIRI has worked as an enabling platform for the target organizations to realize their potential in terms of product and process development and taking them to the market.





Biotechnology Industry Partnership Programme (BIPP) - The end point of the research study is TRL 7 and above

Under the umbrella of i4, BIPP is BIRAC's Flagship "Late Stage Funding" scheme. The Scheme was launched in January, 2009 and serves for scaling and commercializing high risk innovations through cost sharing between BIRAC and the industry. No incremental development is supported under BIPP.



Promoting Academic Research Conversion to Enterprise (PACE)

To encourage/support academia to develop technology/product up to PoC stage and its subsequent validation by an industrial partner, BIRAC operates the PACE Scheme. The Scheme has two components:

- Academic Innovation Research (AIR): Promotes development of Proof-of-concept (PoC) for a process/product by academia with or without the involvement of industry
- **Contract Research Scheme (CRS):** Enables validation of a process or prototype (developed by the academia) by the industry partner.

Some premier institutes like AIIMS, IITs, ICGEB, IISER, THSTI, CDRI, IICT, NCL, etc. along with some northeastern universities have been supported under this Scheme. PACE mainly supports early stage research and is not expected to yield products/technologies with high TRLs. Nevertheless, 6 projects reached TRL7 and 1 project reached up to TRL8/9 since its inception.

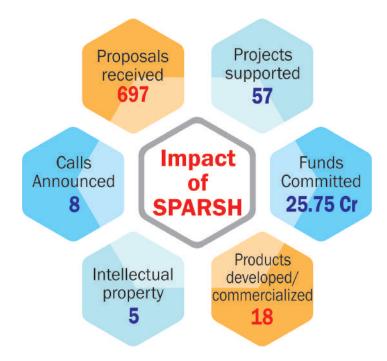




Social Innovation program for Products: Affordable & Relevant to Societal Health (SPARSH)

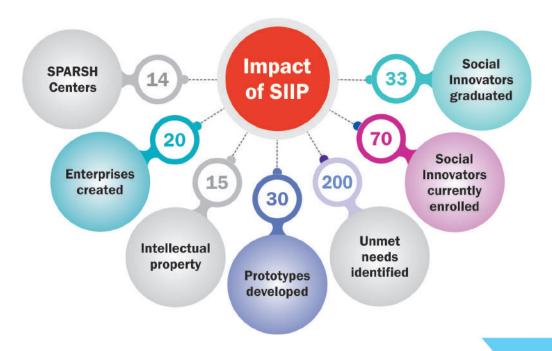
SPARSH is aimed at promoting the development of innovative solutions to society's most pressing social problems through biotechnological approaches. The SPARSH program comprises of two components:

Affordable Product Development- Provides support for development of products, processes and technologies
with well-established Proof of Concept (PoC) that can be commercialized



• **Social Innovation Immersion Program (SIIP)**: SIIP Provides Fellowships to "Social Innovators" for identifying and addressing gaps in social sector and promote social entrepreneurship.

The SIIP fellows are mentored by SPARSH Centres. The programme has already developed clusters across the nation on six thematic areas "Maternal and Child Health" "Ageing and Health" "Food and Nutrition" "Agri-Tech" "Combating Environmental Pollution" and "Waste to Value". These clusters are spread across 14 SPARSH centres across 9 states in India.





PCP: BIRAC launched **Product Commercialization Program Fund** (**PCP Fund**) under the Product Commercialization Program to hasten the product commercialization process by providing support to product technologies, which are at or above TRL-7 stage, developed by Indian Start-ups through funding programs of BIRAC or through support from other sources. Three projects are ongoing and few more projects have been shortlisted for funding support in 2020-21.

Promoting Incubation, Translation and Scaling

BioNEST (Bioincubators Nurturing Entrepreneurship for Scaling Technologies)

BioNEST scheme, earlier known as BISS (Bioincubators supporting Scheme), is a dedicated scheme to create globally competent bioincubation facilities across the country. BioNEST bioincubators are mandated to provide incubation space to entrepreneurs and Start-ups along with access to high end infrastructure, specialized and advanced equipment, business mentorship, IP, legal and regulatory guidance and networking opportunities to start-ups.

BIRAC has established 60 BioNEST bioincubators across the nation with the cumulative area of 6,50,000 sq. ft. Amongst these, 10 new incubators were established during the FY 20-21 and support provided to the rest. These dedicated biotech incubators are placed either within academic/research Institutes, medical hospitals, Biotech clusters or as stand-alone incubators that are supported through private, Central or State Governments.





Equity Funding Schemes

While the Bioincubators are able to support the "Space, Services and Knowledge" requirements of start-ups, a wide gap exists in financial support required by a technology driven start up in the initial phase. Equity schemes of BIRAC offers supports for the early stage start-ups which has potential for differential growth. It also helps the entities to attract investment opportunity from prospective investors.

- SEED (Sustainable Entrepreneurship and Enterprise Development) Fund
- LEAP (Launching Entrepreneurial Driven Affordable Products) Fund
- Biotechnology Innovation (AcE Accelerating Entrepreneurs) Fund of Funds



SEED Fund is the first equity exposure of up to INR 30 lakhs for a selected Start-up that has reached PoC stage with potential for commercialization. SEED support is positioned to act as a bridge between promoters' investment and Venture/Angel investment.

Impact of SEED Fund

SEED Partners

16

Fund Sanctioned **34 Cr.**

Equity Support Provided to each Startups
30 Lakhs

No of Seed Supported Start-ups 71

External Funding Raised by 44 Start-ups (Cr) 125.44

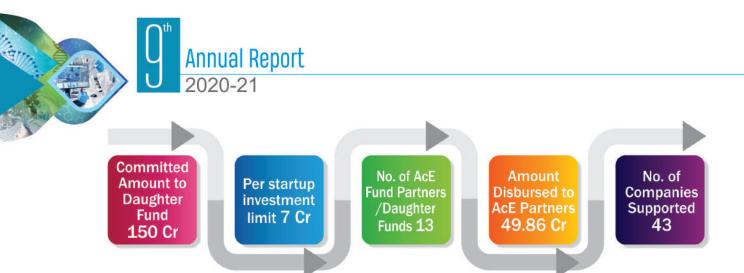
Valuation of 36 start-ups (Cr) 900

LEAP Fund is providing funding support to potential start-ups to pilot/ commercialize their products/ technologies. LEAP provides funding support up to INR 100 lakhs/ Start-up that have reached the pre-commercialization stage to reduce their gestation period. These schemes are implemented through selected BioNEST Incubators who as SEED/ LEAP partners manage the equity.

Impact of LEAP Fund

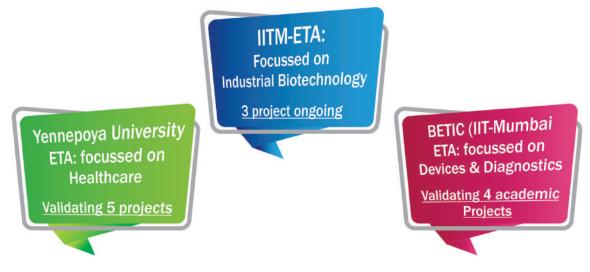


BIRAC AcE (Accelerating Entrepreneurs) Fund: AcE Fund is "Fund of Funds" which aims to foster R&D and innovation in Biotechnology domains by plugging the gap of the "Valley of Death" encountered by the Biotech start-ups during their 'product development cycle' and 'growth phase'. AcE Fund invests and partners with SEBI- registered AIFs (i.e. Venture Funds and Angel Funds), which are professionally managed and desirous of investing in biotech & related sectors. The Daughter Funds are committed to invest 2x of BIRAC's investment amount from fund corpus in Biotech tart-ups. The AcE Fund has been able to infuse INR 300 Cr private equity commitment into the Biotech ecosystem using AcE fund as a catalyst.



ETA

BIRAC has set up **Early Translation Accelerators (ETAs)** to realize academic discoveries into products by providing translational support.



PATH (IPTT)

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

	8 BIRAC beneficiaries were supported under BIRAC-PATH for patent drafting, filing and maintenance of patent applications nationally and internationally
0,	4 IP & Technology Management awareness and capacity building workshops for start-ups, SMEs and academicians were conducted virtually

FIRST (Facilitation of Innovation and Regulations for Start-ups and Innovators) HUB is created at BIRAC to address the queries of Start-ups, Entrepreneurs, Researchers, Academicians, Incubation Centres, SMEs etc. The FIRST HUB has representation from CDSCO, ICMR, DBT, BIS, NIB, GeM and BIRAC along with KIHT. It brings stakeholders to a single F2F platform. FIRST HUB team conducted special virtual session for Covid-19 and addressed queries on a monthly basis in 2020-2021

COVID-19 FIRST HUB Meeting every month

500+ Queries solved

Special
Webinar-150+
special queries on
COVID-19
regulations
solved

Special FIRST HUB session at Global Bio India 2020



Engaging with Regional Communities to map innovations and support entrepreneurs





BIRAC Regional Innovation Centre (BRIC) Mandate of BRIC



- Mapping of regional innovation ecosystem
- Mapping on IP& Technology Management to start-ups and innovators
- Promote Entrepreneurship development

BRIC Impact (2013-2021)

- Pan India Clusters Covered
- 800+ innovators engaged
- 250+ Key Opinion Leaders (KOLs) Connected
- 65+ workshops, idea expositions and network meetings on IP, funding opportunities, regulatory guidance and capacity building through Incubation in Tier II and III cities



BIRAC Regional Entrepreneurship Centre (BREC) Mandate of BREC



- National Life Science Entrepreneurship Awareness Programme
- Entrepreneurship development workshops
- Meet the investors series
- National Bio- Entrepreneurship Boot Camp (NBEC)
- National Bio- Entrepreneurship Competition

BREC Impact (2017-2021)

- 1900+ Students inspired through Awareness Workshops
- 600+ entrepreneurs provided specialized domain
- 500+ One-on-one meetings with between Investors &Startups
- 6300+ Registrations for NBEC from across 32 States, Cash prizes and investment opportunities worth INR 6.00 Cr mobilized
- 175+ entrepreneurs and startups mentored through annual bootcamp involving international faculty





BIRAC Regional Bio-Innovation Centre (BRBC) Mandate of BRBC



- Venture Mentoring Services
- Venture Base camps
- Regulatory Information and facilitation centre
- Bioincubation Practice School for western region

BRBC Impact (2018-2021)

- 250+ entrepreneurs connected with mentors
- 200+ one to one follow up meetings
- 250+ participants provided domain knowledge through Venture Base Camps
- 40 Incubation managers trained
- 350+ students/entrepreneurs provided insights into essentials of scientific entrepreneurship
- 150+ start ups assisted for solving regulatory queries



BIRAC Regional Techno-Entrepreneurship Centre



East and North East Region (BRTC-E & NE)

Mining and assessment of Techno-commercial resource pool in East & North East Region	Roadshows on Essentials of Techno- Entrepreneurship	Capacity building training programs	Training programs for rural women entrepreneurs	North East Immersion Program
	North East showcase Event	Design Workshop	Incubation Practice School	

BRTC Impact (2020-2021)

- 2000+ Innovators reached out through awareness programs such as Roadshows, Training programmes and design workshops
- 85 startups across the NER were provided one-on-one mentoring sessions
- Mobilized 27 Innovative proposals from North East and 90 from East for funding support from BIRAC
- BRTC signed MoU with various institutes like IASST Guwahati, NIPER Guwahati, Manipur University, NEHU, Tura Campus, Tripura University, Rajiv Gandhi University, Itanagar, College of Fisheries, CAU and Green Foundation, Imphal promoting entrepreneurship and technology development
- Launched an initiative to map the Change Makers of Northeast Region to identify the budding entrepreneurs and prepared a compendium of the region.

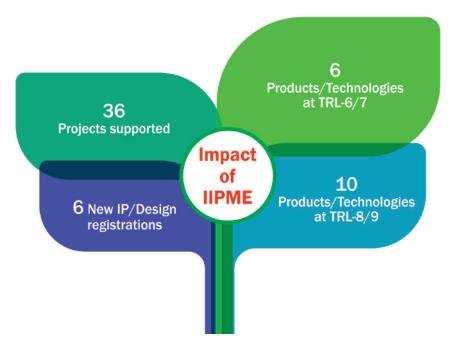
Spreading wings through National & International Partnerships

▶ 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 the Longitude Prize, BIRAC announced a Boost Grant of up to INR 90,00,000 during FY 18-19. Three teams were awarded BIRAC Boost Grant Award and projects are ongoing in FY 20-21.

Biotechnology Industry Research Assistance Counicil



- ▶ BIRAC in partnership with USAID and Indian Council for Agriculture (ICAR) had initiated a five year long project in 2017 for development of high-yielding, heat-tolerant wheat cultivars appropriate for the Indo-Gangetic Plains. Multi-location field trials are in progress to identify the markers for development and release of heat tolerant lines /varieties.
- ▶ 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. Several transgenic events having high PVA content in ripe-fruit-pulp (PVA ≥20µg/g dry wt) have been identified by both NABI and NRCB. The project has moved into its next phase of product development by carrying out the event selection trials.
- 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. Total 36 projects supported under the scheme and the program came to a close in 2020 with very successful outputs and outcome



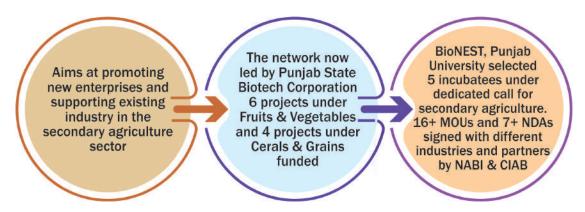
- **BIRAC-TIE WINER Awards:** BIRAC has a partnership TiE-Delhi NCR under which a woman specific award has been constituted, named as WINER Award (Women In Entrepreneurial Research). 4th edition of BIRAC-TIE WINER Award was launched during FY 20-21. 15 women entrepreneurs from the 3rd edition were provided an opportunity to attend a virtual accelerator programme for regulatory, IP, licensing, fund raising, mentoring; and 3 final winners were awarded with the final award of INR 25 lakhs each.
- ▶ SoCH: BIRAC in association with knowledge partner Social Alpha and BIRAC's Bio-NEST Incubator partner Clean Energy International Incubation Centre (CEIIC) launched the 2nd call of the *BIRAC-Innovation Challenge award-SoCH* (Solution for Community Health) 2020-21 focused for the theme "Innovative, Efficient and Affordable Solutions for Clean Cooking in Rural and Community Settings".
- BIRAC in partnership with Social Alpha launched BIRAC-Social Alpha Quest for Assistive Technologies supported by Mphasis in June 2019 to foster an ecosystem to develop, support, and scale Assistive Technologies (AT) solutions from Start-ups. Top 14 Indian start-ups were selected as the winners working for the AT solutions in the areas including speech and hearing impairment, locomotor disability, visual impairment, and intellectual disability for children and adults. The winners were awarded grant prizes up to INR 50 lakh each and an opportunity to get enrolled in a three months accelerator program.
- ▶ BIRAC has partnered with WISH (Wadhwani Initiative for Sustainable Healthcare) Foundation (a Non-Profit Organization involved in taking innovation to the end users) for leveraging the network and engage the SCALE programme of WISH to validate the innovations in Primary Healthcare Centres (PHCs) through state governments. Under this Partnership, BIRAC supported Start-up products/technologies are validated by WISH at different PHCs and so far three products have been validated under the Partnership. As an outcome of the studies, 3 White papers along with recommendations of the studies were handed over to the innovators. Five more innovations are underway for field validation.



▶ University of Cambridge Entrepreneurship Education Programme – IGNITE: BIRAC has partnered with Judge Business School (JBS) at University of Cambridge in 2013 for the Ignite Programme that provides BIG innovators international mentoring opportunity. It enables early stage start-ups to develop international entrepreneurial flair and skills needed to understand the opportunities for successful translation and commercialisation of innovations. Every year, 5 BIG start-ups are selected and supported to attend the week-long boot-camp, IGNITE at JBS, Cambridge, UK. So far, 39 BIRAC supported start-ups have benefitted from the programme.

Make in India facilitation cell:

- Make in India is the flagship program of Govt. of India launched in 2014 to encourage companies to manufacture their products in India, for India and for the world.
- The Make in India cell for Biotechnology was established at BIRAC in 2015. BIRAC along with the Department
 of Biotechnology (DBT) is playing a crucial role in the implementation of these flagship programs of Gol, 'Make
 in India' and 'Start-up India'.
- It maps various activities for Start-up India (number of Start-ups, Incubators, Incubatees, Products, etc), Make In India (Gap analysis, FDI inflow, Strategic Stakeholders connect, Industry Consultations, Key policy/Fiscal recommendations for Budget/ cabinet matters, Investments, Regulatory support, Bio-Economy mapping, Globalization of India's Innovation ecosystem, Fund of Funds) and others.
- The cell connects States, Large Industries, guides the investors, Start-ups and entrepreneurs onto the gamut of business related issues in biotechnology such as regulatory landscape in the country, entry options and procedures, investment opportunities and routes, FDI/ EXIM/ Industrial policies.
- ▶ Secondary Agriculture Entrepreneurial Network (SAEN) in Punjab:- In partnership with Punjab State Biotech Corporation (PSBC), Center of Innovative and Applied Bioprocessing (CIAB), National Agri-Food Biotechnology Institute (NABI) and Bio-NEST-Punjab University (BioNEST-PU to support Industry and Promote Start-ups in Agri-Food Sector in Punjab.



Engagement with stakeholders

The 9th Foundation Day was celebrated on 20th March 2021 via virtual Platform. The theme of the event was "Scaling Biotech Innovations for Societal Unmet Needs"

→ Global Bio-India 2021

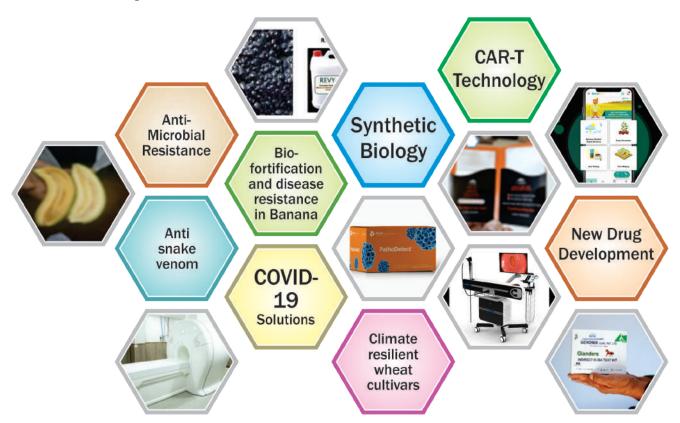
The Department of Biotechnology and BIRAC organized the 2^{nd} edition of Global Bio-India 2021 from 1^{st} - 3^{rd} March 2021 in partnership with Confederation of Indian Industry (CII), Association of Biotechnology Led Enterprises (ABLE) and Invest India. The Make in India Cell at BIRAC established a secretariat at BIRAC for this mega event and steered all activities. The success of this event is a testimony of the growing prowess of the Biotech sector in the country. The three-day long event witnessed a rich technical program and attracted 8000+ delegates representing 42 countries. This business meeting was also graced with the presence of high level dignitaries from GOI, foreign missions in India and others.

Trainings and workshops

To apprise the potential applicants about various funding schemes of BIRAC and on writing effective grant proposals, BIRAC organized 13 webinars with a participation of about 2700 start-ups and academia. The workshop was well received by all participants and all queries related to Funding Schemes at BIRAC and grant writing were addressed.



Niche areas being nurtured:



→ Grand Challenges India (GCI):

Grand Challenges India (GCI) was born out of a partnership of the Department of Biotechnology (DBT), Government of India and the Bill & Melinda Gates Foundation in 2012 with the aim to encourage Indian innovation and research to develop affordable and sustainable solutions to improve health and well-being in India, and across the globe. In 2016, Wellcome Trust also joined the partnership.

GCI was launched with the aim of directing funding and research to address some of the greatest public health challenges that India faces today. GCI is committed to seeking and rewarding established researchers, young entrepreneurs and innovators from both academia and industry.

GCI works across a range of health and developmental priorities ranging from agriculture, nutrition, sanitation, maternal and child health to infectious diseases. GCI aims to help innovators expand the pipeline of ideas for developing new preventive and curative therapies, piloting new technologies, and exploring new ideas to address public health challenges by funding the search and development of tangible solutions

GCI also works across different stages in product development as well as research, and has supported basic research, translational research, intervention trials, clinical trials, data integration and analysis, product and technology development among others. GCI funds projects at various stages in their lifecycle; from basic science research in laboratories, to proof-of-concept projects and potentially to scale-up to innovation projects.

GCI has expanded both as an idea and as a collaboration as India transitions from Millennium Development Goals to Sustainable Development Goals, with our themes and ways of working adapting to meet the ever-changing demands of public health research in India.

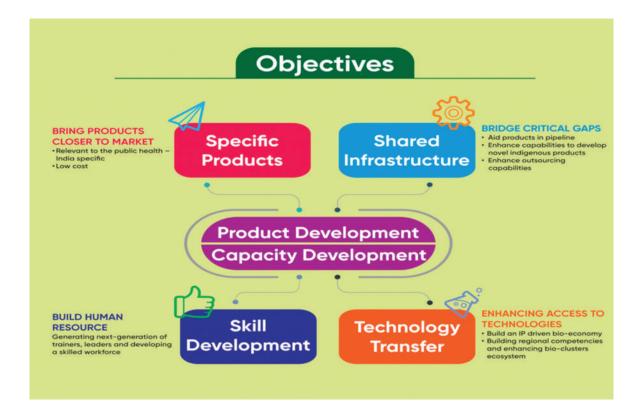
In 2019-2020, GCI added programs to support the nation's fight against Covid-19, such as serosurveillance, sewage surveillance and the development of mobile diagnostic labs.

Today, GCI has supported 129 projects across 22 programs, across the country.

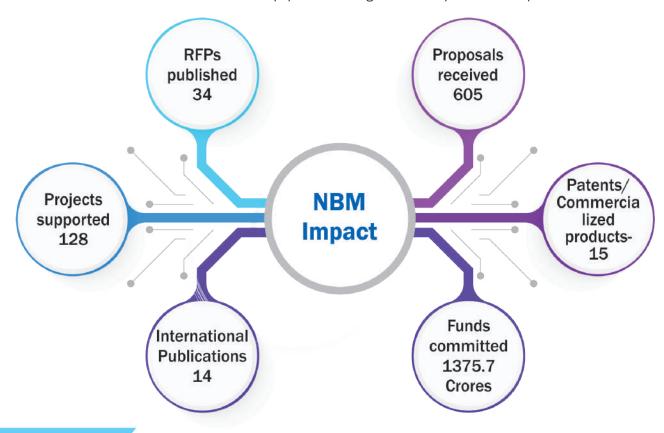
National Biopharma Mission: The National Biopharma Mission (NBM), is a government-industry-academia collaboration dedicated to 'Accelerating Discovery Research to Early Development for Biopharmaceuticals'. funded at a total cost of INR 1500 Cr co-funded by the World Bank at 50% cost sharing. NBM's charter is being implemented by Biotechnology Research Assistance Council (BIRAC), a Public Sector Undertaking, set up by the Department of Biotechnology (DBT).



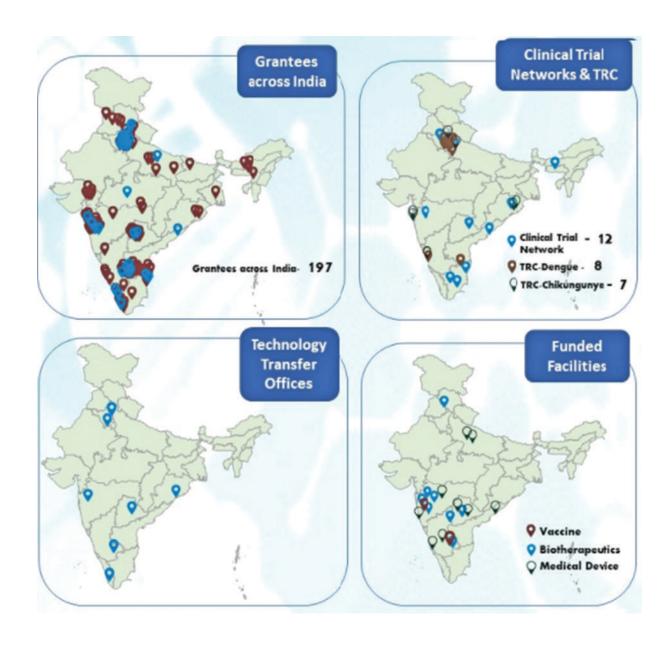




Vision: NBM vision is to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals to a level that will be globally competitive over the next decade, and transform the health standards of India's population through affordable product development.







▶ Ind-CEPI:

The Ind-CEPI Mission is an India centric collaborative mission of Department of Biotechnology (DBT), Govt. of India, aligned to the global initiatives of CEPI (Coalition of Epidemic Preparedness Innovations). The mission will facilitate pathways for vaccine development and assessment, developed in consultation with CEPI. The Mission aims to strengthen the development of vaccines for the diseases of epidemic potential in India as well as build coordinated preparedness in the Indian public health system and vaccine industry to address existing and emerging infectious threats in India. DBT is supporting the implementation of the Ind-CEPIs mission "Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the Coalition for Epidemic Preparedness Innovations (CEPI)", through a dedicated Program Management Unit (PMU) at Biotechnology Industry Research Assistance Council (BIRAC). The Ind-CEPI Mission was approved on 27th March 2019 with a total cost INR 312.92 crore.







Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development

Implemented at BIRAC Department of Biotechnology Govt of India



To strategically engage with CEPI through the Ind-CEPI Mission to develop vaccines to control epidemic outbreaks of infectious disease.

Infrastructure to support the needs of the vaccine industry through an academia industry interface.

To establish an internal coordinated interministerial mechanism for vaccine development.



To build a public health preparedness system to respond to threats.



Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development

Current Vaccine Portfolio:

- mRNA platform for SARS-CoV-2-Gennova Biopharmaceuticals Ltd.
- Inactivated Virus platform for Chikungunya-Bharat Biotech International Ltd.

Skill Development:

E-course series
"Strengthening
Clinical Trial
Research Capacity in
Neighboring
Countries"







Covid-19 Pandemic: BIRAC Response

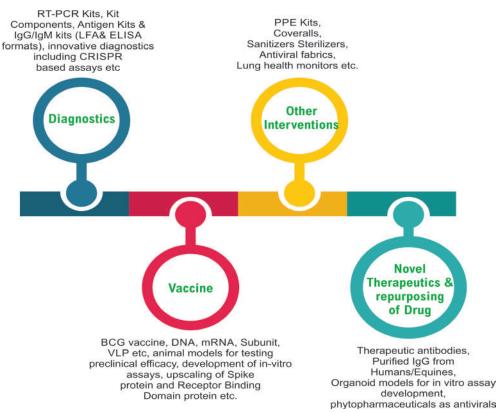
In the wake of the first report of SARS-CoV-2 infection in India, DBT-BIRAC along with its partners have got into action by forming teams to identify the major gaps which existed in knowledge base, technology, facilities, manpower, regulations and funds. BIRAC also worked quickly on bringing in new SOPs for accelerated processing for addressing the challenges posed by COVID-19. As a result of these focused efforts, DBT-BIRAC along with its partners has been able to address most of the identified gaps parallelly through different calls, schemes, mission programs, outreach activities and facilitation. Below section provides a snapshot of all those activities focused on addressing the challenges posed by COVID-19 pandemic.

DBT-BIRAC COVID-19 RESEARCH CONSORTIUM CALL

DBT-BIRAC COVID-19 Research Consortium Call was one of the earliest responses from Govt. side for supporting technologies under Diagnostics, Vaccines, Novel Therapeutics, Repurposing of Drugs or any other intervention for control of COVID-19. This call was announced in March 2020 and received an overwhelming response in the number of applications. In the following month, a follow-up call focused on the same theme was also announced to accommodate the request from both Industry and academia. Overall from two calls, around 1073 applications were received for funding under the consortium and around 120 proposals were selected for support. Out of these, 46 proposals have been supported by BIRAC and remaining under National Biopharma Mission, INDI-CEPI and DBT.



Few of the technologies funded under each of the areas are as follows:





Few Successful Outcome from COVID-19 Consortium funding

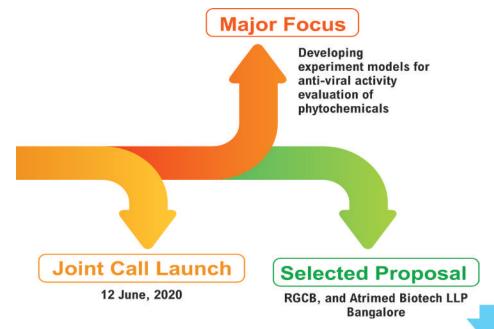


As the pandemic progressed, the need for novel therapeutics or repurposed drugs to treat and manage COVID-19 and related complications had become paramount importance. In continuation to earlier two calls DBT/BIRAC jointly announced a special call in October 2020 for development of therapeutics to create a rapid response towards the COVID-19 outbreak. Under this call a total of 39 proposals were received and finally 05 proposals were supported.

Few projects supported include Repurposing of Anakinra for COVID-19, repurposed metformin as anti-inflammatory drug, validating phytopharmaceutical drug products as anti-SARS CoV-2, setting up pre-clinical drug development and antiviral-activity testing platform etc.

ANTI- SARS-COV-2 /NCOV-2 VIRUS STUDIES USING BOTANICAL INGREDIENTS AND TRADITIONAL FORMULATIONS

BIRAC launched a joint call with DBT on "Anti-SARS-COV-2/NCOV-2 Virus Studies using Botanical Ingredients and Traditional Formulations" to manage COVID-19 pandemic through the application of medicinal and aromatic plants.





FAST TRACKED REVIEW AND FUNDING SUPPORT UNDER COVID-19 FUND

BIRAC has been relentlessly working to collaborate across the healthcare innovation ecosystem ranging from biotech companies to entrepreneurs coming up with innovations to academic institutions to address the COVID-19 global health care crisis. In view of a need to identify and provide fast track support to Health-Tech Start-up solutions for immediate deployment (0-3 months) to address challenges of COVID-19, a Fast track Internal Review Committee was constituted at BIRAC to review and recommend the proposals that can be supported under COVID fund.



Additionally, 2 Co-funding partnerships were established with IKP, Hyderabad & C-CAMP Bengaluru to support 25 Start-ups under the BIRAC's mandate to foster market deployment of innovative solutions addressing COVID-19 challenges.

Start-ups with market ready solutions are:

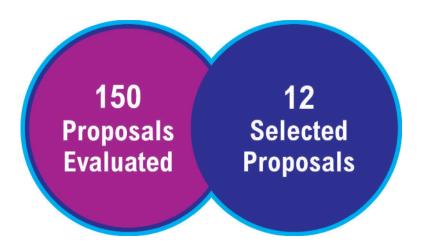
- Aarna Biomedical Products
- Alfa Corpuscles
- MicroGO
- Ubigare Health
- Ayu Devices
- Health Sensei
- DNA Xperts Private Limited





START-UP INDIA CHALLENGE

A joint initiative with DST, Atal Innovation Mission and BIRAC was announced by Start-up India as "Start-up India Challenge" to invite solutions for handling Covid-19 crisis. Amongst more than 150 proposals received for evaluation by BIRAC (projects based on biotechnological interventions), 12 proposals with potential of immediate deployment were identified and provided for consideration of NITI Ayog, and PSA, Government of India. These are taken ahead by the other partners for funding.



• COVID-19 START-UP SOLUTIONS

BIRAC supported 35 technology solutions from Start-ups, relevant for COVID-19 pandemic situation, were identified and compiled into a single booklet for ensuring relevant stake-holder connect to the technologies.

BIRAC SPECIAL COVID-19 CALL UNDER 14

In addition to the above efforts and calls, special calls under i4 (BIPP, SBIRI) and PACE (AIR and CRS) were announced under the area inviting proposals on Biomedical waste treatment/ management in the context of COVID-19, APIs for COVID-19 drugs, indigenous manufacturing of enzymes used in NAAT diagnostic kits, development of anti-viral surface coatings, sanitization and disinfection of food/food-based products.



MISSION COVID SURAKSHA

To ensure a steady supply of vaccines in the next 12-18 months, DBT has established Mission COVID Suraksha under Atma Nirbhar Bharat package 3.0. The focus of this mission is to consolidate and streamline available resources towards a warpath for accelerated vaccine development. This is a National Mission working to bring to the citizens of the country a safe, efficacious, affordable, and accessible COVID vaccine at the earliest with a focus on Atma Nirbhar. The goal is to accelerate development of approximately 5-6 vaccine candidates and ensure that within the next 12 months - The candidates which are Closer to licensure and introduction in market for consideration of emergency use or for licensure by regulatory authorities; Closer to introduction in public health systems by the Ministry of Health and Family Welfare post-approval by National Technical Advisory Group on Immunization (NTAGI), to combat further spread of COVID infection.



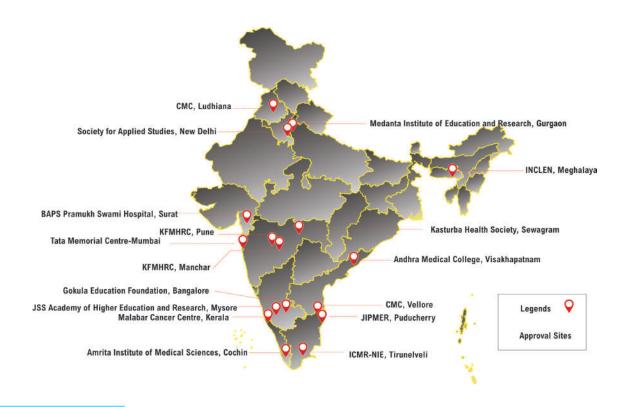
It is being achieved by supporting



Four calls were launched, and 34 proposals are being supported (5 projects pertaining to candidate vaccine development, 6 proposals under capacity enhancement; 3 for Clinical Immunogenicity testing and 3 for BSL-3 Animal facilities, 19 projects for strengthening clinical trial capacities and 4 projects under facility augmentation.

Vaccine projects supported are mainly for completing the Phase I, II or Phase III clinical trials of Recombinant vaccine (CorbeVax) by Biological E Pvt Ltd, RNA Vaccine (HCG019) by Gennova Biopharmaceuticals Pvt Ltd, DNA based vaccine (Zycov D), Nasal vaccine BBV154 (Bharat Biotech Pvt Ltd) and VLP vaccine PRAK-03202 (Genique Life Sciences Pvt Ltd)

Below figure shows geographical location of 19 Clinical trial Sites supported under National Biopharma Mission: Out of the 19 sites, 13 are supporting Covid-19 vaccine trials already or have undergone feasibility study by sponsor.



Biotechnology Industry Research Assistance Counicil



For facility augmentation, four identified PSUs i.e. Haffkine Bio Pharmaceutical Corporation Limited (HBPCL), Indian Immunological Ltd (IIL), Bharat Immunological and Biologicals Corporation Limited (BIBCOL) and Hester Biosciences have been selected for financial assistance to establish/augment the infrastructure to take on the manufacturing of the indigenously developed inactivated COVID-19 vaccine i.e. COVAXIN developed and marketed by Bharat Biotech India Limited (BBIL). BBIL is providing voluntary technology transfer to the identified PCUs under the technology transfer evaluation group formed under BIRAC. The facility augmentation initiative will make available around 8- 100 million doses from all identified facilities by the end of 2021 or early 2022.

Indian Immunological has made progress towards achieving the first phase of production from its repurposed facility and has supplied 2 million doses of Drug Substance to BBIL. The other PSUs i.e. HBPCL and BIBCOL have made significant progress in finalizing the terms and condition of technology transfer, finalizing the facility design and obtained the initial feedback from DCGI.

GRAND CHALLENGES INDIA (GCI)-LED COVID-19 EFFORTS

Grand Challenges India is supporting programs to find solutions for COVID-19 pandemic. Few activities under support are:

COVID-19 SEWAGE Surveillance

Wastewater surveillance
would be a
complementary approach
to measure the presence
and prevalence of COVID-19.2
projects are being supported
in this program. 1 at CMC,
Vellore and another one
at BITS Pilani

Mobile Diaganostic Labs

To establish proofof-concept of Mobile Diagnostics Labs and 4 Mobile labs are being supported by the partinership.

Kawach Model

The mobile lab is planned to be deployed at Pune, Maharashtra. Two units of the Parakh model by the Defense Research and Development Organization (DRDO) are under fabrication and are being developed in Chennai through a private vendor.

COVID-19 Sero-Surveillance

Program help to determine the burden of COVID-19 infection at the community level, to monitor the trends in the transmission of SARS-CoV-2 infection and help generate evidence on the role of asymptomatic and mild infections in transmission.



The Mobile Virology Lab ready for deployment

The program is supporting one site (the King Edward Memorial Hospital and Research Centre, Pune) under the NBM-DBT driven program, out of the 5 sites in this program that are being managed by the National Biopharma Mission. The second investment in this space is for THSTI, Faridabad with TIFRKH, Mumbai for assays to be conducted on a subset of samples collected during a sero-surveillance study in Mumbai to inform about seropositivity.



COVID-19 FIRST-HUB

During COVID-19, the industry has witnessed the challenge of understanding the various new regulations, guidelines, policies and processes for COVID-19 medical products. To mitigate this and facilitate the fast development of COVID-19 products, BIRAC has taken up this important task of providing clear guidance and direction to the start-ups through FIRST HUB. FIRST HUB provided the platform wherein queries related to various governmental organizations like CDSCO, ICMR, DBT, BIS, NIB, GeM, KIHT and BIRAC can be discussed and resolved. In addition to monthly meetings, FIRST HUB team conducted special virtual sessions every month for COVID-19. 500+ queries were discussed during these sessions. One special webinar with 150+ queries on COVID-19 was conducted to provide guidance on the regulations, standards, policies and funding opportunities.

2020-2021 - A Year of the Pandemic







A Year of Science and Technology

Indian Immunologicals receive manufacturing license under Department of Biotechnology - Mission Covid Suraksha Project for Augmentation of Manufacturing Capacity for COVAXIN

Posted On: 13 AUG 2021 5:05 PM by PIB Delhi

Department of Biotechnology and BIRAC under the Mission Covid Suraksha announced by the Government of India, under Atmanirbhar Bharat 3.0 to accelerate the development and production of Indigenous COVID Vaccines, have lauched a project to augment production capacities of Covaxin.

Indian Immunologicals limited, Hyderabad, is the first site under this project to receive from CDSCO, a loan license for supplying Covaxin Drug Substance produced at its repurposed facility to Bharat Biotech, Indian Immunologicals will supply the first lot of commercial Covaxin Drug Substance to Bharat Biotech on 13th August 2021. The facility will produce 2-3 million doses per month initially, and another 4-5 million doses from its new facility at Karkapatla, in next few weeks.



Zydus Cadila's Covid vaccine gets approval, to be administered to children in India

This is the world's first DNA-based vaccine against the coronavirus, and this three-dose vaccine when injected produces the spike protein of the SARS-CoV-2 virus and elicits an immune response.



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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 Ninth Annual General Meeting of the Company will be held on:

Day and Date: Tuesday, 30th November, 2021 **Time:** 4.30 p.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 Statement of the Company as on March 31, 2021 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 2021-22, in terms of provisions of Section 139(5) read with Section 142 of the Companies Act, 2013.

NOTES:

- 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 atleast 48 hours in advance of the meeting so that the information may be made readily available.
- 4. This meeting is being called at shorter notice with the consent of requisite number of shareholders as prescribed under Companies Act, 2013.

By Order of the Board

Sd/-

Kavita Anandani

Company Secretary

Registered Office:

1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi – 110 003,

Date: 26th November, 2021





Dr. Renu Swarup
Secretary, Department
of Biotechnology &
Chairperson, BIRAC

Chairperson's Message

It gives me immense pleasure to reflect upon BIRAC's progress over the past year and I take this opportunity to thank the BIRAC board, the BIRAC team, our experts, partners and grantees for their dedication to our shared mission of strengthening and nurturing the innovation ecosystem. BIRAC has stayed agile in order to meet the changing needs of the innovation ecosystem. This is apparent in the schemes and programs that have been created in response to the innovation ecosystem's increasing needs. BIRAC has seen numerous avenues of progress in recent year and in last 10 years has acted as a catalyst to strengthen the biotech innovation ecosystem.

The COVID-19 pandemic brought in several challenges but I am happy to point out that we were able to convert these challenges into opportunities, through innovation-led entrepreneurship and a supportive start-up ecosystem. DBT- BIRAC's support mechanism to start-ups, researchers, entrepreneurs was able to strengthen the ecosystem, and foster collaboration between the government, biotech industry and the research ecosystem. The Startup solutions for COVID 19 reached more than 130 markets and more than 1000 Startup Solutions were identified. BIRAC's support to the research ecosystem helped develop indigenous biomedical tools and insights that were paramount in the prevention, identification and treatment of the COVID-19 pandemic, thus paving the way for addressing challenges as a nation, through selfreliant solutions. More than 2,600 start-ups benefitted from BIRAC's initiatives and support. Several BIRAC supported start-ups and SMEs have received recognition from other national and international agencies for their products and technology development.

In response to COVID-19; BIRAC took on several initiatives and activities like DBT-BIRAC COVID-19 Research Consortium Call, Fast Track Review, Startup India Challenge, Special Call under i4, COVID-19 first hub, COVID-19 Sewage Surveillance; Mobile Diagnostic Labs, COVID-19 Sero-Surveillance and many more.

Through BIRAC's BioNEST programme, 60 bio incubation facilities have been established across the country. A robust pipeline of biotech entrepreneurs has been created through concerted and renewed efforts through envagelization, awareness programs, mentoring, funding and infrastructure creation through BIG, E-YUVA centres, BIRAC revamped the EYUVA scheme and sanctioned support to 5 new EYUVA Centres taking the total numbers of pre-incubation centres as 10.

During this year BIRAC supported projects in all major areas of biotech sector i.e. Healthcare, Agriculture, Industrial biotechnology, Bioinformatics and Infrastructure for promoting affordable innovation



in key social sectors. The supported startups have come a long way in helping the masses at large.

In the financial year 2020-2021, a total of 234 projects including 65 collaborative projects were supported under i4, PACE and SPARSH. Under these schemes. 302 beneficiaries including industry and academia were catered. 727 beneficiaries were supported by BIRAC under its various schemes during 2020-21.

Department of Biotechnology and BIRAC organized Global Bio-India 2021 to showcase opportunities in Indian Biotechnology sector to the world. It was a mega international congregation of biotechnology stakeholders, including international bodies, regulatory bodies, Central and State Ministries, SMEs, large industries, bioclusters, research institutes, investors, and the start-up ecosystem. About 8000+ delegates from over 50 countries participated in the event.

During this year, BIRAC also launched "जनCARE" Challenge in collaboration with GCI. It is a nationwide "Discover – Design – Scale" program, envisioned to identify Innovative health-tech solutions from Start-ups for strengthening the Healthcare Delivery in India.

During the leap of the time, BIRAC has initiated partnerships with national and global partners to collaborate and deliver the salient features of its mandate. Through our flagship programs such as SBIRI, BIG, and BIPP we continue to provide the better development of the products and technologies which will contribute to improving various sectors like healthcare, food and nutrition, clean energy, wellness, and animal husbandry.

I would like to use this opportunity to thank the BIRAC's team for their dedication and support throughout the time. We at BIRAC will constantly work towards the development and encouragement of the innovations and entrepreneurships to ensure the vision of #AtmaNirbharBharat to the new heights.

Dr. Renu Swarup

Secretary, Department of Biotechnology & Chairperson, BIRAC



MANAGING DIRECTOR'S MESSAGE

The Annual Report presents an opportunity to analyse and review the achievements and the experience that we gain round the year. Writing for this Ninth Annual Report gives me immense satisfaction in bringing out the efforts made by BIRAC to strengthen the Indian innovation ecosystem during the tough times of COVID-19.

BIRAC, a Public Sector Enterprise set up by the Department of Biotechnology, has been working towards promoting and mentoring biotechnology innovation research since its inception. In these nine years, BIRAC has created a vast impact by engaging with numerous stakeholders, including Industry, Academia, National and International organizations and other ministries. Innovations developed with the support of BIRAC proved their competence not only in the national market but also at the global level.

Although the world has been under tremendous pressure due to the prevailing pandemic, yet multiple BIRAC-supported start-ups and SMEs have garnered attention for their product and technology development from institutions across the globe. BIRAC provided assistance to a number of beneficiaries in 2020-21 through its various programs and schemes.

DBT-BIRAC has been at the forefront of tackling global health crisis challenges. Several innovators and entrepreneurs proved their mettle through their products and technologies to tackle the COVID-19 situation in the country with the support of DBT-BIRAC. DBT-BIRAC's COVID-19 Research Consortia and the Government of India's Mission COVID Suraksha have been implemented at BIRAC, to support the nation's warpath against COVID-19, for supporting COVID-19 vaccine research and development, along with diagnostics, therapeutics and related interventions. BIRAC being the implementing agency for the National Biopharma Mission and Ind-CEPI, has worked relentlessly towards intensifying vaccine development and strengthening vaccine capabilities.

BIRAC has been instrumental in supporting the country's innovators, scientists and entrepreneurs for various COVID-19 related and non-COVID interventions. Huge efforts have been made by BIRAC to nurture and empower India's start-up community through a variety of innovative funding schemes that align with national goals such as Start-up India, Make in India, Vocal for Local Products, and Atma Nirbhar Bharat.

Global Bio-India 2021 showcased the zeal of the innovators and entrepreneurs of our country for supporting the biotechnology ecosystem in India, thereby reflecting the competence of the global world. Also, as we take on new challenges, I am optimistic that BIRAC-supported "Make in India" innovations will contribute to constructing a self-sufficient nation of the future with a pan-India and worldwide influence.

Ms. Anju Bhalla

Joint Secretary, DST and MD, BIRAC



Ms. Anju Bhalla

Joint Secretary, Department
of Science & Technology
Managing Director, BIRAC



BOARD OF DIRECTORS

Dr. Renu Swarup : Chairperson

*Ms. Anju Bhalla : Managing Director @Dr. Alka Sharma : Managing Director

Government Nominee Director

**Dr. Mohd. Aslam : Government Nominee Director\$
Mr. Vishvajit Sahay : Government Nominee Director

 * Was appointed as Managing Director on additional charge w.e.f. April 10, 2020 and held position till October 9, 2021

@ Was appointed as Managing Director on additional charge w.e.f. October 10, 2021

**Also held the position of Managing Director on additional charge till April 9, 2020

\$Held position of Government Nominee Director till November 30, 2020

Was appointed as Government Nominee Director w.e.f. December 24, 2020

CHAIRPERSON

Dr Renu Swarup is presently Secretary, Department of Biotechnology (DBT), Government of India. Having served in Department of Biotechnology for over 30 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.

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, Antimicrobial Resistance, Genome India to name a few. She was also a member of the Task Force on Women in Science constituted by the Scientific Advisory Committee to the Prime Minister.

As the Secretary of Government of India, Department of Biotechnology, she leads a Network of 16 Autonomous Research Institutes, 2 Public Sector Undertaking and a R&D Network of more than 5000 projects across more than 100 research institutes, Universities and Laboratories. In the recent COVID Pandemic situation she has led the COVID Vaccine and Diagnostic Mission. The Public Sector BIRAC, for which she is the founding Managing Director and now Chairperson, has supported nearly 3000 Startups and over 50 Incubators.

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. Renu Swarup

Secretary,
Department of Biotechnology
Ministry of Science &
Technology,

Government of India



MANAGING DIRECTOR



Ms. Anju Bhalla
Joint Secretary, DST and
Managing Director, BIRAC

Ms. Anju Bhalla is a Post Graduate from St. Stephens College, Delhi University. She joined the Central Secretariat Service, Government of India in 1990 and has varied experience from her work in the Ministries of Commerce, Industry, Culture, Women & Child Development and Power.

She is currently Joint Secretary in the Department of Science & Technology, Government of India, and holding additional charge as Managing Director of BIRAC, a Section 8 Not for Profit Public Sector Enterprise under the Department of Biotechnology, Government of India.

Her first assignment in Ministry of Commerce involved promotion of Indian investment in joint ventures and subsidiaries abroad, through gradual de-regulation of the sector. Policy and programme interventions for empowerment of women, and development and safety of children in Ministry of Women & Child Development, including the POCSO Act 2012, international cooperation and climate change initiatives in the power sector have been some of the areas of work she was engaged with.



Mr. Vishvajit Sahay Additional Secretary & Financial Adviser, Department of Science & Technology

Government Nominee Director BIRAC

GOVERNMENT NOMINEE DIRECTOR

Mr. Vishvajit Sahay belongs to the 1990 batch of the Indian Defence Accounts Service. An alumnus of St. Stephen's College Delhi, he has diverse experience of working in the Government of India, having earlier served as Jt. Secretary in the department of Heavy Industry and Director in the Ministry of Information & Broadcasting. He has held additional charge of the posts of Chairman & Managing Director, Heavy Engineering Corporation Ranchi, a Schedule 'A' CPSE, CEO & Project Director of National Automotive Testing Research & Development Infrastructure Project (NATRIP) and Director in the Directorate of Film Festivals, Delhi. Within the Defence Accounts Department, he has experience of working in the Acquisitions Wing of the Ministry of Defence as Finance Manager (Land Systems), a cadre post in the MoD. He has also worked in several field and Headquarters Organizations of the Defence Accounts Department with experience of closely working with the MOD, Army and Ordnance Factories.



Dr. Mohd. AslamAdvisor (Scientist 'G' in the Department ofBiotechnology (DBT)

Government Nominee Director
BIRAC

GOVERNMENT NOMINEE DIRECTOR

Dr. Mohd. Aslam, Advisor (Scientist 'G') in the Department of Biotechnology (DBT) held additional charge as Managing Director, BIRAC till April 9, 2020. He has held the position of Government Nominee Director of BIRAC till 30th November, 2020. He was involved in planning, coordination and monitoring of various R&D programmes in plant biotechnology and allied areas. He was handling major programmes of DBT such as Centres of Excellence in Biotechnology, Translational Research in Products and Processed from Medicinal & Aromatic Plants and Technology Development in Silk. Dr. Aslam was the Member Secretary of the Technical Advisory Committee of Centres of Excellence in Biotechnology and DBT's Expert Groups on Translational Research in Products and Processed from Medicinal & Aromatic Plants and Technology Development in Silk. He was also working as the nodal officer in DBT for three autonomous institutions – National Institute of Immunology (NII), New Delhi; Institute of Bioresources and Sustainable Development (IBSD), Imphal, Manipur; and International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi and also for Biotechnology Industry Research Assistance Council (BIRAC), New Delhi.



CORPORATE INFORMATION

REGISTERED OFFICE : 1st Floor, MTNL Building, 9, CGO Complex,

Lodhi Road, New Delhi – 110003 CIN: U73100DL2012NPL233152 Website: www.birac.nic.in Email: birac dbt@nic.in

Email: birac.dbt@nic.in Tel: +91-11-24389600 Fax: +91-11-24389611

Twitter handle: @BIRAC_2012

STATUTORY AUDITORS : SAMPRK & ASSOCIATES

Chartered Accountants 302, Neelkanth House, 3rd Floor S-524, School Block,

Shakarpur, Delhi 110092 Tel: 011-43012132

Email: sharmapanjul@gmail.com

BANKERS : Union Bank of India

Block 11, Ground Floor, CGO Complex

Lodhi Road, New Delhi -110003.

: STATE BANK OF INDIA

Core 6, SCOPE Complex,

Lodi Road, New Delhi -110003.

: HDFC Bank Ltd

A3 NDSE, South Ex Part 1

New Delhi-110049

COMPANY SECRETARY : Ms. Kavita Anandani





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 nine 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, globally competitive products addressing the unmet need. BIRAC's philosophy is rooted in its mission to 'trigger, transform and tend biotech start-ups to translate 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 to facilitate technology adoption for masses. Biotechnology sector has been recognized as a sunshine sector that can potentially steer India to grow to become a knowledge driven economy and Innovation Hub for the world.

Over the last 9 years, BIRAC has been instrumental in creating and expanding the Biotech Start-up ecosystem in the country. This growing ecosystem requires customized handholding, access to opportunities based on constant need identification to expedite the growth. BIRAC known for its agility and strategic initiatives, has revised existing schemes, operationalized few new schemes and expanded the partnership network to bring new value added opportunities for Biotech Start-ups, 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 60 and creation of 7 geographical clusters; expansion of BIG footprint taking total beneficiaries count to 600+; several new partnerships including Estonia Lattitude59, NASSCOM, Innovate-UK, State Connect, BioConnect, United Nations Health Tech India Accelerator, BioAngels, and 4th Edition of BIRAC-TIE WINER Awards – Women Entrepreneurship, among others. BIRAC continues to stay engaged with the whole community of Biotech Start-ups, Entrepreneurs and aspirants through Social Media. Our twitter followership base has crossed 28,000+ mark.

Evangelization and pipeline creation: Students, Entrepreneurs and Start-ups: Building New Pathways for 'Entrepreneurial Journeys' through early stage funding, incubation and equity funding

It is essential to recognise that to build and transform an industry, one has to begin at triggering positive changes at the foundation level. BIRAC's programmes under the umbrella of **SITARE** and **EYUVA** are stimulating a forward change in the biotechnology entrepreneurial drive by inculcating an entrepreneurial culture by igniting the young minds. These programmes capture the entrepreneurial energies of students and nudge them towards greater creativity and innovation. For example, **BIRAC-SRISTI GYTI** awards provide INR 15 lakhs each to student teams in academic institutions to take forward their research ideas under the guidance of an academic mentor (75 such ideas have so far been awarded). Additionally, more than 250 students have been facilitated with INR 1 lakh each award to pursue validation of grass-root ideas. BIRAC & SRISTI also organize 3-4 weeks long residential workshops for UG/PG students in the area of grass-root innovations.

EYUVA focuses on deepening the engagement with universities pro-actively wherein BIRAC has supported 5 universities across the country through Innovation Fellowships and Pre-Incubation space. Thirty Innovation fellows have been benefited through different EYUVA Centres across the country. The scheme is implemented through



E-YUVA Centres (EYCs) housed within the University/ Institute set up and mentored by a BIRAC BioNEST supported bio-incubator (EYUVA Knowledge Partner). Till now there are 5 E-YUVA Centres and 5 new EYUVA Centres were selected and identified in the FY 20-21.

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. 67 SIIP fellows are currently working diligently to identify societal needs in the area of Maternal & Child health, Ageing & Health, Waste to Value, AgriTech, Food and Nutrition and Combating Environment Pollution. 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 programme and it is India's largest early stage program in the biotech space. Through BIG, BIRAC has supported 600+ entrepreneurial ideas which have successfully translated into 60+ market deployed products/technologies while another 30 are in validation stages. In 2020-21, 17th and 18th BIG calls were announced. It is interesting to note that BIG has catalysed setting up of more than 150 new start-ups wherein individual BIG grantees have incorporated their Biotech Enterprises. These start-ups also create intellectual wealth for their cutting edge technologies as indicated by 200+ IP filed by BIG grantees.

Biotech start-ups face an uphill task for commercialisation, as access to infrastructure remains a critical hurdle. Through, BioNEST program, BIRAC has been able to establish 60 bio-incubators across the country. These bio-incubators for biotech entrepreneurs and start-ups provide more than 6,50,000 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 1000+ biotech start-ups and entrepreneurs.

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 34 Crores has been provided to 16 BioNEST Incubators SEED fund partners for investing up to INR 30 lakh per start up against equity. So far, 71 start-ups have received SEED support that has catalyzed INR 125+ Cr follow on funds raised by 44 start-ups through external sources. Cumulative valuation for these start-ups have increased to INR 900+ Cr.

LEAP (Launching Entrepreneurial Driven Affordable Products) is also an equity linked funding scheme launched in 2018-19 for advanced start-ups. LEAP fund is aimed at enabling potential biotech start-ups to pilot/commercialize their products/technologies. Under this, a start-up can be provided up to INR 1 Crore. BIRAC has deployed this funding opportunity through 6 BioNEST incubators recognizing those as LEAP fund partners and sanctioned INR 29.50 Crore. So far, 22 Start-ups have been supported by LEAP fund. This has led to raising of additional follow on funding of INR 140.11 Cr by 14 start-ups, and a cumulative valuation of INR 675+ Cr.

Biotechnology Innovation Fund - Accelerating Entrepreneurs (AcE) is Fund of Funds managed professionally by AIF Fund Managers. AcE daughter Funds are SEBI registered private funds to invest equity in start-ups of up to INR 7 Cr/ Start-up for providing the risk capital to undertake innovation, research and product development AcE fund partner are mandated to invest minimum 2X of BIRAC total committed amount into Biotech start-ups. This has been able to successfully mobilize INR 300 Cr commitment for investment in the Biotech Start-ups. Five AcE Daughter Funds are operational and additional AcE partners are under expansion.

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 into tangible products/ technologies and its commercialisation is one of the core mandates of BIRAC. In this regard many of our flagship programmes such as SBIRI and BIPP provide impetus for pulling the idea past POC stage for 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, biosimilars, stem cells, agriculture, industrial biotechnology and device and diagnostics.

Under the umbrella of i4, SBIRI and BIPP are 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 supports development and initial validation of products/technologies (up to TRL-6). Over the years, SBIRI has supported 311 projects that have resulted in development of 56 product/technologies and 45 IPs being generated.

BIPP is a flagship Late stage funding Scheme and supports validation, demonstration and pre-commercialization of products/technologies (up to TRL-7 and above). Over the years, BIPP has supported 228 projects. 56 products and technologies have so far been developed through BIPP and 32 IPs have been generated.

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 126 projects have been supported under this program.

SPARSH is Social Innovation program for Products: Affordable & Relevant to Societal Health aimed at promoting the development of innovative solutions to society's most pressing social problems through biotechnological approaches. **Social Innovation Immersion Program (SIIP)**, a component of SPARSH is a fellowship program meant to identify specific needs and gaps in socially relevant areas, which can be bridged and serviced through biotechnological interventions. BIRAC has also joined hands with Tata Institute Social Sciences (TISS), Mumbai to help our social innovators.

Similarly, BIRAC has set up Early Translation Accelerators (ETAs) to realize academic discoveries into products by providing translational support. In the FY 2020-21, new proposals have been selected for validation at the two ETAs in the area of Healthcare and Devices & Diagnostics at Yennepoya University and BETIC (IIT-Mumbai). C-CAMP, first ETA has successfully completed the first set of three projects and all the three technologies validated are adopted by industries. Two IPs have been filed from C-CAMP ETA. Three projects are ongoing and one project completed at IIT-Madras Industrial Biotechnology ETA.

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. Three projects started in FY 2019-20 are ongoing under PCP Fund and progress in their activities towards commercialization are being monitored. As per the amended guidelines, any Indian Biotech Start-up with products which are nationally relevant and are above TRL-7 stage are eligible for funding through this scheme. Under this guidelines next set of four projects have been shortlisted by the Steering Committee for Product Commercialization (SCPC) for further approval and funding

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 & North East) at KIIT-TBI.

The BIRAC Regional Innovation Centre was established in partnership with IKP, Hyderabad in 2013 as the first regional centre of BIRAC. Over the 8 years (2013-2021), 3 phases have been completed with the following mandate: RIS Mapping for 23 clusters, Engaging with academia and start-ups on IPR through its IP and Technology Transfer Cell, Entrepreneureship Development.

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 three years of existence, BREC reached out to 1900+ students, mentored 600+ start-ups, facilitated more than 500 one-on-one meetings between start-ups and investors and mobilized 6300+ registrations for NBEC.

BIRAC Regional Bio-innovation Centre (BRBC) provided training to 40 incubation managers and assisted 150+ start-ups for regulatory queries, provided mentor match service to 250+ entrepreneurs, facilitated 200+ one on one meetings with specialized experts. Camps on specialized topics were also organized.

BIRAC Regional Techno-Entrepreneurship Centre for East & North East (BRTC-E&NE) at KIIT-TBI conducted various regional events and reached out to 2000+ innovators in the east and north east region. These dedicated efforts are aimed to facilitate ecosystem biotech innovation ecosystem in the region which is weak at present.

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

The Make in India (MII) Cell at BIRAC ensures wider dissemination of the Government programmes and other information relevant to the establishment and growth of start-ups, 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 MII 2.0 action plan is reviewed by DPITT.

MII cell is also implementing the Start-up India action plan integrating through BIRAC's mandate by facilitating funding and incubation support to start-ups. BIRAC's commitment to Start-up India to build 50 biotech incubators,



5 regional centres and supporting 2000 start-ups by 2020 is facilitated and mapped by this cell. Policy level suggestions, initiatives, India's Bio-economy mapping, sectoral reports, identifying and creating opportunities at national and international forums are also being carried out this cell. Biotech mega event i.e Global Bio-India 2019 and 2021 was steered through secretariat at Make In India 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 will be 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.

National & International Partnerships to Amplify our Mandate

BIRAC is cognisant of the fact that transformation of an idea to product would need joint efforts and engagement of various stakeholders. 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 the **Ministry of Electronics and IT (MeitY)** in the area of medical electronics, Industry Innovation Programme on Medical Electronics (IIPME), 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 diseases. A total of 36 projects were funded in three rounds of selection during 2016-18. More than 70% of the projects yielded successful results. More than 10 products were launched through the support from IIPME.

Grand Challenges India at BIRAC has expanded its scope and programs further into the core areas of maternal and child health, nutrition and agriculture, infectious diseases, and others. IN 2020-2021, in response to the pandemic, GCI has funded programs in the areas of sewage surveillance for Covid-19, serosurveillance and the development of mobile diagnostic labs. Other programs in the areas of capacity building, and others were also under development.

BIRAC has partnered with **WISH** (**Wadhwani Initiative for Sustainable Healthcare**) Foundation (a Non-Profit Organization involved in taking innovation to the end users) for leveraging the network and engage the SCALE programme of WISH to validate the innovations in Primary Healthcare Centres (PHCs) through state governments. Under this Partnership, BIRAC supported Start-up products/technologies are validated by WISH at different PHCs and so far three products have been validated under the Partnership. As an outcome of the studies, 3 White papers along with recommendations of the studies were handed over to the innovators. Five more innovations are underway for field validation.

University of Cambridge Entrepreneurship Education Programme – IGNITE: BIRAC has partnered with Judge Business School (JBS) at University of Cambridge in 2013 for the Ignite Programme that provides BIG innovators international mentoring opportunity. It enables early stage start-ups to develop international entrepreneurial flair and skills needed to understand the opportunities for successful translation and commercialisation of innovations. Every year, 5 BIG start-ups are selected and supported to attend the week-long boot-camp, IGNITE at JBS, Cambridge, UK. So far, 39 BIRAC supported start-ups have benefitted from the programme.

BIRAC has a partnership TiE-Delhi NCR under which a woman specific award has been constituted, named as WInER Award (Women In Entrepreneurial Research). 4th edition of BIRAC-TiE WInER Award was launched during FY 20-21. 15 women entrepreneurs from the 3rd edition were provided an opportunity to attend a virtual accelerator programme for regulatory, IP, licensing, fund raising, mentoring; and 3 final winners were awarded with the final award of INR 25 lakhs each.

Platforms: Bringing the evolving Community together for Collaborations

BIRAC pro-actively nurtures emerging start-ups and SMEs through seminars, workshops and other platforms. In 2020-21 several Roadshows, Grant writing, IP, regulatory and hands-on training, business mentoring workshops were organised. Several seminars and workshops were also conducted through our Partners. In addition, a mega event Global Bio India 2021was also conducted. The theme for GBI 2021 was "Transforming lives" with the tagline "Biosciences to Bio-economy". All together the event witnessed a rich technical program of about 30 sessions including workshops, CEO Roundtable, policy dialogues etc; and Bio-partnering that took place over a period of three days. The event attracted 8400+ delegates, 40+ countries, 50+ international speakers, 1000+Entrepreneurs &start-ups, 23 Awards Facilitated, 140+ investor-start-up meetings, 150+ exhibitors, 350+ Bio-partnering meetings.



We have created platforms such as **Innovators Meet** (conducted as part of Global Bio- India), **Foundation Day** (9th Foundation Day was organised in March 2021) for networking/collaborations and providing a national level outreach platform for Start-ups and Entrepreneurs. The flagship platform for BIG start-ups, the 6th annual BIG Conclave was organised The event with theme 'Resilience Redefined' brought together several Technical Experts, Business Leaders, Innovators and Entrepreneurs on a common virtual platform and showcased the trailblazing innovations supported by BIRAC through its Biotechnology Ignition Grant (BIG) Program.

BIRAC 3i Portal is a providing a user friendly, bilingual and convenient solution for effective management of various funding schemes of Biotechnology Industry Research Assistance Council.

During the period of COVID-19 various schemes were launched through the portal such as COVID-19 Research Consortium, announced to support Research & Development on devices, diagnostics, therapeutics, vaccine candidates and other interventions. The 3i portal provides a single-window access to information and services that are electronically delivered to its user/s. Regular updates are carried to enhance user-interface. Recently, the portal is expanded to manage loan recoveries under BIPP and SBIRI, additionally, data mining and analysis has been made easier through number of newly added reports. The portal continually assists in conducting surveys and generating reports based on the same.

Supplementation of new features in near future includes advance search options such as single click view of all information related to a project. Also it is 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.

Recognition for BIRAC Start-ups & SMEs

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

- 1. Founder of Takachar, incubated at BIRAC supported Clean Energy International Incubator, has been among the seven winners of the prestigious "Young Champions of the Earth" 2020 prize given by the UN environment agency.
- 2. Aspartika Biotech Pvt Ltd has been selected as a Winner of BCIC Emerging Stars Award by the Bangalore Chamber of Industry and Commerce under the category "Social Enterprise in Agritech" in Cleantech & Energy sector,5th February, 2021
- 3. M/s AlgalR Nutra Pharms, Tanjavur Private Limited awarded as under MSME category for commercialization of products based on ingenious technology at National Technology Awards 2020
- **4.** M/s Althion Tech Innovations Private Limited., Hyderabad awarded under NATIONAL AWARD FOR TECHNOLOGY START-UPS for promising new technology with potential for commercialization at National Technology Awards 2020
- 5. M/s KBCols Sciences Private Limited, Pune awarded under NATIONAL AWARD FOR TECHNOLOGY START-UPS for promising new technology with potential for commercialization at National Technology Awards 2020
- 6. **M/s Newndra Innovations Private Limited**, Jaipur awarded under NATIONAL AWARD FOR TECHNOLOGY START-UPS for promising new technology with potential for commercialization at National Technology Awards 2020
- 7. **Padmaseetha Technologies Pvt Ltd** awarded the Runner Up in the Inaugural Healthcare Competition 2021, by ZSPrize.
- 8. **Biodesign Innovation Labs Pvt Ltd** has been awarded the CISCO Global Problem Solver Challenge under the pandemic response in 2021
- 9. M/s Shira Medtech Pvt Ltd wins National Award for Technology Startups 2020
- 10. M/s FibroHeal Woundcare Pvt Ltd wins National Award for Technology Startups 2020
- 11. **E-Spin Nanotech**, incubated at IIT Kanpur, supported by BIRAC received SWASA AWARD, GIBF National Awards for Business excellence 2020, Nano Innovation Award in Bangalore Nano Conference (2020) and "CEO of the Year" by the CEO Insights magazine (2020).
- 12. **Kanpur Flowercycling** for its product "Fleather- animal free Vegan leather and Floral Foam-Eco-friendly styrofoam substitute" received PETA Best Innovation in the Vegan World 2020.



- 13. Predible Health Pvt Ltd for its product LunglQ raised 5cr in capital and got into the list of Forbes 30 Under 30, India 2020.
- 14. **Comofi Medtech Pvt Itd** (incubatee at KIIT TBI) for its product nGuide-PCNL won the second prize for innovation in urology sub speciality, USICON south chapter, Feb 2021.
- 15. **WeGOT Utility Solution Pvt Ltd** for its product "Ven-Aqua" had been a winner in "Innovative Water Saving Product" category of CII National Awards for Excellence in Water Management 2020.
- 16. **Bugworks Research** is a drug discovery company and a BIRAC supported start up and has been chosen by ALCOR funds as one of the top 10 most innovative biotech startups in India, in 2021
- 17. **Blackfrog** is medical grade refrigeration company funded and supported by BIRAC. Blackfrog was the National winner of QDIC in March 2020 with a cash-award and patenting support. Also won the Forbes-Marshall Manufacturing award in Startupreneur awards 2020 and one of the winners in MHRD's SAMADHAN program in 2020 for its efforts in mitigation of the COVID-19 crisis.
- 18. **Mylab Discovery Solutions Pvt. Ltd**, a biotechnology company, supported by BIRAC has received Healthgiri Award 2020 for best innovation for COVID-19 related activity.

Key achievements MOU 2020-21

During the year BIRAC supported projects in all major areas of biotechnology sector i.e. Healthcare, Agriculture, Clean Energy & Environment, Bioinformatics and Infrastructure as part of meeting its objective of promoting affordable innovation in key social sectors. Healthcare covers the areas of Drugs (including drug delivery), Biopharamaceuticals (including Bio-similars and regenerative medicine), Vaccines/Clinical trials & Devices/diagnostics, Bioinformatics covering Artificial intelligence, Big Data Analysis, IoT's & software development, whereas Agriculture covers Marker assisted selection (MAS), RNAi, Transgenics & soil health management and Veterinary & Aquaculture and Clean Energy & Environment includes secondary agriculture.

In the financial year 2020-2021, a total of 234 projects including 65 collaborative projects were supported under i4, PACE and SPARSH. Under these schemes, 302 beneficiaries including industry and academia were catered. Regular mentoring and monitoring of the projects was done leading to successful outcomes in terms of progression of TRL levels and commercialization of products and technologies.

During the year 2020-21, there were 689 incubatees who have been incubated in the bio-incubation system.

During the year, 26 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.

During the year, 42 projects Technology Readiness Level -7 (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, 16 new products/technologies have been market launched/Commercialized (TRL-9) and 11 product/technologies have completed all essential requirements for market launch (TRL-8) with support from BIRAC in 2020-21.

During the year, 84% TRL-3 projects from academia were ready for validation by industry.

727 beneficiaries were supported by BIRAC under its various schemes during 2020-21. 1000+ startups and entrepreneurs have been incubated in the bio-incubation system of BIRAC.

The total amount mobilized from sources other than the Department of Biotechnology (DBT), which is the Administrative Ministry was 34% of the annual allocation from DBT. During the financial year 2020-21, the increase in revenue generated as a percentage of the administrative and office expenses over the previous year was 102%.

The percentage of procurement of goods and services through GeM portal to total procurement of goods and services was 22%.

Over the 9 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 start-ups 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). During the year, BIRAC did not have an Audit Committee as the term of office of the Independent Directors was up to March 15, 2020. The appointment of new non-official directors is under process with the Department of Public Enterprises (DPE).

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. ANNUAL RETURN

Pursuant to Section 92(3) read with Section 134(3)(a) of the Act, the Annual Return as on March 31, 2021 is available on the Company's website on www.birac.nic.in (web link of BIRAC website).

6. NUMBER OF MEETINGS OF THE BOARD

The Board met 5 (Five) 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 and as per relaxation given by MCA during the pandemic times.

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. RT

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 (https://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.

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 committees are covered under this policy.

The organisation has not received any grievances under this Act, during the financial year 2020-21. During the year 2020-21, a workshop was conducted on "Gender Sensitization & Prevention of 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 seventh Memorandum of Understanding (MoU) for the financial year 2020-21 with the Administrative Ministry, the Department of Biotechnology (DBT), Ministry of Science and Technology on November 26, 2020, as per the Guidelines issued by the Department of Public Enterprises.

BIRAC was also awarded 'Excellent' grading for its achievements against the targets set out in the MoU for the year 2019-20 by the Department of Public Enterprises (DPE).

12. PROCUREMENT FROM MICRO AND SMALL ENTERPRISES (MSES)

The Total annual procurement for financial year 2020-21 was 2.26 Crores, out of which the procurement from MSEs was Rs. 2.09 Crores amounting to 92% of the total procurement and the procurement from MSEs owned by Women Entrepreneurs was Rs. 0.40 Crores amounting to 19% of the total procurement from MSEs.

13. DIRECTORS 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. SAMPRK & 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 2020-21). 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:

- Union Bank of India, Block 11, CGO Complex, Lodhi Road, New Delhi 110003.
- State Bank of India, Core 6, SCOPE Complex, Lodhi Road, New Delhi 110003
- HDFC Bank Ltd, A3 NDSE, South Ex Part 1, New Delhi- 110049

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, Secretary, DBT is the Chairperson of BIRAC. Ms. Anju Bhalla, Joint Secretary, DST has been given additional charge as Managing Director, BIRAC from April 10, 2020. The tenure of Dr. Mohd. Aslam, as Managing Director, BIRAC ended on April 09, 2020. Dr. Aslam, however, continued to be the Government Nominee Director on the Board of BIRAC till November 30, 2020. Further, Mr. Vishvajit Sahay, Additional Secretary & Financial Advisor, DBT was appointed as Government Nominee Director on the Board of BIRAC w.e.f. December 24, 2020.

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.)	32,63,09,715	
Foreign Exchange outflow (in Rs.)		
A. Technology Transfer	24,26,601	
B. Books, Journal and Database Subscriptions	27,17,500	
C. Entrepreneurship Development	5,83,200	
D. Advertisement/Publicity/Publication	3,62,550	
E. Foreign Travel and Meetings	4,00,890	
CIF Value of Import	Nil	

19. Particulars of loans, guarantees or investments under Section 186

The details of Loans and investments as covered under the provisions of Section 186 of the Companies Act, 2013 are given in notes no. 7 and 8 of notes forming part of Balance Sheet as on March 31, 2021.

20. BIRAC Review

As a part of the Cabinet note on setting up of BIRAC, DBT had set up an External Expert Committee which Chaired by Shri Kris Gopala Krishnan and other Senior Experts that had done a very detailed review and had greatly appreciated the work BIRAC has done.

i. The Committee reviewed BIRAC for its performance vis a vis its Mandate, its processes and various functions and made recommendations on the activities and functions for the next 5 years; It also made recommendations on the performance measurement parameters for assessment of BIRAC after 10 years.

"Overall Assessment

"Overall, we believe that BIRAC has done an excellent job:"

Programme Design

- BIRAC is certainly a well thought and properly conceived flagship program of DBT which is critical for supporting and scaling innovations.
- BIRAC provides an excellent opportunity for the young biotech entrepreneurs as well as industry to get much needed funding support through a competitive grant system.
- BIRAC is to our knowledge the only government agency across ministries playing such a catalytic role and its activities need to be emulated by similar agencies promoted by other ministries.

Programme Structure

- BIRAC has the whole range of programmes covering all possible innovators (students, academics, individuals, start-ups, etc.)
- BIRAC programmes cover all stages of the innovation life-cycle including ideation, proof-of-concept, trials, commercialisation.
- BIRAC provides outright grants or equity support under different schemes.
- BIRAC has created a decentralised network through incubator partners for better reach.

Process & Culture

- BIRAC has a committed and knowledgeable core team.
- The processes from call for applications to implementation of various schemes and their monitoring are streamlined and working smoothly.



- BIRAC provides connects to other important players including ministries, regulators.
- BIRAC has been effective in mentoring and monitoring of proposals for successful delivery, providing regulatory support to innovators and in organizing niche area meetings to identify areas of interest.
- BIRAC has created the right culture for success of such initiatives all the incubators, Institutes and start-ups they have worked with talk highly about the timely help and support that they have received from BIRAC.
- Failed projects under some schemes like SPARSH, SBIRI, PACE have been foreclosed and the output of all other schemes as perused was good.

Outcomes

- BIRAC has made a significant contribution towards development of innovation ecosystem in biotech & related areas by supporting around 1,200 start-ups and entrepreneurs through its schemes and indirectly a 3,500 start-up strong biotech ecosystem across India.
- 150+ products of BIRAC-supported start-ups have been commercialised. The work that is being done by BIRAC is fundamental for the economic progress of the country and will contribute to large creation of wealth and generation of employment.

21. Corporate Social Responsibility under Section 135 of Companies Act, 2013

BIRAC had achieved the surplus of Rs. 7.95 Crore during the financial year 2019-20. As the surplus/profit is more than Rs. 5 Crore, BIRAC needs to comply with the provisions of CSR as prescribed under Section 135 during the financial year 2020-21.

The Board of BIRAC at its 45th Board Meeting held on February 24, 2021 approved the Corporate Social Responsibility Policy (CSR Policy). The CSR Policy of the BIRAC was formulated in line with the provisions of the Companies Act, 2013 read with the Companies (Corporate Social Responsibility) Rules, 2014 and 'DPE Guidelines'.

Further, as per Companies (Amendment) Act, 2020 (applicable w.e.f. 22nd January, 2021), if the amount to be spent by a company does not exceed fifty lakh rupees, the requirement for constitution of the CSR Committee shall not be applicable and the functions of such Committee provided under Section 135 shall be discharged by the Board of Directors of company.

Hence, as per the above mentioned provision, the Board of Directors of BIRAC shall discharge the function of CSR Committee as prescribed in Section 135 of the Companies Act, 2013 read with Companies (Corporate Social Responsibility Policy) Rules, 2014.

As per Section 135 of Companies Act 2013, the Board has approved the budgetary allocation of Rs. 7,34,647/being 2% of the net surplus/profit made during three immediately preceding financial years for CSR activities During financial year 2020-21.

A detailed report on CSR activities as per the provisions of the Companies Act, 2013 is available at Annexure-1 to this report.

The CSR policy of the Company has been provided on the Company's website at https://www.birac.nic.in/.

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.

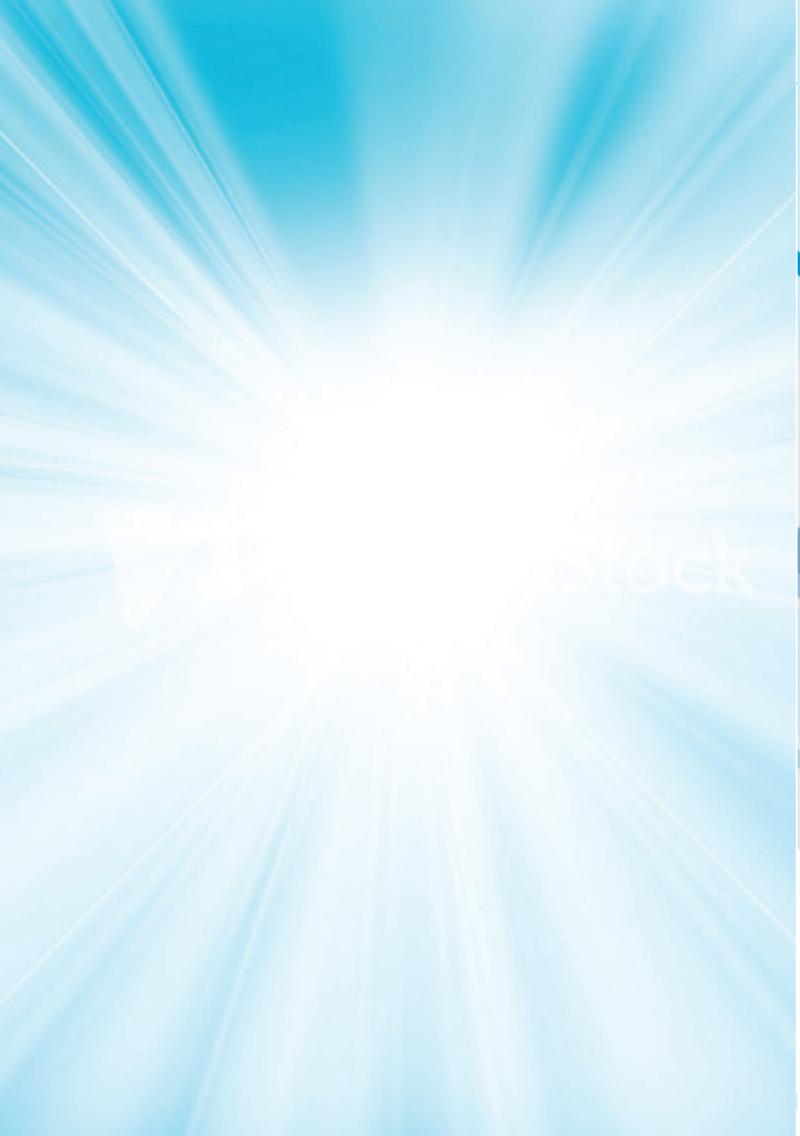
For and on behalf of Board

Sd/- Sd/-

Dr. Alka Sharma
(Managing Director)

Mr. Vishvajit Sahay
(Director)

Date: 30.11.2021
Place: New Delhi



Management Discussion & Analysis



MANAGEMENT DISCUSSION AND ANALYSIS REPORT

(Forming Part of the Directors' Report for 2020-21)

INDUSTRIAL STRUCTURE AND DEVELOPMENT

India's ranking has improved in the Global Innovation Index (GII) 2021 to 46th place among 132 economies, up from 48th in the previous year's ranking. With this, India is among the top 50 most innovative countries globally. Further, India ranks 2nd among 34 lower middle-income group economies and 1st among the 10 economies in Central and Southern Asia. Nurturing innovation and entrepreneurship through Government of India initiatives have also played a critical role towards making this possible.

Biotechnology is recognized as the sunshine sector. India's bioeconomy is expected to reach \$150 billion by 2025 and contribute through a multiplier cascading effect in meeting the target of \$5 trillion economy for the country by 2025.

According to the "Indian Bioeconomy Report" published by ABLE and BIRAC in March 2021, Indian Biotech Industry is valued at \$70.2 billion for calendar year 2020. India registered 12.3 percent growth in BioEconomy compared to the previous year's figure of \$62.5 billion. Year 2020 saw the Covid-19 crisis with the Country-wide lockdown impacting several industries. Yet the Indian BioEconomy has seen many positives. The bioscience-based industry's response to the Covid-19 Pandemic fight back is phenomenal. India's initiatives to deal with Covid-19 succeeded due to the collective, concerted, and continuous efforts of the government (s), industry, academia, and incubators. BIRAC played an enabling role to take research ideas through proof-of-concept to market place. Several pioneering schemes were launched to build an entrepreneur-friendly ecosystem in the country. The industry ramped up its vaccine capabilities, scaled up Covid-19 testing, and looked beyond the normal opportunities to beat the Covid-19 economic stagnation. India now has over 4,237 biotech start-ups, nearly a 25 percent jump in its base since 2019. India's vision is to have 10,000 biotech start-ups by 2024 and be a \$150 billion BioEconomy by 2025 seems on course.

Indian researchers and innovators played a key role in introducing low-cost diagnostics and testing kits; manufacturing Personal Protection Equipment (PPE), masks, and therapeutics; ramping up clinical trials for Covid-19 vaccine, and setting up world-class facilities for manufacture and supply of Covid-19 vaccines. Global and local collaborations with all stakeholders – the governments, the accelerators, private and public sector partnerships, and start-ups – prevailed under one roof.

In 2020 India transformed from an importer to an exporter of essential Covid-19 related products like diagnostic kits, PPEs and vaccines. The year also witnessed steady ramping up domestic production.

The pandemic has provided the country with an opportunity to play the lead role in the global biotech ecosystem. India is on a new path – from being the pharmacy of the world to being the hub of cutting-edge innovation and research.

In 2020, the economy was boosted by the good performance of the BioPharma and BioServices sectors. The Biopharma sector alone contributed to 62 percent share of the total BioEconomy. The BioServices segment's share was 15 percent while the BioIndustrial segment was at 8 percent share. Research services' contribution to BioEconomy along with the BioIT and IT healthcare portfolio is valued at \$10.5 billion. This has grown from \$9.5 billion in 2019. The BioAgri segment accounted for 16 percent share.

The BioEconomy continues to be spearheaded by the BioPharma segment as it alone contributed to 58 percent share of the total BioEconomy by value. Half of the BioPharma economy is through diagnostics and medical devices. Vaccines account for 30 percent of the BioEconomy by value, while biotherapeutics contributed for the rest. BioAgri is the second largest contributor to the country with 19 percent share. Research services' contribution to BioEconomy along with the BioIT and IT healthcare portfolio is estimated at \$9.5 billion. BioIndustrial segment has also performed well. The sector accounted for nearly 8 percent share. However, India continues to import large volumes of products, reagents, components, and raw material. This gap in import and export presents an immense potential that can be harnessed in order to make India a leading producer of Biotechnology and allied products and services.

Government's initiatives and role in harnessing the biotechnology potential of the country have been critical for strengthening the roots of innovations and research and development. BIRAC was set up as a dedicated agency by the Department of Biotechnology for spurring and promoting innovation and entrepreneurship in the Biotech sector.



During the last 9 years of its existence, BIRAC has made 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, SIIP 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 through equity schemes like SEED, LEAP, AcE; as well as forged various national and international partnerships to facilitate networking and stakeholder connects. Through BIRAC's BioNEST programme, 60 bioincubation facilities have been established across the country. BIRAC has been instrumental in connecting its beneficiaries with venture capitalists, biotech/healthcare accelerators and early stage funders. Mechanisms have also been created to provide support for regulatory and IP hurdles (such as FIRST Hub, RIFC and BIRAC PATH). During the COVID days, BIRAC quickly launched initiatives like Covid Research Consortium, Fast Track Review and COVID Suraksha to facilitate start-ups develop effective solutions for combating the pandemic and capacity building for testing services and clinical trials.

The Indian Biotechnology sector has always been the flag bearer for showcasing the country's strength and advancement in the modern technology arena. It was with this intent that a mega international event called Global Bio India was organized in March, 2021 through virtual mode.

Since inception, BIRAC has launched several programmes and initiatives that dynamically align closely with Government of India's national missions such as Start-up India, Make in India, Swachh Bharat, Swasth Bharat, Ayushman Bharat, Doubling farmer's income, Atmanirbhar Bharat etc. The onus now is to handhold, mentor and scale 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 address the unmet needs through technology adoption to the last mile and development of innovative affordable products.

STRENGTH AND WEAKNESSES

BIRAC's vision and mission directly aligns with the National Biotechnology Development Strategy (NBDS), formulated by DBT in 2015 and updated in 2021. BIRAC has nurtured entrepreneurship and innovation ecosystem in the field of biotechnology through several customized innovation's stage-specific programmes as well as in partnership with agencies sharing common goals including Atal Innovation Mission, Ministry of Skill Development & Entrepreneurship, MeitY, ICMR. BIRAC has actively contributed to Make in India Biotech Strategy and Start up India. All such 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 engagement of industry and academia for 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), BioNEST bioincubators, E-Yuva Centres (pre-incubation centres), Technology Transfer Offices (TTOs) and supporting industry-academia collaborative projects.

Regulatory landscape is 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 has been sharing 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.

The biotech innovation ecosystem needs to scale in order to remain competitive and harness full potential. The number of biotech start-ups are expected to grow 2x i.e., from 5000+ in 2021 to 10,000 by 2025. To enable and support scaling of ecosystem, BIRAC must also scale the network of Bioincubation centres, Pipeline of Entrepreneurs, Start-ups and expand provisions for the deployment of innovative products in market. In order to stay effective and meaningful, BIRAC's funding resources need 5x scaling to meet the expected outcome. While public funding resources i.e., parent institution (DBT) kitty size is small, BIRAC may try to complement funding availability from alternate extramural resources, CSR etc.

RISK AND GOVERNANCE

The biotechnology innovation pathway involves long gestation period. This exerts enormous pressure on start-ups that are attempting to build novel, high quality and affordable products in India. For building an excellent bio-economy 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 Start-up 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 Start-up is lack of participation of private equity – (i) Pre-series 'Angel Funding' in the range of INR 1 to 5 Cr, and (ii) Growth capital for potential Biotech start-ups at series A and above. This funding is crucial for start-ups to cross the valley of death. BIRAC in its limited capacity has initiated Biotechnology Innovation Fund - AcE (Accelerating Entrepreneurs) to support up to INR 7 Cr/start-up. This initiative has been able to successfully mobilize a commitment of INR 300 Cr Private equity for biotech start-ups. In Addition to this "BioAngels Network" initiative is in its implement stage which would encourage and mobilize more Private Equity into the ecosystem especially the early stage investments. This platform will lead to creation of a consortium of 50+ Angels, HNIs, early Stage VCs. Such a biotech dedicated investor network does not exist in the country. The platform will be based on open & transparent architecture which allows participants to join. The typical investments range would be as follows:

Up to Rs. 1 crore: 100 Investments
Rs. 3 - 5 crores: 25 investments
Rs. 7 - 10 crores: 20 investments

It is expected that about 150+ Start-ups would receive equity investment over the period of 3 Years.

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.

Global economy risks are influenced by a variety of factors that are beyond the regional control. It also influences the emerging paths of global biotech industries. Pro-actively connecting India's ecosystem with the leading centres across the world e.g., US, UK, Germany, Finland, Singapore, Israel, Japan would make India's innovation ecosystem globally competent otherwise it may not be able to scale.

BIRAC engages into strategic partnerships to bring the best practices knowledge of other ecosystems including biotech industry both within and outside the country.

New partnerships initiative with **DnDi & GARPD (DRUGS FOR NEGLECTED DISEASES)** initiative **& Global Antibiotic Research & Development)** Partnership were announced with an aim to collaborate in taking an end-to-end approach towards R&D for neglected diseases and infectious diseases outbreaks in India, from drug discovery and pre-clinical research to clinical trials and large-scale implementation studies. GARDP's mission is to bring together the public and private sectors to develop new treatments for bacterial infections and ensure responsible and sustainable access, addressing the public health impact of AMR;

BIRAC proactively has established partnerships with other S&T knowledge agencies across the world such as Business Finland, Nesta-UK, UKRI-Innovate UK, BIO-US, Vinnova Sweden to name a few.

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 start-ups.

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 BIG scheme is managed by 8 BIG Partners which are mature BioNEST Bioincubators. These partners provide thorough mentorship (technical, IP, business), handholding and networking support from pre-submission stage to completion of the project (and even after). With a view to expand the outreach of scheme to deeper pockets of the country, 11 additional BioNEST Incubators have been engaged as BIG Associate Partners in FY 2020-21. Associate Partners are responsible for creating awareness about the scheme and mentor aspirants for application submission, especially from Tier 2/Tier 3 cities.

List of 8 BIG partners are as follows:

- Centre for Cellular and Molecular Platforms (C-CAMP), Bangalore
- Foundation for Innovation and Technology Transfer (FITT), New Delhi
- IKP Knowledge Park, Hyderabad
- KIIT-TBI, Bhubaneshwar
- Venture Center-NCL, Pune
- SIIC, IIT-Kanpur
- SINE, IIT Bombay, Mumbai
- A-idea, NAARM, Hyderabad

List of 11 Associate Partners are as follows:

- Bangalore Bioinnovation Centre (BBC), Bangalore
- HTIC, Chennai
- PSG-STEP, Coimbatore
- IKP Eden, Bangalore
- Panjab University, Panjab
- VIT-TBI, Vellore
- Ahmedabad University, Ahmedabad
- IIT Madras Research Park, Chennai
- University of Hyderabad
- RiiDL , Somaiya Vidyavihar, Mumbai
- BSC BioNEST Bio-Incubator, RCB, Faridabad, Delhi-NCR



BIG Partners





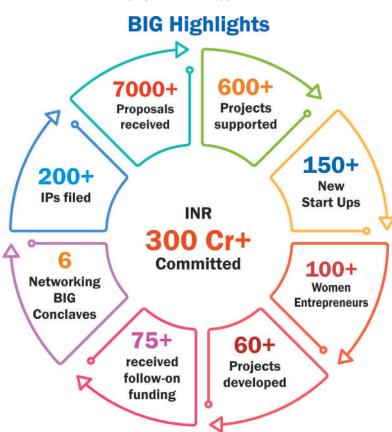
BIRAC Associate Partners

In FY 2020—2021, two new calls: BIG 17 and BIG 18 were launched on 1^{st} August 2020 and 1^{st} January 2021 respectively.

The 16th call of BIG identified 51 proposals for support out of a total of 765 proposals received and BIG 17th call identified 73 projects out of 885 proposals received. In total 124 new projects were supported in FY 2020-21.

BIG IMPACT

The impact made by BIG programme in promoting the entrepreneurial culture in the biotech sector can be easily seen through the tangible outcomes and achievements. 600+ projects have been supported through BIG so far and through these 600+ projects, BIG has facilitated creation of more than 150 new start-ups, supported nearly 100 women entrepreneurs, generated more than 2000 high skilled workforce. Through BIG, BIRAC has committed approximately INR 300.00 crores in the biotech innovation ecosystem. More than 200 IPs have been filed by the BIG grantees during the course of their projects. Another major highlight of the success of this programme is the ability of BIG grantees to secure further follow on funds through other sources including government and private funds.





Some of the BIG Grantees who raised follow on funding from private investors during the FY 20-21 are as follows:

S. No	Innovator/Start-up	Source of funds/Awards
1	Avyantra	Crypto Funding
2	Ameliorate Biotech	IAN
3	Module Innovations	CARB-X
4	KBCols Sciences	Seed Investment from Chiratae Ventures through its Deeptech Innovators Program and other investors including Axilor Ventures & Derbi Fundation)
5	EzeRX Health Tech Pvt Ltd	YourStory, Angel investors, KIIT-TBI
6	InAccel Coeo Labs Pvt. Ltd.	Pre-seriesA led by Mount Judi Ventures
7	Nocca Robotics	IAN
8	Comofi Medtech Pvt. Ltd.	Jain International Trade Organization (JITO) Angel, Capital Incubation Insights Everything (CIIE.CO) & BIRAC LEAP Fund
9	Shilps Sciences	Pre-Series A Funding from AngelList
10	Comofi Medtech Pvt Ltd	JITO Angel & CIIE CO
11	Ameliorate Biotech Pvt Ltd	Villgro USA, Vinners, LetsVenture, SINE IIT Bombay, and DERBI
12	AlgoSurg Inc.	Award of \$200,000 from Intuitive Foundation through
		the Global Surgery Training Challenge.
13	Ruhvenile	Foreign private investor
14	Biomoneta Research	BNV, ArthaVida Ventures and IVF specialist and angel investor,
		Dr. Aniruddha Malpani
15	Muse Diagnostics	BRINC accelerator
16	Log 9 Materials	Marico Innovation Foundation (innovate to beat covid challenge)
17	Pandorum Technologies	Series A round from Indian Angel Network Fund, 021 Capital, 500 Startups and the Karnataka government backed Karnataka Information Technology Venture Capital (KITVEN) fund
18	BugWorks Research	Series B funding round led by University of Tokyo Edge Capital and Global Brain Corporation,
		Along with the participation of existing investor South Africa-based Acquipharma Holdings.
19	Eyestem research	Gert Hoogland, Innovation Quest, CCAMP, Kotak Investments
20	Adiuvo Diagnostics Pvt. Ltd.	Series A from existing investor Menterra Venture Funds and new investor Artha Ventures - 10Cr, NBEC CCAMP -6 L, Qualcomm Design in India - 3L
		Private investor- equity- 50lakhs
21	Intessence Solutions Pvt. Ltd.	Karnataka state Elevate award - 25 Lakhs - received so far- 12.5 L
		NBM- award: total- 2.37 Cr. Of which 1.6 cr is Grant and 0.77 cr is company contribution
		Received- 48 Lakhs of grant amount.
22	Weinnovate Biosolutions Pvt. Ltd	3.5Cr from Chiratae Ventures
22	Weimiovate Diosolutions FVt. Ltd	20L from DERBI foundation



S. No	Innovator/Start-up	Source of funds/Awards
23 Crimson	Crimson Healthcare Pvt. Ltd.	Consortium of Angel and Seed Investors Incl:
		1) CCAMP (Leap fund)
		2) FISE
	Chinson healthcare Fvt. Ltd.	3) Mumbai Angels
		4) Keiretsu Forum
		5) Other Individuals 2.86 Cr
24	Turtle shell (Dozee)	Prime Ventures Capital- 12.5Cr=1250 Lakhs
25	GPS Renewables	Series A funding, led by Netherlands based Hivos-Triodos Fund and Hyderabad-based Caspian.
26	Kanpur Flower Cycle	Pre Seried by IAN Fund.
		1.4 Millon US Dollars (INR 10,17,64,950)



6th BIG Conclave

6th edition of BIRAC's BIG Conclave - an annual congregation of biotech start ups and ecosystem enablers was organized in partnership with one of the BIG Partners-StartUp Incubation and Innovation Centre IIT Kanpur. The event with theme 'Resilience Redefined' brought together several Technical Experts, Business Leaders, Innovators and Entrepreneurs on a common virtual platform and showcased the trailblazing innovations supported by BIRAC through its Biotechnology Ignition Grant (BIG) Program. The event witnessed an overwhelming participation of 56 speakers, 1000+ audience and 50+ virtual booths put together by the biotech start ups.

The two-day event had thematic discussions on topics pertinent to the growth and scaling of start-ups such as Art of Business Negotiations, Product Branding and positioning, Importance of mental health amongst startups and brainstorming thematic confabulations around discussing the aftermath of COVID, its impact on early-stage startups and remedies to defend against the tide across Healthcare, Agriculture, and clean environment sectors.

One of the major highlights of the conclave was 'The Investor-startup duo session' which presented key insights on building the chemistry between startup and its investor. The session featured 2 BIG Grantees who have raised follow funding along with their investors.





Inaugural session at 6th BIG Conclave

2. Intensifying the Impact of Industrial Innovation (i4)

The programme has been initiated to support biotechnological product/technology development by strengthening R&D capabilities of start-ups/companies/LLPs. The programme provides impetus for pulling the translational ideas past PoC and taking them further along the innovation chain for validation, scale-up, demonstration and pre-commercialization of products and technologies. The programme is operated through two schemes based on the Technology Readiness Level (TRL):

- a) Small Business Innovation Research Initiative (SBIRI): Supports development and initial validation of products/technologies up to TRL6. The Scheme offers 100% grant from BIRAC for project up to Rs. 50.0 Lakhs. For projects more than Rs. 50.0 Lakhs, BIRAC contribution is Rs. 50.0 lakhs + 50% of the cost exceeding 50.0 Lakhs.
- b) Biotechnology Industry Partnership Programme (BIPP): Supports validation, demonstration and precommercialization of products/technologies (up to TRL7 and above). Under BIPP, irrespective of the amount, BIRAC contribution does not exceed 50% of the project cost.

There is no ceiling with regard to overall project cost and royalty is admissible as per BIRAC guidelines under both SBIRI and BIPP.

a. 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, 311 projects involving 237 sole companies and 74 collaborative projects have been supported through SBIRI with a commitment of Rs. 278 crores. Under the scheme, 56 products/technologies have been either commercialized, or are market ready or have been transferred. Many technologies have reached the stage of early stage validation. In addition, 45 IPs have been generated through various projects.

In the last financial year, three calls for proposals were processed. The 44th call was regular call 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 43rd and 45th were special calls targeting specific research areas under each theme.



Under 42nd (closed on 30th April, 2020), 43rd and 44th calls 262 proposals were received out of which 11 proposals were recommended for financial support. The 45th Call for proposals, which closed on 31st March, 2021 received 53 proposals which are under consideration.

Of all the recommended projects, 3 projects (as listed below) from BIG scheme matured to secure follow on funding support in SBIRI.

- Clinical testing of a surgical intervention platform, nGuide by Comofi Medtech Pvt Ltd in collaboration of Muljibhai Patel Urological Hospital
- NLite 360 A modular phototherapy device for jaundice neonates by Heamac Healthcare Pvt. Ltd.
- Non-Invasive & Hygienic Faecal Collection Device for Bed-ridden Patients by Kvayat Medical Private Limited.

Serigen Mediproducts Private Limited has also secured follow on funding support for - Clinical Investigation of Serioss: a bone void filler.

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. Due to Covid-19 pandemic, all site visits and presentations took place through online interaction via virtual platform. In 2020-21, 77 unique beneficiaries were supported. Out of these, 67 beneficiaries were companies (SMEs and start-ups) and 10 were academic collaborators. A total of 21 projects got completed.

During the financial year, some products/technologies were either developed fully or are at advanced stages of development:

An artificial insemination gun for use by Indian Dairy sector has been developed by Cigen Biotech Discoveries Private Limited in collaboration with Adiuvo Diagnostic Pvt. Ltd. The gun helps in depositing the semen exactly in the uterus of the animal by direct visualization, combined with data retrievable video app for smart phones.

A smart and easy upper limb functional prosthesis with sense of touch has been developed by Bionic Hope Pvt. Ltd. The device called Grippy provides affordable prosthesis for the people who live their life without prosthesis due to the high treatment cost. Users will be able to use the device on their own with one or two days of training. The device is non-invasive in nature ensuring painless interfacing ensuring the user transitions from feeling disabled to differently-abled

Antibody detection ELISA test kit and Indirect ELISA test kit for Equines has been developed by Genomix Molecular Diagnostics Pvt. Ltd in collaboration with National Research Centre of Equine- ICAR-Hisar.











Technologies which reached early stage validation in the financial year

An endoscopy simulator has been developed by Mimyk Medical Simulations Pvt Ltd. The device called as EndoMimyk is based on virtual Reality together with haptics which enables the doctors to train for complex manoeuvres and hand-eye co-ordination in minimally invasive procedures. It offers realistic visuals, haptic feedback, and auditory guidance for complete immersive.

A state of the art radiolucent carbon fiber truss structure for X ray machine's patient structural support applications has been developed by Unicita Consulting Private Limited. This is an affordable import substitute and improves the quality of health care in India by reducing radio dosage and the occurrence of artifacts.

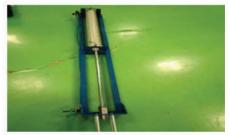
A stable, effective insecticidal formulation from the Hydnocarpus seed oil to control agricultural and forest insect pests has been developed by Varsha Bioscience and Technology India Pvt. Ltd in collaboration with Institute of Forest Genetics & Tree Breeding, Coimbatore. *Hydnocarpus pentandra* 60% EC has been scrutinized by Central Insecticide Board, Faridabad and registration is under process.

Chicken IgY based enteric protected oral formulation has been developed by Cisgen Biotech Discoveries Private Limited. "Parvocure" can be used for treating parvoviral enteritis in dogs. The therapeutic formulation is found to be highly effective in treating the clinical disease the clinical trials. GMP batches manufacturing has been done.

Synthesis of new hybrid orchids using potential parents available in India, particularly in the northeastern states has been achieved by Kwaklei and Khonggunmelei Orchid Pvt. Ltd.

Approximately 100 primary as well as secondary hybrids are maintained in the laboratory and greenhouse. Two hybrids have flowered and have been registered under the grex Renantanda Najma Heptulla (RHS registration No. P. 27000) and as Nobleara N. Biren; (RHS Registration No. P 28557).











b. 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, 228 projects involving 164 sole companies and 64 collaborative projects have been supported under BIPP. A total of 56 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 32 new IPs have been generated.

During 2020-21, a total of 47 projects, including 13 new ones were supported. 9 projects completed during this period. Three new calls (50th, 51st and 52nd) for proposals were announced, out of which 50th and 52nd calls were challenge based calls on identified priority areas. The 51st call was a regular call targeting major thematic areas. Under 50th Call, 44 proposals were received out of which 2 proposals were recommended for support. One project from SBIRI was recommended for support under BIPP. Under 51st Call, 34 proposals were received out of which 3 (one project shifted to SBIRI) proposals were recommended for financial support. Two projects from SBIRI were recommended for support under BIPP. In the 52nd Call for proposals (which was announced on 15th February, 2021 and closed on 31st March, 2021), 34 proposals have been received which are under various stages of technical evaluation.

In the financial year 2020-21, the key achievements of the projects supported under BIPP are as below:



Persistent Systems Pvt. Ltd. has developed and extensively validated i-Doctor, a revolutionary and reliable diagnostic and drug dispensing platform that will provide immediate medical assistance in both urban and rural set up with a deferred live mechanism. It is a secure, sophisticated yet a user-friendly diagnosing algorithm connected seamlessly to multiple point-of-care devices like ECG, BP apparatus, thermometer etc. i-Doctor independently diagnoses most common clinical conditions, it has a follow-up mechanism with an assigned doctor to ascertain the correctness of diagnosis and ensuring the well-being of the patient.



PathShodh Healthcare Pvt. Ltd. has developed anuPath LiTe, which is a Self-Monitoring Glycaemic Control Device (SMGC) based on cutting edge patented technology. The device is capable of measuring three important biomarkers (Blood Glucose, HbA1c and Glycated Albumin) in finger prick blood sample which gives a comprehensive diabetes management. The device has been extensively validated and the Company has all regulatory approvals in place for the product.



String Bio Pvt. Ltd. has set up a pilot scale facility for scale up and validation of a gas-based fermentation process for conversion of methane to microbial protein. Technology involves production of single cell protein from methane. The proposed product will be used for animal feed. The product has been validated on aquatic and poultry species.







Openwater.in Pvt. Ltd. has developed a hassle-free solution to industrial waste water treatment. The system is fully automated, plug-and-play, membrane less, does not use synthesized chemicals, wastes zero water. A 10 KLD treatment unit have been setup at Openwater. in, facility at IISc, Bangalore and have completed more than 35,000L of water treatment. Another plant of same capacity is being set up at a gated community at Kengri, Bangalore (Malhar Residency).





Mallipathra Nutraceutical Pvt. Ltd. has developed a technology for artificial cultivation of medicinal Mushroom. The process of producing Cordyceps at bench scale has been standardized and the same has been commercialized after FSSAI registration. The following products are available: Cordyceps militaris capsules, Cordyceps militaris powder, Cordyceps fruiting body, Snowflake Cordyceps capsules and powder and Cordyceps

In addition, the Companies funded under BIPP have received various awards and recognitions at different forums. Some examples are as below:

- Althion Tech Innovations Pvt Ltd. received the National Technology Award 2020, for commercializing indigenous technology (kidney dialysis ultra pure water plant).
- Padmaseetha Technologies Pvt. Ltd emerged as the Runner Up in the Inaugural Healthcare Competition 2021 by ZSPrize.
- Mallipathra Nutraceutical Pvt Ltd. was selected as a finalist by BCIC (Bangalore Chamber of Industry and Commerce) Emerging Stars Award 2020 under agriculture category. Further, Dr. Mousumi Mondal, the Director of M/s Mallipathra Nutraceutical Pvt. Ltd, received the prestigious "TiE-Biotech Women In Entrepreneurial Research (WInER) Award" in March, 2021
- Aspartika Biotech Pvt Ltd won the BCIC (Bangalore Chamber of Industry and Commerce) Emerging Stars Award by in the category Social Enterprise in Agritech under Cleantech & Energy sector.

3. 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/LLP. 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/LLP. 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/LLP.



Since inception of the scheme, 23 calls have been launched and 126 projects have been supported involving 54 sole and 72 collaborative. So far, 7 technologies/products developed under the scheme have achieved TRL7 and 13 IPs have been generated. Few more technologies and new IP generation are in pipeline. >80% projects funded under AIR category of PACE have achieved TRL3 so far.

During 2020-2021, 65 ongoing projects and 22 new projects involving 89 academic institutions and 24 companies and 47 collaborations were supported. Total committed funds were Rs. 95.92 Crores approximately. During the year, three calls for proposals were announced and processed. The 21^{st} and 23^{rd} were challenge-based call which targeted specific research areas under each theme. 22^{nd} call was regular call targeting the major thematic research areas of BIRAC.

Under the 21st call which closed on 31st August 2020, 231 proposals were received out of which 8 proposals were recommended for financial support. The 22nd call for proposals (which closed on 30th November 2020) received 168 proposals out of which 8 proposals were financially supported. Under 23rd Call (Challenge-based call) that closed on 31st March 2021, 84 proposals were received out of which 3 are under various stages of technical evaluation.

Progress of projects with regard to 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. Some of the successful outcomes of the projects supported under PACE during 2020-21 include:

- Tea Research Association, and Varsha Biosciences Pvt. Ltd conducted in vivo multi-location/ ecological zones trials of biocontrol formulation produced in 20L fermenters for CIB registration.
- Low molecular weight fungal chitosan for healthcare applications developed by NCL, Pune attained TRL7.
- Silkworm sex-limited foundation cross (SLFC27) for cocoon colour with Pure Mysore (PM) race in the production of Cross Breed for Industrial seed production.

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

SPARSH is aimed at promoting the development of innovative solutions to society's most pressing social problems through biotechnological approaches. Since its inception in 2013, the programme has been investing in high impact ideas and innovations that could address neglected unmet needs and challenges. So far 8 calls have been announced on varied themes such as *Maternal & Child Health, Ageing & Health, Food & Nutrition, Soil and Plant Health, Waste to Value, Livestock Health and Improvement, New and Improved Agricultural Tools, Reducing Post-harvest losses and Combating Environmental Pollution.* A total of 697 proposals have been received of which 57 projects have been supported. 18 products/ prototypes/ technologies have been developed along with generation of 5 new Intellectual Property (IP). Total funds committed are 25.75 Cr. 10 women entrepreneurs have been supported to help forge the path for entrepreneurship. Some of the technologies developed during 2020-21 are:

Uniform illumination based two systems have been developed for detection of arsenic from ground water. System 1: This system consisting of uniform illumination based arrangement and image is captured through web camera. Web camera is connected with Smart phone. Android App was developed for image analysis and detection of Arsenic percentage. System 2: This system consisting of uniform illumination based arrangement and Raspberry Pi 4 board and Raspberry Pi Camera module. Arsenic detection software on Raspberry Pi platform was developed for image analysis and detection of Arsenic percentage.

This project helped the company to reduce the consumption of wood considerably by partially replacing the amount of wood fibres used in the production of fibreboards with PMS and to obtain the panels at lower costs. During this work, special attention was given to study the effect of the mixture ratio of PMS and wood pulp by on board density and strength properties so as to improve the quality of the finished products, as specified in the respective Indian Standards, IS 1658:2006 for Hardboard and IS 3348:1965 for Softboard.

DTRONICS TECHNOLOGY PRIVATE LIMITED



THE WESTERN INDIA PLYWOODS LTD





Monitra upBeat ® is bio-sensing platform which makes remote monitoring comfortable and easy. It allows remote monitoring of individual's critical parameters-ECG, Respiration Rate, Pulse Rate/Heart Rate, Sp02 & Temperature. No wires, slim profile, discreet and can be easily worn on the chest. Patients with remote monitoring devices have a probability of survival that is more than 2x greater than those without.

MONITRA HEALTHCARE PVT LTD



It is a Point of Care, multi-parameter (4 tests in 1), portable screening device for Peripheral Neuropathy. It helps the physician to perform basic screening tests for Neuropathy - the monofilament test, vibration perception test, hot and cold perception test and skin temperature measurement. Reports are generated on a cloud server via wireless data transfer after the tests are completed. Innovativeness: As compared to the present innovation, competitive products available are bulky, not portable, expensive and need trained healthcare workers to operate the device

Technology developed is to obtain terra preta compost from waste water. This is basically resource recovery from septage.



BACTREAT ENVIRONMENTAL SOLUTIONS LLP



SPARSH Centres for Social Innovation

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 to promote social entrepreneurship.

The Sparsh Centres provide rural and clinical immersion to the innovators. The innovators are mentored on various skills like systematic clinical & community observation, need assessment, refinement and affordable product development. On completion, the Social innovators reach a point where they can submit an advanced proposal to investors with some preliminary results suitable for seed funding.

Till date 35 social innovators are graduated in three thematic areas namely, "Maternal and Child Health" "Ageing and Health" and "Waste to value. Several novel and interesting ideas to tackle social problems were generated. Some of these ideas were further refined and around 30 prototypes were developed. Most of the Social Innovators mentored through the program have been successful in raising follow-on funding or starting their own enterprise.

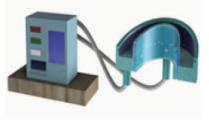
Till date twenty companies are created and 15 IPs are filed by the SPARSH Fellows. Few products developed by "Ageing and Health" batch are:



Dilip Shankar Founder of Accord Innovations Private Limited



Mrs. Sruthi Babu Founder & CEO Dhanvantri Biomedical Pvt Ltd



Dr. Steward Gracian BIG Grantee and Dentist /2018-19



In the financial year 2020-21, 14 SPARSH Centres along with BIRAC successfully recruited 67 Sparsh fellows targeting six thematic areas i.e. Maternal & Child health, Ageing & Health, Waste to Value, AgriTech, Food and Nutrition and Combating Environment Pollution. The fellows after recruitment were inducted through online Pre-Immersion workshop wherein they received mentorship from BIRAC and TISS experts.

The fellows as part of the SPARSH Immersion program, underwent rigorous clinical and rural immersion for four months and came up with 50+ problem statements, ready for further filtration. These ideas were then developed with the help of technology specialists and SPARSH knowledge partner, TISS.



Pre-Immersion Workshop attended by 14 Centres and 67 SPARSH Fellows







Glimpses of Clinical and Rural Immersion



Pre-Pilot Workshop



The virtual Pre-Pilot workshop was conducted for SPARSH fellows during January and February 2021. The workshop helped in developing critical insights among the fellows on the shortlisted problems. It also facilitated the feasibility and risk analysis by critical evaluation of the identified problems. Various master sessions and knowledge web series were organised during the course of the SPARSH fellowship on the topics like Company formation, Regulatory facilitation, IP masterclass, Business plan development, product prototyping etc.

Future Plans:

- During 2021-22, BIRAC in partnership with IKP Knowledge Park shall conduct a Grand Challenge in "Agri-technology Translation to Boost Farmers' Income" with the mandate to identify 'ready to deploy' and 'scalable innovations' in agriculture that will help in increasing the incomes of farming households. In this context, a series of innovative technologies, practices, products, services, business model and/or integrated solutions that have been piloted at a small scale in India will be identified, funded, monitored for field testing over a period of 30 months through a 2-stage process in this program. The focus of the Challenge will be to demonstrate increased incomes through deployment of selected technologies.
- For better outcomes and greater reach, i4 scheme guidelines would be reviewed and modifications introduced based on inputs received from experts and other relevant stakeholders.
- Challenge-based calls would be aligned to existing National Development Programs, Government Missions and Sustainable Development Goals of the Govt. of India.
- Outreach activities shall be strengthened further to popularize the scheme. Webinars/workshops would be conducted to appraise the potential applicants of the funding schemes and key elements of grant writing.
- New initiatives focussed on assisting start-ups along the product development cycle would be initiated.

5. 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), Biotherapeutics including Biosimilars and Regenerative Medicine, Vaccines, Devices and Diagnostics. The other theme areas for which BIRAC provides funding are Agriculture (including Aquaculture and Veterinary Sciences), Clean Energy & Environment (covering Secondary Agriculture) and Bioinformatics (including Artificial intelligence, Big Data Analysis, IoT's & software development).

BIRAC emphasizes that projects supported through its various funding schemes upon conclusion yield the targeted outcome in the form of products, technology, IPR, etc. Towards this end, BIRAC screens proposals under various schemes for their Technological Readiness Level (TRL) on a scale of TRL 1 to TRL 9 and filters in those having potential to reach higher TRLs through BIRAC support. Potential regulatory hurdles in the projects are already identified during the evaluation phase. Supported projects are regularly mentored and rigorously monitored. BIRAC assess the TRL progression of project through progress evaluation by Project Monitoring Committee (PMC) experts, either online or onsite, presentation of progress by project coordinators to 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 Fund (PCP Fund) to address the challenges faced by innovators towards commercial launching of their product and market expansion. BIRAC also facilitates regulatory assistance through FIRST-HUB to accelerate the approval processes.

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 2020-21, 42 projects completed Early stage validation and 27 projects delivered products/technologies which are at pre-commercial stage, market launched or commercialized.

1. Sector-wise

i Healthcare

a. Drugs (Including Drug delivery)

In the area of drug development BIRAC is trying to continuously fill the gaps and provide support for developing drugs to satisfy the needs for affordable treatment for a variety of diseases. The drug development programs at BIRAC includes discovery of small molecules, NCEs, repurposing of drugs, drug delivery platforms, In-vitro and In-vivo screening platforms for potential drugs This area also supports novel drug delivery models and platform technologies for targeted delivery and better bioavailability of various available drugs. The projects supported right

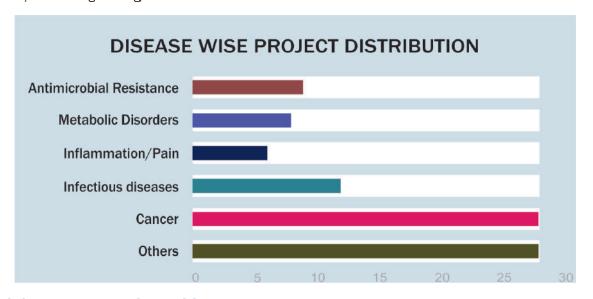


from the ideation or Insilco drug screening, establish proof of concept (PoC), preclinical studies of leads and clinical trials (Phase II and Phase III). The late-stage validation/ clinical trial projects are, the drug products undergoing Clinical trial projects have supported research for diseases such as Community-Acquired Bacterial Pneumonia CABP in Adults, Muscular Dystrophy, Breast Cancer, Solid tumours, Diabetic foot ulcer and inflammatory pain.

BIRAC has recognised few mission programs i.e., antimicrobial resistance and Cancer and therefore started joint programs with DBT where new drug therapies are being supported. The drug development program is focused on priority disease i.e. TB, COPD, CVD and cancers. AMR mission is focused to seek new innovative approaches that have the potential to transform public health action on a national or global scale by identifying and filling gaps in knowledge on the development of new antibiotics and alternatives to antibiotics to counter AMR.

Since March 2020 BIRAC has also provided grants for repurposing of drugs and new screening platforms against COVID-19.

Few platform technologies have successfully accomplished last year and are commercialized or ready to go to the next stage. The disease wise projection under this theme during last year shows that a large number of projects are supported for Cancer, infectious diseases, metabolic diseases and other disease areas such as skin & ear disease/ Tissue engineering/ arthritis.



b. Biosimilars and Regenerative Medicine

Currently a major shift from chemical-based drugs to biologics and biosimilars is being observed, across the globe which is largely driven by the increasing geriatric population, rising chronic diseases, and huge market demand as well as their enhanced acceptance. Also, the market demand for biopharmaceuticals is increasing as they are generally better targeted, come with fewer side effects, and can help to add more healthy years to a patient's life than other forms of treatment.

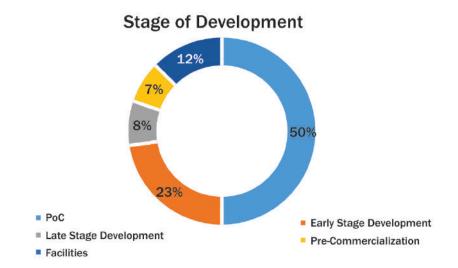
Biopharmaceutical products include monoclonal antibodies, recombinant growth factors, purified proteins, recombinant proteins, recombinant hormones, recombinant enzymes, synthetic immunomodulators, cell and gene therapies, and other products. Biologic drugs include a wide variety of products derived from human, animal or microorganisms using biotechnology and target mostly the genetic disorders and/or excessive immune response (including autoimmunity). In addition to niche indications, biologics are of utmost importance for targeting widespread diseases with an increasingly higher incidence rate and profound implications including cancer. Further, the recent COVID-19 outbreak has been creating a huge burden on healthcare systems which also includes a high demand for monoclonal antibodies targeting COVID-19. The regenerative medicine holds promises for the treatment and, possibly, the cure of a number of challenging conditions in health sciences and relies on the usage of stem cells, tissue engineering, and gene therapy alone or in different combinations towards repair, regenerate, or replace the damaged ones.

BIRAC supports innovative translational research from ideation to commercialization of Biopharma products. To further enhance the research and development of biopharmaceuticals, "National Biopharma Mission" a collaborative mission of industry and academia with a corpus of USD 250 Mn has been implemented by BIRAC (initiated by DBT in collaboration with World Bank). Several projects towards development of different biosimilars & regenerative medicines and the process optimization of existing products and their validation in this area for



increasing the present market share/output in the country have been supported by BIRAC. Further, to nurture the 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. Major areas considered under this theme include media and feed supplements, protein purification technology, IT platforms for quality management systems in biopharmaceutical Industry, Bio-better and biotherapeutics, Antibody Drug Conjugates, CAR-T therapies etc.

Maximum number of supported projects are towards development of Proof of Concept (PoC) or Early Stage Validation of the developed PoC



Stages of different projects under the area of Biosimilars and Regenerative medicine (including other Biopharmaceuticals)

Different diseases like Cancer, Diabetes, Inflammatory diseases, Alzheimer's have been targeted by the BIRAC funded projects. Further development and validation of different platform technologies for producing affordable monoclonal antibodies have also been promoted. The bio-therapeutics under focus include Foligraf, Rasburicase, Trastuzumab, Aflibercept, Sinapultide-A, Bevacizumab, Trastuzumab, Liraglutide, Glargine etc.

Under the thematic area of regenerative medicine, projects have been supported for stem cells isolation (device development, media formulation), their expansion and usage of different stem cells (Embryonic stem cells, Tissue-specific stem cells, Mesenchymal stem cells, induced Pluripotent stem cells) for various disease indications including Periodontal Tissue repair, urethral strictures, urinary incontinence etc have been funded. Conduct of clinical trials in the field of regenerative therapy as well as preparation of Stem cell Bank has also been funded by BIRAC.

Projects supported for Covid-19 treatment:

Various projects have been supported by BIRAC under this thematic area, in search of a promising intervention for Covid-19. Projects that have been funded include usage of therapeutic antibodies from convalescent patient blood or Equine sources, generating antibodies using phage-displayed human antibody library, phase I/II clinical trial for safety and efficacy evaluation of convalescent plasma and novel COV-trap therapy to reduce the Covid-19 Infection intensity. Further, with the aim of developing efficient model systems BIRAC has also funded projects for development of in vitro lung organoid model and human ACE2 transgenic mouse as well as iPSC-derived lung airway and alveolar epithelial cells based model (ready for use for researchers) for screening of different prophylactic and therapeutic candidates against SARS-CoV-2.

Following Products/Technologies have completed early-stage technology Validation in 2020-21.

1. VIRAFIN- Pegylated Interferon alpha-2b in treating moderate COVID-19 infection in adults

BIRAC supported Phase II human trials Zydus for the use of Pegylated Interferon alpha-2b, 'Virafin' in treating moderate COVID-19 infection in adults. Study was conducted on 40 patients. A single dose of the antiviral Virafin administered subcutaneously early on shows significant clinical and virological improvement in moderate COVID-19 adult patients. 91.15% of patients treated with PegIFN were RT PCR negative by day 7. The treatment significantly reduces the hours of supplemental oxygen in the patients.



c. Vaccines

Vaccine development has played an important role in combating infectious diseases and may help tackle outbreaks in the future. Vaccine development require:

- High throughput research and development infrastructure,
- Scale-up facilities
- · Policy driven decisions
- Government prioritization
- Investment and multi-sectoral partnerships.

Covid-19 has taught us to strengthen our preparedness to:

- Explore new and promising vaccine candidates
- Build animal models for fast track clinical trial studies/data
- And scale-up the vaccine production once we have the right candidate (indigenous and/or outside),

Global trends in vaccine development indicates that industries are developing vaccines mostly for the viral diseases followed by bacterial, cancer and protozoan diseases. BIRAC followed the same trend and supported 40 projects (excluding vaccines for Covid-19) for vaccine development through its various schemes.

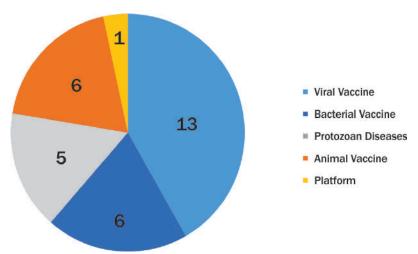


Fig: Indication of vaccines projects supported by BIRAC.

Vaccines for Rota-Virus (Rotavac), Japanese Encephalitis Virus Vaccine (JEEV), and H1N1 swine flu Vaccine (Pandyflu) are in the market. Three Products i.e. Influenza Vaccine & Vaccine for Marek's Diseases and Vaccine for Parovirus is ready for Commercialization while several vaccine candidates are in clinical trials like vaccine for HPV, Pneumococcal vaccine, Para-tuberculosis and more.

World Health Organization declared COVID-19 a global pandemic in March, 2020. There were no vaccines or therapeutics available to control the death rate associated with this pandemic problem. Governments around the world have sought to find ways to suppress the spread of the virus. BIRAC realised the pressing need and immediately formed a Covid consortium research unit and announced a call for proposals to address the Covid-19 problem. Fourteen projects were supported for the Vaccine development and its associates. Eight projects were supported for the development of vaccines utilising different strategies proposed by small and large vaccine Industry and academic Institutes, while 6 projects were supported for the development of different assays, reagents and animal models required for the development of vaccines. Out of the 8 vaccine candidates 4 are in clinical trials and very soon will be available for public uses.



Another major step was **Mission COVID Suraksha**, established by DBT and the implementing agency is BIRAC; the focus of this mission was to consolidate and streamline available resources towards a warpath for accelerated vaccine development. This is a National Mission working to bring to the citizens of the country a safe, efficacious, affordable, and accessible COVID vaccine at the earliest with a focus on Atma Nirbhar Bharat and fulfil our commitment of serving not just the country but the entire globe. The major objective of the mission are as follows:

- Accelerating the production of clinical trial material, and clinical development for licensure of COVID-19 vaccine candidates.
- Establishing clinical trial sites, immunoassay laboratories, central labs and suitable facilities for animal challenge studies, and other testing facilities to support COVID-19 vaccine development

Under Mission Covid Suraksha, the first request for expression of interest (ROEI) was announced in December 2020. Five advanced vaccine candidates were supported under this call.

Following Products/Technologies have completed early stage validation in 2020-21:

1. DNA Vaccine against novel Coronavirus SARS-CoV-2 (Cadila Healthcare Limited)

Zydus DNA vaccine candidate against SARS-CoV-2, ZyCoV-D is a DNA plasmid Vector carrying S gene of 2019-nCoV spike-S protein. The spike(S) region includes the receptor binding domain (RBD), which binds to the human angiotensin converting Enzyme-2 (ACE-2) receptor and mediates the entry of virus inside the cell. This 3-dose

vaccine which when injected produces the spike protein of the SARS-CoV-2 virus and elicits an immune response mediated by the cellular and humoral arms of the human immune system, which play a vital role in protection from disease as well as viral clearance. The plug and play technology on which the plasmid DNA platform is based can be easily adapted to deal with mutations in the virus, such as those already occurring.

This vaccine has already exhibited a robust immunogenicity, tolerability and safety profile in the adaptive Phase I/II clinical trials. Phase III clinical trial is ongoing. Both



the Phase I/II and Phase III clinical trials are being monitored by an independent Data Safety Monitoring Board (DSMB).

2. Asia specific 15 valent Pneumococcal Polysaccharide – CRM 197 Protein Conjugate Vaccine (Tergene Biotech Pvt. Ltd.)

Pneuteger 15 Pneumococcal polysaccharide conjugate vaccine (adsorbed) is a sterile solution of capsular purified antigens (polysaccharides) obtained from Streptococcus pneumoniae serotypes 1, 2, 3, 4, 5, 6A, 6B, 7F, 9V, 12F, 14, 18C, 19A, 19F and 23F individually conjugated to CRM₁₉₇ which acts as a carrier. The program is supported under the National Biopharma Mission for Phase I, II and III human clinical trials. Company has



completed Phase I/II clinical studies. Six batches of PCV-15 have been manufactured for use in Phase III clinical studies. All the six batches were found to be of standard quality by CDL, Kasauli and approved for use in human clinical trials. Phase III CT currently ongoing.

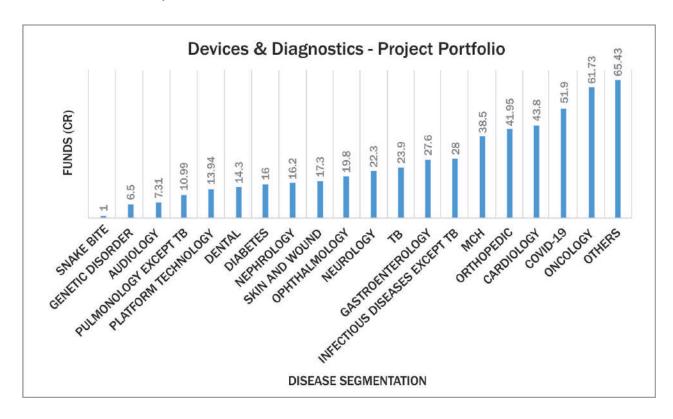


d. Devices and Diagnostics

The medical devices market of India was valued at \$13.60B in 2015, which increased to \$18.20B in 2020 at a CAGR of 5.92%. The medical devices market is expected to grow at a CAGR of 8.15% from \$18.20B in 2020 to \$26.92B in 2025.

The Indian medical devices market is the 4th largest market in Asia and among the top 20 markets in the world. The medical devices industry of India consists of large multinationals as well as small and medium enterprises (SMEs) growing at an exceptional rate. (Source: Global data)

As per the analysis of BIRAC projects, a total number of 526 projects are supported in devices & diagnostics sector with investment of INR 515 Crore. The successful projects under this theme have gone up with 81 commercialised products as compared to 60 products commercialised last year. Number of IP filed also stands increased with 154 IPs as compared to 114 in last year. Regulatory facilitation is provided to 200+ innovators. Oncology is the highest funded sector followed by COVID-19 at BIRAC.



During the pandemic, DBT and BIRAC initiated the COVID-19 Research Consortium to facilitate the holistic development of the diagnostic ecosystem of the country. Under this initiative around 32 projects addressing the different domains of diagnostics development were supported. The projects portfolio includes Nucleic acid detection kits, Antibody and Antigen detection kits and artificial Intelligence based screening platforms. Further, the support was also extended to the development of raw materials like probes, primers, material transport medium, swabs and nucleic acid extraction kits.

To maximise the impact of facilitation provided to the COVID-19 diagnostic innovators, 360-degree guidance was provided through the special sessions of FIRST HUB on COVID-19. The most prominent challenges faced by Startups of the devices and diagnostic sector are improving the quality of products, support for regulatory certifications, clinical investigations, facilitation for GeM registration and access to testing and standardisation labs.



Following Products/Technologies are Market launched or Commercialized in 2020-2021:

1. Diabetes Management Device and Test Strips (PathShodh Healthcare Private Limited)

SMGC is an easy to use handheld IVD diagnostic device based on cutting edge patented technology. The SMGC device is capable of measuring three important biomarkers in finger prick blood samples which gives a comprehensive diabetes management. The current tests are Blood Glucose, HbA1c and Glycated Albumin. AnuPath-Lite Device ready for market launch



2. Emvolio- A portable, battery-powered vaccine carrier (Blackfrog Technologies Pvt. Ltd.)

Emvolio is a portable, battery-powered refrigeration device that will strictly maintain any pre-set temperature for over 12 hours for the last mile transport of vaccines. Emvólio's 2-litre capacity enables it to carry 30-50 vials, which is standard for a daylong immunization campaign. Emvólio device stands apart for its unmatched portability and ease of charging. Blackfrog is an ISO 13485 certified manufacturer of medical-devices and Emvólio has been designed in accordance with WHO-PQS E003 standards. Product was launched during Global Bio-India 2020. Prospective Customers: Non-profits Organizations engaging in Immunization, private hospitals and Government for use in Primary and Sub Health Centres.



3. Grippy™- An Advanced Prosthetic Hand with a sense of touch and multi-grip control (Robobionics Private Limited)

Grippy is 3D printed, lightweight and affordable, battery-powered prosthesis for people with below elbow amputation and aged 15 years and above. Sense of Touch and Multi-grip control features at an affordable price makes Grippy competitive in the market. Product is targeting Limb Fitting Centres, Hospitals with Department of Physical Medicine and Rehabilitation NGOs. Device has passed electrical compliance testing and has received a No Objection certificate from CDSCO for manufacturing and sales. User validation studies have been completed for Grippy and advanced clinical studies are underway. Product was market launched at Global Bio India 2020





4. easyNav[™]- computer-guided C-Arm/CT based Surgical navigation system (Happy Reliable Surgeries Private Limited)

easyNav™ combines precision and simplicity to provide 2D C Arm based navigation experience. The Navigation system is compatible with a wide range of image intensifier C-Arms as well as flat panel C-Arms. Its Automatic Registration is well suitable for open, small incision and minimally invasive spine surgeries. It reduces X-Ray exposure to the surgical team and the patient by reducing the number of C-Arm shots taken during the surgery. In addition, easyNav™ navigation software enables intraoperative integration of 3D C-arm for spine surgeries which allows automatic registration of intraoperative scans. The quick and reliable automatic image registration combined with pedicle screw planning makes surgeries more precise and safer. Axial view acquired from 3D C-Arm ensures better accuracy in minimally invasive surgeries. The product was launched at Global Bio India, 2020.



5. Low cost Face Shields for the Protection against COVID-19 (Alfa Corpuscles Private Limited)

Efficacy of Face Shields Against Cough Aerosol Droplets is well studied and proven and its use can substantially reduce the short-term exposure of health care workers to larger infectious aerosol particles. Alfa Corpuscles Face shield is made up of clear PET plastic, tested for Refractive Index and has comfort fit foam and headband. Through BIRAC support, the manufacturing machinery required for scaled up production was established to meet the market demand. This product is sold in the market at a very competitive price.



6. Affordable Breathable Suraksha PPE Kits (Aarna Biomedical Products Pvt. Ltd.)

The Company has established manufacturing of High quality Affordable Breathable Suraksha PPE Kits - Genuine Heat Taped Coveralls available in reusable and one-time-use configurations for Health and Non-Health workers. The Company uses SITRA certified TPU fabric, has DRDO-INMAS Certification and OFB-MURADNAGAR Certification for the product.





7. GOassure- Automated Hand Sanitization device (MicroGO LLP)

GOassure is an IOT enabled fully automated hand hygiene device which digitalizes the hand hygiene process. GOassure ensures that the users perform hand hygiene as per the WHO recommended six steps of hand hygiene and notify the variation (or non-compliance) to the authorities/health officer/managers. Scale up of the product was supported and the product was deployed at various national airports and various private and public places.



8. PathoDetecttm 2019-nCov RT-PCR kit (Mylabs Discovery Solutions Pvt Ltd)

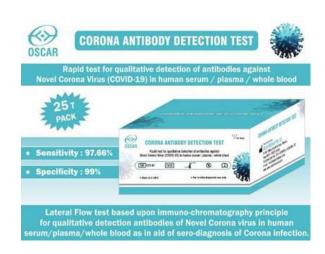
PathoDetect TM is the first RT-PCR diagnostic kit against SARS COV-2 approved CDSCO in India. Scale-up manufacturing and semi-automation of the PathoDetect kit was supported through National Biopharma Mission under Covid-19 consortium funding. Company has done automation processes (Liquid handling systems and other Automation) to enhance their production capacity to 2,00,000 tests per day. In addition, MyLab has optimized the kits to 1 tube 1 step format with 3 markers for COVID-19. MyLab had manufactured over 25 lakhs PathoDetect kits for meeting the emergency requirements of the market.



Lateral flow test for SARS-COV-2 specific IgG & IgM from human sera (Dhiti Life Sciences Pvt. Ltd)

Fully indigenous Novel Coronavirus Antibody Detection Rapid Test which has received approval from ICMR (with 97.66% sensitivity and 99% specificity from three batches). It is a point of care rapid test with testing time less than 30 minutes.

The kit is manufactured and marketed at large scale by sister concern Oscar Medicare Pvt. Ltd using 100% indigenous recombinant antigen specific to novel coronavirus. The Recombinant Antigen (encompassing immuno-relevant fragments of nucleocapsid and spike protein of novel coronavirus) has been developed in the DSIR approved lab of Dhiti Life Sciences Pvt. Ltd after due permission from IBSC. Company has a production capacity of 5 Lakh test/day.





QuantiPlus 2019nCoV RT-PCR Kit & Complete molecular diagnosis solution for Covid-19 multiplex assay (Huwel Lifesciences Private Limited)

Huwel Lifesciences Private Limited have developed and commercialised three products from the project supported. The QuantiPlus 2019nCoV RT-PCR kit was developed and sold about 230 Lakhs tests. Along with the kit they have also developed and commercialised the Molecular Transport Medium/ viral lysis medium (sold 21 Lakhs tests) and the Nucleic Acid Extraction kit (sold 25 Lakhs tests)





RT-PCR Kits, Molecular Transport Medium and Nucleic Acid Extraction kits

11. SENSIT Rapid COVID-19 Ag kit (Ubio Biotechnology Systems Pvt. Ltd.)

Ubio has developed "SENSIT Rapid COVID-19 Ag kit" for rapid and qualitative detection of SARS CoV-2 Nucleocapsid Protein from nasopharyngeal swabs. This ICMR approved kit is a chromatographic immunoassay, which allows the healthcare personnel to visually read the test result. The test works on the principle of sandwich immunoassay and utilizes a pair of monoclonal antibodies which when bound to COVID-19 specific antigen, result in the appearance of a coloured line. The kit exhibits sensitivity and specificity of 86% and 100%, respectively and has a shelf life of 24 months. SENSIT COVID-19 Rapid Antigen Test Kit has been successfully commercialised.



12. SENSIT Covid IgG/IgM Ab Test (Ubio Biotechnology Systems Pvt. Ltd.)

The Company has also developed Sensit Covid IgG/IgM Ab Test. The IgG/IgM test cassette is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to 2019-nCoV in whole blood, serum or plasma specimens. The clinical evaluation data suggests that the test possesses a high degree of sensitivity (93.33 % IgG, 95.00 % IgM) and specificity (100.0% IgG, 92.0% IgM) for detecting SARS-CoV-2 specific antibodies. The kit has been commercialized.





13. Covid MedTech Manufacturing & Development Zone (Andhra Pradesh MedTech Zone LTD)

DBT-AMTZ National COMManD Consortium [COVID MedTech Manufacturing Development] is a national manufacturing facility established to address the shortage of critical medical equipment in India and move progressively towards a stage of self-sufficiency. It is established at Andhra Pradesh MedTech Zone (AMTZ) at Visakhapatnam, Asia's first medical equipment manufacturing ecosystem, uniquely dedicated for MedTech and is supported by the Department of Biotechnology under the National Biopharma Mission. AMTZ COMManD Consortium enabled rapid scale-up of manufacturing of critical medical equipment, such as ventilators, RT-PCR based diagnostic tests, IR thermometers and other diagnostics equipment and reagents were successfully scaled up to address their growing demand across the country. Overall at least 7 of the above product categories were scaled-up and sold in the market as detailed below

The Critical Care Ventilators were Market launched and the model devices Swasit (Basic), Swasit + (Advanced), Numo (Basic), Live Vent 100(Basic and Advanced), Live Vent 1000(Basic and Advanced), 4500+ basic units and 1000+ advanced units have been sold.







Numo Ventilator

Live Vent Ventilator

Swasit Ventilator

They have also developed and Market launched the RT-PCR kits- Covid sure, TrueNat and Covido19 Fast -total of 700 Lakhs+ test sold. Also ErbaLisa Covid-19 Ig-G kit manufactured and market launched







TrueNat RT-PCR kit



Covido19 Fast RT-PCR kit



ErbaLisa COVID-19 IgG



They have also developed and Market launched the Vi-sure and XPERTS Viral Transport Media kits -total of 11 Lakhs+ test sold.



Vi-sure Viral Transport Media kit



XPERTS Viral Transport Media kits

They have also developed and Market launched the Asha Plus- IR Thermometer and a total number of 3000+ units sold.



Asha Plus- IR Thermometer

The first infectious disease mobile laboratory (I-Lab) was developed and deployed for COVID testing in inaccessible areas. This is a mobile diagnostic unit with biosafety facility. The I- lab is a BSL-2 facility with on-site ELISA, RT-PCR, Bio chemistry analysers. It can run 50 RT-PCR reactions and about 200 ELISA in a day.



Infectious disease mobile laboratory (I-Lab)

All these diagnostic kits and equipment have been used as successful intervention measures against COVID-19 pandemic in the country.



Following Products/Technologies have completed technology validation in 2020-21.

1. SARS-CoV-2 qPCR Kit (Yaathum Biotech Private Limited)

Anindigenous multiplex real-time RT-PCR based molecular diagnostic test to detect the SARS-CoV-2 virus in upper and lower respiratory specimens (naso/oropharyngeal swabs) of COVID-19 suspected individuals. The multiplex real-time RT-PCR Kit comprises three primer sets and 3 probes targeting 3 different regions (E, N, orf1ab) in genomic RNA of SARS-CoV-2 and primer and probe set for RNAse-P internal positive control and mastermix. They have been multiplexed to target them within the same PCR reaction. Labelling, Packaging formats and designs finalised. ICMR approval received. Enzyme mixes TaqPol and RT will also be offered separately (if needed at large scale).



2. MagGenome Xpress Molecular Transport Medium and Xpress RNA Viral Kit (MagGenome Technologies Pvt. Ltd)

MagGenome Xpress Molecular Transport Medium is designed and optimized for molecular testing allowing pathogenic samples to be collected, transported and processed safely and efficiently. MTM is produced with molecular grade reagents which are DNase, RNase, and protease-free. The kit components are two sterile swabs (nasal and throat) and the sterile bottle which contains MTM solution. Swabs are made of nylon and MTM is stored in a sterile polypropylene centrifuge tube with a cap. MagGenome's Xpress RNA Viral Kit is designed for rapid and reliable isolation of total viral nucleic acids from oral and nasopharyngeal swabs soaked in virus transport media or other buffers. This kit is highly efficient in viral nucleic acid isolation and the extracted RNA is suitable for direct use in most downstream applications such as one step RT-qPCR, RT-PCR, PCR and nucleic acid amplification. Both MTM and RNA isolation kits developed through BIRAC support have been validated and approved by ICMR.



3. V-Media- Viral Transport Media for SARS-Cov-2 diagnostics (Levram Lifesciences Pvt. Ltd)

Levram has developed Viral Transport Media which can lyse the virus, preserving its DNA/RNA. Levram have completed Multi-Centric Trials at NABL accredited centres and performance evaluation report is submitted to CDSCO for commercial license. The company is awaiting manufacturing license. They have production capacity of 400000 tests / month.

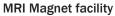




4. Next generation Magnetic Resonance Imaging scanners (Voxelgrid Innovations Pvt. Ltd)

Voxelgrid Innovations Pvt. Ltd has developed India's first MRI scanner. The company has received ISO13485 certification for the manufacturing of MRI scanners. They have completed volunteer studies on 10 individuals for performance evaluation of the MRI scanner.







MRI scanner

DRIPO - Wireless Infusion Controller over IOT mesh network. (Evelabs Technologies Pvt Ltd)

Dripo is a Smart Infusion Monitor Wireless electronic monitor to measure and display the flow rate in gravity infusions and share the data wirelessly. Dripo is a portable connected infusion monitor that helps a health practitioner to set infusion rates accurately and monitor it from anywhere. It counts the drops and calculates real-time drop rate so that the nurse can set fluid flow precisely and efficiently without much training.



I-Doctor: An intelligent diagnosis and drug dispensing platform (Persistent Systems Pvt. Ltd)

I-Doctor is an intelligent platform for diagnosing clinical conditions and deciding on prescription accordingly and also dispensing drugs using drug dispensing platforms. This diagnosing algorithm connected to multiple point-of-care devices like ECG, BP apparatus, thermometer. i-Doctor independently diagnoses most common clinical conditions, it has a follow-up mechanism with an assigned doctor to ascertain the correctness of diagnosis and ensure the well-being of the patient



7. Warrior: Smart Antiviral Coatings (Reinste Nanoventure Pvt Ltd)

The antiviral coatings developed by Reinste based on nano copper are long lasting solutions for making all kinds of surfaces capable of not allowing viruses and microbes to propagate through surfaces. These coatings provide a shield and protects from virus and other bacterial, fungal exposures. The product is backed by silver ions technology that inhibits and deactivates the viruses with-in minutes of exposure to the surface automatically. The product is suited for Hospitals, Home isolation units, Public Transport places, Public places, Offices and buildings where large numbers of people move.





8. Automatic Reprocessing System to reprocess medical devices to meet healthcare demand (Incredible Devices Pvt ltd)

Advanced Reprocessing System is a device which safely reprocesses the parts of ventilators like ventilator circuits and expiration parts, catheters, balloons to ensure doctor & patient safety and resolves all challenges related to manual reprocessing. It is a computer aided fully automatic machine which works on a patented technique. It eliminates human errors.



Field validation of Z-Box: A device to reduce the spread of infection in Healthcare Environments (Biomoneta Research Pvt Ltd)

ZeBox Technology powered devices use air as a carrier medium to extract microbes from air and nearby surfaces and use a proprietary kill mechanism to eliminate viruses, bacteria, fungi and spores with very high efficiency. The devices are capable of eradicating billions of microbes in less than 10 minutes under test conditions.

ZeBox-Mid and ZeBox-Mini devices have been tested at ICU settings to prove its efficacy in reducing microbial loads in a sterile hospital environment. The plug-and-play devices create localized near-sterile bubbles whenever and wherever required. Future studies are underway to show its efficiency in reducing infection rate.



10. EndoMimyk - Immersive Endoscopy Simulation Platform for training (Mimyk Medical Simulations Pvt. Ltd.)

EndoMimyk endoscopy simulator enables the doctors to train for complex manoeuvres and hand-eye coordination in a safe virtual world with haptic feedback. It offers realistic visuals, haptic feedback, and auditory guidance for complete immersion. It also has modules for training in advanced GI diagnostic and therapeutic procedures. Assessment and tracking frameworks implemented into the system will allow for trainees to monitor their progress. Near final version of the device and training algorithm has been developed and enduser feedback received from novices and experts.

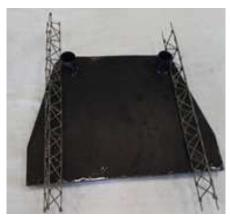




11. Radiolucent carbon Fibre truss Structures for patient support (Unicita Consulting Private Limited)

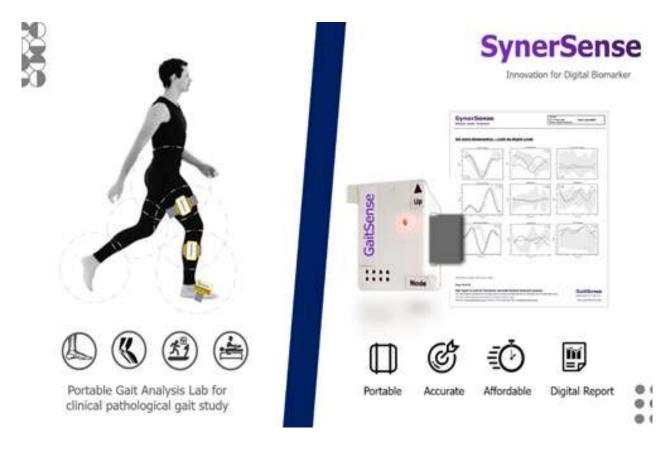
State of the art radiolucent carbon fiber truss structures for X ray machine's patient structural support applications has been developed by Unicita Consulting Private Limited. This is an affordable import substitute and improves the quality of health care in India by reducing radio dosage and the occurrence of artefacts.





12. GaitSense™ - Wearable and portable gait monitoring device (Synersense Pvt. Ltd.)

GaitSense™ is a wearable motion capture patented portable gait analysis system, high accuracy, scientifically validated and cost-effective. It is based on medical innovative technology for Biomechanical Body-Movement, Digital Biomarkers parameters and customized objective digital clinical report in Gait Analytics Software platform to help doctors in orthopaedic, neurological, geriatrics and physiotherapy healthcare segments. Clinical investigation performed on 10 orthopaedic disorder patients and 25 normal subjects. More than 150+ gait tests data points were collected and performed users trial study.



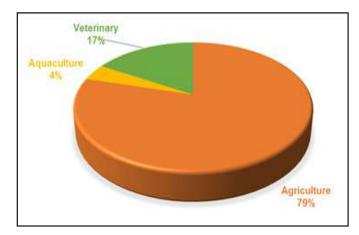


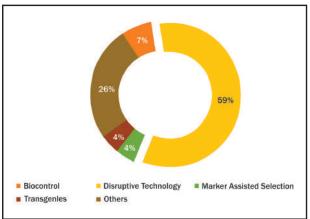
ii. Agriculture

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

BIRAC has been supporting technology intensive projects in agriculture and allied areas like veterinary and aquaculture sciences. Under Agriculture, the pipeline of projects supported have been grouped under five major technology areas i.e., Marker assisted selection, transgenics, biocontrol, disruptive technologies. Major progress has been made under various disruptive technologies which have the ability to transform every link in the food chain. Technologies such as IOT/sensors, Al/machine learning, mechanics, remote sensing, pheromones, food grain storage, drones, nano biofertilizers, genome editing, application development, nanopesticides etc residue testing by Matrix-assisted laser desorption/ionization (MALDI), seed invigoration by magneto-priming, etc. are being encouraged under entrepreneurial ventures to put Indian stakeholders at par with the global players.

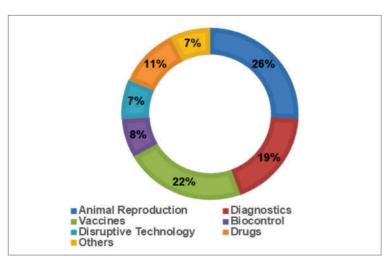
Under aquaculture and marine biotechnology the supported projects mainly deal with disease detection, diagnostics and control. Some of the major projects supported are in the area of WSSV diagnosis and their control for Shrimp. Under veterinary science, some of the research areas supported include animal reproduction, Vaccines, Disruptive technology, Diagnostics, Biocontrol and Drugs.





AREAS WISE DISTRIBUTION OF PROJECTS

RESEARCH AREAS UNDER AGRICULTURE



RESEARCH AREAS UNDER VETERINARY



Following Products/Technologies are Market launched or Commercialized in 2020-2021:

1. Point of care Diagnostics for Equine Glanders and Equine Infectious Anaemia (Genomix Molecular Diagnostics Pvt. Ltd and National Research Centre on Equines, ICAR-Hisar).

Glanders and Equine Infectious Anaemia (EIA) of equines are notifiable diseases in India. Constant surveillance and monitoring are the most important aspects to combat these diseases for which cost effective with good sensitivity and specificity rapid detection tests are important and necessary. Genomix molecular diagnostics developed Point of Care Lateral flow assay and ELISA using recombinant Hep1 protein for Glanders and ELISA using recombinant P26 protein for EIA. The sensitivity of the Lateral flow assay for Glanders developed is only 80% whether Hep1 is used alone or in combination with other proteins. Independent validation of the kits has been done at national level. Developed ELISA kits were tested in house with the sera panel (a total of 400 clinical serum samples out of which 310 negative samples and 90 positive samples for glanders and six positive samples for EIA) and found 99.3% sensitive and 99.6% specific. KIT for Glanders has been validated both at National reference lab as well as OIE reference lab, however KIT for EIA has been validated at National reference lab only. Both the kits have been commercialized.





Following Products/Technologies have completed technology validation in 2020-2021:

1. Decision support system (DSS) for providing information over farms in real-time (Aapah Innovations Private Limited)

The technology supports a Decision Support System (DSS) which provides hyper-local (at 10-20 m) information over farms in real-time. The DSS provides the following information i.e. Crop water stress and crop water requirement, ii) The health of the crop, likely crop yield, iii) Warning for drought and flood, iv) Impact of pest/disease on the crop, v) Regional drainage analysis. Information is targeted at: i) FPOs, cooperatives, etc, ii) Govt departments working for farmers, iii) Agriculture input firms, etc. Acquired paying customers including the start-ups, farmers in different parts of India and globally





2. Technology assistance software and hardware for preventive protection against pests & diseases in crops to reduce the losses and increase the yields (Leancrop technology solutions pvt. Ltd.)

Development of technology for preventive disease management and upgradation to the predictive advisory. Program can predict the occurrence of diseases in advance (4-5 days before any visible symptom) with an accuracy of ~95%. A base algorithm provides preventive actions for saving crop losses. Solution has been developed by the company for the prediction of diseases for crops - Groundnut and Onion (major crops in Maharashtra and Gujrat) Groundnut – Stem rot, Late Leaf spot, Onion - Stemphylium blight, Anthracnose. The current solution is used by 1,50,000+ farmers across Maharashtra. Farm personalization and management is a paid feature and is used by 32,000+ farmers



3. Portable Arsenic testing Kit (Dtronics Technology Private Limited)

The company has developed a colorimetric method based on Arsenic detection from ground water. The uniqueness of the developed system is uniform illumination-based image analysis technique for detection of the arsenic amount in the water samples. Moreover, the developed technique looks into both Arsenic III and Arsenic V for calculating the arsenic amount in the ground water samples.

Conventional kits available in the market develop colour that one has to match this reference colour pallet provided with the conventional kit. Basic problem with this process is that matching the test strip colour with the reference colour through naked eyes is unscientific and results vary from person to person.

Uniform illumination arrangement was introduced for capturing the colour developed due to presence of arsenic. After capturing the image, a soft computing algorithm technique is used for accurate detection of the arsenic amount.

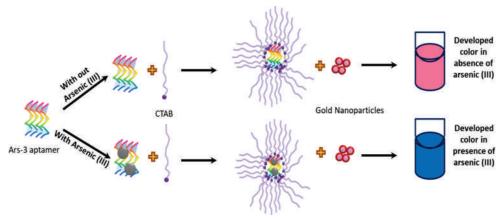


Fig.: Protocol for detection of Arsenic using Gold nanoparticles and Aptamer



Aeroponic technology for the Coleus forskohlii and Vetivera zizanoides for improved production of roots containing active principles (Dr. Gowsiya Shaikh)

Dr. Shaikh has established the aeroponic technology growth under aeroponic technology when compared to soil culture. They have achieved higher levels of metabolites in aeroponics as compared to soil.

5. Soilscape-Point of use soil health analyser (Upsoil **Technologies Pvt. Ltd.**)

A Point-of-Use rapid nutrients testing and soil health analyser or Soilscope (Formerly Soil-Pen) was developed. The prototype is ready and the testing and analysis of the prototype, refining the design by comparing to the existing methods and reiterating the prototyping has been achieved. Product user interface improvement and refining, Analysis of the product achieved in the given timeline and improvements along with sensors. 17 elements and some of the micronutrients are being analysed.



Pesticides are vital in ensuring farm productivity, meeting the domestic need of food produce, and generating revenues by supplying other countries that depend on imports from India. However, excessive pesticide residues are hazardous to health raising a worldwide concern for food safety. To prevent any unwanted toxicities from pesticide content, permissible residue levels are strictly regulated both internally by organizations such as Agricultural and Processed Food Products Export Development Authority (APEDA) and by export market regulators ex. US FDA. Currently, LC-MS is the gold standard testing method used worldwide for the quantitative determination of pesticide residues in various foods. Inherent limitations of LC-MS include high cost infrastructure and recurring costs along with the limited number of samples that can be analyzed (~ 40 per day).

Barefeet Analytics has previously developed and demonstrated the use of an innovative analysis solution along with validating it in a field trial of 20 acres. This approach using an atmospheric pressure (AP) ionization source coupled with mass spectrometer analyses 500-800 samples/day and conforms to the regulatory requirements on par with LC-MS.

commercial aeroponic platform for vetivera and coleus plants under aeroponic conditions. They have achieved 8 folds higher vetivera root growth and 5 times higher coleus rhizome





Bio-pesticide formulation using the seed extract of Hydnocarpus pentandra (Varsha Biosciences Pvt Ltd.)

Insect pests cause major damage to agricultural and forestry crops and pose a big challenge to farmers. Synthetic insecticides were extensively used to control insects leading to serious threat to human health and environment. Botanical biopesticides are environmentally friendly, safer natural alternatives to synthetic insecticides for insect control. They effectively control insect pests through various mechanisms, such as antifeedant, repellent, inhibiting the growth, development and/ or reproduction of pests or pathogens. India, being the tropical country with dynamic plant diversity is the source of plant protection phytochemicals. The potency of phytochemicals in India is not fully explored. This research project brought out the oil formulation from the seeds of a forest plant, Hydnocarpus pentandra grown across Western Ghats. Through the support of BIRAC, Varsha Bioscience and Technology India Pvt Ltd and Institute of Forest Genetics and Plant Breeding have developed a stable, effective insecticidal formulation from the Hydnocarpus seed oil to control agricultural and forest insect pests.





8. Agri Nurture for integrated Soil nutrient management (One Acre Venture Pvt Ltd)

Agri nurture is a digital ICT based application for the soil nutrient management system to improve agricultural productivity and improve the farmers livelihoods. Agri Nurture uses a mobile front-end to capture the soil quality and on the basis of the crop to provide the right recommendation with the right doses of those nutrients which are locally available. A unique mobile based engaged system will be designed to disseminate the information and knowledge on a continuous basis to the farmers. This platform triggers the development of an ecosystem, which uses AI to drive decision-making for small farmers and in the process incentivizes the user [Agri retailer] to maintain continuous and reliable engagement with the farming community. The data is consistently and constantly updated through transactions, enabling the creation of a digitized knowledge, which maps the farmer's cropping journey and his nutrient engagement behaviour. A personalized soil health card/portfolio is maintained on a continuous basis and the farmers are alerted on the soil health to ensure their crop productivity.

9. New Hybrid Orchids (Kwaklei and Khonggunmelei Orchids Pvt. Ltd.)

Utilization of the rich orchid resource of India can be achieved through breeding of the potential species either for pot plant or cut flower. The company has been focusing mainly on synthesis of new hybrid orchids using potential parents available in India, particularly in the north-eastern states. Elite genotypes of the already synthesized hybrids have been selected and propagated. Further breeding work has been carried out.

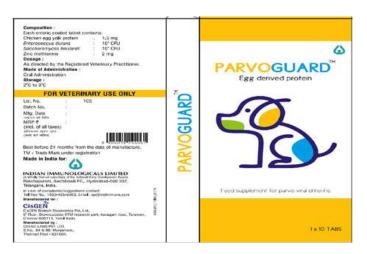
Approximately 100 primary as well as secondary hybrids are maintained in the laboratory and greenhouse. Under this project clonal propagation of some of the elite hybrids is performed. Two hybrids viz., i) Renantanda Kebisana Shija x Vanda coerulea and ii) Renantanda Kebisana Shija x Aerides odorata have flowered. The former hybrid has been registered under the grex Renantanda Najma Heptulla (RHS registration No. P. 27000) while the later as Nobleara N. Biren; (RHS Registration No. P 28557). Newest hybrid has flowered in the current season with variation in the sibling population. Pictures of four of the selected F1 flowers are following:





ParvoGuard[™] - Clinical evaluation and scale-up of a novel therapeutic formulation for treating a fatal viral disease of dogs (Cisgen Biotech Discoveries Pvt. Ltd)

They scaled-up and evaluated "IgY based enteric protected tablets against Canine Paroviral enteritis" The tablets can be used as prophylaxis and treatment against canine Parvoviral enteritis. Enteric protected tablets containing Chicken egg yolk protein, probiotic organisms and Zn methionine as prophylactic feed supplement for Canine Parvoviral enteritis. Indian Immunologicals Ltd. had agreed to sell the prophylactic feed supplement.



11. Synbiotic feed supplement as immune booster against mycoplasma infection in poultry (Sir M Visvesvaraya Institute of Technology, Bengaluru)

Two products were developed through this project for the prevention and treatment of Chronic respiratory disease in poultry. Product 1 comprises the Synbiotic combination consisting of 6 strains of Probiotics developed in synergy with Prebiotics like MOS, FOS and a novel prebiotic-Grape seed extract. This process is easy to scale up to produce a larger quantity of biomass. Trials conducted in broilers, egg layers and breeders with the Synbiotic formulation, depicted an immunity boosting activity in prevention of the occurrence of CRD and other secondary diseases/infections. he results on par with the studies conducted with Antibiotics in terms of maintaining body weight gain, feed consumption, FCR, reduced mortality, reduced prevalence of CRD and other secondary infections. Product 2 which comprises Novel combination of herbal expectorants produced through the Supercritical Fluid Extraction technology is applied in the farms already infected with CRD. Through the trials conducted, it was validated that birds treated with this formulation had reduced signs of mortality, reduced clinical signs of infection and better performance. Product 1 and 2 are given regularly to the farms where the trials were conducted in the area of Dodballapura, Devanahalli and Kolar. There are reduced incidences of the CRD infection in these farms.

12. Marine polysaccharides mediated nanoproducts for shrimp disease management (Suveshika Bi Products Private Limited)

The shrimp farmers and farming industries in India are facing disease problems. Among them, the Vibriosis, APHND, SHIV and WSSV infection is a major threat to aqua farmers and there is no effective treatment/remedies/medicine available so far.

To resolve this issue the product polysaccharide-based nanocomposite feed supplements was formulated and it will be commercialized as a potential feed additive for shrimp aquaculture in order to prevent diseases and protect the industry from huge economic losses. The developed product BIONAN compo will be commercialized as

a potential feed additive for shrimp culture to resolve the above said issue. The BIONAN COMPO feed supplements were now available in 1, 2.5 and 5 L packs. The feed supplement can be mixed with shrimp feed by the aqua farmers.



Biotechnology Industry Research Assistance Counicil



iii. Energy and Environment (including secondary Agriculture)

The replacement of fossil fuels with more carbon-neutral and renewable sources has become a key necessity of the time. Biotechnological approaches are likely the most powerful approach available to address the dual challenges of biomass recalcitrance and large-scale sustainable production. In accordance with this, the clean energy and environment area at BIRAC involves supporting projects which focus on development of an industrial process, industrial product or a platform technology using biotechnology means for promoting development of green technologies.

In the secondary agriculture sub sector, time to time special calls are announced to support the development of technostrategic interventions. Several successful outcomes such as Industrial scale production of tea catechins, stable omega-3 enriched fish oil liquid formulations as emulsion/syrup, supercritical fluid extraction unit for nutraceutical products development are a result of BIRAC's effort to provide adequate funding and mentoring support. Further to promote this area in Northern India, a Network has been supported in Punjab to exploit the resources available at one place. The network in Punjab comprises 4 partners Punjab State Biotech Corporation (PSBC) along with NABI, CIAB and BioNEST-PU to support the food processing industry and promote start-ups in the Agri food sector.

Major focus programs under the Clean energy and environment area:

- Program on synthetic biology
- Innovation clean technology scale up program
- Program on guar gum

There is a high year-to-year variation in production of guar, and consequently in exports of guar and its derivatives. Guar gum is mainly used in the food and bakery industry and the food safety concerns are becoming important for the guar processing industry. The preparedness of guar split and guar gum manufacturing industries for these food safety concerns, high fluctuations in area, production and productivity of guar seed, high volatile prices of guar seed and gum splits, are crucial limitations to the growth of guar industry.

The Guar Industry has evolved from being used for domestic and ruminant feed purposes to finding use in industry. Owing to new technologies and ongoing R & D, the natural gum property of guar can have varied applications from food, pharma industry to oil Industry. The guar industry is poised to grow and develop owing to high focus on research in Universities and technical institutes of the world. Leading players operating in the global guar gum market include Jai Bharat Gum, Vikas WSP, Hindustan Gums, Shree Ram Gum, Cargill Inc., Lucid Group, Ashland Inc., Supreme Gums Pvt. Ltd, India Glycols Ltd, Rama industries and Lamberti.

The Program on Guar gum to be developed by involving relevant industry and academia resulted in 09 projects for funding in the areas of building material mixtures, sealants, bioplastics, biomedical patch and guar derivatives.

During COVID Pandemic, in addition to these programs, special calls under i4 (BIPP, SBIRI) and PACE (AIR and CRS) were announced under the area inviting proposals addressing the following:

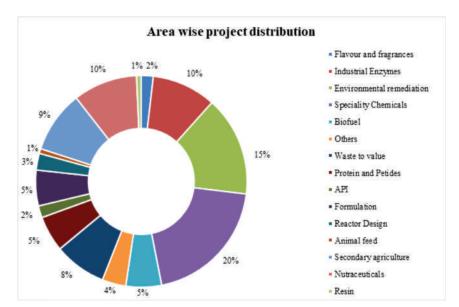
- Biomedical waste treatment/ management including waste generated due to used protective gear in the context of COVID 19
- Cost effective production technologies for (microbial route) API needed for COVID 19 drugs
- Production of enzymes (microbial production) used in COVID19 diagnostics kits
- Development of Anti-viral surface coatings
- Disinfection/ Sanitization technologies for food/ food based products (for use by end users)

Then further to promote self-sufficiency and sustainability, special call under i4 (BIPP, SBIRI) and PACE (AIR and CRS) was advertised to invite proposals emphasizing on development of import substitutes under the following areas:

- Cost effective production technologies for Industrially relevant bio-based import substitutes
- Technologies to enhance shelf life of packaged foods
- Cost effective production technologies for APIs, intermediates, high value products, polymers, surfactants, fine chemicals, dyes, pigments, flavors and fragrances

The projects that have been supported till date involves the use of biotechnological platforms and can be categorized in several sub-areas such as bioenergy, speciality chemicals, industrial enzymes, industrial processes, bioremediation, secondary agriculture, infrastructure support and many other fine chemicals as shown below.





Area wise project distribution- Energy and Environment (including secondary Agriculture)

Following Products/Technologies are Market launched or Commercialized in 2020-2021:

Conversion of paper mill sludge for the manufacturing of wood fibre-based soft boards and hardboards (The Western India Plywoods Ltd)

Under conventional we-mat formation and pressing or drying conditions, the process effectively recycled the paper mill sludge at a wood substitution level of 15 percent (in both hardboard and softboard).





Finished Fibreboards developed by Western India Plywood Ltd using Paper Mill sludge

2. Fully Automated, Continuous Flow, High Throughput Wastewater Treatment System (Openwater.in)

The Company has developed a solution for industrial waste water treatment. The system is fully automated, plugand-play, membrane-less, does not use synthesized chemicals, and wastes zero water. A 10,000 KLD treatment unit has been set up at Openwater.in, facility at IISc, Bangalore and has completed more than 35,000L of water treatment. Another plant of the same capacity is being set up at a gated community at Kengri, Bangalore (Malhar Residency). Another unit has been deployed for ground water treatment in collaboration with Mavallipura Grama Panchayath Limits, Mavallipura, Bangalore.







Mobile Wastewater Treatment Unit by openwater.in

3. Cordyceps (Mallipathra Nutraceutical Private Limited):

The company has developed technology to grow the Cordyceps in novel vegetarian substrate to cater vegetarian population and also in non-vegetative substrate for Nutraceutical application. The major focus of this technology is to develop a Nutraceutical product like fruiting body, Mycelia powder, Cordyceps Capsules, infusion etc., from Cordyceps mushrooms for various lifestyle disorders and ailments. The standardization and validation of the process of producing these Cordyceps in bench scale and the same has been commercialized. About 30 lakhs turnover has been achieved with the available facility and FSSAI registration has been obtained. The company is working towards the creation of a facility for large scale production for continuous production and commercialization of the same in an industrial Area.



Mali's
Cardycaps Fruiting Body

Condyceps Fruiting Body

Range of products being developed by Mallipathra

4. Antimicrobial water bottles (Nanosafe Solutions Pvt. Ltd):

The technology is called AqCureTM which is enabled with Active copper. It has antibacterial, antiviral and antifungal properties and can make the water microbiologically clean within 30 min of storage.



Antimicrobial water storage containers by Nanosafe solutions



Following products/Technologies have completed technology validation in 2020-2021:

Fleather- leather from floral waste (Kanpur Flowercycling Pvt. Ltd):

The technology involves making leather from floral waste. The Fleather sheets showed satisfactory physical and mechanical properties that are comparable to conventional leather. Third party testing involved studying the Skin sensitization, heavy metal test, pesticides, tensile strength, tear strength and thickness and fleather was found to be safe. Pilot facility for scaled up production of Fleather has been set up and is now functional. Commercial sales yet to start.



Fleather sheets by Kanpur Flowercycling Pvt. Ltd

2. CellBrx (OmniBrx Biotechnologies Pvt Ltd.):

A novel Single-Use Bioreactor technology platform based on Dynamic Bed Reactor technology has been developed. Reactor successfully demonstrated at lab scale. Ready for large scale manufacturing.



CellBRx 0.5L Bioreactor system by OmniBrx Biotechnologies Pvt Ltd

3. StringPro (String Bio Private Ltd):

Technology involves production of single cell protein from methane. The proposed product will be used for animal feed. The product is called a PROfit.





String pro/PROfit generated as flakes or as powder by String Bio Pvt. Ltd.



4. Thermo-tolerant and acid stable phytase in a novel SSF bioreactor (Fermentech Labs Pvt Ltd):

The phytase produced is highly thermostable with a half-life of 8.2 h at 70 °C and highly acid stable with pH optima of 1.5 and 5.5. The fermentation time is reduced by 10 h in the novel bioreactor developed by the company. 10 poultry farms and cattle farms near Roorkee have shown interest in using phytase supplemented feed on trial basis. The higher calorific value pellets which were made by blending lignin rich SSF residue (from phytase fermentation) with excess agro-wastes were formed in 4-kg packets and supplied to industries SIIDCUL, Haridwar and few LOIs have been received. For novel bioreactors, expressions of interest have been obtained from IIT Kharagpur and NITK Surathkal for the production of fibrinolytic enzymes and from IIP Dehradun for the production of laccase enzymes.



15 Kg Bioreactor with automation developed by Fermentech Labs Pvt Ltd for the production of phytase enzyme

5. Anaerobic Granulated Sludge for organic waste / wastewater treatment (REVY Environmental Solutions Pvt. Ltd.):

Current product is an Anaerobic granular sludge of 1.5 -2.0 mm size having more than 650 bacteria. This consortium has proven to treat waste water and the treated water can directly be used for irrigation purposes. It has a 94% faster start up of UASB systems leading to faster commissioning of STP/ETP





Anaerobic granulated sludge produced by REVY Environmental Solutions Pvt. Ltd

6. Red wine using black rice (Institute of Advanced study in Science and Technology, Guwahati):

The process has been developed by an academic institute by following a traditional method to convert black ice to red beverage. The technology was officially transferred to Guwahati based company, Golden Beverages for industrial production of the wine.



Wine from Black rice



7. Microbial Pigments (KBcols Sciences Private Limited):

KBCols is exploring microbes as an inexhaustible feedstock of natural colors, as they represent one of the cheapest, most abundant & unexplored biological feedstocks available in large quantities. These natural colors can find applications in food, pharmaceuticals, textiles and cosmetics. The product is now being tested with various Industrial partners with the objective of launching products with KBCols natural bio-colors.



iv. Bioinformatics

66% funds are disbursed through the BIPP for the bioinformatics sector. 55% projects have been successfully reached to pre-commercialized stage. Some of the projects are at early and late stage validation technologies. Few of the projects from the area involved Industry-academia collaborations though many are pursued by industry alone. Artificial intelligence-based call has attracted interest among bioinformatics in the field. Very few projects i.e. <20 have been supported under the theme. Way forward is sharing knowledge with experts, young researchers and students to increase confidence in the academic profiles of future India, hands on training and participation with global community

<u>Various technologies developed under this theme over the years (No technology/product developed in FY 2020-21 under this theme)</u>

- SanGenix named a comprehensive NGS data analysis suite that offers a scalable and user-friendly solution
 with predefined or custom workflows for seamless analysis of NGS data. Product is available on (http://www.sangenix.com/Products.html)
- High computing infrastructure set up for NGS data Analysis with more than 16 NGS pipelines & providing 25% discount price to the Indian academics and institutions. Services are available on (http://www.scigenom.com/bipp)
- A system to track and monitor real-time patient data & predict future disease by using big data analysis on cloud through machine learning methods.
- A machine learning based software for the detection of diabetes retinopathy is developed and validated.
 Software (icheck) has been launched. Currently software has been launched with new Name- ChironEye
- Intelligent health care kiosk for immediate simple healthcare for simple common symptoms is under pipeline. An artificial intelligence-based software for the health care kiosk. This medical kiosk will diagnose the vital symptoms and will provide e-prescription and also dispense the drugs.

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 processes, technologies, commercialization of products/technologies (TRL-8 & 9), technology maturation of projects to Technology Readiness Level-7 (TRL-7) and filing of IPRs. Table below provides information on the products/technologies at validation, pre-commercialization and commercialization stage and IP filed through BIRAC funding during 2020-2021

S. No	Category	Number
1	Products commercialized	16
2	Process/technologies at Pre-commercialization stage	11
3	Number of projects at TRL-7 stage	42
4	IP filed	45

II. Entrepreneurship Development

1. BioNEST (Bioincubators NurturingEnterprises for Scaling Technologies)

BioNEST (Bioincubators Nurturing Entrepreneurship for Scaling Technologies) scheme is BIRAC's flagship scheme to establish globally competent, specialized bioincubation facilities across the country. BioNEST bioincubators are mandated to provide incubation space to biotech entrepreneurs and Startups along with access to high end infrastructure, specialized and advanced equipment, business mentorship, IP, legal and regulatory guidance and networking opportunities that are relevant for biotech ventures.

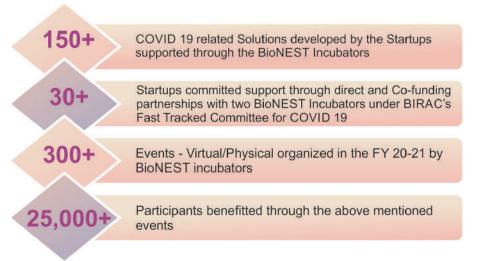
BIRAC through the BioNEST Scheme:

- Provides incubation space to start-ups and entrepreneurs
- Provides world class infrastructure and high end equipment facilities
- Connects industry and academia and enable 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

Impact created by BIRAC's BioNEST Programme

Over the last 9 years, BIRAC has supported **60** BioNEST bioincubators across the country which are hosted in Research Institutes, Academia, Hospitals, Private as well as Public Institutions, and others. This specialized network has started covering emerging clusters, tier 2 cities, besides augmenting the matured clusters in the country. Thus far, BioNEST network has the physical capacity to incubate about **1000+** startups and entrepreneurs in the biotech sector. More than **6,50,000 sqft** of incubation space has been created. **4000+** employment has been generated. **2000+** trainings and workshops have been conducted. More than **250** products/technologies developed by the incubatees are in market.

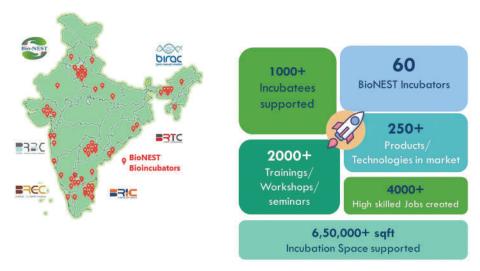
BioNEST incubators also contributed immensely towards battle against COVID crisis





The **10** new incubators sanctioned during the FY 2020-21 are as follows:

IIT Jodhpur, UAS Bangalore, NEHU TURA Campus, NIPER Hyderabad, ILS, Bhubaneswar, MAHE Manipal, VCR Park Vizag, AIIMS Delhi-Jhajjar, NEIST Jorhat, IIT Guwahati.



S. No	List of Bio-incubators supported under BioNEST	State/UT
1	Panjab University	Chandigarh
2	Foundation for Innovation And Technology Transfer (FITT), IIT Delhi	Delhi
3	Zonal Technology Management and Business Promotion Development (ZTM-BPD), Indian Agricultural Research Institute (IARI)	Delhi
4	Clean Energy International Incubation Centre (CEIIC)	Delhi
5	DPSRU Innovation & Incubator Foundation (DIIF)	Delhi
6	University of Delhi, South Campus	Delhi
7	Indigram Labs	Delhi
8	AIIMS Delhi Jhajjar	Delhi & Haryana
9	Regional Centre for Biotechnology (RCB), Faridabad	Haryana
10	Indian Institute of Technology IIT Kanpur	Uttar Pradesh
11	Indian Institute of Toxicology Research (IITR)	Uttar Pradesh
12	Banaras Hindu University	Uttar Pradesh
13	Technology Incubation and Entrepreneurship Development Society (TIEDS), IIT Roorkee	Uttarakhand
14	Indian Institute of Technology IIT Jodhpur	Rajasthan
15	Savli Technology Business Incubator (STBI)	Gujarat
16	Ahmedabad University (AU)	Gujarat
17	SRISTI Innovations	Gujarat
18	B. V. Patel Pharmaceutical Education and Research Development (PERD)	Gujarat
19	National Institute of Pharmaceutical Education and Research (NIPER)	Gujarat
20	Birla Institute of Technology & Science (BITS), Pilani, Goa Campus	Goa
21	Centre for Cellular and Molecular Platforms (C-CAMP)	Karnataka
22	Bangalore Bioinnovation Centre (BBC)	Karnataka
23	Indian Institute of Horticultural Research	Karnataka





S. No	List of Bio-incubators supported under BioNEST	State/UT
24	IKP Eden	Karnataka
25	Mazumdar Shaw Medical Foundation (MSMF), Bengaluru	Karnataka
26	University of Agricultural Sciences UAS Bangalore	Karnataka
27	Manipal Academy of Higher Education MAHE Manipal	Karnataka
28	Venture Center, Pune	Maharashtra
29	Society for Innovation and Entrepreneurship (SINE), IIT Bombay	Maharashtra
30	Research Innovation Incubation Design laboratory Foundation (RiiDL)	Maharashtra
31	IIT Madras Research Park	Tamil Nadu
32	Healthcare Technology Innovation Centre - IIT Madras	Tamil Nadu
33	Golden Jubilee Biotech Park for Women Society	Tamil Nadu
34	PSG College of Technology, Coimbatore	Tamil Nadu
35	Vellore Institute of Technology (VIT), Vellore	Tamil Nadu
36	Crescent Innovation & Incubation Council (CIIC), Chennai	Tamil Nadu
37	Shanmugha Arts, Science, Technology & Research Academy (SASTRA)	Tamil Nadu
38	Tamil Nadu Veterinary and Animal Sciences University (TANUVAS)	Tamil Nadu
39	Sri Ramachandra Institute of Higher Education and Research (SRIHER)	Tamil Nadu
40	Amal Jyothi College of Engineering (AJCE)	Kerala
41	IKP Knowledge Park	Telangana
42	Society for Biotechnology Incubation Centre (SBTIC)	Telangana
43	a-IDEA, National Academy of Agricultural Research Management (NAARM)	Telangana
44	University of Hyderabad (UoH)	Telangana
45	International Crops Research Institute for the Semi-Arid Tropics (ICRISAT)	Telangana
46	L.V. Prasad Eye Institute	Telangana
47	International Institute of Information Technology (IIIT)	Telangana
48	National Institute of Pharmaceutical Education & Research (NIPER), Hyderabad	Telangana
49	SPMVV - Women Biotech Incubation Facility	Andhra Pradesh
50	Andhra Pradesh Med Tech Zone (AMTZ)	Andhra Pradesh
51	VCR Park, Vizag	Andhra Pradesh
52	Kalinga Institute of Industrial Technology (KIIT)	Odisha
53	Institute of Lifesciences ILS, Bhubaneswar	Odisha
54	Institute of Advanced Study in Science and Technology (IASST)	Assam
55	National Institute of Pharmaceutical Education & Research (NIPER), Guwahati	Assam
56	North East Institute of Science and Technology NEIST Jorhat	Assam
57	IIT Guwahati	Assam
58	Mizoram University	Mizoram
59	Institute of Bioresources and Sustainable Development (IBSD) & Bio Resources Development Centre (BRDC)	Meghalaya
60	NEHU, Tura Campus	Meghalaya





2. SEED Fund (Sustainable Entrepreneurship and Enterprise Development Fund

BIRAC launched an equity fund programme (BIRAC SEED Fund) in 2016, which supports Incubators by providing them with capital which can be further invested in biotech startups as equity thus helping start-ups to grow. A significant gap exists for the financing for biotech startups, SEED FUND helps in bridging the Gap & fund the startups to explore angel/VC fund.



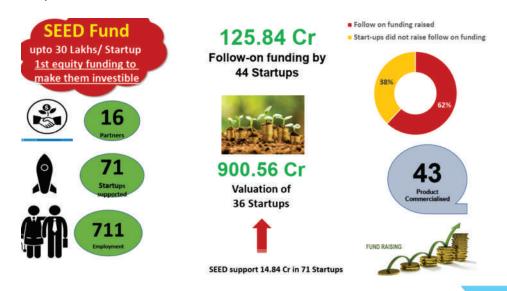


The basic idea of SEED Fund is to provide Capital assistance to start-ups with new and meritorious ideas, innovations and technologies. The seed support would generally cater to early stage financing. This would enable some of these start-ups to graduate to a level where they will be able to raise investments 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:

- 16 BioNEST incubators have been provided upto INR 200 Lakhs for investing in Biotech Startups.
- 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.
- Total Sanctioned Amount under the programme is INR 34 Cr. out of which INR 26.39 Cr. has been disbursed.

Impact created by BIRAC's SEED Fund Programme

Over the years BioNEST has been able to create a nurturing ecosystem for the budding biotech sector entrepreneurs and start-ups. It also provides the first equity exposure to the start-ups and enable them to build confidence to raise the partnered funding from various angels & other Institutional Investors. Till now INR 34.00 Crore have been sanctioned and INR 26.39 Crore has been disbursed under BIRAC SEED Fund program. Till date 16 Seed Fund bio incubators partners has Supported more than 70 Seed Funded Start-ups companies creating a cumulative Valuation of more than INR 900.56 Crore. Among the total supported start-ups, 44 start-ups have raised external (apart from BIRAC Support) funding of nearly amount INR 125 Crore. The startup companies have more that 40 commercialized products in the market.





Various SEED partners have reached the stage, where they have been sanctioned the 2^{nd} Round of SEED Fund support looking their past performance and infusing the additional SEED support. Following are the SEED Fund Partners:

S. No	Name of SEED Fund Partner
1	a-IDEA, NAARM-TBI, Rajendra Nagar, Hyderabad
2.	Bangalore Bioinnovation Centre, Bangalore
3.	C-CAMP Centre for Cellular and Molecular Platforms, Bangalore
4.	ENTREPRENEURSHIP DEVELOPMENT CENTER, Pune
5.	FITT, IIT Delhi
6.	Golden Jubilee Women Biotech Park, Chennai
7.	GUJARAT STATE BIOTECHNOLOGY MISSION, Gujarat
8.	FIRST, IIT Kanpur`
9.	IIT Madras
10.	IKP Knowledge Park P Ltd, Hyderabad
11.	IKP-EDEN, Bangalore
12.	KIIT-Technology Business Incubator, Bhubaneswar
13.	Panjab University, Chandigarh
14.	RiiDL, Somiya Vidyavihar, Mumbai
15.	SINE, IIT Bombay
16.	Vellore Institute of Technology-Technology Business Incubator (VITTBI)

3. LEAP Fund (Launching Entrepreneurial Driven Affordable Products)

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 6 BioNEST incubators recognizing those as LEAP fund partners. Under the SEED fund programme:

- 6 BioNEST incubators have been provided upto INR 500 Lakhs for investing in Biotech Startups.
- The LEAP Fund Partner (Bioincubator) can invest INR 300 100 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.
- Total Sanctioned Amount under the programme is INR 29.50 Cr. out of which INR 22.50 Cr. has been disbursed.





Impact created by BIRAC's LEAP Fund Programme

The basic idea of LEAP Fund is to provide the next level pre-series funding support of up to Rs 1 crore per start-up with new and meritorious ideas, innovations and technologies. This would enable potential start-ups to pilot/ commercialize their products/ technologies. Thus funding support is positioned to act as a catalyst in bringing technologies/ products forward towards piloting/ commercialization and reducing their gestation to commercialization.

Till now INR 29.50 Crores have been sanctioned and INR 22.50 Crores has been disbursed under BIRAC LEAP Fund program. Till date 6 Seed Fund bio incubators partners has Supported more than 20 LEAP Funded Start-ups companies creating a cumulative Valuation of more than INR 675 Cr. Among the total supported start-ups, 14 start-ups have raised external (apart from BIRAC Support) funding of nearly amount INR 140 Cr. The start-up companies have more that 10 commercialized products in the market.



4. Biotechnology Innovation Fund – AcE

BIRAC is implementing AcE Fund on behalf of DBT . Biotechnology Innovation Fund - AcE, 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 partner's and co – invest with SEBI registered Alternate Investment Funds (I,e, Venture Capitals & Angels Funds) that are professionally managed to nudge for investment in the biotech sector. The main role of AvE Fund is to plug the gap of "Vally of Death" encountred by Biotech start-ups during their product development cycle and growth phase. Ace Fund will enable creation of ecosystem that will provide risk capital to young enterprise to undertake research and development of high priority areas. It will, in the process, enrich the intellectual property in the country and encourage more entrepreneurs towards product and technology development of high quality at affordable economies in sustainable manner.

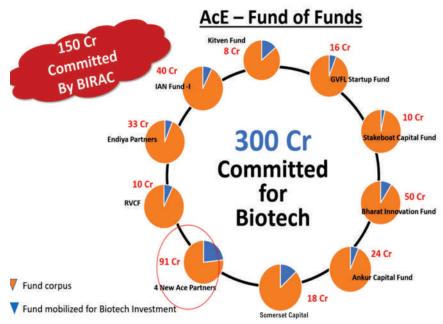
The daughter funds are committed to invest 2X amount of BIRAC's commitment in biotech start-ups. The Daugter funds supported by AcE Fund will support start-ups at an early and growth stage that may ready to receive presseries A or series A funding - with a minimum commitment of towards startup in biotech space. The fund on make maximum capital commitment of Rs 30 Cr or upto 30 % of the total aggregate capital commitment amount (i.e. fund corpus) in each daughter fund. Under the BIRAC's mandate a daughter fund can invest upto INR 7cr in a startup against the equity held by partner. Under this initiative, two national calls have been launched and corpus of INR 150 Cr fund is committed to the 13 Partners.

Impact created by BIRAC's AcE Fund Programme

Currently, there are 10 Active partners who have onboarded with BIRAC. Till now INR INR 49.60 Crores has been disbursed to the Daughter Funds. Till date AcE partners has Supported more than 40 Startups/SMES companies infusing around INR 290 Cr in to the biotech Domain companies which is as per the mandate of the secheme.

Certain AcE partners have started giving returns as well. These are inform of Exits, interest earned or disinvestments.





For the rest partners singing is under process.

The current status of Schemes is follows:

S. No.	Name of AMC/Fund	Total Fund Size (Cr.)	Recommended BIRAC Contribution
1	Bharat Innovation Fund	INR 700 Cr	25 Crore
2	Indian Angel Fund	INR 350 Cr	20 Crore
3	GVFL	INR 150 Cr	8 Crore
4	Stakeboat Capital	INR 250 Cr	5 Crore
5	Kitven Fund	INR 50 Cr	4 Crore
6	Somerset Healthcare Investment Advisors Pvt. Ltd.	INR 300 Cr.	INR 9 Crore
7	Menterra Venture Advisors Private Limited	INR 750 Cr.	INR 12.5 Crore
8	Nabventures Limited	INR 500 Cr.	INR 10 Crore
9	Rajasthan Asset Management Company Private Limited (RAMC)	INR 127 Cr.	INR 5 Crore
10	Endiya Fund Advisor Pvt. Ltd	INR 500 Cr.	INR 16.5 Crore
11	Health Quad Advisors Pvt. Ltd.	INR 1050 Cr.	INR 13.0 Crore
12	IKP Investment Management Company Pvt. Ltd	INR 200 Cr.	INR 10 Crore
13	Ankur Fincon Management Pvt. Ltd	INR 350 Cr.	INR 12 Crore

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

E-YUVA scheme [Earlier University Innovation Clusters (UIC)] is mandated to promote a culture of applied research and need-oriented (societal or industry) entrepreneurial innovation among young students and researchers. The scheme was revised during FY 2019-20 to expand its scope and outreach to Under Graduate level students also in addition to its earlier coverage of Post Graduate and Post Doctoral Students.

The scheme now provides funding support (through fellowship and research grant), technical and business mentoring, exposure to bioincubation model, orientation to entrepreneurial culture etc. to students at various levels including UG, PG and post doctoroal students EYUVA is implemented through dedicated hubs called E-Yuva Centers (EYCs) housed within the University/Institute set up and mentored by a BIRAC BioNEST supported bio incubator. EYCs act as anchors and extend requisite support and mentoring to students.

Biotechnology Industry Research Assistance Counicil



The scheme provides support under following two categories:

- a. BIRAC's Innovation Fellows (for post graduates and above)
- b. BIRAC's E-Yuva Fellows (for under graduate students)

BIRAC supported EYCs encompass the following:

- Pre-incubation space (3,000 sq. ft. or more)
- Manage Fellowships for students as per categories mentioned above
- Conduct Entrepreneurial Awareness Workshops for students

BIRAC's support to the existing 5 UICs (listed below) is now being enhanced further and these centres are being upgraded as E-YUVA centres.

- 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

So far 5 EYUVA Centres have been established which have supported more than 30 fellows.

5 new EYUVA Centres were selected and identified in the FY 20-21:

- 1. Atmiya University, Rajkot, Gujarat
- 2. Adamas University, West Bengal
- 3. GIET University, Gunpur, Odisha
- 4. Career College, Bhopal
- 5. PSGR Krishnammal College for Women, Coimbatore, TN

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

Scheme is aimed at supporting innovative student projects in the area of biotechnology. The scheme's mandate is to promote and encourage young students for embracing translational research to develop innovative products and technologies addressing unmet needs. The scheme also provides an opportunity for orientation, training and mentoring through residential workshops and a provision to incubate in an Incubation centre.

The scheme is presently implemented in association with Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), Ahmedabad and has two components:

- SITARE Gandhian Young Technological Innovation Award Grant (SITARE-GYTI) 15 innovative student projects receive funding support of INR 15 lakhs each. Postgraduate and Doctoral students are encouraged to undertake projects with commercial potential leading to creation of biotech start-ups. There is a provision to incubate in an incubation centre to carry forward the degree work, set up a startup, access business mentoring and file IP.
- SITARE- Appreciation Grant 3-4 weeks long Residential Workshops called Biotech Innovation Ignition School (BIIS) for undergraduate students are organized to provide mentoring and hands-on technical training for problem identification. Up to ten students out of each BIIS workshop receive INR 1 lakh each to encourage their inquisitiveness and sustained efforts towards entrepreneurship. Participation from Aspiration Districts is encouraged.

Impact of SITARE

- SITARE-GYTI Awardees (INR 15 lakh each)
 - 75+ SITARE-GYTI Awardees: Awards are conferred by the Hon'ble President/Vice President/Minister of S&T
 - Five Awardees secured Biotechnology Ignition Grant by BIRAC, and 20 IPs have been filed so far
 - 45 Publications by GYTI Awardees



- Awardees are from various Institutes across the country including BITS-Pilani, IITs Kanpur, KGP, Delhi, Roorkee, Mumbai, Hyderabad, BHU, JNCASR, IISc, Jadhavpur University, ICT-Mumbai, JNU-Delhi, in Stem, NIPER, Mohali etc.
- Projects supported belong to different areas including Healthcare, Life sciences, Devices, Diagnostics, Agriculture, Waste management

• SITARE-Appreciation Grant

- Nine Biotech Innovation Ignition School (BIIS) residential workshops have been organized.
- 500+ students (including many from aspirational districts) have been trained through BIIS workshops.
- More than 250 SITARE-Appreciation awards have been given so far in areas such as grassroot innovations for Joint pain, gastritis, epilepsy, gallstones, bleeding injuries, dysentery, snake bite, rheumatism, toothache, burns, Pest Control, leaf curl disease, sucking pest control, termite control, TMV Control, larval control, plant growth promoters, Back pack for hilly terrains, Diagnostic test Devices etc.



7. BIRAC Regional Innovation Centre (BRIC)

The BIRAC Regional Innovation Centre was established in partnership with IKP, Hyderabad in 2013 as the first regional centre of BIRAC. Over the 8 years (2013-2021), 3 phases have been completed with the following mandate:

- RIS Mapping for 23 clusters
- Engaging with academia and start-ups on IPR through its IP and Technology Transfer Cell
- Entrepreneurship Development

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 with similar mandates was taken up as Phase II 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 policy recommendations to improve and enhance the innovation capacities of the clusters was released in October 2017 during IKMC annual meet.

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 by expanding the study to 13 new clusters covering North and Eastern India and also two clusters in the West and South not covered in the earlier Phases. The clusters covered in the Phase III study were Jaipur-Pilani, Mohali-Chandigarh, Shimla-Palampur-Solan-Jammu, Delhi-NCR, Karnal-Rohtak, Dehradun-Roorkee, Lucknow-Kanpur, Allahabad-Varanasi, Kolkata-Kalyani-Kharagpur, Guwahati-Shillong-Tezpur, Sikkim, Panaji-Goa and Mangalore-Manipal.

The Phase III study was conducted during the time period from Nov 2018 till Feb 2021 with the following new activities namely; Innovator Forums, Idea exposition, and Innovator Exposure Stipends.

Biotechnology Industry Research Assistance Counicil



8. BIRAC Regional Entrepreneurship Centre (BREC)

2nd Regional Centre, BREC at CCAMP, Bangalore completed Phase 1 in January 2020. Highlights of the activities carried out by BREC under Phase 1 are as follows:

- 1900+ Students inspired to pursue bio-entrepreneurship as a career through Entrepreneurship Awareness Workshops
- 600+ entrepreneurs/start ups provided specialized domain knowledge through specialized workshops
- 500+ One-on-one meetings with between Investors &Startups through Investors Meet
- 6300+ Registrations for National Biotech Entrepreneurship Challenge from across 32 States, Cash prizes and investment opportunities worth INR 6.00 Cr mobilized
- 175+ entrepreneurs and startups mentored through intense training through an intense annual bootcamp involving international faculty.

9. BIRAC Regional Bio-Innovation Centre (BRBC)

BIRAC Regional Bioinnovation Centre (BRBC) was created as 3rd Regional Centre in partnership with BIRAC's BioNEST Incubator Venture Centre, Pune. It is mandated to support and promote entrepreneurship in Life Sciences addressing specific gaps in the ecosystem including Regulatory compliance through a Facilitation Centre and Incubation Manager's training through a Practice School besides others.

Activities performed by BRBC annually include:

- Venture Mentoring Service
- Venture Base Camps
- Regulatory Information and Facilitation Center (RIFC)
- BioIncubation Practice School for western regions
- City Camps

BRBC Impact so far is as follows:

- 250+ entrepreneurs connected with mentors
- 200+ one to one follow up meetings
- 250+ participants provided domain knowledge through Venture Base Camps
- 40 Incubation managers trained
- 350+ students/entrepreneurs provided insights into essentials of scientific entrepreneurship
- 150+ start ups assisted for solving regulatory queries

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

BIRAC Regional Techno-Entrepreneurship Centre for East & North East (BRTC-E&NE) was 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. BRTC aims to develop the biotech entrepreneurial ecosystem especially laying a foundation for development of biotech cluster in East and North East Regions including Odisha, Chhattisgarh, Jharkhand, West Bengal and Bihar and the North East (Assam, Meghalaya, Guwahati, Imphal, Manipur, and Tripura).

BRTC Impact (2020-2021)

- 2000+ Innovators reached out through awareness programs such as Roadshows, Training programmes and design workshops
- 85 startups across the NER were provided one-on-one mentoring sessions
- Mobilized 27 Innovative proposals from North East and 90 from East for funding support from BIRAC
- BRTC signed MoU with various institutes like IASST Guwahati, NIPER Guwahati, Manipur University, NEHU, Tura Campus, Tripura University, Rajiv Gandhi University, Itanagar, College of Fisheries, CAU and Green Foundation, Imphal promoting entrepreneurship and technology development



• Launched an initiative to map the Change Makers of Northeast Region to identify the budding entrepreneurs and prepared a compendium of the region.

III. Affordable Product Development

1. Early Translation Accelerator (ETA)

BIRAC is supporting Early Translation Accelerators (ETAs) to focus on catalysing transformation of young academic discoveries (publications/patents) with possible commercial and societal impact into economically viable ventures and technologies. The aim of ETA is to add translational component to establish proof-of-concept/ Validation in line with the BIRAC's mission of facilitating translation of innovative ideas into biotech products 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. ETA will consider discoveries from healthcare, agriculture, industrial biotechnology and other important areas of Biotechnology for validation under Early Translation Accelerator.

Two ETAs have been already established at C-CAMP and IIT-Madras Bio incubator in the field of health care and Industrial Biotechnology respectively. C-CAMP ETA has successfully completed the first set of three projects. All the Technologies developed by C-CAMP ETA were adopted by the Industries. Two patents were also filed by the C-CAMP ETA. IIT-Madras ETA has completed one project and is working to complete the remaining three projects.

In the FY 2020-2021, Projects selection for the two new ETAs established at BETIC-IIT Mumbai and Yenepoya Foundation for Technology Incubation, Yenepoya University (YFTI) in the field of Devices diagnostics and Healthcare respectively, have been completed. BETIC-IIT Mumbai is going to complete validation of 4 academic projects and will make them ready for Industry while YFTI-Yenepoya University is going to validate 5 projects.

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

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

In 2017, 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.

The overall objectives of optimizing marker assisted background selection (MABS) transfer of already available and newly discovered QTLs for heat tolerance to popular, elite wheat cultivars grown in the Indo-Gangetic Plains, and identifying and developing user-friendly DNA markers for heat tolerance by evaluating wheat germplasm.

In Washington State University, the selected lines have been evaluated for drought stress tolerance and double haploid populations have been developed. These have been screened and evaluated for heat tolerance under the controlled conditions. Field trials are on in the relevant Indian institutes to identify the markers and release the heat tolerant varieties.

BIRAC funded partners have made the BC1 population that is needed, which would be screened to make BC2 and from that point onwards it would be selection and seed increase. Further to this, at least two partners have completed their QTL analysis and some part of sequencing-based genotyping has also been completed. Two-year evaluation of all the DH population is also complete. Also, four of the BIRAC funded partners are pursuing one each with a total of four breeding targets.





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 an 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).

Several promising events with high provitamin A content identified by both NABI and NRCB are now ready for Event Selection Trials (EST) and those identified by IIHR and TNAU for event characterization. The event selection trials will be carried out for transgenic banana events with high pro-vitamin A (PVA) content and with high IRON content. Event characterization will be carried for BBTV resistance and FOC resistance in banana.



PVA (33.78µg/g)

Grand Challenge in "Agri-technology Translation to Boost Farmers' Income"

BIRAC through IKP Knowledge Park proposes to conduct a Grand Challenge in "Agri-technology Translation to Boost Farmers' Income" with the mandate to identify 'ready to deploy' and 'scalable innovations' in agriculture that will help in increasing the incomes of farming households.

A series of innovative technologies, practices, products, services, business model and/or integrated solutions that have been piloted at a small scale in India will be identified, funded, monitored for field testing over a period of 30 months through a 2-stage process in this program. The focus of the Challenge will be to demonstrate increased incomes through deployment of selected technologies. To ensure impact the selected innovations in Phase 2 of the program, the start-ups will have to test multiple crops in two agro-climatic zones and the demonstrations should include small and middle landholding farmers.

(iii) Secondary Agriculture

The project was being steered by Punjab State Council for Science & Technology (PSCST), Chandigarh from its launch in February 2018 to January 2020. 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.

However, in 2019 state Govt reorganized Dept. of Science Technology & Environment, and accordingly the project was transferred to Punjab State Biotech Corporation w.e.f. 31st January, 2020 after the approval of BIRAC. Thereafter, the project is being implemented by Punjab State Biotech Corporation (PSBC) as Lead Agency with National Agri-Food Biotechnology Institute (NABI), Center of Innovative and Applied Bioprocessing (CIAB) and BIONEST-PU as the Partner Institutes.

PSBC, during Phase 1 focused on two sectors namely Fruits & Vegetable and Cereal & Grains. The landscape of Agri-Food Processing in Punjab with special reference these two sectors has been mapped through extensive consultations with District Industry Centres and Food Processor Associations. The Unmet needs of these sectors were identified through five clusters viz. Amritsar, Ludhiana, Jalandhar-Hoshiarpur, Patiala-Sangrur and Bathinda linked with Research Institutions namely Guru Nanak Dev University (GNDU), Punjab Agricultural University (PAU), Lovely Professional University (LPU), Sant Longowal Institute of Engineering & technology (SLIET) and Maharaja Ranjit Singh Punjab Technical University (MRSPTU), respectively through Agri-Innovation Fellows. Project proposals for addressing the unmet needs were received from the state institutions for funding support. After rigorous evaluation of the project proposals by the Expert Committee, 6 projects under F&V and 4 projects under C&G sector were sanctioned to NABI, CIAB, PAU and GNDU along with their industry partners at a total cost of Rs 85.66 Lacs for a short duration of 6 months. The outcome of these projects in the form of Products, Technology Prototype and Process Optimizations cover the broad areas of Waste to Wealth, Nutraceuticals/Health Food, Cost-effective Technologies, Low-calorie Foods, Shelf-life extension and Traditional Cluster Strengthening. Two Tech-workshops were conducted for Murabba & Soy cluster by GNDU and PAU respectively.





Fig: Composition of Industry-Academia Cluster



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The Collaborations were facilitated between local units and NABI/CIAB to take forward their developed technologies. Patent landscape study to find out state relevant technologies for crops like Kinnow, Guava, Pear, Amla, Potato, Pea, Chilli, Garlic, Tomato, Maize, Soybean Sugarcane, Turmeric and Honey which are abundant in the state was got done from 3rd party after approval of BIRAC. The Technologies available with research institutions of the state in these two sectors were mapped. For effective and widespread dissemination about SAEN and other useful Data for Secondary Agriculture a weblink has been created. The IP landscape and technology mapping reports are being put up on weblink for dissemination amongst stakeholders.

CIAB has scaled up the process for development of tomato juice-based beverage from 100 Kg tomato. Further, the tomato pomace has been used for the development of bakery products. The developed products (beverage & bakery products) have been assessed for nutritional composition, shelf life, sensory acceptability and Effect of storage on their antioxidant activity, total polyphenol content and moisture content. The tomato beverage and spice mix has been licensed to an industry while for bakery products two industries have expressed their interest. CIAB has also optimized process for whey protein separation using membrane filtration system. Whey left after protein separation, has been used in a scale up process (>100L) for bacterial cellulose production. With the remaining whey that contains galactose after bacterial cellulose recovery was used for D-tagatose production (3g scale). Studies on optimization of low-cost minimal media for the large scale production of D-Tagatose have also been done. One industry has signed agreement for whey protein-based product & two industries have expressed their interest in such products.

NABI has developed edible coating formulation based on wheat straw polysaccharide and stearic acid esterified oat bran polysaccharide to extend the post-harvest shelf life of perishable fruit crops (Apple, Peach and Banana). The 1-2% AX-SABG composite emulsion (w/w 60:40) was used for surface coating. It has the ability to extend the post-harvest quality of various apple varieties (Royal Delicious and Rich Red, Kinnaur) during 30-40 days storage at 22°C and the shelf life of Peach up to 6-8 days and Bananas up to 9 days without significant blackening under ambient storage. The detailed in vivo toxicological studies also suggested the coating material is non-toxic, non-inflammatory and safe for consumption. An Indian patent (Indian Patent Application No 201811032781) has been filed on the developed coating formulation and non-disclosure agreement (NDA) has been signed with R.G. Industries, New Delhi for commercialization of the technology. Colored wheat (black blue and purple) rich in anthocyanins, phenolics and minerals has also been developed by NABI through breeding. The new lines are well adapted to the Indian environment. Different food products (chapatti, bread, biscuit, dalia, vermicelli, roasted snacks etc.) were prepared from the colored wheat and characterized for proximate analysis, anthocyanin content and other bioactive phytochemicals. The high-fat diet mouse model study results suggest that the incorporation of colored wheat (especially black wheat) in the diet can prevent obesity and related metabolic complications. The studies also indicated that Colored Wheat also has prebiotic potential and improved gut health and identified the antimicrobial property of colored wheat extracts against harmful human pathogens. Colored wheat has been approved by FSSAI as anthocyanin biofortified wheat rich in antioxidants for consumption in India. Colored wheat was grown in NABI and stored at NABI storage facility and along with farmers every year which helped in an increase in income generation per acre of land. The wheat was provided to Industry after signing MOU/NDA with them. Total 16 MOUs and 7 NDAs were signed with different industries.



Food products with high Anthocyanin content









BioNEST, Punjab University had selected 5 incubatees under dedicated call for secondary agriculture. The incubatees were provided Infrastructure, incubation space, basic & advanced equipment facility, mentorship to manage the strategy, build a roadmap and to secure intellectual property. The 5 start-ups are Kinvac LLP, which has used agricultural waste as substrate for lipase production and development of an environment friendly and economically viable bioprocess technology for food flavor esters' development, Diovita foods Pvt. Ltd. which has developed protein and fibre rich beverage, Microfoods Pvt. Ltd. which has worked on Processing of surplus fruits & vegetables into vinegars through fermentation, BROE which has developed BROE which has developed a device for the selection and segregation of normal functional seeds from diseased and broken seeds and AVnutricare Ltd which developed and standardized nutritional and functional whey beverage fortified with vitamin D using ultrahigh pressure homogenization. Academia- industry interactions were also held to facilitate idea exchange and technology transfer.

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:

- 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

Department of Biotechnology along with BIRAC is working on the development of a Clean Tech Demo Park at the Barapullah Drain site in Delhi with a view to demonstrate innovative waste-to-value technologies at the site. The park has been inaugurated virtually by Dr. Harsh Vardhan, Honorable Union minister for Health and Family Welfare & Earth Sciences in the presence of Sh. Anil Baijal, Lieutenant Governor of Delhi, Dr. Renu Swarup, Secretary DBT, other officials, scientists and innovators. A large number of waste treatment technologies have been successfully developed through the support of DBT and BIRAC and as a part of demonstration and validation, a few BIRAC supported technologies are being implemented at the park. CEIIC, an international Incubator supported under the BioNEST scheme of BIRAC, is the anchor for supporting the demonstration projects as part of the Clean Technology Demonstration Park.





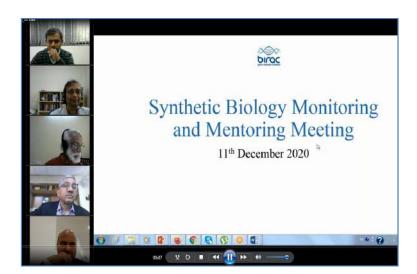
Innovation Clean Technology - Scale up

Under the 100 days agenda of the Department of Biotechnology, few promising technologies in the area of waste management/waste to energy were taken forward for Scale up/implementation at 10 sites/States. The implementation of these technologies had to be done in association with Municipal Corporations/Urban local bodies (ULBs) identified by the companies. Few potential technologies, which had achieved TRL 7, supported by DBT/BIRAC were shortlisted for consideration. Out of these, a total of 5 technologies have been identified which are being implemented in association with the Municipality/ULB of Goa, Bangalore, Thiruvananthapuram and Greater Mumbai. These were officially launched by Dr. Renu Swarup, Secretary, Department of Biotechnology in a Webinar on "Showcasing Demonstrated Waste to Value technologies". The webinar was organized on 1st October 2020 to commemorate the 152nd birth anniversary of Mahatma Gandhi, Father of Nation. Three projects have been funded, so far, for support and are at an advance stage of development.

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.

Two calls for proposals have been announced which led to supporting a total of 11 projects. These projects focus on developing products such as rose oxide, sandalwood sesquiterpenes and biobutanol production. The monitoring and mentoring of the progress of the projects sanctioned in the two call is being regularly conducted. The projects are progressing towards PoC/early stage development.







IV. PARTNERSHIPS

A. Co-funding Partnerships

a) NESTA

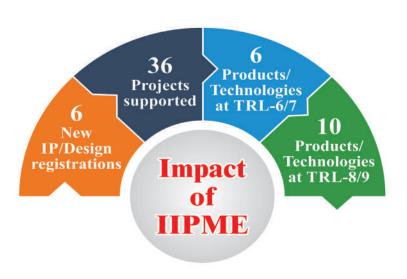
BIRAC has collaborated with NESTA, a UK based innovation charity organization, for creating a pipeline of innovators for the Longitude prize, in the area of anti-microbial resistance (AMR). Longitude prize is an initiative of NESTA focused on finding solutions to help tackle the problems in the AMR domain. Two calls have been announced under NESTA discovery program. In order to build successful collaboration between BIRAC and NESTA the 3rd round of BIRAC NESTA discovery award funding (BIRAC-DAF) is awarded in the form of BIRAC NESTA boost grants. Purpose of these grants is to ensure that the strongest Indian teams have the financial support necessary to complete their projects and to be potential candidates for the Longitude Prize.

Three teams (NanoDx, Module Innovations & OmiX in Collaboration with Spot sense) were awarded in first round of under the BIRAC boost grant. The three proposals focuses on developing rapid and & point of care diagnosis of uropathogens causing urinary tract infection (UTI), point-of-care diagnostic device for rapid identification and stratification of bacterial septicemia in critically-ill patients and detecting urinary tract infections by automation of bacterial DNA extraction process and real-time voltammetric readout during the isothermal amplification process. The projects have been sanctioned and work is ongoing.

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 Ministry of Electronics and Information Technology, Government of India and BIRAC. The programme is mandated to fund 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 fastpaced research and development in this hitherto untouched area. The program was successfully completed in 2020 with the following impact



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.

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. The performances of biotoilet were evaluated for the period of 6 months from 16 sites covering 4 states namely Assam, Meghalaya, Manipur and Tripura by collecting composite samples of 24 hr duration for influent and effluents



c. DBT- BIRAC Mission Program on Anti-Microbial Resistance

The Department of Biotechnology, Government of India has announced this Joint call with the Biotechnology Industry Research Assistance Council (BIRAC) on antimicrobial resistance (AMR). This joint mission program focuses on nurturing collaborations between academia and industry partners to enhance their capabilities for developing new antibiotics and therapeutics for AMR. First joint call has been announced in 2018-19. It was decided that academia will be supported by DBT and Industry will be supported by Industry.

A single proposal from JNU has been awarded in collaboration with Anthem Bioscience in first round of call & is supported for 3 years. The proposal focuses on development of the lead compound PPEF, (bisbenzimidazole) targeting topoisomerase IA from the library of bisbenzimidazoles that have shown to inhibit selectively topoisomerase IA enzyme. The proposal aims to undertake development of bio-enhanced and targeted drug delivery systems (DDS) of PPEF to enable translation of this new lead for clinical application. The proposal is ongoing and will complete in 2023.

d. DBT- BIRAC Program on New Drug Development

DBT-BIRAC has initiated a program on "Drug Development" with a vision to develop indigenous and cost-effective new drugs against the priority disease areas in the country. The joint call is announced in January 2020 and is focused on lead optimization and preclinical testing of candidate therapeutics for the given four diseases i.e. Tuberculosis, Cardio-Vascular Diseases (CVD), Chronic Obstructive Pulmonary Diseases (COPD) and Cancer (oral, head and neck, cervical and breast cancer).

e. DBT-BIRAC program on globally accessible and cost-effective novel antibodies

In order to tap the huge potential of novel antibodies as immune-therapeutics, the DBT has announced a joint call with BIRAC on "globally accessible and cost-effective Novel antibodies". This call will focus on the three prioritized areas-: Antimicrobial resistance (AMR), Human immunodeficiency virus (HIV) and snakebite envenoming (SBE).

Accelerated Translational Grant for Commercialization (ATGC)

Department of Biotechnology (DBT) in collaboration with Biotechnology Industry Research Assistance Council (BIRAC) launched this scheme in 2019-20 with an aim to accelerate translational research leads beyond early stage validation and encourage academia to develop technology/product & processes. The mission of this program is to enable academic researchers to take their laboratory research leads with established proof-of-concept and early stage validation to the next phase via translational research opportunities.

The scheme has two categories

- Academic Lead Translation (ALT)
- Academic Industry Translational Research (AITR)

Academic Lead Translation (ALT)

The objective of Academic Lead Translation (ALT) scheme is to promote validation of demonstrated Proof-of-concept (PoC) for a process/product. The academic institutions could do it independently or collaborate with other academic partners with complimentary expertise to translate the leads or in a contract research mode to develop the leads.

Academic Industry Translational Research (AITR)

The objective of Academic Industry Translational Research (AITR) scheme is to promote validation of Proof-of-concept (PoC) for a process/product by academia with the involvement of industry or for validation by the industry in contract research mode.

DBT will fund the academic partner and industry will be funded by BIRAC.

In the FY 20-21 two projects from Call 3 of ATGC and 6 proposals from call 4 has been recommended under AITR and the process of issuing GLA to the industry partner is under processing.

b. Networks, Platforms and Market Access

1. TATA Trusts's Foundation for Innovation and Social Entrepreneurship-Social Alpha

BIRAC have joined hands with Social Alpha to foster an ecosystem to develop Assistive Technologies (AT) solutions. Social Alpha is a not-for-profit platform created by Foundation for Innovation and Social Entrepreneurship (FISE), sponsored and supported by the Tata Trusts to nurture start-ups through their lab to market journey.



The 'BIRAC-Social Alpha Quest for Assistive Technologies – supported by Mphasis' was launched on 27th June 2019, New Delhi with a view to identify start-ups working in the AT sector.

Out of the 100+ applications received for the quest, top 14 Indian start-ups were selected as the winners and the winning solutions included assistive technologies in speech and hearing impairment, locomotor disability, visual impairment and intellectual disability for children and adults.

So far, these winners have been facilitated with the market access, clinical Trials/validation, and Design for manufacturing support. Most of the awardees have deployed their products in the market and few are in the late validation stage with a plan to get commercialized soon.



 ${\tt Cohort\ of\ 14\ Awardees\ of\ BIRAC-Social\ Alpha\ Quest\ for\ Assistive\ Technologies\ Supported\ by\ Mphasis}$

2. जनCARE Innovation Challenge-Reimagining the Healthcare Delivery in Low Resource Settings

BIRAC and NASSCOM in collaboration with Grand Challenges India (GCI) launched "जनCARE" Innovation Challenge on 28th Dec 2020. This is to discover, design and scale the Health-Tech Innovations that can work in low resource-settings especially in the areas of Cardiovascular Diseases, Maternal & Childcare, Diabetes, COPD, Cancer care, Eye care, and other NCDs. The challenge was launched to identify upto 25 Healthtech solutions from startups and provide pilot test beds in collaboration with State Governments & Industry to help their validation and scale up for adoption. This would further promote customized products developed by startups to address the local challenges and unmet needs and hence, the population of low resource areas; PHCs, CHCs in rural and semi-urban areas are likely to get benefitted through local deployment of the innovative and affordable healthtech solutions.

The Challenge is an industry-wide collaborative effort; AstraZeneca, GE Healthcare, Siemens Healthineers, Medanta Hospitals, St John's Research Institute, Health Care Global Enterprises and TATA AIG have already joined hands with this innovation challenge to provide their support and mentorship to the participating Startups till the end of pilot phase. It was officially launched over a webinar by Dr. Renu Swarup, Secretary, DBT and Chairperson, BIRAC in the presence of Ms. Debjani Ghosh, President NASSCOM, Dr. Naresh Trehan, Chairman & MD, Medanta Hospital, various Industry leaders, and State representatives and other BIRAC and NASSCOM's team members.

Out of the 60+ applications received for the challenge, top 16 Indian start-ups were selected as the winners further segregated under 4 bundles; Chronic Pulmonary Obstructive Disease (COPD), Cancer, Mother and Childcare (MCH), and Non communicable diseases and Telemedicine. Each bundle is having 1 lead innovation and other complementary innovations and would look at a comprehensive package of technologies for therapeutic area(s). The lead innovation would receive Rs 5 lakh award and the complementary innovations would receive Rs 2 lakh award each.

Biotechnology Industry Research Assistance Counicil





Speakers addressing the audience at the Launch of जनCARE Innovation Challenge



Launch of जनCARE Innovation Challenge at MyGov portal

3. Biotech Showcase Portal

Hon'ble Minister of Railways and Commerce, Government of India, Shri Piyush Goyal launched an e-portal (www.biotech-solutions.com) during GBI 2019 that presently features 150+ BIRAC supported commercialized Biotech Products and Technologies.



Biotech Showcase Portal



BIRAC Innovation Challenge Award

BIRAC in association with knowledge partner Social Alpha and BIRAC's Bio-NEST Incubator partner Clean Energy International Incubation Centre (CEIIC) has launched the 2nd call of the BIRAC-Innovation Challenge award-SoCH (Solution for Community Health) 2020-21 in Mar 2020. The challenge is envisioned to identify and facilitate Indian innovators working towards combating clean cooking-based challenges having national and global relevance. The award is focused for the theme "Innovative, Efficient and Affordable Solutions for Clean Cooking in Rural and Community Settings" and the proposals are invited in the areas of Biomass, Electricity, LPG, Solar and Biogas based cooking solutions on MyGov/BIRAC online portal. deployment.

To create awareness for the challenge, BIRAC, in association with Social Alpha and CEIIC conducted a Webinar "Pushing the Envelope on Innovation in Clean Cooking" in July 2020. Later to facilitate the selected applicants in understanding the detailed application form invited under the challenge, a webinar on "SoCH Detailed Application: What and How to Write" was also conducted in Sep 2020.

Out of the 130+ proposals received for the challenge, top 9 SoCH stage-1 awardees were selected and announced by Shri Dharmendra Pradhan, Hon'ble Minister for Petroleum and Natural Gas and Steel, Govt of India in the Global Bio-India 2020-21. Among the awardees, there were 3 companies and 6 individual applicants proposing solutions in the areas of Solar PV Induction based hybrid cooking, Solar PV Salt Battery Induction based cooking, Solar Steamer with Autoclaving for Community Cooking, Biogas based units, Smart packaging for household use, and Improved Biomass Stove. The awardees were further assisted with a grant prize up to INR 5 lakh each meant to support the development of Minimal Viable Prototypes besides Incubation and Mentorship.



Launch of BIRAC-Innovation Challenge Award-SoCH 2020-21



SoCH 1st Webinar- Pushing the Envelope on Innovation in Clean Cooking



SoCH 2nd Webinar-SoCH Detailed Application: What and How to Write



Top 9 Indian SoCH Stage-1 Awardees of BIRAC-Innovation Challenge award-SoCH 2020-21



4. Wadhwani Initiative for Sustainable Healthcare (WISH) Foundation

BIRAC partnered with WISH (Wadhwani Initiative for Sustainable Healthcare) Foundation (a Non-Profit Organization involved in taking innovation to the end users) for leveraging the network and engage the SCALE programme of WISH to validate the innovations in primary healthcare centres through state governments.

Mandate of the partnership: 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

These centers would help to create a pipeline for the state governments to systematically induct promising and high impact innovations on continuous basis.

Under this Partnership, so far eight (8) technologies/products have been validated under the Partnership, as mentioned below:

1. Accurate Tele-ECG On Mobile (ATOM)-12-lead ECG:

- Innovator: Cardea Biomedical Technologies Pvt. Ltd.
- Field validation studies were conducted at PHC at Neendar, Jaipur



Field Visit at PHC Neendar, Jaipur on 30th July, 2019–Technician performing ECG of a patient using ATOM device

2. Sohum- detection of hearing impairment in neonates

- Innovator: Sohum Labs
- Field validation studies were conducted at J K Lone Hospital, Jaipur



Field Visit at J K Lone Hospital on 30th July, 2019–Audiologist measuring hearing ability of an infant using SOHUM device



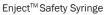
3. Aina- device to measure glycosylated Hb, blood sugar, lipid and creatinine

- Innovator: Jana Care
- Field validation studies were conducted at Tea gardens of Hathikuli and Letekujan, Assam

4. Enject[™] Safety Syringe:

- Innovator: Alfa Corpuscles Private Limited
- Field validation studies were conducted at 6 Tea Estate Smart Hospitals;Lattakujaan, Diffloo, Hathikuli, Sagmootea, Nahorani and Lamabari of Assam







Field validation studies in Assam

5. AyuSynk-Digital stethoscope:

- Innovator: Ayu Devices Pvt. Ltd.
- Field validation studies were conducted at 31 primary healthcare facilities across 13 districts of Rajasthan.



AyuSynk Device



Field validation studies in Rajasthan



6. Neurotouch- Portable Screening Device for Peripheral Neuropathy:

- Innovator: Yostra Labs
- Field validation studies were conducted in 12 PHCs(6 urban and 6 rural) across the state of Rajasthan.





Neurotouch Device

Field validation studies in PHCs at Rajasthan

7. Dozee-Health Monitor:

- Innovator: Turtle Shell Technologies Pvt. Ltd.
- Field validation studies were conducted in 20 PHC facilities (3 in urban and rest in rural area) across twelve districts of the state of Rajasthan







Field validation studies in PHCs at Rajasthan

8. ReMeDi NOVA™ Digital Health Solution:

- Innovator: Neurosynaptic Communication Pvt. Ltd.
- Field Validation studies were conducted in 2 PHCs of district Bundi of Rajasthan



ReMeDi Nova set of Devices



Field validation studies in PHCs at Rajasthan

As an outcome of the studies, 8 White papers along with recommendations of the studies were handed over to the innovators.



i. Business Finland

BIRAC has collaborated with the Finish Funding agency –Tekes now Business Finland, for leveraging the expertise and ecosystem at Finland to boost the capacity and networks of the Indian start-ups working majorly in the medical technology domain.

In 2020, DBT & BIRAC are organized an India-Estonia-Finland Biotech Webinar in collaboration Indian Embassy in Finland & Estonia. The objective of this webinar was to showcase the strengths of Indian, Finnish & Estonian Biotech Hubs.

The theme was "ADVANCING COLLABORATION ACROSS INDIA - FINLAND - ESTONIA Focus: BIOTECH SECTOR".



The webinar also highlighted the Indian Biotech Ecosystem roadmap and discussed the integration of National Mission along with new initiatives like investment facilitation will pave way for joint innovations for the developments of products.

The webinar showcased & discussed few policies such as:

- How the Cluster Level of Innovation, Manufacturing, Technology adoption Policy/ Roadmap attract Collaborations/ Joint Ventures/ FDI
- Potential of Startups, SMEs, Large Industries
- Policy initiatives in the past few years to boost the Biotech Innovation Ecosystem



Glimpses of the webinar "Advancing Collaboraion Across India - Finland-Estonia in the Biotech sector"

a. Latitude 59: It is a largest Annual international start-up Event held in Estonia which brings together the potential investors & start-ups for pitching and matchmaking activities. The event is the opportunity to demonstrate the product & technologies in front of whole tech community and many other potential customers and attending technocrats to get direct feedback and Supports.

BIRAC virtually participated in Latitude 59 held on 27-28th Aug 2020. BIRAC representative from MII cell led the delegation and participated virtually along with 5 supported start-ups:

- Janitri Innovations
- · Adiuvo Diagnostics Pvt. Ltd
- Periwinkle Technologies
- Predible Health
- Ubiquare Health Pvt Ltd

This partnership initiative is a part of BIRAC's efforts to give an international exposure to Indian Start-ups and strengthen India -Estonia – Collaboration in Innovation.

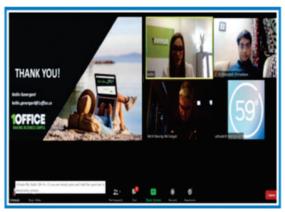


Special Focus area of Event was:

- Focus Area: Future of Technology, Digital Governance, Education
- Matchmaking platforms for attendees
- Mentor Program with Experts worldwide
- Online Demo Area
- Pitching Contest

During the 2 Day long event, delegation attended the event and also availed an oppurtuity to attend online mentoring sessions for important aspects of business such as conflict management, Hiring, talent acquisition, running business on e – residency, fund raising, team integration & partnerships, Market entry options, b2b sales, Business planning etc.





ii. TiE

BIRAC TiE Delhi NCR

The Indus Entrepreneurs (TiE)-Delhi NCR

BIRAC has partnered with TiE-Delhi NCR to leverage each other's strengths for mentoring biotech start-ups and providing continuous platform for BIRAC supported start-ups to interface with funders and investors. Under the umbrella of this partnership, BIRAC and TiE jointly organize two sets of activities every year, viz. BIRAC –TiE WINER Award and BIRAC-TiE Entrepreneurship awareness workshops.

Activities conducted during the FY 2020-21 are mentioned below:

- BIRAC -TiE WinER Award: Women In Entrepreneurial Research (WinER) Award is focused at rewarding the women entrepreneurs in biotechnology. 4th edition of BIRAC-TiE WinER Award was launched during FY 20-21.
 women entrepreneurs from the 3rd edition were provided an opportunity to attend a virtual accelerator programme for regulatory, IP, licensing, fund raising, mentoring; and 3 final winners were awarded with the final award of INR 25 lakhs each.
- 2. BIRAC-TiE Entrepreneurship awareness workshops: Like previous year, BIRAC in collaboration with TiE-Delhi NCR organised 3 virtual mentoring workshops. The initiative aims at spreading awareness about Bio-Entrepreneurship across the country. The conclaves brought together successful Start-up entrepreneurs to share their stories and experiences with students and young entrepreneurs. The young minds were also made aware of BIRAC's role in bolstering the Indian start-up culture as well as exploring avenues for a smoother transition from a university environment to the real world. More than 300 Students and young entrepreneurs from various educational institutions benefitted from discussions on pertinent topics, interesting case studies and introduction to various aspects of entrepreneurship. BIRAC also sponsored a Powered Session "Chamakte Sitare" at Resurgence TiEcon Delhi.

iii. BIRAC-ISBA Partnership

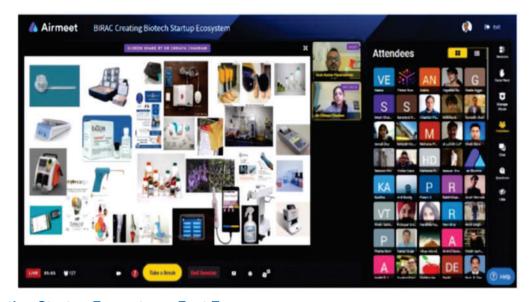
BIRAC and ISBA entered into a partnership in 2017 to strengthen the entrepreneurship development initiatives with a special focus on the BioNEST (Bioincubators for Nurturing Entrepreneurship for Scaling Technologies).



Under the partnership, following events were organised during FY 20-21.

BIRAC Creating Startup Ecosystem - North Zone

"Webinar on BIRAC Creating Startup Ecosystem" was organized by ISBA along with BIRAC on May 20, 2020 through a virtual platform. The programme was supported by ISBA Members, Shri Mata Vaishno Devi University (SMVDU) - TBI, Katra. Jammu & Kashmir and Indian Institute of Technology Catalyst, Mandi, Himachal Pradesh as the Incubation / Outreach Partners. The Special Focus of the programme was to cover the North Zone Institutions, Startups and Innovators. The North Zone focused on states including Jammu & Kashmir, Himachal Pradesh, Punjab, Uttaranchal, New Delhi, and Haryana. The event was attended by around 130 participants from institutions, industry, startups, academia and research scholars from the North Zone.



BIRAC Creating Startup Ecosystem - East Zone

"Webinar on BIRAC Creating Startup Ecosystem" was organized by ISBA along with BIRAC on July 15, 2020 through a virtual platform. The programme was supported by ISBA Member, Incubation Centre - Indian Institute of Technology Patna, Bihar as the Incubation / Outreach Partner. The Special Focus of the programme was to cover the East Zone Institutions, Startups and Innovators. The East Zone focused on states including Bihar, Jharkhand, Odisha, West Bengal, North Eastern States and Union Territories. The session was attended by around 60 applicants from institutions, industry, startups, academia and research scholars from the East Zone.





BIRAC Creating Startup Ecosystem - West Zone

ISBA along with BIRAC organized the "Webinar on BIRAC Creating Startup Ecosystem" on July 29, 2020 through an online platform. The programme was supported by ISBA Member, Research Innovation Incubation Design Labs (Riidl) as the Incubation / Outreach Partner. The Special Focus of the programme was to cover the West Zone Institutions, Startups and Innovators. The West Zone focused on states including Maharashtra, Gujarat, Goa, Karnataka Andhra Pradesh, Telangana. The event witnessed 60 participants from the West Zone.





BIRAC Creating Startup Ecosystem - Central Zone

ISBA along with BIRAC organized the "Webinar on BIRAC Creating Startup Ecosystem" on August 10, 2020 through an online platform. The programme was supported by ISBA Member, JSSATE - Science & Technology Entrepreneurs Park (JSSATE-STEP) as the Incubation / Outreach Partner. The Special Focus of the programme was to cover the Central Zone Institutions, Startups and Innovators. The Central Zone focused on states including Madhya Pradesh, Uttar Pradesh, Rajasthan, and Chhattisgarh. The event was attended by around 75 participants from institutions, industry, startups, academia and research scholars from the Central Zone.

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

Grand Challenges India (GCI) is the Indian arm of Global Grand Challenges, launched in 2012 and is the flagship program managed by the PMU at BIRAC and is collaboratively funded by Department of Biotechnology (DBT), Bill & Melinda Gates Foundation (BMGF), and the Wellcome Trust.

The main aim was to address some of the daunting challenges that we face today and tackle them by encouraging Indian innovation and research to develop affordable and sustainable solutions in order to improve health and well-being in India and then across the globe.

GCI is committed to seeking and rewarding established researchers, young entrepreneurs, and innovators from both academia and industry. GCI aims to help innovators expand the pipeline of ideas for developing new preventive and curative therapies, piloting new technologies, and exploring new ideas.

Over the years, GCI has grown both as an idea and as a partnership covering varied themes from maternal and child health to agriculture, nutrition, infectious diseases etc. in order to respond to the ever-changing needs of research in public health in India.

Presently, GCI supports a range of research and development activities. We have supported basic research, translational research, intervention trials, clinical trials, data integration and analysis, product and technology development. GCI also funds projects at various stages in their lifecycle; from basic science research in laboratories, to proof-of-concept projects and potentially to scale-up to innovation projects. GCI is currently working to expand the funding arenas and mechanisms.

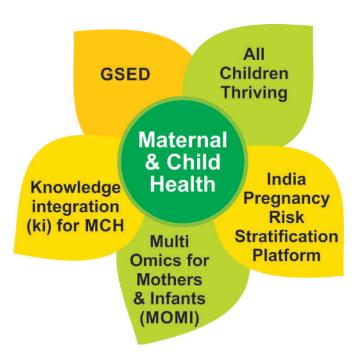
Grand Challenges India works across 4 major themes; Maternal and Child Health, Infectious disease, Agriculture & Nutrition and Medtech development and entrepreneurship support. There is also a suite of cross-thematic programs. Programs in these areas are funded through the open call as well as specialised programs mechanism.



GCI has programs across several themes and approaches. Themes include important areas such as maternal and child health, infectious diseases, medtech development and entrepreneurship support, cross-thematic programs among others. GCI also supports multiple approaches such as supporting basic research, translational research, data analytics programs among others.

MATERNAL AND CHILD HEALTH

To tackle the huge challenge of maternal and child health, especially in developing countries, GCl has made maternal and child health an important vertical to direct investments. The MCH programs under GCl are aimed at ensuring not only the survival of mothers and their children but also ensuring that they lead a healthy and productive life.



All Children Thriving

The Grand Challenges India attempts to address maternal and child health (MCH) issues through different mechanisms, either by funding basic research to understand causal linkages, or by providing opportunities to share data on MCH to understand the important patterns, trends and issues to better target research as well as policy. In line with the same, All Children Thriving (ACT) call was launched under GCI portfolio with the aim to reduce the incidence of low birth weight, reduce child stunting or wasting, reduce micronutrient deficiency and improve cognitive development in children and improve maternal nutrition through novel cost-effective measurement tools, mechanisms and interventions/ interventions packages.

Seven proposals are funded under this program and each project explores a unique aspect of the issue with special emphasis on innovative, impactful research on maternal and child health and development. Three projects are aimed at developing simple low-cost biomarkers that can be applied early in life to detect and predict adverse outcomes in mothers and children.

The most arduous and expensive component of any medical and scientific research is collecting the biological samples with complete clinical and socio-demographic details. The realization of same led to clear necessity of creating bio-banks/ repository for collecting, processing and storage of biospecimens along with their health information to significantly support current and future scientific investigations. In line with the same, one of the projects supported under call supported under ACT call entitled "Creation of a Bio-repository and Imaging Data Bank for Accelerating Evidence Generation to Facilitate Children to Thrive" has created India's first bio-bank or repository and is longitudinally collecting biological specimens from more than 5000 pregnant women, accompanied with well characterized information on the associated environmental, clinical, social and epidemiological determinants through the course of the pregnancy. Serial bio-specimens such as maternal serum, saliva, urine, high vaginal swabs, feces, cord blood, placental punches, paternal saliva and neonatal heel prick venous blood are being collected across pregnancy, delivery and, post-delivery. Besides, biobank the project is also creating imaging databanks by acquiring 3-4 serial ultrasound scans of the pregnant participants, which will be crucial in developing simple non-invasive ultrasound-based image processing tools and methods to assess likely adverse pregnancy outcomes and monitor the pregnancy. By providing access to relevant biospecimens and employing multi-disciplinary approach (clinical, epidemiological, statistical, genetic, microbial, proteomic, and imaging sciences) to address multiple strategic

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priorities in preterm birth, discovery and development. In addition, the infrastructure is also intended to attract young investigators for developing new research questions using stored/ collected data and upgrade scientific community knowledge on maternal and child health through capacity building.

Another main grant supported under ACT call is "Linear Growth study" subsequently renamed as **WINGS study**; **Women and Infants Integrated Growth Study**. The study is aimed at achieving optimal growth and development in infants and children living in low resource settings in India, through integrated delivery of a package of evidence-based interventions endorsed in national programs and by the World Health Organization (WHO). This individually randomized factorial design trial is assessing the impact of a package of health, nutrition, psychosocial care and environmental interventions delivered throughout the pre- and peri-conception period, pregnancy and first 2 years of life on both weight and length and stunting at 2 years of age. The recruitment of target beneficiary i.e 13,500 married women between 18 to 30 years of age in the pre- and peri-conception period have been recruited in the study. The recruited women are randomized to the intervention and control groups and are being followed up for intended outcomes. This trial offers a great opportunity to learn about vertically and horizontally linked intervention delivery that provides continuity of care from pre-pregnancy through early childhood. The learnings may aid in determining future design of health systems. Furthermore, the evidence drawn from the study could address important questions and may also form the basis of ideas for National Nutrition Mission (NNM) in India.

Nutritional Interventions to Improve Linear Growth during Infancy in India (IMPRINT Trial)

This is another specialized program under GCI portfolio that is conducting randomized controlled trial (RCT) with an efficacy model being tested in low resource communities in urban Delhi with high rates of stunting. The trial by enrolling 1800 mother infants' dyads intends to answer relevant scientific questions on the role of improving maternal dietary intake in promoting linear growth during the first 6 months of life. Further it is also testing the benefits of increasing protein quantity and quality in complementary foods to improve linear growth in the second 6 months of life in 1400 infants. Together, both the sub-studies will test approaches that form an overall strategy to achieve accelerated linear growth during infancy. The issues being addressed may be pertinent for future policy intervention, as on date there are no nutritional intervention for lactating mothers as per National guidelines.

Use of the Global Scale for Early Development (GSED) within the Women and Infants Integrated Growth Study (WINGS) for impact evaluation on neurodevelopment

The available evidence strongly supports that the first 1000 days (conception through age 24 months) and the period to the end of the third year of life, are foundational for brain development. Keeping in view the same children in WINGS trial are followed up to 24 months of age to assess their linear growth, with secondary outcomes i.e. neurodevelopment scores and developmental milestones. Although the importance of early development has been well recognized globally, universal measures designed to quantify early child development) are lacking, particularly for the youngest children. In light of existing knowledge gap, recently a new tool termed as "The Global Scale for Early Development (GSED)" has been developed, with the overall intent is to create a harmonized scale to measure child development in children under three years of age. The GSED tools are currently being validated in a cohort of children against available psychometric tools through a rigorous and standardized exercise in six countries that are diverse in terms of geography, language, culture and income i.e., Bangladesh, Pakistan, Tanzania, Brazil, Ivory Coast, and The Netherlands. However, it will still be unknown how the GSED tools perform in an intervention trial setting, specifically in terms of their ability to detect intervention effects on developmental outcomes. The proposed study aims to use the ongoing WINGS trial as a platform to test the GSED tools for their ability to detect effects of intervention on neurodevelopmental outcomes in children aged (6, 12 and 24 months of age). The integration of the GSED tools within the ongoing WINGS trial to help answer relevant question. The study will also provide an opportunity to understand the responsiveness of GSED tools (sensitivity) and validate it against standardized psychometric tools Ages and Stages Questionnaire 3rd Edition (ASQ-3) and Bayley Scales of Infant and Toddler Development- 3rd Edition (BSID-III) while detecting its intervention effects on neurodevelopmental outcomes. Further, this study will provide the prospect of collecting validation data from an additional diverse setting.

Knowledge Integration (ki) Data Challenge

Data Science Challenge, the sixth call under GCI, launched with a goal to foster new approaches in data-driven decisions designed to answer critical scientific questions related to maternal and child health and development outcomes, using innovative data analytics and modelling approaches applied to ki India or to other relevant data sets that applicants can access. The call was synergized with the Grand Challenges calls from Brazil and later with Africa.

Out of 10 shortlisted projects, **seven** projects have been sanctioned and six projects have signed Sub-Grant Agreement and the first tranche to these projects has been released. The projects are **in the early implementation stages**.



The granting process was delayed because of extensive deliberations on **Data Contribution Agreements** and Data **Access Agreements** with **BMGF** given **Indian government laws and policies**. After mutual agreement the issues with data, agreements were resolved and grantee teams have initiated the execution of Data Agreements as appropriate for the respective teams. Therefore, the GCI team then extended the semi-executed Sub-Grant Agreements (SGAs) to the grantees, and on full execution of agreements released the first tranche to initiate the project activities.

The supported teams are using specialized skills and valuable experience that will help interpret conclusive results through additional analyses that may help predict pregnancy outcomes, birth outcomes and childhood health and development patterns.

Multi-Omics for Mothers and Infants (MOMI)

The Grand challenge PTB program - GARBH-Ini – (interdisciplinary Group for Advanced Research on BirtHoutcomes, a DBT India Initiative being coordinated by an interdisciplinary research group has joined the **Multi-Omics for Mothers and Infants (MOMI) Consortium**, which is an international leading experts on maternal, newborn, and child health, and innovative 'omics' technologies ((genetics, metabolome, proteome etc.)

The consortium is supporting the consolidation of data from 17 high-quality cohort studies and biorepository platforms like AMANHI, GAPPs, for prediction models of preterm birth. The overall hypothesis for creating this platform is the analysis of time-series data on a large set of variables including clinical, environmental, genomic, epigenomic, metagenomics and proteomics collected across pregnancy will help in stratifying women into defined risk groups for PTR

This 18-month program is led by the teams at THSTI, NIBMG and RCB. Through the platform Garbhlni is contributing to the development of a standard sample inventory tracker by sharing the clinical/phenotypic data in a harmonized format.

As the Garbhini study began in 2015, the platform is analysing bio-banked placentae samples collected in the first year and the concurrent year for the expected quality that can be used for high throughput downstream assays. The morphological and pathological assessment of 80 placental samples for 40 term-preterm pairs & 10 from mothers delivering before 34 weeks, is being done. The RNA quality and proteome analyses are being assessed by determining the integrity of the isolated RNA through quality assays from the placentas stored in the initial years of the study and the recently banked ones.

For early prediction of PTB as early as in 1st trimester, investigation of placental enriched exosomes as potential immune-modulators during pregnancy is being studied for 15 term - preterm pairs.

The study is also generating data on the biochemical analytes estimated on maternal samples from 26-28 weeks on sera /plasma for 9 parameters. Lifeline laboratory is outsourced partner for biochemical assays. The platforms for analyte measurements are being harmonized with those being used by all consortium members.

Training of young investigators in different domains trained in advanced epidemiological study designs and sample size and power calculation strategies for development and validation of clinical prediction models and modern quantitative methods to derive causal inference from observational data is also planned under the platform.

Garbhini- India Pregnancy Risk Stratification Platform Alignment (GIPA)

Pregnancy risk stratification is critical to reduction in adverse birth outcomes. However, early identification of high-risk pregnancies is challenging in communities where high-quality obstetric care is not available during the antenatal and perinatal periods. Establishment of a Pregnancy Risk Stratification (PRS) platform has been proposed as a surveillance and trial platform at 2 sites in India-Palwal, Haryana and Makunda (Bazaricherra), Assam. Validation of the PRS algorithm is proposed at where there is a baseline understanding of the burden of adverse pregnancy and perinatal conditions, as well as relevant systems-level parameters, including public/private sector linkages, pathways of care, and gaps between practice and basic standard of care. GIPA is part of work already being undertaken in the facility-based Garbhini cohort funded by DBT and the knowledge integration (ki) and Multi-Omics for Mothers and Infants (MOMI) activities funded through the PMU at BIRAC.

The study is led by Christian Medical College, Vellore and is partnering Makunda Christian Leprosy & General Hospital, Karimganj, Assam, Centre for Health Research and Development, Society for Applied Statistics, New Delhi and Transitional Health Science and Technology Institute, Faridabad.

GIPA (Garbhini India Pregnancy Risk Stratification Platform Alignment): GIPA aims at achieving following objectives in phases across 36 months years:

1. Build on the establishment of the community-based pregnancy risk stratification platform to harmonise data

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and sample collection strategies with the global Antenatal/Postnatal Research Collective and with the Garbhini study in India (phases 1a and 2a above)

- 2. Establish data sharing through the ki initiative
- 3. Conduct pilot sampling through the India pregnancy risk stratification platform at Makunda paralleling those processed from Garbhini for the MOMI study
- 4. Validate epidemiological, clinical, ultrasound and socio-demographic risk factors identified by Garbhini in the community-based cohorts
- 5. Build towards validation of biomarkers identified by Garbhini in the community-based cohorts.

INFECTIOUS DISEASES

Recognising the importance of innovation and research in the space of infectious diseases, the partners of Grand Challenges India (GCI) have kept Infectious diseases as an important vertical where innovations/projects are funded.

Immunization Data: Innovating for Action (GCI-IDIA)

The fourth thematic call was launched in 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), who will be providing their valuable technical and practical inputs in selecting and reviewing projects. The overall goal is to seek ideas that should be potentially translatable to practical interventions in India's immunization program.

The supported nine project teams are testing a blend of innovative technologies involving blockchain technologies, data warehousing, mobile applications and development of health monitors for distinct health officials.

In FY 20-21 all the projects undertook their specific activities, supported by mentors and the GCI teams, as well as the state immunization officers and health authorities. The projects were reviewed by the TAG committee.

qHPV Clinical Development

PMU-BIRAC has taken Quadrivalent Human Papilloma Virus (qHPV) phase II/III 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.

Papilloma Virus (HPV) vaccine development initiated in 2011 that DBT funded under BIPP scheme. Serum Institute of India completed a Preclinical and phase 1 clinical trial in India in 2017. The Executive Committee (EC) approved for qHPV Vaccine Phase II/III Clinical Development. International Agency for Research on Cancer (WHO-IARC) is working as an advisory partner. Syngene is working on immunogenicity assays (Multiplexed ELISA and MSD) to analyse phase II/III samples. Rajiv Gandhi Centre for Biotechnology (RGCB) estimating the frequencies of the incident and persistent HPV infections from the vaccine targeted HPV types in the sexually active 15-26 years older women who received the SIIPL vaccine using bead-based Multiplex HPV genotyping assay.

The Drug Control General of India (DCGI) has approved 14 investigator sites across India for conducting Phase II/III clinical trial on 7th June 2018 and obtained the clinical trial Permission No. CT No. CT - 10/2018. The study plans to recruit 600 subjects in Phase II and 1710 subjects in Phase III study. Phase II clinical trial was completed in 2019, and Phase III study was ongoing in 2020-21.

Establishment of UK National Institute of Health Research funded Global Health Research India Unit for Genomic Surveillance of Antimicrobial Resistance

The increasing prevalence of antimicrobial resistance (AMR) threatens to affect healthcare at every level, and is now a major international threat to public health. In order to react to the evolution of bacteria with an increased risk to human health (ability to transmit, cause disease and resist antibiotics) systematic approaches are needed for collecting and identifying these at a local level, and integrated systems to collate data to provide an international overview. This is particularly important in low- and middle-income countries (LMICs) which stand to benefit most from these interventions and are key locations for the prevention of spread locally, nationally and internationally.

The reasons for limited concerted response against AMR are; inadequate focus on microbial genomics; lack of expertise and infrastructure in microbial genomics, and lack of country wide network to address the challenge. The



use of whole genome sequencing (WGS) of bacterial pathogens promises to transform our ability to understand epidemic dynamics. Besides identification of genetic changes responsible for resistance and virulence, WGS allows comparison of clinical isolates genomes from different individuals and locations and infer likely routes of spread. In light of same, the Sanger Institute through funding support of UK National Institute of Health Research (NIHR) had proposed establishment of Global Health Research Unit (GHRU) to strengthen intelligent surveillance network hub for early warning of emerging pathogen and resistance threats.

Considering that there are greater levels of AMR resistance reported from India as compared to developed countries, the Wellcome Trust Sanger aims to establish UK-NIHR funded Global Health Research India Unit (GHRU) at Central Research Laboratory (CRL), KIMS, Bangalore to provide intelligent global surveillance of bacterial pathogens using WGS through appropriate sampling and analysis. The program is aimed at enhancing local capacity of GHRU and equipping it to undertake WGS and generate actionable data that will enable policy makers and public health programs to make informed decisions to respond to AMR in most efficient manner.

Grand Challenges India-Antimicrobial Resistance

Antimicrobial resistance (AMR) has become a major healthcare threat in recent times due to excessive use of antimicrobials, especially antibiotics, leading to dramatic rise in resistance. There are greater levels of AMR resistance reported from India and comparable geographies as compared to developed countries. Given the increasing importance of tackling AMR in these developing geographies, GCI launched a call specific to AMR with the purpose of transforming public health action on a regional or global scale by identifying and filling gaps in knowledge on AMR burden. This program was directed at addressing challenges that are being faced in tackling AMR in India and in comparable geographies. With the increased awareness on the threat of AMR in the last few years, this call was designed specifically to focus on certain areas that are particularly important for India and have had less research and funding.

This program primarily aimed 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.

Given that the Government of India is heavily supporting the setting of traditional surveillance networks and systems through several vertical programs, under surveillance mandate, the call focused on innovations in new data sources, analytical methods and new biomarkers for surveillance.

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.

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 active pharmaceutical ingredients (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.

In line with the call mandate the shortlisted projects are mainly supporting projects that are broadly aimed at addressing big gaps in the surveillance and response system for infectious diseases threats.

In FY 2020-21, the program saw some delays in project implementation due to Covid-19 and the review of the program and project activities was undertaken.

AGRICULTURE AND NUTRITION

Agriculture and nutrition have been one of the oldest themes supported by the GCI program. The programs in this theme focus on the intersection of agriculture and nutrition to improve health and livelihoods.





Nutrition-Sensitive Agriculture

The project entitled 'Food-based nutritional security for malnourished rural households through capacity building and establishment of Nutri-gardens' is being implemented by M. S. Swaminathan Research Foundation in collaboration with four State Agriculture Universities and Krishi Vigyan Kendras (KVKs) at Palghar, Maharashtra; Thirur, Tamil Nadu; Kanpur Dehat, Uttar Pradesh; Jeypore Campus of MSSRF, Odisha.

The overall impact of the project will be an improvement in Diet Diversity Score of the undernourished farm households' up to 60% from base level and appropriate awareness through training at the grassroots level (farmers and malnourished sections of the society) and other stakeholders including policymakers to come out with enabling policies that will eradicate malnutrition.

The third 'Virtual' SAC meeting was conducted in April 2021 to review the project activities for mid-term evaluation and through detailed interactions between stakeholders, mentors and the grantee, the project team will follow the recommendations and key action points and accordingly plan future activities for effective implementation of the program to achieve the desired results.

It was unanimously agreed that the program progress aims to deliver results for the benefit of the nation and can bring substantial benefit to communities if scaled to other geographies with evidence-based data. The field operations were affected because of the Covid-induced lockdown and therefore the program was extended for a year to bring substantial evidence from the communities.

The MSSRF team presented detailed project activities and implementation strategies for all four sites, participants, inclusion criteria and baseline report.

Glimpses of program activities





Current Progress Updates of all four sites:

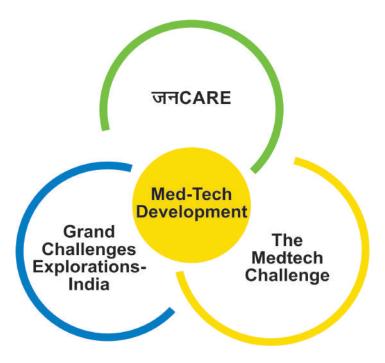
The program has completed one year of its implementation and has been reviewed by the Scientific Advisory Group constituted for this program.

The program has achieved the following during the reporting period.

- Nutri-gardens were established with different nutrient section in all the four sites.
- Mother nursery is established in all sites (Minimum 150 germplasm of nutri-rich plants collected in each site).
- Interpretation centres established in each site to create nutrition literacy to various stakeholders.
- Selected nutri-rich plant species such as Orange Fleshed Sweet potato, Drumstick, Guava, Lemon, Mango, Sapota, and West Indian cherry and other important plants were propagated and distributed to the members of the Farmer Self Help groups.
- Propagation centres established in all the four sites and focusing on multiplying plants using vegetative propagation methods cuttings, layering, stems, leaves and roots.
- Seed banks and polyhouses were established and seeds of selected nutri-rich plants were distributed to small and marginal farmers in all the four sites bhindi, brinjal, radish, greens and legume vegetables.
- 20 Farmers Self Help Groups (25 members/ group) were formed in each site.
- Training programs on vegetable cultivation to consumption were conducted to the small and marginal farm families (members of the Farmer Self Help groups participated in the program)
- 30 master trainers were shortlisted in each site and they were provided orientation to train the small and marginal farmers on various aspects of nutri-rich plants cultivation to consumption.
- In each site 5 Community Hunger Fighters were selected from individuals with ability to reach out to the village communities in spreading nutrition literacy.

MEDTECH DEVELOPMENT AND ENTREPRENEURSHIP SUPPORT

GCI supports this theme with two unique programs in this space which support innovators and entrepreneurs in the early as well as late-stages of the developmental pipeline.





Grand Challenges Explorations- India

Grand Challenges Exploration (GCE)-India is one of the initiatives under GCI ambit that has been launched with the aim of identifying health care innovation that will enable the goal of equitable health care in India and beyond. The GCE-India intends to provide seed funding to the highly innovative ideas at the pre-proof concept stage in an effort to develop a sustainable mechanism for supporting health and development innovations in the exploratory domain of India. The initiative basically seeks to validate ideas from talented and motivated individuals that lend themselves to be incubated in start-ups with the aim to encourage entrepreneurship.

Being managed and administered by GCI team at BIRAC, the program is implemented by IKP Knowledge Park, Hyderabad. The ultimate goal for the program is a quest for new medical technology devices, drug delivery systems, diagnostics, and technology enabled service models that can potentially be made available to people from all socioeconomic strata. In view of the important public health goals, the call mandates are explicitly drawn from the domain of maternal and child health, wearables, diagnostics and devices, cervical cancer, antimicrobial resistance (AMR), agriculture and nutrition, geriatric care, and water sanitation & Hygiene (WASH).

In the last five years total 1958 applicants have applied to 58 grand challenges that were defined across global health priorities. Total 35 awards have been made so far with majority of awardees working on areas such as Maternal Child Health, Geriatric Care, Infectious Diseases, Antimicrobial Resistance followed by Nutrition, Sanitation etc. Total number of awardees developing medical diagnostics are 15, Devices 10, Medical technologies 6, Nutrition and Sanitation 3 and 2 respectively. GCE-India awardees are located across 14 states in India with majority of them from Karnataka, New Delhi and Maharashtra. The number of awardees having their own ventures are 21 candidates, while the remaining 13 are from Academia and 1 from NGOs.

The GCI team ensures that besides granting funding assistance, the investigators also receive access to technical and regulatory advisors along with a network of market entry/business development professionals to help refine the proposed solutions proposed and take the ideas to the next stage of realization. Besides, leveraging the mentorship, resources, successful projects also have the opportunity to apply for follow-on funds from BIRAC.

Of supported projects, total of 7 awardees have their prototype/ product ready for further validation (field/clinical) or deployment. Efforts are being made that prototypes and proof of concept (pertaining to diagnostics and devices) that are ready for validation and deployment should be linked or reach out to diagnostic companies or commercial partners. The overarching aim of the program is to encourage technology-oriented research and contribute to value creation.

The Medtech Challenge: Market Acceleration Training & Award Program

The MedTech Challenge: Market Acceleration Training & Award program is designed around the needs of Indian innovators and entrepreneurs working in the areas of developing medical technologies for public health who have a validated proof-of-concept for their technology and are in the process of taking their product to the market.

The program aims to fill the gap in the development and delivery of affordable medical technologies in India and plans to address the low movement of affordable technologies through the development pipeline. It will therefore select and mentor Indian entrepreneurs to further develop their medical technology innovations, which will already have strong proof-of-concept data.

The funded projects will also be mentored from a business-readiness perspective to deliver affordable medical technologies which would have maximum access through public and private markets and fulfil a strong unmet medical need.

An international technical facilitator VentureWell provided the technical assessment as well as curate and deliver the workshop to the selected applicants.

The initial submissions and interviews for assessment were completed in Jan/Feb 2020. The Joint Triage Committee had it meeting to select the applicants for the workshop was held via video conferencing on 2nd March 2020 and after due approvals, the selected applicants were informed of their selection via email on 6th March 2020.

There was a total of 22 submissions for the challenge. All applicants were assessed, and the Joint Triage Committee recommended that all 22 applicants be selected for the workshop.

The MedTech workshop was due to be held from 21-25th March 2020 in Delhi. However, due to the Covid-19 pandemic, several international restrictions were put into place at the time. Therefore, it was decided to postpone the workshop.

The partners then decided that the workshop would be held over a 5-week period starting 1st September 2020, through a virtual mode, with simultaneous mentorship. The workshop ended on 12th October 2020, which was followed by 4 weeks of mentorship till 9th November 2020.



Virtual Workshop

To accommodate time zones and manage online meeting fatigue, the weekly plan for the conduction of the workshop was planned such that Mondays focused on presentations and introduction of key topics, Wednesdays on networked learning, where teams participate in group discussions and attend breakouts with mentors and instructors to discuss lecture topics, customer discovery interviews, and activities in the workbook and Friday focused on 'individual check-ins" between teams and mentors to receive feedback on their work and how it applies to their ventures.

The workshop was inaugurated on 1st August 2020 and the 5-week workshop period came to an end on 12th October 2020 and then mentorship period continued for another 4 weeks where innovators had individual check in times with their assigned and other mentors.

The reception of the workshop was very positive with all the innovators who appreciated the content, design and delivery of the workshop.



The Virtual workshop Orientation

The MedTech Accelerator grant application was opened on the BIRAC portal on 13th October 2020 and closed, 45 days on 26th November 2020, at 1700hrs.

At the close of the deadline, 20 applications were received on the BIRAC portal.

A unique aspect of this program was also the Pre-Accelerator Grant that was provided to the applicants who attended the workshop and mentorship period, and submitted the Accelerator Grant Application on the BIRAC portal successfully by the deadline. This Pre-Accelerator Grant was for upto INR 3 lakhs per team for this duration.

The Funding Committee to select and recommend the projects for the Accelerator Grant was held in February 2021, in a completely virtual mode, with experts in the area of product development, entrepreneurship and investment as all part of the committee. The 20 applicants presented their projects to this committee and the Committee recommended 4 proposals as fully recommended and 1 proposal as conditionally recommended.

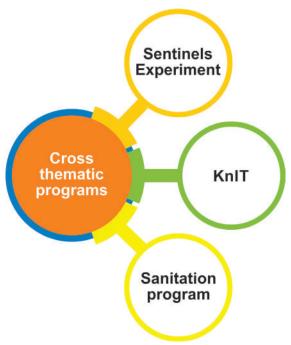
जनCARE Innovation Challenge:

অনCARE" Innovation Challenge-Reimagining the Healthcare Delivery in Low Resource Settings. BIRAC, NASSCOM and NASSCOM Foundation launched Innovation Challenge-जनCARE" in collaboration with GCI, a nationwide "Discover – Design – Scale" program, envisioned to identify Innovative health-tech solutions Start-ups for strengthening the Healthcare Delivery in India. The platform is looking for technology interventions that can positively impact healthcare delivery, especially the affordability, accessibility, and quality of services—focusing on Cardiovascular Diseases, Maternal & Childcare, Diabetes, COPD, Cancer care, Eyecare, and other NCDs. Seventeen Healthtech solutions were identified that are TRL 7 for an opportunity of Field validation in Test Beds located at the Low Resource settings. Real-life set up at selected PHCs, CHCs, Sub-Centers, etc., in rural and semi-urban locations. Field Validation duration would be up to 6 months. NASSCOM team has been empowered with dedicated resources to support the testbeds through BIRAC/ GCI and Program Partners.



CROSS-THEMATIC PROGRAMS

The programs supported in this area cross-cut across multiple themes and also include our policy oriented programs such as KnIT.



Knowledge Integration and Translational Platform (KnIT)

KnIT is a unique knowledge synthesis platform that has been launched with the aim to bridge the gap between research and policy and facilitate evidence-based policy making in public health.

KnIT was designed to address a particular set of challenges that the states in India face today, with respect to designing evidence- based policy for public health.

The first of these challenges is that while there is a large quantum of research studies and demographic data being carried out and collected across the country, there is no formal and scientifically rigorous mechanism that collaboratively assesses existing relevant information to inform states and provide them with actionable interventions to address their particular challenges.

Second, given India's population, unique demographics and the particular problems that we face in public health, it is important that this information comes from Indian data, or data from comparable geographies.

Third, there is no mechanism that packages data and information for policymakers such that they receive the pertinent details that will enable them to compare interventions to choose the most relevant to their context.

The design and mandate of KnIT is to address these challenges, in the detailed and scientifically rigorous manner to ensure scientific credibility. KnIT as a platform is responsible for collating and analyzing available evidence within India, to inform bureaucrats and health authorities and aid in the development of evidence-based policy to address the inequalities in the health outcomes in our country.

This platform specifically targets Indian policymakers as the end users of the knowledge synthesized, specifically at the State level, in keeping with the current health policy structure, where health is a state subject. This is to ensure that the data and evidence collection is done with the overarching goal of developing and implementing cost-effective, sustainable interventions or packages of multi-sectoral health interventions that are appropriate to the context of different states.

The platform identifies gaps in our knowledge and policy, and synthesizes currently available evidence to improve our understanding of current or new interventions or packages of interventions to address the major health issues in our country.

The platform works by conducting extensive systematic reviews and conducts workshops and other meetings to widely share the findings of these studies through domain centers which are the units that work on specific areas of public health, as decided by the KnIT platform and the Scientific Advisory Committee.

Currently, KnIT focuses on two tracks, maternal and child health issues and nutrition and has two Domain centers working in these areas.

The Society for Applied Studies, New Delhi is the Nutrition Domain Center. The International AIDS Vaccine Initiative, New Delhi is the maternal and child health domain center.



In 2020-21, the SAC committee reviewed the program and given the importance of the work that the platform and the domain centers are doing, decided to extend the program for the 4th Year.

The team is also preparing a policy brief or compilation of all the work done by the program in its 4 years.

The Nutrition Domain Center

The Nutrition track examines public health and medical interventions to mitigate stunting, wasting, severe malnutrition, low birth weight, optimal body composition and metabolic unfitness or obesity. The nutrition track has worked on areas where there are important questions to be addressed such as low-birth weight babies, anaemia, complementary feeding and diarrhea among others.

The nutrition track works primarily in the secondary data analysis space, using national survey data, or by conducting systematic reviews to present the current state of knowledge as well as identify gaps in research.

The center also conducts consultative meetings as a part of its methodology to understand and reach consensus regarding issues.

The Nutrition track examines public health and medical interventions to mitigate stunting, wasting, severe malnutrition, low birth weight, optimal body composition and metabolic unfitness or obesity. The nutrition track is previously worked on four areas where there are important questions to be addressed; low-birth weight babies, anaemia, complementary feeding and diarrhea. In 19-20 the Domain Center focused on weight gain in pregnancy and growth in early life as well as on analysing the factors that contribute to different outcomes in states with the Covid-19 disease.

In Year IV the Domain centre will continue working on the nutritional status of children in India with specific focus on low birth weight and anaemia. They also plan to expand to understand the nutritional status among adolescents in India. The team will conduct secondary analysis of data rom nationally representative surveys, large intervention trials or cohorts and systematic reviews and meta-analyses to answer these questions.

The Maternal and Child Health Domain Center

MCH focuses on identifying the health system challenges that are barriers to effective, equitable, impactful delivery of health services and identifies strategies how to overcome them. It also focuses on designing delivery strategies based on evidence, and piloting and evaluating programs aimed at improving program delivery, directing implementation research to optimize primary and secondary level healthcare, and generating evidence-based, human resource linked strategies relevant to MCH.

The MCH team was originally focused 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 findings from the qualitative and quantitative surveys (including facility assessments) were triangulated to provide recommendation of care of small and sick babies in the district and are in the process of being disseminated through the state of Himachal Pradesh which faced delays due to the pandemic in 2020-21.

In Year IV the Domain centre will be working on a study which will generate evidence on the population, need and product, market, program and policy level factors to enable access to novel biotherapeutic interventions like monoclonal antibodies through the public health system for Covid-19 disease treatment. The team will continue working on the assessment of interventions for Respiratory Syncytial Virus in children and the exemplar study on factors associated with decline in stunting across states in India. The results of these studies are expected in 2021-2022.

Sentinels Initiative

The Gates Foundation institutionalized 'Sentinels Experiment' in India as an open initiative and supported seven explicit innovation practitioners that are focused on exploring, the unique aspect of the health issues with special emphasis on innovative, impactful research in existing strategies or creating completely new opportunities and pathways to the outcomes sought on the broader global health challenges.

The experiment used special administrative mechanisms to provide awards of INR 50,00,000/- to each innovative project to generate proofs-of-concept.

The seven supported projects aiming to solve a wide range of problems are enlisted below: piloting and testing varied concepts

• Two projects are exploring the nutrition predictive metrics and nutrient uptake and metabolism coordinates, one, through protein synthesis dynamics in the brain, in rat models and later is studying the Environmental Enteric Dysfunction (EED) in Drosophila Melanogaster (vinegar fly) a low-cost animal model.

Biotechnology Industry Research Assistance Counicil



- The other two projects are studying Mycobacterium tuberculosis, likely to identify the potential 'anti-latency' lead molecule(s) and the other is trying develop a novel mycobacterium OMV coated nanoparticle (OMV-particles) for efficient vaccine delivery system.
- One team plans to test a technique to establish a gene drive method and engineer into the carrier of Flaviviral infections, *Aedes aegypti* population without disturbing the ecological niche.
- A Pune based company, Module Innovations plans to establish proof of concept for a novel system to determine
 antibiotic resistance profile of 4 major uropathogens against a panel of 8 antibiotics used in current clinical
 practice, these 4 bacteria include E. coli, Klebsiella, P. aeruginosa and Enterococci spp.
- Lastly, Sea6 Energy Private Limited, Bangalore aims to improve upon the prototype product by conducting
 extensive field trials, and developing next-generation products by blending the active ingredients of existing
 products with the potential active ingredients from other red seaweed species.

These seven projects are at different stages on implementation and there were delays in project activities due to COVID Situation. The COVID situation has slowed down the progress of the projects and the Sentinels are requesting an extension for the project duration, since no work has been done since March 2020 as the institutes were still not operational as students/ fellows are not allowed to return to the institute. Given that limited progress has been made since March 2020 and the Sentinels faced supply limitations for consumables, reagents, and other radioactive material needed for the work. Considering this, it is unlikely that sentinels would be able to meet the set project milestones, the projects were extended with appropriate approvals for a period requested by the Sentinels.

Reinvent the Toilet Challenge:

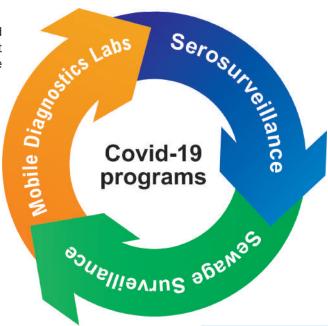
"Reinvent the Toilet Challenge - India", a program directed at addressing the problems in sanitation and especially needed in the rural and urban areas, where billions of people are only capturing and storing their waste, with no sustainable way to handle it once their on-site storage—such as a septic 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 per cent 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 that can be incorporated into a next-generation toilet that will reduce the burden of excreta-related disease and improve 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.

Grand Challenges India led COVID-19 efforts

Grand Challenges India is supporting programs to find solutions for the most pressing global threat of the current COVID-19 pandemic, on Sewage Surveillance, Mobile Diagnostics Labs, Sero-surveillance etc.





COVID-19 Sewage Surveillance

Wastewater surveillance would be a complementary approach to measure the presence and prevalence of COVID-19. Two projects are being supported in this program.

CMC, **Vellore** is developing sewage/ sludge sampling - processing protocols and assays to identify COVID-19 viral RNA fragments to initiate community sewage surveillance by different partners across India.

BITS Pilani, is working on wastewater-based epidemiology and screening for COVID-19.

Mobile Diagnostic Labs

To establish proof-of-concept of Mobile Diagnostics Labs and 4 mobile labs are being supported by the partnership. Kawach model, is developed by a private company based in Mumbai, Science by Design Lab systems (I) Pvt. Ltd. and is ready for deployment. The mobile lab is planned to be deployed at Pune, Maharashtra.



The Mobile Virology Lab ready for deployment.

PARAKH model of Defence Research and Development Organisation (DRDO), for which PSA's office received donations of two chassis from Daimler, are under fabrication and are being developed in Chennai through a private vendor. These two mobile labs will be deployed at IITM, Chennai and IIT Guwahati each.

COVID-19 Sero-Surveillance

Population-based sero-epidemiological studies help determine the burden of COVID-19 infection at the community level, to monitor the trends in the transmission of SARS-CoV-2 infection and help generate evidence on the role of asymptomatic and mild infections in transmission. The program is supporting one site under the NBM DBT DRIVEN program, the King Edward Memorial Hospital and Research Center, Pune, of the 5 sites in this program that are being managed by the National Biopharma Mission.

The second investment in this space is for Translational Health Science and Technology Institute, Faridabad with Tata Institute for Fundamental Research and Kasturba Hospital, Mumbai for assays to be conducted on a sub-set of samples collected during a sero-surveillance study in Mumbai to inform about seropositivity.



CONVENINGS

Grand Challenges Annual Meeting 2020

The Grand Challenges Annual Meeting convened virtually from 19th - 21st October, 2020 bringing together policymakers, scientific leaders calling for deepened scientific collaborations in solving global health problems, with great emphasis on COVID-19 with an "India for the World" framing. The GCAM 2020 was originally scheduled to be held in New Delhi, the virtual meeting continued to be supported by key partners in India, including the Department of Biotechnology, Ministry of Science & Technology, Government of India (DBT) and the Indian Council of Medical Research (ICMR). The meeting was co-hosted by the Government of India, Grand Challenges Canada, the United States Agency for International Development, Wellcome Trust and the Bill & Melinda Gates Foundation.

The Grand Challenges Meeting 2020 focused on the momentum of the growing global partnerships and evergrowing Grand Challenges community to help end the threat of



the COVID-19 pandemic more sooner than later, particularly during times of incredible global need.

Hon'ble Prime Minister, Narendra Modi inaugurated the Grand Challenges Annual Meeting 2020 and delivered the keynote address. The Prime Minister elaborated on the key initiatives taken for managing the pandemic and spotlighted India's commitment to accelerate progress on public health goals through science and innovation. He also appreciated the commendable efforts of the Grand Challenges program and stressed on the efforts taken against the COVID-19 pandemic by the global partnerships. The PM elaborated on various steps taken by India in fighting the pandemic. The keynote address also highlighted how India is investing in innovation to advance health solutions and prevent another pandemic like COVID-19.



Mr. Bill Gates, Co-Chair and Trustee, Bill & Melinda Gates Foundation, delivered the plenary framing conversation and focused on lessons from the COVID-19 pandemic to inform R&D going forward in vaccine platforms, monoclonal antibody platforms and diagnostic platforms.

Dr. Harsh Vardhan, Union Minister for Health & Family Welfare, Science & Technology & Earth Sciences delivered the opening remarks for the plenary program of the Grand Challenges Annual Meeting 2020. He stressed that global collaborations are paramount and we should focus on creating an effective health system to improve pandemic preparedness.

Dr. Renu Swarup, Secretary, Department of Biotechnology and Chairperson, BIRAC delivered the host country welcome at the Inaugural plenary session. She elaborated on how the power of collaborations was immense and by harnessing this power we will be able to deliver the promise of innovation to find solutions to this pandemic.

Day 2 of the Grand Challenges Annual Meeting featured a high-level panel discussion which explored the Indian experience in managing COVID-19 from a scientific and disease management perspective. The session was moderated by Dr. Swarup who outlined the country's efforts to mitigate the challenges of the pandemic. The session had participation of national and international key policy makers and eminent researchers who provided the global



views of the Indian response to the COVID-19 pandemic. The session was divided into two panels that discussed strategies and methods of "Managing the pandemic" and "Scientific intervention for fighting the pandemic".



Dr. Renu Swarup also participated on a panel on "From the Frontlines to Labs to Boardrooms: Women & Girls at the Center of Global Health & Development Innovation" – that will discuss how COVID-19 is exacerbating existing gender, racial, economic and social inequities; explore strategies to actively center the needs of women and girls in the COVID-19 response and the global health and development innovation agenda; and identify pathways to elevate more women leaders. The panel was moderated Anita Zaidi, Director, Vaccine Development, Surveillance, and Enteric & Diarrheal Diseases, Bill & Melinda Gates Foundation and had Melinda Gates, Co-Chair, Bill & Melinda Gates Foundation with leading experts in the field.



The three- day program featured leaders talks, panel discussions and virtual informal conversations on different topics ranging from scientific interventions for fighting the pandemic, managing the pandemic and accelerating the development and implementation of global solutions to combat this pandemic and prevent the next one.

Political world leaders, eminent scientists and researchers from across the globe joined this annual meeting to discuss key priorities for accelerating progress across the Sustainable Development Goals in the post-pandemic world and elaborated on addressing the challenges to manage COVID-19.

Additionally, the meeting orchestrated concurrent sessions over three days on following:

- → Enabling Crop Analytics at Scale
- → Smart Farming Innovations for Small Scale Producers

Biotechnology Industry Research Assistance Counicil



- → Optimizing Birth, Growth and Development
- → Global Partnerships & Grand Challenges
- → Leveraging Pathogen Genetic Sequencing
- → Vaccines & Global Health Technology
- → Optimizing Drug Discovery and Translation
- → Radical Thinking to Tackle Mental Health/Supporting Youth Mental Health
- → Digital Health From Impact to Scale

The virtually organized meeting was attended by over 1700 delegates from over 75 countries.

Women Leaders in Global Health Conference 2020

The 4th Annual Women Leaders Global Health Conference 2020 was convened virtually from 13-15th October, bringing together policymakers, researchers, frontline health workers and youth leaders calling for urgent action on diverse leadership in global health.

The event was expected to happen in India this year, however, due to the pandemic, the event was moved digitally. The theme of this year's conference was Connect, Commit and Act. Approximately 1500 people participated from across the different parts of the world.

This year's conference provided an opportunity to reach a broader audience, elevating new voices and further facilitating geography-specific discussion, while maintaining the sense of global community, learning and passion.

The Conference was spanned over three days with dynamic sessions and speakers each day. The sessions were open to everyone and the first two days were geographic-specific with focus on women's leadership in South Asia and Africa. The third day highlighted the global dialogue.

WLGH2020 hosted over 20+ sessions; 50+ influential speakers from diverse sectors in global health around the globe who were a part of plenary sessions, panel discussions, networking and mentoring opportunities.

The Day 1 of WLGH 2020 had the spotlight on South Asia. Some thought-provoking sessions inspired global dialogue around leadership and development challenges focussing on gender equality and parity. Some of the sessions included:

- South Asia women shaping health
- Prioritizing the Mental Health of Women in the Workforce During Emergencies Elevating Women's Voices in Popular Culture and the Media
- Learning How to Advocate for Change
- Leadership During Crisis: A Conversation
- Making policy with a gender lens

Secretary, Department of Biotechnology and Chairperson, BIRAC, Dr. Renu Swarup, and Executive Vice Chairperson, Apollo Hospitals, Dr. Shobana Kamineni were the Co-Champions for the WLGH 2020 Conference and also the Co-Chairs of WLGH-International Steering Committee. Dr. Swarup announced that the Global Women Leaders in Global Health conference will take place in India in 2021 and will be hosted by DBT& BIRAC.





Dr Swarup in a session with Dr.Shobana Kamineni on "Leadership during Crisis" gave an overview about the status of vaccine development in India and how with the pandemic; leadership approach has been tailored to meet the needs of masses. She also talked about the gender imbalances in the organisation and outlined the common roadblocks for women advancing their careers in STEM in India and broadly South Asia.

Several other officials and dignitaries from the global scientific community also participated in the event.

Communications

The GCI Communications team maintains and manages the GCI microsite, hosted on the BIRAC website.

Grand Challenges India's outreach activities are supported by the Communication team. The communication team also supports BIRAC in organizing and implementing communication efforts, as well as representation at various online and offline events.



The communication team is in charge of social media platforms, press releases, and event management, as well as pre- and post-event reporting in various formats-digital and offline. In addition, the team creates content for articles and editorials, as well as providing support for opinion-editorials, questionnaires, and media reports. The team has also reflected the DBT-BIRAC COVID efforts in various publications.



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

The National Technical Board on Nutrition was constituted in 2017 under the Chairmanship of Dr. V K Paul, Member (Health), to provide evidence-based recommendations on policy relevant issues pertaining to nutrition of women and children. To support NTBN, a Scientific Sub Committee of National Technical Board on Nutrition (SSC-NTBN) was set up by NITI Ayog. The Committee is Co-Chaired by Secretary, DBT and Secretary, DHR & DG, ICMR and the mandate of the Committee is to provide technical evidence-based recommendations to NTBN by providing recommendations on strategies to mitigate anemia, micronutrient and protein malnutrition and other relevant issues brought up by NITI Aayog. The Secretariat of SSC-NTBN is housed at BIRAC and the Program Management Unit-BIRAC (GCI) manages its activities.

Since its constitution, four meetings of SSC-NTBN have been held to provide technical recommendations on;

- 1. Infant and Young Child Feeding (Ministry of Women and Child Development, Gol)
- 2. Prevention of Malnutrition and Community Based Management of Severe Acute Malnutrition (Ministry of Women and Child Development, Gol)
- 3. Nutritional Guidelines on low-birth-weight infants (NITI Aayog),
- 4. Midline evaluation survey proposal of POSHAN (NIN, Hyderabad), and
- 5. Counselling Note for IYCF.
- 6. "Appetite Assessment Test" mentioned in Operational Guidelines for prevention of Malnutrition and Community based Management of Severe Acute Malnutrition (C-SAM),

Apart from these, the Committee is additionally looking to identify the research priority areas in the field of Public Health and nutrition. The fourth meeting of SSC-NTBN was held on January 27, 2021 to relook into the recommendations of SSC-NTBN on the 'Appetite Test' (Operational Guidelines for prevention of Malnutrition and Community – based Management of Severe Acute Malnutrition (C-SAM)). The operational issues of conducting the Appetite Assessment Test on field were deliberated in details. The Committee also discussed the tentative list of research areas to be pursued by Ministry of Science and Technology recommended by Hon'ble Minister WCD w.r.t the Women in Science and Technology (STEM) meeting and was in agreement for most of the research areas to be taken as priority.





SSC-NTBN fourth meeting

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

Accelerating discovery research to early development for biopharmaceuticals

[1] Overview:

The Industry-Academia Collaborative Mission of Department of Biotechnology (DBT), Govt of India for accelerating discovery research to early development for Biopharmaceuticals was approved by the Cabinet for a total cost of INR 1500 Cr and 50% co-funded by the World Bank. The program, referred to as National Biopharma Mission (NBM), is being implemented by Biotechnology Research Assistance Council (BIRAC) and this program is aligned with the national mission of Make-in India.

Key Components:

- Development of product leads that are at advanced stages of the product development lifecycle and relevant to the public health need in vaccine, biosimilar and medical devices & diagnostics.
- Establishing and strengthening shared infrastructure facilities for product development and validation.
- Developing human capital by providing specific training to address the critical skills gap across the product development value chain.
- Creating and enhancing technology transfer and intellectual property management capacities and capabilities.

[2] Vision & Mandate:

This program encourages collaborations and development of product platform technologies; creating a global network of experts/mentors/advisors; consolidating resources for building centers of excellence; strengthening existing infrastructure, capacities and technical know-how to enable development of specific products and aid in development of a pipeline for products.

Vision:

To enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals to a level that will be globally competitive over the next decade, and transform the health standards of India's population through affordable product development.





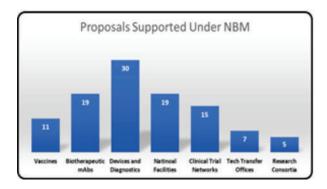
[3] Major Initiatives taken in financial year 2020-2021

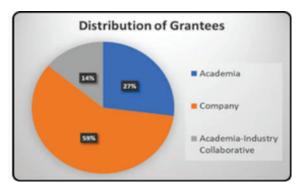
Proposals submitted under the new call were evaluated by the Scientific and Technical Advisory Groups.

Calls launched in 2020			
1.	Clinical Development of novel/new/next-generation vaccine candidate(s)	31 st Jan 2020	09 th Mar 2020
2.	Translational Research Consortia (TRC) for Malaria, Hep E and RSV	31 st Jan 2020	09 th May 2020

[4] Significant Outcomes

Under this program there are 8 identifiable components namely: Vaccines, Biotherapeutics, Devices and Diagnostics, shared facilities, clinical trial networks, technology transfer offices, training and scientific research programs which are financially supported. A total of 34 Grant-in-Aid Letter Agreements were signed from October 2020 till 31st March 2021 and a total of 14 Scientific Advisory Group, 3 Technical Advisory Group, 1 inter ministerial Steering committee meetings were held in this period. Since the inception of the Mission a total of 209 beneficiaries are being supported.





4.1 Products

The Mission is supporting product categories in the area of Medical Devices and Diagnostics, Vaccine and Biotherapeutics.

Product Category	Products Supported	
Vaccine	Universal Flu Vaccine, Cholera Vaccine, Dengue Vaccine (live attenuated and recombinant), Chikungunya vaccine, Pneumococcal Vaccine and SARS-CoV-2 vaccine candidates,	
Biotherapeutics	Herceptin, Insulin Glargine, Liraglutide, Ranibizumab, Human Serum Albumin, rHu Biosimilar Lispro, Ustekinumab, Palivizumab and Aflibercept are supported for different development stages. and Ramucirumab, Golimumab and Factor VIII are supported for Biosimilar clone development.	
	Antibody-drug conjugate (ADC) for small cell lung cancer, an anti-VGEF biologic for, diabetic retinopathy, cocktail of recombinant mAbs for Rabies, bio-better for genetic disorder, bi-specific nanobodies for cancer and indigenously developed Chimeric T-cell Receptor therapies are supported and therapeutic mAbs for SARS CoV-2 in novel Biologics category.	
Medical Devices and Diagnostics	Raw materials for bio-absorbable implants (bone implants), room temperature stable molecular diagnostic reagents, slip ring CT scanners, next generation endoscopes, next generation MRI scanners, medical grade camera for surgeries and laparoscopic surgery systems, diagnostics for SARS CoV2	



Major milestones achieved under Vaccines

National Biopharma Mission intends to expedite the augmentation of novel vaccines for complex infections by bolstering the Indian industry ecosystem, via improving de-risking and success rates for product development. Also, the program supports R&D activities of industry and academia for economical, safer and efficacious vaccine development

- Pneumococcal vaccine candidate, a 15 valent pneumococcal vaccine successfully completed the Stage-1 (Phase I/II CT) and is currently being supported for Phase III CT.
- Two (02) Dengue vaccine candidates supported for pre-clinical studies, Indian Immunological Ltd. (Live attenuated platform, in-licensed technology from NIH, USA) and Sun Pharmaceuticals Ltd. (VLP based platform, indigenous novel technology) have now transitioned to Stage-2 and have been recommended for support for Phase I human clinical trials.
- Chikungunya vaccine candidate: received NOC from DCG(I) to commence Phase II part of the Phase II/III trials of the candidate Chikungunya vaccine BBV87.
- From the new call in 2020, two projects **Dengue vaccine candidate** (**Panacea Biotech**) and **Rabies vaccine candidate** (Cadila Pharmaceuticals) have also been recommended for support.

Major milestones achieved under Biotherapeutics

The Mission is working to bring biosimilar products (therapeutic proteins and monoclonal antibodies) closer to market. The product category of biotherapeutics supports development of novel cell line, biosimilar clones, and different developmental stages (of biosimilars from process development, characterization to establish biosimilarity, preclinical toxicity studies in animals, clinical material manufacturing in a cGMP facility and clinical trial, Phase to Phase III

- In the Diabetes area, biosimilar Insulin Glargine by Stelis Biopharma Progressed to Phase I clinical Trial.

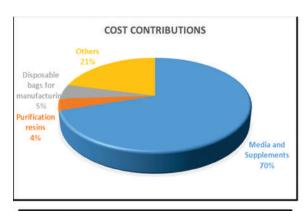
 Biosimilar Liraglutide has initiated Phase III Clinical trial.
- Three (03) Biosimilar projects Trastuzumab for breast cancer, Ustekinumab for Psoriasis by Serum Institute India Limited and Aflibercept (Lupin Ltd) have completed the preclinical toxicity study.

While India is a leader in innovation in South Asia, innovation in India is mostly incremental or imitative, as illustrated by the strong generics industry. India's output of patents and trademarks is small, business expenditure on R&D is low, and there is a limited skills base for innovation. With the exception of world-class players in a few sectors and localized centres of excellence, there is a low degree of novelty innovations in India, and the economy underperforms relative to other middle-income peers on several related indicators.

With the aim to build an environment that will stimulate innovation in the development of novel products and therapies, NBM is supporting several projects to boost the biotherapeutic production in India. Novel Biologics, Antibody Drug conjugates, Chimeric Antigen Receptor T-cell Therapy (CAR-T therapy), biobetters that are risk intensive projects

attracting lesser investment of management of even large companies and can be prohibitively costly for smaller firms. To ensure data integrity and compliance NBM is also supporting the development of indigenous quality and data management system software which meets the regulatory requirements of USFDA 21 CFR Part 11 and ICH guidelines and complies with the GAMP 5 requirements.

Cell culture media, Feed, bioreactors for upstream manufacturing, high throughput platform for process development and screening and resins, for downstream manufacturing of Biologics consume significant cost of biologics manufacturing. Indigenous development of these is supported to boost the innovation quotient and reduce overall cost of production and dependence on imports. A total of 14 new GLAs were signed in this segment.



Raw material for biopharmaceutical manufacturing

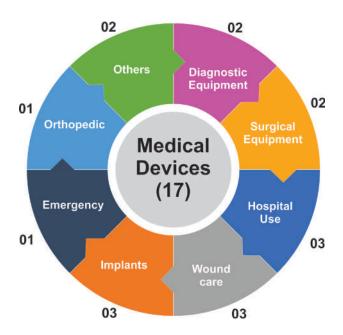
Ref: Anurag S. Rathore, Peter Latham, Howard Levine, John Curling, and Oliver Kaltenbrunner 2004;17(2):46,48–50,52,53–55 Costing Issues in the Production of Biopharmaceuticals: Manufacturing costs are crucial to overall profit margins.



Major milestones achieved under Medical Devices

The National Biopharma Mission's goal is to improve core technologies in the medical device industry. Proposed technologies must be strategic, consumer-oriented, application-based, and revolutionary, with the ability to improve domestic industry of related medical goods in a significant and equitable way. The technologies for Infectious Diseases, Imaging Technologies, Implants, Wound Management, and Trauma and Emergency Medicine (Figure below) are expected to:

- Enable indigenous manufacturing of core technologies
- Improve compatibility with existing medical devices
- Are safer and/or cost-effective replacements to current choices



- Working prototype endoscopes made by Grantees Univlabs Technologies Pvt. Ltd. and Irillic Pvt. Ltd.. An ISO 13485 facility established for biological grade polylactic acid production by Orthocrafts Innovations Pvt. Ltd.
- Another ISO certified facility established for development of MRI scanners by Voxelgrids Innovations Pvt. Ltd. along with setting up of completely indigenous MRI machine scanners at several hospital sites in India. Recruitment of patients for clinical trials of heart valves initiated by TTK Healthcare Ltd.. Advanced Multi spectral Flexible Video Endoscope, a next generation, 4K+, 60 fps flexible video endoscopy system with multi spectral imaging and intelligent image fusion techniques for multi modal tissue visualization for improved diagnosis, set up by HealthCare Technology Innovation Center at IIT Madras.

4.2 Shared Facilities

Creating an enabling ecosystem for affordable product development in the country viz-a-viz creation of GLP, GMP, GCLP facilities besides cell line repositories and facilities for medical device testing and prototyping. The Mission is currently supporting the establishment of 19 national facilities, out of which 11 are already operational. Some of the notable contributions by these facilities are:

- The manufacturing facility at AMTZ has manufactured the following products: RT-PCR tests 900 lakhs; Tests, ELISA Test Kits- 900 lakh, Viral Transport Medium 11 lakh units; IR Thermometers 3000 units. Ventilators 11,000 units. Pulse oximeters 2000 units
- Huwel Lifesciences facility developed 200 lakh RT-PCR diagnostic kits, 20 lakhs vial material transfer medium, 24 lakhs nucleic extraction kits and have initiated the commercial production of fluorescent probes for molecular diagnostics assays.
- The Good Clinical Lab Practices (GCLP) facility focusing on Pneumococcal (bacterial) assays in Bangalore Karnataka and another in Pune are targeting serological assays for major viral diseases affecting the Indian subcontinent (Dengue and Chikungunya). IRSHA facility at Pune has completed validation and NABL Accreditation of Chikungunya assay: IgG ELISA, IgG isotyping and re-accreditation of the Chikungunya PRNT50

assay. The facility of IRSHA, inaugurated in 2020 is providing services to industry and academia. The facility also established the immunogenicity evaluation assays for COVID-19 vaccines.

- The Centre for Advanced Protein Studies at Syngene has served 10 National clients including 5 under start-ups or academia for analytical services for Biologics. Entrepreneurship Development Centre, Syngene and CSIR-IICT are providing services to the industry and academia
- The cGMP manufacturing facility at Shilpa Biologicals, Dharwad, Karnataka is manufacturing clinical trial lots for biologics products from India and other countries. The facility is also leveraging its capacity to manufacture COVID-19 vaccine Sputnik-V Drug Substance. MJ Biopharm and Gennova Biopharmaceuticals Private Limited are also providing PDL services while expanding their facility to serve different clientele.
- The cell line repositories at National Centre for Cell Science (NCCS) and CSIR-IMTECH are under development. Activities are in progress for facility establishment and establishing MTAs with the international repositories for acquiring the cell line strains. These will be developed as national centres for cell banking and cell line characterization services.

The complete list of facilities under NBM

Product vertical supported	Facility Type	Number of facilities
Biotherapeutics	GLP compliant facilities for analytical characterization of biotherapeutics	03
	PDL-GMP manufacturing facilities for biotherapeutics (Mammalian & Microbial)	03
	Cell line repositories (Mammalian & Microbial)	02
	Lentivirus manufacturing Facilities	02
	Medical Device and diagnostics rapid prototyping facilities	04
Medical Devices and Diagnostics	Large animal facility for preclinical testing	01
	EMI/EMC safety testing facilities	01
	Large scale manufacturing DBT-AMTZ CoMMAND strategy.	01
Vaccines	Facilities covered under COVID-19 consortium	02
	GCLP compliant clinical immunogenicity labs for supporting Vaccine clinical trials: Viral and Bacterial vaccines	02

Expected Impact of Facilities					
• Ease of access	• Sub	sidized cost	Reduction in time-to-market		Local expertise
Certified facilities for quality		High-end equipment		Located near start-up hubs	
Requirements available in one area		Skilled manpower generation			
	• Co	nformity with r	egulatory require	ments.	

4.3 Translational Research Consortium

Under the aegis of National Biopharma Mission, Translational Research Consortia (TRC) is a Partnership Platform to ensure the translational ecosystem to improve, standardize and provide support for advancing development and evaluation of vaccines and monoclonal antibodies the most prevalent viral diseases in the country.

The first call in this category sought applications for Dengue, chikungunya, influenza and RSV, based on disease burden in India in 2017-2018. One project each in Dengue and Chikungunya are supported from the first call.

• The project "Translational Research Consortium for Establishing Platform Technologies to Support Prophylactic and Therapeutic Strategies for Dengue Discovery to Proof-of-Concept" is carried out by a consortium of eight (08) leading institutes of the country. The aim of the consortium is to assemble, coordinate and develop research activity for building sustainable capacity in India, and generate outputs such as well-characterized virus biorepository, serum bank, optimized and validated immunological assays for monitoring vaccine induced and neutralizing antibody responses, small animal model systems for testing and evaluation of future dengue vaccine candidates.

Biotechnology Industry Research Assistance Counicil



- The roles of consortia members in each activity and their interconnectivity are being periodically reviewed, once a quarter. Major accomplishments include:
 - Identification of potent mAbs against Dengue in nm activity against all 4 serotypes of Dengue and standardized high throughput assays to monitor neutralizing antibody responses.
 - Serum bank establishment with hyperimmune sera of 100 Dengue exposed patients at the lead institute ICGER
 - Establishment of Biorepository with about 50 well characterized strains at THSTI, the collaborating institute a
 - The team at THSTI is setting up animal of Dengue in AG129 mice. The standard strains of Dengue virus have been procured and model development is in progress.
 - A provisional patent is filed on Design of dengue 4 constructs (DENV4 TVP/360 prM-E4v.2 and DENV4 TVP/360 prM-E4v.3) that leads to generation of soluble, cleaved, well-ordered, dimeric, native-like envelope (E) protein from mammalian expression system". The envelope proteins will be used as antigen baits to potent identify mAbs
- The project "Translational Research Consortia TRC for Chikungunya Virus" is carried out by consortium of six (06) leading institutes of the country. The aim is to establish a research consortium to provide resources and tools for translational research in Chikungunya with the objective to establish Chikungunya clinical cohorts and a CHIKV clinical sample serum biobank. The roles and responsibilities of each consortia members is being periodically reviewed, once a quarter. The main achievements are as follows:
 - MAHE had implemented the serum Bio-Banking for CHIKV and so-far approximately 3000 aliquots have been banked (including 300 virus positive aliquots). MAHE had performed whole genome sequencing (WGS) of 24 CHIKV clinical isolates selected by ICGEB based on mutational and epidemiological analysis.
 - ➤ ICGEB had completed quantitative antibody testing- both IgM and IgG for 170 samples received from MAHE. Out of all the clinical symptoms, joint pain had a significant co-relation with CHIKV IgM positivity.
 - ILS is in the process of developing chikungunya acute and chronic model using reference strains (\$ 27/ DRDE-06) in adult (4-6 weeks) C57BL/6 mice.

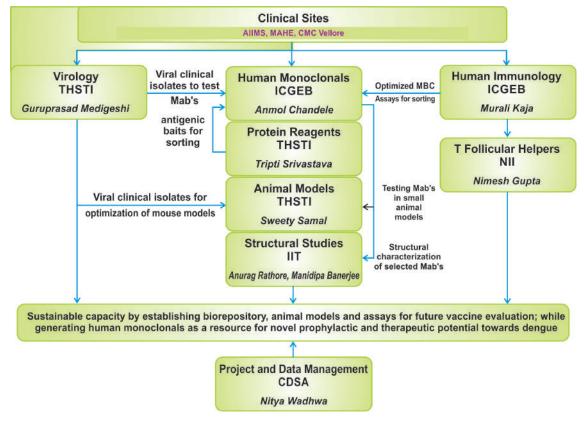
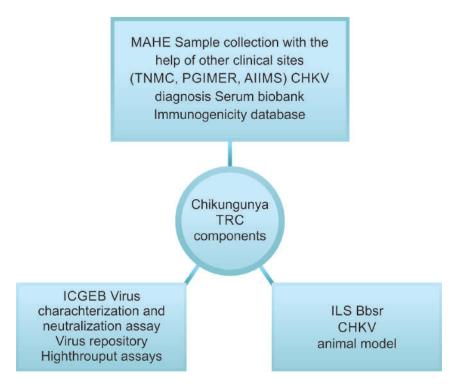


Figure TRC - Dengue Program Summary





Proposals selected from Second call: Under the proposals selected from new call, 3 GLAs were signed comprising 2 consortia, 1 GLA is under execution.

Hepatitis E-Translational Research Consortium (TRC-HEV):

Hepatitis E virus [HEV] is the most common cause of enterically-transmitted viral hepatitis worldwide. Currently, there is only one licensed vaccine globally viz. Hecolin from Innovax in China and is not available in India. The Mission is supporting two (02) TRCs for HEV.

Cadila Healthcare Ltd. has developed a recombinant subunit vaccine expressed in prokaryotic system, against HEV infection in humans targeting the immunodominant epitope in HEV ORF2 protein. The vaccine candidate has been found to be safe in preclinical toxicology studies. The Mission is supporting collaboration between industry (Cadila) and academic partners, led by JIPMER. The team will undertake Phase II/ III clinical trials of candidate vaccine in India and evaluate T-cell response to the vaccine, identify the immunological determinants of antibody responses and to determine neutralization potential of the antibodies using an *in vitro model*.

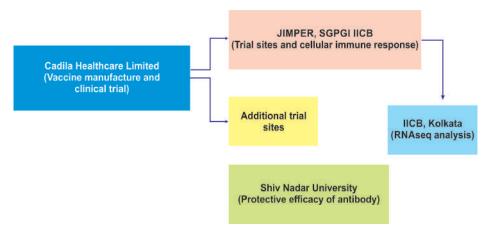


Figure: TRC-JIPMER-HEV Co-ordinator



THSTI-HEV Translational Research Consortium (THSTI-HEV-TRC):

The proposal "Development of a recombinant vaccine against the Hepatitis E virus and immunological characterization of Hepatitis E immune cohort and potential vaccine recipient" is led by Translational Health Science and Technology (THSTI), New Delhi. Consortia partners include VaxFarm Life Sciences, a Start-up company, All India Institute of Medical Sciences (AlIMS), New Delhi, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh, Regional Centre for Biotechnology (RCB), Faridabad. The objective of the consortia is to develop a novel vaccine against the Hepatitis E virus, establishment of immune cohort and clinical and immunological characterization of the cohort.

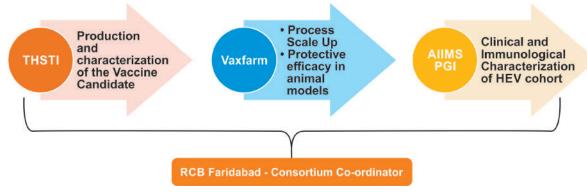


Figure: TRC-THISTI-HEV Coordinator

Malaria Translational Research Consortium (TRC-Malaria):

The nation-wide malaria burden was identified as a major health challenge encountered by India. A multi-institute, multi-expertise, multi-disciplinary approach was adopted towards tackling the unmet need of effective anti-malarial vaccines.

The Malaria Translational Research Consortium is between Regional Medical Research Center, Bhubaneswar, National Institute of Immunology, New Delhi, ICMR- National Institute of Malaria Research, New Delhi and Multi Vaccines Development Program, New Delhi. A novel combination of antigens will be evaluated as potential vaccine candidates. The antigens will target different stages of the malarial parasite *Plasmodium falciparum* such as the sexual stage and pre-erythrocytic stage to try to generate effective antimalarial efficacy. The evaluation will be done in small animal models, transgenic parasites and validated using complex assays which include SMFA. Epidemiological findings from high endemicity areas will provide additional information in support of the antigenic candidates under consideration.

4.4 Clinical Trial Network - Field sites for Vaccines

Access to healthy population cohorts for clinical trials in the community, has been a major need identified by the Indian Vaccine Industry. Good Clinical Practice (GCP) trained manpower and well-equipped clinical trial sites has been a major bottleneck and often leads to delay in the clinical development of vaccines. To solve this bottleneck, DBT's National Biopharma Mission (NBM) is supporting the establishment of Clinical Trial Networks (CTN) and Strengthening Clinical Trial Capacity in the country. Efforts are directed towards strengthening already existing Health and Demographic Surveillance Systems (HDSS) and establishing new HDSS sites at different locations in the country. In view, of the COVID-19 pandemic, these efforts are steered to address the current crisis, at hand.

Selection of sites

A DBT's Resource of Indian Vaccine Epidemiology Network (DRIVEN) has been established comprising of 11 DHS/HDSS sites in different geographical locations in the country along with central laboratories and IT data management systems to ensure paperless data management.

Seroepidemiology Site:

 05 field sites in different geographical locations throughout India have established healthy cohorts and are being supported for initiating serial Serosurveillance of COVID-19, Dengue and Chikungunya studies through a common protocol.

In order to realize the preparedness of these sites, the following efforts are underway:

Sero-surveillance studies: The study protocol, Informed Consent Documents (ICD), Subject Information Sheets (SIS), Case Record Forms (CRFs), Blood sample management and testing manual; and training



manuals were being developed. The protocol has planned 5000 subjects to be enrolled and followed up prospectively at each site for the first serology sampling.

- Preparation for conduct trials as per Good Clinical Practices (GCP) Guidelines: Efforts are being made to ensure that the sites are prepared for conduct of regulatory clinical trials as well as observational studies following good clinical practices. This includes, access to Ethics Committee, ensuring CTRI registrations, approvals from District Health Authorities, trained manpower, participant recruitment strategy, following Standard Operating Procedures (SOPs,) SAE's and Informed Consent processes, and establishment and maintenance of basic infrastructure. All these 05 sites have access to existing cohort of around 100,000+ healthy subjects and the sites are mentored by NBM.
- NBM, DBT is also establishing **06 new Demographic and Health Surveillance (DHS)** or Health and Demographic Surveillance System (HDSS) or Demographic, Development and Environmental Surveillance System (DDESS) sites across different locations in the country having access to urban/ semi-urban/ rural and tribal populations. The size of each cohort being established is equivalent to or higher than **01** Block or **50,000** population.

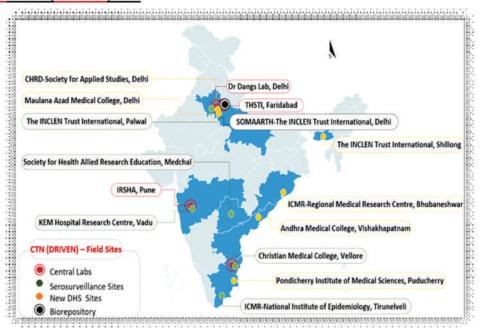
Central Labs for Serology and Biochemistry: Dr Dang's lab in Delhi and Virology as well as Biochemistry Labs at CMC Vellore are participating as central laboratories for serology and biochemistry evaluations.

Central Biorepository: The biorepository established at THSTI, Faridabad is a part of the DRIVEN network to ensure long-term storage of the samples.

Central Laboratory for Neutralisation assays: IRSHA and THSTI are participating as a central laboratory for PRNT (neutralisation) assays for SARS-COV-2, Dengue and Chikungunya.

Monitoring: Clinical Development Services Agency (CDSA) as NBM consultancy partner, monitors the project activities to ensure the sites follow the recommended procedures in compliance with GCP, GDP and GLP at these sites in order to achieve the overall goal of these studies by regular remotely and on-site monitoring visits, mentoring the study staffs by providing trainings, in direct consultation with NBM concerned team members.

DBT's Resource of Indian Vaccine Epidemiological Network (DRIVEN) 2020



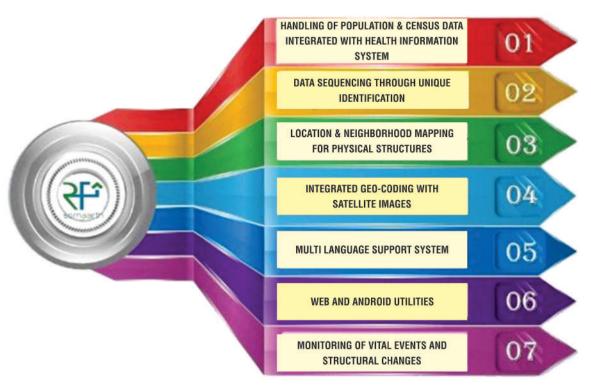
Geographical locations of the DRIVEN sites

Electronic data management (SOMAARTH platform)

Within the network, paperless e-data management has been ensured through different platforms developed for the studies at DRIVEN sites. The INCLEN Trust International, New Delhi has developed an electronic data management platform namely SOMAARTH-1 and SOMAARTH-3 for collecting data, reporting, analysis and archival of community-based demographic, development and environmental surveillance sites and associated studies.



These network sites are being sought to bring harmonization in the processes and uniformity in the methodology and steps to be followed in carrying out the study which would ensure quality of data collected from all the sites and preparedness of all these sites for future clinical trials.



Expected Impact

- Over 300,000 population data including health parameters, household characteristics and other environmental factors mapped.
- SARS-CoV-2 seroprevalence data in 25000 population
- Dengue and Chikungunya Incidence data over a period of 03 consecutive years
- Planning Complex epidemiological studies (presently constrained due to non-availability of data)
- Community engagement strategies for trials in traditional tribal groups of North-East India

Clinical Trial Networks of Hospital Sites

For testing any one biosimilar typically 200-300 patients are recruited in each trial to test the efficacy in the primary indication of the Biosimilar. Presently, the Indian Biotech companies are facing numerous challenges in identifying adequate number of clinical trial sites which have the required infrastructure, capacity, trained manpower, harmonised processes and background data on disease incidence at their respective sites and access to disease registries, at institutional, local, regional/state, and national levels.

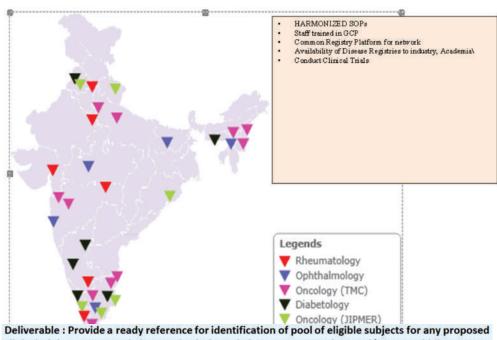
Considering the limited capacity of Indian hospitals in handling regulatory compliant multiple clinical trials, it is anticipated that delay in conduct of clinical trials can impact the development timelines of biosimilars and thereby delay launch of affordable biosimilars for the Indian population.

TO address this gap, the Mission is supporting establishment of Clinical Trial Networks (CTNs) for hospital-based trials. This **C**onsortia of **H**ospitals in the areas of **O**ncology, **O**phthalmology, **R**heumatology and **D**iabetology, **CHOORD**, has a wide geographical spread across India, having at least 6 sites in one network.

Each network is developing an electronic Registry Database on a common platform for all sites of the network, the sites have trained manpower in GCP, NCDT rules, SOPs harmonized across sites and will be ready to take up clinical trials as a network. Clinical Development Services Agency (CDSA) as NBM consultancy partner, monitors the project activities to ensure the sites follow the recommended procedures in compliance with GCP in order to achieve the overall goal. by regular remotely and on-site monitoring visits, mentoring the study staffs by providing trainings, under guidance from the Project Monitoring Committees of NBM.



Geographical locations of the CTN sites



Deliverable: Provide a ready reference for identification of pool of eligible subjects for any proposed clinical trial Form protocols for Standard of care in low resource settings and/or Low Middle Income regions and conduct GCP compliant trial

4.5 Technology Transfer Offices (TTO)

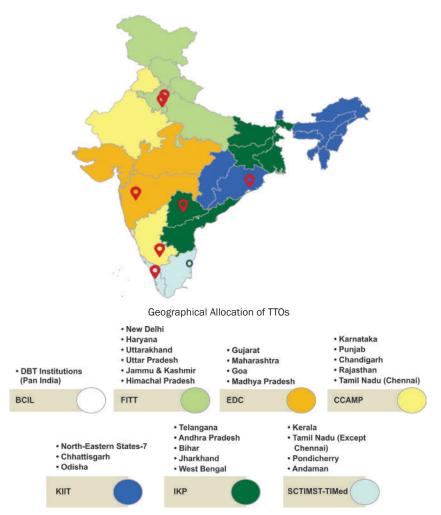
The Mission is supporting establishment of seven (07) TTOs which are geographically spread across the country, the goal is to establish/expand/thrive chosen entities designated as Regional Technology Transfer Offices (RTTOs). They will function as strategic drivers of innovation within the host institution and vitally engage with number of affiliate and non-affiliate institutions within a geographical region to bring in transformative approach to recognition of the value of academic research results and their translation to markets. These are located at:

- 1. Innovation Technology Transfer Office (iTTO), IIT Delhi
- 2. TechEx.in, Pune
- 3. Office of Technology Transfer (OTT), Bangalore
- 4. IKP-Platform for Regional IP Management Ecosystem (IKP-PRIME), Hyderabad
- 5. KIIT-TBI Technology Transfer Office (KIIT-TBI TTO), Bhubaneshwar
- 6. Technology Transfer Office @ BCIL (TTO@BCIL), New Delhi
- 7. Technology Transfer & Intellectual Property Services @ SCTIMST-TIMed (TIPS@SCTIMST-TIMed), Trivandrum

In partnership with Society for Technology Management (STEM), NBM supported a series of basic to intermediate courses in Intellectual property management and Technology Transfer and also an advanced training program in order to strengthen- core foundation of the applied and multi-disciplinary skill needed for accelerating technology commercialization. In an effort towards the same 25 candidates from the courses have secured their Registered Technology Transfer Professional (RTTP).

The TTOs have been provided access to capacity building and professional mentoring support by **Sathguru Management Consultants**, **the technology management enterprise recognized** globally for spearheading academic innovations to enterprises. They have worked on Defining business model & nature of relations for RTTOs and Reviewing and implementing the TTO office management tools. Other activities also included Mentoring with domestic (monthly) & international (bi-monthly) mentors and Monitoring and Review of activities & operations. They have also collaborated with STEM, conducted Virtual webinars to aid capacity building initiatives for the new members in ecosystem.





4.6 Skill Development

Conducting trainings and workshops-across various relevant thematic areas are an integral part of the National Biopharma Mission's (NBM's) mandate. During the pandemic, NBM maintained an on-line calendar of workshops, classes and webinars to build the knowledge building pipeline on various mission relevant topics including mapping best practices in clinical research; understating importance of regulatory compliances and understanding technology transfer mechanisms. Several trainings on 'Good Clinical Practice' (GCP), 'Good Clinical Lab Practice' (GCLP) and 'Bioethics' were held in collaboration with CDSA, Faridabad. These were some of the prominent programs that benefitted the stakeholders associated with clinical research in the country.

Workshops in the areas of clinical research, regulatory compliances, technology transfer, biopharmaceuticals and medical devices have been majorly supported.

The Mission supports trainings and workshops as per its mandate. Workshops in the areas of clinical research, regulatory compliances, technology transfer, biopharmaceuticals and medical devices have been majorly supported.

Total Trainings: 42 Total Trained: 6968

Female Participation: 3641

Environment & Safety monitoring activity for NBM projects

The Department of Biotechnology (DBT) along with its PSU, BIRAC and the National Biopharma Mission envisions 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 i3 Program, the following elements become inevitable such as compliance to corresponding environmental legislations, good practices in research and development methods, enhanced awareness on social and environmental risk management procedures, adherence to bioethics principles, capacity building of key stakeholders.



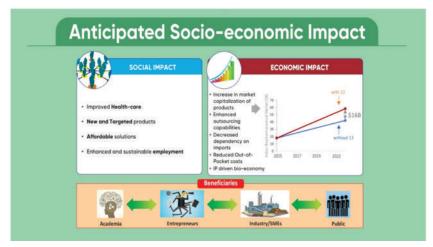


Figure 27: Anticipated socio-economic impact of NBM

With a wider perspective to improve the social and economic status of the citizens of not only our country, but world as well, NBM's impact has improved the healthcare, provided affordable solutions, developed indigenous products, and improved the employment opportunities within the country. This has further led to increase in outsourcing capabilities, reduction in the imports, and has enabled an IP driven bio-economy.

Major Highlights And Outcomes From The Mission

- The Mission is supporting 211 grantees across the country with more that 90% of the 1500 Crores funds committed till June 2021.
- From the projects supported under the Mission, 15 patents and 14 international publications have been done by grantees.

New Initiatives

- Under Translational Research Consortia, three projects; 2 for Hepatitis E virus and one for Malaria initiated. The
 consortia are industry-academia partnerships of 5 organizations in each.
- E-Brochures prepared for clinical trial sites funded under the Mission
- Projects related to Covid-19 vaccine manufacturing, Diagnostic Kits and facilities under Covid-19 Research Consortium, supported by the Mission grant
- Launch of Med Tech Facilities, a Biologics Manufacturing facility and Immunoassay Laboratory for vaccine testing in Global Bio India 2021.

Future Plans

The grantees will continue to be monitored through a rigorous Project Review Monitoring process and evaluated for their technical milestones and fund utilization. All the four Scientific Advisory groups:

SAG-BIO, SAG-Vaccines, SAG D&D, SAG-Clinical trials will meet at least three to four times a year to evaluate all the funded proposals.

- Initiation of Stage-2 projects under Vaccines Dengue and Pneumococcal vaccine candidates
- Launch of new call under Mission AMR in collaboration with DBT
- Evaluation/Identification of funded projects with potential for support funding for advance stage projects
- Constitution of Project Monitoring Committee and Product development Units for new projects 3 TRCs; 2 HEV and 1 Malaria, 3 CAR-T Projects, 2 Vaccines, 1 Scientific Research (Biologics project).
- Training of Clinical trial network hospital sites in GCP and Bioethics
- Training programs in the Biotherapeutics and Medical Devices area
- Fraining planned: ISO 9001: 2015 (500 participants), ISO 13485:2016 (~250 participants), ISO 14971:2019 (~250 participants), internal auditor and lead auditor training (~ 20 participants each).
- > Trainings in Biotherapeutics in the area of upstream and downstream processing
- Leverage the Technology Transfer Offices (TTOs). TTOs can work on catalysing and connecting the biotechnology
 ecosystem and translational research capacity in India. Trained personnel are in place who know intellectual
 property and transactional aspects of development and commercialization early-stage biotechnology
 innovation assets. These personnel can be challenged, trained, and leveraged to expand their role and become
 translational research project managers and "connectors" creating and nurturing connections with significant
 translational research assets and resources across the Indian biotechnology ecosystem.

Biotechnology Industry Research Assistance Counicil



Activities planned for the 7 TTOs

- Hiring of team members
- > IP awareness programs
- Forging partnerships
- Sensitization of inventors
- Technology marketing and outreach
- Environment due diligence activities for all funded projects and seeking quarterly reports on compliance from grantees
- Increase the market orientation of the project's monitoring committees (PMCs) and product development units (PDUs). Given the project's large portfolio, a key task for the PMCs and PDUs is to ensure that products with market potential complete their development cycle. For all projects in advance/ clinical stage landscaping report is prepared and discussed with PMC and SAG for advice. The support is obtained from the technical Knowledge partner, IAVI India to make the report.
- Raise awareness of the new ecosystem and promote networks. Connecting the growing ecosystem with the
 rest of the biotechnology community can put the ecosystem into a higher gear. Therefore, it would be important
 for the project to raise awareness among the Indian biotechnology research community and key players in the
 biotechnology translational ecosystem. Outreach activities for utilization of capacity created under the Mission,
 shared facilities, clinical trial networks, in coordination with NBM Technical Partner IAVI will be done.
- **NBM Communications Plan:** To foster this aim of the Mission, it becomes an immediate requirement for carrying out efforts for strategic communication and public engagement for wider dissemination of the Mission's vision and the impact it has created over the years since its inception.

The major objectives of the Communications for National Biopharma Mission are:

- To disseminate major activities of the Mission to reach widest possible audience.
- To strengthen networks and leverage upon existing strengths.

For fulfilling these objectives, the following are planned:

- Launch of NBM E-Book (second version) through social media/ BIRAC's website/ NBM microsite.
- Wider dissemination of activities, such as trainings, webinars etc carried out by NBM and NBM supported ecosystems via social media engagement and through BIRAC's website.
- Regular updating the NBM microsite.
- Press releases of updates on a regular basis.
- Articles covering the efforts and impact of NBM, carried out either through COVID/non-COVID projects, to be published either in National Dailies or journals.

National Biopharma Mission's response to the COVID-19 crisis

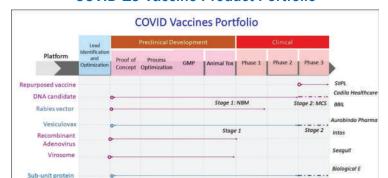
The Department of Biotechnology and Biotechnology Industry Research Assistance Council (BIRAC) together strategized both immediate and long-term research and development efforts recognizing the urgent need for addressing the COVID-19 pandemic. A "Request for Proposal (RFP) was published for COVID-19 Research Consortium". This consortia platform aimed at leveraging capacity and strengths established across the pyramid of academicians, researchers, innovators, large industries, and MSMEs and to prioritize research and scientific interventions so as to deliver solutions for the pandemic

Major efforts are ongoing under the National Biopharma Mission/ i3. Some notable scientific and technical achievements in the projects that are funded un der the Mission are as follows:

- Zydus Cadila received approval for Emergency Use Authorization (EUA) from the DCGI for ZyCoV-D on 20/08/2021, the world's first and India's indigenously developed DNA based vaccine for COVID-19 to be administered in humans including Children and adults 12 years and above, ZyCoV-D has been supported under COVID-19 Research Consortia through National Biopharma Mission for Preclinical studies, Phase I and Phase II Clinical Trials and under the Mission COVID Suraksha for Phase III Clinical Trial.
- Recombinant BCG, repurposed COVID vaccine candidate of Serum Institute of India is undergoing Phase III clinical trial.
- DBT-BIRAC supported Nation's first mRNA-based vaccine found to be safe gets a nod from the Drugs Controller General of India DCG(I) to move into Phase II/III trial. HGCO19 has been supported under COVID-19 Research Consortia through National Biopharma Mission for Preclinical studies, Phase I and Phase II Clinical Trials and under the Mission COVID Suraksha for Phase III Clinical Trial.

DCGI approved the emergency use for Zydus Cadila's Pegylated Interferon alpha-2b 'Virafin' for treating moderate COVID-19 infection for adults, was supported under NBM

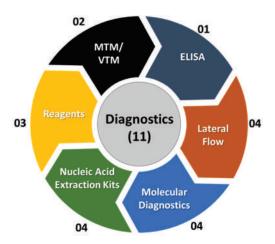
- Immunoglobulin (antibody) therapy the plasma of COVID-19 recovered patients clinical trial is ongoing
- Mylab Discovery Solutions supported for production scale up of RT PCR kits diagnostic tests for SARS-CoV-2.
 Over 25 lakh RT-PCR tests and 33 lakh antigen detection rapid tests sold in market.
- The Andhra Pradesh Med-tech zone (AMTZ) developed 700 lakh RT-PCR diagnostic kit tests, 4500 ventilators, 2000 IR thermometers, 500 pulse oximeters and 8 lakh vials viral transfer medium.
- Huwel Lifesciences has produced and marketed 200 lakhs Covid detection kits, **12 lakh units of Molecular Transport Medium** (MTM) and 24 lakh nucleic acid extraction kits for sample preparation
- Levram Lifesciences has initiated production of Viral Transport Medium and sample collection swabs.
- Antibody detection kit by Ubio is developed and is in market having sold over 1 lakh tests. The two commercialized. products are SENSIT COVID IgG/IgM Kit and SENSIT COVID Antigen Kit.



COVID-19 Vaccine Product Portfolio

Schematic representation of covid vaccines funded under NBM upto Phase II Clinical Trial (MCS: Mission COVID Suraksha)

Stage 2: MCS



Schematic representation of 11 Covid Diagnostic technologies funded under NBM

PRESS RELEASES

Zydus Cadila Receives Emergency Use Authorization

World's First COVID-19 DNA vaccine developed in partnership with

DBT-BIRAC under Mission COVID Suraksha

Posted On: 20 AUG 2021 7:04PM by PIB Delh

Zydus Cadila has received approval for Emergency Use Authorization (EUA) from the Drug Controller General of India (DCGI) for ZyCoV-D today i.e 20/08/2021, the world's first and India's indigenously developed DNA based vaccine for COVID-19 to be administered in humans including Children and adults 12 years and above. Developed in partnership with the Department of Biotechnology, Government of India under the 'Mission COVID Suraksha' and implemented by BIRAC, ZyCoV-D has been supported under COVID-19 Research Consortia through National Biopharma Mission for Preclinical studies, Phase I and Phase II Clinical Trials and under the Mission COVID Suraksha for Phase III Clinical Trial. This 3 dose vaccine which when injected produces the spike protein of the





Way Forward

In order to maximize the impact and value being created through the initial i3 project period, the following may be considered for way forward:

- a) Leverage the Technology Transfer Offices (TTOs). TTOs can work on catalysing and connecting the biotechnology ecosystem and translational research capacity in India. Trained personnel are in place who know intellectual property and transactional aspects of development and commercialization early-stage biotechnology innovation assets. These personnel can be challenged, trained, and leveraged to expand their role and become translational research project managers and "connectors" creating and nurturing connections with significant translational research assets and resources across the Indian biotechnology ecosystem.
- b) Increase the market orientation of the project's monitoring committees (PMCs) and product development units (PDUs). Given the project's large portfolio, a key task for the PMCs and PDUs is ensure that products with market potential complete their development cycle. Therefore, their composition and responsibilities should allow them to facilitate smart and risk-tolerant funding at the right time in the translational and early-stage commercialization processes.
- c) Raise awareness of the new ecosystem and promote networks. Connecting the growing ecosystem with the rest of the biotechnology community can put the ecosystem into a higher gear. Therefore, it would be important for the project to raise awareness among the Indian biotechnology research community and key players in the biotechnology translational ecosystem so that connections, partnerships, and resources are being leveraged at the right time and in the right way. Given the current pandemic, the use of digital tools should be leveraged to create connections across geographic boundaries.





Ind-CEPI MISSION

[1] About the Mission:

The Ind-CEPI Mission is an India centric collaborative mission of Department of Biotechnology (DBT), Govt. of India, aligned to the global initiatives of CEPI (Coalition of Epidemic Preparedness Innovations). The mission will facilitate pathways for vaccine development and assessment, developed in consultation with CEPI. The Mission aims to strengthen the development of vaccines for the diseases of epidemic potential in India as well as build coordinated preparedness in the Indian public health system and vaccine industry to address existing and emergent infectious threats in India. DBT is supporting the implementation of the Ind-CEPIs mission "Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the Coalition for Epidemic Preparedness Innovations (CEPI)", through a dedicated Program Management Unit (PMU) at Biotechnology Industry Research Assistance Council (BIRAC). The Ind-CEPI Mission was approved on 27thMarch 2019 with a total cost INR 312.92 crore.

Objectives:

- To strategically engage with CEPI through the Ind-CEPI Mission to develop vaccines to control epidemic outbreaks of infectious disease.
- To build a public health preparedness system to respond to threats.
- Infrastructure to support the needs of the vaccine industry through an academia industry interface.
- To establish an internal coordinated inter-ministerial mechanism for vaccine development.

Current Vaccine Portfolio:

1.mRNA platform for SARS-CoV-2-Gennova

Biopharmaceuticals Ltd.

2. Inactivated Virus platform for Chikungunya-Bharat Biotech International Ltd.

Skill Development:

E-course series

"Strengthening

Clinical Trial

Research Capacity in

Neighboring

Countries"





[2] Supporting Vaccine Development:

Mission Ind-CEPI is taking decisive steps towards development of key vaccine candidates and supporting the same through clinical trials. In the endeavor to provide effective vaccines, mission Ind-CEPI has supported the mRNA vaccine candidate by Gennova Biopharmaceuticals Ltd. The supported mRNA vaccine candidate is the only of its kind being developed in India. To make the last mile delivery of the vaccine candidate more effective, vaccine candidate is designed to be thermo tolerable and can be transported at 4-8°C. Apart from the response to the COVID-19 pandemic, mission Ind-CEPI is also supporting the development of Chikungunya vaccine candidate by Bharat Biotech international Ltd. An efficacious vaccine candidate against chikungunya has been a long-standing need to immunize millions throughout the world especially the in the developing countries. By the supportive action of the mission Ind-CEPI along with CEPI, our country is stepping towards delivering on yet another vaccine needed by the global community. Details of the both the vaccines currently being supported under mission Ind-CEPI are mentioned below.

Disease Area	Platform	Title	Grantee	Duration	Endpoint
SARS-CoV-2	mRNA vaccine	"Next-generation mRNA vaccine against COVID-19 to provide long-term protection to the population within its national/ international territories"	Gennova Biopharma- ceuticals Limited, Pune	18 months	Manufacturing of vaccine candidate, and safety and immunogenicity in Phase I/II clinical trial.
Chikungunya	Inactivated virus	"Global Chikungunya Vaccine Clinical Development program" (GCCDP)	Bharat Biotech International Ltd (BBIL)	24 months	GMP manufacturing of the vaccine in India and subsequent manufacture of clinical trial materials.

[3] Skill Development:

The Department of Biotechnology, Ministry of Science and Technology, Government of India is supporting the implementation of the Ind-CEPIs mission "Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the Coalition for Epidemic Preparedness Innovations (CEPI)", through a dedicated Program Management Unit (PMU) at Biotechnology Industry Research Assistance Council (BIRAC). Supporting skill development, capacity building, regional networking and development of surveillance frameworks is one of the important mandates of the Ind-CEPI Mission. Aimed at this, the Mission initiated and completed an eCourse Series "Strengthening Clinical Trial Research Capacity in Neighbouring Countries" in collaboration with CDSA, Faridabad. This training envisaged an in-depth coverage of Good Clinical Practice, Ethical considerations in clinical research, Good Clinical Laboratory Practice and Novel vaccine development and immunization policy Each program closed with exit examinations, after which certifications were issued.

Participating Countries:

Afghanistan, Bangladesh, Bhutan, Maldives, Mauritius, Nepal and Srilanka

Training Topics:

- 1) Good Clinical Practice 313 participants in 4 sessions
- 2) Ethical Considerations in Clinical Research 204 participants in 2 sessions
- 3) Good Clinical Laboratory Practice (GCLP) 141 participants in 2 sessions
- 4) Novel vaccine development and immunization policy in a pandemic 113 participants in 2 sessions









Glimpses from the Session on Ethical Considerations in Clinical Research e-Course

Biotechnology Industry Research Assistance Counicil



Series 2: After the successful completion of the first E-course series, the Mission initiated an eCourse Series entitled "Strengthening Clinical Trial Research Capacity in India's Friendly Countries". This is also a 4 Programs-10 sessions series that commenced on 5th Feb till 30th Apr 2021.

Training Topics:

- 1) Good Clinical Practice 836 participants in 4 sessions
- 2) Ethical Considerations in Clinical Research 350 participants in 2 sessions
- 3) Good Clinical Laboratory Practice (GCLP) 294 participants in 2 sessions
- 4) Novel vaccine development and immunization policy in a pandemic 259 participants in 2 sessions

Participating Countries:

Bahrain, Bhutan, Kenya, Myanmar, Nepal, Oman, Somalia, Vietnam



Glimpses from the Sessions on Novel vaccine development and immunization policy in a pandemic







Glimpses from the Sessions on Ethical Considerations in Clinical Research





[4] EOI's Published:

An expression of interest (EOI) for establishing Quality Management System (QMS) For Immunogenicity laboratories and animal challenge study facilities under Mission Ind-CEPI was announced on 26th January 2021. This EOI aimed at providing accreditation to laboratories and animal facilities being strengthened under Mission COVID Suraksha. This call was relaunched on 14th May 2021.



Press Release:

India's First COVID-19, mRNA vaccine developed in partnership with DBT-BIRAC under Mission COVID Suraksha

Posted On: 24 AUG 2021 3:07PM by PIB Delhi

Gennova Biopharmaceuticals Ltd., the Pune-based biotechnology company, working on the nation's first mRNA-based COVID-19 vaccine, submitted the interim clinical data of the Phase I study to the Central Drugs Standard Control Organisation (CDSCO), the Government of India's National Regulatory Authority (NRA).

Vaccine Subject Expert Committee (SEC) reviewed the interim Phase I data and found that HGCO19 was safe, tolerable, and immunogenic in the participants of the study.

Gennova submitted the proposed Phase II and Phase III study entitled "A Prospective, Multicentre, Randomized, Active-controlled, Observer-blind, Phase II study seamlessly followed by a Phase III study to evaluate the Safety, Tolerability, and Immunogenicity of the candidate HGCO19 (COVID-19 vaccine) in healthy subjects" which was approved by the office of the DCG(I), CDSCO.

The study will be conducted in India at approximately 10-15 sites in Phase II and 22-27 sites in Phase III. Gennova plans to use the DBT-ICMR clinical trial network sites for this study.

Gennova's mRNA-based COVID-19 vaccine development program was partly funded by the Department of Biotechnology (DBT), Govt. of India under Ind CEPI, way back in Jun 2020. Later on, the DBT further supported the program under the Mission COVID Suraksha- The Indian COVID-19

VI. Specialized services

1. Intellectual Property & Technology Management

- BIRAC in-house IP & Technology Management group 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, marketing and drafting of license agreement and negotiation.
- BIRAC conducts an extensive IP evaluation for grant proposals that it receives under its flagship
 programmes such as BIPP, PACE, SBIRI, IIPME, SPARSH, BMGF, Wellcome Trust, National Bio-Pharma
 Mission and BIG. In addition to this, the group also provides guidance 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) scheme
 that extends support to protect the intellectual property which emerges out from the innovative projects
 funded by BIRAC and facilitate transfer of technology and commercialization. BIRAC-PATH provides
 facilitation of supporting the patent filing in India as well as to International jurisdictions.



Mandate of BIRAC-PATH Scheme

- 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.
- BIRAC-PATH program was launched in 2013 and under the program, 18 patent filings for start-ups, academic institutions and SMEs have been supported so far. In 2020-21, a total of 8 BIRAC beneficiaries were supported under BIRAC-PATH for patent drafting, filing and maintenance of patent applications nationally and internationally.
- Patent filing support has been extended for Provisional and Complete Indian filing, PCT filing and national
 phase entries in different countries such as US, EU, China, Japan, Australia, and India. These patent
 applications are filed mainly in the area of secondary agriculture, agriculture, Industrial Biotechnology
 and healthcare.
- List of the Patent applications supported under BIRAC-PATH

S. No.	Name of Company & Scheme	Project	Jurisdictions/Patent maintenance/prosecution supported
1.	Anna University (PACE)	Production of L-2-Aminobutyrate From Pyruvate/Citrmalate/ Citraconate by biotransformation and Cell Free System	National Phase filing in India, USA, Japan, EU, China
2	Windmill Health (BIG)	Foot Pedal	Prosecution and annuity maintenance supported for India, US and EU patent application
			Patent Granted: In India and USA
			Jurisdictions supported: India, US & EU
3	Carot Labs Pvt Ltd (SBIRI)	A Capillary Bioreactor For Algal Bioprocess	Complete Filing in India
4.	NIAB (PACE)	Rapid and Differential detection of Cobra and Krait venom using monoclonal antibody	Provisional filing in India
5	TestRight Nanosystems	Spectrometer and method for measuring the spectral characteristics thereof	Annuity maintenance supported for India as well as EU
	Private Limited (BIG)		Jurisdictions supported: EU, India & US
6	University of Burdwan	A testing kit and method for rapid screening of carriers and patients of haemoglobinopathies	Provisional Filing in India
7	Nesa Medtech (BIG)	A system and method for the ablation of uterine fibroids	National Phase filing in US, China, EU, India
8	Pentavalent Biosciences	Live attenuated universal influenza virus vaccines, methods and uses thereof	Complete and PCT filing
9	Osind Meditech	A Self Driven Rehabilitation Device and Method Thereof	Complete and PCT filing
10	Alfa Corpuscles	Single use safety syringe and method thereof	Complete and PCT filing

- BIRAC works closely with Bio-incubators and Regional Centres to provide the whole gamut of IP & Technology Management services to the ecosystem. To begin with, IP & Technology Management group initiated "IP & Technology Management Law Clinic Connect" for the start-ups, innovators, scientists to provide a platform for one-to-one interaction with the experts in the domain of IP & Technology Transfer. In 2020-2021, 5 such IP & Technology Management Law Clinic Connect were conducted virtually.
- Apart from the various IP & Technology Management offerings, the BIRAC IP & Technology Management group also organize several IP & Technology Management awareness and capacity building workshops for start-ups, SMEs and academicians. In 2020-21, four such virtual workshops were organized.





IP & Technology Management Law Clinic Connect



IP & Technology Management Workshop



VII. Mentoring and capacity building

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

University of Cambridge Entrepreneurship Education Programme – IGNITE: BIRAC has partnered with Judge Business School (JBS) at University of Cambridge in 2013 for the Ignite Programme that provides BIG innovators international mentoring opportunity. It enables early stage start-ups to develop international entrepreneurial flair and skills needed to understand the opportunities for successful translation and commercialisation of innovations. Every year, 5 BIG start-ups are selected and supported to attend the week-long boot-camp, IGNITE at JBS, Cambridge, UK. So far, 39 BIRAC supported start-ups have benefitted from the programme.

VIII. Regulatory Facilitation

1. FIRST HUB

FIRST HUB is an interactive platform created by DBT-BIRAC, as per the recommendations of Niti Aayog, for addressing the queries of the innovators. During COVID-19, the industry has witnessed the challenge of understanding the various new regulations, guidelines, policies and processes for COVID-19 medical products. To mitigate this and facilitate the fast development of COVID-19 products, it was important to provide a clear direction to the start-ups. To address this challenge and the dire need of nation, FIRST HUB provided the platform wherein queries related to various governmental organisations like CDSCO, ICMR, DBT, BIS, NIB, GeM, KIHT and BIRAC can be discussed and resolved. In addition to monthly meetings, FIRST HUB team conducted special virtual sessions every month for COVID-19. 500+ queries were discussed during these sessions. One special webinar with 150+ queries on COVID-19 was conducted to provide the guidance on the regulations, standards, policies and funding opportunities. Further, a special FIRST HUB session was conducted during the Global Bio India event. BIRAC is committed to develop the start-up ecosystem in India and facilitate the innovators in their product development journey. The queries can be submitted through FIRST HUB portal available at BIRAC website.





Special FIRST HUB Webinar

COVID-19 Virtual Sessions





FIRST HUB special session during Global Bio India Event

Biotechnology Industry Research Assistance Counicil



2. BIRAC Regulatory Cell

BIRAC Regulatory Cell was created in November 2018 with a mandate "To facilitate the process of interpreting the rules and regulations and fostering innovation through helping entrepreneurs pass through regulatory hurdles". It has carried out all the activities successfully.

Two meetings of Regulatory Advisory Committee were organized on July and December 2020 respectively. Total number of 25 and 23 proposals respectively were discussed for identifying probable regulatory issues in the area of Biosimilars, 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, PACE, SPARSH and NBM programs of BIRAC.

3. 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. PCP fund addresses few of these critical requirements through target funding.

The main objectives of PCP Fund 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.

Besides BIRAC supported start-ups, Indian Biotech start-ups with products/technologies of nationally importance, developed through support from other sources, and which are at TRL-7 or above are also eligible. PCP fund application if submitted online throughout the year and is evaluated once every quarter.

A BIRAC internal PCU Committee identifies 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 are placed for the consideration of SCPC committee which identifies the specific needs of the project and accordingly recommends and decide the funding support and deliverables.

Projects following three start-ups funded under PCP Fund in 2019-2020 and all three projects are ongoing

- 1. Production & Commercialization of Omega 3 Fatty Acids based products and nutraceuticals using Supercritical fluid extraction technology by Aspartika Biotech Pvt. Ltd, Bangalore
- 2. Deployment of physical trial based Sampoorti-Poorti system for post-surgical rehabilitation of mastectomies pan-India by Aarna Biomedical Products Pvt. Ltd
- 3. **Tracheo-Esophageal Voice Prosthesis for Laryngectomy Patients** by Innaumation Medical Devices LLP Projects from four more Start-ups recommended by the SCPC committee in 2020-2021, and are awaiting final approval

IX. **NEW Initiatives**

In December 2020, BIRAC, NASSCOM and NASSCOM Foundation Innovation Challenge has launched "जनCARE" in collaboration with GCI. It is a nationwide "Discover – Design – Scale" program, envisioned to identify Innovative health-tech solutions from Start-ups for strengthening the Healthcare Delivery in India. The affordable HealthTech solutions could potentially address the unmet needs of about 65% of population which is deprived of adequate primary health care. The challenge focuses mainly on innovations that can work in low resource settings at Public Healthcare Centres (PHCs), Community Healthcare Centers (CHCs), and Sub-Centers etc. in rural and semi-urban locations across the Nation.



- BIRAC revamped the EYUVA scheme and sanctioned support to 5 new EYUVA Centres taking the total numbers of pre-incubation centres as 10. These centres are mandated to promote a culture of applied research and need-oriented (societal or industry) entrepreneurial innovation among young students and researchers.
- Department of Biotechnology and BIRAC organized Global Bio-India 2021 to showcase opportunities
 in Indian Biotechnology sector to the world. It was a mega international congregation of biotechnology
 stakeholders, including international bodies, regulatory bodies, Central and State Ministries, SMEs,
 large industries, bioclusters, research institutes, investors, and the start-up ecosystem. About 8000+
 delegates from over 50 countries participated in the event. The event was held for the first time in a fully
 virtual mode. Make In India cell at BIRAC steered the program through support from BIRAC, DBT, CII and
 Invest India.

X. Supporting National Programs

1. Make in India Facilitation Cell for Biotechnology

Make in India (MII) Facilitation Cell for Biotechnology at BIRAC is spearheading MII programme, 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. The Make-in-India Cell ensures wider dissemination of information related to various Government programs and other information relevant to the establishment and growth of Start-ups, SMEs and companies in the country.

The cell guides the investors, Start-ups and entrepreneurs onto the gamut of business-related issues in biotechnology such as regulatory landscape in the country, entry options and procedures, investment opportunities and routes, FDI/ EXIM/ Industrial policies. After the successful completion of Make in India 1.0, a new and focused roadmap for Make in India 2.0 was formulated for biotechnology sector for next 4 years after several meetings amongst the Ministries. Under Make in India 2.0, the government has identified 15 sectors which have potential to become global champions and drive double digit growth in manufacturing. Among these 15 sectors, Biotechnology has been identified for renewed focus.

MII cell is also implementing the Start-up India action plan integrating through BIRAC's mandate by facilitating funding and incubation support to start-ups. BIRAC's commitment to Start-up India to build 50 biotech incubators, 5 regional centres and supporting 2000 start-ups by 2020 is facilitated and mapped by this cell. Policy level suggestions, initiatives, India's Bio-economy mapping, sectoral reports, identifying and creating opportunities at national and international forums are also being carried out this cell. Biotech mega event i.e Global Bio-India 2019 and 2021 was steered through secretariat at Make In India Cell.







Activities 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 Start-ups, SMEs and companies by communicating policies and incentives extended by the Government for the programme
- Support the Make in India programme by addressing the queries received from various stakeholders

Major activities of Make in India in FY 2020-21:

Global Bio-India 2021

The Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India along with its Public Sector Undertaking, Biotechnology Industry Research Assistance Council (BIRAC) organized the second edition of Global Bio-India 2021 from 1st -3rd March 2021 on a digital platform. The associated partners for this event were Confederation of Indian Industry (CII), Association of Biotechnology Led Enterprises (ABLE) and Invest India.

The event showcased India's potential in the biotech sector both within the country and to the international community. The theme for GBI 2021 was "Transforming lives" with the tagline "Biosciences to Bio-economy". All together the event witnessed a rich technical program of about 30 sessions including workshops, CEO Roundtable, policy dialogues etc; and Bio-partnering that took place over a period of three days. The event attracted 8400+ delegates, 40+ countries, 50+ international speakers, 1000+Entrepreneurs &start-ups, 23 Awards Facilitated, 140+ investor-start-up meetings, 150+ exhibitors, 350+ Bio-partnering meetings.

The multi-faceted three-day event showcased the strengths and opportunities of India's biotechnology sector at the national level and to the global community. The knowledge that has been generated requires wider dissemination throughout the biotech sector, from academia, researchers, innovators, startups to industry stakeholders to work in a collaborative manner for developing a \$100 Bn Bio-manufacturing Hub and achieving the target of \$150 Bn Bioeconomy through Biosciences by 2024-25.















Strategy Meets & Stakeholders' Discussion

• COVID Impact on Startups' Sustenance: Risk Mitigation Stakeholder's Discussion Meeting: BIRAC's Make in India Facilitation Cell organized a stakeholder Discussion Meeting on April 23, 2020 through VC to discuss current challenges faced by Startups & remedial measures to support Startup survival through this difficult time. Startup ecosystem stakeholders including Mentors, Experts, Angel Investors, Venture Funds, Incubators representatives, MD, BIRAC and Make in India, BIRAC officials participated in deliberations and shared their opinion on the subject matter.

Outcome: INR 100.00 Cr sanctioned against the detailed proposal submitted to MoE





• Stakeholders Meet for Establishing Technology Clusters: Make in India Cell organized a Stakeholders' discussion on 12th November 2020 to discuss the implementation strategy for establishing Technology Clusters in the country. The meeting was chaired by Dr. Renu Swarup, Secretary DBT and Chairperson BIRAC. A working Group was constituted to prepare a concept paper, which was chaired by Dr. Kiran Majumdar CMD Biocon Itd.



Outcome: The report of the working group along with the concept paper has been submitted to MoE through DBT for further processing.

• Stakeholders Consultation Meeting for National Biotechnology Development Strategy (NBDS) 2020-25: A high-level stakeholder consultation meeting was organized by Make in India Cell of DBT/BIRAC on 19th February 2021 through VC to discuss this and prepare a well-defined National Biotechnology Development Strategy 2020-2025. The meeting with key opinion leaders and stakeholders from Industry, Startups, Incubators, Investors, Industry Associations and Academia hosting incubators was conducted to seek key recommendations, identifications of gaps and opportunities critical measures for preparing the strategy document and finalizing National Biotechnology Development Strategy 2020-2025. The meeting was chaired by Dr. Renu Swarup, Secretary DBT.

Outcome: Inputs from Industry, Startups & ecosystem enablers submitted for formulation of NBDS 2021-25 – MII Cell's Inputs were incorporated in **NBDS**





Regulatory Facilitation to Startups/ Entrepreneurs & SMEs

- FIRST (Facilitation of Innovation & Regulation for Start-ups and Innovators) Hub: FIRST Hub, a facilitation unit, set up by BIRAC, to address the queries of Start-ups, Entrepreneurs, Researchers, Academicians, Incubation Centres, SMEs, etc. completed 2 years of successful operation with support from DBT, CDSCO, ICMR, NIB & BIS. FIRST Hub has addressed 250+ queries till date.
- Special Session of FIRST HUB for COVID-19 Solution Weekly: BIRAC has conducted special dedicated sessions of FIRST HUB every Friday of the week since 3rd April 2020 only for COVID-19 solutions and has handled 150 + queries of the innovators, Startups.
- The Regulatory Information And Facilitation Center (RIFC): RIFC is a joint initiative of Venture Center and BIRAC under the BIRAC Regional Bio-Innovation Center (BRBC) program. The RIFC aims to assist bio-entrepreneurs in planning, seeking and securing regulatory approvals by providing information in an entrepreneur-friendly manner, providing access to experts and regulators, providing access to practical insights from other entrepreneurs, providing services and organizing relevant and useful events.

State Connect Activities

- **MoU signing with Rajasthan:** A Memorandum of Understanding has been signed with DST Rajasthan recognizing BIRAC as a knowledge partner to jointly promote Biotech Innovation Ecosystem in the state of Rajsthan.
- Discussion is underway with the State of Karnataka, Odisha and Uttarakhand for signing an MoU to strengthen the biotech ecosystem in these States.

Publications / Sector Reports

- India Bio-Economy Report 2021: The India BioEconomy Report (IBER) is an effort to map India's BioEconomy and monitor the extent to which policies adapt to growth, resilience and sustainability needs. While growth in demand presents significant opportunities for application of biotechnology, government policies have a proactive role in addressing challenges such as increasing productivity growth, enhancing environmental performance and adaptation to climate change, and improving resilience of unforeseen circumstances. These reports have been compiled in collaboration with ABLE (Association of Biotech Led Enterprises).
- Realizing Investment Potential For Indian State by Institute of Competitiveness: This report is released for mapping the State-specific investment potential, which would highlight the strengths and areas of improvement for different states with regard to biotech policies and would also serve as guidance for new policy initiatives, investors to assess potential at state as well as national level.







• BIRAC Compendium: DBT-BIRAC Supported Products & Technologies: On the occasion of National Technology Day (11th May), BIRAC launched COVID-19: DBT-BIRAC Supported Products & Technologies Compendium showcasing Products in Market, Products to be in Market in 3-6 Months & COVID-19 Research pipeline additional facilitations.

Showcasing of Innovation Technologies at National and International Levels

- **Product launch at Global Bio India 2021:** The Product Launch session at the event provided a unique opportunity to the selected BIRAC supported start-ups to launch their product in front of the global community. the following 5 products were launched:
 - Emvolio A portable, battery-powered refrigerator for Vaccine delivery from Blackfrog Technologies Pvt. Ltd.
 - Grippy Battery powered prosthetic hand with a sense of touch and multi-grip control from Bionic Hope Pvt. Ltd.
 - ➤ KEYAR Wireless intrapartum monitoring device with DAKSH mobile application for monitoring risky pregnancies from Janitri Innovations Pvt. Ltd.
 - easyNav Computer-guided Surgical navigation system for neuro-surgery Happy Reliable Surgeries Pvt Ltd.
 - VoDCa Vortex Devices based on Cavitation Technology for waste water treatment by Vivira Process Technologies Pvt. Ltd
- Latitude 59, Estonia: Latitude 59, 2020 was held virtually on 27th -28th August 2020. Latitude59 is the largest annual international start up event in Estonia. The event brings together potential investors & start-ups for pitching, wooing and matchmaking activities. Latitude59 is an opportunity to demonstrate the product in front of the whole tech community in Estonia and many other relevant visitors including investors, media, potential customers and attending techies to get their direct feedback and support. BIRAC along with 5 Start-ups participated in Latitude59, virtually from27-28th Aug 2020. BIRAC delegation to the event was represented by Dr.Bhuvnesh Shrivastava, Manager Make in India Cell along with representatives from following 5 Start-ups:
 - > Janitri Innovations
 - ➤ Adiuvo Diagnostics Pvt Ltd.
 - > Periwinkle Technologies
 - > Predible Health
 - Ubigare Health Pvt Ltd

The event gave Indian Start-ups an opportunity to meet EU Start-ups, international investors and industry leaders from Estonia as well the Estonian Start-up ecosystem. Likewise this engagement brought awareness to Estonian/EU participants about the Indian Biotech ecosystem.

Webinar on Advancing Collaboration Across India - Finland – Estonia:

An international webinar was organized by MII Cell of BIRAC along with the Embassy of India in Finland and Estonia in partnership with Invest India on 25th June, 2020. The theme of the webinar was "Advancing Collaboration Across India -Finland-Estonia (Focus: Biotech Sector)" to showcase Indian, Finnish &Estonian Biotech Ecosystem strengths for introducing opportunities of Biotech collaboration.





Key Regular Inputs by MII cell

- > DBT Output Outcome Monitoring Framework (OOMF) Quarterly
- Cabinet Summary Monthly
- Budget Implementation update for Sectoral Groups of Secretaries (SGoS) -Monthly
- E-Samiksha updates- Quarterly
- Parliament Questions During the Sessions
- Invest India Queries Regarding Investments
- Startup India Updates- Action Plan, Progress Report
- DPIIT Monitoring Committee- Quarterly
- Regulatory Facilitation to Startups/ Entrepreneurs & SMEs FIRST HUB at Fortnight basis
- Resolving Queries related to Startup India and Make in India
- Dashboards/Monitoring Platforms Updation- Quarterly

New Initiatives steered by Make-in-India Cell during FY2020 - 21

• Bio-Manufacturing Hub:

During the Indian Science Congress held on 7th January, 2020 at Bengaluru, Hon'ble PM announced creation of a USD 100 Bn Bio-manufacturing Hub in the country. This could be central to scaling up of Indian Bioeconomy to USD 150 Bn by 2024-25. The Startup ecosystem is expected to grow 4 -5 times in the next 5 years. Likewise Large Industry growth, FDI, capacity building, policy initiatives and global partnership activities, need to be scaled up. Make in India Cell is spearheading this initiative and a strategic roadmap is being drawn through various stakeholders' consultation. The activities of the **Working Group** constituted by competent authority are also being coordinated by MII Cell.

Establishment of Technology Clusters:

The Technology Cluster initiative proposed by Make-in-India Cell was accepted and adopted at the Centre and Union ministry level. In Union Budget 2020, it was announced to create common infrastructure facilities for PoC to Pilot and Pilot to Manufacturing of innovative products and technologies by Start-up companies. In the next 5 years, 10 Technology Clusters would be established for sub-sectors of biotechnology. Make in India Cell is the focal point to draw the roadmap to establish the Technology Clusters across the country. Various Stakeholders consultations have been conducted through Make in India Cell and the Interim Report of the Working Group along with the detailed Budget proposal has been submitted to MoE through DBT.

Project Development Cell for Biotechnology:

After Cabinet's approval, DPIIT in June 2020 had instructed the ministries and departments, including Department of Biotechnology to set up a Project Development Cell (PDCs) that will work with Centre and States to create an investment friendly ecosystem, strongly supporting the domestic investor and FDI and issue resolution with highest level intervention through the Empowered Group of Secretaries (EGoS). Invest India will be the complementary agency to work with PDCs.

The Project Development Cell (PDC) for Biotechnology was launched during Global Bio India 2021 by Dr. Renu Swarup, Secretary DBT. The competent authority has also directed to establish the Biotech PDC unit with-in the Make in India Facilitation Cell at BIRAC. The Project Development Cell (PDC) is being set up at BIRAC to closely work with Invest India and identify and create Project Proposals for attracting investments in the Biotech Sector. The PDC for Biotechnology at BIRAC would function within MII Cell for carrying out investment facilitation activities.

National Investment Clearance Cell:

Government of India through DPIIT has mandated to have an Investment Clearance Cell – a Single window system for Regulatory compliances to promote Ease of Doing Business (EoDB). National Investment Clearance Cell would facilitate the Regulatory Clearances using single window system. India has moved up to 48th position in the Ease of Doing Business and aspires to further improve its EODB. Biotech sector involves a complex and multi-agency regulatory clearance requirement for manufacturing, product registration and development in India. The Investment Clearance Cell (ICC) would report to DBT Nodal Officer and would also function within Make-in-India Cell PMU at BIRAC.



2. Startup India:

Start-up India is a flagship initiative of the Government of India, intended to build a strong eco-system for nurturing innovation and start-ups in the country that will drive sustainable economic growth and generate large scale employment opportunities. The Government through this initiative aims to empower start-ups to grow through innovation and design. The Hon'ble Prime Minister of India formally launched the initiative on January 16, 2016. The Department of Biotechnology and BIRAC endeavours to scale up the number of Start-ups in the sector by handholding them from ideation to commercialization of their products/ technologies. Make in India Cell at BIRAC is also implementing, monitoring and reporting Start-up India Action plan with key stakeholders i.e. Start-up India Team, Invest India, etc.

Major Achievements under Start-up India Initiative:

- Startups supported: BIRAC has so far supported 1000+ Startups, Entrepreneurs & SMEs creating Intellectual wealth (210+ IP filed) and a robust pipeline of 130+ commercialized products and technologies across the country.
- **Bio-Incubators:** 60 Bioincubators have been set up across India creating a total incubation space of 640000 +sq. ft. for budding entrepreneurs. More than 680 incubates have been supported through the scheme so far.
- **BioNEST clusters:** Seven BioNEST clusters have also been recognized to promote networking & resource sharing among BioNEST incubators.
- Equity Funding: Fund of Fund Biotechnology Innovation Fund AcE (Accelerating Enterprises) is mandated to encourage private equity mobilization for Biotech Startups through co-investing in SEBI registered AIF. The assistance to a start-up will be up to INR upto 7 crores against equity. Total corpus of INR 150 Crores is fully committed in 13 AcE Daughter Funds for investment upto INR 7 Cr/ startup. SEED, LEAP and AcE Fund of Funds schemes are operational to provide equity based capital assistance to start-ups and act as a bridge between promoters' investment and venture/angel investors.
- **Biotech Clusters**: Biotech Clusters have the core emphasis on innovation that is critical for the growth of biotechnology entrepreneurship.
 - DBT has supported 4 Bio-clusters (NCR, Kalyani, Bangalore and Pune) till date.
- Regional Centers: BIRAC has created 4 Regional Centers (BRIC, BREC, BRBC, BRTC-E&NE) as extended arms to implement BIRAC's mandate in the country.
 - (i) BRIC at IKP Hyderabad
 - (ii) BREC at C-CAMP Bengaluru
 - (iii) BRBC at Venture Centre Pune
 - (iv) BRTC at KIIT-TBI Bhubaneshwar
- Bio-Connect offices: A total no. of 05 bio-connect offices were operational in 2020-21:
 - (i) CCAMP, Bengaluru with California Institute for Quantitative Biosciences (QB3)
 - (ii) CCAMP- Sister Innovation HUB with Roslin Innovation Centre, University of Edinburgh, UK
 - (iii) CEIIC BioNEST with European Union
 - (iv) KIIT BioNEST with TECHNOPORT SA BELVAL Business Incubator, Luxembourg
 - (v) KIIT BioNEST with Start-Life Centre, Wageningen University Netherland
- Technology Transfer Offices: Technology Transfer Offices (TTOs) were established to enhance academiaindustry inter-linkages, strengthen bio-cluster ecosystems and provide increased opportunities for academia to translate knowledge into products and technologies. Six TTOs have operational in 2020-21.
 - (i) FITT, Delhi
 - (ii) C-CAMP, Bengaluru
 - (iii) IKP Knowledge Park, Hyderabad
 - (iv) KIIT-TBI, Bhubaneshwar
 - (v) EDC, Pune
 - (vi) BCIL, New Delhi



XI. Facilitating Industry Academic Interaction

1. Foundation Day

Biotechnology Industry Research Assistance Council (BIRAC) celebrated its 9th Foundation Day on 20th March 2021 via virtual Platform. Since its inception, BIRAC has been diligently working towards the enabling & empowering the biotech innovation ecosystem of the country. The theme was this year Foundation day was" Scaling Biotech Innovations for Societal Unmet Needs".

Ms. Anju Bhalla Joint Secretary DST & Managing Director of BIRAC, Welcomed all participants at the outset of the event and congratulated team BIRAC on successful completion of 9 Years. She inspired the BIRAC team to continue creating the success stories in the future, especially in unprecedent times like the current pandemic.





Secretary, Department of Biotechnology and Chairperson, BIRAC, Dr Renu Swarup shared BIRAC's inspiring journey highlighting the initiatives and achievements and congratulated the entire team. A shot video featuring the wonderful journey of BIRAC for Nine Years was captured, showcasing the schemes, Partnerships, success stories, impact created, efforts of COVID- 19 & highlights of various training session and workshops.

Mr. Binod Kumar Bawri, Founder, Think India Foundation delivered the Keynote lecture on "Scaling Biotech Innovations for Societal Unmet Needs". He highlighted in this talk that there will be evolutionary changes in the way proteins are prepared over the next decade.

A panel discussion was also organized with the innovators. Representatives from MicroGo, BioPrime Agri Solutions Pvt Ltd, Hanugen Therapeutics, Molbio Diagnostics Pvt Ltd were some of the supported innovations that were a part of the panel discussion discussing how start-ups are scaling up to meet societal needs.



2. Outreach Initiatives

a. Communications

The Communications Team at BIRAC is responsible for promoting the brand presence of BIRAC through a variety of platforms: digital, print and social media. The BIRAC communication team provides support to the various departments and verticals and is in charge of conveying the organization's activities to a wide range of people, including innovators, scientists, academicians, policymakers, investors, and others. The team regularly contributes for content on social media platforms and closely works with the DBT- Communications team for press releases and other event-related and outreach activities.

For the year 2020-21, the team started on with the Vigyan se Vikas - a weekly feature that highlights the supported innovations and now is working on the weekly social media campaign- Lab 2 Market- BIRAC supported innovations commemorating the Azadi ka Amrit Mahotsav.

A quarterly publication of BIRAC Newsletter i3 which features cover stories, expert opinions, innovator opinions, BIRAC events and program updates . This year's publication touched upon various themes centred around how BIRAC has been at the forefront in the fight against the pandemic.

The communication team actively supported the virtual edition of **BIG Conclave 6.0** and **Global Bio India- 2021.** The communication team managed the pre and post-event activities along with the social media outreach and press releases.

Biotechnology Industry Research Assistance Counicil













Outreach Activities

The team is also a part of the DBT Communications ecosystem and regularly contributes to the Vigyan Samachar initiative. The team regularly submits stories on innovations, products & technologies, workshops and trainings for the Minister's Office.

BIRAC participated in a number of virtual events and webinars around the year to interact with the target audience and to aware people of various programs and schemes under BIRAC. Some of the events were: Vaccine Webinar, National Technology Day Webinar, SITARE GYTI Awards Ceremony, Launch of DBT-BIRAC CleanTech Demo Park, Jancare Innovation Challenge, BIRAC 9th Foundation Day, BIG Conclave, Global Bio-India and more.

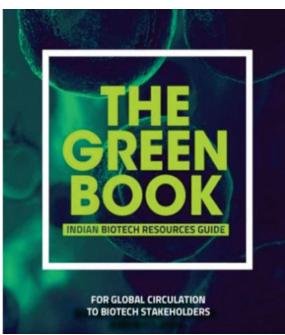
BIRAC has been at the forefront in the times of COVID and several press releases have been done in regards to potential covid solutions and vaccine efforts to inform the media and further the masses at large to aware them of the work done by the organization to fight against this pandemic.

The communication team also provides in-house support with compendium and other publications and works closely with DBT to support various outreach activities.

b. BIRAC's presence at BIO International Convention 2020

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also organizes the BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world. However due to pandemic, the event went fully online for the first time. ABLE coordinated the INDIA e- Pavilion.. This Year ABLE -INDIA published a booklet i.e. **The GREEN BOOK - An Indian Biotech Resources Guide** covering areas 11 Crucial Areas for the Growth of India's Bioeconomy. The Green Book published by ABLE- India to was released on the Online – Event. The guide would help the Indian Organizations achieve their business development & outreach goals. The book will Contained relevant information that would be available for members of various National Biotech & Pharma organization and ensure outreach to thousands of Biotech Stakeholders across the globe.





The Different 11 section areas are of books were:

- AG Biotech
- Biologics (vaccines, biosimilars, stem cells etc.),
- Industrial Biotech
- Contract Services
- Diagnostics & Medical Devices,
- Drug Discovery,
- I.P. Services
- Incubators,
- I.T
- Suppliers,
- Central & State Govt. Organizations &Dept./ Agencies/ Institutes

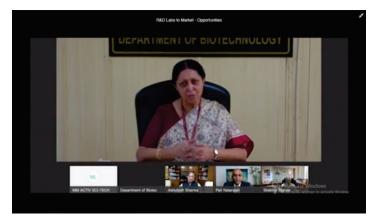
The Soft copies of **The GREN BOOK** was circulated to almost 30 country/ regional member associations of ICBA (International Council of Biotechnology Association) with thousands of members, well in advance for International events planned for the year.

c. BIRAC's presence in Bengaluru TECH Summit 2020

A digital event of Bengaluru Tech Summit 2020 ("Next is Now") was held on 19th to 21st November 2020. It was jointly organised by Karnataka government's Department of Electronics, Information Technology, Biotechnology and Science & Technology and it was India's flagship event.



BIRAC actively participated in the event. Dr Renu swarup, Secretary DBT & Chairman BIRAC was a distinguished speaker of the Day 2 session on "R&D Labs to Market". The panel deliberated upon success stories and challenges faced by the start-ups from lab to market. Panel also deliberated upon possible solutions like "Atmanirbharta comes from Atmavishwash". Co-panellists included Prof Ashutosh Sharma, Secretary, DST; Dr. Shekhar Mande, Secretary DSIR & DG-CSIR.





The three-day event saw participation from 25+ countries; around 250 speakers and 5000 attendees, participated in 4 Parallel Conference Tracks on IT, BT, GIA and Start-Up. More than 146 start-ups showcased innovation in IT, electronics, IoT, healthcare, Medtech, Agritech, Fintech, Edtech, and mobility sectors at the BTS 2020.

d. BioAsia 2020:

The BioAsia 2020 was held during 17 -19th Jan 2020 at HICC, Hyderabad. The 17th Edition of the Event theme was "Today for Tomorrow's" which was inaugurated by Minister of Commerce & IT of Government of Telangana. It is an annual flagship of the state which saw participation of various communities representation from Industry, Government, Scientist Community, Academia & Start-ups.

3 Representative from BIRAC participated in this event. BIRAC stall received a high response from start-ups, students, academicians and researchers showing great interest to know about the various schemes and activities of BIRAC. Young start-ups and researchers exhibited enthusiasm to know about our new initiatives, incubators, time of various calls and possibilities of collaborations in different capacities.

BIRAC also sponsored panel discussion on Collaborative R&D: Unlocking the potential of public and private partnerships was held on Day 2 of the event. The session converged upon establishing various ways and mechanisms to develop programs based on public-private partnerships for solving global health problems.

BIRAC co-sponsored the start-up stage awards that concluded on day 3 of the event. Mr. KT Rama Rao; Hon'ble Minister for Industries and Commerce, Government of Telangana graced the award ceremony. The top 5 awardees receiving this prestigious award were Heamac Healthcare Pvt. Ltd., Callzy, Flexmotiv, Lycan 3D, Oncosimis Biotech Pvt. Ltd

















Glimpses from BioAsia 2020

Future Plan:

Grand Innovation Challenge program 'Amrit Grand Challenge- जनCARE'

The idea behind this initiative is to identify, fund and support 75 Digital Healthtech Innovations by Start-ups/Individuals/Companies in Telemedicine, Digital Health, and mHealth that make use of Big Data, Al, ML, blockchain and other technologies for robust and high quality healthcare delivery in every corner of the country. This program was announced by the Hon'ble Prime Minister on 27th September 2021, and is also aligned with the National Digital Health Mission (NDHM).

Resource Mobilization

BIRAC as Implementing/ Knowledge partner to co-promote Entrepreneurial & Startup activities with Ministries/ States/ Corporates (CSR).

AcE Fund

Attempt to expand the corpus for Ace Fund/ roll out AcE 2.0 with expansion of 10 more AcE Fund partners from existing.



Global Bio-India 2022

A 3 day international mega event will be led by DBT and co-steered by BIRAC through Make In India Facilitation Cell. About 10,000+ delegates including Industry, Research Institutes, Policy Makers, Regulatory Agencies, Ministries, States, Departments, Startups, Investors and Biotechnology sector related stakeholders would be targeted.

XII. 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 mission programmes schemes National Biopharma Mission, and Covid Suraksha 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 & Administration

The HR & Administration Department in BIRAC is an essential component which is primarily focused on maximising the potential of the Human resources of the organisation to attain specific as well as organizational goals in an effective and efficient manner. 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.

The HR Strategy of BIRAC is aligned to the concept of transforming culture and envisages powerful interventions in the areas of workforce planning, HR analytics, Employee Engagement, Capacity Building and Skill Development.

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.

Learning and development programs are designed for the employees to upgrade their skills both in their domain areas and the soft skills. These programs 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 2020-21, more than 170 man-days training have been imparted to BIRAC Employees including domain specific trainings and soft skill trainings.

Biotechnology Industry Research Assistance Counicil



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 Swachhata Pakhwada, Hindi Maha, Yoga Day, Constitution Day, Women's Day etc. are also observed in BIRAC with fervour and zeal.

1. Swachhta Pakhwada

Swachhta Pakhwada is observed in BIRAC every year in the month of May. In order to ensure preventive measures to contain spread of COVID-19 in workplace, Swachhta Pakhwada was not observed in BIRAC in FY 2020-21. However, regular cleaning and sanitization activities are being carried out in timely manner in BIRAC.

Daily cleaning of the entire office premises including high touch surfaces is rigorously done. Provision of thermal scanning at the entrance of office and sanitizer dispenser at prominent location is also made available.

BIRAC has also educated its workforce by issuing Circulars in line with Government Guidelines and regularly communicated with its employees.

Safeguarding the health of employees is BIRAC's top priority therefore for deep cleaning special Sanitization & Fumigation drive on fortnightly or monthly basis or as and when required is being arranged from an outside agency.

In addition to this, there is a regular coverage of all activities related to COVID-19 on Twitter and Website of BIRAC.

2. Yoga Day

06th International Yoga Day has been observed in BIRAC on 21st June 2020 with the theme "GHAR GHAR me Yog". The event commenced with the address of Ms. Anju Bhalla, Joint Secretary DST & MD BIRAC followed by a guided yoga session through online platform for BIRAC employees and their families.

The common yoga viz. Suksham Vyayam / Bramri / Nadi shodhan pranayam / Bhastrika pranayam / Chakra Meditation beneficial for stress busting, relaxing, increasing immunity, improving lung capacity and enhancing energy has been performed by the employees under the guidance of Yoga Instructor.

Employees have also been encouraged to participate in Common Yoga Protocol (CYP) drill at 7.00 am on 21st June 2020, quiz and other competitions being organized by Ministry of AYUSH.

3. Hindi Maha

Hindi Diwas is celebrated on 14 September with great pride and vigour as Hindi was adopted as the Official Language of our nation, India on September 14, 1949.

This year Biotechnology Industry Research Assistance Council observed Hindi Maha from 01st September 2020 to 30th September 2020.

To promote and propagate the use of our national language, following competitions / activities were organized online during the Hindi month:

- Essay Writing on Importance of Hindi Language.
- Slogan Writing on Current Scenario.
- Maximum Hindi email communication till 30 September 2020 by Departments.
- Digital display of important quotations in Hindi.

All employees participated with great enthusiasm in this event.

4. Jan Andolan Campaign on COVID-19

Jan Andolan Campaign was launched by Hon'ble Prime Minister Shri Narendra Modi on 08th October, 2020 in order to spread awareness about the safety precautions for COVID-19. As per instructions from DBT, the activities organized in BIRAC are as given below:

- As retention of information is much higher by visual means, e-banners and poster on awareness about Jan Andolan Campaign on Covid-19 were displayed at prominent locations.
- Information about the Jan Andolan Campaign on Covid-19 was circulated to BIRAC employees and displayed on BIRAC 3i Portal and BIRAC Intranet system.



- BIRAC disseminated the information to its beneficiaries and network in order to promote the campaign at a large scale.
- Pledge was administered through online platform.

5. Constitution Day

26th November was celebrated as Constitution Day to commemorate the adoption of the Constitution of India.

BIRAC commenced the event by reading out The Preamble of Indian Constitution at 11:00 AM on 26th November 2020 reaffirming our commitment to uphold its ideology. As retention of information is much higher by visual means, e-banners on Constitution Day were displayed at the office entrance, Reception and BIRAC Website.

A talk was organised on Constitutional Values highlighting the importance of fundamental duties and their relevance in the 21st century. The session outlined the significance of the day along with acknowledgement and gratitude towards Dr. B.R. Ambedkar (Father of Indian Constitution) and his other team members. The lecture also spoke on how fundamental duties are imperative to the citizens of a country as much fundamental rights are.

Photo / videos of the activities are also uploaded on twitter handle of BIRAC

6. Vigilance Awareness & National Unity Day

Vigilance Awareness Week and Rashriya Ekta Diwas was observed in BIRAC from 27th October 2020 to 02nd November 2020 and on 31st October 2020 respectively. The observance of the Vigilance Awareness Week and Rashriya Ekta Diwas commenced with the "Integrity Pledge" and "Rashtriya Ekta Diwas Pledge" taken by all employees of BIRAC.

7. Workshop on Gender Sensitization & Prevention of Sexual Harassment at Workplace

As per the provisions of "Sexual Harassment of women at work place (Prevention, Prohibition and Redressal) Act, 2013", BIRAC organises workshops and awareness programmes at regular intervals for sensitising the employees.

In-house Workshop on Gender Sensitization & Prevention of Sexual Harassment at Workplace has been organised on 10th February 2021.

The training is to equip employees with necessary skills to combat sexual harassment faced in their daily working life and create a stress free work environment conducive for higher performance.

8. Women's Day

International Women's Day is observed on March 8th 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 addressed employees virtually.

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.

9. Workshop on Official Language Act

In line with the implementation of Official Language Act, a workshop was organised in each quarter for BIRAC employees to acquaint the employees with the importance and provisions of the Official Language. The workshop helped employees in understanding the constitutional provisions of Official Language Act and on implementing official language in day to day official correspondence.

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.



Constitution Day 26 November



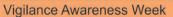


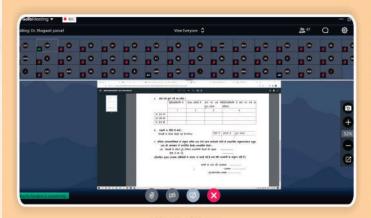
Yoga Day Celebration



Jan Andolan Campaign on Covid-19







Hindi Diwas



Report on Corporate Governance



REPORT ON CORPORATE GOVERNANCE

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 3 (three) Directors viz. an Executive Chairperson, an Executive Managing Director and a Government Nominee Director.

Five Board meetings of the Company were held on the following dates: August 27, 2020, September 24, 2020, November 19, 2020, December 18, 2020 and February 24, 2021.

The details of the Directors and the Board meetings attended are as follows till 31st March, 2021:

Name of the Director	Category	Directorships in other	Committe	chairman of es in other canies	Board Meetings Attended	Attendance at last AGM
Director		companies	Member	Chairman	(Nos.)	
Dr. Renu Swarup	Chairperson (Executive)	Nil	Nil	Nil	5	Yes
Dr. Mohd. Aslam*	Government Nominee Director	1	Nil	Nil	3	Not Applicable
Ms. Anju Bhalla**	Managing Director (Executive)	Nil	Nil	Nil	5	Yes
Mr. Vishvajit Sahay #	Government Nominee Director	1	Nil	Nil	1	Not Applicable

^{*}Dr. Mohd Aslam was the Managing Director of BIRAC upto April 9, 2020; Also, his term as Government Nominee Director ends on November 30, 2020.

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

During the year, BIRAC did not have Audit Committee as the term of the independent directors was ended on March 15, 2020. The appointment of non-official directors is in process with Department of Public Enterprises (DPE).

4. REMUNERATION COMMITTEE

During the year, BIRAC did not have the Remuneration Committee as the term of the independent directors was ended on March 15, 2020. The appointment of non-official directors is in process with Department of Public Enterprises (DPE).

^{**}Ms. Anju Bhalla, Joint Secretary, DST was appointed as the Managing Director of BIRAC w.e.f. April 10, 2020

[#] Mr. Vishvajit Sahay, was appointed as Government Nominee Director w.e.f. December 24, 2020



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, 2021

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
	President of India	9000	90,00,000	90
Shareholding of Promoter	Dr. Renu Swarup (held on behalf of the President of India)	900	9,00,000	9
and promoter category	Ms. Anju Bhalla (held on behalf of the President of India)	100	1,00,000	1
	GRAND TOTAL	10000	1,00,00,000	100

7. GENERAL BODY MEETINGS

The details of general body meetings are as follows:

Period ended on	Venue	Date	Time
31.03.2019	Department of Biotechnology, 2, CGO Complex, 7 th floor, Lodhi Road, New Delhi – 110003	23.09.2019	10.15 a.m.
31.03.2020	MTNL Building, 1 st Floor, 9, CGO Complex, Lodhi Road, New Delhi – 110 003	18.12.2020	05:45 p.m.
31.03.2021	Department of Biotechnology, 2, CGO Complex, 7 th floor, Lodhi Road, New Delhi – 110003	30.11.2021	04.30 p.m.

8. 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 F.No. DPE/14/(38)/10-Fin. dated 26.04.2021, advised all CPSEs to submit an annual compliance report on implementation of policies and guidelines issued by DPE by 30th June, 2021 for financial year 2020-21. 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.

9. 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.



10. 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, Company Secretaries, New Delhi confirming the compliance of the provisions of Corporate Governance forms a part of the report on Corporate Governance.

11. REMUNERATION OF DIRECTORS

No remuneration paid to directors during the period as BIRAC does not have any functional directors.

12. 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 2020-21. 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, 2021".

Sd/- Sd/-

Dr. Alka SharmaMr. Vishvajit Sahay(Managing Director)(Director)

Date: 30.11.2021
Place: New Delhi



Annexure - 1

ANNUAL REPORT ON CSR ACTIVITIES

1. Brief outline on CSR Policy of the Company:

Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Section 8, Schedule B, Public Sector Enterprise, set up by Department of Biotechnology (DBT), Government of India.

The Board of BIRAC at its 45th Board Meeting held on February 24, 2021 approved the Corporate Social Responsibility Policy (CSR Policy). The CSR Policy of the BIRAC was formulated in line with the provisions of the Companies Act, 2013 read with the Companies (Corporate Social Responsibility) Rules, 2014 and 'DPE Guidelines'.

Vision and Mission Statement for CSR Policy:

Vision Statement: BIRAC, through its CSR initiatives, will continue to enhance value creation in the society and in the community in which it operates, through its services, conduct & initiatives, so as to promote sustained growth for the society and community, in fulfilment of its role as a Socially Responsible CPSE.

Mission Statement: In line with the Companies Act, 2013 and DPE guidelines this policy aims at developing Company specific social responsibility strategies in long, medium and short term period with built in mechanism for implementation and monitoring towards creating a Societal impact.

- 2. Composition of CSR Committee: As per Companies (Amendment) Act, 2020 (applicable w.e.f. 22nd January, 2021), if the amount to be spent by a company does not exceed fifty lakh rupees, the requirement for constitution of the CSR Committee shall not be applicable and the functions of such Committee provided under Section 135 shall be discharged by the Board of Directors of company.
 - Hence, as per the above mentioned provision and as per the CSR Policy of the BIRAC, the Board of Directors shall discharge the function of CSR Committee as prescribed in Section 135 of the Companies Act, 2013 read with Companies (Corporate Social Responsibility Policy) Rules, 2014.
- 3. Web-link where Composition of CSR committee, CSR Policy and CSR projects approved by the board are disclosed on the website of the company: www.birac.nic.in
- 4. Details of Impact assessment of CSR projects carried out in pursuance of sub-rule (3) of rule 8 of the Companies (Corporate Social responsibility Policy) Rules, 2014, if applicable (attach the report): Not Applicable
- 5. Details of the amount available for set off in pursuance of sub-rule (3) of rule 7 of the Companies (Corporate Social responsibility Policy) Rules, 2014 and amount required for set off for the financial year, if any: Not Applicable

SI. No.	Financial Year	Amount available for set-off from preceding financial years (in Rs.)	Amount required to be set-off for the financial year, if any (in Rs.)
		Not Applicable	

- 6. Average net profit of the company as per section 135(5): Rs. 3,67,32,355/-
- 7. (a) Two percent of average net profit of the company as per section 135(5): Rs. 734,647/-
 - (b) Surplus arising out of the CSR projects or programmes or activities of the previous financial years: Not Applicable
 - (c) Amount required to be set off for the financial year, if any: Not Applicable
 - (d) Total CSR obligation for the financial year (7a+7b-7c): Rs. 734,647/-
- 8. (a) CSR amount spent or unspent for the financial year:

		Amount Unspent (in Rs.)								
Total Amount Spent for the Financial Year.	to Unspent	nt transferred CSR Account tion 135(6).	Amount transferred to any fund specified under Schedule VII as per second proviso to section 135(5).							
(in Rs.)	Amount	Date of transfer	Name of the Fund	Amount	Date of transfer					
734,647/-	Not Applicable									



(b) Details of CSR amount spent against ongoing projects for the financial year

(1)	(2)	(3)	(4)	((5)	(6)	(7)	(8)	(9)	(10)	(:	11)
SI. No.	Name of the Project	Item from the list of activities in Schedule VII to the Act	Local area (Yes /No)	7 7 7 7	on of the oject District	Project durat- ion	Amount allocated for the project (in Rs.)	Amount spent in the current fina-ncial Year (in Rs.)	Amount transferred to Unspent CSR Account for the project as per Section 135(6) (in Rs.)	Mode of Implem- entation- Direct (Yes / No)	Implen – Th Imple	de of nentation irough menting ency CSR Registration number
						Not A	Applicable					

(c) Details of CSR amount spent against other than ongoing projects for the financial year:

(1) SI. No.	(2) Name of the Project	(3) (4) Item from the list of area (Yes/No)			(5) ion of the roject	(6) Amount spent for the	Amount Mode of spent implementor the tation -	(8) Mode of implem Through imple Agenc	menting
		in schedule VII to the Act	NO)	State	District	project (in Rs.)	Direct (Yes/ No)	Name	CSR registra- tion number
1.	Contribution to Swachh Bharat Kosh	Item (i)	No	All India	All India	734,647	Yes	Swachh Bharat Kosh	NA
		Total			734,647				

- (d) Amount spent in Administrative Overheads: Nil
- (e) Amount spent on Impact Assessment, if applicable: Nil
- (f) Total amount spent for the Financial Year (8b+8c+8d+8e): Rs. 734,647/-
- (g) Excess amount for set off, if any: Nil

SI. No.	Particular	Amount (in Rs.)
(i)	Two percent of average net profit of the company as per section 135(5)	734,647/-
(ii)	Total amount spent for the Financial Year	734,647/-
(iii)	Excess amount spent for the financial year [(ii)-(i)]	Nil
(iv)	Surplus arising out of the CSR projects or programmes or activities of the previous financial years, if any	Nil
(v)	Amount available for set off in succeeding financial years [(iii)-(iv)]	Nil

Biotechnology Industry Research Assistance Counicil



9. (a) Details of Unspent CSR amount for the preceding three financial years:

SI. No.	Preceding Financial Year	Amount transferred to Unspent CSR Account under section 135 (6) (in Rs.)	Amount spent in the reporting Financial Year (in Rs.).		nsferred to any dule VII as per s if any. Amount (in Rs)		Amount remaining to be spent in succeeding financial years. (in Rs.)		
	Not Applicable								

(b) Details of CSR amount spent in the financial year for ongoing projects of the preceding financial year(s):

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)		
SI. No.	Project ID.	Name of the Project	Financial Year in which the project was commenced.	Project duration.	Total amount allocated for the project (in Rs.)	Amount spent on the project in the reporting Financial Year (in Rs)	Cumulative amount spent at the end of reporting Financial Year. (in Rs.)	Status of the project -Completed / Ongoing		
	Not Applicable									

- 10. In case of creation or acquisition of capital asset, furnish the details relating to the asset so created or acquired through CSR spent in the financial year (asset-wise details): Not Applicable
 - (a) Date of creation or acquisition of the capital asset(s): Not Applicable
 - (b) Amount of CSR spent for creation or acquisition of capital asset: Not Applicable
 - (c) Details of the entity or public authority or beneficiary under whose name such capital asset is registered, their address etc.: Not Applicable
 - (d) Provide details of the capital asset(s) created or acquired (including complete address and location of the capital asset): Not Applicable
- 11. Specify the reason(s), if the company has failed to spend two per cent of the average net profit as per section 135(5): Not Applicable

Sd/-

Dr. Alka SharmaMr. Vishvajit Sahay(Managing Director)(Director)

Date: 30.11.2021 Place: New Delhi



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 financial year ended on March 31, 2021 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 and we have obtained, 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 Guideline of DPE, for the period under review.

We further state that such certification of compliance is for limited purpose and is neither an assurance as to the viability of the Company nor of the efficiency or effectiveness with which the management has conducted the affairs of the company.

Place: New Delhi

Date: 29th October 2021

Sd/-(P. N Gupta) Practicing Company Secretary FCS- 4430 C.P No- 6778 UDIN: F004430C001327873

Auditors' Report & Annual Accounts



SAMPRK & ASSOCIATES

Chartered Accountants

INDEPENDENT AUDITOR'S REPORT

To the Members of M/s. Biotechnology Industry Research Assistance Council

Report on the Financial Statements

Opinion

We have audited the accompanying financial statements of M/s. Biotechnology Industry Research Assistance Council which comprises the Balance Sheet as at March 31, 2021, the Statement of Income and Expenditure for the year, the statement of Cash Flow 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, 2021, its Income and its cash flow 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 thereunder, 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.

Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Reporting of key audit matters as per SA 701, Key Audit Matters are not applicable to the Company as it is an unlisted company.

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 ("the Act") with respect to the preparation of these financial statements that give a true and fair view of the financial position and financial performance 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.



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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 are not applicable to the company.

As required by Section 143(3) of the Act, we report that:

- a. 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.
- b. 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.
- c. The Balance Sheet, the Statement of Income & expenditure and the Cash Flow dealt with by this Report are in agreement with the books of account.
- d. 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.
- e. We have been informed that the provisions of Section 164(2) of the Act in respect of disqualification of directors are not applicable to

- the Company, being a Government Company in terms of notification no. G.S.R.463 (E) dated 5th June, 2015 issued by Ministry of Corporate Affairs, Government of India.
- f. With respect to the adequacy of Internal financials controls over financial reporting of the company and the operating effectiveness of such control, refer to our separate Report in "Annexure A"
- g. 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:
 - The Company has disclosed the impact of pending litigations on its financial position in its financial statements
 - ii. 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 contracts
 - iii. There has been no delay in transferring amounts, required to be transferred, to the Investor Education and Protection Fund by the Company.

Further as per the direction of Controller and Auditor General of India, we are reporting on the points as asked u/s 143(5) as given below:-

S.N.	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 financial implications, if any, may be stated.	Yes, the company has system in place to process all the accounting transactions through IT system.
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.	No, there is no restructuring/ waiver/ write off of any debt/loan availed by the company.
3.	Whether funds received/receivable for specified schemes from central/state agencies were properly accounted for/utilized as per its term and conditions? List the case of deviation.	Yes, funds received/receivable for specific schemes from central/state agencies have been properly accounted for/ utilized as per its terms and conditions.

For S A M P R K & Associates Chartered Accountants Firm Regn. No. 013022N

Sd/-

CA. Keshav Kumar Partner M. No.088271

UDIN: 21088271AAAAED2418

Place: Delhi Date: 21.09.2021



SAMPRK & ASSOCIATES Chartered Accountants

Annexure 'A'

Report on Internal Financial Controls over Financial Reporting

Report on the internal financial controls over financial reporting 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 M/s. Biotechnology Industry Research Assistance Council ("the Company") as at March 31, 2021, 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 board of directors of the Company 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, 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 internal financial controls over financial reporting of the Company 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") issued by the Institute of Chartered Accountants of India and the standards on auditing prescribed under Section 143 (10) of the Companies Act, 2013, to the extent applicable to an audit of internal financial controls. 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 were 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 judgement, including the assessment of the risks of material misstatement in 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 control 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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 authorisations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorised acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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 of override of controls, material misstatements due to error or fraud may occur

Biotechnology Industry Research Assistance Counicil



Place: Delhi Date: 21.09.2021

SAMPRK & ASSOCIATES

Chartered Accountants

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 and according to the information and explanations given to us, the Company has, in all material respects, an adequate internal financial control system over financial reporting and such internal financial controls over financial reporting were operating effectively as at March 31, 2021, 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 S A M P R K & Associates Chartered Accountants Firm Regn. No. 013022N

Sd/-

CA. Keshav Kumar Partner M. No.088271

UDIN: 21088271AAAAED2418



Biotechnology Industry Research Assistance Council (BIRAC) BALANCE SHEET AS AT 31ST MARCH 2021 CIN U73100DL2012NPL233152

(Amount in Rs.)

Particulars	Note No.	As at 31.03.2021	As at 31.03.2020
I. EQUITY AND LIABJLITIES			
(1) Shareholder's Funds			
(a) Share Capital	1	1,00,00,000	1,00,00,000
(b) Reserves and Surplus	2	1, 18,80,30, 158	1, 1 0,88,57,922
(2) Deferred Government Grant	3	84,77,797	64,60,831
(3) Non Current Liabilities	4	70,98,06,022	74,50,77,006
(4) Current Liabilities	5	3,93,58,61,214	2, 90, 76, 70,653
TOTAL		5,85,21,75,191	4,77,80,66,413
II ASSETS			
(1) Non-Current Assets			
(a) Fixed Assets			
(i) Tangible Assets	6	82, 19,792	61,83,601
(ii) Intangible Assets	6	2,58,004	2,77,230
(b) Non-Current Investments	7	44,48,99,034	25,82,03, 152
(c) Long-Term Loans and Advances	8	48,83,04,269	78,58,02,624
(2) Current Assets			
(a) Cash and Cash Equivalents	9	4,65,44,72,734	3,35,58,04,654
(b) Other Current Assets	10	25,60,21,357	37,17,95,151
TOTAL		5,85,21,75,191	4,77,80,66,413
Significant Accounting Policies and the accompanying Notes to Accounts.	16 & 17		

The notes referred to above form integral part of Financial Statements.

Auditors Report

As per our report of even date attached For SAMPRK & Associates

Chartered Accountants Firm Reg.No. 013022N

For and on behalf of Board of Directors

Sd/-Sd/-Sd/-Sd/-C.A. Keshav KumarKavita AnandaniAnju BhallaRenu Swarup

(Partner)(Company Secretary)(Managing Director)(Chairperson)Membership No. 088271DIN 06981734DIN 01264943

Place: New Delhi

Date: 21st September' 2021



Biotechnology Industry Research Assistance Council (BIRAC) STATEMENT OF INCOME & EXPENDITURE FOR THE PERIOD ENDED 31ST MARCH 2021. CIN U73100DL2012NPL233152

(Amount in Rs.)

Particulars	Note No.	For the Period ended 31.03.2021	For the Period ended 31.03.2020
(1) INCOME			
Grants Received as Utilised	11	1,64,45,31,524	1,78,75,32,847
Extra-Mural Grants Received as Utilised	13A-I	4,20, 14,00,423	2,35,05,83,379
Other Income	12	7,00,51,512	8,52, 13,524
Total Revenue		5,91,59,83,458	4,22,33,29, 750
(2) EXPENDITURE			
Programme Expenditure	13	1,49,22,52,092	1,64,62,44,684
Extra-Mural Programme Expenditure	13A-I	4,20, 14,00,423	2,35,05,83,379
Employee Benefit Expenses	14	7,99,80,799	7,04,34,781
Depreciation & Amortisation Expenses	6	21,56,077	27,80,888
Other Expenses	15	7,22,98,632	7,37,40,742
Total Expenses		5,84,80,88,024	4, 14,37,84,473
(3) Surplus of Income over Expenditure before exceptional and extraordinary items		6, 78,95,435	7,95,45,277
Less: CSR Expenditure	17.16	7,34,647	
Add/ (Less): Prior Period Income/ (Expenditure) (net)		-	-
(4) Surplus before extraordinary items		6, 71,60, 788	7,95,45,277
Add/(Less): Extraordinary Items		-	-
(5) Income before tax		6, 71,60, 788	7,95,45,277
Less: Provision for Income Tax		-	-
Surplus Carried Forward to Reserve & Surplus Ale		6, 71,60, 788	7,95,45,277
Earning per equity share:			
(I) Basic		6,716	7,955
(2) Diluted		6,716	7,955
Significant Accounting Policies and the accompanying Notes to Accounts.	16 & 17		

The notes referred to above form integral part of Financial Statements.

Sd/-

Auditors Report

As per our report of even date attached For SAMPRK & Associates

Chartered Accountants

Firm Reg.No. 013022N Sd/-

(Partner) Membership No. 088271

Place: New Delhi

C.A. Keshav Kumar

Date: 21st September' 2021

For and on behalf of Board of Directors

Sd/-Sd/-

Kavita Anandani Anju Bhalla Renu Swarup (Company Secretary) (Managing Director) (Chairperson) DIN 01264943 DIN 06981734





Biotechnology Industry Research Assistance Council (BIRAC) Cash Flow Statement for the Period Ended 31st March 2021 CIN U73100DL2012NPL233152

(Amount in Rs.)

		For the Period ended	For the Period ended
Particulars Particulars		31.03.2021	31.03.2021
Cash Flow from Operating Activities:			
Net Surplus as per Income & Expenditure Account		6, 71,60, 788	7,95,45,277
Adjustments for:			
Depreciation		21,56,077	27,80,888
Management Expenses		(11,01,695)	(7,16,495)
Foreign Exchange Fluctuation		118	1,93,725
Interest Income		(5,46,69,733)	(7,31,44,340)
Operating Profit before Working Capital changes		(5,36, 15,232)	(7,08,86,222)
Increase/(Decrease) in Provisions & Payables		18,63,59,882	13,85,32,977
Increase/(Decrease) in Grant Utilisation		88,71,76, 150	1,54,26,40,878
Increase/(Decrease) In Capital Reserve/Deferred Income		20,16,966	(16,60,015)
Fund Utilisation Towards PPP Activities (Net)		(2,32,59,536)	(26,43,312)
Provision for Sub-Standard & Doubtful Assets		-	-
(Increase)/ Decrease in Other Current Assets		(12,77,40,591)	(5,51,99,489)
(Increase)/Decrease in Advances PPP Activities (Net)		31,00, 72,965	24,64,43,525
		1,23,46,25,835	1,86,81, 14,564
Cash Generated from/ (used in) Operations		1,24,81, 71,391	1,87,67,73,619
Income Tax Refund / (Paid)		-	-
Net Cash from (Used in) Operating Activities	(A)	1,24,81, 71,391	1,87,67,73,619
Cash Flow From/ (Used In) Investing Activities:			
Purchase of Fixed Assets			
Net Cash from/(Used in) Investing Activities	(B)	(41, 73,043)	(6,74,431)
Cash Flow From/ (!!sed In) Financing Activities:			
Interest Income		5,46,69,733	7,31,44,340
Net Cash from/(Used in) Financing Activities	(C)	5,46,69,733	7,31 ,44,340
Net Increase in Cash and Cash Equivalents	D=(A+B+C	1,29,86,68,080	1,94,92,43,528
Cash and Cash Equivalent at beginning of the year	(E)	3,35,58,04,654	94,65,06,431
Cash and Cash Equivalent at end of the year (Refer Note 17.15)	F=(D+E)	4,65,44, 72,734	2,89,57,49,959

Auditors Report

As per our report of even date attached For SAMPRK & Associates

Chartered Accountants Firm Reg.No. 013022N

 Sd/ Sd/ Sd/

C.A. Keshav KumarKavita AnandaniAnju BhallaRenu Swarup(Partner)(Company Secretary)(Managing Director)(Chairperson)Membership No. 088271DIN 06981734DIN 01264943

For and on behalf of Board of Directors

Place: New Delhi

Date: 21st September' 2021



Biotechnology Industry Research Assistance Council (BIRAC) NOTES TO FINANCIAL STATEMENTS

1. Share Capital (Amount in Rs.)

Particulars Particulars	As at 31.03.2021	As at 31.03.2020
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 31.03.2021 No, of Shares	As at 31.03.2020 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 shares of the company

	As at 31.0	03.2021	As at 31.	03.2020
Name of Shareholder	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%
Dr. Renu Swarup (held on behalf of President of India)	900	9%	900	9%

E. Other details and Rights

The company has only one class of equity shares issued at par value of Rs. I 000 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 31.03.2021	As at 31.03.2020
I. Other Reserve		
Funds Utilised for Loans under PPP Activities after 31/03/2014	43,45,14,184	56,10,23,150
Less: Provision for Sub-Standard & Doubtful Assets (Refer Note 17.3)	(1,75,40,104)	(1,05,97,382)
Post BIRAC Realised	54,93,69,293	40,39,06, 157
(B)	96,63,43,373	95,43,31,925
II. General Reserve		
Surplus		
Opening Balance	15,45,25,997	7,49,80,720
Appropriation :		
Add: Transfer from Statement of Income & Expenditure	6,71,60,788	7,95,45,277
(C)	22, 16,86,785	15,45,25,997
TOTAL (A+B+C)	1,18,80,30,158	1,10,88,57,922

3. Deferred Government Grant#

(Amount in Rs.)

Particulars Particulars	As at 31.03.2021	As at 31.03.2020
Opening Balance		
Deferred Government Grant Transferred from Capital Reserve (Refer Note 16.2.4A)	64,60,831	85,67,288
Add: On Account of Capital Expenditure during the Period	41,73,043	6,74,431
Less: On Account ofDeoreciation on Fixed Assets during the Period	(21,56,077)	(27,80,888)
TOTAL	84,77,797	64,60,831

[#] Refer Note 16.2.4A

4. Non Current Liabilities

Particulars	As at 31.03.2021 As at 31.03.2020
Pre-BIRAC Unrealised Portfolio	
Pre-BIRAC Unrealised Portfolio	80,86,17,743 99,21,81,742
Less: Provision for Sub-Standard & Doubtful Ass (Refer Note 17.3)	ets 54,37,10,754 50,53,07,888
	(A) 26,49,06,988 48,68,73,854
ACE Funding (Refer Note 17. 17.1)	(B) 44,48,99,034 25,82,03,152
TOTAL (A-	-B) 70,98,06,022 74,50,77,006



5. Current Liabilities (Amount in Rs.)

Particulars Particulars	As at 31.03.2021	As at 31.03.2020
	AS at 31.03.2021	As at 31.03.2020
Unutilised Grant (Refer Note 17.12)		
Unutilised Grant (BIRAC)	27,85,087	-
Unutilised Grant (PPP Activities)	78,93,758	-
Unutilised Grant (DBT-BMGF-WT PMU) #	87,96,18,563	90,81,35,134
Unutilised Grant (Make in India Facilitation Cell)	67,88,428	-
Unutilised Grant (Bio-toilets in schools from North East Region)	3,71,413	3,76,583
Unutilised Grant (National Biopharma Mission -13)	27,20,10,312	35,70,59,491
Unutilised Grant (MeitY)	21,821	-
Unutilised Grant (SSC NTBN)	2,80,039	53,95,564
Unutilised Grant (Ind CEPI)	20,14,74,100	28,63,81,459
Unutilised Grant (GBI)	1,31,62,464	-
Unutilised Grant (Covid Surkasha)	1,22,55,97,324	-
(A)	2,61 ,00,03,308	1,55, 73,48,231
DBT AcE Fund (Refer Note 17.12)		
Unutilised AcE Fund (B)	65,70,54,774	82,25,33,701
Trade Payables		
Trade payables dues to micro and small enterprises (Refer Note 17.14)	-	23,36,541
Trade payables other than due to micro and small enterprises	2,03,60,549	4,97,62,538
(C)	2,03,60,549	5,20,99,079
Other Payables		
Pre-BIRAC Realised Portfolio	64,32,71,316	46,81,02,757
Less: Refunded to DBT	-	-
(D)	64,32,71,316	46,81,02,757
Statutory Liabilities	44,37,582	58,11,391
Provision for Gratuity & Leave Encashment	7,33,685	17,75,494
(E)	66,88,03,132	52,77,88,721
TOTAL (A+B+C+D+E)	3,93,58,61,214	2,90,76,70,653

[#] Unutilised Grant under DBT-BMGF-WT PMU is to be utilised over a period of three years.



6. Schedule of Fixed Assets	d Assets									(Amount in Rs.)
		Gross	Gross Block			Depreciation	ation		Net	Net Block
Particulars	As at	Addition	Sales/ Adjustments	Asat	As at	For the Period	Adjust- ments	As at	WDV as at	WDV as at
	1-Apr-2020	2020-21	2020-21	31-Mar-21	1-Apr-2020	2020-21	2020-21	31-Mar-21	31-Mar-21	31-Mar-2020
Tangible Assets										
Furniture & Fixtures	2,65,92,815	39,96,394	1	3,05,89,209	2,13,10,278	15,95,883	'	2,29,06,161	76,83,048	52,82,537
Office Equipment	7,03,473	6,649	1	7,10,122	4,03,080	1,32,189	1	5,35,269	1,74,853	3,00,393
Computers	55,08,100	1	1	55,08,100	4,907,429	2,38,780	1	51,46,209	3,61,891	6,00,671
Total Tangible Assets	3,28,04,388	40,03,043	ı	3,68,07,431	26,620,787	19,66,852	1	2,85,87,639	82,19,792	61,83,601
Intangible Assets	10,87,386	1,70,000	1	12,57,386	8,10,156	1,89,225	1	9,99,382	2,58,004	2,77,230
Total Intangible Assets	10,87,386	1,70,000	ı	12,57,386	8,10,156	1,89,225	I	9,99,382	2,58,004	2,77,230
Total	3,38,91,774	41,73,043	•	3,80,64,817	2,74,30,943	21,56,077	1	2,95,87,020	84,77,797	64,60,831
Previous Year Figures	3,32,17,343	6,74,431	ı	3,38,91,774	2,46,50,055	27,80,888	ı	2,74,30,943	64,60,831	85,67,288



7. Non-Current Investments

(Amount in Rs.)

Particulars	As at 31.03.2021	As at 31.03.2020
Others (held on behalf of DBT)		
AcE Funding (Refer Note 17.18.1)	44,48,99,034	25,82,03,152
	44,48,99,034	25,82,03,152

8. Long Term Loans & Advances

(Amount in Rs.)

Particulars Particulars	As at 31.03.2021	As at 31.03.2020
Security Deposit		
Security Deposit	1,05,39,969	1,23,39,969
Long Term Loans and Advances		
(Secured against Bank Guarantee/ Hypothecation/ Personal Guarantee) *		
"Loans Portfolio (Including Interest on Loan Accounts PPP Activities"	1,24,31,31,924	1,55,32,04,889
Less: Current maturities of Long Term Loans & advances reflected under Current assets	20,41,16,766	26,38,36,963
Less: Provision for Doubtful Assets (Refer Note 17.3)	52,62,63,671	45,71,18,201
Less: Provision for Sub-Standard Assets (Refer Note 17.3)	3,49,87,188	5,87,87,069
	47,77,64,300	77,34,62,655
TOTAL	48,83,04,269	78,58,02,624

^{*} Refer 17.3

9. Cash & Cash Equivalents

(Amount in Rs.)

Particulars Particulars	As at 31.03.2021	As at 31.03.2020
Cash in Hand	16,449	23,824
Balances with Banks: (Refer Note 17.15)		
In Current Accounts	20,104	118,223
In Saving Accounts	88,25,42,392	1,18,61,23,739
In Fixed Deposits	3,77,18,93,789	2,16,95,38,868
TOTAL	4,65,44,72,734	3,35,58,04,654

10. Other Current Assets

		(/
Particulars Particulars	As at 31.03.2021	As at 31.03.2020
"Current maturities of Long Term Loans and Advances:(*)"	20,41,16,766	26,38,36,963
(Secured against Bank Guarantee/Hypothecation/ Personal Guarantee)		
Other Assets		
Accrued Interest-FD & Saving Account (PPP, DBT / WT)	1,18,89,827	1,41,94,501
Recoverable from Government Agencies (Tax Credit)	1,49,28,723	1,46,23,563
Prepaid Expenses	22,43,514	25,99,112
Recoverable from DBT & Sponsors- GBI Events	-	5,59,00,000
Other Recoverable	2,28,42,528	2,06,41,012
TOTAL	25,60,21,357	37,17,95,151

^{*} Refer 17.3



11. Income (Amount in Rs.)

Grants Received as Utilised	For the Period ended 31.03.2021	For the Period ended 31.3.2020
PPP Activities	13,76,069,966	14,72,147,432
BIRAC Activities	26,84,61,557	31,53,85,415
TOTAL	1,64,45,31,524	1,78,75,32,847

12. Other Income (Amount in Rs.)

Particulars	For the Period ended 31.03.2021	For the Period ended 31.3.2020
Royalty	61,75,751	43,26,833
Management Fee - BMGF	11,01,695	11,01,695
Interest Received - Bank Accounts	5,46,69,733	7,31,44,340
Additional Interest	36,61,556	11,96,449
Other Receipts	22,86,700	26,63,319
Amortised Deferred Government Grant	21,56,077	27,80,888
TOTAL	7,00,51,512	8,52,13,524

13. Programme Expenditure

(Amount in Rs.)

Particulars	For the Period ended 31.03.2021	For the Period ended 31.3.2020
Grants Disbursed		
PPP Activities	1,35,61,13,869	1,42,24,28,681
BIRAC Activities	11,61,82,126	17,22,44,052
Programme Expenditure		
PPP Activities (Operational expenditure on Advertisement, Meeting and PMC)	1,99,56,097	5,15,71,950
Total	1,49,22,52,092	1,64,62,44,684

13A. Programme Management Unit DBT & BMGF

			(/)
Particulars		For the Period ended 31.03.2021	For the Period ended 31.3.2020
Programme Expenditure (GCI)		38,97,25,761	21,88,83,872
Operational Expenditure		4,33,06,949	4,76,33,390
Operational Non Recurring Expenditure		-	-
	(A)	43,30,32,710	26,65,17,262
Less:			
Programme Funds from DBT (GCI)		10,14,90,940	10,49,18,330
Programme Funds from BMGF (GCI)		21,66,56,590	11,39,65,542
Programme Funds from US AID (GCI)		-	-
Programme Funds from WT		15,55,742	
Programme Funds from WT Sanger (GCI)		7,00,22,489	-
	(B)	38,97,25,761	21,88,83,872
Less:			
Operational Fund from DBT		52,32,055	56,40,468
Operational Non Recurring Fund from DBT		-	-
Operational Fund from BMGF		3,72,74,894	3,62,48,120
Operational Non Recurring Fund from BMGF		-	-
Operational Recurring Fund from WT		8,00,000	57,44,802
	(C)	4,33,06,949	4,76,33,390
(Refer to Note: 17.13.3)	(A-B-C)	-	0



13B. Extra-Mural Programme - MeitY

(Amount in Rs.)

Particulars		For the Period ended 31.03.2021	For the Period ended 31.3.2020
Programme Expenditure		-	1,48,79,667
Operational Expenditure		-	4,71,632
	(A)	-	1,53,51,299
Less:			
Programme Funds from MeitY		-	1,48,79,667
	(B)	-	1,48,79,667
Less:			
Operational Fund from MeitY		-	4,71,632
	(C)	-	4,71,632
(Refer to Note: 17.13.4)	(A-B-C)	-	-

13C. Extra-Mural Programme - Make In India

(Amount in Rs.)

Particulars		For the Period ended 31.03.2021	For the Period ended 31.3.2020
Programme Expenditure		24,06,913	34,19,079
Operational Expenditure		33,01,987	29,07,270
	(A)	57,08,900	63,26,349
Less:			
Programme Funds from Make in India		24,06,913	34,19,079
	(B)	24,06,913	34,19,079
Less:			
Operational Fund from Make in India		33,01,987	29,07,270
	(C)	33,01,987	29,07,270
(Refer to Note: 17.13.5)	(A-B-C)	-	-

13D. Extra-Mural Programme - Biotoilets in Schools from NER

Particulars		For the Period ended 31.03.2021	For the Period ended 31.3.2020
Programme Expenditure		-	-
Operational Expenditure		15,000	79,781
	(A)	15,000	79,781
Less:			
Programme Funds from Biotoilets in NER School		-	-
	(B)	-	-
Less:			
Operational Fund from Biotoilets in NER School		15,000	79,781
	(C)	15,000	79,781
(Refer to Note: 17.13.6)	(A-B-C)	-	-



13E. Extra-Mural Programme - National Biopharma Mission (Innovate in India)

(Amount in Rs.)

			(/ linearie in rie:)
Particulars		For the Period ended 31.03.2021	For the Period ended 31.3.2020
Programme Expenditure		3,00,51,30,999	1,93,37,69,420
Operational Expenditure		8,14,87,968	8,20,69,275
	(A)	3,08,66,18,967	2,01,58,38,695
Less:			
Programme Funds from National Biopharma Mission (I3)		3,00,51,30,999	1,93,37,69,420
	(B)	3,00,51,30,999	1,93,37,69,420
Less:			
Operational Fund from National Biopharma Mission (I3)		8,14,87,968	8,20,69,275
	(C)	8,14,87,968	8,20,69,275
(Refer to Note: 17.13.7)	(A-B-C)	0	-

13F. Extra-Mural Programme - AcE Fund

(Amount in Rs.)

Particulars		For the Period ended 31.03.2021	For the Period ended 31.3.2020
Operational Expenditure		85,441	3,01,867
	(A)	85,441	3,01,867
Less:			
Operational Fund from AcE Fund		85,441	3,01,867
	(B)	85,441	3,01,867
(Refer to Note: 17.13.8)	(A-B)	-	-

13G. Extra-Mural Programme - DBT-BIRAC-SSC(NTBN)

Particulars		For the Period ended 31.03.2021	For the Period ended 31.3.2020
Operational Expenditure		49,91,025	26,35,725
	(A)	49,91,025	26,35,725
Less:			
Operational Fund from DBT-BIRAC-SSC(NTBN)		49,91,025	26,35,725
	(B)	49,91,025	26,35,725
(Refer to Note: 17.13.9)	(A-B)	-	-



13H. Ind CEPI (Amount in Rs.)

		For the Period ended	For the Period ended
Particulars		31.03.2021	31.3.2020
Programme Expenditure		7,57,52,025	4,35,32,400
Operational Expenditure		1,00,80,157	-
	(A)	8,58,32,182	4,35,32,400
Less:			
Programme Funds from National Biopharma Mission (I3)		7,57,52,025	4,35,32,400
	(B)	7,57,52,025	4,35,32,400
Less:			
Operational Fund from National Biopharma Mission (I3)		1,00,80,157	-
	(C)	1,00,80,157	-
(Refer to Note: 17.13.10)	(A-B-C)	-	-

13I. Covid Suraksha

(Amount in Rs.)

Particulars		For the Period ended 31.03.2021	For the Period ended 31.3.2020
Programme Expenditure		58,35,43,000	-
Operational Expenditure		15,73,197	-
	(A)	58,51,16,197	-
Less:			
Programme Funds from National Biopharma Mission (I3)		58,35,43,000	-
	(B)	58,35,43,000	-
Less:			
Operational Fund from National Biopharma Mission (I3)		15,73,197	-
	(C)	15,73,197	-
(Refer to Note: 17.13.12)	(A-B-C)	(0)	-

14. Employees Benefit Expenses

Particulars	For the Period ended 31.03.2021	For the Period ended 31.3.2020	
Salary & Allowances to Staff	7,19,57,505	6,45,32,135	
Employer's Contribution to Provident Fund & Other Funds	80,23,294	59,02,646	
TOTAL	7,99,80,799	7,04,34,781	



15. Other Expenses (Amount in Rs.)

Particulars	For the Period ended 31.03.2021	For the Period ended 31.3.2020
(A) Rent	4,06,64,749	4,08,50,712
(B) Advertisement & Publication	16,12,423	26,65,812
(C) Journal & Subscription	860	9,745
(D) Meetings:		
Meetings & Conferences	1,14,434	14,35,176
Sitting Fees & TA and DA	18,000	4,67,772
(E) Office and Administration Expenditure:		
Travel	30,22,353	35,10,588
Office Expenses	1,40,21,041	1,15,51,532
AMC Computer	13,74,784	12,15,020
Legal & Professional	6,34,540	1,49,260
Postage & Telephone Expenses	5,65,243	5,70,979
Power & Electricity	19,19,355	24,58,368
Printing & Stationery	2,18,729	3,98,464
Internet Expenses	17,07,313	17,07,313
(F) Training Expenses	2,44,835	9,04,642
(G) Consultancy Fee	59,86,808	56,31,398
(H) Statutory Audit Fees	1,93,048	1,85,850
(I) Miscellaneous Expenses	-	-
(J) Foreign Exchange Fluctuation	118	28,111
TOTAL	7,22,98,632	7,37,40,742

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.

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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.

2.14 Corporate Social Responsibility (CSR) on BIRAC:

The Ministry of Corporate Affairs (MCA) vide notification dated 27th February, 2014 has notified the enforceability of Section 135 of Companies Act, 2013 (i.e. provision for CSR) and Companies (Corporate Social Responsibility Policy) Rules, 2014 with effect from 01.04.2014.

CSR is applicable to every company which meet least of the following threshold during the immediately preceding financial year (F.Y.): -

Either Net worth of Rs. 500 Crore (Rupees Five Hundred Crore) or more;

Or

Either Turnover of Rs. 1,000 Crore (Rupees One Thousand Crore) or more;

Or

Net profit of Rs. 5 Crore (Rupees Five Crore) or more.

"Net profit" shall not include such sums as may be prescribed, and shall be calculated in accordance with the provisions of Section 198 of Act.

Year of Applicability of CSR on BIRAC : F.Y. 2019-20 (Triggered year)

Reason : BIRAC has achieved the surplus of Rs. 7.95

Crores during the financial year 2019-20.

As BIRAC falls under clause (c), provisions of CSR is applicable from financial year 2020-21.



17. Notes to Accounts for the period ended 31st March 2021.

- **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		
Particulars	Disbursement For the period ended 31.03.2021	Disbursement For the period ended 31.03.2020	
PPP Activities			
Biotechnology Industry Partnership Programme (BIPP)	13,50,53,522	251,974,249	
Small Business Innovation Research Initiatives (SBIRI)	3,98,39,064	66,365,626	
Bio- Incubators support Scheme (BISS)	39,20,12,093	354,647,114	
Biotech Ignition Grant (BIG)	34,00,00,000	435,000,000	
University Innovation Cluster (UIC)	-	15,940,000	
Translation Accelerator (TA)	2,01,48,904	7,445,950	
Contract Research Scheme (CRS)	5,95,85,905	102,947,508	
Social Innovation programme for Products: Affordable & Relevant to Societal Health (SPARSH)	5,64,21,730	56,644,734	
Seed Funding for Incubators	4,09,78,541	48,000,000	
Product Commercialization Unit (PCU)	1,85,00,000	41,000,000	
SRISTI	2,00,00,000	40,000,000	
Mission Program on Anti Microbial Resistance (AMR)	70,88,000	16,948,000	
Innovation Clean technologies	1,00,36,000	18,200,000	
Covid_(A) Fast Track	5,49,40,000	-	
Covid_(b) Research Consortium	13,15,45,110	-	
LEAP Fund	3,00,00,000	-	
Total	1,35,61,48,869	1,455,113,181	
BIRAC Activities			
Partnership Program	3,98,70,545	9,38,88,961	
Capacity Building & Awareness	44,73,594	71,57,304	
Technology Transfer / Acquisition	2,29,12,785	10,84,257	
IP Services	52,00,185	1,05,51,797	
Entrepreneurial Development / Regional Centres	4,37,25,017	5,95,61,733	
Total	11,61,82,126	17,22,44,052	

Biotechnology Industry Research Assistance Counicil



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.

17.3(a) 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 are done on annual basis.

(Amount in Rs.)

Particulars		As on 31.3.2021	As on 31.3.2020
Standard Asset	А	45,92,62,056	69,59,60,876
Standard Asset - Rescheduled	В	8,25,32,146	12,63,41,155
Sub Standard Assets	С	4,38,47,741	21,59,00,560
Doubtful Assets	D	65,74,89,987	51,50,02,305
Total Assets	E (A+B+C+D)	1,24,31,31,930	1,55,32,04,895
Provision on Substandard Assets	F	3,49,87,188	5,87,87,069
Provision on Doubtful Assets	G	52,62,63,671	45,71,18,201
Total Provision	H(F+G)	56,12,50,858	51,59,05,270
Interest derecognised	I	77,05,646	76,26,731

The settlement committee has been constituted to examine substandard accounts and doubtful assets and write off proposals. They are considered on case to case basis.



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	Remark for Reschedule with name of approval authority and its impact		3 nos. of Loan account has been	transferred to Substandard as per ageing	
	No. of Parties		1		71
	Closing balance as on 31.03.2021	l= A+B-C- D+E+F-G	45,92,62,055.72	l= A+B-C-D+E+F- G-H	71
	Number of parties of closed Accounts	Ŧ	ı	I	16
SUE	Recovery during the FY 2020 -21	5	1,92,62,937.00 35,000.00 1,70,56,753.62 23,45,27,635.37	_ഗ	0
Movement of Loans Disburse Interest Recognised Juring the During the year	ш	1,70,56,753.62	ш	0	
Mover	Disburse- ment during the year	ш	35,000.00	ш	0
	Transfer from Standard Asset to Sub Standatd during the year	Q	1,92,62,937.00	Q	м
	Transfer from Standard Asset Reschedule during the year	ပ	•	O	0
Opening Transfer to Balance as on Standard O1.04.2020 Asset-Reschedule during the year	m	,	ω	0	
	Opening Balance as on 01.04.2020	4	Standard 69,59,60,875.00 Asset	∢	06
17.3 (b) - I	S. No. Particular		Standard Asset		Numbers of Parties
17.3	v, Š			Н	

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9
7.3

Remark for Reshedule with name of approval authority and its impact			NI	
No. of Parties				4
Closing balance as on 31.03.2021	l= A+B-C- D+E+F-G	8,25,32,146.26	= A+B-C-D+E+F- G-H	4
Number of parties of closed Accounts	Ξ		I	Н
Recovery during the FY 2020 -21	g	4,50,53,812.00	g	0
Interest Recognised During the year	ш	12,44,805.47	ш	0
Disburse- ment during the year	ш	ı	ш	0
Increase in standard Assets Reshedule as transfer Frrom Sub Standard Asset	Q	1	۵	0
Decrease in Standard Assets reshedule as transfer to Standard Asset	ပ	1	U	0
Increase in Standard Assets reshedule as transfer from Standard Asset	ш	ı	ш	0
Opening Balance as on 01.04.2020	4	Standard 12,63,41,154.62 Assets eshedule	∢	ശ
Particular		Standard Assets reshedule		Numbers of Parties
ν, ο <mark>ς</mark>			N	



Remark for Reshedule with name of approval authority and its impact		3 nos. of Loan account has been	transferred from Standard	and 9 nos. of account transferred to doubtful as per ageing
"Net Closing Balance as on 31.03.2021 (after provisions)"	K=I-J	88,60,553.39		,
Provisions on Substandard Assets	ſ	3,49,87,187.89		
No. of Parties		ı		7
Closing balance as on 31.03.2021	l= A+B-C- D+E+F-G	4,38,47,741.28	l= A+B-C- D+E+F-G-H	۲
Number of parties of closed Accounts	Ŧ		I	0
Recovery during the FY 2020 -21	g	1,16,20,359.96	Ŋ	0
Interest Recognised During the year	ш	10,36,655.70	ш	0
Disbursement during the year	ш		ш	0
Decrease in Sub standard as transfer to Doubt full Assets	Q	18,07,32,049.00	۵	თ
Decrease in Sub standard as transfer to Standard loan Reshedule	ပ		O	0
"Increase in Sub standard as transfer from Standard Asset reshedule/ Standard Assest"	В	1,92,62,937.00	ш	ო
Opening Balance as on 01.04.2020	۷	21,59,00,560.03	ď	15
Particular		Sub Standard Assets		Numbers of Parties
ν, <mark>ο</mark>		ო		

17.3 (b) - III



J-Z	Remark for Reshedule with name of approval authority and its impact		9 nos. of Loan account has been	transterred from Substandard as per ageing	and 3 nos. of account has been settled as per board approval
	"Net Closing Balance as on 31.03.2021 (after provisions)"	K=I-J	13,12,26,316.47		
	Provisions on Doubtful Assets	7	52,62,63,670.53		
	No. of Parties		1		38
	Closing balance as on 31.03.2021	l= A+B-C- D+E+F-G	65,74,89,987.00	l= A+B-C- D+E+F-G-H	38
	Number of parties of closed Accounts	Ξ		I	2
	Written Off during the FY 2020 -21	5	89,22,930.00	g	ю
	Recovery during the FY 2020 -21	ш	2,94,29,884.00	ш	0
	Interest Recog- nised During the year	ш	1,08,445.00	ш	0
	Disbursement during the year	Q	ı	۵	0
	Decrease in Doubtful assets as transfer to Sub Standard Assets	ပ	ı	O	0
	Increase in Doubtful assets as transfer from Sub Standard Asset	В	18,07,32,049.00	ш	თ
	Opening Balance as on 01.04.2020	۷	51,50,02,304.69	ď	34
17.3 (b) - IV	Particular		Doubtful Assets		Numbers of Parties
17.3	ν, ο,			4	

68,18,81,071.84
56,12,50,858.42 68,18,81,07;
120
1,24,31,31,930.26
Gross Total Value as per Balance sheet (I+II+III+IV)



17.4 (Amount in Rs.)

Age Wise Overdue Position		As on 31.3.2021	As on 31.3.2021
Upto one year	(A)	93,24,303	3,76,15,170
More than one year accumulated	(B)	63,18,12,438	63,32,46,121
	Total (A+B)	64,11,36,741	67,08,61,291

17.5 Suit Filed Accounts:

17.5.1 Suits filed by the company: 2

(Amount in Rs.)

	As o	on 31.3.2021	As on 31.3.2021		
	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 17.13.4
- (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 17.13.5
- (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 17.13.6
- (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 17.13.7
- (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 Notes Refer Note 17.13.8
- (f) SSC(NTBN): BIRAC is undertaking a programme on Setting up of secretarial for scientific sub committee (SSC-NTBN) under the national Technical Board on Nutrition (NTBN). Refer Notes Refer Note 17.13.9
- (g) **CEPI:** BIRAC is undertaking a programme on Setting up of Epidemic preparedness through rapid vaccine development : support of Indian Vaccine development aligned with the global initiative of the Coalition for Epidemic preparedness Innovative (CEPI). Refer Notes **Refer Note 17.13.10**
- (h) GBI: Global Bio India 2019, A mega Biotech event was organised by DBT along with BIRAC on 21-23 Nov 2019, New Delhi. BIRAC implemented the event through Make in India (MII) cell at BIRAC with others partners. The event witnessed a participation of 2500+ participants from Academia, Industry, Startups Investors National & International fraternity. Refer Notes Refer Note 17.13.11
- (i) The Indian COVID 19 Vaccine Development Mission "COVID SURAKSHA". Accelerating pre-clinical & clinical development and licensure of COVID-19 vaccine candidates that are currently in clinical stages or ready to enter clinical stage of development. Establishing clinical trial sites. Immunoassay laboratories, central labs and suitable facilities for animal studies, production facilities and other testing facilities to support COVID-19 vaccine development. Supporting development of common harmonized protocols, trainings data management systems, regulatory submissions, internal and external quality management systems and accreditations, to accelerate clinical development and licensure of COVID-19 vaccine candidates that have targets identified. Supporting capabilities for process development, cell line development and manufacturing of GMP batches for animal toxicology studies and clinical trials. Ensuring all vaccines being introduced through the Mission have preferred characteristics applicable for India. Refer Note 17.13.12

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.

17.10 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.32,63,09,715/- (Previous Year Rs. 15,59,58,464)

B. Expenditure:

S. No.	Particulars	For the Period ended 31.03.2021	For the Period ended 31.03.2020
(i)	Technology Transfer	24,26,601	4,58,339
(ii)	Books, Journal and Database Subscriptions	27,17,500	46,18,556
(iii)	Entrepreneurship Development	5,83,200	24,60,077
(iv)	Advertisement/Publicity/Publication	3,62,550	12,73,625
(v)	Foreign Travel and Meetings	4,00,890	5,46,055

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	28,02,24,610	27,74,39,523	27,85,087
2	PPP Activities	1,38,52,22,223	1,37,73,28,465	78,93,758
3	PMU - DBT/BMGF:			
	(i) Operational	21,87,31,238	4,33,52,449	17,53,78,789
	BMGF	21,33,63,252	3,72,74,894	17,60,88,358
	DBT Operational	45,73,581	52,77,555	(7,03,974)
	DBT - Non Recurring	-	-	-
	WT Operational	7,94,405	8,00,000	(5,595)
	(ii) Projects	1,09,90,26,815	39,47,87,041	70,42,39,774
	BMGF	82,13,92,733	21,66,56,590	60,47,36,143
	DBT	18,43,51,291	10,65,52,220	7,77,99,071
	USAID	1,43,66,453	-	1,43,66,453
	GCI_Innovation Challenge	50,00,000	-	50,00,000
	WT Projects	-	15,55,742	(15,55,742)
	WT SANGER Projects	7,39,16,339	7,00,22,489	38,93,850
	Total	1,31,77,58,053	43,81,39,490	87,96,18,563
4	MeitY(IIPME)	21,821	-	21,821
5	Make in India Facilitation Cell	1,30,68,237	62,79,809	67,88,428
6	Bio-toilets in schools from NER	3,86,413	15,000	3,71,413
7	National BioPharma Mission (I3)	3,37,38,08,400	3,10,17,98,088	27,20,10,312
8	AcE Fund	84,38,36,096	18,67,81,322	65,70,54,774
9	SSC(NTBN)	54,85,353	52,05,314	2,80,039
10	IndCEPI	29,25,01,141	9,10,27,041	20,14,74,100
11	GBI	1,53,74,915	22,12,451	1,31,62,464
12	Covid Surksha	1,81,07,13,521	58,51,16,197	1,22,55,97,324



17.13 Supplementary Schedule on Scheme Balances as on 31.03.2021

17.13.1 PPP Activities Funds

(Amount in Rs.)

	Particulars		AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance		-	-
Add:	Funds received from DBT	1,37,15,00,000		1,50,00,00,000
Add:	Interest Income	24,86,691		12,23,499
Add:	Recoveries from unspent grant	1,12,35,532	1,38,52,22,223	36,08,433
			1,38,52,22,223	1,50,48,31,932
Less:	Amount disbursed during the year :			
	Grants Disbursed	1,35,61,13,869		1,42,24,28,681
	Loans Disbursed	35,000		3,26,84,500
	Programme Expenses	1,99,56,097		5,15,71,950
	Interest Refund to DBT	12,23,499	1,37,73,28,465	-
			78,93,758	(18,53,200)
Add:	Surplus Redeployed towards Expenses		-	18,53,200
	Unutilised Balance Carried Forward		78,93,758	-

17.13.2 BIRAC Funds

(Amount in Rs.)

				(Amount in Rs.)
	Particulars		AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance		-	-
Add:	Received from DBT		28,00,00,000	31,00,00,000
Add:	Interest Income		2,24,610	3,62,793
Add:	Recoveries from unspent grant		-	56,97,053
			28,02,24,610	31,60,59,846
Less:	Amount disbursed for Grants			
	Partnership Programmes	3,98,70,545		9,38,88,961
	Technology Transfer & Acquisition	2,29,12,785		10,84,257
	Intellectual Property	52,00,185		1,05,51,797
	Entrepreneurial Development	4,37,25,017		5,95,61,733
	Capacity Building & Awarness	44,73,594		71,57,304
		-	11,61,82,126	-
			16,40,42,484	14,38,15,794
Less:	Utilisation towards:			
	Manpower Expenses	7,99,80,799		7,04,34,781
	Non-Recurring Expenses	89,77,966		6,74,431
	Recurring Expenses	7,22,98,632	16,12,57,397	7,37,40,742
			27,85,087	(10,34,160)
Add:	Surplus Redeployed towards Expenses		-	10,34,160
	Unutilised Balance Carried Forward		27,85,087	-



17.13.3 BMGF PMU (Amount in Rs.)

	Doublesdays		AC ON 24 02 2004	AC ON 24 02 2020
	Particulars		AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance			
	Operations Fund	16,83,44,552		15,03,15,724
	Project Fund	73,97,90,582	90,81,35,134	51,15,07,693
Add:	Received From BMGF - Project	25,70,60,305		33,29,22,981
	Received From BMGF - Operations	3,88,49,720		4,89,82,139
	Received From DBT - Project	-		10,40,00,000
	Received From DBT - Operations	62,40,603		-
	Received From WT SANGER	7,37,07,943		
	Received From WT - Operations	7,84,665	37,66,43,236	12,76,327
Add::	Bank Interest & Unspent Grant	3,29,79,683	3,29,79,683	2,56,47,532
			1,31,77,58,053	1,17,46,52,396
Less:	Project Disbursement			
	GCI: GSED	78,93,117		-
	GCI: ACT	5,27,88,000		9,99,66,000
	GCI: IKP	1,98,29,000		-
	GCI: IDIA	1,20,56,400		2,78,14,548
	GCI: HPV	10,29,12,000		5,45,80,254
	GCI: AMR	1,36,92,000		1,45,10,500
	GCI: Ki Data Challenge	95,96,150		10,547
	GCI: Sentinels	75,00,000		2,16,75,618
	GCI: MSSFR	1,20,00,000		-
	GCI: RTTC	49,88,540		-
	GCI: GIPA	2,06,71,105		-
	GCI: Covid 19	2,07,60,528		-
	GCI: WT Sanger	3,30,40,735		-
	GCI: MOMI	7,00,22,489		-
	GCI: Med Tech	19,75,697	38,97,25,761	3,26,405
Less:	Activities Expenditure			
	HBGDki	-		5,45,000
	KSTIP (KnIT	1,25,99,000		1,04,00,000
	Communication Support	17,94,654	1,43,93,654	20,68,016
Less:	Operational Expenditure			
	Manpower Expense	1,12,29,445		94,85,333
	Meeting Expenses	22,28,433		58,80,202
	Expenses for Space	1,17,97,634		1,13,26,070
	Administrative Expenses	17,56,088		10,82,272
	Equipment Expenses	-		-
	Wellcome Trust- Manpower	8,00,000		48,20,782
	Wellcome Trust- Travel	-		9,24,020
	Management Expenses	11,01,695	2,89,13,295	11,01,695



Particulars		AS ON 31.03.2021	AS ON 31.03.2020
Balance Fund			
BMGF - Projects	60,47,36,143		54,42,14,056
DBT - Projects	7,77,99,071		18,15,77,050
USAID - Projects	1,43,66,453		1,39,99,477
BMGF - Operations	17,60,88,358		17,00,06,136
DBT - Operations	(7,03,974)		(16,67,022)
WT SANGER	38,93,850		-
GCI_Innovation Challenge	50,00,000		
WT Projects	(15,55,742)		-
WT- Operation	(5,595)	87,96,18,563	5,438
		87,96,18,563	90,81,35,134

17.13.4 MeitY(IIPME)

(Amount in Rs.)

	Particulars	AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance	-	53,51,299
	Received during the period	-	1,00,00,000
		-	1,53,51,299
Add:	Bank Interest	-	-
	Recoveries from unspent grant	21,821	-
		21,821	1,53,51,299
Less	Programme Expenditure*	-	2,35,98,124
	Operational Expenditure	-	4,71,632
		21,821	(87,18,457)
Add:	Fund Redeployed towards Expenses from BIRAC	-	87,18,457
	Unutilised Balance Carried Forward	21,821	-

^{*} The programme Expenditure includes loan disbursed amounting to Rs. NIL (Previous Year Rs. NIL) having the total outstanding of Rs. 63,39,096/- (including accrued interest) (Previous Year Rs. 62,20,796/-).

17.13.5 Make in India Facilitation Cell

(Amount in Rs.)

	Particulars	AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance	-	62,20,460
	Received during the period	1,30,40,000	-
		1,30,40,000	62,20,460
Add:	Bank Interest	28,237	1,05,889
		1,30,68,237	63,26,349
Less:	Operational Expenditure	60,58,900	63,26,349
	Interest Refund to DBT	2,20,909	
	Unutilised Balance Carried Forward	67,88,428	-



17.13.6 Bio-toilets in schools from North East Region

(Amount in Rs.)

	Particulars	AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance	3,76,583	4,44,505
	Received during the period	-	-
		3,76,583	4,44,505
Add:	Bank Interest	9,830	11,859
		3,86,413	4,56,364
Less:	Programme Expenditure	-	79,081
	Operational Expenditure	15,000	700
	Unutilised Balance Carried Forward	3,71,413	3,76,583

17.13.7 National Biopharma Mission (Innovate in India)

(Amount in Rs.)

	Particulars	AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance	35,70,59,491	87,79,84,456
	Received during the period	3,00,00,00,000	1,50,00,00,000
		3,35,70,59,491	2,37,79,84,456
Add:	Recoveries from unspent grant	73,81,202	-
	Bank Interest	93,67,707	1,51,79,121
		3,37,38,08,400	2,39,31,63,577
Less:	Programme Expenditure	3,00,51,30,999	1,93,37,69,420
	Operational Expenditure	8,14,87,968	8,20,69,275
	Interest Refund to DBT	1,51,79,121	2,02,65,390
	Unutilised Balance Carried Forward	27,20,10,312	35,70,59,491

17.13.8 AcE Fund (Amount in Rs.)

	Particulars Particulars	AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance	82,25,33,701	68,77,24,686
	Received during the period	-	30,00,00,000
		82,25,33,701	98,77,24,686
Add:	Bank Interest	2,13,02,395	2,72,53,317
		84,38,36,096	1,01,49,78,003
Less:	Ace Funding	18,66,95,882	19,21,42,435
	Operational Expenditure	85,440	3,01,867
	Unutilised Balance Carried Forward	65,70,54,774	82,25,33,701



17.13.9 SSC(NTBN) (Amount in Rs.)

	Particulars	AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance	53,95,564	78,17,000
	Received during the period	-	-
		53,95,564	78,17,000
Add:	Bank Interest	89,789	2,14,289
		54,85,353	80,31,289
Less:	Operational Expenditure	49,91,025	26,35,725
	Interest Refund to DBT	2,14,289	-
	Unutilised Balance Carried Forward	2,80,039	53,95,564

17.13.10 Ind CEPI (Amount in Rs.)

	Particulars	AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance	28,63,81,459	-
	Received during the period	-	32,47,19,000
			-
		28,63,81,459	32,47,19,000
Add:	Bank Interest	61,19,682	51,94,859
		29,25,01,141	32,99,13,859
Less:	Programme Expenditure	7,57,52,025	4,35,32,400
Less:	Operational Expenditure	1,00,80,157	-
Less:	Interest Refund to DBT	51,94,859	-
	Unutilised Balance Carried Forward	20,14,74,100	28,63,81,459

17.13.11 GBI (Amount in Rs.)

	Particulars	AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance	(5,59,00,000)	-
	Received from DBT	6,95,80,000	1,34,00,000
	Sponsorship	16,94,915	10,00,000
		1,53,74,915	1,44,00,000
Add:	Bank Interest	-	-
		1,53,74,915	1,44,00,000
Less:	Operational Expenditure	22,12,451	7,03,00,000
	Recoverable from DBT and Sponsors/Unutilised Balance carried forward	1,31,62,464	(5,59,00,000)



17.13.12 Covid Suraksha (Amount in Rs.)

	Particulars	AS ON 31.03.2021	AS ON 31.03.2020
	Opening Balance	-	-
	Received from DBT	1,80,00,00,000	-
		1,80,00,00,000	-
Add:	Bank Interest	1,07,13,521	-
		1,81,07,13,521	-
Less:	Operational Expenditure	58,51,16,197	-
	Unutilised Balance carried forward	1,22,55,97,324	-

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 31.03.2021	AS ON 31.03.2020
(i)	Principal amount remaining unpaid to MSME suppliers as at the end of the reporting period.	-	23,36,541
(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	-	23,36,541

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-21	31-Mar-20
In Current Accounts		
Corporation Bank (DBT-BMGF PMU)	20,104	1,18,223
In Saving Accounts		
Corporation Bank/Union Bank (BIRAC/Make In India/Bio-Toilets/MeitY)	68,60,20,092	10,41,87,771
HDFC Bank (BIRAC)	28,03,067	64,67,600
State Bank of India (PPP Activities/AcE,NBM)	8,67,08,876	68,78,45,811
State Bank of India (DBT-NBM PMU)	6,87,36,365	14,91,37,746
State Bank of India (DBT-BMGF PMU)	3,82,73,992	23,84,84,811
	88,25,42,392	1,18,61,23,739
In Fixed Deposits		
- Maturity More than 12 Months	-	-
- Others	3,77,18,93,789	2,16,95,38,868
	3,77,18,93,789	2,16,95,38,868

Biotechnology Industry Research Assistance Counicil



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 Disclosure of CSR Expenditure

- a. Gross amount required to be spent by the company during the year Rs. 7,34,647/-
- b. Amount approved by the Board to be spent during the year Rs. 7,34,647/-
- c. Amount spent during the year on Construction / acquisition of any asset or purposes other than (i) above (NA)
- d. Details of related party transactions, e.g., contribution to a trust / society / section 8 company controlled by the company in relation to CSR expenditure as per Accounting Standard (AS) 18, Related Party Disclosures (NA)
- e. Amount of Rs. 7,34,647/- has been contributed during the year 2020-21 to the Swachh Bharat Kosh which is one of the listed activities specified in schedule VII of Companies Act 2013.

17.17 Disclosure pursuant to Accounting Standard (AS) 15 Revised "Employee Benefits":

I Assumptions as at

Particulars -	Financial Year ending	
Particulars	2020-21	2019-20
Interest / Discount Rate	5.71%	6.78%
Rate of increase in compensation	3.00%	3.00%
Rate of return (expected) on plan assets	5.71%	6.78%
Employee Attrition Rate(Past Service (PS))	OPS: 0 to 42: 15%	OPS: 0 to 42: 15%
	-	-
Expected average remaining service	5.25	6.10

II Changes in present value of obligations

Dowlingland	Financial Year ending	
Particulars -	AS ON 31.03.21	AS ON 31.03.20
Defined Benefit Obligation at the beginning	90,01,084	87,35,999
Add :- Current Service Cost	26,70,198	18,85,909
Add :- Interest Cost	5,68,538	6,68,304
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	-5,07,953	-
Add/Less:-Net transfer in/(out) (including the effect of any business combinations/divestitures)	-	-
Add/Less:- Actuarial Loss / (Gain) on Obligation	6,067	-22,89,128
Defined Benefit Obligation at the end	1,17,37,934	90,01,084



III Changes in fair value of plan assets

Dowling	Financial Year ending	
Particulars Particulars	AS ON 31.03.21	AS ON 31.03.20
Opening balance of the fair value of the plan assets	99,11,021	68,26,041
Add: Adjustment to Opening balance	-	-
Add: Expected Return on plan assets	6,94,164	6,13,885
Add: Contributions by Employer	24,58,941	23,97,186
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)	23,666	73,909
Less: Benefits Paid	-5,07,953	
Closing balance of the plan assets	1,25,79,839 99,11,02	

IV Fair Value of Plan Assets

Destination	Financial Year ending	
Particulars Particulars	AS ON 31.03.21	AS ON 31.03.20
Opening balance of the fair value of the plan assets	99,11,021	68,26,041
Add: Adjustment to Opening balance	-	-
Add: Actual Return on plan assets	7,17,830	6,87,794
Add: Contributions by Employer	24,58,941	23,97,186
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	-5,07,953	
Fair value of the plan assets at the end	the end 1,25,79,839 99,11	
Funded Status (including unrecognised past service cost)	8,41,905	9,09,937
Excess of Actual over estimatedd return on Plan Assets	23,666	73,909



V Experience History

Dowling	Financial Year ending	
Particulars Particulars	2020-21 2019-20	
(Gain)/Loss on obligation due to change in Assumptio	5,48,368	-38,37,086
Experience (Gain)/ Loss on obligation	-5,42,301 15,47,9	
Actuarial Gain/(Loss) on plan assets	23,666 73,	

VI Actuarial Gain/(Loss) Recognized

Doublesslave	Financial Year ending	
Particulars Particulars	2020-21	2019-20
Actuarial Gain/(Loss) for the period (Obligation)	-6,067	22,89,128
Actuarial Gain/(Loss) for the period (Plan Assets)	23,666	73,909
Total Gain/(Loss) for the period	17,599	23,63,037
Actuarial Gain/(Loss) recognized for the period	17,599	23,63,037
Unrecognized Actuarial Gain/(Loss) at end of period	-	-

VII Past Service Cost Recognised

Particulars	1-APR 20 to 31 -Mar -21	
Past Service Cost- (non vested benefits)	-	
Past Service Cost -(vested benefits)		
Average remaining future service till vesting of the benefit	-	
Recognised Past service Cost- non vested benefits	-	
Recognised Past service Cost- vested benefits	-	
Unrecognised Past Service Cost- non vested benefits	-	

VIII Amounts to be recognized in the balance sheet and statement of profit & loss account

Dowling	Financial Year ending	
Particulars Particulars	AS ON 31.03.21	AS ON 31.03.20
Present Value of Obligations at end of period	1,17,37,934	90,01,084
Fair Value of Plan Assets at end of period	1,25,79,839 99,11,02	
Funded Status	8,41,905	9,09,937
Unrecognized Actuarial Gain/(Loss)	-	-
Unrecognised Past Service Cost- non vested benefits	-	
Net Asset/(Liability) recognized in the balance sheet	8,41,905 9,09,9	



IX Expense recognized in the statement of P & L A/C

Dowlingland	Financial Year ending	
Particulars Particulars	AS ON 31.03.21	AS ON 31.03.20
Current Service Cost	26,70,198	18,85,909
Interest Cost on Obligation	5,68,538	6,68,304
Past Service Cost		
Expected return on Plan Assets	-6,94,164 -6,13,88	
Amortization of Prior service cost	-	-
Net acturial (Gain)/Loss to be recognised	-17,599	-23,63,037
Transfer In/Out	-	
Curtailment (Gain)/Loss recognized	-	
Settlement (Gain)/Lossrecognised	-	-
Expense recognised in Profit & Loss account	25,26,973 -4,22,70	

X Movements in the Liability recognized in Balance Sheet

Doublesslave	Financial Year ending	
Particulars Particulars	AS ON 31.03.21	AS ON 31.03.20
Opening Net Liability	-9,09,937	19,09,958
Adjustment to opening balance	-	-
Expenses as above	25,26,973	-4,22,709
Expected return on Plan Assets	-6,94,164	-6,13,885
Transfer in Liability	-	-
Transfer in Fund	-	-
Transfer out Liability	-	-
Transfer out Fund	-	
Benefits Paid By The Company -		-
Contribution paid	-24,58,941	-23,97,186
Closing Net Liability	-8,41,905	-9,09,937

XI Schedule III of The Companies Act 2013

Dowlingland	Financial Year ending	
Particulars Particulars	AS ON 31.03.21	AS ON 31.03.20
Current Liability	17,78,061	12,31,137
Non-Current Liability	99,59,873	77,69,947

XII Projected Service Cost 31 Mar 2022 28,51,238



XIII Asset Information

Particulars	AS ON 31.03.21	
Particulars	Total Amount	Target Allocation %
Cash and Cash Equivalents Gratuity Fund (SBI Life Insurance)	1,25,79,839	100.00%
Debt Security - Government Bond	-	-
Equity Securities - Corporate debt securities	-	-
Other Insurance contracts	-	-
Property	-	-
Total Itemized Assets	1,25,79,839	100.00%

XIV Effects of changes in assumptions

Discount Rate : The discount rate has decreased from 6.78% to 5.71% and hence there is an increase in liability leading to actuarial loss due to change in discount rate.

Salary Escalation Rate: The salary escalation rate has remain unchanged and hence there is no change in liability resulting in no actuarial gain or loss due to change in salary escalation rate.

17.18.1 Other Non-Current Investment

C No.	Dawtiaulawa	Financial Year Ending	
S. No.	Particulars Particulars	31-Mar-21	31-Mar-20
1	Other Non-Current Investment (unqouted)		
a)	GVFL Startup Fund	5,04,93,467	4,11,60,000.00
b)	IAN Fund	14,48,60,339 10,02,53,839.00	
c)	Stakeboat Capital Fund	2,73,72,602 2,60,42,579.00	
d)	Bharat Innovation Fund	13,27,25,064 8,05,66,734.00	
e)	Kitven Fund - 3	2,32,98,000 1,01,80,000.00	
f)	Ankur Fund II	2,19,50,222 -	
g)	Endiya Partners Trust	1,91,99,340 -	
h)	RVCF India Growth Fund	2,50,00,000 -	
		44,48,99,034	2,58,203,152

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 sciencesand holds all investments 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. 50.01 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
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	SBH	State Bank of Hyderabad
33	SBIRI	Small Business Innovation Research Initiative
34	SPARSH	Social Innovation programme for Products: Affordable & Relevant to Societal Health





S.No.	Abbreviation	Description		
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		
39	CEPI	Coalition for Epidemic preparedness Innovative		
40	GBI	Global Bio India		

Auditors Report

As per our report of even date attached For SAMPRK & Associates

Chartered Accountants Firm Reg.No. 013022N

For and on behalf of Board of Directors

Sd/-Sd/-Sd/-Sd/-C.A. Keshav KumarKavita AnandaniAnju BhallaRenu Swarup(Partner)(Company Secretary)(Managing Director)(Chairperson)Membership No. 088271DIN 06981734DIN 01264943

Place: New Delhi

Date: 21st September' 2021



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 31ST MARCH 2021.

The preparation of financial statements of Biotechnology Industry Research Assistance Council for the year ended 31st March 2021 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 auditors appointed by the Comptroller and Auditor General of India under section 139 (5) of the Act are 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 is stated to have been done by them vide their Audit Report dated 21.09.2021.

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 31st March 2021 under section 143 (6)(a) of the Act.

Place: New Delhi Date: 29.10.2021 For and on behalf of the Comptroller & Auditor General of India

Sd/-

Director General of Audit (Environment & Scientific Department)



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

ATTENDANCE SLIP

Name of the Member/proxy (In Block Letters)	
Address of Member / Proxy:	
Folio No. :	
No of Shares Held	
l certify that I am a member / proxy for the memb I hereby record my presence at the 9 th Annu 30 th November, 2021 at 4.30 p.m. at Departme Lodhi Road, New Delhi – 110003.	al General Meeting of the Company held on
	Member's / Proxy's Signature



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

FORM NO. MGT-11 (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 t	he Member(s):					
Registered	d Address:					
E-mail ID:						
Folio No.						
I / We, beir	/ We, being the holder (s) ofshares of the above named Company, hereby appoint:					
1. Name:	:Address:					
E-mail	ID: Signature:					
as my/our proxy to attend and vote (on a poll) for me/us and on my/our behalf at the 9 th Annual Genera Meeting of the Company held on 30 th November, 2021 at 4.30 p.m. at Department of Biotechnology, 2, CGO Complex 7 th Floor, Lodhi Road, New Delhi – 110003 and at any adjournment thereof in respect of such resolutions as are indicated below:						
indicated b	elow:					
Sr. No.	elow: Resolutions		F	or	Aga	inst
		r with the Reports of nts of the Comptroller	F	- For	Aga	inst
Sr. No.	Resolutions To receive, consider and adopt the Audited F the Company as on March 31, 2021 togethe the Directors and Auditor thereon and comme & Auditor General of India in terms of Section	r with the Reports of nts of the Comptroller tion 143(6)(b) of the	F	For Tor	Aga	inst
Sr. No. 1 2 Signed to Signature	Resolutions To receive, consider and adopt the Audited F the Company as on March 31, 2021 togethe the Directors and Auditor thereon and comme & Auditor General of India in terms of Sectompanies Act, 2013 To fix the remuneration of the Statutory Audito 2021-22, in terms of provisions of Section 138	r with the Reports of ints of the Comptroller tion 143(6)(b) of the r for the financial year 9(5) read with Section	F	Ai	Aga ffix enue	inst

NOTES:

- 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.
- 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.

Biotechnology Industry Research Assistance Counicil



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Biotechnology Industry Research Assistance Council

A Government of India Enterprise, Under Department of Biotechnology, Ministry of Science & Technology, Government of India

CIN No.: U73100DL2012NPL233152

1st Floor, MTNL Building, 9 CGO Complex, Lodhi Road, New Delhi-110003 E-mail: birac.dbt@nic.in, website: www.birac.nic.in, Twitter handle @birac_2012