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Interventions in VACCINE development

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Ignite Innovate Incubate

Biotechnology Industry Research Assistance Council
(A Government of India Enterprise)

Apr.-Jun. 2021
No. 2 Vol. 8

birac

EDITORIAL COMMITTEE

DESIGN AND PRODUCTION
Goldmine Advertising Ltd., 4834/24,1st Floor,Kiran Mansion, Ansari Road,New Delhi-110002

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Leader's Message

Dr. Renu Swarup
Secretary, DBT
& Chairperson, BIRAC

It's been more than a year that the country has been under the pressure to combat COVID-19. With the constant support from the Government of India, the Department of Biotechnology and its PSU, BIRAC, have worked relentlessly to provide support to the innovators, entrepreneurs and other frontline workers against their warpath towards overcoming the COVID-19 situation. Although scientists have worked tirelessly to bring out the eligible COVID-19 vaccines in a short period, this has also given a boost to the Indian Biotech Ecosystem. Even during these tough times, the scientists, innovators and entrepreneurs provided the Nation with novel vaccines, diagnostics, therapeutics and other related interventions to cope up with the COVID-19 pandemic, ranging from Inactivated virus vaccine, Dozzee, Hybrid multiply masks, PPE kits, Face shields, Automated hand sanitizer, Diagnostic kit, Bluetooth enabled smart stethoscope, Remote monitoring system etc. These innovations gave a global thrust to the Indian Biotechnology Innovation Ecosystem, showing the world the efficiency of India as "AtmaNirbhar Bharat".

India also showed the real meaning of 'VasudhaivaKutumbakam' by selflessly providing the countries to vaccinate their population. However, as the vaccination drive for COVID-19 raced up in our country, alongside the surge in the cases affecting lakhs of people, the Government of India planned to pace up the production of the indigenously developed COVAXIN by technology transfer to three Public Sector Undertakings/ entities, viz, Indian Immunological Ltd. (IIL), Bharat Immunologicals& Biologicals Corporation Ltd. (BIBCOL), and Haffkine Bio-Pharmaceutical Corporation Ltd. (A Government of Maharashtra Undertaking). This facility augmentation has been considered under the National Mission 'Mission COVID Suraksha'. The developer of COVAXIN i.e Bharat Biotech International Ltd. is also recommended for support for scaling-up the production from the current capacity of 15 million doses/month to 50 million doses/month. The Government of India is also intalks with other vaccine manufacturing companies for such technology transfer to ramp-up the production of vaccines in India. This initiative would not only vaccinate a large population of India but also strengthen our fight against COVID-19.

Companies like Gennova Biopharmaceuticals Ltd. have been working on developing indigenous mRNA Vaccine, and as per many reports, mRNA platform has proved fruitful in providing better efficiency towards combating COVID-19.Also, several research in the country is ongoing to develop single-dose vaccine for ramping up the vaccination percentage by the end of this year.Although scientists and researchers have been working with great efforts, a proper follow of COVID appropriate behaviour has always been the core of preventing the COVID-19 infection.

Ms. Anju Bhalla
Joint Secretary-DST &
Managing Director-BIRAC

Chief Editor's Take

As the pandemic enters its second year and continues to wreak havoc on global economies, Department of Biotechnology and BIRAC continues to remain at the forefront in the fight against the pandemic. The second wave of cases has not only produced a health catastrophe, but it has also had an effect on the economy, which will take years to recover from.

DBT and BIRAC together have strategized to fast-track R & D efforts especially for vaccine development, diagnostics, drug repurposing, therapeutics and testing. The development of indigenous vaccines has been the top priority of the Department of Biotechnology and BIRAC had been the nodal agency for implementing the Mission COVID Suraksha, a National Mission for Vaccine Research and Development. Different vaccine development strategies have been recommended that are proposed by small and large vaccine industry and academic institutes. Some of the candidates are Serum Institute of India Pvt Ltd- Recombinant BCG vaccine for Phase III trial for high-risk group, Zydus Cadila- DNA Vaccine, Biological E- Subunit Vaccine, Bharat Biotech International Ltd.- Inactivated Virus Vaccine, THSTI- mRNA Vaccine, Gennova Biopharmaceuticals- mRNA vaccine, Intas Biopharmaceuticals. Along with the product development, others efforts have also been put in place to support vaccine development and testing are the development of an animal model-based vaccine evaluation platform that would test the immunogenicity of any vaccine candidate, development of a DNA Electroporation device for DNA vaccine delivery, and many more.The Department of Biotechnology is developing mechanisms to promote end-to-end development and vaccine pipeline testing by strengthening the vaccine pipeline. Global collaborations are crucial to the efficient, effective, and equitable delivery of the vaccine.

BIRAC from its onset has been promoting an entrepreneurial mindset with the support of DBT and GoI. It gives me great pleasure to mention that BIRAC-supported inventors have come out with prospective COVID solutions that have proven to be extremely useful during these trying times. The innovations have ranged from as basic as sanitisers, PPE kits to Dozzee'sMillionICU initiative, etc. The advancements through these innovations will not only have dramatic implications for people and society but also help reshape the vast sectors of the world economy. BIRAC has been constantly striving to understand the current and future needs of bio-enterprises and bring about transformative change through supporting and sustaining cutting-edge technologies to ensure the vision of AtmaNirbhar Bharat.

DBT-BIRAC's Efforts In Supporting Vaccine Development for COVID-19

1. COVID-19 Research Consortium:

After WHO declared COVID-19 as a pandemic due to alarming levels of its spread and severity, a deemed necessity for accelerating the development of diagnostics, vaccines, novel therapeutics and re-purposing of drugs for this novel coronavirus arose. To promote the preparedness, readiness and response for COVID-19, two "Request for Proposal (RFP) for DBT-BIRAC COVID-19 Research Consortium" were published in early 2020. Project proposals were solicited for developing Diagnostics, Vaccines, Novel Therapeutics, Repurposing of Drugs or any other intervention for control of COVID-19 by Industry/Academia/ Industry-Academia participation.

Under the 'Vaccine' category, a total of 14 proposals have been recommended for support by BIRAC. Different vaccine development strategies have been recommended that are proposed by small and large vaccine industry and academic institutes.The National Biopharma Mission, Ind-CEPI, and BIRAC are all working with DBT to support the recommended proposals under COVID-19 Research Consortium.Some of the candidates are Serum Institute of India Pvt Ltd-recombinant BCG vaccine for Phase III trial for high-risk group, Zydus Cadila- DNAVaccine, Biological E- Subunit Vaccine, Bharat Biotech International Ltd.- Inactivated Virus Vaccine, THSTI- mRNA Vaccine, Gennova Biopharmaceuticals- mRNA vaccine, Intas Biopharmaceuticals, and Seagull Biosolutions and more. The companies/entities recommended for vaccine development under COVID-19 Research Consortium are:

[1] Serum Institute of India Pvt. Ltd.
[2] Gennova Biopharmaceuticals Ltd.
[3] Bharat Biotech International Ltd.
[4] Biological E Ltd.
[5] AUROBINDO PHARMA LTD.
[6] National Institute of Immunology New Delhi
[7] Cadila Healthcare Ltd.
[8] Enzene Biosciences Ltd.
[9] Seagull BioSolutions Pvt. Ltd and Syngene International Ltd.
[10] Intas Pharmaceuticals Ltd.
[11] Sahajanand laser Technology Limited and Intas Pharmaceutical Ltd.
[12] St John's Research Institute
[13] Indian Institute of Technology Indore and NCCS Pune
[14] THSTI

Along with product development, others efforts tosupport vaccine development are the development of an animal model-based vaccine evaluation platform that would test the immunogenicity of any

vaccine candidate, development of a DNA Electroporation device for DNA vaccine delivery, and many more.

2. **Mission COVID Suraksha:**

In response to the COVID-19 pandemic, the Department of Biotechnology (DBT), Ministry of Science and Technology, had been working relentlessly to address the requirement of a COVID vaccine with high-priority. DBT has identified Biotechnology Industry Research Assistance Council (BIRAC), a Government Enterprise, to be capable of effectively implementing Mission COVID Suraksha, through the establishment of a Mission Implementation Unit (MIU).

DBT established Mission COVID Suraksha, with the mandate, to integrate and to streamline available resources towards a warpath to fast-track vaccine development. This being a National Mission aimed at bringing a safe, effective, convenient, and available COVID vaccine to the citizens of the country as soon as possible, with a focus on Atma Nirbhar, and keeping our responsibility to serve not just our country, but the entire world, with a focus on 'Vasudhaiva Kutumbakam'.

In order to ensure that all vaccines being introduced through the Mission have preferred characteristics applicable for India, it was proposed to be achieved by strengthening the following functional domains:

- Accelerating the production of clinical trial material, and clinical development for licensure of COVID-19 vaccine candidates

- Establishing clinical trial sites, immunoassay laboratories, central labs and suitable facilities for animal challenge studies, manufacturing facilities and other testing facilities to support COVID-19 vaccine development

In order to fulfil these requirements, three (03) Request for Expression of Interest (s) were published, and under each REOI, a number of companies/entities submitted their proposals. These proposals were evaluated and analysed through a series of rigorous steps and by eminent experts. The first Requests for Expression of Interest (REOI) focused on 'Development of VaccineCandidate(s)', in which five proposals for thedevelopment of vaccine candidates have been recommended for support.The second REOI was for the 'Enhancement of Capacity to Support COVID-19 Vaccine Development' to improve service facilities available to COVID-19 vaccine developers for the conduct of animal studies and immunological assays.Six projects have been recommended for financialsupport under REOI-2.

The mandate of the third REOI 'Enhancing the Capacity to Conduct Human Clinical Trials For COVID-19 Vaccine Candidates' is to ensure the accessibility andavailability of Good Clinical Practice (GCP) compliant clinical trial sites to vaccinedevelopers. A total of 19 sites, including hospital and/or community settings, have been identified across the country, each with trained staff, clinical trial infrastructure, a volunteer database of at least 2000 subjects, and community engagement programmes.With the Mission's support, the sites will be ready for vaccine manufacturers to expedite COVID-19 vaccine trials, candidate vaccine development in the country, and bridging trials of in-

licensed or imported vaccines. The companies/entities recommended for support under the Mission COVID Suraksha are:

Request for Expression Of Interest (REOI)	Companies/Entities	Purpose of Funding (Support for)
REOI 1 -Development of COVID-19 vaccine candidate(s)	Biological E Ltd.	Clinical Trial material generation and Phase III Clinical Trials
	Gennova Biopharmaceuticals Ltd.	Clinical Trial material generation and Phase III Clinical Trials
	Cadila Healthcare Ltd.	Phase III Clinical Trials
	Bharat Biotech International Ltd.	Clinical Development of the vaccine candidate
	Genique Lifesciences Pvt. Ltd.	Animal challenge studies and Phase I Clinical Trials
REOI 2 -Enhancement of Capacity to support COVID-19 vaccine development	ILS Bhuwaneshwar	For establishing facilities for Animal Challenge Studies
	IISc, Bangalore	
	National Centre for Biological Sciences, Bangalore	
	Interactive Research School for Health Affairs (IRSHA), Pune	For establishing Clinical Immunogenicity Laboratory
	Syngene International Limited	
	THSTI NCR Biotech Science Cluster	
REOI 3 -Enhancing capacity for conduct of Human clinical trials for COVID-19 Vaccine candidates	Medanta Institute of Education and Research	Enhancing and strengthening the institutional capacity for conduct of Phase I/II/III clinical trials for COVID-19 vaccine candidates
	ICMR - National Institute of Epidemiology	
	Kasturba Health Society	
	Tata Memorial Centre	
	Gokula Education foundation	
	Malabar Cancer Centre	
	BAPS Pramukh Swami Hospital	
	Amrita Institute of Medical Sciences and Research Centre	

	JSS Academy of Higher Education and Research	
	Christian Medical College Vellore Association	
	JIPMER	
	Society for Applied Studies	
	Andhra Medical College	
	KEM Hospital Research Centre, Pune (Field Site)	
	KEM Hospital Research Centre, Pune (Hospital Site)	
	The INCLEN Trust International	
	Symbiosis International University	
	SRM Institutes for Medical Science	
	Christian Medical College Ludhiana	

Apart from this, facility augmentation for supporting the COVAXIN vaccine manufacturing has been considered under the Mission COVID Suraksha to support the demand for vaccine in the country. The following public/private entities have been recommended for facility augmentation for COVAXIN manufacturing/Scale-up in India:

1. Bharat Biotech International Ltd. (BBIL)
2. Indian Immunological Ltd. (IIL)
3. Bharat Immunologicals & Biologicals Corporation Ltd. (BIBCOL)
4. Haffkine Bio-Pharmaceutical Corporation Ltd. (A Government of Maharashtra Undertaking)

Also, under Mission COVID Suraksha, a follow-on call has been announced inviting REOI-2 for Enhancement of Capacity to Support COVID19 Vaccine Development. The proposals received under this call are under evaluation currently.

BIIS-9 online school

SITARE-BIIS: Honing skills and capabilities of young students

Biotech Innovation Ignition School (BIIS) is upto 4weeks long residential workshop organized by BIRAC's SITARE Partner, SRISTI. Upto four such workshops are conducted annually and are focused at providing hands-on-training to undergraduate students for biotech entrepreneurship and grassroots innovations. The BIIS empowers students to work towards developing solutions with grassroots applications for societal good through validation of traditional knowledge, value-addition and product development.

During COVID-19 pandemic, five virtual sessions of BIIS have been organized. Ninth BIIS workshop (BIIS-9) was organized from 20th May to 9th June, 2021. The focus, as before, was to build the capacity of primarily undergraduate students to develop skills in the field of phytochemistry, pharmacognosy, extraction and separation of phytocompounds, microbial diversity screening, pest control and understanding of the inherent processes including patent process, biostatistics etc.

Prof. Samir K. Brahmachari, Founder Director CSIR - IGIB, Former Director General –CSIR delivered the inaugural address for BIIS-9. He emphasisedon the need to learn, unlearn and relearn toinnovate in addition to creative problem solving, and entrepreneurshipfrom the course. He also encouraged students to dream, to be passionate and to stay persistent for it.

(Inaugural lecture link: https://www.youtube.com/watch?v=_bNiqY-E8Tc&t=1190s)

A total of 67 students participated in the course (including students from aspirational district and from tier-II and tier-III cities). More than 30 Expert live lectures, videos and live experiments were used to build the capabilities of the students. BIIS develops a nursery of young minds for pursuing start-up/entrepreneurial opportunities in future. The pursuit of excellence was reinforced through learning about the real life stories and interaction with distinguished scientists of the country.

The online school offered a rich learning programme comprisinglectures by experts in domains viz.,research methodologies and IPR, innovations and bio entrepreneurship, microbiology, agriculture and veterinary biotechnology, pharmacognosy, herbal drugs and regulatory aspects, data science and bioinformatics, biomedical sciences and bioengineering. SRISTI team conducted live experiments and demonstrations using various lab equipment. Ms Shilpy Kochhar, Sr Manager, Entrepreneurship Development, BIRAC raised awareness among the students about entrepreneurship opportunities in biotech sector.Representative Startups& entrepreneurs shared their journeys whileBioincubator heads presented the spectrum of support services offered by the Incubation system.

Dr.Sanjay Kumar, Director, CSIR-Institute of Himalayan Bioresource Technology (IHBT) delivered the valedictory address tracing the journey of an unmet need to a final product taking examples of numerous

new product and technology launches by IHBT. Prof. Anil Gupta chaired the valedictory session and Dr. Manish Diwan, Head, Strategy Partnerships and Entrepreneurship Development, BIRAC delivered a keynote address to the students about the need to take some of the outstanding home experiments to the next level. He hoped that some of these students in future will become GYTI and BIG awardees.

(Valedictory lecture link: https://www.youtube.com/watch?v=0AnFRLliakU)

Key benefits of BIIS to undergraduatestudents include skill and perspective development about:

- basic concepts in applied biotechnology
- latest technological advancements in life sciences and bio-engineering
- validation of grassroots innovations and other applications in life sciences and
- taking up simple experiments at home during online learning to develop basis for solving practical problems.

BIIS-9, Day-1: Inaugural address by Prof. Samir K. Brahmachari, Director CSIR - IGIB

BIIS-9, Day-21:Valedictory address by Dr. Sanjay Kumar, Director, CSIR-IHBT, Palampur

BIRAC's BioNEST Acceleration Program At Indigram Labs Foundation (ILF) (Krishi Utthan Incubation Centre)

Providing scale up support to Indian startups working in Agritech and Foodtech sectors is an unmet challenge. BIRAC has initiated a unique acceleration program to address this issue. The current program is a sector focused acceleration program for TRL8 (Pre-Commercialization) level startups conducted through BIRAC's BioNEST scheme at Indigram Labs Foundation. The vision is to hand-hold the startups at pre-commercialization stage so that they successfully graduate to the scale-up stage.

The program was kickstarted on 1 January, 2021 with a national level call to eligible startups. One hundred and five applications were received out of which 45 were found to be eligible. A national level selection committee was formed with reputed experts from the ecosystem who screened the applicants after a virtual pitching session held during 18th-20th March 2021. After meticulous screening, 10 startups were selected for the first cohort of the acceleration program. The following MVP-crossed Agritech/ Foodtech startups were selected for the first cohort:

1] Vesatogo Innovations Pvt Ltd
2] Shuvoneel Ras System Pvt Ltd
3] Vir Naturals Pvt Ltd
4] Agsmartic Technologies Pvt Ltd
5] ChlorohempAgrotech Pvt Ltd
6] Ai-Genix International Pvt Ltd
7] RaavTechlabs Pvt. Ltd
8] Mandigate Pvt Ltd
9] Greenpod Labs Pvt Ltd
10] Freshet Spring Pvt Ltd

The startups are undergoing intensive acceleration through Indigram Labs Foundation after a grand bootcamp launch event (Fig 1& 2) held on 17th and 18th May, 2021. The following support is being provided to the startups:

- Mentor-led assistance in business plan and team refinements, scale up planning & go-to-market strategy development
- Providing networking support to the startups through various Workshops/ events
- Mentor-led business Boot Camps (Finance/ Talent Acquisition Management Practices/ VC/ Finance & Accounts Etc)
- Assistance in business networking, sales and distribution and advisory on one cycle of product sales to payment
- Mentor-led coaching for investor pitching and providing one actual
- Investor pitching opportunity during Dem Day presentations
- Connecting the startups to R & D institutes for their scale up technology requirement

The intensive bootcamp will end with a Demo Day Investor pitching session on 29 July, 2021. The startups will be coached before presenting their business plan in front of the top-notch investors in the ecosystem. This will be a golden opportunity for the startups to secure funding and scale up rapidly.

Fig. 1 Bootcamp Launch event- BioNEST acceleration program at ILF

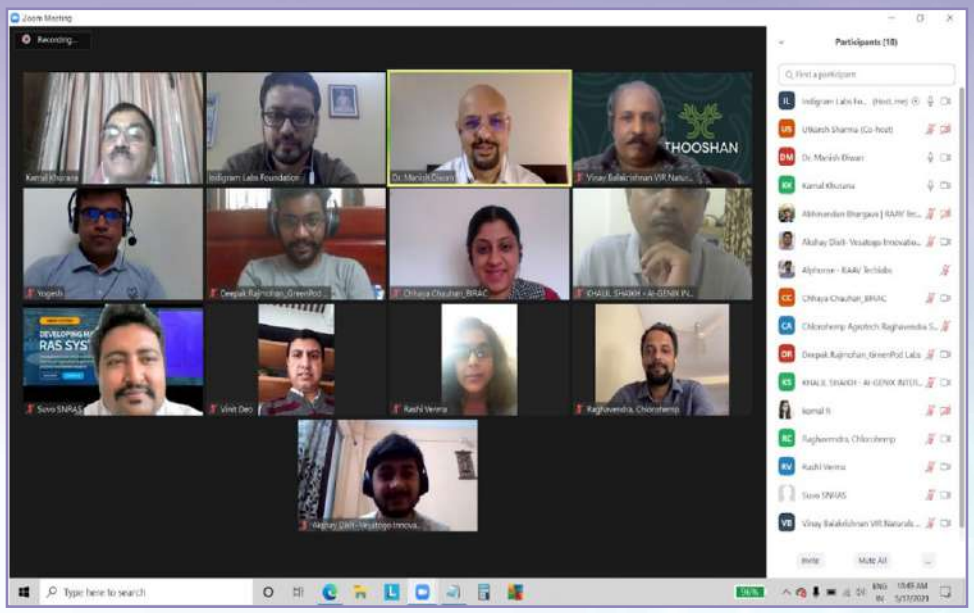
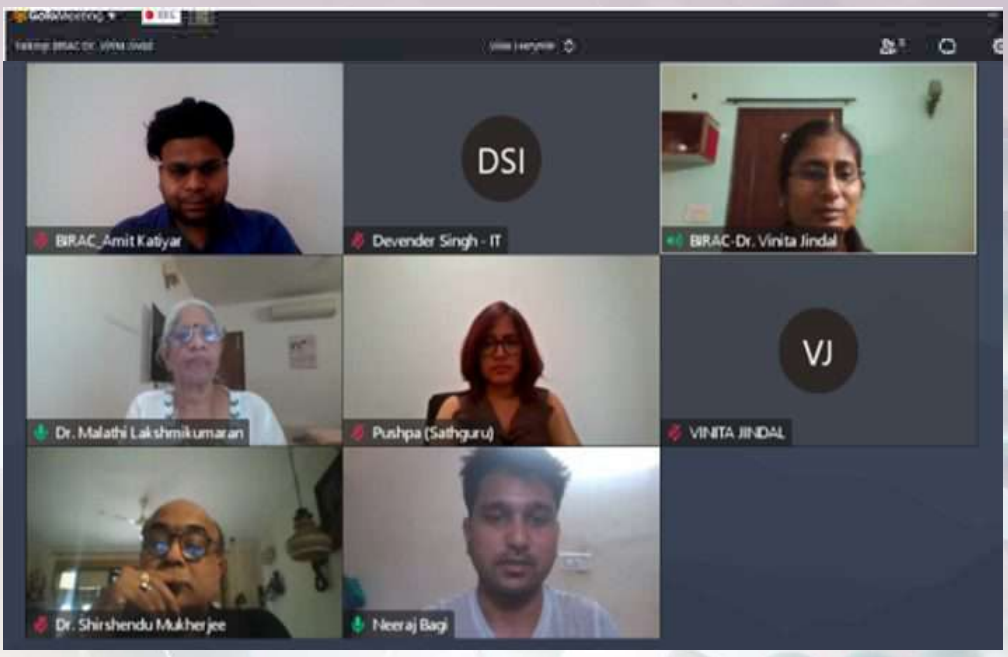


Fig. 2 Bootcamp Launch event- BioNEST acceleration program at ILF

IP & Technology Management Law Clinic Connect

BIRAC conducted two (2) sessions of ***"IP & Technology Management Law Clinic Connect"*** program for the Startups, Institutes, and Entrepreneurs to advise and mentor on Patentability Criteria, different Patentable subject matter as per Indian Patent Act, strategy for Foreign patent filing, Technology Transfer and Commercialization Process and Strategy, Sessions were well attended by 10 Start-ups and entrepreneurs as per their allotted slots.



Glimpses of IP & Technology Management Law Clinic Connect


GoToMeeting
REC
Talking: BIRAC_Amit Katiyar
View Everyone
BIRAC_Amit Katiyar
BIRAC Dr. Vinita Jindal
Abhijit Nair
Pushpa Vijayaraghavan
Malathi Lakshmikumaran
Dr. Tarun K Kumawat
Mic
Camera
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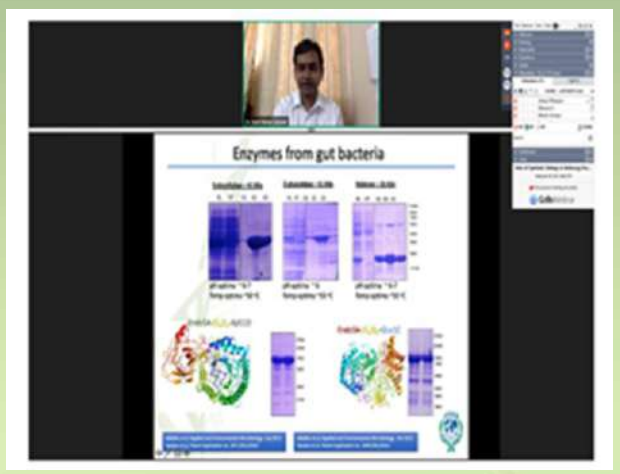
Leave

Webinar on "Role of Synthetic Biology in BioEnergy Research and Value added Biomolecule Production"

A three day BIRAC – ICGEB webinar series was conducted on the "Role of Synthetic Biology in BioEnergy Research and Value added Biomolecule Production" on 19th -20th April 2021 & 20th May 2021. More than 300 participants joined the webinar from various industries and academic institutions.

There were talks from eminent scientists like Dr. K.J. Mukherjee, IIT Delhi; Dr Guhan Jayaraman, IIT Madras; Dr B Gopal, IISc Bangalore; Dr. S Ramalingam, Anna University; Dr. Zia Fatma, University of Illinois; Dr. ShamalanReshamwala, DBT-ICT Centre for Energy Biosciences and Dr. Shams Yazdani, ICGEB.The lectures emphasized on developing various molecular tools for the model and non-model bacteria, yeast and fungi for performing various synthetic biology operations. Further, efforts of engineering these microbes for production of enzymes for 2G biofuels, and other energy dense advanced biofuels molecule, such as butanol, long chain alcohol and alkanes were discussed. In terms of value added molecules, recent development on biopolymers and organic acid production were discussed.


Enzymes from gut bacteria


Education tells you what synthetic biology can and cannot do
What products can potentially be made
Which microbe/ cell will be the best chassis
How many modifications will be required to develop the cell line into a production host (designing the cell factory).
How much time, money and resources will it take?
How can you further improve upon the design
If you only repeat what others have done you are planning to fail
If you want to succeed in the world, you don't have to be much cleverer than other people. You just have to be one day earlier."
— Leo Szilard Discoverer of the Atomic bomb

BioNEST- Panjab University

The primary goal of BioNEST Panjab University (BN-PU) at Panjab University, Chandigarh is to promote Life science and technology based entrepreneurship and thereby cater to the needs of start-ups in North India by the practical application of knowledge at large scale. We target to catalyze not only the process of enthusing a young mind but also its translation to commercialization. To hand hold and gain trust of the idea throughout the journey right from point of care generation, prototype development and testing.In this journey key steps of partner networking, value configuration and proposition, cost structure, intellectual property management are catered to.

Focus area:

1. Bioprocess Technologies/Fermentation-based products and technologies
2. Biomedical/therapeutic products and devices
3. Food and agriculture-based products and technologies

- **Location-** New Hospital Building, South campus, Panjab University, sector 25, Chandigarh, India
- **Total space (Incubation, Lab space, common area etc)-**

Requirement	Area	Percentile
Central Instrumentation Facility	3000 sqft	30%
Incubation/wet lab space	4000 sqft	40%
Office space	1500	15%
Seminar/meeting room (2)	500 sqft each	10%
Café/Library	500 sqft	5%

- **No. of Incubatees supported till now - >20**
- **Total Products/technologies commercialized-**
  a. Number of products launched/commercialized= 4
  b. Number of IP backed services offered by start-ups= 9
- **Total IPs facilitated- 9**
- **Facilities offered and unique features-**

General infrastructural services	Bioprocess, Bio-pharmaceutical, Food processing, cell culture, cold room, biosafety level-2, scale-up facility, library, cafeteria, board room, meeting room, 3D Graphics room, plug and play wet lab facility.
Scientific support services	Scal-up (upto 250L) facility, protein purification, complete down-stream facility, cell culture facility.
Advisory and mentoring services	1. Mentoring for grant writing/generation/presentation 2. Patent drafting/filing 3. Technology licensing 4. IPR Management 5. Business development models 6. Go to market strategy upgradation and designing 7. Valuation of profitability 8. Viable value proposition estimation 9. Market analysis 10. Turnover estimations and appreciating strategy designing 11. Covering commercialization gaps
IT Service	**library, database access**

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Visit us @ www.bionest.puchd.in
Write to us @ bionestpu@pu.ac.in

Dr. Rohit Sharma, Project Leader, BioNEST at Panjab University
9914461545

Star Incubatees of Incubator

Logo & Picture	Description about the startup & technology/product	Name/Description of Product /Technology developed/commercialised
	MicroRadical 360 Pvt. Ltd	Novice vide, novideseri, novice zyme
	Mritarch Assiduities Pvt. Ltd.	Cancer injectables
	BioBridge Healthcare Solutions Pvt. Ltd.	Vaccines
	Kinvac Innovations LLP	Food esters and enzyme,lipase
	Microfoods Pvt. Ltd.	Vinegar, gluten free wheat
	Dr.VanditaKakkar	Tacroplus
	AV NutricarePvt. Ltd.	Vit d beverage
	DiovitaPvt. Ltd.	Diovita beverage
	Oniosome Healthcare Pvt. Ltd.	Cancer therapy
	BioAgeLifeSciencesPvt. Ltd.	Water purifying raisins

BioNEST- IKP EDEN

About the Incubator:

IKP EDEN is India's premier Startup Incubator for hardware startups. We help startups build world class products faster. EDEN stands for Engineering, Design, and Entrepreneurship Network, and hosts a range of prototyping, research and manufacturing facilities(www.ikpeden.com). IKP EDEN is probably the best hardware product incubator in India, with a focus on medical devices, IoT and robotics.

IKP EDEN was set up by IKP Knowledge Park, India's leading Life Science Park, and has hosted over 120 startups and a total of 200 teams since 2015. BIRAC has supported IKP EDEN with the setup of the wet lab facility under the BioNEST scheme. IKP EDEN is also a beneficiary of NSTEDB's NIDHI-TBI scheme.Satellite Centers along the lines of IKP EDEN have been replicated in Mangalore, Belgaum, Jalahalli, Shimoga, and Mysore with funding from the Karnataka Government.

Across the 25,000 sft, we have a metal working shop, a wood working shop, 3D printing, electronics assembly, injection molding, 3D printing, and a biotech-chemistry lab. The biolab has a class 10k clean room. The 1000 sft wet-laboratory is equipped with state-of-the-art equipment such as Biochemistry Analyser, Thermal Cycler, Class II Biosafety Cabinets along with ISO7 clean room to meet cell culture and tissue engineering demands. The Molding and CNC milling machines have a 5-micron precision. There is also office space for over 250 people, conference rooms, a classroom, cafeteria and more.

Focus Areas:

Medical Technologies, Diagnostics, Devices, Digital Health, Clean Energy, Agri-Tech, Technology Based Healthcare Delivery Systems, Robotics and Automation in Healthcare

- **Location-** Bangalore
- **Total space (Incubation, Lab space, common area etc)-**
- **Total Area:** 25216 sft, with 6850 dedicated to BioNEST
- **No. of Incubatees supported till now**–125, of which 39 are under BioNEST
- **Total Products/technologies commercialized**– 25 (under BioNEST)
  a. Number of products commercialized = 19(under BioNEST)
  b. Number of IP backed services offered by start-ups = 6(under BioNEST)
- **Total IPs facilitated**- 12
- **Rentals**–

  Per bench – INR 18,000 per month and upwards

  Per Prototyping facility access – INR 8,000 per month and upwards

Facilities offered and unique features-

General infrastructural services	RT-PCR, UV Spectrophotometer, BSL-II Cabinet (3 numbers), Phase Contrast Microscope, Inverted Microscope, Compound Microscope, Multi-Mode reader, CO2 Incubator, Micro Volume Spectrophotometer, UV Spectrophotometer, Freeze (-80°C), MilliQ Water system, Biochemistry Analyser, Automated Cell counter, Flow Cytometer, PCR, Compound Microscope, Micro centrifuge (refrigerated), Mini Micro centrifuge (refrigerated), Shaker incubator with sticky mat, Small Shaker Incubator, Small incubator, Freezers (-20°C, -80°C), Water Purifier (Elix-5), Autoclave, Vortex Mixer, pH meter, Magnetic Stirrer with heater, Nano Drop Spectrophotometer, Ultra Sonicator, Gel rocker, Hot air oven, Water Bath, Dry Bath, Colony Counter, Portable Autoclave, Electrophoresis unit, Ice crusher, Microwave oven, Refrigerator, Weighing balance, Electrophoresis Unit, Western Blot device
Scientific support services	Engineering and Prototyping Services, Design tools available are SolidWorks, ANSYS, MATLAB, etc, Cloud Computing Services, Hardware prototyping including a metal working shop, a wood working shop, plastics and composites shop, electronics, 3D printers and laser cutting for fluidics and medical devices startups.
Advisory and mentoring services	IKP EDEN has a shared mentor pool of over 50 mentors across various sectors and specialization. The alumni community provides continuous support to the new joinees.
Information services (library, database access)	Access to Online Tutorials on Business plans and finance Access to IKP PRIME's IP services
	SEED Fund program under BIRAC PRAYAS Program from DST
	Access to Analytical services of IKP Knowledge Park, including NMR, LCMS, GC, etc.
	Access to Tracxn Database,

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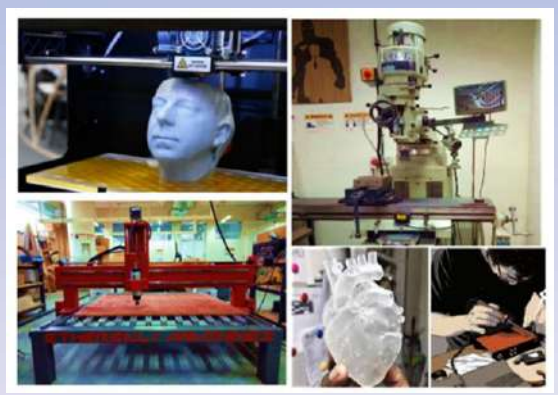


- **About the Team (Pictures of members-Group picture)**

- Deepanwita Chattopadhyay, President IKP EDEN
- Vikraman Venu, Secretary and CEO, IKP EDEN
- Dr. Priyankana Mukherjee, Manager Wet Lab at BioNEST
- Pratik Yagnik, Manager, Incubation and PRAYAS

Star Incubatees of Incubator

Logo	Picture	Description about the startup & technology/product
inito		Inito is a 30-member team, developing India's first FDA approved home diagnostic. Inito is used for ovulation cycle and fertility monitoring be measuring luteinizing hormone and oestrogen, and progesterone levels from urine. Inito is funded under BIRAC's Seed Fund program, and has raised over USD 5 Million. Over 20,000 devices of INITO have been sold.
SKYLARK DRONES		Skylark Drones has developed several solutions for tracking crop status and health. Their drones are able to cover 200 acres of farms / forest within 20 minutes, and their AI platform Spectra gives quantitative analysis from the videos and images captured. Skylark has raised over USD 3.5 Million, and clocked over USD 500k in FY 2020-21. Skylark is funded under the LEAP Fund program.
dozee		Dozee is the pioneer in contactless, continuous remote patient monitoring (RPM) in hospitals & at home, delivering unparalleled patient safety & maximizing utilization of ICU beds. Its AI-based module - Advanced Health Intelligence - detects early signs of health deterioration by continuously assessing the patient's vitals data (such as heart rate, respiration rate, heart rate variability, blood pressure, blood oxygen) and further conducting a risk analysis. Dozee has raised over USD 10M, and has deployed over 4000 devices. Dozee is funded under the SEED and the LEAP Fund program.
HealthCube		Healthcubed is a portable, battery powered device which can conduct. over 30 tests at the point of care. Healthcubed has reached over 500,000 patients, and has raised over USD 4Million.
biodesign innovation labs		Biodesign Innovation Labs have developed Respiraid. As winners of the CamtechX Hackathon, Biodesign was founded as a startup. They have received support from BIRAC under the BIG program, they have deployed 20 devices across the nation.

Predible		Predible Health has developed LungIQ which uses artificial intelligence for the analysis and reporting of COVID19 and other lung conditions from radiology imaging. They have been deployed in over 20+ hospitals, have processed over 80,000 patients, and also entered into a distribution agreement with GE Healthcare. They have raised more than USD 700,000 from VCs and other sources. Predible is funded under the BIG and SEED Fund program.
Niramai		Niramai has developed a novel AI -based, non-invasive, non-contact, privacy aware and non-radiationbased breast cancer screening solution for women of all age-groups. Niramai uses a fusion of Machine Intelligence and Thermal Imaging. Niramai has completed more than 36K screenings and is available at 60+ locations pan-India. Niramai has extended its's Thermalytix platform to deliver several other solutions related to COVID-19. Niramai has raised over USD 7 million in funding from VCs.
Janitri		Janitri has developed KEYAR, an affordable and easy to use patch-based wearable for maternal-fetalmonitoring device for intrapartum period. KEYAR also communicates with DAKSH, a mobile application for the intelligent alerts and remote monitoring. They were winners of 4th Commonwealth Digital Health Merit award in the Maternal & Neonatal Health Category. They have raised over USD 375,000

BioNEST-KIIT

The BIRAC supported BioNEST- KIIT Bio-Incubator focuses on establishing innovation led technology ventures in various realm of life science.The KIIT Bio-Incubator is recognised as the implementing partners for various flagship start-ups programs of BIRAC like the prestigious Biotechnology Ignition Grant (BIG), Social Innovation Fellowship (SIIP) program, BIRAC SEED Fund, LEAP Fund. With a built-up space of 120,000 sq ft including 40,000 square feet, Bio-Incubator provides state the of art prototyping and analytical facilities which is well matched to the cutting-edge technology of today's and tomorrow. The Digital Fabrication Lab, Bio Design Lab, Bio process Lab, NABL accredited Food testing Lab, Analytical Lab, Cell culture Lab and Animal facility helps start-ups in developing new know how and technology to find solutions for a more sustainable future.

BIRAC established its Regional Centre at KIIT BioNESTcalled the BRTC centre (BIRAC Regional Techno Entrepreneurship Promotion Centre) on 12th July, 2019 for creating a vibrant innovation and start-up ecosystem in NE & E by providing mentorship support to incubators and entrepreneurs across all states of NE including Meghalaya, Mizoram, Sikkim, Manipur, Assam, Tripura, Sikkim, Arunachal Pradesh, Bihar, West Bengal, Chhattisgarh, Jharkhand and Odisha.Over the past two years, BRTC has worked aggressively on reaching out to budding startups, innovators across all the states of NE and East and has implemented many capacity-building workshops and new initiatives that allow innovators to address their product development, regulatory, IP and commercialization queries. In this regard, a total of 42 intensive total training programs are conducted so far with 7 NE: 3 E mandate including roadshows, design workshop and training programs on various facets of innovation, including IP, grant writing, regulatory matters have been organized. Through these programs, approximately 3600 innovators have been supported across all states of NE including Meghalaya, Mizoram, Sikkim, Manipur, Assam, Tripura, Sikkim, Arunachal Pradesh, Bihar, West Bengal, Chhattisgarh, Jharkhand and Odisha.

KIIT TBI Technology Transfer Office (KIIT TBI TTO), one of the seven Technology Transfer Offices has been set up under the National Bio-pharma Mission, BIRAC, Department of Bio-technology, Govt of India.Since its inception with the support of BIRAC and National Biopharma Mission (NBM), KIIT-TBI TTO has worked aggressively on reaching out to inventors, academicians, researchers as well as start-ups across all the states of East and North-east in order to facilitate translation of publicly funded research results into products and their delivery to markets bylicensing innovation to enterprises for commercialization.

Recently,BIRAC Launched the East & North East Cluster on 20th May, 2021 to foster deep engagement and peer to peer learning across all the BioNEST supported incubators from the East and Northeast Region of India with a mission of building a vibrant innovation and startup ecosystem in the region. KIIT BioNEST BRTC Centre has been recognized as the lead Incubator for East & NE Cluster Network comprising of Mizoram University, NIPER, Guwahati, IASST, Guwahati, IBSD & BRDC, IIT Guwahati, NEHU, Tura Campus, NEIST Jorhat, ILS Bhubaneswar. The details of the E&NE cluster can be found at https://www.enerbiocluster.com/.

Enablers at KIIT BioNEST: Bhubaneswar City Knowledge Innovation Cluster (BCKIC), KIIT TBI Technology Transfer Office (TTO), supported by NBM BioPharma Mission and KIIT Technology Enabling Centre (TEC), supported by DST, Government of India.

Location: Bhubaneswar, Odisha

Website: https://kiitincubator.in/

Total space: 40,000 sq. ft.

Impact:

- Number of incubatees supported till now:129
- Biotech Startups catalyzed: 86
- Women-led biotech enterprises: 50+
- Fund Raised by startups from Govt. Agencies: 400 million +
- Jobs created: 1000+
- Equity fund raised by biotech startups: 3 billion
- IP created: 79
- Products commercialized: 47
- Collaborations & Partnership Forged by the Bioincubator: 40
- Startups worth 1Cr or more valuation: 11

Focus areas: Healthcare: Devices & Diagnostics, Drugs & Biosimilars, Industrial Biotechnology, Agriculture, Food technology, clean technology & waste management, and IoT & AI/ML

Rentals: INR 55 per sq. ft.

Facilities offered:

1. General infrastructural services

The KIIT TBI Bioincubator provides plug and play company specific office suites with high-speed internet connectivity and teleconferencing facility. Additionally, the startups and innovators can access the common meeting rooms, board rooms, and conference rooms with projection equipment.

2. Scientific support services

a. High end plug and play Bioincubation facility for the startups, BIG applicants and other innovators and entrepreneurs. The common lab space includes facilities like - Biosafety cabinet, Gas distribution facility, Orbital shaker, Incubator, Thermomixer, Cold centrifuge, -80&-20˚C freezers, Weighing balance, Microcentrifuge, Spectrophotometer, Nanodrop,Water bath, PCR machine, Small instrumentation facility such as Magnetic stirrer, pH meter, Vortexer, Agarose and SDS-PAGE apparatus with, Millipore water facility, Ice flaking machine, Realtime PCR. Furthermore, a dedicated cell culture facility is also there at KIIT Bioincubator.

b. Sophisticated analytical facility having high end bioanalytical instruments like – GC-MS/MS, LC-MS/MS, FTIR, MP-AES, ICP-OES, UV Vis Spectrophotometer, DLS, CD Spectrophotometer, and HPLC.

c. Prayas Shala - Rapid Prototyping Labprovides an integrated platform for rapid prototyping, product design and technology development. It is equipped with high precision laser cutting machine, a CNC router, 3D printers, advance electronics assembly, wood working and power tools, PCB design and fabrication machine and many other tools and equipment.

d. Plant tissue culture facilityalong with transgenic polyhouse and green house as per DBT/IBSC/GEAC guidelines. Dedicated 500 sq ft Plant tissue culture Facility with 500 sq ft poly house with micro climatic control condition.

e. Protein production facilityincluding biosafety cabinets, shake flask incubators, fermenter/bioreactor- 7.5 L and 14.0 L capacity, bench-top centrifuge- 3L and 1.5L capacity, ultrasonicator, and AKTA Pure protein purification systems.

3. Advisory and mentoring services

Besides, the infrastructural and scientific support, KIIT BioNEST offers a wide range of mentoring and advisory services to the startups and innovators. The mentoring and advisory services listed below are tailor-made and customized services as per the requirements of the startups.

- Assistance in product development, manufacturing, and validation
- Assistance in developing business growth strategy and market feasibility assessment
- Assistance in conducting marketing trails, branding, and marketing support
- Facilitating startups to raise public and private funds
- Conducting training on marketing skills, finance, accounting, etc.
- Conducting IP planning sessions and sasistance in IP filing by experts, IP attorneys at nominal charges
- Assistance to conduct clinical trials and validation studies
- Assistance in publications, 3D graphical representation & CAD modeling
- Providing recruitment advice and HR management strategies
- Connecting startups with State and Central Govt. facilitators and enablers.
- Networking with national and international investors and mentors through various programs.
- Connecting research institutions, academia, industry and corporates towards creation of a Hub & Spoke Model, activelyfacilitating innovation and knowledge creation.

Photos of facility and team:

Star Incubatees:

1. Cygenica Private Limited

Founder: Dr. Nusrat Jahan Mobassarah Sanghamitra

Sector: Drug Delivery

Contact: info@cycaonco.comWebsite: https://cygenica.com/

About the Innovation: Cygenica is working towards developing “CyCa-dds” which is a molecular nanomachine that serves as a unique drug delivery system. It employs a unique, non-endocytic mechanism that delivers molecular payloads into live cells by mechanically penetrating the cell membrane without damaging the cells. It translocates through the bilayer of the cell membrane reducing drug dosage and increasing functionality of therapeutic molecules. It is a highly efficient drug delivery system based on novel non endocytic cell entry mechanism. Recently, Cygenica has raised 1.4 million USD in seed round led by SOSV Ireland.

2. EzeRx Health Tech Private Limited

Founder: Mr. ParthaPratim Das Mahapatra

Sector: Medical devices and diagnostics

Contact: partha2610@gmail.comWebsite: https://ezerx.in/

About: EzeRx is medtech company which has developed a device called “EzeCheck”whichis a non-invasive, portable device that can detect anemia and predict liver and lung problems in less than a minute without taking even a drop of blood from your body. It detects Hemoglobin levels which helps to predict anemia, Bilirubin levels which help in identifying various liver problems and Oxygen saturation, which aids in examining lungs conditions.EzeRx has raised a follow-on funding of almost 3.3 Cr from angel investors, IOCL startup grant, and BIRAC LEAP fund.

3. Prantae Solutions Private Limited

Founders: Dr. Aseem Mishra and Dr. SumonaKarjee Mishra

Sector: Medical devices and diagnostics

Contact: sumonakarjee@gmail.comWebsite: https://www.prantae.solutions/

About:Prantae is technology based company working on the healthcare domain and has formulated multiple products like:

- Embargo® Viral Nucleic Acid Isolation Kit is designed for quick and reproducible isolation of viral nucleic acid from biological fluids. This is made possible by specially manufactured nanoscale magnetic beads with a unique surface coating that binds selectively to DNA/RNA in the extract.
- Embargo® Plasmid Extraction Kit is designed for quick and reproducible isolation of plasmids from bacterial cells. This is made possible by specially manufactured nanoscale magnetic beads with a unique surface coating that binds selectively to DNA/RNA in the extract.
- ProFlo-U®: An innovation in self-health monitoring that enables you to keep track of your kidneys function.
- EyeRa®: A wide range of nanosensor for biosensing applications.
- EyeRa-SenseTM: State-of-the-art spectroscopes for smartly measuring the ultra-sparse biomarkers.

4. ComofiMedtech Private Limited

Founder: Dr. Satish Kalme

Sector: Medical devices

Contact: contact@comofimedtech.comWebsite: https://www.comofimedtech.com/

About: Comofi is medtech company which has developed cutting-edge technology platform in surgical intervention space, and innovative COVID-19 sample collection mask. Rooted in science, driven by engineering, and united by purpose, the company drive progress by blending the deep customer knowledge and unrivaled expertise in applied science and engineering to meet the global challenges in health care industry.Comofi has been supported under the BIRAC BIG grant to develop the robotic surgical device and DST CAWACH for the development of NT-Mask. Furthermore, they have raised 2.15 Cr from JITO Angel and BIRAC LEAP fund.

विज्ञान से विकास–प्रौद्योगिकी से प्रगति

Road Shows organized by BioNEST Incubators

Incubation 101 Series

Organised by, BioNEST Incubator at Ahmedabad University

Date: 20th and 27th March, 2021

BIRAC supported BioNEST Incubator at Ahmedabad University has initiated **Incubation 101 Series** wherein several Webinars comprising practicing experts from various domains is are being organised to give the audience a robust understanding about the critical aspects that an entrepreneur should keep in mind during their entrepreneurial journey. This platform is designed to enable an innovator/ entrepreneur to systematically take the entrepreneurial journey with a Learn-Experience-Execute methodology.

Two Webinars were organised on 20th March and 27th March on the topics mentioned below:

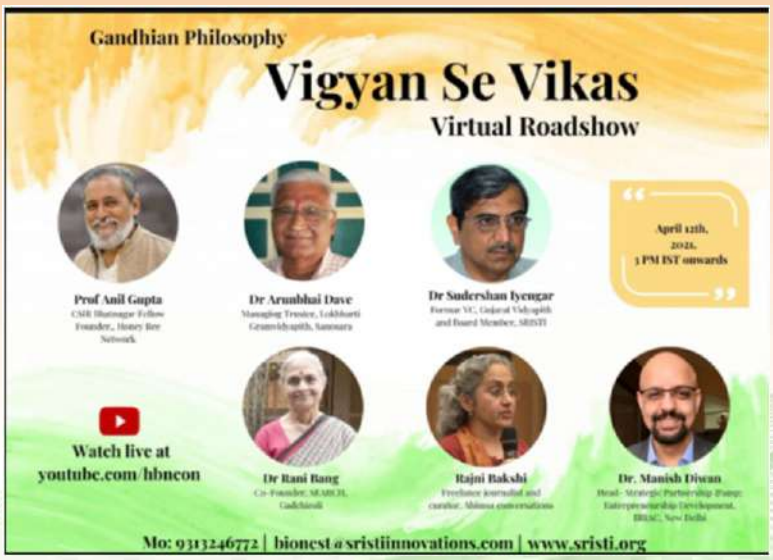
1) **Its Logical: Innovating Profitable Business Models**
2) **Funding Landscape in India**

Gandhian Vision of Science and Technology for the Development of Rural India

Organised by, SIIE SRISTI BioNEST, Ahmedabad

Date: 12th April, 2021

A virtual event was organised by the various BioNEST incubators at Ahmendabad. The event brought the startup incubatees from incubation centres across Gujarat on a common platform for shared learning. Also Gandhian perspective on business principles was shared by various eminent speakers- Prof. Anil Gupta, Dr. Arunbhai Dave, Dr. Sudershan Iyengar, Dr. Rani Bang and Dr. Manish Diwan. A panel discussion was also organised on the theme "Supporting Frugal Innovations for Atmanirbhar Bharat". Panellists included CEOs/ Incubation Managers of all Gujarat Bio-Incubators. The event ended with the Startup showcasing session on "Gandhian spirit of AtmaNirbharta for Start-Ups of tomorrow".



HTIC Conclave

Organised by: BioNEST IITM HTIC Medtech Incubator, Chennai

Date: 21st April, 2021

Date: 21.04. 2021

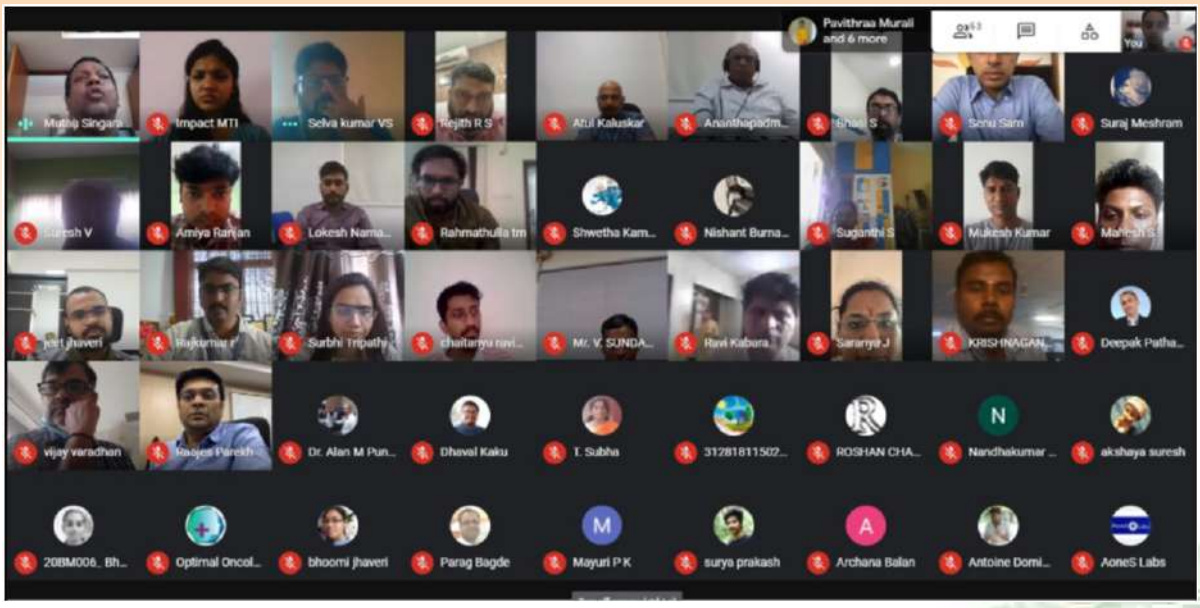
The IIT Madras HTIC Medtech Incubator oganised “HTIC Healthcare Conclave” on April 21st, 2021. The aim of this series is to bring successful entrepreneurs, Technical and Business experts from different domains under health care to share insights and to discuss the upcoming trends, Innovation, technologies and bottlenecks. The conclave brought best of minds in the medical and healthcare industry, to share the progress and the challenges in the different sectors. The HTIC Healthcare Conclave will be conducted once every quarter, the April 2021 conclave comprises two panel discussions (Building Start-up ecosystems through Incubators & AI, ML, & Blockchain in healthcare) , two expert sessions (Emerging trends in Advanced Artificial Intelligence & Emerging trends in Block chain in healthcare)and start-ups demonstrations (4 HTIC Incubated start-ups are C3 MedTech, Ubiqare Health, Mocero health solutions & Zasti). The event also witnessed the participation of 9 BioNest Tamil Nadu incubators, 5 BioNest from around India plus 1 Atal Incubator. The Tamil Nadu BioNEST Cluster website was also launched during the event.

Hospital Accelerated Pre Incubation Program (HAPI)

Organised by: BioNEST IITM HTIC Medtech Incubator and BioNEST Sri Ramachandra Innovation and Incubation Centre (SRIIC), Chennai

Date: 19th April, 2021

IIT Madras HTIC MedTech Incubator launched the Hospital Accelerated Pre-Incubation (HAPI) Program for 3 months, starting from April 2021 to Jun 2021 in collaboration with Sri Ramachandra Innovation Incubation Centre (SRIIC). The objective of HAPI is to provide Pre-incubation support to budding innovators and start-ups in the Medtech space who would like to get finally incubated at the prestigious IIT Madras HTIC MedTech Incubator and SRIIC. The start-ups will get Technical support from HTIC and Clinical support from SRIIC. The 3 month programs would include customer discovery, building a business model, developing product timeline and Clinical mentoring, guidance & validation for their products/services. (The Pre-Incubation period has no charge for rental or any services offered by the incubator). Upon successful completion of the 3 months program the 12 start-ups would be considered for incubation subject to IIT Madras and SRIIC terms and conditions. Incubation can be virtual or resident



Launching ceremony of E&NE BioNEST Cluster

Organised by: KIIT BioNEST

Date: 20th May, 2021

The BIRAC's East & NE BioNEST cluster was launched on 20th May 2021. Various dignitaries including Secretary Department of Biotechnology Dr. Renu Swarup addressed the gathering. Representatives from KIIT BioNEST, lead incubator and other member incubators Mizoram Univ, IBSD Imphal, IASST Guwahati, NIPER Guwahati, IIT Guwahati, NEIST Jorhat, NEHU Tura campus & ILS Bhubaneswar also participated and showcased their strength and opportunities. A dedicated website and a brochure for the cluster was also launched in the presence of the dignitaries.

Panel Discussion on Medtech Opportunities In India

Panel Discussion on Medtech Opportunities in India

Organised by: BioNEST SASTRA TBI (ABLEST) & SASTRA Deemed University, Thanjavur, Tamilnadu

Date: 24 & 25 May, 2021 (6 Virtual Sessions)

This event was organized as a part of Azadi Ka Amrit Mahotsav and aimed to discuss the challenges and unmet needs in clinics in areas of Cardiology, Orthopaedics, Transplantation, Oncology, Neurology and Ophthalmology. These sessions were addressed by leading clinicians and benefited innovators and entrepreneurs in the MedTech area to develop technologies to address the pain points in each domain. As clinicians are the key players to articulate the unmet MedTech challenges, this event provided a new

Women Entrepreneurs in Agriculture

Organised by: BioNESTAgri-innovation centre, UAS, & C-CAMP

Date: 27th May, 2021

The Agri Innovation Centre of the University of Agricultural Sciences Bangalore is supported by the BioNEST scheme of BIRAC, GoI. BIRAC alongwith its Incubation centres is celebrating India's 75th year of Independence this year under the AzadiKaAmritMahotsav theme. The topic of Women Entrepreneurship is relevant to this programme as potential showcasing of the Incubation centres was done to attract and create awareness among women entrepreneurs. The event was organised to encourage Urban and rural

women to take up Entrepreneurship in Agriculture and related areas such as food processing, value addition etc. and to give a glimpse of the ideal settings and environment, facilities and mentorship available at the UAS, B for incubation of Agri technology based start ups.

'Vigyan se Vikas - Pradyogiki ke Pragati'

Organised by: BioNEST NIPER Guwahati

Date: 31st May, 2021

This event was organised with an aim aligned to the 'Vigyan se Vikas' Mahotsav as it focused on nurturing and celebrating the achievements of science startup ecosystem. The event was organised to create awareness, promotion and foster innovation and entrepreneurship culture among masses.

Innovation and Entrepreneurship- Key drivers revolutionising Vigyan se Vikas

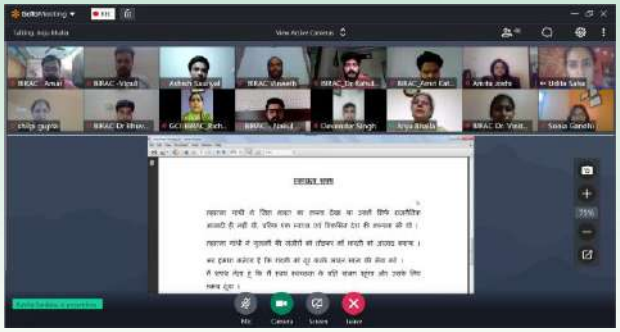
Organised by: Entrepreneurship Development Center (Venture Center)

Date: 10th June 2021

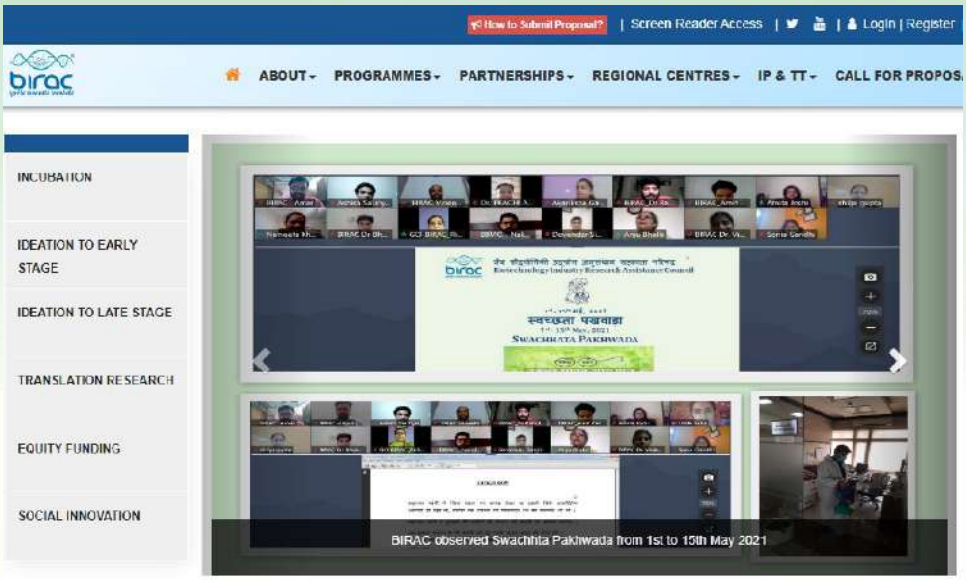
The objective of the event was to emphasize and illustrate the role of innovation and entrepreneurship as vehicles for revolutionising the Vigyan se Vikas and Atmanirbhar Bharat campaign. The program highlighted the best practices being followed at R and D organizations and Incubators which enable a concept to mature to a technology spinoff/start up. The event also covered the challenges and how the innovation ecosystem can address these challenges. The event reinforced India's ability to develop and commercialize technology by showcasing and experience sharing by all the indigenous 'First in India' developed technologies and products by Venture Center supported start-ups.

Swachhata Pakhwada 2021

BIRAC observed Swachhata Pakhwada from 1st May to 15th May 2021. Swachhata pledge was administered virtually by Managing Director - BIRAC. All employees have taken a pledge to devote 100 hours in a year as 'Shramadaan' to ensure cleanliness of the work area & surroundings. The message and the objectives of 'Swachh Bharat Mission' were shared among all the employees. In order to contain spread of COVID-19 at workplace, routine cleaning and disinfection of office premises especially high-touch surfaces are being carried out in timely manner in BIRAC. Safeguarding the health of employees is BIRAC's top priority, therefore, sanitization of the entire office premises is being carried out on weekly basis. BIRAC has also educated its workforce by issuing Circulars in line with Government Guidelines and regularly communicated with its employees. Also, the process for a paperless office has been initiated by implementation of E-Office platform in BIRAC, which shall not only reduce carbon footprints by limiting the printouts and photocopies but it's significant for contributing to a sustainable society.

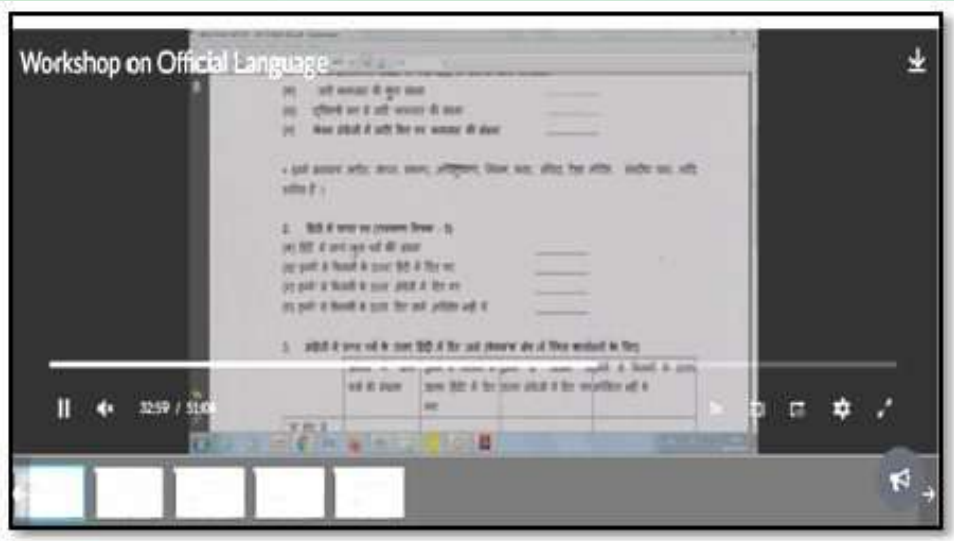


In addition to this, coverage of activities was uploaded on Twitter handle and Website of BIRAC.



Workshop on Official Language Act

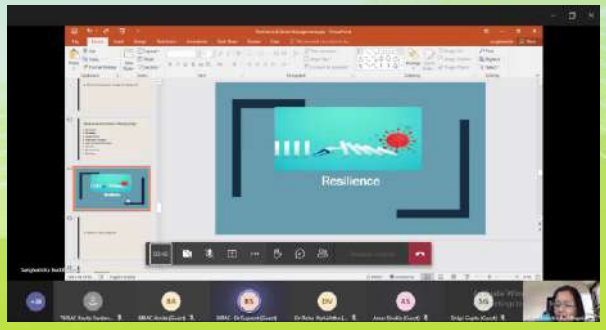
In line with the implementation of Official Language Act, a virtual workshop was organised for BIRAC employees on 21st May 2021 to acquaint the employees with the importance and provisions of the Official Language. The workshop helped employees in understanding the constitutional provisions of Official Language Act and on implementing official language in day to day official correspondence.



Training on Resilience and Stress Management

Organisational work is stressful and the ongoing pandemic has added to the workplace stress leading to fear, anxiety and adverse impact on professionals' performance as well as organisational outcomes. In order to help employees manage their stress and focus on their work, in-house training on Resilience and Stress Management has been organised for BIRAC employees on 04th June 2021 from Fore School of Management.

The training helped employees understand their source of stress and its impact. It also helped employees on how being resilience can help them manage stress effectively. The training also included hands-on exercises which helped employees in giving and receiving candid and constructive feedback.



Grand Challenges India

Nutrition-Sensitive Agriculture - Third SAC Meeting || April 2021

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.

Grand Challenges India, Governing Board members met virtually and reviewed the proposed new programs || April 2021

The virtual meeting of the GCI Governing Board was conducted in April to discuss a diverse range of health and developmental priorities. The XIIth Joint Steering Committee and Executive Committee meeting proceedings were carried out virtually amid the travel restrictions and to follow the Covid-related protocols.

Dr Shirshendu Mukherjee, Member Secretary to JSC, welcomed all the members and thanked the leadership of the joint EC Chairs and the JSC members for their strong leadership, unflinching support and valuable guidance which has been instrumental in GCI's growth over the past 9 years

Dr Renu Swarup, Secretary, DBT & Chairperson, BIRAC, welcomed all the members, mentioning that GCI is one of the longest partnerships for DBT and it is important to move forward to see how this partnership can become stronger. She also echoed that this partnership should become stronger and whether it is research, capacity building and all activities have had an impact.

Mr Hari Menon, Country Director, India Office, Bill & Melinda Gates Foundation, emphasized that there are opportunities to explore where this partnership can go in the future, not just in public health for India and but also in broader global areas. He also added that Covid-19 has shown the importance of India's innovation capabilities in research, diagnostics, vaccines etc, which mirror the mandates of GCI and leveraging this momentum to move to the extension phase of the partnership is important.

Ms Anju Bhalla, Joint Secretary, DST & MD, BIRAC; the JSC Co-chair, welcomed all the members and thanked them for support to the flagship program. She mentioned that the new programs being proposed would add value to this partnership in supporting innovations for the global health challenge that the world is facing today.

Ms Kedest Tesfagiorgis, Deputy Director, D&TS, BMGF also the JSC Co-chair, welcomed all members and wished for a productive meeting.

The Board discussed, reviewed, and approved the new programs for implementation across sectors likely, Neglected Tropical Diseases, fellowship program, new partnerships, evidence synthesis work, and non-hormonal contraceptives studies among others. These research-driven and technology-based interventions will be initiated with strategically important multi-way stakeholder specific approaches.

The Governing Board meeting concluded with a concurrence that the partnership has given excellent outputs so far and with the upcoming projects should have more positive outcomes.

ki Data Challenge - TAG Meeting || June 2021

The ki Data Challenge Second TAG Meeting of the Knowledge Integration Grand Challenges (ki-GC) grantees: Data Science Approaches to Improve Maternal and Child Health of India, was held virtually for two consecutive days in June 2021

The goal of the meeting was to facilitate conversations between the stakeholders, mentors and grantees and to review the progress of all seven supported projects and planned the next steps for the program. The grantee teams shared their progress against the project activities, challenges, and experiences through the presentation and interactive sessions.

The program is in early- implementation activities and teams will shortly initiate validating their data analytics approaches of the harmonized data of interests in the field.

Officers from the ki Group at the Foundation also joined the meeting to help facilitate the data access and contribution discussions.

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

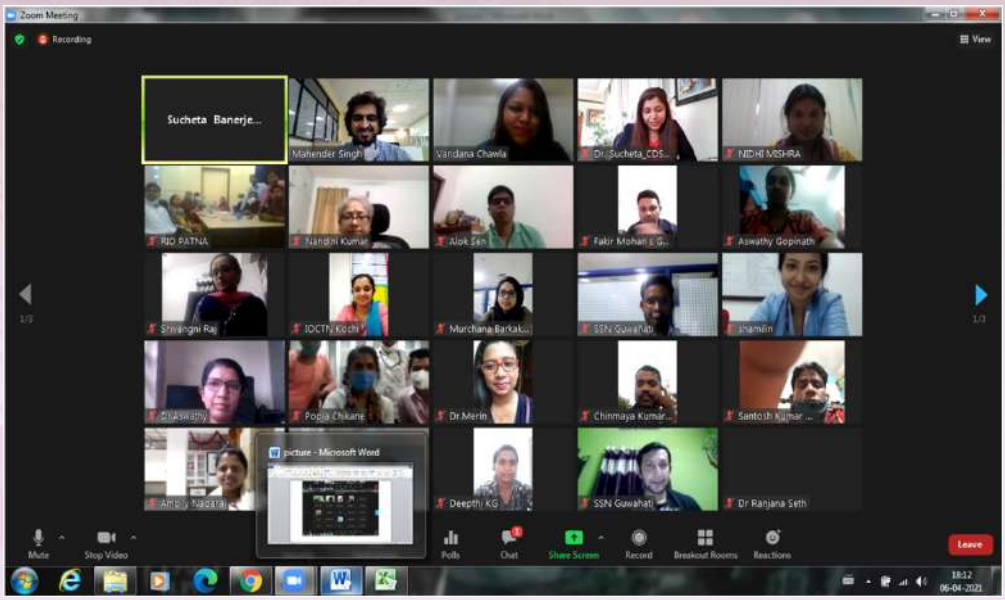
National Biopharma Mission

Innovate in India for Inclusiveness (I3)

Lecture Series on Good Clinical Practice (GCP) and Bio Ethics for Clinical Trial Network (CTN) for Hospital based specialities

- The training for Ophthalmology network was conducted with six (06) hospital sites. Each training program had three (03) webinars of four (04) hours each with session breaks, interactive quizzes, individual or group exercises/case studies, and each followed by an exit assessment (online auto-proctored, single log-in, open for 48 hours).

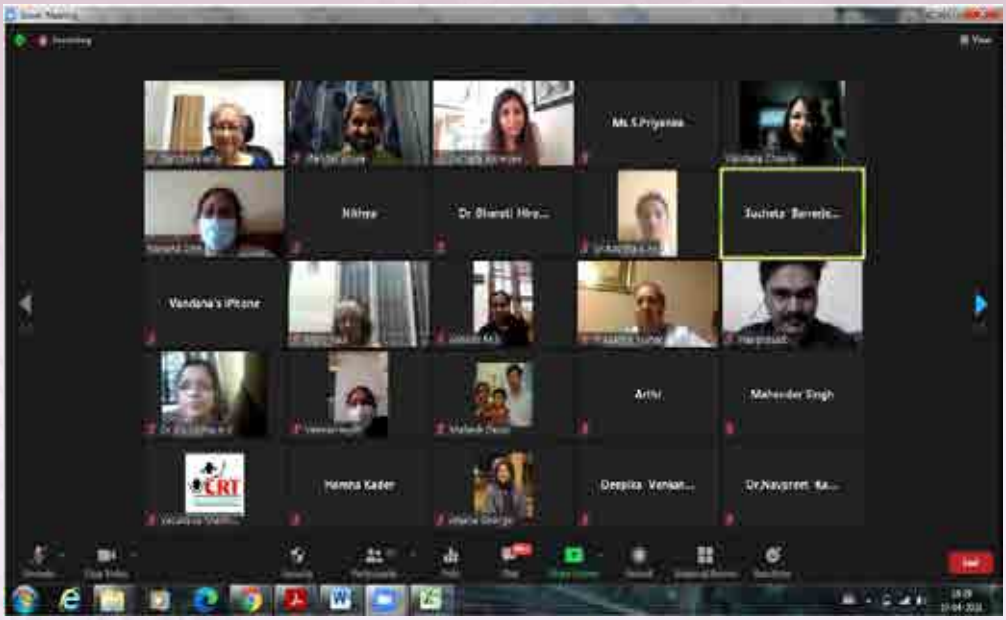
1. The first module "Ethical Considerations And Roles And Responsibilities Of Stakeholders" was conducted online via GoToMeeting platform, on April 06, 2021, and observed a participation from 75 participants.
2. The second module "Regulatory Requirements For Conducting Trials, Clinical Trial Planning, Conduct And Safety Reporting" was observed a participation from 69 participants. and was conducted online via GoToMeeting platform, on April 13, 2021.
3. The training for the third module "Clinical Trial Documents, Records Management, Quality Control (QC) And Quality Assurance (QA)" held online via GoToMeeting platform, on April 20, 2021, and was attended by 63 participants.

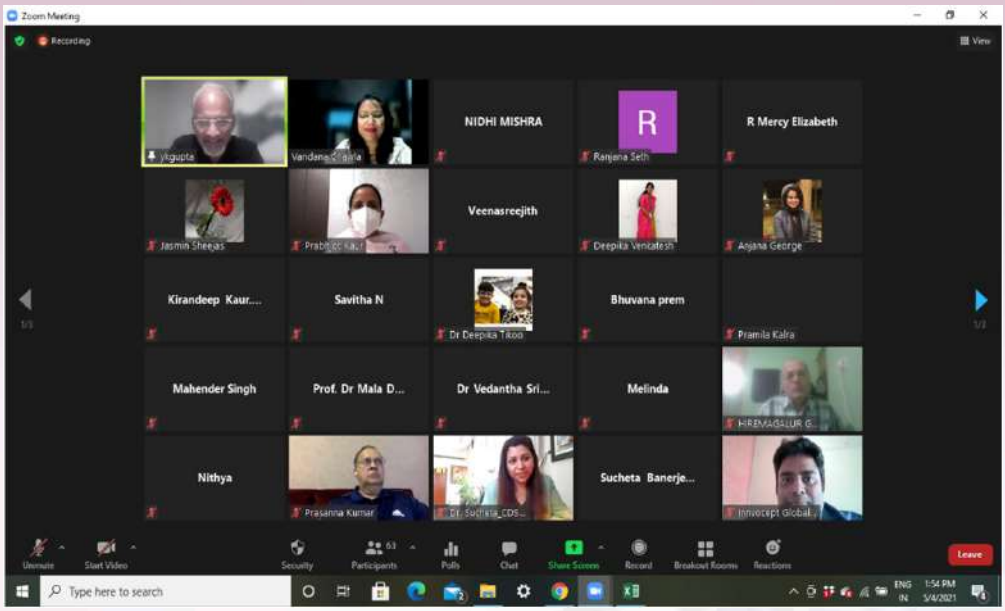


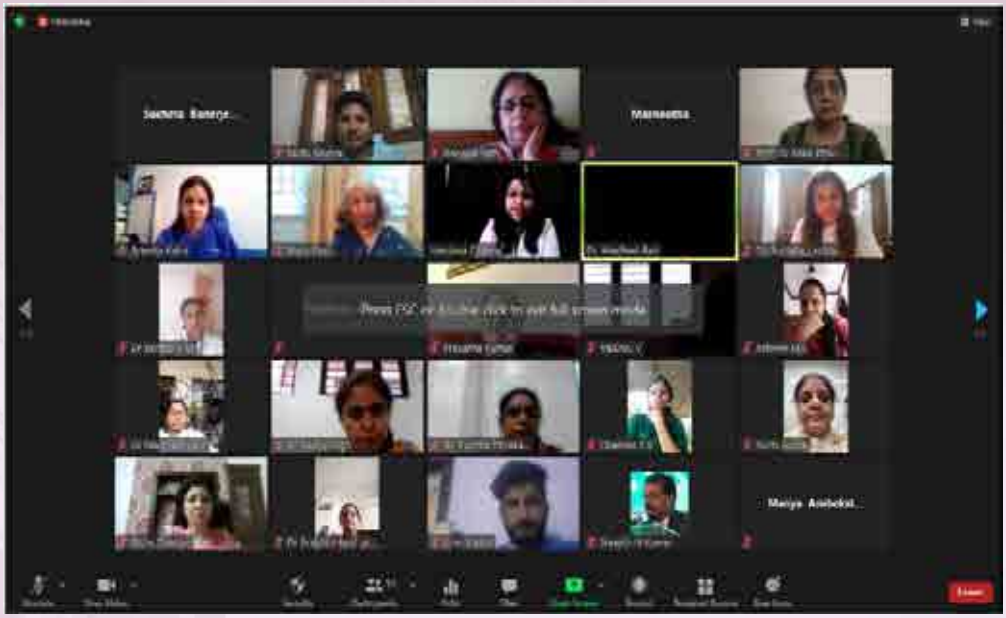
Glimpses from the training for Ophthalmology network

- The training for Diabetology network was conducted with six (06) hospital sites. Each training program has three (03) webinars of four (04) hours each with session breaks, interactive quizzes, individual or group exercises/case studies, and each followed by an exit assessment (online auto-proctored, single log-in, open for 48 hours).

1. The training for the first module "Ethical Considerations And Roles And Responsibilities Of Stakeholders" was conducted online via GoToMeeting platform, on April 27, 2021, and observed a participation from 63 participants.
2. The second module "Regulatory Requirements For Conducting Trials, Clinical Trial Planning, Conduct And Safety Reporting" held online via GoToMeeting platform, on May 03, 2021, and was attended by 61 participants.
3. The third module "Clinical Trial Documents, Records Management, Quality Control (QC) And Quality Assurance (QA)" was attended by 62 participants. and was conducted online via GoToMeeting platform, on May 11, 2021.



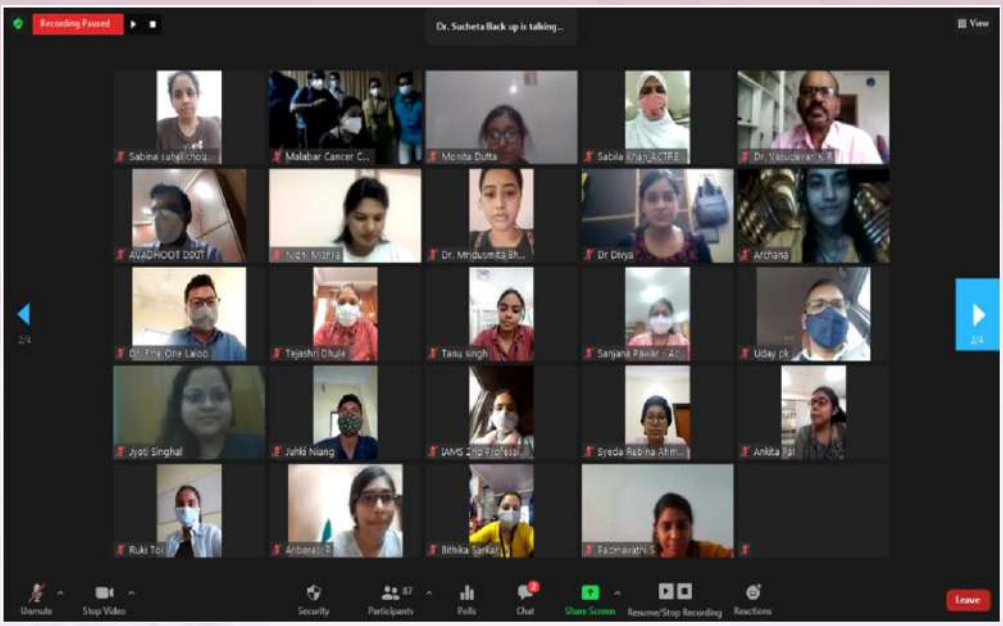


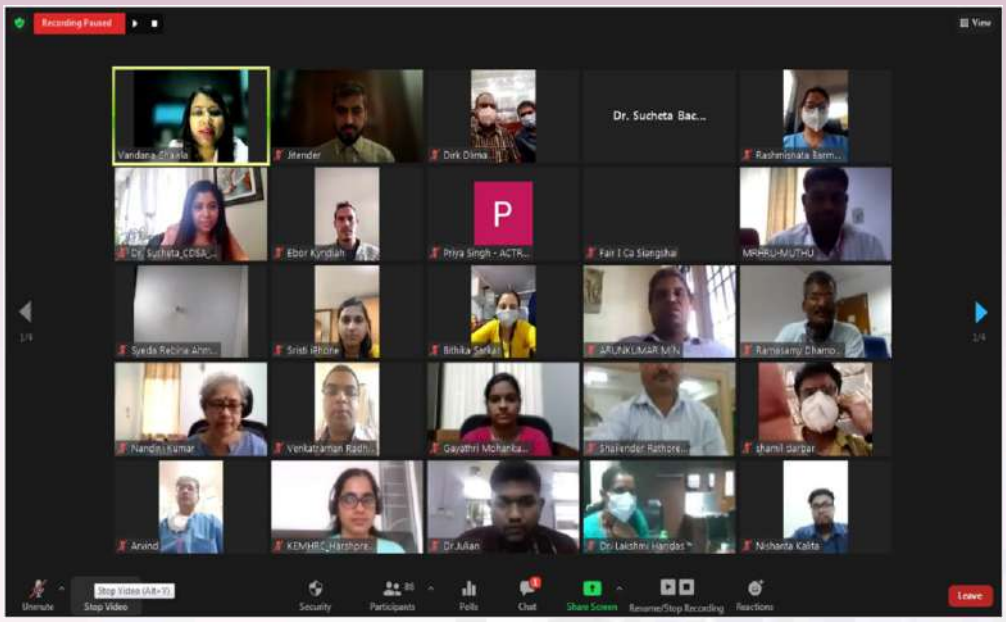


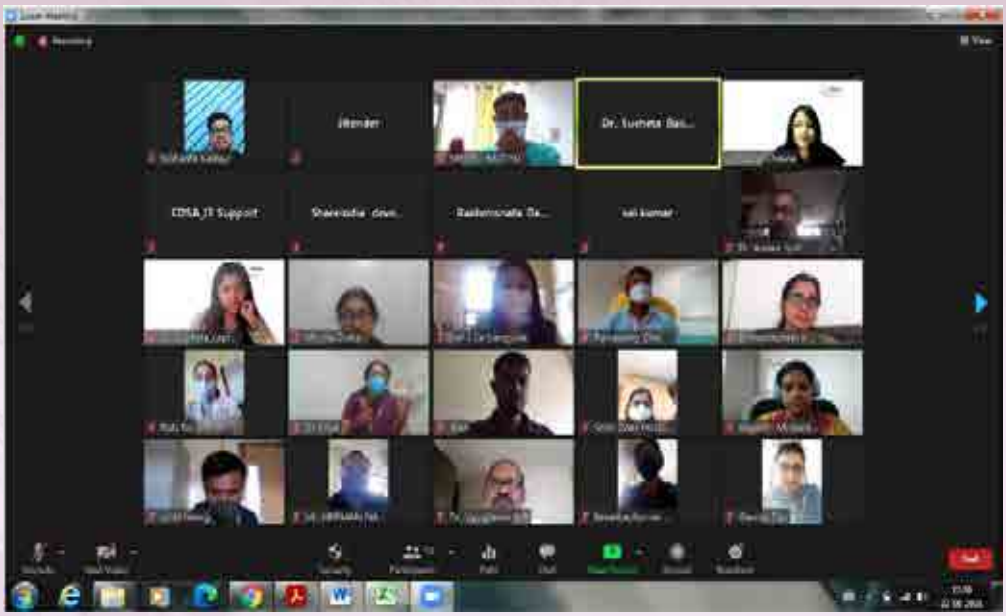
Glimpses from the training for Diabetology network

- The training was conducted for the Oncology network where total 11 hospital sites were involved. Each training program have 3 webinars of 4 hours with session breaks, each followed by an exit assessment (online auto-proctored, single log-in, open for 48 hours), including interactive quizzes and individual or group exercises/case studies.

1. The first module on “Ethical Considerations And Roles And Responsibilities Of Stakeholders” was conducted via GoToMeeting platform on June 15, 2021, and was attended by 78 participants.
2. The training for the second module on “Regulatory Requirements For Conducting Trials, Clinical Trial Planning, Conduct And Safety Reporting” held via GoToMeeting platform on June 22, 2021, and was attended by 89 participants.







Glimpses of the training for the Oncology network

Census Enumeration Data Management Training

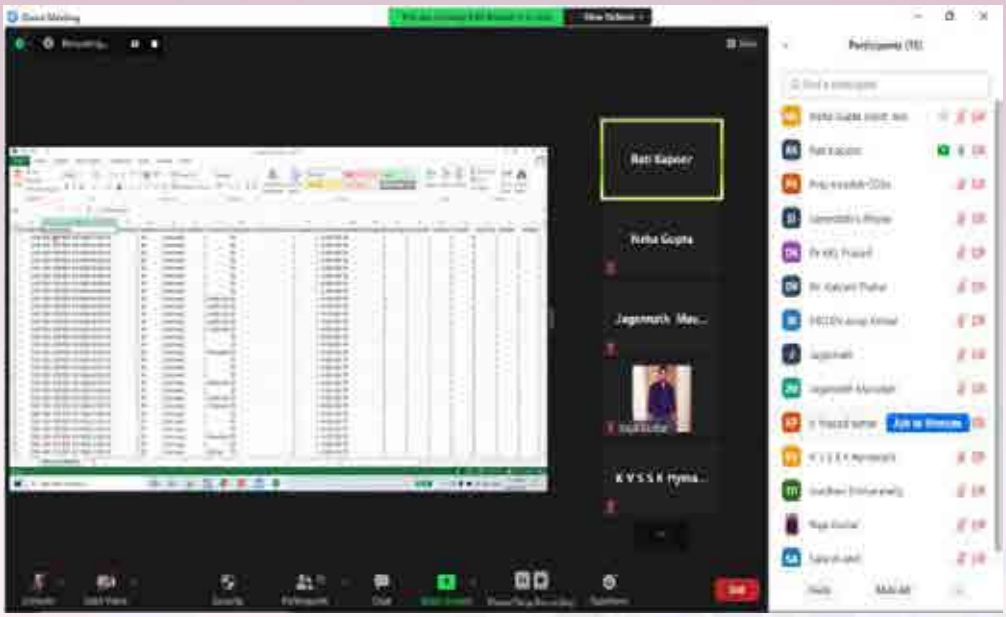
Establishment of new DSS/DHS/DDESS sites within the country to have complete geographical representation of potential trial sites and to study epidemiology of Dengue & Chikungunya in different age-groups at these sites*

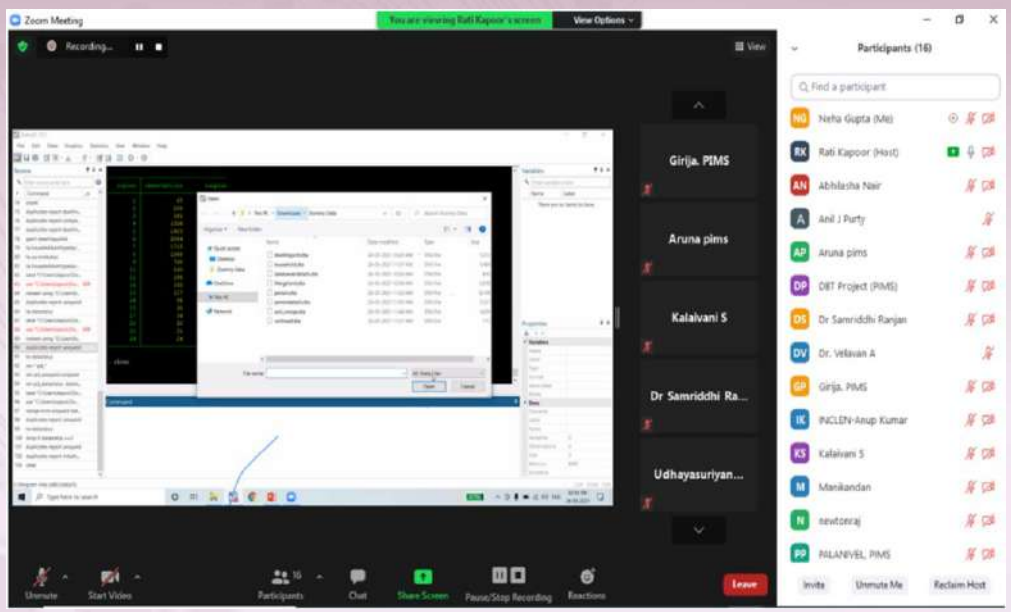
Six (06) new DHS Clinical Trial Network field sites under DBT's Resource of Indian Vaccine Epidemiology Network (DRIVEN) funded under National Biopharma Mission, were trained on Data Management of Census Enumeration by The INCLEN Trust International with an objective to go through the data generated after initial data collection of census enumeration; and to understand the codebook and data merging process in SOMAARTH-1 platform which is developed and maintained by The INCLEN Trust International, Delhi. These data were collected electronically from the selected cohort in the study population. Trainings were conducted with each site individually through a virtual platform from May 20 to 28, 2021 where a total of 52 project staffs including 21 women participated with an intension to make the project staff understand the process of data mining, cleaning and merging for SOMAARTH 1 software.

Details are as under;

S. No.	Site Name	Date	No Of Female Participants	Total Participants
1.	Maulana Azad Medical College, Delhi	May 20, 2021	5	7
2.	Andhra Medical College, Visakhapatnam	May 26, 2021	3	9
3.	Pondicherry Institute of Medical Science, Puducherry	May 26, 2021	2	9
4.	ICMR – Regional Medical Research Centre, Bhubaneshwar	May 27, 2021	1	9
5.	CHRD – Society for Applied Studies, Delhi	May 27, 2021	5	10
6.	The INCLEN Trust International, Delhi	May 28, 2021	2	4
7.	CDSA team	-	3	3
8.	NBM team	-	0	1
TOTAL			**21**	**52**

Re-training planned: A review meeting was held in June 2021 with all the sites to discuss queries related with data cleaning and merging process.





Glimpses of the trainings conducted for DHS sites

Press release on "Department of Biotechnology supported First CAR-T cell therapy conducted at ACTREC, Tata Hospital in Mumbai"

A press release was published on June 08, 2021 depicting the support provided by the Department of Biotechnology (DBT) and the National Biopharma Mission which is implemented at Biotechnology Industry Research Assistance Council (BIRAC), for conducting Phase I/II trial of the CAR-T product of the TMC-IIT Bombay team.

The Chimeric Antigen Receptor T-cell (CAR-T) therapy has emerged as a cancer treatment breakthrough. Clinical trials conducted around the world have yielded promising results in end-stage patients, particularly those with Acute Lymphocytic Leukemia. Despite the fact that this technology has tremendous therapeutic potential for cancer patients, it is currently unavailable in India.CAR-T cell therapy costs approximately 3-4 crores for each patient (INR). The cost of therapy is largely due to the manufacturing complexity.As a result, the challenge is to develop this technology in a cost-effective way and make it available to patients. In the last two years, BIRAC and DBT have taken initiatives and launched specialised calls for proposals to promote and support the development of CAR-T cell technology against cancer and other diseases.

On June 04, 2021, First CAR-T cell therapy (a type of gene therapy) was done at the Bone Marrow Transplant unit at ACTREC, Tata Memorial Center in Mumbai. The CAR-T cells were designed and manufactured at Bioscience and Bioengineering (BSBE) department of IIT Bombay.This work is partly supported by BIRAC-PACE scheme. This is a "first in India" gene therapy in early phase pilot clinical trial and the dedicated efforts and excellent collaboration between IIT Bombay and Tata Memorial Hospital, Mumbai.

Ministry of Science of Technology

Department of Biotechnology supported First CAR-T cell therapy conducted at ACTREC, Tata Hospitalin Mumbai

DBT/BIRAC-NBM Supported Phase I/II Clinical Trials

Posted on: 08 JUN 2021 11:12AM by PIB Delhi

The National Biopharma Mission is also assisting two other organisations with the development of a lentiviral vector manufacturing facility for packaging plasmids used to transfer the modified T cell inside the body, as well as a cGMP facility for T-cell transduction and expansion for CAR T-cell manufacturing.DBT is supporting the development of CAR-T cell technology for diseases such as acute lymphocytic leukemia, multiple myeloma, glioblastoma, hepatocellular carcinoma, and type-2 diabetes.

Ind-CEPI MISSION

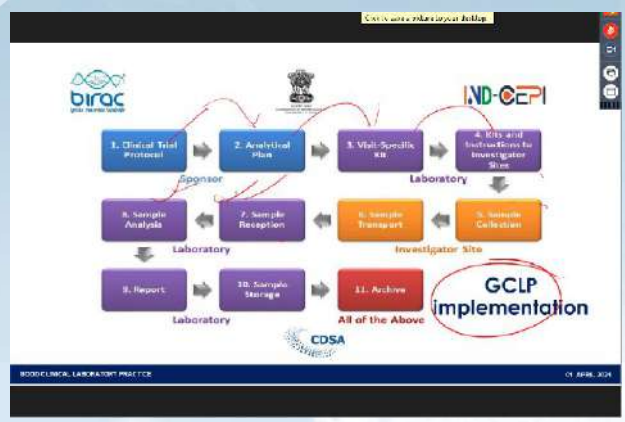
Ind-CEPI: Epidemic preparedness through rapid vaccine development

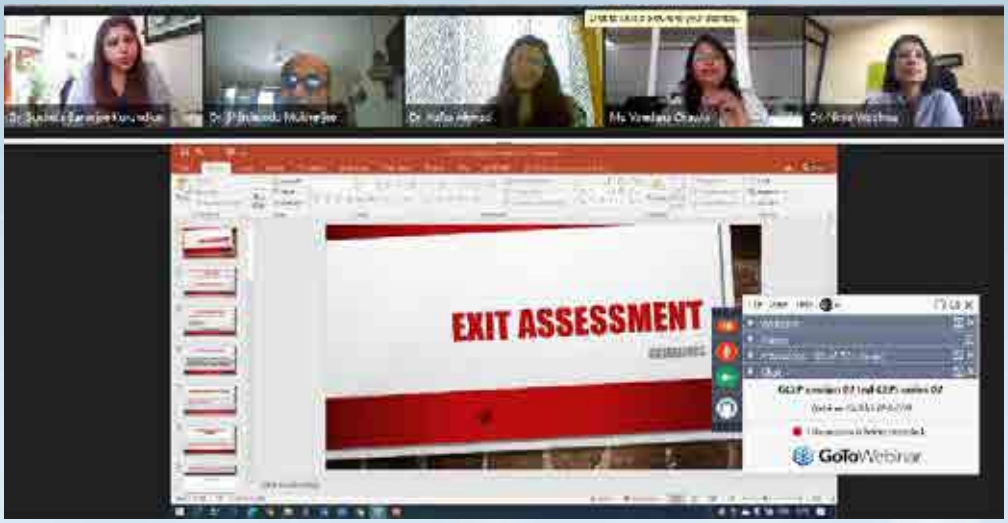
The Department of Biotechnology, Ministry of Science and Technology, Government of India is supporting the implementation of the Ind-CEPIs mission "Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the Coalition for Epidemic 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. After the successful completion of the first E-course series, the MissioninitiatedaneCourse Series entitled"Strengthening Clinical Trial Research Capacity in India's FriendlyCountries" in collaboration with CDSA, Faridabad.An orientation session to this training program was conducted on 21stJan 2021 through online platform. This training envisagesan in-depth coverage of Good Clinical Practice, Ethical considerations in clinical research, Good Clinical Laboratory Practice and Novel vaccine development and immunization policy in a pandemic across a 4 Programs and 10 sessions during 5th Feb to 30th Apr 2021. Each program closes with exit examinations, after which certifications would be issued.

Participating Countries:
Bahrain, Bhutan, Gambia, Kenya, Myanmar, Nepal, and Vietnam

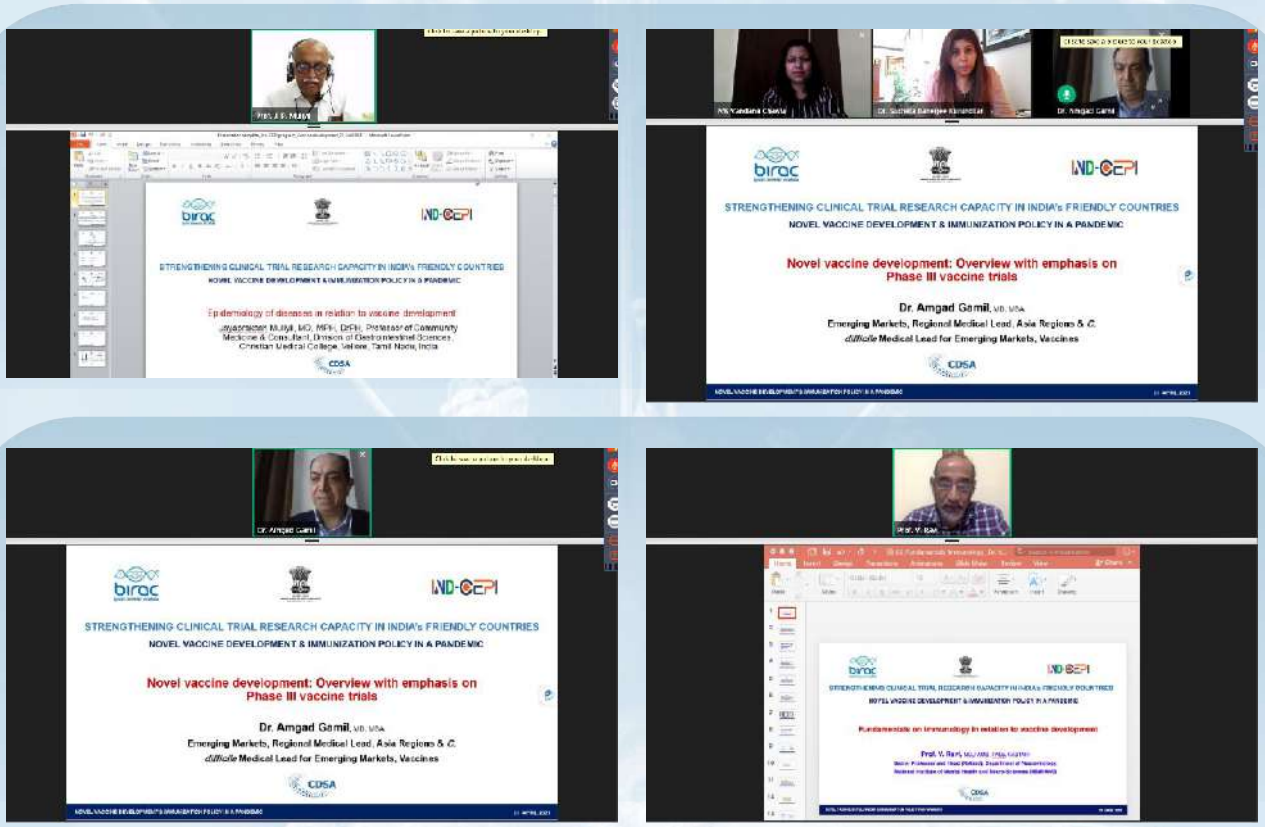
Program 3-Good Clinical Laboratory Practice (GCLP): 2 sessions were held on 1stand 9thApr 2021 that were attended by 158 and 136 participants respectively. Major topics covered included Laboratory Quality Management System (LQMS), GCLP principles andguidelines, infrastructure, equipment, reagents & consumables, sample management: the cradle to grave journey, pre-examination, examination and post-examination procedure, sample acceptance/rejection, discussion on writing SOPs, sample storage & disposal, internal quality control, external quality assessment/ proficiency testing, internal audit, quality indicators, safety in laboratories, ethical considerations, risk management and data management.

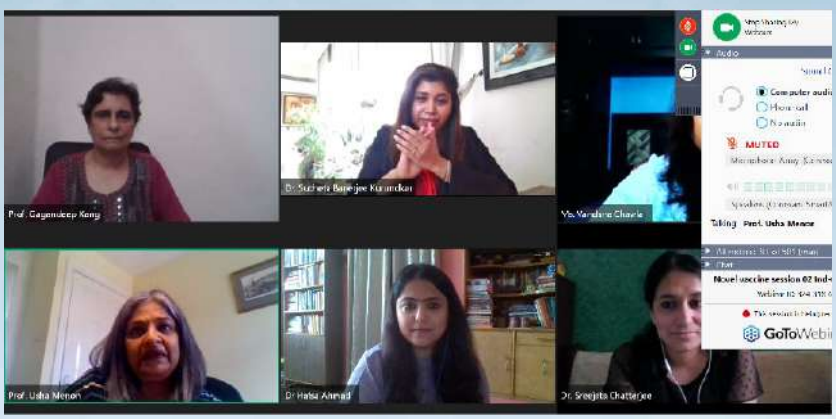




Glimpses from the Sessions on GCLP

Program 4-Novel vaccine development and immunization policy in a pandemic: 2 sessions were held on 23rd and 30thApril 2021; attended by 142 and 117 participants respectively. Major topics covered included introduction to vaccine development, epidemiology and fundamentals on immunology in relation to vaccine development, vaccine pre-clinical development and manufacturing, novel vaccine development: overview with emphasis on Phase III vaccine trials, Good Participatory Practice (GPP): participant screening, eligibility, consent, retention in population-based studies, adverse event following immunization during clinical trials and after licensure, challenges of delivering vaccine trials during a pandemicand public and stakeholder engagement during clinical development and policy impact post-licensure.





Glimpses from the Sessions on Novel vaccine development and immunization policy in a pandemic

1280
Beneficiaries supported

60
Bioincubator's supported

4
Regional & Entrepreneurship Development Centres

₹ 2735 Cr.
Funding support by BIRAC

₹ 1513 Cr.
Industry Commitment

329
Academic Institutes Supported

Ignite Innovate Incubate

₹ 4248
Crore Total funding

10000+
People enhanced skills and accessed networks

640349
sq. ft. of incubation space

250 Cr+
Committed through Equity fund

773
Companies Supported

16
Bioincubators Supported under Equity based SEED fund

297
Patents filed

150+
Products & Technologies

1000+
Start-ups, Entepreneurs and SMEs

For further information please contact:

Biotechnology Industry Research Assistance Council (BIRAC)

1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi-110003, INDIA

Tel: +91-11-24389600 | Fax: +91-11-24389611

E-mail: birac.bdt@nic.in | Web: www.birac.nic.in

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