World Health Organization India

Ministry of Health & Family Welfare

2019 World Conference on Access to Medical Products: Achieving the SDGs 2030

19–21 November, 2019 | New Delhi, India

Posters

General Instructions:

Posters will be displayed from 19-21 November 2019, all day long and presenters should be available during the lunch timing 1:30 pm- 2:30 pm.

The posters to be kindly printed by participant himself/herself. Please adhere to the exact dimensions of 100cm by 75 cm and use the template provided.

- Posters may not contain any commercial/industry logos (as per WHO regulations), only contact information.
- Your poster should include your poster number assigned to you by organizers (will be shared in due course) on the upper right corner.
- All posters must include a Disclosure indicating source/s of funding and any conflicts of interest, if applicable.
- You are responsible for ensuring the high quality resolution poster to be sent in soft copy as well through the website dashboard.
- The poster presentation is intended to communicate information rapidly. It is supposed to represent a well-designed and engaging display of information. Therefore, information must be presented in an easy-to-comprehend way and should be readable from approximately 1 meter away.
- You are responsible for putting up your poster on the day of your presentation, before 08:30 AM. You will be provided with pins and/or tape. For any support regarding the same please approach the registration desk at the venue.
- At the end of the day, you are kindly requested to take down the poster at 18:00. If you do not take down the poster yourself, it will be removed.

Abstracts for Poster Presentation

19 November 2019

Name	Poster Number and date	Abstract
Ms Saisri Akondi, Nidhi EIR Fellow, Venture Center, NCL, India	**01 19 November 2019**	**Sustainable Low Cost Medical Devices Innovation Pathways** The power of exhibiting Frugal Innovations helps in creating a sustainable lifestyle and improving the efficacy of already existing ideas. The key is to create adversity into opportunity and understand the need for the society instead of trying to create your own problems. Observation is a cue for problem solving and resource constraints is not a liability but an opportunity, one that favors agility over efficiency. Frugal organizations donâ€™t seek to wow customers with technically sophisticated products, but instead strive to create good-quality solutions that deliver the greatest value to customers at the lowest cost. Relying solely on in-house capabilities and resources will not work as a strategy. Instead of wasting time and money trying to reinvent the wheel, start-ups must encourage their organizations to effectively crowdsource problems and improve on solutions. While developing Low Cost Medical Devices, there is a pattern which can be seen in innovations which includes the process starting from ideation to product development. It is also necessary for these low cost devices to fit well with the regulatory framework to fit under the safety route. This poster will focus on discussing the innovation pathways/steps to be followed for creating low cost devices.
Mr Pawan Kumar, Fellow, NHSRC, Delhi, India Co-presenters: Mr Pawan Kumar Mr Ajai Basil Mr Mohammad Ameel Mr VigneshWaran PS Mr Aanjaney Shahi Mr Bharat Dahiya	**02 19 November 2019**	**Medical Equipment Radiation Safety Compliance Study Among 12 States/UT In India** Background: Indian Public health standards emphasize on radiation-based diagnostic facilities as essential from Community health center to District hospital. For ensuring radiological safety as well as environmental safety in India, it is mandatory for all the users of x-ray equipment, to obtain license from Atomic Energy Regulatory Board (AERB) for doing any of the diagnostic radiation-related activities. Objective: The aim is to estimate the percentage AERB compliance of x-ray equipment in Public Health facilities till Secondary care in 12 States/UT in India. Methods: Comparative analysis of x-ray equipment from state equipment maintenance dashboards and approved equipment for operation from AERB website. Result: It is found that out of 12 only 3 states (D&N Haveli, Daman and Diu and Puducherry) are having more than 50% compliance. Analysis to identify compliance in each category of medical device (Fixed X-ray, Mobile X-ray, C-

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		arm, CT scan and Mammography) among States/UTs, revealed flat 50% non-compliance in all category of device. The lowest observed was for Fixed X-ray, 31.6% and highest for Mobile X-ray 51.4%. Conclusion: It is found that most of the states, AERB compliance is very less than satisfactory level. Results shows that patient, worker and environment safety associated with radiation-based medical device needs to improvise in India.
Ms Simran Khanijo, Student, Post graduate institute of medical education and research , Chandigarh, India Co-presenter: Ms Simran Khanijo Ms Geetika Arora Dr Gopal Vishwas Ms Gomata Bhusal Dr Ashish Kakkar	**03** **19 November 2019**	**Cost Analysis Of Cardiovascular Drugs Available In The Indian Market: Impact Of Pharmaceutical Price Control** Objectives: We investigated cost variations present among cardiovascular(CVS)-drugs available in the Indian market and compared them among drugs listed in the National List of Essential Medicines (NLEM) and non-NLEM drugs. Methods:We included drugs indicated orally for the management of angina,hypertension,arrhythmias, and heart-failure. The unit drug cost for the selected strengths mentioned in the standard online and offline sources was used to calculate cost per defined daily dose(DDD). Comparison was done among individual drugs and groups(NLEM vs. NNLEM) by cost/DDD in terms of % cost variations and cost-ratios. Results:Significant cost variation was found for the study drugs, with highest in the NLEM group being 3766.6% for metoprolol. Cost-ratios were found to be highest for antianginal drugs(1057.14) and lowest for antihypertensive drugs(84.24). NLEM-drugs were found to be more economical than the NNLEM-drugs except for heart failure. Wide variation was found for both minimum and maximum-cost/DDD for antianginal and antihypertensive medications in the NNLEM group and for maximum cost/DDD for antianginal and heart failure drugs in NLEM group. Conclusions:The study highlights wide variation in the cost of non-NLEM as well as NLEM drugs. There is still room to consider the cost-effectiveness of all classes of cardiovascular drugs during the future revisions of NLEM.
Dr Amit Kondal Scientist-1, National Institute of Pharmaceutical Eduction & Research,India	**04** **19 November 2019**	**Newer approaches and web resources as an application tool in Clinical trials: "A transitional shift in the Pharmaceutical Industry"** Introduction: Clinical drug development (CDP) is visualizing major transformation owing to new digital data sources and computing power to adopt the technological inventions. Pharmaceutical industry still use paper based documentation. We aimed to review emerging software tools for CDP

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Co-presenter: Dr Dipika Bansal		and innovations; virtual trials and digital biomarkers. Methdology: Data was retrieved using publicly available sources; company websites, Crunchbase, TheConferenceForum.org, clinicaltrials.gov.in, 21CFR part11. Results: 6 online databases are available for protocol violations helping in minimizing duplicate enrolments, feedback tools for participants and registration of all past and present clinical trials. 9 web resources have ability to analyze protocols, site selection, deliver investigator training and have eConsenting products. They have an advantage of providing an end to end study platform. 18 web resources provide solutions to recruit patients and apply artificial intelligence to medical records to find patients. 11 web resources integrates data with EDC and provide platform that works across multiple smart devices associated with randomization and drug supply chain. Conclusions: Healthcare companies that support CDP have been slow to adopt technological innovations. With the rise of computing power, and USFDAâ€™s revised stance on digital tools, the software enabled tide is rising. Henceforth we are poised for a transitional shift in clinical research.
Mr Shahrukh Khan M.Tech. Research scholar, IIT BHU (Varanasi), India Co-presenter: Mr Sachin Negi	**05** **19 November 2019**	**An Energy-Effcient Insole: A Wearable Device For Gait Monitoring In Daily Life** Gait analysis plays an important role in medical diagnosis and has numerous applications in rehabilitation, healthcare, sports and therapy. Gait disorder, a major cause of illness in elder people, is one of the primary symptoms of Parkinsonâ€™s disease. Piezoelectric ceramic disc transducer is an active transducer, means it doesnâ€™t require external power supply for the functioning of transducer and also it is a low cost. By applying these ceramic discs on the foot insole system, we can collect the pressure data at specific points on the foot that can be wirelessly collected at remote point by using nRF24L01+ transceivers. Gait variability in the patients with Parkinsonâ€™s disease (PD) and other diseases can be accessed by monitoring stride interval and its two phases- stance phase and swing phase. Keywords: Gait analysis; gait disorder; piezoelectric transducer; wearable foot insole; nRF24L01+ transceivers.
Mr Paras Rajoriya Fellow, National health systems resource centre, India	**06** **19 November 2019**	**Analysis of Maharashtra BMMP programme** As per the observation of our Honorable Prime minister stating that the equipment in various Public Health Hospitals was either unused or not maintained properly thereby resulting in wastage of resources. The Ministry of Health and Family Welfare devise an appropriate mechanism to ensure

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Co-presenters: Mr Mohammad Ameel Mr Anjaney Mr Vertika Agrawal Mr Ajai Basil Mr Vigneshwaran Mr Bharat Bhushan		the maintenance of equipment beyond their guarantee period. A comprehensive guidance document on Biomedical Equipment management and maintenance programme (BMMP) was prepared and disseminated to all states. To ensure the timely availability and proper functioning of medical equipment, BMMP was implemented in Maharashtra in the FY 2016-17. The state monitors BMMP through an online dashboard. Post implementation, there was a increase of 37% equipment from 62085 to 85139. Around 30302 complaints were resolved within the given time period of 7 days from complaint registration.3137 equipments were identified as non-functional during the initial tagging. At present, the BMMP is implemented effectively in Maharashtra as an upkeep of 95% for all equipment. The number of Non-functional equipment till September 2019 is only 258. The state successfully maintained a compliance rate of 99.69% in the implementation of BMMP.
Dr Pavan Asalapuram, CEO, EMPE Diagnostics AB, Stockholm, Solna, Sweden	**07** **19 November 2019**	**Mflodx® - An Innovative Technology For MDR-TB Antibiotic Resistance Profiling** The occurrence of multi-drug resistant tuberculosis (MDR-TB)—close to 600.000 reported cases in 2017 —is a global public health concern. Available tests for the detection of MDR-TB often deliver incomplete diagnoses and are either time demanding or costly. Further, currently used molecular tests require dedicated costly equipment and/or trained personnel. Therefore, rapid and accurate diagnosis of drug-resistant TB is urgently needed to facilitate early detection, restrict disease transmission and the timely onset of effective treatment. Easy to use and affordable diagnostic tools would enable point-of-care testing in high TB burden low- and mid-income countries. EMPE Diagnostics (Sweden) has developed a low-cost diagnostic platform called mfloDx® technology for precise detection of the drug-resistant TB cases (Figure 1) within 2 hours. The mfloDx® technology utilizes specialized probes that amplify specific regions of M. tuberculosis DNA and detect mutations that confer resistance to the most important anti-TB drugs, enabling early-stage effective and personalized treatment.
Mr Shashi Bhushan Sinha, President, Biomedical Society of India, Manipal, Karnataka, India	**08** **19 November 2019**	**Non Invasive Glucometers- Global Partnership For Management Of Diabetes** Diabetes is a chronic metabolic disorder and affects about 415 million people worldwide diagnosed with diabetes in 2015. The complications in unmanaged diabetes lead to serious health problems . It further leads to cardiovascular complications. Evidence demonstrates that diabetes-related complications can be prevented or delayed by maintaining tight glycemic control.. Self-monitoring of blood glucose (SMBG) was shown to be a vital component in achieving this goal. Managing

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		diabetes involves frequent pricking the fingers or taking blood from the blood vessels to see the glucose level in the blood. This is painful and also costly. Non Invasive Glucose monitoring device is a need for self-monitoring of diabetes. Non invasive glucometers are being clinically validated and will be soon be available in the market. One of the technology where the high frequency radio waves are utilised to scan the signals from the ear lobes or finger. The results suggest that the performance does not depend on demographic profiles of its users and it is thus suitable for various people with type 2 diabetes. Another technology analyses the acetones in the breath as acetone generation in the breath is related to the glucose level in the body.When patients blow into the device, it immediately takes a reading of the acetone level in their breath which is correlate to a blood glucose level. Early clinical results show clear correlations between blood glucose levels and breath acetone, according to the researchers. Global participation is required for adopting the innovative technologies of Non Invasive Glucose Monitoring so that it can be upscaled and is affordable and accessible to the global community.
Dr Kalaiselvan Vivekanandan, Principal Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad, India	**09 19 November 2019**	**Vigilance For Medical Products** Title: Medical Devices Adverse Events Reporting in India: Current status Author/Speaker's Affiliation: Dr. V. Kalaiselvan, Principal Scientific Officer, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India, Ghaziabad The Materioviglance Programme of India (MvPI), a system to monitor the safety of medical devices is managed by Indian Pharmacopoeia Commission-National Coordination Centre (IPC-NCC). The MvPI has been set up in line with Pharmacovigilance Programme of India, by identifying the hospitals/teaching hospitals as Medical Devices Adverse Events Monitoring Centres (MDMCs). The IPC provides necessary administrative, logistic and technical support to the MDMCs to establish the system and foster the culture of reporting. The tools for medical devices adverse events reporting/surveillance system such as customized reporting form, field safety corrective action form, voluntary recall notification form have been developed. The NCC-MvPI continuously assesses the adverse events associated with the use of medical devices; the current trends of reports reveals that majority the reported events are due to clinical conditions of the patients and procedural errors. Further, continuous monitoring /surveillance and assessment are essential in ensuring the safety of medical devices.

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Shweta Sharma, ScientisT C, Indian Council of Medical Research, India Co-presenters: Dr Shweta Sharma Prof Rajib Dasgupta Dr Ravinder Singh	**10** **19 November 2019**	**Through The UHC Lens: Role of Assistive Health Technologies And Devices For NCDs, PwDs And Ageing Population In India** A growing body of evidence suggests that owing to global demographic and epidemiological transition NCDs, ageing and injuries will continue to show an upward trend. Following the trail, will be a manifold rise in disabilities and functional impairments. WHO points out that 90% of the Persons With Disabilities (PWDs) have no access to Assistive technology (AT). Assistive technology â€˜enables people to live healthy, productive, independent and dignified lives, promoting participation in education, the labour market and social lifeâ€™. In absence of adequate financial support to afford or maintain assistive devices and technology, result is social exclusion, poverty, and increasing support needs from their families and society and loss of national productivity. The 71st World Health Assembly deliberations focused on 2030 agenda for SDGs. It was reiterated that all signatory countries and India being one of them should work towards leaving no one behind, rendering SDGs for UHC relevant for all health provisioning needs including those who require devices such as ATs This paper illustrates the relevance in foresight of strategizing and aligning our research and programmatic goals in identifying and addressing the current challenges and making health service systems prepared with scientific evidence of making our systems responsive to the goal of providing quality health for all under UHC. In order to step closer to the â€œtriple billionâ€ targets that are at the core of WHOâ€™s strategic plan for the next five years: one billion more people benefitting from universal health coverage (UHC); one billion more people better protected from health emergencies; and one billion more people enjoying better health and well-being, assistive technologies are the need of the hour as they are required by those who are suffering from functional impairments associated with varied disabilities, ageing and non-communicable diseases

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Prof Sangeeta Abrol, Deputy Director General, ICMR, New Delhi, India Co-presenters: Prof Sangeeta Abrol Dr Ravinder Singh	**11** **19 November 2019**	**Positioning of ATs in Health** With futuristic vision and ageing of the population, use of assistive technologies (ATs) will become inclusive in our health policies. This shall decrease the burden on our country, by making them work to their full potential and ultimately making them self-sufficient.
Dr Nidhi Singh, Scientist C, Department of Health Research, India	**12** **19 November 2019**	**Pathways Towards Development of Molecular Diagnostics Innovation System In India: Analysis of Issues And Challenges** The complex technological nature of Molecular Diagnostics (MDs) scientific landscape shows clearly that the performance of innovative actors depends considerably on the organisational structure and institutional rules and policy apparatus of the State. The level of organisational linkages and interdependencies is found to have significant impact on the nature of innovation effort by the MDs actors. Being an emerging biomedical scientific field, the creation and diffusion of MDs knowledge to meet country specific health challenges is found to be depended upon building an effective inter-active explorative learning and competence building under resource poor economic context. The study finds that innovative actorâ€™s effort towards knowledge creation and development is hampered through the presence of several system failures. There is lack of thrust towards creating exploratory learning, valorisation and applied scientific research in MDs. The thrust towards Translational research from research lab to clinical laboratories involving multi-disciplinary fields is found to emerge considerably late in India. Some of the major barrier for inadequate socially responsible scientific research is the failure to engage and collaborate with industry and other academic research organisations. The absence of targeted research and inadequate fund mobilization create unfavorable environment for knowledge creation at both scientific and industry segment.
Mr Ramakrishna Pidaparti,	**13** **19 November**	**Global Regulatory Convergence through Harmonization**

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AVP, L&T Technology Services, Peoria, IL, United States	**2019**	Medical Device Regulations globally are undergoing lot of changes to adapt to a new common theme of Total Product Life Cycle approach that ensures Safety, Efficacy and Performance of the Medical Devices all through their life, for patients, supported by robust Clinical evaluation to maintain the Benefit Risk ratio of the device continuously in near real time. Evolving new technologies, especially Software as a Medical Device coupled with Artificial Intelligence and Machine Learning lead to new Quality and Compliance requirements, especially Cyber security, as important patient data moves around that can impact safety and privacy. To comply with these common requirements, Global Medical Device Manufacturers need good harmonized regulations and standards soon, to ensure easy access to the Medical Products for patients in local geographies. This requires substantial collaboration among global regulators, Notified Bodies and Manufacturers to create frameworks that makes it least burdensome for Medical Device Manufacturers for compliance to ensure easy access to Safe and Effective Medical Products that perform well over time for their intended use. This will need collaboration of competing Medical Device Manufacturers to expedite the finalization of the new framework to make it operational for easy access to safe and Medical Products for patients.
Dr Shashi Gogia President, SATHI, India	**14** **19 November 2019**	**Home based care for Filarial and other forms of Lymphedema** The Global Program for Elimination of Lymphatic Filariasis (GPELF) has been languishing more the MMDP component - which at least in India constitutes only leg washing, has not delivered outcomes. Alongside Lymphoedema is now estimated to effect between 100 - 300 million across the globe - including in advanced countries due to other causes like cancer, obesity, trauma, venous disease, old age etc. SATHI has been coordinating with many agencies like AIIMS, Delhi, and Bhubhaneshwar, Goa Medical College as well as other places to do research as well as create an a cost effective home based care program for Lymphoedema. We believe that Lymphoedema beyond a certain stage, ven following Filariasis behaves like a chronic disease which carries on relentless whatever the initial cause. A community based group care approach has been developed which needs only a small investment not so much in the materials - which are very much affordable and can be made even more so if do mass production, but in the personnel who need knowledge and training. They can even be village level volunteers as well as entrepreneurs. We have done programs at the village level and shown outcomes as good or even better.

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Dr Ranjna Dutta, Director, Excel Matrix bio limited Co-presenter: Dr Aroop Dutta	**16** **19 November 2019**	**Nanoscale ECM Mimicking For Ex Vivo Tissue Modelling** Cells co-exist with their extracellular matrix (ECM) microenvironment that is mainly constituted of bio-polymers like collagen, glycosaminoglycans and proteoglycans organized as woven fabric. Similar to fabric, multiple compositions are possible based on the type, length, branching and other possible variance of these molecules, which eventually impart specificity to different organs and tissues. It is well recognized now that cells have a dynamic relation with their immediate microenvironment through which their fate could be controlled to a great extent. Precision of studying and supporting biological processes therefore relies on faithful and efficient reconstitution of in vivo like ECM microenvironment. 3D scaffolds with optimized porosity that provides physical space similar to ECM have proved fundamental in yielding tissue like cell mass. Numerous fabrication processes are now available that promise to generate matrix for 3D culture. However, optimized control over functional and mechanical attributes of matrices for specific tissues is still a challenge in Tissue engineering and Regenerative medicine.
Mr Md Sahidul Arefin Audiologist and Speech Language Pathologist, IPGMER and SSKM Hospital, India	**17** **19 November 2019**	**Detection of auditory dysfunction in early prevention for pediatric population with acoustic based Poly (VDF-TrFE) nanofiber sensor** Auditory dysfunction in early days of infants increased absolute number of cases globally. Sensor based applications to detect early stage dysfunction of infant is gaining global interest. Development of numerous acoustic sensors has already been started based on various transducing principles such as piezoelectricity, piezo-resistance, piezo-capacitance and piezo-optics. Piezoelectric polymer based acoustic sensors are distinct from the others in that they have higher sensitivity with flexibility and can be processed into wide geometries. In particular, Polyvinylidene Fluoride-co- Trifluoroethylene (PVDF-TrFE) nano fibres sensor fabricated by electrospinning has shown significant mechanical energy to electricity conversion ability. In this work it is demonstrated that electrospun poly (VDF-TrFE) nano fibres have a strong acoustic- to-electric conversion ability within the audible range of infants and can detect the acoustic response of infant's sensory unit. In addition, region of low response or no response can also be detected by this sensor with better accuracy comparable with other sensors. Utilizing poly (VDF-TrFE) as a standard β-phasic perovskite polymer with a sensing assembly that transfers convergent sound directly to the nano fibre

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		layer may be useful for developing high-performance acoustic based bio medical sensors for point of care applications in pediatric cases. Keywords: Auditory dysfunction, Auditory sensor, Pediatric sensor, Portable sensor, Point of care sensor.
Dr H. Purushotham, Chairman & Managing Director, National Research Development Corporation, Delhi, India	**18** **19 November 2019**	**Role Of Intellectual Property In Transfer Of Health Technologies : Indian Experience** Role of Intellectual Property in Transfer of Health Technologies : Indian Experience Dr. H. Purushotham, Chairman & Managing Director, National Research Development Corporation 20-22, Zamroodhpur Community Centre Kailash Colony Extn. New Delhi - 110048 Abstract Intellectual Property Rights (IPRs) and Technology Transfer are the key drivers for growth of the highly knowledge intensive health technologies. Indiaâ€™s health technologies including bio-technology industry to reach the ambitious target of US$ 100 billion by 2025 perhaps may be a daunting task without giving adequate thrust to promotion of IPRs and technology transfer management issues. In order to promote IPRs and technology transfer, in the country, Govt. of India established National Research Development Corporation (NRDC) under the administration control of Department of Scientific & Industrial Research, Ministry of Science & Technology. NRDC is primarily engaged in the development, promotion of Intellectual Property Protection and transfer of technologies including health technologies like medical devices, medicines, vaccines and systems emanating from various national R&D labs/institutions/universities in the country and acting as an effective catalyst in translating innovative research into marketable industrial products/processes and services through its unique value added services. NRDC has the largest repository of Indian technologies and licensed about 5000 technologies to entrepreneurs/ SMEs/ start-ups / corporates and filed over 2000 patents in India & abroad. In this presentation the value added services being offered by NRDC for making the early stage innovations (TRL 1-4) in to a matured and ready for commercialisation (TRL 5-8) stage technologies and the mechanisms of technology transfer will be presented with few health technology case studies.

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Mr Nitesh Jangir Co-founder and Director, Coeo Labs, India	**15 20 November 2019**	**The Process And Framework of Innovating Medical Technology For Low Resource Settings** Most of the low resource countries have limited access to medical technologies. Most of these medical technologies are not designed for the low resource settings and besides being of the high cost they do not deliver the optimum care in these environments. There is a huge need for medical device innovation done by the collaboration of local engineers and clinicians but often there is a lack of training in medical technology innovation process. This presentation is about an innovation framework derived from the successful Stanford biodesign process. This process has been validated and successfully applied in multiple countries in low resource settings and got innovative medical products which are saving lives in low resource settings. This process involves need identification, product innovation and commercialization aspects of the medical technology development program.
Dr Md Ashrafuzzaman, Major (Associate Professor),	**19 20 November 2019**	**Inevitability for Establishment of Medical Device Testing Center (MDTC) to achieve healthcare SDG in Bangladesh by 2030**

Military Institute of Science and Technology, Dhaka, Bangladesh		The Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh is the Drug Regulatory Authority of the nation, has circulated and implemented a medical device registration guideline in 2015. Several documents intended for registration have been looked into and endorsement and approval were given through the administrative specialized technical committee for medical devices. A national guideline for the medical device manufacture and equipment assembling are in advancement but to distribute by the DGDA following other universal rules including ISO and IMDRF by 2019. With governmentâ€™s recent initiative, only 5790 CET and a mere 203 BME/CE exist in country for a population of 167 million. Further, these CE/CET professionals are yet to certify. Since the population of Bangladesh is anticipated to be 194 million continuously 2030, more than 62,000 BME/CE/CET will be required to fulfill the developing need of social healthcare infrastructure. At that stage it would not be possible for DGDA alone to supervise the medical devices with proper management during registration, inspection during import, quality product while manufacturing. Foundation of a Medical Device Testing Center (MDTC) in Bangladesh will be obligatory in near future. It is evident that drastic measures are required for Bangladesh to develop its own self-sufficient workforce consisting of biomedical engineers. A devoted MDTC workforce can fill these gaps right away for accomplishing the global Sustainable Development Goal in healthcare sector by 2030. This shall promote identification, recipe formulation, and regulation of medical device manufacturing, testing of devices with accepted quality and standard, which will implement timely quality control and upgrade the overall HTM in Bangladesh. The accessibility of these administrations by MDTC at all 64 districts of Bangladesh will empower the accessibility to quality control of medical devices, allowing no compromise with healthcare.
Mr Dinesh Songara State Program and Technical Head, Lords Education & Health Society (LEHS|WISH), India	**20** **20 November 2019**	**Evaluating the feasibility of rolling out universal hearing screening for infants in India using SOHUM, an artificial intelligence-driven low cost innovative diagnostic solution** This prospective study was undertaken with an objective to measure agreement between SOHUM, an artificial intelligence-driven low cost innovative diagnostic solution, and the conventional Brainstem Evoked Response Audiometry (BERA) on various parameters of diagnostic importance and to investigate the feasibility of SOHUM as a universal hearing screening modality in India for neonates and infants. Our results statistically validate that the waveform generated by SOHUM is clinically at par with that generated using BERA. Moreover, SOHUM smartly obviates existing challenges to universal hearing screening implementation in India such as huge infrastructural requirement, limited capacity of frontline health workers, and high costs of contemporary hearing screening modalities such as conventional BERA. Additionally, as an implementation of SOHUM

		scales up across geographies and diverse demographic segments, its artificial intelligence-driven diagnostic algorithm would progressively become more robust and efficient.
Dr Dipika Bansal Assistant professor, NIPER, India Co-presenters: Dr Dipika Bansal Mr Chandrasekhar Boya	**21** **20 November 2019**	**A Systematic review and meta-analysis of Prevalence of antibiotic use in India** Antimicrobial resistance accounts for the greatest threat to the health system. Countries with high per-capita antibiotic consumption have higher rates of antibiotic resistance, which in turn threatens our ability to treat infectious diseases. Hence systematically reviewing the prevalence of antibiotic usage in India is helpful to curb this menace. Electronic databases PubMed, Embase, Medline were searched to identify the studies that reported antibiotic usage in India irrespective of healthcare setting. Meta-analysis was performed using R software. Antibiotics usage was stratified according to location, age, wards and healthcare level. Thirty studies met the eligibility criteria and 49889 subjects were pooled. Antibiotic usage pooled prevalence rate (PPR) ranged from 14-94%. Random-effects overall pooled prevalence was 61.6% (95%CI 52-70%). PPR was higher in private (68%; 95%CI 55-82%) compared to government hospitals (56%; 95%CI 44-69%). Central India (67%; 95%CI 64-70%) have higher prevalence compared to south (58%; 95%CI 45-70%) and north India (59%; 95%CI 40-77%). Outpatient PPR is less (56%; 95%CI 37-69%). Compared to inpatient setting (65%; 95%CI 59-70%). This study concludes that the prevalence of antibiotics is very high in India. It is recommend that all health-care professionals prescribing antibiotics take responsibility and understand the adverse consequences of inappropriate and over antibiotic usage.
Dr Deepika Murugesan Scientist-C, Bioethics Unit – ICMR, India Co-presenters: Dr Deepika Murugesan Dr Roli Mathur	**22** **20 November 2019**	**Artificial Intelligence in Healthcare in India - Ethical Considerations** Artificial Intelligence (AI) is percolating our lives at a rapid pace across all sectors with a vision of automation of the globe. AI machine learning works on the principle of Deep Neural Network (DNN) which interprets input data in a complex algorithm comprising of 5-1000 hidden layers to give an output. Although at the face value, the technology is said to eliminate human errors and improve efficiency, there is a need to oversee its real world performance and safety. Several AI prototypes have been implemented in several hospitals across India with little accountability due to the lack of a regulatory body to authorise them. Most of these proprietary systems are of foreign origin with access to sensitive health information of the Indian patients. This review aims to perform a thorough

		analysis of the pertaining cases in India with detailed breakdown of our existing regulatory networks that will lead to an understanding of the ethical considerations in implementing AI in healthcare. This will further pave way for the development of a progressive yet, safe framework to protect the values and interests of the Indian citizens.
Dr. Manjunath MD,DM, Assistant Professor, Dept. of Clinical Pharmacology, ACTREC, Tata Memorial Hospital, Navi Mumbai	**23 20 November 2019**	**Role Of Quantitative Pharmacology In Patient Management** Pharmacometrics combines principles from pharmacology (pharmacokinetics and pharmacodynamics), statistics, and computational modeling to support drug development and optimize the use of already marketed drugs. Various applications of pharmacometric models are: • Provide a quantitative understanding of the desired and adverse responses to drugs, and their relationships to exposure and long-term clinical outcome. • Useful in comparing candidate biomarkers through quantification of their relation to drug exposure and clinical outcome. • Help in early identification of patients who are most likely to benefit from treatment. • Pharmacometric clinical trial simulations help to reduce cost of clinical trials. • Improves attrition rates in drug approvals • Used to study the differences in drug response w.r.t. ethnicity and race in order to make the best estimate of genetic variability. • Aids clinician in optimizing treatment in routine clinical practice by tailoring the treatment to suit the appropriate subpopulation of patients, or in deciding the right dose for therapeutic efficacy, or in identifying a companion diagnostic or predictive biomarkers for faster clinical intervention in the specific patient population. In our institute, we did undertake these pharmacometric based dose optimization studies and provided individualized dosing strategies for drugs like rituximab, pemetrexed, paclitaxel, docetaxel, MMF, 6-MP and Meropenem.
Prof Rajiv Janardhanan, Director & Head, Amity Institute of Public Health, India	**24 20 November 2019**	**Inferring CVD Anomaly from ECG** ABSTRACT: WHO reports that Cardiovascular diseases(CVDs) including coronary heart disease and stroke cause an estimated 3.7 million deaths or a quarter of all deaths annually(2.0 million among males and 1.7 million among females) in South-East Asia Region indicating that it is an unmet clinical need and an emergent public health issue of enormous proportions. This forms the

Co-presenter: Prof Priya Ranjan		premise to design and develop a platform-agnostic diagnostic system using ECGs collected from Indian patients for learning and classification algorithms. The proposed digital health platform has the ability to interpret the ECG reports automatically and even rank different CVD conditions from NSR (Normal Sinus Rhythm) to MI (Myocardial Infarction) or even Tachycardia and will help in provisioning of affordable and accessible healthcare options to marginalized sections of the society. It offers tremendous opportunity to be used as an aid to the Cardiologists/Medical Professionals for automatic classification, enhanced visualization and precision oriented interpretation of ECG traces. A large scale testing is needed to ascertain the real life validity of these tools and how they should be deployed. Further, this work is adding new dimensions by learning psychosocial aspects from the community which is a work in progress. Keywords: Electrocardiograph (ECG), Earth Movers Distance (EMD), Cardiovascular Diseases (CVD), Automated Diagnosis, Myocardial Infarction, Tachycardia We have developed modern technology to detect CVD anomalies and it should be shown in action to understand its usage in reality.
Ms Aarti Halwai, Student/Research Ethics Scholar, Yenepoya University, Mkarnataka/Mangalore, India Co-presenters: Dr Vina Vaswani	**25** **20 November 2019**	**Does India Need CHIM Studies** Global Burden of disease study (2010) estimates that India contributed to 34% of dengue infections.[5] Typhoid contributes to 20% of disease burden and flaviviruses transmitted by mosquitoes infect 400 million each year.[7] India ranks fourth in the world in malaria (Lancet Commission 2019 report). Controlled Human Infection(CHI) studies can reduce disease burden. Exposure of volunteers to infectious agents being aimed in the development of effective vaccines or treatments in a controlled set up by using specific strain, standard dose and route of administration. Smaller sample size, time required and possible reduced cost are the advantages with CHI. A CHI study involving 20 healthy volunteers to evaluate the induction of immunity and protective efficacy of anti-tuberculosis BCG vaccine against a controlled human malaria infection[3] has revealed that vaccinated volunteers showed early clinical symptoms with reduced parasitemia as compared to controls. Introduction of CHI studies in developing country like ours will need capacity building in Clinical infrastructure, transport, diagnostic investigation/treatment[4], and regulatory framework. CHIM model does expose the participants to risk, but it is not disproportionate. As we move ahead with innovations it is our extended duty to do research in the field, which will open doors for better treatment, care and safeguard equity.

Dr Vijesh Sreedhar K, MD, Scientist E, Vector Control Research Centre (Indian Council of Medical Research), INDIA Co-presenters: Jambulingam Purushothaman Subramanian Swaminathan Nanda Bhaskar Srividya Adinarayanan Krishnamoorthy Kalianagounder	**26** **20 November 2019**	**Safety, Efficacy, Effectiveness And Acceptability Of Co-Administration Of Ivermectin, Diethylcarbamazine And Albendazole Compared To That Of Diethylcarbamazine And Albendazole For Lymphatic Filariasis Elimination: An Open Label Community Study In India** **Objectives:** Drug regimens with better efficacy than that of the current regimen (diethylcarbamazine and albendazole, DA) used in mass drug administration (MDA) for lymphatic filariasis (LF) can accelerate the progress to elimination. This study evaluated the safety, efficacy, effectiveness and community acceptability of a newer triple drug regimen (ivermectin, diethylcarbamazine and albendazole, IDA) for LF elimination. **Methods:** This two arm (IDA and DA arms) open label community study was conducted in selected LF endemic villages of Yadgir, Karnataka as part of the multi-country studies (India, Indonesia, Haiti, Papua New Guinea and Fiji). Study villages were block randomized to either arm. Participants were tested for filarial antigenemia and microfilaraemia and MDA with IDA or DA were carried out. Participants were actively followed up for adverse events (AEs). Acceptability of MDA was assessed by a community survey (qualitative and quantitative). Infected individuals were re-tested after a year for efficacy assessment. A community prevalence survey was done to assess effectiveness. **Results:** 4787 participants received IDA; 4273, DA. Baseline antigenemia and microfilaraemia rate was 26.4% and 6.8% in IDA arm and 24.2% and 6.2% in DA arm. AE rates were 8% in IDA arm and 6.2% in DA arm(P<0.05), more common among persons with filarial infection. No serious AEs occurred and all AEs resolved with symptomatic management. Complete clearance of Mf was observed in 84% and 62% of Mf positives in IDA and DA arms respectively(P<0.05). Community Mf prevalence reduced from 6.8% to 3.5% in IDA arm and 6.2% to 5.4% in DA arm(P<0.05). Mean acceptability score of treatment was 27 and 26 in IDA and DA arms respectively, well above the acceptable critical level of 18. **Conclusion:** IDA was safe, acceptable to the community and had superior efficacy and effectiveness. Based on results from multiple countries, WHO has recommended IDA as an alternative MDA tool in special situations.
Mr Chandranand PS, Scientist, National Institute of Biologicals, Noida, Uttar Prtadesh, India	**27** **20 November 2019**	**Role Of NIB As "Support Cell For WHO Pre-Qualification Programme For In-Vitro Diagnostics"** National Institute of Biologicals (NIB) is one of the support cells for implementation of World Health Organisation Pre-Qualification Programme (WHO-PQ) for in-vitro diagnostics in India. NIB's frequent interactions (three interactions) with indigenous stakeholders in strengthening their in-

Dr. Reba Chhabra, Dr. Harish Chander, Dr.Richa Baranwal, Dr.Madhur Gupta, Dr. Gaby Vercauteren		house Quality Control (QC) activities have consistently echoed issues pertaining to the lack of basic understanding of the WHO-PQ programme in totality. Issues such as programme fee, understanding of the PQDx formats and CTD modules with regard to WHO-PQ, abridged PQ, non availability of global QC panels / reference standards, assessment and change assessment target timelines etc have been the bottlenecks, thus keeping the indigenous manufacturers in a wait and watch mode. Having understood the issues that these manufacturers are facing, NIB with assistance from relevant experts from WHO country office – India, Global Office-Geneva, the National Drug Regulatory Body-Central Drugs Standards Control Organisation (CDSCO), the industry interface agency-Biotechnology Industry Research Assistance Council (BIRAC-DBT), National Biopharma Mission (NBM-DBT), NIB's role in facilitating the indigenous stakeholders and as a support cell for successful implementation of WHO-PQ programme has gained enthusiasm and participation from the industry partners Association of Indian Medical Device Industry (AIMED), Association of Diagnostics Manufacturers of India (ADMI) and indigenous stakeholders. NIB Support Cell is also involved in creating awareness to indigenous stakeholders for participation in WHO-PQ requirements. In its frequent interactions with these stakeholders: Observations and outcomes of the two meetings held at NIB are: a. Requirement of global panels for internal Quality Control testing. b. Facilitation in pre-submission PQDx15 format, Preparation & Review of Product Dossier as per PQDx_018. c. NIB has developed a template to collate information for building up a database with regard to readiness for participation in WHO-PQ. d. Requirement of joint trainings from both WHO & CDSCO.
Mr Chandranand PS, Scientist, National Institute of Biologicals, Noida, Uttar Prtadesh, India Co-presenters: Mr Chandranand PS* Dr. Reba Chhabra Mrs.Sudha.V.Gopinath Dr.Madhur Gupta	**28 20 November 2019**	**Advantages Of An In-House Developed Cost Effective Laboratory Information Management System (LIMS) In A Regulatory Environment** The National Institute of Biologicals (NIB), NOIDA is an autonomous Institute under the administrative control of the Ministry of Health & Family Welfare, Government of India. The mandate of the Institute includes ensuring provision of quality biological drugs i.e. In-vitro diagnostics, Vaccines and Biotherapeutics, including therapeutic monoclonal antibodies used by patients suffering from cancer and autoimmune diseases by undertaking high end science based testing with R&D interface for application of science. Quality Control (QC) Testing Laboratories like NIB, that have added responsibility as a National Control Laboratory supporting the National Drugs Regulator, across the globe face the continuous

		challenge to cut high investments, contrive lab output and improvise the quality of data with complete traceability to its life cycle and audit trail. Initially it is important to understand the role of each laboratory, its functions and work flow to exhibit, the potential of each of these laboratories. The challenges are managing time, available resources to improvise data quality, remove transcriptional errors, data integrity of laboratory results, turn-around time, and automation of laboratory work flows. Most of the laboratories aspire to improvise their data quality; but are not specific on investing in cost-effective process automations like Laboratory Information Management System (LIMS) to manage their laboratory workflow and data quality. Those having LIMS are not future ready with regard to advancements in information technologies. Majority of the laboratories habitually continue to use hand written records, spreadsheets, self-made in-house data management systems, or a combination of these to manage their data, not recognizing the disadvantages of using these traditional and primitive data management practices. Here, we try to highlight the challenges faced by QC testing labs like NIB, repositories and how switching to a cost-effective Artificial Intelligence based LIMS can help to improve laboratory output by automating various workflows.

Ms Poornima Arun Kumar, Managing Director, Hemex Dx, Bangalore, Karnataka Presenters: Mr Pramendra Hitkari	**29** **20 November 2019**	**Performance Of A Novel One-Minute, Portable Diagnostic Test To Detect Malaria Parasites In India** Malaria remains a major public health concern in India and the epidemiology differs across the country. India has greatest Plasmodium Vivax burden than any country. According to National Vector Borne Control Program (NVBCP) P. vivax constitutes one third of all malaria cases in India. The mainstay of malaria diagnosis has been microscopic examination of blood and more recently, rapid diagnostic tests (RDTs). Given the practical limitations of microscopy, RDTs and nucleic acid-based detection strategies such as PCR, it is noted that significant gaps remain in diagnosis of malaria for efficient population-based management programs. There is an acute need for improved malaria diagnostics that are not only affordable but also rapid, easily administered, and highly accurate, that detect species and strains that other diagnostics may miss, such as P. vivax and P. falciparum with HRP2 deletion. In this study, we evaluated the performance of Gazelle TM , a point of care malaria diagnostic device which employs the principle of Magneto-Optical Detection (MOD) to detect hemozoin (a paramagnetic by-product of all malaria parasite species) in symptomatic blood samples for diagnosis of malaria at Kasturba Medical College, Manipal in India. Primary species in this study is P. vivax. The study is still ongoing. So far 95 patients have been enrolled. All the samples were tested with Gazelle as well as RDTs and compared with microscopy. PCR results are pending, and they will be presented at the conference. Preliminary results from this study showed very promising results for Gazelle with excellent sensitivity (100%) and specificity (97%) for P. vivax. There is no variation in the parasite counts for venous blood draws and finger prick samples. Gazelle TM may be an alternative potential diagnostic solution for settings where there is a need for speed, accuracy and ease of use.
Ms Ankita Dutta Intern, WHO-SEARO, India	**30** **20 November 2019**	**Availability of essential medicines in four countries of WHO South-East Asia Region** Access to essential medicines is key for providing quality health services and achieving Universal Health Coverage. The monitoring of medicine availability is not regularly performed by most countries in the region. The objective of our study was to assess essential medicines availability from large health facility surveys conducted in selected countries in South East Asia. Methods: We performed a secondary analysis of medicines availability data reported in recent Service Availability and Readiness Assessment (SARA) and Service Provision Assessment (SPA) surveys (as part of Demographic Health Surveys, DHS) in four countries; namely Bangladesh, Myanmar, Nepal, and Sri Lanka. Results: We observed an overall lower than the 80% availability in the public facilities compared to that in the private facilities for all countries, except Sri Lanka. The low availability of

		medicines needed for the management of non-communicable diseases was common in Bangladesh, Myanmar, and Nepal which is particularly a cause for concern, in light of the rapidly increasing burden of these chronic diseases. Conclusion: Our findings underscore the urgent need for improving the availability of essential medicines, especially at the primary care level by improving financing, procurement, and distribution systems to ensure sustained access.
Dr Sucheta Banerjee Kurundkar, Director Training, CDSA, THSTI, Faridabad India	**31** **20 November 2019**	**Human Capital Investment In Regulatory Science** The knowledge of current regulatory requirements can empower people to bring innovations from bench to bedside faster. CDSA is engaged in enhancing this human resource development in India through its various outreach initiatives. These include but not limited to new drugs, medical devices, in vitro diagnostic (IVD) kits, biopharmaceuticals, phytopharmaceuticals. CDSA has adopted a hybrid model to maximise its possible outcome through online courses, face-to-face programs, live streaming of interactive sessions, etc. All programmes involving dissemination of information on regulatory issues was with strong support from the Indian drug regulators, CDSCO (Central Drugs Standard Control Organisation). During 2019, CDSA launched online courses (clinical trials; medical devices and IVD) in collaboration with NPTEL-IIT Madras and CDSCO that were attended by 1047 (217 passed) and 657 (96 passed) participants respectively. An interactive meet on New Drugs & Clinical trials Rules: Its understanding and impact was attended by 371 participants from 175 institutions. This meet was live-streamed for a wider outreach across the globe. A national six face-to-face workshop series on regulatory compliance for accelerating innovations received wide media coverage. It was attended by 648 participants from 360 institutions. More than 50 CDSCO officials contributed to this initiative. All the above outreach platforms were offered at no cost to registered participants.
Dr Balu Venugopal, Scientist C, Department of Health Research, India Co-presenters: Dr Sujata SInha Mr Yogesh Kumar	**32** **20 November 2019**	**National Ethics Committee Registry For Biomedical And Health Research (NECRBHR)** Ethics Committees (ECs) for biomedical and health research are entrusted with the responsibility of scientific and ethical review of research proposals to safeguard the dignity, rights, safety and well-being of the human participants. Currently ECs for Biomedical research function as self-sufficient independent bodies without proper composition and regulatory monitoring. According to the New Drugs and Clinical Trials Rules, 2019 (Chapter IV), notified by MoHFW, any organisation engaged in the conduct biomedical and health research shall be required to have an EC to review and oversee the conduct of such research as specified in ICMR National Ethical Guidelines, 2017 and shall be required to register with the designated authority, Department of Health Research (DHR).

		DHR has set up the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR) for facilitating EC registrations. The authority will initially grant a provisional registration for two years, further will review all the documents submitted for the grant of final registration. Final registration granted will be valid for a period of five years. The registry is expected to bring out the much-needed transparency, accountability and organizational structure in the area of biomedical health research.
Mr Kumar Dron Shrivastav Senior Research Fellow, Amity Institute of Public Health, India	**33** **20 Nov 2019**	**Cervigram Based Early Detection of Cervical Cancer** ABSTRACT: Cervical cancer, besides being highly preventable and curable, it remains the major cause of mortality and morbidity, especially in low & middle income countries like India. Conventional techniques of pathology still continue to be the gold standards for cancer diagnosis, which makes the precision oriented early diagnosis of cervical cancer clumsy and time-consuming. To reduce time and complexities associated with early diagnosis of cervical cancer, we need to identify abnormal features and anomalies as compared to healthy state in settings with minimum resources. This formed the rationale to develop an algorithm for identification of abnormalities, thereby providing a platform for provisioning of healthcare to the marginalized sections of the society as a part of Digital Health. The technology has the ability to automatically identify and quantify the morphological features, color intensity, sensitivity and other parameters digitally to identify and delineate malignant lesions, which improve and accelerate screening and early diagnosis. After testing the application on 1426 cervigrams acquired from Intel Kaggle web repository for classification of cervix with 100% accuracy, we tested it on 302 India specific cervigrams with 83.64% accuracy. Next step is to explore the psychosocial aspects of cervical cancer and how they can help in early detection. KEYWORDS: Cervical Cancer, Cervigrams, Early Detection, Digital Pathology, Large-Scale Screening.
Dr Beena Joshi Scientist F, ICMR-NIRRH, Mumbai, India Co-presenters: Dr Beena Joshi	**34** **20 November 2019**	**Is Nexplanon (Sub dermal contraceptive implant) a cost-effective option for India's Family Welfare Programme? An economic evaluation** Introduction: India is the second most populated country as of 2019; with a population of 1.3 billion and an annual population growth rate of 1.037%. Indiaâ€™s policies reflect its commitment to stabilize population. The objective of our study was to determine the cost effectiveness of adding a contraceptive sub dermal Etonorgestrel Implant (Nexplanon) to the existing contraceptive basket within the public health system of India Methods: To aid the policy decision to introduce Nexplanon

Dr Kusum Moray Dr Oshima Sachin Dr Shahina Begum Mr Himanshu Chaurasia		into Indiaâ€™s public health program, an economic evaluation was undertaken; comparing the current available contraceptive options with a scenario of Nexplanon added to it through public health system of India. A decision analytical model (Markov cohort type) was conceptualized from a societal perspective. The hypothetical population going through the model were 15-year old girls, who were followed up through their reproductive lifespan. The inputs for the model were derived from secondary data analysis (switching between contraceptives from National surveys), systematic review (for clinical effectiveness of Nexplanon) and primary costing study (for costs of services and contraceptive use, side-effects, unintended pregnancy) and targeted reviews (for probabilities, utility scores). The model was built in Microsoft Excel. One-way and probabilistic sensitivity analyses were done. Results: The base-case Incremental Cost Utility ratio (ICUR) between the two comparators was INR 16,776. Hence addition of Nexplanon to the contraceptive basket would prove to be cost-effective for India. One-way sensitivity analysis showed that percentage of people who use contraceptives, costs of managing side-effects and utility-score of Nexplanon use were among the top parameters that influenced the ICUR. Probabilistic sensitivity analysis showed that of the 1000 Monte Carlo simulations that were run, all (100%) ICUR values were cost-effective. Conclusions: Results from this economic evaluation, recommended that Nexplanon could be introduced into the public system in India after conducting feasibility studies.
Dr Hafsa Ahmad Consultant (Comm), BIRAC, New Delhi, India Co-presenters: Dr Hafsa Ahmad Dr Kavita Singh Dr Shirshendu Mukherjee	**35** **20 November 2019**	**A Holistic Approach In R&D Funding To Facilitate Innovative Healthcare Solutions** Developing countries such as India are confronted with a host of daunting challenges such as poverty, malnutrition and an enormous disease burden. Low public investment in preventive healthcare is one of the key reasons behind the poor health of the average Indian. Despite best efforts to promote healthcare, there is a major lacuna in programmes related to public funding. Additionally, India is hamstrung by weak public healthcare infrastructure, lack of advanced laboratory facilities and equipment, and an inadequate health workforce, along with a poor healthcare delivery mechanism. Affordable innovation is the only way forward. Biotechnology Industry Research Assistance Council (BIRAC) is a Public Sector Enterprise, within the aegis of Department of Biotechnology (DBT), Government of India, was conceptualized with the aim to identify and bridge the gaps, by being an interface between industry and academia to strengthen the emerging biotech enterprises.A major national â€œInnovate in Indiaâ€• program i.e. the National Biopharma Mission has been jointly funded by the World Bank. Another major global partnership, Grand Challenges India co-funded by DBT & BMGF. Both the above programs fund innovations at various stages in their life cycles from basic science research in laboratories, to proof of concept and to potentially scale up innovations.

Sanghamitra Pati Director, ICMR-RMRC Bhubaneswar, Odisha, India Co-presenters: Dr Sanghamitra Pati Dr Rinshu Dwivedi Dr Krushna Chandra Sahoo Dr Debdutta Bhattacharya Dr Ramesh Athe Dr Shalu Jain	**36** **20 November 2019**	**Use of Portable Automated ABR for universal Neonatal Hearing Screening- Evidences from Health Technology Assessment in India** The global health priority are encapsulated in the Sustainable Development Goals (SDGs) which aims to minimise health inequalities for addressing the range of factors underpinning childhood disabilities, particularly associated with hearing-impairment under Universal-Neonatal-Hearing-Screening program. Hearing-impairment among children constitutes a serious obstacle to their optimal development and education, including language acquisition, cognitive skills. In India, where non-institutional deliveries are still not a prevalent practice, the vast majority of the infants are left out from the early detection and intervention. Deliveries at Community and Primary-Health-Centres and community-level are also among the few missed cases of hearing-screening. Therefore, early detection is must for providing appropriate support to deaf and hearing impaired babies. There is a need for a technology which can detect the hearing-impairment through first level of screening with better diagnostic accuracy with minimal infrastructural requirements. The present study was undertaken for Health-Technology-Assessment-in-India (HTAIn) of the Portable-Automated-ABRâ€™. We have compared other hearing-screening test which is commonly used under RBSK program with â€˜Portable-Automated-ABRâ€™. It was found that device under consideration can perform hearing test with better accuracy among newborns; user-friendly; does not require considerable reliance on high manpower. It is also clinically-efficient and cost-effective, which has been assessed in the present study.
Santanu Dhara, Professor, IIT Kharagpur, India	**37** **20 November 2019**	**Collagen – A Major Extracellular Matrix Component: Important Molecule for Health and Disease** Niche extracellular matrix (ECM) components influences organ specific cellular behavior in the temporospatial tissue turnover. ECM acts as scaffolds for cellular adhesion, migration and tissue microenvironment. Collagen, being a major extracellular matrix component, plays critical role in maintaining tissue homeostasis with dynamic microenvironment. Under health/disease condition, remodeling of collagen phenotype is instructive niches for oriented tissue regeneration. Healing of chronic wounds like diabetic ulcers require collagen dressing to minimize matrix metalloprotease enzyme activity and thereby accelerating granulation tissue formation. Besides wound healing,

		collagen and collagen derived peptides have diverse applications in healthcare, cosmetics and food processing sectors. Ethically sourced collagen through cost effective technology would be a trump card to facilitate unmet need. Herein, Amnivor Medicare Pvt. Ltd. developed a simplified cost-effective high throughput technology for extraction of collagen utilizing bio-wastes from fish market. BIRAC BIG scheme was very critical to develop this novel technology. Under this scheme, the collagen and collagen derivatives are utilized in formation of various downstream products like wound dressing, collagen based hemostat, bio ink for 3D printing, 3D matrix for cell expansion etc.
Mr Vishesh Sinha Chief Administrative Officer, Ayu Devices Pvt. Ltd, Mumbai, Maharashtra	**38** **20 November 2019**	**Medical Innovation for a Healthier Tomorrow** "Health is a fundamental Human Right" - as adopted in WHO Constitution. The rapid increase in heart and lung diseases which are the top two killers in India, requires an effective yet low-cost solution for early screening. We have tried our bit to help control the number of cases of misdiagnosis of the heart and lungs problems especially at an early stage. AYU DEVICES is our startup spun out of BETIC, IIT Bombay . We have developed an electronic device which can be connected to any normal analog stethoscope thus converting it into a digital stethoscope. Our electronic stethoscope facilitates amplification of Heart Sounds up to 16 times, recording and playback, noise filtration and sharing of auscultated sounds. Our stethoscopes can be used in Primary Health care Centers to record abnormal auscultated sounds which can be sent to expert physicians for further diagnosis, thereby overcoming the problem of low ratio of doctors to the number of people in India (1:1800) which is considerably low when compared to the minimum recommended doctor to population ratio of 1:1000. Our Digital Stethoscope will create a repository of recorded abnormal sounds, thus providing a rapid learning curve to the medical students who are the future to a Healthier Tomorrow.
Dr. Kalyani Thakur Scientist C, ICMR Bioethics Unit, National Centre for Disease Informatics and Research, (Indian Council of Medical Research)	**39** **20 November 2019**	**Ethical issues related to Reuse of Cardiovascular Catheters** Cardiovascular catheters are designed and labelled for single use. They do not come with appropriate instructions for cleaning, disinfecting or sterilization after use and reuse may compromise original standards for safety, quality and performance with increased risk to patients. The disposable devices also generate toxic biodegradable waste. There are ethical issues related to obtaining informed consent for reused devices. Most of the patients are economically incompetent to afford the expensive catheters. Many developing nations are considering the reuse

		to reduce the economic burden. While Canada, Germany and AustraDrlia have permitted reuse, UK has banned the reuse. US-FDA developed strict regulations to monitor reprocessing by hospitals and third-party reprocessors. WHO guidelines on Reprocessing of Medical Devices, 2016 states that reuse should not be done and if it is done, a very good reprocessing systems must be in place. Reuse of cardiovascular catheters in India is currently not regulated. There are several reports regarding reuse of catheters without informing the patient and not passing the economic advantage to them. However, in the absence of any guidelines or policies, there are ethical issues related to patient rights, safety, sterilization, quality, cost-effectiveness that must be addressed while considering the Reuse of Cardiovascular Catheters in India.
Dr Natarajan Sriraam India, Professor and Head, Dept of Medical Electronics, Ramaiah Institute of Technology	**40** **19 November 2019**	An External Cardiac Loop Recorder[ECLR] is proposed with Wearable textile sensors for real-time recording of cardiac signals and early screening of episodes for beat classification as well as Arrhythmia detection
Souly Phanouvong Director, United States Pharmacopeia, Singapore	**41** **20 November 2019**	**Integrated Regulatory Information Management System (IRIMS): A Tool to Improve Access to Quality Medicines to Protect Public Health** Statement of the problems: Most medicines regulatory agencies (MRAs) in low- and middle-income countries (LMICs) experience backlogs and delays in marketing authorization approval due, in part, to ineffective informaiton management system. Review processes are often inconsistent; lack transparency and/or efficiency; and may miss critical information on safety, quality, and efficacy. These poor practices encourage unnecessary efforts in inspections, surveillance, and testing of samples. Inadequate and inefficient review processes also delay access to lifesaving medicines and expose the public to unsafe medical products. Furthermore, once the products are approved, post-approval quality and safety surveillance practices are not properly implemented and quality checks and testing results are not shared publicly to facilitate enforcement actions to deter the entry of additional substandard and falsified medicines into the market. Key message: The authors in this presentation will describe the “what and how” of a well-designed technology platform for integrated regulatory information management systems (IRIMS) and describe how IRIMS can be a solution to help improve MRA practices and functions in streamlining the dossier evaluation and review process, and increasing transparency, productivity and effiency. IRIMS would also increase the connectivity, coordination, and communication between functional departments within an MRA. Addtionally, it would facilitate electronic and online communication with key stakeholders, including the suppliers, manufacturers, distributors, pharmacy outlets, hospitals/health facilities, healtcare

		professionals, and patients. Methodology: USP is the legally recognized pharmacopeia in more than 40 countries worldwide. It sets the standards for quality medicines. We bring to bear the collective expertise and resources afforded through our regional and global network building MRAs' regulatory capacity toward becoming fully functional in line with the WHO's GBT. The session will describe how USP can support MRAs to adopt/adapt a customiseable IRIMS modules that can be tailored to the needs of the country. For instance, an MRA may start with registration and post-marketing surveillance modules, and gradually add others (e.g., licensing, pharmacovigillance, and quality control laboratory modules). USP will also facilitate the country MRA to adopt most common international data standards (i.e., ACT, ICD, INN, MedDRA, UNII) and help in developing the National Drug Code. Outputs of the Session: Clear understanding or requirments for IRIMS, introduction process in a country, maintenance and sustanability of the program tool.