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

19-21 November, 2019 | New Delhi, India

TAKING THE AGENDA FORWARD...
2019
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Acknowledgements
Access to medicines is a critical factor for success of the 2030 Sustainable Development Goals (SDGs) that aims to ensure healthy lives and promote well-being of all people of all ages. Assuring access to medical products is key to advancing Universal Health Coverage (UHC). The main objective of the Conference is accelerating access to medical products for achieving universal health coverage in the context of SDGs.

The Ministry of Health and Family Welfare, Government of India and World Health Organization would like to thank the following for their support and contribution to the ‘2019 World Conference on Access to Medical Products-Achieving the SDGs 2030’:

- Indian Council of Medical Research
- Translational Health Science and Technology Institute
- Biotechnology Industry Research Assistance Council
- Biotech Consortium India Limited
- Ministry of Culture, Government of India
**Working Group Members for Conference**

- Dr Mandeep Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Government of India - Chairman (Working Group)
- Dr Manisha Shridhar, Regional Advisor, Intellectual Property Rights and Trade and Health, World Health Organization South-East Asia Regional Office
- Dr Madhur Gupta, Technical Officer-Pharmaceuticals, World Health Organization Country Office for India
- Mr Rajiv Wadhawan, Director, Ministry of Health and Family Welfare, Government of India
- Mr RG Singh, Under Secretary, Ministry of Health and Family Welfare, Government of India
- Dr Alka Sharma, Advisor, Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India
- Dr Gagandeep Kang, Executive Director, Translational Health Science and Technology Institute (THSTI), Department of Biotechnology, Government of India
- Dr R R Gangakhedkar, Scientist G, Indian Council of Medical Research, Government of India
- Dr VG Somani, Drugs Controller General of India, CDSCO, Government of India
- Dr Eswara Reddy, Joint Drugs Controller, CDSCO, Government of India
- Dr K Bangarurajan, Joint Drugs Controller, CDSCO, Government of India
- Dr R Chandrasekhar, Deputy Drugs Controller, CDSCO, Government of India

**Conference Secretariat**

- Dr Manisha Shridhar, Regional Advisor, Intellectual Property Rights and Trade and Health, World Health Organization South-East Asia Regional Office
- Dr Madhur Gupta, Technical Officer-Pharmaceuticals, World Health Organization Country Office for India
- Dr Purnima Sharma, CEO, Biotech Consortium India Limited
- Dr Sanchita Chaudhary, Assistant General Manager, Biotech Consortium India Limited
- Ms Preeti Kharb, Consultant, WHO Country Office for India
- Mr Santhana Krishnan V.S, Drug Regulation Division, Ministry of Health & Family Welfare, Government of India
- Ms Garima Singh, Consultant, World Health Organization South-East Asia Regional Office
- Dr Smriti Chawla, Consultant, Translational Health Science and Technology Institute (THSTI)
- Ms Kanika Dasan, Consultant, World Health Organization South-East Asia Regional Office
- Ms Barkha Budhiraja, Project Executive, Biotech Consortium India Limited

**Overall Leadership, Guidance and Useful Inputs**

- Ms Preeti Sudan, Secretary, Ministry of Health and Family Welfare, Government of India
- Dr Arun Panda, Secretary, Ministry of Micro Small and Medium Enterprises, Government of India
- Mr Arun Singhal, Special Secretary, Ministry of Health and Family Welfare, Government of India
- Dr VK Paul, Member, NITI Aayog, Government of India
- Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India
• Dr Balram Bhargava, Secretary, Department of Health Research and Director-General, Indian Council of Medical Research, Ministry of Health and Family Welfare, Government of India
• Dr Guruprasad Mohapatra, Secretary, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India
• Dr Vaidya Rajesh Kotecha, Secretary, Ministry of AYUSH, Government of India
• Mr P D Vaghela, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India
• Dr Anup Wadhawan, Secretary, Ministry of Commerce, Government of India
• Mr Ajay Prakash Sawhney, Secretary, Ministry of Electronics and Information Technology, Government of India

World Health Organization
• Dr Mariângela Batista Galvão Simão, Assistant Director General for Prequalification and Technology Assessment, World Health Organization
• Dr Henk Bekedam, WHO Representative, WHO Country Office for India
• Ms Payden, Deputy WHO Representative, WHO Country Office for India
• Dr Hilde Renne Susanne De Graeve, Team Leader, Health Systems, WHO Country Office for India
• Dr Manisha Shridhar, Regional Advisor, Intellectual Property Rights and Trade and Health, World Health Organization South-East Asia Regional Office
• Dr Madhur Gupta, Technical Officer-Pharmaceuticals, World Health Organization Country Office for India

Grateful for overall Support

Ministry of Health and Family Welfare
• Honorable Dr Harsh Vardhan, Union Minister, Ministry of Health and Family Welfare, Science & Technology and Earth Sciences, Government of India
• Honorable Mr Ashwini Kumar Choubey, Minister of State, Health & Family Welfare, Government of India

World Health Organization
• Dr Tedros Adhanom Ghebreyesus, Director-General, World Health Organization
• Dr Soumya Swaminathan, Chief Scientist, World Health Organization
• Dr Poonam Khetrapal Singh, Regional Director, World Health Organization South-East Asia Region
General Advisory for the Sessions: Chair, Co-Chair, Key Note Speakers and Panelist

Role of the Chair
1. Meet the speakers at least 30 minutes before your session to discuss the modalities of the session and issues pertaining to it.
2. Introduce the Session and moderate the Q&A.
3. Ensure that the Session is managed to include maximum discussion on the issues and remains on schedule.
4. Open the Panel, briefly introduce the panel topic, and promote lively and focused discussions on the topic of the Panel.
5. Ensure that equal time is allotted to presenters.
6. Engage the audience and offer opportunities for brief questions and answers at the end of the sessions.
7. Share a Summary of Discussions of the session at the end.
8. At all times insist on collegiality and a tone of respect.

Further suggestions for the Chair:
2. Moderate the session. Each speaker has 10 minutes.
3. Closing Remarks: 2 Minutes. Identify the main points made during the Session for inclusion in the session summary. May like to take notes and offer any contextual thoughts or questions when the panelists complete their talk.

Role of the Co-Chair
1. Facilitate Questions & Answers, moderate audience participation.
2. Closing Remarks at the end of the session (and hand over to the Chair): 1-2 minutes

Responsibilities of Key Note Speakers:
1. Focus on key aspects of the session theme and set the tone of discussions for the session, highlighting main points for discussion.
2. Make a presentation for 10-12 minutes. Please keep to the time limit.
3. Please use the presentation template shared with you from the organizers.
4. Summarize the three (or a meaningful number of) most important points of the presentation.
5. Summarize contributions for suggested outcomes/recommendations of the session.

Responsibilities of the Panelists
1. Focus on key aspects of the session theme and highlight main points for discussion.
2. Make a presentation/talk for 8-10 minutes. Please keep to the time limit.
3. If you wish to make a presentation, please use the presentation template shared with you from the organizers.
4. Summarize the three (or a meaningful number of) most important points of the presentation.
5. Summarize contributions for suggested outcomes/recommendations of the session.
The Sustainable Development Goals (SDGs) are the blueprint to achieve a better and more sustainable future for all. They address the global challenges and aim to leave no one behind by 2030. Further, in September 2019, Member States renewed their commitment to Universal Health Coverage in the United Nations General Assembly (UNGA) to achieve SDGs and promote the health and well-being of their populations. A number of the 17 Sustainable Development Goals of the 2030 Agenda have health-related targets. The SDG 3 aims to “ensure healthy lives and promoting well-being for all at all ages”.

The associated targets relate to reduce the global maternal mortality ratio; end preventable deaths of newborns and children; end the epidemics of AIDS, tuberculosis, malaria and other communicable diseases; reduce mortality from non-communicable diseases; strengthen the prevention and treatment of substance abuse; halve the number of deaths and injuries from road traffic accidents; ensure universal access to sexual and reproductive health-care services; achieve universal health coverage; and reduce the number of deaths and illnesses from hazardous chemicals and pollution.

Universal Health Coverage in the SDG 2030
Universal health coverage (UHC) is an important objective in the SDGs. The goal of UHC is to provide accessible, quality essential health services without financial hardship to individuals, families and communities.

Target 3.8 (Achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all) has two indicators: 3.8.1 on coverage of essential health services and 3.8.2 on the proportion of population with large household expenditures on health. These indicators represent the latest efforts to monitor the world’s path towards universal health coverage.

UHC envisages a strong primary health-care (PHC) focus, promoting the individual’s engagement in their health, and assuring community-level access to the full spectrum of services, from health promotion and prevention to treatment, rehabilitative and palliative care. PHC services rely on access to health products, including medicines, vaccines, medical devices, diagnostics, protective equipment and assistive devices. Ensuring that appropriate health products are available and affordable for primary care depends on policy decisions and processes related to the selection, pricing, procurement, supply chain management, maintenance (in the case of medical devices), prescribing and dispensing (in the case of medicines) and use of health products.

[^3]: A72/14
To address the multi-sectoral nature of health determinants, the health sector should promote “Health in All Policies”-an approach to public policies across sectors that systematically takes into account the health implications of decisions, seeks synergies and avoids harmful health impacts in order to improve population health and health equity, and address the social determinants of health. Areas of particular relevance include trade and intellectual property, sustainable energy, income inequality, migration, food security, and sustainable consumption and production.

“Universal health coverage is ultimately a political choice. It is the responsibility of every country and national government to pursue it. It is more of a political than an economic challenge” Dr Tedros Adhanom Ghebreyesus, WHO Director-General

There is a need for strong, continuous political commitment and support, more government fiscal space specifically dedicated to health, more investment in health delivery systems, primary health care and a committed health workforce, and strengthened implementation capacities. All these elements are equally important to achieving universal health coverage.

Thirteenth General Programme of Work 2019-2023
The Thirteenth General Programme of Work, 2019–2023 of the WHO is aligned to the SDG agenda and sets out three strategic priorities for ensuring healthy lives and well-being for all at all ages: achieving universal health coverage, addressing health emergencies and promoting healthier populations. These strategic priorities are supported by three strategic shifts: stepping up leadership; driving health impact in every country; and focusing global public goods on impact.

Access is a global concern, given the high prices of new pharmaceuticals and rapidly changing markets for health products that place increasing pressure on all health systems’ ability to provide full and affordable access to quality health care. The high percentage of health spending on medicines (20–60% as demonstrated in a series of studies in selected low- and middle-income countries) impedes progress for the many countries that have committed to the attainment of universal health coverage. Furthermore, it is known that a large proportion of the population in low-income countries who spend for health do pay out-of-pocket for medicines. With the rise in noncommunicable diseases – many of which are chronic conditions that require long-term treatment – the financial burden on both governments and patients will become even greater.

Access to medical products is key to advancing UHC. The World Health Assembly adopted decision WHA71(8), which led to road map 2019–2023 for access to medicines, vaccines and other health products.

In the WHO South-East Asia Region (SEAR), access to essential medicines is a priority in the Regional Flagship on UHC. The Health Ministers of the Member States of the WHO SEAR, participating in the 71st session of the WHO Regional Committee for SEAR at New Delhi, India adopted the Delhi Declaration on ‘Improving access to essential medical products in the South-East Asia Region and beyond’.

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5 Thirteenth General Programme of Work 2019−2023 (http://www.who.int/about/what-we-do/gpw-thirteen-consultation/en/)
7 Delhi Declaration on ‘Improving access to essential medical products in the South-East Asia Region and beyond’ (https://apps.who.int/iris/bitstream/handle/10665/274331/Delhi-Declaration.pdf?sequence=5&isAllowed=y)
India
India is committed to UHC. Ayushman Bharat\(^8\) will be a major contributor to UHC in India and is the largest public health initiative in the world planning to cover 100 million families across the country. The scheme has two main components: one that envisages the transformation of 1,50,000 primary healthcare centres and sub-centres into “wellness centres” that would lay stress on prevention of illness, and second, a health insurance package of ₹5 lakh (approximately 7000 USD) for each of the 100 million families being covered.

‘Universal Health for all, a disease-free India and global standards of excellence in healthcare is our aim for a new India’, said Dr Harsh Vardhan, Union Minister, Ministry of Health and Family Welfare at 72nd Session of Regional Committee Meeting for SEAR. He also stated that under the visionary Prime Minister, India is on the brink of a healthcare sector revolution and is moving with urgency to change the health landscape of India.

Reiterating the commitment of the government to UHC, the Union Health Minister said that Ayushman Bharat is India’s road to UHC. The first component of this is establishing 1,50,000 Health and Wellness centres by the year 2022, which shall provide an entire gamut of preventive healthcare. Already more than 20,000 Health and Wellness centres have been operationalised. The second component, Pradhan Mantri Jan Aarogya Yojana (PM-JAY), is aimed at providing health protection cover to over 100 million poor and vulnerable families for secondary and tertiary care including pre- and post- hospitalisation expenses. Key features include health cover of upto INR 5 hundred thousand per family. A total of 17000 hospitals have been empanelled so far under this scheme. More than 4.1 million persons have become beneficiaries under this scheme and have saved a total of approximately INR 120 billion on health expenditure.

The National Health Policy, 2017\(^9\) has specified targets for universalising primary health care, achieving further reductions in infant and under-5 mortality, preventing premature deaths due to non-communicable diseases as well as increasing government expenditure on health. A composite index is being used to monitor and incentivise improvements in health services delivery across states in the country. The government is aiming to immunize all unimmunized and partially immunized children against vaccine preventable diseases by 2020. Towards achieving universal health coverage, a health insurance cover of INR 100,000 (USD 1,563) is being extended to all poor families.

Universal Health Coverage: Moving together to build a healthier world (UN General Assembly (UNGA) Meeting 2019)

Governments gathered at the World Health Assembly (WHA) agreed on four resolutions related to universal health care (UHC), addressing primary healthcare, the role of community health workers, emergency care systems and the UN General Assembly (UNGA) High-Level Meeting on UHC.

A high-level United Nations Political Declaration on universal health coverage (UHC) was adopted on September 23, 2019. In adopting the declaration, U.N. Member States have committed to advance towards UHC by investing in four major areas around primary health care. These include mechanisms to ensure no one suffers financial hardship because they have had to pay for healthcare out of their own pockets and implementing high-impact health interventions to combat diseases and protect women’s and children’s health. In addition,

\(^8\) https://www.abnhpm.gov.in/
\(^9\) https://mohfw.gov.in/sites/default/files/9147562941489753121.pdf
countries must strengthen health workforce and infrastructure and reinforce governance capacity. They will report back on their progress to the U.N. General Assembly in 2023.

On September 24, 2019, at the United Nations General Assembly, 12 multilateral agencies launched a joint plan to better support countries over the next 10 years to accelerate progress towards the health-related Sustainable Development Goals (SDGs). Developed over 18 months, Stronger Collaboration, Better Health: Global Action Plan for Healthy Lives and Well-being for All outlines how a dozen multilateral health, development and humanitarian agencies will collaborate to be more efficient and provide more streamlined support to countries to deliver universal health coverage and achieve the health-related SDG targets.

A UN General Assembly resolution established 12 December as ‘Universal Health Coverage Day.’ In the resolution titled, ‘Global health and foreign policy: addressing the health of the most vulnerable for an inclusive society’ (A/72/L.28), UNGA reaffirms the Sustainable Development Goals (SDGs) and several other international goals and agreements, including the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) promoting access to medicines for all.

The objective of the session is to discuss the following:
- Contribution of 13th GPW for Access to Medical Products to achieve SDG 2030 Goals
- Health focus in 2019 UN General Assembly-Universal Health Coverage
- Achieving Universal Health Coverage and bringing Healthcare to the People in India

Questions to spur thinking:
- How political Declaration from UNGA 2019 on Universal Health Coverage is boosting the political commitment on UHC globally?
- How Delhi Declaration has supported and strengthened the political commitment for achieving Universal Health Coverage in South Asia Region?
- How intergovernmental collaborations including at the UN general assembly and with other stakeholders lead to attainment of SDG3?
- Will WHO’s first ever investment case in the organization for the achievement of 13 GPW provide greater impetus for national and international donors to invest for public health?
- How will the Ayushman Bharat Programme- accelerate the achievement of Universal Health Coverage in India?
- How technical support in health financing, including cross-country learning, might be adapted to better support countries to build their own capacity and institutions?
- Explore and synthesize key lessons from country experience with the implementation of UHC and draw out the implications of these lessons for accelerated action?

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<td><strong>Universal Health Coverage-WHO Triple Billion Targets: Moving Together to Build a Healthier World</strong></td>
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<td><strong>Chair:</strong> Honorable Dr Harsh Vardhan, Union Minister, Ministry of Health and Family Welfare, Science &amp; Technology and Earth Sciences, Government of India</td>
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<td><strong>Co-chair:</strong> Dr VK Paul, Member, NITI Aayog, Government of India</td>
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<td>1. Honorable Mr Zahid Maleque, Minister of Health and Family Welfare, Ministry of Health and Family Welfare, Government of the People’s Republic of Bangladesh</td>
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<td>2. Honorable Ms Lyonpo Dechen Wangmo, Minister for Health, Ministry of Health, Royal Government of Bhutan</td>
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<td>5. Dr Nata Menabde, Executive Director, World Health Organization Office at the United Nations, United States of America- <em>Moving forward from United Nations General Assembly (UNGA) 2019 on UHC</em></td>
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CV of Chairs

Dr Harsh Vardhan, Union Minister, Ministry of Health and Family Welfare, Science & Technology and Earth Sciences, Government of India

Dr Harsh Vardhan, is currently Union Minister for Ministry of Health and Family Welfare, Science & Technology and Earth Sciences, has a long and distinguished record of public service, leaving his indelible mark in all fields of activity undertaken. An ENT surgeon by profession to start with, Dr Vardhan branched out into public life in 1993, when he got elected to the Delhi Assembly and four more successive terms (1998, 2003, 2008 and 2013) and later to Lok Sabha in 2014.

Dr Vardhan’s public life has been marked by standout achievements in the fields of health, education, law, science & technology and environment. He was instrumental early in public life, through his mass, country-wide campaign, in wiping out polio from the face of India. Subsequently, he was at the forefront of the battle against tobacco and drug abuse and was instrumental in the enactment of several laws including the Delhi Prohibition of Smoking in Public Places & Non-Smokers Health Protection Act to tackle these problems. He for the first time implemented the Rational Drug Policy which was recognised by the WHO as the Delhi Model and was adopted by many countries. Dr Vardhan’s focus has been to motivate the country’s scientists to come up with new technologies, processes and products that can provide innovative solutions to people’s problems. He is committed to setting up a roadmap for the implementation of the ‘Make in India’ programme, for building a robust R&D infrastructure and promoting synergies between industry and scientific research institutions.

Dr VK Paul, Member, NITI Aayog, Government of India

The Government of India appointed Dr Paul as a Member of the National Institution for Transforming India, the NITI Aayog, in August 2017 where he leads the Health and Nutrition verticals. He has played a pivotal role in formulating the POSHAN Abhiyaan and the Ayushman Bharat initiative. Prior to bring appointed as Member, NITI Aayog, Dr. Paul has been a member of the faculty at the All India Institute of Medical Sciences, New Delhi for over 32 years and Head of the Department of Pediatrics for nearly a decade. Dr. Paul is an internationally renowned paediatrician, academic, medical research and public health exponent. He was conferred the prestigious Ihsan Dogramaci Family Health Foundation Prize by WHO at the 2018 World Health Assembly. Prof. Paul has recently been appointed as the Chairman of The Board of Governors of Medical Council of India.
## CVs of Special Addressee’s

<table>
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<th>Mr Zahid Maleque, Minister of Health and Family Welfare, Ministry of Health and Family Welfare, Government of the People’s Republic of Bangladesh</th>
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<td>Mr. Zahid Maleque, MP, on January 7, 2019 took oath as a Minister for Ministry of Health and Family Welfare. Mr. Zahid Maleque obtained Masters Degree with Honours in English Literature and Language from University of Dhaka. Besides politics, he is actively involved in various social welfare services. He played a pioneer role in establishing different educational, religious and social development institutions in Dhaka and Manikgonj. He is an eminent entrepreneur. He served successfully as the chairman of Bangladesh Thai Aluminum Ltd., Sunlife Insurance Co. Ltd., BD Thai Food and Beverage Ltd., Rahat Real Estate and Construction Ltd., BD Sunlife Securities Ltd. from 1984 to 2014.</td>
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<td>He has initiated ‘Colonel Maleque Medical College Hospital in Manikgonj, Mr. Zahid Maleque has lead the development work in Manikgonj. Some of the mentionable projects are: 1) 250 Beded District Hospital, 2) Medical Assistant Training School (MATS), 3) Institute of Health Technology, 4) Manikgonj Diabetic Hospital, 5) Agriculture Training Institute, 6) Bridges, Roads and Rural Electrification.</td>
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<td>At present he is working relentlessly to establish a service-oriented dynamic health sector. He has contributed significantly in ensuring good governance, Transparency and introducing efficiency in health services management. The following are the list of welfare organizations which were established by H. E. Mr. Zahid Maleque: 1) Col. Maleque High School, 2) Col. Maleque Govt. Primary School, 3) Fowzia Maleque Govt. Primary School, 4) Zahid Maleque Govt. Primary School, 5) Maleqia Ashraful Ulm Madrasa, 6) Isatunnesa Forkania Madrasa, Nobograom Pourasova, Manikganj, 7) Zarina Khanam Jame Mosque, Garpara, Manikgonj.</td>
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<th>Ms Lyonpo Dechen Wangmo, Minister for Health, Ministry of Health, Royal Government of Bhutan</th>
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<td>Her Excellency Dechen Wangmo is the current Health Minister who formally took charge of the Ministry of Health on 7th November 2018. Her Excellency has more than ten years of experience working across the cross-section of organizations and individual in the field of public health and social development. Professional experience includes public health research development and implementation; National Policy review and formulation; and development of strategic plan for government and Civil Society Organizations. Primary focus over the years has been in developing and strengthening health system and governance. Having worked across countries in the region, Her Excellency, is a passionate public health advocate and social worker at heart. Her Excellency has a master in public health (MPH) from Yale University, New Haven, USA and a bachelor in Cardio pulmonary Science (magna cum laude) from Northeastern University, Boston, USA.</td>
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Mr Upendra Yadav, Deputy Prime Minister and Minister of Health and Population, Ministry of Health and Population, Government of Federal Democratic Republic of Nepal

Upendra Yadav is a Nepalese politician serving as the Deputy Prime Minister and Health Minister of Nepal. He is also chairman of the central committee of the Samajbadi Party, Nepal. He is one of the most renowned politician in Nepalese politics. He and his party has been fighting against political elites and ruling class of Nepal demanding proportional representation, equality and end of discrimination towards the Madhesi and indigenous Janjati and Adivasi people such as Maithali, Tharu, Rai, Limbu, Magar, Tamang including Women and politically backward ethnic groups. Following the April 2008 Constituent Assembly election, the MJF (now, FSF Nepal) agreed to join a government headed by Prachanda, the chairman of the Communist Party of Nepal (Maoist). Yadav was subsequently appointed as Minister of Foreign Affairs and sworn in on 22 August 2008; he was one of four MJF members included in the Cabinet.

Dr Arun Panda, Secretary, Health, Ministry of Health and Family Welfare, Government of India

Dr Arun Kumar Panda joined the Indian Administrative Service (IAS) in 1984 in Odisha. Presently, he is holding the charge of Secretary, Ministry of Health and Family Welfare and Ministry of Micro, Small and Medium Enterprises and leads the Ministry for fulfilling the vision of employment generation, and the development of the MSME Sector.

In his 35 years of service, Dr. Panda has served as an administrator, policy maker, public health strategist besides holding a wide range of assignments both at the provincial and Central level in the field of Health, Urban Development and Rural Development. He also served as Additional Secretary and Mission Director of National Health Mission in the Ministry of Health and Family Welfare.

He earned his Master’s Degree in Political Science from University of Delhi and received Ph.D Degree from the Department of Economics, University of Southern California, Los Angeles, USA. Dr. Panda also attended programmes on leadership and management in Cambridge University and in the Kennedy School of Government, Harvard University.

Dr Nata Menabde, Executive Director, World Health Organization Office at the United Nations, United States of America

Dr Nata Menabde is Executive Director of WHO Office at the United Nations, New York since May 2015. Prior to her current role, since 2010, Nata Menabde was WHO Representative to India where she has led a large team of thousands of dedicated professionals across India supporting the governments’ efforts in tacking health and health systems challenges, such as eradication of polio and saving lives from vaccine preventable diseases, promoting universal health coverage for sustainable development, combatting TB, reversing growing trend of noncommunicable diseases, amongst others. Preceding her assignment in India Nata Menabde was the Deputy Regional Director of WHO’s
European Regional Office and, among other initiatives, has successfully led WHO’s European work on Health Systems.

Dr Menabde has a robust public health academic background and above 30 years of professional experience, during which she has built an extensive track record in public health and health systems at country and international levels. She holds a PhD degree in Clinical Pharmacology, diplomas in Health Management and Leadership from USA and in Health Care Economics from UK. She also studied Public Health at Nordic School of Public Health, Sweden. Her current interests are linked to universal health coverage and sustainable development, health and foreign policies, global health governance, emergency preparedness and crises response, health systems performance, as well as addressing public health in other sector policies.
19 November 2019-Tuesday, 12:00-13:30

Parallel Session 1: Roundtable Panel- Updates on Access to Medical Products and Progress from 2018 World Conference on Access to Medical Products-Achieving the SDGs 2030- State Health Ministers, Union Government Secretaries and Principal Secretaries from States

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<td>Tuesday, 12:00-13:30</td>
<td><strong>Roundtable Panel- Updates on Access to Medical Products and Progress from 2018 World Conference on Access to Medical Products-Achieving the SDGs 2030- State Health Ministers, Union Government Secretaries and Principal Secretaries from States</strong></td>
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<td><strong>Chair:</strong> Honorable Dr Harsh Vardhan, Union Minister, Ministry of Health and Family Welfare, Science &amp; Technology and Earth Sciences, Government of India</td>
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<td><strong>Co-chair:</strong> Honorable Mr Ashwini Kumar Choubey, Minister of State, Ministry of Health &amp; Family Welfare, Government of India; Dr VK Paul, Member, NITI Aayog, Government of India</td>
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<td><strong>Keynote Addresses:</strong></td>
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<td>• Dr Arun Panda, Secretary, Health, Ministry of Health and Family Welfare, Government of India</td>
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<td>• Dr Balram Bhargava, Secretary, Department of Health Research and Director-General, Indian Council of Medical Research, Ministry of Health and Family Welfare, Government of India</td>
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<td>• Mr PD Vaghela, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India</td>
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<td>• Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India</td>
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## CV of Chairs

**Dr Harsh Vardhan, Union Minister, Ministry of Health and Family Welfare, Science & Technology and Earth Sciences, Government of India**

Dr Harsh Vardhan, is currently Union Minister for Ministry of Health and Family Welfare, Science & Technology and Earth Sciences, has a long and distinguished record of public service, leaving his indelible mark in all fields of activity undertaken. An ENT surgeon by profession to start with, Dr Vardhan branched out into public life in 1993, when he got elected to the Delhi Assembly and four more successive terms (1998, 2003, 2008 and 2013) and later to Lok Sabha in 2014.

Dr Vardhan's public life has been marked by standout achievements in the fields of health, education, law, science & technology and environment. He was instrumental early in public life, through his mass, country-wide campaign, in wiping out polio from the face of India. Subsequently, he was at the forefront of the battle against tobacco and drug abuse and was instrumental in the enactment of several laws including the Delhi Prohibition of Smoking in Public Places & Non-Smokers Health Protection Act to tackle these problems. He for the first time implemented the Rational Drug Policy which was recognised by the WHO as the Delhi Model and was adopted by many countries. Dr Vardhan’s focus has been to motivate the country’s scientists to come up with new technologies, processes and products that can provide innovative solutions to people’s problems. He is committed to setting up a roadmap for the implementation of the ‘Make in India’ programme, for building a robust R&D infrastructure and promoting synergies between industry and scientific research institutions.

**Mr Ashwini Kumar Choubey, Minister of State, Health & Family Welfare, Government of India**

Mr Ashwini Kumar Choubey, Minister of State, Health & Family Welfare, Government of India. He was sworn in as Minister of State for Health and Family Welfare, on 3rd Sept, 2017. He represents the Buxar Lok Sabha Parliamentary Constituency (spread over the entire district of Buxar and partly over Kaimur and Rohtas Districts) of Bihar. He has been elected again from Buxar Lok Sabha Constituency (2nd time) in 2019 and sworn-in as MOS, H&FW in June 2019. Earlier, in Bihar, he was Minister for Urban Development from 2005 – 2008, Minister for Public Health Engineering Department between 2008 - 2010 and Minister of Health between 2010 - June, 2013.

He was Member for 5 consecutive terms of Legislative Assembly of Bihar from 1995 - 2013. He holds a Degree in B.Sc. (Hons.) Zoology and was educated in Science College, Patna University, Bihar. He has been all long a crusader for civil liberties and was in custody under DIR and MISA.

As a social and cultural activist from his student days upto his graduation into politics, he organized many blood donation camps, health awareness programmes, anti-tobacco campaigns and cancer awareness programmes in Bihar. He has also launched #War against Cancer recently and pursuing various research projects in the field of cancer treatments. As Minister for Health in Govt. of Bihar, he organized 11000 Health Camps for health awareness and “Bihar Gram Gaurav Yatra”. He
also coined and propagated the slogan “Ghar-Ghar me ho shouchalaya ka nirman, tabhi hoga laddi bitiya ka kanyadaan” – (let there be a toilet in each house before you give away your affectionate daughter in matrimony). He caused construction of 11000 toilets for Mahadalit families. His special interest is ‘Upliftment of the poor’ and his favourite pastime is Yoga, Music and watching Kathak Dance.

Dr VK Paul, Member, NITI Aayog, Government of India

The Government of India appointed Dr Paul as a Member of the National Institution for Transforming India, the NITI Aayog, in August 2017 where he leads the Health and Nutrition verticals. He has played a pivotal role in formulating the POSHAN Abhiyaan and the Ayushman Bharat initiative. Prior to bring appointed as Member, NITI Aayog, Dr. Paul has been a member of the faculty at the All India Institute of Medical Sciences, New Delhi for over 32 years and Head of the Department of Pediatrics for nearly a decade. Dr. Paul is an internationally renowned paediatrician, academic, medical research and public health exponent. He was conferred the prestigious Ihsan Dogramaci Family Health Foundation Prize by WHO at the 2018 World Health Assembly. Prof. Paul has recently been appointed as the Chairman of The Board of Governors of Medical Council of India.

CV of Key Note Speakers

Dr Arun Panda, Secretary, Health, Ministry of Health and Family Welfare, Government of India

Dr Arun Kumar Panda joined the Indian Administrative Service (IAS) in 1984 in Odisha. Presently, he is holding the charge of Secretary, Ministry of Health and Family Welfare and Ministry of Micro, Small and Medium Enterprises and leads the Ministry for fulfilling the vision of employment generation, and the development of the MSME Sector.

In his 35 years of service, Dr. Panda has served as an administrator, policy maker, public health strategist besides holding a wide range of assignments both at the provincial and Central level in the field of Health, Urban Development and Rural Development. He also served as Additional Secretary and Mission Director of National Health Mission in the Ministry of Health and Family Welfare.

He earned his Master’s Degree in Political Science from University of Delhi and received Ph.D Degree from the Department of Economics, University of Southern California, Los Angeles, USA. Dr. Panda also attended programmes on leadership and management in Cambridge University and in the Kennedy School of Government, Harvard University.
Dr Balram Bhargava, Secretary, Department of Health Research, and Director General, Indian Council for Medical Research, Ministry of Health and Family Welfare, Government of India

Professor Balram Bhargava, Secretary, Department of Health Research, (Ministry of Health & Family Welfare), Government of India and Director General, Indian Council of Medical Research (ICMR) joined on 16th April, 2018. Prof. Bhargava is Professor of Cardiology at All India Institute of Medical Sciences (AIIMS), New Delhi and also serves as the Executive Director for Stanford India Biodesign Centre, School of International Biodesign (SiB). Professor (Dr) Balram Bhargava is an outstanding cardiologist, one of the foremost leaders in biomedical innovation, public health, medical education and medical research.

Professor Bhargava has excellent leadership qualities; and has established the India-Stanford Biodesign programme, a unique interdisciplinary fellowship programme to foster innovation, design in low cost implants/devices. This programme has led to the establishment of the School of International Biodesign (SIB) at AIIMS and development of 30 low cost medical devices leading to 10 startups. Four of the low cost devices are in the Indian market and one device has been approved by the USFDA.

He developed the indigenous Platinum Iridium coil coronary stent and has been instrumental in clinically evaluating and establishing the use of two other laser cut medicated Indian stents. The philosophy of the programme has been “More for less for more” with a mandate to promote Global Affordable Need Driven Healthcare Innovation (GANDHI).

He set up the c-GMP Centre for Excellence for Stem Cell Studies, at AIIMS which has initiated treatment of patients with dilated cardiomyopathy; this has benefitted number of no-option heart failure patients waiting on the cardiac transplant list.

He is currently developing the Chest Compression Device for Sudden Cardiac Death patients; funded by the Wellcome Trust, London. He has led two major trials in India funded by the NIH, Bethesda, USA which has changed clinical practice. He has pioneered several techniques in interventional cardiology.

He has been awarded the SN Bose Centenary award by the Indian National Science Congress and National Academy of Sciences Platinum Jubilee Award, Tata Innovation Fellowship and Vasvik Award for Biomedical Technology Innovation, Ranbaxy Award and the OP Bhasin Award in the field of Health and Medical Sciences. He is the Founding, Editor in Chief of the British Medical Journal Innovations (BMJi). He has been awarded the ‘Padma Shri’ high civilian award by the Honourable President of India and the UNESCO Equatorial Guinea International Prize for research in Life Sciences at Paris.
Mr P D Vaghela, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

Mr P.D. Vaghela, a Gujarat-cadre IAS officer, is Secretary, Department of Pharmaceuticals (DoP), under the Ministry of Chemicals and Fertilizers. Earlier, Mr Vaghela was commissioner of commercial tax in Gujarat. He is counted among the key officers who played a crucial role in the rollout of the Goods and Services Tax (GST) in 2017. He was the convener of important central committees on GST, and shuttled between Gujarat and Delhi to attend various meetings before the implementation of the single tax regime. Under his new responsibility, Vaghela will primarily be looking at controlling the prices of medicines and medical devices.

Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India

Dr Renu Swarup is currently Secretary, Department of Biotechnology (DBT). She has served in Department of Biotechnology for nearly 29 years and was holding the position of Senior Advisor/Scientist ‘H’ till she was appointed a Secretary to Government of India on 10th April, 2018. She also holds position of Chairperson, Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Company incorporated by the Government to nurture and promote innovation research in the Biotech Enterprise with special focus on Start-ups and SMEs.

A PhD in Genetics and Plant Breeding, Dr. Renu Swarup completed her Post Doctoral at The John Innes Centre, Norwich UK, under Commonwealth Scholarship and returned to India to take up the assignment of a Science Manager in the Department of Biotechnology, Ministry of Science and Technology, GoI, in 1989. As a Science Manager issues related to policy planning and implementation are a part of her assignment. She was actively engaged in formulation of the Biotechnology Vision in 2001, National Biotechnology Development Strategy in 2007 and Strategy II, 2015-20 as the Member Secretary of the Expert Committee.

Dr. Renu Swarup has also been closely involved in Programmes and activities related to Women and Science. She was responsible for getting implemented the DBT Scheme on Biotechnology Career Advancement for Women Scientists – BioCARe. She was also a member of the Task Force on Women in Science constituted by the Scientific Advisory Committee to the Prime Minister.

Dr. Renu Swarup also held charge of Managing Director, Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Company incorporated by the Government of India to nurture and promote innovation research in the Biotech Enterprise with special focus on Start-ups and SMEs till she took over the charge of Chairperson. Through Biotechnology translational research and industry academia partnerships she has supported more than 1000 Startups and Entrepreneurs, and nearly 500 small companies for innovation research and product development.

A Member of the National Academy of Sciences (NASI) India. She is also a Member of Governing Body of National Institutes, Universities and Centers. She was awarded the “BioSpectrum Person of the Year Award” in 2012. She also received the “National Entrepreneurship Awards 2017”.
Session Brief

Different funding organizations across the globe support R&D in healthcare based on their priority areas for access to affordable medical products. However, effective knowledge sharing, collaboration and coordination of these efforts are needed to improve responses to epidemics and ensure that identified R&D gaps are filled effectively. The involvement of funding organizations, regulators, public as well as private sector in a coordinated manner is essential to reap the benefits of investments made. It is also agreed that epidemiological and clinical research should be incorporated under the umbrella of the coordination mechanism, with product R&D before and during public health emergencies.

Challenges to innovation affect all stages of product development – discovery, development and delivery; necessitating improving the quality and breadth of the data available and accessible. Further, improving use of data in tracking investments in R&D is required to facilitate devising sustainable approaches of making investments available for high priority medical products. In addition, an immediate focus on addressing patient needs through customized short, medium- and long-term approaches is required. Another important aspect that needs to be addressed is capacity building for streamlining procurement of medical products, which is critical in providing access to affordable healthcare for all.

The availability and appropriate use of correct data on investments made in health care is an immediate need and agreed globally by governments, policy-makers, funders, researchers and civil society. This has led to development of several initiatives for tracking investments in R&D for healthcare. The Global Observatory on Health R&D of the WHO, result of resolution WHA66.22 is a global-level initiative that aims to help identify health R&D priorities based on public health needs, by:

- consolidating, monitoring and analyzing relevant information on the health R&D needs of developing countries;
- building on existing data collection mechanisms; and
- supporting coordinated actions on health R&D.

G-Finder Survey, funded by the Bill & Melinda Gates Foundation, and conducted by Policy Cures Research, tracks public, private, and philanthropic funding of basic research and product development (R&D) for global health priorities, particularly neglected diseases in LMICs. G-Finder reports include data on all types of product-related R&D, including basic research, discovery and pre-clinical, clinical development, Phase IV and pharmacovigilance studies, and baseline epidemiological studies. Product gaps, needs, market failure are the criteria for neglected diseases in G-Finder; and its data is used as the primary source of neglected disease.

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14 https://gfinder.policycuresresearch.org/
R&D funding data for WHO Global Observatory on Health R&D. The drug development portfolio of the Drugs for Neglected Diseases initiative (DNDi) is also aligned with the findings of G-Finder. G-Finder also tracks funding for emerging infectious diseases (EIDs), and sexual and reproductive health (SRH) issues.

Hosted by National Institutes of Health, USA, World RePORT is another open-access, interactive mapping database project highlighting biomedical research investments and partnerships from some of the world’s largest funding organizations. Data updates are collected annually from each funding organization and the data feeds into WHO Global Observatory on Health R&D.

The various initiatives for tracking investments in health R&D provide a better understanding of current investment trends; products in the pipeline and clinical trials; country and disease specific information such as burden of disease; global indicators on health R&D in the context of the Sustainable Development Goals (SDGs). The publications, databases, classifications, standards and other resources of these tracking initiatives facilitate discussions and consensus to harmonize approaches to collect and share R&D data.

Based on the national and global health indicators, international and national public and non-profit organizations are investing in specific areas of healthcare. Indian government departments have also been actively engaged in healthcare R&D funding. For example, Grand Challenges initiatives are being steered by the Department of Biotechnology (DBT) through an umbrella Memorandum of Understanding (MOU) with BMGF for mission-directed research and build Grand Challenges India to support health research and innovation. The MOU aims to support initiatives that could dramatically change the health and development landscape in India and other countries facing similar challenges. India has also entered into collaboration with UK for strengthening healthcare delivery through AI and digital health.

The objective of the session is to discuss the following:

- Policy for data collection, sample access and creation of National Repositories
- Overview, pros and cons of databases for R&D investments in healthcare – WorldRePORT and G-Finder
- Tracking investments in biotechnology research and development – India perspective

Questions to spur thinking:

- Could a national-level R&D observatory be developed with linkages with data tracking initiatives such as G-FINDER and World RePORT, with WHO Global Observatory on Health R&D?
- What mechanisms could catalyze funding in priority areas of healthcare through improved information on R&D investments?
- How to align drug development portfolio with immediate R&D needs nationally, regionally and globally?
- What are the ways to facilitate policy initiatives through tracking investments in product R&D?

15 https://www.who.int/research-observatory/monitoring/inputs/neglected_diseases/en/
17 https://worldreport.nih.gov/app/
18 http://www.birac.nic.in/desc_new.php?id=103
19https://mea.gov.in/bilateral-documents.htm?dtl/29831/IndiaUK_List_of_MOUsAgreementsInitiatives_during_the_visit_of_Prime_Minister_to_UK_London_April_18_2018
**19 November 2019-Tuesday, 12:00-13:30: Parallel Session 2: Funding and Investments in Medical Products R&D: Role of Data Tracking Initiatives**

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| Tuesday, 12:00-13:30 | Funding and Investments in Medical Products R&D: Role of Data Tracking Initiatives  
**Chair:** Dr Henk Bekedam, WHO Representative to India  
**Co-chair:** Dr Michael Cheetham, Manager, Division of International Relations, Fogarty International Centre, National Institute of Health, United States of America | Durbar Ballroom  |
| **Keynote Addresses** | Dr Michael Cheetham, Manager, Division of International Relations, Fogarty International Centre, National Institute of Health, United States of America- **Global Health R&D: What the WorldRePORT Tells Us** |                  |
| **Panelists** | 1. Dr Anthony D So, Professor of the Practice and Director, IDEA (Innovation + Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, United States of America- **The Role of Transparency in Ensuring Fair Returns from Pharma R&D** |                  |
|                | 2. Dr Nick Chapman, Chief Executive Officer, Policy Cures Research, Australia- **Tracking R&D for Health Security** |                  |
|                | 3. Dr Harish Iyer, India Country Lead, R&D and Senior Scientific Advisor, Bill & Melinda Gates Foundation, India Country Office-  
**Promoting R&D in Global Health with Industry and in Philanthropy to Accelerate Progress on Diseases** |                  |
|                | 4. Dr Purnima Sharma, Managing Director, Biotech Consortium India Limited, India- **Holistic Approach for Effective Technology Translation** |                  |
|                | 5. Professor Maria Zambon, Director of Reference Microbiology Services, Public Health England- **New Childhood Influenza Vaccine Programme in UK: Role of Programme Evaluation** |                  |
CV of Chairs

**Dr Henk Bekedam, WHO representative to India**

Henk Bekedam is the WHO Representative to India; he took up his role on 27 November 2015. He is a Dutch national and a medical doctor by training. He acquired his MSc in Economics from the London School of Economics in 1996.

Prior to his arrival in India, Dr Bekedam was the WHO Representative to Egypt where he took up his position in 2013. He and the team focused WHO's support on scaling-up treatment and prevention of hepatitis C; strengthening the response to the largest outbreak of avian flu in humans and maintaining Egypt's polio free status. Dr Bekedam was for six years the Director of Health Sector Development in the WHO Western Pacific Region. He led a team that provided policy support to 37 countries and areas in Universal Health Coverage, health planning, financing, human resources, information systems, pharmaceuticals and service delivery. Antimicrobial resistance and the establishment of the Asia Pacific Observatory on Health Systems and Policies with other development partners were among his key responsibilities.

Dr Bekedam was the WHO Representative to China from 2002 to 2007. His team was instrumental in supporting China successfully contain the SARS outbreak in 2003. Prior to his time in China, Dr Bekedam worked in Cambodia for six years. He led a health sector reform project, working with Ministries of Health and Finance, State Council and partners to rebuild the health system in post-Khmer Rouge period.

**Mr Michael Cheetham, Manager, World RePORT, Fogarty International Centre, National Institute of Health, United States of America**

Mr. Cheetham is a start-up specialist with more than 20 years of experience working at the intersection of government, academia, and industry. He has a proven track record building strategic partnerships across the spectrum of science, engineering, and health.

His work is focused on building and strengthening global research networks – particularly with low and middle-income countries – with a goal of improving translational opportunities. He manages World RePORT - https://worldreport.nih.gov/- an open-access, interactive mapping database highlighting biomedical research investments from some of the world’s largest funding organizations. He also works on developing innovation hubs to support scientist entrepreneurs, developing networks to bring affordable devices and diagnostics to market in LMICs.
CV of Panelists

Dr Anthony D So, Professor of the Practice and Director, IDEA (Innovation + Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, United States of America

Anthony D. So, MD, MPA, is Professor of the Practice and Founding Director of the Innovation+Design Enabling Access (IDEA) Initiative. Based in Health Systems in the Department of International Health, the IDEA Initiative will foster innovation and design of new technologies for greater health access and impact. He also serves as thematic lead of the Transformative Technologies and Institutions arm of the Johns Hopkins Alliance for a Healthier World. As Director of the Strategic Policy Program of ReAct--Action on Antibiotic Resistance, he works with a global network dedicated to meeting the challenge of antimicrobial resistance, with regional nodes in Africa, Latin America, Asia and Europe.

Dr. So received his BA in philosophy and biomedical sciences and his MD from the University of Michigan as well as a MPA from Princeton University as a Woodrow Wilson Scholar. He has been a member of the Expert Advisory Group of the UN Secretary-General's High-Level Panel on Access to Medicines and of the Technical Working Group of the Equitable Access Initiative (convened by Global Fund to Fight AIDS, Tuberculosis and Malaria and other multilateral institutions), and a member of the Expert Commission on Addressing the Livestock Contribution to the Antibiotic Resistance Crisis (convened by Antibiotic Resistance Action Center, Milken Institute School of Public Health and Natural Resources Defense Council).

Dr Nick Chapman, Chief Executive Officer, Policy Cures Research, Australia

Dr Nick Chapman has extensive experience in health policy and practice as a doctor, researcher and analyst, specialising in innovation and neglected disease policy since 2010. In his previous positions as Director of Research and then Executive Director of Policy Cures, Nick has managed projects for governments, major philanthropic organisations and public-private partnerships. His experience includes work on research tracking, strategy development, funding gap analysis and innovative financing mechanisms. Nick also played an active role in Policy Cures’ efforts to raise the profile of global health R&D in Australia.

Nick is a guest lecturer at the University of Sydney, an expert advisor on R&D to the Access to Medicines Index, and in 2013 was recognised by the Lowy Institute for International Policy as one of its ‘new voices’ in international policy.

Nick began his career as a doctor, before obtaining a Master’s degree in human rights, focusing on international development and international law. Prior to joining Policy Cures, Nick worked with Oxfam Australia and the Australian Human Rights Commission, predominantly on policy solutions to Indigenous health inequality.
Dr Harish Iyer, India Country Lead, R&D and Senior Scientific Advisor, Bill & Melinda Gates Foundation, India Country Office

Harish Iyer is India Country Lead, R&D and Senior Scientific Advisor at the Bill & Melinda Gates Foundation India Country Office and leads the Scientific Programs in the country for the Foundation. Harish is deeply interested in the role of innovation, science and technology in improving health & accelerating economic development. As Senior Advisor, he is a strategic partner between Indian researchers, global partners and the Foundation's Global Health team in critical R&D work including in vaccine-preventable diseases, understanding causes of childhood mortality and new approaches to treating neglected diseases.

Prior to his role at the Foundation, Harish was the CEO of Shantha Biotech from 2011-2015. Harish has also worked in various R&D roles in several biotech companies including as Head of R&D at Biocon, and at Biogen-IDEC and Genentech, and by education has a PhD in chemical engineering.

Dr Purnima Sharma, Managing Director, Biotech Consortium India Limited, India

Dr Purnima Sharma is the Managing Director of Biotech Consortium India Limited (BCIL), New Delhi, India. BCIL is a public limited company promoted by the Department of Biotechnology, Ministry of Science and Technology, Government of India and the all India financial institutions for facilitating biotechnology commercialization. The company has been in existence for almost three decades and has made a significant contribution to biotech sector by providing valuable services in areas such as technology evaluation and transfer, IP management, consultancy, biosafety, capacity building and manpower development to the Central and State Governments, academia, research institutions and industry.

Dr. Sharma is a doctorate from Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, the prestigious institution of national importance of the Ministry of Health, Government of India with Post Doctoral experience from Indian Institute of Technology, Mumbai and has to her credit many awards for excellence in academics.

She has vast experience in the area of issues related to commercialization of biotechnology products and processes and is coordinating a diverse range of biotech programmes of national and international relevance aimed at development and commercialization of biotechnology. She is also extensively engaged in development of bio-entrepreneurship. She is a member of a number of national and state level committees responsible for biotech development and commercialization. She is also a member of The National Academy of Sciences, India (NASI), the first science academy of the country dedicated towards cultivation and promotion of science & technology in the country.
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<th>Professor Maria Zambon, Director of Reference Microbiology Services, Public Health England</th>
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<td>The remit of Public Health England (PHE) includes infectious disease surveillance, specialist reference microbiology &amp; virology, outbreak investigation and response. Maria Zambon is Head of Influenza and Respiratory Virology and Polio Reference Service within PHE and Co-Director of the NIHR Respiratory Health Protection Unit with Imperial College London. She serves as the UK National Microbiology Focal Point, and is a member of the WHO IHR Emergency committee. Maria’s research group is involved in respiratory virus diagnosis, surveillance and integrated clinical research programmes involving vaccines and anti-virals.</td>
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The nations of the world have expressly committed to achieving universal health coverage (UHC) as part of the Sustainable Development Goals. The vision of UHC is that all people should have access to the services they need without facing financial hardship. Ensuring equitable access to appropriate and affordable antimicrobial medicines is a fundamental part of that vision.

Antibiotics have been a critical tool since the discovery of penicillin in 1928, saving the lives of millions of people and animals around the world. The increasing emergence and spread of antimicrobial resistance (AMR) over the last few decades is reducing the efficacy of these lifesaving drugs and is now a major threat to global health. This, coupled with the lack of new treatments, preventive measures, diagnostics and alternatives to antimicrobials emerging from the clinical pipeline, has emphasized that urgent and coordinated action is required. Antimicrobial resistance is a global threat to health, livelihoods and the achievement of the Sustainable Development Goals specifically SDG3 that seeks to ensure healthy lives and promote wellbeing for all. This critical issue has been discussed in many countries and at a range of international fora including the United Nations General Assembly (UNGA), the World Health Assembly (WHA), the G7 and the G20 resulting in high political interest and commitment.

Antibiotics, antivirals, antiparasitic agents and antifungals are increasingly ineffective owing to resistance developed through their excessive or inappropriate use, with serious consequences for human and animal health, and possibly for plant health, and negative impacts on food, the environment and the global economy. Furthermore, as new and remaining antibiotic developers struggle to mobilize financial resources, a coordinated effort between actors spanning research and development through to sustainable access is urgently needed to ensure both new and improved antibiotics remain available and effective to those who need them for generations to come.

While AMR has the highest burden in low to middle income countries, high income countries are also greatly affected. In fact, around 2.4 million people could die in high income countries between 2015 and 2050 without a sustained effort to contain AMR. Addressing AMR will be key to achieving Universal Health Coverage and meeting the Sustainable Development Goals.

In 2001, WHO adopted a global strategy for containment of AMR, which followed resolutions from the World Health Assembly dating back as far as 1984. In May 2015, the World Health Assembly endorsed a global action plan on AMR to tackle antimicrobial resistance, including antibiotic resistance, the most urgent drug resistance trend. The goal of the plan is to ensure, for as long as possible, continuity of successful treatment and prevention of infectious diseases with effective and safe medicines that are quality-assured, used in a responsible way, and accessible to all who need them. The plan follows the One Health approach, looking at actions on human and animal health care areas, the food chain and the
environment. AMR has topped agendas at G7 and G20 Summits, the UN General Assembly, the World Health Assembly and World Economic Forum.

In order to address the crucial problem of Antimicrobial Resistance, WHO has taken its leadership with its Global Action Plan on Antimicrobial Resistance (GAP-AMR) which combines new medicines, discovery development and stewardship (WHO Secretariat (2016) Global action plan on antimicrobial resistance (A69/24 Add.1).

The 72nd WHA adopted a Resolution on antimicrobial resistance. It calls for continued high-level commitments to implement and finance multi-sectoral national action plans, and enhance participation in the Global Antimicrobial Surveillance System. The Resolution outlines a number of actions for the WHO to support countries in implementing national action plans and maintaining the WHO list of ‘Critically Important Antimicrobials for human medicine.’

The ‘Political Declaration of the High-Level Meeting of the UNGA on Antimicrobial Resistance’ (UNGA Resolution 71/3, 2016) recognizes that prevention and control of infections in humans and animals are the key to tackling AMR. It also calls for: innovative research and development; affordable and accessible antimicrobial medicines and vaccines; improved surveillance and monitoring; and increased international cooperation to control and prevent AMR. The Declaration also includes a commitment to mobilize adequate, predictable and sustained funding and human and financial resources and investment through national, bilateral and multilateral channels to support the development and implementation of NAPs, research and development on existing and new antimicrobial medicines, diagnostics and vaccines, and other technologies, and strengthening of related infra-structure.

In 2017, the G20 expressed its support to move towards universal health coverage (UHC) in line with national contexts and priorities, improved preparedness against health threats which highlighted the importance of resilient health systems in this regard, including infectious disease outbreaks, and discussed ways to strengthen the prudent use of antimicrobials and to boost the pharmaceutical R&D pipeline. They called for a new international R&D Collaboration Hub to maximize the impact of existing and new research initiatives as well as product development.

Noting the ongoing work done by Global AMR R&D Hub, G20 leaders have called on interested G20 members and Global AMR R&D Hub to analyze push and pull mechanisms to identify best models for AMR R&D and to report back to relevant G20 Ministers.

According to the Global tuberculosis report 2018, drug-resistant tuberculosis continues to be a public health crisis. Among cases of multidrug-resistant tuberculosis in 2017, 8.5% were estimated to have extensively drug-resistant tuberculosis.

The high rates of Neglected Tropical Diseases Drug Efficacy in sub-Saharan Africa and South-East Asia are expected to contribute to the emergence of resistance to anthelminthic medicines; the Working Group’s seventh meeting in 2018 articulated such concerns in relation to resistance to treatment for soil-transmitted helminthiases.

To optimize the use of antimicrobial medicines in human and animal health- WHO in its Model List of Essential Medicines (2019), adopted a new AWaRe classification for antibiotics.

20 WHO AMR 72 assembly
to guide optimal use of antibiotics and reduce resistance, comprising three groups: (a) Access antibiotics (b) Watch antibiotics; (c) Reserve antibiotics.

WHO anticipates that the introduction of the “AWaRe” framework will reduce the use of antibiotics in the Watch and Reserve groups, while the accessibility of those in the Access group will expand. Furthermore, all newly registered antibiotics will be reviewed and classified in AWaRe categories to guide stewardship programmes and define research gaps in the definition of their role in therapy.

In order to foster investment in new antimicrobials, as well as in safe and effective alternatives to antimicrobials for human, animal and plant health, the private sector, philanthropies and government institutions need to closely coordinate their efforts. The Tripartite Organizations engage in ongoing dialogue with development partners and civil society organizations so as to support antimicrobial resistance initiatives within the broader sustainable development agenda. One such initiative, a global antibiotic research and development partnership, jointly developed by WHO and the Drugs for Neglected Diseases initiative, is aimed at developing new treatments for bacterial infections. Through the partnership, WHO and the Drugs for Neglected Diseases initiative have launched programmes to address sepsis in newborns and to develop a new first-in-class treatment for drug-resistant gonorrhoea, which is entering the third phase of clinical trials.

Research priorities are embedded in WHO’s action plans:
- WHO has published a list of 12 groups of pathogens (the global priority pathogens list), some of them causing common infections such as pneumonia or urinary tract infections that are increasingly resistant to existing antibiotics and urgently in need of new treatments; the aim is to guide and promote research and development.
- The Global Antibiotic Research and Development Partnership (GARDP) has been created to develop new antibiotic treatments addressing antimicrobial resistance, while ensuring equitable access for all in need. GARDP is being incubated by the Drugs for Neglected Diseases initiative (DNDi) in collaboration with the World Health Organization (WHO).
- Joint programming initiative on AMR (JPIAMR) has been set up to streamline the European research efforts in AMR by joint planning, implementation and evaluation of national research programmes; it coordinates annual joint calls for new research projects on AMR with EU or national funding.
- The Commission funds several antimicrobial resistance projects through its Health Programme and its research programmes.
- The development of cheap rapid diagnostic tests is also key to guide the appropriate use of antibiotics thereby reducing overuse and misuse.

In 2019, WHO issued a revised global priority list of antibiotic-resistant bacteria that pose the greatest threat to human health. The list, which is aimed at guiding research into and the discovery and development of new antibiotics, will be updated regularly to catalyse public and private funding for research and development. 

The Global Antimicrobial Resistance (AMR) Research and Development (R&D) Hub was launched in May 2018, following a call from G20 Leaders to address challenges and improve coordination and collaboration in global AMR R&D using the One Health approach. The Global AMR R&D Hub will support global priority setting and evidence-based decision-making on the allocation of resources for AMR R&D through the identification of gaps, overlaps and potential for cross-sectoral collaboration and leveraging in AMR R&D.
US Food and Drug Administration (US FDA) and EMA currently routinely discuss development plans for new antimicrobials; discussions are also ongoing on the possibility of establishing standardised protocols agreed by the two agencies. Recent harmonisation efforts between EMA,

US FDA and the Japanese regulatory authority (PMDA) through which tri-partite meetings are organised twice a year to agree on concrete areas of convergence. Proposals for convergence were agreed for example in the context of the development of medicines for urinary tract and intra-abdominal infection trials.

Sustainable access for health systems and patients is an essential & dynamic balance between stewardship, innovation and access. Developing new economic models to incentivise antibiotic discovery and development is the need of the hour despite knowing the disadvantages for putting R&D for antibiotics, as antibiotics are relatively cheap medicines with low return on investment. Initiatives that aim to explore new business models:

- "Push" incentives that support discovery and early phases of development: e.g. US government’s Biomedical Advanced Research and Development Authority (BARDa), JPIAMR, Wellcome Trust provide funding to the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), World Health Organization (WHO) and the Drugs for Neglected Diseases initiative (DNDi) have created the Global Antibiotic Research and Development Partnership (GARDP), supported by several European governments, the government of South Africa and the NGO Médecins Sans Frontières (MSF)

- “Pull” incentives that delink payment from prescribing volume and involves the promise of a reward for the development of new antimicrobials that target pathogens that represent a high AMR risk; eg, United States’ Generating Antibiotic Incentives Now (GAIN) Act- grants an additional five years of market exclusivity for companies developing antibiotics that target a selected group of qualifying pathogens.

- Platforms to discuss approaches, e.g. TATFAR, Duke-Margolis PAVE, DRIVE-AB, German Global Union for Antibiotics Research and Development (GUARD) Initiative and the UK Review on AMR.

- A European Union-based joint programming initiative on antimicrobial resistance has mapped the funding of research on antimicrobial resistance in relation to therapeutics, diagnostics, surveillance, transmission, the environment and interventions.

- The creation of a global antimicrobial resistance research and development hub by the Federal Ministry of Education and Research of Germany; the launch of the “Grand challenges” initiative of the Bill and Melinda Gates Foundation; the establishment of a research and development centre for antimicrobial resistance in the United Kingdom; the creation of an antibiotic development platform in the Netherlands; and the creation of a fund known as the “Replenishing and enabling the pipeline for anti-infective resistance impact fund”.

Because the development of new anti-bacterials may have fallen behind the rate of antibacterial obsolescence, incentives for new drug development are needed. Recent reports have suggested that government incentives are essential to encourage research and development (R&D) for novel anti-bacterials. It is also important that such incentives do not undermine efforts to preserve the effectiveness of existing drugs, and indeed, they could be targeted to promote such preservation.

New antibacterial drugs should fulfil three criteria: first, they should be drugs to which resistance has not developed and that do not exhibit cross-resistance with other drugs; second, they should have a narrow spectrum of activity to reduce the likelihood of resistance; and third, they should directly address public health needs.
**Global AMR R&D Hub**

It will also promote coordination among governments in the fight against AMR. It is a global partnership currently consisting of 16 countries, the European Commission and two philanthropic foundations and four international organisations (as observers).

India, which is among countries with the highest bacterial disease burden in the world, has become a part of the Global Antimicrobial Resistance Research and Development Hub on September 12, 2019. With India as a member, the Hub now represents more than half the world’s population.

This session aims to inform the ongoing discussions and processes on developing a new business model for antibiotics. It is based on the premise that delinkage, seeking to separate the return on investment from antibiotic sales volumes, should be the principle underpinning any new business model. It calls on governments to invest significantly in antibiotic R&D by financing a broad menu of incentives across the antibiotic life-cycle, with the highest incentives targeted at the development of antibiotics directed at the greatest health threats arising from antibiotic resistance. Contributions from countries should be coordinated within a globally agreed framework. Global access along with conservation should be a priority for any new business model fostering innovation.

The objective of the session is to identify the gaps in R&D and opportunities in the wake of tackling AMR and define priorities for investments including priority setting and coordination in R&D. The following topics are proposed for discussion:

- Discussing how push funding initiatives (e.g. GARDP and CARB-X) and pull incentives can be leveraged with improved access to new and existing antimicrobials; and, in turn, how widening access in low-income settings can be balanced with better stewardship and more prudent use of antimicrobials
- Role of Product Development Partnerships for Access to Health Technologies

Questions to spur thinking:

- Discuss for changing the Innovation Ecosystem for Antimicrobials
- How can new and sustainable models of R&D be made to address the crucial issue of Antimicrobial Resistance?
- To what extent global efforts on AMR are integrated with the work needed to achieve the Sustainable Development Goals and Universal Health Coverage (Mainstreaming AMR into all relevant SDGs)?
### Incentives for Development in Antibiotics, Global Anti-Microbial Resistance R&D Hub

**Chair:** Dr Balram Bhargava, Secretary, Department of Health Research and Director-General, Indian Council of Medical Research, Ministry of Health and Family Welfare, Government of India

**Co-chairs:** Dr Anthony D So, Professor of the Practice and Director, IDEA (Innovation + Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, United States of America

**Keynote Address**

Dr Anthony D So, Professor of the Practice and Director, IDEA (Innovation + Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, United States of America- *Alternative Production and Delivery Models for Sustainable Access to Antibiotics*

**Panelists**

1. Ms Michelle Childs, Head of Policy Advocacy, Global Antibiotic Research and Development Partnership (GARDP)/ Drugs for Neglected Diseases initiative (DNDi), Switzerland- *Sustainable Financing and Incentives for R&D including GARDP Perspective*

2. Dr David Kaslow, Vice President, Essential Medicines Director, PATH, United States of America- *Incentivizing R&D and Promoting Access*

3. Dr Kamini Walia, Scientist E, Indian Council of Medical Research, Government of India- *Antimicrobial Resistance Surveillance & Research Network in India*

4. Dr Anand Anandkumar, Chief Executive Officer, Bug Works, India- *Raising Financial Capital for R&D in AMR*
CVs of Chairs

Dr Balram Bhargava, Secretary, Department of Health Research, and
Director General, Indian Council for Medical Research, Ministry of
Health and Family Welfare, Government of India

Professor Balram Bhargava, Secretary, Department of Health Research, (Ministry of Health & Family Welfare), Government of India and Director General, Indian Council of Medical Research (ICMR) joined on 16th April, 2018. Prof. Bhargava is Professor of Cardiology at All India Institute of Medical Sciences (AIIMS), New Delhi and also serves as the Executive Director for Stanford India Biodesign Centre, School of International Biodesign (SIB). Professor (Dr) Balram Bhargava is an outstanding cardiologist, one of the foremost leaders in biomedical innovation, public health, medical education and medical research.

Professor Bhargava has excellent leadership qualities; and has established the India-Stanford Biodesign programme, a unique interdisciplinary fellowship programme to foster innovation, design in low cost implants/devices. This programme has led to the establishment of the School of International Biodesign (SIB) at AIIMS and development of 30 low cost medical devices leading to 10 startups. Four of the low cost devices are in the Indian market and one device has been approved by the USFDA. He developed the indigenous Platinum Iridium coil coronary stent and has been instrumental in clinically evaluating and establishing the use of two other laser cut medicated Indian stents. The philosophy of the programme has been “More for less for more” with a mandate to promote Global Affordable Need Driven Healthcare Innovation (GANDHI).

He set up the c-GMP Centre for Excellence for Stem Cell Studies, at AIIMS which has initiated treatment of patients with dilated cardiomyopathy; this has benefitted number of no-option heart failure patients waiting on the cardiac transplant list.

He is currently developing the Chest Compression Device for Sudden Cardiac Death patients; funded by the Wellcome Trust, London. He has led two major trials in India funded by the NIH, Bethesda, USA which has changed clinical practice. He has pioneered several techniques in interventional cardiology.

He has been awarded the SN Bose Centenary award by the Indian National Science Congress and National Academy of Sciences Platinum Jubilee Award, Tata Innovation Fellowship and Vasvik Award for Biomedical Technology Innovation, Ranbaxy Award and the OP Bhasin Award in the field of Health and Medical Sciences. He is the Founding, Editor in Chief of the British Medical Journal Innovations (BMJi).

He has been awarded the ‘Padma Shri’ high civilian award by the Honourable President of India and the UNESCO Equatorial Guinea International Prize for research in Life Sciences at Paris.
Dr. Anthony D. So, Professor of the Practice and Director, IDEA (Innovation + Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, United States of America

Anthony D. So, MD, MPA, is Professor of the Practice and Founding Director of the Innovation+Design Enabling Access (IDEA) Initiative. Based in Health Systems in the Department of International Health, the IDEA Initiative will foster innovation and design of new technologies for greater health access and impact. He also serves as thematic lead of the Transformative Technologies and Institutions arm of the Johns Hopkins Alliance for a Healthier World. As Director of the Strategic Policy Program of ReAct--Action on Antibiotic Resistance, he works with a global network dedicated to meeting the challenge of antimicrobial resistance, with regional nodes in Africa, Latin America, Asia and Europe.

Dr. So received his BA in philosophy and biomedical sciences and his MD from the University of Michigan as well as a MPA from Princeton University as a Woodrow Wilson Scholar. He has been a member of the Expert Advisory Group of the UN Secretary-General’s High-Level Panel on Access to Medicines and of the Technical Working Group of the Equitable Access Initiative (convened by Global Fund to Fight AIDS, Tuberculosis and Malaria and other multilateral institutions), and a member of the Expert Commission on Addressing the Livestock Contribution to the Antibiotic Resistance Crisis (convened by Antibiotic Resistance Action Center, Milken Institute School of Public Health and Natural Resources Defense Council).

CVs of Panelists

Ms Michelle Childs, Head of Policy Advocacy, Global Antibiotic Research and Development Partnership (GARDP)/ Drugs for Neglected Diseases initiative (DNDi), Switzerland

Michelle Childs became Head of the policy advocacy team at DNDi in 2016. The policy advocacy team is a shared resource with GARDP. Ms Childs has an extensive experience in proposing and advocating for solutions to access and innovation barriers faced by developing countries and health providers. She has helped to develop several proposals on innovation using open knowledge principles for Chagas disease, TB and was a co-author of the original proposal for the creation of a patent pool for HIV medicines by UNITAID. She was an expert adviser for the WHO to help further develop four open knowledge demonstration projects from India, Brazil, South Africa and Thailand.

She has worked for leading consumer, health and knowledge rights organizations and public authorities including as Director of Policy Advocacy at the Access Campaign of Médecins Sans Frontières (MSF). She started her career as a lawyer in a City of London law firm.

Dr David Kaslow, Vice President, Essential Medicines Director, PATH, United States of America

David Kaslow, MD, is the vice president for Essential Medicines at PATH, which includes our Drug Development Program and the PATH Center for Vaccine Innovation and Access (CVIA). As the director of CVIA, he leads work to accelerate the development and introduction of lifesaving
Dr Kaslow has more than 25 years of experience in vaccine research and development. Before joining PATH in 2012 as director of MVI’s work to drive the development of safe and effective vaccines against malaria, he held key advisory positions with MVI and the Bill & Melinda Gates Foundation related to malaria vaccines. Prior to that, he oversaw project leadership and management of Merck Research Laboratories’ vaccine pipeline and founded the Malaria Vaccine Development Unit at the National Institutes of Health.

As a basic research scientist, Dr. Kaslow completed the molecular cloning and characterization of several proteins involved in malaria parasite sexual development. He also has directed product development, including field studies, of several malaria vaccine candidates.

Outside the malaria field, Dr. Kaslow has contributed to the vaccine application of tools originally developed for gene therapy. He holds or co-holds more than a dozen patents and has published more than 150 scientific papers. Dr Kaslow received his medical degree from the University of California, San Francisco.

Dr Kamini Walia, Scientist E, Indian Council of Medical Research, Government of India

Kamini Walia, PhD MPH, is a microbiologist by training and has subsequently trained in public health from Johns Hopkins. She is working as Senior Scientist in the Division of Epidemiology and Communicable Diseases Division of Indian Council of Medical Research. She spent 2 years in PATH, as Director, Research and Development. During her 19 years of experience in public health space, she has initiated and successfully steered numerous projects and programs of public health importance in the field of infectious diseases, reproductive and child health and non-communicable diseases. Dr Walia’s experience spans working on infectious diseases, including HIV/AIDS programs and health technologies including vaccines and diagnostics. Dr Walia is currently leading the Antimicrobial Resistance Initiative of ICMR. This initiative focuses on capacity building for AMR, undertaking research and surveillance and building antimicrobial stewardship activities. ICMR is also working with relevant partners to build capacities for integrated surveillance from animals and humans. Dr Kamini Walia is also steered the development of Essential Diagnostics List for India in collaboration with the relevant stakeholders.

She is recipient of ICMR’s Shakuntala Amir Chand award and Indian National Science Academy, Young Scientist Award. She has received numerous fellowships and trainings from WHO, NIH, USA, IVI, Seoul, Pasteur Institute, France.
Dr Anand Anandkumar, Chief Executive Officer, Bug Works, India

Dr Anand Anandkumar is the Co-founder of Bugworks Research a drug discovery company that aims to discover a new class of broad-spectrum antibiotics to handle the worst superbug infections in hospital and community settings. Bugwork’s solutions also find applications in Bio-Defense area. The company has won many national and international innovation awards including the Best bio-start-up in India (2015), Economic Times Top Innovator award (2017), first company outside North America and Europe to win the coveted US Government CARB-X grant and prominently featured in the CB-InSights 2019 list of top 36 global start-ups. Anand is a global KOL in the global AMR ecosystem.

Bugworks was spun-out from Cellworks (in which Anand is a co-founder), a company that pioneered solutions for personalized medicine in the Oncology space. Prior to working in Biotech, Anand was associated with the semiconductor industry where he spent 18 years specializing in Electronic Design Automation (EDA) Software products, IC design and in setting up and running global operations in Emerging markets India and China. Before co-founding Bugworks, Anandkumar was the founding Managing Director of the India operations of Magma Design Automation.

Anandkumar received his MS and PhD in Biomedical & Electrical Engineering from George Washington University, Washington DC and his BTech in EE from Anna University. He is a co-founder of the India semiconductor association, Executive committee member and treasurer of ABLE and board member of the global AMR Industry alliance.
Session Brief

The fundamental scientific value of being able to control the nature and timing of infection and interventions in well-characterised human subjects remains unchanged, but it is now greatly enhanced by advances in immunology, functional genomics, microbiomics, pharmacogenetics, pharmacokinetics and pharmacodynamics.

CHIM studies offer an efficient model for the selection of the most promising agents from a diversity of available candidates for further product development, and are increasingly being utilised to efficiently bridge safety and immunogenicity testing and phase II/III efficacy studies. CHIM studies not only allow efficacy data to be generated quickly, they also facilitate the identification of good immune correlates, the down-selection of vaccine candidates and early vaccine formulation decisions, thus avoiding unnecessary and costly large-scale trials. There are unique ethical, safety and scientific challenges associated with CHIM studies that mean that robust governance and appropriate regulation is essential to their effective use and continued growth.

Although CHIM studies have been performed since the pre-1940s, it is only in the last 10 to 15 years that the methodology has seen a resurgence, driven by the development of new therapeutics and vaccines against a range of organisms. CHIM studies offer an efficient model for the selection of the most promising agents from a diversity of available candidates for further product development, and are increasingly being utilised to efficiently bridge safety and immunogenicity testing and phase II/III efficacy studies. CHIM studies not only allow efficacy data to be generated quickly, they also facilitate the identification of good immune correlates, the down-selection of vaccine candidates and early vaccine formulation decisions, thus avoiding unnecessary and costly large-scale trials.

University of Oxford has also designed, developed and done clinical evaluation of vaccines including those for meningococcal disease and enteric fever and leads studies using a human challenge model of (para)typhoid. University of Maryland School of Medicine, Center for Vaccine Development, Baltimore, USA has developed human infection challenge models for Shigella, diarrheagenic E. coli, and cholera to assess efficacy of new vaccine candidates.

In Europe and the United States (US), CHIM studies are regularly performed using various viruses, bacteria and parasites. Globally, clinical trials are increasingly being conducted in less wealthy countries outside of the US and Europe, where the cost of running trials is substantially lower. CHIM studies, however, are still in infancy in Asian countries.

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Global Regulatory Considerations for Human Challenge Studies

The regulatory requirements for CHIM studies vary according to countries. The major difference lies in the requirements for the challenge pathogen. These include differences in the level of release testing required as well as the requirements set by the regulatory agency for the challenge pathogen to be deemed suitable for use before subjects are challenged in a clinical trial.

For instance, FDA considers live organisms to be ‘biologics’ and has declared that an “Investigational New Drug Application (IND) is required for challenge studies in which live organisms (e.g., virus, bacteria, or fungi that is modified or wild-type) is administered to subjects to study the pathogenesis of disease or host response to the organism”. This is not, however, the position of the European Economic Area (EEA), which considers the challenge agent as a Non-Investigational Medicinal Product (NIMP). This means that it does not fall within the rules for manufacturing of medicinal products, as set out in Title IV of Directive 2001/83/EC, or the rules for manufacturing of IMPs, as set out in Article 13 of Directive 2001/20/EC, Article 9 of Commission Directive 2005/28/EC and Commission Directive 2003/94/EC. While NIMPs do not have a marketing authorisation in the EU, they have to be manufactured under GMP guidelines, such that they are as safe for subjects as an IMP would be.

In this context, India Volunteer Research Infection Consortium (IVIRC) has been created and the first meeting of the India Volunteer Research Infection Consortium (IVIRC) was held on July 3rd, 2019 at the Translational Health Science and Technology Institute (THSTI), Faridabad. The consortium will debate and discuss various aspects (laboratory, clinical research, clinical care, ethics, engagement etc.) of such studies and will develop a white paper for CHIM studies in India. In the recently held 3rd Annual Regulators Conclave for Central and State Regulatory Authorities in India, jointly organized by CDSCO with WHO, Controlled Human Infection Model Studies was one of the sessions in the conclave. It was recommended that:

(i) A regulatory pathway guidance for Controlled Human Infection Model Studies in India needs to be developed by CDSCO, including ethical considerations with the support of THSTI, DBT, ICMR and WHO. A white paper in this regard may be prepared by THSTI and other stakeholders and shared with CDSCO.

(ii) In India, human challenge trials could be considered as an innovative translational approach for certain public health solutions.

Case Example

Typbar TCV® from Bharat Biotech, World’s First Typhoid Conjugate Vaccine Prequalified by WHO

Bharat Biotech’s Typbar TCV®, the world’s first clinically proven Typhoid Conjugate Vaccine against typhoid fever has received prequalification from World Health Organisation (WHO). This enables the procurement and supplies of this life saving vaccine to UNICEF, Pan-American Health Organization (PAHO) and GAVI supported countries. Typbar TCV® is the first typhoid vaccine, clinically proven to be administered to children from 6 months of age to adults and confers long term protection against typhoid fever. Typbar TCV® has been evaluated in Human Challenge Studies at Oxford University and typhoid conjugate vaccines have been recommended by WHO’s Strategic Advisory Group of Experts on Immunization (WHO-SAGE).

Objective of the session is to discuss the following:
To discuss the current regulatory and ethical landscapes for Controlled Human Infection Studies (CHIM) studies, globally and discuss the way forward for establishing the regulatory and ethical pathways in other countries

Questions to spur thinking:
- What are the current models of regulation being used in Africa, Europe, USA, Japan, Australia, UK, South East Asia Region?
- What is the current ethical landscape for CHIMS globally?
- How can regional networks be leveraged for CHIMS regulatory and ethical approval?
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<th>Time</th>
<th>Parallel Session 4- Tuesday, 19 November 2019</th>
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| Tuesday,     | Controlled Human Infection Model (CHIM) Studies-Regulatory and Ethical Considerations  
| 14:30-15:45  | *Chair*: Dr Gagandeep Kang, Executive Director, Translational Health Sciences and Technology Institute, India  
|              | *Co-chair*: Ms Shobana Balasingam, Programme Officer, Vaccines, Wellcome Trust, United Kingdom  
|              | **Keynote Addresses**  
|              | 1. Dr Wilbur Chen, Associate Professor, University of Maryland School of Medicine, United States of America-  
|              | **CHIMS to Promote Regulatory Approval**: Vaxchora Licensure for Cholera by USFDA  
|              | 2. Ms Shobana Balasingam, Programme Officer, Vaccines, Wellcome Trust, United Kingdom- **CHIMS-Present Position and Next Steps for National, Regional and Global Engagement**  
|              | **Panelists**  
|              | 1. Ms Katherine Littler, Senior Ethics Specialist, Global Health Ethics, World Health Organization-Geneva, Switzerland-  
|              | **WHO Guidance for CHIMS**  
|              | 2. Dr Jeffrey D’Souza, Research Associate, Institute on Ethics & Policy for Innovation, McMaster University, Canada-  
|              | **Ethical Implications of Conducting Multi-jurisdictional Clinical Trials in Low-Resource Settings**  
|              | 3. Dr Diadié Maïga, Regional Vaccine Regulatory Officer, World Health Organization, Regional Office for Africa-  
|              | **Supporting Regional Collaboration in CHIMS in Networks such as African Vaccine Regulatory Forum (AVAREF)**  
|              | 4. Dr Chris Ockenhouse, Director, Medical and Clinical Operations, Malaria Vaccine Initiative, PATH, United States of America-  
|              | **CHIMS Considerations in Malaria Vaccine Initiative**  
|              | 5. Dr Bernhards Ogutu, Chief Research Officer, Kenya Medical Research Institute (KEMRI) and Director for Centre for Research in Therapeutic Sciences, Strathmore University, Kenya-  
|              | **Clinical Therapeutics Development through Engagement in CHIMS: Malaria Perspective**  
|              | 6. Dr Pieter Neels, CEO & Scientific Advisor at Vaccine-Advice, Belgium-  
|              | **Aspects for Consideration by Regulator and
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<th>Vaccine Developers in CHIMS</th>
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<td>7. Dr Melissa Kapulu, Research Scientist in Infectious Diseases, Kenya Medical Research Institute (KEMRI), Kenya- <strong>Immunological Aspects of Malaria Transmission- Identifying and Developing Vaccine Candidate Targets</strong></td>
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<td>8. Dr Nilima Kshirsagar, National Chair Clinical Pharmacology Indian Council of Medical Research, Government of India- <strong>Scientific and Ethical Considerations in India for CHIMS</strong></td>
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<td>9. Dr Rob Lambkin-Williams, Executive Scientific Advisor, hVIVO &amp; Virology Consult, United Kingdom- <strong>Manufacturing of Human Viral Challenge Agents For Use In Clinical Studies To Accelerate The Drug Development Process</strong></td>
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CVs of Chairs

Dr Gagandeep Kang, Executive Director, Translational Health Science and Technology Institute, India

Dr Gagandeep Kang, MD, PhD is the Executive Director, Translational Health Science Technology Institute (THSTI), an autonomous institute of the Department of Biotechnology, Ministry of Science & Technology, Government of India. Over two decades, she has built a research program that has conducted key studies to understand enteric infectious diseases in impoverished communities. She is known for her inter-disciplinary research studying the transmission, development and prevention of enteric infections and their sequelae in children in India. To develop practical approaches to support public health, she has also built national rotavirus and typhoid surveillance networks, established laboratories to support vaccine trials and conducted phase 1-3 clinical trials of vaccines, a comprehensive approach that has supported two WHO pre-qualified vaccines, made by two Indian companies. She is investigating the complex relationships between infection, gut function and physical and cognitive development, and seeking to build a stronger human immunology research in India.

Dr. Kang has published over 300 papers in national and international journals. She is on several review committees for national and international research funding agencies. Her groundbreaking work has been recognized with numerous awards and honors. These include Woman Bio-scientist of the Year from the Government of India (2006); election to Fellowship of the American Academy of Microbiology (2010), the Indian Academy of Sciences (2011), National Academy of Sciences (2013), the Faculty of Public Health in the UK (2015), and the Indian National Science Academy (2016). She is the First Indian Woman To Receive The Fellowship Of The Royal Society in 2019.

Ms Shobana Balasingam, Programme Officer, Vaccines, Wellcome Trust, United Kingdom

Ms Shobana Balasingam is a Programme Officer in the Vaccines department at Wellcome Trust. Shobana’s role focuses on the expansion of Controlled Human Infection Models in endemic settings to accelerate vaccine development and to ensure that vaccines are relevant to the people most at risk. To enable this, Wellcome will support targeted community and political engagement, ethics research, regulatory strengthening, and capacity building. We will also promote harmonization, protocol, data and sample sharing wherever possible in accordance with our commitment to Open Research.
### CVs of Keynote Speaker

**Dr Wilbur Chen, Associate Professor, University of Maryland School of Medicine, United States of America**

Dr Chen is an adult infectious disease physician-scientist with a specific interest in clinical vaccinology. He is chief of the Adult Clinical Studies section within the Center for Vaccine Development and director of the UMB Travelers’ Health Clinic. His primary research interests are two-fold: developing vaccines for the elderly (a rapidly growing segment of the global population which is susceptible to infection) and developing vaccines for enteric pathogens (diseases chiefly of resource poor and economically disadvantaged countries).

Dr Chen is active investigator within the NIAID-supported Vaccine and Treatment Evaluation Unit (VTEU), composed of 9 academic centers throughout the U.S., and was the principal investigator of the NIAID-supported Food and Waterborne Diseases Integrated Research Network Clinical Research Unit. He has been a PI on vaccine trials for: influenza (Seasonal, Pandemic 2009 H1N1, and Avian H5N1 influenza), agents of bio-terror (Tularemia and Staphylococcal enterotoxin B), and enteric pathogens (typhoid, cholera and enterotoxigenic E. coli); including human experimental challenge studies with wild-type V. cholerae and enterotoxigenic E. coli.

### CV of Panelists

**Ms Katherine Littler, Senior Ethics Specialist, Global Health Ethics, World Health Organization-Geneva, Switzerland**

In October 2018, Katherine Littler joined the Global Health Ethics Team at the World Health Organization in Geneva as Senior Ethics Specialist and Co-lead. Current areas of focus, include: emerging technologies, particularly human genome editing; genomics; human challenge studies; and epidemic preparedness and response. Prior to this, Katherine co-led the Global Policy Team at Wellcome. She has a background in medical law and ethics and during her time at Wellcome provided strategic advice on regulatory, governance and ethical issues. She led a programme of work focusing on research ethics, global governance and advocacy, epidemic preparedness, genomics and emerging technologies, and evidence into policy. She has sat on many oversight bodies, including: the PHE Ebola Governance Group; the IDDO Ebola Platform Steering Committee; the H3Africa Ethics and Regulatory Working Group and she was the chair of the GLOPID-R data sharing working group.
| Dr Jeffrey D’Souza, Research Associate, Institute on Ethics & Policy for Innovation, McMaster University, Canada |
Dr. Jeff D’Souza is a Research Associate at the Institute on Ethics and Policy for Innovation (IEPI) at McMaster University, Canada. He works on identifying, managing, and providing solutions to ethics challenges, ethics-related risks, and policy gaps in global health research. His interests are in global health ethics and health equity, broadly construed, and he currently leads the Ethics of Clinical Trials research portfolio at IEPI. Current projects include an examination of innovative approaches in public health for improving health equity, and the ethics of conducting controlled human infection model (CHIM) studies in high-resource and low-resource settings. Dr. D’ Souza holds a PhD in Philosophy specializing in ethics and has recently published multiple papers in virtue ethics. |
| Dr Diadié Maïga, Regional Vaccine Regulatory Officer, World Health Organization, Regional Office for Africa |
Diadié is Regional Vaccine Regulation Officer at the WHO Regional Office for Africa. With 20 years’ experience, Diadié is an expert in the development, implementation and evaluation of regulatory strategies for pharmaceuticals and national pharmaceutical policies in least developed countries. He has served, for many years, as a Pharmaceutical Systems Officer and Deputy General Director at the Pharmacy Department of the Ministry of Health in Mali. Diadié successfully led the pharmaceutical regulatory unit at the Ministry of Health and numerous working groups in several pharmaceutical system areas, including medicines policies, good practices, pre-market evaluation of medicines, and clinical trials authorization. Under the umbrella of USAID technical assistance to the Government of Haiti, Diadié served for over two years as the Pharmaceutical Policy Advisor at the Haitian Ministry of Health. One of his greatest accomplishments was to advise the Government to adopt and launch the first National Pharmaceutical Policy which is now one of the pillars of the health system in Haiti. He subsequently developed a three-year strategic plan, also adopted by the Ministry of Health, to facilitate its implementation. Before joining WHO/AFRO, Diadié held the position of Principal Technical Advisor in Pharmaceutical Systems for the USAID/SIAPS Programme in Arlington, USA. Diadié holds a degree in pharmacy from the Faculty of Medicine and Pharmacy of Mali, a Master in Public health from University Libre of Brussels and a Ph.D. in public health from the University of Montreal, Canada. |
Dr Christian Ockenhouse, Director, Medical and Clinical Operations, Malaria Vaccine Initiative, PATH, United States of America

Chris Ockenhouse provides scientific and clinical guidance to translational project teams in charge of early clinical development, working closely with MVI staff, partners, and academic investigators. He also provides medical and scientific expertise on clinical malaria, clinical immunology, and trial design. He serves on the Malaria Disease Area Translational Leadership Team.

Chris has over 25 years of experience leading R&D programs focused on discovery, process development, manufacture, and early clinical testing of multiple vaccine candidates against Plasmodium falciparum and P. vivax malaria. Prior to joining MVI, Chris was Director of the Malaria Vaccine Program at the Walter Reed Army Institute of Research (WRAIR), where he directed the formation and operations of the first joint US Army-Navy Military Malaria Vaccine Program dedicated to developing malaria vaccines within the Department of Defense. He retired from active duty as a Colonel in the US Army. Chris received his medical degree from the Medical College of Pennsylvania in Philadelphia, a PhD in immunology & parasitology from the Sackler Institute for Biomedical Sciences at New York University, an MS in parasitology from the Tulane University School of Tropical Medicine and Hygiene in New Orleans, and a BS (honors) from Wheaton College. Chris has also published more than 150 articles in scientific and medical literature.

Dr Bernhards Ogutu, Chief Research Officer, Kenya Medical Research Institute (KEMRI) and Director for Centre for Research in Therapeutic Sciences, Strathmore University, Kenya

Dr Bernhards Ogutu is currently the Chief Research Officer with the Kenya Medical Research Institute (KEMRI) and Senior Clinical Trialist with the Malaria Clinical Trials Alliance of the INDEPTH-Network. Ogutu is also Director for the Centre for Research in Therapeutic Sciences (CREATEs) at Strathmore University in Nairobi. He has authored more than 150 peer reviewed publications. His areas of research expertise include clinical trials, disease pathogenesis, and clinical therapeutics with a bias in malaria and clinical trials capacity development.

Dr Ogutu received his MBChB, MMed and PhD from the University of Nairobi. Dr Ogutu is a board certified Medical Practitioner, Paediatrician and Clinical Pharmacologist.

Dr Pieter Neels, Associate Professor University of Namur, Chair Human Vaccine Committee, International Alliance for Biological Standardization (IABS), Belgium

Dr Pieter Neels is a native of Belgium where he trained as an MD (University of Antwerp, 1985) and was boarded as a general practitioner. In 1997, he joined the Belgian Ministry of Public Health as a senior evaluator of the clinical part of registration files in the field of cardiology, nephrology, endocrinology (diabetes). In 2001 he was appointed CPMP member. In 2002 he was asked to take over all Belgian central vaccine rapporteurships.

He was elected vice-chair of Vaccine Working Party, a CHMP
workgroup for vaccines for discussion on development and evaluation of registration files for vaccines until June 2013. WHO has asked Dr Neels to attend many meetings on vaccine development all over the world in order to share the EU regulatory requirements/competence in vaccinology. Dr Neels is also a member of the world wide network on vaccine promotion as he is asked to attend the ADVAC course (Foundation Mérieux) and the IABS conferences.

In 2013 Dr Neels was nominated associate Professor at the Namur University for a course in Vaccinology. In June 2013 Dr Neels stepped down from the CHMP and left the Belgian Federal Agency to start his own consultancy company “Vaccine-Advice” in order to be able to support vaccine development in a more efficacious way.

In 2014 Dr Neels was elected board member of IABS-EU and in 2016 he accepted to chair the Human Vaccine Committee of IABS.

**Dr Melissa Kapulu, Research Scientist in Infectious Diseases, Kenya Medical Research Institute (KEMRI), Kenya**

Melissa is a research scientist in infectious disease with a background in immunology and vaccinology. Her main interests are in utilising human infection models to understand immunological aspects of infectious diseases with the aim of identifying, developing, and evaluating vaccine candidate targets. Her key interests are particularly in malaria (transmission stages) and shigella which are infections of major public health importance focusing on their epidemiology and immunology with the aim of characterising targets for vaccine design and efficacy evaluation. This is alongside building African research capacity and science communication.

She attended the University of Zambia (1999-2004) where she undertook a BSc in Molecular biology and Genetics. Upon receipt of a Commonwealth Scholarship, Melissa moved to London where she read for an MSc in Immunology of Infectious Diseases (2006-2007), at the London School of Hygiene and Tropical Medicine. She returned to Zambia and worked at the University of Zambia (Biological Sciences Department and School of Medicine) where she also undertook research in the Tropical Gastroenterology & Nutrition Group looking at oral immune responses to vaccination (2007-2009). In 2009, she received further Commonwealth Scholarship funding for DPhil research on malaria transmission-blocking vaccines in Adrian Hill's lab, Jenner Institute, University of Oxford (2009-2014). In May of 2013, Melissa took up a post-doctoral position at the KEMRI-Wellcome Trust Research Programme in Kilifi working on malaria transmission studies and establishing human infection models.
Dr Nilima Kshirsagar, National Chair Clinical Pharmacology Indian Council of Medical Research, Government of India

Dr Kshirsagar is currently National Chair of Clinical Pharmacology, ICMR, Govt of India, New Delhi, Member of International Committees viz, WHO Committees on, Safety of Medicinal Products (ACSoMP) Product development, Drug statistics Methodology, Member SAC, Drugs for neglected diseases initiative, DNDi, Board member of FDEC, Govt. of India Committees viz. DTAB (Drug technical Advisory Board), IND Committee, Chairperson FDC Subcommittee, Chairman core training Panel PvPI, Fellow of Royal College of Physicians, Faculty of Pharmaceutical Medicine UK and Fellow of American College of Clinical Pharmacology, USA.

Dr Kshirsagar was former acting Vice-Chancellor at the State Health Science University, and also Dean Director of medical education and research, and Prof. Head Clinical Pharmacology G.S. Medical College KEM hospital, Parel, Mumbai and at T. N. Medical College Mumbai, (Founding) President, South Asian chapter of American college of clinical Pharmacology, President of the Indian Pharmacology Society and Infectious Disease Society, India, Member Governing Council & Chairman Academic Committee AIIMS, Govt. of India, Delhi.

She has won many national and international awards e.g. University awards, gold medals, B.C. Roy National Award, Vasvik Award for industrial research, developing and patenting liposomal drug delivery system, Mayor’s award three times, Nathaniel Kwit award of ACCP USA. Dr Kshirsagar as published over 200 publications featuring in the Lancet, Lancet Global Health, Lancet infectious diseases, British Journal of Clinical Pharmacology, The American Journal of Tropical Medicine and Hygiene and WHO publications on safety of Medicines in public Health and pediatrics, among others. edited books and contributed chapters to national and international books Some of her areas of expertise include; clinical trials, pharmacovigilance, drug development, tropical diseases, drug resistance, and medical education.

Dr Rob Lambkin-Williams, Executive Scientific Advisor, hVIVO & Virology Consult, United Kingdom

The Controlled Human Infection Model (CHIM) can be conducted using a variety of pathogens, and specifically, the Human Viral Challenge Model (HVCM) has, for many decades, helped in the understanding of respiratory viruses and their role in disease pathogenesis. Along with colleagues, Dr Rob Lambkin-Williams has worked with viral challenge agents, manufactured to the most appropriate GMP standard, since 2001. In 2001, Dr Rob Lambkin-Williams designed and implemented the first HVCM study to be conducted in Europe in the 21st century. He designed the first series of pilot studies, accommodating the regulatory challenges that this presented. He wrote the original protocols, ethics committee submissions, and oversaw the appropriate GMP quality standards for the virus used, the conduct of the studies in temporary, and purpose-built, quarantine facilities and the analysis of the data.

He has developed and supervised multiple studies for large pharma, biotechs, the US and UK governments, the European Union and a
varied collection of academic groups; he has been the Principal Investigator on many. He conducted his PhD on flu at the University of Warwick; his PhD was co-sponsored by the National Institute of Biological Standards and Control. His interests also include other respiratory viruses and HIV. He is Member of the Royal Pharmaceutical Society, Fellow of the Royal Society of Medicine and Member of the International Society for Influenza and Other Respiratory Virus Diseases (ISIRV). With others, he has published extensively based on CHIM work.
Session Brief

Health technology assessment (HTA) is a multidisciplinary approach that uses clinical effectiveness, cost-effectiveness, policy and ethical perspectives to provide evidence upon which rational decisions on the use of health technologies can be made. It can be used for a single stand-alone technology (e.g. a drug, a device), complex interventions (e.g. a rehabilitation service) and can also be applied to individual patient care and to public health. Health Technology has emerged as an important tool for supporting core functions of health care system. These activities in the country help to facilitate the process of transparent and evidence informed decision making in the field of health. The Health Technology Assessment starts with structured study protocol for clear analysis and identification of PICO. The PICO stands for Patient (Disease or Condition), Intervention, Comparison and Outcome. Finally, informing Systematic literature review to identify evidence to answer healthcare issues4.

The drive to achieve Universal Health Coverage raises the need to choose and manage effective technologies that are to be adopted within countries' health systems, particularly in a context of limited resources. Developing and strengthening national capacity will have to build on established best practices, information exchange and collaborative approaches to make the best use of limited resources and yield robust scientific assessments.

To facilitate the process of transparent and evidence informed decision making in the field of health, Government of India has created an institutional system called the Health Technology Assessment India (HTAIn) has been set up under Department of Health Research, Government of India to undertake the various approaches to HTA, which is dealing with safety, efficacy/effectiveness, economic, organizational, ethics, social and legal aspects in the HTA process. This is a landmark step that establishes our foundation of moving towards efficient and effective implementation through evidence based decision making in the healthcare system. This structure that is both comprehensive and inclusive which defines HTAIn as whole. Health Technology Assessment has emerged as an important tool for supporting core functions of health care system26.2

Over the last couple years, a national health technology intervention assessment (HITA) body, the HTAIn, was set up in the Department of Health Research (DHR), Ministry of Health and Family Welfare, to develop and coordinate HTA activities in the country. These efforts have gained prominence in view of the recently announced initiative by the Government of India, ‘Ayushman Bharat Programme’, which aims to strengthen primary health care (through health and wellness centers) and provide financial protection to poor and vulnerable people. Activities of HTA In are as follows:
1. To support the process of decision making in healthcare at the Central and State policy level by providing reliable information based on scientific evidence.

26 https://dhr.gov.in/about-mtab
2. Develop Systems and mechanisms to assess new and existing health technologies by transparent and inclusive processes.

3. To collect and analyze evidence in a systemic and reproducible way and ensure its accessibility and usefulness to inform health policy.

4. Disseminate research findings and resulting policy decisions to educate and empower the public to make better informed decisions for health.

The rapid emergence of new and expensive drugs, devices, technologies, diagnostics etc. coupled with the growing public expectation for accessing such treatments at an affordable level has led to the pressure of delivering high quality health care with constrained public funds. These conditions heighten the importance of evidence – based decision making for resource allocation and strategic planning of policymakers and other key stakeholders.

**Objectives of this session is to discuss the following:**
- Health Technology assessment frameworks at national and global levels and case examples of how these principles have translated into practice

**Questions to spur thinking:**
- How to develop and strengthen national capacity to build on established best practices, information exchange and collaborative approaches to make the best use of limited resources?
- What is the role of HTAIn of evidence based policy making in India?
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<td>Health Technology Assessment as a Tool for Evidence Based Decision Making in Healthcare</td>
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<td>16:15-17:30</td>
<td>Chair: Dr Balram Bhargava, Secretary, Department of Health Research and Director-General, Indian Council of Medical Research, Ministry of Health and Family Welfare, Government of India</td>
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<td>Co-chair: Mr Manoj Jhalani, Director, Health Systems, WHO South East Asia Region</td>
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<td><strong>Keynote Address</strong></td>
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<td>1. Ms Anu Nagar,</td>
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<td>2. Dr Kavitha Rajsekhar, Scientist E, Indian Council of Medical Research, Government of India- Supporting HTA for Access to Better Health Care</td>
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<td>3. Dr Shankar Prinja, Additional Professor- Health Economics, Postgraduate Institute of Medical Education and Research (PGIMER) - Chandigarh, India- Health Technology Assessment Evidence for Pricing Decisions and Standard Treatment Guidelines</td>
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<td>4. Dr T Sundararaman, Advisor, Center for Technology and Policy, IIT Madras- Health Technology Assessment Support for Advocacy in Health Policy</td>
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<td>5. Dr Francoise A Cluzeau, Associate Director, Global Health and Development Group, Imperial College London, United Kingdom- Promoting Quality Standards through Quality Improvement Programs</td>
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<td>6. Professor Stephen Jan, Head of Health Economics and Process Evaluation Program and Co-Director, Health System Science Professor of Health Economics, Faculty of Medicine, UNSW Sydney, Australia- International Health Technology Assessment Regulations and Policy Making: Global and Indian Perspective</td>
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CVs of Chairs

Dr Balram Bhargava, Secretary, Department of Health Research, and Director General, Indian Council for Medical Research, Ministry of Health and Family Welfare, Government of India

Professor Balram Bhargava, Secretary, Department of Health Research, (Ministry of Health & Family Welfare), Government of India and Director General, Indian Council of Medical Research (ICMR) joined on 16th April, 2018. Prof. Bhargava is Professor of Cardiology at All India Institute of Medical Sciences (AIIMS), New Delhi and also serves as the Executive Director for Stanford India Biodesign Centre, School of International Biodesign (SiB). Professor (Dr) Balram Bhargava is an outstanding cardiologist, one of the foremost leaders in biomedical innovation, public health, medical education and medical research.

Professor Bhargava has excellent leadership qualities; and has established the India-Stanford Biodesign programme, a unique interdisciplinary fellowship programme to foster innovation, design in low cost implants/devices. This programme has led to the establishment of the School of International Biodesign (SiB) at AIIMS and development of 30 low cost medical devices leading to 10 startups. Four of the low cost devices are in the Indian market and one device has been approved by the USFDA. He developed the indigenous Platinum Iridium coil coronary stent and has been instrumental in clinically evaluating and establishing the use of two other laser cut medicated Indian stents. The philosophy of the programme has been “More for less for more” with a mandate to promote Global Affordable Need Driven Healthcare Innovation (GANDHI).

He set up the c-GMP Centre for Excellence for Stem Cell Studies, at AIIMS which has initiated treatment of patients with dilated cardiomyopathy; this has benefitted number of no-option heart failure patients waiting on the cardiac transplant list.

He is currently developing the Chest Compression Device for Sudden Cardiac Death patients; funded by the Wellcome Trust, London. He has led two major trials in India funded by the NIH, Bethesda, USA which has changed clinical practice. He has pioneered several techniques in interventional cardiology.

He has been awarded the SN Bose Centenary award by the Indian National Science Congress and National Academy of Sciences Platinum Jubilee Award, Tata Innovation Fellowship and Vasvik Award for Biomedical Technology Innovation, Ranbaxy Award and the OP Bhasin Award in the field of Health and Medical Sciences.

He is the Founding, Editor in Chief of the British Medical Journal Innovations (BMJi). He has been awarded the ‘Padma Shri’ high civilian award by the Honourable President of India and the UNESCO Equatorial Guinea International Prize for research in Life Sciences at Paris.
Mr Manoj Jhalani, Director, Health Systems, WHO South East Asia Region

Mr Manoj Jhalani, is currently the Director, Health Systems, WHO South East Asia Region. Mr. Jhalani was the Special Secretary in the MOHFW. He was involved in implementing Ministry's flagship programme of National Health Mission (NHM). He was also actively involved in the design of a package of services including provision of comprehensive primary healthcare services and continuity of care from community level to tertiary level facility that will be provided in an assured mode. He has an extremely rich and wide experience in leading, coordinating, and monitoring the design and implementation of policies and programmes of social and economic development at national, state and district level. He has been entrusted the responsibilities of heading some of the key social sector departments at the state level e.g. Department of Panchayat, Department of Social Justice, Department of Public Health and Family Welfare, Department of Planning, Department of School Education. Mr Jhalani holds an MBA in Public Service from the University of Birmingham, U.K. with distinction, and B. Tech. in Electrical Engineering from I.I.T., Kanpur.

CVs of Panelists

Ms Anu Nagar, Joint Secretary, Department of Health Research, Government of India

Ms. Anu Nagar is the Joint Secretary in the Ministry of Health and Family Welfare, Department of Health Research (DHR), Government of India. She is responsible for implementation of schemes relating to DHR. She is also responsible for programs/activities relating to Health Technology Assessment in India, National Ethics Committee Registry for Biomedical and Health Research and International Health related matters at DHR. She also coordinates administrative activities pertaining to Indian Council of Medical Research including International Health related matters at DHR.

Dr Kavitha Rajsekhar, Scientist E, Indian Council of Medical Research, Government of India

Dr. Kavitha Rajsekhar is a Senior Scientist at Department of Health Research, Ministry of Health and Family Welfare, Government of India. Kavitha holds a MSc, MPhil, PhD in Biochemistry and Molecular Biology from the University of Madras, India. Kavitha has to her credit diploma courses in Health Technology Assessment from University of Sheffield. Kavitha has almost 22 years of experience in teaching, research and administrative positions.

Dr. Kavitha is Coordinating the Health Technology Assessment in India under Department of Health Research, India. Kavitha has also been a part of the team that has drafted the Surrogacy Regulation Bill 2019 under the Ministry of Health and Family Welfare. She is a part of many Technical Committees. She is also supervising the National Costing Study for Health care services in India.
Dr. Shankar Prinja, Additional Professor of Health Economics at the PGIMER Department of Community Medicine and School of Public Health, received his Masters in health economics at the London School of Hygiene and Tropical Medicine and London School of Economics. His research interests include economic evaluation of health care interventions and programs, costing of health care services, and analyzing impact of health financing policies in the context of universal health coverage.

He is a member of several high level policy groups including the subgroups of Prime Minister's Economic Advisory Council on “Investment in Human Resources and Infrastructure” as well as “Converging Health Care and Social Security Financing Platforms”, Government of India’s taskforce on costing for health care services; Technical Appraisal Committee for Health Technology Assessment Board; and the Research Advisory Council of the Public Health Foundation of India. He has been a Consultant to World Bank, WHO, UNFPA and UNICEF. He has set up the Regional Resource Centre for India’s Health Technology Assessment Board; and the Innovation and Learning Centre for Health and Wellness Centres in Punjab.

He is currently leading a national study to determine the payment rates under the Ayushman Bharat Prime Minister’s Jan Arogya Yojana. He has authored 150 research papers in leading national and international peer-reviewed scientific journals. He is also an Academic Editor of the PLoS One and member of the editorial board of Pharmacoeconomics Open.

Dr T Sundararaman is an MD in Internal Medicine from Madras University. He spent the first 22 years of his professional life as a member of the faculty and Professor of Department of Internal Medicine, JIPMER in Puducherry.

He then moved to working with public health systems and was head of the State Health Resource Center Chhattisgarh from 2002 to 2007 where he pioneered the Mitanin programmes and State health sector reforms. As executive director of National Health Systems Resource Center, from 2007 to 2014 he developed and led an institution providing technical support to the many initiatives undertaken under the National Rural Health Mission.

He is known for his work with community health workers and with the development of health policy and strategies for primary health care. He is currently an Advisor in the Centre for Technology and Policy, IIT Madras, and chair of the Technical Advisory Committees for Health Technology Assessment and Operational Research of the Department of Health Research, Government of India. He has served as a member of a number of expert committees related to health policy and planning and has authored a number of publications in journals and a number of books.
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<th><strong>Dr Francoise A Cluzeau, Associate Director, Global Health and Development Group, Imperial College London, United Kingdom</strong></th>
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| Dr Francoise Cluzeau is a Senior Policy Fellow at Imperial College London and affiliated to the Centre for Global Development with over fifteen years’ experience working in Low and Middle Income countries on Health Technology Assessment (HTA) and Health Priority Setting. She leads the international Decision Support Initiative (iDSI) Programme in India that provides technical assistance to the HTAIn. She has worldwide experience on Standard Treatment Guidelines (STGs) and quality standards, including in India, Thailand, Ghana and Sri Lanka. Dr Cluzeau worked with the Ministries of Health in Turkey, Georgia, Vietnam and Tunisia on their quality improvement programmes. She was a Senior Technical Adviser for 14 years for the National Institute for Care Excellence (NICE) where she developed the guidelines methods. She led the international Research collaboration of 19 countries that developed the AGREE Instrument for STGs. 

A psychology graduate by training, she holds a masters’ degree in medical demography from the London School of Hygiene and Tropical Medicine and a doctorate in Health Services Research from the University of London. She remains research active in the field of STGs and quality standards with international research groups. |

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<th><strong>Professor Stephen Jan, Head of Health Economics and Process Evaluation Program and Co-Director, Health System Science Professor of Health Economics, Faculty of Medicine, UNSW Sydney, Australia</strong></th>
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| Professor Stephen Jan is Co-Director, Health System Science at the George Institute for Global Health and Conjoint Professor at the University of New South Wales, Australia. He is also an Honorary Professor at the University of Sydney, and serves on the Board of Directors of the Sax Institute – a non-government, non-profit research centre in Sydney. He is a current NHMRC Principal Research Fellow and a Fellow of the Australian Academy of Health and Medical Sciences. He has been a member of the Lancet Taskforce for NCDs and Economics. 

Stephen has over 20 years of experience in health economics and health systems research, has published over 200 scientific articles and authored two textbooks in health economics. He has worked closely with governments of different levels, both in Australia and overseas, and with international agencies such as the WHO, and with industry. His areas of expertise are economic evaluation, health financing, health sector priority setting, Indigenous and global health issues and the economics of chronic disease. |
Access to quality medical products is crucial for achieving Universal Health Coverage (UHC) and in reaching the Sustainable Development Goals (SDG) for health. Regulators face a number of challenges related to the wide variety of medical products that they have to deal with (medicines, vaccines, diagnostics and medical devices). In this context, there is need of a new strategic and smart regulatory approach to ensure product safety, efficacy, and quality. Regulatory networks play an important role in this direction.

South-East Asia Regulatory Network (SEARN)
WHO South-East Asia Region member states launched the South-East Asia Regulatory Network (SEARN) to enhance information sharing, collaboration and convergence of medical product regulatory practices across the Region to guarantee access to high-quality medical products. The SEARN includes 11 Member States: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor-Leste. The identified priority areas for SEARN are (1) Quality assurance and standards of medical products, including labs (2) Good regulatory practices including GMP, GDP etc (3) Vigilance for medical products and (4) Information sharing platform and (5) Medical device and Diagnostic. SEARN aims to promote efficiencies and enable availability of affordable and quality medical products through collaboration and reliance among regulators which will help to address challenges emerging due to country specific standards-review procedures.

The SEARN Information sharing platform (ISP) Gateway was highlighted in the Access to medical products roundtable in the Ministerial Conference in 2018 Regional Committee. The Delhi Declaration 2018 “Improving access to essential medical products in the South-East Asia Region and beyond” encouraged Member states to “Continue the momentum to strengthen regulatory cooperation and collaboration to improve the availability, quality and safety of essential medical products through SEARN”.

In India, Ministry of Health and Family Welfare, Government of India is responsible for laying down the standards and ensuring safety, efficacy & quality for Drugs. The e-governance portal (SUGAM portal) has been set up to provide a “single window” for multiple stakeholders (Pharma Industry, Regulators, Citizens) involved in the processes of Central Drugs Standards Control Organization (of the MOH, GOI) and enable simplicity, transparency, reliability, accountability, and timeliness and also simplified ease of business. The objective of the Sugam project is to consolidate the Indian Drug Regulatory Framework by streamlining the CDSCO processes, to enable paperless grant of various clearances by CDSCO and to enable higher level of transparency in Drug regulatory processes.27

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27 https://www.cdac.in/index.aspx?id=st_egov_sugam_ad
PAN America Health Organization28

The Pan American Network for Drug Regulatory Harmonization (PANDRH) is an initiative of the national regulatory authorities within the Region, and PAHO, that supports the processes of pharmaceutical regulatory harmonization in the Americas, within the framework of national and sub-regional health policies and recognizing pre-existing asymmetries.

The regulatory exchange platform (REPs) was launched as a digital tool to support the secure exchange of non-public information between regulatory authorities in the Americas and elsewhere. The platform seeks to improve the exchange of information, streamline the use of resources, and promote regulatory harmonization and convergence in the Region. Created with the financial support of the United States, Brazil, and Canada, and with PAHO acting as Secretariat in charge of its development,

European medicines regulatory network29

The European medicines regulatory network coordinates and supports interactions between over fifty national competent authorities for both human and veterinary medicines. These national authorities supply thousands of European experts to take part in EMA's scientific committees, working parties and other groups including European Commission, whose principal role in the European system is to take binding decisions based on the scientific recommendations delivered by EMA. By working closely together, this network ensures that safe, effective and high-quality medicines are authorized throughout the European Union (EU), and that patients, healthcare professionals and citizens are provided with adequate and consistent information about medicines.

The Benefits of the network for EU citizens –

- Enables Member States to pool resources and coordinate work to regulate medicines efficiently and effectively
- Creates certainty for patients, healthcare professionals, industry and governments by ensuring consistent standards and use of best available expertise
- Reduces the administrative burden through the centralized authorization procedure, helping medicines to reach patients faster
- Accelerates the exchange of information on important issues, such as the safety of medicines

The African Vaccine Regulatory Forum (AVAREF) is a regional regulatory network founded by WHO in 2006, and focuses on clinical trials of vaccines began to shift from developed countries to developing countries, including those in sub-Saharan Africa. The network brings together national regulatory authorities (NRAs) and ethics committees of the countries in the WHO African Region (23 members). AVAREF promotes convergence towards harmonization of regulatory practices and processes to ensure timely regulatory evaluations and approvals of clinical trial applications and products. Key among AVAREF’s achievements has been establishment of innovative regulatory pathways for clinical trials, development and use of common guidelines for submission of clinical trial applications, and use of joint reviews of multi-country clinical trial applications and joint good clinical practice (GCP) inspections. AVAREF has proven to be instrumental in providing regulatory support to accelerate product development during public health emergencies, as exemplified with products in development against Ebola.

These achievements will also support the work of African regulators on vaccines for diseases such as HIV, tuberculosis and malaria, which are affecting many millions of people in the African region.30.

The African Medicines Regulatory Harmonization (AMRH) Program is a partnership initiative formalized in 2009 and launched throughout the East African community in 2012 (Tanzania, Uganda, Kenya, Burundi, Rwanda). This program was created through a joint initiative of the New Partnership for Africa’s Development (NEPAD), the Pan African Parliament (PAP), and the African Union Commission (AUC), in collaboration with the World Health Organization (WHO), the World Bank, the Bill & Melinda Gates Foundation (BMGF), and the United Kingdom’s Department for International Development (DFID). The main objective of the AMRH program is to create regulatory mechanisms that are effective, efficient and transparent to achieve faster approval and subsequent availability of the products in various African markets. The strategy of this program is to develop regional regulatory platforms with harmonized standards (technical requirements/guidelines), joint regional dossier assessments and Good Manufacturing Practice (GMP) inspections, including work-sharing and streamlined decision making processes. Together, the NEPAD Agency (a technical body of the African Union) and the AUC defined and endorsed the regional networks for implementation of the AMRH program.31

The objectives of this session are to discuss the following:

- Discussion on how to leverage regulatory networks for accelerating access to quality and safe medical products
- Sharing knowledge on collaborative regional guidances and best practices
- Look at digital platforms and their role in regulatory systems strengthening

Questions to spur thinking:

- How the collaborative networks at sub-regional, regional and international level can be capitalized to reduce duplication of regulatory efforts and enhance early access.
- How the Information Sharing Platforms can support accelerating the regulatory procedures
- What is the current experience with regional testing laboratories and how the same can be developed to share resources, technical expertise & Quality Assurance Programmes.

30 https://www.who.int/medicines/publications/doiinformation/WHO_DI_29-2_RegulatoryCollaboration.pdf?ua=1
20 November 2019- Wednesday, 09:00-10:30: Plenary Session 3: Leveraging Regulatory Networks for Access to Quality, Safe and Affordable Medical Products Including Digital Tools for Strengthening Regulatory Systems

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<tr>
<th>Time</th>
<th>Plenary Session 3- Wednesday, 20 November 2019</th>
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| Wednesday, 9:00-10:30 | Leveraging Regulatory Networks for Access to Quality, Safe and Affordable Medical Products Including Digital Tools for Strengthening Regulatory Systems  
Chair: Mr Arun Singhal, Special Secretary, Ministry of Health & Family Welfare, Government of India  
Co-chair: Mr Jaideep Kumar Mishra, Joint Secretary, Ministry of Electronics and Information Technology, Government of India | Durbar Ballroom |

**Keynote Address**

Dr Soumya Swaminathan, Chief Scientist, World Health Organization (Video Address)

Dr Manisha Shridhar, Regional Advisor, World Health Organisation South-East Asia Regional Office- Promoting Access to Medical Products through SEARN

**Panelists**

1. Dr Raj Long, Deputy Director, Global Health, Bill and Melinda Gates Foundation, United Kingdom- Accelerating the Product Development through Networks and Partnerships

2. Dr Diadié Maïga, Regional Vaccine Regulatory Officer, World Health Organization Regional Office for Africa- Strengthening the Regulatory Systems through Networks- The AVAREF Experience


4. Mr R Chandrashekhar, Deputy Drugs Controller of India, Central Drugs Standard Control Organisation, Government of India- E-Governance Initiatives in the Indian Drug Regulatory System

5. Dr Ramesh Krishnamurthy, Senior Advisor, Division of Data, Analytics and Delivery, World Health Organization- Digital Technology to Advance UHC

6. Dr Oommen John, Senior Research Fellow, The George Institute for Global Health, India- Strengthening Health Systems through Leveraging Digital Health Interventions
CV of Chairs

Mr Arun Singhal, Special Secretary, Ministry of Health & Family Welfare, Government of India

Arun Singhal currently posted as Special Secretary in the Ministry of Health & Family. Mr Arun Singhal belongs to the 1987 Batch of Indian Administrative Service. He has currently posted as Additional Secretary in the Ministry of Health & Family. His responsibilities include Drugs & Food Regulation, medical education, and implementation of Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) under which new AIIMS are being set up in the country.

He has been closely associated with reforms in medical education over the past 2 years. Successful implementation of National Eligibility-cum-Entrance Test (NEET) and ensuring transparency in medical admissions by way of making common counselling mandatory have been priority areas of work for him. He has also been associated with drafting of the National Medical Commission Bill and Allied and Healthcare Profession Bill. After completing B.Tech. and M.Tech. from IIT, Kanpur in Electrical Engineering, Shri Singhal joined IAS,1987. He has rich and varied experience of administrative work in diverse areas such as Petroleum and Natural Gas, Industrial Development, Rural Development, Agriculture Marketing and Health & Family Welfare. He has also functioned as Chief Electoral Officer of UP in addition to serving in various capacities in the Central and State Governments.

Mr Jaideep Kumar Mishra, Joint Secretary, Ministry of Electronics and Information Technology, Government of India

Dr. Jaideep Mishra is currently serving as Joint Secretary in the Ministry of Electronics & Information Technology and handles the subjects relating to Human Resources Development in Electronics and IT&ITES skilling, e-Governance projects including the India Stack, the Health Stack, the IndEA framework and the IT Standards. He also handles the work related to Internet Governance and represents the country in the Government Advisory Committee of the ICANN. Presently he is also holding the additional charge of Director General of the National Institute of Electronics and IT.

He has over 26 years of experience having served across several ministries of Government of India including the Ministries of Finance, Science & Technology, Road Transport and Commerce. He has been closely involved in various financial and accounting systems design, development and implementation, including the Public Financial Management System (PFMS) being implemented in the Government of India.

He has considerable experience of working in the area of Public Financial Management (PFM) and implementation of large IT systems with several multilateral organisations including the International Monetary Fund and the United Nations across several countries in South-East and Middle-East Asia and Africa, both as a long term resident advisor and short term expert.

Dr Mishra is an engineering graduate with a Doctor of Philosophy (PhD), both from the Indian Institute of Technology, New Delhi and is also a post-doctoral fellow of the Japan Society for Promotion of Science (JSPS).
CV of Keynote Speaker

**Dr Soumya Swaminathan, Chief Scientist, World Health Organization**

Dr Soumya Swaminathan was most recently WHO's Deputy Director-General for Programmes. A paediatrician from India and a globally recognized researcher on tuberculosis and HIV, she brings with her 30 years of experience in clinical care and research and has worked throughout her career to translate research into impactful programmes. Dr Swaminathan was Secretary to the Government of India for Health Research and Director General of the Indian Council of Medical Research from 2015 to 2017. In that position, she focused on bringing science and evidence into health policy making, building research capacity in Indian medical schools and forging south-south partnerships in health sciences. From 2009 to 2011, she also served as Coordinator of the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases in Geneva. She received her academic training in India, the United Kingdom of Great Britain and Northern Ireland, and the United States of America, and has published more than 350 peer-reviewed publications and book chapters. She is an elected Foreign Fellow of the US National Academy of Medicine and a Fellow of all three science academies in India.

**Dr Manisha Shridhar, Regional Adviser, World Health Organization South-East Asia Regional Office**

Dr Manisha Shridhar is Regional Advisor for Intellectual Property, Trade and Public Health at the World Health Organization Regional Office for South-East Asia (WHO/SEARO). She works on the interface of Intellectual Property Rights (IPRs) and trade for health and medical products (medicines, vaccines, diagnostics and medical devices). She has worked extensively on trade and legal issues relating to public health e.g. in areas of pandemic influenza preparedness framework, traditional medicines, international health regulations, non-communicable diseases (NCDs), tobacco control and nutrition. Dr Shridhar received her Master's degree in Intellectual Property Law with specialization in Patent and Biotechnology Law and is a certified Mediator for IPRs disputes from Franklin Pierce Law Center, Concord, USA.

Dr Shridhar has written extensively on various subjects. As Head of Training Research and Development Wing in the National Academy of Administration, Mussoorie, she designed and conducted training programs for senior Civil Servants from India and Sri Lanka on IPR and WTO issues. She prepared case studies, study material for courses, and has written and produced a film on IPRs for World Intellectual Property Organization. She assisted United Nations Industrial Development Organization for development of Geographical Indications for traditional products. Dr Shridhar is fluent in Hindi, English and French.
### CVs of Panelists

<table>
<thead>
<tr>
<th>Dr Raj Long, Deputy Director, Global Health, Bill and Melinda Gates Foundation, United Kingdom</th>
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<tr>
<td>She is currently a Deputy Director at the Bill &amp; Melinda Gates Foundation (BMGF). Dr. Raj Long has 20 years of experience in drug development and brings a unique strategic expertise blending private health and public health sectors including having worked with the EU EMA, US FDA, China CFDA, India DCGI and other regulatory authorities. Previously, she was the Global Head of Regulatory GEHC-MDx in the UK, Head of Regulatory International AGL in Novartis, Switzerland and Vice-President – Regulatory International at Bristol-Myers Squibb, Princeton, USA. Additionally, Raj serves as an expert with the EC Innovative Medicines Initiative 2, UK Innovative Medicines and Medtech Review Advisory Group, UK NICE Expert Advisory Group (EXAG), advisory role to WHO on R&amp;D to Access and the Vice-Chair of the World Dementia Council. Raj has a double Masters in Psychology and in N. Ed. (Psychology) from the University of Glasgow and Edinburgh, Scotland respectively.</td>
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<th>Dr Diadié Maïga, Regional Vaccine Regulatory Officer, World Health Organization, Regional Office for Africa</th>
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<td>Diadié is Regional Vaccine Regulation Officer at the WHO Regional Office for Africa. With 20 years’ experience, Diadié is an expert in the development, implementation and evaluation of regulatory strategies for pharmaceuticals and national pharmaceutical policies in least developed countries. He has served, for many years, as a Pharmaceutical Systems Officer and Deputy General Director at the Pharmacy Department of the Ministry of Health in Mali. Diadié successfully led the pharmaceutical regulatory unit at the Ministry of Health and numerous working groups in several pharmaceutical system areas, including medicines policies, good practices, pre-market evaluation of medicines, and clinical trials authorization. Under the umbrella of USAID technical assistance to the Government of Haiti, Diadié served for over two years as the Pharmaceutical Policy Advisor at the Haitian Ministry of Health. One of his greatest accomplishments was to advise the Government to adopt and launch the first National Pharmaceutical Policy which is now one of the pillars of the health system in Haiti. He subsequently developed a three-year strategic plan, also adopted by the Ministry of Health, to facilitate its implementation. Before joining WHO/AFRO, Diadié held the position of Principal Technical Advisor in Pharmaceutical Systems for the USAID/SIAPS Programme in Arlington, USA. Diadié holds a degree in pharmacy from the Faculty of Medicine and Pharmacy of Mali, a Master in Public health from University Libre of Brussels and a Ph.D. in public health from the University of Montreal, Canada.</td>
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Mr Esteban Burrone, Head of Policy, Medicines Patent Pool, Switzerland

Esteban Burrone works at Medicines Patent Pool since 2010. He is the Head of Policy of the Medicines Patent Pool, an institution he contributed to setting up in 2010 to promote access to affordable and appropriate medicines in developing countries, through the licensing of key patents. As Head of Policy, Esteban works on partnership with a large number of organisations and stakeholders, including governments, intergovernmental organisations and civil society organisations. He is part of the senior management team and has overall responsibility for Patents and Licences Database MedPaL and for the annual prioritization report. Esteban has more than 15 years of experience working in the field of innovation, IP rights and access to medicines with a focus on developing countries. Esteban holds a Master of Science in Development Studies from the London School of Economics and a Master in Business Administration from the International University in Geneva.

Mr R Chandrashekhar, Deputy Drugs Controller of India, Central Drugs Standard Control Organisation, Government of India

He is currently working as Deputy Drugs Controller of India at Central Drugs Standard Control Organization Headquarter. He is having more than 29 years of experience as a regulator in various capacities. He currently attends to the matters relating to the regulation of Vaccines and r-DNA based drugs, Intelligence Cell and E-Governance. He is instrumental in establishing e-Governance systems at CDSCO, especially launch of SUGAM portal in the country. He was earlier in-charge of IND and New Drugs division, BA/BE studies division, Drug legislation, Legal Cell, International affairs, etc. earlier. He has degree in pharmacy from Birla Institute of Technology and Science, Pilani, PG in Pharmacy from Nagpur University. Also holds degrees in Law and Patent Law.

Dr Ramesh Krishnamurthy, Senior Advisor, Department of Information, Evidence and Research, Health Systems & Innovation Cluster, WHO

Dr. Krishnamurthy serves as a senior technical officer and the focal point for eHealth standardization and interoperability efforts at the World Health Organization in Geneva, Switzerland. He has extensive experience in designing, implementing, coordinating, and managing national and subnational eHealth systems and services, including health information systems, emergency operations centers, and public health surveillance information systems.

Dr. Krishnamurthy has also assisted numerous countries in all of the six WHO Regions in their development and implementation of national and sub-national eHealth strategies, standardization and interoperability of eHealth systems and services, and utilization of strategic information for evidence-based public health decision-making.
Dr Oommen John, Senior Research Fellow, The George Institute for Global Health India; Secretary, Asia Pacific Association for Medical Informatics

Oommen John is an Internist, specialized in Internal Medicine from Christian Medical College, Ludhiana and an Executive MBA from Indian Institute of Management, Calcutta. He has over 20 years of experience in designing and implementing health systems strengthening interventions and health management information systems. He leads a number of innovative public health interventions in low and middle-income country settings. His interests and expertise are in areas of applying design thinking, developing and evaluating digital health interventions for health systems strengthening in the LMIC settings.

He has worked with the WHO, leading the implementation of a large vaccine development project and information systems based monitoring for data and quality tracking system. He has also served on the WHO Digital Health Guidelines Development Group.

He is a founding director of the Digital Health India Association and serves on the International Advisory Board of the Commonwealth Centre for Digital Health, Scientific Advisory Board of Foundation for Innovative Diagnostics, Geneva. He is a member of the technical advisory group of Health Informatics Sectional Committee at the Bureau of Indian Standards. He is also a member of the working group on Telehealth at the International Association for Medical Informatics and the ITU WHO Focus group on AI for Health.
Session Brief

There is an evolving product landscape with New vaccines, drugs, and diagnostics specifically developed for countries with the disease burdens for these diseases – countries are no longer able to rely on post-market safe surveillance from developed economies as the products are not launched there.

Smart Safety Surveillance is collaborative effort among Regulators, Immunization programme and key stakeholders for vigilance in India to strengthen pharmacovigilance capacity. Supported by the Bill and Melinda Gates Foundation (BMGF), WHO is promoting the Smart Safety Surveillance (3S) approach, to strengthen PV systems in developing countries, that are introducing new health products, for the safe and effective use of these products.

Three priority health products are being used as pathfinders, to introduce and test the 3S approach: Rotavac (rotavirus vaccine) for the prevention of rotavirus diarrhoea in young children, in India; bedaquiline, a product used in MDR-TB and tafenoquine, for treating P. vivax malaria

The approach has strengthened pharmacovigilance capacity in these countries and, in the long-term, establish end-to-end safety surveillance of products from their clinical development to the post-market stages. This was achieved by implementing smart safety surveillance systems for three pilot products (two medicines and one vaccine) in a few pilot countries of varying PV readiness by:

I. Strengthening the functionality of current PV systems
II. Building capacity to analyses safety data
III. Improving capacity to use PV data for regulatory decision-making

Supporting the collaboration between public health programmes and the PV community.

India

The activities undertaken in 2019 as part of the smart safety surveillance activities focussed on strengthening the collaboration of key stakeholders on vigilance for vaccines for the focus areas: Adverse Events following Immunization (AEFI) collection for vaccines, ICSR preparation and reporting, Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP) writing and assessment, Signal Detection Management, and Benefit and Risk Evaluation of vaccines.

WHO, in collaboration with the Medicines Healthcare Products Regulatory Agency (MHRA) worked with the Ministry of Health and Family Welfare of India (MoHFW) and Central Drugs Standard Control Organization (CDSCO) to form a PV strengthening work plan, following an initial baseline assessment using the WHO PV preparedness tool. The tool identified gaps in the PV system, so that resources could be “smartly” allocated to bridge these gaps. The 3S focus in India was to link PV activities between different stakeholders, for data sharing, signal detection, risk assessment, risk management, risk communication, and benefit harm evaluation for regulatory decision making.
Currently, India has data on Rotavirus vaccine safety from various sources. The data being collected at sentinel sites such as Translational Health Sciences & Technology Institute (Department of Biotechnology, Ministry of Science & Technology), Adverse event following immunization (AEFI) Secretariat (Immunization Division), INCLEN, Centre for Health Research and Development, Society for Applied Studies, among others. In addition, the Central Drugs Standard Control Organization (CDSCO) is receiving the safety reporting data periodically as PSURs. There has been a data triangulation conducted under this approach for Rotavirus vaccine safety data by all stakeholders jointly and a White Paper has been prepared.

The activities this undertaken and the safety data outcomes published as a White paper would help better characterize the safety profile of Rotavirus vaccine, and use the Rotavirus vaccine as a pathfinder to enhance national pharmacovigilance systems that support regulatory decisions for all vaccines throughout their lifecycle.

Africa
The ultimate goal of Project 3-S is to establish end-to-end pharmacovigilance systems, with timely and adequate reporting of adverse drug reactions, followed by timely review and any needed regulatory action. A holistic plan for pharmacovigilance will be developed in each country, covering: (1) Policy, law and regulation, (2) system, structure and stakeholder coordination, (3) signal generation and data management, (4) risk assessment and evaluation, and (5) risk management, communication and allocation of commensurate resources. Project 3-S will serve as a pathfinder pilot for this approach in the area of pharmacovigilance. Work-sharing and joint activities in ongoing initiatives such as the African Medicines Regulatory Harmonization (AMRH) and the African Vaccines Regulatory Forum (AVAREF) could create significant synergy and enhance impact. For example, a product could be monitored intensively in one or two countries and the data made available to neighbouring countries, or regional risk-assessment committees could jointly review data on priority products for mutual learning and regional decisions.

The objective of this session is to discuss the following:
- Discussion of learnings of smart safety surveillance approach in countries for monitoring safety of medical products
- Development of sustainable PV systems

Questions to spur thinking:
- What are the newer approaches for robust pharmacovigilance system?
- What are the tools for early stage engagement between regulators and other stakeholders to implement smart safety surveillance from early stage of product development?
- How to leverage newer approaches for harmonizing the data on safety in line with international best practices?
- What are capacity building/training needs to strengthen reporting system and streamline process for vigilance of medical products?
### Plenary Session 4- Wednesday, 20 November 2019

**Smart Safety Surveillance for Strengthening Pharmacovigilance Systems- Progress Updates and Next Steps**

**Chair:** Dr Nata Menabde, Executive Director-United Nations, World Health Organization

**Co-chair:** Dr Mandeep K Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Government of India

**Keynote Address**

Dr Raj Long, Deputy Director, Global Health, Bill and Melinda Gates Foundation, United Kingdom - **Triple-S (3S)**

*Smart Safety Surveillance for Strengthening Vigilance of Medical Products*

**Panelists**

1. Dr Madhur Gupta, Technical Officer-Pharmaceuticals, World Health Organization Country Office for India - **Strengthening Collaboration amongst Vaccine Vigilance Stakeholders in India- The Rotavac Vaccine Experience and Learnings**

2. Ms Swati Srivastava, Deputy Drugs Controller of India, Central Drugs Standard Control Organisation, Government of India - **Strengthening Pharmacovigilance Systems and Smart Safety Surveillance in India**

3. Dr MK Aggarwal, Deputy Commissioner, Universal Immunisation Programme, Ministry of Health and Family Welfare, Government of India - **Safety Monitoring of Vaccines in India: The Rotavirus Smart Safety Approach**

4. Dr Mick Foy, Head of Pharmacovigilance Strategy, Vigilance, Intelligence and Research Group, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom - **Clinical Safety and Pharmacovigilance Systems at MHRA**


6. Dr Gagandeep Kang, Executive Director, Translational Health and Sciences Technology Institute, India - **Safety Surveillance of Medical Products- The Sentinel Site Perspective**
CV of Chairs

Dr Nata Menabde, Executive Director, World Health Organization
Office at the United Nations, United States of America

Dr Nata Menabde is Executive Director of WHO Office at the United Nations, New York since May 2015. Prior to her current role, since 2010, Nata Menabde was WHO Representative to India where she has led a large team of thousands of dedicated professionals across India supporting the governments’ efforts in tackling health and health systems challenges, such as eradication of polio and saving lives from vaccine preventable diseases, promoting universal health coverage for sustainable development, combatting TB, reversing growing trend of noncommunicable diseases, amongst others. Preceding her assignment in India Nata Menabde was the Deputy Regional Director of WHO’s European Regional Office and, among other initiatives, has successfully led WHO’s European work on Health Systems.

Dr Menabde has a robust public health academic background and above 30 years of professional experience, during which she has built an extensive track record in public health and health systems at country and international levels. She holds a PhD degree in Clinical Pharmacology, diplomas in Health Management and Leadership from USA and in Health Care Economics from UK. She also studied Public Health at Nordic School of Public Health, Sweden. Her current interests are linked to universal health coverage and sustainable development, health and foreign policies, global health governance, emergency preparedness and crises response, health systems performance, as well as addressing public health in other sector policies.

Dr Mandeep K Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Government of India

Dr Mandeep K Bhandari is Joint Secretary of Ministry of Health and Family Welfare, Government of India. He is MBBS (Gold Medalist) from Dayanand Medical College, Ludhiana. He joined Indian Administrative Service in 2001. He served as Secretary Health and Medical Education in the Government of Jammu and Kashmir. At present, his brief duties include: Drugs and Cosmetics Act (Strengthening of State Regulatory systems), Strengthening of Food Regulatory System, Central Drug Standard Control Organization, Indian Pharmacopoeia Commission, National Institute of Biologicals etc. He received Jammu & Kashmir State Award for meritorious public service in 2017.
### CV of Keynote Speaker

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<th>Dr Raj Long, Deputy Director, Global Health, Bill and Melinda Gates Foundation, United Kingdom</th>
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<td>She is currently a Deputy Director at the Bill &amp; Melinda Gates Foundation (BMGF). Dr. Raj Long has 20 years of experience in drug development and brings a unique strategic expertise blending private health and public health sectors including having worked with the EU EMA, US FDA, China CFDA, India DCGI and other regulatory authorities. Previously, she was the Global Head of Regulatory GEHC-MDx in the UK, Head of Regulatory International AGL in Novartis, Switzerland and Vice-President – Regulatory International at Bristol-Myers Squibb, Princeton, USA. Additionally, Raj serves as an expert with the EC Innovative Medicines Initiative 2, UK Innovative Medicines and Medtech Review Advisory Group, UK NICE Expert Advisory Group (EXAG), advisory role to WHO on R&amp;D to Access and the Vice-Chair of the World Dementia Council. Raj has a double Masters in Psychology and in N. Ed. (Psychology) from the University of Glasgow and Edinburgh, Scotland respectively.</td>
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<tr>
<th>Dr Madhur Gupta, Technical Officer - Pharmaceuticals, World Health Organization, Country Office for India</th>
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<tr>
<td>Dr Madhur Gupta has done Doctorate (DM) in Clinical Pharmacology from All India Institute of Medical Sciences and MD in Pharmacology from Lady Hardinge Medical College, Delhi. Dr Gupta is currently working as Technical Officer (Pharmaceuticals) with the Office of the WHO Representative to India.</td>
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<td>As Technical Officer (Pharmaceuticals), her responsibilities include providing policy advice, technical and managerial support to the development and implementation of WCO-India biennial work-plans in the area of pharmaceuticals (including vaccines, pharmaceuticals, medical devices and diagnostics). She has provided strategic direction, technical and managerial support to the development and implementation of the activities in the Pharmaceuticals Area in WHO India. She has also been engaged in supporting the implementation of the Institutional Development Plan for NRA Strengthening in India, including strengthening Adverse Events Following Immunization (AEFI) Surveillance. She has been instrumental in strengthening the technical support for preparation of guidelines, manuals and reference documents related to drug policy implementation, including capacity building of national regulatory authorities to improve access to medical products, providing support for strengthening of vigilance of medical products including integrated reporting on medical product safety for TB, HIV-AIDS, NTDs, vaccines, and as a facilitator for the Working Group on Vigilance for medical products under the South East Asia Regulatory Network.</td>
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<tr>
<td>Ms Swati Srivastava, Deputy Drugs Controller of India, Central Drugs Standard Control Organisation, Government of India</td>
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<td>Dr Mick Foy, Head of Pharmacovigilance Strategy, Vigilance, Intelligence and Research Group, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom</td>
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Professor Aggrey Ambali, Head of Industrialization, Science, Technology and Innovation, New Partnership for Africa’s Development (NEPAD) Agency, Africa

Prof. Aggrey Ambali is currently serving as Head of Science, Technology and Innovation Hub (NSTIH) at the New Partnership for Africa’s Development (NEPAD) Agency, where he oversees development and implementation of programs in education, health, and science and technology. He has also served in other positions at the NEPAD Agency, including Director of Policy Alignment and Program Development, Coordinator of the African Biosciences Initiative, and Coordinator of Science and Technology for the Southern Africa region.

Dr Gagandeep Kang, Executive Director, Translational Health Science and Technology Institute, India

Dr Gagandeep Kang, MD, PhD is the Executive Director, Translational Health Science Technology Institute (THSTI), an autonomous institute of the Department of Biotechnology, Ministry of Science & Technology, Government of India. Over two decades, she has built a research program that has conducted key studies to understand enteric infectious diseases in impoverished communities. She is known for her interdisciplinary research studying the transmission, development and prevention of enteric infections and their sequelae in children in India. To develop practical approaches to support public health, she has also built national rotavirus and typhoid surveillance networks, established laboratories to support vaccine trials and conducted phase 1-3 clinical trials of vaccines, a comprehensive approach that has supported two WHO pre-qualified vaccines, made by two Indian companies. She is investigating the complex relationships between infection, gut function and physical and cognitive development, and seeking to build a stronger human immunology research in India.

Dr. Kang has published over 300 papers in national and international journals. She is on several review committees for national and international research funding agencies. Her groundbreaking work has been recognized with numerous awards and honors. These include Woman Bio-scientist of the Year from the Government of India (2006); election to Fellowship of the American Academy of Microbiology (2010), the Indian Academy of Sciences (2011), National Academy of Sciences (2013), the Faculty of Public Health in the UK (2015), and the Indian National Science Academy (2016). She is the First Indian Woman To Receive The Fellowship Of The Royal Society in 2019.
Session Brief

The rise of multi-regional clinical trials (MRCTs) has led to several harmonization initiatives between ICH (International Conference on Harmonization) member countries and non-ICH member countries to streamline the trial processes to identify regulatory, oversight, and ethics issues and facilitate solutions in clinical trials around the world. The ICH E17 guideline defines the factors that must be considered in planning, designing, and executing MRCTs. MRCTs can facilitate simultaneous global development of a drug and reduce the number of clinical studies conducted separately in each region, thereby minimizing unnecessary duplication of studies.32

Different national health authorities are also supporting guidance for MRCTs. The US Food and Drug Administration adopted the International Council for Harmonization’s (ICH) guidance aimed at supporting drug sponsors in the collection of data from multi-regional clinical trials (MRCTs). It is important for MRCT data to be accepted by regulatory authorities across regions and countries as the primary source of evidence to support marketing approval of drugs. Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) became the first ICH member to adopt the guidance in June 201833. The Pharmaceuticals and Medical Devices Agency (PMDA) in Japan has made concerted effort for standardization so that more and more MRCTs are conducted in the country and drug lag is reduced.

Several harmonization initiatives exist between Asian countries to support easy data acceptability and reduce drug approval timelines in the region. Other collaborations exist among APAC countries. China, Japan, and South Korea’s Tripartite Cooperation on Clinical Research aims to improve the landscape of clinical trials among the three countries34.

Ministry of Health and Family Welfare, Government of India has notified vide (G.S.R.227 (E) dated 19 March 2019) the Drugs and Clinical Trials Rules, 2019 with an aim to promote clinical research in the country. The new rules will change the regulatory landscape for the approval of new drugs and conduct of clinical trials in the country. The new regulations cover provision for promoting clinical research as well as complex topics such as orphan drug, post-trial access and also for clinical trials in 30 working days for indigenous drugs also will speed up the clinical trial process and encourage local drug development. The conditions of waiving local clinical trials under these rules will help provide patients with earlier access to drugs. The approval for clinical trials in 30 working days for indigenous drugs will also speed up the trial process and encourage local drug development. Provision for accelerated product approval under some conditions, along with provision of pre and post submission meeting with the CDSCO office, would add predictability and confidence in the system.35

MRCTs can facilitate simultaneous global development of a drug and reduce the number of clinical studies conducted separately in each region, thereby minimizing unnecessary duplication of studies.

The objective of this session is to discuss the following:
The objective of this session is to discuss the approaches and mechanisms which can expedite global clinical development to bring new medicines to patients globally and reduce the drug lag in a harmonized environment. The following topics are proposed for discussion:
- Regulatory convergence within multiple regions to early access of medicines to the patients through harmonized clinical trial ecosystem
- Clinical trial framework with a view to support R&D and access initiatives including predictable regulatory pathways for emergencies

Questions to spur thinking:
- How the MRCT can reduce the time lag in drug development and parallel availability of newer medicines in developed and developing market?
- How the convergence of country specific regulations and international guidelines can accelerate simultaneous development to enhance early access?
- How to enhance collaboration among different stakeholders to shift focus from the conventional designs to the Innovative clinical-trial designs?
- Capacity building of regulators, investigators, ethics committees and clinical research personnel for adaptation of international guideline of MRCTs.
- What are the challenges in implementation of MRCT from regulators, sponsors and ethics committees?
**Parallel Session 5: Moving Towards Smarter Clinical Trials—Changing the Paradigm in the Context of Global and Multi Regional Clinical Trials**

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<th>Time</th>
<th>Parallel Session 5–Wednesday, 20 November 2019</th>
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<td>Wednesday, 12:15-13:30</td>
<td>Moving Towards Smarter Clinical Trials—Changing the Paradigm in the Context of Global and Multi Regional Clinical Trials</td>
<td>Jehangir Hall</td>
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**Chair:** Dr Anup Wadhawan, Secretary, Ministry of Commerce, Government of India

**Co-chairs:** Dr Stephen Kennedy, Principal Investigator, PREVAIL: Joint US-Liberia Research Partnership, University of Liberia, Liberia; Dr VG Somani, Drugs Controller General of India, Central Drug Standard Control Organization, India

**Keynote Addresses**

1. Dr Stephen Kennedy, Principal Investigator, PREVAIL: Joint US-Liberia Research Partnership, University of Liberia, Liberia - *The Experience of Ebola Vaccine Clinical Trial in Liberia*

2. Dr Rakesh Aggarwal, Director, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), India - *Innovative Strategies in Recent Vaccine Trials- The Case of Malaria, Dengue, Ebola Vaccines*

**Panelists**

1. Dr Francis P Crawley, Coordinator, European Fellowship in Research Ethics (EFRE), Belgium - *Moving from Capacity building to Capacity sharing in Clinical Trials: Sharing Knowledge, Frameworks, and Data on the Critical Pathways for Access to Medicines*

2. Dr Jeffrey D'Souza, Research Associate, Institute on Ethics & Policy for Innovation, McMaster University, Canada - *Ethical and Regulatory Considerations on Clinical Trials*

3. Ms Catherine Tregunno, Senior Scientific Assessor- Vaccines, Anti-infectives and Advanced Therapies Unit, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom - *Monitoring Safety in the Post-Marketing Period- Safety Data From Clinical Trials to Form a Risk Management Plan*

4. Dr A K Pradhan, Deputy Drugs Controller, Central Drug Standard Control Organization, India - *An Overview on the New Drugs and Clinical Trials Rules 2019 in India*
| 5. Dr Bernhards Ogutu, Chief Research Officer, Kenya Medical Research Institute (KEMRI) and Director for Centre for Research in Therapeutic Sciences, Strathmore University, Kenya- *Malaria Clinical Trials in Kenya- Best Practices* |
CV of Chairs

Dr Anup Wadhawan, Secretary, Ministry of Commerce, Government of India

He is presently Secretary in the Department of Commerce. A former director in the PMO, a veteran in economic and commerce departments and also a PhD in economics. He was special secretary in the department of commerce. Till July 31, he will serve as the officer on special duty (OSD) in the commerce department before taking over as its secretary.

In 2015-17, he was the Director General of Foreign Trade (DGFT), and then, additional secretary and special secretary in the department of commerce and also the joint secretary and additional secretary in the department of financial services under the Ministry of Finance. Between 2001 and 2006 he was a director in the Prime Minister's Office (PMO). He thus worked in both Atal Bihari Vajpayee’s and the Dr Manmohan Singh’s PMO. Wadhawan worked as additional collector in Almora and also collector in Etawah district of Uttar Pradesh. Dr Wadhawan is an MA and PhD in economics and studied from St. Xavier School, Delhi.

Dr Stephen B Kennedy, Principle Coordinator for EVD Research, Incident Management System

Dr Stephen B. Kennedy is trained in general medicine, infectious disease epidemiology, biomedical research, and international health from Liberia, United States (U.S.) and Zambia, respectively.

Presently, Dr. Kennedy serves as Liberia’s Co-Principal Investigator (PI) and one of the lead Liberian Research Scientists for the EVD Vaccine Clinical Trial of the Liberia-US Joint Clinical Research Program of the Partnership for Research on Ebola Vaccines in Liberia (PREVAIL); Co-PI for a four-country EVD Vaccine Clinical Trial (PREVAC) of a multinational (NIH, INSERM, LSHTM) and sub-regional countries (Sierra Leone, Guinea, Liberia & Mali) consortium; Technical Lead for Research & Capacity Enhancement for the West African Taskforce for the Control of Emerging and Re-emerging Infectious Diseases (WATER); Member of the Core Working Group (CWG) of the West African Consortium (WAC) of the Sub-Regional Collaboration Research Group on EVD Vaccines, Therapeutics & Diagnostics; and member of the Action Committee on Viral Hemorrhagic Fevers (VHF) for the West African College of Physicians (WACP), respectively. Dr. Kennedy is Fellow of the Liberia College of Physicians (FLCP) and Fellow of the West African College of Physicians (FWACP).

Dr Kennedy possesses nearly three decades of experience as a public health practitioner, researcher, scientist and/or medical doctor in Sub-Saharan Africa and nearly two decades of experience in biomedical and clinical-based research, research ethics in the tropics and clinical trials in HIV/AIDS, STDs, Malaria, Tuberculosis (TB), community health, and Ebola Virus Disease (EVD).

Previously, Dr. Kennedy served as Commissioner for Programs & Policy at the National AIDS Commission (NAC), Secretary General (SG) of the Liberia College of Physicians & Surgeons (LCPS), and Coordinator for EVD Research at the Liberia’s Emergency Operations
Center (EoC) of the Incident Management System (IMS) of the Ministry of Health (MoH) in Liberia.

Dr V G Somani, Drugs Controller General (India), Dte.GHS, Ministry of Health and Family Welfare, (MoH&FW) Government of India

Currently he is holding the post of Drugs Controller General (India), under Dte.GHS, MoH&FW, Government of India. He has done his M. Pharm and PhD in Pharmaceutical Sciences. He is cworking in CDSCO for last 21 years and having vast experience in the field of GMP, GCP, GRP, GDP, Dossier Review, GLP etc. and has also worked on all the posts in the hierarchy of Central Drugs Control Department including as Drugs Controller Genera of India. Being meritorious student, he was awarded scholarship/fellowships since schooling days. He has been selected and now working as Chairman of WHO’s Member State Mechanism (MSM) of 194 countries on substandard and falsified medical products at Geneva, Switzerland vide World Health Assembly (WHA) resolution 65.19 which is very prestigious opportunity for India to safeguard global interest for making affordable generic medicines acceptable in the world. He is well-known speaker and trainer of various national and international/ WHO scientific bodies. He has been involved in formulating various national regulatory guidelines like guideline on similar biologics and contributed to various WHO guidelines on Drugs, Devices and Vaccines related issues. His focus areas are simplification of regulation and access to quality medical products through Good Regulatory Practices and strengthening regulatory systems.

CV of Keynote Speaker

Dr Rakesh Aggarwal, Director, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), India

Dr. Rakesh Aggarwal (born 1961) is an Indian gastroenterologist and currently the Director of Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER). His previous post was of Professor of Gastroenterology at the Sanjay Gandhi Postgraduate Institute of Medical Sciences. Known for his studies on Gastrointestinal diseases, Liver diseases, and Viral Hepatitis, Dr. Aggarwal is an elected fellow of all the three major Indian science academies namely National Academy of Sciences, India, the Indian Academy of Sciences and the Indian National Science Academy, and of the National Academy of Medical Sciences. The Department of Biotechnology of the Government of India awarded him the National Bioscience Award for Career Development, one of the highest Indian science awards, for his contributions to biosciences in 2002.
## CV of Panelists

<table>
<thead>
<tr>
<th>Dr. Francis P. Crawley, Coordinator, European Fellowship in Research Ethics (EFRE), Executive Director, Good Clinical Practice Alliance-Europe (GCPA), Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Belgium</th>
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<td>He is Ethics adviser, ethics advisory board member, and data protection officer on several European Commission, IMI1 and IMI2 funded projects. Steering committee member and participant in several European Commission projects. He also participant in WHO-funded, EDCTP-funded, and NIH-funded projects and participated in the development of international ethics and regulatory guidances and regulations as an expert for the European Commission, European Parliament, European Medicines Agency, Council of Europe, World Medical Association, CIOMS, UNAIDS, and the World Health Organization (WHO). His specialties, creation of European &amp; international networks for ethics committees, patients, and researchers; Research ethics, research integrity, publication ethics, GCP, and regulatory science training.</td>
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<tr>
<th>Dr. Jeffrey D'Souza, Research Associate, Institute on Ethics &amp; Policy for Innovation, McMaster University, Canada</th>
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<tr>
<td>Dr. Jeff D'Souza is a Research Associate at the Institute on Ethics and Policy for Innovation (IEPI) at McMaster University, Canada. He works on identifying, managing, and providing solutions to ethics challenges, ethics-related risks, and policy gaps in global health research. His interests are in global health ethics and health equity, broadly construed, and he currently leads the Ethics of Clinical Trials research portfolio at IEPI. Current projects include an examination of innovative approaches in public health for improving health equity, and the ethics of conducting controlled human infection model (CHIM) studies in high-resource and low-resource settings. Dr. D’ Souza holds a PhD in Philosophy specializing in ethics and has recently published multiple papers in virtue ethics.</td>
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<tr>
<th>Ms Catherine Tregunno, Senior Scientific Assessor- Vaccines, Anti-infectives and Advanced Therapies Unit, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom</th>
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<tr>
<td>Currently a senior scientific assessor in the Benefit-Risk Management Group of the Vigilance and Risk Management of Medicines Division, Catherine has over 14 years’ experience in Pharmacovigilance, having worked in many areas from adverse event case processing, signal detection and assessment, risk management, risk-benefit evaluation and risk communication. Catherine is currently responsible for monitoring the safety of a range of anti-infective agents, vaccines and immunoglobulins and has also has expertise in the risk management of advanced therapy products.</td>
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Dr A K Pradhan, Deputy Drugs Controller, Central Drug Standard Control Organization, India

Mr. Pradhan, a post graduate in Biochemistry from Kolkata University started his career in Central Drugs Laboratory, Kolkata, an appellate laboratory of Govt. of India, where he worked in the Department of Pharmacology for more than seven years. He joined Central Drugs Standard Control Organization in 1996 where he is currently Dy. Drugs Controller (India) looking after the Divisions of New Drugs, Subsequent New Drugs, Ethics Committee for clinical trial, etc.

He has more than 23 years of experience in regulation of new drug and clinical trial. He has been instrumental in drafting various rules under the Drugs and Cosmetics Act, 1940 and regulatory guidelines especially in respect of regulation of new drug and clinical trial. The recent such major documents are the " New Drugs & Clinical Trials Rules, 2019" notified on 19.03.2019 and the “Guidelines for Evaluation of Nanopharmaceuticals in India” released on 24.10.2019.

Dr Bernhards Ogutu, Chief Research Officer, Kenya Medical Research Institute (KEMRI) and Director for Centre for Research in Therapeutic Sciences, Strathmore University, Kenya

Dr Bernhards Ogutu is currently the Chief Research Officer with the Kenya Medical Research Institute (KEMRI) and Senior Clinical Trialist with the Malaria Clinical Trials Alliance of the INDEPTH-Network. Ogutu is also Director for the Centre for Research in Therapeutic Sciences (CREATEs) at Strathmore University in Nairobi. He has authored more than 150 peer reviewed publications. His areas of research expertise include clinical trials, disease pathogenesis, and clinical therapeutics with a bias in malaria and clinical trials capacity development.

Dr Ogutu received his MBChB, MMed and PhD from the University of Nairobi. Dr Ogutu is a board certified Medical Practitioner, Paediatrician and Clinical Pharmacologist.
Session Brief

The use of medical devices is crucial to achieve Universal Health Coverage (UHC), respond to health emergencies, and keep populations safe. In the World Health Assembly resolution WHA60.29 in May 2007, Member States recognized that medical devices are indispensable for health care delivery; however their development, selection, regulation and use present enormous challenges. Medical devices range from simple tongue depressors and hospital gowns to complex programmable pacemakers and robotic surgical systems; and also include in vitro diagnostics.

WHO released the second edition of the Essential Diagnostics List (EDL) in 2019, covering over 122 categories of tests, including general laboratory tests, and specific tests for high burden infectious diseases and non-communicable diseases. Following this, India is the first country to launch the National Essential Diagnostics List (NEDL) in August, 2019 to strengthen easy access of safe, effective and affordable good quality diagnostics to reduce both direct costs, out of pocket expenditure on health and improve patient outcomes.

The United States leads in the medical device innovation with the help of Centre for Devices and Radiological Health (CDRH) of the USFDA, which ensures access of all new technologies and next-generation products to patients with improved safety and effectiveness of medical devices, classified based on their regulatory requirements. The 510(k) program (Guidance for Industry and Food and Drug Administration Staff) submission of the CDRH for ‘Evaluating Substantial Equivalence in Premarket Notifications’, mandates adequate performance data to confirm that the proposed device is as safe and effective as the chosen predicate device. This is aimed not only at improving the safety and effectiveness of medical devices but also to increase the ability of innovating companies to attract investors, estimate costs, and more quickly bring products to market. In order to address the continuously changing healthcare needs and innovation landscape, the FDA has worked to strengthen the 510(k) Program to meet both patient needs and changes to the device marketplace.

In the European Union, medical devices have to undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. EU Member States can designate accredited notified bodies to conduct conformity assessments. The requirement to conduct a clinical evaluation, submit a Clinical Evaluation Report (CER), and receive a CE Mark evidences a strong upfront obligation to ensure quality and anticipate impacts. For in vitro diagnostics (Companion Diagnostics in EU), the in-vitro diagnostic regulation (IVDR) introduces a new classification system and an...

36 https://www.who.int/medical_devices/global_forum/4th_gfmd/en/
37 https://www.fda.gov/medical-devices/products-and-medical-procedures
38 https://www.who.int/medical_devices/publications/Standalone_document_v8.pdf?ua=1
41 https://www.fda.gov/media/82395/download
42 https://www.fda.gov/media/118500/download
obligation to undergo a conformity assessment by a notified body. The notified body must seek a scientific opinion from EMA or a national competent authority on the suitability of the companion diagnostic to the medicinal product concerned.

The Government of India has taken various steps to make India a vibrant hub for medical devices backed with strong regulatory framework. The National Health Policy 2017 recommends strengthening regulation and establishing regulatory body to unleash innovation and entrepreneurial spirit for manufacture of medical devices in India. Some of the initiatives are newly implemented country-wide Medical Device Rules 2017\textsuperscript{44}, Materiovigilance Program of India (MvPI)\textsuperscript{45}, Medical Technology Assessment Board (MTAB)\textsuperscript{46}, strengthened Health Technology Management, enabling landscape created to foster research and innovation under ‘Make in India vision to enable access to affordable, safe and effective medical devices globally. The Indian Government policy wants to stimulate innovation and new drug discovery as needed, to meet health needs and to ensure that new drugs discovered and brought into the market are affordable to those who need them most.\textsuperscript{47}

It is evident that the updation and enforcement of regulations, even by well-resourced authorities needs to keep pace with the innovation and technology development for facilitating access to medical products and achieving UHC and towards the SDGs. In 2018, 11 Member States of WHO South East Asia Region launched South East Asia Regulatory Network (SEARN) to enhance information sharing, collaboration and convergence of medical products regulatory practices. One of the strategic priorities is the focus on Medical Devices and Diagnostics in the South East Asia Region. The role of SEARN is instrumental in exchange of information, updates and best practices on regulatory framework for medical devices and diagnostics including safety monitoring systems and enhancing capacity-building in quality control of diagnostics.

In addition to favourable national policies and aligned regulations, trained medtech workforce is one of the key drivers for success of the global agenda of access to medical technologies. Capacity building is therefore, a prerequisite and has been recognized as a need by countries across the globe. Several medtech innovation training platforms have been developed and implemented worldwide using need-driven design approaches to health technology innovation. These include the Stanford India Biodesign Program, Singapore-Stanford Biodesign Program, BioInnovate Ireland, Japan Biodesign, Clinical Innovation Fellowships in Sweden, BioInnovate Ireland and d·HEALTH Barcelona to name a few. The Government of India, through its Department of Biotechnology (DBT), has taken several initiatives - School of International Biodesign (SIB) Programme\textsuperscript{48} and parks dedicated for Medical Device Manufacturing as a one-stop-solution for medical devices to make healthcare products affordable and accessible not only for India but for world at large.

The objective of this session is to discuss the following:

- Addressing diagnostics challenges and facilitate access to medicines or diagnostics development and delivery
- Leveraging Assistive Technologies to achieve Universal Health Coverage

\textsuperscript{44} https://mohfw.gov.in/sites/default/files/Medical%20Device%20Rules%2C%202017.pdf
\textsuperscript{45} http://nhsrcindia.org/archive/terms-reference-research-associates-%E2%80%93-materiovigilance-program-india-mvpi
\textsuperscript{46} https://dhr.gov.in/mtab
\textsuperscript{47} https://mohfw.gov.in/sites/default/files/9147562941489753121.pdf
\textsuperscript{48} http://www.biodesignschool.in/
Questions to spur thinking:

- How to develop global standards for medical devices and diagnostics and provide a platform for implementing the latest and globally acceptable guidelines?

- What are the mechanisms for quality benchmarking of innovative medical devices and diagnostics for which international quality standards are not available (such as CE/BIS certifications)?

- How to facilitate robust innovation ecosystem for enabling startups in healthcare to deliver affordable medical products accessible to all through mentoring and financial support?

- Would the establishment of an advisory body for regulation of new medical products comprising regulatory agencies and standards control organization, e.g. Bureau of Indian Standards (BIS) promote access and local manufacturing?
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<th>Time</th>
<th>Parallel Session 6- Wednesday, 20 November 2019</th>
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<tr>
<td>Wednesday, 12:15-13:30</td>
<td>Medical Technology Pathways for Innovative Medical Devices</td>
<td>Durbar Ballroom</td>
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<td><strong>Chair:</strong> Dr VK Paul, Member, NITI Aayog, Government of India</td>
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<td><strong>Co-chair:</strong> Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India</td>
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<td><strong>Keynote Address</strong></td>
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<td>Dr Alka Sharma, Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India</td>
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<td><strong>Steering the Innovation Ecosystem in India – Department of Biotechnology Initiatives for Medical Technology Pathways</strong></td>
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<td><strong>Panelists</strong></td>
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<td>1. Dr Sanjay Sarin, Head, Foundation for Innovative New Diagnostics (FIND), India - <strong>Diagnostics Development and Delivery-Newer Approaches for Collaboration</strong></td>
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<td>2. Dr Sandeep Singh, Professor (Cardiology), Executive Director, School of International Biodesign, All India Institute of Medical Sciences-Delhi, India - <strong>School of International Biodesign (SiB)- Innovation Initiatives</strong></td>
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<td>3. Dr Prakash Bachani, Scientist E &amp; Head (Medical Equipment &amp; Hospital Planning Deptt.), Bureau of Indian Standards (BIS), Government of India - <strong>Standardization of Medical Products</strong></td>
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<td>4. Dr Ravinder Singh, Scientist C, Division of Non Communicable Diseases, Indian Council of Medical Research, Government of India - <strong>Leveraging Assistive Technologies and Innovative Medical Devices towards Achieving Universal Health Coverage</strong></td>
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<td>5. Mr Ajay Pitre, Managing Partner, Pitre Business Ventures LLP, India - <strong>Emerging Market Opportunities, Challenges and Key Drivers</strong></td>
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<td>6. Dr Reba Chhabra, Director, In-charge, National Institute of Biologicals-Noida, India - <strong>Quality Control of Diagnostics and Fostering Local Production of Innovative Medical Devices</strong></td>
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<td>CV of Chairs</td>
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<td><strong>Dr VK Paul, Member, NITI Aayog, Government of India</strong></td>
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<td>The Government of India appointed Dr Paul as a Member of the National Institution for Transforming India, the NITI Aayog, in August 2017 where he leads the Health and Nutrition verticals. He has played a pivotal role in formulating the POSHAN Abhiyaan and the Ayushman Bharat initiative. Prior to being appointed as Member, NITI Aayog, Dr. Paul has been a member of the faculty at the All India Institute of Medical Sciences, New Delhi for over 32 years and Head of the Department of Pediatrics for nearly a decade. Dr. Paul is an internationally renowned paediatrician, academic, medical research and public health exponent. He was conferred the prestigious Ihsan Dogramaci Family Health Foundation Prize by WHO at the 2018 World Health Assembly. Prof. Paul has recently been appointed as the Chairman of The Board of Governors of Medical Council of India.</td>
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| **Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India** |
| Dr Renu Swarup is currently Secretary, Department of Biotechnology (DBT). She has served in Department of Biotechnology for nearly 29 years and was holding the position of Senior Advisor/Scientist ‘H’ till she was appointed a Secretary to Government of India on 10th April, 2018. She also holds position of Chairperson, Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Company incorporated by the Government to nurture and promote innovation research in the Biotech Enterprise with special focus on Start-ups and SMEs. |
| A PhD in Genetics and Plant Breeding, Dr. Renu Swarup completed her Post Doctoral at The John Innes Centre, Norwich UK, under Commonwealth Scholarship and returned to India to take up the assignment of a Science Manager in the Department of Biotechnology, Ministry of Science and Technology, Govt, in 1989. As a Science Manager issues related to policy planning and implementation are a part of her assignment. She was actively engaged in formulation of the Biotechnology Vision in 2001, National Biotechnology Development Strategy in 2007 and Strategy II, 2015-20 as the Member Secretary of the Expert Committee. |
| Dr. Renu Swarup has also been closely involved in Programmes and activities related to Women and Science. She was responsible for getting implemented the DBT Scheme on Biotechnology Career Advancement for Women Scientists – BioCARe. She was also a member of the Task Force on Women in Science constituted by the Scientific Advisory Committee to the Prime Minister. |
| Dr. Renu Swarup also held charge of Managing Director, Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Company incorporated by the Government of India to nurture and promote innovation research in the Biotech Enterprise with special focus on Start-ups and SMEs till she took over the charge of Chairperson. Through Biotechnology translational research and industry academia partnerships she has supported more than 1000 Startups and Entrepreneurs, and nearly 500 small companies for innovation research and product development. |
A Member of the National Academy of Sciences (NASI) India. She is also a Member of Governing Body of National Institutes, Universities and Centers. She was awarded the “BioSpectrum Person of the Year Award” in 2012. She also received the “National Entrepreneurship Awards 2017”. This is a Special Jury recognition Award for Government Mentor.

**CV of Keynote Speaker**

Dr. Alka Sharma, Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India

Dr. Sharma completed her Ph.D. from Banaras Hindu University, and joined Institute of Genomics and Integrated Biology, Council of Scientific Research (CSIR), New Delhi as Project Scientist. As a team member, she has developed various technologies and transferred to the entrepreneurs. She has co-guided post-graduate and Doctoral Fellows for their research work. She has several international and national patents to her credit; and also published research papers and articles in reputed international and national Journals.

In her present role, she deals with research and policy issues in the emerging areas of biotechnology in the Government of India such as stem cells & regenerative medicine; biomedical engineering & biodesign; medical technology innovation; National Biopharma Mission; vaccine research; public health nutrition, make in India programme, Bioclusters, etc. She is member of various policy related Committees of the Government of India. She has received training at the Department of Microbiology and Infectious Diseases, NIH, USA for the management of extramural programmes. She is the recipient of “CSIR Technology Award for Innovation” for her work.

**CV of Panelists**

Dr. Sanjay Sarin, Head, Foundation for Innovative New Diagnostics (FIND), India

Dr. Sanjay Sarin is currently the Country Head, India at Foundation for Innovative New Diagnostics (FIND) where he is responsible for providing leadership and strategic direction to FIND’s development and access teams and projects in India and representing FIND to local and international stakeholders.

Prior to that, Sanjay has held multiple roles in Becton Dickinson, a global medical device and diagnostic company. As the Regional Director, Global Health for BD in Asia Pacific he was responsible for design, development, and implementation of BD’s public health and partnership strategies towards accomplishment of company’s overall strategic goals through an extensive network of external partners and stakeholders. During his stint with BD, he also served as the Business Director of the Preanalytical Systems business vertical for BD in India and South Asia; and as member of the BD’s Country leadership team and the Worldwide Extended Leadership team.

He has previously been an entrepreneur, served as a Senior Manager with the Apollo Hospitals followed by a stint as Regional Lab Advisor.
Sanjay has close to 20 years of experience in health policy, market development, and business management with specialization in the development of strategic initiatives for driving access to critical healthcare technologies in emerging markets. Sanjay is a member of the rGLC of WHO SEARO for Programmatic Management of DR-TB and also serves on the National Lab Technical Resource Group of National AIDS Control Organization of India.

Dr. Sandeep Singh, Professor (Cardiology), Executive Director, School of International Biodesign, All India Institute of Medical Sciences-Delhi, India

Dr. Sandeep Singh is a Professor of Cardiology at the prestigious All India Institute of Medical Sciences (AIIMS), New Delhi. He has vast teaching experience, spanning over thirty years in the fields of Medicine & Cardiology. Presently, he is involved in various multi-centre trials on cardiac devices and has authored more than 80 peer-reviewed publications and many chapters in the books. He has also been awarded the International Award of ‘Excellence in Cardiology’ during the VIII World Congress on Clinical, Preventive Cardiology and Imaging-2013. He has held the positions of Editorial Secretary for the Indian Heart Journal and as an Executive Member of the Cardiological Society of India (Delhi Branch).

He also holds the position of Executive Director at the ‘School of International Biodesign’ at AIIMS, New Delhi focussing on frugal innovation of biomedical devices and strengthening the roots of biodesign process in India and internationally. His post-doctoral certification in the Stanford-India Biodesign Program in the year 2008 gave him the platform to be co-inventor of many cost-effective novel devices and have several patents on his name. He has been awarded the prestigious ‘Tata Innovation Award’ of the Department of Biotechnology, Government of India in recognition of his outstanding contribution in translational research and creation of innovative platform technologies. He was the winner of the ‘BMJ India Award’ in the field of Innovation in Healthcare Technology in the year 2014.

Dr Prakash Bachani, Scientist E & Head (Medical Equipment & Hospital Planning Department), Bureau of Indian Standards (BIS), Government of India

Dr Prakash Bachani is currently working as Scientist E & Head (Medical Equipment Planning, Head Bureau of Indian Standards, Government of India. He worked with Engineers India Ltd in installation, testing and commissioning of Smelter Plant in NALCO project before joining BIS (erstwhile ISI) in 1984. Presently, he has 34 years experience in Bureau of Indian Standards, the National Standards Body of India, having worked in Standard Formulation, Laboratory and Certification Activities. At the Technical level, he has overseen Product Certification, System Certification (QMS), Hallmarking of Gold and Silver, Standards Formulation (Electrotechnical and Medical Equipment & Hospital Planning), Laboratory Management. He has participated in various international seminars and meetings organized in the country in the field of electrotechnical as well as in Medical Equipment and Devices. He has also presented several papers on Standardization, Certification etc. in the field of Electrical Engg. and Medical Equipment at various National and
International meetings/ seminars. He is GOLD MEDALIST in MIE (Electrical Engg.), Institution of Engineers, India.

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<thead>
<tr>
<th>Dr Ravinder Singh, Scientist C, Division of Non Communicable Diseases, Indian Council of Medical Research, Government of India</th>
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<tr>
<td>Dr. Ravinder Singh is a medical graduate with doctorate training in public health. He is looking after the areas of mental health, disability, rehabilitation and assistive technologies at ICMR Headquarters (DHR, Ministry of Health &amp; Family Welfare, Government of India), New Delhi. He has experience of more than two decades in research. He is editor of many national and international journals. He is Chairperson of Ethics Committee of Sudha Rustagi Dental College, Faridabad and member of Ethics Committee of DY Patil University, Pune. He has published papers in national and international journals. He is visiting faculty of many national and international universities.</td>
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<td>He has travelled many countries to push the agenda of mental health, disability, rehabilitation and assistive technologies. He has initiated many task force studies in related areas.</td>
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<td>He is working on positioning the Assistive Technologies in Indian Health System in collaboration with World Health Organisation (WHO) Geneva, WHO-SEARO and WHO-India. He has contributed chapters in many books. He has been awarded ‘Distinguished Service Award’ by Delhi Medical Association. He is consultant/expert in Ministry of Social Justice and Empowerment, Govt. of India. He is member of Governing Council and Executive Council of Rehabilitation Council of India. He has developed Courses for Health Communication and Public Health Nutrition.</td>
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<th>Mr Ajay Pitre, Managing Partner, Pitre Business Ventures LLP, India</th>
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<td>Mr. Pitre took charge of the Sushrut-Adler group operations as ‘Managing Director’ in 1987 after he graduated in commerce. He further completed a course in ‘Management for Small and Medium Enterprises’ at The Indian Institute of Management, Ahmedabad. Mr. Pitre’s has long been convinced about the relevance of Indian Innovation in medical technology and business models to help meet the growing need of the emerging non-affluent world that constitutes more than 80% of the global population. After enabling the Sushrut- Adler Group to take larger steps by becoming part of Smith &amp; Nephew, a global orthopaedic leader, Mr. Pitre supported the acquired organization as its Chief Mentor. Now as Managing Partner of Pitre Business Ventures LLP., he continues his connect with the Medical Technology Industry by engaging in various activities including assisting, consulting and enabling various MedTech companies and innovators.</td>
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<td>He has been invited to speak at various National &amp; International forums in India and various countries such as Australia, Switzerland, USA etc.</td>
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<td>His professional affiliations include Member &amp; Past Chairman, CII, Medical Technology Division; Advisor &amp; Past Co-Chair, FICCI, Medical Device Forum. He is also a member of TiMED Governing Board; SCTIMST Research Council; Central Manufacturing Technology Institute Governing Board, Maharashtra Chamber of Commerce &amp; Industry Governing Council and CII, Pune Zonal Council.</td>
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Dr Reba Chhabra, Director In-charge, National Institute of Biologicals-Noida, India

Dr Reba Chhabra is Director In-charge, National Institute of Biologicals, Ministry of Health and Family Welfare, Government of India. She is a pioneer contributor in the field of Quality Control Evaluation of Immunodiagnostics Kits for more than 25 years, resource person for NACO activities relating to conducting HIV EQAS & strengthening Quality Management System.

She has undergone international trainings at Centre for Biologics Evaluation and Research Food & Drugs Administration (CBER/FDA), USA, at National Serology Reference Laboratory, Melbourne, Australia. She has also attended national level trainings, conducted workshops and participated in WHO collaborative studies. She is invited as a Panelist in FICCI/CII forums, is a lead auditor for ISO 9001: 2008, member of Asia Harmonization Working Party Technical Committee (AHWPTC) working group AHWPWG1a-IVDD (In Vitro Diagnostic Devices) since September 2013. She is also notified Government Analyst and Medical Device Testing Officer in respect of In-vitro Diagnostics kits for HIV, HCV & HBsAg.

Under her able guidance, NIB has initiated training programmes in line with Pradhan Mantri Kaushal Vikas Yojna (PMKVY) like National Skill Development and Hands on Training on Quality Control of Biologicals for Post Graduate Students as well as Training of Trainers for Strengthening of Blood Services in collaboration with Blood Cell, National Health Mission (NHM), Ministry of Health and Family Welfare, Government of India for blood bank officials of various states and union territories in India.
Session Brief

Tuberculosis, HIV/AIDS, malaria and other communicable diseases affect billions of people worldwide causing more than 4 million deaths each year⁴⁹. ‘Transforming our world: the 2030 Agenda for Sustainable Development’ was adopted by the UN General Assembly in 2015⁵⁰. The Sustainable Development Goal 3 (SDG3): Ensure healthy lives and promote well-being for all at all ages; targets to end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and to combat hepatitis, water-borne diseases and other communicable diseases by 2030⁵¹.

**HIV/AIDS**

Globally, 37.9 million people were living with HIV in 2018. Global activities to battle HIV/AIDS were initiated as early as 1980s, with the establishment of Joint United Nations Programme on HIV/AIDS – UNAIDS in 1994, and adoption of a resolution A/RES/S-26/2 for Declaration of Commitment on the HIV/AIDS “Global Crisis – Global Action” by the UN General Assembly (UNGA), in its Twenty-sixth special session (2001)⁵². Resolution A53/6 on HIV/AIDS at the 53rd World Health Assembly, 2000 also urged WHO Member States to increase access to treatments for HIV-related illnesses and undertake renewal of efforts to make drugs more available and affordable to developing countries⁵³. The 2016 UNGA Political Declaration on Ending AIDS: on the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030; called for reducing new HIV infections, reducing AIDS-related deaths and eliminating HIV-related stigma and discrimination⁵⁴.

The 2019 WHO guidelines provide reassurance of Dolutegravir (DTG) as the preferred antiretroviral (ARV) drug in first- and second-line regimens⁵⁵. This reassurance comes at a time when pretreatment resistance to non-nucleoside reverse-transcriptase inhibitors (NNRTI) is increasing in low- and middle-income countries, creating demand for access to alternative non-NNRTI ARV drugs. UNAIDS and the Global Fund to fight AIDS, Tuberculosis and Malaria have signed a strategic framework for cooperation and collaboration to strengthen and accelerate support to countries’ efforts to end AIDS⁵⁶.

**India Initiatives:** India’s National AIDS Control Organization (NACO), in its approach to reach ‘the last mile’ has implemented a seven-year National Strategic Plan on HIV/AIDS and Sexually Transmitted Infections (STI), 2017-24⁵⁷. By 2020, the focus of the national programme will be on achieving the following fast track targets⁵⁸.

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⁴⁹ [https://www.who.int/about/structure/organigram/htm/en/](https://www.who.int/about/structure/organigram/htm/en/)
(i) 75% reduction in new HIV infections,
(ii) 90-90-90: 90% of those who are HIV positive in the country know their status, 90% of those who know their status are on treatment and 90% of those who are on treatment experience effective viral load suppression,
(iii) Elimination of mother-to-child transmission of HIV and Syphilis, and
(iv) Elimination of stigma and discrimination Paving Way for an AIDS Free India

By 2024, the further achievements envisaged are:
(i) 80% reduction in new HIV infections,
(ii) Ensuring that 95% of those who are HIV positive in the country know their status, 95% of those who know their status are on treatment and 95% of those who are on treatment experience effective viral load suppression

To this effect, two key achievements in early 2017 to ‘Ending of AIDS by 2030’ include the enactment of the ‘HIV/AIDS Bill’ as a law protecting the rights of people living with and affected by HIV as well as the announcement and implementation of the ‘Test and Treat’ policy in line with global guidelines.

**Tuberculosis**

Tuberculosis (TB) is one of the top 10 causes of death worldwide. In 2017, TB caused an estimated 1.3 million deaths (range, 1.2-1.4 million) among HIV-negative people and there were an additional 300,000 deaths from TB (range, 266,000-335,000) among HIV-positive people. Two-thirds of the cases were in eight countries: India (27%), China (9%), Indonesia (8%), the Philippines (6%), Pakistan (5%), Nigeria (4%), Bangladesh (4%) and South Africa (3%)\(^{59}\). Drug-resistant TB, resistant to rifampicin and/or isoniazid is a public health crisis and constitutes a significant number of affected cases. The launch of the directly observed treatment, short course (DOTS) strategy for TB, implementation of Stop TB Strategy; and adoption of resolution WHA62.15 on the prevention and control of multidrug-resistant TB and extensively drug-resistant TB by the Sixty-second World Health Assembly in 2014 have helped to accelerate the global expansion of TB care and control\(^{60}\). WHO End TB Strategy has saved 54 million lives and achieved 33% reduction in TB deaths between 2000 and 2017.\(^{61}\)

The First WHO Global Ministerial Conference on Ending TB held in Moscow in November, 2017 focussed on accelerating the response to meet the targets agreed under the End TB Strategy and SDGs, through increased national and global commitments\(^{62}\). The participating 118 national delegations adopted the “Moscow Declaration to End TB” addressing commitments for the outcome areas - advancing the TB response within the SDG agenda; ensuring sufficient and sustainable financing; pursuing science, research and innovation; and developing a multi-sectoral accountability framework\(^{63}\). The first-ever UN General Assembly high-level meeting on tuberculosis on 26 September 2018 endorsed an ambitious and powerful political declaration to accelerate progress towards End TB targets. This declaration was subsequently adopted by the

General Assembly on 10 October 2018\(^{64}\). The new treatment guidelines of the WHO for multidrug-resistant TB (2018) prioritize oral drugs, such as bedaquiline (diarylquinoline
antimycobacterial agent), and minimize injectables, which can cause patients pain and distress and serious adverse events that lead to interruption of treatment\textsuperscript{65}.

Several organizations such as TB Alliance and Stop TB Partnership are actively engaged in discovery, development and access and delivery of better, faster-acting and affordable tuberculosis drugs.

**India Initiatives:** India has a Revised National Tuberculosis Control Programme (RNTCP) to prevent and control TB in the country with integrated four pillars of “detect – Treat – Prevent – Build” (DTPB) and aims to eliminate TB by 2025\textsuperscript{66}. In the High Level Meeting on Tuberculosis at 73rd session of United Nations General Assembly (UNGA), Union Health Minister Shri JP Nadda stated that Prime Minister Shri Narendra Modiji has shown personal commitment to tackle TB head-on as India plans to eliminate TB by 2025, five years ahead of the SDG target of 2030, by launching the TB Free India Campaign.

The UN General Assembly adopted a new resolution that calls on Member States to provide, with the support of development partners, universal access to existing life-saving tools for the prevention, diagnosis and treatment of malaria, in particular to the package of core interventions recommended by WHO. The resolution also calls for equity in access to health services for all people at risk of contracting malaria, especially the most vulnerable and hard-to-reach populations.

**Malaria**

Malaria caused approximately 219 million deaths in 2017 worldwide. Almost 80% of the global Malaria burden is carried by fifteen countries in sub-Saharan Africa and India\textsuperscript{67}. WHO recommends artemisinin-based combination therapies (ACTs) for the treatment of malaria\textsuperscript{68}. The Global Malaria Eradication Programme was launched by WHO as early as 1955\textsuperscript{69}; however, renewed interest was seen in a ministerial conference on malaria organized in Netherlands in 1992. The conference attended by 65 countries adopted a World Declaration on the Control of Malaria, endorsed by the World Health Assembly in 1993\textsuperscript{70}.

The World Health Assembly, in 2015 approved WHO’s Global Technical Strategy for Malaria 2016–2030, a 15-year blueprint for all countries working to control and eliminate malaria. The strategy set ambitious but attainable targets for 2030, including reducing malaria case incidence and death rates by at least 90%, eliminating malaria in at least 35 countries, and preventing the reintroduction of malaria in all countries that are malaria free\textsuperscript{71}. In 2016, WHO identified 21 countries with the potential to eliminate malaria by the year 2020. WHO is working with the governments in these countries – known as “E-2020 countries” – to support their elimination acceleration goals\textsuperscript{72}.

In 2018, the UN General Assembly adopted a new resolution on Consolidating gains and accelerating efforts to control and eliminate malaria in developing countries, particularly in Africa by 2030\textsuperscript{73, 74}.

\textsuperscript{65} https://www.who.int/tb/features_archive/updated-treatment-guidelines-multigrug-rifampicin-resistant-TB/en/
\textsuperscript{66} https://www.nhp.gov.in/revised-national-tuberculosis-control-programme_pg
\textsuperscript{67} https://www.who.int/malaria/media/world-malaria-report-2018/en/
\textsuperscript{68} https://www.who.int/malaria/areas/treatment/overview/en/
\textsuperscript{69} https://apps.who.int/iris/handle/10665/171557
\textsuperscript{70} https://www.who.int/malaria/areas/treatment/overview/en/
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\textsuperscript{72} https://www.who.int/malaria/media/world-malaria-report-2018/en/
\textsuperscript{73} https://www.un.org/en/ga/search/view_doc.asp?symbol=A/72/L.68
\textsuperscript{74} https://www.who.int/global-coordination-mechanism/working-groups/STKH-3TB-Global-Fund-Shakarishvili.pdf
**Initiatives by India:** India’s National Framework for Malaria Elimination (NFME) 2016-2030 was launched on in 2016. It lays out the vision, mission, broad principles and practices to achieve the target of malaria elimination by 2030 in synchronization with the Global Technical Strategy (GTS) for Malaria 2016-2030 of WHO.

In alignment with the global strategies, India’s National Framework for Malaria Elimination (NFME) 2016–2030 has been developed under the National Vector Borne Diseases Control Programme (NVBDCP) with the aim to eliminate malaria nationally and contribute to improved health, quality of life and alleviation of poverty. It lays out the vision, mission, broad principles and practices to achieve the target of malaria elimination by 2030 in synchronization with the Global Technical Strategy (GTS) for Malaria 2016-2030 of WHO. The NFME has clearly defined goals, objectives, strategies, targets and timelines and will serve as a roadmap for advocating and planning malaria elimination throughout the country in a phased manner.

Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks are also being worked on for diseases such as AIDS, Tuberculosis, Malaria, and Hepatitis.

**The objective of the meeting is to discuss the following:**
- Current landscape of elimination of HIV/AIDS, Tuberculosis and Malaria in national and global context
- Policy initiatives facilitating expeditious elimination of HIV/AIDS, Tuberculosis and Malaria
- Innovative medical products for end game and expeditious access.

**Questions to spur thinking:**
- What are the possible mechanisms for fostering collaboration between national government agencies and international players on delinking the costs of R&D for diseases of public health importance from price of treatment?
- What are best practices to review access and affordability to key treatment regimes for HIV, TB, Malaria?
- How to promote capacity building of local manufacturers for large scale production of quality drugs towards endgame?

75 [https://apps.who.int/iris/bitstream/handle/10665/246096/national_framework_malaria_elimination_india_2016_2030.pdf?sequence=1&isAllowed=y](https://apps.who.int/iris/bitstream/handle/10665/246096/national_framework_malaria_elimination_india_2016_2030.pdf?sequence=1&isAllowed=y)
### 20 November 2019- Wednesday, 14:30-16:00: Parallel Session 7: Medical Products for End game for HIV/AIDS, Tuberculosis, Malaria

<table>
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<tr>
<th>Time</th>
<th>Parallel Session 7- Wednesday, 20 November 2019</th>
<th>Room</th>
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<tr>
<td>Wednesday, 14:30-16:00</td>
<td>Medical Products for End game for HIV/AIDS, Tuberculosis, Malaria</td>
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**Chair:** Mr Vikas Sheel, Joint Secretary, Ministry of Health and Family Welfare, Government of India  
**Co-chair:** Dr Raman R Gangakhedkar, Scientist G and Head, Epidemiology and Communicable Diseases, Indian Council of Medical Research, Government of India

**Keynote Address**

Dr KS Sachdeva, Deputy Director General, Tuberculosis, Ministry of Health & Family Welfare, Government of India - National Tuberculosis Elimination Plan-Role of Newer Medical Products

**Panelists**

1. Dr Brenda Waning, Chief, Global Drug Facility, STOP TB, Switzerland - Access to Medicines and Diagnostics in Resource Limited Settings

2. Dr Stephen Kennedy, Principal Investigator, PREVAIL: Joint US-Liberia Research Partnership, University of Liberia, Liberia - Endgame of HIV/AIDS, Tuberculosis, Malaria: Strategy, Implications and Future Directions

3. Mr Carlos A Grabois Gadelha, Oswaldo Cruz Foundation (Fiocruz), Research Leader, The Health Economic-Industrial Complex and Innovation Research Group, Brazil - Development, Innovation and Health: The Brazilian Perspective

4. Dr Chris Ockenhouse, Director, Medical and Clinical Operations, Malaria Vaccine Initiative, PATH, United States of America - Clinical Development for Innovative Point-of-Care Medical Products

5. Dr Suman Rijal, Director, Drugs for Neglected Diseases initiative (DNDi), India - Partnerships to Develop and Ensure Access to New Medicines for HIV-infected Children

6. Ms Anjali Sharma, Clinical Instructor, Global Health, Centre for Infectious Disease Research in Zambia (CIDRZ) - Delivering Anti-retroviral Therapies in Low Resource Settings
CV of Chairs

Mr Vikas Sheel, Joint Secretary, Ministry of Health and Family Welfare, Government of India

Mr Vikas Sheel (IAS-batch 1994) has studied BE (Electrical) from Birla Institute of Technology and Science, Pilani and ME from IIT Roorke. He is currently Joint Secretary, Ministry of Health and family Welfare. He has held various portfolios such as Health and Family Welfare, Food, Civil Supplies & Consumer Affairs and General Administration as Joint Secretary, Government of Chhattisgarh.

Dr Raman R Gangakhedkar, Scientist G and Head, Epidemiology and Communicable Diseases, Indian Council of Medical Research, Government of India

Dr Raman R Gangakhedkar is the Head, Division of Epidemiology & Communicable Diseases, Indian Council of Medical Research. Prior to initiating work on HIV disease in 1989, he was working on Sickle Cell Disease. Between 1989 to 2018, he worked on HIV disease comprehensively. He was transferred as Head of Epidemiology & Communicable Diseases to Delhi in January 2018. ICMR has 25 National Institutes for various diseases, I look after 14 institutes. The Nipah outbreak occurred in May 2018 which he coordinated successfully. He was leading the effort from the Headquarter. He managed to work on Nipah comprehensively. He managed to establish presence of Zika in Rajasthan and have started comprehensive projects on Zika. And also initiated studies on Dengue, AES on every possible aspects. He is member of many national and international expert groups. He has published over 178 papers.

CV of Keynote Speaker

Dr KS Sachdeva, Deputy Director General, Tuberculosis, Ministry of Health & Family Welfare, Government of India

A qualified Public Health/Health Management and Chest and TB Specialist with more than thirty years of experience and has been holding Senior Managerial level for last 19 years.

He currently leads the National TB Control Programme of Government of India and also serves as a nodal officer for Country Coordination Mechanism of Global Fund for TB, HIV and Malaria in India. He has 12 years of experience in TB and HIV/AIDS Control. Prior to this he has led the Essential Drugs Programme for Government of NCT Delhi for three years and also have two decades of clinical experience at a tertiary care hospital.

He has also served as an expert in various committees and technical working groups at national and international level and has more than 50 publications in peer-reviewed journals.
## CV of Panelists

### Dr Brenda Waning, Chief, Global Drug Facility, STOP TB, Switzerland

Brenda Waning, PhD, MPH, RPh as the new Chief of the Global Drug Facility (GDF). Dr Waning is an expert in developing, implementing, and analyzing pharmaceutical policies and market approaches to improve access to medicines and diagnostics in resource-limited settings.

Most recently, Dr Waning was the Coordinator of Market Dynamics at UNITAID where she led efforts related to UNITAID’s technical strategy, market assessments, and strategic investments. Prior to joining UNITAID, Brenda served as Director of Pharmaceutical Policy at Boston University School of Medicine where she authored numerous peer-reviewed studies on pharmaceutical policy at global, regional, and national levels.

### Dr Stephen B Kennedy, Principle Coordinator for EVD Research, Incident Management System

Dr Stephen B. Kennedy is trained in general medicine, infectious disease epidemiology, biomedical research, and international health from Liberia, United States (U.S.) and Zambia, respectively.

Presently, Dr. Kennedy serves as Liberia’s Co-Principal Investigator (PI) and one of the lead Liberian Research Scientists for the EVD Vaccine Clinical Trial of the Liberia-US Joint Clinical Research Program of the Partnership for Research on Ebola Vaccines in Liberia (PREVAIL); Co-PI for a four-country EVD Vaccine Clinical Trial (PREVAC) of a multinational (NIH, INSERM, LSHTM) and sub-regional countries (Sierra Leone, Guinea, Liberia & Mali) consortium; Technical Lead for Research & Capacity Enhancement for the West African Taskforce for the Control of Emerging and Re-emerging Infectious Diseases (WATER); Member of the Core Working Group (CWG) of the West African Consortium (WAC) of the Sub-Regional Collaboration Research Group on EVD Vaccines, Therapeutics & Diagnostics; and member of the Action Committee on Viral Hemorrhagic Fevers (VHFs) for the West African College of Physicians (WACP), respectively. Dr. Kennedy is Fellow of the Liberia College of Physicians (FLCP) and Fellow of the West African College of Physicians (FWACP).

Dr Kennedy possesses nearly three decades of experience as a public health practitioner, researcher, scientist and/or medical doctor in Sub-Saharan Africa and nearly two decades of experience in biomedical and clinical-based research, research ethics in the tropics and clinical trials in HIV/AIDS, STDs, Malaria, Tuberculosis (TB), community health, and Ebola Virus Disease (EVD).

Previously, Dr. Kennedy served as Commissioner for Programs & Policy at the National AIDS Commission (NAC), Secretary General (SG) of the Liberia College of Physicians & Surgeons (LCPS), and Coordinator for EVD Research at the Liberia’s Emergency Operations Center (EoC) of the Incident Management System (IMS) of the Ministry of Health (MoH) in Liberia.
Mr Carlos A Grabois Gadelha, Oswaldo Cruz Foundation (Fiocruz), Presidency/National School of Public Health, Research Leader, The Health Economic-Industrial Complex and Innovation Research Group, Brazil

Carlos A. Grabois Gadelha holds a PhD in Economics from the Economics Institute Federal University of Rio de Janeiro (IE-UFRJ). Coordinator of Prospecting Activities of the Presidency of Fiocruz, he is also a professor and researcher of the Department of Administration and Planning in Health and Coordinator of the Professional Master in Policy and Management of Science, Technology and Innovation in Health of the National School of Public Health Sérgio Arouca (DAPS/ENSP/FOCRUZ). He has a vast scientific production in articles, chapters and books, and is Leader of the Research Group on Development, Economic-industrial Complex and Innovation in Health, a concept developed by him that guided several public policies. He was Vice-President of Production and Innovation in Health at Fiocruz; Secretary of Regional Development Programs at the Ministry of National Integration; Secretary of Science and Technology and Strategic Products at the Ministry of Health; and Secretary of Industrial Development and Competitiveness at the Ministry of Industry Development and Foreign Trade.

Dr Christian Ockenhouse, Director, Medical and Clinical Operations, Malaria Vaccine Initiative, PATH, United States of America

Chris Ockenhouse provides scientific and clinical guidance to translational project teams in charge of early clinical development, working closely with MVI staff, partners, and academic investigators. He also provides medical and scientific expertise on clinical malaria, clinical immunology, and trial design. He serves on the Malaria Disease Area Translational Leadership Team.

Chris has over 25 years of experience leading R&D programs focused on discovery, process development, manufacture, and early clinical testing of multiple vaccine candidates against Plasmodium falciparum and P. vivax malaria. Prior to joining MVI, Chris was Director of the Malaria Vaccine Program at the Walter Reed Army Institute of Research (WRAIR), where he directed the formation and operations of the first joint US Army-Navy Military Malaria Vaccine Program dedicated to developing malaria vaccines within the Department of Defense. He retired from active duty as a Colonel in the US Army. Chris received his medical degree from the Medical College of Pennsylvania in Philadelphia, a PhD in immunology & parasitology from the Sackler Institute for Biomedical Sciences at New York University, an MS in parasitology from the Tulane University School of Tropical Medicine and Hygiene in New Orleans, and a BS (honors) from Wheaton College. Chris has also published more than 150 articles in scientific and medical literature.
Dr Suman Rijal, Director, Drugs for Neglected Diseases initiative (DNDi), India

Dr Suman Rijal joined DNDi in 2014 as the Managing Director of the Regional Office in India. Before joining DNDi he was Professor of Internal Medicine and Chief, Tropical and Infectious Diseases Centre, at B.P. Koirala Institute of Health Sciences, Nepal. Since the last 20 years he has been working in the field of neglected tropical diseases particularly kala-azar. He has coordinated several collaborative research projects and participated in the development of guidelines for the control of kala-azar in the region.

He undertook his medical training in Kolkata, India and the United Kingdom and was awarded a PhD from the University of Gent, Belgium. He is a member of several national and international committees including the WHO Expert Panel on Parasitic Diseases (Leishmaniasis), Geneva, and Regional Technical Advisory Group on VL Elimination at SEARO/WHO.

Dr Anjali Sharma, Senior Research Technical Advisor, Centre for Infectious Disease Research in Zambia (CIDRZ)

Anjali Sharma is a qualitative researcher based at the Centre for Disease Research Zambia (CIDRZ) supporting implementation science to improve HIV, women's health, and child health services. She also supports prevention and vaccines research related to gastro-enteric diseases. Her main research has focused on examining different models of delivering Anti-Retroviral Therapy (ART) to make recommendations for effectiveness (viral load suppression), cost-effectiveness and efficiencies. More recently, Anjali has become interested in regulatory and ethical frameworks for the conduct of Human Infection Studies in Low and Medium Income Countries. Anjali is setting up a social and behavioral science research group in CIDRZ to further develop qualitative and intervention design skills among young Zambian Global Health scientists.
Session Brief

Achieving the goal of healthy lives and well-being for all can be accelerated through investments in research and innovation, made accessible on an equitable basis. Today, there is a vibrant community of researchers and innovators across the academic and private sector working to develop solutions for health problems, from basic, fundamental science, to new medical products and devices, to system-level and social sciences research.

Various World Health Assembly Resolutions, have been focusing on the need of promoting innovation to achieve the SDGs such as WHA69.11 (2016): Health in the 2030 Agenda for Sustainable Development, WHA69.20 (2016): Promoting innovation and access to quality, safe, efficacious and affordable medicines for children and WHA68.18 (2015): Global strategy and plan of action on public health, innovation and intellectual property.

A strong evidence base will need to be developed, such as analyses of product pipelines and funders' portfolios to identify gaps and areas of action which will help in identifying much larger areas for collaboration and future mobilisation of the global health research community post-UNGA 2019.

In line with the Global strategy and plan of action on public health, innovation and intellectual property, which recommends prioritizing needs for and promoting research and development, WHO is playing a role in facilitating research and development for neglected areas, where there is a compelling unmet public health need for new products, including by coordinating the efforts of different actors, setting research and development priorities, identifying associated gaps, defining desired product profiles and facilitating the development of affordable, suitable health products. The Global Observatory on Health Research and Development is central to setting priorities for product development and contributing to coordinated actions on health research and development. The R&D Blueprint supports the development of a global preparedness plan for addressing future epidemics. WHO, together with the Drugs for Neglected Diseases initiative, has set up the Global Antibiotic Research & Development Partnership to develop new treatments for bacterial infections.

Many potential solutions that could have significant positive impact on realizing SDG 3 have been successfully tested in the pilot phase. Yet there are often barriers and delays to the adoption of these solutions, sustainably and at scale, in the countries that need them most. The research accelerator will, through a time-bound process, establish a sustainable roadmap for global health research, development, innovation and access to 2030 and beyond.
In addition to the overarching aim of realigning (international and domestic) research investments with country needs to achieve universal health coverage (UHC), healthier populations and protection from health emergencies, the roadmap will include the following four elements:

- Sustaining investment in new ideas: the accelerator will identify best practices for research and pipeline coordination, innovation hubs and other routes for generating new knowledge and propositions for health-improving innovation.
- Ensuring that promising innovations reach those who need them: organizations will work together to identify promising innovations ready to transition to scale, and participate in partnerships with governments, funders and the private sector to help innovations translate to impact.
- Optimising the path to scale-up: the accelerator will look at existing routes to scale (including the role of tools such as technical guidance and innovation marketplaces) and recommend improvements to ensure that barriers are quickly removed.
- Enabling sustainable scale-up at the country level: the accelerator will explore how to shift priorities for research and innovation to the country level (particularly in LMICs), with assistance provided to countries to establish local priorities and modalities for bringing innovations to scale and ensuring equitable access.

There is a need to address three areas: Optimising the global research system for identifying international systems-level improvements which require coordination and alignment across the sector, Scaling up innovation for identifying catalytic actions for national and international organisations to work together to achieve scale up and impact and elevating country priorities for consulting directly with countries to create better alignment between national needs and internationally-commissioned research and innovations¹.

WHO Health Innovation Group (WHIG) is a voluntary group of interested WHO colleagues who jointly promote and pursue health innovation within the Organization. The group also strives to promote WHO’s image and position on health innovation to the outside world. WHIG is open to all WHO staff and it offers an open forum on health innovation, limited to only product development.

Effective partnerships can enhance access to innovation, reduce risk, and manage costs and may provide a means for steering research and development investment to address societal objectives. The numerous public-private partnerships (PPPs) that have emerged over the past 20 years reflect different models of operation and different approaches to aspects such as the partnership objective, participants and their roles, intellectual property (IP) policies, funding sources, and governance.

Technological innovation in medicine covers the wide range of events by which a new medical technology is discovered or invented, developed, and disseminated into health care. One of the most vulnerable links in the innovation chain is the development phase, the “D” of R&D, in which research findings are brought into clinical practice.²

For drug discovery, FDA is conducting a Model-Informed Drug Development (MIDD) Pilot Program to facilitate the development and application of exposure-based, biological, and statistical models derived from preclinical and clinical data sources, referred to as MIDD approaches. MIDD approaches use a variety of quantitative methods to help balance the risks.

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¹ Accelerator paper 5
and benefits of drug products in development. When successfully applied, MIDD approaches can improve clinical trial efficiency, increase the probability of regulatory success, and optimize drug dosing/therapeutic individualization in the absence of dedicated trials.⁷⁹

**Artificial Intelligence in Drug Discovery and Development: Emerging Technologies and Applications**⁸⁰: Quantum computing tools have the potential to address many early-phase biopharmaceutical challenges such as reaction rate prediction, combinatorial optimization, and accurate simulation of atoms and molecules. Metabolomics another emerging field that analyzes metabolites to determine their biological function can be enhanced with AI-based data processing and analysis to better understand disease pathway activity and identify appropriate interventions. In addition to helping identify digital biomarkers to power new and less fragile endpoints, AI-based approaches could influence a number of clinical research functions from protocol design and patient identification to endpoint selection and process automation.

During the last decades, the majority of the 20 largest research-based pharmaceutical companies have increased efforts to provide access to essential medicines in developing countries, e.g., by supporting or participating in product development partnerships (PDPs).⁸¹ The PDP model ensures a holistic pipeline approach rather than being limited to a single portfolio. These efforts de-link the cost of final products from R&D expenditures by recruiting diverse funding sources rather than relying on retroactive cost recuperation via the exercise of IP rights⁸².

The Medical Technology landscape is changing, with challenges in the form of dynamic regulatory requirements, market forces driving the need to introduce new medical device and diagnostic products, and innovative combination products, under difficult pricing and profitability conditions. There is a continuous need for specialist guidance and solutions throughout the entire product lifecycle, from concept-to-market.

**BARD A** is responsible for developing and procuring technologies and countermeasures to protect the nation against natural and man-made threats. BARD A has delivered solutions to protect our country and the world from threats like Anthrax, Smallpox, Ebola, Pandemic Influenza, and many others.

**DRIV e (Division of Research, Innovation, and Ventures)** was established by the Biomedical Advanced Research and Development Authority (BARD A), part of the Assistant Secretary for Preparedness and Response (ASPR), within the United States Department of Health and Human Services (HHS). DRIV e is forming novel Public-Private Partnerships, and an ecosystem of restless innovation. Approaches could include non-dilutive funding through DRIVe-X or dilutive funding through DRIVe Launch or DRIVe Ventures. DRIVe is building an ecosystem of restless innovators that includes investors, companies, and research teams offering solutions to a broad range of national health security threats.

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⁷⁹ [https://www.fda.gov/drugs/development-resources/model-informed-drug-development-pilot-program](https://www.fda.gov/drugs/development-resources/model-informed-drug-development-pilot-program)
⁸⁰ [https://www.diaglobal.org/en/resources/inside-access?utm_medium=email&utm_source=db&utm_content= PUB_GF_Sept_2019-09-07&utm_campaign=globalforum&utm_type=aq&mkid=ejyJpljioWmizarZME89XrT1Vd1QwWdKaCjsojiOjPQj5QGRjTkkVI pCOGxxT0wVj0mS3jJ8USUVjmoqE#YqjgpWGDmCmpzQmJjnpaUXZ3Rk2lrVRdpa3ZWTBoUENoVfuYkpG2orSLBZaD VDRhncis3dhRQdU9HSFpTQUh9t11WXU1015dGQrdnFHac2F2Y3hPMOErZyJ9g87UHleoQrb3hI8.99
⁸¹ [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5725781/#B19
⁸² [https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/11869/Tuttle%20Thesis%204-25.pdf]
The African Network for Drugs and Diagnostics Innovation (ANDI), has also been created to develop sustainable platform for R&D innovation in Africa to address Africa’s own health needs.

It mission is to promote and sustain African-led health product innovation that addresses African public health needs through the assembly of research networks, and build capacity to support human and economic development.

In the late 1990s an innovative collaboration model for R&D for neglected diseases emerged in the form of public-private partnerships (PPPs) that came to be known as product development partnerships (PDPs). PDPs were created with a desire to generate innovative approaches to alleviate the global burden of neglected diseases by taking the expertise and knowledge of both the private and public sectors, and exploiting each of their strengths to find the most efficient and effective solutions. PDPs address the lack of commercial incentive to undertake R&D for vaccines, diagnostics, and drugs for neglected diseases of the developing world.

The GARD-P addresses global public health and the specific needs of low- and middle-income countries and targets products that industry will not develop due to foreseen lack of incentives, pilots the use of alternative incentive models that support conservation of and access to new antibiotics based on DNDi’s experience in implementing alternative R&D models for neglected diseases, ensures that new antibiotics are affordable to all in need worldwide.

The Drugs for Neglected Diseases initiative (DNDi), DNDi has promoted overall drug discovery research including the screening of drug candidates, hit to lead, lead optimization, pre-clinical and clinical studies in the area of infectious diseases with a focus on malaria, sleeping sickness (human African trypanosomiasis; HAT), Chagas disease, leishmaniasis, filarial diseases and pediatric formulations for HIV treatment. DNDi’s achievements include the development of novel therapies based on patient needs through innovative partnerships with over 130 organizations in industry, government, academia, and public institutions around the world. To date, DNDi has registered 6 novel treatments adapted to the needs of patients in poor countries, and has another 12 novel entities in development.

Malaria Medicines Venture (MMV) is another leading PDP in the field of antimalarial drug research and development. Its mission is to reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial drugs. Since its foundation in 1999, MMV has developed and brought to registration four new medicines with its partners: Pyramax®, co-developed with Shin Poong; Eurartesim® with Sigma-Tau; Guilin’s artesunate injection for the treatment of severe malaria, Artesun®; and Coartem® Dispersible, a child-friendly formulation developed with Novartis. Since 2009, over 200 million courses of Coartem Dispersible treatment have been supplied to 50 malaria-endemic countries; and since prequalification in 2010, an estimated 12 million vials of artesunate injection have been delivered, saving 80,000 - 90,000 additional lives. Managing the largest portfolio of antimalarial R&D projects ever assembled, of over 65 projects, MMV has seven new drugs in clinical development addressing unmet medical needs in malaria, including medicines for children, pregnant women and relapsing malaria, and drugs that could support the elimination/eradication agenda.

83 https://www.mmv.org/partnering/pdp-model
Other Product development partnerships (PDPs) focusing on drugs are Institute of One World Health (http://www.iowh.org/) and Global Alliance for TB Drug development (http://tballiance.org/).

**Public–private partnerships** leverage knowledge and technology transfer of new medical technologies to both developed and developing countries.

For example, the mobile health application (mHealth) Text4Baby, providing free health information to expectant mothers by means of text messages, is a PPP that, through a network of hundreds of partners, scales up its services. PPPs can improve both health products and services delivery by scaling their programs to a national level, involving health workers and communities\(^84\), \(^85\).

In 2001, Nelson Mandela’s government asked Indian generic manufacturer, Cipla, to make ARV drugs for the South African public at prices they could afford. The backlash from pharmaceutical companies and developed countries was immense, but with the support of civil society groups that successfully argued against the logic of big pharma, the South African government successfully utilized a TRIPS-compliant compulsory license and parallel importation provisions to lower the price of ARVs to about US$113 per person per year. With generic drugs available at this cost, the country has been able to increase coverage and lower expenditure at the same time, thus slowing a mounting epidemic\(^86\), \(^87\).

**Biotechnology Industry Research Assistance Council (BIRAC)** is a not-for-profit Section 8, Schedule B, Public Sector Enterprise, set up by Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs. BIRAC is a industry-academia interface and implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring innovation excellence to the biotech firms and make them globally competitive. In its Five years of existence, BIRAC has initiated several schemes, networks and platforms that help to bridge the existing gaps in the industry-academia Innovation research and facilitate novel, high quality affordable products development through cutting edge technologies.

**Objectives of the session are to discuss the following:**

- To discuss the Global partnerships/ collaborations and drug discovery models such as Artificial Intelligence, MIDD
- Discuss the Role of PDPs in for Drug discovery, Innovation, Technology development and translation of Medical Products

**Questions to spur thinking**

- How to leverage the global partnerships for drug discovery and technology development?
- What are the approaches to foster drug discovery and scale up adaptive technology solutions?

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\(^{84}\) https://www.ncbi.nlm.nih.gov/pubmed/23353680/  
\(^{85}\) https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/11869/Tuttle%20Thesis%204-25.pdf  
\(^{86}\) https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/11869/Tuttle%20Thesis%204-25.pdf  
\(^{87}\) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5725781/#B4
### 20 November 2019 - Wednesday, 14:30-16:00: Parallel Session 8: Global Partnerships for Drug Discovery, Innovation and Technology Development: Scaling up Adaptive Technology Solutions for Medical Products

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<th>Time</th>
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| Wednesday, 14:30-16:00 | **Global Partnerships for Drug Discovery, Innovation and Technology Development: Scaling up Adaptive Technology Solutions for Medical Products**  
*Chair:* Dr Vaidya Rajesh Kotecha, Secretary, Ministry of AYUSH, Government of India  
*Co-chairs:* Dr Stephen Whitehead, Senior Scientist, National Institute of Health, United States of America  

**Keynote Address**

Dr Stephen Whitehead, Senior Scientist, National Institute of Health, United States of America - *Live Attenuated Vaccines for Dengue: Possibilities and Challenges*

Ms Heather Stone, Public Health Analyst, United States Foods and Drug Administration, United States of America - *Role of USFDA in Strategic Partnership to Foster Drug Discovery and Innovation*

**Panelists**

1. Dr Manica Balasegaram, Executive Director, Global Antibiotic Research and Development Partnership (GARDP)/ Drugs for Neglected Diseases initiative (DNDi), Switzerland - *Scaling up R&D for New Treatments – The GARDP Experience*

2. Professor Stephen Matlin, Visiting Professor, Institute of Global Health Innovation, Imperial College London, United Kingdom - *Changing Landscape of Health Innovation Networks to Foster Research and Development*

3. Dr Shirshendu Mukherjee, Mission Director, Grand Challenges, India - *Facilitating Innovation Ecosystem through Grand Challenges India Initiative*

4. Dr Vipul Chowdhary, Analyst, Global Health Research & Development, Policy Cures Research, Australia - *Neglected Disease Research and Development: Reflecting on a Decade of Global Investment*

5. Dr Mohammad Ameel, Senior Consultant, Healthcare Technologies (Medical Devices), National Health Systems Resource Centre, Government of India - *Health Technology Innovations under Public Health Programs*
CVs of Chairs

Mr Vaidya Rajesh Kotecha, Secretary, Ministry of AYUSH, Government of India

Vaidya Rajesh Kotecha is an Indian Ayurveda physician who received a Padmashri Award for Medicine in 2015. He is appointed as Special Secretary in the Ministry of AYUSH, Government of India. He is the former Vice Chancellor of Gujarat Ayurveda University, Jamnagar. He founded Chakrapani Ayurveda Clinic & Research Center in Jaipur, India in 1998. Rajesh Kotecha completed his Bachelor of Ayurveda Medicine & Surgery (BAMS) from Gujarat Ayurveda University, Jamnagar in 1985 and Doctor of Ayurveda Medicine (M.D. Ayurveda) from Gujarat Ayurveda University, Jamnagar in 1991. He is the author of two books Concept of Atattvabhinivesha In Ayurveda which discusses minor psychiatric disorders in Ayurveda parameters and A Beginner's Guide to Ayurveda which is about Ayurveda principles and day to day life practices to keep oneself healthy. He received the Global Ayurveda Physician Award in 2007, Ayurveda Ratna Award in 2008 and Padmashri Award for Medicine in 2015.

Dr Stephen Whitehead, Senior Scientist, National Institute of Health, United States of America

Dr. Stephen Whitehead is currently a Senior Associate Scientist in the Laboratory of Viral Diseases at NIH in Bethesda, MD. He joined the NIH in 1995 with a primary interest in the development of vaccines against respiratory syncytial virus. However, Stephen has spent the last 18 years focused on the development and evaluation of live vaccine candidates for dengue virus and in 2018 received the Maurice Hilleman Award in recognition of his efforts. Over the course of the project he has developed various live attenuated vaccine candidates, with a lead tetravalent candidate currently undergoing Phase III clinical evaluation in Brazil. His clinical group has also implemented a dengue virus challenge model that has been used to assess vaccine-induced protection in humans. He is an inventor on numerous patents and the dengue vaccine technology has been licensed around the world to companies interested in controlling dengue disease. He also currently supervises the development of vaccines for Zika and Japanese encephalitis virus.

Ms Heather Stone, Public Health Analyst, United States Foods and Drug Administration, United States of America

Ms Stone is working as a Health Science Policy Analyst in the Center for Drug Evaluation and Research at the FDA. Her focus is on projects to improve drug development prospects and access to treatment for neglected tropical diseases and other infectious diseases. She also works on topics related to antimicrobial resistance and clinical trial design – including opportunities to use new sources of data. She completed a Masters in Public Health, concentrating in Epidemiology at the University of Maryland in 2012 and her thesis focused on factors associated with tuberculosis outcomes in a district in Himachal Pradesh, Northern India, based upon collaborative work with Lady Willingdon Hospital Manali. Her primary area of interest is in global health and especially the cycle between extreme poverty and infectious diseases. Her background is also in...
Anthropology and Development Studies and she seeks to approach issues of global health and development from a holistic perspective, seeking to understand the many complex connections and interactions between social and biological sciences.

CV of Panelists

**Dr Manica Balasegaram, Director, Global Antimicrobial Research and Development Partnership (GARDP), DNDi, Switzerland**

Dr Manica Balasegaram trained as a medical doctor at the University of Nottingham, UK from where he started his career in internal and emergency medicine. From 2001 onwards, he worked as a doctor and researcher in several countries in Sub-Saharan Africa and Southern Asia. He also gained significant experience working in humanitarian emergencies and responses, largely with Médecins sans Frontières (MSF).

At the end of 2007 he joined the Drugs for Neglected Diseases initiative (DNDi) as Head of Leishmaniasis Clinical Program – a position he held for four years before returning to MSF as Executive Director of their Access Campaign. He was appointed director of GARDP in June 2016. He is also a board member of the Medicines Patent Pool as well as member of FIND’s Scientific Advisory Committee.

Manica’s experience spans clinical and public health practice in infectious diseases, international work on health policy & access to medicines where he has served on numerous international technical and health policy panels and experts groups. He also has substantial experience in clinical trials and drug development working as a site investigator, principal investigator, and project manager.

**Professor Stephen Matlin, Visiting Professor, Institute of Global Health Innovation, Imperial College London, United Kingdom**

He was educated in chemistry at Imperial College London, Stephen worked in academia for over 20 years in medicinal, biological and analytical chemistry. He was Professor of Biological Chemistry at City University London and Warwick University. This was followed by periods as Director of the Health and Education Division in the Commonwealth Secretariat, Chief Education Adviser at the UK Department for International Development and Executive Director of the Global Forum for Health Research, Geneva.

Stephen has served as Kelvin Lecturer of the British Association for the Advancement of Science, Vice-President of the Royal Institution, member of the governing bodies of the Alliance for Health Policy and Systems Research, Child Health and Nutrition Research Initiative, Initiative for Cardiovascular Health in Developing Countries and member of the External Reference Group on the WHO Health Research Strategy and the Steering Committee of the Netherlands Global Programme in Health Policy and Health Systems Research. He was a co-founder and co-chair of Global Health Europe.

He is currently an Adjunct Professor in the Institute of Global Health Innovation, Imperial College London, Secretary and Head of Strategic Development for the International Organization for Chemical Sciences in Development, Senior Fellow in the Global Health Centre at the Graduate
**Institute of International and Development Studies, Geneva and a member of the Advisory Council of the RISE Institute (Institute for Reconstruction and International Security through Education). He is co-principal investigator in a project studying political and governance dimensions in polio eradication, funded by the Bill and Melinda Gates Foundation.**

**Dr Shirshendu Mukherjee, Mission Director, Programme Management Unit, Biotechnology Industry Research Assistance Council, India**

Dr. Shirshendu Mukherjee, trained as a Medical Microbiologist brings with him more than 25 years of experience in academic institutes, Pharma companies and decade long experience in national, international philanthropic and Government funding agencies and has been instrumental in supporting the innovation ecosystem in India and beyond.

Dr Mukherjee is currently the Mission Director of the Grand Challenges India, the flagship program of the partnership between the Department of Biotechnology, the Bill & Melinda Gates Foundation and Wellcome Trust. This platform supports initiatives that could dramatically change the health and development landscape in India.

Dr. Mukherjee holds Ph.D. in Microbiology, Law graduate, leadership course form Said Business school, University of Oxford and Global Health Leadership course from London School of Health & Tropical Medicine (LSHTM). Dr Mukherjee is also the Country Ambassador in India for the Royal Society of Tropical Medicine & Hygiene (RSTMH).

**Dr Vipul Chowdhary, Analyst, Policy Cures Research, Australia**

Dr. Vipul Chowdhary has over 10 years’ experience in the field of global health, working initially in India with the Department of Health. Vipul has worked for the international aid organisation Médecins Sans Frontières (MSF) since 2004, initially as a field doctor. He was recently the Country Representative for MSF in Liberia for the Ebola epidemic response, prior to that he was the head of MSF operations in Nigeria and Yemen. Vipul has worked in various positions with MSF in developing country contexts, including in Haiti, Iran, Iraq, Sudan, Liberia, Malawi, Sri Lanka and Yemen. He was involved in the G-FINDER project from inception and supported the research team of Policy Cures as a consultant working on the Indian neglected disease R&D funding landscape. Vipul has a Bachelor of Medicine/Bachelor of Surgery from University of Pune, and a Master of Public Health from the University of New South Wales.

**Mr Mohammad Ameel, Senior Consultant & Incharge, Healthcare Technology Division, National Health Systems Resource Centre, Government of India**

Mr Mohammad Ameel is currently working as a Senior Consultant & incharge, Healthcare Technology Division at National Health Systems Resource Centre and as Head, WHO collaborating center for priority medical devices & health technology policy. He is a graduate biomedical Engineer by training and an MBA in Healthcare Administration from Faculty of Management Studies, University of Delhi. He spearheads the work of establishing technical specifications of medical devices for procurement under the National Health Mission (NHM). He also leads the work of identification and uptake of innovations that are of value in public health programs. The division of Healthcare technology also leads the work on Biomedical Equipment Maintenance Program, National Free Diagnostics.
Program (which includes free pathology service and radiology services), National Dialysis Program and other technology intensive healthcare Programs under National Health Mission (NHM).

He earlier served as the Head, Biomedical Engineer at Era’s Lucknow Medical College & Hospital while also consulting other hospitals around the region on engineering services especially for NABH. He is a technical columnist for various National Magazines on the topics of medical devices & Healthcare Technologies. He was recently conferred with prestigious award ‘100 most impactful healthcare leaders’ (Global listing, 2018).
Drug discovery and development is an expensive, time-consuming, and risky process. In order to accelerate the drug development process with reduced risk of failure and relatively lower costs, drug repositioning has been adopted as an alternative approach. The process of finding new uses of existing drugs outside the scope of the original indication is variously referred as repositioning, redirecting, repurposing, and reproofing.

Repositioned drugs have the advantage of decreased development costs and decreased time to market than traditional discovery efforts, due to availability of previously collected pharmacokinetic, toxicology, and safety data. In fact, this strategy of using existing therapeutics for new indications has demonstrated success through previous observational studies, such as sildenafil (Viagra), a phosphodiesterase inhibitor initially developed to treat angina and now repurposed as a medication for erectile dysfunction, as well as metformin (Glucophage), a common diabetes medication that is now the active chemical in 100+ ongoing Phase II and Phase III clinical trials as a cancer therapeutic. Other examples include plerixafor, studied as an inhibitor of HIV but subsequently launched in 2009 for mobilization of hematopoietic stem cells in the treatment of multiple myeloma, and milnacipran, initially developed and launched outside the US as an antidepressant and later approved in the US for the treatment of fibromyalgia in 2009. Bupropion, originally used for depression, was repurposed for smoking cessation; and thalidomide, once a treatment for morning sickness, is now used for multiple myeloma.

In the context of cancer, the safety, efficacy, and toxicity of an existing drug have been extensively studied and robust data have already been collected toward gaining approval by the United States (US) Food and Drug Administration (FDA) and/or the European Medicines Agency (EMA) for a specific indication. Since data already exist, repurposing saves time and money, which provides hope to patients with rare cancers further; repurposed drugs are generally approved sooner (3–12 years) and at reduced (50–60%) cost.

Approaches in Repurposing
In the US, there are three separate regulatory approval pathways that allow for the registration of distinct classifications of drugs, as outlined in the Food, Drug and Cosmetics Act, although only one of these [i.e., “505(b)(2)"], is relevant to drug repurposing. All drug candidates for repurposing must be submitted through Section 505(b) (2), regardless of whether it is for cancer therapeutics or alternate diseases. Section 505(b) (2) became available in 1984 under the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Amendments). Such efforts can offer temporary protection for: i) new molecular entities, NMEs; ii) new dosage forms; iii) new administration routes; iv) new indications; and v) new NME combinations.

88 http://www.jgmmonline.com/article.asp?issn=0022-3859;year=2011;volume=57;issue=2;spage=153;epage=160;aulast=Padhy
89 https://www.ncbi.nlm.nih.gov/pubmed/25333032
90 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5963941/
In Europe, a parallel approval pathway is regulated by the EMA under Article 10 of Directive 2001/83/EC. However, in contrast to section 505(b)(2) of the Food, Drug and Cosmetics Act, which allows the use of non-proprietary studies that have previously achieved a high standard of quality and safety to support any part of an application, Article 10 concerns drugs that require studies tailored to the differences from reference listed drugs—it does not provide a legal basis for the use of non-proprietary studies.

**National Institutes of Health Model**

National Institutes of Health has created National Centre for Advancing Translational Sciences (NCATS) in 2012 to provide governmental financial support for drug repurposing to aid in the generation and implementation of novel therapeutics. Thus NCATS has dedicated resources for drug repurposing efforts. Further, NCATS offers research grants for various stages of drug repurposing, from early to late-stage clinical trials.

**Early-Stage Repurposing:** A common first step in repurposing is to screen libraries of already approved compounds against a disease-specific biological assay. From such screens, researchers can select a subset of bioactive compounds for further investigation and development in secondary and tertiary assays evaluating relevant aspects of disease biology and molecular pathophysiology.

**Late-Stage Repurposing:** Post identification of promising approved or existing molecule through initial screening and validation, NIH experts aid further clinical investigators by supporting the development of regulatory-quality data packages, which enable the drug’s entry into clinical trials for the new disease indication.

The launch of two major initiatives in the US, Clinical and Translational Science Award (CTSA), which supports clinical and translational research, and the Molecular Libraries Program which supports primarily research in chemical probe development; as well as a complementary initiative in Europe, the Innovative Medicines Initiative, IMI— which fosters joint projects between academic and pharmaceutical research units; and last but not least the increasing amount of public and open source data, knowledge and software that can be utilized for drug repurposing projects.

These changes have been accelerated by NIH programs that support drug discovery and development as well as clinical trials such as the National Cancer Institute's Experimental Therapeutics Program (NExT91) and the NIH Rapid Access to Therapeutic Development Program (RAID) to be relaunched as (BRIDGS92) which has led several institutions to collect, use, and report on approved drugs to make available collections of molecules that have been previously used in clinical trials (NIH Clinical Collections93) for repurposing.

**The CTSA Pharmaceutical Assets Portal:** The CTSA Pharmaceutical Assets Portal project was initiated by the consortium of universities linked by the Clinical and Translational Science Award (CTSA). The drug rescue and repurposing project is part of the National Center for Advancing Translational Sciences (NCATS). They are making comprehensive and conscious efforts to identify appropriate abandoned compounds and potential partners, and making data and resources available to the pharma industry.

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91 [http://next.cancer.gov/default.htm](http://next.cancer.gov/default.htm)
93 [http://nctt.nih.gov/now](http://nctt.nih.gov/now)
The objective of this session is to discuss the following:

- Approaches and learnings with repurposing of medicines including Translation of available scientific information into biological insights and to new therapeutics
- Roles of Industry, Academia and regulators

Questions to spur thinking:

- How to adopt innovative approaches to accelerate the access to medical products.
- How to leverage on collaboration among regulators, academia and industry to identify resource and methodology for drug repurposing.
- How to develop Roadmap for policy initiatives on repurposing of drugs based on international practices.
- What are the different regulatory approaches for drug repurposing across the globe and how to evolve the same in India.
- Pathway for creation of data base for identification of appropriate compounds for repurposing and to provide the information to researchers and industries.
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<tr>
<td><strong>Wednesday, 16:15-17:30</strong></td>
<td>Re-purposing of Medicines for Reduced Approval Timeframe, Decreased Costs and Making Use of Existing Data</td>
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**Chair:** Dr Dharmendra Singh Gangwar, Additional Secretary & Financial Advisor, Ministry of Health and Family Welfare, Government of India

**Co-chairs:** Ms Heather Stone, Public Health Analyst, United States Foods and Drug Administration, United States of America; Dr VG Somani, Drugs Controller General of India, Central Drug Standard Control Organization, India

**Keynote Addresses**

1. Ms Heather Stone, Public Health Analyst, United States Foods and Drug Administration, United States of America - **Overview of Drug Repurposing – US FDA Perspective**

2. Mr Igor Da Silva Barbosa, Premier-secretaire, Permanent Mission of Brazil to the UNOG and other organizations in Geneva - **Re-purposing of Medicines: Complimentary Approaches to Lower Cost and Early Access of Medical Products**

**Panelists**

1. Dr S Eswara Reddy, Joint Drugs Controller, Central Drug Standard Control Organization, Government of India - **Re-purposing of Medicines to Accelerate Access-The India Perspective**

2. Ms Shobana Balasingam, Programme Officer, Vaccines, Wellcome Trust, United Kingdom - **Value of CHIMs - The Wellcome Trust Initiatives**

3. Ms Ciska Verbaanderd, University of Leuven & Anticancer Fund, Belgium - **Drug Re-purposing to Provide Safe, Affordable and Effective Treatments-Focus on Oncology Products**

4. Dr Ian Hudson, Senior Adviser, Bill & Melinda Gates Foundation and Former Chief Executive, MHRA, United Kingdom - **Novel Regulatory Approaches in the MHRA for Re-purposing of Medical Products**

5. Dr Nilima Kshirsagar, National Chair Clinical Pharmacology, Indian Council of Medical Research, Government of India - **Repurposing of Drugs–Role of Academic Clinical Trials**
Dr Dharmendra Singh Gangwar, Additional Secretary & Financial Advisor, Ministry of Health and Family Welfare, Government of India

A professionally qualified Indian Administrative Service Officer with diverse administrative experiences of more than thirty years in different sectors at policy formulation and implementation levels in central and state government, Public Sector enterprises, and World Health Organization. Earlier he was Additional Secretary & Financial Advisor at Ministry of Culture and Additional Secretary at Ministry of Food Processing Industries. He also worked as Chief Vigilance Officer in the State Trading Corporation of India Ltd, Joint Secretary, Ministry of Rural Development, and Additional Development Commissioner (Handlooms) at Ministry of Textiles. He had held various portfolios in Government of Bihar such as Special Secretary, Additional Secretary, Joint Secretary and Principal Secretary to Chief Minister of Bihar, Department of General Administration, Education, Planning and Development and Finance.

He has completed Bachelor of Medicine, Bachelor of Surgery (M.B.B.S.) Medicine, Surgery from King Georges Medical college Lucknow UP. He has done training programme on “Infrastructure Development and Financing” at IIM Ahmadabad, “Behavioral Insights for Public Policy” at Harvard Kennedy School, USA and Advanced Management Development Program in Public Financial Management from Duke University, USA.

Ms Heather Stone, Public Health Analyst, United States Foods and Drug Administration, United States of America

Ms Stone is working as a Health Science Policy Analyst in the Center for Drug Evaluation and Research at the FDA. Her focus is on projects to improve drug development prospects and access to treatment for neglected tropical diseases and other infectious diseases. She also works on topics related to antimicrobial resistance and clinical trial design – including opportunities to use new sources of data. She completed a Masters in Public Health, concentrating in Epidemiology at the University of Maryland in 2012 and her thesis focused on factors associated with tuberculosis outcomes in a district in Himachal Pradesh, Northern India, based upon collaborative work with Lady Willingdon Hospital Manali. Her primary area of interest is in global health and especially the cycle between extreme poverty and infectious diseases. Her background is also in Anthropology and Development Studies and she seeks to approach issues of global health and development from a holistic perspective, seeking to understand the many complex connections and interactions between social and biological sciences.
Dr V G Somani, Drugs Controller General (India), Dte.GHS, Ministry of Health and Family Welfare, (MoH&FW) Government of India

Currently he is holding the post of Drugs Controller General (India), under Dte.GHS, MoH&FW, Government of India. He has done his M. Pharm and PhD in Pharmaceutical Sciences. He is cworking in CDSCO for last 21 years and having vast experience in the field of GMP, GCP, GRP, GDP, Dossier Review, GLP etc. and has also worked on all the posts in the hierarchy of Central Drugs Control Department including as Drugs Controller Genera of India. Being meritorious student, he was awarded scholarship/fellowships since schooling days. He has been selected and now working as Chairman of WHO’s Member State Mechanism (MSM) of 194 countries on substandard and falsified medical products at Geneva, Switzerland vide World Health Assembly (WHA) resolution 65.19 which is very prestigious opportunity for India to safeguard global interest for making affordable generic medicines acceptable in the world. He is well-known speaker and trainer of various national and international/ WHO scientific bodies.

He has been involved in formulating various national regulatory guidelines like guideline on similar biologics and contributed to various WHO guidelines on Drugs, Devices and Vaccines related issues. His focus areas are simplification of regulation and access to quality medical products through Good Regulatory Practices and strengthening regulatory systems.

CV of Keynote Speaker

Mr Igor Da Silva Barbosa, Premier-secrétaire, Permanent Mission of Brazil to the UNOG and other organizations in Geneva

Igor Barbosa is a Brazilian diplomat since 2008. Graduated in Law (2007) and in the Rio Branco Institute, the diplomatic academy of Brazil (2010). Has worked, in Brasilia, with Legal Affairs, Intellectual Property and Trade Dispute Settlement. Abroad, was posted in Haiti (2010-2012); Zimbabwe (2014) and, since 2017, is the Health Attaché at the Permanent Mission of Brazil to the United Nations Office in Geneva (UNOG). Has been responsible for following, among other issues, the access to medicines agenda in WHO and other relevant fora.
CV of Panelists

Dr S Eswara Reddy, Joint Drugs Controller, Central Drug Standard Control Organization, Government of India

At CDSCO, Dr. Reddy headed various internal divisions like medical devices, biologicals, new drugs, import & registration and others. Read more at Business Medical Dialogues: Eswara Reddy has been appointed as Drugs Controller General of India in 2018.

Dr. Reddy started his career in 1998 as a Drugs Inspector at CDSCO, West Zone, Mumbai. At CDSCO, Mumbai he has conducted GMP, GCP and GLP audits. He promoted as Assistant Drugs Controller of India in 2009 and appointed as Deputy Drugs Controller (India) in 2012. In 2014, he was appointed as Joint Drugs Controller (India).

Dr. Reddy is recipient of Best Drugs Inspector Award in 2005, Best Drugs Control Officer in 2016 and Distinguished Alumni Award from Manipal Academy of Higher Education, Manipal.

With the vision to promote public health, he was actively involved in framing of Medical Devices Rules 2017, 12th Five Year Plan for strengthening of Indian Drugs Regulatory System and international matters related to MOUs, SOI, and other quality issues. He has organized numerous trainings for CDSCO officials to enhance their knowledge and make them competent. He has conducted Risk Based Inspections to ensure the quality of drugs being marketed India. Dr. Reddy did his PhD from J.N.T.U, Hyderabad. He has vast experience in manufacturing of pharmaceuticals, academic research and drug regulations.

Ms Shobana Balasingam, Programme Officer, Vaccines, Wellcome Trust, United Kingdom

Ms Shobana Balasingam is a Programme Officer in the Vaccines department at Wellcome Trust. Shobana's role focuses on the expansion of Controlled Human Infection Models in endemic settings to accelerate vaccine development and to ensure that vaccines are relevant to the people most at risk. To enable this, Wellcome will support targeted community and political engagement, ethics research, regulatory strengthening, and capacity building. We will also promote harmonization, protocol, data and sample sharing wherever possible in accordance with our commitment to Open Research.

Ms. Ciska Verbaanderd, Researcher at KU Leuven in collaboration with the Anticancer Fund

Ciska Verbaanderd currently works at the Clinical Pharmacology and Pharmacotherapy unit at the University of Leuven in Belgium. She collaborates closely with the Anticancer Fund, a Belgian not-for-profit organization dedicated to expanding the range of treatment options available to cancer patients, regardless of commercial value. Ciska's PhD research focuses on diverse legal, regulatory and financial aspects of drug repurposing in oncology, with the overall aim to facilitate the implementation of repurposed drugs in clinical practice.
Dr Ian Hudson, Senior Adviser, Bill and Melinda Gates Foundation and former Chief Executive, MHRA, United Kingdom

Dr Ian Hudson practiced as a paediatrician for a number of years before working in research and development at SmithKline Beecham for 11 years. Subsequently, in 2001, he joined the MHRA as Director of Licensing and was the UK delegate to EMA’s scientific committee, CHMP, latterly its Vice Chair. In 2013 Dr Hudson became CEO of the MHRA, also a member of the EMA management Board and part of the Heads of Medicines Agencies Management Group. He was also Chair of the International Coalition of Medicines Regulatory Authorities between 2016 and 2019. Dr Hudson joined the Bill and Melinda Gates Foundation as Senior Advisor, Regulatory Affairs, Integrated Development in September 2019.

Dr Nilima Kshirsagar, National Chair Clinical Pharmacology Indian Council of Medical Research, Government of India

Dr Kshirsagar is currently National Chair of Clinical Pharmacology, ICMR, Govt of India, New Delhi, Member of International Committees viz, WHO Committees on, Safety of Medicinal Products (ACSoMP) Product development, Drug statistics Methodology, Member SAC, Drugs for neglected diseases initiative, DNDi, Board member of FDEC, , Govt. of India Committees viz. DTAB (Drug technical Advisory Board), IND Committee, Chairperson FDC Subcommittee, Chairman core training Panel PVPi, Fellow of Royal College of Physicians, Faculty of Pharmaceutical Medicine UK and Fellow of American College of Clinical Pharmacology, USA.

Dr Kshirsagar was former acting Vice-Chancellor at the State Health Science University, and also Dean Director of medical education and research, and Prof. Head Clinical Pharmacology G.S. Medical College KEM hospital, Parel, Mumbai and at T. N. Medical College Mumbai, (Founding)President, South Asian chapter of American college of clinical Pharmacology, President of the Indian Pharmacology Society and Infectious Disease Society, India, Member Governing Council & Chairman Academic Committee AIIMS, Govt. of India, Delhi.

She has won many national and international awards e.g. University awards, gold medals, B.C. Roy National Award, Vasvik Award for industrial research, developing and patenting liposomal drug delivery system, Mayor’s award three times, Nathaniel Kwit award of ACCP USA. Dr Kshirsagar as published over 200 publications featuring in the Lancet, Lancet Global Health, Lancet infectious diseases, British Journal of Clinical Pharmacology, The American Journal of Tropical Medicine and Hygiene and WHO publications on safety of Medicines in public Health and pediatrics, among others edited books and contributed chapters to national and international books Some of her areas of expertise include; clinical trials, pharmacovigilance, drug development, tropical diseases, drug resistance, and medical education.
Workshop Brief

The Risk Assessment on drug development workshop is an interactive course directed towards participants who wish to update their understanding of global regulations, the translational sciences and drug development. Efficiency and Quality compliance are critical to achieve innovation and affordability. This comprehensive course will provide an overview of the basics and multi-dimensional nature of drug development utilizing technology, statistical and quality considerations. The workshop will focus on development of novel drugs, including recombinant proteins, monoclonal antibodies, fusion proteins, cell therapy, gene therapy and gene editing technologies.

### 20 November 2019-Wednesday, 16:15-18:30: Workshop for Drug Development-Risk Assessment through Data Analytics

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<th>Time</th>
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<tr>
<td><strong>Wednesday, 16:15-18:30</strong></td>
<td>Workshop for Drug Development-Risk Assessment through Data Analytics</td>
<td>Jehangir Hall</td>
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<td></td>
<td>1. Dr Narendra Chirmule, Chief Scientific Advisor, Immuneel Therapeutics Ltd; ex-Head of R&amp;D at Biocon</td>
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<td>2. Dr Robert Poolman, Director of Discovery and Preclinical Products, Clarivate Analytics</td>
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<td>3. Dr Timea Gombos MD, PhD, Director Translational Sciences and Biostatistics, Accelsiors, Hungary</td>
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<td>4. Dr Guljit Chaudhri, MD, Bioinnovat Ltd., CEO, Innonation / Sr. Advisor, ABLE</td>
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## CV of Panelists

### Dr Narendra Chirmule, Chief Scientific Advisor, Immuneel Therapeutics Ltd; ex-Head of R&D at Biocon

Narendra Chirmule, PhD is Senior Vice President, and Head of R&D at Biocon Research Labs, Bangalore, India. He has responsibility for the development of the pipeline of Novel Biologics and Biosimilars. He has led the Biocon team in first ever approvals of biologics for Biocon, and any company in India, for trastuzumab biosimilar and insulin glargine biosimilar by FDA and EMA respectively. R&D at Biocon comprises the chevron of processes, ranging cell line engineering, upstream and downstream process development of drug substance and drug product, toxicology, physico-chemical and bio-analytical, clinical, regulatory and intellectual property groups. Dr. Chirmule’s specific expertise is in the area of immunology, including immunogenicity assessment of biologics and development of immune-toxicology strategies, immunology of infectious diseases such as HPV and HIV, and immune response to vectors and transgenes for gene therapy.

The journey for his immunology research began with a Masters in Zoology and PhD in Applied biology from University of Bombay, where he worked on development of an anti-leprosy vaccine. Studying leprosy was the first lesson in immunology, as the disease spans a wide spectrum of both cell-mediated and humoral immune responses. A lesson learned during the work was that the subject of PhD is a means of learning the method and process of conducting scientific research. Next, Dr. Chirmule did his post-doctoral research in the pathogenesis of AIDS at Cornell-University Medical College, North Shore University Hospital, in New York.

### Dr Robert Poolman, Director of Discovery and Preclinical Products, Clarivate Analytics

Dr. Robert Poolman is the Discovery and Preclinical Products Director in the Life Sciences division of Clarivate Analytics. He has over 20 years’ experience in the life sciences industry.

After completing his PhD in Biochemistry, he spent some time in academia as a post-doctoral scientist investigating alterations in cell cycle biology in cancer cells. He then entered the pharmaceutical industry to pursue a career in competitive and business intelligence where he supported the information needs and product strategy for R&D, Commercial and Legal. During this time he held positions of increasing responsibility at Pfizer and Novartis. Having completed his MBA in 2014, he moved into a commercial setting where he led the product development team at Minesoft and most recently at Clarivate Analytics.

### Dr Timea Gombos, Director Translational Sciences and Biostatistics, Accelsiors, Hungary

Dr. Gombos is a medical doctor, gained PhD in clinical sciences, and has clinical experience as an internist. She holds a master’s degree in Statistics and has over 5 years of academic research experience as a research fellow and consultant statistician. She is the author on a number of scientific papers, and she is the secretary of the Hungarian Society for Clinical Biostatistics. She is a biostatistician and translational scientist at Accelsiors Ltd, Hungary.
Dr Guljit Chaudhri, MD, Bioinnovat Ltd., CEO, Innovation / Sr. Advisor, ABLE

Guljit started her career with international business, strategic alliances including joint ventures and domestic marketing of pharmaceuticals, polymers with leading corporates – Ranbaxy, Reliance where she has managed profit cost centres as Vice President. Thereafter she has been developing biotechnology initiatives over the last two decades as Director - Corporate Affairs for Monsanto with the first regulatory approval of ag-biotech Bt Cotton and later as Sr. VP Jubilant Organosys Ltd. handling Strategic Business Development and Corporate Communication and was a founder member of Jubilant Biosys.

Founded Bioinnovat a Professional Knowledge Resource organisation on drug development, regulatory, compliance services, staffing and real world clinical outcomes for lifecycle management. Since 2005 till 2014 has been responsible for setting up and scaling the operations of leading 4 global Clinical Research organisations in India namely Kendle i3 Research & INC Research which have now merged as Syneos, a leading global CRO; followed by Research Pharmaceutical Services.

By academic training she is an Economics (Hons.) graduate from Lady Shri Ram College Delhi University, and MBA from Jamnalal Bajaj Institute (full time), Mumbai University. She is a Post Graduate in international marketing from IIFT Delhi and PhD fellow from University of Pune. As Sr. Advisor, ABLE (Association of Biotechnology Led Enterprise) has been the nodal industry convenor for drafting of Guidelines for Similar Biologics. As CEO, INNONATION (ABLE) is developing an aggregator platform identifying innovation in life sciences and health care founded or led by Indians for showcasing to PE, venture funds and investors globally.
Session Brief

The adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in the WTO almost 25 years earlier is continuing to influence access to medicines and medical products.

The World Trade Organisation (WTO) deals with the rules of trade between nations at a near-global level; responsible for negotiating and implementing new trade agreements; and in charge of policing member countries’ adherence to all the WTO agreements, signed by the majority of the world's trading nations and ratified in their parliaments. WTO is mandated to review the national trade policies and to ensure the coherence and transparency of trade policies through surveillance in global economic policy making. With the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS in 1994), Intellectual Property Rights (IPRs) on the part of WTO member states, are obligations of commercial policy that require compliance. Adoption and enforcement of at least the minimum standards will procure considerably stronger global protection of intellectual assets.

With the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS in 1994), Intellectual Property Rights (IPRs) on the part of WTO member states, are obligations of commercial policy that require compliance. Adoption and enforcement of at least the minimum standards will procure considerably stronger global protection of intellectual assets. TRIPS, the first international agreement to mandate nations to provide “minimum” standards of IP protection, which resulted in countries to retain some domestic discretion to tailor intellectual property rights in accordance with their policy preferences.

Articles 7 and 8 of TRIPS Agreement or the subsequent Doha Public Health Declaration are designed to promote interpretations that foster public health. In addition, newer free trade agreements with investment chapters typically have an IP chapter that has even stronger IP protections than TRIPS which enables an intrusion onto TRIPS flexibilities. Modest strategies are required to counter regime shifting of IP enforcement to ensure the bona fide authority of governments to protect public health by defining and clarifying key terms to minimize harm to domestic sovereignty and TRIPS flexibilities.

Flexibilities under the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement allow countries to gain access to medicines that in other countries may still be under patent, in the interest of public health. Equitable access to essential, high-quality and affordable essential medicines and other medical technologies depends on affordable and fair pricing and effective financing schemes. Promoting affordable and fair prices and cost-effective interventions is central to the achievement of universal health coverage.

There is a need to increase synthesis of intellectual property and trade rules, and use of TRIPS flexibilities to expand access to new therapies. Many World Health Assembly resolutions in WHO have requested WHO to address the impact of trade agreements and intellectual property protection on public health and access to health products.

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95 https://www.piie.com/publications/working-papers/regulatory-standards-wto
96 18 mnjlst 427: regime shifting of ip lawmaking and enforcement from the wto to the international investment regime
97 18 mnjlst 427: regime shifting of ip lawmaking and enforcement from the wto to the international investment regime
98 https://www.who.int/medicines/areas/access/en/
The Global strategy and plan of action on public health, innovation and intellectual property (World Health Assembly resolution WHA61.21), along with other relevant resolutions, constitutes the basic mandate for WHO’s work in this area.

WHO’s Global Strategy and Plan of Action also identified the need to improve access to patent information to facilitate the determination of the patent status of health products. It urges stakeholders to:

- Facilitate access to user-friendly global databases which contain public information on the administrative status of health-related patents. This includes supporting existing efforts for determining the patent status of health products, and to
- Promote further development of such global databases including, if necessary, compiling, maintaining and updating such global databases.

As a direct result of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of 2008 (WHA61.21), UNITAID established an Medicines Patent Pool (MPP), a United Nations-backed organization for HIV medicines in 2010. Access to affordable generic medicines can be achieved through licensing agreements. The MPP initially focused on patents related to HIV medicines to promote low-cost generic production and the development of fixed-dose combinations and paediatric formulations. The MPP has expanded its mandate to cover hepatitis C and tuberculosis.

The rationale for having patents is to make investment in innovation attractive and to offer a mechanism which ensures that the knowledge contained in the patent application is accessible to society. Among others, the obligation of patent owners to publicly disclose their inventions enables society to know, and eventually use, the knowledge contained in patent documents. However, the use of the exclusive right can itself contribute to a market distortion and can lead to a situation characterized by inefficiencies, high prices and the under provision of goods.

Patents present substantial challenges to medicines availability. However, TRIPS flexibilities in patent law have been used by a number of countries to secure access to generic medicines. The most frequently deployed flexibilities are compulsory licensing of medicines, government use of patents, and the waiver that allows LDCs to postpone granting or enforcing medicines patents and test data protection until 2033. These options have been used more widely than is usually assumed. New figures show that since 2001, there have been 34 instances of compulsory licensing (CL) of medicines by 24 countries, 51 instances of government use of patents by 35 countries, and 32 of non-enforcement of patents by 24 World Trade Organization LDC Members. The peak of these instances falls between 2004 and 2008, coinciding with increased global funding for HIV. Although originally focused on HIV, 23 out of 85 total instances of CL and government use have concerned non-HIV medicines, including seven instances for cancer medicines between 2008 and 2014, of which five were granted. These measures have improved access to medicines. For example, in Thailand, CLs for erlotinib, docetaxel, letrozole, and clopidogrel save the health-care system $142 million per year. In the past decade and a half, some countries have amended their patent laws to reflect health concerns. For example, India rewards innovation but prevents trivial patents and so-called ever-greening of patents.

Patent landscaping can potentially assist the generic industry, researchers, government and policy makers, by facilitating generic industry and thereby promoting competition. Although patents require publication, determining patent status of medicines can be extraordinarily difficult. Additionally, patent landscapes may be contained within bilateral commercial
licenses, these licenses are not publicly accessible. Thus, it is an enormous advantage that the MPP has succeeded in requiring originators to disclose the patents that are pending or granted in licensed territories. This information is helpful to advocates, countries, and generic producers weighing options to pursue generic competition in non-licensed territories, whether by permitted extra-territorial sales or via compulsory or government-use licenses.

Patent landscape provides a snapshot of the patent situation of a specific technology, either within a given country or region, or globally. They can inform policy discussions, strategic research planning or technology transfer. They may also be used to analyze the validity of patents based on data about their legal status. As a result of generic industry penetration, prices of medicines will come down promoting affordability and access.

As mandate by WHA61.21, WHO has intensified its collaboration with other relevant international organizations, in particular through trilateral collaboration with WIPO and WTO, as well as with other organizations, including UNCTAD and UNDP. Trilateral cooperation with WIPO and WTO is fostering a better understanding of the linkage between public health and intellectual property policies and enhancing a mutually supportive implementation of those policies (Access to medicines and vaccines 4 April 2019 - WHA72.17).

The patent system discloses:

- Legal information, including published details of what material is patented, with what legal scope, in what countries, in whose name, and when it passes into the public domain;
- Technological information, such as a patent's so-called ‘teaching’ or technical disclosure, which is required to give a skilled reader all the information needed to put the new technology into practical effect.

The Objective of the session is to discuss the following:

- discuss the importance of patents and IPR in access to medical products
- How patent landscaping contributes to public health-oriented licensing agreements and transparency on patent status of existing and new health technologies.

Questions to spur thinking:

- Importance of IPR and patents in medical products accessibility
- How patent landscaping can promote information on patenting in the pharmaceutical producing countries.

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99 https://www.medspal.org/?page=1
100 https://www.wipo.int/patentscope/en/programs/patent_landscapes/
### Plenary Session 6: Patent Landscaping for Health Products (WHA 72/17, 2019)

**Time**: Thursday, 09:00-10:30

**Room**: Durbar Ballroom

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<td>Thursday, 09:00-10:30</td>
<td>Patent Landscaping for Health Products (WHA 72/17, 2019)</td>
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<td><strong>Chair</strong>: Dr Guruprasad Mohapatra, Secretary, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India</td>
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<td><strong>Co-Chair</strong>: Mr Ram Mohan Mishra, Additional Secretary, Ministry of Micro, Small and Medium Enterprises, Government of India</td>
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**Keynote Address**

Dr Manisha Shridhar, Regional Adviser, World Health Organization South-East Asia Regional Office

**Panelists**

1. Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia- *Intellectual Property and Access to Medicines: Frameworks for Access*


3. Mr Joy Goswami, Assistant Director, Technology Transfer & Corporate Partnerships, Office of Economic Innovation & Partnerships, University of Delaware, United States of America- *Innovation Landscape for Facilitating Translation of Health Products to Enable Affordable Access*


5. Dr KS Kardam, Former Senior Joint Controller of Patents and Designs, Indian Patent Office, India- *Intellectual Property Considerations Interfacing the Access to Medical Products*
CV of Chairs

Dr Guruprasad Mohapatra, Secretary, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India

An Indian Administrative Service (IAS) officer of 1986 batch, Guruprasad Mohapatra, on Thursday assumed charge as the secretary of the Department for Promotion of Industry and Internal Trade (DPIIT). Prior to taking over as the secretary of DPIIT, he served as the chairman of the Airports Authority of India (AAI). He had earlier served as a joint secretary in the Department of Commerce, where he worked for the promotion of special economic zones (SEZs), public procurement and project exports (financing and insurance). He held the portfolio of municipal commissioner in Surat, Gujarat, and was involved in the process of converting Surat into one of the models of urban governance with its thrust on solid waste management, quality infrastructure and sound financial management. As the municipal commissioner of Ahmedabad, he was instrumental in developing several urban projects such as the Sabarmati riverfront, BRTS, Kankaria lakefront and heritage promotion. He also served as the transport commissioner and commissioner (commercial taxes) in Gujarat.

Mr Ram Mohan Mishra, Additional Secretary, Ministry of Micro, Small and Medium Enterprises, Government of India

In his role as the Additional Secretary to the Government of India and Development Commissioner for the Ministry of MSME Shri Ram Mohan Mishra works on comprehensive policy making for the SME sector in India. He has over 30 years of experience as an Indian Administrative Service officer having worked in the field of General Administration, Mines and Minerals, Programme Implementation, Planning, Banking and Institutional Finance, Revenue, Environment & Forests, Water Resources, Commerce & Industry, Personnel Management, Home Affairs, Land Revenue, etc. He is a Law Graduate, Masters in Geography and has studied Public Finance at Maxwell School of Syracuse University. He has been CEO of a Government company working for promoting and facilitating inclusive growth, entrepreneurship development, climate change adaptation and sustainable development.
CV of Keynote Speaker

Dr Manisha Shridhar, Regional Adviser, World Health Organization South-East Asia Regional Office

Dr Manisha Shridhar is Regional Advisor for Intellectual Property, Trade and Public Health at the World Health Organization Regional Office for South-East Asia (WHO/SEARO). She works on the interface of Intellectual Property Rights (IPRs) and trade for health and medical products (medicines, vaccines, diagnostics and medical devices). She has worked extensively on trade and legal issues relating to public health e.g. in areas of pandemic influenza preparedness framework, traditional medicines, international health regulations, non-communicable diseases (NCDs), tobacco control and nutrition. Dr Shridhar received her Master’s degree in Intellectual Property Law with specialization in Patent and Biotechnology Law and is a certified Mediator for IPRs disputes from Franklin Pierce Law Center, Concord, USA.

Dr Shridhar has written extensively on various subjects. As Head of Training Research and Development Wing in the National Academy of Administration, Mussoorie, she designed and conducted training programs for senior Civil Servants from India and Sri Lanka on IPR and WTO issues. She prepared case studies, study material for courses, and has written and produced a film on IPRs for World Intellectual Property Organization. She assisted United Nations Industrial Development Organization for development of Geographical Indications for traditional products. Dr Shridhar is fluent in Hindi, English and French.

CVs of Panelists

Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia

Dr Olasupo Owoeye is a law academic with expertise in International Intellectual Property Law. He is admitted to the legal profession in Nigeria, New Zealand and Australia. Dr Owoeye practised as a counsel at Punuka Attorneys and Solicitors, a top tier Lagos law firm, before he became a law academic. He is a Senior Lecturer in Law at the Graduate School of Business and Law, RMIT University, Melbourne. He previously taught at both undergraduate and postgraduate levels at the University of Tasmania, the RMIT International University, Vietnam, and the University of South Australia. He was also a Humboldt Research Fellow at the University of Augsburg, Germany and the Catholic University of Lyon, France in 2015. Dr Owoeye is the author of Intellectual Property and Access to Medicines in Africa: A Regional Framework for Access (Routledge, 2019). Dr Owoeye has published over twenty articles in refereed international journals. He has also been a resource person for different academic institutions, national governments and inter-governmental organisations.
Ms Erika Dueñas Loayza, Technical Officer – Intellectual Property, Department of Health Products Policy & Standards, World Health Organization, Switzerland

Erika Dueñas works at WHO HQ/Division of Medicines and Health Products providing technical advice on the interfaces between innovation, access to treatments, and intellectual property (IP). She also supports activities to build and strengthen national and regional capacities on the intersections between public health, trade and IP. She worked at the Medicines Patent Pool and has more than 20 years of experience in the field of access to medicines, innovation and IP. As a career diplomat, she worked many years for the Bolivian government, participating in international negotiations related to IP at the Andean Community, WHO, WTO, and WIPO. After her diplomatic mission at the Embassy in Washington as Chargée d’Affaires, she was Vice-Minister at the Ministry of Foreign Affairs in Bolivia. Erika holds a Master’s degree in International Law and Economics (LLM) from the World Trade Institute / Universities of Bern, Fribourg & Neuchâtel – Bern, Switzerland.

Mr Joy Goswami, Assistant Director, Technology Transfer & Corporate Partnerships, Office of Economic Innovation & Partnerships, University of Delaware, United States of America

Joy is the Assistant Director of the Office of Economic Innovation and Partnerships, where he oversees and manages technology transfer activities and corporate partnerships for the University of Delaware. Among his other roles, Joy is actively involved in managing intellectual property, assisting in establishing start-up and spin-off companies and bringing forth university-industry collaborations & partnerships. He has more than twenty years of experience in the field of business development and a career that has produced highly regarded commercialization strategies and outreach practices of novel technologies in engineering, biotechnology, agriculture and biomedical sector. Joy is a Registered Patent Agent for the US Patent & Trademark Office. He is also a Small Business Innovation Research (SBIR/STTR) reviewer for the National Institutes of Health (NIH) and a Howard Bremer Scholar. Joy earned his Bachelor’s and Master of Science in Biology from Delhi University South Campus, and his MBA from the Herberger’s College of Business, St. Cloud State University, Minnesota, USA. He earned his Registration as a Technology Transfer Professional (RTTP) from the Alliance of Technology Transfer Professionals.

Dr Unnat Pandit, Program Director, Atal Innovation Mission, NITI Aayog, Government of India

He is Program Director at Atal Innovation Mission, NITI Aayog. He is also engaged in formulation of policy for promotion of innovation and entrepreneurship under Atal Innovation Mission a nodal agency of NITI Aayog to review and implement various initiatives of Government of India. He was also Member of IPR Think Tank constituted by Department of Industrial Policy and Promotion (DIPP), Government of India to draft National IPR Policy of India. Dr. Pandit is now actively engaged in the field of Strategic management of Intellectual Property and Innovation, Incubation management and Deployment of technologies and knowledge for societal benefits, IP Management, patent filing & prosecution, Technology Licensing & IP due diligence,
Corporate social responsibility and its initiatives linked to business strategy.

Dr KS Kardam, Former Senior Joint Controller of Patents and Designs, Indian Patent Office, India

Dr. Kardam has worked in the Indian Patent office for about 37 years and held various positions. He was holding the post of Senior Joint Controller of Patents & Designs since 2014 and was also Head of Delhi Patent Office. He completed post-graduation in Organic Chemistry from Agra University, Agra and post-graduation in Law from Delhi University. He holds Ph.D degree in the Intellectual Property Law.

He was also appointed one of the members of task force constituted by the Government of India for Traditional Knowledge Digital Library (TKDL) for protecting Indian Traditional Knowledge and played important role in designing the structure for electronically capturing the information in the Traditional Knowledge Digital Library (TKDL) and Traditional Knowledge Resource Classification (TKRC) as a classification similar to International Patent Classification (IPC).

He has been actively involved in bilateral co-operations with various IP Offices specially EPO and JPO, UKIPO, SWEDEN, SINGAPORE, FRANCE etc. He has also played major role in functioning of Indian Patent Office as International Searching Authority and International Preliminary Examining Authority in 2013.

He has published several papers in various journals on the topic related to Intellectual property. When India joined WTO and TRIPS, he had actively participated in the process of amendments to the Patents Act 1970 done in the year 1999, 2002 and 2005 and consequent revisions in the Patents Rules. He also conducted 6 months research study in Japan program on utility model and its economic and technological significance in IPRs.
Improving access to medical products has been a central focus of global health efforts over the past two decades. Apart from community mobilisation and competition law challenges, many global initiatives aim to broaden access to health technologies by improving the public health.

The countries are burdened with diseases relating to communicable diseases (CDs), non-communicable diseases (NCDs) and the risk of new diseases. Access to medicines is critical for health outcomes. Policies and approaches for the pricing and procurement of health technologies are vital to ensure the availability and affordability of essential medicines and health products for their populations. Many medical products (i.e., drugs, vaccines, and diagnostics) are unaffordable to the populations in need, one of the battling factors in the developed and developing economies.

Access to medicines depends on multiple factors like use of drugs, adequate and sustainable financing, affordable prices and reliable supply systems. In developed countries, expenditure on pharmaceuticals for the population is largely publicly funded through reimbursement and insurance schemes, while in developing countries, typically, the cost of 50–95% of drugs are out-of-pocket expenditure by the patients themselves. The 2001 Doha Declaration on TRIPS and Public Health signed by all WTO Member States noted that intellectual property protection was important for the development of new medicines, and also recognized the concerns about its effects on prices.

Public health and Intellectual Property rights go hand in hand in terms of innovation in treatments and development of medications. The legal structures such as patents are designed in a way to encourage innovation and to offer a system which ensures the benefits accessible to the society.

The inclusion of universal health coverage (UHC) in the Sustainable Development Goals has led to countries focusing to build health systems that provide access to high-quality essential health care services; safe, effective, and affordable essential medicines and vaccines for all; as well as financial risk protection (SDG target 3.8).

In this context, access to medical products is ensured by:

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102 https://pdfs.semanticscholar.org/8f64/028dd8d2e50b6a36005fd/35e6719203ed70.pdf
106 https://apps.who.int/iris/bitstream/handle/10665/258915/TRIPS.pdf?sequence=1&isAllowed=y
107 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/ : IPR: An overview and implications in pharmaceutical industry
108 https://iris.wpro.who.int/bitstream/handle/10665.1/12880/sdg_poster_goal3_3.8_eng.pdf
• Parallel importation that allows for importation of the patented product from a third country where it is sold at a lower price.
• Out-licensing which could be implemented as long as the terms and conditions are clearly defined which includes medicine, country of sale, production, enforcement measures, rights granted to the manufacturer and royalties to be paid.
• Compulsory license, issued by a competent public authority, to use a patented invention without the authorization of the patent holder which can be used to authorize the import, production and sale of a generic version of a patented product before relevant patents expire.
• Voluntary licensing (VL) that authorizes a generic manufacturer to distribute a patented medicine in certain countries and it is a strategy to increase access to medicines by facilitating low-cost production of medicines for low-income populations.
• A government use authorization can be considered as a special case of compulsory licensing, i.e. when the government issues compulsory license for its own purposes, for instance to ensure the availability of medicines in public health facilities. The TRIPS Agreement allows countries to issue compulsory licenses (including government use authorizations), and leaves countries free to decide the grounds, or reasons, for issuing a compulsory license.

In 2005, India was the first country to incorporate a provision in its law that specifically aimed at preventing the grant of “evergreening” patents. The Indian law also allows for pre- and post-grant patent oppositions. Public interest groups in India have successfully used these provisions to oppose patent applications on several medicines of public health importance, including the following ARVs: nevirapine hemihydrate, tenofovir, abacavir, ritonavir, and the combination of lopinavir and ritonavir, among others.

At the Sixty-first World Health Assembly in 2008, the World Health Organization (WHO) called to “examine the feasibility of voluntary patent pools to promote innovation of and access to health products and medical devices." At this time, patent pools in public health did not exist. New, safe and effective patented therapies were out of reach of LMICs' populations. While the concept of patent pools was not certain that such a model could effectively accelerate access to treatment.

Medicines Patent Pool (MPP) established by UNITAID seems to have provided countries with an efficient alternative. Pools in general facilitate the licensing agreements for sharing of data and expertise under concrete terms and conditions between originators and generic manufacturers for the production of antiretrovirals for hepatitis C, HIV and tuberculosis.

It has been stated that pharmaceutical companies must take seriously their baseline responsibility to respect the right to health and comply with the provisions contained in national patent laws that are designed to facilitate access to medicines.

Certain new licensing arrangements have evolved where voluntary licensing has been promoted. E.g. for tackling Hepatitis C. The originator companies Gilead and Bristol Myers Squibb (BMS) have signed voluntary license agreements with Indian drug companies that

110 https://apps.who.int/iris/bitstream/handle/10665/272976/Public-health-protection.pdf?sequence=1&isAllowed=y
112 http://www.wpro.who.int/health_research/wha61_21_global_strategy_poa_health_innovation_may2008.pdf
114 The never-ending story of access to medicines: W.I.P.O.J. 2016, 8(1), 54-63
115 Defining the right to health responsibilities of patent-owning pharmaceutical companies: I.P.Q. 2019, 1, 43-60
enable producers to manufacture and/or sell generic versions of sofosbuvir, ledipasvir, velpatasvir (Gilead) and daclatasvir (BMS) in countries listed in the agreements (“the territory” of the license). Consequently, all countries that are included in these agreements can procure generic Direct Acting Antivirals (DAAs) from the licensees at generally more affordable prices.116

Summary of DAA procurement situation in countries, mid-2017

Access Strategies, Patent Pool Mechanisms and Licensing for Medical Products and Health Technologies including the Role of Pharmaceutical Sector

The objective of the session is to discuss the following:

- Access strategies such as fostered through patent pooling for public health
- Innovative Licensing Mechanisms for access to medicines

Questions to spur thinking:

- What are the mechanisms for increasing access to medicines through-licensing encourage adoption of TRIPS flexibilities and patent licensing for public health priority diseases such as HIV, Tuberculosis, Malaria and Neglected Tropical Diseases?

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116 https://apps.who.int/iris/bitstream/handle/10665/260445/WHO-CDS-HIV-18.4-eng.pdf?sequence=1
117 https://apps.who.int/iris/bitstream/handle/10665/260445/WHO-CDS-HIV-18.4-eng.pdf?sequence=1
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<tr>
<td><strong>Thursday, 11:00-13:00</strong></td>
<td><strong>Access Strategies, Patent Pool Mechanisms and Licensing for Medical Products and Health Technologies including the Role of Pharmaceutical Sector</strong>&lt;br&gt;<strong>Chair:</strong> Mr Sudhanshu Pandey, Additional Secretary, Ministry of Commerce, Government of India&lt;br&gt;<strong>Co-chairs:</strong> Mr Richard Wilder, General Counsel and Director of Business Development, Coalition for Epidemic Preparedness Innovations, Norway</td>
<td>Durbar Ballroom</td>
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**Keynote Addresses**

1. Mr Richard Wilder, General Counsel and Director of Business Development, Coalition for Epidemic Preparedness Innovations, Norway- *Development of Vaccines Against Emerging Infectious Diseases - The CEPI Experience*

2. Professor Brook K Baker, Northeastern University School of Law and Senior Policy Analyst, Health Global Access Project, United States of America- *Expanding and Improving Voluntary Licenses and Accelerating Registration at the MPP*

**Panelists**

1. Dr Manica Balasegaram, Executive Director, Global Antibiotic Research and Development Partnership (GARDP)/ Drugs for Neglected Diseases initiative (DNDi), Switzerland- *Challenges in Antibiotics Access from Early Stage Research to Delivery and Stewardship*


3. Mr Esteban Burrone, Head of Policy, Medicines Patent Pool, Switzerland- *Role of MPP in Facilitating Affordable Access to Newer Technologies*

4. Dr K. Bangarurajan, Joint Drugs Controller, Central Drug Standard Control Organization, Government of India- *Facilitating Access through Licensing Options for Newer Medicines of Public Health Importance*
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<td>5.</td>
<td>Dr Ashish Mungantiwar, Executive President, Medical Services, Macleods Pharmaceuticals Limited, India- <strong>Bringing Tomorrow’s Anti-TB Medicines Today</strong></td>
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<td>6.</td>
<td>Mr Sandeep Juneja, Senior Vice President- Market Access, TB Alliance, United States of America (Video Conference)- <strong>Strategies for Access to New TB Regimens</strong></td>
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# CV of Chairs

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<thead>
<tr>
<th>Mr Sudhanshu Pandey, Additional Secretary, Ministry of Commerce, Government of India</th>
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<tr>
<td>Mr. Sudhanshu Pandey joined Indian Administrative Service of Government of India in the year 1987. Has experience of over 31 years in different senior policy positions in State Government / Government of India. Present responsibilities, as Additional Secretary, Trade Policy Division in the Department of Commerce include RMTR and UNCTAD, Regional Comprehensive Economic Partnership (RCEP) negotiations, EP (Services), Implementation of the foreign Trade Policy Statement (2015-2020), FT (Australia and New Zealand), IIFT and General Agreement on Trade in Services to cover all service negotiations and services exports in India, TRIPS negotiations and Intellectual Property Rights related issues in WTO, Sanitary &amp; Phytosanitary Agreement and Technical Barrier to Trade Agreement related issues and negotiations. National agenda on Standards and Global engagements on services are also being driven. In addition, also served in senior policy positions in the provincial government in the Deptt. of Industry &amp; Commerce, Energy, Finance apart from working with the Indian Mission in Germany. Led many high level trade delegations to various countries, conducted Services and Trade negotiations and negotiations in various areas and chaired many high level committees. He has been recipient of Governor's Medal, Chief Minister's Gold Medal, National Award by Akhil Bhartiya Vidvat Parishad, Varanasi &amp; Government of India Commendation Certificates.</td>
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<tr>
<th>Mr Richard Wilder, General Counsel and Director of Business Development, Coalition for Epidemic Preparedness Innovations, Norway</th>
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<tr>
<td>Mr. Wilder is General Counsel and Director of Business Development at the Coalition for Epidemic Preparedness Innovations (CEPI). There he and his team are responsible for drafting and negotiating legal instruments necessary to progress CEPI's mission and to support its administrative requirements. He and his team also support external engagement with the wide range of actors that form the CEPI coalition. He previously had a similar role in the Global Health Program at the Bill &amp; Melinda Gates Foundation. In that capacity he has responsibility for providing legal support in a range of projects for the development and delivery of drugs, vaccines and diagnostics in the developing world. Prior to that, he was Associate General Counsel for Intellectual Property Policy at Microsoft Corporation where he was responsible for defining and driving the company-wide policy in all areas of intellectual property. He also practiced in the field public health – including on access to existing medicines and the development of new ones, with particular focus on developing country needs. Mr. Wilder has taught law – including until recently at Georgetown University and earlier at the University of Malaya, Malaysia. Mr. Wilder has an engineering degree from the University of Washington, Seattle, Washington and practiced as a power generation engineer for several years in locations outside the United States. He has a law degree (Juris Doctorate) from the School of Law of the University of New Hampshire.</td>
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CV of Keynote Speaker

Professor Brook K. Baker teaches at Northeastern University School of Law and is currently a Resident Fellow at its Center for Law, Innovation and Creativity and a co-director of its Program on Human Rights and the Global Economy. He is a Senior Policy Analyst for Health GAP (Global Access Project) and actively engaged in campaigns for universal access to treatment, prevention, and care for people living with HIV/AIDS, especially expanded and improved medical treatment. He has written and consulted extensively on intellectual property rights, trade, investor-state dispute settlement, access to medicines, and medicines regulatory policy, including with the African Union, NEPAD, South Africa, Uganda, ASEAN, Thailand, Indonesia, Brazil, Venezuela, CARICOM, UK DFID, the World Health Organization, the Millennium Development Goals Project, the Global Fund to Fight AIDS, Tuberculosis and Malaria, Open Society Institute, UNAIDS, UNDP, Unitaid, the Medicines Patent Pool, the Global Commission on HIV and the Law, and others. He currently serves as a key advisor to NGO delegation to Unitaid after having previously served as the NGO Board Member to Unitaid.

CVs of Panelists

Dr Manica Balasegaram, Director, Global Antimicrobial Research and Development Partnership (GARDP), DNDI, Switzerland

Dr Manica Balasegaram trained as a medical doctor at the University of Nottingham, UK from where he started his career in internal and emergency medicine. From 2001 onwards, he worked as a doctor and researcher in several countries in Sub-Saharan Africa and Southern Asia. He also gained significant experience working in humanitarian emergencies and responses, largely with Médecins sans Frontières (MSF).

At the end of 2007 he joined the Drugs for Neglected Diseases initiative (DNDi) as Head of Leishmaniasis Clinical Program – a position he held for four years before returning to MSF as Executive Director of their Access Campaign. He was appointed director of GARDP in June 2016. He is also a board member of the Medicines Patent Pool as well as member of FIND’s Scientific Advisory Committee.

Manica’s experience spans clinical and public health practice in infectious diseases, international work on health policy & access to medicines where he has served on numerous international technical and health policy panels and experts groups. He also has substantial experience in clinical trials and drug development working as a site investigator, principal investigator, and project manager.
Ms Margo Warren, Government Engagement Manager, Access to Medicine Foundation, The Netherlands

Margo Warren is the Government Engagement & Policy Manager and is a member of the Strategy team at the Access to Medicine Foundation. Before taking on this role, she was a Researcher for the Access to Medicine Index.

Prior to joining the Foundation, Margo worked for the Ministry of Health and Long-Term Care in Ontario, Canada, in strategic health policy. In her position at the Ministry, Margo led the development of new initiatives pertaining to improving access to medicine, health system strengthening and capacity building.

Margo has held various health research and policy positions focused on partnerships for development, improving access to care, and addressing the social determinants of health both in Canada and globally. Margo holds both a Bachelor’s degree and a Master's degree in international development with a focus on health policy. Her Master’s thesis explored the complexities of producing affordable generic medications in low- and middle-income countries. To support this work, she completed an independent field study, analysing the domestic production of anti-retrovirals in Uganda as a viable option to help increase access to medicine.

Mr Esteban Burrone, Head of Policy, Medicines Patent Pool, Switzerland

Esteban Burrone works at Medicines Patent Pool since 2010. He is the Head of Policy of the Medicines Patent Pool, an institution he contributed to setting up in 2010 to promote access to affordable and appropriate medicines in developing countries, through the licensing of key patents. As Head of Policy, Esteban works on partnership with a large number of organisations and stakeholders, including governments, intergovernmental organisations and civil society organisations. He is part of the senior management team and has overall responsibility for Patents and Licences Database MedPaL and for the annual prioritization report. Esteban has more than 15 years of experience working in the field of innovation, IP rights and access to medicines with a focus on developing countries. Esteban holds a Master of Science in Development Studies from the London School of Economics and a Master in Business Administration from the International University in Geneva.

Dr K. Bangarurajan, Joint Drugs Controller, Central Drug Standard Control Organization, Government of India

Dr K. Bangarurajan did his Degree in Pharmacy from Madras Medical College, and M.Pharmacy, from Banaras Hindu University, Varanasi in the Year 1984 and was awarded Ph.D. by Tamil Nadu Dr MGR Medical University in the Year 2000. He began his career as a lecturer at J.S.S. College of Pharmacy – Ooty. He joined the Drugs Control Department, Tamil Nadu, in the Year 1986 as a Drugs Inspector and served as a Senior Drugs Inspector and Assistant Director of Drugs Control. He was awarded as “Best Drugs Inspector” in the year 2005. He joined the Central Drugs Standard Control Organization, New Delhi in the Year 2010 and from 2014 to 2017 he is posted at Central Drugs Standard Control Organization, West Zone, Mumbai. At present he is...
serving as Joint Drugs Controller (India), CDSCO, New Delhi.

Awarded with IPA-AU PACT Dr M. Venkateswarlu Memorial Lecture Award – 2019. He has made remarkable contributions in National and International seminars, workshops and represented India as National Drug Regulator in International Forums.

Dr Ashish Mungantiwar, Executive President, Medical Services, Macleods Pharmaceuticals Limited, India

Dr. Ashish Mungantiwar, is President - Medical Services in Macleods Pharmaceuticals Ltd. R and D centre. He heads Bioequivalence, Medical Services, Clinical Trials, Pharmacovigilance and Domestic Formulation Development. He has a rich experience of 20 years in the Pharma field. Dr. Ashish completed his PhD in Pharmacology from Bombay College of Pharmacy, Mumbai. He has served as a study director for more than 2000 BA/BE studies (in vivo and invitro BE studies). Conducted BE studies on oral solids, Inhaler and Invitro binding studies. Also overseen bioequivalence study on topical product (Vaso constriction study).

Dr. Ashish supervises the activities of clinical, bio-analytical, PK and statistical section of Bioequivalence Department. He has successfully handled more than 25 regulatory inspections like USFDA, WHO, UKMHRA, ANVISA (Brazil), MCC (South Africa), IDA (Netherlands), GLP Compliance monitoring authority-Thailand, CDSCO (India), DCGI and various consultant audits. As Head of Pharmacovigilance, he ensures Benefit-Risk Management of all Macleods Pharmaceuticals drugs throughout their life cycle and ensures all required pharmacovigilance obligations. He has obtained various new drug approvals from DCGI for first time launch in India. He also plays a vital role in new product selection for Domestic and Regulated Market. As Head – Clinical Trials he has successfully completed various multicentric Phase III clinical trial studies for various therapeutic segments. He has been invited as Speaker in various International and Indian Conferences. He has more than 25 publications. Dr. Ashish has been granted three patents.

Mr Sandeep Juneja, Senior Vice President- Market Access, TB Alliance, United States of America

Sandeep Juneja joined the TB Alliance in May 2018. As Senior Vice President of Market Access, he is responsible for leading the TB Alliance’s work in the design and implementation of market interventions and access strategies for rapid adoption and uptake of new TB regimens globally and in countries most affected with tuberculosis.

Mr. Juneja is passionate about shortening the gap between R&D and market availability of novel medicines, especially in developing countries. Prior to joining TB Alliance, Mr. Juneja worked as the head of business development at the Medicines Patent Pool, Geneva where he forged alliances with pharmaceutical industry, research institutes and other public health stakeholders to increase access to TB, HIV, and HCV medicines. Previously, he spent 17 years in the pharmaceutical industry in diverse roles including marketing, M&A, investor relations and was responsible for building an HIV and Malaria franchise in developing countries that resulted in access to HIV
medicines in 60+ countries and development of an NCE for Malaria. He has served on several committees and panels related to Access to Medicines, such as the Advisory Board of the Medicines4All Institute, Steering Committee on Universal Access, Global Fund Procurement Advisory Panel, and Global Fund Market Dynamics Advisory Group.

An engineer by training, Mr. Juneja has a bachelor’s degree in technology from the Indian Institute of Technology and holds an MBA in International Business from the Indian Institute of Foreign Trade.
The World Health Organization (WHO) has developed guidelines for biosimilars (called ‘similar biotherapeutic products’ or SBPs) and biosimilar monoclonal antibodies, with the aim of providing guidance to regulatory agencies worldwide. These WHO guidelines incorporate many of the scientific principles used by EMA and its scientific committees in EU guidelines, as EU experts have been closely involved in the preparation of the WHO guidelines\(^ {118}\).

The US Food and Drug Administration (USFDA) has separate centers for regulation of pharmaceutical drugs and biologics (including biosimilars). While the pharmaceutical drugs are evaluated and regulated by the FDA’s Center for Drug Evaluation and Research (CDER)\(^ {119}\), the Center for Biologics Evaluation and Research (CBER) regulates biologics products under a variety of regulatory authorities including the Public Health Service Act and the Food Drug and Cosmetic Act\(^ {120}\). There are different applications for approval of drugs classified based on different requirements procedures\(^ {121}\):

1. Investigational New Drug (IND) Application
2. New Drug Application (NDA)
3. Abbreviated New Drug Application (ANDA)
4. Therapeutic Biologics Applications (BLA)
5. Drug Applications for Over-the-Counter (OTC) Drugs

The data generated by pharmaceutical drug developer on the drug’s effects are reviewed by CDER, and if the drug is determined to provide benefits that outweigh its known and potential risks for the intended population, it is approved.

The European medicines regulatory system is based on a network of around 50 regulatory authorities from the 31 countries of the European Economic Area (EEA), the European Commission and European Medicines Agency (EMA)\(^ {122}\). EMA provides marketing authorization to medicines through different routes viz. centralized or national (decentralized/mutual recognition) procedures. The centralised procedure allows the marketing of a medicine on the basis of a single EU-wide assessment; is valid throughout the EU; and is compulsory for most innovative medicines, including medicines for rare diseases. EMA’s Committee for Medicinal Products for Human Use (CHMP) carries out a scientific assessment of the marketing authorization application and gives a recommendation to the European Commission on whether or not to grant a marketing authorisation. Rules and requirements applicable to pharmaceuticals in the EU are the same, irrespective of the authorisation route for a medicine.

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\(^ {119}\) https://www.fda.gov/drugs/development-approval-process-drugs
\(^ {120}\) https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber
\(^ {121}\) https://www.fda.gov/drugs/development-approval-process-drugs/how-drugs-are-developed-and-approved
Biosimilars under review by EMA

<table>
<thead>
<tr>
<th>Common name</th>
<th>Therapeutic area</th>
<th>Number of applications</th>
<th>EMA-approved originator(s)</th>
<th>Originator company(ies)</th>
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<tbody>
<tr>
<td>Adalimumab</td>
<td>Immunosuppressant</td>
<td>3</td>
<td>Humira</td>
<td>AbbVie</td>
</tr>
<tr>
<td>Etanercept</td>
<td>Immunosuppressant</td>
<td>1</td>
<td>Enbrel</td>
<td>Amgen/Pfizer</td>
</tr>
<tr>
<td>Pegfilgrastim</td>
<td>Immunostimulant</td>
<td>1</td>
<td>Neulasta</td>
<td>Amgen</td>
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<tr>
<td>Rituximab</td>
<td>Antineoplastic medicine (anticancer)</td>
<td>2</td>
<td>MabThera/Rituxan</td>
<td>Roche</td>
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<tr>
<td>Total</td>
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In 2012, US Food and Drug Administration Safety Innovations Act (FDASIA) was implemented which allows the FDA to base accelerated approval for drugs for serious conditions that fill an unmet medical need on whether the drug has an effect on a surrogate or an intermediate clinical endpoint. Using surrogate or intermediate clinical endpoints can save valuable time in the drug approval process. USFDA also employs the following drug development designations to encourage the development of certain drugs:

1. **Fast Track**: To facilitate the development and advance the review of drugs that treat serious conditions, and fill an unmet medical need, based on promising animal or human data. Fast tracking can get important new drugs to the patient earlier.

2. **Breakthrough Therapy**: Expedites the development and review of drugs intended to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy. A drug with Breakthrough Therapy designation is also eligible for the Fast Track process.

3. **Priority Review**: FDA aims to take action on an application within six months, compared to 10 months under standard review. A Priority Review designation directs attention and resources to evaluate drugs that would significantly improve the treatment, diagnosis, or prevention of serious conditions.

In line with the Breakthrough Therapy Designation system in 2012 in the US, the Sakigake Designation was introduced in 2015 in Japan, and PRIME (PRIority MEdicines) was started in 2016 in the European Union. Each system aims at giving patients better access to innovative drugs and regenerative medicine products by providing product developers with generous regulatory and scientific support from an early development stage.

Similar to the pharmaceutical drugs, the USFDA-approved biological products, including reference, biosimilar, and interchangeable products, undergo a rigorous evaluation to ensure that patients can rely on their efficacy, safety, and quality.

The approval of biosimilar products can improve access to care for patients by increasing the number of medication options and potentially lower costs.

The Biologics Price Competition and Innovation Act of 2009 was enacted as part of the Affordable Care Act. This statute created an abbreviated pathway to approve biosimilar...

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124 [https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval](https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval)
125 [https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track](https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track)
126 [https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy](https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy)
128 [https://www.fda.gov/drugs/biosimilars/biosimilar-product-information](https://www.fda.gov/drugs/biosimilars/biosimilar-product-information)
As per USFDA regulations, it is required to demonstrate biosimilarity between the proposed biosimilar product and the reference product, not to independently establish the safety and effectiveness of the proposed product. Biosimilar manufacturers do not need to conduct as many expensive and lengthy clinical trials, potentially leading to faster access to these products, additional therapeutic options, and reduced costs for patients.

The first medication to be approved as a biosimilar product was Zarxio (filgrastim-sndz) in March 2015. This medication is the biosimilar of Neupogen (filgrastim)\(^\text{131}\). Zarxio is approved for the same indications as Neupogen; however, patients using Zarxio save an estimated 15% of the cost of originator - Neupogen\(^\text{132}\). USFDA has approved 21 biosimilars till date with 7 approvals so far in 2019 – 3 for trastuzumab, and one each for bevacizumab, adalimumab, rituximab and etanercept\(^\text{133}\).

With the objective of ensuring patient safety, USFDA provides ‘MedWatch Safety Alerts’ which include timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics\(^\text{134}\). The Sentinel Initiative of USFDA enhances its ability to proactively monitor the safety of medical products after they have reached the market\(^\text{135}\).

The Center for Biologics Evaluation and Research (CBER), USFDA regulates cellular therapy products, human gene therapy products, and certain devices related to cell and gene therapy. CBER uses both the Public Health Service Act and the Federal Food Drug and Cosmetic Act as enabling statutes for oversight\(^\text{136}\). Cellular therapy products include cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications, including hematopoietic stem cells and adult and embryonic stem cells. Human gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use. In addition to regulatory oversight of clinical studies, CBER provides proactive scientific and regulatory advice to medical researchers and manufacturers in the area of novel product development.

In EMA, gene and cell therapies are approved under ‘Advanced therapy medicinal products’ (ATMPs) - medicines for human use that are based on genes, tissues or cells. ATMPs are further classified into gene therapy medicines (recombinant genes), somatic-cell therapy medicines (manipulated cells or tissues); and tissue-engineered medicines (modified cells or tissues for repair and regeneration). Stems cells are categorised as ATMPs when these cells undergo substantial manipulation or are used for a different essential function. They can be somatic-cell therapy products or tissue-engineered products, depending on how the medicine works in the body. All ATMPs benefit from a single evaluation and authorisation procedure under EMA\(^\text{137}\).

EMA also gives scientific support to developers to help them design pharmacovigilance and risk management systems used to monitor the safety of these medicines.

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\(^\text{130}\) fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/ucm216146.pdf
\(^\text{131}\) fda.gov/pressannouncements/ucm436648
\(^\text{133}\) https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
\(^\text{135}\) https://www.fda.gov/safety/fdas-sentinel-initiative
\(^\text{136}\) https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products
It is agreed that the national regulations must keep pace with technological developments and play a facilitative role in improving access to medicines to the public. This is ensured through proactive policy decisions in the interest of public health.

The objective of the session is to discuss the following:
- Regulatory approaches for Pharma, Biosimilar drugs, Gene and Cell Therapies

Questions to spur thinking:
- What are the key US regulations in facilitating expedited approval of essential medicines?
- Biosimilar approvals by the USFDA
- How to expedite regulatory approvals for medical products in European Union, Japan and other countries?
- Effective communication strategies during early drug development for improved transparency between the regulators and the industry to enable decisions (explore US CDER (Center for Drug and Evaluation and Research) model?)
- Explore quicker access to medicines through alternate models like PRIME, Breakthrough, SAKIGAKE, etc?
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<th>Time</th>
<th>Parallel Session 9- Thursday, 21 November 2019</th>
<th>Room</th>
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<tr>
<td></td>
<td><strong>Regulatory Approaches for Approval of Pharma &amp; Biosimilar Drugs, and Gene and Cell Therapies- USFDA, EMA Models</strong></td>
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<td><strong>Chair</strong>: Mr Sudhansh Pant, Joint Secretary, Ministry of Health and Family Welfare, Government of India</td>
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<td><strong>Co-chair</strong>: Dr Sanjay Tyagi, Director General of Health Services Ministry of Health and Family Welfare, Government of India</td>
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<td><strong>Keynote Address</strong></td>
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<td></td>
<td>Dr VG Somani, Drugs Controller General of India, Central Drug Standard Control Organization, Government of India- <em>Indian Regulatory Framework for Biosimilars for Accelerating Access</em></td>
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<td>Mr Pankaj Patel, Chairman, Zydus Cadila Healthcare Limited, India- <em>Accelerating Access: The Pharmaceutical Sector Perspective</em></td>
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<td><strong>Panelists</strong></td>
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<td></td>
<td>1. Mr James Love, Director, Knowledge Ecology International, United States of America- <em>Innovation and Access for Biosimilars and New Cell and Gene Therapies</em></td>
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<td>2. Dr Ian Hudson, Senior Adviser, Bill &amp; Melinda Gates Foundation and Former Chief Executive, MHRA, United Kingdom - <em>EMA Regulatory Guidance for Biosimilars and other Advanced Therapeutics</em></td>
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<td>3. Dr Anurag S. Rathore, Coordinator, DBT Center of Excellence for Biopharmaceutical Technology &amp; Professor, Department of Chemical Engineering, Indian Institute of Technology, Delhi, India- <em>Affordability of Biosimilars</em></td>
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<td>5. Dr Rob Lambkin-Williams, Executive Scientific Advisor, hVIVO &amp; Virology Consult, United Kingdom- <em>Human Viral Challenge Model for Accelerating Drug Development Process</em></td>
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<td>6. Dr Pieter Neels, CEO &amp; Scientific Advisor at Vaccine-Advice, Belgium- <em>EU Regulatory Requirements in Vaccinology</em></td>
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CV of Chairs

Mr Sudhansh Pant, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

Shri Sudhansh Pant holds a B. Tech (Hons.) degree from IIT Kharagpur. He joined the Indian Administrative Service (IAS) in the year 1991 in the Rajasthan Cadre.

In the early years of his service he has worked as Collector & District Magistrate in the districts of Jaisalmer, Jhunjhunu, Bhilwara and Jaipur. He has also worked as Chairman and Managing Director of the State Power Transmission Corporation, the State Power Distribution Companies and the State Renewable Energy Corporation. He has been Secretary in the Mines and Petroleum Department in Government of Rajasthan besides having worked as Commissioner of the Jaipur Development Authority and Secretary in the Urban Local Bodies and Housing Department. Prior to joining the Department of Health and Family Welfare, Ministry of Health and Family Welfare in March 2018, he worked as Joint Secretary in the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, besides holding the charge of Chairman-cum-Managing Director, Indian Drugs and Pharmaceuticals Limited, a Government of India undertaking. He has a long experience in working in the Cooperative Sector and has headed several Co-operative Institutions.

He is at present working as Joint Secretary in the Department of Health and Family Welfare and deals with administration, Medical Education, Allied Health Services, Institutes of National Importance and Procurement. He is also holding the charge of DG& CEO, Central Medical Services Society.

He has received several awards from the Government of Rajasthan, Government of India and the Election Commission of India for meritorious achievement in different fields during the course of his career.

Dr Sanjay Tyagi, Director General of Health Services Ministry of Health and Family Welfare, Government of India

Prof (Dr.) Tyagi is an eminent Cardiologist, renowned medical teacher; an outstanding researcher in the field of Cardiovascular diseases of the country. For over three decades Prof Tyagi has inspired, nurtured, empowered several generations of cardiologists of the country. Prof Tyagi has been Head, Dept of Cardiology, Director of G B Pant Institute of Postgraduate Medical Education; Dean of Maulana Azad Medical College which are ranked as one of the best in the country.

He has done extensive genomic; proteomic research in the coronary artery disease, hypertension in young and acute myocardial infarction. He has been pioneer in starting life-saving coronary, vascular and valvular nonsurgical interventional treatment in India. He has done extensive research which has been published in most prestigious international, peer-reviewed medical Journals like American Heart Journal, Circulation (Journal of American Heart
Association), Pediatrics (Journal of American Society of pediatric) etc. and has been quoted in Text Books of Cardiology. He has over 300 publications in leading national and international journals (e.g. Circulation, American Heart Journal etc.) and books.

He is credited with starting the first state of the art 24X7 emergency angioplasty services for acute heart attack acute stroke treatment in Govt G B Pant Medical Institute, Delhi. He is also Fellow of National Academy of Medical Sciences, Fellow European Society of Cardiology (FESC), Fellow Society of Cardiovascular Angiography Interventions (USA), Fellow American College of Cardiology (FACC), USA. He has been awarded several orations awards including ‘State Award’ for outstanding services by the Government of Delhi in 2004, Prestigious Dr B C Roy Award in 2009 by President of India. Best Challenging case Award by the Cardiovascular Research Foundation (USA) in 2012, Dr S Radhakrishnan Memorial National Teacher Award in 2014. ‘Legends in Cardiology’ Award 2017 by Times of India. Platinum Jubilee Outstanding Contribution Award by Health Minister of India 2018.

CV of Keynote Speakers

Dr V G Somani, Drugs Controller General (India), Dte.GHS, Ministry of Health and Family Welfare, (MoH&FW) Government of India

Currently he is holding the post of Drugs Controller General (India), under Dte.GHS, MoH&FW, Government of India. He has done his M. Pharm and PhD in Pharmaceutical Sciences. He is cworking in CDSCO for last 21 years and having vast experience in the field of GMP, GCP, GRP, GDP, Dossier Review, GLP etc. and has also worked on all the posts in the hierarchy of Central Drugs Control Department including as Drugs Controller General of India. Being meritorious student, he was awarded scholarship/fellowships since schooling days. He has been selected and now working as Chairman of WHO’s Member State Mechanism (MSM) of 194 countries on substandard and falsified medical products at Geneva, Switzerland vide World Health Assembly (WHA) resolution 65.19 which is very prestigious opportunity for India to safeguard global interest for making affordable generic medicines acceptable in the world. He is well-known speaker and trainer of various national and international/ WHO scientific bodies.

He has been involved in formulating various national regulatory guidelines like guideline on similar biologics and contributed to various WHO guidelines on Drugs, Devices and Vaccines related issues. His focus areas are simplification of regulation and access to quality medical products through Good Regulatory Practices and strengthening regulatory systems.
Mr Pankaj Patel, Chairman, Zydus Cadila Healthcare Limited, India

Pankaj Ramanbhai Patel is a businessperson who founded Zydus Hospitals & Medical Research Pvt Ltd. and who has been the head of 13 different companies. Presently, he occupies the position of Non-Executive Chairman for Cadila Healthcare Ltd., Chairman & Managing Director at Zydus Cadila Healthcare Ltd. (a subsidiary of Cadila Healthcare Ltd.), Chairman & Chief Executive Officer at Zydus Hospitals & Medical Research Pvt Ltd., Chairman for Bayer Zydus Pharma Pvt Ltd., Chairman for The Gujarat Cancer & Research Institute and Non-Executive Chairman for Bayer CropScience Ltd. (India). Mr. Patel is also Chairman-Governors Board at Indian Institute of Technology Bhubaneswar, Chairman at Gcs Medical College, Executive Chairman & Vice President at The Gujarat Cancer Society, Chairman-Governors Board at Indian Institute of Management Udaipur, Member-Governing Board at Gujarat Law Society, Member-Management Board at Narsee Monjee Institute of Management Studies, Member-Governing Board at Nirma University, Member-Management Board at The Indian Institute of Foreign Trade, Member-Governing Board at Anant National University and Secretary of B. V. Patel Pharmaceutical Education & Research Development and on the board of 26 other companies.

Pankaj Patel is a graduate from Gujarat University, and holds a degree as Bachelor of Pharmacy. He went on to pursue M.Pharma in Pharmaceutics & Pharmaceutical Technology from L. M. College of Pharmacy.

CVs of Panelists

Mr James Love, Director, Knowledge Ecology International, United States of America

James Love is Director of Knowledge Ecology International. His training is in economics and finance, and work focuses on the production, management and access to knowledge resources, as well as aspects of competition policy. The current focus is on the financing of research and development, intellectual property rights, prices for and access to new drugs, vaccines and other medical technologies, as well as related topics for other knowledge goods, including data, software, other information protected by copyright or related rights, and proposals to expand the production of knowledge as a public good. James Love holds a Masters of Public Administration from Harvard University's Kennedy School of Government and a Masters in Public Affairs from Princeton's Woodrow Wilson School of Public and International Affairs. He advises UN agencies, national governments, international and regional intergovernmental organizations and public health NGOs, and is the author of a number of articles and monographs on innovation and intellectual property rights. Prior to his work at KEI, Love was Senior Economist for the Frank Russell Company, a lecturer at Rutgers University, and a researcher on international finance at Princeton University.
Dr Ian Hudson, Senior Adviser, Bill and Melinda Gates Foundation and former Chief Executive, MHRA, United Kingdom

Dr Ian Hudson practiced as a paediatrician for a number of years before working in research and development at SmithKline Beecham for 11 years. Subsequently, in 2001, he joined the MHRA as Director of Licensing and was the UK delegate to EMA's scientific committee, CHMP, latterly its Vice Chair. In 2013 Dr Hudson became CEO of the MHRA, also a member of the EMA management Board and part of the Heads of Medicines Agencies Management Group. He was also Chair of the International Coalition of Medicines Regulatory Authorities between 2016 and 2019. Dr Hudson joined the Bill and Melinda Gates Foundation as Senior Advisor, Regulatory Affairs, Integrated Development in September 2019.

Dr Anurag S. Rathore, Coordinator, DBT Center of Excellence for Biopharmaceutical Technology & Professor, Department of Chemical Engineering, Indian Institute of Technology, Delhi, India

He has obtained his Ph.D. from Yale University, CT, USA, in 1998 and then worked in the Process Development groups at Pharmacia Corporation, St. Louis, USA, and Amgen, Inc., Thousand Oaks, USA before joining the Department of Chemical Engineering, IIT Delhi in 2009. He is an active member of the Parenteral Drug Association (PDA) and American Chemical Society (ACS) and have authored more than 400 publications and presentations in these areas. Presently serving as the Editor-in-Chief of Preparative Biochemistry and Biotechnology and Associate Editor for the Journal of Chemical Technology and Biotechnology and PDA Journal of Science and Technology. He also serves on the Editorial Advisory Boards for Biotechnology Progress, BioPharm International, Pharmaceutical Technology Europe and Separation and Purification Reviews. Dr. Rathore have edited books titled Novel Bioprocessing Technology for Production of Biopharmaceuticals and Bioproducts (2018), Preparative Chromatography for Separation of Proteins and Peptides (2017), Quality by Design for Biopharmaceuticals: Perspectives and Case Studies (2009), Elements of Biopharmaceutical Production (2007), Process Validation (2005), Electrokinetic Phenomena (2004) and Scale-up and Optimization in Preparative Chromatography (2003).

Dr Geeta Jotwani, Scientist F, Indian Council Of Medical Research, Government of India

Dr. Geeta Jotwani has a PhD in Medical Sciences from All India Institute of Medical Sciences, New Delhi, India. She has also received a specialized training in Bioethics and Ethics Committee Administration under a WHO-NIH Program at University of Washington Olympia, Washington, USA (certified WIRB Professional: (Western Institutional Review Board). She is currently working with Indian Council of Medical Research, an Apex advisory body under Department of Health Research, Ministry of Health & Family Welfare. She has over 30 years of experience in biomedical research and management. She has research experience in various fields like infectious diseases, developmental neurobiology and cancer genomics, stem cell and cell research.
Since 2001, she has been involved with the management of biomedical research and policy making for upcoming bio-technologies under the aegis of ICMR. She is governing the progress of emergent research areas like Genomics & Molecular Medicine, Stem Cell Research & Therapy (SCRT), Nanomedicine, Gene Therapy and Immunotherapy in India. She is instrumental in defining national (Indian) guidelines and regulations governing research and development/medical practices in various innovative fields of science and technology. She has immensely contributed to the field of Stem Cell and Cell Based Research & Therapy, through nationally coordinating several activities including National Apex Committee for Stem Cell Research, ICMR-DBT Joint Working Group on Gene Therapy, Cell Biology Based Therapeutic Drug Evaluation Committee (CBBTDEC) of CDSCO, Awareness Programmes, Interagency/Inter-Ministerial Harmonization of Policies/Regulations, Dissemination of National Guidelines for Stem Cell Research etc.

**Dr Rob Lambkin-Williams, Executive Scientific Advisor, hVIVO & Virology Consult, United Kingdom**

The Controlled Human Infection Model (CHIM) can be conducted using a variety of pathogens, and specifically, the Human Viral Challenge Model (HVCM) has, for many decades, helped in the understanding of respiratory viruses and their role in disease pathogenesis. Along with colleagues, Dr Rob Lambkin-Williams has worked with viral challenge agents, manufactured to the most appropriate GMP standard, since 2001. In 2001, Dr Rob Lambkin-Williams designed and implemented the first HVCM study to be conducted in Europe in the 21st century. He designed the first series of pilot studies, accommodating the regulatory challenges that this presented. He wrote the original protocols, ethics committee submissions, and oversaw the appropriate GMP quality standards for the virus used, the conduct of the studies in temporary, and purpose-built, quarantine facilities and the analysis of the data.

He has developed and supervised multiple studies for large pharma, biotechs, the US and UK governments, the European Union and a varied collection of academic groups; he has been the Principal Investigator on many. He conducted his PhD on flu at the University of Warwick; his PhD was co-sponsored by the National Institute of Biological Standards and Control. His interests also include other respiratory viruses and HIV. He is Member of the Royal Pharmaceutical Society, Fellow of the Royal Society of Medicine and Member of the International Society for Influenza and Other Respiratory Virus Diseases (ISIRV). With others, he has published extensively based on CHIM work.
Dr Pieter Neels, CEO & Scientific Advisor at Vaccine-Advice, Belgium

Dr Pieter Neels is a native of Belgium where he trained as an MD (University of Antwerp, 1985) and was boarded as a general practitioner. In 1997, he joined the Belgian Ministry of Public Health as a senior evaluator of the clinical part of registration files in the field of cardiology, nephrology, endocrinology (diabetes). In 2001 he was appointed CPMP member. In 2002 he was asked to take over all Belgian central vaccine rapporteurships. He was elected vice-chair of Vaccine Working Party, a CHMP workgroup for vaccines for discussion on development and evaluation of registration files for vaccines until June 2013. WHO has asked Dr Neels to attend many meetings on vaccine development all over the world in order to share the EU regulatory requirements/competence in vaccinology. Dr Neels is also a member of the world wide network on vaccine promotion as he is asked to attend the ADVAC course (Foundation Mérieux) and the IABS conferences.

In 2013 Dr Neels was nominated associate Professor at the Namur University for a course in Vaccinology. In June 2013 Dr Neels stepped down from the CHMP and left the Belgian Federal Agency to start his own consultancy company “Vaccine-Advice” in order to be able to support vaccine development in a more efficacious way. In 2014 Dr Neels was elected board member of IABS-EU and in 2016 he accepted to chair the Human Vaccine Committee of IABS.
The 72nd session of the World Health Assembly adopted a resolution on improving the transparency of markets for medicines, vaccines and other health products in an effort to expand access. The resolution aims to help Member States make more informed decisions when purchasing health products, negotiate more affordable prices and ultimately expand access to health products for the populations.

Affordability is the key to accessibility. The cheaper generic medicines for Africa's AIDS patients had transformed potential of affordability. However, affordability is not simple to implement, to deliver affordability, innovation is required—innovation in discovering drugs, developing therapeutics and delivering healthcare. The price of medicines is a barrier to treatment and access for poor people in developing countries due to their low purchasing power and the limited availability of public or private insurance. It has been estimated that between fifty percent and ninety percent of pharmaceutical expenditures in developing countries are paid out-of-pocket.

Using affordable generic versions and biosimilar products that advance treatment for Hepatitis, HIV/AIDS, cancer and other diseases can improve access. WHO added several such “high-cost” medicines to its Model Essential Medicines List, and support their inclusion in national lists. WHO will also work with Member States to increase their capacity to use TRIPS flexibilities to get better prices, especially for high-cost therapies.

Affordable prices can be promoted through various policies which include:

- National clinical guidelines which recommend essential medicines for which generic products are available;
- Therapeutic substitution;
- Reimbursement measures (e.g. reference pricing);
- Differential pricing;
- Local production through voluntary licenses;
- Flexibilities of international trade agreements to introduce generics while a patent is in force, such as government use and compulsory licenses for local production or importation.

Patents are not the only type of intellectual property rights addressed in TRIPS, and some of the other forms of intellectual property can also have implications for access to drugs. For example, TRIPS mandates protection of undisclosed data submitted to national drug regulatory authorities in order to obtain marketing authorization for new drugs.

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139 https://www.sciencedirect.com/science/article/pii/S0970389617305384#bfn0010
141 https://apps.who.int/iris/bitstream/handle/10665/258815/sea-rc70-9.pdf?sequence=1&isAllowed=y
142 https://www.who.int/medicines/areas/policy/access_noncommunicable/NCDbriefingdocument.pdf?ua=1
These registration data have to be protected against disclosure, and against unfair commercial use. Thus, the national authorities may not share them with competing (e.g. generic) companies. TRIPS, however, mandates data protection, but not data exclusivity, and national laws need not have requirements that are more stringent than TRIPS\textsuperscript{143}.

**Non-communicable Diseases**

WHO set a target of 80% availability of affordable essential medicines, including generics, to treat major non-communicable diseases (NCDs), in the public and private sectors of countries by 2025. Attention is growing on preventing and treating non-communicable diseases (NCDs). Over 36 million people die annually (63% of global deaths) from NCDs, mainly cardiovascular diseases, cancer, chronic respiratory diseases and diabetes. Of these, 80% occur in low- and middle-income countries\textsuperscript{144}.

The WHO recognised this and included in the Global Action Plan for prevention of NCDs 2013–2020 (GAP) a voluntary target of 80% availability of affordable basic technologies and essential medicines, including generics, required to treat major NCDs in both public and private facilities by 2025\textsuperscript{145}.

The underlying feature of trade agreement is a commitment to lower barriers to trade (both tariff and non-tariff). Governments should explore the ways for effectively using the public health-related provisions in the WTO system and in other trade agreements. The opportunities created by collaboration between trade and health in the prevention and management of NCDs include:

- Potential for new strategic policy directions and innovation in NCD prevention;
- Development of more feasible multisectoral health interventions to prevent NCDs;
- Pro-active engagement with trade negotiations to ensure public health is protected\textsuperscript{146}.

The objective of the session is to discuss the following:

- National regulation for affordable access to medical products
- To facilitate affordable access to medicine through international bilateral and multilateral agreements including leveraging the TRIPS flexibilities

Questions to spur thinking

- How to leverage the strengths of the SEAR-Region as a major manufacturer of essential medical products especially generic medicines for affordable medicines?
- Promote regulatory mechanisms to develop affordable drugs including relating to NCDs

\textsuperscript{143} https://apps.who.int/iris/bitstream/handle/10665/258915/TRIPS.pdf

\textsuperscript{144} UN General Assembly. Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable diseases. https://www.who.int/nmh/events/un_ncd_summit2011/political_declaration_en.pdf


\textsuperscript{146} https://www.who.int/nmh/events/2013/trade_agreements2013.pdf
21 November 2019-Thursday, 14:00-15:30: Parallel Session 10: National Regulation and International Agreements including Pricing of Medical Products for Affordable Access

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<tr>
<td>Thursday, 14:00-15:30</td>
<td>National Regulation and International Agreements including Pricing of Medical Products for Affordable Access</td>
<td>Jehangir Hall</td>
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Chair: Ms Shubhra Singh, Chairman, National Pharmaceutical Pricing Authority, Government of India

Co-chairs: Ms Ritu Dhillon, Joint Secretary, Department of Pharmaceuticals, Member Secretary, National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Government of India; Dr Arun Kumar Agarwal, Ex-Dean, Maulana Azad Medical College, India

Keynote Address

Mr Richard Wilder, General Counsel and Director of Business Development, Coalition for Epidemic Preparedness Innovations, Norway- *Strategies to Accelerate Affordable Access to Vaccines*

Panelists

1. Professor Brook K Baker, Northeastern University School of Law and Senior Policy Analyst, Health Global Access Project, United States of America- *Overcoming Monopolies on Medicines in Domestic Legislation, Treaties, and Allowing Price Controls*

2. Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia- *Patents and Intellectual Property Standards to Facilitate Affordable Access to Medicines*

3. Mr Frans Stobbelaar, Chief Executive Officer and Senior Consultant, Pharmaceutical Management Consultants BV, Netherlands- *Fostering Landscape of Active Pharmaceutical Ingredients (API) for Convergence Towards International Quality Standards*

4. Mr Harry Krishna Bucktowar, Deputy Director Pharmaceutical Services, Ministry of Health and Quality of Life, The Republic of Mauritius-*Strengthening the supply chain Management of Pharmaceuticals- The Mauritius Perspective*

5. Dr Ellen't Hoen, Medicines Law and Policy, France (Video Conference)- *Invoking TRIPS Flexibilities for Public Health to ensure Access to Medicines: The TRIPS Flexibilities Database*

6. Dr Narveshwar Sinha, Chairman, IDEAL Charity, United Kingdom-*Access to Cochlear Implants: Leveraging National Essential Medication Lists*
CV of Chairs

Ms Shubhra Singh, Chairman, National Pharmaceutical Pricing Authority, Government of India

Ms. Shubhra Singh, IAS (RJ-89), is serving as Chairman, National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals, Ministry of Chemical & Fertilizer, Govt, since Dec. 2018. This is her third stint at Government of India, having earlier served as Director, Department of Family Welfare, Govt, (2000-2005), Joint Secretary, Department of Industrial Policy Promotion and ED ITPO, Department of Commerce (2011-17).

She reported Guinea worm eradication as the Executive Director of UNICEF funded Sanitation Water & Community Health (SWACH) project in the tribal belt of Rajasthan in 1995. She is acknowledged for her sterling contribution in the conceptualisation and roll out of the National Rural Health Mission (NRHM) in 2005, during her stint in Ministry of Health and Family Welfare, Government of India. She has also served as Secretary Family Welfare and Mission Director NRHM, Govt of Rajasthan. She is credited with various initiatives during her tenure as Commissioner Sarva ShikshaAbhiyan, Secretary Khadi Board and District Collector, Karauli.

As Joint Secretary in Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce and Industry, Government of India she contributed significantly to the thrust of the new Government on introducing Ease of Doing Business, Defence Licensing and Make in India campaign.

She was awarded the Silver Medal and Certificate by the Hon’ble President of India for Outstanding Service for conduct of Census – 2011 in Rajasthan. She is a Post Graduate in Political Science and double Gold Medalist at R G Girls College, Meerut University.

Ms Ritu Dhillon, Member Secretary, National Pharmaceutical Pricing Authority and Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

Ritu Dhillon IAAS is Member Secretary, National Pharmaceutical Pricing Authority and Joint Secretary, Pharmaceuticals, Government of India. In her 23 years of service she has served in various senior capacities with the government across sectors. Her experience with the health sector includes being the Senior Financial Advisor and Chief Vigilance Officer with Indian Council Of Medical Research, the apex national biomedical research body and Financial Advisor of PGIMER, at Chandigarh. She has served as Principal Director with Comptroller and Auditor General of India apart from holding posts of Assistant and Deputy Accountant General of Punjab and Haryana, earlier. She has served as Additional Chief Administrator with Punjab Urban Planning Authority. She has participated in a NIH Funds Management Programme. Her short audit assignments include the procurement audit of UN headquarters at New York and heading the Aviation sector audit of UNHAS at WFP, Rome. She speaks English, Hindi, Punjabi and French.
Dr Arun Kumar Agarwal, Ex-Dean, Maulana Azad Medical College, India

Dr Arun Kumar Agarwal has been a teacher for over 35 years and is an honorary faculty member and Director of the Department of Medical Education in Maulana Azad Medical College. He has had a long association with The National Board of Examinations and is responsible for pioneering and introducing the technique of OSCE (Objective Structured Clinical Examination) in the country through the Board. On an international level, he is the Coordinator for the ENT Medical Education all over the globe, under the aegis of the International Federation of Otolaryngological Societies (World ENT Association). At present he is Medical Advisor- Innovation, Education and Clinical Excellence with Apollo Hospitals Group.

CV of Keynote Speaker

Mr Richard Wilder, General Counsel and Director of Business Development, Coalition for Epidemic Preparedness Innovations, Norway

Mr. Wilder is General Counsel and Director of Business Development at the Coalition for Epidemic Preparedness Innovations (CEPI). There he and his team are responsible for drafting and negotiating legal instruments necessary to progress CEPI’s mission and to support its administrative requirements. He and his team also support external engagement with the wide range of actors that form the CEPI coalition. He previously had a similar role in the Global Health Program at the Bill & Melinda Gates Foundation. In that capacity he has responsibility for providing legal support in a range of projects for the development and delivery of drugs, vaccines and diagnostics in the developing world. Prior to that, he was Associate General Counsel for Intellectual Property Policy at Microsoft Corporation where he was responsible for defining and driving the company-wide policy in all areas of intellectual property. He also practiced in the field public health – including on access to existing medicines and the development of new ones, with particular focus on developing country needs. Mr. Wilder has taught law – including until recently at Georgetown University and earlier at the University of Malaya, Malaysia. Mr. Wilder has an engineering degree from the University of Washington, Seattle, Washington and practiced as a power generation engineer for several years in locations outside the United States. He has a law degree (Juris Doctorate) from the School of Law of the University of New Hampshire.
**CVs of Panelists**

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<tr>
<th><strong>Professor Brook K Baker, Northeastern University School of Law and Senior Policy Analyst, Health Global Access Project, United States of America</strong></th>
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<td>Professor Brook K. Baker teaches at Northeastern University School of Law and is currently a Resident Fellow at its Center for Law, Innovation and Creativity and a co-director of its Program on Human Rights and the Global Economy. He is a Senior Policy Analyst for Health GAP (Global Access Project) and actively engaged in campaigns for universal access to treatment, prevention, and care for people living with HIV/AIDS, especially expanded and improved medical treatment. He has written and consulted extensively on intellectual property rights, trade, investor-state dispute settlement, access to medicines, and medicines regulatory policy, including with the African Union, NEPAD, South Africa, Uganda, ASEAN, Thailand, Indonesia, Brazil, Venezuela, CARICOM, UK DfID, the World Health Organization, the Millennium Development Goals Project, the Global Fund to Fight AIDS, Tuberculosis and Malaria, Open Society Institute, UNAIDS, UNDP, UNITAID, the Medicines Patent Pool, the Global Commission on HIV and the Law, and others. He currently serves as a key advisor to NGO delegation to UNITAID after having previously served as the NGO Board Member to UNITAID.</td>
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<th><strong>Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia</strong></th>
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<td>Dr Olasupo Owoeye is a law academic with expertise in International Intellectual Property Law. He is admitted to the legal profession in Nigeria, New Zealand and Australia. Dr Owoeye practised as a counsel at Punuka Attorneys and Solicitors, a top tier Lagos law firm, before he became a law academic. He is a Senior Lecturer in Law at the Graduate School of Business and Law, RMIT University, Melbourne. He previously taught at both undergraduate and postgraduate levels at the University of Tasmania, the RMIT International University, Vietnam, and the University of South Australia. He was also a Humboldt Research Fellow at the University of Augsburg, Germany and the Catholic University of Lyon, France in 2015. Dr Owoeye is the author of Intellectual Property and Access to Medicines in Africa: A Regional Framework for Access (Routledge, 2019). Dr Owoeye has published over twenty articles in refereed international journals. He has also been a resource person for different academic institutions, national governments and inter-governmental organisations.</td>
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Mr Harry Krishna Bucktowar, Deputy Director Pharmaceutical Services, Ministry of Health and Quality of Life, The Republic of Mauritius

Mr Harry Krishna Bucktowar, Deputy Director Pharmaceutical Services, Ministry of Health and Quality of Life, The Republic of Mauritius He is presently serving the Ministry of Health & Quality of Life, Mauritius, as the substantive Deputy Director for Pharmaceutical Services and has also been involved at the Mauritius Institute of Health and University of Mauritius as visiting lecturer to teach Pharmacology and Pharmaceutics for various audiences. He is an elected member of the Pharmacy Council of Mauritius. After his secondary studies at the prestigious Royal College (Curepipe), he was awarded scholarship under the Indian Council for Cultural Relations (ICCR) Scholarship to study, for his first degree in Pharmacy at the then Bombay University, precisely at the Goa College of Pharmacy. He served as Community Pharmacist for a couple of years in the Private Sector and later joined the Public Sector as a Hospital Pharmacist and Head of Pharmacy Department at Hospital level. He followed further training in Clinical Pharmacy Practice at the Hope Hospital, Manchester University. He was then offered a Post-Degree training under the University of Montpellier I, related to the procurement of pharmaceuticals and related products for the public sector.

He was involved in the mounting of Essential Drug List for hospitals in Mauritius. His training further involved inspection activities at clinical trial sites under the USFDA in various SADC countries He was also the focal person for WHO International Programme for Adverse Reaction Monitoring as Principal Pharmacist heading the Pharmacovigilance Unit, which consequently led to the adherence of Mauritius as the 118th full member country to the programme.

He served as the Registrar of Pharmacy Board, Mauritius, involved in Regulation Issues, which includes registration and access to Pharmaceuticals and related products in Mauritius. He also chaired the Committee for Herbal Supplements mandated to look into market authorization in Mauritius.

Dr Ellen ‘t Hoen, Medicines Law and Policy, France

Ellen ‘t Hoen (1960) is a lawyer and researcher with over 30 years of experience working on pharmaceutical and intellectual property policies. She works as an independent consultant in medicines law and policy for international organisations and governments and does research in the field of intellectual property and health.

From 1999 until 2009 she was the director of policy for Médecins sans Frontières’ Campaign for Access to Essential Medicines. In 2009 she joined WHO/UNITAID to set up the Medicines Patent Pool (MPP), an initiative that negotiates patent licenses to ensure access to affordable generic medicines in low and middle income countries. She was the MPP’s first executive director until 2012.

Since 2012 she directs Medicines Law; Policy, a group of legal and policy experts offering services to international organizations, governments and non-governmental organisations. She has been a consultant to the World Health Organization, UNITAID, Drugs for Neglected Diseases Initiative/GARDP, OXFAM, Southern African
Development Community, the European Commission and the Government of the Netherlands. Since 2016, she is affiliated as a researcher with the Global Health Unit of the University Medical Center Groningen (UMCG).

She was a member of the Lancet Commission on Essential Medicines Policies, and serves on the Advisory Board of Universities Allied for Essential Medicines (UAEM), the Medicines Patent Pool, and the Utrecht Centre for Affordable Biotherapeutics. She is a member of the Editorial Board of the Journal of Public Health Policy.

In 2005, 2006, 2010 and 2011 she was listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property. She has published widely and is the author of several books. In 2017 she received the Prix Prescrire for her latest book “Private Patents and Public Health: Changing intellectual property rules for public health.” She holds a Masters in Law from the University of Amsterdam and a PhD (cum laude) from the University of Groningen, The Netherlands.

Dr Narveshwar Sinha, Chairman, IDEAL Charity, registered with Charities Commission of England and Wales, United Kingdom

Dr Narveshwar Sinha is an Indian born doctor based in the UK. His vision is that the expensive cochlear implants used for the treatment of childhood deafness are made affordable and accessible to the poor who are most in need of this technology. Dr Sinha is a post graduate in Ear, Nose and Throat Surgery (ENT) from Aligarh University in India and also from the Royal College of Surgeons of England. Dr Sinha moved to the United Kingdom in 1988, with a brief spell in India between 1992-1995 when he was a senior ENT Consultant at Apollo Hospital, New Delhi. He was awarded a PhD by the University of Cambridge in UK on his work on cochlear implant technology transfer from USA to five Latin American countries.

He has been involved in the field of cochlear implants in India for over two decades. He had arranged the training of the early cochlear implant teams in London in early 1990s. He visited all the cochlear implant manufacturers in the world to advocate access of this technology for the poor population of the world.

Dr Sinha is the Chairman of IDEAL Charity, registered with the Charities Commission of England and Wales. The charity is involved with working with deaf children in the less developed countries. He has been advocating that cochlear implants be included in the National Essential Medication List in India so that this national regulation could help fixing the cost of the implant so that it is affordable to all.