Pandemic Preparedness in India:
Roundtable Dialogues with Subject Matter Experts and Leaders
The role of technologies in outbreak preparedness and response

Introduction:

The COVID-19 pandemic was an unprecedented global crisis that exposed significant vulnerabilities in public health systems and outbreak preparedness mechanisms worldwide. While many countries and stakeholders have begun resuming normal operations, it is imperative to reflect on the lessons learned from the pandemic and integrate them into future preparedness strategies. A systematic and well-documented approach to capturing these insights is essential for strengthening crisis response frameworks and ensuring greater resilience against future public health emergencies.

Recognizing this critical need, the Isaac Centre for Public Health (ICPH), Indian Institute of Science (IISc), Bengaluru, in collaboration with the Asia Centre for Health Security, National University of Singapore, and the South Asian Field Epidemiology and Technology Network, India, convened a high-level expert roundtable discussion. The objective of this initiative is to foster meaningful dialogue among experts, policymakers, and practitioners to assess India's capabilities in outbreak preparedness, with a particular focus on technological innovations.

The first Expert Roundtable Panel, titled "The Role of Technologies in Outbreak Preparedness and Response," was held on November 29, 2024, at IISc, Bengaluru. The discussion, conducted under Chatham House rules, brought together 15–20 distinguished experts and leaders from various sectors to deliberate on key thematic areas, including vaccine and therapeutic development, novel diagnostic technologies, and biosecurity concerns in biotechnology and biological research. Through a structured series of sessions, participants identified challenges, opportunities, and actionable recommendations to enhance India's pandemic preparedness and response capacity.

This report synthesizes the key discussions, insights, and policy recommendations that emerged from the roundtable. It aims to serve as a reference for stakeholders across government agencies, research institutions, healthcare organizations, and the private sector in shaping a robust and technologically advanced framework for outbreak preparedness in India and the Southeast Asian region.

Methods:

The expert roundtable discussion on "The Role of Technologies in Outbreak Preparedness and Response" was designed as a structured yet open dialogue among key stakeholders in the fields of biotechnology, public health, and pandemic preparedness. The primary objective was to assess India's capabilities, challenges, and opportunities in leveraging biotechnology for outbreak preparedness and response, while synthesizing lessons from the COVID-19 pandemic.

a. Roundtable Structure and Format:

The roundtable was convened on [date] at the Indian Institute of Science (IISc), Bengaluru, in collaboration with the Asia Centre for Health Security, National University of Singapore, and the South Asian Field Epidemiology and Technology Network, India. The discussion followed Chatham House rules, ensuring open and candid exchange of ideas while maintaining participant confidentiality.

The session was structured into five to six thematic discussions, each lasting 1 to 1.5 hours, focusing on critical aspects of biotechnology in pandemic preparedness (Agenda in Annexure 1). Each session was designed to facilitate:

- Expert-led discussions on key challenges and emerging trends.
- Knowledge exchange among stakeholders, including policymakers, industry leaders, and researchers.
- Consensus-building on short- and long-term strategic action points.

b. Participant Selection

The roundtable brought together around 20 distinguished experts (Annexure 2) from diverse backgrounds, including:

- Public health policymakers and government officials.
- Leaders from the vaccine and pharmaceutical industry.
- Scientists specializing in virology, diagnostics, and biosecurity.
- Representatives from regulatory bodies and research institutions.
- Experts in clinical trials, drug regulation, and health economics.

Participants were identified based on their expertise and contributions to pandemic preparedness and response. Invitations were extended to ensure representation across academic, industry, and government sectors to foster a multidisciplinary dialogue.

c. Discussion Topics

The expert panel engaged in discussions on the following key themes:

- Vaccines and Therapeutics – Rapid development, testing, manufacturing, and deployment strategies.
- New Diagnostic Technologies – Innovations for detecting unknown and high-risk pathogens.
- Biosecurity in Biotechnology and Research – Risk mitigation for laboratory spillovers and dual-use research concerns.

d. Data Collection and Documentation

A dedicated facilitation team moderated the discussions, ensuring that key insights, challenges, and recommendations were systematically captured. The proceedings were documented through:

- Session notes and thematic summaries compiled by rapporteurs.
- Expert consensus statements on critical action points.
- Post-discussion synthesis of lessons learned and strategic recommendations.

The findings from this roundtable will inform future policy discussions, research priorities, and strategic initiatives aimed at strengthening India's pandemic preparedness framework.

Key Discussions:

Session 1: Bio-threats in India: Current concerns and future preparedness

This session focused on identifying and discussing the bio-threats that India should prioritize over the next 5 to 10 years. Discussions revolved around those threats receiving attention in India, those that are being overlooked as well as ways to improve the focus on underappreciated risks. Drawing lessons from the COVID-19 pandemic and recent Mpox outbreaks, the discussion looked at the importance of proactively identifying potential threats and preparing for them.

Potential Biothreats of Concern for India

There was consensus among the experts present that the priority concerns are:

- Nipah virus - Although this is currently confined to Kerala, there was concern that the virus could have already or could in the near future extend its range in bats and other reservoirs and occasionally spillover into human populations in other states in India that are less aggressive about testing and identifying small clusters of cases or outbreaks. Thus, a naturally developed variant form of Nipah virus that has higher person to person transmission potential could emerge and go undetected early on when containment is easiest. Due to Nipah virus's very high virulence and our limited understanding of this virus and why the large Kerala outbreaks occurred, there was a consensus that India should prioritize this pathogen.
- Avian influenza - Influenza has traditionally been the pathogen most likely to result in a new pandemic due to its high degree of virulence, transmissibility, and rapid genetic change. Zoonotic influenza viruses are known to reassort with human influenza viruses which can lead to sudden development of a new pandemic strain. The expansion of commercial poultry farming and swine farming in Asia over the past 30 years increases this risk. H5N1 variants are infecting both wild and domesticated birds and random spillovers to human farm workers is happening in the Asia region. For these reasons, the experts all agreed that Avian influenza should remain a priority pathogen in India for both the human health sector and the livestock and wildlife sectors.
- Pathogens of potential use as bioterrorism or germ warfare agents - The major concerns are synthetic pathogens such as Smallpox or a genetically altered form of influenza or another respiratory virus, or a genetically altered form of Nipah or another hemorrhagic/encephalitic virus. The roundtable participants were not explicit in their specific fears partly because it is not their area of study and expertise. However, most agreed that some preparation for a potential Smallpox or lethal form of Mpox release should be made by the Government of India and other countries. The participants did not discuss whether neurotoxins and other toxins should be a

priority in India.

- Bacterial antimicrobial resistant pathogens - The experts agreed that this is currently India's biggest infectious diseases threat. It is estimated that resistant pathogens lead to 1-2 million excess deaths in India each year. And the scale and degree of resistance continues to get worse each year as antibiotic consumption grows unchecked and these resistant pathogens spread person to person at home and in hospitals. The experts thought that multidrug resistance in tuberculosis, salmonella typhi, klebsiella, e coli, and staph aureus were most concerning from a public health perspective. Much can be done to address this current and future threat if the political will to do so grows and right strategies are then deployed broadly.
- Pathogens currently in India but at lower risk of becoming a epidemic or pandemic of high societal consequence (Kyasanur Forest Disease, Chikungunya, Dengue, Scrub Typhus, etc.) - Kyasanur Forest Disease (KFD) is a zoonotic viral pathogen that is endemic in India only and thus global understanding of it remains limited. It is a viral pathogen that our experts believe is important to prioritize in India for these reasons. It is currently not especially virulent nor contagious but there is some fear that the virus could evolve into something more concerning as a public health threat. Vector borne viral and rickettsial pathogens are currently major public health issues but the expert participants did not believe they were likely to evolve into diseases that would kill millions or disrupt society in major ways and thus are less likely to be pandemic or bio-threat risk.
- Pathogens not currently found in India but at risk of importation (Yellow Fever, Crimean-Congo Hemorrhagic Fever (CCRF), Ebola, new Monkeypox strains, etc) - Vigilance against yellow fever is required as India possesses vectors and environmental conditions conducive to its spread, despite no recorded cases so far. Ebola, Mpox, CCRF, Rift valley fever are unlikely to pose serious or immediate threats to India unless a new strain develops and spreads in Africa that has pandemic potential.

Challenges in Addressing Biothreats and Preparedness in India

Certain biothreats may receive limited attention owing to their localized prevalence, such as Nipah in Kerala and the Chandipura virus in Gujarat, which may result in their exclusion as a national priority. It also leads to fragmented preparedness strategies rather than a unified national approach. India's diagnostic capacity faces challenges, with limited availability of timely and effective diagnostic tests for detecting new or re-emerging pathogens. This increases the risk of spreading pathogens and hinders the capacity to address biothreats proactively. The COVID pandemic brought to front the need for preparedness for pathogens like coronaviruses. The investments in studying SARS and MERV and understanding their virology were incredibly important in understanding and addressing SARS-COV2 once it emerged. Such lessons should not be forgotten.

Key recommendations from expert participants

1. As an important part of pandemic preparedness efforts, formal pathogen prioritization exercises should be conducted at the national level and at the state level. Although our discussion of the various pathogen threats to India was rich and enlightening, it was not a decision making process. Formalizing this can result in more focused bio threat preparedness and prevention initiatives in India such as stronger surveillance efforts looking for specific pathogens, more robust vaccine and therapeutic development initiatives, more research funding into specific pathogens, and more

focused crisis management simulation exercises.

2. Nipah, avian influenza, and AMR pathogens emerged from our discussions as the most pressing bio-threats. Many of India's experts already are aware of this. But it remains unclear if this is being productively channelled into priority research and development and multi-sectoral crisis management planning activities. National and state level AMR containment action plans need to be robustly implemented with antibiotic consumption reduced by perhaps 50%.

3. Smallpox appears to be an under-appreciated bio-threat for the obvious reason that it is not a naturally occurring health threat in the 21st century. However, the threat of a Smallpox or other pox virus deliberate release event is real. Therefore, one recommendation is to elevate India's preparedness for Smallpox including the development and manufacturing of Smallpox vaccine and Smallpox rapid diagnostic tests (RDTs) and the creation of Smallpox specific crisis management planning exercises.

4. India should expand its human resource expertise in specific pathogens of high risk including more virologists, epidemiologists, and crisis management experts that work on these pathogens either part time or full time.

Session 2: Biosecurity in biotech and biological research

The session focused on strategies to mitigate the risk of biosecurity events in both public and private sector laboratories. Discussions revolved around systems for identifying and monitoring high-risk research laboratories, as well as the challenges in enforcing policies for biosecurity. Topics included policies for managing moderate to high-risk labs and regulating dual-use research. Other points for discussions included monitoring DNA synthesis activities and ensuring proper oversight of organizations involved in selling DNA sequences, highlighting the need for robust policies and enforcement mechanisms to manage these risks effectively.

Laboratory safety and biosecurity levels

Our expert participants believed that most BSL-3 and BSL-4 laboratories have robust measures in place to maintain biosafety. However, BSL-2 labs in academic and industrial settings face challenges in awareness and monitoring. The practice of reporting and learning from lab leaks or near misses is weak and piecemeal. The participants thought that new strategies that de-emphasize punitive measures and focus more on corrective lessons should be a national priority. Cybersecurity is equally important to protect sensitive laboratory data and should receive more attention than it currently does. The participants urged a smarter, more institutionally driven approach to non high risk/high security laboratories in order to avoid over-regulation and cost inefficiencies. Participants suggested a focus on awareness and training, especially for BSL-2 labs, ensuring balanced regulation, systems to learn from near miss lab incidents, and strengthening cybersecurity protocols. Expanding national laboratory networks and prioritising monitoring and capacity building across all safety levels will help tackle these concerns.

Strengthening biosecurity policies and modernizing regulations in India

Biosecurity policies in India are currently guided by the Disaster Management Act which is due for an upcoming revision along with the amendment of the Crisis Management Committee. The Epidemic Diseases Act of 1897, which was invoked during COVID-19 lacks provisions for modern biosecurity challenges like DNA synthesis and sequencing oversight. Cybersecurity in genomic sequencing facilities is an area of concern, emphasizing the need for robust regulations to manage data and prevent misuse.

Biosecurity regulations and international collaboration

There is a need for a dedicated agency to focus on bio-warfare deterrence and the establishment of a regulatory framework for biosecurity. Collaborations with countries like the U.S.A and regional initiatives such as the Quad could facilitate the sharing of best practices. Participants thought that engagement of the National Security Council and the security sector more generally would bring new insights and approaches including a better focus on assessing real laboratory spillover and cyber risks within the research and biomedical sciences sectors.

Laboratory safety in high-risk research

Participants agreed that laboratory safety in high risk research facilities that conduct gain-of-function studies and DNA synthesis needs careful regulation. While BSL categories are useful for risk assessment, a focus on the specific research conducted is necessary. India's regulations, particularly for gain-of-function research are robust, but challenges persist in implementation. Some institutions have trained biosecurity officers, but there is a need to prioritise the roles of the biosecurity officers, particularly in academic settings. The key is to avoid over-regulation, focusing instead on educating researchers and using empowered and well trained biosecurity officers to improve adherence to existing regulations.

Key recommendations

1. A national inventory of high risk research laboratories in the academic, government/defense, and biotech industry sectors should be conducted regularly. Clear definitions of high risk research and high risk laboratories are needed. The Ministry of Health (ICMR), the Department of Biotechnology, and the National Security Council should jointly own this responsibility. With this information, a network of well trained and empowered biosecurity/biosafety officers can ensure these laboratories are safe and learning from near miss incidents.

2. There is a need to address changes in biosecurity guidelines, particularly the code of conduct for scientists. The changes can include four key elements, namely:

    - ***Awareness****: Educating scientists on applicable national and international laws.*
    - ***Ethical Research****: Clear guidelines for responsible research conduct are essential, with effective dissemination and adoption across all labs.*
    - ***Institutional Oversight****: Strong mechanisms are required to mitigate risks, especially in dual-use research scenarios and to respond to potential leaks.*
    - ***Culture of Safety****: Building a robust safety culture through training, monitoring, and*

desktop exercises to assess preparedness.

3. Capacity building through training, workshops and audits are crucial to educate researchers and scientists on risks, threats and compliance requirements. Table-top exercises with the inclusion of real life scenarios can be adopted to make training more effective. Similar to mandatory microbiology and infection control courses for medical practitioners, research scholars should undergo compulsory training on risk assessment methodologies, dual-use concerns and gain-of-function research protocols.

4. To encourage reporting of incidents (e.g., spills or accidents), punitive actions should be balanced to avoid fear of punishment, ensuring a culture of transparency and accountability. The practice of sharing near-misses can be adopted, which is a significant learning opportunity.

5. The development of a 'READ' framework that emphasizes reviewing systems to identify gaps, enhancing education, assessing research vulnerabilities and documenting best practices can help in the strengthening of biosafety and biosecurity efforts.

6. Industries with established SOPs and good laboratory practices can share these with academic and lesser-known institutions to improve compliance and practices. Workshops can facilitate this knowledge transfer.

Session 3: Advanced therapeutics

The session explored the state of monoclonal antibodies (mAbs), anti-toxins, therapeutic vaccines, and advanced small molecule pharmaceuticals in India, with a focus on bio-threat preparedness. The main themes explored in this session were related to a) Government and international agency policies, funding, and incentives to strengthen advanced therapeutics development and scale production; b) Biotech industry capacity and commitment to rapidly develop new advanced therapeutics.

Lessons learnt from SARS-CoV-2 experience

- COVID specific monoclonal antibodies (bamlanivimab/etesevimab and casirivimab/im-devimab) received initial emergency use authorization in India in May 2021 (during the peak of the delta wave). However, India was not prepared to effectively scale up the use of these advanced biologics due to a) excessive cost (high priced western drug plus high import duty), b) somewhat limited initial evidence of its effectiveness especially outside of US/Europe, c) the need to give early on in a high risk patient's covid illness before the patients becomes severely ill or hospitalized, d) lack of awareness among clinicians and the general public of its use and benefits, e) lack of a Government of India strategy for its use. Therefore the drug was not used frequently and investments in Indian manufacturing were not prioritized.
- Some efforts to spearhead the emergent development of effective monoclonal antibodies for treatment were made. One example was an IAVI, Merck, and Serum Institute collabo-ration announced in October 2020. However, it is unclear why this investment initiative

did not succeed. Perhaps it is a lesson that such initiatives need to begin before a bio-threat crisis begins or in the first 100 days of a crisis.

- Tocilizumab, an anti-inflammatory mAb, was extensively used during the pandemic but faced pricing issues due to import dependence.
- The antiviral medicine Remdesivir was manufactured in India early in the pandemic and was somewhat widely used across India despite its mixed evidence for any significant effectiveness. Other drugs such as ivermectin were widely used despite no evidence of its effectiveness. This is evidence that India can scale up production and distribution of small molecule medicines in crisis situations. It is also evidence that India can improve the process of deciding which medicines to promote and distribute and how to regulate the use of ineffective medicines during a health crisis.
- The antivirals molnupiravir (developed by Merck) and nirmatrelvir/ritonavir (trade name of Paxlovid developed by Pfizer) were generally not widely used in India despite there proven effectiveness in preventing severe illness in high risk patients treated early in their COVID illness. 19 Indian pharmaceutical companies submitted requests to manufacture a generic form of Paxlovid under the UN medicines patent pool (MPP). At least 2 companies (Zenara and Hetero) began producing and selling Paxlovid in India by late 2022. The cost was reasonable at 5200 INR ($60 US) per treatment course compared with a retail price of over $1500 in the US. The main reason for it's limited use was a lack of promotion of this medicine by the Government of India or medical professional bodies in India. It was not included in COVID treatment guidelines. This was likely due to the fact that this antiviral medicine became available only in later 2022 when COVID was no longer viewed as a major public health issue in India. The milder omicron variant was predominant and most clinicians and the public did not believe that early treatment was required to prevent severe illness or long covid even among high risk populations. This was in marked contrast to many other countries including the US, UK, and Singapore that had large numbers of high risk patients and saw early Paxlovid treatment as a cost effective way to reduce hospitalizations and long covid. This particular experience in India has many lessons for future health crisis management decision making in India.
- COVID-19 demonstrated that sudden, ad hoc funding did not yield effective outcomes. Routine funding modalities from national level funders do not distinguish between strategic research versus other research projects. To further strengthen preparedness, India should consider establishing a dedicated organization similar to the Biomedical Advanced Research and Development Authority (BARDA) in the United States to facilitate research, funding, and rapid deployment of countermeasures during emergencies.

Monoclonal Antibodies

- **Broader applications of monoclonal antibodies:** Our expert participants believed that foundational platforms already exist, as antibodies are being developed for autoimmune disorders, inflammation, and cancer**.** The existing platforms can be leveraged and these antibodies can be repurposed and extrapolated to address specific indications during a pandemic.

- **Regulatory bottlenecks in development of biosimilars:** Current biosimilar development timelines in India span 5–6 years due to lengthy clinical trials. Global regulatory agencies (FDA, EMA) are exploring fast-tracking approaches by tailoring trial designs (e.g., reduced duration or sample size) in active collaboration with pharma companies.

- **Possible solutions for shortening timelines**: For pandemic countermeasures, phase 3 efficacy trials are often infeasible due to limited cases. To address this, the Federal Drug Administration Authority, USA, employs the Animal Rule, allowing phase 1, phase 2, and robust animal challenge studies to support emergency use or limited-use licensure. This approach is vital for diseases with pandemic potential too, such as for Nipah, Ebola, KFD, CCHF. However, animal challenge studies require a good animal model, and facilities harbouring such models are rare across the world. India should pre-emptively develop robust animal models for priority pathogens (e.g., Nipah, H5N1, Ebola) to facilitate swift countermeasure testing.

- **Alternative approaches to aid/accelerate mAb development:** One strategy is to expedite mAb development is targeting receptors rather than specific strains, as receptors remain constant even when strains mutate. This approach could significantly shorten timelines; however, it carries the risk of potential adverse reactions**.** An alternative is to develop polyclonal antibodies**,** a method that has been successfully tested in the US during COVID-19. This method reduces constraints by covering broader immunogenicity and represents an advancement in translating innovative concepts into tangible outcomes. While these approaches improve flexibility and scientific rigor, they do not yet enable mAb development within 100 days**,** highlighting the need for further breakthroughs in the field.

- **Focused funding and capacity for monoclonal antibody development:** There are international examples of dedicated Government funding to the companies developing mAbs for indications relevant to emergency public health needs. In India, while funding mechanisms like BIRAC exist, there is a lack of dedicated, focused funding for companies exclusively working on mAbs for neglected diseases. Establishing such targeted funding could bridge this gap and accelerate progress in this critical area. Several companies, with approximately 90% focus on mAbs, are transitioning from being innovators to developing biosimilars. Many are keen to collaborate with Indian manufacturers due to India's significantly lower drug production costs. Thus, India already has sufficient capacity in terms of platforms, manufacturing infrastructure, researchers, laboratories**,** and expertise in monoclonal antibody development. The key requirement is a trigger to channel these resources toward addressing priority pathogens**.**

<u>Limitation of mAbs</u>:

- It is challenging to develop mAbs within a 100-day timeline, making them impractical as immediate pandemic countermeasures. The effectiveness of mAbs depends heavily on the pathogen and stage of the disease. Hence, mAbs may not work against all pathogens. High mutation rates, the need for large doses, and the lack of robust efficacy models further complicate their development. Given these challenges, developing mAbs for novel pathogens is a high-risk endeavor, requiring significant investment and careful consideration of both scientific and commercial viability.

Bridging academia, industry, and government for collaborative research:

The current engagement between academia, industry, and government in India remains insufficient for effective mapping of research efforts to industrial applications. While numerous biotech programs exist across universities, their research often lacks direct applicability for industry adoption. Large-scale, coordinated research and stronger technology transfer offices are critical to bridging this gap. Organizations like the Association of Biotechnology Led Enterprises (ABLE) have initiated efforts to improve academia-industry engagement, but much more needs to be done to align research with industrial and societal needs.

Key recommendations

1. It is clear that India already has expertise and systems to develop and manufacture new monoclonal antibodies and pharmaceuticals. Some shift in mindset and investment is needed toward new therapeutics instead of a concentrated focus on creating bio-equivalents and generic versions of existing therapeutics. The biggest priority is establishing clear communications and policies to motivate the biotech and pharmaceutical sectors to invest in monoclonal antibodies and small molecule drug development and manufacturing against potential severe biologic threats in India. This should be aimed at private biotech industry leaders and startups, academic research institutes, and government research institutions. International partnerships should also be encouraged.

2. The most effective way to stimulate investment is by communicating the demand for bio-threat countermeasures and establishing government commitment to purchase and stockpile effective therapeutic countermeasures. Once this demand side is established, India's research and biotech sectors will likely respond. Of course, India can make this path easier by reducing tariffs on imported supplies needed for bio-threat countermeasure production and by creating clear and feasible pathways for approval of new therapeutics aimed at pandemic risk pathogens.

3. Safe and effective animal models for testing potential therapeutic countermeasures are needed. Mapping existing animal facilities and leveraging resources like GCLP labs funded by DBT such as NIAB, Hyderabad would enhance preparedness and facilitate efficient mAb research and development.

4. Developing steady production supplies and robust demand for monoclonal antibodies against known pathogens (such as for RSV), toxins, and diseases (cancer, autoimmune diseases, etc.) would clearly help the sector develop the capacity to take on bio-threat countermeasures as well. Therefore, efforts should be made to stimulate this aspect of medical therapeutics development, testing, and manufacturing in India.

5. Regulatory and therapeutic drug development and testing experts should convene a working

group to determine the optimal way to evaluate future monoclonal antibiotics and small molecule drugs aimed at pathogens and toxins deemed to be high risk bio-threats to India. It is hard to study the efficacy of such new countermeasures given how rare these pathogens and toxins are in India currently. Thus, creative strategies to address this are needed immediately.

Session 4: India's vaccine preparedness and challenges

The session focused on India's readiness to develop vaccines for epidemic and biothreat pathogens and also addressed the 100-day challenge. Key discussions revolved around vaccine evaluation, manufacturing capacity and prioritizing high-risk populations. Emphasis was placed on streamlining regulatory processes, fostering global partnerships and establishing government incentives for vaccine innovation. Gaps in vaccine development, trial efficiency and post-vaccination safety monitoring were identified, along with the need for rapid production capacity and investment in epidemic preparedness.

Phases of pandemic preparedness in vaccine development

Pandemic preparedness with regards to vaccine development can be thought to encompass three phases, namely the pre-pandemic, pandemic and post-pandemic phases. The pre-pandemic phase includes stockpiling 100,000 to 5 million doses for high-risk pathogens to enable prompt ring-fencing of front-line workers and containment of spread. This can be exemplified by the success in developing a vaccine for the Ebola virus in 62 days and the development of an experimental Nipah vaccine using the adenovector platform. For the pandemic phase, up to 5-10 billion doses of vaccines will need to be produced, distributed and monitored for safety and effectiveness potentially using multiple vaccine platforms in order to give governments and the public vaccine choices. Post-pandemic, honest and detailed after action reviews and documentation of lessons learned in the vaccine sector are required if improvements and new strategies are to be developed and properly funded.

It is important to note that the efficacy and real world effectiveness of vaccines against a bio-threat pathogen is not a certainty. The world and India was fortunate that vaccines against SARS-COV2 were rapidly developed and proven effective in reducing the risk of severe disease and thus saved millions of lives. This was in part due to the fact that virologists and vaccinologists had spent 17 years studying SARS and then MERV which are similarly structured coronaviruses and had identified a viral surface receptor spike (S) protein as a relatively stable and effective vaccine target. In fact, all of the licensed SARS-CoV2 vaccines create enough immune protection to prevent much hospitalization and death but not enough immune protection to eliminate infection or prevent the ongoing spread of disease.

The global vaccine community has not been as successful with some other high priority pathogens. Despite 30+ years of investments, an effective HIV vaccine has not been developed. Influenza vaccines must be modified and re-manufactured each year and typically create no more than 50% effectiveness and sometimes much less. Effective vaccines against tuberculosis, Hepatitis C, Herpes Simplex virus (HSV), staph aureus, most enteric bacteria (Klebsiella, E. coli, etc.), syphilis, rickettsia, and many other pathogens are still being developed and evaluated and may or may not eventually prove effective. Vaccines against dengue, ebola, RSV, malaria are just now being evaluated and licensed globally despite 20-40 years of research and clinical trial investments. The bottom line lesson from all this is that investments in vaccine development take much time and investments and are not guaranteed to be successful. But as the science of immunology, virology and microbiology, and toxicology continues to grow and the techniques for vaccine development improve and grow, the chances of at least partial effectiveness of new vaccines against new pathogens will improve, assuming investments also grow.

Challenges in regulatory processes and industry collaboration

A key challenge in India is the lack of a streamlined regulatory framework for handling emergencies like pandemics which cause delays in approvals for vaccine production and trials. For example, developing a vaccine for Nipah requires numerous permissions—up to 39 in some cases—including approvals from regulatory bodies even for initial R&D. There is a critical need for reducing timelines and minimizing permission bottlenecks, especially for pandemic-critical products. Instead of prolonged waiting periods, there should be a clear deadline of limited days for regulatory decisions, enabling faster innovation and deployment during national health emergencies. A system can be created where after a company with proven GMP standards submits an application, they can proceed with manufacturing while awaiting final approvals. This parallel processing would significantly expedite vaccine readiness. While traditional platforms like inactivated vaccines remain a priority, newer technologies like DNA, mRNA and subunit vaccines must be embraced in India. Regulators should focus on data-driven decisions without bias toward specific platforms.

Creating a demand environment for new vaccines

Creating demand for new vaccines in India and the global vaccine market should be the number 1 priority of the vaccine sector in India. Of course, new vaccines must undergo rigorous safety and efficacy testing and generally should be cost-effective. But despite this requirement, India has been generally slow to introduce and promote new vaccines in both the public and private sectors. Seasonal influenza vaccines, HPV vaccines, meningococcal vaccines, typhoid vaccines, cholera vaccines, RSV vaccines, and COVID booster vaccines are under-utilized in India. This sends a message to the business and research sectors that the market for vaccines in India is uncertain and thus a risky investment. Having said this, India remains generally pro-vaccine with little public anti-vaccine sentiment. And policy makers generally understand the value of vaccines in preventing disease and promoting health. Thus, the demand challenge appears to be in the process of evaluating new candidate vaccines and getting new vaccines into the routine adult and childhood vaccine schedule.

There is also a need for dedicated funding to support vaccine research for diseases with low commercial interest but high public health importance. Attracting private investors remains challenging due to the delayed return on investment in pandemic vaccine development, making government support vital through substantial funding and incentives. Global organizations play a crucial role by providing financial resources, technical expertise and support for infrastructure and global research collaborations. Such collaborative efforts between international bodies and the Indian government have significantly enhanced India's capacity to respond to public health challenges, including influenza and Nipah vaccine development. While industry invests in vaccines with market potential, it often neglects those meant for stockpiling due to limited financial returns. To address this, government agencies should step in to fund preclinical research, clinical trials and stockpiling for such vaccines. A new funding mechanism has been established to drive industry-academia collaboration, ensuring the development of critical vaccines for pandemic preparedness despite low market incentives. But it is yet to be seen whether this new funding mechanism is robust and streamlined enough to push vaccine R&D to the next level and stimulate neglected vaccine development, evaluation, and stockpiling. That is much to ask under a single government initiative. Additional government initiatives and CSR initiatives are needed to support robust new vaccine development in India.

Strategic investments and infrastructure for long-term preparedness

Pandemic preparedness must be recognized as a strategic sector that requires long-term investment and preparedness, even when the threat appears intangible and distant. Challenges beyond technical readiness, such as supply chain dependencies on raw materials and equipment from abroad, require smart self-sufficient manufacturing capabilities. Addressing these gaps systematically during non-pandemic times will ensure timely response during future outbreaks.

The platform needed at the time of a pandemic is not always known and therefore, establishing versatile technology platforms for pandemic preparedness will enable a rapid response to emerging threats. Moreover, setting up and qualifying production facilities for pandemic response can take months, making it impractical to establish them during a crisis. Instead, facilities can be kept "warm" by producing other products, which can then be converted into the required platform to allow quick vaccine production when needed. Thus, general investments and streamlined processes to bring new non-pandemic vaccines to market in India and globally will have a positive spillover impact on pandemic vaccine preparedness capacities and systems.

The 100 day Challenge and India's Capacity to Meet this Challenge

Globally pandemic vaccine preparedness has begun to focus on the challenge of producing an effective vaccine within 100 days of the onset of the biologic crisis. As a comparison, it took approximately 300 days from the announcement of a new coronavirus outbreak in China for the first global COVID vaccine to be licensed for use. And for COVID vaccines, the global vaccine community had a headstart in that vaccines for SARS and MERV were being researched prior to COVID's onset. There are many obstacles to meet the 100 day challenge, but the biggest obstacle appears to be the ability to rapidly evaluate candidate vaccines to decide which are safe and effective.

Participants in our roundtable recognized this major obstacle and saw overcoming this as both a mindset challenge and a logistical challenge. The mindset challenge is to understand that evaluating and approving candidate vaccines in under 100 days requires new approaches to evaluation science and new criteria for emergency use approval of candidate vaccines for public use. Large randomized controlled vaccine field trials among healthy volunteers are too slow and often inconclusive, especially if the risk of infection in the study population is low or sporadic. For candidate vaccines to be evaluated and licensed in less than 100 days, focus may need to turn to the following:

- Use of animal models and human immunologic markers to reduce the number of candidate vaccines down to 5 or less for full evaluation.
- Separate safety studies from efficacy studies. In other words, safety studies can be organized ahead of time and some even conducted before a biologic crisis event and can grow in size and duration once initial basic safety is ensured.
- Efficacy studies may require establishing clinical challenge study protocols and institutional capacity to do so safely and effectively. A clinical challenge study is one in which participants are intentionally exposed to the pathogen or toxin and evaluated in terms of how well they are able to fight off infection or reduce the severity of illness. Thus, the ethics of these types of studies need to be well vetted and discussed ahead of a crisis.
- Rapid efficacy studies may also entail evaluating candidate vaccines in the most at-risk populations in terms of exposure risk and severity risk. In an outbreak setting, this might entail studying candidate vaccines in outbreak affected communities or in frontline populations. These need to be designed and organized ahead of time.
- Committees and agencies responsible for weighing the evidence on vaccine safety and efficacy need to be trained on how to evaluate candidate vaccines in a crisis situation using these alternative study designs. Without this, the wrong vaccine candidates may be approved or delayed unnecessarily, costing lives and reducing the chances of bio threat containment.
- It is also possible that effectiveness of a vaccine against a pandemic pathogen may be inconclusive and decisions will need to be made whether to use such vaccines anyway and study their effectiveness as part of the vaccine introduction (a phase 4 post introduction vaccine effectiveness assessment). India needs to contemplate and be prepared for these very difficult decisions.

Key recommendations

1. The Government of India should fully commit the country to achieving the 100 day challenge (from discovery of a new bio threat to public access to a new vaccine). To achieve this, India will need to increase investments into new vaccines against bio-threat pathogens, create vaccine templates and stockpiles, and develop new strategies and processes to evaluate candidate vaccine safety and efficacy among at-risk populations.
2. Incentives for Indian vaccine developers/manufacturers to create vaccines against potential pandemic pathogens and toxins should be smartly implemented. One example is for the Government of India to guarantee purchase of these new vaccines for emergency stockpiling, assuming the new vaccine is proven to be safe and likely to be effective.
3. The Government of India should be more aggressive about signaling to the vaccine industry that new vaccines are in demand and likely to be incorporated into the adult and childhood vaccination recommendations. This will stimulate the Indian vaccine industry to invest in new partnerships and new vaccine products and thus build strong capacity in this aspect of health security for India.
4. Animal models and human immunologic markers of protection should be developed and validated which will strengthen the evidence for and against the clinical efficacy of candidate vaccines during emergencies and thus improve the vaccine vetting process.
5. Regulatory pathways and vaccine licensing reviews should be simplified by pre-defining protocols, removing redundant steps and adopting fast-track approval mechanisms as part of

India's pandemic preparedness initiatives and during a bio-threat crisis.

6. Critical vaccine production materials, such as reagents, equipment and gene/protein synthesis capabilities, are often sourced internationally, causing delays. Establishing local manufacturing and technologies will help mitigate reliance on global supply chains.
7. The Government of India should convene a series of roundtable meetings to develop strategies to evaluate new vaccines against bio-threat pathogens for safety and efficacy that are both time sensitive and realistic. This should include development of guidelines and processes for human challenge studies and phase 4 vaccine effectiveness assessments during outbreaks.

Session 5: New diagnostics for known and unknown pathogens

Discussions in this session revolved around current laboratory capability to identify novel pathogens or toxins accurately and efficiently using whole genome sequencing or other techniques; past experience in India with the development, production and field use of new rapid diagnostic tests (for SARS-CoV2, Nipah virus, Mpox, TB, Influenza, RSV, Typhoid, HIV, Hepatitis, etc.); likely role of new diagnostics including new point of care tests in India in the next 5 years or during a new bio threat outbreak/pandemic; and incentives for the Indian biotech industry to invest in new disease diagnostics; structures and capacities to evaluate new diagnostics in real world setting.

Lessons from India's experience in developing, producing, and deploying new diagnostic tests during COVID-19

The expert participants agreed that India responded well overall to the COVID-19 pandemic in terms of laboratory testing. India rapidly developed molecular testing capacity, initially in a few reference centers and then broadly across public and private sector laboratories in a coordinated way. The cost of testing was initially far too expensive from an equity standpoint. Public-private partnerships enabled the establishment of rapid diagnostic manufacturing capabilities, reducing costs from $60 to $3 per test. This along with state and national policy changes related to consumer price limits, made COVID testing less expensive and more equitable. Timeliness of test result reporting was at times a major issue and highlights the importance of developing point of care rapid tests to avoid delays in clinical and public health decision making.

Despite these general positive developments, the creation and manufacturing of diagnostics faced significant hurdles in establishing supply chains, including reagents, antibodies, testing paper and equipment, which worsened during lockdowns. Access to clinical samples for validation was cumbersome due to bureaucratic procedures, hampering timely development. However, post-pandemic, India developed clearer protocols for accessing bio-samples and set up multiple bio-depositories with defined mandates. Ecosystem improvements include creating local supply chains and supporting diagnostic innovation through initiatives like INDX. An important issue that was faced during COVID-19 was that research institutions simultaneously acted as developers of new diagnostics and as regulatory authorities, creating conflicts of interest and confusion. Post-COVID, the distinction between research and regulatory roles has been clarified.

It is important to note that India did not generally embrace the development and use of point of care rapid diagnostic tests (RDTs). Many other countries (i.e., US, UK, Singapore) switched to RDTs in 2022 as the first line diagnostic test. India did not. This needs further exploration as to the reasons and lessons from this.

Role of diagnostics in pandemic preparedness and India's current capacity

Our expert panel agreed that accurate and easy to use diagnostics are of vital importance in identifying, containing, and managing a biologic crisis. There are 2 main categories of diagnostic tests to consider. 1) tests that identify new or growing threats that are employed as part of public health surveillance systems and/or for more accurate clinical diagnosis and care; 2) tests that can be readily scaled up and distributed as point of care diagnostics during a biologic crisis.

In the case of tests to identify new threats, the main focus has been on whole genome sequencing (WGS) and multiplex PCR assays. WGS has an important role in identifying pathogens previously not known to cause illness in India or globally or identify a cause of illness missed by clinicians and more routine diagnostics (PCRs and cultures). It is also important for identifying and tracking pathogen evolution as a potential early warning tool and a genetic epidemiology tool. India has a growing capacity to use WGS in tertiary public health labs such at the National Institute of Virology in Pune, in research institutions, and in a number of commercial laboratories. It is unclear how much on-the-ground capacity there is to interpret and use WGS to confirm the etiology of clusters of unknown illness or to "fingerprint" cases separated by time and place to better understand outbreak size and evolution. WGS also likely has a role in environment surveillance such as wastewater surveillance in urban areas.

Multiplex PCR tests are currently much more conventionally available in India and used clinically, in epidemiologic research, and in outbreaks. The cost continues to drop which makes it more likely to be used. One challenge is which diseases to include in the multiplex assays. Another challenge is interpretation since the sensitivity of PCR testing is low for some diseases (i.e., rickettsia, leptospirosis, typhoid) or non-specific for other diseases (some enteric infections and respiratory infections where non ill persons can carry non-virulent forms of these virus and bacteria and thus be PCR positive). Despite this, multiplex PCR testing has the potential to be very useful for India in bio-threat preparedness and early warning surveillance.

In the case of scaling up point of care testing either before or during a biologic crisis, India appears to have mixed capacity. COVID-19 showed that molecular testing can be scaled up quickly using a combination of public and private laboratories. And that capacity to conduct molecular testing is not going away. A single company in India can currently produce 350,000 PCR test kits daily, with the capability to meet 40% of a demand for 1 million kits. The majority of diagnostic tests, except for TB, are currently utilized in the private sector. TB remains the most significant public procurement example. The bottleneck may be in local production capacity as raw ingredients for PCR reagents are often imported into India. Another bottleneck may be clear validation and licensing approval in a rapidly evolving crisis and procurement delays and indecision from state or national government health ministries. PCR-based diagnostics for Tuberculosis is a good example of the challenges of scaling up from both a demand and supply standpoint. The clinical and public health evidence of the value of more sensitive PCR-based tests for Tuberculosis has been clear for many years and yet the ground level availability of this testing for suspected TB patients is only now growing and has not reached its full potential. Cost was one bottleneck but even that has been addressed by local Indian diagnostic test manufacturers.

Point of care testing is unfortunately less developed and available in India for a combination of reasons. The biggest reason appears to be a lack of demand for these tests by health officials, professional bodies that develop guidelines, microbiologists, and clinicians themselves. There is a bias against point of care diagnostics likely for financial reasons and due to a lack of clarity on how best to incorporate point of care testing into clinical decision making and routine surveillance. PCR-based diagnostics and microbiologic culturing has set the standard for test sensitivity and specificity in India which makes rapid diagnostic tests (RDTs) more challenging to get approved and get used. This demand issue results in a lack of investment funding as return on investment is currently low. Of course, there are also challenges in creating RDTs (point of care tests) that are cheap, accurate, and easy to use in small clinics and field settings. These challenges need to be overcome as the availability and use of accurate point of care tests are potential game changers during a significant biological crisis. The best examples are point of care tests for HIV and malaria which have revolutionized the public health approach to these global challenges.

Diagnostic capabilities for well known toxins like lead and arsenic are limited to a few specialized centers and mass spectrometry systems, which are scarce and expensive. The average blood lead level test currently costs around 2000 INR ($25) per test in India which makes screening implausible. Due to this, toxicology testing lacks scale and accessibility. Even drug toxicology screening tests are expensive and inaccessible in most of India. The situation is even worse when it comes to testing for rare or unknown toxins in India. There are 41 GLP certified toxicology testing labs in India but it is unclear how many of them can rapidly test for unknown or rare human toxins.

Diagnostics for animal health are often neglected due to economic constraints in the animal husbandry sector, which operates with minimal profit margins. Zoonotic diseases often lack concurrent utility for farmers, as diagnosing animals offers little actionable benefit without affordable treatments or compensation strategies. Unlike human health systems, diagnostics for animals are rarely prioritized unless tied to public health or economic incentives. Human health diagnostic platforms can be used to enhance animal health capabilities. This cross-utilization of platforms was a success story when applied in the case of lumpy skin disease outbreak and used for environmental surveillance and sequencing efforts. There is a need to focus on diseases with severe impacts and develop vaccine and diagnostic platforms for economically significant diseases rather than expending resources on low-priority issues. India is now producing kits specifically designed for environmental surveillance, which is critical for sensitive pathogen detection in non-human samples.

Ecosystem challenges and structured support for startups

The expert participants felt there was a public health need for diagnostics for diseases like Nipah virus, Mpox, scrub typhus, chikungunya, influenza, and a broad array of virus encephalitic pathogens. There is also a need for point of care diagnostics for common multi-drug resistance bacterial pathogens and for common toxins of public health importance. However, there is limited emphasis on formal diagnosis for common diseases, where symptomatic treatment often suffices. Diagnostics are often used only when a patient becomes critically ill rather than as a proactive tool for clinical evaluation and disease surveillance. Routine testing for common syndromes like fever and pneumonia are rare, leading to gaps in understanding disease profiles. For instance, scrub typhus likely accounts for 10–30% of fever cases but is rarely tested. Another example is the paucity of clinical testing for influenza which if properly diagnosed would promote early viral treatment and public health responses such as increased influenza vaccination of high risk groups. A cultural shift is needed to prioritize formal diagnosis in patient care, which would naturally increase the importance and adoption of diagnostics.

Limited interaction between technology developers and public health professionals leads to missed opportunities for integrating innovative solutions into health systems. Many promising technologies with high potential for addressing leading pathogens remain underutilized due to lack of validation and field testing. Newer technologies such as TruNat, hand-held x-ray machine could be pathbreaking. Despite numerous innovations reaching TRL-3 (Technology Readiness Level 3), there is limited support to commercialize and scale products to impact. Transitioning designs to scalable, regulatory-compliant manufacturing remains a significant challenge, requiring expertise in industrial design and global regulatory standards.

Health technology assessments (HTA) are now mandatory for evaluating the cost, effectiveness, and budget impact of technologies before central government adoption. However, a lack of robust evidence on the effectiveness of technologies complicates rapid assessments during pandemics. There is a need for models that adapt to technological evolution and predict future impacts on cost-effectiveness and health outcomes. Technologies aimed at pandemic preparedness should also demonstrate daily health system benefits, reinforcing their value beyond emergencies. Positioning technologies as dual-purpose (routine health improvement and pandemic readiness) can strengthen government buy-in and funding justification. Pandemics are inevitable; the focus should be on proactive investment to minimize future catastrophic costs. Upfront funding for health technologies, though small relative to potential pandemic losses, is critical for system readiness and resilience.

Key recommendations

1. The Government of India should invest in diagnostic platforms for pathogens and toxins considered to be potential biologic threats that are cost efficient, scalable, and generate quick results. Point of care rapid diagnostic tests (RDTs) should be part of the mix and should be used in routine surveillance platforms and also stockpiled for emergency use. Tests for zoonotic pathogens of importance to the animal livestock sector should be included in this initiative.

2. Pre-pandemic guidelines should outline diagnostic standards, sample access mechanisms, and regulatory roles to ensure readiness during emergencies. Harmonizing regulatory protocols at regional and global levels remains critical to ensure mutual recognition of data and streamline approvals. While emergency use authorizations during COVID-19 expedited kit approvals, these mechanisms need to be refined for consistent application in future pandemics.

3. Invest in domestic production of critical components such as reagents, antibodies, and other raw materials. Streamline and reduce import duties on essential raw materials required for diagnostic manufacturing to lower costs. Promote routine diagnostics for common syndromes

like fever and pneumonia to create a detailed disease profile for public health planning. Develop strategies to stabilize supply chains.

4. Maintain distinct roles for research organizations and regulatory bodies to ensure transparency and fairness. Establish mechanisms to guarantee procurement and integration of diagnostic tools into public health programs, ensuring availability at all healthcare levels. Prioritize field-level research and validation of existing technologies with potential for immediate application in public health.
5. Develop dynamic HTA frameworks to account for evolving technology and long-term effectiveness. Emphasize the dual-use benefits of health technologies in communications to stakeholders, linking routine health system strengthening to pandemic preparedness.

Annexure 1: Pandemic Preparedness in India - Agenda

Time	Topics
9:30 - 9:50 a.m.	Introductions
9:50 - 10:40 a.m.	**Session 1. The biothreats in India and the region that we are currently worried about in the next 5-10 years.** **Lead discussants**: Sindura Ganapathi, Nivedita Gupta, Pragya Yadav, MK Sudarshan, Shirshendu Mukherjee *Key discussion questions/Themes:* a) What are the bio-threats that we believe India should be most worried about? These include resistant bacteria, existing viruses circulating in humans in India, viruses that could spillover from animals to humans, viruses that could be created or manipulated by people, existing known toxins, newly created toxins, etc. b) Which of these bio-threats is currently getting attention in India and why? c) Which of these bio-threats is currently not getting enough attention in India and what can be done to change that? d) What can be learnt from the COVID pandemic and recent Mpox outbreaks about identifying potential bio-threats and proactively preparing for them? e) In general, what could be done to better prevent or prepare for these threats?
10:50 - 11:40 a.m.	**Session 2. Biosecurity in the biotech and biological research sectors** **Lead discussants**: Sindura Ganapathi, Nivedita Gupta, PM Murali, Naga Suresh Veerapu, Deepwita Chattopadhyay, Abijit Poddar, SR Rao *Key discussion questions/Themes:* *Main questions:* 1. What are the main strategies in place or being developed to reduce the risk of a biosecurity event or leak in both public and private sector laboratories 2. What are the challenges to effective implementation of these strategies and monitoring the implementation of these strategies *General thematic topics for discussion:* a) Systems to identify and monitor high-risk laboratories (especially research laboratories) b) Policies and enforcement systems for biosecurity of moderate-risk and very high-risk laboratories c) Policies and enforcement systems regarding identification, isolation, and contact tracing of high-risk laboratory workers with unexplained illnesses d) Policies regarding dual use research e) Systems to monitor research centers conducting dual use research f) Policies regarding DNA synthesis g) Systems to identify and monitor research organizations and companies using DNA synthesis or selling DNA sequences
11:50 a.m. - 12:50 p.m.	**Session 3. Advanced therapeutics**

	Lead discussants: Suranjana Haldar, Siddarth Jhunjhunwala, Deepwita Chattopadhyay, Satya Prakash Dash, Shirshendu Mukherjee The session may explore the overall situation in India for monoclonal antibodies, anti-toxins, therapeutic vaccines, and advanced small molecule drugs and how this relates to bio-threat preparedness. *Key discussion questions/Themes:* *Part 1: Advanced Biologicals (monoclonal antibodies, immune enhancers, etc.)* a) What can we learn from India's experience with SARS CoV2 monoclonal antibodies, RSV monoclonal antibodies, cancer-specific monoclonal antibodies, snake anti-toxins, etc. b) Biotech industry capacity and commitment to rapidly develop new advanced therapeutics (based on track record during COVID or other evidence of capacity and new action plans or funded initiatives) c) The degree of government & biotech industry collaboration, and networking with other industry leaders globally or regionally on new emergency advanced therapeutics development strategies; or plans for rapid scale up of production capacity. d) Ability of government to procure advanced therapeutics in an emergency situation e) Ability of the host country to organize, conduct and evaluate phase 2, phase 3, and phase 4 clinical trials of various advanced therapeutics candidates in a health emergency *Part 2: Anti-viral Drug Development (small molecule pharmaceuticals)* a) What can we learn from India's experience with the development and production of anti-viral drugs (such as drugs for HIV, Hepatitis B and C, Influenza, etc.) b) Is India's pharma industry or government research institutes investing time and funds into new anti-viral drugs that could be of use during a new viral pandemic or epidemic?
1:00 - 2:00 p.m.	**Lunch and informal discussions**
2:00 - 3:45 p.m.	**Session 4. Vaccines** **Lead discussants:** Varadarajan Ragavan, Pragya Yadav, Umesh Shaligram, Bhavesh Choudhary, Nikhil Tamhankar, Saumitra Das, Niranjan Joshi, Siddharth Jhunjhunwala, Sudhir Krishna *Key discussion questions/Themes:* a) Introductory tabletop scenario - hypothetical Nipah virus crisis and emergency vaccine need b) India's situation with other vaccines against pathogens that have epidemic or bio-threat potential 1. Smallpox/Mpox 2. Influenza 3. Coronaviruses 4. Other hemorrhagic fever viruses (KF, CCHF, Marburg, Ebola, etc.) c) The 100 day challenge: What is India doing to address this 100 day challenge and what are the biggest challenges and opportunities for India related to this?

	1. Is India creating vaccine templates and pre-clinical studies on potential epidemic pathogens? 2. Does India have a strategy to rapidly evaluate a vaccine candidate or compare vaccine candidates in a 30-60 day time frame? Any thoughts on how to accomplish this? 3. Is the Indian drug administration actively discussing this issue and prepared to make swift decisions on new vaccines during a major crisis? 4. How can India best invest in rapid vaccine manufacturing capacity in a cost-conscious way? 5. Is India equipped to identify and introduce new vaccines during a crisis, prioritizing high-risk populations such as healthcare workers, the elderly, and other frontline workers? Additionally, are systems in place to monitor the vaccine's real-world safety and effectiveness post-vaccination? What mechanisms are currently established to support these efforts? d) Global partnerships and networks: What incentives can the Government of India/global donors/investors establish to address the challenges identified today? 1. Partnerships with CEPI, ADB, or World Bank (example, new CEPI relationships with Serum Institute) 2. Technical or investment partnerships with global pharmaceutical companies 3. What is the status and importance of international patent agreements? 4. What policies or incentives should the Government of India create to help with vaccine innovation and investments related to pandemic threats and preparedness? e) Status of the system components of the India vaccine industry (what are the gaps in the following areas) 1. Early vaccine development including pathogen understanding and immune response 2. Vaccine template technology including mRNS tech 3. Phase 1 and 2 trial efficiency 4. Phase 3 trial efficiency (how fast and accurate can this be done) 5. Vaccine challenge studies (can this be done in India and should this be done in India) 6. New vaccine evaluation reviews and authorization process 7. Phase 4 safety and field effectiveness studies for new vaccines 8. Rapid production capacity and incentives for having such capacity
3:45 - 4.00 p.m	**Coffee break and informal discussions**
4:00 - 5:00 p.m.	**Session 5. New diagnostics for known and unknown pathogens** **Lead discussants:** Taslimarif Saiyed, Chandrasekhar Nair, Satya Prakash Dash, Saumitra Das, Anurag Aggarwal, Sindura Ganapathi, Sumirtha Gandhi, Shirshendu Mukherjee, MK Sudarshan, Sudhir Krishna *Main Questions:* 1. What are the key lessons from India's experience with the development, production and field use of new diagnostic tests (for SARS-CoV2, Nipah virus, MPox, TB, Influenza, RSV, Typhoid) 2. Which investments in laboratory diagnostics are highest priority for India in terms of pandemic/bio threats identification and response

	3. What are the gaps and new opportunities in the field of infectious disease or toxin-related diagnostics *Key discussion questions/Themes:* a) Current laboratory capability to identify novel pathogens or toxins accurately and efficiently using whole genome sequencing or other techniques b) Likely role of new diagnostics including new point-of-care tests in India in the next 5 years or during a new bio threat outbreak/pandemic c) Incentives for the Indian biotech industry to invest in new disease diagnostics; structures and capacities needed to evaluate new diagnostics in real world settings
5:00 - 5:45 p.m.	**Wrap-up and summary** *Key discussion questions/Themes:* a) What are the key take-home messages from today? b) What are the high priority actions steps that this group recommends? c) What areas are we highly uncertain about (due to insufficient information, lack of knowledge, or differing opinions)? d) What are we most worried about?
5:45 p.m.	**End of the roundtable panel discussion**

Annexure 2: List of experts attended the roundtable discussion:

Sl No	Name	Designation	Institution
1	Abijit Poddar	Assistant Professor	MGM Advanced Research Institute, Puducherry.
2	Anurag Aggarwal	Dean, Trivedi School of Biosciences	Ashoka University
3	Bhavesh Choudhary	HOD, Recombinant Vaccines and biotherapeutics	Serum Institute
4	Nikhil Tamhankar	Business Development, Product Portfolio and Strategic Alliance Management	Serum Institute
5	Niranjan Joshi	Program Lead, Digital Health and Innovation	C CAMP
6	Satya Prakash Dash	Bigtec / Founding Head Strategy BIRAC	Bigtec
7	Siddharth Jhunjhunwala	Associate Professor, Department of Bioengineering	IISc, Bengaluru
8	Sindura Ganapati	Visiting PSA Fellow	Office of the PSA, GOI
9	Sumirtha Gandhi	Asst Professor (HTA expert), Department of Management Studies	IISc, Bengaluru
10	Suranjana Halder	Principal Scientific Manager	Biocon
11	Sudhir Krishna	Professor	NCBS, Bengaluru
12	Varadarajan Raghavan	Professor, Molecular Biophysics unit	IISc, Bengaluru
13	Taslimarif Saiyed*	CEO & Director	C CAMP
14	Deepwita Chattopadhyay*	Chairman & CEO	IKP Knowledge Park
15	Naga Suresh Veerapu*	Associate Professor, Department of Life Sciences	Shiv Nadar University
16	Nivedita Gupta*	Scientist G & Head, Communicable Diseases Division	ICMR
17	PM Murali*	Chairman	Golden Jubilee Biotech Park & CMD-Jananom Pvt Ltd
18	Pragya Yadav*	Scientist-F and Group Leader	ICMR-NIV, Pune
19	Shirshendu Mukherjee*	Former Director, GCI, BIRAC / Managing Director Wadhwani Foundation	Wadhwani foundation
20	Saumithra Das*	Chair & Prof, Microbiology & Cell Biology	IISc
21	SR Rao *	Founder & Director	Genentech Regulatory Solutions LLP, India
22	MK Sudarshan*	Retired Dean, Public health expert	KIMS Bengaluru
23	Umesh Shaligram*	Executive Director & Board Member	Serum Institute
24	Chandrasekhar Nair*	Director	Molbio Diagnostics Private Limited

*Online