

## MEETING REPORT

# STRENGTHENING COOPERATION TO ENABLE SUSTAINABLE DEVELOPMENT AND MANUFACTURING OF EFFECTIVE, QUALITY AND AFFORDABLE DIAGNOSTIC COUNTERMEASURES

A G20 side event hosted by the Department of Pharmaceuticals, Government of India, FIND and Unitaid, with support from Market Access Africa (MAA), on 16 April 2023 at the Novotel Candolim Hotel, Goa, India



Ministry of Health & Family Welfare  
Government of India



Department of Pharmaceuticals  
Ministry of Chemicals and Fertilizers  
Government of India



भारत 2023 इंडिया  
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DEPARTMENT OF BIOTECHNOLOGY  
Ministry of Science & Technology  
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# INTRODUCTION

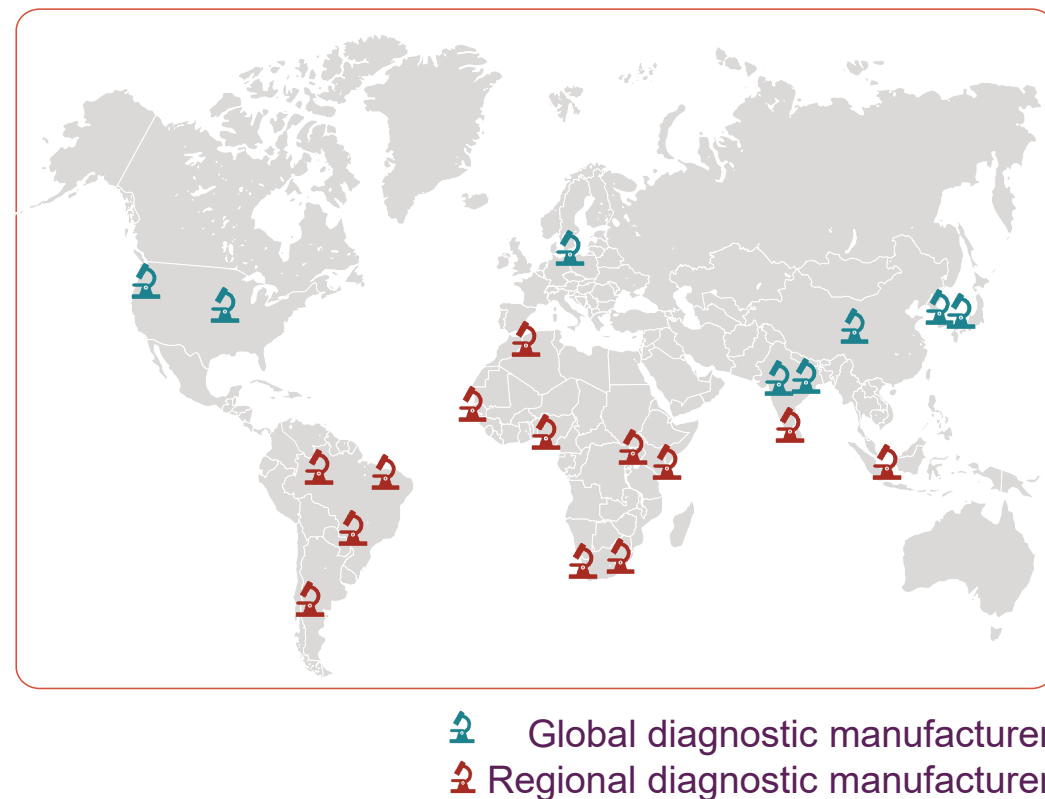
**The second G20 Health Working Group meeting was held between 17 and 19 April 2023 in Goa, India.** Prior to this, on 13 and 14 April, a two-day convening was organized by FIND and Unitaid and attended by 23 diagnostics manufacturers from 13 countries, representing Asia, Africa, Latin America, Europe and North America. The decision to convene these manufacturers arose from a growing recognition within the global health community that most countries are dependent on a limited number of global actors for vital medical technologies, such as diagnostics. This over-dependence has been further highlighted by the COVID-19 pandemic, which revealed the fragility of global supply chains and the disparities in access to essential products, including diagnostics, between the Global North and South.

This convening was followed, on 16 April 2023, by a high-level meeting hosted by the Department of Pharmaceuticals, Government of India, FIND and Unitaid, to strengthen cooperation and enable the sustainable development and manufacturing of effective, quality and affordable diagnostics. The high-level meeting was titled *Strengthening Cooperation to Enable Sustainable Development and Manufacturing of Effective, Quality and Affordable Diagnostic Countermeasures*, based on one of the key priorities under the Health Track of the Indian G20 presidency. Stakeholders in attendance included representatives of the Government of India and G20 Member States (Australia, Brazil, France, Indonesia, Russia and the United Kingdom, plus observers from Mauritius, the Netherlands and Oman), international organizations, and regional and global diagnostic manufacturers (**Fig. 1**) who had attended the earlier two-day convening. A copy of the meeting agenda, including a list of the attendees, moderators and panellists, can be found in **Annex 1**.

**It was intended that the outcomes of this high-level meeting would contribute to the continuation of the Indonesian presidency's agenda and provide input for the upcoming Brazilian presidency** on the creation of regional research and development (R&D) and manufacturing networks for medical countermeasures, along with a collaborative research network for vaccines, therapeutics and diagnostics (VTDs). This will be achieved by providing an initial basis for Member States and partners to develop a roadmap towards establishing and strengthening regional development and manufacturing capacities, especially for diagnostics, and to support the establishment of manufacturer networks to support this goal.

**Manufacturers in attendance at the two-day convening had previously been interviewed and were aligned on the need to accelerate regional production of diagnostics for low- and middle-income countries (LMICs), in LMICs.** As a result of the convening, manufacturers expressed their interest in establishing partnerships to facilitate the transfer of technology, know-how and capacity strengthening. They also highlighted the need for countries to develop national diagnostic strategies, with concrete budget allocations and procurement frameworks that prioritize the sourcing of regionally manufactured tests. Furthermore, the manufacturers emphasized that governments and partners must continue developing regulatory mechanisms, including the World Health Organization (WHO) prequalification system for diagnostics. It will also be important to obtain clear commitments from relevant stakeholders to facilitate regulatory harmonization and fast-track regulatory processes for regionally manufactured products. Finally, and in line with the India G20 presidency goals, manufacturers advised that funding should be made available to create and maintain capacity for a coordinated global network for diagnostics, R&D, manufacturing and technology transfer.

In summary, the meeting on 16 April 2023 provided an opportunity for representatives of the Government of India and G20 delegates to hear the consensus opinion of LMIC-based manufacturers on the strategic actions necessary to create sustainable and resilient ecosystems for the distributed manufacturing of rapid diagnostics in LMICs.



**Fig. 1:** Countries represented by the manufacturers invited to the convening. Note the deliberate emphasis on representation from LMICs.

## SUMMARY OF THE MEETING

The meeting was held in-person, in Goa, India, at the Novotel Candolim hotel on 16 April 2023. The agenda included two speaker sessions, preceded by **opening remarks made by S. Aparna, Secretary, Department of Pharmaceuticals, Government of India, and Dr Marta Fernandez Suarez, Chief Technological Officer, FIND.**

**The first session of the day focused on reviewing the current diagnostics landscape, to understand the challenges and opportunities for the resilient regional manufacturing of diagnostics.** Speakers highlighted the urgent need to address the unmet demand for quality and affordable diagnostics in LMICs. The importance of diagnostics in achieving Universal Health Coverage (UHC) was emphasized. The challenges faced by different regions, including Africa, Latin American and the Caribbean (LAC) and India, were discussed, along with initiatives to strengthen infrastructure, regulatory processes and R&D capacity.

**The second session focused on discussing the draft recommendations from regional manufacturers and mapping a way forwards.** The session featured a panel discussion with representatives from selected manufacturers, who shared recommendations to advance networks for diagnostics. These recommendations included the establishment of regional/national diagnostic strategies, allocation of national budgets for regional manufacturing, development of preferential procurement policies, improved regulatory timelines, and the easing of business and trade between countries.

**At the end of second session, closing remarks were made by Robert Matiru, Director of Programmes at Unitaid, and Dr Rajiv Bahl, Secretary, Department of Health Research and Director-General of the Indian Council of Medical Research (ICMR).** They framed the issues and offered a fresh perspective, specifically that new and stronger networks for VTD manufacturing are required to supplement and strengthen existing capacity, not to replace it. Dr Bahl reminded the stakeholders present that the unmet need was huge and hence “all hands were needed on deck”.



# MEETING REPORT

## SESSION 1:

### Review of the landscape, challenges and opportunities for resilient regional manufacturing for diagnostics

The first session commenced with an overview of the landscape, challenges and opportunities for resilient regional manufacturing of diagnostics. Speakers included representatives from WHO, ICMR, the Africa Public Health Foundation, and the manufacturers Fiocruz and Moldiag. Each speaker provided insights into the current state of access to diagnostics and diagnostic manufacturing in different regions, along with the initiatives that have already been taken to address challenges and leverage opportunities. **The discussions emphasized the need to prioritize diagnostics, strengthen infrastructure, improve regulatory processes and foster collaboration between countries.**

Specifically, the following issues were raised:

1. **THE SUBSTANTIAL UNMET NEED FOR QUALITY AND ACCESSIBLE DIAGNOSTICS IN LMICs.** The critical role of effective diagnostics in enabling successful vaccine and therapeutic development and linkage to treatment and care cascades were underscored.
2. **EXAMPLES OF HOW PROGRESS COULD BE MADE IN STRENGTHENING DIAGNOSTIC MANUFACTURING INFRASTRUCTURE.** The rapid growth of India's in vitro diagnostic (IVD) market was used as an example to discuss the challenges faced in relation to policy, supply chains, infrastructure, regulatory processes and health technology assessment (HTA). Various successful interventions to address these challenges were described, including foreign direct investment (FDI) policies, creation of medical device "parks", regulatory harmonization, and HTA capacity strengthening.
3. **OPPORTUNITIES AND CHALLENGES FOR DIAGNOSTIC MANUFACTURERS IN AFRICA.** Africa's young population, endemic infectious diseases, increasing prevalence of non-communicable diseases, and underdeveloped manufacturing architecture were identified as the primary challenges. Recent positive developments in Africa that have contributed to an optimistic forecast for the continent were outlined, including regulatory maturity achievements, the establishment of the African Pharmaceuticals Manufacturing Foundation, and considerable procurement commitments by PEPFAR for diagnostics manufactured in Africa.
4. **THE ROLE OF PUBLIC RESEARCH INSTITUTIONS IN STRENGTHENING PUBLIC HEALTH DELIVERY.** The manufacturer Fiocruz was used as an example to illustrate the role public institutions can play in supporting public health systems, with a focus on Brazil and Latin America. Fiocruz's production capacities for vaccines, biological drugs and IVD products were highlighted, together with their expansion of testing capacity during the COVID-19 pandemic and agility in pivoting this capacity for other healthcare needs in the post-pandemic period. In addition, the example of Fiocruz drew attention to the potential of public institutions to supply public-sector laboratories with resources during surge periods when there is a need for particular technologies, as well as their capacity to provide continuous training and support at the national, regional and cross-regional levels, which is critical for future pandemic preparedness. →

**4.** → Similarly, the work of the Moroccan Foundation for Advanced Science, Innovation and Research (MAScIR) in developing diagnostic tests and creating startups or spin-offs intended to close gaps in access to diagnostics was presented as a model that should be emulated elsewhere. Moldiag, a startup founded by MAScIR, has made important contributions in the manufacture and distribution of tests for COVID-19, as well as other registered products for diseases such as tuberculosis and hepatitis C. The example of Moldiag highlighted some challenges in creating startups, related to limited investment in R&D, regulatory processes, importation of raw materials, and government support. The discussion that followed led to recommendations to address these issues, including increased R&D budgets, improved regulatory processes and more private-sector investment in R&D.

The discussion raised additional issues pertaining to WHO support of relevant actors through the use and/or future establishment of expedited regulatory pathways and the prequalification process and the potential benefits this could bring to manufacturers and countries. It also highlighted adoption of the WHO essential diagnostics list by G20 nations as a crucial policy intervention to ensure access to quality diagnostics suitable for local use.

With respect to countries, emphasis was placed on the importance of standalone innovations in diagnostics, advocating for investments in early disease detection and surveillance to enhance pandemic preparedness, and the need for increased research collaboration between countries to advance R&D efforts in diagnostics and support decentralized manufacturing processes. More broadly, this underlined the importance of policies enabling such efforts, provision of sufficient funding, and appropriate investments in infrastructure. It also highlighted the need to prioritize cost-effectiveness studies, pre-clinical testing, and clinical validation for phase 1 to 3 trials. All of these elements will be necessary to successfully advance technologies through the development pipeline and enable these technologies to reach those in need of them.

**In summary, the session shed light on the challenges and opportunities facing the resilient regional manufacturing of diagnostics.** The presentations showcased efforts made in different regions to address these challenges, including policy interventions, infrastructure development, regulatory harmonization and research collaboration. The remarks and questions constituted a comprehensive evaluation of the current diagnostics landscape. By implementing the recommendations put forth by the speakers and addressing the concerns raised, the path towards the resilient regional manufacturing of diagnostics can be eased, leading to improved healthcare outcomes worldwide.

## SESSION 2:

### Advancing networks for diagnostics and mapping a way forwards: consideration of the draft recommendations from regional manufacturers

This session brought together a wide array of speakers, including Dr Soumya Swaminathan (former Chief Scientist, WHO, and FIND Board member), who via a video shared her thoughts on strengthening regional manufacturing. Other panellists included representatives from the Department of Biotechnology, India, the Ministry of Health, Indonesia, The Global Fund, FIND, and a selection of four diagnostics manufacturers (Abbott, Life Assay, Revital and SD Biosensor).

During this session, the speakers provided perspectives on the importance of diagnostics in achieving UHC and pandemic preparedness, as well as the need to strengthen diagnostic manufacturing capacity in LMICs. Manufacturers shared recommendations to support local (national) and regional manufacturing. The recommendations arising from the two-day convening were also presented in this session. This resulted in a rich discussion focused on the importance of local ownership, building trust in local products, collaboration, and the balance between the efficiency of regional production and self-sufficiency.

#### The following key issues were raised:

- 1. THE IMPORTANCE OF DIAGNOSTICS IN ACHIEVING UHC AND FUTURE PANDEMIC PREPAREDNESS** and the need for essential diagnostic lists at the national level. Strengthening diagnostic manufacturing capacity was emphasized for global and regional pandemic preparedness, as was support for procurement, supply-chain strengthening and the need to incentivize regional manufacturing through, for example, global tenders.
- 2. THE UNMET NEED FOR DIAGNOSTICS IN LMICS AND THE CHALLENGES IN ACCESS.** As also highlighted in Session 1, there is substantial unmet need for diagnostics in LMICs. Local manufacturing was advocated as a solution to address the shortcomings in global manufacturing.
- 3. EXAMPLES FOR CREATING AN ENABLING ENVIRONMENT.** The Department of Biotechnology's initiatives focusing on biotechnology research and industrial development, including support for startups and biomedical engineering programmes, were used as examples for the creation of a robust foundation for diagnostics manufacturing. A second example, from Indonesia, was provided, involving the use of government policy to transform health systems and make them more resilient, enabling among other things the local production of medical devices and diagnostics. Indonesia reformed its policies to allow it to promote the resilience of medical devices and rapidly scale-up support to manufacturers through policies for preferred procurement. These policies are now benefitting 80 local diagnostics manufacturers.
- 4. KEY PRIORITIES IDENTIFIED FOR MANUFACTURERS** included the establishment of regional diagnostic strategies, preferential procurement policies, fast-tracked regulatory processes and standardized regional regulatory mechanisms. During the meeting, the **OUTCOMES DOCUMENT FROM THE WORKSHOP WITH MANUFACTURERS FROM LMICS, HELD EARLIER IN THE WEEK, WAS PRESENTED.** This document outlined the key issues and included a call to action aimed at diagnostics manufacturers, G20 countries, and development partners including development banks, LMIC governments and multilateral actors; details are provided below.



**The outcomes document from the two-day manufacturer convening includes stakeholder-validated recommendations to support sustainable regional manufacturing in LMICs.**

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#### **PRIORITY 1 RECOMMENDATIONS ON FINANCE, INVESTMENTS AND INCENTIVES**

- National governments and development partners should support the creation of regional diagnostics industry networks, facilitating funding, pooled procurement of raw materials, training, and knowledge exchange, and advocating for regionally manufactured products.
- National governments should review their policies, with a view to the creation of enabling environments for diagnostics industry investment. In particular, it is necessary for countries to re-evaluate their tariff and non-tariff barriers on raw materials, as well as tax concessions and incentives for potential investors.
- National governments should increase investment in public utilities and infrastructure; reduce trade barriers; and cooperate to facilitate regional trade, raw material flow and supply resilience.
- Regional development partners, development banks and donors should support revised policies aligned with these recommendations.

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#### **PRIORITY 2 RECOMMENDATIONS ON DEVELOPING AND SCALING-UP MANUFACTURING CAPACITY**

- Development partners, private investors and donors should invest adequate resources in a variety of business models, supporting the entire value-chain of diagnostics production, including regional R&D, manufacturing infrastructure, capacity strengthening and early-stage financing for small and medium-sized enterprises.
- Governments, development partners (including multilateral development banks) and private investors should provide early-stage financing and support to small and medium-sized enterprises.

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#### **PRIORITY 3 RECOMMENDATIONS ON REGULATION**

- National governments should establish transparent, harmonized and accelerated regulatory pathways for regional manufacturers of diagnostics.
- Multilateral agencies should collaborate with others to develop regional regulatory mechanisms and policies that multiple national authorities can rely on, fostering harmonization.
- At the regional and multilateral levels, countries should invest in fast-track regulatory processes for regionally manufactured products and strengthen global regulatory processes, including World Health Organization (WHO) prequalification, to enhance access.
- Multilateral actors should ensure that global and regional procurement instruments consider a wider array of regulatory authorities, to supplement WHO prequalification.

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#### **PRIORITY 4 RECOMMENDATIONS ON ADOPTION OF REGIONALLY PRODUCED DIAGNOSTICS**

- Manufacturers highlight the lack of reliable information in support of the quality of new products and the maturity of regulatory authorities as barriers to consumer confidence and demand. Therefore, diagnostics industry associations and partners, as well as multilateral agencies, should support evidence-generation and advocacy to increase trust in regionally made products.
- Buyers and institutional procurers, such as donors, ministries of health and private health networks, should establish preferential procurement policies for quality-assured regional manufacturers through plurilateral and/or bilateral guidelines.

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#### **PRIORITY 5 RECOMMENDATIONS ON PROCUREMENT**

- National governments and development partners should establish global, regional and national procurement guidelines that favour regional manufacturers based on the overall benefits they offer beyond product costs. National governments should align their tendering processes with policies that support local manufacturing.
- Multilateral agencies should assist in gaining a better understanding of markets, including assessing potential demand for priority products; they should also support evidence-generation and the adoption of new diagnostic technologies.
- Regional industry associations should assist with connecting manufacturers with distributors; global multilateral agencies and donors can support these efforts.

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#### **PRIORITY 6 RECOMMENDATIONS ON INNOVATION AND DEVELOPMENT**

- Developers should proactively establish and strengthen R&D and manufacturing partnerships in diverse locations, including in LMICs, to facilitate technology transfer and maintain a balanced product portfolio aligned with global and regional health needs.
- National governments should develop and share national diagnostic strategies with dedicated budgets for R&D, with the aim of promoting industrial parks, simplifying business registrations and attracting investments, while also addressing infrastructure and transportation barriers.
- Multilateral agencies should facilitate public-private partnerships between manufacturers in countries of differing incomes, promoting technology transfer, mentorship and capacity strengthening. This includes fostering collaboration between established and potential manufacturers, including North-South, South-South and triangular cooperation.
- Multilateral agencies should also facilitate knowledge sharing among manufacturers and continue to support them throughout the product development process.

**A consensus was reached that, by implementing these recommendations, progress can be made towards creating resilient ecosystems for the distributed manufacturing of diagnostics in LMICs and ultimately improving healthcare outcomes worldwide.**

## REMARKS AND QUESTIONS FROM ATTENDEES AND CLOSING REMARKS

**A G20 country delegate from the Netherlands noted that the issues of local ownership and building trust in local products stood out as important long-term investments to ensure sustainability.** Investments in structural solutions should be the priority, to build and strengthen the ecosystem and infrastructure for diagnostics manufacturing. WHO and the Netherlands have agreed to organize the 2nd World Local Production Forum in November 2023, in the Netherlands, and FIND and Unitaids' input and support would be greatly appreciated.

**A representative of the Department of Pharmaceuticals (India) stated that it will be important to prioritize collaboration between laboratories at the product development stage, as this will help to build trust and minimize inefficiencies.**

The Secretary of the Department of Pharmaceuticals, S. Aparna, added that local production in every country is not the goal but rather that regional production is the most efficient and practical way to scale-up manufacturing, because the infrastructure required for the efficient manufacture of diagnostics simply does not exist in every country.

Dr Rajiv Bahl, Secretary, Department of Health Research, India, and Robert Matiru, Director of Programmes, Unitaids, gave closing remarks to end the meeting. It was articulated that regional manufacturing should be viewed not as a replacement to global manufacturing but rather as supplementing existing capacity, as this is required to meet the unmet and increasing demand for diagnostics in LMICs. The G20 should focus on increasing investments in diagnostics, similar to the investments made in vaccines and therapeutics, as well as building trust in the ecosystem so that manufacturers do not see themselves as competitors but as partners, especially during the R&D phase.

**The recommendations from the meeting on 16 April 2023 were presented during the final Health Working Group meeting, in June 2023,** hosted by the Government of India and were officially shared by the Department of Pharmaceuticals, Government of India with the G20 Secretariat as input for the Health Ministers' Meeting outcome document.





## ANNEX 1

### Strengthening Cooperation to Enable Sustainable Development and Manufacturing of Effective, Quality and Affordable Diagnostic Countermeasures

The following crucial actions were put forth as recommendations to strengthen regional manufacturing in LMICs by diagnostic manufacturers during the 2-day technical workshop organized by FIND and Unitaid on 13-14 April in Goa.

GOVERNMENT OF INDIA WITH FIND/UNITAID  
APRIL 16, 2023  
0900 – 1700 IST  
NOVOTEL GOA CANDOLIM

## AGENDA

09:00 – 10:30 ➤ Transport from Grand Hyatt to Novotel Goa Candolim (for G-20 delegates)

10:00 – 10:15 ➤ Tea/coffee

### 10:15 – 10:30 WELCOME AND CONTEXT SETTING

➤ **S. Aparna**, Secretary, Department of Pharmaceuticals, Government of India

➤ **Dr. Marta Fernandez Suarez**, Chief Technological Officer, FIND

### 10:30 – 12:30 SESSION 1: REVIEW OF THE LANDSCAPE, CHALLENGES, OPPORTUNITIES FOR RESILIENT REGIONAL MANUFACTURING FOR DIAGNOSTICS

CHAIR: ROBERT MATIRU, DIRECTOR OF PROGRAMMES, UNITAID (50')

RAPPORTEUR: MAA

- **Dr. Bruce Aylward**, Senior Advisor to the Director-General and Assistant Director-General ad interim, External Relations and Governance, WHO
- **Dr. Ebere Okerere**, CEO, Africa Public Health Foundation
- **Marco Aurelio Krieger**, Vice-president of Health Production and Innovation in Health, Fiocruz
- **Prof Hassan Sefrioui**, Director and member of the Executive Board, Moroccan Foundation for Advanced Science, Innovation and Research (MAScIR)
- **Dr. Suchita Markan**, Scientist E & Mission In-Charge, Medical Device and Diagnostics Mission Secretariat (MDMS), ICMR

INTERVENTIONS/REMARKS (65')

- Participants from G20 countries / Invited International Organizations / Partners

CHAIR'S SUMMATION (5')

12:30 - 14:00 ➤ Lunch

### 14:00 - 16:00 SESSION 2: ADVANCING NETWORKS FOR DIAGNOSTICS AND MAPPING A WAY FORWARD: CONSIDERATION OF DRAFT RECOMMENDATIONS FROM REGIONAL MANUFACTURERS

CHAIR: DR. AYOADE ALAKIJA, BOARD CHAIR, FIND (60')

RAPPORTEUR: MAA

- **Panel discussion with manufacturers:** Abbott, Life Assay, Revital, SD Biosensor
- **Dr. Soumya Swaminathan**, Former Chief Scientist, WHO and Board member, FIND (video)
- **Dr. Sundeep Sarin**, Scientist 'G', Department of Biotechnology
- **Dr. Rizka Andalusia**, Director General, Pharmaceutical and Medical Devices, Ministry of Health, Republic of Indonesia
- **Francoise Vanni**, Director, External Relations and Communications, The Global Fund
- **Dr. Marta Fernandez Suarez**, FIND

INTERVENTIONS/REMARKS (55')

- Participants from G20 countries / Invited International Organizations / Partners

CHAIR'S SUMMATION (5')

### 16:00 – 16:30 CLOSING REMARKS AND NEXT STEPS: CO-HOSTS

➤ **Dr. Rajiv Bahl**, Secretary, Department of Health Research

➤ **Robert Matiru**, Unitaid

16:30 – 18:00 ➤ Departure to Grand Hyatt (for G-20 delegates)



