Highlights of the CREATInG Initiative International Roundtable: "Impactful Interventions for In-Vitro Diagnostics (IVD) Access in Global Markets"

14 – 15 July 2025

A Collaboration of the Gates Foundation, Duke-NUS Centre of Regulatory Excellence (CoRE) and Duke Kunshan University

Gates Foundation

DukeNUS Medical School | Centre of Regulatory Excellence

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The CREATInG Initiative

CoRE and Duke-Kunshan
Regulatory strengthening project
Enabling
Access
To
In-vitro diagnostics for
Global health needs

Commissioned by the Gates Foundation, the CREATInG Initiative is a project co-led by the Duke-National University of Singapore (NUS) Medical School Centre of Regulatory Excellence (CoRE) and Duke Kunshan University (DKU) that aims to accelerate access to in-vitro diagnostics (IVD) for critical global health needs.

With a focus on infectious diseases and maternal and foetal health, the CREATInG Initiative aims to bridge regulatory and access gaps, and help ensure that timely, reliable IVD reach the communities that need them the most.

The project:

- Facilitates regulatory dialogue among IVD manufacturers and regulators in China, Southeast Asia and South Korea to accelerate market access of essential IVD for Low and Middle-Income Countries (LMIC)
- Develops executive strategic leadership skills and deepens regulatory knowledge for diagnostics manufacturers in China to align and comply with external global regulatory requirements and standards
- Supports the Gates Foundation EDGE* Team's core strategic pillar to develop manufacturing of affordable point-of-care diagnostics
  (* Enterics, Diagnostics, Genomics & Epidemiology)

Additional details on the Gates, CoRE and DKU Regulatory Strengthening Project can be accessed on the project website.

Contents

1 Executive Summary

This summary report highlights key points from discussions at the CREATInG Initiative International Roundtable on "Impactful Interventions for In-vitro Diagnostics (IVD) Access in Global Markets", held from 14 to 15 July 2025 in Singapore. This by-invitation meeting which was the inaugural event of the CREATInG Initiative was hosted by the Duke-National University of Singapore (NUS) Centre of Regulatory Excellence (CoRE), in partnership with the Gates Foundation and Duke Kunshan University (DKU). The Roundtable convened over 50 delegates from 11 countries comprising speakers and participants from international organisations, regulatory agencies, manufacturers and other stakeholders of the global IVD ecosystem.

Recognising that the challenges in facilitating access to timely and reliable IVD in Low and Middle-Income Countries (LMIC) requires collective action, participants at the International Roundtable gathered to discuss key issues and innovative approaches, focusing on the following objectives:

1. Identify priorities to enable and support a sustainable IVD ecosystem to ensure access to quality health;
2. Formulate appropriate strategies to facilitate market entry of IVD to global markets;
3. Determine action items to promote timely IVD access to LMIC.

The key takeaways were to:

1. **Build sustainable IVD ecosystems:** This requires trusted stakeholder partnerships, strong political will, regulatory harmonisation and flexible regulatory approaches, sustainable funding resources, and local and regional strategic measures to strengthen the ecosystems.
2. **Facilitate access to IVD:** Accessibility of a product goes beyond market entry and includes successful market adoption. An end-to-end approach is needed in the development of innovative products with the needs of diverse stakeholders in mind. The go-to-market strategy requires a sustainable business model with practical implementation considerations including coordinated responses to regulatory and market access requirements. Assessment of market readiness as well as supportive resources such as open data, biobanks, market insights and laboratory facilities are especially critical for new innovative platforms such as targeted next generation sequencing (tNGS).
3. **Enhance regulatory strategies in IVD development:** Multi-stakeholder collaboration on regulatory strategies can facilitate IVD global access. Key approaches include (1) early multi-market compliance built into product development by manufacturers, (2)

harmonising technical standards, (3) facilitating cross-border data access and certification acceptance through leveraging existing regulatory frameworks and resources by regulators, and (4) regulatory capacity building supported by key stakeholders.

4. **Support IVD access for LMIC markets:** This requires all stakeholders in the ecosystem to work on overcoming the challenges and collaboratively finding innovative solutions to facilitate quality, safe and cost-effective IVD products.

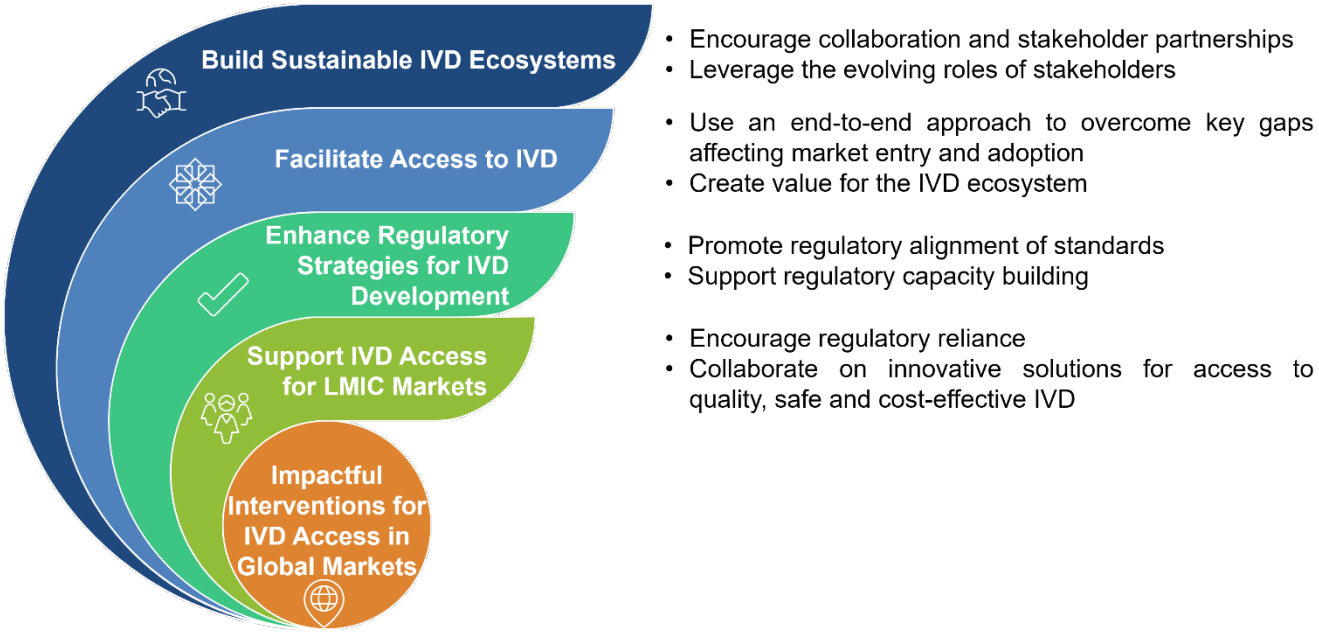

Figure 1: Key Takeaways

2 Opening Remarks

2.1 Remarks from CoRE

Professor John Lim, Executive Director, CoRE, Duke-NUS Medical School, Singapore

Prof Lim in his Welcome address highlighted the CREATInG Initiative's overarching project goal to bridge regulatory and access gaps to accelerate market access to essential IVD in Low and Middle-Income Countries (LMIC). Given the increasingly interconnected nature of the world in spite of current deglobalisation trends, Prof Lim emphasised the need for collective action involving a broad range of stakeholders, including IVD manufacturers, regulators, non-profit organisations and funding bodies. He highlighted the role of the CREATInG Initiative's inaugural Roundtable in promoting dialogue on key issues and innovative approaches to improve access to timely and reliable diagnostics for people in LMIC.

3 Summary of Presentations and Discussion

3.1 Build Sustainable IVD Ecosystems

The first session set the stage for discussing high-level systemic barriers, global uncertainties, and challenges in the IVD sector, and highlighted the need for an ecosystem approach to accelerate IVD access. Presentations focused on identifying priorities, opportunities and strategic measures to support IVD manufacturers in commercialisation. Concluding the session, a panel of experts shared insights on regional regulatory initiatives and partnerships, underscoring the role of diverse stakeholder collaborations in building stronger and more sustainable IVD ecosystems.

3.1.1 Remarks from the Economic Development Board (EDB) of Singapore

Ms Goh Wan Yee, Senior Vice President, Head of Healthcare, EDB, Singapore

In the context of rising chronic diseases and the shift towards preventive healthcare and precision medicine, Ms Goh highlighted the growing significance of IVD in healthcare and Asia Pacific as a key growth market. Ms Goh emphasised the need to build sustainable ecosystem capabilities to drive the IVD sector's growth in the region and advance global public health outcomes. She cited the example of Singapore's national initiatives to support IVD innovation

and accelerate commercialisation which strengthen the IVD ecosystem both nationally and regionally.

Key Takeaways:

- **Strengthen Singapore's capabilities in diagnostics:** Singapore's DxD hub plays a crucial role as a national platform, building strong local capabilities in developing and commercialising diagnostics. Singapore's Ministry of Health (MOH) has established a research programme to strengthen research capabilities, translational platforms and collaborations to develop diagnostics, therapeutics and vaccines. Together, these efforts help meet the clinical and healthcare needs of Singapore and the region.
- **Establish Singapore as a trusted innovation hub in Asia**: Established research and development (R&D) centres, manufacturing facilities and skilled workforce highlight Singapore's strong talent pool and supportive ecosystem for growth of biopharma and medical technology sectors. For example, R&D centres foster strategic partnerships among multinationals, academic researchers and local start-ups in developing innovative products. Likewise, local contract manufacturers with packaging and filling capabilities attract global players to manufacture diagnostics for global markets from Singapore.
- **Develop strategic measures to strengthen IVD ecosystem**: Singapore's dual-pronged approach of attracting leading multinationals and foreign start-ups to establish and grow their local presence, while supporting the growth of domestic IVD companies through national platforms and innovative collaborations, is expected to further strengthen the IVD ecosystem both nationally and regionally.
- **Spur innovation through adaptive regulatory systems:** To support growth of IVD companies in the region and beyond, it is critical for health and regulatory systems to evolve alongside innovation trends, establish regulatory frameworks aligned to global standards, and continually improve regulatory processes to facilitate timely access to safe and effective IVD to market.

3.1.2 Remarks from the Gates Foundation

Dr Wenfeng Gong, Deputy Director, Health Innovation and Partnerships, China Country Office, Gates Foundation

As nearly 47% of the world's population lacks adequate access to diagnostics, Dr. Gong shared the Gates Foundation's efforts to reduce the diagnostics gap – critical in achieving universal health coverage goals. His remarks focused on the Foundation's refreshed strategic approach to accelerate access to point-of-care (PoC) diagnostics for high priority diseases, aiming to reach 1 billion people by 2035.

Key Takeaways:

- **Build healthy product pipelines for high priority use cases:** The shift in approach from investing in a subset of platform technologies to prioritising disease specific development pipelines allows (1) identification of unmet needs in diagnostics use cases and (2) delivery of quality PoC diagnostics covering tuberculosis (TB), malaria, women's health and sexually transmitted infections such as HIV, syphilis and gonorrhoea.
- **Incentivise the manufacturing of affordable and innovative IVD solutions:** There has been a shift toward (1) advancing high-scale manufacturing innovation and (2) engaging with manufacturing ecosystems in LMIC that helps lower manufacturing costs of innovative IVD in LMIC, thus incentivising sustainable scale-up of affordable and reliable diagnostics. These efforts are paying off, with a steadily growing portfolio of low-cost near PoC diagnostics aligned with World Health Organization's (WHO) Target Product Profile and signs of maturing markets (e.g., Gates Foundation TB diagnostic and screening strategy).
- **Strengthen IVD ecosystems through local and global collaborations:** Facilitating public, private and philanthropic partnerships - particularly the Global Diagnostics Coalition (GDC) - is critical not only for making disease specific diagnostics available, accessible, and affordable at the primary healthcare level, but also for establishing in-country routine data collection for diagnostics. The impact evaluation and evidence generation helps support strategic decision making and fund deployment**.**

3.1.3 Addressing the Global Uncertainties – What are the Implications for IVD Manufacturers?

Dr Chandrasekhar Nair, Director and Chief Technical Officer, Molbio Diagnostic Ltd and Co-founder of Bigtec Labs

Dr Nair highlighted that global uncertainties, particularly reduction in public health funding, jeopardises the operational capacities of key global health organisations, threatening equitable access to essential healthcare services and further marginalising LMIC populations. He elaborated on the debilitating impact of the funding crisis on the IVD ecosystem, with shifts from global to local procurement driving up costs and making cost the primary barrier to new technology adoption rather than capability. As the way forward to achieving the shared goal of improved global health, he pinpointed four key priority areas and highlighted EDGE 2.0 as an example of a structured partnership to align efforts on overcoming public health challenges.

Key Takeaways:

- **Achieve consensus on priority diagnostics to realise public health goals:** While the vision of equal access to affordable diagnostics is clear, bridging the gap between ambition and execution remains a significant challenge in healthcare when there are constantly shifting priorities and goals. Achieving positive health outcomes and

improving public health requires consensus on priority diagnostics and alignment on a common set of goals to ensure maximum public health impact.

- **Encourage harmonised regulation:** Despite rapid technological advancements, fragmented regulatory frameworks and extensive country-specific requirements pose a high risk of uncertainty for technology adoption. Streamlined approval pathways such as reliance and recognition mechanisms that acknowledge decisions by stringent regulatory authorities (SRAs) can vastly reduce the time manufacturers spend on duplicative evidence generation, thereby accelerating technology implementation.
- **Foster innovation through sustainable funding:** At a time when global uncertainties are further straining already limited public health budgets, there is a pressing need for governments to step up and prioritise resource allocation to health infrastructure. Sustainable funding is essential to translate innovative diagnostics from idea to scale up and ultimately to real-world impact.
- **Create opportunities for structured partnerships:** Transforming the IVD landscape requires collaboration and collective action involving multiple stakeholders - manufacturers, regulators, funders and implementing partners. Structured partnership programmes like the EDGE 2.0 programme by Molbio and Bigtec mentors promising growth stage start-ups to scale up transformative technologies. Such initiatives illustrate how targeted mentoring and support can accelerate commercialisation to overcome the "valleys of death" that hinder innovative solutions from reaching the market.

3.1.4 Updates from the CREATInG Initiative – Opportunities for Stronger Collaborations Among IVD Stakeholders

Professor Fujie Xu, Co-Director, Global Health Program, Duke Kunshan University, and Assistant Professor Tan-Koi Wei Chuen, Lead, Regulatory Systems Strengthening, CoRE

Highlighting the recommendations from the Lancet Commission on Diagnostics on governance and regulatory frameworks to support diagnostic quality and safety, Prof Xu presented the CREATInG Initiative's goals, approaches, and potential impact. The project aims to build a stronger ecosystem that facilitates regulatory dialogue among IVD manufacturers and regulators in the region, ultimately accelerating access to essential, low-cost diagnostics. Following this, Asst. Prof Tan-Koi shared preliminary findings from the needs analysis study on (1) understanding the driving forces, challenges, and barriers faced by regional manufacturers aiming to go global, and (2) identifying the technical and regulatory support required to bring innovative IVD products to the global market.

Key Takeaways:

- **Go global as a business strategy:** Intense domestic competition, macroeconomic pressures, and the desire for value enhancement and revenue growth were identified as the main external and internal drivers for regional manufacturers to go global.

- **Develop global business and regulatory strategy:** The main business considerations influencing target market selection include market size, ease of product registration, procurement of high-quality materials, distribution models and the identification of reliable distribution partners. Challenges faced by new entrants and existing players were shared. New entrants often lack strategic roadmaps and find the complex regulatory and reimbursement pathways both unfamiliar and challenging. On the other hand, existing players cite geopolitical volatilities, global uncertainties and funding shortages as key challenges.
- **Formulate strategies to leverage existing regulatory mechanisms:** The key regulatory considerations influencing target market selection include availability of facilitated regulatory pathways for mutual recognition and reliance on stringent regulatory authorities (SRAs), as well as adoption of a harmonised product risk classification and common submission template. IVD manufacturers can leverage existing regulatory mechanisms to overcome some of the regulatory challenges, such as diverse regulatory requirements, extended approval timelines and limited access to sample banks for clinical validation.
- **Collaborate on finding solutions together:** To build a sustainable IVD ecosystem, stakeholders must work together to overcome regulatory barriers, address business challenges and close key access gaps. Strategic partnerships and setting clear measures and milestones are critical to accelerate the availability of essential diagnostics, particularly for LMIC.

3.1.5 Panel Discussion: The Evolving Roles of Stakeholders in Facilitating a Stronger and Sustainable IVD Ecosystem

Panellists: Dr Wenfeng Gong; Dr Chandrasekhar Nair; Ms Wong Woei Jiuang, Assistant Group Director, Medical Devices Cluster, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore; and Dr Gonzalo Domingo, Global Program Leader, Diagnostics Program, PATH. Moderated by Professor John Lim, Executive Director, CoRE, Duke-NUS Medical School, Singapore

The panel discussed how IVD stakeholder collaboration could improve global market access. The panel further explored the lifecycle approach and the role of non-profit entities in de-risking innovative diagnostics. Panellists emphasised the need to develop sustainable and practical solutions from both regional and global perspectives, and a clear roadmap to support manufacturers in navigating regulatory issues and lowering cost barriers**.**

Key Takeaways:

- **Rethink regulation as an enabler of innovation:** Contrary to the commonly held view of regulation as a barrier to innovation, regulatory cooperation on harmonisation and reliance helps streamline regulatory processes and is a facilitator for market entry of

innovative IVD. Initiatives and platforms include the Association of Southeast Asian Nations (ASEAN) Medical Device Directive (AMDD) and the International Medical Device Regulators Forum (IMDRF), and regulatory reliance programmes involving Thailand, Singapore and Australia.

- **Adopt fit-for-purpose regulation:** The IVD landscape is inherently heterogeneous, shaped by diverse healthcare systems and varying public health needs across regions. As such, benefit–risk analyses may differ significantly depending on local clinical practices, population health needs, and infrastructure capabilities. While reliance approaches can enhance regulatory efficiency, adopting a "one-size-fits-all" approach may not be suitable across all settings. Instead, there is a clear need for agile, flexible regulatory approaches that are context-sensitive and patient-centric to support commercialisation.
- **Nurture trusted stakeholder partnerships:** Addressing gaps in the IVD value chain and overcoming funding constraints require a collaborative, rather than siloed, approach. Strategic partnerships are useful to attract investment, access resources and to facilitate harnessing the strengths of each stakeholder in closing existing gaps. Strong political will is critical to build public trust, help strengthen communication among government agencies and multi-stakeholder platforms, drive innovation and ultimately facilitate IVD access.
- **Build consensus on a common set of goals for sustainable impact:** Regulators, innovators, manufacturers, and funders share the common public health goal of bringing high-impact, innovative IVD to market. However, achieving sustained impact requires alignment on shared goals. Clear communication of regulatory and technical requirements helps manufacturers focus on scalability and sustainability in global markets.

3.2 Facilitate Access to IVD

Experts discussed design, development, productisation and access for diagnostic innovations, focusing on key gaps affecting IVD access and adoption. The breakout discussions focused on group-assigned topics of the health and regulatory system for (a) regulators and (b) industry and innovators for industry, academia and other stakeholders. The active exchange among experts on recent IVD trends provided valuable context for identifying innovative approaches to improve access.

3.2.1 Learnings from Bringing IVD to Other Markets

Dr Sidney Yee, Adjunct Associate Professor, CoRE, Duke-NUS Medical School, Singapore

Dr Yee highlighted that IVD access in the global market should look beyond market entry and adopt the long-term lens of market adoption. Considerations include affordability, usability and timeliness of results, systemic integration into the healthcare system, and reimbursement

issues. These considerations could also be influenced by local social or cultural sensitivities, as illustrated by the Human Papillomavirus Virus swab test in Southeast Asia case study. Another case study on ovarian cancer diagnosis highlighted the need to engage and align the interests of diverse stakeholders such as patients, clinicians, operating theatre nurses, laboratory technicians, pathologists, hospitals and distributors.

Key Takeaways:

- **Consider both market entry and market adoption in facilitating access to IVD:** Sustained access requires a holistic approach that considers aspects including regulation, affordability, usability, timeliness and system integration.
- **Adopt an end-to-end approach in developing innovative products:** Product development should adopt a product life cycle approach from raw materials to finished product, and include considerations of storage, logistics and last mile user adoption.
- **Account for diverse stakeholders' needs:** The needs of various stakeholder groups, while diverse, can contribute to successful and sustainable market adoption. These stakeholders include patients, clinicians, operating theatre nurses, laboratory technicians, pathologists, hospitals and distributors.
- **Recognise the role of public-private partnerships in establishing the value of innovative IVDs:** Public-private partnerships such as with reimbursement entities can help establish the value of these products and are essential for building a sustainable business model to access innovative IVD.

3.2.2 Adoption of New IVD in Health Systems

Ms Anita Suresh, Director, Genomics and Diagnostics Development, FIND

Ms Suresh encouraged the use of open data, resources and insights for product design and development. For example, Target Product Profiles can be used to inform product design and development, and biobank services can be leveraged to speed up development and evaluation. National strategic plans guiding evidence to adoption would be valuable to IVD manufacturers.

A case study on targeted next generation sequencing (tNGS) for drug resistant TB (DR-TB) diagnosis in LMIC was shared. While TB is treatable and curable with early detection and the right treatment, delayed and inaccurate diagnosis can exacerbate DR-TB. Hence, there is a critical need to diagnose DR-TB in a more accurate and timely manner. However, using tNGS to diagnose DR-TB requires availability of end-to-end in-country capacity to support successful adoption. Ultimately, the clinicians who are the end-users should also be engaged to highlight the usability and adoption of the IVD.

Key Takeaways:

- **Harness the potential of new platforms in global health:** There is potential for tNGS to replace conventional testing methods and address pressing global health needs. To

achieve successful rollout, a clear strategy spanning evidence generation, policy formulation and adoption needs to be considered.

- **Utilise open-source data and resources to facilitate product design and development:** Resources such as Target Product Profiles, biobanks, market insights and technology landscape reports, and test directories are helpful to facilitate development of IVD that are fit-for-purpose for local needs.
- **Implement contextualised solutions:** Optimal implementation models and algorithms are context dependent and need consideration of local conditions and practices.
- **Adopt a coordinated approach to overcome non-regulatory barriers**: Non-regulatory barriers include access to reagents, instrument maintenance, procurement and usage issues such as the ability to forecast demand. Overcoming these barriers requires taking a coordinated approach across the product life cycle.
- **Assess country readiness for implementation of NGS and other innovative IVD:** Practical considerations include assessing a country's readiness, availability of laboratory facilities, training, global procurement lists, cost-effectiveness, budget impact and forecasting. Resources such as FIND's genomics costing tool and diagnostic network optimisation support assessments of a country's diagnostic network, optimise the geographical coverage of diagnostic interventions and aid in decisions around integration of tests into existing devices and health systems.

3.2.3 Breakout Session: Key Gaps Affecting IVD Access and Adoption

Group Comprising Health and Regulatory System Officials

Chairperson: Mr John Jamieson, Assistant Secretary, Medical Devices Authorisation Branch, Australian Government, Department of Health Disability and Ageing, Therapeutic Goods Administration (TGA)

Groups Comprising Industry and Innovators

Chairpersons: Mr Wong Fatt Heng, Founder, Shanghai IVD Consulting Company; Dr Justin Im, Director, Programs & Strategy, RIGHT Foundation; and Ms Anita Suresh, FIND

All groups comprising health and regulatory system officials, industry and innovators collectively discussed and highlighted key gaps affecting IVD access and adoption. Gaps include lack of regulatory harmonisation and a fragmented ecosystem with diverse actors. Solutions to bridge the gaps include bilateral reliance and the Medical Device Single Audit Programme (MDSAP). The groups noted that MDSAP could be a tool to encourage reliance instead of focusing on the ideal but more challenging goal of achieving regulatory harmonisation.

Other innovative solutions including an Asian CE mark system were also proposed. However, the groups acknowledged that Asia and ASEAN are not economic blocs, unlike the European

Union (EU), and a different approach from the CE mark would probably be required. A parallel regulatory and health technology assessment approach was also proposed as a possible way to facilitate access.

On consolidation of efforts, neutral entities such as academia and the Gates Foundation can play important roles in bridging the regulatory and access gaps. The ecosystem approach such as the one adopted by this CREATInG International Roundtable is a positive way to help address the gaps.

Key Takeaways:

- **Engage regulators early in product development:** Early engagement with regulators helps provide greater clarity in regulatory requirements to facilitate market entry.
- **Encourage mutual regulatory reliance mechanisms:** Bilateral reliance such as that practised by Australia and Singapore can be modelled by other countries to facilitate IVD access to their markets.
- **Facilitate regulatory reliance and harmonisation through strong governmental support:** Strong governmental support of international regulatory cooperation and participation such as MDSAP can facilitate regulatory reliance and harmonisation to lower barriers to market entry.
- **Adopt an ecosystem approach to address challenges in market access:** A consolidated approach supported by neutral entities such as academia and the Gates Foundation can help convene diverse stakeholders to address the challenges in regulatory and market access for sustainable market entry and adoption.
- **Invest and build supportive infrastructure:** Supporting laboratories, storage and other facilities are important for successful market adoption.
- **Drive regulatory innovation:** Innovative approaches could include a regional mechanism for market authorisation or a parallel regulatory and reimbursement pathway.
- **Provide sustainable financing and support for the IVD ecosystem:** Beyond providing sustainable funding for innovative developers, funders play an important role in understanding the issues faced in the IVD ecosystem and bringing stakeholders together to address these challenges.

3.3 Enhance Regulatory Strategies in IVD Development

The experts focused on stakeholder collaboration for global IVD market entry. Manufacturers shared market entry experiences alongside expert insights on regulatory pathways, particularly for WHO, Africa, and ASEAN regions. The session concluded with a panel discussion on regulatory challenges.

3.3.1 Optimising IVD Regulatory Strategy for the Global Market

Mr Derek Lee, Chief Strategic Officer, iGENETECH Inc.

Mr Lee shared challenges faced by IVD manufacturers and proposed solutions. The post-pandemic transition from Emergency Use Listing (EUL) to standard regulatory pathway has extended approval timelines, posing significant challenges for companies at all stages due to longer market entry period, higher business costs, and uncertain returns. To foster a sustainable market environment, he recommended enhancing regulatory efficiency in Asia and providing incentives for local manufacturing.

Key Takeaways:

- **Facilitate timely regulatory approvals:** Mechanisms that accelerated regulatory approval during the pandemic, such as WHO EUL, contributed to the subsequent procurement and availability globally, which enabled IVD manufacturers to scale-up production rapidly.
- **Spur innovation by encouraging healthy competition:** Healthy competition accompanied by tailored support for companies at various growth stages can help drive innovation, especially as companies shift focus towards high-margin platforms and products to ensure sustainable profitability and growth.
- **Achieve greater regulatory efficiencies in Asia through collaboration:** Regulatory efficiency can be achieved through partnerships between Asian countries. Regional or international regulatory networks such as the WHO Collaborative Registration Procedure (CRP) and a new dedicated regional regulatory authority in Asia can be explored. The development of Asia-focused procurement agencies could also be part of the IVD ecosystem.
- **Introduce incentives to encourage local manufacturing:** Incentives are critical for supporting scale up of IVD manufacturers who face intense competition regionally and globally. This can foster a sustainable ecosystem to encourage increased regional capacity and engagement in the IVD market.

3.3.2 Navigating Through Challenges to Market IVD Innovation

Mr Rui Yao, Marketing Manager, Wantai Biopharm International BU

Mr. Rui Yao outlined the regulatory challenges Chinese companies encounter when entering international markets based on his company's experience. He presented possible solutions and concluded by calling for collective and coordinated action by stakeholders in the IVD ecosystem such as manufacturers, regulators and investors to address the challenges.

Key Takeaways:

- **Provide targeted assistance to companies especially those without prior experience in WHO Prequalification (PQ):** WHO PQ is a preferred regulatory pathway for IVD manufacturers but can be a costly endeavour. In addition, companies applying to the WHO PQ pathway must invest substantial resources to thoroughly understand the WHO PQ requirements. Assistance from experienced expertise including external consultants and technical guidance from the WHO PQ team can help companies avoid costly pitfalls in navigating some of these challenges.
- **Address the regulatory challenges faced by IVD manufacturers in accessing global markets:** These common hurdles can delay and complicate the regulatory approval process. They include differences in regulatory requirements between countries, such as the need for stability data at discrete temperatures versus across a range of temperatures, or the need to present multi-country clinical data or local validation data as part of clinical evidence requirements, different Quality Management System (QMS) standards, lengthy regulatory timelines contributed by multiple rounds of regulatory queries and inadequate post-market surveillance systems.
- **Proactively consider regulatory requirements of target markets at early product design stage:** Comparing regulatory requirements of target markets during the R&D phase can be a strategy that ensures regulatory compliance is in-built for multi-country access and minimises the need for product changes at a later stage.

3.3.3 Understanding the Regional Regulatory Landscape

WHO Prequalification

Dr Susie Braniff, Scientist, Prequalification IVD Assessment Team, Health Systems Division, World Health Organization (WHO)

Dr Braniff explained the aim, scope and main components of the WHO IVD PQ assessment, as well as post-assessment activities, including assessments of commitments made on the part of manufacturers and manufacturer-initiated change requests. The PQ assessment comprises dossier review, site inspection, performance evaluation, and labelling review. The Technical Specification Series (TSS) outlines performance requirements for IVD products and is referenced during the dossier review stage by expert assessors. Performance evaluation follows a standard PQ protocol and is conducted by a WHO collaborating centre or a designated performance evaluation laboratory. Manufacturing site inspections are carried out by the WHO PQ inspection team.

Africa Continent

Dr Paulyne Wairimu, Chair, African Medical Devices Forum (AMDF), African Medicines Harmonization Initiative, Lead, Medical Devices and Diagnostics, Pharmacy and Poisons Board

Dr Wairimu updated on the African Medicines Agency (AMA) and the Medical Device Authority-Technical Committee (MDA-TC), the scientific arm of the African Medical Devices Forum (AMDF). The MDA-TC is responsible for the technical review and evaluation of IVD. She shared on the IVD framework in the African continent, a harmonised process which leverages on existing regulatory resources, designed to ensure rapid and reliable access to diagnostics across Africa.

Within this framework, the AMDF oversees the adoption of procedures, the MDA-TC conducts scientific evaluations, and the Diagnostics Advisory Committee (DAC) validates performance. The IMDRF Table of Contents (ToC) is being adopted as the standardised structure to facilitate harmonisation and reduce duplication. The guiding principles align with those of the WHO and include prioritisation based on Africa Communicable Disease Centre's list of priority diseases, independent evaluation of publicly listed IVD against international standards of quality, efficacy, and performance, and inspection of manufacturing sites for QMS compliance.

The recent Mpox outbreak accelerated the urgent need for this framework, highlighting the critical importance of regional self-reliance in IVD validation and assessment. Dr Wairimu provided an update on the MDA-TC's response to Mpox, highlighting that nine Mpox IVD are currently being evaluated under the Expedited Collaborative Review and EUL frameworks at the continental level. She outlined the AMDF and MDA-TC's upcoming priorities, which include capacity building, stakeholder engagement, and ongoing stakeholder support.

ASEAN

*Dr Ruifen Weng, Chief Executive Officer, Diagnostics Development Hub, Agency for Science, Technology and Research (A*STAR), Singapore*

Dr Weng presented regulatory strategies for global market entry from the perspective of IVD manufacturers, focused on the ASEAN region. She highlighted ASEAN's significance as a rapidly growing market with high demand for imported medical devices, including IVD, driven by both economic growth and a rising burden of disease.

She noted that the absence of a centralised regional regulator has led to country-specific divergences in both pre- and post-market requirements. However, ongoing harmonisation efforts, particularly through the ASEAN AMDD, aim to reduce technical barriers and facilitate trade within the region. Key provisions in the AMDD that support harmonisation include standardised registration criteria, risk classification guidelines, pre-market technical

documentation via the Common Submission Dossier Template (CSDT), and a coordinated post-market alert system. Practical considerations for manufacturers include country-specific requirements on language translation for labels and instructions for use, in-country testing provisions (with some exceptions for high-risk or novel IVD), and the need for a Local Authorised Representative (LAR) in each ASEAN market.

The progress of AMDD implementation across member states was also discussed, noting that timelines are determined by consensus and national discretion. Additionally, she highlighted the growing adoption of regulatory reliance programmes in the region, which support expedited multi-country access when leveraging approvals by recognised reference agencies. An example is Singapore's reliance programme, which leverages the regulatory decisions made by five reference regulatory agencies under specific conditions. Challenges with reliance pathways include limited predictability, varying country-specific requirements, and uncertain review timelines.

Key Takeaways:

- **Leverage the WHO PQ pathway as part of the global regulatory strategy:** WHO PQ is often regarded as a mark of quality, safety and performance. Companies developing IVD suited for resource-limited settings can leverage the WHO PQ pathway as part of their global regulatory strategies. The scope of IVD eligible for WHO PQ continues to expand beyond the list of priority diseases, which is determined in consultation with WHO disease programmes and based on public health needs. IVD that have been WHO prequalified are listed in a public report and are eligible for procurement by international procurement organisations such as WHO and United Nations (UN), as well as the Collaborative Registration Procedure (CRP) pathway for accelerated regulatory approval in participating countries.
- **Promote regional regulatory cooperation:** The African continental IVD framework accelerates access to IVD across multiple African countries, especially for emergency use and strengthens Africa's regulatory capacity.
- **Encourage multistakeholder collaboration and regulatory alignment:** Key stakeholders include national regulatory authorities, manufacturers and international organisations. The Mpox Expedited Collaborative Review and EUL frameworks in Africa highlight the importance of effective partnerships among stakeholders to align and streamline regulatory processes to enhance readiness for public health emergencies.
- **Further regulatory harmonisation efforts in ASEAN:** Regional initiatives like the AMDD provide a common framework for registration and technical requirements, streamlining the process for manufacturers. However, country-specific differences remain, and companies must still address specific regulation, language requirements, and approval processes in accordance with individual ASEAN member states.
- **Enhance the predictability of regulatory reliance-based pathways:** Leveraging the regulatory decisions of reference agencies can significantly shorten time to market and

reduce duplication of effort. However, variability in how each country implements reliance can contribute to the unpredictability faced by manufacturers. One way to address this is transparency in publishing regulatory timelines and documentation requirements for reliance-based pathways.

3.3.4 Effective Capacity Building and Enabling

Dr L. Rizka Andalucia, Director General, Pharmaceutical and Medical Devices, Ministry of Health, Indonesia

Dr Andalucia described effective capacity building as a key enabler for IVD development, providing insights from the perspective of the Indonesian Ministry of Health. She shared an overview of the current medical device landscape in Indonesia and recent initiatives of the Indonesian Health System Transformation, specifically in the medical devices and IVD sectors. These initiatives align with the government's broader public health objectives, particularly the eradication of TB.

Key Takeaways:

- **Capitalise on Indonesia's health transformation efforts:** Indonesia's health transformation efforts include promoting national screening and diagnostic programmes to improve public health. This is supported by national plans to ramp up production of locally manufactured, high quality and affordable IVD.
- **Strengthen regulatory systems and industry readiness:** Providing structured and sustained support for regulatory capacity building to regulators and manufacturers strengthens regulatory systems and industry readiness.
- **Build regulatory capacity among regulators:** The three pillars of regulatory capacity building are (1) human resource development, which aims to equip regulators with technical skills benchmarked against international best practices for regulatory approval and subsequent adoption of emerging technologies, and includes comprehensive training in technical standards and a thorough understanding of international best practices, (2) organisational development, through active participation in regional and international regulatory organisations, as well as collaboration with identified key stakeholders to advance IVD development, and (3) creation of an enabling environment, which includes funding allocation for regulatory capacity building activities, deployment of digital systems and strong government commitment.
- **Build regulatory capacity among IVD manufacturers and innovators:** The three pillars are (1) technical training and mentorship that enhance industry's understanding of regulatory expectations, (2) supporting the industry through market entry and establishing laboratory infrastructure for clinical evaluation and performance validation, and (3) creating an enabling regulatory environment, which includes establishing effective feedback mechanisms between regulators and innovators, and providing clear regulatory timelines and guidance.

3.3.5 Clinical Trials Support for IVD Innovations

Mr Alfred Kwek, General Manager, Tigermed Asia Pacific Private Limited and Talons Laboratories Pte Ltd, Professor, GHWP Academy, South China University of Technology

Mr Kwek outlined four key objectives of clinical performance studies required for IVD under the EU IVD Regulation (IVDR) and shared his company's experience as a contract research organisation (CRO) operating in Congo in relation to the Mpox IVD test kit approved for use under the EUL.

Key Takeaways:

- **Consider obtaining CE mark as a regulatory strategy:** CE marking is one of the preferred regulatory routes, offering a clear regulatory directive, has well-established and funded test laboratories, and is widely recognised and accepted internationally in many major global markets.
- **Understand the objectives of clinical performance studies under IVDR:** Objectives are to (1) demonstrate clinical performance in line with the manufacturer's intended purpose, (2) support CE marking under the IVDR (Annex XIII and XIV), (3) confirm the analytical performance of the IVD, and (4) generate evidence for sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and usability.
- **Provide a clear intended purpose statement:** It should clearly define the intended use, including the target population, specific condition or disease, sample type, and testing environment. Clinical claims must be supported by evidence, and the intended user should be specified (e.g., layperson, healthcare professional, or for self-testing).
- **Clearly define the roles and responsibilities for clinical performance studies:** The different roles and responsibilities include sponsors who oversee the study and regulatory submissions; clinical research associates who manage the clinical sites, participant recruitment, and data collection; principal investigators who provide clinical oversight; technology providers who offer device support, technical training, and data retrieval; and CROs who handle study monitoring, data management, and the development of the statistical analysis plan.
- **Consider the support from CROs:** The case example of the clinical performance study conducted by the CRO in Congo for the Mpox IVD test kit that differentiates Clade II from the more transmissible and severe Clade Ib highlights the significant role CROs can play. In this case, CROs accelerate market entry for startups and support the allocation and conservation of critical hospital resources in resource-limited settings.

3.3.6 Panel Discussion: Addressing Regulatory Barriers for IVD

Panellists: Dr L. Rizka Andalucia; Mr Alfred Kwek; Dr Gonzalo Domingo, Global Program Leader, Diagnostics Program, PATH; and Assistant Professor Tan-Koi Wei Chuen, Lead, Regulatory Systems Strengthening, CoRE. Moderated by Professor Fujie Xu, Co-Director, Global Health Program, Duke Kunshan University

The panel discussed types of regulatory barriers manufacturers face when getting IVD into the global market, and how these barriers can be addressed through strategic collaborations, use of publicly shared resources, and capacity building.

Key Takeaways:

- **Encourage collaboration between regulators and manufacturers, especially for first-in-class IVD:** Manufacturers often lack experience with clinical studies and regulatory submissions. Having close engagement with regulators from the early design phases supports regulatory strategy development, guides adequate evidence generation, and helps manufacturers work through language and timeline constraints more effectively. This can also help address the unique operational and reporting challenges faced when conducting clinical studies in LMIC**.** Limited infrastructure and experience in these settings can create barriers in sample collection and participant recruitment needed for study preparation and submission of performance reports.
- **Build quality systems:** With the aim of providing access to affordable and quality IVD, Indonesia is working to incorporate international best practices in its processes such as international guidelines in clinical validation and testing, while concurrently building an ecosystem of quality infrastructure, such as Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) certified facilities.
- **Utilise publicly available resources to support global regulatory strategy:** Public resources include global clinical trial protocol templates available on the PATH website.
- **Contextualise regulatory decisions in adopting regulatory reliance:** Different countries may have different regulatory considerations and contexts that need to be accounted for in the practice of reliance. For example, leveraging the regulatory evaluation of an IVD approved by the United States Food and Drug Administration (FDA) for use in a hospital and clinical setting would require different regulatory considerations when evaluated for use in a resource-limited setting.
- **Leverage the WHO PQ pathway as part of the global regulatory strategy:** WHO PQ is widely regarded as a benchmark of quality. Incorporating this pathway as part of a global regulatory strategy can help streamline global distribution, accelerate market entry and facilitate regulatory consensus across multiple markets.
- **Integrate regulatory and business strategies:** These should be holistically considered and include regulatory pathways, market size, competitors, profit margins, clinical needs, and the need to balance investment and timelines. Strategic business planning is crucial for managing challenges including unpredictable timelines from IVD

development through revenue generation. Companies should anticipate the need for substantial upfront investments, depending on the regulatory pathway selected and market objectives.

- **Develop strategic leadership capabilities alongside regulatory capacity building:** The CREATInG project aims to support IVD manufacturers and business leaders by honing decision-making capabilities and regulatory expertise, which can help address some of the key regulatory and business challenges in the IVD ecosystem.

3.4 Support IVD Access for LMIC Markets

In this session, a wide range of issues related to IVD access for LMIC markets throughout the product development cycle were discussed, with perspectives from the industry, funders, regulators and international organisations. These issues include market entry and adoption, sustainable financing, innovative business models and regulatory mechanisms that can better support the development of innovative and contextualised IVD solutions, such as access to biobanks and a wider adoption of risk-based regulatory reliance. The session concluded with a call to collective action, for each stakeholder to be proactive in engaging one another and form partnerships to facilitate IVD access for LMIC markets.

3.4.1 Considerations for Entering LMIC Markets

Professor Tan Sze Wee, Advisor, Temasek International, Adjunct Professor, Duke-NUS Medical School and Nanyang Technological University's Lee Kong Chian School of Medicine, Singapore

Prof Tan highlighted key considerations in entering LMIC markets including contextualising diagnostic solutions, recognising the resource limitations in these settings, forging multistakeholder and private-public partnerships for sustained impact, and building a sustainable business model that adds value to payors and the healthcare system.

Key Takeaways:

- **Contextualise diagnostic solutions:** These include considering the local disease burden and epidemiology, roles and the extent of influence of various stakeholders such as the private sector and donors, level of economic development, level of governance, degree of regulatory maturity, and government policies that influence decisions on manufacturing base and supply chain aspects.
- **Recognise resource limitations in LMIC settings:** These can range from the availability of financial resources such as subsidies and national insurance schemes to access diagnostics, physical constraints that can limit implementation of a new diagnostic at existing laboratory facilities in public hospitals, and resources available for capacity building among care providers to be competent in using the IVD.

- **Establish multistakeholder partnerships for sustained impact:** This is especially important when implementing first-in-class technologies. For example, in tackling antimicrobial resistance, achieving sustained impact from rapid identification of resistant genes through the Advancing Clinical Evidence in Infectious Diseases (ADVANCE-ID) initiative is contingent on stakeholders working together to update hospital protocols and change clinical practice on antimicrobial use.
- **Adopt a whole-of-ecosystem approach with regulation as a key enabler:** The Fortitude™ SARS-CoV-2 RNA RT-PCR test kit is an example of private-public partnership, where early engagement with regulators to prioritise quality production contributed to the successful deployment and international distribution of the test kit to more than 35 countries including LMIC.
- **Build a sustainable business model that adds value to payors and the healthcare system:** A competitive advantage could be data integration of point-of-care IVD, with data output presented on a user-friendly interface that can be used for monitoring and reporting of outcomes.

3.4.2 Regulatory Understanding to Facilitate IVD Access for LMIC

Dr Susie Braniff, Scientist, Prequalification IVD Assessment Team, Health Systems Division, WHO

Dr Braniff shared on the WHO CRP, which leverages the WHO PQ procedure to accelerate in-country registration of prequalified IVD products.

Key Takeaways:

- **Leverage the CRP to accelerate access to LMIC markets:** CRP is voluntary, where the manufacturer of a prequalified IVD can submit an expression of interest to the national regulatory authority (NRA) that is participating in the CRP to use this pathway to accelerate market authorisation in that country. The transparency of the CRP facilitates market access as it assures buyers that the product registered has the same essential features as the prequalified product.
- **Capitalise on the CRP to support regulatory capacity building:** Regulatory reliance by the participating NRA leveraging the WHO PQ procedure reduces duplicative work and saves resources in the assessment of prequalified IVD products, while supporting capacity building of participating NRA staff.
- **Create a legal framework for regulatory reliance:** Countries of NRAs participating in the CRP will need to have a legal framework in place to adopt regulatory reliance.
- **Raise awareness on the CRP:** Creating awareness among local registrants to use the CRP pathway and encouraging NRA participation can facilitate wider CRP adoption.

3.4.3 Utility of Regulatory Reliance for Facilitating Access to IVD

Dr Rama Sethuraman, APAC Head, Quality and Regulatory, Roche Diagnostics Asia Pacific Pte Ltd, Singapore

Dr Sethuraman spoke on regulatory reliance as a tool to facilitate access to quality healthcare. She described the WHO Good Reliance Practice, the various forms of reliance and shared examples in Asia and the Pacific region.

Key Takeaways:

- **Encourage regulatory reliance:** Regulatory reliance can be defined as the act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to another regulatory authority or trusted institution in reaching its own decision. It is practised even by advanced regulatory authorities, with the sovereignty, accountability and independence of decision-making held by the regulatory authority practising reliance.
- **Practise smart regulation through reliance:** In practising regulatory reliance in various regulatory activities across the product life cycle, regulatory resources can be reprioritised to facilitate access to innovative clinical technologies. The revised reliance pathway of Australia's TGA contributed to reduced timelines and submission requirements following updates from the EU on the IVDR in 2021. Examples of abridged pathways are the Expedited Pathway of Singapore's HSA and the Concise Pathway of Thailand's FDA, where assessments by identified reference agencies are leveraged.
- **Build regulatory capacity and trust among regulators:** The pilot exercise of the Thailand-Singapore Reliance Process built trust between both regulatory authorities. Information sharing facilitated a deeper mutual understanding of each NRA's processes and supported the development of regulatory capabilities and competence.
- **Provide predictability and transparency of regulatory decisions:** Industry participating in the pilot exercise of the Thailand-Singapore Reliance Process benefitted from the predictability in regulatory evaluation turnaround time, which reduced from between 6 to 8 months to 3 months, and transparency in how regulatory decisions were made.
- **Work towards achieving greater levels of regulatory efficiency among regulatory authorities:** An example of regional reliance is EU Notified Bodies for centralised assessment within the EU region. Mutual recognition is the mutual acceptance of assessments by a trusted institution or regulatory authority, such as the mutual recognition of conformity assessments between Australia and EU. Increasing levels of trust and regulatory efficiency are seen when NRAs engage in greater levels of regulatory reliance such as in regional reliance and mutual recognition mechanisms.

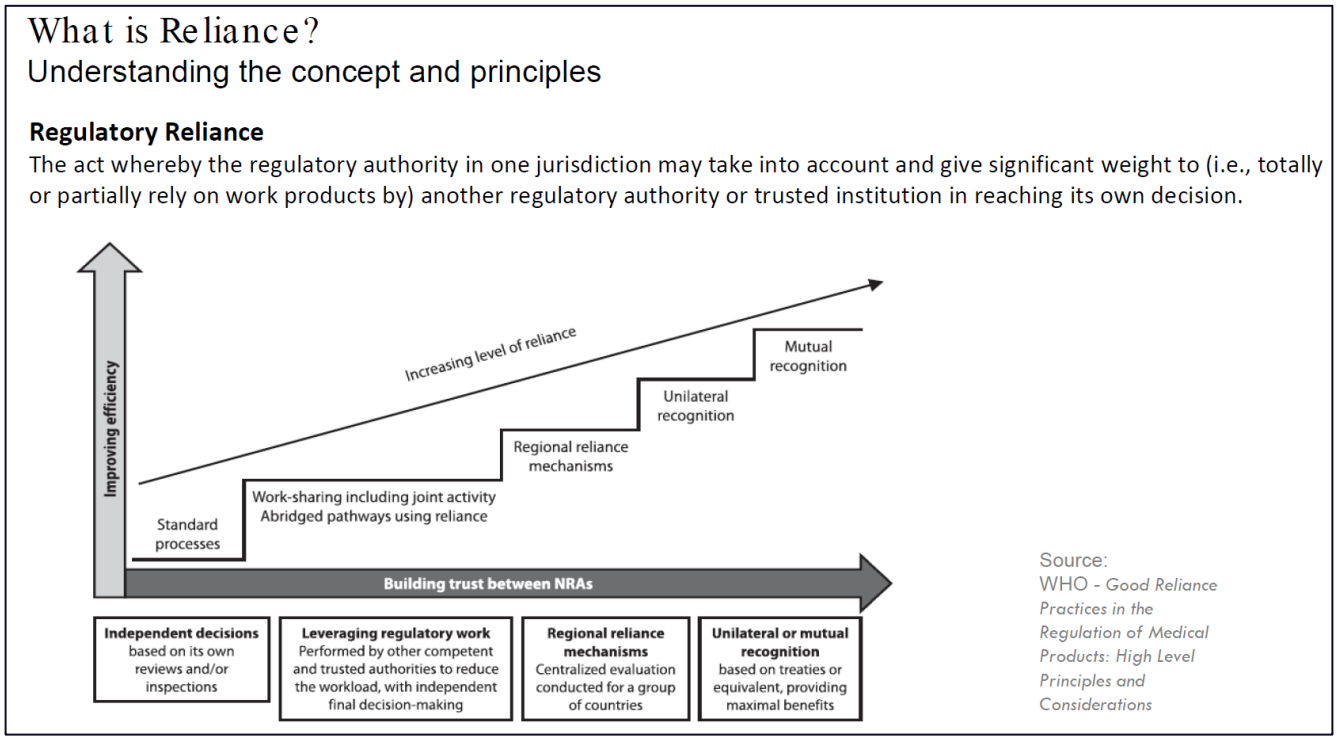

Figure 2: What is Reliance? WHO Good Reliance Practice

3.4.4 Panel Discussion: Stakeholder Partnerships to Facilitate IVD Access for LMIC

Panellists: Professor Tan Sze Wee; Dr Rama Sethuraman; and Dr Jennifer Granger, Senior Programme Officer, EDGE Diagnostics Team, Global Health, Gates Foundation. Moderated by Professor Christopher Woods, Wolfang Joklik Distinguished Professor of Health, Professor of Medicine and Pathology, Duke University, Chief, Infectious Diseases, Durham VA Health System

Panellists discussed both intra and inter stakeholder partnerships. They explored the roles and relevant issues of each stakeholder group. Panellists advocated for early engagement among all groups to facilitate IVD access. Companies can proactively engage end users, local governments and regulators to contextualise IVD solutions and drive regulatory changes. The panel also urged regulators to work on regulatory alignment and toward increasing levels of reliance.

Key Takeaways:

- **Understand the local context:** A key obstacle is the limited understanding of the local setting. It is helpful for IVD companies to have a good grasp of the operational issues end users face on the ground. This can promote the correct use of products, especially for complex technologies such as tNGS technologies.

- **Engage funders, local governments and communities to develop bespoke data-driven IVD solutions:** The Gates Foundation recognises its role as investing in and creating an ecosystem where local governments and communities are involved, with stakeholders driving collective action and policy change. It is important to have consensus on outcomes established at the beginning of a partnership. With local governments often being a key payor, bespoke, data-driven and digitally enabled IVD solutions add value to payors and the healthcare system and can be a major opportunity for companies in developing a sustainable business model.
- **Proactively engage regulatory authorities:** The panel urged companies to actively engage regulatory authorities and participate in regulatory activities such as public consultations to drive the change they wish to see.
- **Promote regulatory alignment:** Align to internationally recognised regulatory standards and guidelines. It can be helpful for companies to understand where the regulatory differences are. Regulatory messaging should be consistently presented in a manner that companies can understand and for companies to have access to the right information.
- **Encourage regulatory reliance:** Regulatory authorities will have to consider their local context, clinical practice and needs in making their own independent risk-benefit assessments when practising regulatory reliance. Regulatory authorities in the region can work towards increasing levels of reliance, such as joint assessment pathways.

3.4.5 Panel Discussion: Measures and Milestones for Facilitating IVD Access

Panellists: Mr Wong Fatt Heng, Founder, Shanghai IVD Consulting Company; Dr Paulyne Wairimu, Chair, African Medical Devices Forum (AMDF), African Medicines Harmonization Initiative, Lead, Medical Devices and Diagnostics, Pharmacy and Poisons Board; Professor Christopher Woods, Wolfang Joklik Distinguished Professor of Health, Professor of Medicine and Pathology, Duke University, Chief, Infectious Diseases, Durham VA Health System; and Ms Mariammah Krishnasamy, Deputy Director, Policy and Guidance Document Section, Medical Device Authority (MDA), Ministry of Health Malaysia. Moderated by Dr Sidney Yee, Adjunct Associate Professor, CoRE, Duke-NUS Medical School, Singapore

The panel discussed measures and milestones to guide policy development, balancing quality, safety, performance and cost-effectiveness of IVD products to facilitate market entry and adoption.

Key Takeaways:

- **Employ a risk-based regulatory reliance approach:** The risk-based regulatory reliance approach employed by the MDA of Malaysia in referencing the regulatory decisions by Singapore and Thailand include differentiated requirements based on the class of IVD products.

- **Formalise regional cooperation:** The African Union Model Law provides a common legal framework for African countries to cooperate. The regulation of health products including IVD is within the ambit of the AMA. There is also a component of market intelligence within the AMA that supports resource allocation across the continent. One pillar of the AMDF strategic plan 2022 to 2027 is supporting the strengthening of African regulatory authorities, by identifying their needs, developing internationally recognised and harmonised documents that manufacturers can understand, and strengthening laboratory systems.
- **Adopt sustainable financing and innovative business models:** Sustainable financing is a key consideration for companies seeking to venture into global markets. A decision-making framework for these companies could encompass a broad assessment of the political, environmental, social and technological aspects. These include (1) defining customers and their needs, (2) adopting innovative IVD solutions and business models, such as one where the payor pays for the information and the data that the product provides rather than reagents and consumables, (3) understanding the competition, (4) performing a SWOT analysis of one's own company, and (5) developing a clear business strategy for execution.
- **Facilitate access to biorepositories and explore regulatory sandbox approach:** More support for IVD product innovation could be provided through sharing access to biorepositories and adopting a regulatory sandbox approach that facilitates early collaboration among regulators, innovators and other experts for end-to-end total product development.
- **Establish greater levels of regulatory reliance:** Facilitated pathways towards multinational or even regional regulatory approval can support market entry and access to IVD.

4 Closing Remarks

4.1 Remarks from CoRE

Professor John Lim, Executive Director, CoRE, Duke-NUS Medical School, Singapore

Prof Lim thanked the speakers and participants for the enriching dialogue and the organising teams comprising the Gates Foundation, CoRE and DKU for the successful inaugural Roundtable of the CREATInG Initiative. He highlighted three key takeaways: (1) promoting the convergence of regulatory standards and working towards greater levels of regulatory reliance, including increasing access to biobanks and samples, (2) the need to consider IVD access beyond regulation and address issues of cost-effectiveness and sustainable financing, and (3) engaging with the wider ecosystem so that the interventions discussed can deliver a global impact. He called for participants to develop a wider movement and community of practice with everyone functioning as advocates and ambassadors proactively engaging one another and the wider ecosystem to influence positive change, so that IVD products can reach LMIC and global communities that need them.

5 Key Takeaways

1. **Build sustainable IVD ecosystems:** This requires trusted stakeholder partnerships, strong political will, regulatory harmonisation and flexible regulatory approaches, sustainable funding resources, and local and regional strategic measures to strengthen the ecosystems.
2. **Facilitate access to IVD:** Accessibility of a product goes beyond market entry and includes successful market adoption. An end-to-end approach is needed in the development of innovative products with the needs of diverse stakeholders in mind. The go-to-market strategy requires a sustainable business model with practical implementation considerations including coordinated responses to regulatory and market access requirements. Assessment of market readiness as well as supportive resources such as open data, biobanks, market insights and laboratory facilities are especially critical for new innovative platforms such as targeted next generation sequencing (tNGS).
3. **Enhance regulatory strategies in IVD development:** Multi-stakeholder collaboration on regulatory strategies can facilitate IVD global access. Key approaches include (1) early multi-market compliance built into product development by manufacturers, (2) harmonizing technical standards, (3) facilitating cross-border data access and certification acceptance through leveraging existing regulatory frameworks and resources by regulators, and (4) regulatory capacity building supported by key stakeholders.

4. **Support IVD access for LMIC markets:** This requires all stakeholders in the ecosystem to work on overcoming the challenges and collaboratively finding innovative solutions to facilitate quality, safe and cost-effective IVD products.

6 Next Steps Forward

Mr Liang Yu, Associate Director, Executive Education and Lifelong Learning at Duke Kunshan University (DKU)

The CREATInG Initiative's next major activity is the Executive Development Programme, designed to enhance C-suite executives' capabilities in sustainable business development and strategic planning for global market expansion. This is scheduled for 27 to 29 September 2025 and will be held at DKU, featuring site visits and dialogue with experienced global IVD companies.

7 Attendance

1. The Roundtable attracted over 50 participants, representing government and regulatory authorities (21%), IVD manufacturers (41%), stakeholders (24%), and observers (14%).
2. Participants came from 11 countries: Australia, People's Republic of China, India, Indonesia, Kenya, Malaysia, Republic of Korea, Singapore, Switzerland, Thailand, and the United States of America.
3. Representatives from not-for-profit and international organisations included ASK Health Asia, Singapore's Diagnostics Development Hub (DxD), Singapore Economic Development Board (EDB), FIND, Gates Foundation, PATH, RIGHT Foundation, Temasek International, and the World Health Organization (WHO).

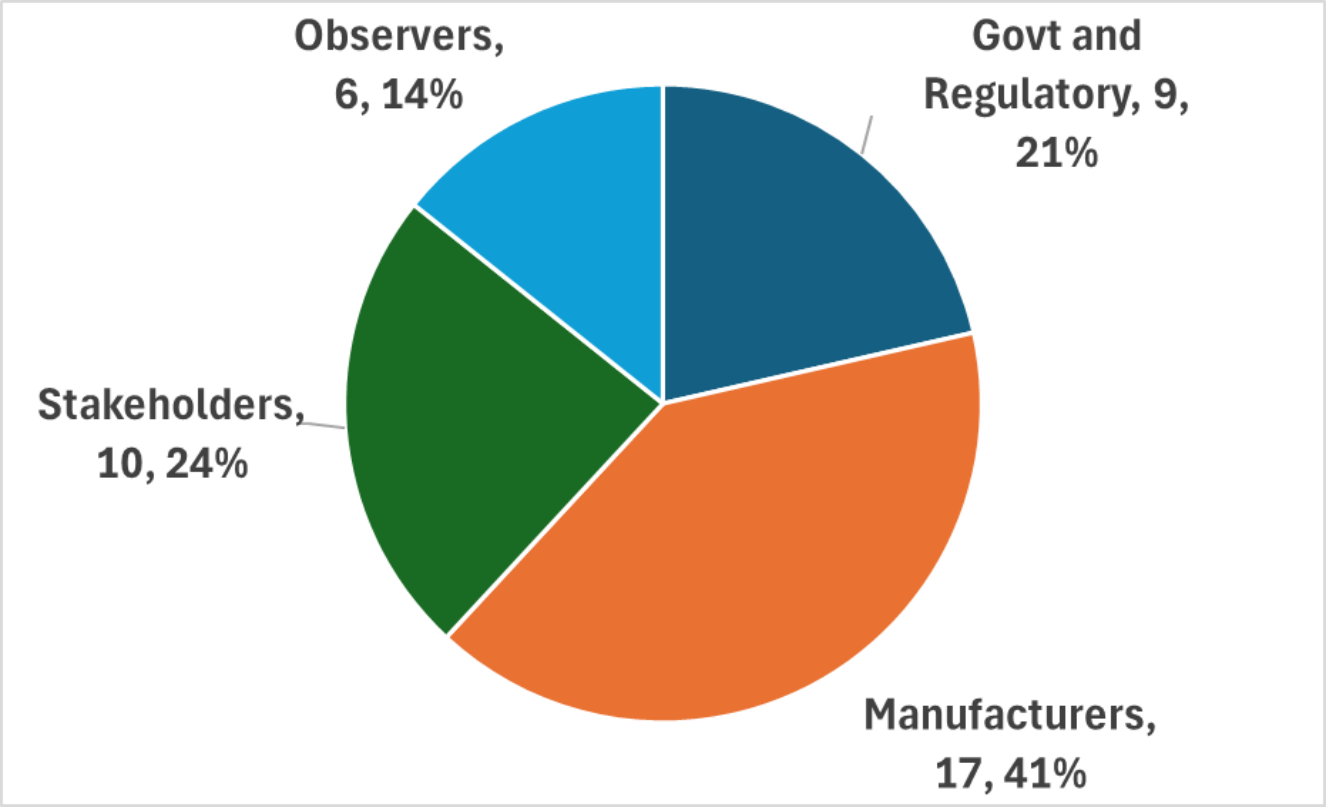

Figure 3: Profile of Attendance

8 Annexes: Programme Brochure

[See link]

9 Acknowledgements

We thank the speakers, moderators and participants for their deep insights and enriching dialogue on facilitating safe, quality and cost-effective to LMIC and global communities that need them.

This report was prepared by Ms Chan Mei Xuan Jessalyn, Dr Rathi Saravan, Ms Faith Tan and Asst. Prof Tan-Koi Wei Chuen, with input from Asst. Prof James Leong, and approved by Professor Silke Vogel and Professor John Lim.

The views presented in this report are those of individual contributors and do not represent formal consensus positions of the authors' organisations or CoRE.

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"Only with the right diagnosis, can we begin to find a cure."