CREATInG Initiative International Roundtable

Grand Copthorne Waterfront Hotel, Singapore

14 and 15 July 2025

AGENDA

Objectives

1. Identify priorities to enable and support a sustainable IVD ecosystem to ensure access to quality health
2. Determine action items to promote timely IVD access to Lower- and Middle-Income Countries (LMIC)
3. Distinguish appropriate strategies to facilitate market entry of IVD to global markets

*The Programme is accurate as of 17 June 2025 and may be subjected to further revisions.

CREATInG Initiative International Roundtable

Impactful interventions for IVD access in Global Markets

14 and 15 July 2025

Day 1 – 14 July, Monday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Welcome**	**Prof John LIM** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School Singapore Senior Advisor Ministry of Health Singapore
9.10am	**Opening remarks by Guest-of-Honour**	**Ms GOH Wan Yee** Senior Vice President Head of Healthcare Economic Development Board (EDB) Singapore
9.20am	Plenary Session **Equitable access to IVD – Paradigm shifts in enabling stakeholders**	**Dr Wenfeng GONG** Deputy Director Health Innovation and Partnerships China Country Office Gates Foundation
Building a sustainable ecosystem for IVD		
10.00am	**Addressing the global uncertainties – What are the implications for IVD manufacturers?**	**Dr Chandrasekhar NAIR** Director and Chief Technical Officer Molbio Diagnostic Ltd India
10.30am	**Refreshment Break**	
11.00am	**Opportunities for stronger collaborations among IVD stakeholders** - Overview of project objectives - Findings from user needs analysis - The Chinese IVD landscape	**Prof Fujie XU** Co-Director Global Health Program Duke Kunshan University **Asst Prof TAN-KOI Wei Chuen** Lead, Regulatory Systems Strengthening CoRE Duke-NUS Medical School

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11.45am	Panel Discussion **Evolving the roles of stakeholders towards a stronger and sustainable ecosystem for IVD**	Moderator **Prof John LIM** CoRE Panellists **Dr Wen Feng GONG** Gates Foundation **Dr Chandrasekhar NAIR** Molbio Diagnostic Ltd **Ms WONG Woei Jiuang** Asst Group Director Medical Devices Cluster Health Products Regulation Group Health Sciences Authority Singapore **Dr Gonzalo DOMINGO** Global Program Director Diagnostics Program PATH
12.30pm	**Lunch**	
Facilitating access to IVD		
1.30pm	**Challenges in bringing IVD to other markets**	**Dr Sidney YEE** Adjunct Associate Professor CoRE Duke-NUS Medical School Singapore
2.00pm	**Adoption of new IVDs in health systems**	**Ms Anita SURESH** Director Genomics and Sequencing Unit FIND

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2.30pm	Breakout Session **Key gaps affecting the IVD access and adoption**	Health and Regulatory System Chairperson: **Ms Anita SURESH** FIND Industry and Innovators Chairperson: **Mr WONG Fatt Heng** Founder Shanghai IVD Consulting Company Chairperson: **Dr Justin IM** Director Programs & Strategy RIGHT Foundation Chairperson: **Mr John JAMIESON** Assistant Secretary Medical Devices Authorisation Branch Australian Government Department of Health Disability and Ageing Therapeutic Goods Administration
3.30pm	**Refreshment Break**	
4.00pm	**Presentations from Breakout Session** • Rapporteur for Health and Regulatory Systems • Rapporteurs for Industry and Innovators	
4.45pm	**Conclusion for Day 1**	
5.00pm	**End**	

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Day 2 – 15 July, Tuesday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Enhancing regulatory strategies in IVD development		
9.00am	**Optimising IVD regulatory strategy for the global market**	**Mr Derek LEE** Chief Strategic Officer iGENETECH Inc.
9.15am	**Navigating through challenges to market IVD innovation**	**Mr Ray YAO** Project Manager International Business Development Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.
9.30am	**Understanding the regional regulatory landscape** - **WHO Pre-qualification** - **Africas / South Africa** - **ASEAN**	**Dr Susie BRANIFF** Scientist In Vitro Diagnostics Assessment Team Prequalification Unit | Regulation and Prequalification Department World Health Organization **Dr Paulyne WAIRIMU** Chair African Medical Devices Forum (AMDF) African Medicines Harmonization Initiative **Dr Ruifen WENG** Chief Executive Officer Diagnostics Development Hub (DxDHub) Singapore
10.30am	**Refreshment break**	
11.00am	**Effective capacity building and enabling**	**Dr Dra Lucia Rizka ANDALUCIA** Director General Pharmaceutical and Medical Devices Ministry of Health Indonesia
11.20am	**Clinical trials support for IVD innovations**	**Mr Alfred KWEK** General Manager Tigermed Asia Pacific Private Limited

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11.40am	Panel Discussion **Addressing regulatory barriers for IVD**	Moderator **Prof Fujie XU** Duke Kunshan University Panellists **Mr Alfred KWEK** Tigermed Asia Pacific Private Limited **Dr Gonzalo DOMINGO** PATH **Dr Dra Lucia Rizka ANDALUCIA** Ministry of Health Indonesia **TBC**
12.30pm	**Lunch**	
Supporting IVD access for LMIC markets		
1.30pm	**Considerations for entering LMIC markets**	**Prof TAN Sze Wee** Advisor Temasek International
1.50pm	**Regulatory understanding to facilitate IVD access for LMIC**	**Dr Susie BRANIFF** Scientist In Vitro Diagnostics Assessment Team Prequalification Unit Regulation and Prequalification Department World Health Organization
2.10pm	**Utility of regulatory reliance for facilitating access to IVD**	**Dr Rama SETHURAMAN** Head of Quality and Regulatory, APAC Roche Diagnostics Asia Pacific
2.30pm	Panel Discussion **Stakeholder partnerships to facilitate IVD access for LMIC**	Moderator **Prof Christopher WOODS** Wolfgang Joklik Distinguished Professor of Global Health Professor of Medicine and Pathology Duke University Panellists **Prof TAN Sze Wee** Temasek International **Dr Rama SETHURAMAN** Roche Diagnostics **Dr Susie BRANIFF** World Health Organization
3.00pm	**Refreshment Break**	

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3.30pm	Polling **What would progress look like in 3 years?**	
3.45pm	Panel Discussion **Measures and milestones for facilitating IVD access**	Moderator **Dr Sidney YEE** Adjunct Associate Professor CoRE Duke-NUS Medical School Singapore Panellists **Mr WONG Fatt Heng** Shanghai IVD Consulting Company **Dr Paulyne WAIRIMU** African Medicines Harmonization Initiative **Prof Christopher WOODS** Duke University **TBC**
4.30pm	**Conclusion and Next Steps**	**Prof John LIM** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School Singapore Senior Advisor Ministry of Health Singapore
5.00pm	**End**	

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