CREATInG Initiative International Roundtable

Impactful Interventions for IVD Access in Global Markets

PROGRAMME BOOKLET

14 – 15 July 2025

Grand Copthorne Waterfront Hotel

Singapore

CONTENTS

Welcome Message

On behalf of the Duke-NUS Centre of Regulatory Excellence (CoRE), the Duke Kunshan University (DKU) and the Gates Foundation, we welcome you to the **CREATInG Initiative International Roundtable: "Impactful Interventions for IVD Access in Global Markets"**.

The CREATInG Initiative, a project commissioned by the Gates Foundation and co-led by Duke-NUS CoRE and DKU, aims to accelerate access to in-vitro diagnostics for critical global health needs. With a focus on infectious diseases as well as maternal and fetal health, this initiative aims to bridge regulatory and access gaps, ensuring timely, reliable diagnostics reach the communities that need them most.

Recognising that such challenges require collective action, we welcome a broad range of stakeholders to address regulatory and access gaps in our increasingly interconnected world. This by-invitation international roundtable will use an interactive approach for regional and global speakers and participants from international organisations, global regulatory experts, in-vitro diagnostic manufacturers and other stakeholders to collectively discuss issues and consider innovative approaches to facilitate access of timely and reliable diagnostics to support optimal care to populations.

We look forward to your active participation during the discussions and trust that you will find this roundtable both relevant and enriching and help contribute to strengthening healthcare systems globally.

Prof John Lim
Executive Director
Centre of Regulatory Excellence
Duke-NUS Medical School
Senior Advisor
Ministry of Health, Singapore

Prof Fujie Xu
Co-Director
Global Health Program
Duke Kunshan University
China

Programme Directors

Professor John Lim

Professor John CW Lim is the founding Executive Director of the Duke-NUS Centre of Regulatory Excellence (CoRE), where he promotes capacity building, scientific excellence, and innovation for health regulation and systems across Southeast Asia and the Asia-Pacific. He concurrently serves as Senior Advisor at Singapore's Ministry of Health (MOH), and Policy Core Lead at the SingHealth Duke-NUS Global Health Institute.

Formerly Chief Executive Officer of Singapore's Health Sciences Authority and Deputy Director of Medical Services in MOH, Professor Lim has also held other senior positions in Singapore's Health and Education ministries. His expertise and interests focus on Asia-Pacific regulatory harmonisation and innovation initiatives, regulatory agility, and the converging of health products and health services regulation that impacts trending areas including AI/digital health, precision public health, advanced therapies and patient engagement.

Prof Lim graduated in medicine from NUS and has postgraduate degrees in public health from NUS and health policy and management from Harvard University. Professor Lim has joint academic appointments at Duke-NUS and the NUS Saw Swee Hock School of Public Health.

Professor Silke Vogel

In her role as Senior Associate Dean of Graduate Studies, Prof Silke Vogel leads the administrative, academic and educational affairs of three PhD programmes with the goal to enable each graduate student to achieve academic excellence in their PhD degree and realise their career goals. Since taking on the role of Deputy Director at the founding of CoRE in 2014, Prof Vogel drives the implementation of the strategic goals of the Centre and continously advances CoRE as a dedicated training platform for regulatory science. Under her leadership, the Graduate Certificate programmes was established as CoRE's flagship programme and is the first dedicated academic regulatory training program in Asia.

Stemming from her work with the Graduate Programmes and CoRE, Prof Vogel is passionate about providing opportunities for working professionals who strive to upskill and advance their careers. Building on this, she is heads the Centre for Lifelong Learning (CLL) at Duke-NUS with the overarching goal to establish a comprehensive learning hub for healthcare professionals. Under the CLL umbrella, several NUS accredited programs as well as short courses are being offered with a planned expansion over the next year.

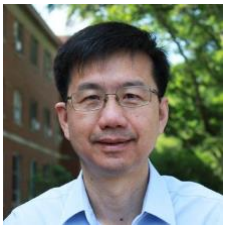
Dr Fujie Xu

Prof Fujie Xu co-directs the Global Health Program at Duke Kunshan University (DKU), China. Prior to her appointment at DKU in January 2025, she was the Deputy Director for Health Innovation and Partnership at the Gates Foundation's China Country Office. Dr Xu's research interests focus on outbreak detection and health emergency response, and she was a "disease detective" in the global response to epidemics and pandemics, including the SARS outbreak and the H1N1 influenza pandemic. During "peace" time, her research focuses on the introduction of new vaccines, diagnostics and treatments against infectious diseases in the United States, China and other Asian countries.

She has published widely on various aspects of infectious diseases, particularly HIV/STD, viral hepatitis infections, and emerging and re-emerging infections and has extensive experience in health product innovations and in developing clinical and public health guidelines.

Dr Fujie Xu received her medical training at Peking University in China and earned a doctoral degree in epidemiology at Emory University in the United States. She also completed her post-doctoral training as an Epidemic Intelligence Service officer at the US Centers for Disease Control and Prevention, where she worked for 17 years.

Dr Shenglan Tang



Dr Shenglan Tang is a faculty member at Department of Population Health Science in the Duke University School of Medicine and Research Professor of Global Health in the Duke Global Health Institute (DGHI). He is also Professor of global health at Duke Kunshan University, and SingHealth-Duke-NUS Global Health Institute in Singapore. Recently Dr Tang is co-director for global health at Duke Kunshan University, China.

Dr Tang has more than 30 years of experience undertaking research on health systems reform, disease control and maternal and child health in China and other countries, and has provided consultancy services on health systems strengthening to many international organizations and governments of developing countries. At present, he is directing an innovation lab for vaccine delivery research funded by the Gates Foundation.

In 2012, Dr Tang came to Duke from the UNICEF/UNDP/World Bank/World Health Organisation (WHO) Special Program for Research and Training in Tropical Diseases (TDR), based in Geneva, where he was Unit Leader for TB/HIV and Health Systems. Before his assignment at WHO, Dr Tang was a faculty member at Liverpool School of Tropical Medicine in UK and at the School of Public Health of Fudan University (formerly Shanghai Medical University).

Programme

14 July 2025, Monday Venue: Level 3, Lyrebird Room, Grand Copthorne Waterfront Hotel, Singapore		
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 Co-founder Bigtec Labs
10.30am	**Photo-taking & Refreshment Break**	
11.00am	**Updates from CREATInG Project - Opportunities for stronger collaborations among IVD stakeholders**	**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, Singapore

11.45am	**Panel Discussion** Evolving the roles of stakeholders towards a stronger and sustainable ecosystem for IVD	Moderator **Prof John LIM** CoRE Panellists **Dr Wenfeng 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 Leader Diagnostics Program PATH
12.30pm	**Lunch**	
Facilitating access to IVD		
1.30pm	**Learnings from 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 Diagnostics Development FIND
2.30pm	**Breakout Session** Key gaps affecting the IVD access and adoption	<u>Health and Regulatory System</u> Chairperson: **Mr John JAMIESON** Assistant Secretary Medical Devices Authorisation Branch Australian Government Department of Health Disability and Ageing Therapeutic Goods Administration (TGA) <u>Industry and Innovators</u> Chairperson: **Mr WONG Fatt Heng** Founder Shanghai IVD Consulting Company Chairperson: **Ms Anita SURESH** FIND

		Chairperson: **Dr Justin IM** Director Programs & Strategy RIGHT Foundation
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**	**Mr Min YANG** Senior Programme Officer Health Innovation and Partnerships China Country Office Gates Foundation
5.00pm	**Networking session**	
6.00pm	**End**	

15 July 2025, Tuesday

Venue: Level 3, Lyrebird Room, Grand Copthorne Waterfront Hotel, Singapore

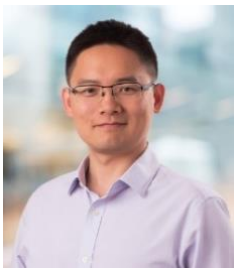
Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Enhancing regulatory strategies in IVD development		
9.00am	**Optimising IVD regulatory strategy for the global market**	**Mr Derek LEE** Chief Strategic Officer iGENETECH Inc.
9.15am	**Navigating through challenges to market IVD innovation**	**Mr Rui YAO** Marketing Manager Wantai Biopharm International BU
9.30am	**Understanding the regional regulatory landscape** - **WHO Pre-qualification** - **Africas / South Africa** - **ASEAN**	**Dr Susie BRANIFF** Scientist Prequalification IVD Assessment Team Health Systems Division World Health Organization (WHO) **Dr Paulyne WAIRIMU** Chair African Medical Devices Forum (AMDF) African Medicines Harmonization Initiative Lead, Medical Devices and Diagnostics Pharmacy and Poison Board

		Dr Ruifen WENG Chief Executive Officer Diagnostics Development Hub Agency for Science, Technology and Research (A*STAR), Singapore
10.30am	**Refreshment break**	
11.00am	**Effective capacity building and enabling**	**Dr L. 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 and Talons Laboratories Pte Ltd. Professor GHWP Academy South China University of Technology
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 L. Rizka ANDALUCIA** Ministry of Health, Indonesia **Asst Prof TAN-KOI Wei Chuen** CoRE
12.30pm	**Lunch**	
Supporting IVD access for LMIC markets		
1.30pm	**Considerations for entering LMIC markets**	**Prof TAN Sze Wee** Advisor, Temasek International Adjunct Professor Duke-NUS Medical School and Nanyang Technological University's Lee Kong Chian School of Medicine, Singapore
1.50pm	**Regulatory understanding to facilitate IVD access for LMIC**	**Dr Susie BRANIFF** WHO
2.10pm	**Utility of regulatory reliance for facilitating access to IVD**	**Dr Rama SETHURAMAN** APAC Head Quality and Regulatory Roche Diagnostics Asia Pacific Pte Ltd Singapore

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 Chief, Infectious Diseases, Durham VA Health System Panellists **Prof TAN Sze Wee** Temasek International **Dr Rama SETHURAMAN** Roche Diagnostics **Dr Jennifer GRANGER** Senior Programme Officer EDGE Diagnostics Team Global Health, Gates Foundation
3.00pm	**Refreshment Break**	
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** CoRE Panellists **Mr WONG Fatt Heng** Shanghai IVD Consulting Company **Dr Paulyne WAIRIMU** African Medical Devices Forum (AMDF) African Medicines Harmonization Initiative **Prof Christopher WOODS** Duke University **Ms Mariammah KRISHNASAMY** Deputy Director, Policy and Guidance Document Section Medical Device Authority (MDA) Ministry of Health Malaysia
4.30pm	**CREATInG – Executive Development Programme**	**Mr Liang YU** Associate Director Executive Education and Lifelong Learning Duke Kunshan University
4.45pm	**Conclusion and Next Steps**	**Prof John LIM** CoRE
5.00pm	**End**	

Speakers

Name	Designation & Biography
Day 1: 14 July 2025, Monday	
Ms GOH Wan Yee **Senior Vice President** **Head of Healthcare** **Economic Development Board (EDB)** **Singapore** 	Ms Goh Wan Yee is the Senior Vice President and Head for Healthcare in the Singapore's EDB. She oversees the industry development strategies and engagement of international companies to facilitate investments in Singapore and works closely with relevant stakeholders to enhance our public research and innovation ecosystem. Ms Goh is a board member of the CRIS and serves on the board oversight committees of Precision Health Research Singapore (PRECISE) and Advanced Cell Therapy and Research Institute, Singapore (ACTRIS). She is also on the governing board of Experimental Drug Development Centre (EDDC) and the steering board of Pharmaceutical Innovation Programme Singapore (PIPS). She co-chairs Singapore's Biopharmaceutical Manufacturer's Advisory Council (BMAC) and is on the industry advisory council of Singapore Institute of Technology's (SIT) Pharmaceutical Engineering programme. Prior to this, Ms Goh led EDB's Human Capital team and was responsible for working closely with companies, industry associations, unions and Singapore's manpower agencies to attract and develop talent for our wide range of industries. She also spent some time in EDB's Human Resources and has a depth of knowledge across various HR functions. Ms Goh started her EDB career in the then nascent Biomedical Sciences cluster and was part of the team that spearheaded the growth of this industry. This included a stint in Bio*One Capital, a venture capital arm of EDB that invests in biotechnology and medical technology start-ups.

Name	Designation & Biography
Dr Wenfeng GONG **Deputy Director** **Health Innovation & Partnerships** **China Country Office** **Gates Foundation** 	Dr Wenfeng Gong leads a portfolio of health product development collaborations in China and other geographies, working to accelerate the translation, development, and commercialization of medical products— including drugs, vaccines, monoclonal antibodies, diagnostics, medical devices, and vector control technologies—to improve health outcomes in LMICs. His team plays a critical role in advancing the foundation's global strategies for the prevention, control, and elimination of priority infectious diseases, including vaccine-preventable diseases, malaria, tuberculosis, HIV, polio, and pneumonia. His work also supports maternal, neonatal, and child nutrition and health innovations, ensuring that life-saving interventions reach those in need. With over 15 years of experience in global health innovation and access, Wenfeng has led a wide range of high-impact projects. In previous roles, he led a portfolio of projects to monitor global vaccine demand and understand vaccination drivers using a combination of social science methods, epidemiology, and advanced analytics. He co-designed a strategy to accelerate new vaccine introductions in China through financial innovation, advocacy, and implementation science. He conducted consulting projects for Gavi and WHO, advising on investment strategies, program monitoring, technology transfer mechanisms, and vaccine cost-effectiveness assessments. He led a two-year research project in Pakistan, pioneering statistical and implementation innovations to enhance the efficiency and effectiveness of immunization program monitoring. In addition to his role at the foundation, Dr Gong is an Adjunct Associate Professor at the Duke Global Health Institute, where he also serves on the Board of Advisors. He is a standing member of the Council for the Promotion of International Vaccine Cooperation under the China Association for Vaccines and previously served as a member of the WHO Expert Working Group on Behavior and Social Drivers of Vaccination. He also proudly volunteer as the co-president of the Parent Support Organization at the Concordia International School of Shanghai.

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Dr Chandrasekhar NAIR **Director & Chief Technical Officer** **Molbio Diagnostics** **Co-founder** **Bigtec Labs** 	Dr Chandrasekhar Nair holds an M.E. in Chemical Engineering from BITS Pilani and a Ph.D. in Bio-MEMS from VIT Vellore. With over 34 years of experience in MedTech and BioTech R&D, he has played a pivotal role in advancing India's healthcare innovation by pioneering scalable diagnostic technologies. His work has significantly impacted global public health, particularly through the Truenat platform, which enables early detection of infectious diseases, including Tuberculosis. His innovations have been instrumental in improving access to rapid and accurate diagnostic solutions, especially in resource-limited settings. In recognition of his contributions to healthcare, he was awarded the Infosys Prize in Engineering and Computer Sciences in 2021.
Asst Prof TAN-KOI Wei Chuen **Lead** **Regulatory Systems Strengthening** **CoRE, Duke-NUS Medical School** 	Asst. Prof Tan-Koi Wei Chuen is Lead of Regulatory Systems Strengthening at CoRE. Her work focuses on health policy research and capacity building in biomedical innovation and regulatory science. Her portfolio includes international capacity building programmes, as well as regulatory systems strengthening projects funded by the Asian Development Bank and the Gates Foundation on vaccine and in-vitro diagnostic regulation. Prior to joining Duke-NUS Medical School, Asst. Prof Tan-Koi was Regulatory Consultant and Team Lead of the Regulatory Research and Risk Communication teams at the Singapore's Health Sciences Authority. A pharmacist by training, Asst. Prof Tan-Koi was awarded the Singapore Health Manpower Development Plan Fellowship for Graduate Research Programme in Public Health and received her doctoral degree from the NUS Saw Swee Hock School of Public Health.
Ms WONG Woei Jiuang **Assistant Group Director** **Medical Devices Cluster** **Health Products Regulation Group** **Health Sciences Authority** **Singapore**	Ms Wong Woei Jiuang serves as the Assistant Group Director of Medical Devices Cluster within the Health Products Regulation Group at Singapore's Health Sciences Authority (HSA). A registered pharmacist with a Master of Science in Applied Gerontology, she brings over two decades of regulatory expertise to her role. Her leadership extends beyond Singapore through her former chairmanship of the ASEAN Medical Device Committee and

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	current position as a management committee member of the International Medical Device Regulators Forum. Ms Wong has been appointed as a member of the Strategic and Technical Advisory group on Medical Devices (STAG MEDEV) since 2023.She has made significant contributions to global regulatory frameworks, notably through her involvement in developing the WHO's Global Regulatory Framework for Medical Devices and in vitro diagnostics. Her expertise has also been instrumental in shaping the WHO Global Benchmarking Tool for medical devices, further strengthening international regulatory standards.
Dr Gonzalo DOMINGO **Global Program Leader** **Diagnostic Program** **PATH** 	Dr Domingo has extensive experience in leading and managing product development efforts from early concept development through verification and validation, regulatory submissions, and registration and introduction. Dr Domingo leads the Diagnostics Program at PATH, which seeks to increase availability and access to diagnostics that improve health outcomes of people and communities. He drives this mission by fostering a portfolio of diagnostic technologies and leading a multidisciplinary team to support these products through all stages of development, from early research and development to introduction. He manages complex collaborations involving public-sector organizations, diagnostic technology companies, research institutions, and both in-country and global partners and stakeholders.
Dr Sidney YEE **Adjunct Associate Professor** **CoRE, Duke-NUS Medical School** 	Dr Sidney Yee is founding CEO of Diagnostics Development (DxD) Hub a national platform hosted by Singapore's Agency for Science, Technology and Research (A*STAR). DxD Hub is a design, development and productization hub for diagnostics innovations, with expertise and capability to rapidly translate R&D output from public and private sectors, into deployable products in the market. During COVID-19 pandemic, the capabilities of DxD Hub helped to develop and deploy several COVID-19 diagnostics products within months. These products included conventional RT-PCR test Fortitude, serological test C-Pass, and direct PCR test RESOLUTE. Fortitude was the first diagnostic kit to be granted provisional authorisation by Singapore's Health Sciences Authority (HSA) and was deployed in more than 45 countries globally. C-Pass is the

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	only COVID-19 neutralising antibody test approved by HSA, US-FDA and CE. For her contributions during the pandemic, Dr Yee was conferred the Public Administration Gold Medal by the Prime Minister's Office. Dr Yee is founding co-chair of the ASEAN Diagnostics Development Initiative, which was endorsed by ASEAN Committee of Science, Technology and Innovation in May 2018. Its mandate is to develop diagnostic products that address unmet clinical needs in ASEAN by ASEAN Member States. The objectives are diagnostics capacity building in ASEAN Member States, with a focus on bridging translation gap to develop implementable diagnostics solutions and to improve human health and healthcare industry in ASEAN.
Ms Anita SURESH **Director** **Genomics and Diagnostics Development** **FIND** 	Ms Anita Suresh is the Director of Genomics and Diagnostics Development at FIND, a global health nonprofit, where she drives development of and access to diagnostic tools for major global health threats. She has led a multidisciplinary team to evaluate genomic technologies for tuberculosis (TB), antimicrobial resistance and pandemic preparedness. Under her leadership, the Seq&Treat initiative directly informed the first-ever global policy from the WHO endorsing sequencing for drug-resistant TB diagnosis in 2024 - a landmark moment in precision public health. Ms Suresh has 20 years of experience across the diagnostics value chain, including upstream and downstream IVD commercialization, technology assessment, clinical and scientific programme management, R&D and public policy.
Mr WONG Fatt Heng **Founder** **Shanghai IVD Consulting Company** 	Mr Wong Fatt Heng is a distinguished leader in the healthcare and diagnostics industry with over 40 years of experience. As the Founder and General Manager of IVD Consulting Co. Ltd. since 2023, he leverages his extensive expertise to provide strategic guidance to industry stakeholders. Previously, Mr Wong held key leadership roles including CEO of DIAN Diagnostics Co., Ltd., and General Manager at Roche Diagnostics Shanghai Limited. His tenure with Roche spanned over two decades, where he held pivotal roles across Asia Pacific, Malaysia, and Shanghai, driving growth and innovation in the diagnostics sector. Starting his career as a Medical Technologist at The American Hospital of Singapore.

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	Mr Wong's dedication to advancing diagnostic solutions has made a lasting impact across the region. Mr Wong has received numerous accolades in recognition of his contributions, including the prestigious Chinese Government Friendship Award in 2016, the Shanghai Honorary Citizen title, and multiple Shanghai Magnolia Awards. His Outstanding Entrepreneur Award from the Shanghai Waigaoqiao Free Trade Zone further highlights his exceptional leadership. Through his strategic vision and commitment to medical innovation, Mr Wong continues to influence and inspire the healthcare diagnostics industry.
Dr Justin IM **Director** **Programs & Strategy** **RIGHT Foundation** 	Dr Justin Im is Director of Programs & Strategy at RIGHT Foundation, a non-profit global health R&D funding organization based in South Korea. In this role, he serves as senior responsible manager for RIGHT Foundation's investment portfolio spanning grants in diagnostics, vaccines, therapeutics, biologics, and digital health technologies. Dr Im was formerly a Research Scientist at the International Vaccine Institute, where he spent over a decade leading studies on infectious disease epidemiology and vaccine development programs focusing on typhoid fever and cholera in sub-Saharan Africa. He holds a DPhil from the University of Oxford and an MSc in Epidemiology from the London School of Hygiene and Tropical Medicine.
Mr John JAMIESON **Assistant Secretary** **Medical Devices Authorisation Branch, Australian Government Department of Health Disability and Ageing, Therapeutic Goods Administration (TGA)** 	Mr John Jamieson is the Assistant Secretary of the Medical Devices Authorisation at the TGA, Australia. Mr Jamieson also represents the TGA on the International Medical Device Regulators Forum (IMDRF) Management Committee and on the Regulatory Authority Council of the Medical Devices Single Audit Program (MDSAP).

Name	Designation & Biography
Mr Min YANG **Senior Programme Officer** **Health Innovation and Partnerships** **China Country Office** **Gates Foundation** 	Mr Min Yang is a Senior Program Officer at the China Office, Gates Foundation, responsible for global health innovation partnership in China and market access of key medical products in LMICs. Mr Min Yang has more than a decade of experience of promoting equitable access to essential global health technologies and products. Prior to Gates Foundation, he served as a life science strategy consultant, providing portfolio management and market access strategy services for numerous global pharmaceutical and med tech enterprises. He also worked at WHO and conducted market access analysis for the novel Hep-C medicines. Min Yang holds dual Bachelor's degrees in Health Policy and Statistics from the University of North Carolina at Chapel Hill, and a Master's degree in Management from Tsinghua University's Schwarzman College.
Day 2: 15 July 2025, Tuesday	
Mr Derek LEE **Chief Strategic Officer** **iGENETECH** 	Mr Lee is a seasoned leader in the in vitro diagnostics (IVD) industry with expertise spanning immunoassay, molecular diagnostics, and next-generation sequencing (NGS). He currently serves as the Chief Strategic Officer at iGENETECH, a precision diagnostics company based in South Korea, where he leads global strategy, partnerships, and innovation initiatives. He began his academic journey with a Bachelor of Medical Science from the Australian National University, followed by an MBA from Sungkyunkwan University (SKKU) in Korea, equipping him with a strong foundation in both biomedical science and business strategy. His professional career includes pivotal roles in leading Korean biotech companies. At Macrogen, a global genomics service provider, he led the Strategic Planning Team, overseeing business development and cross-border collaborations. He then joined SD Biosensor, a major player in diagnostics, as Director of Global Health Affairs Department, where he worked closely with global health organizations and stakeholders on infectious disease diagnostics and access initiatives. With a deep understanding of both the science and business of diagnostics, Mr Lee brings a global perspective and

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	mission-driven approach to healthcare innovation, especially in the areas of emerging infectious diseases and public health.
Mr Rui YAO **Marketing Manager** **Wantai Biopharm International BU** 	Focusing on IVD overseas business for over 10 years, In-depth insights on the marketing and sales strategy of IVD products in the global market with proven expertise in local registration, market access, and go-to-market execution across multiple countries.
Dr Susie BRANIFF **Scientist** **Prequalification IVD Assessment Team** **Health Systems Division** **World Health Organization** 	Dr Susie Braniff is a scientist in the Prequalification IVD Assessment Team within the Health Systems Division at WHO Headquarters. Key responsibilities of her role are coordination of product dossier review and team focal point for the Collaborative Registration Procedure. For over a decade she has been working in the field of quality assurance of diagnostics tests, including working with public health laboratories and regulatory authorities in LMIC to deliver high quality diagnostic testing. Prior to joining WHO in 2019, she was the Team Lead of the IVD Evaluations department at the National Reference Laboratory in Melbourne, Australia. Dr Braniff obtained her PhD in Molecular Biology from Monash University in 2007 and Master of Public Health from the University of Melbourne in 2015.
Dr Paulyne WAIRIMU **Chair** **African Medical Devices Forum** **African Medicines Harmonization Initiative** **Lead** **Medical Devices and Diagnostics** **Pharmacy and Poison Board**	Dr Paulyne Wairimu is the Medical Devices and diagnostics lead at the Pharmacy and Poison Board, the regulatory authority for Kenya and whose work in regulatory framework development spans 15 years. She has pioneered regulatory system development in her Country, developing the Medical Devices regulatory framework at PPB Kenya, to a globally recognized institution. Her recent focus on Software as a Medical Device, seeks to bring the new frontier of use of AI in SaMDs and SiMDs to the regulatory space. She is also the Chair of the African Medical Devices Forum- the continental technical committee under the African Union. She has championed and advocated for the adoption

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	of international standards in the African continent through the IMDRF, supported health system strengthening through the AMDF with development of the technical tools such as guidelines and workshops for use across the African region. She is a public health expert with International Relations Masters in Advanced Studies from the Geneva Graduate Institute, and Master of Pharmacy Graduate from the Welsh School of Pharmacy, Cardiff University UK.
Dr Ruifen WENG **Chief Executive Officer** **Diagnostics Development Hub** **Agency for Science, Technology and Research (A*STAR)** **Singapore** 	Dr Ruifen Weng is currently the CEO at the Diagnostics Development Hub (DxD Hub), a national platform hosted by Singapore's Agency for Science, Technology and Research (A*STAR). Prior to her CEO appointment, Dr Weng led partnership and product development in the areas of In-Vitro Diagnostics (IVD), Software as a Medical Devices (SaMD) and Point-of-Care Diagnostics at DxD Hub, as its Deputy CEO and CTO. Dr Weng is deeply passionate about the enabling roles of diagnostics in healthcare, with a proven tracked record in technology evaluation, in bringing diagnostics solution to market from conceptualization through design, development, clinical deployment and regulatory strategies. Over the years, Dr Weng has led the productization and commercial launch of 10+ In Vitro Diagnostics and Software as Medical Devices, including GASTROClear, FortitudeTM, Resolute, United500, etc, contributing to the growth of local companies such as MiRXES, Lucence, Nalagenetics and Kyan Therapeutics. As a visiting advisor to the National Centre for Infectious Diseases (NCID) in Singapore, Dr Weng leads the Diagnostics Co-Op under the Program for Research in Epidemic Preparedness and Response (PREPARE), a dedicated research program supported by MOH's National Medical Research Council and administered by NCID. Dr Weng holds a PhD in biomedical sciences from the National University of Singapore, and an Executive MBA from INSEAD.

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Dr L. Rizka ANDALUCIA **Director General** **Pharmaceutical and Medical Devices** **Ministry of Health** **Indonesia** 	Dr L. Rizka Andalucia, M.Pharm is a distinguished health professional with deep expertise in global health governance and a proven track record of driving strategic decision-making. She currently serves as the Director General of Pharmaceuticals and Medical Devices at the Ministry of Health of Indonesia, where she plays a critical role in shaping policies that advance equitable access to essential medicines, vaccines, and medical technologies particularly in Low-and-Middle Income Countries (LMICs). Dr Rizka's leadership is built on a solid foundation. Beginning her professional journey as a pharmacist, her academic path continued with advanced studies, culminating in a Doctorate in Biomedical and Medical Sciences. With a public service career spanning more than three decades since 1994, she has consistently brought together science and policy to lead in critical areas such as pharmaceutical development, regulatory governance, and resource mobilization, all aligned with the broader goals of global health equity. Driven by a strong vision to strengthen local production as a cornerstone of national health resilience, Dr Rizka leverages her influential international roles to advance this mission. Her expertise is sought globally, serving as a Board Member for the Coalition for Epidemic Preparedness Innovations (CEPI), a member of the M72 Advisory Board, the Focal Point for the Regional Vaccine Manufacturing Collaborative (RVMC), and an advisory board member for The Indonesian Association for the Study of Medicinals (IASMED). This global presence, including in forums like the G20, allows her to bridge international priorities with local realities, fostering a robust R&D ecosystem that supports long-term healthcare sustainability.
Mr Alfred KWEK **General Manager** **Tigermed Asia Pacific Private Limited and Talons Laboratories Pte Ltd.** **Professor** **GHWP Academy** **South China University of Technology**	In his public service career, Mr Alfred Kwek was co-head of the Centre for Medical Device Regulation at the Health Sciences Authority of Singapore. He was part of the team that setting up the medical device regulatory system in Singapore. He co-chaired the ASEAN Medical Device Product Working Group, and was one of the authors for the ASEAN Medical Device Directive and Common Submission Dossier Template (CSDT). Mr Kwek is a member of the Strategic Advisory Board (SEB) of the Global Harmonization Working Party (GHWP). He is on the Board of Trustee of the GMDN Agency, and is also a

Name	Designation & Biography
	member of the Curriculum Committee, Centre for Regulatory Excellence, Duke-NUS Medical School. Mr Kwek graduated with a Master of Bioengineering, and Bachelor of Engineering, and attended the Harvard Advanced Management Program. He is a registered Professional Engineer with the PE Board Singapore.
Prof TAN Sze Wee **Advisor, Temasek International** **Adjunct Professor** **Duke-NUS Medical School &** **Nanyang Technological University's** **Lee Kong Chian School of Medicine** **Singapore** 	Prof Tan Sze Wee, is currently the Advisor to Temasek International from 2025. Prof Tan's career spans across public sector, corporate and industry start-ups. He spent more than a decade between a US corporate and biotech start-up. Prof Tan's career in A*STAR started in 2009 and he spent his time across the Science and Engineering Research Council, Biomedical Research Council as a well as the Innovation and Enterprise Division. This involves the executive leadership and governance of the 17 Research Institutes as well as National Platforms Diagnostic Development Hub (DxDHub) and Experimental Drug Development Centre (EDDC). Professor Tan has also promoted international research, innovation and enterprise partnership between Singapore, A*Star and its key scientific international partners. He is a speaker at international conferences and advises academic, corporate and not for profit organisations for wide range of topics. Professor Tan is Adjunct Professor at Nanyang Technological University's (NTU) Lee Kong Chian School of Medicine, as well as an Adjunct Professor at Duke-NUS Medical School Singapore. Professor Tan was a former Nominated Member of Parliament of Singapore. He is the recipient of the Singapore Public Administration Medal (Silver) and Singapore (Covid-19) Public Administration Medal (Silver). He is also a recipient of Friend of Labour Award. Professor Tan is a board member of Singapore Eye Research Institute (SERI) and member of SERI's Incubator Advisory Board. He is a member of the Board Oversight Committee of ACTRIS and STCC. He is a council member of the Singapore Medical Association (SMA), as well as aboard director for SMA Pte Ltd. He is also the Chairman of the NUS Medicine Industry Advisory Board for Non-Clinical Post Graduate Courses. Prof Tan is also the Chairman of Unlocking ADHD Ltd.

Name	Designation & Biography
Dr Rama SETHURAMAN **APAC Head** **Quality and Regulatory** **Roche Diagnostics Asia Pacific Pte Ltd** **Singapore** 	Dr Rama Sethuraman is the APAC Head of Quality and Regulatory in Roche Diagnostics Asia Pacific. She leads the regional quality and regulatory functions covering diagnostics and digital products, in the APAC region. She has over 15 years of experience in medical device quality and regulatory functions. Prior to joining Roche, Dr Sethuraman was the Director, Medical Devices in the Health Sciences Authority (HSA), overseeing the pre- and post-market regulatory activities for all medical devices. She represented Singapore as a member of the Management Committee of the International Medical Device Regulators Forum (IMDRF), Primary Representative for Singapore in the Global Harmonisation Working Party (GHWP) and as the head of delegation for Singapore in the ASEAN Medical Device Committee (AMDC). Dr Sethuraman has also participated and contributed to the development of Software as Medical Device (SaMD) clinical evaluation guidance by IMDRF, Regulatory considerations on AI for health guidance by the WHO and AI in healthcare guidelines in Singapore. She holds a PhD from the Faculty of Medicine, National University of Singapore. Her research focused on chronic neuropathic pain, identifying novel biomarkers related to pain and developing novel diagnostic methods using principles of chemistry in analysis of biological samples.
Prof Christopher WOODS **Wolfgang Joklik Distinguished Professor of Global Health** **Professor of Medicine and Pathology** **Duke University** **Chief, Infectious Diseases,** **Durham VA Health System** 	Prof Woods is the Executive Director of the Hubert-Yeargan Center for Global Health and Director of the Center for Infectious Disease Diagnostic Innovation (CIDDI). He is also Professor in the Departments of Medicine and Pathology at Duke University and serves as an adjunct professor in the Emerging Infectious Diseases Program at Duke-National University of Singapore Medical School. Clinically, he is Chief of Infectious Diseases at the Durham VA Health System. Prof Woods is the co-founder of Predigen, Inc., and currently serving as Acting Chief Medical Officer for Biomeme, Inc. Dr Woods is board-certified in internal medicine, infectious diseases, and medical microbiology. Prof Christopher Woods attended the Yale University and pursued his medical education and training at Duke University, and public health training at University of North Carolina - Chapel Hill. He developed his interest in global health at Tenwek Hospital in Bomet, Kenya during his internal medicine residency. He is a graduate of the Epidemic Intelligence

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	Service (EIS) of the Centers for Disease Control and Prevention (CDC), where he served in the Meningitis and Special Pathogens Branch of the National Center for Infectious Diseases. While at the CDC, Dr Woods performed programmatic work and outbreak investigations throughout the U.S. and the developing world.
Dr Jennifer GRANGER **Senior Programme Officer** **EDGE Diagnostics Team** **Global Health** **Gates Foundation** 	Dr Jennifer Granger's experience spans *in vitro* diagnostics and medical devices, pure and applied science in academic settings, industrial instrumentation, product development, and drug discovery application support. After earning advanced degrees in Organic and Analytical Chemistry, she gained valuable industry experience as a research scientist at Waters Corporation, contributing to the advancement of liquid chromatography-mass spectrometry (LCMS) product lines in proteomics and metabonomics. This experience led to a management role at AstraZeneca Pharmaceuticals, where she led a team providing critical analytical support to drug discovery efforts. From industry, Dr Granger returned to an academic research environment at the University of Utah where she was challenged to develop *in vitro* diagnostics tailored for underserved communities. Over a decade, her team achieved significant milestones in the development of *in vitro* diagnostics for infectious diseases, biological warfare agents, and cancer biomarkers in multiple formats ranging from benchtop to point of care. Leveraging this experience, she moved on to join the PharmaDx team at ARUP Laboratories, who partners with pharma to develop companion diagnostics (CDx) to support gene therapy programs. In this capacity, she managed product development, co-authored regulatory submissions and commercialized the AAV5 DetectCDx, an immunoassay-based CDx, which has been FDA approved and CE-marked under the European Union's In Vitro Diagnostic Medical Devices Regulation (IVDR).

Name	Designation & Biography
Ms Mariammah KRISHNASAMY **Deputy Director** **Policy and Guidance Document Section** **Medical Device Authority (MDA)** **Ministry of Health Malaysia** 	Ms Mariammah Krishnasamy, currently serves as the Deputy Director of the Policy and Guidance Document Section at the Medical Device Authority (MDA), Ministry of Health in Malaysia. With over 29 years of experience in the public health sector, she has held key positions including Medical Laboratory Technologist at the Institute for Medical Research, Assistant Director at the Health Technology Assessment Division, and Principal Assistant Director and Head of the Medical Device Registration Section. She holds a Bachelor of Science (Hons) in Biomedical Sciences, a Master of Philosophy in Biomedical Engineering and Health Sciences, and a Diploma in Medical Laboratory Technology.
Mr Liang YU **Associate Director of Executive Education and Lifelong Learning** **Duke Kunshan University** 	Mr Liang Yu is passionate about business education, leadership development and entrepreneurship. He has over 20 years of experience in the corporate education sector, and his responsibilities include strategic planning and execution, educational startup, product development, program design, marketing & complex sales and operational excellence. Mr Yu currently works in Duke Kunshan University overseeing its executive education business. He partners with leading companies to grow their leadership and organizational capability and enjoys the process of designing transformational learning journey for leaders around the world. Prior to Duke Kunshan, Mr Yu has worked for Deloitte Consulting in organizational change practice and Duke Corporate Education in Senior Executive Development. Mr Yu is passionate about developing future leaders in the digital age in a responsible and sustainable manner. His current research focuses on developing purposeful and collaborative global leaders in the digital age, and his research paper is included in edited volumes with Routledge and Palgrave Macmillan. The case Mr Yu authored *Finding Balance Between Flexibility and Stability* has won Harvard Business Review's (Chinese Edition) Ram Charan Management Practice Award in 2024. He translated Giving Voice to Values, a masterpiece for value-driven leadership that was written by Prof Mary Gentile, into Chinese. Mr Yu loves reading about philosophy, ethics, politics, entrepreneurship, higher education, cross culture leadership and linguistics.

Name	Designation & Biography
	He holds an MBA degree from Fuqua School of Business at Duke University where he served as a COLE Leadership Fellow during 2012-2013. He lives in Kunshan China with his family.
Asst Prof LEONG James **Head** **Health Products & Regulatory Science** **CoRE** 	As the Head of Health Products & Regulatory Science at the Centre of Regulatory Excellence, Asst Prof James Leong is in charge of identifying the educational needs for the various stakeholders involved in regulatory affairs in the Asia Pacific region, and establishing education roadmaps, priorities and deliverables. In this role, he actively conducts roundtable discussions on policy with regulatory affairs professionals across Asia Pacific, as well as research on advancing regulatory sciences. He draws his regulatory experience from his years as a senior regulatory specialist with the Health Sciences Authority of Singapore, where he is a clinical reviewer in addition to managing the post-market benefit-risk assessments and regulatory actions, as well as oversees the training of clinical assessors. In addition to his Masters in clinical pharmacy, he is also Board-certified in pharmacotherapy. His previous clinical experiences include leading the hospital drug information services and heart failure clinic. He obtained his PhD from Cardiff University, focusing on benefit-risk assessment frameworks, communication of regulatory decisions and innovation of regulatory approaches.

List of Attendees

Name Designation	Organisation
Paulyne Wairimu Chair African Medical Devices Forum (AMDF-TC)	African Medicines Harmonization Initiative
Alex Thian Managing Director	AITbiotech Pte Ltd
Chang Liu CEO and Founder	ASK Health Asia
Runhui Lin Director of International Affairs	Beijing Hotgen Biotech Co., Ltd.
Angel Tan General Manager & Head of Pharmacist	CorDx
Tan Hwee Ee Founder & Principal Consultant	DH RegSys
Andrew Ho Co-Founder & Business Development Director	DH RegSys
Eustace Chai Regulatory Affairs Consultant	DH RegSys
Ruifen Weng Chief Executive Officer	Diagnostics Development Hub
Ang Wei Jun Quality and Regulatory Manager	Diagnostics Development Hub
Hon Qi Partnerships Manager	Diagnostics Development Hub
Fujie Xu Co-Director Global Health Program	Duke Kunshan University
Liang Yu Associate Director Executive Education and Lifelong Learning	Duke Kunshan University
Shaojun Ma Senior Research Consultant	Duke Kunshan University
Christopher Woods Wolfgang Joklik Distinguished Professor of Global Health Professor of Medicine and Pathology	Duke University

John Lim Executive Director Centre of Regulatory Excellence	Duke-NUS Medical School
Silke Vogel Deputy Director Centre of Regulatory Excellence	Duke-NUS Medical School
Sidney Yee Adjunct Associate Professor Centre of Regulatory Excellence	Duke-NUS Medical School
Rena Dharmawan Assistant Dean and Asst Professor Innovation Education & Ecosystem Development	Duke-NUS Medical School
James Leong Assistant Professor Head, Health Products & Regulatory Science Centre of Regulatory Excellence	Duke-NUS Medical School
Tan-Koi Wei Chuen Assistant Professor Lead, Regulatory Systems Strengthening Centre of Regulatory Excellence	Duke-NUS Medical School
Sherna Wadia Associate Director Centre of Regulatory Excellence	Duke-NUS Medical School
Khoo Yoong Khean Assistant Professor Centre of Regulatory Excellence	Duke-NUS Medical School
Rathi Saravanan Lead, Education Associate Centre of Regulatory Excellence	Duke-NUS Medical School
Faith Tan Education Associate Centre of Regulatory Excellence	Duke-NUS Medical School
Jessalyn Chan Research Associate Centre of Regulatory Excellence	Duke-NUS Medical School
Sabiha Khan Senior Executive Centre of Regulatory Excellence	Duke-NUS Medical School
Serene Ng Senior Executive Centre of Regulatory Excellence	Duke-NUS Medical School
Ronal Simanjuntak President Director	Equilab International
Yudha Fariska Director	Esora Medika Indonesia
Anita Suresh Director Genomics and Diagnostics Development	FIND
Guo Wen Hu Vice President	Fuzhou Agenmic Biotechnology, Co. Ltd.

Wenfeng Gong Deputy Director Health, Innovation & Partnerships China Country Office	Gates Foundation
Jennifer Granger Senior Program Officer EDGE Diagnostics Team Global Health	Gates Foundation
Min Yang Senior Program Officer Health, Innovation & Partnerships China Country Office	Gates Foundation
Xiaofan Zeng Senior Program Officer	Gates Foundation
Tianyang Wang Consultant	Gates Foundation
Wong Woei Jiuang Assistant Group Director Medical Devices Cluster Health Products Regulation Group	Health Sciences Authority, Singapore
Beverly Liew Senior Assistant Director Head of Medical Devices Innovation Office	Health Sciences Authority, Singapore
Han Xia Chief Executive Officer	Hugobiotech Co., Ltd.
Derek Lee Chief Strategic Officer	iGENETECH Inc.
Alice Li Regulatory Affairs Manager	Kawin Biosciences Singapore
Lim Li Sze Co-founder and Operations Director	Medical Innovation Ventures (Mediven)
Lucia Rizka Andalucia Director General Pharmaceutical and Medical Devices	Ministry of Health, Indonesia
Lora Agustina Health Administrator Team Leader for Import In Vitro Diagnostic Evaluation of the Directorate of Production and Distribution of Medical Devices	Ministry of Health, Indonesia
Raih Rona Althof Health Administrator	Ministry of Health, Indonesia
Mariammah Krishnasamy Deputy Director, Policy and Guidance Document Section Medical Device Authority (MDA)	Ministry of Health, Malaysia
Phanumas Chuenchudet Medical Technologist, IVD review Food and Drug Administration	Ministry of Public Health, Thailand
Chandrasekhar Nair Director and Chief Technical Officer	Molbio Diagnostics Ltd.
Haris Ong Director of Marketing, APAC	MP Biomedicals

Gonzalo Domingo Global Program Leader Diagnostics Program	PATH
Justin Im Director of Programs & Strategy	RIGHT Foundation
Rama Sethuraman APAC Head, Quality and Regulatory	Roche Diagnostics Asia Pacific Pte Ltd Singapore
Ge Yun Fan Cooperative Strategy Head	Shanghai BioGiox Technology(BioGerm)
Wong Fatt Heng Founder	Shanghai IVD Consulting Company
Goh Wan Yee Senior Vice President Head of Healthcare	Singapore Economic Development Board
Ma Qianhui Senior Manager	Singapore Economic Development Board
Atiqah Ahmad Manager	Singapore Economic Development Board
Tan Sze Wee Advisor	Temasek International
Manjie Xing Associate Director	Temasek Foundation
John Jamieson Assistant Secretary Medical Devices Authorisation Branch Australian Government Department of Health Disability and Ageing	Therapeutic Goods Administration
Zou Jiayi Head of Overseas Business	Tianjin Bremer Bio-Engineering Co., Ltd.
Alfred Kwek General Manager	Tigermed Asia Pacific Private Limited
Hao Zou Senior Director R&D Reagent	Virtue Diagnostics
Rui Yao Marketing Manager	Wantai Biopharm International BU
Susie Braniff Scientist Prequalification IVD Assessment Team Health Systems Division	World Health Organization
Qian Sun Executive Vice-President	Yinjia Bioscience

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