DIA Singapore Annual Meeting 2025

Charting the Future : Navigating the Evolving Healthcare Landscape and Trends in Asia

15-16 July 2025
One Farrer Hotel, Singapore

Overview

Charting the Future: Navigating the Evolving Healthcare Landscape and Trends in Asia

Drug development and healthcare innovation in Asia are being rapidly reshaped by advancements in digital technologies (e.g., artificial intelligence [AI], cloud platforms), changing regulatory guidelines, and innovative clinical trial methodologies. These transformations are accelerating drug development, streamlining regulatory review processes, and enhancing patient engagement. To harness the full potential of these emerging opportunities and foster a dynamic and robust regulatory and clinical trial ecosystem, close collaborations among regulators, academia, patients, and industry are necessary.

The DIA Singapore Annual Meeting 2025 invites all stakeholders to share and review the evolving healthcare landscape challenges faced and lessons learned, and to identify future trends in the clinical research and regulatory environment in Asia

In-depth discussions will focus on key topics such as:

- The role of AI and digital tools in clinical trials, regulatory affairs, and pharmacovigilance
- Optimizing the implementation of regulatory pathways
- Real-World Data (RWD) and digital innovations to enhance regulatory decision-making
- Multi-Regional Clinical Trials and simultaneous global drug development
- Decentralized Clinical Trials (DCTs) and AI implementation in clinical trials

Join us at DIA Singapore 2025 to navigate these transformative changes and shape the future of healthcare in Asia.

Objective

Participants Participants will gain an enhanced understanding of major global regulatory developments in recent years. This insight will support proactive preparation for future changes and their implications in Asia, while broadening strategic perspectives.

The knowledge gained can be applied within their organizations to inform clinical development strategies and regulatory submission planning.

Who should attend?

- Regulatory authorities.
- Professionals in Clinical Research, Pharmacovigilance, Product Development, and Regulatory Affairs.
- Patient associations

Program Chairs

Chair. Finny Liu, MSc, RPh
APAC Regional Regulatory Policy Lead, Roche

Co-Chair. Helene Sou, MSc, RAC
Global Regulatory Policy and Innovation, Takeda Pharmaceutical Company Limited

Program Committee

Sandy Chan
Associate Director, Global Regulatory Policy and Intelligence, Johnson & Johnson

Martin Lim, MBA
Co-Founder and CEO, ONWARD Health Research

Thean Soo Lo, BPharm(Hons), MSc
Regulatory Affairs Management Consultant, TS Consulting

Edana Loke
Director, JAPAC Regulatory Policy and Intelligence, AbbVie

Karin Markgraf
Head of Regulatory Affairs Asia Pacific, Merck Healthcare

Audrey Ooi, MSc
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Huey Bee Pey
Executive Director, Project Management , Parexel International

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AGENDA | July 15, 2025 | Day 1 | ALL TIMINGS IN SGT

8.00 – 8.45 am	Registration
8.45 – 9.00 am	**Opening Remarks**
	Young Joo Park, Vice President, Korea, Singapore and SEA, DIA **Jing Ping YEO,** Vice President, Clinical Operations & Head, Asia Pacific Precision for Medicine
9.00 – 10.30 am	**Plenary Session -** **Navigating Regulatory Transformation: Insights and Innovations in Asian Healthcare**
	In this session, senior regulators from Asia will provide an update on their current regulatory landscape, initiatives and plan to reflect the changing regulatory landscape, including adoption of innovative digital tools. In the Panel Discussion, Regulators, Patient and Industry Representative will discuss and make recommendations on new ways of working to ensure that the regulatory system is efficient, sustainable and fit-for-purpose to enable faster approval of innovative healthcare products, as well as what should be considered regarding regulatory agility, alignment and convergence.
Session Chairs	**Finny Liu, MSc, RPh** APAC Regional Regulatory Policy Lead Roche, Singapore **Helene Sou, MSc, RAC** Global Regulatory Policy and Innovation, Takeda Pharmaceutical Company Limited, Singapore
9.00 – 9.10 am	Introduction
	Finny Liu, APAC Regional Regulatory Policy Lead, Roche
9.10 – 9.30 am	Vietnam Latest Regulatory Updates
	Thu Hien NGO, New Drug Registration, Drug Administration of Vietnam (DAV)
9.30 – 9.50 am	Hong-Kong Latest Regulatory Updates
	Ambrose WONG, Principle Medical & Health Officer (Medical Device), Hong-Kong DOH
9.50 – 10.10 am	Thailand Latest Regulatory Updates
	Pramote AKARAPANON, Head of New Drug and Investigational Drug, Medicines Regulation Division, Thai Food and Drug Administration
10.10 – 10.30 am	Advancing regulatory practices and processes globally: Insights, New Ways of Working and Impact
	Neil McAuslane, Scientific Director, Centre for Innovation in Regulatory Science (CIRS)
10.30 - 11.00 am	**Break**
11.00 am – 12.00 pm	**Panel Discussion**
	Moderator : **John C W Lim,** Executive Director of Duke-NUS Centre of Regulatory Excellence
	Panelists: **Neil McAuslane**, CIRS **Carlos Garner**, SVP, Global Regulatory Affairs, Eli Lilly **Thu Hien Ngo**, DAV **Ambrose Wong**, HK DOH **Pramote AKARAPANON**, Thai FDA
12.00 – 1.10 pm	**Lunch & Network**
1.10 – 1.50 pm	**Sponsor's Innovation Hub**
	Sergey Denisov, Sr. ML Engineer, Selta Square Inc.
	Greg Michels, CEO, PV.app

AGENDA | July 15, 2025 | Day 1 | ALL TIMINGS IN SGT

1.50 – 5.00 pm	**Session 1** **Transforming Regulatory Affairs and Clinical Research with Use of Digital Tools & Use Cases in Regulatory affairs, Drug Development and Pharmacovigilance**

In the rapidly evolving biopharmaceutical industry, digital tools have become transformative enablers across various domains such as regulatory affairs, clinical development, and pharmacovigilance. As we navigate the complex healthcare environment, integrating digital technologies presents opportunities to enhance efficiency, accuracy, and collaboration.
Indeed, digital technologies and AI are streamlining processes, enhancing decision-making, and improving patient outcomes across the drug development lifecycle. From AI-powered regulatory submissions to digital biomarkers in clinical trials, these innovations are reshaping the industry landscape.
While embracing these advancements, the sector must address challenges related to data security, privacy, and ethical considerations.
In this session, regulators, industry leaders, and Clinical Research Organizations will present their latest innovations and insights. They will discuss the benefits and challenges of adopting digital tools in their fields and share their perspectives on future trends.

Part 1 Session Chairs

Karin Markgraf
Head of Regulatory Affairs Asia Pacific, Merck Healthcare

Edana Loke
Director, JAPAC Regulatory Policy and Intelligence, AbbVie

Huey Bee Pey
Executive Director, Project Management, Parexel International, Singapore

1.50 – 2.00 pm	**Introduction**
	Huey Bee Pey, Executive Director, Project Management Parexel International (Singapore) PTE LTD
2.00 – 2.20 pm	Navigating the Future: Trends and Strategic Path for Healthcare AI Regulation
	Kavitha Palaniappan, Assistant Professor, Centre of Regulatory Excellence (CoRE)
2.20 – 2.40 pm	AI in Industry: Ethical Implementation and Adoption Strategies
	Ekta Gandhi, Founder, Unity7AI
2.40 – 3.00 pm	Enhancing Customer Experience through Digital Labeling
	Shekhar Nambi, Director, Digital Identification and Traceability, Johnson & Johnson
3.00 – 3.30 pm	**Break**
3.30 – 3.50 pm	Advancing Pharmacovigilance and Patient Safety through Synergistic Innovation with AI/ ML (LLM and NLP)
	Byron Webb Romero, Pharmacovigilance and Patient Safety, APAC &China, Roche
3.50 - 4.10 pm	Accelerating Access: Harnessing Automation, AI and Cloud Technologies for Simultaneous Regulatory Submission and Review
	Kabir Ahluwalia, Manager, Global Regulatory Affairs, Amgen
4.10 - 4.50 pm	**Panel Discussion**
	Moderator : **Karin Markgraf** Panelists: **Byron Webb Romero**, Roche **Shekhar Nambi**, Johnson & Johnson **Kabir Ahluwali**, Amgen **Ekta Gandhi**, Unity7AI **Kavitha Palaniappan**, CoRE
4.50 – 5.00 pm	Closing remarks of Day 1
	Helene Sou, Regulatory Policy and Innovation, Growth and Emerging Markets, Takeda

AGENDA | July 16, 2025 | Day 2 | ALL TIMINGS IN SGT

8.30 am – 12.00 pm	**Session 2a. Clinical Parallel Session** **Innovative Approaches in Clinical Trials**
	The clinical trial landscape is undergoing a transformative shift, driven by cutting-edge innovations and evolving regulatory frameworks that enhance trial design, efficiency, and accessibility. This session will feature expert speakers who will explore how emerging technologies—particularly artificial intelligence (AI), real-world data (RWD), and decentralized clinical trials (DCTs)—are reshaping the future of clinical research. Additionally, the session will address how the implementation of ICH E6 (R3) will impact the modern trial conduct. Attendees will gain a deeper understanding of the ways these advancements are shaping a more agile, patient-centric, and data-driven future for clinical research.
Session Chairs	**Audrey Ooi, MSc** Head- Business Development Clinical Research Malaysia, Malaysia **Martin Lim, MBA** Co-Founder and CEO ONWARD Health Research, Singapore
8.30 – 8.50 am	A Closer Look at Data Interoperability, EMR Adoption, and Bridging the Digital Divide in APAC
	Andrew Wiltshire, Head, Healthcare Policy, Public Policy APJ, Amazon Web Services
8.50 – 9.10 am	Digitalization and AI Implementation in Clinical Trials
	Tony Guo, SVP, Head of Statistics and Data Science, BeOne Medicine.
9.10 – 9.30 am	Trial to Treatment: Harnessing the role of RWE in Innovative Clinical Trial Designs and Bridging the Gap to Medical Practice
	Lakshmi Sameera Dumpala, Associate Principal, Medical Affairs Lead, Real World Solutions, APAC IQVIA
9.30 – 9.50 am	Strengthening and Harmonizing Safety Surveillance and Pharmacovigilance as a Strategy to Increase Clinical Trials in Southeast Asia
	Pipasha Biswas, Vice President, Symogen Limited
9.50 – 10.00 am	Q&A
10.00 – 10.30 am	**Break**
10.30 – 11.00 am	Driving Clinical Research Forward: The Power of Collaboration
	Patrice Wright, Director of Health Authority Engagement, TransCelerate Biopharma Inc.
11.00 – 11.20 am	Enabling DCT in an Ulcerative Colitis Trial: The Malaysia Story
	Nor Hafiza Johari, Clinical Operations Manager, Clinical Research Malaysia
11.20 – 11.40 am	Digital Transformation in Clinical Trials: Our Experience with eConsent Implementation
	Rosalind Oei, Head of Clinical Trial Management, Global Development Organization, MERCK
11.40 – 12.15 pm	Clinical Trials Through Every Lens : Trial Participant, Investigators and the Industry
	Moderator : **Martin Lim** Panelists: **Patrice Wright,** TransCelerate **Calvin Chin,** Professor, Senior Consultant and Clinician Scientist at National Heart Center Singapore **Nidhi Swarup**, Alliance of Patients' Organizations Singapore (APOS) **Mei Fong**, Former Clinical Tral participant
12.15 – 1.30 pm	**Lunch & Network**

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8.30 am – 12.00 pm	**Session 2b. RA Parallel Session** **OPTIMIZING REGULATORY ECOSYSTEM through Innovation, Collaboration & Convergence**
	Regulatory systems are becoming more and more mature with the establishment of various new regulatory pathways to allow expedited approval of innovative drugs. In addition, in recent years, we have seen a global trend toward the establishment of formal regulatory reliance and collaborative pathways among regulators. However, there are challenges in implementing effectively these new pathways. In this session, we will discuss updates in regulatory environment in Asia. Through case studies and pilots, we will examine challenges and discuss best practices and potential ways to optimize the regulatory ecosystem through the use of Innovation, Collaboration and Convergence.

Session Chairs

Sandy Chan
Associate Director, Global Regulatory Policy and Intelligence,
Johnson & Johnson

Helene Sou, MSc, RAC
Global Regulatory Policy and Innovation,
Takeda Pharmaceutical Company Limited, Singapore

8.30 – 8.35 am	Introduction
	Helene Sou, Director, Global Regulatory Policy and Innovation, Growth and Emerging Markets, Takeda
8.35 – 8.45 am	Current look at the regulatory environment in Asia
	Stephanie Chen, Associate Director, Regulatory Policy APAC, MSD
8.45 – 9.05 am	Bringing reliance into action - our exciting journey "from pilots to practice"
	Susanne Ausborn, Global Head International Regulatory Policy, Roche
9.05 – 9.25 am	Updates on ASEAN Joint Assessment Procedure
	Noraisyah Mohd Sani, Head of the New Drug Product Section, NPRA
9.25 – 9.40 am	HSA's approach to regulatory efficiency
	Yee Hoo LOOI, Deputy Director, Therapeutic Products Branch, HSA
9.40 – 10.00 am	**Panel Discussion**
	Moderator : **Helene Sou** Panelists: **Noraisyah Mohd Sani,** NPRA **Yee Hoo LOOI**, HSA **Stephanie Chen,** MSD **Susanne Ausborn,** Roche
10.00 – 10.30 am	**Break**
10.30 – 10.50 am	Thai FDA Experience with WHO Collaborative Registration Procedure after SRA approval
	Preeyaphon PUTTIJUGLUKSA, New Drug and Investigational Drug, Medicines Regulation Division, Thai FDA
10.50 - 11.15 am	**Panel Discussion |** Joint industry perspectives and recommendations
	Moderator : **Sandy Chan** Panelists : **Preeyaphon PUTTIJUGLUKSA**, Thai FDA **Noraisyah Mohd Sani,** NPRA **Harriet Min**, Vice President, Head of APAC Regulatory Affairs, Johnson & Johnson **Wipada Rodtanaporn**, Head of Regulatory Sciences, Pfizer (Thailand) Limited **Somprasong Preuttanuparp**, Head of Regulatory Affairs - Thailand and Frontier Markets, Astrazeneca
11.15 – 11.30 am	Transforming Regulatory Reliance with Digital Innovation: Integrating Reliance Frameworks with Accumulus at Sanofi
	Stephanie Ong, Regulatory Affairs Head, Singapore, Malaysia and Brunei, Sanofi
11.30 – 11.45 am	Regulatory Innovation: International Clinical Line Extension Reliance Pilot & the Journey
	Anna Litsiou, Regulatory Policy & Intelligence Director AstraZeneca
11.45 – 12.00 pm	Orphan Drug Designation Pathways: Regulatory Challenges and Opportunities in Asia
	Elaine Blair, Senior Director, Regulatory Affairs APAC, PTC Therapeutics
12.00 – 12.15 pm	Q&A

AGENDA | July 16, 2025 | Day 2 | ALL TIMINGS IN SGT

12.15 – 1.30 pm	**Lunch & Network**

1.30 – 3.00 pm	**Session 3** **Unlocking Potential: A Status Check on Multi-Regional Clinical Trials for Global Drug Development**

Asia-Pacific, home to over half of the global population, is emerging as a key hub for clinical trials due to lower costs, diverse patient pools and a supportive regulatory environment. This session examines the evolving landscape of Multi-Regional Clinical Trials (MRCTs) in accordance with the ICH E17 guideline. This guideline is designed to streamline global drug development to reduce time taken to bring medications to patients around the world through minimizing unnecessary duplication of local or regional studies.

Session Chairs

Edana Loke
Director, JAPAC Regulatory Policy and Intelligence
AbbVie, Singapore

Martin Lim, MBA
Co-Founder and CEO
ONWARD Health Research, Singapore

1.30 – 1.35 pm	Introduction
	Martin Lim, Co-Founder and CEO, Onward Health Research
1.35 – 1.50 pm	Unlocking Potential: A Status Check on Multi-Regional Clinical Trials for Global Drug Development
	Rominder Singh, Professor of Practice, Regulatory Sciences, Northeastern University, USA (virtual)
1.50 – 2.05 pm	Implementing ICH E17 in Taiwan: Insights, Challenges, and Opportunities from Taiwan CDE's Perspective
	I-Chun (Jean) Lai, Senior Director, Division of Consultation, Center for Drug Evaluation, Taiwan
2.05 – 2.20 pm	Indonesia – Building the Clinical Research Ecosystem
	Dona Arlinda, Clinical Research Manager, INA-CRC, Indonesia MOH
2.20 – 2.35 pm	Conducting MRCTs in Asia-Pacific: Industry Perspective on Regulatory Opportunities and Challenges
	Bindoo Chahal, JAPAC Regulatory Affairs, Therapeutic Area Head, AbbVie
2.35 – 3.00 pm	**Panel Discussion**
	Moderator : **Edana Loke** Panelists: **I-Chun (Jean) Lai**, Taiwan CDE **Bindoo Chahal**, AbbVie **Indri Rooslamiati**, Head of BB Binomika (Parent Organization of INA-CRC), Indonesia MOH
3.00 - 3.30 pm	**Break**

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3.30 – 5.00 pm	**ASEAN Townhall**
	The ASEAN Town Hall event at DIA Singapore allows ASEAN regulators and industry regulatory professionals to discuss current topics of interest evolving within the regulatory environment in ASEAN. Current "hot topics" in the evolving regulatory landscape includes the acceptance of the reliance pathway, the ASEAN JA procedures and AI & Precision Medicine. These "hot topics" necessitates the allocation of resources by HA. Optimal use of limited capacity can be a challenge amongst smaller HAs in ASEAN. Collaboration with the larger HA in AP may provide a pathway to mitigate optimal use of resources and capacity building in ASEAN. It is proposed that the ASEAN Town Hall for DIA 2025 allows ASEAN regulators and industry regulatory professionals to have a constructive discussion of these "Hot Topics" and identify challenges and the best path forward to deliver optimal health care to ASEAN patients.

Session Chairs

Sandy Chan
Associate Director, Global Regulatory Policy and Intelligence,
Johnson & Johnson

Thean Soo Lo, BPharm(Hons), MSc
Regulatory Affairs Management Consultant
TS Consulting

3.30 – 3.35 pm	Introduction
	Thean Soo, Regulatory Affairs Management Consultant, TS Consulting
3.35 – 3.55 pm	PMDA Collaboration initiatives and capability building support in ASEAN
	Rei NAKAGAWA, Principal Coordinator, Office of International Strategy and Planning, PMDA, Japan
3.55 – 4.15 pm	Regulator's sharing
	Thu Hien NGO, New Drug Registration, Drug Administration of Vietnam (DAV)
4.15 – 5.00 pm	**Panel Discussion**
	Moderator : **Sandy Chan** Panelists: **Thu Hien NGO**, Vietnam DAV **Yee Hoo LOOI**, Singapore HSA **Noraisyah Mohd Sani,** NPRA **Rei Nakagawa**, PMDA **Pramote AKARAPANON**, Thai FDA **Neil McAuslane**, CIRS **Kum Cheun Wong**, APRIA
5.00 – 5.15 pm	Wrap up and closing remarks
	Finny Liu, APAC Regional Regulatory Policy Lead, Roche, Singapore **Young Joo Park,** Vice President, Korea, Singapore and SEA, DIA

REGISTRATION FORM : Register online or forward to DIA
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DIA Singapore Annual Meeting 2025

Event #85125 • 15-16 July 2025 | One Farrer Hotel, Singapore

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CONTACT INFORMATION

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DIA Terms and Conditions

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Administrative fee that will be withheld from refund amount: the administrative fee that will be withheld from refund amount is 25 % of the delegate fee

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid.

Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but **membership is not transferable**. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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The personal information you request will be used for the purpose of sending conference information from DIA. In addition, in the web conference, we will use the information with the name of the company or organization and the name of everyone who participates, and it will be used for networking with participants, related parties, exhibiting companies for the period and about two weeks after the event. By submitting this application form, it is interpreted that you have consented to the above handling of personal information, but if you do not agree, please contact DIA.

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