VIRTUAL MEETING

DIA-CoRE Singapore Annual Meeting 2021

Catalysts for Changes – *Preparing for the Future of Healthcare*

Organised by DIA and CoRE

7 - 8 JULY 2021

PROGRAMME CO-CHAIRS

Program Chair
Dorothee GRIMALD
Director
Global Regulatory Policy
MSD Singapore

Program Co-Chair
James LEONG
Head, Health Products & Regulatory Science
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

ADVISORY COMMITTEE

Shun JIN
Head, Regulatory Affairs
APMA
Sandoz

Kum Cheun WONG
Head Asia Pacific
Regulatory & Development Policy, Novartis Asia Pacific
Pharmaceuticals Pte Ltd

Jing Ping YEO
Director, Research Integrity, Compliance and Ethics
Singapore Health Services Ptd Ltd

Vicky HAN
Senior Director
Policy Group Lead for Asia Pacific, Global Regulatory Affairs, Janssen Asia Pacific

Technology driven innovations are creating a paradigm shift in healthcare and research post COVID-19. Healthcare needs to implement new technology and innovation at an unprecedented pace. A rapidly changing world demands efficient adoption of new tools and smart solutions. At the DIA-CoRE Singapore Annual Meeting, experts from around the ASEAN region unveil their best practice cases in technology implementation, covering all perspectives of the professional spectrum.

This online conference provides you the latest insights on how smart technology advances drug development, regulatory processes, and clinical trials. Hear from ASEAN industry professionals, pharmaceutical and medical technology innovators, as well as regulators how they have embraced new technologies to reinvent healthcare and its systems with the use of smart solutions. Experience applied knowledge and exclusive insights with keynotes, plenary sessions and townhall formats presented by leading experts from industry, science, and regulation.

Key Topics

- Explore new technology adoptions in revolutionizing healthcare for better diagnostics and patient outcomes
- Receive updates on regulatory processes, policies, innovative drug review pathways, software regulations and adoption of virtual inspections.
- Learn how clinical trials are taking a more patient centric approach and the implementation of remote monitoring in Asia and the challenges that arise.
- Understand the regulations surrounding nutraceuticals/nutrition and its role in today's healthcare
- ASEAN Townhall

Who should attend

- Industry professionals in pharmaceuticals and medical technologies involved in Research & Development, Regulatory Affairs, Access and Medical Affairs
- Regulators and personnel from health authorities and ministries
- Representatives from patient associations and patient support groups
- Academia and researchers

EARLY BIRD REGISTRATIONS OPEN

PROGRAM COMMITTEE

Audrey Ooi
Head - Business Development
Clinical Research Malaysia

Finny Liu
APAC Regional Regulatory Policy Lead, PDR
Roche, Singapore

Jack Wong
Founder
Asia Regulatory Professionals Association (ARPA)

Mei Ding
JAPAC Regional Lead,
Regulatory Policy and Intelligence
AbbVie Pte. Ltd

Thean Soo (TS) Lo
Regulatory Affairs
Management Consultant

Vicky Hsu
Corporate Vice President
Head of Biotech Operations APAC
Parexel International

Yasha Huang
Regional Regulatory Affairs and Policy Lead
Roche Diagnostics Asia Pacific

8.45–9.00AM

Welcome and Opening Remarks

Dorothee Grimald
Director
Global Regulatory Policy
MSD Singapore

Shun JIN
Head - Regulatory Affairs
APMA
Sandoz

9.00–10.30AM

Opening Plenary Session

This Session will bring together Key Industry opinion leaders to deliberate on how technology in healthcare system is redefining the future of healthcare from treatment to prevention and increasing the value to patients. The readiness of the regulatory frameworks to cope with the changes in the future of healthcare.

Session Chair(s)

Dorothee Grimald
Director
Global Regulatory Policy
MSD Singapore

James Leong
Head - Health Products & Regulatory Science
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

9.00–9.30AM

Technology in Healthcare System – Increasing Value to Patients

Speaker Invited
(Awaiting Confirmation)

9.30–10.00AM

Future of Healthcare – From Treatment to Prevention

Steven Tucker
Founder
Tucker Medical Singapore

10.00–10.30AM

Readiness of Regulatory Frameworks for Future of Healthcare

Cheng Leng Chan
Group Director - Health Products Regulation Group
Health Sciences Authority Singapore

10.30–11.00AM

Tea / Coffee Break

11.00–12.00noon

Panel Discussion : Optimising contributions to healthcare systems

Moderator
TBC

Panelists

Cheng Leng Chan
Group Director - Health Products Regulation Group
Health Sciences Authority
Singapore

Steven Tucker
Founder
Tucker Medical Singapore

Speaker Invited
(Awaiting Confirmation)

Nidhi Swarup
Founder & President
Crohn's & Colitis Society of Singapore

12.00–1.00PM

Lunch Break

1.00–2.00PM

Innovation Hub

Session 1

2.00–3.30PM

Innovations for Better Patient Outcome

Advances in digital health technology and patient-centric solutions are transforming the future of healthcare and improving patient care, Patient centricity is now here to stay and promises better outcomes. This session will bring perspectives from pharmaceutical experts, mobile nursing provider and patients on the benefits and barriers to adoption of health technologies in today's world.

Session Chair
Audrey Ooi
Head - Business Development
Clinical Research Malaysia (CRM)

2.00–2.20PM

Digital Transformation in Healthcare Brought About by the COVID-19 Pandemic

Speaker Invited
(Awaiting Confirmation)

2.20–2.40PM

Patient Response to Digital Transformation

Jessie Lee
Director
Patient Recruitment Solutions and Clinical Trials Educator
IQVIA

2.40–3.00PM

Bringing healthcare to patients – Why its more important than ever

Kevin Wightman
Senior Director
Business and Corporate Development Asia Pacific
Illingworth Research

3.00–3.30PM

Panel Discussion: Does healthcare Innovations really improve the patient experience'

Moderator
Audrey Ooi
Head - Business Development
Clinical Research Malaysia (CRM)

Panellists

Kevin Wightman
Senior Director
Business and Corporate Development Asia Pacific
Illingworth Research

Nidhi Swarup
Founder & President
Crohn's & Colitis Society of Singapore

Jessie Lee
Director
Patient Recruitment Solutions and Clinical Trials Educator
IQVIA

Speaker Invited
(Awaiting Confirmation)

3.30–4.00PM

Tea / Coffee Break

Session 2

4.00–5.30PM

ASEAN Townhall

This session will provide the sharing from various representatives of ASEAN regulatory authorities on their new initiatives and the progress on regulatory cooperation initiatives. Hear from the ASEAN regulators about their efforts on harmonization of product registration systems and work sharing, as well as thoughts on new approaches to optimise regulatory efficiency and effectiveness, such as measures of progress and implementation outcome.

Session Chair(s)

Thean Soo (TS) Lo
Regulatory Affairs
Management Consultant

Finny Liu
APAC Regional Regulatory Policy Lead
PDR Roche, Singapore

4.00–4.30PM

Update on ASEAN Harmonisation & Revolution Efforts – Pharma Perspective
Speaker Invited

Update on ASEAN Harmonisation & Revolution Efforts – Device Perspective
Speaker Invited

Update on ASEAN Harmonisation & Revolution Efforts – Industry Perspective
Industry speakers invited

4.30–5.30PM

ASEAN TOWNHALL

Moderator

Thean Soo (TS) Lo
Regulatory Affairs
Management Consultant

Panellists

Jesusa Joyce N. CIRUNAY, RPh
Director IV
Center for Drug Regulation and Research
Food and Drug Administration Philippines

Rosliza binti Lajis
Head of New Drug Product Section
Centre of Product & Cosmetic Evaluation
NPRA, Ministry of Health Malaysia

Kum Cheun WONG
Head Asia Pacific
Regulatory & Development Policy
Novartis Asia Pacific Pharmaceuticals Pte Ltd.

Additional ASEAN REGULATORS INVITED

Session 3

9.00–10.30AM **Innovative Processes for Regulatory Review**

Fast evolving new technologies as well as innovative advances create new values and bring dramatic changes to regulatory processes. COVID pandemic accelerates new initiatives, implementation in regulatory framework and reconfirm importance of collaborations between regulators across countries and regions.
In this session, the latest updates about new ICH guidelines development, novel submission technology and innovative regulatory initiatives would be shared by key opinion leaders

Session Chair(s)

Mei Ding
JAPAC Regional Lead
Regulatory Policy and Intelligence
AbbVie Pte. Ltd

Finny Liu
APAC Regional Regulatory Policy Lead
PDR Roche, Singapore

9.00–9.20AM **Expedited pathway for COVID-19 treatment/vaccine in emergency use**

Mei-Chen Huang
Section Chief - Division of Medicinal Products
TFDA

9.20–9.40AM **Cloud Submission**

Speaker Invited

9.40–10.00AM **Regulatory Convergence in Product Lifecycle Management: Opportunities and Challenges**

Nina Cauchon
Director Regulatory Affairs CMC
Amgen

10.00–10.30AM **Panel Discussion: How innovative advances are reshaping regulatory process**

Moderator

Shun JIN
Head, Regulatory Affairs
APMA
Sandoz

Panellists

Yuta Maeda
Coordinator - Division of Asia II
Office of International Programs
Pharmaceuticals and Medical
Devices Agency (PMDA)

Mei-Chen Huang
Section Chief
Division of Medicinal Products
TFDA

Nina Cauchon
Director
Regulatory Affairs CMC
Amgen

10.30–11.00AM Tea / Coffee Break

Session 4

11.00–12.30PM

Medical Devices and Technology

With the rapid advancement in medical technology and digital solutions, are the current regulatory mechanism still fit for purpose? What are the regulatory agility elements that we have observed from the COVID-19 journey could potentially accelerate patient access to innovative technologies? Please also join our prestigious panelists to take a closer look at the real world evidence and how could it be leveraged in clinical evaluation to support innovation and improve patient access

Session Chair
Yasha Huang
Regional Regulatory Affairs and Policy Lead
Roche Diagnostics Asia Pacific

11.00–11.30AM

Roundtable: Fit-For-Purpose Regulations for Software / Digital Solutions

Roberta Sarno
Digital Health Committee
APACMed

John Richard Thornback
Chief Operating Officer
Diagnostics Development Hub

Varun Veigas
Regional Regulatory Affairs and Policy Lead, Asia Pacific
Roche Diagnostics Asia Pacific Pte. Ltd

Manan Hathi
Sr. Manager, Regulatory Affairs – Software
Stryker

11.30–11.50AM

Regulatory Agility / Reliance in the Background of COVID-1

Rama Sethuraman
Director
Medical Devices Branch
Singapore Health Sciences Authority

11.50–12.30PM

Panel Discussion : Key considerations in utilizing real world evidence for regulatory decisions

Moderator
Nicholas J. Diamond
Director
C&M International

Panellist

Liu Yanfang
Senior Director Epidemiology
Johnson & Johnson

Elodie Baumfeld Andre
Head of Real World Data, DIS
Roche

Rama Sethuraman
Director
Medical Devices Branch
HSA (Singapore)

Sebastian Schneeweiss
Department of Epidemiology
Harvard Medical School

12.30–1.30PM Lunch

1.30–2.00PM Innovation Hub

Session 5

2.00–3.30PM **Paradigm shift in Clinical Trials**

The COVID-19 pandemic and the maturation of technology has accelerated a much needed second order change in the way we conduct clinical trials and generate data to answer important healthcare questions. In today's session we will learn about these key changes and discuss the practicalities of converting them to reality with experts from the various part of the research ecosystem.

Session Chair(s)

Vicky Hsu
Corporate Vice President
Head of Biotech Operations APAC
Parexel International

Senthil Sockalingam, M.D,
Head of IQVIA Biotech, JAPAC
Chief Medical Officer, IQVIA, APAC
IQVIA

2.00–2.20PM **Pandemic Setting for Trials**

Daniel Tan
Senior Consultant Medical Oncologist
Division of Medical Oncology
National Cancer Centre Singapore

2.20–2.40PM **New Approaches in Clinical Trials from logisitcs perspective**

Jeff Ten
Director Project Management & Delivery Regional Head
Paraxel

2.40–3.00PM **Presentation Title (TBD)**

Senthil Sockalingam, M.D,
Head of IQVIA Biotech, JAPAC, Chief Medical Officer, IQVIA, APAC
IQVIA

3.00–3.30PM **Panel Discussion: Managing CTs for patients well being**

Daniel Tan
Senior Consultant Medical Oncologist
Division of Medical Oncology
National Cancer Centre Singapore

Jeff Ten
Director Project Management & Delivery Regional Head
Parexel

Senthil Sockalingam, M.D,
Head of IQVIA Biotech, JAPAC,
Chief Medical Officer, IQVIA, APAC
IQVIA

3.30–4.00PM Break

Session 6

4.00–5.30PM **Learning from Other Regulatory Systems**

Regulatory systems in different sectors (e.g. medical device, nutritional, OTC etc) face similar challenges. This session will have regulatory experts from these different sectors share common challenges and good practices and exchange learnings to discuss and have meaningful outcomes on a reasonable way forward.

Session Chair
Jack Wong - Founder - Asia Regulatory Professionals Association (ARPA)

Current Regulatory trends in the post Covid-19 environment: Common challenges & Risk Management of the Regulators from experience
Sunitha Shanmugam - Senior Regulatory Affairs Director SEAT, GSK Consumer Health

OTC across APAC Future of OTC reforms and landscape with focus on China
Janie Heywood - APAC Head of Regulatory Affairs, Bayer Consumer Health

APAC Harmonization of Regulation: Why is it important for Health & Food Supplements
Sherry Wang - Head of Regulatory Services, IQVIA

Challenges of regulatory system in a changing landscape and Lessons learnt from Medical devices
Jack Wong - Founder - Asia Regulatory Professionals Association (ARPA)

Panel Discussion

Moderator (s)

Jack Wong
Founder - Asia Regulatory Professionals Association (ARPA)

Swapna Kondapuram
Principal Consumer Health, Global R&D/ RWE , IQVIA

Panellists

Sunitha Shanmugam
GSK

Janie Heywood
Bayer Consumer Health

Sherry Wang
IQVIA

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Organised by DIA and CoRE
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CANCELLATION POLICY: ON OR BEFORE JUNE 6, 2021

- Cancellations must be in writing and received by June 6, 2021. Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.
- DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.
- UPON CANCELLATION, the administrative fee that will be withheld from refund amount is 25 % of the delegate fee

FULL MEETING CANCELLATION

- All refunds will be issued in the currency of the original payment

REGISTRATION FEES FOR TWO DAYS CONFERENCE

Early Bird (Until 7th May 2021) (Subject to Payment Realization)

			(Exchange rate: I USD = 1.36 SGD) Registration Fee (SGD)
Member	**Industry**	Early-bird	550
		Standard	650
Non-Member	**Industry**	Early-bird	650
		Standard	750
Academia		Early-bird	250
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A student is an undergraduate/graduate who can document enrollment in a signature accredited, degree granting, academic program. Please send completed registration form, payment and copy of student identification.

DIA INDIA PRIVATE LIMITED

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