

DIA - CoRE Singapore Annual Meeting 2019

- Advancing Health In Asia Through Innovation

Organised by DIA and CoRE

March 5-6, 2019

DIA

CoRE
Centre of Regulatory Excellence
at Duke-NUS Medical School

11

Countries Represented

26

Faculty Members

From pharmaceutical and medical device industry sectors, regulators, and healthcare institutions



abbvie

APACMed
ASIA-PACIFIC MEDICAL TECHNOLOGY ASSOCIATION



BIORITIM

ICON

HSA
Health Service Authority

財團法人醫藥品查驗中心
Center for Drug Evaluation, Taiwan

Biogen

gsk
GlaxoSmithKline

CRM
CLINICAL RESEARCH MALAYSIA
Lower Clinical Submissions in Clinical Trials

MSD

NPRA
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medidata

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SAP

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Microsoft

NOVARTIS

Pfizer

PMDA

Roche

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Defining Tomorrow's Medicine

Syneos
Health



UCARE.AI
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Introduction

The Duke-NUS Centre of Regulatory Excellence (CoRE) and the DIA jointly organised the second DIA-CoRE Annual Meeting in Singapore from 5 – 6 March 2019.

With the overarching theme of “Advancing Health in Asia Through Innovation”, the two-day conference explored the emerging health trends and innovations in Asia and how these developments are changing healthcare delivery and driving better health outcomes for patients. Bringing together over 110 stakeholders from multiple backgrounds, the conference provided a platform to understand the diverse ecosystem of player and partners and the roles they play in driving health innovations and enabling access to patients

Keynote Lecture: Artificial Intelligence in Healthcare



Keynote speaker, Dr Helmi Zakariah, Chief Executive Officer of Artificial Intelligence in Medical Epidemiology (AIME), shared his experience in using artificial intelligence (AI) to drive public health in the area of dengue disease surveillance in Penang, Malaysia.

Describing the prevalence of dengue in Malaysia, Dr Zakariah highlighted how the current system of passive surveillance had been inadequate in ensuring timely and accurate response to dengue outbreaks (i.e. lack of data integration and insufficient data analytics expertise). A shift from passive to active surveillance was critical to urgently generate faster and better response to dengue outbreaks.

The AIME's AI-based dashboard allows for data integration – eliminating data duplication and redundancy – and enables real-time case updating and outbreak forecasting. These features help to inform decision-makers for faster and better outbreak response, protecting the population by preventing further spread and harm to health as well as supporting the planning and allocation of resources in a more prudent manner.

Sharing the key lessons in implementing AI in addressing a public health need, Dr Zakariah stressed that effective deployment essentially required ensuring that a proper ecosystem was in place. This included components such as an IT and data infrastructure, the capacity of the health system to carry out subsequent measures, and close collaboration with health decision-makers and other relevant health-related services.

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Innovations Advancing Health in Asia

Digital health can transform healthcare in several ways

Over two days, the conference sessions featured a variety of health innovations across the digital health, pharmaceuticals, biotechnology, and medical devices sectors in Asia.

A major focus at the conference was on digital health applications and their various impacts on healthcare.



Transform patient engagement

The patient's journey through healthcare can often be complicated and overwhelming. Digitally-enabled platforms and mobile applications can improve the patient's experience by simplifying and streamlining the numerous interactions within and beyond the healthcare system. Electronic labelling, or e-labelling, of health products is also an emerging discussion among healthcare stakeholders which aims to change the way health-related information is communicated to and accessed by patients and consumers.



Empower patients for self-care

Digital health can enable and enhance self-management of health, which is increasingly being recognised as an important factor to driving successful health outcomes alongside efforts to strengthen healthcare systems and services. Examples of such tools include mobile health applications, wearable devices, and internet-connected devices.



Optimise clinical and operational effectiveness

Various AI and machine learning applications have been developed to inform and aid clinical decision-making by physicians as well as operational decisions by healthcare providers. Advanced imaging technology merged with machine learning capabilities help increase efficiency for anatomical reviews and clinical diagnosis, especially in enabling predictive modelling to identify early risks of secondary conditions associated with chronic diseases. AI-enabled algorithms have also been developed (i.e. cost and risk predictors) to inform hospitals and payers making operational decisions.



Boost clinical research

The high costs, long timelines, and complex processes associated with current approaches to drug discovery and development have been long identified as problems to be addressed with new approaches. Digital applications for clinical research offer promising opportunities across the entire lifecycle from pre-clinical (i.e. machine learning to identify new targets and biomarkers), to clinical (i.e. machine learning to identify suitable trial participants) and post-market phases (i.e. digital platforms to aid post-market safety monitoring). Digital tools coupled with advanced data analytics also enable the harnessing of real-world data for translation into meaningful evidence for the benefit of patients.

Innovations Advancing Health in Asia

Innovation in pharma, biopharma, and medical devices continues to advance

In the pharma and biopharma space, research on cancer therapies continues to dominate the sector. Examples discussed at the conference included next-generation antibody drug conjugates and virus-specific T-cells for solid tumour immunotherapy. Other emerging areas of research highlighted included the development of lipid-based drug delivery systems (LDDS) enabling targeted delivery and sustained release of drugs, and a renewed interest in botanical drug development using innovative technologies to support quality development of these alternative drugs.

In the MedTech space, in addition to digital health, other innovations featured include the potential application of blockchain in the healthcare supply chain and the ongoing efforts to address needs in developing countries by creating technology that are usable and implementable at low costs.

Facilitating Access to Health Innovations

With the fast advent of innovations across the healthcare landscape, what is being done to ensure that patients and consumers have access to these innovations? A series of talks by regulatory affairs professionals in NRAs and industry illuminated the breadth of efforts undertaken in the regulatory space to support innovation and facilitate timely access by patients.



Panel moderators Mr Thean Soo Lo (J & J Singapore) with the panelists, addressing topics on facilitating efficient and effective regulation for timely access in ASEAN and Asia.

The acceptance of digital health requires a re-imagining of the regulatory paradigm.

The diversity of digital health applications presents challenges for existing medical devices regulatory frameworks. Simply viewing digital health applications as medical devices is an inadequate approach as these applications may be designed for and used by patients and consumers under clinical and non-clinical indications. Stakeholders agree that a risk-based, fit-for-purpose regulatory framework for digital health is needed.

A number of NRAs and international regulatory platforms have embarked on various forms of pilot regulatory mechanisms to meet this need: the US Food and Drug Administration's Digital Action Plan, the International Medical Device Regulators Forum's 'Software as a Medical Device' (SaMD) definition, Singapore's regulatory sandbox programme with telemedicine as a focus area, and other efforts undertaken by NRAs in Europe, Japan, Canada, and Australia to focus on digital health.

NRAs across Asia are responding by actively supporting health innovation through advancing regulatory science and promoting multi-stakeholder collaboration.

Regulatory mechanisms to facilitate access and support innovation

Most NRAs in Asia have put in place expedited registration pathways designed to shorten regulatory timelines. Inter-agency regulatory collaboration such as reliance, work-sharing, and joint assessments are relatively new mechanisms that aim to address resource and capacity constraints faced by NRAs. Other regulatory efforts highlighted included the development of guidelines by the National Pharmaceutical Regulatory Agency (NPRA) to support and promote conduct of first-in-human studies in Malaysia and the launch of the Medical Products Consortium of Thailand to boost domestic innovative health products through strong multi-stakeholder collaboration.

Emphasis on advancing regulatory science

Regulatory stakeholders recognise the critical need to keep up with the rapidly advancing science and technology behind innovative products. Discussions at the conference highlighted that regulatory stakeholders must expect to undergo mindset changes and strengthen understanding of regulatory science, which is evolving to ensure that quality, safety, and efficacy of these products could be properly assessed without stifling innovation. For instance, the use of manufacturing innovations to accelerate development would require re-thinking of quality control strategies and specification acceptance criteria. Other developments in regulatory science included the multiple regulatory science-based strategies carried out by Japan's Pharmaceuticals and Medical Devices Agency (PMDA), the Taiwan Food and Drug Administration's (TFDA) consideration of real-world evidence in regulatory decision-making, and the Singapore Health Sciences Authority's (HSA) use of big data analytics for active post-marketing safety surveillance.

The Way Forward

Worldwide, the demand for healthcare is rising rapidly and innovators are responding with vigor to meet patients' needs. In a highly diverse region such as Asia, the overlap between healthcare trends and needs with varying political, socio-economic, and environmental contexts inevitably results in numerous opportunities as well as challenges for healthcare stakeholders. The wealth of information presented at the conference has highlighted the unstoppable wave of innovation in Asia, and at the same time signalled an urgency for all stakeholders to work together to pave the way for greater patient access to the fruits of innovation. As underlined by Professor John Lim (Executive Director of CoRE) and Dr Youngshin Lee (Senior Vice President & Managing Director of DIA South Korea and ASEAN) in their welcome remarks, it is absolutely vital for stakeholders to unite in the effort to advance health, scientific and regulatory excellence. All stakeholders have a hand in supporting and driving patient-focused goals within a continually improving, data-driven health system.

