DIA

7 September
8.45am - 5.00pm (SGT)
VIRTUAL MEETING

2021 ASIA MEETING

THE EVOLUTION OF CLINICAL TRIALS AND REGULATORY SCIENCE IN A POST-PANDEMIC DIGITAL WORLD IN ASIA

AN OUTLOOK ON THE MAIN TOPICS OF THE DIA ASIA 2021 CONFERENCE

with inputs from Kum Cheun Wong (Novartis), Jing Ping Yeo (Consultant), Shun Jin (Sandoz, Programme Chair), and James Pan (Janssen China)

The last year was an exciting time for pharma and biotech, with a continuing evolution in 2021. The COVID-19 pandemic is showing that the industry plays a critical role in finding solutions to the current crisis. We also see arising opportunities and needs for new technologies and innovative methodologies.

> *"All these led to the industry being rewarded with stronger stock market valuations and many biotech companies are able to raise considerable equity capital through IPOs, private placements and other financing"*, says **Jing Ping Yeo**, **Consultant - Clinical,** about current market opportunities.

Also clinical trial design is undergoing an evolution. At DIA Asia 2021, **James Pan**, **Head of Statistics and Decision Sciences at Janssen China** talks about Clinical Trial Design during and post COVID-19, where attendees can expect *"Complex innovative designs (CID) with a focus on master protocols, illustrated through recent exciting case studies."*

Real-world evidence fundamentally changes healthcare

On these grounds, drug development is evolving rapidly. To assess the safety and efficacy of investigational new drugs, randomized controlled clinical trials will remain the gold standard. But clinical trial data alone often does not accurately reflect how a drug would affect the larger patient population in the real-world setting, due to the strict inclusion and exclusion criteria. Here Real-world evidence (RWE) comes into the equation.

Kum Cheun Wong, **Head Asia Pacific Regulatory & Development Policy at Novartis, Singapore**, is looking at what will be a major discussion at DIA Asia 2021: *"Real World Evidence (RWE) is changing the landscape of drug development, clinical trials and regulatory decision-making process, touching the entire chain of healthcare. It is beginning to transform the direction from the historical use for post-marketing safety monitoring to adoption to support clinical trial design and studies to generate better treatment outcomes."*

Historically used for post-marketing safety monitoring, there is now happening a transformation towards supporting clinical trial design and studies to generate better treatment outcomes. With RWE, collecting and utilizing data from clinical practices, from robust electronic health records, or from settings that reflect the reality of day-to-day healthcare delivery, becomes increasingly important in the approval process. This will broaden the development of drugs and ensures a better understanding of patient population risks and benefits. To discuss these opportunities, DIA Asia 2021 gathers leading experts sharing their insights on the current status, best practices and examples.

Building innovative and sustainable ecosystems

The growth potential of Asian pharmaceutical and life science industries is astounding over the past few years. Despite Asia being a collection of markets with very diverse sets of regulatory environments, demographics, economic impact, and disease profiles, the regional ecosystem is investing in its capabilities to advance patient centricity in the healthcare and life science sector. The scientific and technological developments in cell and gene therapies, mRNA, digital analytics capabilities, patient centric delivery, and smart health devices are changing the current business models and driving cross-sector economy.

Jing Ping Yeo sees the conference as a unique forum to get a real understanding about the special structure of the region, as *"The audience has the opportunities to hear directly from the relevant stakeholders and also to sense the Asian environment directly."*

It is key to build an innovative and sustainable structure where bioventures, mega pharmas, and small startups collaborate with governments and regulators to support the transformation into a patient centric, value-focused research landscape. Especially small startups can profit from reliable networks to increase their chances of building a sustainable business model.

Fostering solutions in a multi-stakeholder, neutral forum

DIA Asia 2021 will be the first transnational post-COVID conference connecting industry experts and regulators to discuss key learnings and takeaways in the clinical trial and regulatory space across the Asia region. Looking at cooperation and networks, regulatory convergence plays a critical role in enhancing clinical trials in a connected and digitalized world.

> **Shun Jin** is **Head, Regulatory Affairs at Sandoz and Programme Chair,** and looks at the transnational focus of the conference: *"Regulatory convergence is always a hot topic. Especially with the recent global political environment change, how would such political environment change impact the healthcare policy convergence? We will especially focus on the difference between Asia countries and Westerner countries on vaccines, control, testing, and more."*

Overall, new technology adoptions will help developing better diagnostics to reach improved patient outcomes. To enable this, the close cooperation between industry and regulation on neutral ground is a promising way to establish a forward-thinking research ecosystem.

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