BioPharma Asia Convention

22 – 23 March 2017

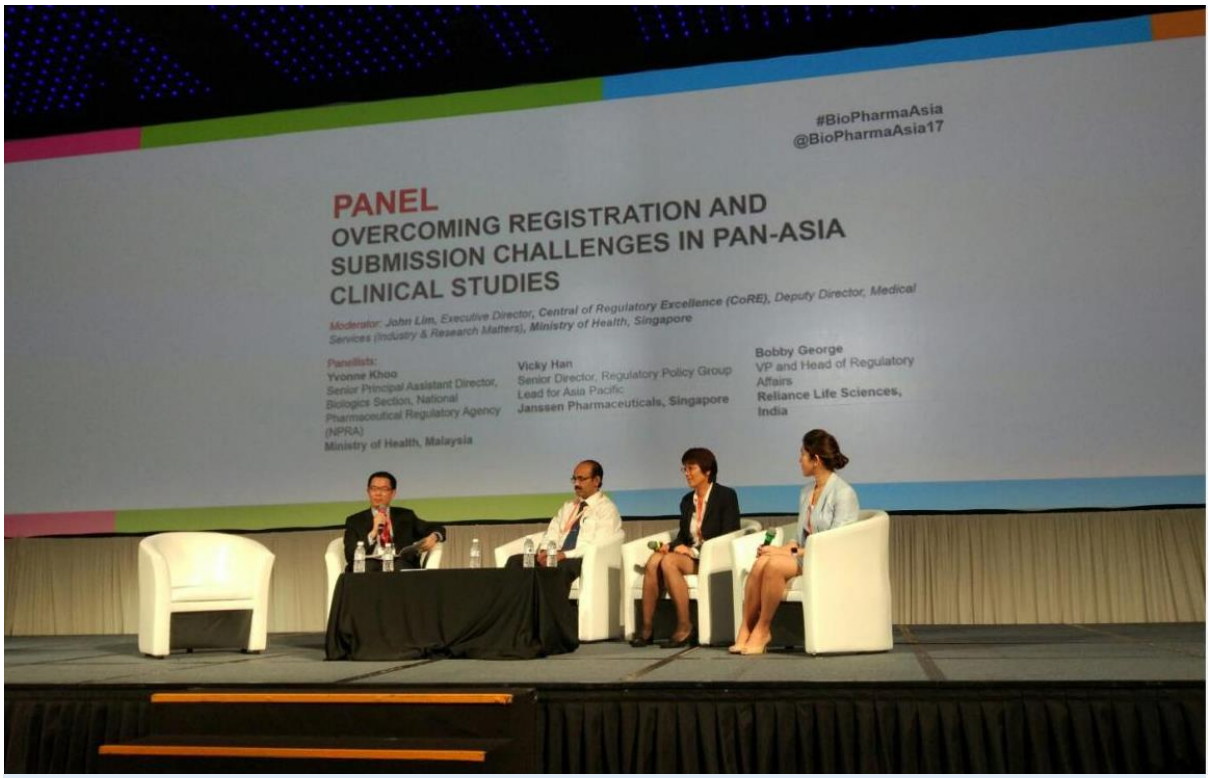
DukeNUS Medical School

CoRE Centre of Regulatory Excellence @ Duke-NUS Medical School

BioPharma Asia Convention 2017

At the BioPharma Asia Convention 2017 held in Singapore from 22nd -23rd March, A/Prof John Lim was invited to chair a panel discussion on “Overcoming registration and submission challenges in pan-Asia clinical studies” as part of a conference track focused on regulatory affairs in clinical trials.

The distinguished panellists included Dr Yvonne Khoo from Malaysia’s National Pharmaceutical Regulatory Agency (NPRA), Ms Vicky Han from Janssen Pharmaceuticals Singapore, and Dr Bobby George from Reliance Life Sciences in India.



A/Prof John Lim chairing a panel discussion on “Overcoming Registration and Submission challenges in pan-Asia clinical studies” at the BioPharma Asia Convention 2017

Discussing the current outlook of pan-Asia clinical studies, the panel highlighted considerable efforts and progress that had been made to facilitate such studies and address the key challenge of regulatory heterogeneity. Notable examples of positive moves across Asia included the pilot ASEAN-WHO SIAHR joint assessment project[1] led by NPRA Malaysia, and recent regulatory reforms in various jurisdictions (e.g. India and China).

Sharing the opinion that more could be done moving forward, the panel discussed the importance of improving communication between regulators and the industry in facilitating good regulatory policies and processes. A key recommendation was to leverage capacity building initiatives to foster trusting relationships and enable understanding of the scientific basis to regulatory requirements, while also creating opportunities for dialogue to address divergence and promote convergence.

[Weblink: http://npra.moh.gov.my/index.php/announcement/1104-asean-joint-assessments-procedure-for-pharmaceutical-products-information]

[1] ASEAN-WHO SIAHR Joint Assessment Project: With support from the World Health Organisation (WHO), the joint assessment project on Supporting the Implementation of ASEAN Harmonised Requirements for Drug Registration (SIAHR) was recently implemented in January 2017 for a two-year pilot period.

Acknowledgements

The views presented in this publication are those of individual contributors and do not represent formal consensus positions of the authors' organisations or CoRE.

CoRE CN: 2017_EP003_ BioPharma Asia Convention

Contact us

Tel: +65 6601 5147
Email: CoRE@duke-nus.edu.sg

Duke-NUS Medical School
8 College Road
Singapore 169857
www.duke-nus.edu.sg/core

centre-of-regulatory-excellence

CoREDukeNUS

CoREDukeNUS

https://tinyurl.com/watchCoREhere