ICMRA Session 2 – Evolution of Clinical Trials

Tuesday November 14, 2023, 11:15h – 12:45h

Co-chairs: HC (Ms Pam Aung-Thin) and HPRA (Dr Lorraine Nolan)

Theme: What innovative clinical trials of the future will look like and what solutions are regulators considering to address the challenges.

Time*	Presentation topics	Speaker (Reg Agency)
11:15 – 11:25	Opening remarks	Co-chair, Ms Pam Aung-Thin
11:25– 11:35	How can regulators set direction and be proactive, rather than reactive, to promote designs that are focused on patient involvement?	Dr. Lars Bo Nielsen, Director General, Danish Medicines Agency
11:35 – 11:45	The introduction and policy of Central Institutional Review Board (IRB) and Decentralized Clinical Trial (DCT) in Republic of Korea	Dr. Seogyoun Kang, Director General, Ministry of Food and Drug Safety, Republic of Korea
11:45 – 11:55	How do we ensure that we have best practices and other measures to strengthen the global clinical trial ecosystem for clinical trials particularly in LMIC?	Hiiti B. Sillo Unit Head, Regulation and Safety Regulation and Preq ualification Department, WHO
11:55 – 12:05	How do we ensure that there is greater transparency and data sharing globally among regulators, specifically from the perspective of countries (e.g. Brazil) that are not typical locations for Phase 1 and phase 2 CTs?	Dr. Antonio Torres Brazilian Health Regulatory Agency (ANVISA)
12:05-12:15	Open Q&A for speakers	All (moderated by Co-Chair, Dr. Lorraine Nolan)
12:15 – 12:45	Closing remarks, including next steps for ICMRA	Co-chair, Dr. Lorraine Nolan