APEC Harmonization Center Workshop:
Post-Pandemic Regulatory Environment Changes in Clinical Trials

October 23rd – 24th, 2023 I COEX at Seoul, Korea (Hybrid format)

Description: The COVID-19 pandemic has transformed the global regulatory environment, accelerating the use of innovative measures & regulatory flexibility to support development of safe, quality medical products in timely manner. In clinical trials, use of decentralized clinical trials (DCTs) became more and more relevant, highlighting the critical benefits of virtual trials and recruitment of diverse patient population while lowering the burden. Digital Technologies also brought significant improvements, enabling real-world data collection outside the traditional clinical context.

As such, this 2-day hybrid workshop will explore how the pandemic catalyzed the regulatory changes in clinical trials with focus on the use of DCTs and Digital Technologies by examining its current regulatory landscape and discussing future opportunities & challenges.

Day 1 : October 23rd (Mon)		
Time	**Topic**	**Speaker**
Welcome and Introduction		
09:00 - 09:05	Welcoming Remarks	AHC
Session 1: How Pandemic impacted Global Regulatory Environment		
09:05-09:25 (20min)	Setting the Scene: - COVID-19 Pandemic's impact in global regulatory environment; How it catalyzed use of regulatory flexibility & innovative measures in clinical trials	Sumitra Sachidanandan (HSA)
Session 2: Decentralized Clinical Trials		
09:25-09:50 (25min)	Deep Dive into Decentralized Clinical Trials (DCTs) - Overview on DCTs & its recent trend: evolution of DCT concept, key aspect, benefits, etc. Q&A (5 min)	Yvanka Maria Gilliam (SCRI)
09:50-11:10 (80min)	Current Regulatory Landscape for DCTs - Introducing regulatory frameworks DCT, Lessons learned, benefits, challenges, etc. • Economy 1 (Chinese Taipei)	Yi-Hsuan Hsu (TFDA)

	• Economy 2 • Economy 3 Q&A (5 min)	TBC TBC
11:10-11:55 (45min)	Industry & Practitioner perspectives on DCTs - Experience sharing & Case Study: Practical considerations in using DCTs • Industry • Practitioner (Hospitals, CROs) Q&A (5 min)	Carmel Devlin (Pfizer - TBC) Jiyeon Park (SNU Hospital)
11:55-12:00	Closing Day 1	

Day 2 : October 24th (Tues)		
Time	**Topic**	**Speaker**
09:00-09:30 (30min)	Quality Risk Management for DCTs - Using Risk-Based Monitoring (RBM) strategies in DCT - Maintaining regulatory compliance in DCTs Q&A (5 min)	Lilith Hayakawa Mist (Merck)
09:30-10:00 (30min)	Data Management and Analysis in DCTs - Data Quality & Integrity: Ensuring reliable and accurate data collection - Statistical Considerations in DCTs: Addressing potential biases and limitations Q&A (5 min)	Aparajeeta Priyadarasani (Medidata Solutions)
10:00-10:30 (30min)	Future of DCTs: Regulatory Opportunities & Challenges	Kwunho Jeong (JNP MEDI)
Session 3: Digital Technology in Clinical Trials		
10:30-11:00 (30min)	Use of Data Science in Clinical Trials - How Data Science can support collecting, management and analysis of clinical data as well as reducing clinical trial timeline	TBC
11:00-11:30 (30min)	Use of Real-World Evidence/Data in Clinical Study Design & Research - How RWE/RWD support regulatory-decision making, supplement existing data and inform study design; Its benefits & future opportunities for clinical trials	TBC
11:30-12:00 (30min)	Application of AI in Drug Development	Eun Young Park (AinB)

12:00-12:05	Wrap Up & Closing	AHC