GOOD RELIANCE PRACTICES

(conducted via Zoom)

Workshop 2 (Using Reliance Approaches for Product Evaluation)

27-29 September 2021

WORKSHOP PROGRAMME

Learning outcomes

- Assess the suitability of risk-based and regulatory reliance approaches for the local regulatory environment
- Describe the various models and process requirements in regulatory reliance, including the use of datasets from innovative trials and for urgent public health situations
- Apply benefit-risk assessment in regulatory reliance approaches for product evaluations
- Describe the utility of regulatory reliance for the product life cycle and the involvement on a regional level

Day 1	Application of Reliance Approaches	
9.00am	**Workshop Briefing**	
9.05am	**Welcome and Opening remarks**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.15am	**Photo-taking**	
9.20am	**Principles of reliance in regulatory management of health products** • Application across product life cycle • Agility and robustness in decision-making	**Dr Marie Valentin** Technical Officer Regulatory Convergence and Networks Team WHO
9.45am	**Innovation in Clinical Trials** • Novel therapeutics and Trial Designs • Value of reliance for clinical trial applications	**May Mo** Executive Director Design and Innovation, Center for Design and Analysis Amgen
10.30am	**Break**	
11.00am	**Basic requirements for regulatory reliance** • Technical competency and processes • Role of the local evaluators • Common reasons for divergent regulatory outcomes	CoRE
11.30am	**Benefit-risk assessment for regulatory reliance** • Refresher on benefit-risk assessment of pharmaceuticals • Considerations for benefit-risk assessments in regulatory reliance	CoRE
12.30pm	**Lunch**	
2.00pm	Group Activity • Use a benefit-risk assessment framework to support regulatory decision-making	CoRE
4.00pm	**Break**	
4.30pm	**Experience sharing: African Vaccine Regulatory Forum (AVAREF)**	
5.30pm	**End**	

Day 2	Reliance Approaches in Product Evaluation for Market Authorisations	
9.00am	**Clinical Evaluation using reliance approaches** • Principles for robust clinical assessment • Use of reference reports	CoRE
9.30am	Group Activity • Assess non-clinical and clinical data using reference reports	TGA and CoRE
10.30am	**Break**	
11.00am	Group Activity (cont'd)	TGA and CoRE
11.45am	**Use of non-traditional clinical datasets for marketing authorisation** • Case examples of Precision Medicines/ Cell, Tissue and Gene Therapies	**Dr Kaye Robertson** Acting Section Head, Medical Officer Medicines Regulation Division Health Products Regulation Group Therapeutics Goods Administration (TGA) Australia
12.30pm	**Lunch**	
2.00pm	**Applying reliance approaches in CMC evaluation** • Existing tools for facilitating reliance • Gaps in regulatory cooperation for assessing CMC	**Dr Sannie Chong** Asia Pacific Technical Regulatory Policy Roche
2.30pm	Group Activity • Identify challenges and opportunities for implementing reliance approaches for CMC evaluation	CoRE
3.00pm	**Break**	
3.30pm	**Risk Management Plans** • Insights into RMP customisation by industry applicants • Common challenges faced by industry applicants	**Ms Yeo Aik Peng** Director Global Safety, JAPAC Amgen
4.15pm	Group Activity • Assess a referenced RMP for local use	CoRE
5.30pm	**End**	

Day 3	Reliance Approaches in Post-Market Activities	
9.00am	**Regulatory reliance for medical devices**	
9.45am	**Product Quality Surveillance (PQS)** • Role of PQS in supporting regulatory cooperation • Required local capabilities in monitoring product quality • Platforms and partners for sustaining effective PQS	**Ms Ruth Lee** Associate Director Govt Policy and Regulatory Affairs Global External Affairs APAC US Pharmacopeia (USP)
10.30am	**Break**	
11.00am	Group Activity • Developing a local sampling plan for PQS	CoRE
12.00pm	**Applying the reliance and work-sharing principles to pharmacovigilance** • Contribution of post-market activities and PV in regulatory cooperation • Required capabilities • Approaches for sustaining local PV activities	**Dr Jean-Christophe Delumeau** Head Pharmacovigilance Policy Strategy (Global) Bayer
1.00pm	**Lunch**	
2.30pm	**Exploring reliance approaches for post-approval CMC variations** • Address source of existing application backlogs • Optimise product quality monitoring	**Dr Sannie Chong** Asia Pacific Technical Regulatory Policy Roche
3.00pm	Panel Discussion • Practical solutions to enhance post-market capabilities to support reliance pathways	
3.45pm	**Closing remarks**	
4.00pm	**End**	