ICMRA 2023 SUMMIT MELBOURNE

ICMRA Session 1 – Artificial Intelligence and Machine Learning

Tuesday November 14, 2023, 09:00h -10:40h

Co-chairs: TGA (Prof Robyn Langham) and EMA (Ms Emer Cooke)

Theme: What are the challenges in developing regulatory best-practice when incorporating artificial intelligence (AI) and machine learning (ML) in the regulation of medicines?

Time*	Presentation topics	Speaker
09:00 – 09:05	Opening Remarks Setting the scene – introducing the topic	Co-chair Prof Robyn Langham (TGA)
09:05 – 09:25	Transforming data into knowledge: Mining the global kidney disease knowledge network for molecular targeted therapy development. - Drug development – what's in the pipeline and what is already going live - What are the regulatory challenges from a non-regulator perspective? - Interdisciplinary data integration of large-scale data sets which enable precision medicine – NIH tools - Use of AI and ML in new disease predictors, new drug development and successful clinical trials of novel therapeutic modalities in chronic kidney disease - How can we share data – global challenges	Prof Matthias Kretzler (Uni of Michigan) Head of computational medicine and bioinformatics
09:25 – 09:35	AI for effective medicines regulation – opportunities and challenges from an European perspective - How to build AI competence and capacity - How do we regulate use of AI in the medicinal product lifecycle? - How to develop, deploy and share AI/ML systems - How to use AI at an agency level for effecting medicines regulation	Gabriel Westman (SMPA) Head of Artificial Intelligence at the Swedish Medical Products Agency

09:35 – 09:45	'Large Language Models (LLMs) Taskforce: An initiative to promote shared best practices and strengthen interagency collaboration' The LLM Taskforce established in June 2023, focuses on the transformative power of LLM models in different areas of regulatory sciences. It comprises representatives from multiple agencies, including Swissmedic and the FDA. It aims to understand the potential hazards and risks and develop best practices and is therefore overarching the individual agency areas such as clinical drug development or pharmacovigilance.	Dr Joerg Schlapfer – (Swissmedic) Head Chief of staff and Head of external relations
09:45 – 09:55	AI and ML landscape – Highlight themes of what FDA is seeing - Share results of a study looking at different uses of AI across incoming applications - How do we adapt our policies to support and encourage new innovation? Engagement with researchers and academics - How COVID was a catalyst – pushed us to look at innovation and we need to capitalise on this moving forward - Share themes Discussion paper – what were the themes from the response	Dr Khair ElZarrad (FDA) Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER)
09:55 – 10:05	Use of AI for supply chain/shortages purposes - BfArM had supply chain database since 2013 - Currently building a new system incorporating AI to combine big data – from manufacturers and manufacturing sites to new active substances and finished products in order to develop an early warning system so more time for mitigation – share tools, challenges for BfArM, lessons /benefits for other regulators etc	Dr Karl Broich (BfArM) Head and President of the BfArM (Federal Institute for Drugs and Medical. Devices, Germany)
10:05 – 10:35	Panel Discussion – Open Q&A for speakers	ALL

10:35 – 10:40	Closing remarks Session outcome - where to from here in a global collaborative sense? What does this mean for regulators? For ICMRA? ICMRA AI WG – things have moved on since report? What do we need? Best way of helping each other at a national and regional level, sharing international approaches and getting alliance	Co-chair - Ms Emer Cooke (EMA)

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	Dr. Antonio Torres Brazilian Health Regulatory Agency (ANVISA)

	countries (e.g. Brazil) that are not typical locations for Phase 1 and phase 2 CTs?	
12:05 - 12:35	Open Q&A for speakers	All (moderated by Co-Chair, Dr. Lorraine Nolan)
12:35 – 12:45	Closing remarks, including next steps for ICMRA	Co-chair, Dr. Lorraine Nolan

ICMRA Session 3 – Advanced Medical Products

Tuesday November 14, 2023 14:00 – 15:40

Co-chairs: MHRA (Dame June Raine) and PMDA (Dr Yasuhiro Fujiwara)

Theme: What have we learnt from the regulatory journey so far, and where are we going?

Time*	Presentation topics	Speaker(Reg Agency)
14:00 – 14:05	Opening Remarks Set the scene – introduce topic and order of session	Co-chairs
14:05 – 14:25	Pre-clinical focus Stem cell technology What are the regulatory challenges from a non-regulator perspective?	Prof Melissa Little, AC Chief Scientist, Group Leader (Kidney Regeneration) Murdoch Children's Research Institute
14:25 – 14:30	The challenges of Gene Therapy	Dr Tony Gill (TGA)
14:30 – 14:40	Focus on Product Quality – how is quality assured and monitored for these products? manufacture – models outside of standard manufacturing models; including point of care, home based, mobile etc. Challenges, controls and regulatory approaches – what is likely to come? What framework change is required? (legal framework updates, links with other regulators e.g hospitals, health professionals) An opportunity to develop internationally harmonised guidelines from the inception	Dr Ian Rees previously Manager for the Inspectorate Strategy and Innovation Unit (MHRA)

14:40 – 14:50	Regulatory decision making Clinical trial design Balancing risks Future proposal for advanced therapies	Dr Yasuhiro Fujiwara - Chief Executive of Pharmaceuticals and Medical Devices Agency (PMDA)
14:50 – 15:00	The role of real-world evidence and observational studies Data sharing and advanced therapies registry development (international repository)	Turki Bin Hammad - Epidemiologist – Team lead methodology and biostatistics (Saudi FDA)
15:00 – 15:05	The promise and the challenges of advanced/gene therapies for LMICs	Moji Christianah Adeyeye, PhD, FAS Director-General (NAFDAC)
15:05 - 15:35	Panel Discussion – Open Q&A for speakers	All
15:35 – 15:40	Closing remarks Session outcome - where to from here - in a global collaborative sense? What does this mean for regulators? For ICMRA?	Co-chair(s)