Regulatory Science Convergence in response to a global Public Health Emergency
Emer Cooke, Chair ICMRA
ICMRA was established in 2013 with the mandate to “better safeguard public health by facilitating greater co-operation and to enable Heads of Medicines Regulatory Authorities to exercise collective and concerted strategic leadership over existing and new international initiatives and enablers, as well as over shared regulatory issues and challenges.”

ICMRA has currently 37 members, and WHO as observer.
Examples of ICMRA led regulatory convergence achievements during the COVID-19 pandemic

- In March 2020, global regulators met under the auspices of ICMRA to discuss regulatory considerations related to the development of SARS-CoV-2 vaccine candidates and preclinical data requirements to support proceeding to First in human (FIH) clinical trials.

- In June 2020, ICMRA met again to discuss and reach convergence on preclinical and clinical data requirements to support proceeding to Phase 3 clinical trials with SARS-CoV-2 vaccine candidates. In addition, participants discussed concepts of trial design for these studies including trial population, endpoints and statistical considerations. This was followed by an [ICMRA statement on clinical trials](#).

- Vaccine confidence has been a priority for many public health authorities to promote uptake. ICMRA and WHO jointly issued a statement in May 2021 urging publication of clinical trial reports for new medicines and vaccines without redactions to ensure that research results are publicly accessible to all those involved in healthcare decision-making. [ICMRA-WHO joint statement on transparency](#).

- Addressing public health needs requires a multi-sectoral approach that goes beyond regulators. ICMRA for example has organized a number of workshops with public health authorities, WHO, industry on vaccines and variants, including the most recent [Omicron variant workshop](#) in early January of this year. The workshop concluded with a number of recommendations, including the importance of global coordination of changes in vaccine composition to cover potential variants of concern.
Public Health Emergency Clinical Trials Working Group

- The Public Health Emergency Clinical Trial Working Group agreed to be established (Sept. 2021)
- Terms of Reference now finalized
- Objective: Facilitate the international acceptability of the use of a core protocol for multinational/multiregional platform trials of vaccines and therapeutics in a cross-border public health emergency context
- 13 regulatory authorities from around the world are part of this group: MHRA, EMA, HPRA (Ireland), PMDA/ MHLW, FDA, Health Canada, AIFA (Italy), HSA (Singapore), ANMAT (Argentina), FDA Ghana, SAHPRA (South Africa), Saudi FDA, NMPA (China), in addition to WHO and the European Commission.
Deliverables:

▪ Reflection paper with considerations focusing on protocol design for platform trials to enable regulatory approval and efficient implementation in more than one territory.

▪ Facilitate a shared understanding of obstacles (and potential solutions to these) and enablers to the implementation of multinational/multiregional platform clinical trials during public health emergencies.

▪ Develop and publish key considerations for protocols to support initiation of such platform clinical trials in a public health emergency
• Value of regulatory convergence in clinical trials to ensure we have well powered and robust clinical trials that are meaningful and actionable for regulators and public health authorities. We also need to be prepared to consider alternative clinical trial designs, particularly in global health emergencies where it may not be realistic or ethical to find naïve patients. Trials need to be large enough and able to add new treatment arms at different intervals, taking advantage of existing investigation networks.

• This work is especially important in the context of ensuring preparedness for future epidemics and pandemics.
For any questions following the meeting, please contact:
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