ICMRA Working Group on Real-World Evidence for public health emergencies

Mandate

The International Coalition of Medicines Regulatory Authorities (ICMRA) is a voluntary, executive-level, and strategic leadership entity of medicines regulatory authorities providing a global architecture to support enhanced communication, information sharing, crisis response and address regulatory science issues.

ICMRA is led by its Executive Committee, which manages day-to-day matters as they arise, and which keeps an oversight on approved "projects". These "projects" are coordinated by dedicated working groups (WG). ICMRA currently counts several ICMRA WG, including the WG on real-world evidence for public health emergencies, the mandate for which is described in this document.

More information can be found here: ICMRA and TERMS OF REFERENCE AND RULES OF PROCEDURE.

1. Background

The ICMRA COVID-19 Real-World Evidence (RWE) and Observational Studies Working Group (WG), co-chaired by the European Medicines Agency (EMA) and Health Canada (HC), was created in April 2020 with the intention to collaborate on observational studies to characterise COVID-19 disease, to identify links between clinical outcomes and medication use (including during pregnancy), and to monitor the safety and effectiveness of vaccines and treatments (Global regulators commit to cooperate on observational research in the context of COVID-19). The willingness and need for collaboration beyond the COVID-19 pandemic were subsequently emphasized by ICMRA through a statement published in July 2022 on international collaboration to enable RWE for regulatory decision-making.

To inform the reflection on the achievements and experience gained over four years of activities (2020 to 2023), the WG conducted a survey to gather insights on lessons learned and suggestions for improvement. The feedback received demonstrated the added value of such a WG to ensure connection between regulatory agencies and to facilitate sharing of information, data and expertise on topics of high public health interest. As an outcome of this survey, EMA and HC recommended to the ICMRA Summit in November 2023 to repurpose the WG to focus on RWE generation with a focus on public health emergency preparedness. The proposal was fully supported by ICMRA.

This document lays down the mandate of the ICMRA WG on Real-World Evidence for public health emergencies (WG-RWE for PHE).

2. Objectives

The goal of this strategic WG is to create a forum to facilitate international collaborations between interested regulatory agencies to proactively enhance the efficiency of critical responses in case of

new public health emergencies (PHEs) through collaborative studies. This will be achieved thanks to the establishment of agile governance principles and processes, with a view to improve the timeliness of relevant evidence generation for prompt regulatory actions. The WG strives to optimise preparedness by leveraging existing infrastructures in the different jurisdictions represented in the WG, in order to test the measures in place and to keep governance, processes 'ever-warm' i.e., ready to rapidly conduct studies in an emergency situation.

Close interactions with other ICMRA WGs, and other relevant structures, including the ICMRA Vaccines Pharmacovigilance Network, and the EU Vaccines Monitoring Platform, are maintained by the WG in order to continually share relevant intelligence and to streamline evidence generation based on identified needs, whilst avoiding duplication of efforts.

Information and knowledge sharing may be strengthened through periodic workshops, such as on the progress of collaborative studies. Transparency is ensured through the publication of study protocols and results in publicly available registers to improve outreach and foster preparedness and engagement.

The WG regularly evaluates processes to continuously improve efficiency in line with its strategic objectives.

3. Membership

The WG is established following a call for expression of interest launched among ICMRA members and alternate members.

It is co-chaired by EMA and HC.

The WG is composed of 18 contributors as follow (in alphabetical order of the organisations' name):

- National Health Surveillance Agency (ANVISA), Brazil;
- Dutch Medicines Evaluation Board (CBG-MEB), The Netherlands;
- Danish Medicines Agency (DKMA), Denmark;
- Egyptian Drug Authority (EDA);
- European Medicines Agency (EMA), European Union;
- Food and Drug Administration (TFDA), Chinese Taipei;
- Food and Drug Administration (FDA), United States;
- Health Canada (HC), Canada;
- Health Sciences Authority (HSA), Singapore;
- Medsafe, New Zealand;
- Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency (MHLW/PMDA), Japan;
- Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom;
- Paul-Ehrlich-Institut – German Federal Institute for Vaccines and Biomedicines (PEI), Germany;
- South African Health products Regulatory Agency (SAHPRA), South Africa;
- Saudi Food and Drug Authority (SFDA), Saudi Arabia;
- Swissmedic, Switzerland;
- National Medical Products Administration (NMPA), China;

- World Health Organisation (WHO)

4. Operations

4.1. General principles for the conduct of collaborative studies

The WG envisions a dynamic and strategic approach to international collaborations and proposals for studies of shared interest and of international impact.

Collaborative studies are conducted in accordance with the governance principles, processes and templates established by the WG. This will include a specific provision on confidentiality arrangements on the conduct of collaborative studies.

4.2. Meetings

The full WG holds two to three virtual meetings per year to promote information exchange on the ongoing preparedness studies.

The Co-Chairs are responsible for preparing the agendas and circulating them to the WG prior to upcoming meetings. Members assist in identifying issues and topics for consideration. The Co-Chairs prepare meetings minutes and circulate them for comments to the members.

Additional ad-hoc virtual meetings are held among members participating in collaborative studies based on study milestones as needed.

5. Workplan 2024-2025

5.1. 2024

Within the first year of its creation, the WG aims to begin the following activities:

- Survey among members on capacity to conduct and/or commission studies, and on members' priority topics in order to set the baseline for future collaborative work on RWE;
- Kick-off discussions on governance principles and processes for the setting up and conduct of collaborative studies for preparedness on PHEs. Methodological issues linked directly to specific problems/barriers identified during the COVID-19 response will be taken into account;
- Draft list of topics for future collaborative studies, including a draft outline if possible. Examples include, but are not limited to, the generation of background incidence rates for adverse events of special interest across medicinal products (such as vaccines), alignment on case definitions and phenotypes for specific outcomes, characterisation of specific populations of interest, studies on safety concerns of interest, and studies in rare disease contexts.

5.2. 2025

In its second year of operation, the WG intends to continue the work initiated in 2024, and in addition, will strive to launch the first collaborative study on a topic agreed by the WG.

6. Reporting

The Co-Chairs will provide summary updates of the activities to the ICMRA members at a minimum of once a year at the time of the ICMRA annual summit, and on an ad-hoc basis as requested.

7. Amendments to the mandate

The mandate may be amended at any time, at the discretion of the Co-Chairs and in agreement with the ICMRA Executive Committee.