



ICMRA statement on international collaboration to enable real-world evidence (RWE) for regulatory decision-making

1. Background

The role of real-world data (RWD) and real-world evidence (RWE) in supporting the development of medicines across their different stages of development and use is evolving rapidly. However, challenges exist, due for example to heterogeneous data sources, different levels of data quality, and various governance models for data sharing and access. Close collaboration between regulators across the world can help address these challenges. ICMRA can play an important role by catalysing increased cooperation on the use of RWE for regulatory decision-making.

The timely work undertaken by regulators and researchers to address the unprecedented challenge of the COVID-19 pandemic, as well as lessons learnt throughout the last two years, have led regulators to establish or reinforce collaborations allowing efficient sharing of data and experience. These collaborations can be further leveraged to medicines regulation beyond the pandemic.

In June 2022, EMA, FDA, and HC co-chaired an ICMRA workshop (programme in Annex) to share experience on accomplishments and challenges of RWE in medicines regulation, and to identify opportunities for future regulatory collaboration.

2. Opportunities for collaboration

The June 2022 ICMRA workshop on RWE identified four areas of opportunities for regulatory collaboration which could help address common challenges and further enable the integration of RWE into regulatory decision-making.

- **Harmonisation of RWD and RWE terminologies:**

- Generate common operational definitions of RWD and RWE, with clear scope and level of granularity (e.g., pertaining to RCTs and observational studies);
- Leverage existing ICH activities, such as M14 on *“General principles on planning and designing pharmacoepidemiological studies that utilize real-world data for safety assessment of a medicine”*.

- **Convergence on RWD and RWE guidance and best practice, including:**

- Common principles for RWD quality;
- Metadata to enable characterisation and discoverability of RWD;
- Suitable scenarios where RWE may contribute to regulatory decision-making, building on existing use-cases;
- Templates for study protocols/reports that can be used in multiple regulatory jurisdictions.

- **Readiness**

- Through the strengthening of international regulatory collaboration on RWE, enable the rapid creation of expert groups on specific topics of interest, including in case of emerging health threats;
- Foster collaboration on governance and processes to enable the efficient conduct of studies based on RWD from different countries to address important public health challenges.

- **Transparency**

- Define common principles and practices for the systematic registration of pre-specified study protocols (including description of feasibility assessments) and study results in publicly available registries;
- Promote publication of study results in open-source, peer-reviewed journals.

These potential areas for regulatory collaboration on RWD and RWE could be taken forward through a variety of existing fora including ICH, international standardisation bodies, and clusters of interested regulators. ICMRA remains committed to steering this work in the interests of patient health and innovation.

Annex

Sessions	Outputs	Chairs and Speakers
RWE terminology	Review of existing definitions of RWD/RWE	John Concato – US FDA Andrew Raven - HC
From RWD to RWE	Lessons learnt from RWE evaluations, successes, and pitfalls	John Concato – US FDA Gustavo Mendes Lima Santos - ANVISA Boitumelo Semete - SAHPRA Fawaz F. Al-Harbi - SFDA Daniel Lottaz & Lorenzo Hess - Swissmedic
Landscape analysis of international initiatives	Learnings from ICH and other initiatives about challenges and opportunities, gaps, and future activities	Melissa Kampman – HC Ron Milo - Weizmann Institute of Science Corinne de Vries - EMA David Moeny - US FDA David Brown - MHRA
Data sources and metadata	Lessons learnt from using different data sources and perspectives for data discoverability (metadata) and data quality assessment	Xavier Kurz – EMA Ana Cochino - EMA Sreemanee Dorajoo - HSA Jun Zhao - NMPA/CDE Peter Mol - CBG-MEB
Federated and other Data Networks	Exploration of existing federated data networks used worldwide including their challenges and opportunities	Melissa Kampman – HC Jesper Kjaer - DKMA Azumi Takano - PMDA Patricia Bright - US FDA
Other topics of interest	Insight into specific topics of interest in the different regions (e.g. pharmacogenomics)	Catherine Cohet – EMA Sarah Vaughan - MHRA Maria Gordillo-Maranon - EMA
Conclusion	Draft statement on international coordination of activities to advance RWE	Peter Arlett – EMA Melissa Kampman – HC John Concato – US FDA