Health Canada Santé Canada

Canada

Real-World Evidence (RWE) International Collaboration and Next Steps

EU Big Data Stakeholder Forum

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Background

- The availability of Real-World Data (RWD) has been steadily increasing worldwide and evidence from the analysis of such data can help in the assessment of drug safety, efficacy and effectiveness

- The role of RWD/RWE in the therapeutic product life cycle continues to evolve and is an area of focus for regulators, health technology assessors, industry, and other stakeholders

- Several initiatives have been launched in different regions, e.g., posting a Notice and accompanying RWD/E Quality document in Canada, the HMA/EMA Big Data initiative in EU, and the RWE framework in the US

- But challenges remain with respect to definitions, data sources, fitness, quality, methodological challenges, data sharing and access

- A common theme from stakeholders is a call for international convergence and harmonization, where possible

COVID-19 – An Opportunity for Collaboration

- The *ICMRA COVID-19 Real World Evidence and Observational Studies Working Group*, co-chaired by the EMA and HC, was created in April 2020

- Regulators from more than 20 member agencies have participated to:
  - discuss observational studies to characterise COVID-19 disease, links between clinical outcomes and concomitant medication use, and the safety and effectiveness of vaccines and of treatments
  - explore information exchanges on research questions, protocols and results
  - explore the feasibility of collaboration on specific research questions

- Three technical work streams for collaboration:
  - Collaboration on pregnancy studies (EMA)
  - Building international cohorts of COVID-19 patients (HC)
  - Vaccine surveillance and vigilance (MHRA/TGA)

- Has resulted in new collaborations, effective sharing of data, knowledge and experience in relation to observational studies

ICMRA Workshop on RWE

- Building on the ICMRA COVID-19 collaborations for observational studies, an ICMRA workshop was held June 29-20, 2022 to identify areas for RWD/RWE international collaboration

Co-chaired by EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH; Health Canada; FDA U.S. FOOD & DRUG ADMINISTRATION

In-person participants at EMA offices in Amsterdam

250 online participants (ICMRA regulators)

40 countries represented + WHO

ICMRA Workshop on RWE Program

Session	Output
RWE terminology	Review of existing definitions of RWD/RWE
From RWD to RWE	Lessons learnt from RWE evaluations, successes, and pitfalls
Landscape analysis of international initiatives	Learnings from ICH and other initiatives about challenges and opportunities, gaps, and future activities
Data sources and metadata	Lessons learnt from using different data sources and perspectives for data discoverability (metadata) and data quality assessment
Data Networks	Exploration of existing federated data networks used worldwide including their challenges and opportunities
Regional topics of interest	Insight into specific topics of interest in the different regions (e.g. pharmacogenomics)
Conclusion	Draft statement on international coordination of activities to advance RWE

Outcome of the Workshop

- An ICMRA statement was published in July 2022 on international collaboration to enable RWE for regulatory decision-making

- 4 focus areas were agreed upon for future regulatory cooperation:
  - Harmonisation of terminologies for RWD and RWE
  - Regulatory convergence on RWD and RWE guidance and best practice
  - Readiness to address public health challenges and emerging health threats
  - Transparency

- It was concluded that, to progress the work, existing fora should be leveraged wherever possible
  - E.g., ICH, EMA/FDA/HC RWE Cluster, ICMRA

Focus Areas for Collaboration

- **Harmonisation of RWD and RWE terminologies globally**
  - Alignment of operational definitions across stakeholders to ensure common understanding of the scope, types and purposes when such data are submitted in medicines applications
  - Common principles for characterizing RWD quality to inform selection of data and interpretation of study results, in turn supporting the evaluation of the evidentiary value of studies
  - Internationally recognised metadata to enable description and characterization of RWD and enable data discoverability

- **Convergence on RWD and RWE guidance and best practice, including**
  - Templates for study protocols/reports that can be used in multiple regulatory jurisdictions
  - Suitable scenarios where RWE may contribute and has contributed to regulatory decision-making, building on existing use cases (e.g., rare diseases)

Focus Areas for Collaboration (cont'd)

- **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

Next Steps

- Document lessons learned and determine the path forward for the ICMRA RWE and Observational Studies Working Group

- Determine the appropriate forum to advance each area of focus identified through the ICMRA Workshop on RWE

- Continue to advance and leverage the solid collaborative foundation amongst international regulators established to date

Questions?