Terms of reference for the EMA – FDA – HC Cluster on Real World Data (RWD)

The European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and Health Canada agree on the following:

1. Goal and Objectives

The primary goal of the EMA-FDA-HC collaboration on Real World Data (RWD) is to support regulatory decision-making through information sharing and the development of new approaches for the assessment of evidence derived from RWD or other big data sources. The collaboration will seek to foster a consistency of approach across regulatory jurisdictions, aim to resolve common challenges, leverage data, network and expertise resources available to the two organisations and facilitate advances in regulatory science. Specifically, the work should:

- Enable collaboration on the scientific methods for the collection, transformation, and analysis of RWD. This will particularly focus on methodologies to be applied to regulatory use cases where experience of RWD is limited including in the evaluation of efficacy.
- Allow the coordination of collaborative work between the three agencies where sharing of information, results or conclusions may be of mutual benefit. This may include validation of methods developed in one jurisdiction through use of different types of RWD available in the other.
- Identify specific data sets, projects or networks where trans-Atlantic collaboration could add value. This might include work to converge approaches for specific registries.
- Identify opportunities for upstream regulatory convergence for example in the development of key principles, good practice or guidance.
- Identify specific activities beyond the bilateral collaboration (e.g. started within multilateral international fora) where coordination of input may provide mutual benefit.

In addition, concrete case examples may help to inform underlying principles and hence may be discussed in this context.

2. Membership

The list of core members is continuously maintained by each Agency and can be found here: Master list-meetings, docs, and participants.xlsx (see tabulation "*Core composition*").

3. Timing

One-hour teleconferences will be scheduled monthly at the beginning of each year.

Ad-hoc meetings, usually teleconferences, on policies, guidance documents, regulations, or scientific methodologies can be held at any time.

4. Working arrangements

The teleconferences will be chaired by each Agency on a monthly rota-system.

The Agency chairing the meeting will be responsible for the agenda and recording of action points. The topics should be selected on the grounds that they are of major relevance to the three agencies, and meet the objectives laid out in Section 1.

The topics may concern medicinal products within the scope of the EMA, the US FDA and HC activities. The Agency proposing a product's discussion should first liaise internally with other regulators' clusters (e.g. rare disease, methodology, ATMP, therapeutic area clusters) to avoid overlap and duplication.

If possible, a proposed draft agenda will be sent about two weeks in advance of a teleconference to verify topic proposals for mutual agreement. Urgent topics may be added shortly before the teleconference by mutual agreement.

Additional participants from the three Agencies who are not part of the core composition may join depending on the topics.

5. Confidentiality

The work of the collaboration is conducted within the confidentiality arrangements in place between the participating parties. The participation builds on the long-standing collaboration between the EMA, the US FDA and HC under these confidentiality arrangements.

The EMA, the US FDA and HC agree that observers from regulatory authorities of other regions may participate in collaboration activities subject to appropriate confidentiality arrangements being in place.

6. Reaching Agreement

Not applicable

7. Workplan and Reporting

The Cluster does not have a workplan per se as its main goal is to facilitate information and learnings sharing on the use of RWD/Big Data for regulatory purposes.

However, the three Agencies have developed a rolling list of topics which can be updated as needed. The Agency chairing the meeting chooses the topic to be discussed based on this list: Master list- meetings, docs, and participants.xlsx (see tabulation "*Rolling list of topics*").