



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Outcome of the public consultation on the Data Quality Framework for EU Medicines Regulation: application to Real-World Data

Summary report of comments received during the public consultation and next steps

1. Background and consultation

The [European Medicines Regulatory Network \(EMRN\) Data Quality Framework \(DQF\) for EU Medicines regulation](#) was first published in 2022, and provides general considerations on data quality that are relevant for regulatory decision-making. The 'Data Quality Framework for EU Medicines Regulation application to Real-World Data', hereafter referred to as RW-DQF, focuses on data quality underpinning real-world evidence generation encountered in medicines regulation.

The RW-DQF underwent public consultation on 29 November 2024, and various stakeholder groups were invited to provide their comments until 28 February 2025. The consultation attracted a wide range of comments from multiple types of stakeholders, including academia, industry, regulators, contract research organisations, and data holders, demonstrating the wide relevance of the framework. Comments covered both editorial and content improvements related to definitions, clarity, scope, and feasibility.

Overall, respondents expressed strong support for the initiative and its aim to strengthen data quality assurance for real-world data (RWD), while seeking:

- Greater clarity and consistency in terminology
- More precise definitions (e.g., RWD vs RWE, primary vs secondary use)
- Practical guidance and threshold requirements for data quality metric assessment
- Feasible, proportionate expectations for data providers and sponsors

2. Contributors

In total, there were 25 unique respondents from the main EMA stakeholder groups: industry, academia, regulatory authorities, healthcare practitioners, and patients and consumers. The distribution of the respondents by EMA stakeholder group is illustrated in the chart below.

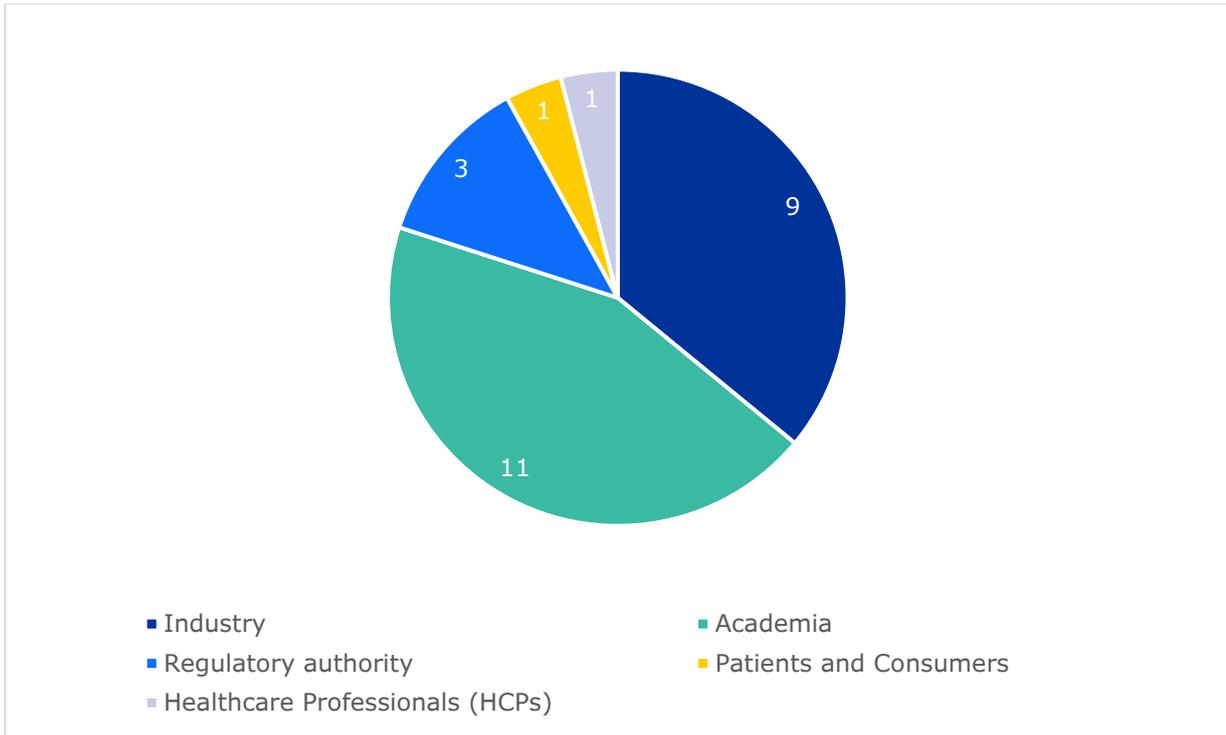
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3. Summary of the main points raised during the consultation

The public consultation of the RW-DQF yielded over 600 comments and suggestions from stakeholders. All feedback received during the consultation has been carefully analysed individually.

Overall, respondents expressed support for the initiative, highlighting its timeliness for EU medicines regulation and its added value in assessing and ensuring the quality of RWD used in regulatory decision-making.

Across the consultation, several recurring themes emerged. Many contributors requested clearer and more consistent terminology, particularly regarding definitions of RWD vs real-world evidence, primary vs secondary use, and key quality concepts such as reliability, extensiveness, and fitness-for-use.

Stakeholders also emphasised the need for practical guidance, including clearer expectations for data holders and sponsors, improved descriptions of roles and responsibilities, and realistic approaches that reflect the operational constraints of accessing and evaluating RWD. Several comments concerned the feasibility of implementing certain requirements, particularly where sponsors depend on data holders for access, internal processes, and documentation.

Stakeholders also provided detailed feedback on metadata, vocabularies, and catalogue requirements. Many suggestions aimed to enhance clarity, interoperability, and flexibility, while reducing unnecessary burden. Several proposals, such as glossary additions, rewording for clarity, and restructuring of tables and sections, were incorporated into the revised document. Other suggestions, particularly those related to real-world evidence methodologies that do not directly pertain to RWD quality but instead to evidence generation, were considered out of scope for this document. Novel data types (e.g., wearables, patient-generated data) were likewise noted as out of scope.

Finally, while some commenters stressed the importance of maintaining flexibility in implementation given the diversity of data sources and use cases, others requested prescriptive thresholds. These comments were carefully considered, and the updated version of the document clarifies that the RW-

DQF is intended as a best practice framework, promoting transparency and contextual fitness-for-use rather than imposing rigid requirements.

Overall, the consultation provided valuable insights that have resulted in an improved framework with clearer definitions, strengthened explanations, and better structure, substantially enhancing the usability and applicability of the RW-DQF.

4. Next steps

The feedback received has materially shaped revisions to the RW-DQF. The updated RW-DQF had been adopted by the Methodology Working Party (MWP), the Network Data Steering Group (NDSG) and the Committee for Medicinal Products for Human Use (CHMP) and was published on the EMA website in March 2026.