EMA
EUROPEAN MEDICINES AGENCY

Focus group

on use of RWD and generation of RWE

Update – July 2025

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Reminder – Overall objective

Share knowledge and experience

with use of RWD and generation of RWE

to advance integration of relevant and reliable RWE

in regulatory decision making

And it works well!

2 meetings took place in 2025

March

Feasibility assessment

- What are the core elements that should be addressed during an initial feasibility assessment?
- What is the role of the PICO framework to ensure a systematic approach for the feasibility assessment?
- How might the target trial framework be used in feasibility assessments?
- How could a milestone approach be applied to feasibility assessments, given that the assessment is likely to be iterative?
- Which principles should be applied for conducting feasibility assessments (e.g. Define clear decision criteria for what is considered "feasible" / "infeasible")?
- How does the feasibility assessment relate to the data quality dimension "relevance"?

May

Leveraging the HMA-EMA Catalogues of real-world data sources and studies for evidence generation by the EMA and the industry

- Share experience on how the RWD Catalogue is currently used by industry / Reflect on how the Catalogue could be more widely utilised within industry
- Share suggestions on how the Catalogue could be improved to better support RWD discoverability and RWE assessment
- Share industry's feedback on the available supporting material (e.g., metadata list, Good Practice Guide, etc.)
- With regards to expanding the Catalogue of RWD sources, share feedback on industry's preference on volume (number of data sources registered) vs depth (completeness of available records in the Catalogue)

Trialogue between Registry holders /Regulator /Industry

- What are the expectations?
- How could we put this idea in action?

Next meeting on Sept. 23

Role of RWE across the product lifecycle

- Use cases in early and late stages
- How can RWE be used for pre-authorization (e.g., external controls) and post-authorization (effectiveness, safety e.g., PASS, label expansion) purposes
- Role of causal inference methods

Data quality and DQF in study planning

How should the dimensions proposed by the EMA inform feasibility and protocol development?

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Thank you

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