Stakeholders feedback from pre-meeting survey: Session 1 Feedback process overview

Technical workshop on real-world metadata for regulatory purposes
Virtual meeting, April 12, 2021

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Survey questions

1. Are there metadata variables required for characterising real-world data sources and the regulatory use cases they will support that you would like to see included in the catalogue, which are not included in the current preliminary list? If so, can you provide your suggestion(s) with a description of the meaning(s) of the variable(s)?
2. Please share any questions or comments relating to the preliminary definitions, structure of the proof-of-concept catalogue and its organisation into six key domains: institution, data source, data bank, common data model, network, study.
3. Please share any comments or suggestions on the preliminary options for the sustainability and process for metadata collection.

Survey questions (continued)

4. Please share any questions or comments regarding the functionality of the envisioned catalogue (what you would want to see from the perspective of an individual browsing the catalogue, or as an individual who may enter metadata into the catalogue).
5. Please share any other questions or comments you may have.

Responses by sector

- Agencies: EU 7, ex EU 1 (FDA)
- ENCePP: 3 (including a network)
- BD4BO/EHDEN/OHDSI: 2
- CRO: 1
- HCP network: 1
- EFPIA and other pharma: 7

Feedback addressed

Some feedback will be addressed through the presentations in the sessions, selected feedback will be addressed in the discussion of each the sessions

- Questions 1-2 (metadata and domains) – Session 2
- Question 3 (sustainability and data collection) – Session 3
- Question 4 (tool) – Session 4
- Question 5 (other) – as applicable in above session

All feedback will support the work during the remaining activities of the project.

Thank you!

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