



## Stakeholders feedback from pre-meeting survey: Session 4 Proof-of Concept catalogue tool



---

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

**Presented by Dr. Morris Swertz**  
University Medical Center Groningen



## Survey question 4

Question 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).

# Feedback

- The work done to put together this preliminary catalogue is remarkable.
- None / not at present: 7

## On: Visualisation/presentation

- ✓ The first level of meta-data should in a **quick glance allow the researcher to determine if the data source might at all be of interest** to the planned analysis i.e. ensuring the tool is "easy-to-use"
- ✓ A way to provide **recommendations or suggestion on additional variables** to be collected or clarified.
- ✓ A user would like to be able to **compare databases and visualize the differences** and be able to assess the usefulness of a data source for a specific question at an early stage.
- ✓ **Accessibilities conditions should be clearly** stated both when you browse the catalogue and when you enter metadata into the catalogue.
- ✓ A data dictionary **with statistical variables and comparability** across various fields are useful, inc the duration of the available data, time periods, patient counts

## On: Search & filter capabilities

- ✓ **Classic browsing** functionalities including ways (key words, menu, ...) to sort and to search differently, to edit the data partially and fully (in different formats)...
- ✓ Search data sources/banks **filter by important characteristics** (e.g. Country, Third Party access, Lag time) and availability of important information, specialist prescribing; therapeutic area, study types (PASS studies, Oncology/vaccines; specific outcomes (drawn from EU PAS register)
- ✓ **Link between the different set of metadata searchable** in order to identify the right data source for a study on an easy and trusted way, on the model of the search page for the ENCePP resource database (which can be improved).
- ✓ Search function supports **use of logical operators**, e.g. to specify multiple mandatory requirements.

## On: Data stewardship

- ✓ Information should be **provided by general users** of the catalogue (e.g. data owners, data users for non-EMA observational studies etc); Draw study-level information from EUPAS register
- ✓ A **pre-specified list** of institutions might help the user entering the metadata. Very valuable if more information can be made available on the actual content of the data source. As a data partner the process needs to be **mainly automated** to provide characteristics on the data itself.
- ✓ Cross link across tables to **avoid data entry repetition**; We recommend revising the structure of the underlying datamodel and apply agreed best practices with respect to model normalization

***Indeed, the data model of the catalogue prototype is normalized, and has methods for automated data ingest***

## On: FAIRness

- ✓ The catalogue should allow for the situation that the *source of truth for those is published elsewhere*. For example, allow for **linking of external PURLs such as DOIs and ORCIDs**. Institutions to the list should avoid name redundancies.
- ✓ Catalogue in a **shared standard format** so that a different tool (user interface) would be able to process it and navigate through it (decouple development of (meta)data standards and implementation of the catalogue; contribute to community standards (e.g. DCMI / DCAT, bioschemas.org, FDO..)).
- ✓ For all **vocabularies, versions** should be captured, e.g. ICD-10 has several versions and national modifications. Also CDMs versions should be tracked

***Indeed, we propose all entities have PURL (DOI/handle); work with other tool developers on metadata standard (as separate result); and we add mappings to standards (DCAT, bioschemas etc)***

# Thank you!

---

**For any question on this presentation, please contact:** [Malgorzata.Durka-Grabowska@ema.europa.eu](mailto:Malgorzata.Durka-Grabowska@ema.europa.eu)

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000