HMA EMA BDSG Recommendation 3: Enable data discoverability. Identify key meta-data for regulatory decision-making on the choice of data source, strengthen the current ENCePP resources database to signpost to the most appropriate data, and promote the use of the FAIR principles (Findable, Accessible, Interoperable and Reusable).

Achievements:
- Creation of the 1st list of RW Metadata for regulatory purpose
  - Informed by consultation with stakeholders (dedicated workshop, surveys, presentations)
  - Including definitions, a 1st list of criteria for inclusion of databases in the RW metadata catalogue (=data source catalogue) and processes
- Deliver the proof-of-concept RW metadata catalogue

Future highlights:
- Publication of the agreed RW Metadata for regulatory purpose (v.1.0), together with its good practice guide
- Public launch of the RW metadata catalogue and start populating the agreed RW metadata
- Launch of enhanced catalogue for observational studies
- Future proof current activities with other initiatives including TEHDAS

Benefits:
- enhanced **transparency** with regards to observational studies in the regulatory context and increased quality of these,
- enhanced **discoverability** of studies and data sources
- support to **judge the evidentiary value of observational studies and real-world data sources** when used in the regulatory context

Note: Key links with DARWIN EU and Network processes

How to engage with the ongoing activities:
- Participate in stakeholder consultation (i.e. workshop, webinar, survey)
  - ongoing survey on metadata and observational studies for industry (January)
- Follow announcements on EMA website

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