

PPO2: Assessing relevance and provenance of real-world data



Relevant highlights from the (draft) FDA guidance*:

Ensure data reliability:

- *Data accuracy*
- *Completeness*
- *Provenance***
- *Traceability*

Ensure data relevance by availability of:

- *Exposure*
- *Outcomes*
- *Covariates*

*Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products, Draft FDA Guidance, September 2021

** A record trail that accounts for the origin of a piece of data (in a database, document or repository). The documentation of where a piece of data comes from and the processes and methodology by which it was produced.

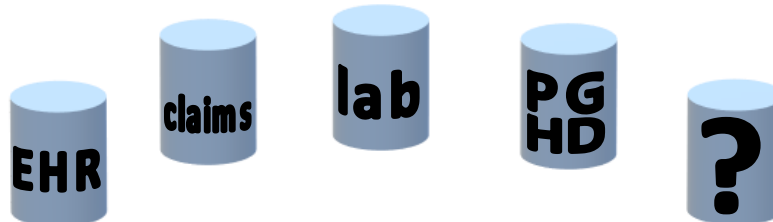


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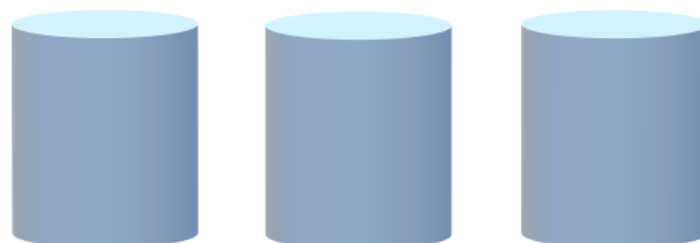
Source data



Data warehouse



Analysis Datasets



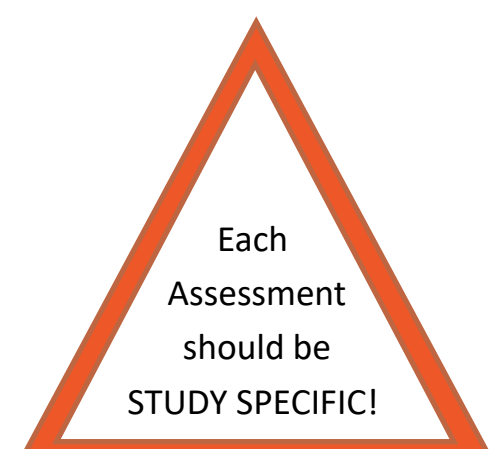
Selected, Standardized, Deidentified

Necessary steps in real-world data source selection:

- Study Design outline with relevant stakeholders
- Vendor selection & data quality assessments
- Alignment with regulators
- Protocol & Analysis plan
- Study Analysis & Reporting

How to assess the Vendor?

- RFI
 - *Relevance*
 - *Reliability*
 - *Governance*
- Audit
- Data Feasibility, bias and Integrity test



How to assess relevance?

- All selection criteria available?
 - *Indication*
 - *Medication*
- Representative coverage of population?
 - *Enough patients?*
 - *No bias in population of interest?*
- Main variables of interest available?
 - *Index dates*
 - *Outcome variables*
- sufficient coverage of co-variables?
 - *% missing not too high?*
 - *Observation periods sufficient?*
- No bias

How to assess provenance?

- Who collected/entered the data?
 - *What was the real-world data setting?*
 - *Applicable real-world practice guidelines*
- How is the data collected?
 - *What information system?*
 - *What options for entry?*
 - *Guidelines for entering data?*
- Is the source collection metadata information available??
- Can we use metadata information to test for variation in:
 - *Data accuracy*
 - *Completeness*
- Is the provenance information FAIR?



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