Drafting a data quality framework structure

"Data Quality Framework for medicines regulation" workshop 7 April 2022
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Data quality framework – proposed drafting content

I. Overarching principles governing over good data quality for medicine regulation:

- ✓ Define a robust and consistent terminology related to data quality, harmonised with other similar initiatives where applicable and appropriate (e.g.: TEHDAS)
- ✓ Establish data quality dimensions and/or data quality maturity models to be used within the regulatory process, to be adapted as required by each regulatory purpose and type of dataset
- ✓ Describe the procedures to follow
- ✓ Communication guidelines on clarity and transparency principles for data quality issues;

II. Deep-dive in a series of applied use-cases and examples for regulatory purposes – starting with Real-World Data

- ✓ Focus the general guiding principles defined previously in drafting specific data quality dimensions
- ✓ Build incrementally on further use cases within the identified priorities of the regulatory network

Quality Control Systems - Dimensions

We are creating a **formal structure** to **qualify** the use of data as **fit** for **purpose**.

1. **Scope:** What data?
2. **Purpose:** Fitness against what needs, which are defined how?
3. **Audience:** Who has which responsibilities?
4. **Evidence:** What are the quality metrics, and how are they documented?

1. Scope – which data should be prioritised?

- Secondary use data
- Data generation not under control
  - ➢ Focus on quality detection and documentation
- Longitudinal data
- Clinical data of patients

Points for discussion

- Primary purpose data
- Snapshot data
- Social, biological, process data

2. Purpose – fit for what?

- Regulatory decision making
- Understanding the Real World
- Defined use cases:
  - Utilisation of medicines
  - Estimation of benefit/risk
- Supporting relative rather than absolute evidence
- Supporting probabilistic evidence

3. Audience – who is responsible for quality?

- Data generator
- As close to the primary generation process as possible

Points for discussion

- Role of sponsor, investigator, researcher?
- Separation of quality control/assurance from evidence generation
- Soft criteria like “experience”?

4. Evidence – which metrics?

- Comprehensive rather than spot check
- Maturity levels
- Measures/estimates
  - Sensitivity, specificity, PPV, PNV
  - Timeliness
  - Consistency
  - Uniqueness
  - Plausibility
  - Conformance with standard

Points for discussion

- How many checks is enough?
- Should source record validation be mandated?

4. Evidence – documented how?

- Standardised
  - Measures/tests/checks
  - Documentation
  - Auditability
- Supported by standard organisation
- Framework versions over time

Points for discussion

- Are SOPs of “best practices” good enough?
- Do we need independent certification?

1. All points for discussion

Data

- No Primary purpose data
- No Snapshot data
- No Social, biological, process data

Purpose

- Supporting relative rather than absolute evidence
- Supporting probabilistic evidence

Audience

- Role of sponsor, investigator, researcher
- Separation of QA/QC from evidence generation
- Soft criteria like “experience”

Metrics

- How many checks?
- Source record validation
- SOPs of “best practices” good?
- Independent certification

Input required!

For any question on this presentation, please contact: DataQualityFramework@ema.europa.eu
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