EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 1: Data Quality Framework published document

EU Data Quality Framework and development of the RWD deep-dive

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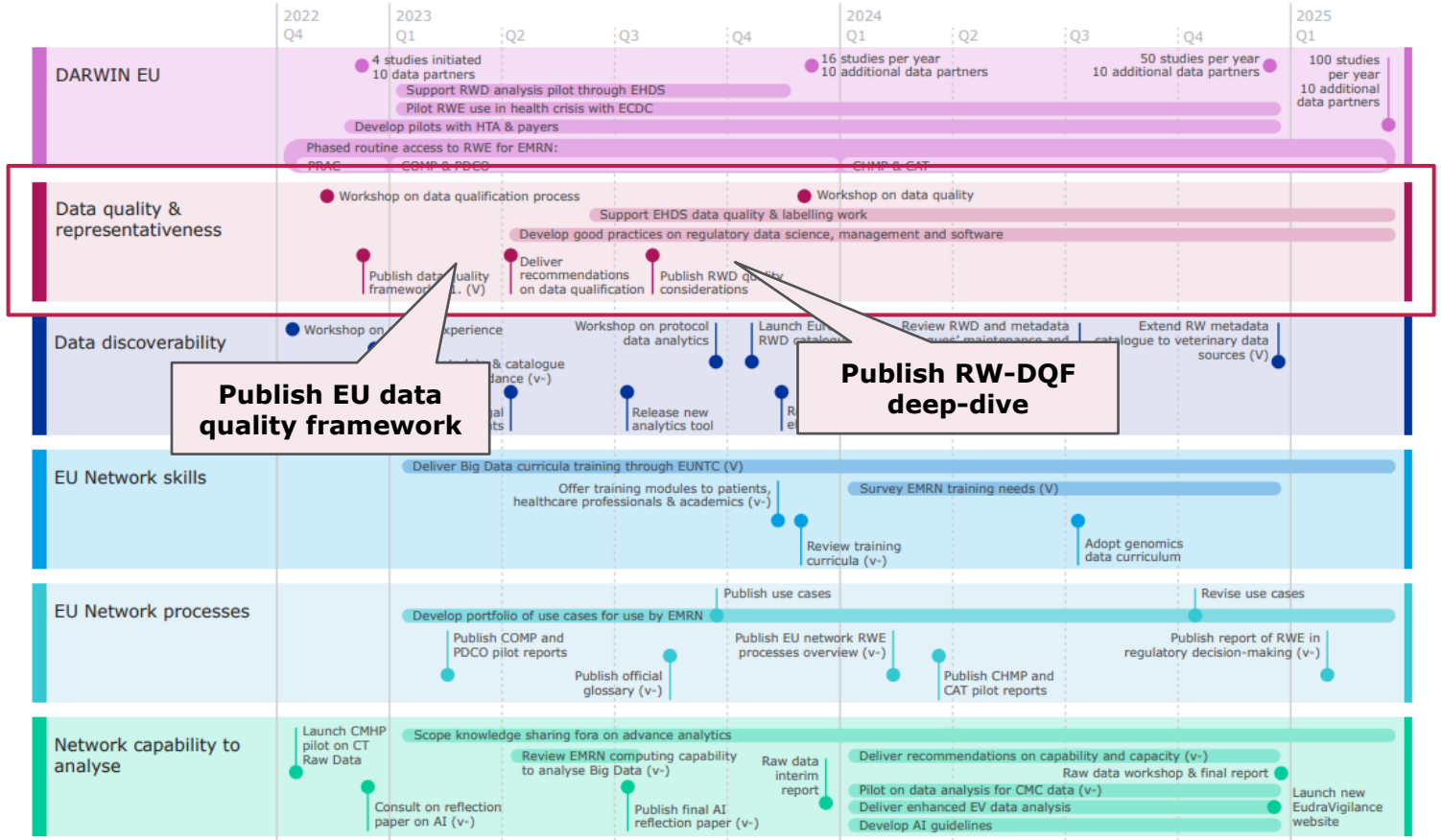
Multi-stakeholder workshop on RWD quality and experience in use of RWE for regulatory decision-making – 26 06 2023

Topics outline

1. Background and scope
2. EU-DQF : timeline and next steps
3. Concepts walkthrough
4. Public consultation comments
5. Real-World application of the DQF

1 Data Quality Framework published document

Joint HMA-EMA BDSG work plan 2022-2025



2 Data Quality Framework published document

EU Data Quality Framework (EU DQF) – background and scope

- The drafting work started under BDSG (Big Data Steering Group) recommendation (HMA-EMA joint working group) on **developing a Data Quality Framework**
- After the **set-up of the MWP** (Methodological Woking Party) **of the CHMP**, the sponsorship of this deliverable has been co-shared between the two groups
- The document has been developed in close **collaboration with TEHDAS Joint Action** (Towards the European Health Data Space)
- EU DQF is describing concepts **applicable to all data sources used in medicine regulation** across EU regulatory network
- **Further deep-dives** (= applications, specific use cases) will be developed in the following iterations
- **Real-World Data deep-dive** (RW-DQF) is the first such extension

EU Data Quality framework (update)

2022:

January – February: research and documentation on existing data quality frameworks

April: Data Quality Workshop

October: EU Data Quality Framework for medicine regulation published

November: written public consultation

2023:

January – February: Processing comments following the public consultation

Re-drafting of the DQF according to feedback received + internal review

July: Expected publication of the re-drafted version

the EU DQF, we partition data quality aspects ("determinants") in three different categories

What pertains to quality that cannot be assessed or measured without a defined research question and method

What quality aspects can be assessed or stated about a dataset, independently from the way this was generated

What contributes to the quality of a dataset, that is not part of a dataset itself

Main dimensions of quality as outlined in the general Data Quality framework

Is the data correct?

Is it representing what is meant to represent?

RELIABILITY

How much data is there?

EXTENSIVENESS

Can data be analysed as a whole?

COHERENCE

Is data available at the right time?

TIMELINESS

Is this the kind of data I need?

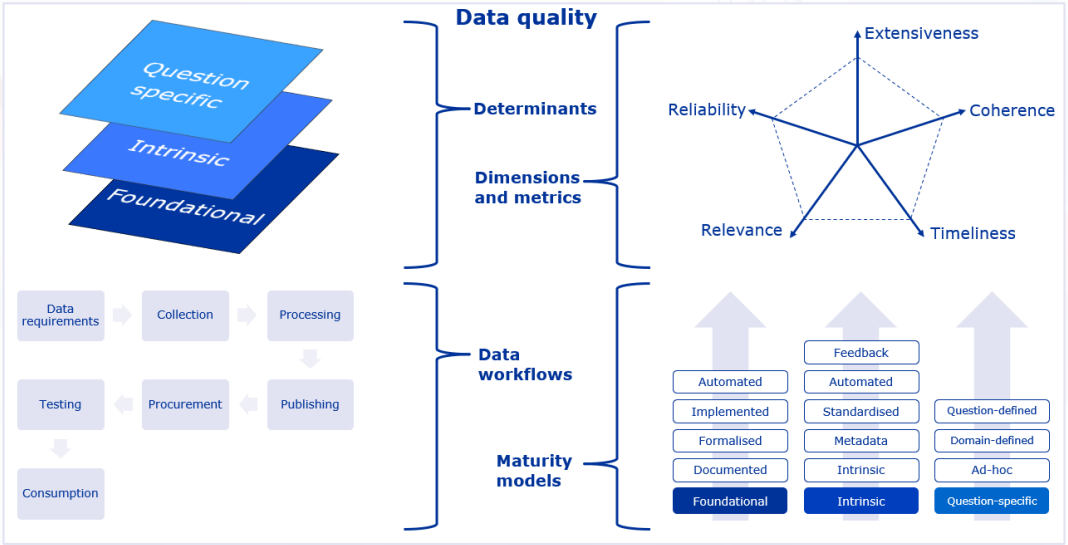
RELEVANCE*

*Relevance should be considered as the suitability to a research question

Fundamental concepts described

Data Quality can be characterised using *different concepts*

- **Determinants**
- **Dimensions and metrics**
- **Data workflows**
- **Maturity models**



Public consultation comments – topics and examples

~ 500 comments from various categories of stakeholders (industry, learned societies, academia, software vendors, EU and international regulators)

Comments were addressed, document re-drafted and due to be republished in July along with a **summary of comments and their resolution**; examples of comments below

Comments on scope of the DQF:

- Address applicability to non-EU data sources and alignment with other DQFs

Comments around deep-dive in other use-cases

- Guidance or tools to help implement the maturity model for different regulatory use cases would be beneficial (e.g., checklists, score cards, details about required documentation for quality reports)

Specific technical comments

- Coherence and intrinsic determinant: granularity of the data might not impact the validity for studies in some situations - allow for flexibility in DQ indicators

Public consultation comments – Real-World data specific examples

- **Implications for data holders** and data submitters should be well articulated
- RWD use is also increasing to **directly support regulatory submissions**, for example, using external control arms for label extension. Such use cases require careful consideration of data quality issues.
- **Opportunities for international convergence** across RWE and RWD frameworks should be considered
- The **difference between rare and common diseases** needs to be addressed
- The **heterogeneity of EU databases** needs to be considered when describing extensiveness
- In relation with some research questions, it might be sufficient to **request descriptive documentation** on data reliability and relevance, as opposed to validation/verification

Developing RW - Data Quality Framework

- **Initial exploratory phase** and a very early draft has been produced
- **Input from this workshop** will be included, followed by some rounds of consultation with the regulatory network, before proposing a draft for public consultation

Approximate timeline February-November 2023 – DQF RWD chapter