EU Data Quality Framework for medicines regulation – launch and collaboration

3rd Big Data Stakeholder Forum – 1 December 2022

Presented by Ana Cochino
Healthcare Data Workstream, Data Analytics and Methods Task Force, EMA

Outline

1. Data quality framework objectives & milestones
2. Steps in drafting the Data Quality Framework
3. Overview of the Data Quality Framework & main concepts around data quality
4. Comments from the public consultation
5. What's next

Data Quality Framework – objectives

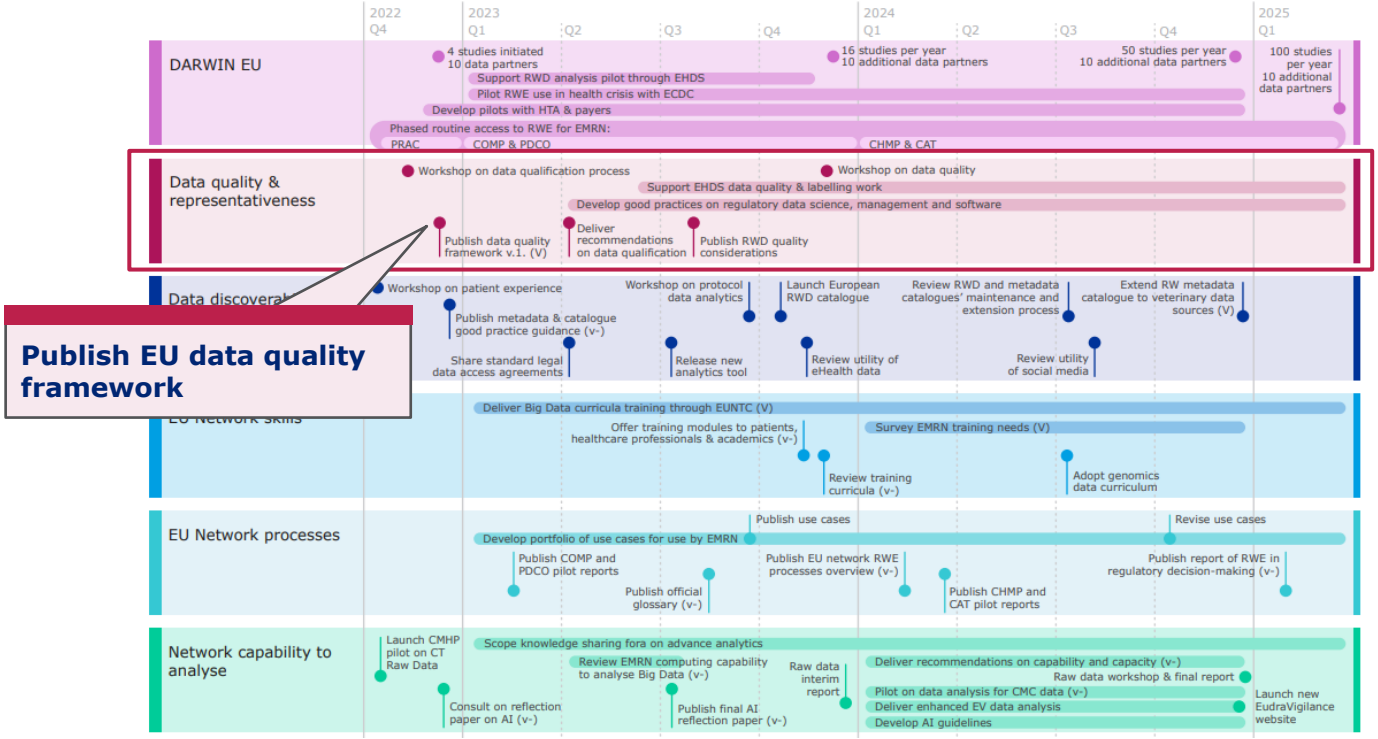
Objectives

- Improve **consistency** in the evaluation of the quality of the data used by regulators
- Enable the development of a **standardised approach** for data quality across all data sources
- Facilitate a more **systematic use of data** for regulatory decision-making
- Support the **trust of stakeholders** in the data that underpinned regulatory decisions

First draft of the Data Quality Framework

- Provides **general considerations** that can be applied to a wide range of data sources for the purpose of characterising and assessing data quality for decision making
- Outlines how to **measure data quality** in different scenarios where real-world data need to be used for regulatory decision-making
- Intended to serve as an **overarching framework** from which more focused data quality recommendations can be derived for specific regulatory applications
- Produced in a **collaborative process** by EMA, HMA and Towards the European Health Data Space (TEHDAS) Joint Action in consultation with a **wide range of stakeholders**

Workplan – Data Quality milestones



Publish EU data quality framework

Steps in drafting the Data Quality Framework

The following activities have been carried out in preparation of the current Data Quality Framework draft

A revision of **existing Data Quality Frameworks** (landscape analysis):

- Drafting from January to April approved by the revision committee
- Used as a **starting point** for further drafting of the data quality framework

A **dedicated Data Quality workshop** with external stakeholders – April 2022

Agreement on a **table of contents** for drafting

Dedicated **sessions with topic experts** to further refine/get input/familiarise with content

Dedicated **sessions with TEHDAS** to align on principles/data maturity model proposed

TEHDAS joint action advances the cross-border secondary use of health data in Europe to improve public health.

TEHDAS Towards European Health Data Space

Data Quality Framework document - overview

Purpose

The Data Quality Framework provides a set of definitions, principles and guidelines that can coherently be applied to a **wide range of data sources** to support **regulatory decision making**

Content

1. Provides a **general framework** that is meant to be extensible to a wide range of data types and processes:
   - Defines **terminology** and general principles
   - Describes a range of **metrics** and **dimensions**
   - Defines **data maturity models** for regulatory decision
2. In a next step aims to address specific use cases
   - Deep-dive on use of Real-World Data for medicine regulation
   - ……

Final goal

Establish an **EU framework for data quality and representativeness**. Develop guidelines, a strengthened process for **data qualification** through scientific advice, and promote across Member States the uptake of electronic health records, registries, genomics data, and secure **data availability**

How data quality is characterised

Data quality is assessed from the point of view of ***fitness for purpose*** for users' needs

It is the sum of several features of data, including its **representation** as well as its **correspondence to reality**

For the purpose of this document, data quality is described with the goal of supporting **regulatory decision-making**

5 dimensions have been described to define data quality

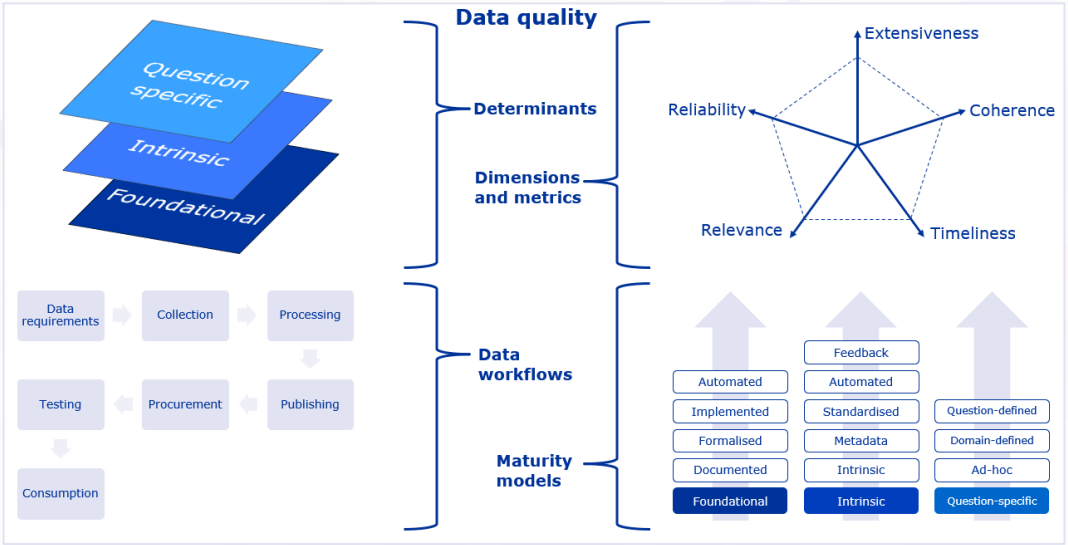
Reliability **Coherence** **Extensiveness**

Relevance **Timeliness**

1. Fundamental concepts described

Data Quality can be characterised using ***different concepts***

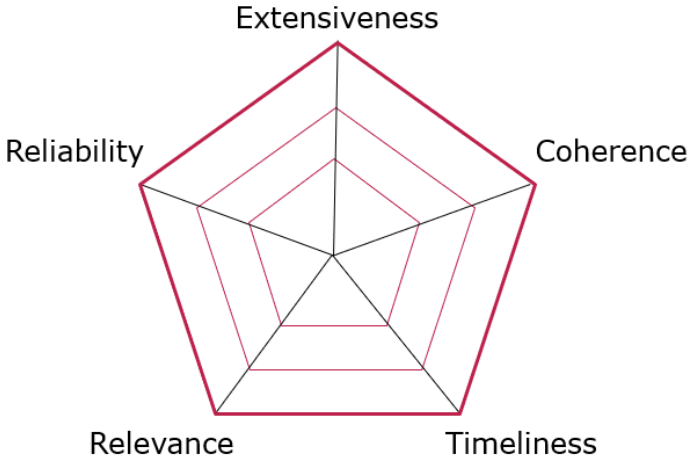
- **Determinants**
- **Dimensions and metrics**
- **Data workflows**
- **Maturity models**



2. Dimensions and metrics

Dimensions can be classified in five main categories

- The quality of data is the sum of several features of data, including its representation as well as its **correspondence to reality**
- Useful to categorise such features in **dimensions,** that is a set features whose measure reveals independent aspects of DQ
- Different dimensions answer different **distinct DQ questions**



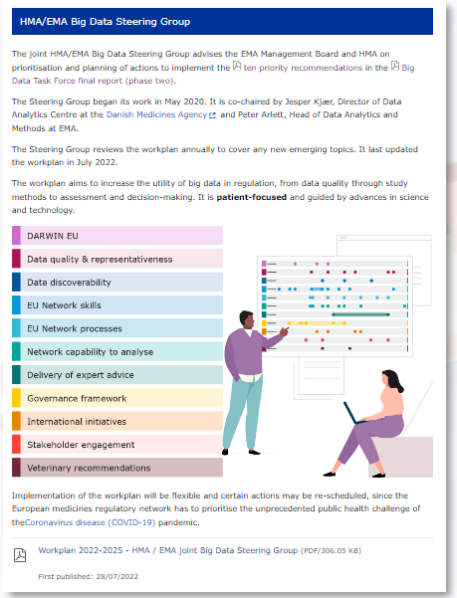
3. Maturity models

Levels of maturity

Foundational	Intrinsic	Question-specific
01 Documented	01 Intrinsic	01 Ad hoc
02 Formalised	02 Metadata	02 Domain-specific
03 Implemented	03 Standardised	03 Question-specific
04 Automated	04 Automated	
	05 Feedback	

Some comments from the public consultation

Thanks to all who contributed!



HMA/EMA Big Data Steering Group

The joint HMA/EMA Big Data Steering Group advises the EMA Management Board and HMA on prioritisation and planning of actions to implement the ten priority recommendations in the Big Data Task Force final report (phase two).

The Steering Group began its work in May 2020. It is co-chaired by Jesper Kjær, Director of Data Analytics Centre at the Danish Medicines Agency and Peter Arlett, Head of Data Analytics and Methods at EMA.

The Steering Group reviews the workplan annually to cover any new emerging topics. It last updated the workplan in July 2022.

The workplan aims to increase the utility of big data in regulation, from data quality through study methods to assessment and decision-making. It is **patient-focused** and guided by advances in science and technology.

- DARWIN EU
- Data quality & representativeness
- Data discoverability
- EU Network skills
- EU Network processes
- Network capability to analyse
- Delivery of expert advice
- Governance framework
- International initiatives
- Stakeholder engagement
- Veterinary recommendations

Implementation of the workplan will be flexible and certain actions may be re-scheduled, since the European medicines regulatory network has to prioritise the unprecedented public health challenge of theCoronavirus disease (COVID-19) pandemic.

Workplan 2022-2025 - HMA / EMA joint Big Data Steering Group (PDF/306.05 KB)

First published: 28/07/2022

We received contributions from regulatory network, data holders, industry, medical associations, etc.

Comments were mainly related to:

Scope and interoperability

- Opportunities for international collaboration on RWE regulatory frameworks (namely ICMRA)
- Scope and applicability of the DQF (which type of data will be assessed)

Terminology and definition

- Harmonization on terminologies across different DQ frameworks
- Action items on validation and verification

Maturity models

- Consistency across regulations such as ACT EU, GDPR, etc.
- Better definition of maturity models
- Privacy protection

What's next – after the public consultation

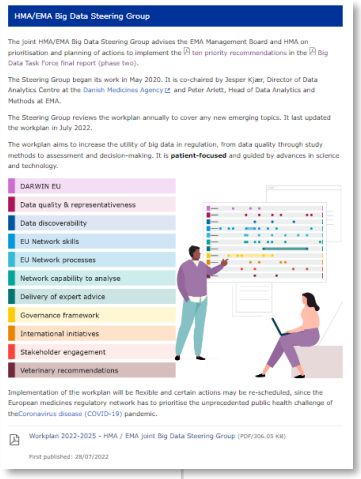
Next steps

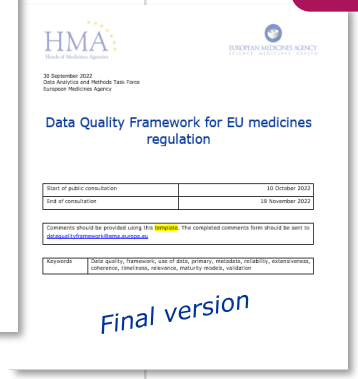
6 weeks public consultation (ended 18 Nov)

Implementation of comments and input from stakeholders

Final 1st version of the Data Quality Framework

RWD Quality considerations (TBD)





AUG | SEP | OCT | NOV | DEC | JAN

2022 | 2023

Thank you for listening

Email: dataqualityframework@ema.europa.eu

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union