



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Data Quality Framework (1st draft)

Multi-stakeholder webinar to support the consultation on the draft Data Quality Framework for EU medicines regulation

Welcome, introduction and opening remarks

Peter Arlett

Co-chair Big Data Steering Group, EMA





- The main objectives of this webinar are:
 - Inform the stakeholders about the public consultation on the draft Data Quality Framework.
 - Provide a walkthrough of the Data Quality Framework document and process of developing it.
 - Collect initial feedback and answer questions in a dedicated Q&A session via Slido.



- On the 10 October 2022, the Agency launched the public consultation for the first draft of the “Data Quality Framework for EU medicines regulation” . The consultation will close on the **18 November**
- Comments should be submitted to dataqualityframework@ema.europa.eu using the specific template linked at the beginning of the Data quality framework document itself
- The Agency will collect all comments received and will review the data quality framework accordingly.
- The aim is to publish the final first version of the data quality framework in Q1 2023



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Data Quality Framework (1st draft)

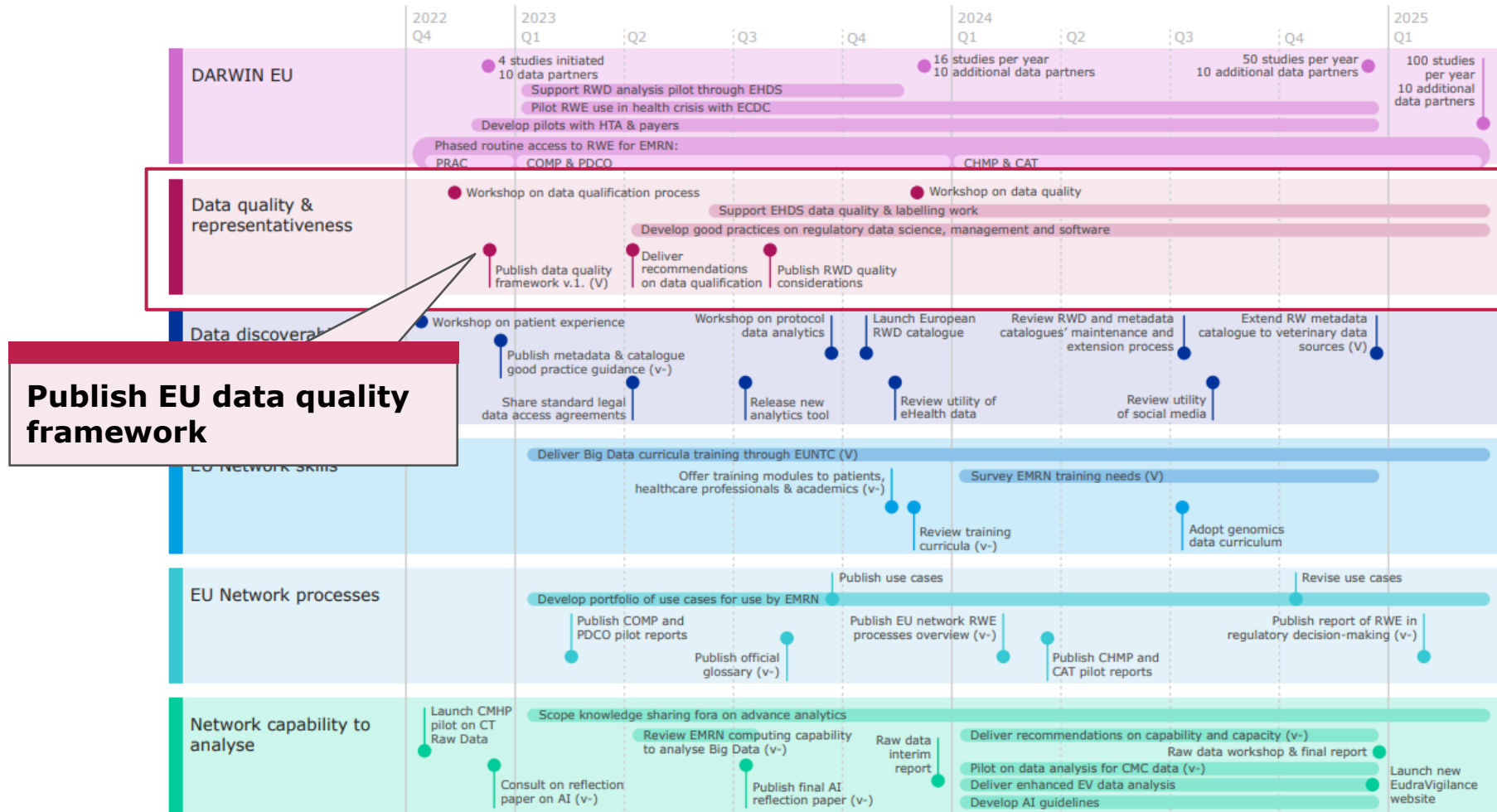
Multi-stakeholder webinar to support the consultation on the draft Data Quality Framework for EU medicines regulation

Presented by Ana Cochino, 18th October

Healthcare Data Workstream, Data Analytics and Methods Task Force, EMA



Joint HMA-EMA BDSG work plan 2022-2025



Publish EU data quality framework

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**



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**



Public consultation
Data Quality Framework
Deadline: 18 November 2022

EMA
EUROPEAN MEDICINES AGENCY

The banner features an illustration of a person sitting on a laptop, a large computer monitor displaying a data visualization with a magnifying glass over it, and another person standing next to the monitor. The EMA logo is in the bottom left corner.

 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.



Scope



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
 -

Next steps



6 weeks public consultation
(start 10 Oct – ends 18 Nov)

Implementation of
comments and input
from stakeholders



Final 1st version of
the Data Quality
Framework

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

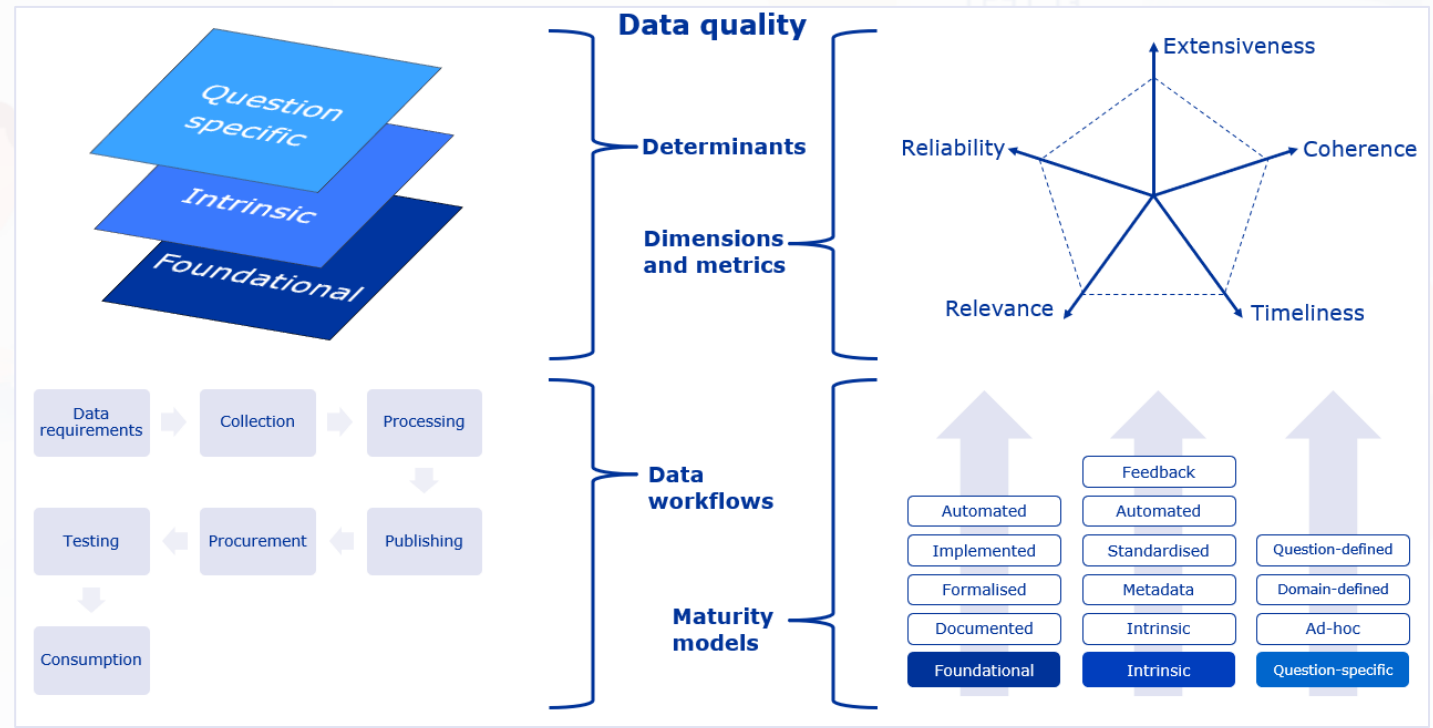
Extensiveness

Relevance

Timeliness

Data Quality can be characterised using *different concepts*

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



1) Open the Data Quality Framework draft from the Big Data website

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 10 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 the **Coronavirus disease (COVID-19)** pandemic.

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

First published: 28/07/2022

2) Click the link template to find the comments file

HMA
Heads of Medicines Agencies

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30 September 2022
Data Analytics and Methods Task Force
European Medicines Agency

Data Quality Framework for EU medicines regulation

Start of public consultation	10 October 2022
End of consultation	18 November 2022

Comments should be provided using this **template**. The completed comments form should be sent to dqframework@ema.europa.eu

Keywords	Data quality, framework coherence, timeliness, n
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Template

3) Add your comments with the relevant details and send back the template to:

DataQualityFramework@ema.europa.eu

<Date of submission>

Submission of comments on "Data Quality Framework for EU medicines regulation" (EMA/798293/2022)

Comments from:

Name of organisation or individual	
(Optional) Email address to be contacted by EMA for further clarification	

Disclaimer:

Please fill in the optional email address field and mark this checkbox if you consent to be contacted by the European Medicines Agency for the purpose of obtaining further clarifications on your comments.

For further information regarding the protection of your personal data in relation to the processing of this questionnaire, please find annexed a data protection statement.

Please note that these comments, the identity, and the affiliation of the sender may be published unless a specific objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).



Public consultation

Data Quality Framework

Deadline: 18 November 2022





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Questions and Answers session

Jesper Kjær

Co-chair Big Data Steering Group, DKMA

Webinar on Data Quality Framework
18 October 2022 15.00 – 16.00

