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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

Introduction to the webinar

- 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.

Introduction to the webinar

- 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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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

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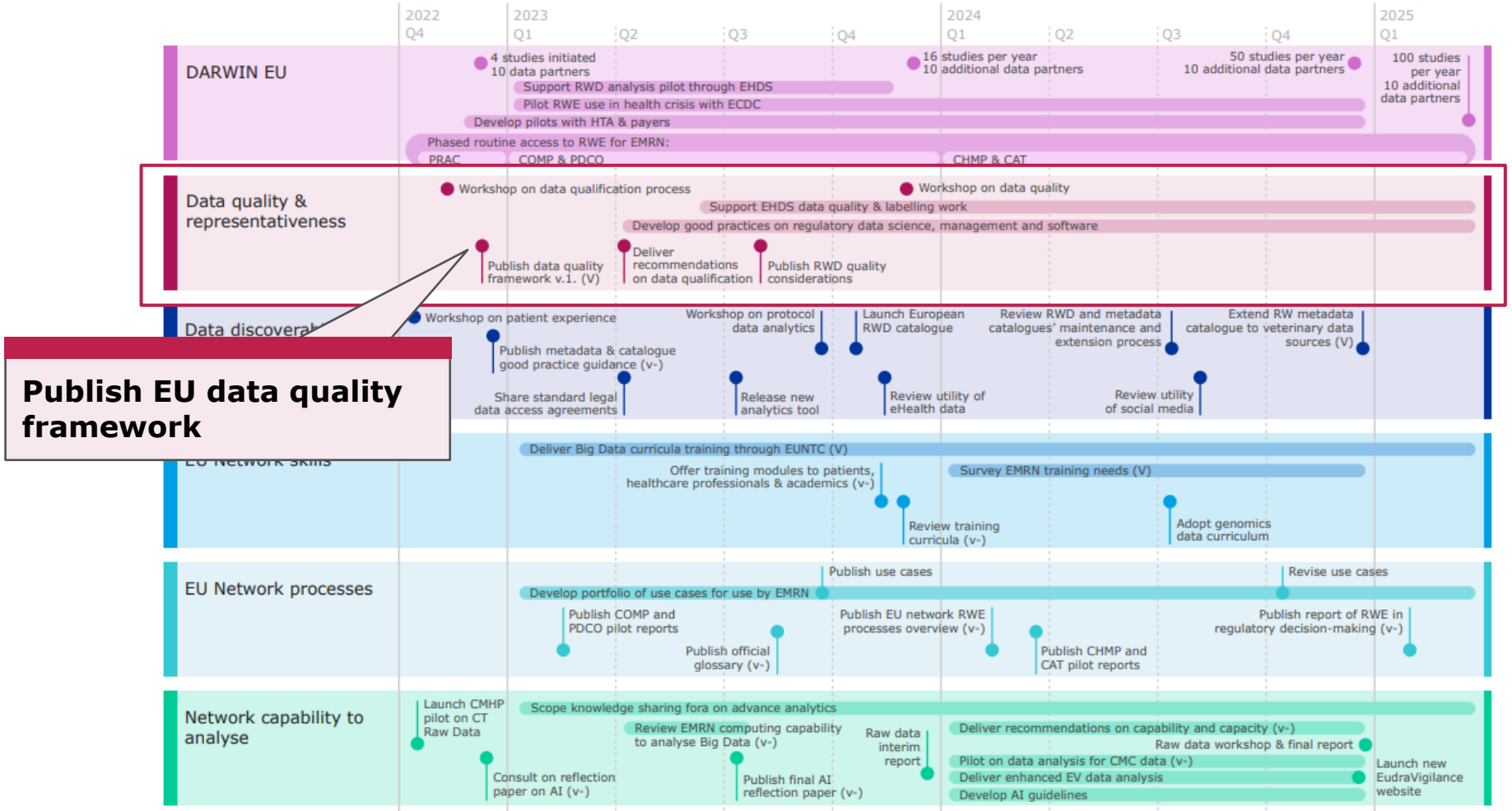

Publish EU data quality framework

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**

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**

Steps in drafting the Data Quality Framework

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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 - overview

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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

How is Data Quality characterised?

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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**	

Fundamental concepts described

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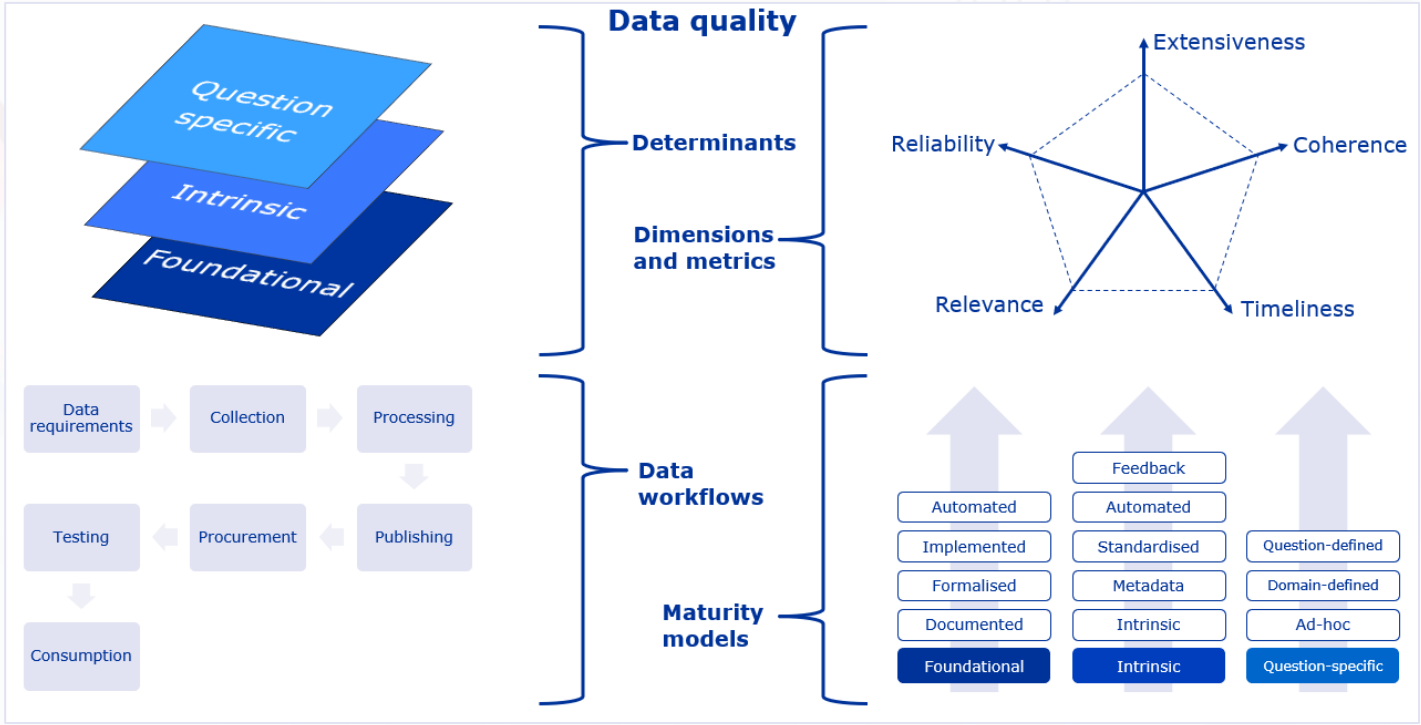
Data Quality can be characterised using ***different concepts***

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



Your contribution is important!

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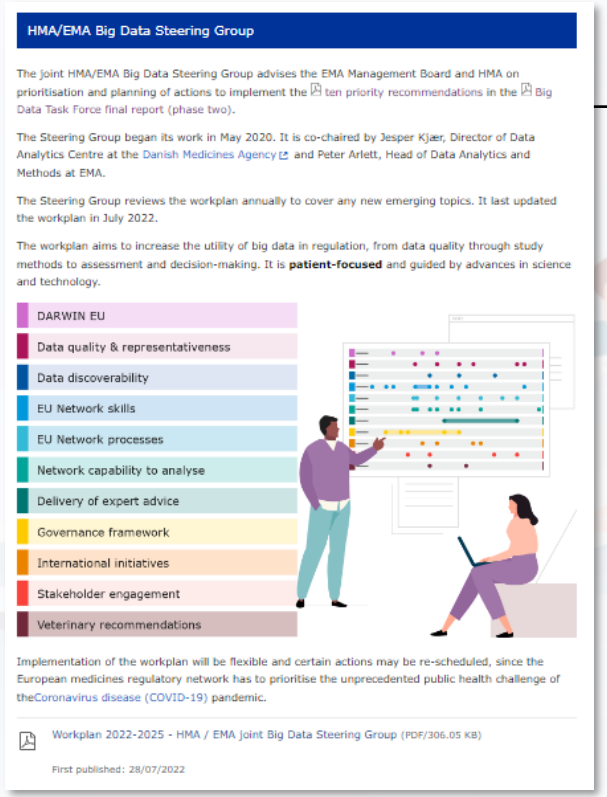
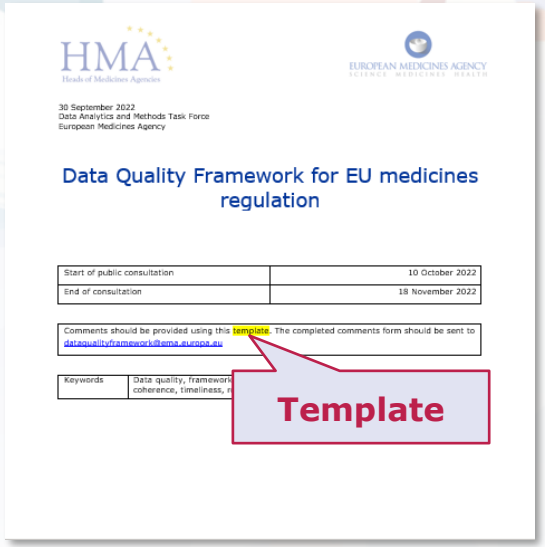
1) Open the Data Quality Framework draft from the Big Data website

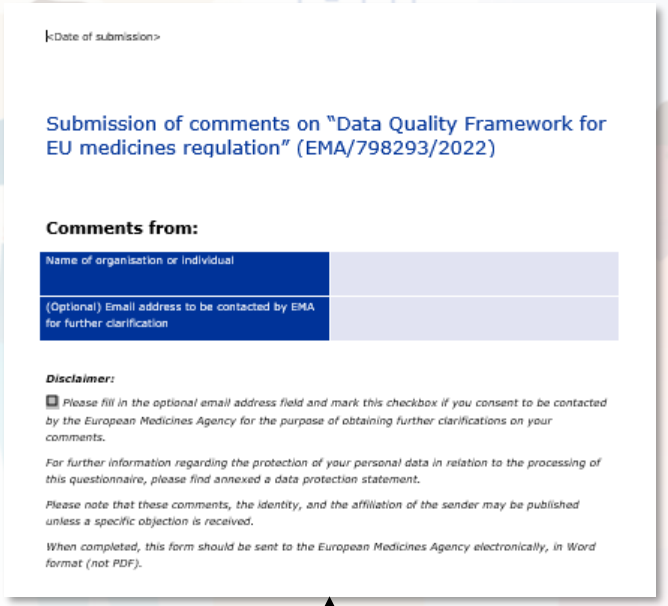


2) Click the link template to find the comments file



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

DataQualityFramework@ema.europa.eu



Public consultation

Data Quality Framework

Deadline: 18 November 2022

EMA
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Questions and Answers session

Jesper Kjær
Co-chair Big Data Steering Group, DKMA