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SCIENCE MEDICINES HEALTH

EMA Data Quality Framework and the EMA RWD Strategy

BBS/BES Seminar: Real-World Data Quality – Assessing data quality and demonstrating fitness-for-purpose

Presented by Dr Daniel Morales, 15th March

RWE Workstream, Data Analytics and Methods Task Force, EMA

Disclaimer

The views expressed in this presentation are mine and should not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

Areas where RWD can support EMA scientific committees

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1 Support the planning and validity of applicant studies

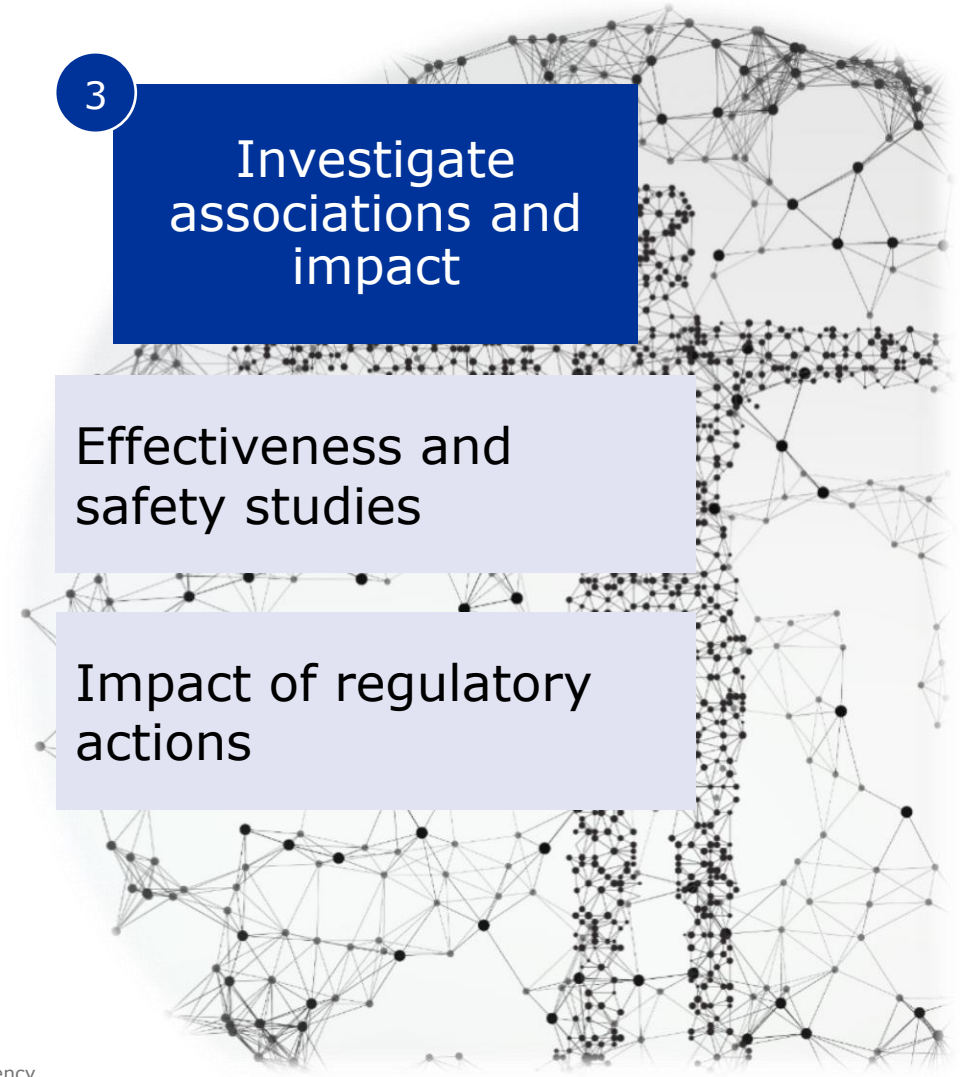
- Design and feasibility of planned studies
- Representativeness and validity of completed studies

2 Understand the clinical context

- Disease epidemiology
- Clinical management
- Drug utilisation and monitoring

3 Investigate associations and impact

- Effectiveness and safety studies
- Impact of regulatory actions



How does EMA generate Real-World Evidence

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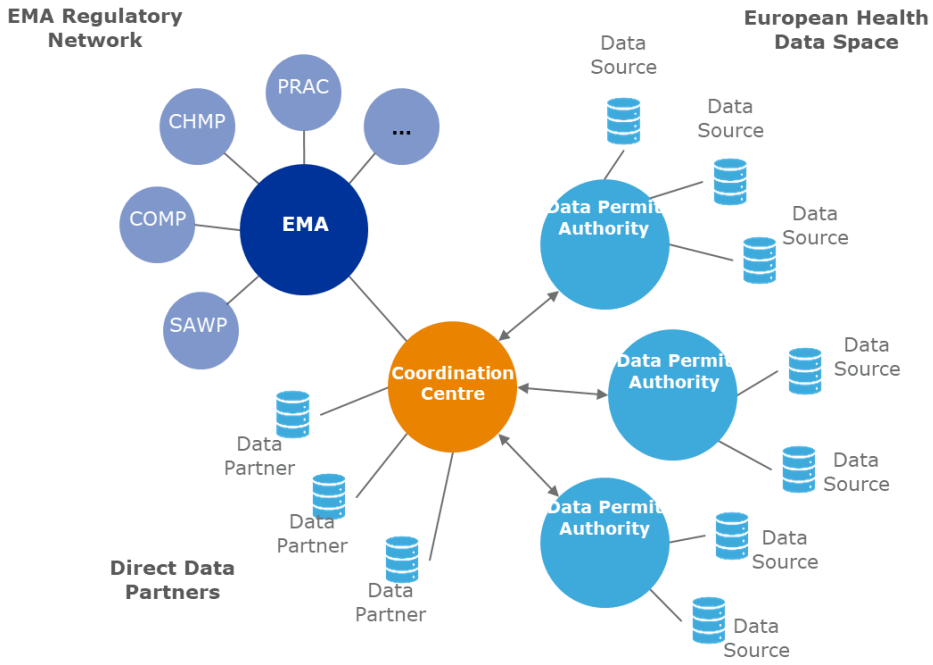
EMA studies using in-house databases

- Primary care health records from the **UK, France, Germany, Italy, Spain and Romania**

Studies procured through EMA FWCs

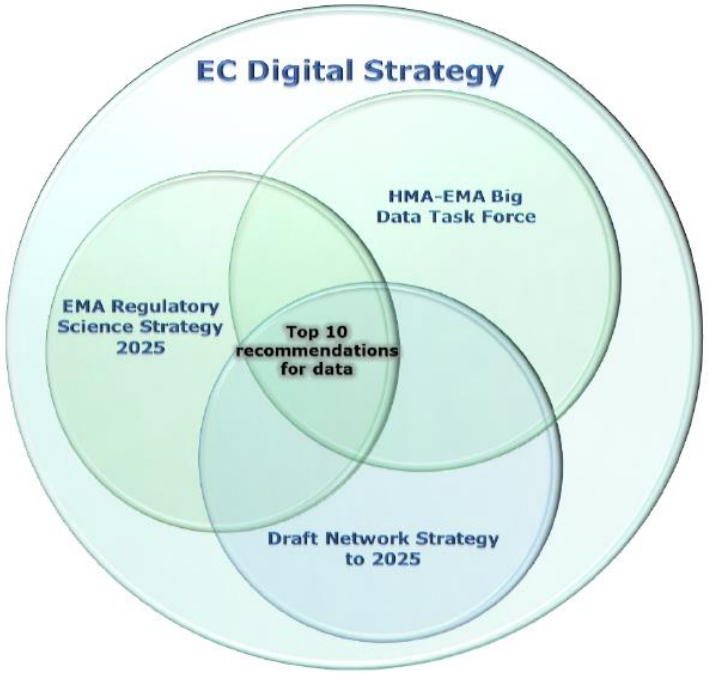
- Current framework contract since September 2021: services of **8 research organisations** and academic institutes
- Access to **wide network of data sources**: 59 data sources from 21 EU countries
- Ability to leverage external **scientific expertise**

DARWIN EU®



Background to the EMA Data Quality Framework

The EMA and HMA set up a joint task force to **describe the big data landscape from a regulatory perspective** and identify practical steps for the European Medicines Regulatory Network to make best use of big data. This led to the creation of the Joint HMA/EMA **Big Data Steering Group** and **Big Data Steering Group Work Plan**.



"By delivering the vision of a regulatory system able to integrate Big Data into its assessment and decision making, we can support the development of innovated medicines, deliver life-saving treatments to patients more quickly and optimize the safe and effective use of medicines through measurement of a products performance on the market."

Big Data Task Force final report December 2019

Joint HMA-EMA BDSG work plan 2022-2025

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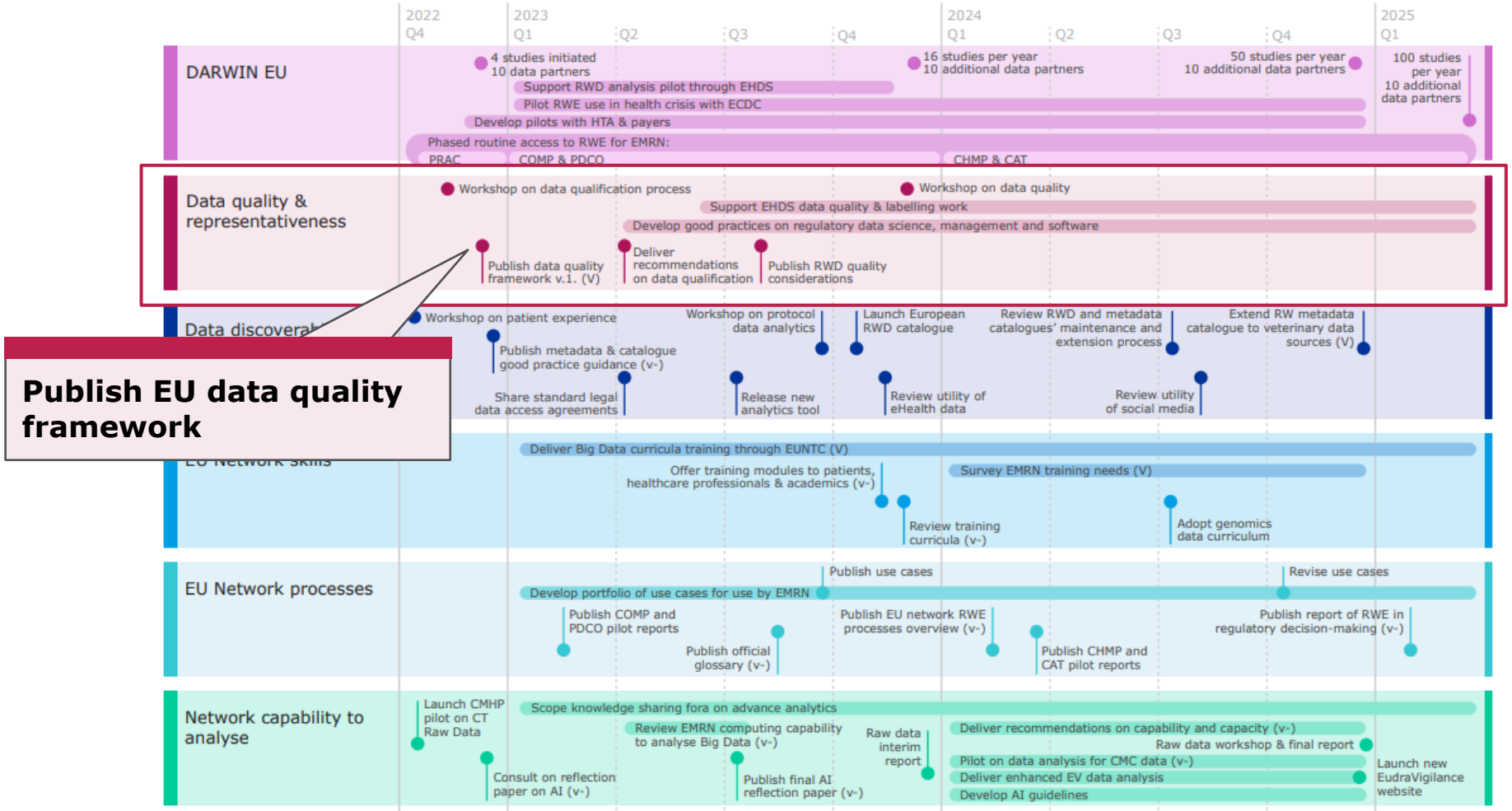

Publish EU data quality framework

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**

Challenges for Data Quality Frameworks

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- Real-world data have been **collected for another purpose**
- Different data quality frameworks exist
- Most DQFs provide general recommendations on dimensions to be addressed and analyses to be performed, but **few provide practical tools**
- The implementation of DQFs and the analyses of the different dimensions **generally requires access to the whole set of raw data** and can best be performed by the data owners.
- The **interpretation** of results of implementation of DQFs **requires experience or guidance** for reading and interpreting a large number of tables and figures containing a lot of metadata.
- **Criteria needed** to be developed and applied for quality assessment

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
- Introduces an **approach to evaluate the performance** of the framework and the need for its improvement to support 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**

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

Secondary use DQF analysed for Data Quality Dimensions

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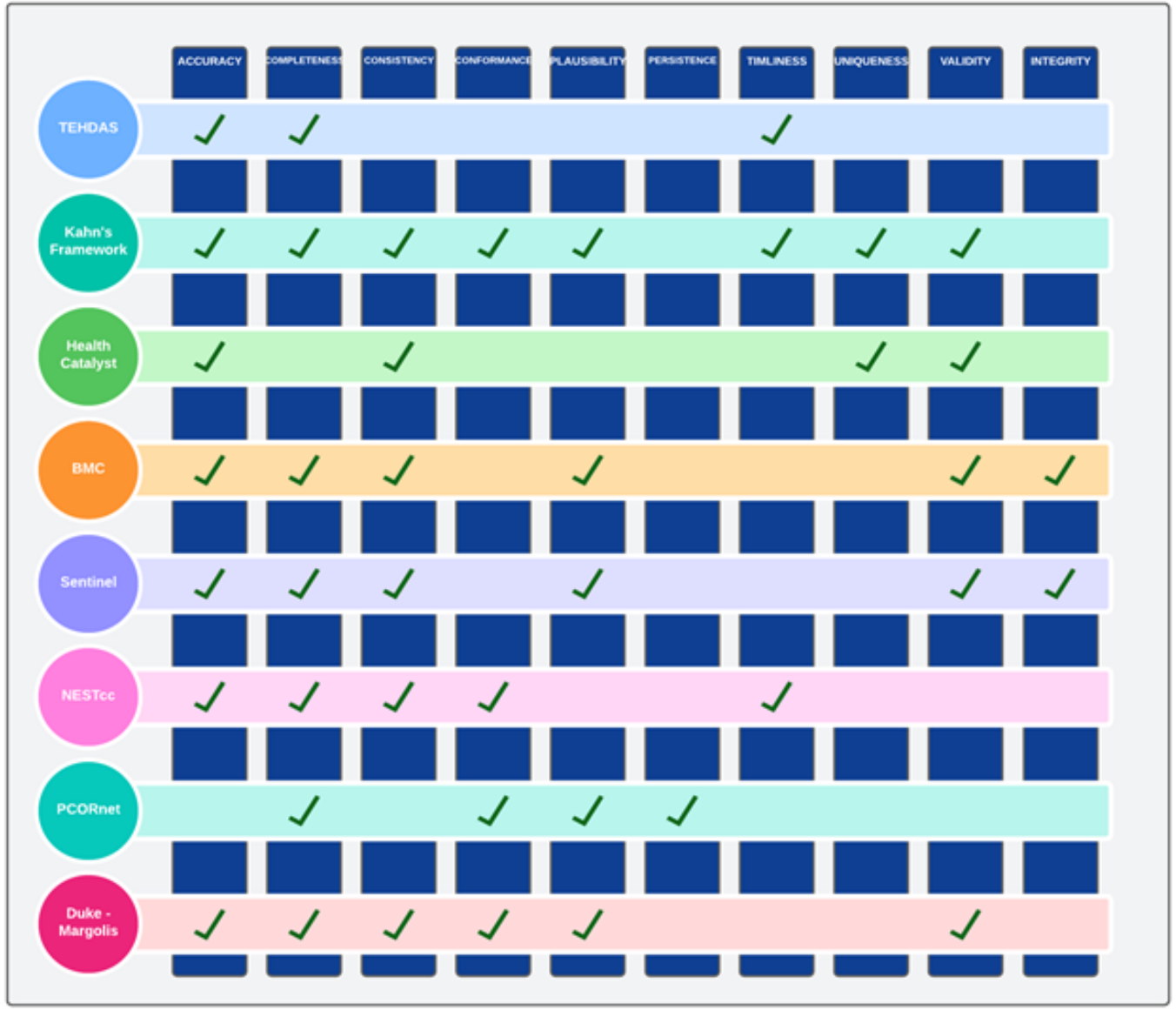
Each DQF concentrates on certain data quality dimensions.

The dimensions are used to determine if the analysed data is fit-for regulatory purpose for a particular use case.

The more dimensions the framework covers, the more extensible the framework is for other data types.



Results from a landscape analysis

What is Data Quality?

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

It is described by 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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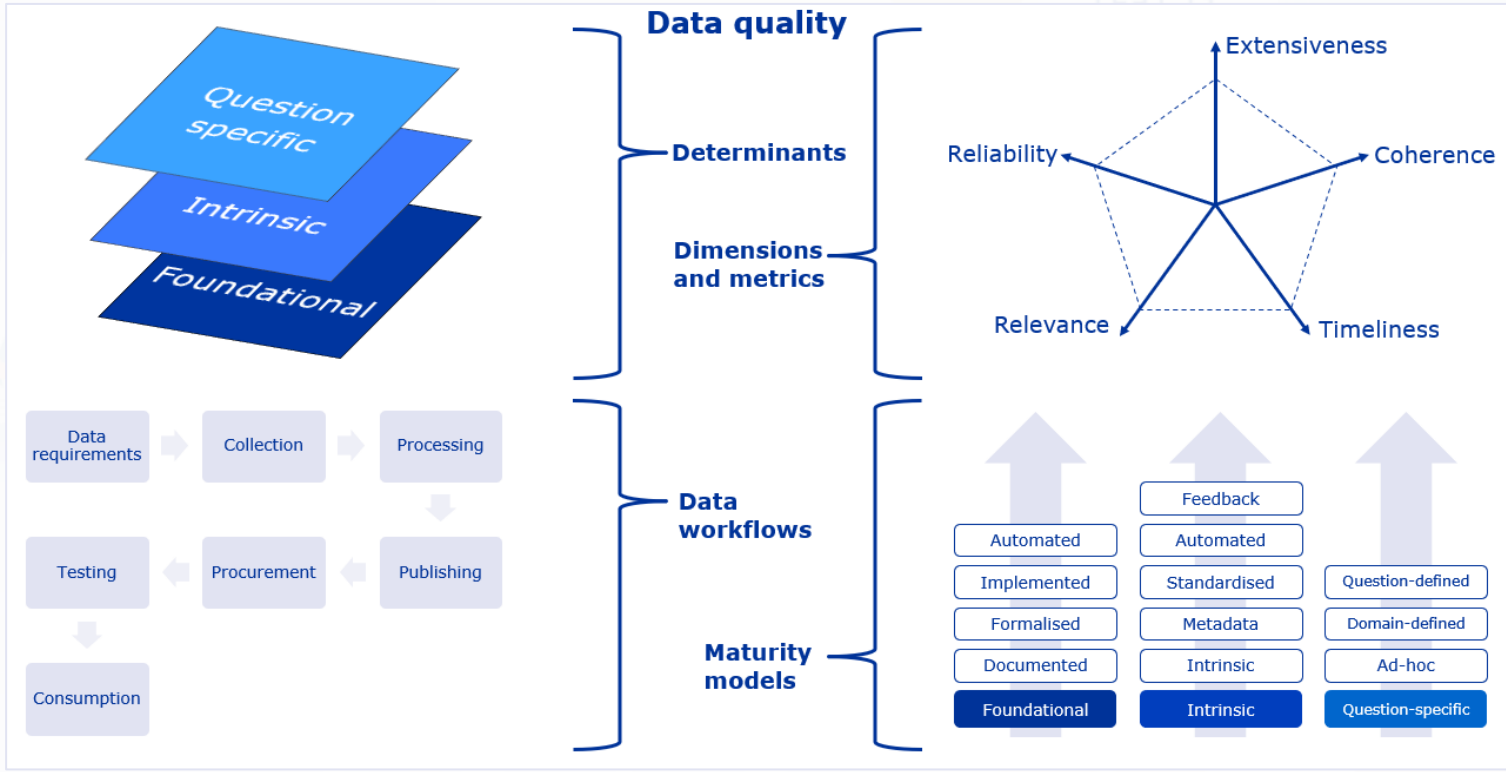
Data Quality can be characterised using *different concepts*

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



Dimensions of Data Quality

Reliability: "… how closely the data reflect what they are designed to measure",

- Validity, plausibility, accuracy and precision.

Extensiveness: ".. relates to the amount of data available"

- Completeness and coverage.

Coherence: "… how different parts of a dataset are consistent in their representation/meaning",

- Format, structural and semantic coherence, uniqueness

Timeliness: "… availability of data at the right time for regulatory decision making",

- Currency and lateness.

Relevance: "… the extent to which a dataset presents data elements useful to answer a research question"

DARWIN EU and the Data Quality Frameworks

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Reliability: generate data characteristics (age distribution, condition prevalence per year, data density, measurement value distribution)

Extensiveness: checks for whether tables and fields of the OMOP CDM are populated, person completeness domain (e.g. how many persons have no drug exposures).

Coherence: checks for: data type, unique fields, foreign keys, standard/non-standard concepts.

Timeliness: generate data density plots showing per month the number of records per OMOP domain.

Relevance: evaluates phenotype algorithms and includes cohort characteristics, record counts, index event misclassification, captured observation windows and basic incidence proportions for age, gender and calendar year (**study specific**)

Thank you!

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