HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview of the project Metadata for data dIscoverability aNd study rEplicability in obseRVAtional studies (MINERVA) (EMA/2017/09/PE/16)

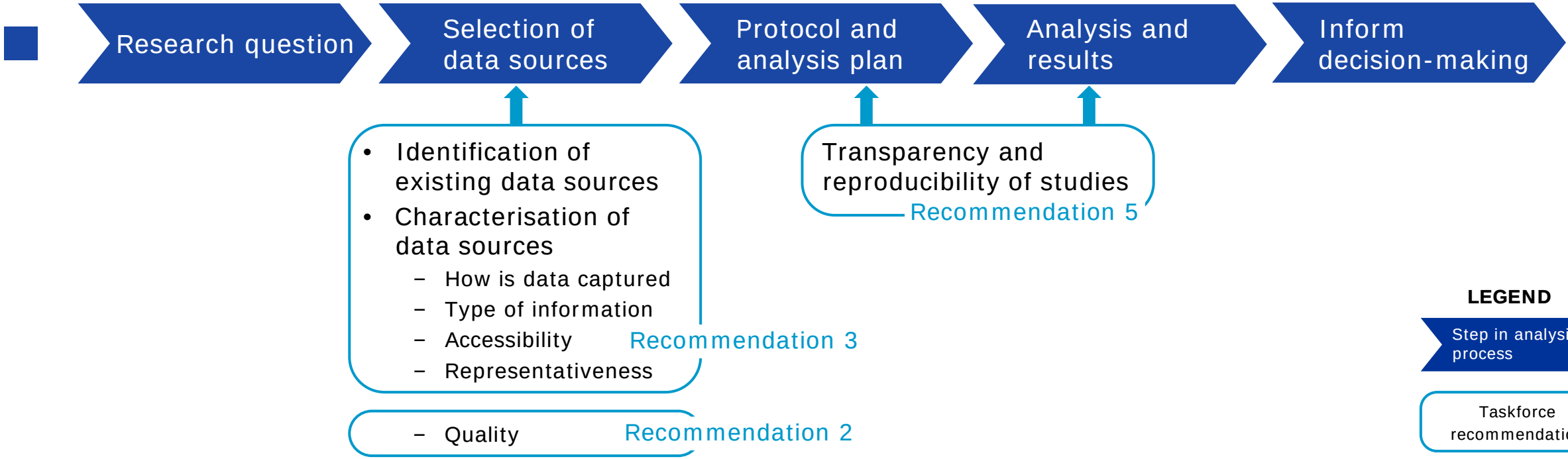
Technical workshop on real-world metadata for regulatory purposes
Virtual meeting, April 12, 2021

Presented by Dr. Susana Perez-Gutthann
RTI Health Solutions

Agenda

1. Background: EMA call and project objectives
2. Consortium, data sources, and countries
3. Tasks and timelines
4. Workshop focus

Generating and assessing Real World Evidence to inform regulatory decision-making



Adapted from presentation by EMA at ENCePP Plenary, 20 Dec 2020

EMA call project objectives

1. To define a list of criteria to identify relevant real-world data sources from which the data sources to be included in this study will be selected
2. To identify a list of minimum 10 data sources to use in the study
3. To **define a set of metadata** that should be collected from real-world data sources
4. To conduct an **in-depth stakeholders' consultation** on the metadata identified
5. To **define a process** to collect the set of metadata for the data sources included in the study
6. To collect the defined set of metadata for data sources included in the study
7. To develop or **provide a tool** enabling access to the metadata collected (e.g., through a dynamic dashboard)
8. To draft a **good practice guide** with the description of the metadata defined and recommendations on the use of metadata for the purpose of identifying real-world data sources for a specific study purpose

1-year metadata study timeline

Nov 2020 — **Contract signed**

Jan 2021 — **Study plan** finalisation and approval

Mar 2021 — **List of criteria & selection of limited set of databases for POC**

- Define a list of criteria that should be met by real-world data sources in order to be included in the database catalogue (EU Resource database) & select a limited number of data sources for the POC
- Data sources allowing linkage of drug utilisation data to clinical events and demographic variables for individual patients : i) primary care, ii) specialist care and iii) hospital care data from EHRs, iv) claims databases, v) disease registries, vi) longitudinal drug prescription, dispensing or other drug utilisation
- Data sources allowing to measure for each individual patient the duration of use and the cumulative doses of medicines prescribed/delivered: Longitudinal drug prescription, dispensing, or other drug utilisation

Define preliminary set of metadata

- Review metadata used by other regulators or organisations
- Metadata should include information on source, spectrum, quality of datasets, measures such as quality indicators, data flows, distribution of the population by key characteristics, representativeness of the population covered

Apr 2021 — **Stakeholders' consultation & workshop**

- Build agreement on the set of metadata
- Output of the consultation to be used to finalise the set of metadata

Adapted from EMA project update, March 2021

1-year metadata study timeline

May 2021

Final list of metadata with definitions

Oct 2021

Collection of metadata & tool

- Tool to enable access to the metadata collected including search and visualisation capabilities

Report on data collection process & tool

- Description of how the metadata have been collected, limitations of the process and the visualisation tool as well as possible improvements

Dec 2021

Good practice guide

- Description of the metadata defined
- Recommendations on the use of metadata for the purpose of identifying real-world data sources for a specific study purpose, assessing suitability of data sources used in studies and contributing to assess the evidentiary value of study results
- Provision of regulatory use cases and examples on use of the metadata

Adapted from EMA project update, March 2021

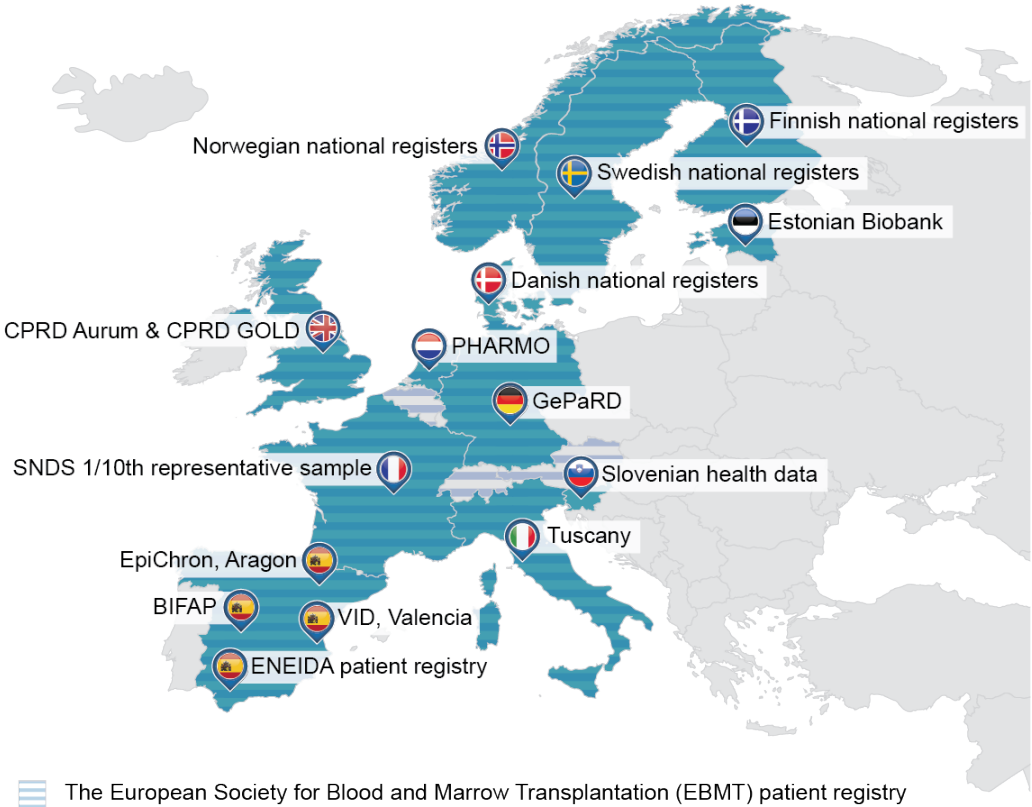
Focus of the project

- Definition of the set of metadata and engagement with stakeholders to reach broad agreement
- Good practice guide (description of the metadata defined and recommendations on the use of metadata)
- The visualisation tool will act more as a proof of concept on how the data can be used and visualised

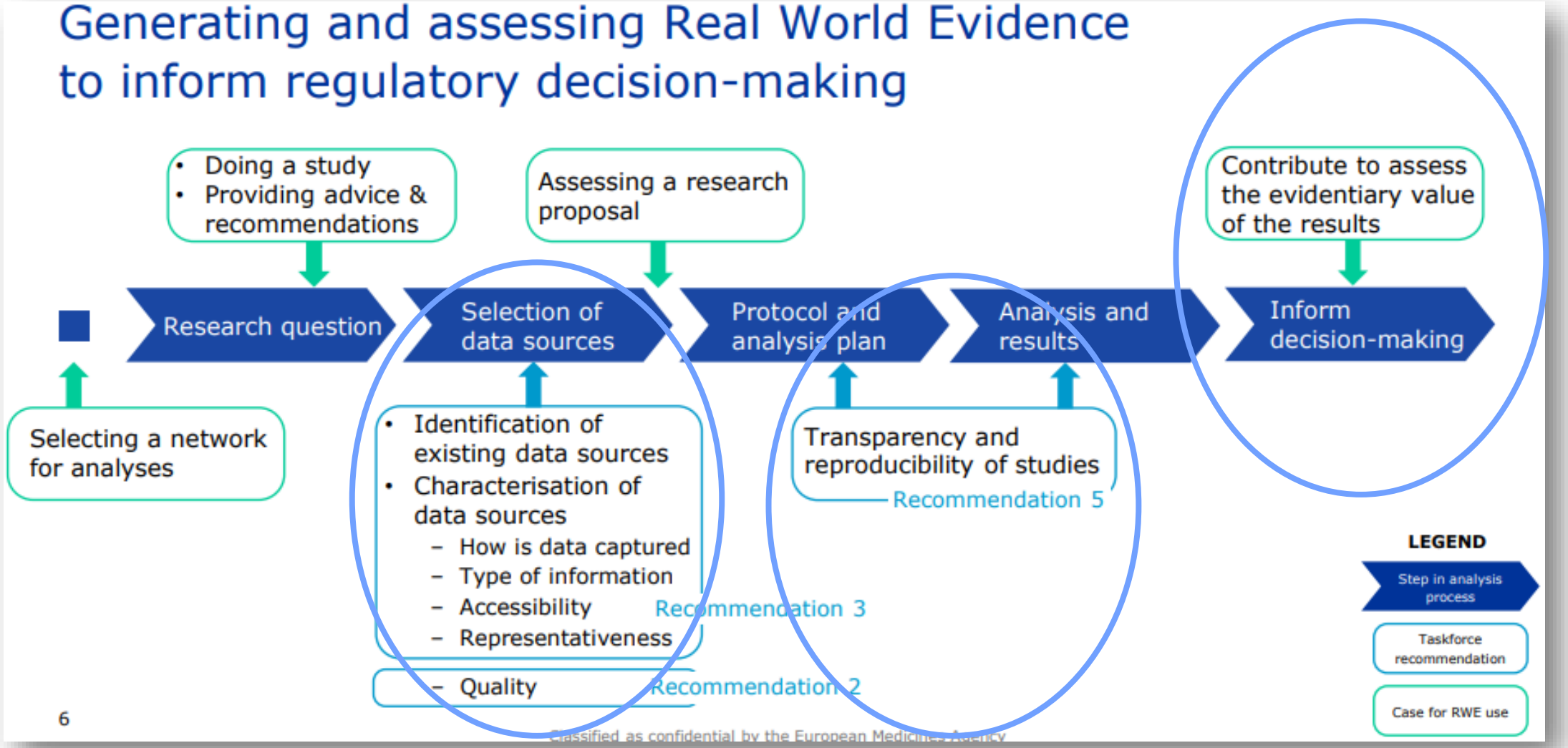
MINERVA consortium, data sources, and countries

MINERVA

- **15** population databases and patient registries in **12** countries
- **18** research centers in **12** countries



Regulatory use cases



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Data sources selection criteria

1. Data sources collecting health data routinely
   - Electronic healthcare databases, claims databases, disease registries, or genomics data sets covering defined populations at a local or national level in countries in Europe. Other types of data sources will not be excluded.
2. Data sources collecting patient-level data collected in a data source through a single data bank or through linkages of multiple data banks, specifically data on medicinal products utilisation and demographic variables including at least one of the following settings:
   - Primary care: data from primary care/general practice
   - Specialist care: data from outpatient hospital clinics or specialised outpatient centres
   - Hospital care: data from inpatient hospital settings, which may or may not include emergency care data
3. Data sources collecting detailed patient-level measures of medicinal product use.
   - Timing of prescription/dispensing/administration/delivery of medicinal drugs are the critical elements
   - Allow estimation of duration of use and the cumulative doses. Capture of use of biologics, medical devices and other medical products is of value

Data sources selection criteria (cont.)

4. Data sources with continuous and consistent data capture
    - Absence of systematic or prolonged temporal gaps in data collection
5. Data sources where structured data is collected
    - Data sources that have not converted to an existing CDM will be eligible for inclusion in the proof-of-concept catalogue.
    - Data sources that have converted to an existing CDM will be described to facilitate inclusion in the proof-of-concept catalogue
6. Data sources with procedures in place to comply with applicable patient data privacy and confidentiality rules, allowing use of data for public health research

Workshop focus: preliminary metadata definition, collection process, and proof of concept tool

Report shared with participating organizations

- Description and definition of preliminary list of metadata that should be collected from real-world data sources
  - Publicly available information
  - Structured interviews with organisations
- Proposed options for the process to collect the metadata and to update them
- Proposed catalogue proof of concept tool to use for accessing, searching, and visualising the metadata collected

Thank you!

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