HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview of the HMA-EMA Big Data Taskforce priority 3: recommendation to enable data discoverability

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

Presented by Stefania Simou
European Medicines Agency (EMA), Healthcare Data, Data Analytics and Methods Task Force

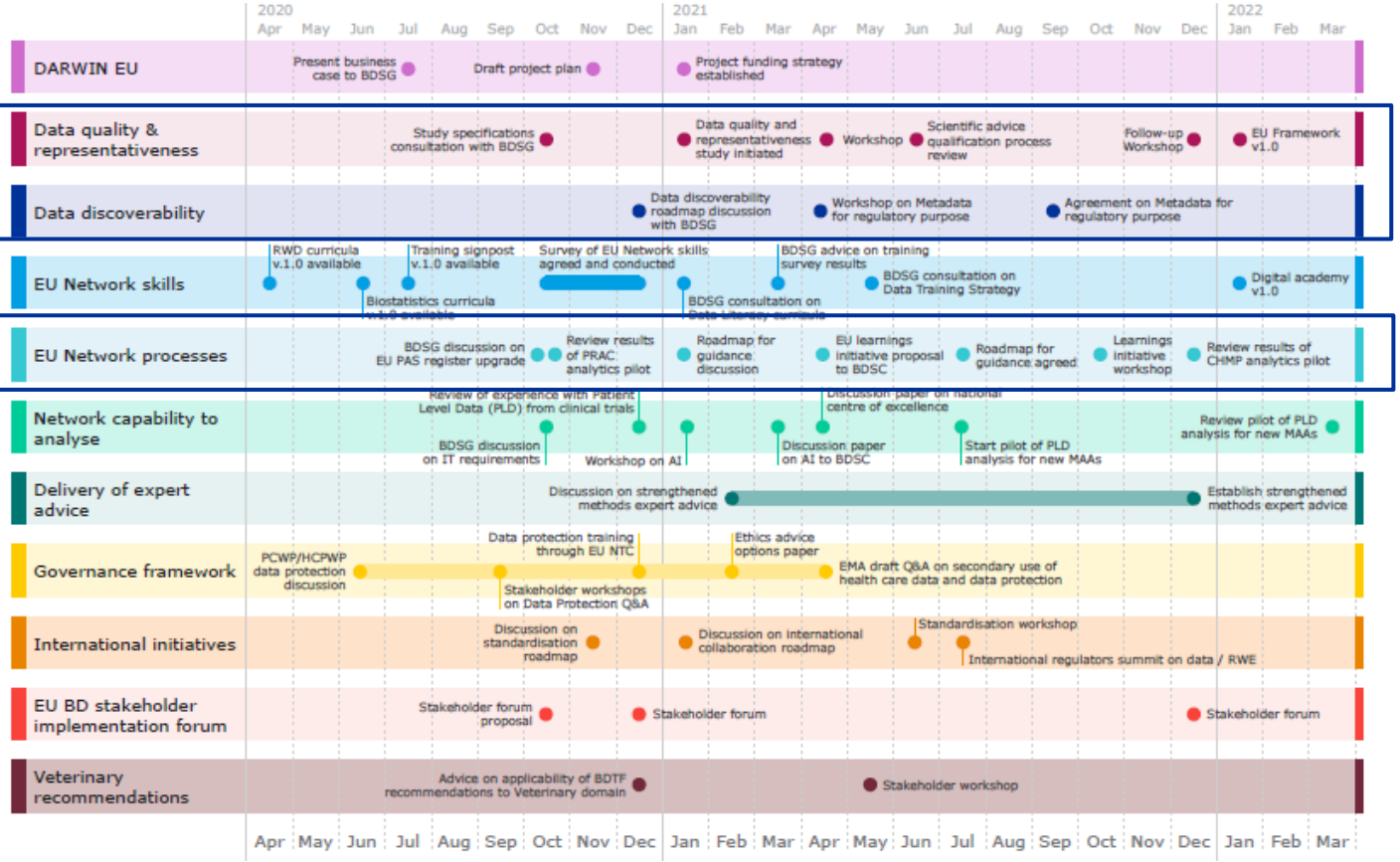
Agenda

1. Current challenges
2. HMA-EMA Big Data taskforce recommendations
3. Generating and assessing Real World Evidence to inform regulatory decision-making
4. Metadata for data discoverability and study replicability in observational studies (MINERVA)
5. Data discoverability – steps and timelines

Current challenges

- Identification of appropriate real-world data sources is becoming an increasing need in regulatory decision making
  - Examples: long-term follow up of innovative medicines, post authorisation obligations for products authorised with a conditional authorisation
- Data needs are becoming more complex
  - Need for data sources of sufficient depth and details in several European Member States
- Lack of standardised information and statistics on real-world data sources
  - Data sets can be siloed by country, language, region, hospital and even department
  - Resource intensive to find suitable data sources, assess their characteristics and quality
  - Pharmaceutical companies may establish new data sources; duplication of effort and further fragmentation of the data landscape

THE HMA-EMA JOINT BIG DATA STEERING GROUP WORKPLAN



HMA-EMA Big Data taskforce recommendations

Three recommendations strengthen the need to have a comprehensive knowledge of what data sources are available and their characteristics, and transparency on study methods:

Recommendation 2: Establish an EU framework for data quality and representativeness

- Develop guidelines on data quality
- Strengthen the process for data qualification through Scientific Advice

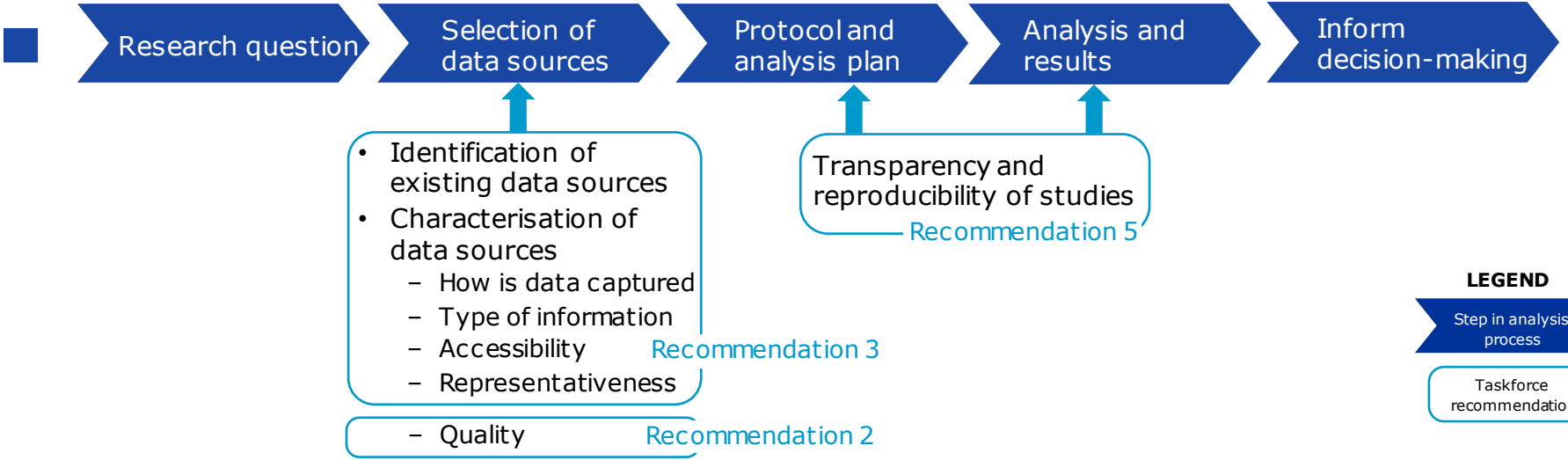
Recommendation 3: Enable data discoverability

- Identify key meta-data for regulatory decision-making on the choice of data source
- Strengthen the current ENCePP resources database

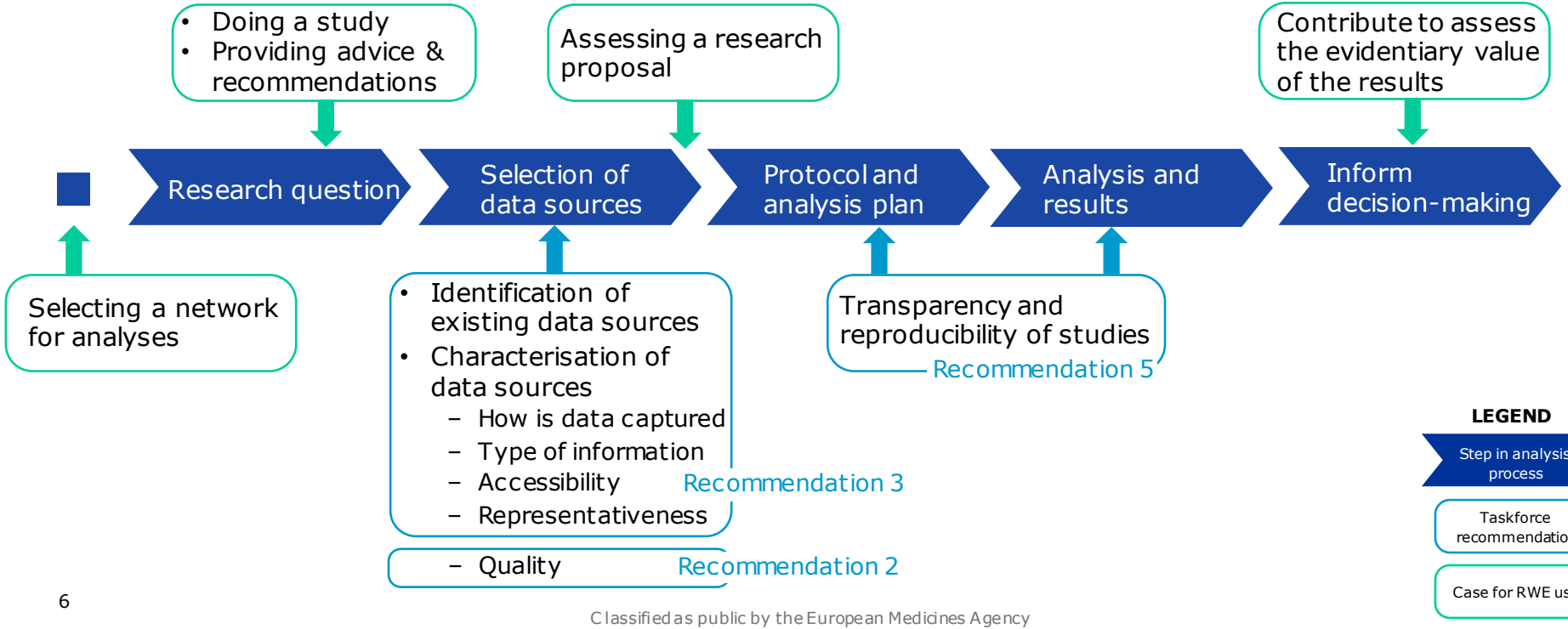
Recommendation 5: Strengthen EU Network processes for Big Data submissions

- Develop guidelines on study conduct and reporting
- Enhancement of the existing EU PAS register

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



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



Metadata for data discoverability and study replicability in observational studies (MINERVA)

- Launched by EMA in November 2020
- Contracted to RTI Health Solutions, which has formed a consortium, *the MINERVA Consortium,* including 18 research centres in 12 countries
- Planned duration: 1 year
- To note: the concepts presented during this workshop are drafts for consultation purposes only. Those should not be interpreted as representing the formal position of EMA or HMA.

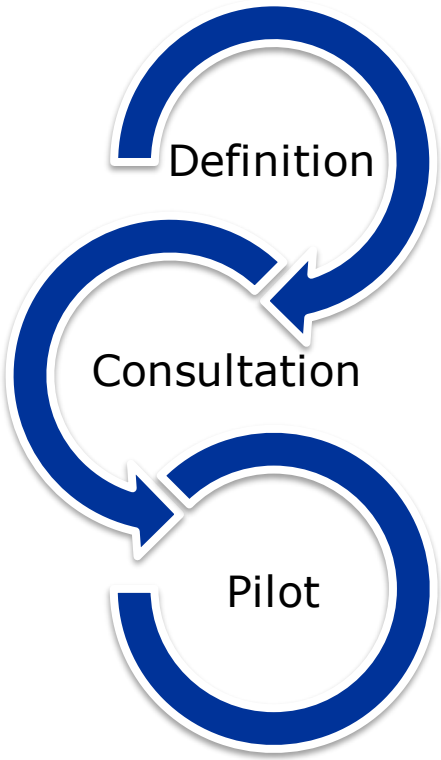
Metadata for data discoverability and study replicability in observational studies (MINERVA)

Reasons for undertaking the study:

- Definition of the set of metadata for identification of data sources and description of their characteristics in order to:
  - Select suitable data sources to address specific regulatory use cases
  - Assess data sources proposed in studies
  - Contribute to the assessment of the evidentiary value of study results
  - Guide the initial selection of data sources when creating a network

- Pilot the process of collecting the data sources and their metadata including the development of a proof of concept for a tool to collect, search and visualise the metadata

Data discoverability – steps and timelines



Definition of set of metadata relevant for regulatory decision making from real-world data sources looking at metadata used by other regulators or organisations

Stakeholder engagement, consultation and workshop are part of the work plan for 2021

Delivery of the final list of metadata by the end of 2021. The metadata collection will be piloted for a limited set of data sources (covering different type of RWD sources and formats). Delivery of a good practice guide on data discoverability (including description of the metadata and advice on use) by the end of 2021

Thank you!

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**