

11 April 2021
EMA/139729/2021
Data Analytics and Methods Task Force

Agenda for “Technical workshop on real-world metadata for regulatory purposes”

12 April 2021,
Virtual meeting, European Medicines Agency



Objectives

The objective of this workshop is to review and gather stakeholders' feedback on:

- preliminary list of metadata required for characterising real-world data sources and definitions to fulfil regulatory use cases;
- proposed options for metadata from real-world data sources collection and maintenance processes;
- proof-of-concept catalogue of data sources and metadata.

Agenda details

Monday, 12 April 2021

13:00 Connection to virtual room and technical checks

13:30 Welcome and introduction

Welcome and housekeeping

Paolo Alcini, EMA

Opening remarks

Nikolai Brun, Big Data Steering Group Co-chair (DKMA)

10'

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

Stefania Simou, EMA

10'

Overview of the project Metadata for data dIscoverability aNd study rEplIcability in obseRVAtional studies (MINERVA)

Susana Perez-Gutthann, MINERVA Consortium, RTI Health Solutions, Barcelona

10'

14:00 Session 1: Conceptual framework, definitions and use cases

Chair: **Xavier Kurz**, EMA

Overview of the regulatory use case

Romin Pajouheshnia, MINERVA Consortium, Utrecht University, Utrecht

5'

Underlying conceptual framework and definitions

Rosa Gini, MINERVA Consortium, ARS Toscana, Florence

20'

Overview of Stakeholders feedback process

Susana Perez-Gutthann, MINERVA Consortium, RTI Health Solutions, Barcelona

5'

Discussion

Xavier Kurz, EMA

30'

15:00 Session 2: Preliminary set of metadata and definitions

Chair: **Xavier Kurz**, EMA

Preliminary list of Metadata

Romin Pajouheshnia, MINERVA Consortium, Utrecht University, Utrecht

35'

Summary of feedback from Stakeholders

Romin Pajouheshnia, MINERVA Consortium, Utrecht University, Utrecht 10'

Discussion

Xavier Kurz, EMA 45'

16:30 Break

16:50 Session 3: Process to Collect metadata and sustainability

Chair: **Jesper Kjær**, DKMA

FAIR Catalogue sustainability and metadata collection process

Miriam Sturkenboom, MINERVA Consortium, University Medical Centre Utrecht, Utrecht 20'

Summary of feedback from Stakeholders

Miriam Sturkenboom, MINERVA Consortium, University Medical Centre Utrecht, Utrecht, and **Rosa Gini**, MINERVA Consortium, ARS Toscana, Florence 5'

Discussion

Jesper Kjær, DKMA 20'

17:35 Session 4: Proof-of-Concept catalogue

Chair: **Jesper Kjær**, DKMA

Preliminary Proof-of-Concept catalogue tool

Morris Swertz, MINERVA Consortium, University Medical Centre Groningen, Groningen

Eleanor Hyde, MINERVA Consortium, University Medical Centre Groningen, Groningen 15'

Summary of feedback from Stakeholders

Morris Swertz, MINERVA Consortium, University Medical Centre Groningen, Groningen 5'

Discussion

Jesper Kjær, DKMA 20'

18:15 Concluding remarks

Peter Arlett, Big Data Steering Group Co-chair (EMA) 10'

18:30 End of the meeting
