

11 March 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 a:

- preliminary list of metadata required for characterising real-world data sources, and their definitions;
- proposed process to collect and maintain metadata from real-world data sources;
- proof-of-concept catalogue of data sources and metadata currently being developed.

Agenda details

Monday, 12 April 2021

13:00 Connection to virtual room and technical checks

13:30 Welcome and introduction

Workshop co-chairs: Paolo Alcini (EMA) & **Jesper Kjær** (DKMA)

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: Preliminary Set of Metadata and Definitions, Process and Catalogue Tool

Chair: **Paolo Alcini**, EMA

Introduction to MINERVA proof of concept tool

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

Underlying conceptual framework

Rosa Gini, MINERVA Consortium, ARS Toscana, Florence 20'

Preliminary Proof-of-Concept Catalogue Tool

Morris Swertz, MINERVA Consortium, University Medical Centre Groningen, Groningen 20'

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

Preliminary List of Metadata

Romin Pajouheshnia, MINERVA Consortium, Utrecht University, Utrecht 20'

Process/Sustainability

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

15:30 Break

15:45 **Session 2: Feedback from Stakeholders. Discussion, Questions & Answers**

Chair: **Jesper Kjær**, DKMA

Summary of Feedback from Stakeholders

Susana Perez-Gutthann, MINERVA Consortium, RTI Health Solutions, Barcelona 15'

Discussion

Jesper Kjær, DKMA 60'

17:00 **Concluding remarks**

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

17:10 **End of the meeting**
