

10 May 2021
EMA/346477/2020
Data Analytics and Methods Task Force

Agenda: Data Standardisation Strategy - stakeholder workshop

18 May 2021
Virtual meeting, European Medicines Agency



Objectives

- Why do we need standardised data and what is the business value of data standards.
- Present the current status of the draft EMRN Data Standards Strategy development.
- Present the stakeholder survey results.
- Gather stakeholders' perspectives and use cases.

Agenda details

Tuesday, 18 May 2021

13:00 Connection to virtual room and technical checks

13:30 Welcome and introduction

Chair: **Peter Arlett**, EMA, Big Data Steering Group Co-chair

Welcome

Peter Arlett, EMA, Big Data Steering Group Co-chair

10'

Opening remarks

Emer Cooke, Executive Director, EMA

10'

Importance of Data Standardisation in Europe

Licinio Kustra-Mano, DG Sante, EC

10'

Overview of the HMA-EMA Big Data Taskforce priority 9 and the need for the EMRN Data Standardisation Strategy

Jesper Kjær, DKMA

10'

Update on the status of the Veterinary Data Strategy

Ilaria del Seppia, EMA

10'

14:20 Session 1: EMRN Data Standards Strategy

Chair: **Hilmar Hamann**, EMA

EMRN Data Standardisation Strategy: development process and status

Nick Halsey, EMA

10'

Stakeholder consultation: (preliminary) main highlights

Nick Halsey, EMA

30'

Potential synergies from existing standards and projects

Wayne Kubick, HL7

10'

Christian Hay, ISO/CEN

10'

Peter Rijnbeek, EHDEN/OHDSI

10'

Dave Evans, CDISC

10'

Enrique Bernal-Delgado, TEHDAS

10'

15:50 Break

16:10

Session 2: Stakeholder's perspectives and use cases

Chair: **Jesper Kjær**, DKMA

Rapporteur: **Nick Halsey**, EMA

Stakeholder perspective and use cases – Patients/Consumers

Marilena Vrana, European Heart Network

10'

Stakeholder perspective and use cases –Healthcare professionals

Ioana Agache, European Academy of Allergy and Clinical Immunology

10'

Stakeholder perspective and use cases – Pharmaceutical industry: EFPIA/EuropaBio

Vada Perkins, EFPIA/EuropaBio

10'

Stakeholder perspective and use cases – Pharmaceutical industry: Medicines for Europe

Kelly Zou, Medicines for Europe

10'

Stakeholder perspective and use cases – Pharmaceutical industry: EUCOPE

Todd Case / Mats Ericson, EUCOPE

10'

Stakeholder perspective and use cases – Researchers

Jan-Willem Boiten, Health-RI/Lygature

10'

Stakeholder perspective – European Network Data Board

Peter Bachman, BfArM

10'

Panel discussion

50'

18:10

Concluding remarks

Peter Bachman, BfArM

5'

Peter Arlett, EMA, Big Data Steering Group Co-chair

5'

18:20

End of the meeting
