06 December 2021
EMA/109720/2020
Data Analytics and Methods Task Force

Agenda for "EU Big Data Stakeholder Forum 2021"

7 December 2021,
Virtual meeting, European Medicines Agency

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Objectives

The pace of change in technology, in data science and in healthcare is unprecedented and keeps bringing new opportunities to better the health of European citizens through innovation, better regulation, and learning from healthcare data. The European Commission's Digital and Data Strategies, adopted in early 2020, set out a bold vision for health data including the creation of a European Health Data Space. In 2022, this will be further realised through a legislative proposal for the European Health Data Space. The European Commission's Pharmaceutical strategy for Europe is also being developed with legislative proposed anticipated. In this context, in early 2020 HMA and EMA Management Board adopted the Big Data Task Force recommendations to deliver data-driven medicine regulation. To deliver these recommendations, the second workplan of the HMA-EMA joint Big Data Steering Group (BDSG) 2021-2023 was published in August 2021.

To foster collaboration and to engage stakeholders the European Medicines Regulatory Network is organising a second annual Big Data Multi-Stakeholder Form. The main objectives of the Forum are:

- To inform stakeholders on the delivery of the data pillar of the Network Strategy 2025 via the HMA-EMA joint Big Data Steering Group (BDSG) 2021-2023.
- To listen to stakeholders' views and feedback.
- To discuss areas for collaboration.

Agenda details

Tuesday, 7 December 2020

08:30 Connection to virtual room and technical checks

09:00 Welcome and introduction

Emer Cooke, *Executive Director, EMA* *5'*

09:05 Opening remarks

Karl Broich, *HMA Chairperson*, *BfArM* *10'*

Andrzej Rys, *Director - Health Systems, Medical Products and Innovation, DG SANTE, EC* *10'*

Marco Greco, *President*, *EPF* *10'*

09:35 Session 1: Report on implementation of the HMA-EMA Big Data Task Force priority recommendations

Chair: **Jesper Kjær,** *DKMA*

Overview of 2021 deliverables and plan for 2022

Peter Arlett, *EMA* *20'*

Veterinary recommendations

Ilaria Del Seppia, *EMA* *15'*

10:10 Session 2: Big Data - enabling use and establishing value

Co-chairs: **Peter Arlett**, *EMA* and **Jesper Kjær**, *DKMA*

DARWIN EU

Presenter: Marilena Vrana*, EHN* *5'*

Panel discussion *20'*

Patients: Elizabeth Vroom*, UPPMD*
Healthcare professionals: Aldo Pietro Maggioni*, ANMCO*
Data permit authorities: Roman Khonsari*, Health Data Hub*
European Commission: Ioana Gligor
Health Technology Assessment bodies: Niklas Hedberg*, EUnetHTA*
Pharmaceutical industry: Álmath M. Spooner*, EFPIA*

Questions and answers *5'*

Data quality & representativeness
Presenter: César Hernández García*, AEMPS* *5′*

Panel discussion *20′*
Patients: Jaivir Pall, *IDF- Europe*
Healthcare professionals: Christian Gisselbrecht, *EHA*
TEHDAS: Enrique Bernal-Delgado
Contract Research Organisations: Alan Yeomans*, EUCROF*
ENCePP: Gianluca Trifirò*, University of Verona*
Pharmaceutical industry: Kelly Zou, *Medicines for Europe*

Questions and answers *5′*

11:10 Break

11:30 Session 2: Big Data - enabling use and establishing value (cont.)

Data discoverability
Presenter: Eleonora Agricola*, AIFA* *5′*

Panel discussion *20′*
Patients: Julian Isla*, Dravet Syndrome European Federation*
Healthcare professionals: Ioana Agache, *EAACI*
ENCePP: Susana Perez-Gutthann*, RTI*
Academia: Denis Lacombe*, EORTC*
Pharmaceutical industry: Sigrid Behr, *EFPIA*

Questions and answers *5′*

Skills
Presenter: Jörg Zinserling, B*fArM* *5′*

Panel discussion *20′*
Patients: David Haerry*, EATG / EUPATI*
Academia: Daniel Prieto-Alhambra*, University of Oxford, EHDEN*
Healthcare professionals: Patrick Ouvrard*, UEMO/WONCA-Europe/EFPC*
EU Regulatory Network: Bruno Delafont*, ANSM*

Questions and answers *5′*

Regulatory processes for data
Presenter: Marjon Pasmooij*, MEB* *5′*

Panel discussion *20′*
Patients: Virginie Hivert*, EURORDIS*
EU Regulatory Network: Željana Margan Koletić, *Halmed*
Healthcare professionals: Raymond Anderson
Pharmaceutical industry: Kelly Zou, *Medicines for Europe*
SME: Brian Bradbury*, EUCOPE*

Questions and answers *5′*

Regulatory capability to analyse data

Presenter: Anja Schiel, *NOMA* *5′*

Panel discussion *20′*
Patients: Michele Calabro*, EPF*
Healthcare professionals: Aldo Pietro Maggioni, ANMCO
EU Regulatory Network: Liam Childs*, Paul-Ehrlich-Institut*
Pharmaceutical industry: Ramon Hernandez, *EFPIA*

Questions and answers *5′*

13:30 Break

14:30 Session 2: Big Data - enabling use and establishing value (cont.)

Delivery of expert advice

Presenter: Alar Irs, *Ravimiamet* *5′*

Panel discussion *20′*
Patients: Kieran Breen*, EPDA*
Healthcare professionals: Anita Simonds, *European Respiratory Society*
Academia: Marieke De Bruin*, University of Utrecht*
Pharmaceutical industry: Solange Rohou, *EFPIA*

Questions and answers *5′*

Data governance

Presenter: Anja Schiel, *NOMA* *5′*

Panel discussion *20′*
Consumers: Jelena Malinina*, BEUC*
Data permit authorities: Johanna Seppanen*, Findata*
TEHDAS: Michel Silvestri
Data protection: Anastassia Negrouk*, Mydata-trust*

Questions and answers *5′*

International initiatives

Presenter: Peter Bachman*, BfArM* *5′*

Panel discussion *20′*
International regulator: John Concato*, FDA*
International regulator: Melissa Kampman*, Health Canada*
International regulator: Yoshiaki Uyama*, PMDA*
Pharmaceutical industry: Patrice Verpillat*, (EFPIA - ICH M14)*

Questions and answers *5′*

16:00 Concluding remarks

Marco Greco, *EPF* *10'*

How to get involved: 2022 events and consultations
Peter Arlett, *EMA* *10'*

16:20 End of the meeting

NOTE:

At certain points throughout the meeting, participants will be able to give their input via the audience interaction tool Slido. Please go to www.slido.com and enter the event code "7December". Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.

Abbreviations

AEMPS - Spanish Agency of Medicines and Medical Devices

AIFA - Italian Medicines Agency

ANMCO - National Association of Hospital Cardiologists

ANSM - National Agency for the Safety of Medicines and Health Products, France

BEUC - The European Consumer Organisation

BfArM - The Federal Institute for Drugs and Medical Devices, Germany

DKMA – Danish Medicines Agency

EAACI - European Academy of Allergy and Clinical Immunology

EATG - European AIDS Treatment Group

EC – European Commission

EFPIA - European Federation of Pharmaceutical Industries and Associations

EFPC - European Forum for Primary Care

EHA - European Hematology Association

EHDEN - European Health Data Evidence Network

EUPATI - European Patients' Academy on Therapeutic Innovation

EHN - European Heart Network

EMA – European Medicines Agency

ENCePP - European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

EORTC - European Organisation for Research and Treatment of Cancer

EPDA - European Parkinson's Disease Association

EPF - European Patients' Forum

EUCOPE - European Confederation of Pharmaceutical Entrepreneurs

EUCROF - European CRO Federation

EUnetHTA - European Network for Health Technology Assessment

EURORDIS - Rare Diseases Europe

FDA - Food and Drug Administration

HMA - Heads of Medicines Agencies

ICH - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

IDF- International Diabetes Federation

Halmed - Croatian Agency for Medicinal Products and Medical Devices

MEB - Medicines Evaluation Board, The Netherlands

NOMA – Norwegian Medicines Agency

PMDA - Pharmaceuticals and Medical Devices Agency, Japan

RAVIMIAMET - State Agency of Medicines, Estonia

RTI - Research Triangle Institute

TEHDAS - Towards the European Health Data Space

UEMO - European Union of General Practioners

UPPMD- World Duchenne Organization

WONCA- World Organization of Family Doctors