# EMA/HMA Big Data Stakeholder Forum 2022

**1 December 2022, 09:00 – 17:55 (CET)**

VIRTUAL MEETING

## Background and objectives

As we continue our journey towards the vision for the data-driven medicines regulation, active dialogue with our partners and stakeholders remains key. Incorporating feedback from experts and stakeholders, the updated HMA-EMA Big Data Steering Group workplan was published in August 2022. Knowing when and how to have confidence in novel technologies and the evidence generated from Big Data will benefit public health by accelerating medicines development, improving treatment outcomes and facilitating earlier patient access to new treatments.  In this context, the third annual Big Data multi-stakeholder forum will take place on 1 December 2022 and will aim to:

- inform stakeholders on the delivery of data activities of the Network Strategy 2025;
- strengthen engagement and collaboration with stakeholders;
- look through a medicines regulatory lens to the European Health Data Space (EHDS).

# EMA/HMA Big Data Stakeholder Forum 2022

**08:30**    Connection to virtual room and technical checks

## 09:00    Welcome and introduction

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

## 09:05    Opening remarks

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

**Olga Solomon**                                                                          **10'**
*Head of Unit "Medicines: policy, authorisation and monitoring", EC*

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

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

*Chair: Jesper Kjær, DKMA*

**Overview of 2022 deliverables and the new plan for 2022-2025**                          **15'**
*Peter Arlett, EMA*

Questions and answers                                                                     **10'**

## 10:00    Session 2: Big Data - DARWIN EU ® and data quality

*Chair: Peter Arlett, EMA*

**DARWIN EU ® – first experiences and regulatory use case**                               **15'**
*Xavier Kurz, EMA*

Use case examples                                                                         **15'**
*Health Technology Assessment bodies: Niklas Hedberg, TLV*
*Payers: Wim Goettsch, Zorginstituut Nederland*

Questions and answers                                                                     **10'**

**EU Data Quality Framework for medicines regulation – launch and collaboration**         **10'**
*Ana Cochino, EMA*

| | Front row comments with stakeholders | **20'** |
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*TEHDAS: Enrique Bernal Delgado*
*Pharmaceutical industry: Lisa Hampson, EFPIA*
*Health Care Professionals: Aldo Pietro Maggioni, ANMCO*
*Patients: George Paliouras, Duchenne Data Foundation*

| | Questions and answers | **10'** |
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| **11:20** | **Coffee break** | |
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| **11:40** | **Session 3: Big Data - data discoverability, skills, processes and capability** | |
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*Chair: Hilmar Hamann, EMA*

| | **EU Real World metadata list, good practice guide and catalogues of data sources and studies** | **10'** |
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*Katerina Deli, EMA*

| | Front row comments with stakeholders | **25'** |
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*Healthcare professionals: Rosa Giuliani, ESMO*
*ENCePP: Rosa Gini, ARS Toscana*
*Research organisation: Irene Kesisoglou, Sciensano*
*Pharmaceutical industry: Gianmario Candore, EFPIA*
*Pharmaceutical industry: Kelly Zou, Medicines for Europe*

| | **Artificial Intelligence in Medicines Regulation – taking stock of initiatives following the AI workshop** | **10'** |
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*Gabriel Westman, MPA*

| | Front row comments with stakeholders | **20'** |
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*Academia: Andre Dekker, Maastricht University*
*Pharmaceutical industry: Thomas Brookland, EFPIA*
*Patients: Julian Isla, Dravet Syndrome European Federation*
*Healthcare professionals: Aldo Pietro Maggioni, ANMCO*

| | Questions and answers | **10'** |
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| **12:55** | **Lunch break** | |
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| **14:00** | **Session 3: Big Data - data discoverability, skills, processes and capability (cont.)** | |
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*Chair: Hilmar Hamann, EMA*

| | **Regulatory capability to analyse data – Clinical Trial Raw Data analysis in medicine evaluation** | **10'** |
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*Joerg Zinserling, BfArM*

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| | Front row comments with stakeholders | **15'** |

*Patients: Angela Bradshaw, Alzheimer Europe*
*Pharmaceutical industry: Hans Ulrich Burger, Roche*
*SME: Prafulla Girase, Alexion*

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| | Questions and answers | **10'** |

## 14:35     Session 4: Big Data - data governance, international and veterinary

*Chair: Peter Bachmann, BfArM*

**Data governance in the European Union – connecting the dots in the medicines regulation area**

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| **European Health Data Space** | **10'** |
| *Jerome de Barros, EC* | |

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| **Towards European Health Data Space - TEHDAS** | **10'** |
| *Shona Cosgrove, TEHDAS* | |

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| **EHDS2 Pilot** | **10'** |
| *Mario Jendrossek, French Health Data Hub* | |

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| Front row comments with stakeholders | **15'** |

*Health Care Professionals: Ilaria Passarani, PGEU*
*Patients: Julian Isla, Dravet Syndrome European Federation*
*SME: Michael Bierl, EUCOPE*

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| **Implementation status of the ERMN Data standardisation strategy** | **10'** |
| *Nick Halsey, EMA* | |

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| Questions and answers | **5'** |

## 15:35     Coffee break

## 15:50     Session 4: Big Data - data governance, international and veterinary (cont.)

*Chair: Peter Bachmann, BfArM*

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| **Collaboration on international initiatives** | **10'** |
| *Sean Barry, HPRA* | |

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| **RWE international collaboration and next steps** | **10'** |
| *Melissa Kampman, Health Canada* | |

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| Questions and answers | **10'** |

**Advanced analytics to support animal and public health - Report from the 2nd Veterinary Big Data Stakeholders Forum** 10'

*Ilaria Del Seppia, EMA*

Questions and answers 5'

## 16:35 View into the future

*Chair: Jesper Kjær, DKMA*

**Overview of research Big Data & RWE under Horizon Europe** 30'

*Christina Kyriakopoulou, EC*

Questions and answers 5'

**Preparing for the future - horizon scanning for big data topics** 10'

*Ralf Herold, EMA*

Front row comments with stakeholders 15'

*Patients: Kaisa Immonen, EPF*

*HTA: Niklas Hedberg, TLV*

*Tech-Medical Devices industry: Giedre Kvedaraviciene, COCIR*

**Opportunities for engagement and concluding remarks** 10'

*Jesper Kjær, DKMA*

*Peter Arlett, EMA*

## 17:45 End of the meeting

## Abbreviations

ANMCO - National Association of Hospital Cardiologists

ARS Toscana - Regional Health Agency of Tuscany

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

COCIR - European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

DKMA – Danish Medicines Agency

EC – European Commission

EFPIA - European Federation of Pharmaceutical Industries and Associations

EMA – European Medicines Agency

ESMO - European Society for Medical Oncology

ENCePP - European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

EPF - European Patients' Forum

EUCOPE - European Confederation of Pharmaceutical Entrepreneurs

HMA - Heads of Medicines Agencies

HPRA - Health Products Regulatory Authority, Ireland

MPA - Medical Products Agency, Sweden

PGEU - Pharmaceutical Group of the European Union

TEHDAS - Towards European Health Data Space

TLV - Dental and Pharmaceutical Benefits Agency, Sweden

## 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, enter the event code "bdforum2022" and passcode "xe6w13". 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.