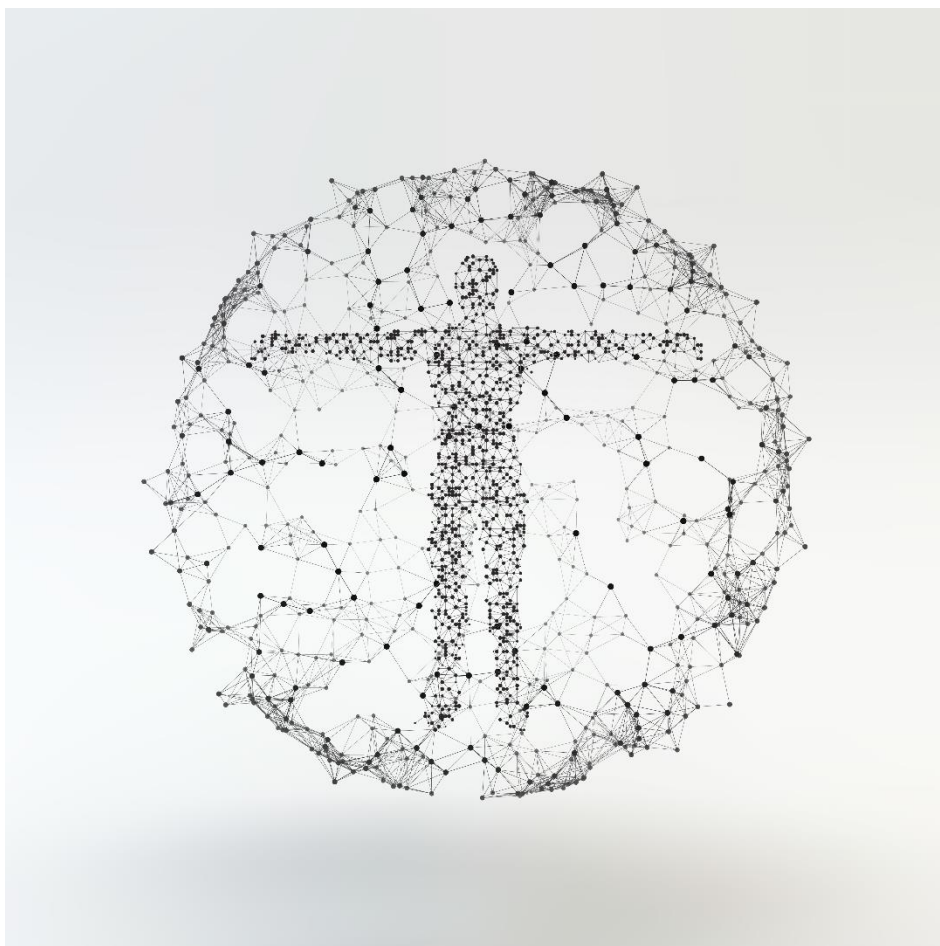


22 February 2022
EMA/77537/2022
Data Analytics and Methods

DARWIN EU®: Multi-stakeholder information webinar

10.30-12.00 CET, Thursday, 24 February 2022

Virtual meeting, European Medicines Agency



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Objectives

In February 2022, EMA initiated the establishment of the Coordination Centre for the Data Analysis and Real World Interrogation Network ([DARWIN EU®](#)). DARWIN EU® will deliver real-world evidence from across Europe on diseases, populations and the uses and performance of medicines.

EMA is working with Erasmus University Medical Center Rotterdam to establish the DARWIN EU® Coordination Centre. The role of the Coordination Centre will be to develop and manage a network of real-world healthcare data sources across the EU and to conduct scientific studies requested by medicines regulators, and later, for other stakeholders. The Coordination Centre will also maintain a catalogue of real-world data sources and metadata for use in medicine regulatory activities.

DARWIN EU® will also act as a pathfinder for the [European Health Data Space \(EHDS\)](#) and will ultimately connect to the EHDS services, enabling the use of the EHDS in the context of medicines regulation in Europe.

DARWIN EU® is the first priority [deliverable](#) of the EMA-HMA Big Data Steering Group workplan and contributes to the delivery of the [European Medicines Agencies Network Strategy to 2025](#).

To foster collaboration and keep DARWIN EU® stakeholders informed, EMA is organising an information webinar on DARWIN EU®. The main objectives of the webinar are to:

- Introduce DARWIN EU® and its aims, goals and deliverables as well as benefits and use cases;
- Present the selected Coordination Centre;
- Inform on next steps and opportunities for collaboration;
- Answer questions from stakeholders.

Agenda

10:00 **Connection to virtual room and technical checks**

10:30 **Welcome and introduction** 10'

Emer Cooke, *Executive Director of EMA and co-chair of the DARWIN EU® Advisory Board*

Karl Broich, *President of BfArM, Chair of HMA Management Group and co-chair of the DARWIN EU® Advisory Board*

10:40 **DARWIN EU®**

Chair: **Peter Arlett**, *EMA*

Introduction to DARWIN EU® 15'

Xavier Kurz, *EMA*

Use cases for Real-World Evidence 10'

Gianmario Candore, *EMA*

Setting up the DARWIN EU® Coordination Centre 15'

Peter Rijnbeek, *Erasmus MC*

Outlook for 2022 5'

Andrej Segec, *EMA*

11:25 **Questions and Answers** 35'

Chair: Peter Arlett, *EMA*

Panellists:

DARWIN EU® Advisory Board members:

NCA Representative and BDSG co-chair: Jesper Kjaer - *DKMA, DK*

EU Payers association representative: Wim Goettsch, *ZINL, NL*

HTA representative: Niklas Hedberg, *TLV, SE*

Data Permit Authorities representative: Katharina Schneider – *BfArM, DE*

TEHDAS representative: Markus Kalliola – *SITRA, FI*

EU Patient association representative: Elizabeth Vroom - *UPPMD*

EU Healthcare professional associations representative: Aldo Maggioni – *ESC*

European Pharmaceutical industry observer: Almath Spooner – *EFPIA, EuropaBio, EUCOPE*

Big Data Steering Group Patient Representative: Marilena Vrana, *EHN*

DARWIN EU® Coordination Centre Representatives: Peter Rijnbeek, Dani Prieto-Alhambra and Katia Verhamme – *Erasmus MC*

EMA topic experts: Xavier Kurz, Gianmario Candore, Andrej Segec, Sabine Brosch and Petroula Lisgara

12:00

End of 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 "DARWINEU". 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

BDSG – [Big Data Steering Group](#)

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

DARWIN EU® – [Data Analysis and Real World Interrogation Network](#)

DKMA – Danish Medicines Agency

EFPIA – European Federation of Pharmaceutical Industries and Associations

EHN – European Heart Network

EMA – [European Medicines Agency](#)

Erasmus MC – Erasmus University Medical Center

ESC – European Society of Cardiology

EUCOPE – European Confederation of Pharmaceutical Entrepreneurs

GDPR – General Data Protection Regulation

HMA – [Heads of Medicines Agencies](#)

SITRA – Finnish Innovation Fund

TEHDAS – [Towards the European Health Data Space](#)

TLV – Dental and Pharmaceutical Benefits Agency, Sweden

UPPMD – World Duchenne Organization

ZINL – Zorginstituut Nederland