DARWIN EU®: Multi-stakeholder information webinar

10.30-12.00 CET, Thursday, 24 February 2022
Virtual meeting, European Medicines Agency
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

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®
Xavier Kurz, EMA

Use cases for Real-World Evidence
Gianmario Candore, EMA

Setting up the DARWIN EU® Coordination Centre
Peter Rijnbeek, Erasmus MC

Outlook for 2022
Andrej Segec, EMA

11:25 Questions and Answers

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](http://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](http://www.ema.europa.eu).
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