

BIG DATA HIGHLIGHTS

Quarterly update on implementation activities of the
HMA-EMA Big Data Steering Group workplan

An agency of the European Union



Editorial



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Welcome to the first edition of the newsletter on Big Data which reports on the implementation of the [HMA-EMA Big Data Steering Group workplan 2021-2023](#) and the data and digital pillar of the [Network Strategy 2025](#).

The BDSG was established in May 2020 with the mandate to take forward and advise on implementation of the priority recommendations set out in the [Big Data Task Force final report \(phase two\)](#). The vision, set out by the Big Data Taskforce that guides delivery of the workplan is that:

“ *by delivering a regulatory system able to integrate Big Data into its assessment and decision making, we can support the development of innovative treatments more quickly and optimise the safe and effective use of medicines.* ”

Big Data Task Force Final Report, Dec 2019

Already in 2021, we have seen an impressive array of activities and outputs that support transformation to data-driven medicines regulation. These include the finalisation of the [network's data standardisation strategy](#) and a series of technical workshops covering standardisation, real-world data, artificial intelligence, veterinary data and real-world evidence. More details on the 2021 deliverables are included later in this newsletter.

Moving forward, we are excited to be able to share with you more regular updates on big data and the implementation of the BDSG workplan via this newsletter. We look forward to collaborating and leveraging the work of stakeholders to increase the utility of big data in medicines regulation.

[The Big Data Steering Group](#) welcomes your feedback and questions you may have by email at bigdata@ema.europa.eu.

We hope you find the Big Data Highlights informative!

Featured topics

DARWIN EU®: initiation of Coordination Centre



On 9 February 2022, EMA initiated the establishment of the Coordination Centre for the Data Analysis and Real World Interrogation Network ([DARWIN EU®](#)): see [EMA press release](#)

The role of the Coordination Centre is 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, at a later stage, also requested by other stakeholders.

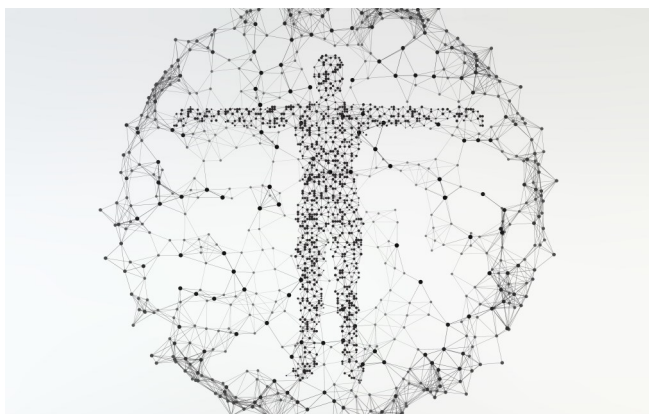
By supporting decision-making on medicines, a wide range of stakeholders will benefit, from patients and healthcare professionals to health technology assessment bodies, payers and the pharmaceutical industry. Additionally, DARWIN EU® will provide an invaluable resource to prepare for and respond to future healthcare crises and pandemics.

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.

EMA will be working with Erasmus University Medical Center Rotterdam to establish the DARWIN EU® Coordination Centre. The contract was awarded to Erasmus University Medical Center Rotterdam following an open call for tender for a service provider published in June 2021.

A [multi-stakeholder webinar](#) to introduce the establishment of DARWIN EU®, highlight opportunities for collaboration and answer questions will be held on 24 February 2022.

Further information: [DARWIN EU® webpage](#).



Regulatory capability to analyse data: pilot on raw data use

EMA, in partnership with the Advisory Group on Raw Data comprising representatives of the Big Data Steering Group, NCAs, EMA committees and working parties and patients representatives, is preparing a pilot to clarify the benefits and practicalities of access to individual (raw) patient data from clinical trials in the assessment of medicines. The pilot, which is expected to start in the second quarter of 2022, will analyse raw data from selected marketing authorisation applications to support the CHMP assessment. The results of the pilot, expected in 2023, will help the EU medicines regulatory network to make an informed decision on the place of raw data in regulatory decision-making.

International initiatives: data standardisation strategy

In December 2021, EMA and HMA published the [European Medicines Regulatory Network data standardisation strategy](#). The strategy sets out principles to guide the definition, adoption and implementation of data standards according to the network's needs related to data submitted throughout the lifecycle of medicinal products. It aims to:

- Enable quicker uptake of international data standards across the EU;
- Improve data quality;
- Enable data linkage and data analysis to support regulatory decision-making.

The strategy will support the creation and implementation of internationally applicable data standards in line with the data pillar of the [Network Strategy to 2025](#). The strategy is a living document and will be updated over time to reflect changing priorities and new requirements.

Big Data Steering Group Annual Report 2021

The second [BDSG workplan 2021-2023](#) was published in August 2021 to continue progressing activities launched in 2020 and to address new topics.

Despite a challenging year posed by the ongoing COVID-19 pandemic, significant progress continued in 2021 to realise the Big Data Steering Group workplan and to enable the data transformation of the EU regulatory network in line with the [EU Network Strategy to 2025](#).

Summary of BDSG highlights 2021

DARWIN EU®

Progress on the DARWIN EU® Coordination Centre selection • Support to the EHDS pilot planning • Establishment of the DARWIN EU® Advisory group

Data quality & representativeness

Selection of the Consortium to deliver a draft EU data quality framework

Data discoverability

Study of metadata for real-world data completed • POC for metadata repository delivered • Consultation on metadata for real-world data, including a stakeholder workshop

EU Network skills

Big Data training signpost made available in EU-NTC • Data science curriculum adopted • Survey of skills completed • Market research for training delivery outsourcing completed

EU Network processes

Learnings initiative workshop held • RWE use cases developed / pilot initiated with PRAC, PDCO, COMP, SAWP • Discussion initiated with CAT, CMDh, CHMP • Exploratory discussion initiated with HTA bodies and payers

Network capability to analyse

Pre-pilot on raw data analysis completed • Design initiated of CHMP pilot for clinical raw data analysis of MAAs • Advisory Group on Raw Data established • Scientific information dossier pilot on advanced analytics initiated • Discussion on Clusters of Excellence • AI workshop held

Delivery of expert advice

EMA Management Board agreed on the creation of a methodologies working party • ENCePP RWE methods guide updated • New CHMP guideline on registry based studies published

Governance framework

BDSG recommendations on ethics advice completed • Collaboration with EC on EHDS and TEHDAS initiated

International initiatives

Progress on RWE international Collaboration Roadmap • Data standardisation strategy published, including a stakeholder workshop • Collaboration workshops on COVID-19 observational studies organised through ICMRA

EU stakeholder implementation forum

2nd Big Data multi-stakeholder forum held

Veterinary recommendations

Workshop on the Veterinary Data Strategy held

Veterinary data strategy

In November 2021 the Veterinary Big Data team, comprising of EMA and NCAs representatives, has shared the first proposal to establish an EU Veterinary Big Data strategy with Heads of Medicines Agencies. Active discussion on the use of big data in the veterinary domain is ongoing and an update will be included in a future issue of the Big Data Highlights.

Getting involved

Upcoming events

Multi-stakeholder information webinar on DARWIN EU®

24 February 2022



Industry and ENCePP consultation on creation of a real-world data resource and studies catalogues

February 2022

Multi-stakeholder workshop on Data Quality

Q1 2022 (Date TBC)

Recent events

Learnings initiative webinar for optimal use of big data for regulatory purpose

30 November 2021



EU Big Data Stakeholder Forum

7 December 2021



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