

Third Veterinary Big Data Stakeholder Forum

23 November 2023

Session 1: Progress update and report at EU-level - EMA/HMA Big Data Steering Group

Presented by Jesper Kjaer
DKMA, Co-chair of HMA-EMA Big Data Steering Group

Content



Drivers for change



HMA EMA Big Data Task Force vision and Big Data priority recommendations



Key achievements in 2023



BDSG workplan 2023-2025 - Future highlights

- EU network mandate:
 - HMA EMA Big Data Task Force recommendations
 - EU Regulatory Network Strategy to 2025
- Changing policy environment:
 - European Health Data Space
 - Pharmaceutical Strategy for Europe
- Changing technological environment:
 - importance of AI to the work of EU network has increased significantly
 - Experimentation on AI and analytics has also increased significantly
- Slow speed of product development
- Burden of unmet medical need
- Better:
 - healthcare data access,
 - study methods
 - advanced analytics



*"By delivering the vision of **a regulatory system able to integrate Big Data into its assessment and decision making**, we can support the development of innovated medicines, deliver life-saving treatments to patients more quickly and optimise the safe and effective use of medicines through measurement of a products performance on the market."December 2019*

*"**Knowing when and how to rely in novel technologies, and the evidence generated from Big Data**, will benefit public health"December 2019*

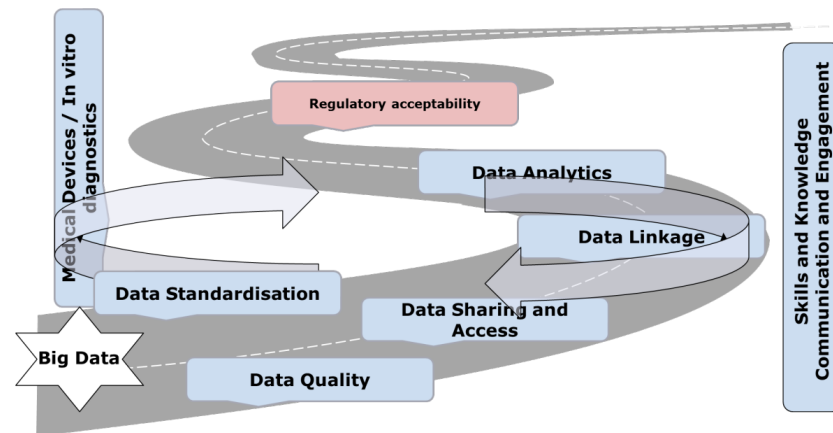


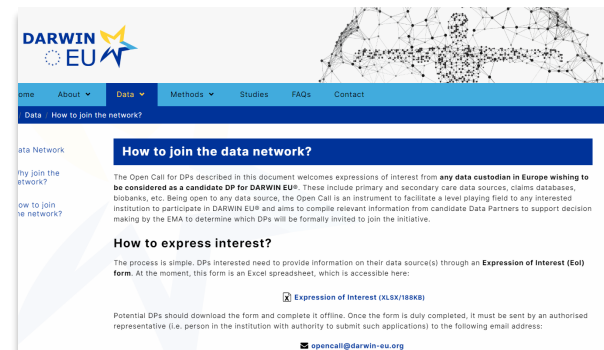
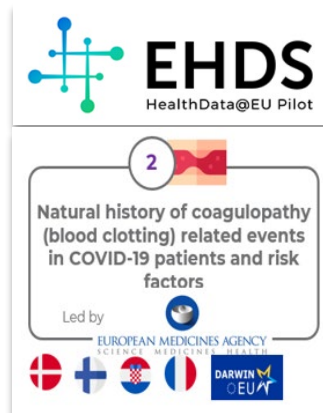
Figure 1: The Road to Regulatory acceptability: an integrated strategy reflecting core recommendations to support the use of Big Data in the assessment and monitoring of medicinal products in Europe. The individual steps are not necessarily sequential, may not be required across all datasets, many are interdependent and all will require active and iterative communication between all stakeholders.

4th Big Data Workplan 2023-2025 published in July 2023

Key achievements in 2023

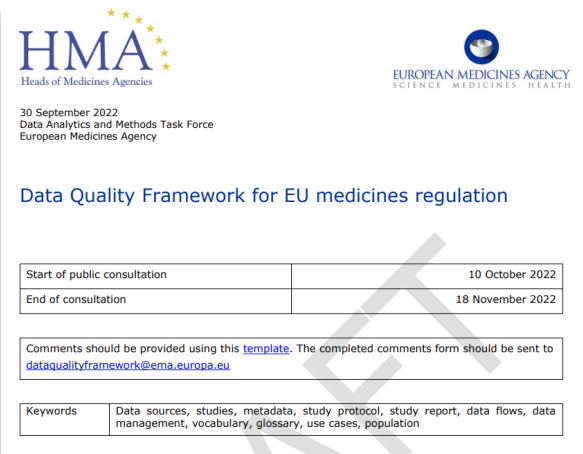
1. DARWIN EU ®

- DARWIN EU celebrates 1st birthday:
 - 2nd year of operation: Support majority of Committees in decision-making with reliable RWE
 - 2nd call for 10 additional data partner → +108 million active patients
 - 19 studies planned (incl. ECDC, Vaccines Monitoring Platform, HTA/Payers) and 5 studies already completed
 - Launch of [DARWIN EU® website](#)
- [EHDS HealthData@EU Pilot](#): EMA/DARWIN EU use case on coagulopathy of COVID-19



2. Data quality & Representativeness

- Adoption of data quality framework for EU Medicines regulation by MWP and CHMP - publication by end of 2023
- Preparation of RWD/RWE data quality consideration for public consultation in early 2024



Key achievements in 2023

3. Data discoverability

- Early 2024: Launch catalogues & updated Good practice guide the use of real-world metadata
- Catalogue of data sources → enhance & replace the [ENCePP Resources Database](#)
- Catalogue of non-interventional studies → enhance & replace the [European Union electronic register of post-authorisation studies](#) (EU PAS Register®)

Search Catalogues

Filter options

Document type

☐ Data source

☐ Institution

☐ Network

☒ Study

Country

Select Value

Data source type

Choose

ENCePP Seal

☒ Yes

Study type

Choose

Scope of the study

Select Value

Study topic

Select Value

Results (4)

Sort by: Relevance first

Study

Long term, prospective, observational cohort study evaluating the safety profile in patients with highly active relapsing multiple sclerosis (RMS) newly started on oral cladribine (CLARION)

Australia First published: 19/09/2023 Last updated: 19/09/2023

Canada

Denmark

Norway

Study Ongoing

France

Accuracy of Pleth Variability Index (PVI) in Predicting Response to Intravenous Fluid load During Scoliosis Surgery in Children.

First published: 19/09/2023 Last updated: 19/09/2023

Study Planned

United States

Misuse and Abuse of Loperamide in the United States

First published: 19/09/2023 Last updated: 20/09/2023

Study Studied

The risk of cardiovascular adverse effects associated with JAK inhibitors in rheumatoid arthritis: a protocol for a systematic review and meta-analysis

Italy

Spain

First published: 19/09/2023 Last updated: 19/09/2023

Study Studied

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

1 September 2022
EMA/787647/2022
European Medicines Agency

Good Practice Guide for the use of the Metadata Catalogue of Real-World Data Sources
V 1.0

Start of public consultation	27 September 2022
End of consultation	16 November 2022

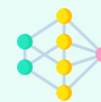
Comments should be provided using this [template](#). The completed comments form should be sent to metadata@ema.europa.eu

Keywords	Data sources, studies, metadata, study protocol, study report, data flows, data management, vocabulary, glossary, use cases, population
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Enhanced Data Visibility and Accessibility



Continuous Improvement and Interoperability



Transparency and Collaboration



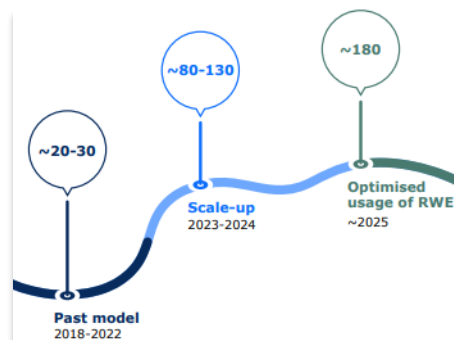
4. EU Network skills

- Preparation of the roll-out of the first training modules for the EU regulatory network on Data Science and Pharmacoepidemiology.

Key achievements in 2023

5. EU Network processes

- Publication of RWE study review , incl. use cases
- RWE studies for COVID-19
- RWE Pilots with EMA Scientific committees: PDCO, COMP, SAWP, CAT, CHMP, CMDh



EMA's 3 main pathways for RWE generation

RWD can come from marketing authorisation applicants/holders, academia or national competent authorities. EMA can access RWD as follows:



EMA studies

Conducted by EMA's RWD analysts in collaboration with requester through direct access to 6 European primary healthcare data sources.



Framework contracts

Studies commissioned to research organisations and consortia with access to specialised data and expertise.

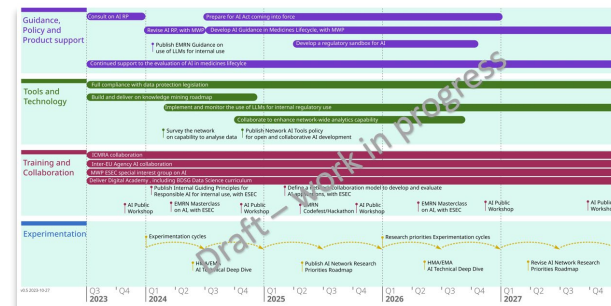


DARWIN EU®

Studies conducted via a federated network of data, expertise and comprehensive services with access to data partners and sets of analyses.

6. EU Network capability to analyse

- 5th product data submitted for CHMP clinical trial raw data pilot
 - Interim report planned in 2024
- Adoption of Multi-year AI workplan
- Experimentation of advanced analytics, including AI, and preparation for next year release of the 1st AI knowledge management tool for core regulatory processes, starting with Scientific Advice Working Party



Key achievements in 2023

7. Delivery of expert advice

- Methodology Working Party (MWP) established - [2nd workplan](#) under public consultation
- MWP ESEC established with more than 180 experts , including AI (51) and RWE (79)
- Public consultation on the [reflection paper on the use of AI in the medicinal product lifecycle](#)

30 October 2023
EMA/CHMP/478317/2023
Human Medicines Division

Draft revised consolidated 3-year work plan for the Methodology Working Party (MWP)

Chairperson:	Kit Roes
Vice chair:	Kristin Karlsson

Agreed by Methodology Working Party	October 2023
Adopted by PRON for release for consultation	30 October 2023
Start of public consultation	1 November 2023
End of consultation (deadline for comments)	30 November 2023

Comments should be provided using this [EUSurvey form](#). For any technical issues, please contact the [EUSurvey Support](#).

13 July 2023
EMA/CHMP/CVMP/63633/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle
Draft

Draft agreed by Committee for Medicinal Products for Human Use (CHMP) Methodology Working Party	July 2023
Draft adopted by CVMP for release for consultation	13 July 2023
Draft adopted by CHMP for release for consultation	10 July 2023
Start of public consultation	19 July 2023
End of consultation (deadline for comments)	31 December 2023

Comments should be provided using this [EUSurvey form](#). For any technical issues, please contact the [EUSurvey Support](#).

8. Governance framework

- Annual update of the [BDSG workplan 2023-2025](#)
- Review of Network data governance completed with updated [mandate](#) and [membership](#): strengthen representation of EHDS, CTCG, HTA/Payers, ethic bodies or networks
- Data protection training for medicines and public health delivered to experts in National competent authorities
- Support EHDS and Pharma Strategy

Big Data Workplan 2023-2025

HMA/EMA joint Big Data Steering Group



A European Health Union:
Pharmaceutical strategy for Europe

Key achievements in 2023

9. International initiatives

- Planning of RWE guidance
- Consultation on [ICH reflection paper on RWE terminologies and studies](#): 150+ comments received
- Consultation on [ICH M14 Use of RWD for safety assessment of medicines](#)
- ICMRA support to re-purpose the COVID-19 Real-World Evidence and Observational Studies Working Group to focus on RWE in public health emergencies



ICH harmonisation for better health

30 June 2023
EMA/CHMP/ICH/255401/2023
Committee for Human Medicinal Products

ICH Reflection paper on proposed international harmonisation of real-world evidence terminology and convergence of general principles regarding planning and reporting of studies using real-world data, with a focus on effectiveness of medicines

Transmission to CHMP	30 June 2023
Adoption by CHMP	30 June 2023
Release for public consultation	30 June 2023
Deadline for comments	30 September 2023

10. Stakeholder engagement

- [Workshop on RWD quality and RWE use](#)
- [2nd AI workshop – smart regulation in a rapidly evolving world](#)
- Two Bi-annual BDSG and industry meetings
- [Big data newsletters](#)
- [4th Big Data multistakeholder forum](#)

Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) AI workshop – Smart regulation in a rapidly evolving world

Table of contents

- Event summary
- Documents
- Registration

📅 **Date:** 20/11/2023 to 21/11/2023

📍 **Location:** European Medicines Agency, Amsterdam, the Netherlands

Event summary

The joint HMA/EMA workshop is one of the priorities identified in the HMA/EMA Strategic Plan 2022-25, focusing on these priorities as well as on digital transformation.

The objectives of this workshop are to:

- engage stakeholders with a focus on medicines RWE
- inform on the HMA/EMA and EMA activities
- discuss with stakeholders a



Multi-stakeholder workshop on Real World Data (RWD) quality and Real World Evidence (RWE) use

26-27 June 2023
Hybrid meeting / EMA, Amsterdam

03 June 2023

HMA
Heads of Medicines Agencies

EMA
European Medicines Agency

BIG DATA HIGHLIGHTS

Quarterly update on implementation activities of the Joint Big Data Steering Group workshop

Editorial

Big data for medicines regulation and better health: publication of Big Data Steering Group workshop 2022-25

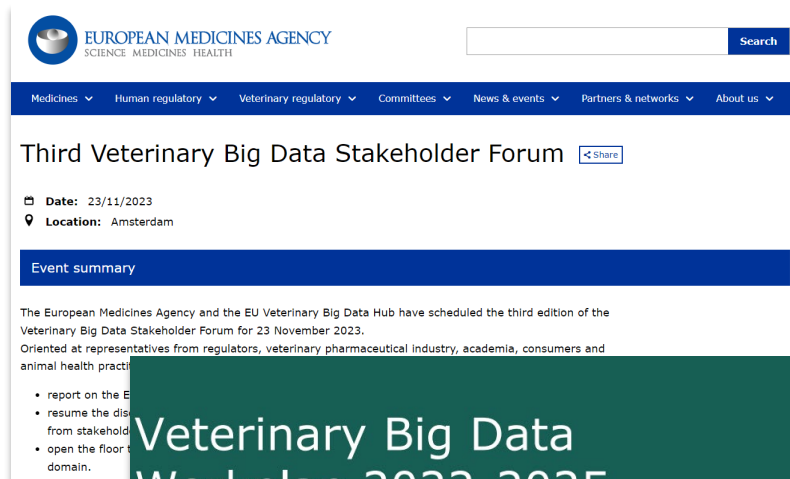
Profer Artelt
Co-Chair of Big Data Steering Group, EMA

Jesper Kjær
Co-Chair of Big Data Steering Group, EMA

The workshop was held on 26-27 June 2023, in Amsterdam, the Netherlands. It was the first of a series of workshops that will be held in 2023 and 2024. The workshop was held in a hybrid format, with participants attending in person and online. The workshop was held in a hybrid format, with participants attending in person and online. The workshop was held in a hybrid format, with participants attending in person and online.

11. Veterinary recommendations

- Adoption of the [EU Veterinary Big Data Workplan to 2022-2025](#)
- Establishment of the EU Veterinary data hub establishment
- 3rd Veterinary Big Data stakeholder forum



The screenshot shows the European Medicines Agency (EMA) website. The header includes the EMA logo and navigation links: Medicines, Human regulatory, Veterinary regulatory, Committees, News & events, Partners & networks, and About us. A search bar is located in the top right. The main content area is titled 'Third Veterinary Big Data Stakeholder Forum' with a 'Share' button. Below the title, the date is listed as 23/11/2023 and the location as Amsterdam. A section titled 'Event summary' follows, containing text about the forum's purpose and a bulleted list of topics to be discussed.

EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

Medicines ▾ Human regulatory ▾ Veterinary regulatory ▾ Committees ▾ News & events ▾ Partners & networks ▾ About us ▾

Third Veterinary Big Data Stakeholder Forum [Share](#)

📅 **Date:** 23/11/2023
📍 **Location:** Amsterdam


Event summary

The European Medicines Agency and the EU Veterinary Big Data Hub have scheduled the third edition of the Veterinary Big Data Stakeholder Forum for 23 November 2023. Oriented at representatives from regulators, veterinary pharmaceutical industry, academia, consumers and animal health practitioners, the forum will:

- report on the E
- resume the dis
- from stakehold
- open the floor
- domain.

Veterinary Big Data
Workplan 2022-2025

BDSG workplan 2023-2025 - Future highlights

<p>DARWIN EU ®</p> 	<p>Gradual increase of studies and data partners Support national regulatory use cases continued leanings from RWE pilots EMA committees phased routine access to RWE</p>	<p>Review use of CT Raw POC of nonclinical raw data analysis Experimentation of advanced analytics, incl. AI</p>	<p>EU CAPABILITY TO ANALYSE</p>
<p>DATA QUALITY AND REPRESENTATIVENESS</p>	<p>Real World Data (RWD) quality considerations Advice on revised data qualification process Continued collaboration with EHDS</p>	<p>Plan for RWE guidance at EU and International level Strengthen EU Specialist Expert Community Publish AI reflection paper</p>	<p>DELIVERY OF EXPERT ADVICE</p>
<p>DATA DISCOVERABILITY</p>	<p>Launch real-world data and studies catalogues Intensification of engagement with patients' organisations on patient experience data Review utility of eHealth data and social media</p>	<p>Deliver Network Data Strategy Support TEHDAS, EHDS and Pharma Strategy</p>	<p>GOVERNANCE FRAMEWORK</p>
<p>EU NETWORK SKILLS</p>	<p>Roll-out training to regulators on pharmacoepidemiology and data science Targeted training for patients, HCPs & academics Adopt genomics curriculum</p>	<p>Strengthen ICMRA collaboration on RWE in public health emergencies Plan for RWE guidance at ICH international level</p>	<p>INTERNATIONAL INITIATIVES</p>
<p>EU NETWORK PROCESSES</p>	<p>Report on RWE in regulatory decision-making Development of use cases for genomics & PED data</p>	<p>Workshops on RWE methodologies/research Workshop on registries Continue stakeholder engagement</p>	<p>STAKEHOLDER ENGAGEMENT</p>
		<p>Implementation of the Veterinary big data workplan 2022-2025 data strategy Develop data sources catalogue Continue stakeholder engagement</p>	<p>VETERINARY RECOMMENDATIONS</p>

More information



[Big Data](#)

[Clinical Trials and ACT EU](#)



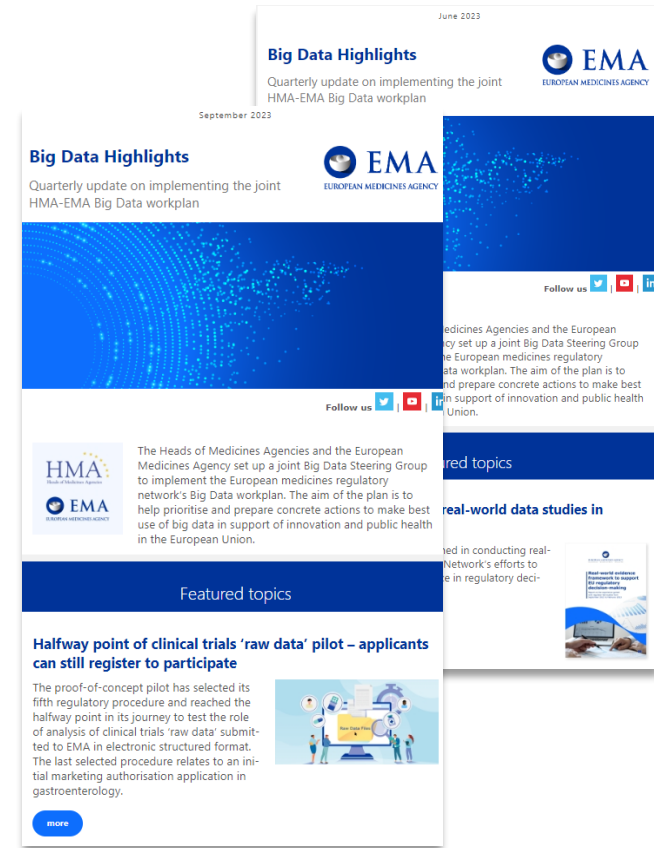
[Big Data Highlights](#)

(Subscribe at: bigdata@ema.europa.eu)

[Clinical Trials Highlights](#)



[EMA events](#)



Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is
an agency of the European Union

