

## EU Big Data Stakeholder Forum 2023

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04 December 2023

Session 1: Report on implementation of the HMA-EMA Big Data Task Force priority recommendations - 4th year into our journey to data driven regulation

Presented by Dr. Peter Arlett  
Head of Data Analytics and Methods Task Force (EMA), 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



Future perspective on Clinical evidence

- 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
- 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 on novel technologies, and the evidence generated from Big Data**, will benefit public health" ....December 2019*

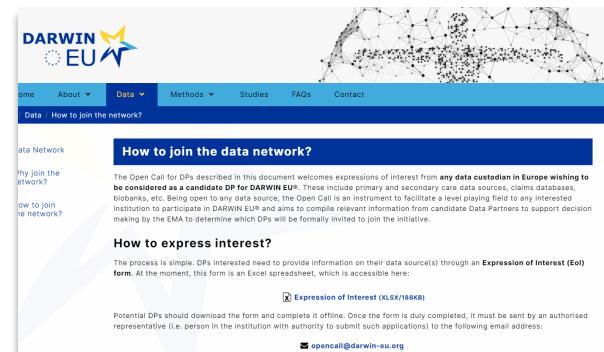
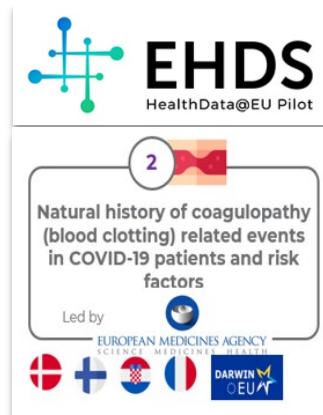


[4<sup>th</sup> Big Data Workplan 2023-2025](#) published in July 2023

# Key achievements in 2023

## 1. DARWIN EU ®

- DARWIN EU celebrates 1<sup>st</sup> birthday:
  - 2<sup>nd</sup> year of operation: Supports EMA Committees in decision-making with reliable RWE
  - 2<sup>nd</sup> call for additional data partner → 20 data partners by Q1 2024
  - 19 studies initiated (including 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 CHMP - publication by end of 2023
- RWD/RWE data quality consideration in progress (for public consultation in early 2024)

30 October 2023  
Data Analytics and Methods Task Force  
EMA/326985/2023

### Data Quality Framework for EU medicines regulation

Draft agreed by BDSG for release for consultation	10 October 2022
End of consultation (deadline for comments)	18 November 2022
Agreed by BDSG and MWP	30 June 2023
Adopted by CHMP	30 October 2023

Keywords	Data quality framework, medicines regulation, data quality dimensions, primary and secondary use of data
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# Key achievements in 2023

## 3. Data discoverability

- Early 2024: Launch catalogues of real-world data and evidence
- 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:

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 Finalised

Italy The risk of cardiovascular adverse effects associated with JAK inhibitors in rheumatoid arthritis: a protocol for a systematic review and meta-analysis First published: 19/09/2023 Last updated: 20/09/2023

Study Finalised

Spain

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

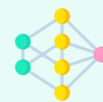
Comments should be provided using this [template](#). The completed comments form should be sent to [metadata@ema.europa.eu](mailto:metadata@ema.europa.eu)

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



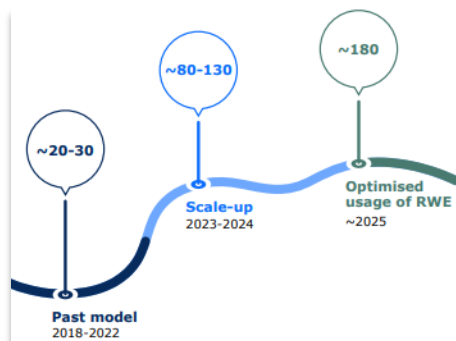
## 4. EU Network skills

- Roll-out of the first training modules for the EU regulatory network:
- Data Science curriculum
- Pharmacoepidemiology curriculum.

# Key achievements in 2023

## 5. EU Network processes

- Publication of RWE study review
- RWE studies delivered for COVID-19
- RWE studies: routine support to PRAC
- RWE Pilots with: 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.



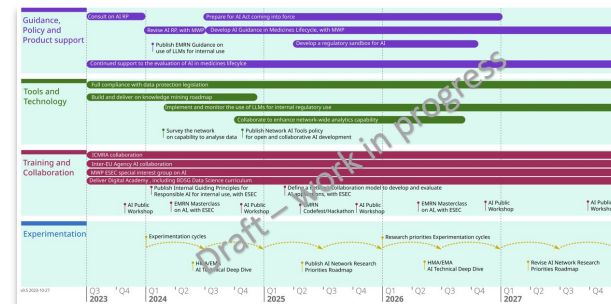
**Framework contracts**  
Studies commissioned to research organisations and consortia with access to specialised data and expertise.



**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

- Data of 5<sup>th</sup> product submitted for CHMP clinical trial raw data pilot
  - Interim report planned in 2024
- Adoption of Multi-year AI workplan
- 1<sup>st</sup> AI knowledge management tool released to the Network in Q1 2024 - starts with Scientific Advice Working Party



# Key achievements in 2023

## 7. Delivery of expert advice

- Methodology Working Party (MWP) established - [2<sup>nd</sup> workplan](#) under public consultation
- MWP ESEC (expert community) 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/CHMP/63853/2023  
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

- 4<sup>th</sup> annual update of the [BDSG workplan 2023-2025](#)
- Review of Network data governance completed with updated [mandate](#) and [membership](#) for BDSG and Network Data Board
- 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 existing COVID-19 Real-World Evidence Working Group to focus on RWE in public health emergencies



ICH  
harmonisation for better health

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SCIENCE MEDICINES 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

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- Documents
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Event summary

The joint HMA/EMA workshop is...

Location: European Medicines Agency, Amsterdam, the Netherlands

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HMA  
Heads of Medicines Agencies

EMA  
EUROPEAN MEDICINES AGENCY

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  
EMA Big Data Steering Group workplan

Editorial

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

Peter Artelt  
Chairman of Big Data  
Steering Group, EMA

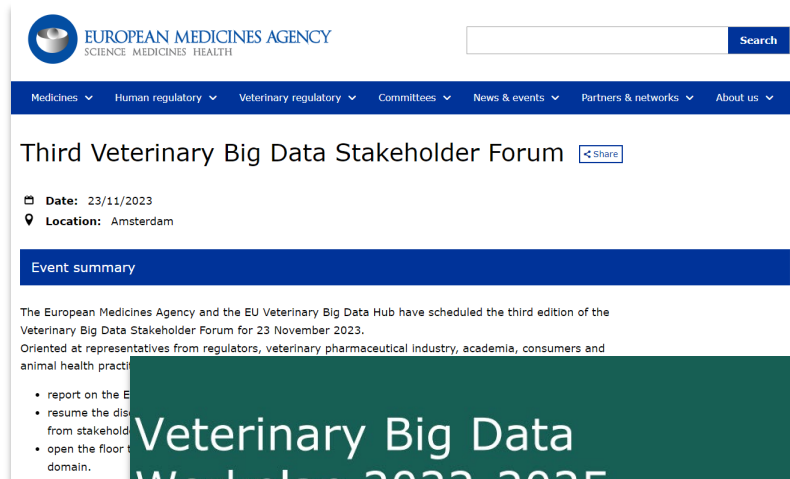
Jesper Kjær  
Chairman of Big Data  
Steering Group, EMA

The new steering data initiative and the  
increased use of Big Data for medicines  
regulation and evidence. In a world of ever-increasing  
data, the challenge is to harness this data to  
improve medicines regulation and evidence.  
The EMA Big Data Steering Group workplan  
2022-25 outlines the strategy for this.  
The workplan focuses on the  
quality of data, the use of data, and the  
governance of data. The workplan  
is a key document for the EMA  
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Steering Group and will be updated  
in 2025 to the next Big Data  
Steering Group workplan.

## 11. Veterinary recommendations

- Adoption of the [EU Veterinary Big Data Workplan to 2022-2025](#)
- Establishment of the EU Veterinary data hub
- 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 features the title '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 a paragraph about the forum 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:

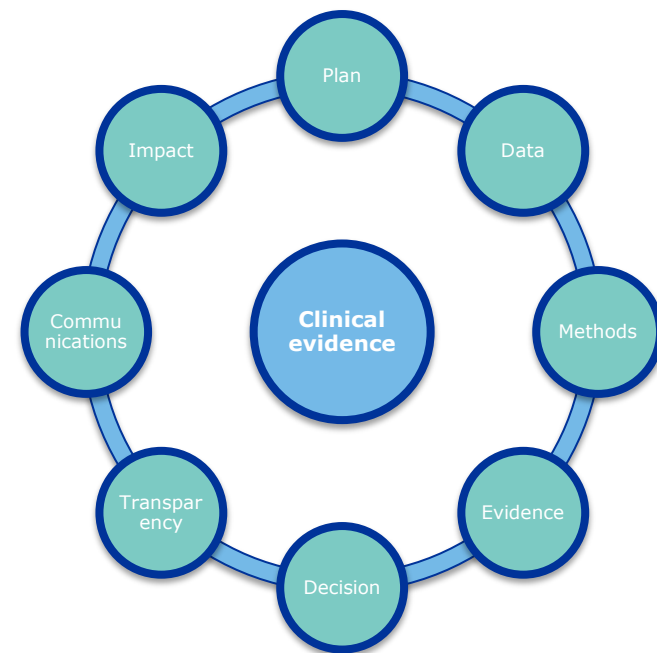
- report on the E
- resume the dis
- from stakehold
- open the floor
- domain.

Veterinary Big Data  
Workplan 2022-2025

# BDSG workplan 2023-2025 - Future highlights

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

- Evidence generation is planned and guided by data, knowledge, and expertise
- Research question drives evidence choice: embraces spectrum of data and methods
- Clinical trials remain core but are bigger, better and faster
- Evidence generated from Real-world data, clinical trial raw data and patient experience data is enabled and value is established
- Evidence generation and assessment are supported by advanced technologies including AI
- Through public searchable catalogues, data are discoverable and of known quality and representativeness
- Suite of EU and international guidelines and standards available will help industry and regulators develop and supervise medicines
- The patient and healthcare professional voices guide every step of the way and high levels of transparency underpin societal trust
- HTAs/Payers benefits from additional evidence



Big Data Workplan  
2023-2025

HMA/EMA joint Big Data Steering Group

# More information



[Big Data](#)

[Clinical Trials and ACT EU](#)



[Big Data Highlights](#)

(Subscribe at: [bigdata@ema.europa.eu](mailto:bigdata@ema.europa.eu))

[Clinical Trials Highlights](#)



[EMA events](#)



# Thank you for listening

## Further information

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### See websites for contact details

**Heads of Medicines Agencies** [www.hma.eu](http://www.hma.eu)  
**European Medicines Agency** [www.ema.europa.eu](http://www.ema.europa.eu)

The European Medicines Agency is  
an agency of the European Union

