HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Drivers for change

- 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

HMA EMA Big Data vision and Big Data Priority Recommendations

*"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

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

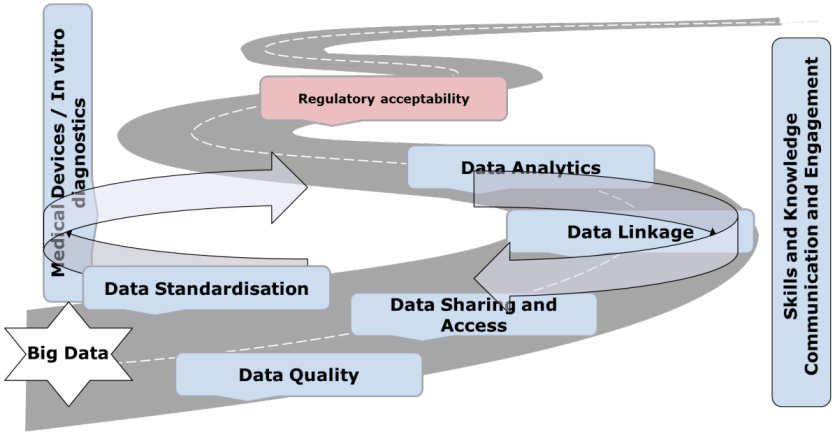


Figure 1: The Road to Regulatory acceptability: an integrated strategy reflecting core recommendations to support the use of Big Data in the assessment and monitoring of medicinal products in Europe. The individual steps are not necessarily sequential, may not be required across all datasets, many are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

Key achievements in 2023

1. DARWIN EU ®

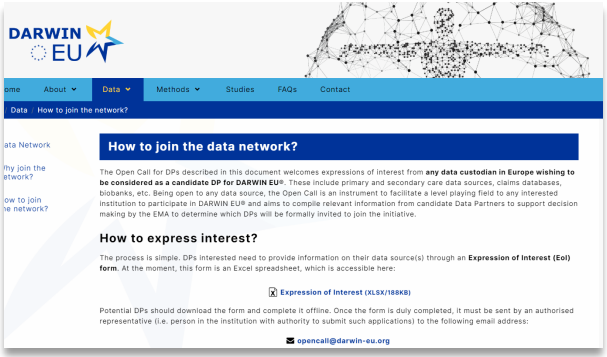
- DARWIN EU celebrates 1st birthday:
  - 2nd year of operation: Support majority of Committees in decision-making with reliable RWE
  - 2nd call for 10 additional data partner → +108 million active patients
  - 19 studies planned (incl. ECDC, Vaccines Monitoring Platform, HTA/Payers) and 5 studies already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

EHDS HealthData@EU Pilot

2

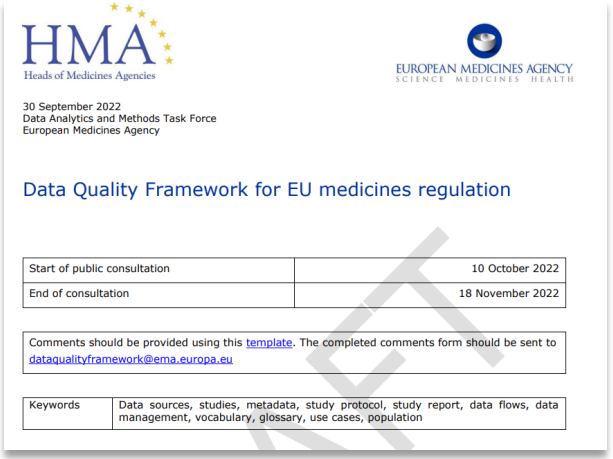
Natural history of coagulopathy (blood clotting) related events in COVID-19 patients and risk factors

Led by EUROPEAN MEDICINES AGENCY



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



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EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

30 September 2022
Data Analytics and Methods Task Force
European Medicines Agency

Data Quality Framework for EU medicines regulation

Start of public consultation	10 October 2022
End of consultation	18 November 2022

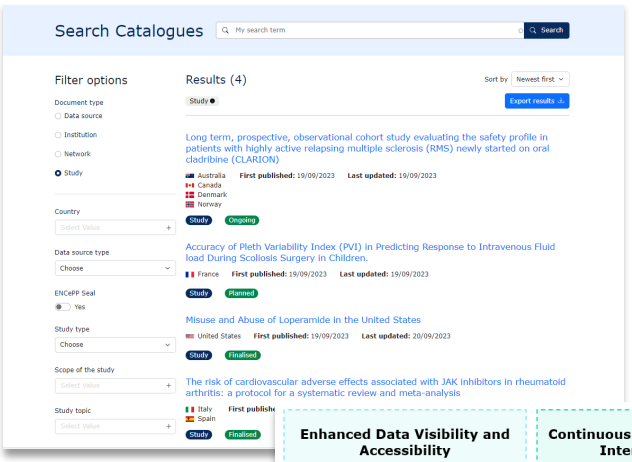
Comments should be provided using this template. The completed comments form should be sent to dataqualityframework@ema.europa.eu

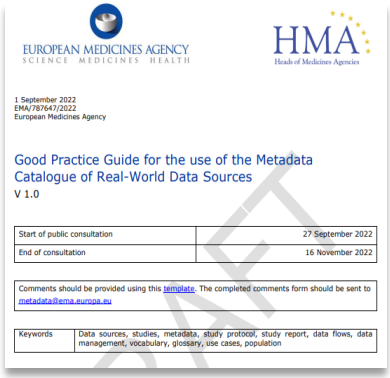
Keywords	Data sources, studies, metadata, study protocol, study report, data flows, data management, vocabulary, glossary, use cases, population

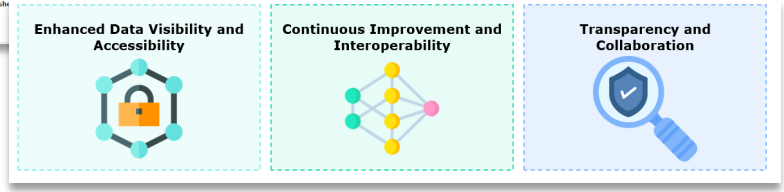
Key achievements in 2023

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®)







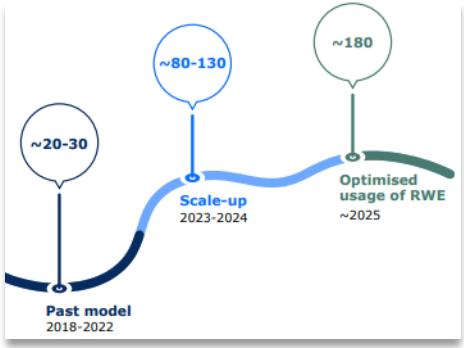
4. EU Network skills

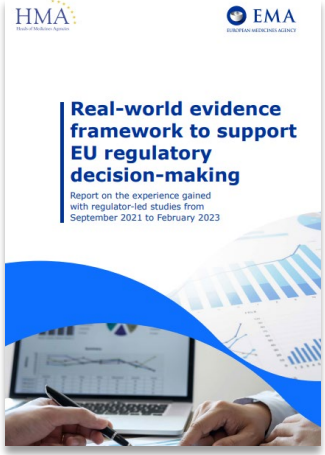
- Preparation of the roll-out of the first training modules for the EU regulatory network on Data Science and Pharmacoepidemiology.

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:

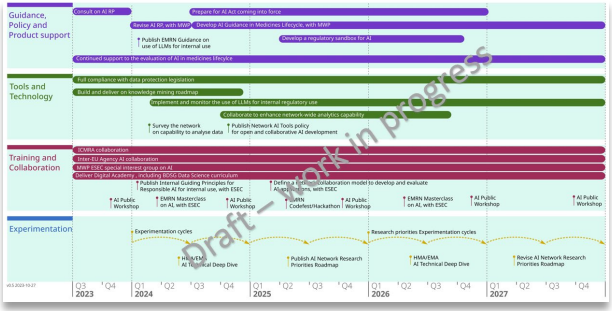
EMA studies
Conducted by EMA's RWD analysts in collaboration with requester through direct access to 6 European primary healthcare data sources.

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

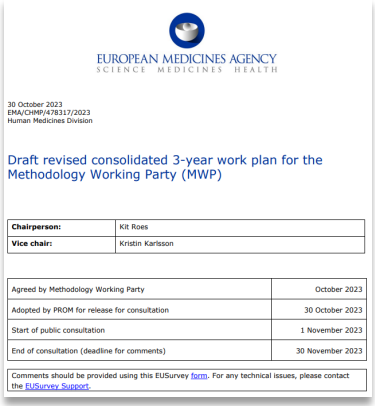
- 5th product data submitted for CHMP clinical trial raw data pilot
  - Interim report planned in 2024
- Adoption of Multi-year AI workplan
- Experimentation of advanced analytics, including AI, and preparation for next year release of the 1st AI knowledge management tool for core regulatory processes,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



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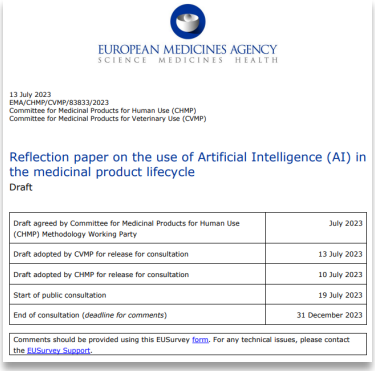
30 October 2023
EMA/CHMP/47817/2023
Human Medicines Division

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 PROM 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.



EUROPEAN MEDICINES AGENCY
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13 July 2023
EMA/CHMP/CVMP/83833/2023
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

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

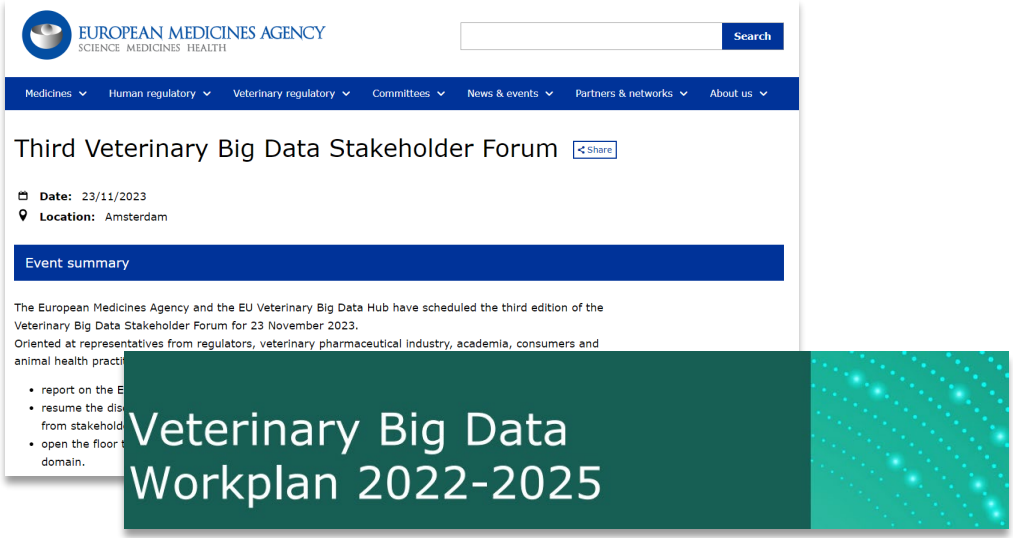
10. Stakeholder engagement

- 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

Key achievements in 2023

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



BDSG workplan 2023-2025 - Future highlights

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

More information

Big Data

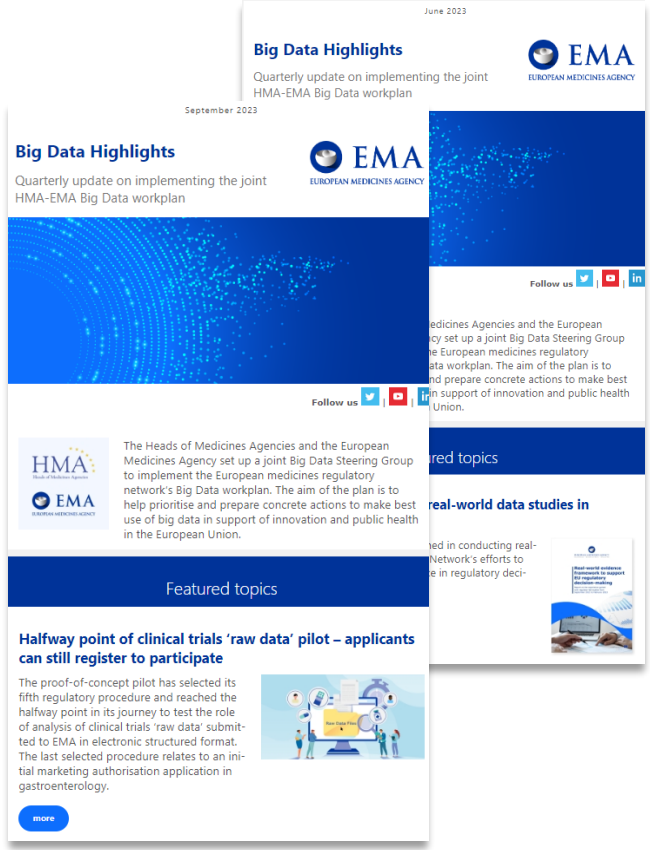
Clinical Trials and ACT EU

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

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European Medicines Agency www.ema.europa.eu

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