



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMA Big Data Steering Group: recommendations & workplan

23 November 2022

Session 1: Advancements in the area of Big Data and digitalisation in the veterinary domain

2nd Veterinary Big Data Stakeholder Forum

Presented by Peter Arlett
Head of Data Analytics and Methods Task Force (EMA),
Co-chair of HMA-EMA Big Data Steering Group





Content

- Drivers for change
- Future perspective on Clinical evidence
- HMA EMA Big Data Task Force: vision, Big Data priority recommendations and workplan
- Key achievements in 2022
- BDSG workplan 2022-2025 - 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
 - Revised Pharmaceutical Strategy for Europe
- Slow speed and high cost of product development
- Burden of unmet medical need, need for medicines for small populations
- Pandemic shows new ways of working
- Opportunity of greater healthcare data access, better study methods and advanced analytics



Future perspective on Clinical evidence

- 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
- Real world evidence is enabled, value is established and complementary to CT data
- The patient voice guides every step of the way
- Healthcare systems are supported in their choices
- High levels of transparency underpin societal trust



Big Data Steering Group

Big Data Workplan 2022-2025

“At the core of a successful MA dossier is excellent clinical evidence”

HMA EMA Big Data Task Force vision

"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

Big Data Priority Recommendations and workplan



Big Data Steering Group

Big Data Workplan 2022-2025

The vision on Big Data is a **strengthened regulatory system that can efficiently integrate data analysis into its assessment processes** to improve decision making.

Knowing when and how to have confidence in novel technologies and the evidence generated from Big Data will benefit public health by accelerating medicines development, improving treatment outcomes and facilitating earlier patient access to new treatments.

[3rd Big Data Workplan 2022-2025 \(europa.eu\)](#) published
in July 2022

1. DARWIN EU ®

- Coordination Centre appointed & establishment started
- First 10 data partners onboarded
- First studies initiated (COMP, PRAC, WHO)
- Participation into EHDS2 pilot
- HTA/Payers workshop
- Complete Data Protection Impact assessment and share learning with EU network



Initiation of DARWIN EU® Coordination Centre advances integration of real-world evidence into assessment of medicines in the EU [↗ Share](#)

News 09/02/2022

EMA is initiating today the establishment of the Coordination Centre for the Data Analysis and Real World Interrogation Network (DARWIN EU®).

The role of the Coordination Centre is to develop and manage a network of real-world evidence across the EU and to conduct scientific studies requested by medicines regulators requested by other stakeholders.

The vision of DARWIN EU® is to give EMA and national competent authorities in EU access to valid and trustworthy real-world evidence, for example on diseases, patient population and effectiveness of medicines, including vaccines, throughout the lifecycle of a medicine.



2. Data quality & Representativeness

- Joint EMA TEHDAS multi-stakeholder workshop
- Public consultation on the 1st EU data quality framework for medicines regulation



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



Data Quality Framework for EU medicines regulation

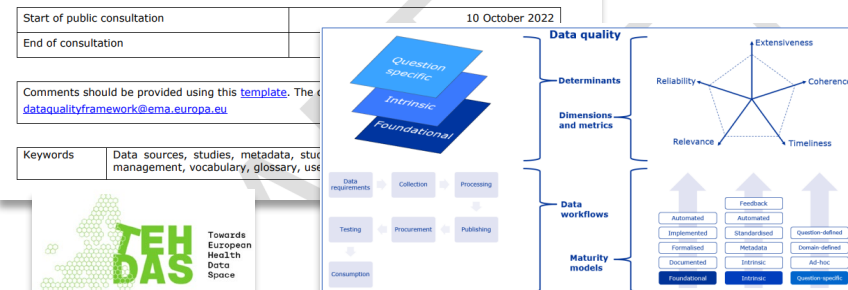
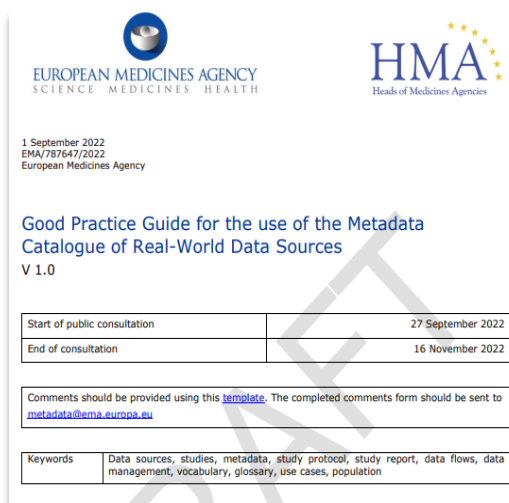


Fig 1. - Representation of the key points of the Data Quality Framework

3. Data discoverability

- Publication of EU metadata list for RWD data sources and studies
- Public consultation on Good practice guide for the use of EU metadata catalogue of RWD sources



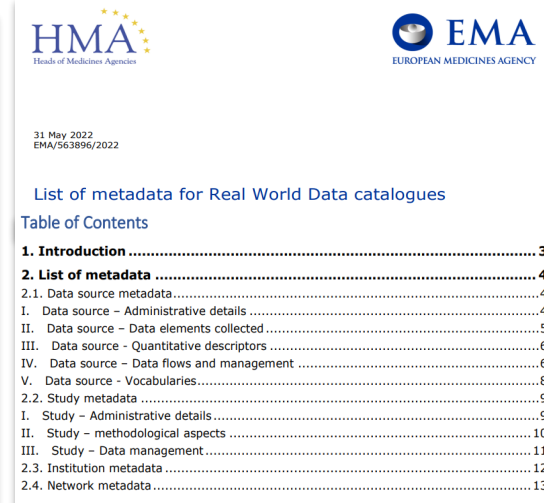
1 September 2022
EMA/787647/2022
European Medicines Agency

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



31 May 2022
EMA/563896/2022


List of metadata for Real World Data catalogues

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4. EU Network skills

- Launch selection of training provider for Data Science curriculum, Pharmacoepidemiology and Real-world Evidence curriculum and Biostatistics and Clinical Trial Methodology curriculum



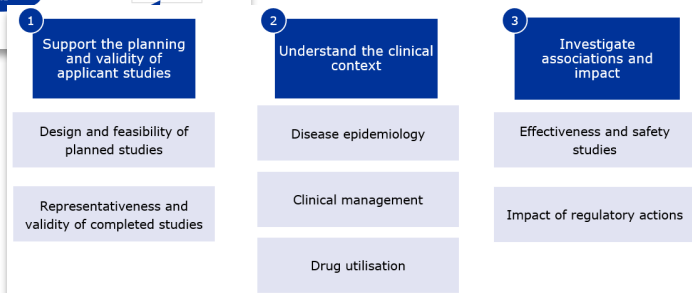
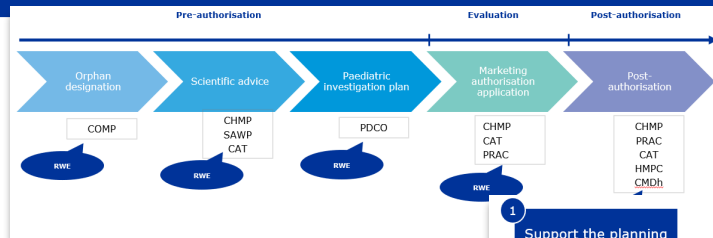
Ted-eTendering
Calls for tenders from the European institutions

Call for tenders' details

| | |
|------------------------------------|---------------------------------|
| Title: | Big Data Curriculum |
| Contracting authority: | European Medicines Agency (EMA) |
| TED publication date: | 13/04/2022 |
| Time limit for receipt of tenders: | 31/05/2022 |
| Status: | Closed |

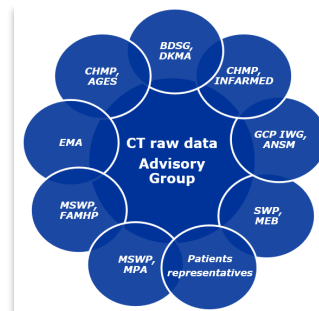
5. EU Network processes

- Pilots of RWE integration with EMA Scientifics' committees (PDCO, COMP, SAWP, CAT, CHMP, CMDh)
- Routine support to PRAC with RWE studies



6. EU capability to analyse

- CHMP raw data pilot launched:
 - Advisory group + Industry focus group established
 - Processes & safeguards established
 - DPIA initiated
 - [Q&A for industry](#)
 - 1st product submitted for analysis
- Drafting of AI reflection paper
- Cluster of excellence paper
- Support Horizon Europe projects



The building blocks for CoE



- Data access
- Legal aspects
- Capabilities
- Infrastructure
- Method development
- AI
- Use cases: Securing medical supply

7. Delivery of expert advice

- Establishment of Methodology Working Party (MWP)
- 1st work plan being finalized

Methodology Working Party [Share](#)

The **Methodology Working Party (MWP)** was established by the **Committee for Medicinal Products for Human Use (CHMP)** in order to pool and use expertise in key areas such as **biostatistics, modelling and simulation, pharmacokinetics, pharmacogenomics, and real-world evidence.**

The MWP's tasks include:

- providing product-related support when requested by [EMA Committees](#) and the [Scientific Advice Working Party](#);
- engaging with stakeholders including international regulators, associations of pharmaceutical companies, and patient and healthcare professional organisations;
- preparing, reviewing and updating [guidelines](#) and [concept papers](#);
- providing training and workshops to assessors.

8. Governance framework

- Progress on the review of Network data governance – i.e. review of the Big Data Steering Group and EU Network Data Board mandates.
- Support EHDS and Pharma Strategy



A European Health Union:

Pharmaceutical strategy for Europe



9. International initiatives

- Publication of the [ICMRA statement on international collaboration on RWE](#)
- Public consultation on ICH M11 clinical electronic structured harmonised protocol (CeSHaRP)

ICMRA statement on international collaboration to enable real-world evidence (RWE) for regulatory decision-making

ICH HARMONISED GUIDELINE
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHaRP)
M11
Draft version
Endorsed on 27 September 2022
Currently under public consultation



10. Stakeholder engagement

- Workshop on Patient experience data in medicines development and regulatory decision-making
- 3rd Big Data multistakeholder forum
- Two Bi-annual BDSG and industry meetings
- Big data newsletters

21 September 2022, 10:00 – 16:30 (CEST), EMA, Amsterdam

Background and objectives

Patients have valuable insights and perspectives from living with a condition and its treatment. This includes symptoms, natural history, quality of life, unmet needs, which outcomes are important and preferences for future treatments. Input from patients, as users of medicines, can inform medicine development, enhance regulatory decision-making and result in more patient-relevant outcomes.

EMA's Regulatory Science Strategy for 2022 recognises the need to identify optimal approaches for engaging patients in medicine development and benefit-risk assessments, including the development of standards for designing, conducting, analysing and reporting relevant studies incorporating patient experience data for regulatory submission, and to elucidate how such data can best inform regulatory decisions.

This multistakeholder workshop will bring together patients, healthcare professionals, academia, regulators, and industry to discuss ways to improve the collection and use of patient experience data to achieve patient-centred medicine development and regulation.

03 **02** **01**

BIG DATA HIGHLIGHTS
Quarterly update on implementation activities of the work plan for Big Data Strategy

Editorial
Patients' perspective on real-world evidence in regulatory decision-making

Patients are generally supportive of sharing their data for research.

They perceive that data generated could be used to improve medicines and that this could benefit patients.

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11. Veterinary recommendations

- 2nd Veterinary Big Data stakeholder forum
- EU Veterinary Big Data strategy 2022-2027
- Cooperation with International Regulators (e.g. FDA and Health Canada)




EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 June 2022
EMA/648865/2021
Veterinary Medicines Division

European Veterinary Big Data strategy 2022- 2027

A strategic vision towards implementation of new digital solutions in the Veterinary regulatory domain

The EU Veterinary Big Data Strategy is defined based on the following pillars:






EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 September 2022
EMA/777506/2022
Veterinary Division

DRAFT Agenda - 2nd Veterinary Big Data Stakeholder Forum

23 November 2022, 09:30-17:00 CET
Virtual event

| Time | Title |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 09:20 | Connection to virtual room and technical checks |
| 09:30 | Welcome remarks |
| 09:45 | Session 1: Advancements in the area of Big Data and digitalisation in the veterinary domain <i>This session will focus on the EU policy framework and initiatives of the EMA/HMA Big Data Steering Group</i> |
| 10:35 | Coffee break |
| 11:00 | Session 2: Stakeholders' insights on key business areas <i>This session will focus on the survey results and prioritised veterinary use cases. It will provide views and recommendations from Regulators, Pharmaceutical Industry, Veterinarians, Academia and other animal healthcare professionals</i> |
| 12:30 | Lunch break |
| 13:40 | Session 2: Stakeholders' insights on key business areas (CONT) |
| 15:15 | Coffee break |
| 15:45 | Session 3: Big Picture on Big Data <i>This session will provide insight of the application of digital technologies in cross-domain fields such as food, environment, and animal welfare</i> |
| 16:30 | Round table and open discussion |
| 16:50 | Closing remarks |
| 17:00 | End of session |

| | | | |
|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <p>DARWIN EU @</p>  | <p>Gradual increase of studies and data partners RWE pilots in health crisis, HTA and Payers EMA committees phased routine access to RWE</p> | <p>Implement use of CT Raw & explore CMC data Enhance EudraVigilance safety data analysis Reflect on AI use and develop guidance Knowledge sharing platform on advance analytics Network computing capability to analyse data</p> | <p>EU CAPABILITY TO ANALYSE</p> |
| <p>DATA QUALITY AND REPRESENTATIVENESS</p> | <p>Data quality framework roll-out & RWD considerations Good practices on regulatory data science, management and software Strengthen data qualification Activity links to EHDS</p> | <p>Consolidate Methodology Working Party Data and methods guidance roadmap EU Specialist Expert Communities: AI and RWE Launch Cluster of Excellence for Clinical Trials</p> | <p>DELIVERY OF EXPERT ADVICE</p> |
| <p>DATA DISCOVERABILITY</p> | <p>Publish real-world data and studies catalogues Explore patient experience data analysis Review utility of eHealth data and social media Clinical trials protocol analytics</p> | <p>Review BDSG mandate Strengthen engagement of ethics expertise Roll out of data protection training Support TEHDAS & EHDS, assess impact of EHDS Support Pharma Strategy</p> | <p>GOVERNANCE FRAMEWORK</p> |
| <p>EU NETWORK SKILLS</p> | <p>Deliver training to regulators on biostatistics, pharmacoepidemiology and data science Adopt genomics curriculum Explore training needs for patients, HCPs & academics</p> | <p>Continue RWE framework collaboration Build on ICMRA recommendations Implement data standardisation strategy Clinical trial protocol conceptual model - ICH M11</p> | <p>INTERNATIONAL INITIATIVES</p> |
| <p>EU NETWORK PROCESSES</p> | <p>Publish portfolio of RWE use cases Harmonise RWE terminology EU network RWE processes overview Report of RWE in regulatory decision-making</p> | <p>Annual multi-stakeholder platform meetings Biannual industry meetings Workshops on DARWIN EU and RWE benefits Network change management</p> | <p>STAKEHOLDER ENGAGEMENT</p> |
| | | <p>Implement vet data strategy and antimicrobials sale & use database Develop data sources catalogue & Progress metadata analysis Continue stakeholder engagement</p> | <p>VETERINARY RECOMMENDATIONS</p> |

In 2025... transformation to data-driven regulation

- **The use of RWE will have been enabled and its value will have been established** across the spectrum of regulatory use cases.
- **Clinical trial raw data analysis** will support regulatory decision-making.
- **DARWIN EU network as part of the EU Health data space** will support better decision-making. via access to data and established analyses.
- **Data will be discoverable and of known quality and representativeness** allowing choice of optimal data source, enabling regulators to guide development and expertly assess study results.
- **EU Network will have knowledge and experience** in data science, methods and analytics to advise companies developing products and to expertly assess application dossiers.
- **Suite of EU and international guidelines and standards available** will help industry and regulators develop and supervise medicines
- **Continued full compliance with data protection and ethics** of data sharing
- **Guided by patients and working with stakeholders to deliver data transformation to support the development and use of better medicines for patients.**

“At the core of a successful MA dossier is excellent clinical evidence”



[Big Data](#)

[Clinical Trials and ACT EU](#)



[Big Data Highlights](#)

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

[Clinical Trials Highlights](#)



[EMA events](#)



03 Issue 3
September 2022

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BIG DATA HIGHLIGHTS

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

10 Issue 10
July 2022

HMA
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Clinical Trials HIGHLIGHTS

Quarterly update on implementation activities of the HMA-EMA Clinical Trials Steering Group workplan

Editorial

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

Peter Arlett
Co-chair of Big Data Steering Group/ Head of Data Analytics and Methods Task Force, EMA

The rapidly changing data landscape and the increased use of Big Data force us, as medicines regulators, to evolve in the way we access, manage and analyse data. The Big Data vision aims to improve regulatory decision making by strengthening the place of data analysis into medicines assessment. Guided by this vision, we have updated the [EMA and HMA Big Data Steering Group workplan](#) (see [EMA news announcement](#)). Taking into account the feedback from experts and stakeholders, this update sets big data actions that will deliver transformation to data-driven medicines regulation and will be completed between 2022-25.

Jesper Kjaer
Co-chair of Big Data Steering Group/ Director of Data Analytics Centre, DKMA

The key deliverables include building up to more than 100 real-world evidence studies per year via DARWIN EU8, a proof-of-concept pilot on raw data from clinical trials, a data quality framework for medicines regulation and the launch of a real-world data (RWD) catalogue based on the recently adopted [list of metadata](#). The workplan foresees collaboration and support to the proposed European Health Data Space and is organised according to the [public recommendations](#) for regulators on the best approaches to use and generate data set in 2020 by the former Big Data Task Force.

“ We believe that using novel technologies and the evidence generated from big data will benefit public health by accelerating medicine development, improving treatment outcomes and facilitating earlier patient access to new treatments ”

Engagement with partners and stakeholders and leveraging their work remain key to ensuring successful delivery of the workplan.

ACT EU multi-stakeholder events

EMA seeks to engage all clinical trials stakeholders to support inclusive patient-centred medicines development and delivery. The ACT EU programme will host stakeholder events on a variety of clinical trials topics throughout 2022 and 2023.

The ACT EU programme will host a [multi-stakeholder workshop on shared clinical trials \(DCT\)](#) on behalf of the EU DCT project. The DCT group consists of a core team of clinical trial experts from the Clinical Trials Regulation Group (CTRG), ethical experts from the Commission Expert Group on Clinical Trials (CTEG) and Good Clinical Practice (GCP) Inspectors from the GCP Forum Working Group (GCP IWG). The workshop will provide an opportunity for participants to discuss and provide input to the content of the upcoming consultation paper on the use of decentralised elements in clinical trials, due for publication in Q4 2022. The event will include a live broadcast virtual session, open to all interested parties, where the work of the European Regulatory Network (EMRN) on the DCT recommendation paper will be presented, and in-person breakout sessions for invited attendees to discuss topics related to decentralised clinical trials.

Thank you

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