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

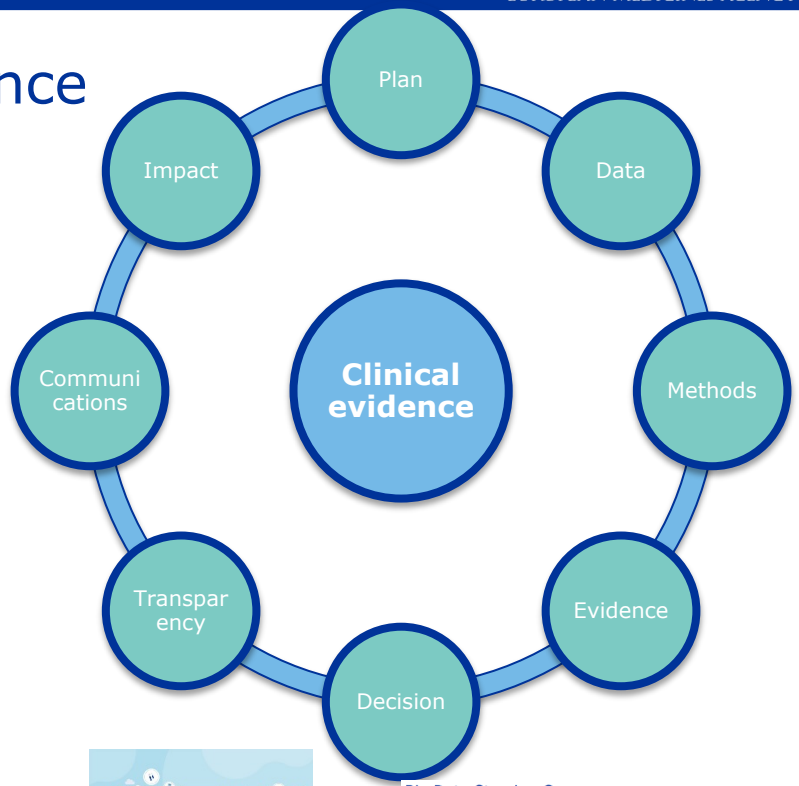
- Drivers for change
- Future perspective on Clinical evidence
- HMA EMA Big Data Task Force: vision, Big Data priority recommendations and workplan
- Key achievements in 2022
- BDSG workplan 2022-2025 - Future highlights

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

Key achievements in 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

DARWIN EU

EHDS HealthData@EU Pilot

Initiation of DARWIN EU® Coordination Centre advances integration of real-world evidence into assessment of medicines in the EU

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-w 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 E valid and trustworthy real-world evidence, for example on diseases, patient popu and effectiveness of medicines, including vaccines, throughout the lifecycle of a n

TEHDAS Towards European Health Data Space

2. Data quality & Representativeness

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

HMA Heads of Medicines Agencies

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	

Comments should be provided using this template. The
dataqualityframework@ema.europa.eu

Keywords	Data sources, studies, metadata, stu management, vocabulary, glossary, us

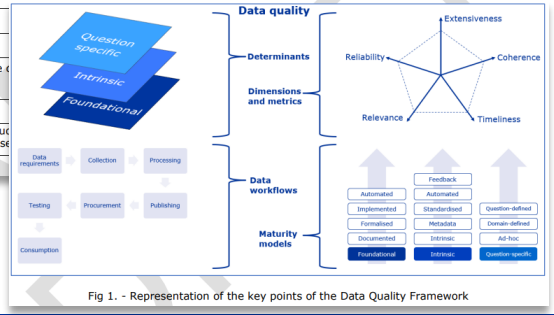


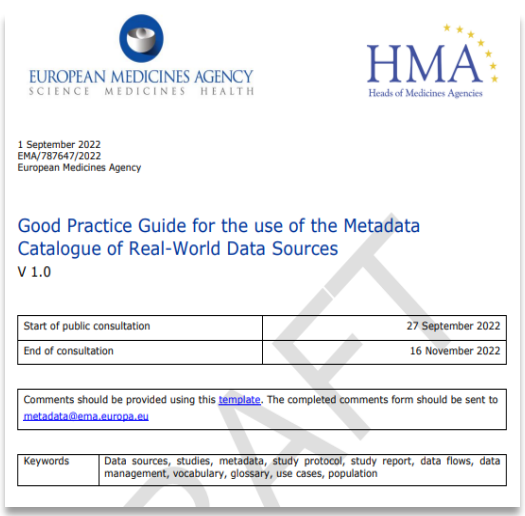
Fig 1. - Representation of the key points of the Data Quality Framework

TEHDAS Towards European Health Data Space

Key achievements in 2022

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 metada catalogue of RWD sources



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

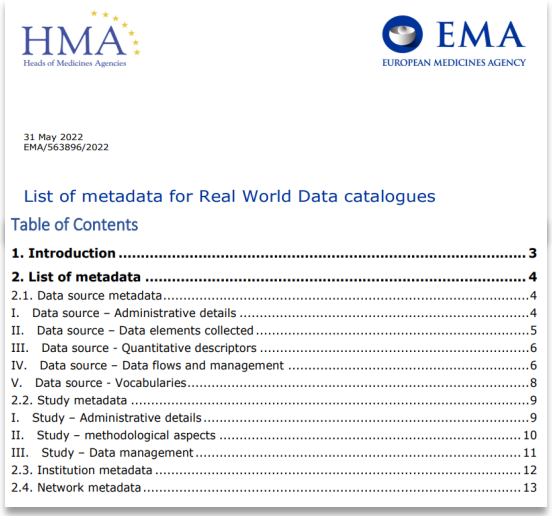
1 September 2022
EMA/787647/2022
European Medicines Agency

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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EMA
EUROPEAN MEDICINES AGENCY

31 May 2022
EMA/563896/2022

List of metadata for Real World Data catalogues

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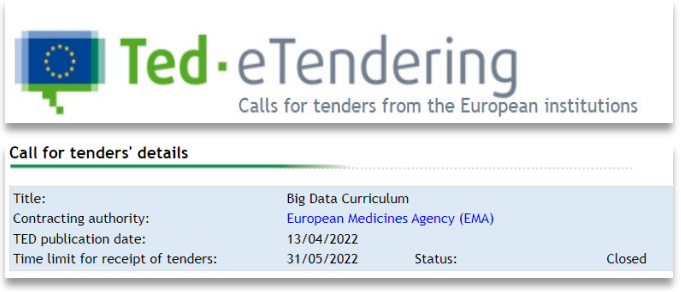
4. EU Network skills

- 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

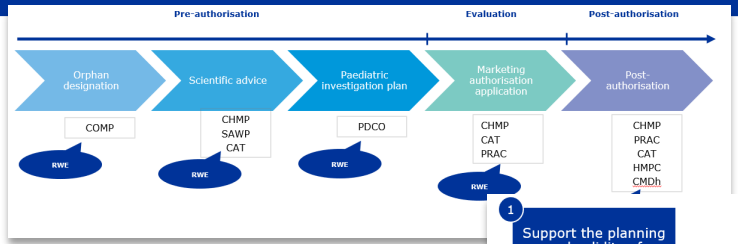
Call for tenders' details

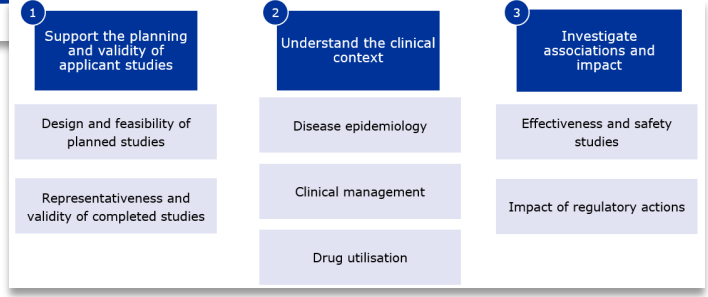
Title:	Big Data Curriculum		
Contracting authority:	European Medicines Agency (EMA)		
TED publication date:	13/04/2022		
Time limit for receipt of tenders:	31/05/2022	Status:	Closed

Key achievements in 2022

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

Key achievements in 2022

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.

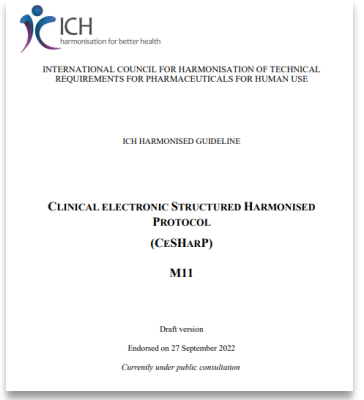
8. Governance framework

- 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

Key achievements in 2022

9. International initiatives

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



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

Key achievements in 2022

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)

HMA Heads of Medicines Agencies

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:

HMA Heads of Medicines Agencies

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** *This session will focus on the EU policy framework and initiatives of the EMA/HMA Big Data Steering Group*
10:35	Coffee break
11:00	**Session 2: Stakeholders' insights on key business areas** *This session will focus on the survey[1] results and prioritised veterinary use cases. It will provide views and recommendations from Regulators, Pharmaceutical Industry, Veterinarians, Academia and other animal healthcare professionals*
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** *This session will provide insight of the application of digital technologies in cross-domain fields such as food, environment, and animal welfare*
16:30	Round table and open discussion
16:50	Closing remarks
17:00	End of session

BDSG workplan 2022-2025 - Future highlights

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

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"

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

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