EU Big Data Stakeholder Forum 2022

01 December 2022

Session 1: Report on implementation of the HMA-EMA Big Data Task Force priority recommendations - Overview of 2022 deliverables and the new plan for 2022-2025

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

Content

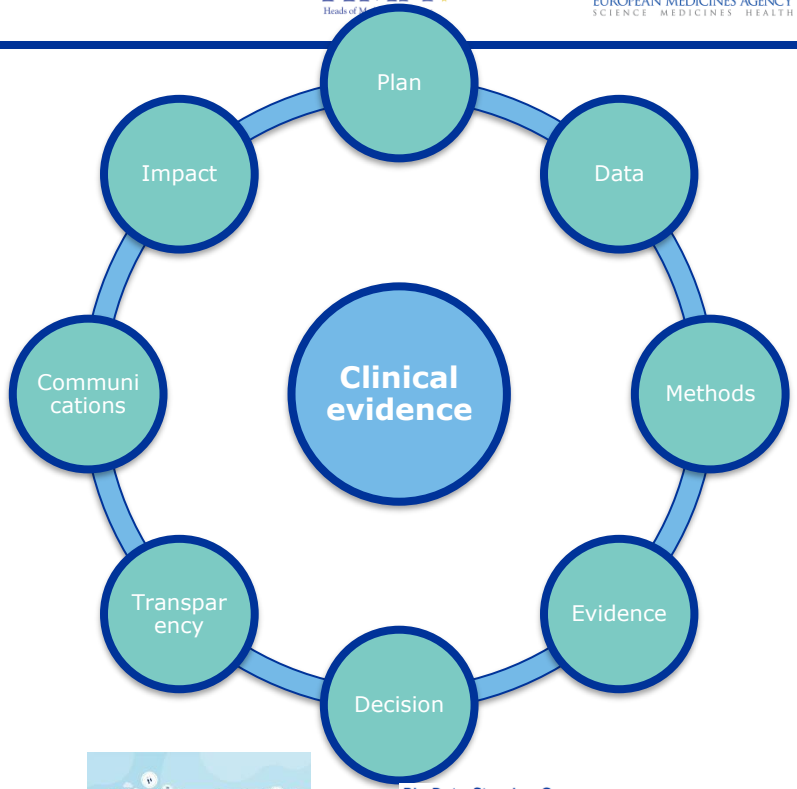
- Drivers for change
- Future perspective on Clinical evidence
- HMA EMA Big Data Task Force: vision, Big Data priority recommendations and workplan
- Key achievements in 2022
- BDSG workplan 2022-2025 - Future highlights

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
  - Pharmaceutical Strategy for Europe
- Slow speed of product development
- Burden of unmet medical need
- Pandemic shows new ways of working
- Better:
  - healthcare data access,
  - study methods
  - 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 and value is established
- 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 & 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

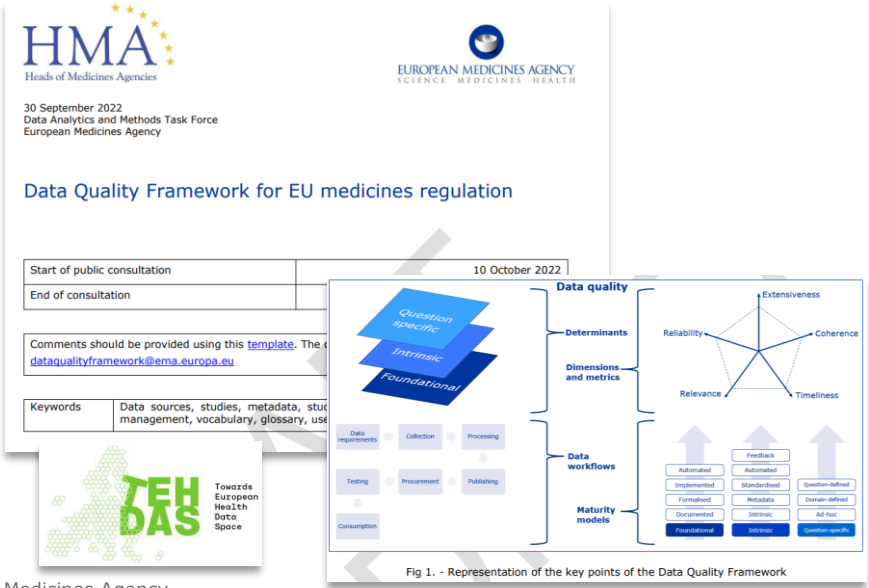
Key achievements in 2022

1. DARWIN EU ®

- Coordination Centre established
- First data partners onboarded
- First studies initiated
- HTA/Payers workshop

2. Data quality & Representativeness

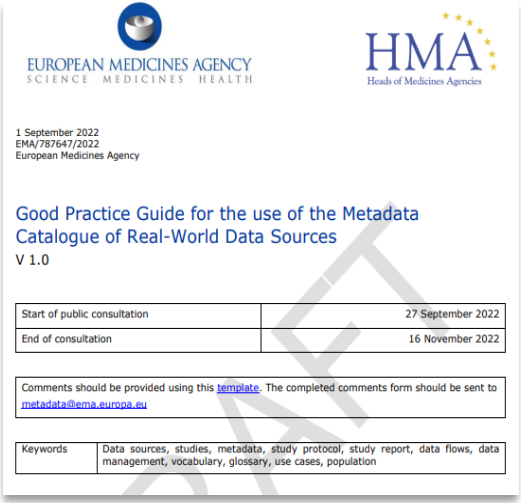
- EMA-TEHDAS multi-stakeholder workshop
- Consultation on data quality framework for medicines regulation



Key achievements in 2022

3. Data discoverability

- Publication of EU metadata list for RWD data sources
- Consultation on Good Practice Guide for the use of real-world metadata
- Work started on catalogues of RWD sources and studies



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

1 September 2022
EMA/787647/2022
European Medicines Agency

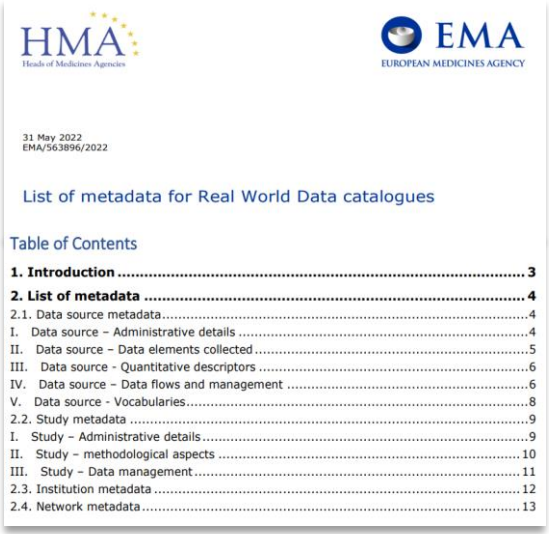
Good Practice Guide for the use of the Metadata Catalogue of Real-World Data Sources
V 1.0

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

DRAFT



HMA
Heads of Medicines Agencies

EMA
EUROPEAN MEDICINES AGENCY

31 May 2022
EMA/563896/2022

List of metadata for Real World Data catalogues

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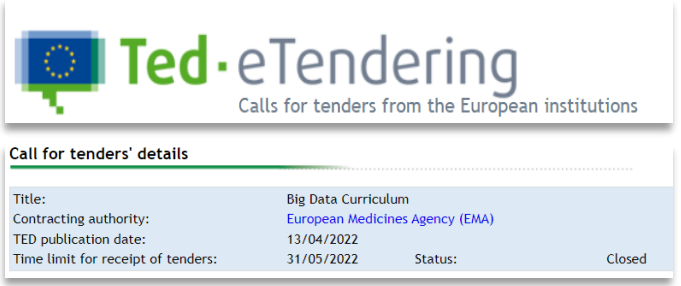
4. EU Network skills

- Selection of training provider for Data Science curriculum
- Selection of training provider for real world evidence



Ted·eTendering
Calls for tenders from the European institutions

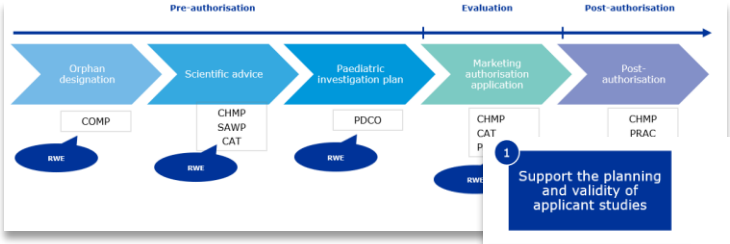
Call for tenders' details

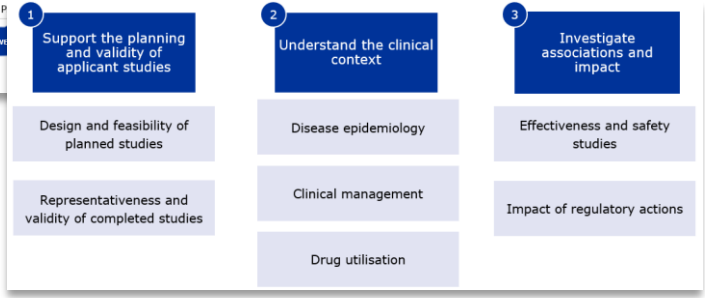
Title:	Big Data Curriculum		
Contracting authority:	European Medicines Agency (EMA)		
TED publication date:	13/04/2022		
Time limit for receipt of tenders:	31/05/2022	Status:	Closed

Key achievements in 2022

5. EU Network processes

- RWE studies for COVID-19
- RWE studies: routine support to PRAC
- RWE Pilots with EMA Scientific committees: PDCO, COMP, SAWP, CAT, CHMP, CMDh





6. EU capability to analyse

- CHMP clinical trial raw data pilot launched:
  - Advisory group + industry focus group established
  - Processes established
  - Q&A for industry
  - 1st product submitted for analysis
- Initiation of AI reflection paper
- Principles agreed on Clusters of Excellence

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

- Methodology Working Party (MWP) established
- MWP: 1st work plan near final

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.

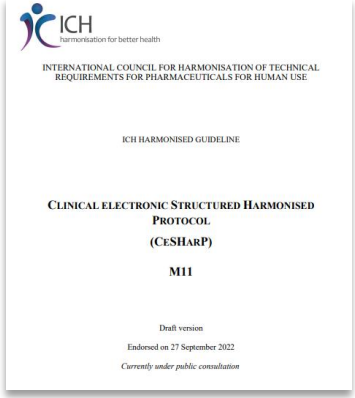
8. Governance framework

- Review of Network data governance – initiated
- Participation into EHDS2 pilot
- Contribution to Pharma Strategy

Key achievements in 2022

9. International initiatives

- ICMRA statement on international collaboration on RWE
- Consultation on ICH M11 clinical electronic structured harmonised protocol (CeSHarP)



10. Stakeholder engagement

- Workshop on Patient experience data
- Two Bi-annual BDSG and industry meetings
- Big data newsletters
- Big Data multistakeholder forum

Key achievements in 2022

11. Veterinary recommendations

- EU Veterinary Big Data strategy 2022-2027
- 2nd Veterinary Big Data stakeholder forum
- Cooperation with International Regulators

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 Develop **AI guidance** **Knowledge sharing** on advance analytics Assess **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 Review **data qualification** Collaboration with **EHDS**	Further strengthen **Methodology Working Party** **Data and methods** guidance **roadmaps** **EU Specialist Expert Communities**: in methodology Launch **Cluster of Excellence for CT** analytics	**DELIVERY OF EXPERT ADVICE**
DATA DISCOVERABILITY	Launch **real-world data and studies catalogues** Explore **patient experience** data analysis Review utility of **eHealth data** and **social media**	Review **Network Data Governance** Strengthen engagement of **ethics expertise** Roll out of **data protection training** Support **TEHDAS & EHDS** Support **Pharma Strategy**	**GOVERNANCE FRAMEWORK**
EU NETWORK SKILLS	**Deliver training to regulators** on biostatistics, pharmacoepidemiology and data science Adopt **genomics** curriculum Targeted training for **patients, HCPs** & **academics**	Build on **ICMRA RWE recommendations** Implement **data standardisation strategy** **Clinical trial protocol** - ICH M11	**INTERNATIONAL INITIATIVES**
EU NETWORK PROCESSES	Publish **portfolio of RWE use cases and terminology** EU network **RWE processes overview** **Report on RWE** in regulatory decision-making	Annual **multi-stakeholder** platform 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.
- **Through public searchable catalogues 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 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