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HMA Heads of Medicines Agencies

EMA EUROPEAN MEDICINES AGENCY

BIG DATA
HIGHLIGHTS

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

An agency of the European Union

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Editorial

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

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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.

The key deliverables include building up to more than 100 real-world evidence studies per year via DARWIN EU®, 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 priority 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 this workplan.

Featured topics

Big Data priority recommendations

Data discoverability

Metadata list describing real-world data

EMA has published a list of metadata describing real-world data sources to help pharmaceutical companies and researchers to identify and use such data when investigating the use, safety and effectiveness of medicines. RWD are routinely collected data relating to patient health status or the delivery of health care from a variety of data sources. Making use of these data sources can improve the evidence available to support benefit-risk decisions and facilitate faster access to better medicines to patients.

This metadata list will feed into two future EU catalogues on RWD sources and studies:

- The **catalogue of data sources** will cover information on real-world databases, replacing the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) catalogue;
- The **catalogue of studies** will cover studies performed on the data sources, enhancing and replacing the European Union electronic register of post-authorisation studies (EU PAS Register).

The catalogues on RWD sources and studies aim to:

- Help regulators, researchers and pharmaceutical companies identify studies and data sources suitable to address research questions, based on 'FAIR' (findable, accessible, interoperable and reusable) data principles;
- Boost transparency of observational studies;
- Improve the ability to assess evidence from observational studies and real-world data sources.

The metadata list was produced through the extensive consultation with big data community stakeholders including regulators, industry, academia, patients and research organisations. A **best practice guide** for using the real-world metadata will be released for public consultation in the coming weeks.

Network capability to analyse

Analysis of raw data from clinical trials: launch of pilot

The EMA Committee on Human Medicinal Products (CHMP) has launched a pilot to assess the benefits and practicalities of access to individual patient data from clinical trials (raw data) in the assessment of medicines (see EMA news announcement). Potential benefits of the raw data analysis include better informed medicines regulatory decision making and faster access to innovative, safe and effective medicines for patients.

The pilot is open to applicants or MAHs when they submit marketing authorisation applications or post-authorisation applications. If selected, they will include raw data as part of their submissions. More information on the pilot's objectives and terms of participation is available in the description of the pilot to industry. Moreover, an Industry Focus Group has been set up to share their views on specific design elements concerning the pilot and a kick-off meeting took place on 3 August 2022.

The pilot is expected to last up to two years and will include 10 regulatory procedures submitted to EMA from September 2022. Learnings from the pilot will help the EU medicines regulatory network to make an informed decision on the place of raw data in regulatory decision-making.

International initiatives

International collaboration on real-world evidence

EMA and the International Coalition of Medicines Regulatory Authorities (ICMRA) has issued a joint statement calling for international collaboration to enable the generation and use of real-world evidence for regulatory decision-making (see EMA news announcement).

In the statement, ICMRA members identify four focus areas for regulatory cooperation on real-world evidence integration into medicines assessment:

- Harmonisation of terminology for RWD and RWE;
- Regulatory convergence on RWD and RWE guidance and best practice;
- Readiness to address public health challenges and emerging health threats;
- Transparency.

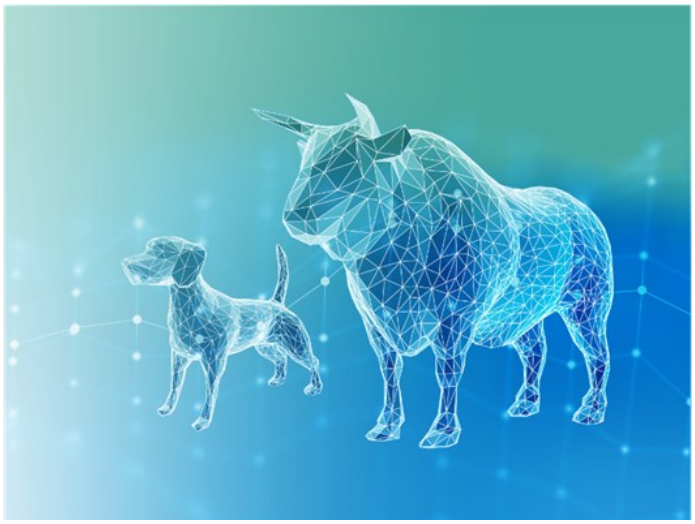
This statement is the outcome of an ICMRA workshop on real-world evidence co-organised by EMA, US FDA and Health Canada, held in Amsterdam in June 2022. Participants from more than 40 countries, representing medicines regulatory authorities globally as well as representatives from the World Health Organization (WHO), shared their experiences as well as challenges in generating RWE to support the evaluation of medicines.

Veterinary recommendations

Big Data strategy for veterinary medicines in the EU

In July 2022 the EMA and HMA published the joint European Veterinary Big Data strategy 2022-2027 (see EMA news announcement). The strategy sets out how the European medicines regulatory network for veterinary medicines will make use of big data to support regulatory activities. It builds upon key objectives of the recently implemented Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) and aims to converge traditional regulatory practice with innovative digital solutions.

The Veterinary Big Data strategy proposes phased implementation and will impact different business areas, such as pharmacovigilance, the fight against antimicrobial resistance (AMR) and innovation of veterinary medicinal products development.



Getting involved

Upcoming events

Q&A session for assessors on the Raw Data pilot – 20 and 23 September 2022

Public consultation on Data Quality Framework - Q4 2022

Public consultation on Metadata Good Practice Guide – Q4 2022

2nd Veterinary Big Data Stakeholder Forum - 23 November 2022

3rd Big Data stakeholders forum – 1 December 2022

Recent events

Big Data Steering Group meeting with industry stakeholders – 30 May 2022

ICMRA workshop on real-world evidence
29-30 May 2022

Read the previous issue of the newsletter

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List of acronyms

AI: Artificial Intelligence
AMR: Antimicrobial Resistance
BDSG: Big Data Steering Group
CAT: Committee for Advanced Therapies
CMDh: Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CHMP: Committee for Medicinal Products for Human Use
COMP: Committee for Orphan Medicinal Products
CT: Clinical Trials
EHDS: European Health Data Space
EMRN: European medicines regulatory network
HMA: Heads of Medicines Agencies
ICH: International Council for Harmonisation of Technical Requirements Registration Pharmaceuticals Human Use
ICMRA: International Coalition of Medicines Regulatory Authorities
OMOP CMD: Observational Medicinal Outcomes Partnership Common Data Model
PDCO: Paediatric Committee
PRAC: Pharmacovigilance Risk Assessment Committee
RWD: Real-world data
RWE: Real-world evidence
SAWP: Scientific Advice Working Party
TEHDAS: Towards the European Health Data Space

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