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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The Newsletter is moving to a new platform – **Newsroom**, which is used by the European institutions and agencies to create and disseminate information online.

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The next issue due in June 2023 will only be sent, via email, to readers who signed up and agreed to data privacy policy using the link provided.

Editorial

The Methodology Working Party sets its first workplan

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In February 2023, the newly established Methodology Working Party (MWP) published its first workplan. As the co-chairs of MWP we are honoured to lead this ambitious programme of work which covers all the expertise brought in under one umbrella. The main focus, aligned with the workplans of the other working parties within the network, is on guidelines to be developed, meetings and workshops, and developing training curricula for the network. The workplan also prioritises those activities that need to be launched in the first year.

In terms of guidances, the workplan is particularly ambitious. Due to Brexit and COVID-19 pandemic business continuity working, the development of many guidelines was put on hold. Restarting this work, whilst also generating new guidelines for the data of the future, will be challenging. Consequently, MWP has arranged these guidelines into four strategic areas:

- Clinical Pharmacology, including guidance on pharmacokinetics, modelling and simulation, and supporting bioequivalence to support a thriving generics industry;
- Pharmacogenomics, with a particular focus on biomarker driven development, being aware of the new In Vitro Diagnostics Regulation;
- Modernising Clinical Trials, including embedding of the ICH guidelines agreed since 2018;
- Real World Evidence and Artificial Intelligence.

The MWP is also establishing a methodology 'European Specialist Expert Community' or ESEC to build capability and capacities across the spectrum of methodology domains. ESEC will work closely with both the Big Data Steering Group and the ACT EU Steering Group to ensure training, communication and stakeholder engagement are streamlined and effective.

BDSG annual report 2022

The report on the key achievements of the Big Data Steering Group in 2022 is available on the EMA big data webpage. Significant progress in the transformation to data-driven regulation continued, in line with the Network Strategy to 2025 and Big Data Steering Group workplan.

Featured topics

Big Data priority recommendations

DARWIN EU®

DARWIN EU® completes first studies and calls for new data partners

DARWIN EU®, the Data Analysis and Real-World Interrogation Network, has accomplished its first year of establishment: see EMA's news announcement. Following the set-up of the DARWIN EU® Coordination Centre in February 2022, the first ten data partners were onboarded. The network also initiated its first four studies using real-world data (RWD) from across Europe to better understand diseases, populations and the uses and effects of medicines.

The first studies start to demonstrate the benefits of DARWIN EU®. Use of a common data model, standardised analytics and agile processes allow faster performance of studies, increased capacity, and lower costs. Results from these studies have been shared with EMA committees, and the protocols and results are also available publicly in the EU PAS Register. The network will onboard ten additional data partners this year. The DARWIN EU® Coordination Centre, in collaboration with EMA, has launched an open call for expression of interest from potential data partners. More information can be found on www.darwin-eu.org. Throughout 2023, DARWIN EU® will continue its collaboration with stakeholders and is working on use case pilots with the European Centre for Disease Prevention and Control (ECDC) and bodies responsible for Health Technology Assessments (HTA) and bodies representing payers. Furthermore, DARWIN EU® is participating in a pilot for the European Health Data Space (EHDS), exploring the network's role as a research and data node (see next article).

DARWIN EU as a research and data node in the European Health Data Space (EHDS) pilot

The European Health Data Space (EHDS) aims at enabling the effective use of health data in EU for the benefit of patients, healthcare delivery, research and innovation. It covers two aspects: the primary use of health data for care (MyHealth@EU) and the re-use or secondary use of health data (HealthData@EU). To achieve these goals, it is necessary to establish the relevant legal, governance, infrastructure, data quality, capacity and digitalisation frameworks. While legal proposals are progressing through the European Parliament and Council of Ministers, to explore the secondary use of data, a pilot (referred to as "HealthData@EU pilot" or "EHDS2 Pilot") started in October 2022 for a 2-year period. It comprises five use cases to inform the design, development, and deployment of these frameworks.

DARWIN EU® is participating in the EHDS2 Pilot with a use case that addresses the risk of blood clots in COVID-19 patients and persons vaccinated against SARS-CoV-2 when the Omicron variant of the virus became dominant. This use case is led by EMA and involves research teams and data nodes from Finland, France, Denmark, Croatia and Germany. The goal of this use case is to test and inform the integration of DARWIN EU® as a node within EHDS and demonstrate the capacity of EHDS data partners to handle different levels of complexity of regulatory related research questions.

For more information https://www.ehds2pilot.eu/

Network capability to analyse data

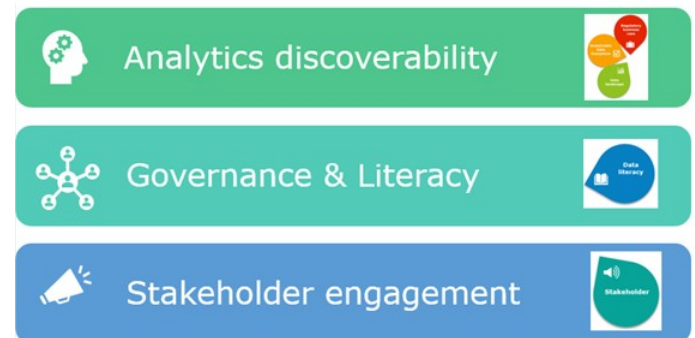**Clinical Trials Raw Data Pilot: application of EMA's data transparency principles**

The Clinical Trials Raw Data Pilot team, in consultation with the Industry Focus Group on Raw Data, has developed a paper on the application of EMA's data transparency principles to the pilot. This paper was produced to support and provide clarification to interested applicants and Marketing Authorisation Holders (MAHs) on EMA's existing data transparency principles, including its current practice and processes that will apply during the conduct of the pilot.

The pilot has now selected its second regulatory procedure to assess the place of raw data in regulatory decision making. This procedure will entail a biosimilar application in the area of endocrinology.

Applicants or MAHs that are about to submit marketing authorisation applications or post-authorisation applications are welcome to register their interest in participating in the pilot with a specific procedure by contacting rawdatapilot@ema.europa.eu.

Participation in the pilot offers a unique opportunity to applicants and MAHs to contribute to the pilot's learnings which will in turn assist the EU Medicines Regulatory Network to make an informed decision on the place of raw data in regulatory decision-making. Pilot related guidance for applicants and MAHs can be found on EMA's Big Data webpage.

Veterinary recommendations

Progressing the big data vision in the veterinary regulatory domain

The EU veterinary big data team is progressing its work taking into account the recommendations and conclusions from the 2nd Veterinary Big Data Stakeholder Forum in November 2022. Specifically, stakeholders agreed that, whilst progressing on enriching and increasing data quality in the veterinary systems established under Veterinary Regulation (2019/06), an EU Veterinary Workplan should be developed to identify and prioritise digital use cases for the coming years. Furthermore, the EU veterinary big data discussion is moving *from vision to action* with the transposition of the European Veterinary Big Data strategy's 2022-2027 pillars into the following actionable workstreams:

Further information can be requested from vet-bigdata@ema.europa.eu.

Getting involved

Upcoming events

- [EMA multi-stakeholder workshop on qualification of novel methodologies, 17-18 April 2023](#)

- Bi-annual Big Data Steering Group and industry stakeholders meeting: 26 May 2023

- Multi-stakeholder workshop on data quality including real world data consideration: June 2023 (date TBC)