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The Big Data Steering Group set up by EMA and the Heads of Medicines Agencies (HMA) has published its third workplan that sets key actions to be delivered between 2022–25.

The new workplan will allow to further enhance the efficient integration of data analysis into the evaluation of medicinal products by regulators. 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.

The former Big Data Task Force carried out a thorough assessment of the challenges and opportunities posed by big data in medicines regulation, which culminated in 2020 in the publication of priority recommendations for regulators on the best approaches to use and generate data. The joint HMA-EMA Big Data Workplan 2022–2025 follows the key recommendations and includes mainly activities related to medicines for human use. However, the scope of some activities covers veterinary aspects, and a separate section in the workplan is fully dedicated to veterinary medicines.

The workplan lays out deliverables and timelines including for the following areas:

- The Data Analysis and Real World Interrogation Network (DARWIN EU), EMA’s network of data and services in Europe for a better use of real-world evidence when assessing medicines: the workplan foresees more than one hundred DARWIN EU studies per year by 2025;
- Data quality: a data quality framework for the EU regulatory network is to be delivered by the end of 2022, following the analysis and exchanges on data quality with a wide range of stakeholders including patients, healthcare professionals, regulators, pharmaceutical industry and academia;
- Data discoverability: the workplan foresees the publication of a good practice guide on real-world metadata and a public catalogue of European real-world
data. In addition, searching for information from regulatory documents will be enhanced through the development of analytics tools and the development of standardised clinical trial protocols;

- EU network skills: the workplan includes the delivery of training on biostatistics, pharmacoepidemiology and data science for regulators with targeted access for patients, healthcare professionals and academics.

Big data are extremely large, rapidly accumulating datasets captured across multiple settings and devices, for example through wearable devices and electronic health records. Coupled with rapidly developing technology, big data can complement the evidence from clinical trials by filling knowledge gaps on a medicine, and can help to better characterise diseases, treatments and the performance of medicines in individual healthcare systems.

The work carried out by the Big Data Steering Group builds on the Regulatory Science Strategy to 2025, published in March 2020, and will support the European Medicines Agencies Network Strategy to 2025.

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