

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

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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-world healthcare data sources across the EU and to conduct scientific studies requested by medicines regulators and, at a later stage, requested by other stakeholders.

The vision of DARWIN EU® is to give EMA and national competent authorities in EU Member States access to valid and trustworthy real-world evidence, for example on diseases, patient populations, and the use, safety and effectiveness of medicines, including vaccines, throughout the lifecycle of a medicinal product.


By supporting decision-making on the development, authorisation and surveillance of medicines, a wide range of stakeholders will benefit, from patients and healthcare professionals to health technology assessment bodies and the pharmaceutical industry.

Additionally, DARWIN EU® will provide an invaluable resource to prepare for and respond to future healthcare crises and pandemics.

For example, the availability of timely and reliable real-world evidence can lead to innovative medicines becoming more quickly available to patients. Better evidence also supports more informed regulatory decision-making on the safe and effective use by patients of medicines on the market.

EMA will be working with Erasmus University Medical Center Rotterdam to establish the DARWIN EU® Coordination Centre. The contract was awarded to Erasmus University Medical Center Rotterdam following a call for tender for a service provider published in June 2021. The contractor will set up the necessary infrastructure of the Coordination Centre and establish the required business services. It will run scientific studies to answer research questions that come up during the evaluation of medicines in the EU and also maintain a catalogue of real-

world data sources and metadata for use in medicine regulatory activities. All studies will be published in the EU catalogue of observational studies.

DARWIN EU<sup>®</sup> will also act as a pathfinder for the [European Health Data Space \(EHDS\)](#)  and will ultimately connect to the EHDS services, enabling the use of the EHDS in the context of medicines regulation in Europe.

The first DARWIN EU<sup>®</sup> pilot studies will be delivered in 2022. EMA will oversee the Coordination Centre, connect it to the work of the EMA medicines committees and monitor its performance.

A [multi-stakeholder information webinar](#) to introduce the establishment of DARWIN EU, highlight opportunities for collaboration and answer questions will be organised by EMA on 24 February 2022.

DARWIN EU<sup>®</sup> is the first [priority deliverable](#) of the [EMA-HMA Big Data Steering Group workplan](#) and contributes to the delivery of the [European Medicines Agencies Network Strategy to 2025](#). Further information will be made available on the [DARWIN EU<sup>®</sup> webpage](#).

## Related content

- [Data Analysis and Real World Interrogation Network \(DARWIN EU\)](#)
- [DARWIN EU: multi-stakeholder information webinar \(24/02/2022\)](#)
- [Big data](#)
- [European medicines agencies network strategy](#)
- [Ten recommendations to unlock the potential of big data for public health in the EU \(20/01/2020\)](#)

## External links

- [European Health Data Space \(EHDS\)](#) 

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