



DARWIN EU® has completed its first studies and is calling for new data partners

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DARWIN EU®, the Data Analysis and Real-World Interrogation Network, has accomplished its first year of establishment. 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.

DARWIN EU® is a platform to generate real-world evidence (RWE) to support the decision-making of EMA scientific committees and national competent authorities in EU Member States throughout regulatory processes. RWE refers to information derived from analysis of RWD, which is routinely collected data about a patient's health status or delivery of healthcare. RWE complements the evidence generated by randomised controlled clinical trials and contributes to more data-driven regulatory decision making.

DARWIN EU® has ambitious plans for 2023. The network will onboard ten additional data partners and initiate around 16 studies. Data partners can be public or private institutions with access to real-world healthcare data from a variety of sources such as hospitals, primary care, health insurance, registries and biobanks. They will collaborate with the DARWIN EU® Coordination Centre to enable analyses of their data to deliver RWE.

The call for expressions of interest from potential data partners is now open. Interested data partners are invited to visit the [DARWIN EU® website](#) for further information.

The first four studies start to demonstrate the benefits of DARWIN EU®. The use of a common data model, standardised analytics and agile processes allow faster performance of studies, increased capacity, and lower costs. The design and conduct of these first studies have also supported the establishment of analytical pipelines and processes. The studies were not linked to individual medicines currently under evaluation procedures but selected based on previous procedures and requests for RWE from EMA committees.

The protocols and results of these studies are publicly available in the EU PAS Register:

- DARWIN EU®'s [first disease epidemiology study](#) investigated the prevalence of rare blood cancers in five European countries.

- The [second study](#) focused on the use of medicines containing valproate and alternative therapies among girls and women between 12 and 55 years of age, in light of the potential of these types of medicines to cause harm to unborn babies.
- The [third study](#) aimed to characterise prescription patterns for 141 antibiotics from the Watch list of the [WHO AWaRe classification](#). The results will serve as additional evidence in the monitoring of antibiotic use as part of the work on antimicrobial resistance and help to guide [product information](#) and [guideline review](#).
- The [fourth study](#) is on severe asthma and its final results are expected in spring 2023. The study will inform the safety assessment of all products authorised or under development for the treatment of severe asthma in adolescents and adults.

Results from the completed studies have been provided to the relevant EMA committees to support their future work.

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. Further, 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. DARWIN EU® acts as a pathfinder for the EHDS and will ultimately connect to the EHDS services.

By 2025 DARWIN EU® will be fully operational, delivering around 150 RWE studies per year. The EU's vision is that by then the use of RWE will have been enabled and value established across the spectrum of regulatory use cases.

Related content

- [Data Analysis and Real World Interrogation Network \(DARWIN EU\): Data partners](#)

External links

- [EU PAS Register](#)
- [DARWIN EU - Prevalence of rare blood cancers in Europe](#)
- [DARWIN EU - Drug utilisation of valproate-containing medicinal products in women of childbearing potential](#)
- [DARWIN EU - DUS of Antibiotics in the 'Watch' category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use](#)
- [DARWIN EU - Background rates of serious adverse events to contextualise safety assessments in clinical trials and non-interventional studies in adolescent and adult patients with severe asthma](#)
- [World Health Organization - AWaRe classification of antibiotics](#)
- [Darwin EU website](#)
- [European Centre for Disease Prevention and Control \(ECDC\)](#)
- [European Health Data Space \(EHDS\)](#)

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