

MEP Heart Group Statement

EHDS and Registries: Restoring the EU's primacy in research

The European Health Data Space (EHDS) has the potential to drastically accelerate the use of health data in the EU by creating an ecosystem of common standards and practices supported by a strong governance framework.

Leveraging health data is crucial to improving healthcare provision and research. However, several obstacles have been limiting its full potential so far, including different standards and interoperability issues across Member States, as well as unclear and fragmented legal frameworks around data protection. The EHDS Regulation should make it possible to overcome existing barriers and help tackle specific pathologies, especially when it comes to high-burden diseases, such as cardiovascular disease (CVD).

Cross-border continuous registration of harmonised patient data for specific diseases is already underway, thanks to the work done by scientific societies to run registries such as the [EuroHeart](#) project, initiated by the European Society of Cardiology¹ helping to define standards, minimum data fields and other dataset elements.

The introduction of disease-specific harmonised templates would further facilitate interoperability and the achievement of comparable real-world data at European level. However, investment and sustainability of CVD registries is not guaranteed remains the leading cause of death in the EU and worldwide, with more than 60 million people living with CVD in the EU and nearly 13 million new cases diagnosed each year², meaning there is a significant gap between the cost to human life and the investment made in reducing the burden of CVD. The collection and analysis of real-world data remains a cornerstone for continuous improvement of the quality of care of CVD patients.

The EHDS must ensure that data is worth sharing. This means heavy investment in the creation of disease-specific registries at EU level, starting with CVD as it is the biggest killer.

Healthcare professionals will be considerably affected by the new framework in relation to both primary and secondary use of electronic health data. Professionals who work with electronic health data need to be trained on the regulatory requirements for accessing and sharing European health data, for instance with reference to electronic health data registration.

The involvement of patients and healthcare professionals at every step will be key to ensuring the effective operation of the EHDS.

The MEP Heart Group issues the following recommendations to the European Commission and Council:

¹ The EuroHeart Project aims to improve cardiovascular care in Europe by recording individual patient data. The project provides a common IT and dataset infrastructure in participating countries to undertake continuous quality improvement, as well as offering a platform for observational and randomized research. Initially focusing on four common disease areas - ACS-PCI, valve disease, heart failure and atrial fibrillation - standardized datasets and quality indicators will be developed before being rolled out across more ESC member countries to improve standards of care. European Heart Journal (2019) 40, 2745–2759 doi:10.1093/eurheartj/ehz599

² MEP Heart Group, Facts and Figures, <https://mepheartgroup.eu/facts-figures/>, last accessed 24 April 2023

Recommendation #1: The MEP Heart Group calls on the European Commission and Member States' regulatory authorities to leverage existing stakeholder expertise with registries and data-sharing initiatives for the definition of standards and minimum data sets.

Recommendation #2: The MEP Heart Group urges the European Commission to secure appropriate EU investment for cardiovascular disease registries within its existing funding programmes such as EU4Health or Horizon Europe

Recommendation #3: The MEP Heart Group recommends involving academia and health professionals' organisations through consultation in the drafting of implementing and delegated acts and ensuring they are regularly represented in the EHDS Board and participate in its activities.

Recommendation #4: The MEP Heart Group calls for the delivery of training initiatives for healthcare professionals concerning the rights, rules and obligations deriving from the EHDS Regulation.