

The European Society of Cardiology welcomes the European Commission's initiative to create a European Health Data Space for better healthcare, research, and policymaking.

The COVID pandemic has clearly shown the weakness to overcome healthcare challenges and lack of collaboration between Member States and their data exchange due to national legal constraints. It has also shed light on the benefits that better sharing and use of health data can bring to healthcare in the EU.

The European Health Data Space shall allow to exploit the potential of ever-growing data in a trustworthy European framework where Member States are encouraged and supported to better align their use of health data, to stimulate research and enable data-driven healthcare for citizen benefits while protecting their privacy.

The European Society of Cardiology fully endorses the vision for using and combining patient data for the continuous improvement of patient care and health outcomes. To this end it has developed over twenty registries covering a range of cardiovascular diseases within its [EURObservational Research Programme \(EORP\)](#) with more than 140.000 patients enrolled overall.

Additionally, it has recently started a new initiative [called EuroHeart](#), which aspires to a more comprehensive and unified patient registry approach across Europe. EuroHeart is designed for the continuous improvement of patients care, easier recruitment of patients in clinical studies, the conduct of pragmatic randomised clinical trials, the post-marketing surveillance of drugs and devices, and supporting the planning of health care investments. It is a collaboration between national registries providing continuous data collection of standardised and/or harmonised variables in common cardiovascular diseases (i.e. acute coronary syndromes, heart failure, atrial fibrillation, valve diseases), including therapy, medical and instrumental interventions, and long-term outcomes. EuroHeart reports will be based on analyses of aggregated data sets originating from synchronised performance of identical analyses in the individual countries. Based on the development of the EHDS we also foresee opportunities to use federated databases allowing analyses based on anonymized individual data including AI methodologies.

EuroHeart will make comparable real word data in cardiovascular disease available at European level, significantly contributing to the EHDS vision and ambition. Cardiovascular disease is the main cause of mortality in Europe (and globally). In the EU there are more than 60 million people living with cardiovascular disease and nearly 13 million new cases of cardiovascular disease diagnosed each year.

Harmonised, comparable real-world data on cardiovascular disease would therefore be a huge asset for the realisation of the EHDS and therefore ESC supports the EHDS Nodes Concept, including research infrastructure and is willing to support its development with ESC expertise gathered in EORP and EuroHeart Programmes.

### **Recommendations**

The European Society of Cardiology puts forward the following recommendations to ensure that the European Health Data Space is deployed and delivered successfully:

- Member States should be supported to increase the “digital maturity” of their systems. Adequate EU funding should be made available to support the development of digital infrastructures and facilities which will contribute to a strong European Health Data Space
- EU funding should also be made available to support ambitious projects aiming at unifying patient data across Europe through the use of common datasets in key clinical areas, such as the EuroHeart project.

- EU Codes of Conduct, especially for health research and secondary use of health data, should be adopted to facilitate cross-border exchange of data. Scientific societies, such as the European Society of Cardiology, should be closely consulted and associated to this process
- Due to the sensitivity of the data to be processed within the EHDS, the boundaries of what constitutes a lawful processing of the data must be crystal-clear for all the stakeholders involved. Therefore, transparency on processing in the EHDS will be key to ensure public trust in the initiative.
- The implementation of GDPR rules covering health research at member state level is fragmented. This situation is a clear barrier for the development of European research and hence for the innovation and progress of the EU health systems. Therefore we call the Commission to assess GDPR level of fragmentation on research and address this problem with regulatory non-binding and when possible regulatory binding measures.