The European Health Data Space: health data moves across borders for research purposes

Cross-border health data has not been appropriately utilised in research and decision-making in Europe. There is a strong desire in the EU to create infrastructure for the secondary use of health data and sensitive genomic data. The European Health Data Space (EHDS) and specifically its HealthData@EU environment is being established for this purpose.

The pandemic caused by the COVID-19 virus revealed significant shortcomings in the sharing and coordination of health data in Europe. It was recognised how crucial it is to ensure secure access to health data across Member States, especially when people were moving freely within the EU during the pandemic. Decision-makers faced difficulties during the pandemic in obtaining the necessary electronic health information. Individualised drug treatments are also possible only if patient data is available and stored, pre-processed and classified in a consistent manner in all countries.

Sharing health data across borders has been surprisingly difficult. The availability of personal health information and genetic data in digital form varies between Member States. Legislation also varies. The EHDS ensures the coordination and consistency of primary and secondary use of health data. Permanent structures are now being established for collaboration.

The EHDS will markedly transform healthcare in the coming decades. The EHDS creates a common space for managing and transferring electronic health data, such as patient records, patient registers and genomic data. It also gives researchers the opportunity to access health data reliably. Privacy protection is also maintained.
While discussing the legislative framework in Europe, infrastructure is being built to move forward. What’s positive is that the views of experts, such as researchers, have been taken into account in legislation. Large pilot projects were initiated even before the legislative work began,” says Persephone Doupi, Senior Medical Officer at the Finnish Institute for Health and Welfare (THL). She works in THL’s Data and Analytics Unit as the coordinator for international secondary use data management projects. The unit promotes the diverse use and interoperability of data resources. One of its tasks is to develop open data interfaces and services.

“We need to consider the entire lifespan of data, the model and the approach as a whole. This is especially evident when talking about data quality and standardisation – particularly, how information in different systems is semantically interoperable. We should understand this early enough. What’s absolutely central is how healthcare professionals document health data in different countries,” says Doupi.

Secondary use of data
THL and Finland’s ELIXIR Node CSC – IT Center for Science were involved in a project called Towards the European Health Data Space (TEHDAS), which included 25 countries and concluded in July 2023. TEHDAS was a collaborative project that conducted preparatory work and provided recommendations to promote the implementation of the EHDS. According to Doupi, the wider utilization of health data imposes new requirements, particularly when it comes to cross-border secondary use.

“The goal of the TEHDAS project was to determine how cross-border/EU-level secondary use of data could be organised and what kind of legislation is needed. What would be the governance model and tasks of data permit authorities, and how could access to data be organised? At the same time, the project involved investigating what kind of information-system architecture and technical solutions would be most suitable, how to ensure data quality and the interoperability of datasets, and what standards are available.”

TEHDAS continues with the TEHDAS-2 project. It includes a work package that addresses secure environments, with the goal of creating sustainable solutions for the secure management of data.

“CSC is involved in the development of secure environments. The biggest question concerns the definitions, administrative mod-
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CSC has had a central role from the beginning, especially when considering datasets related to genomics. In Finland, there are no other actors besides CSC that could provide similar expertise in this regard.

Doupi points out that even if the legislative work makes progress, it will still take years to see the true impact of secondary data use on research. Even at this stage, however, collaboration between different authorities has increased and has even become mandatory, which Doupi sees as a positive development.

“The EHDS enables the study of complex and significant diseases in a more reliable way in the future. In the Nordic countries, for instance, it has been acknowledged that there is not sufficient data for every research subject individually. When we combine all the datasets from the Nordic countries, we get more reliable data for research. This is crucial when studying rare diseases, for example, or the safety and efficacy of medications. The dataset of just one country is not sufficient for studying such topics.”

Over a million European genomes
One good example Doupi mentions is the European Union’s 1+ Million Genomes initiative (1+MG). The initiative aims to enable secure access to genomic data and related clinical datasets to support better research and decision-making. National collections, combined through the 1+MG initiative, together form the Genome of Europe, a vast European database. Over a million genomes had been sequenced by the end of 2022.

1+MG and its follow-up project Beyond 1 Million Genomes (B1MG) are among the world’s largest projects in their category. Operative infrastructure will be in place in 15 countries by 2026. 1+MG and B1MG collaborate closely with the EHDS. The future looks promising, Doupi says.

“I assume that awareness of data quality will increase. At the same time, interdisciplinary collaboration will break down unnecessary silos. Hopefully this will also initiate a societal discussion, for example about the use of artificial intelligence. The processing of large datasets requires artificial intelligence, and there must be a flexible approach to it. We must be constantly vigilant in adapting to new information and changing environments. That will happen through the EHDS.”

12.12.2023 | Ari Turunen

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http://www.elixir-finland.org
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MORE INFORMATION:

ELIXIR FINLAND
Tel. +358 9 457 2821s  e-mail: servicedesk@csc.fi
www.elixir-europe.org/about-us/who-we-are/nodes/finland

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