European Health Data Space (EHDS) – key duties for health data holders

What is the European Health Data Space?

The European Health Data Space (EHDS) Regulation is an EU common framework that will make large, anonymised datasets available for research, innovation and policy-making. The aim is to improve healthcare and health outcomes by supporting better research, stronger policies, improved planning and more informed decisions across health systems.

Who is a health data holder?

If you control or process electronic health data, you are a health data holder and have obligations under the EHDS Regulation.

Health data holders include:

Registries and research institutions

Healthcare providers, such as hospitals

Public authorities or agencies involved in health or healthcare services

Health insurers and organisations managing care reimbursement systems

Developers of health-related products and services, including wellness applications

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An Roinn Sláinte
Department of Health

HRB
An Bord Taighde Sláinte
Health Research Board

What are my obligations as a health data holder under the EHDS Regulation?

Personal data provision

Health data holders must provide data to the national Health Data Access Body (HDAB) within three months of an approved data request. A HDAB is a service that allows data users to apply for access to health data for research, education, policy-making and statistics.

This can be extended by a further three months in certain circumstances. The timeline begins when the HDAB notifies the health data holder of the approved request.

Non-personal data provision

If a health data holder processes non-personal health data this data must be made available via open public databases that follow clear rules to ensure openness, good information management and long-term access.

Security and privacy requirements

Data must be kept safe and secure, with robust security and privacy measures in place.

Data must be prepared (for example, anonymised and quality checked) before it is reused.

Dataset description and data quality and utility label (metadata)

A health data holder must ensure that metadata describing the datasets is submitted to the national dataset catalogue* and is reviewed and updated at least once a year.

*A national data catalogue is a central, accessible register of datasets and their metadata, helping data users find, understand and use data.

Example of non-personal health data

Anonymised health data, synthetic datasets or datasets comprising of data that does not relate to individuals