HealthData@IE – setting up health data access body services in Ireland

Preparing for the establishment of a health data access body services in Ireland

Guidance for data holders

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1. Introduction

The European Health Data Space (EHDS) Regulation requires that EU Member States establish health data access body (HDAB) services to facilitate the secondary use of electronic health data. Having entered into force in March 2025, the EHDS Regulation will be implemented on a phased basis. Chapter IV of the regulation, which relates to the secondary use of health data, will be implemented between 2029 and 2031. Data holders will be expected to provide metadata descriptions to the HDAB in order to populate a national health dataset catalogue. Data holders will in turn be expected to provide their data to the HDAB when data permits have been issued to data users.

Through the work being undertaken as part of the HealthData@IE project, health data access services are being established in Ireland. While the focus of the project is on developing some of the national infrastructures needed for data access, an emphasis is also being placed on supporting data holders to understand their specific obligations under the regulation. These include obligations to make their metadata and data findable and accessible, and to use standards to ensure interoperability and the safe and secure transfer of data between systems.

1.1 Purpose of this guidance

This guidance document outlines what the EHDS Regulation is, with a particular focus on what it will mean for the secondary use of health data and the implications for Ireland. It describes the process of applying for, and accessing, datasets through a HDAB service and sets out a number of specific obligations which will be placed upon data holders when the EHDS Regulation comes into force. This guidance aims to support data holders to better understand these obligations and to assist them in identifying where organisational changes are required to achieve compliance with the EHDS Regulation.

It is important to highlight that this document has captured information published by the European Commission as of March 2025, primarily using the EHDS Regulation and associated frequently asked questions document as sources of information. Further information and technical details will be provided by way of implementing acts and national level policy which will be developed over the coming years, at which point this guidance document will be reviewed and may be revised where appropriate.

2. Understanding the EHDS Regulation

2.1 Background to the EHDS

The European data strategy, announced in February 2020, sets out to create common European data spaces in a number of strategic fields, including finance, agriculture and health, with the ultimate aim of creating a single market for data across all EU Member States.[2] These data spaces will facilitate the reuse of data across different sectors of the economy and society. Two crucial pieces of legislation, the Data Governance Act and the Data Act, have been put in place to provide the legislative basis and regulatory framework for achieving the objectives of the strategy.[3, 4] The European Commission has also prioritised the development of the necessary technological systems and infrastructures to optimise data use and reuse across the EU and drive innovation. The EU's Digital Decade policy programme, launched in January 2023, sets out targets and objectives for 2030 in a number of key areas, including the digitalisation of public services and ensuring all citizens have access to their medical records online.[5] The European Health Data Space (EHDS) is the first common data space to emerge from the European data strategy.

There are key terms used throughout this document which are directly relevant the EHDS Regulation, these are described in Table 1.

Table 1 Description of key terms, as set out in the EHDS Regulation

Group	Description
Health data user	Any individual who has received a data permit (see below for definition) and thus has lawful access to personal or non-personal electronic health data for secondary use.
Health data holder	Services, or organisations who process personal health data that falls in to any one of the categories of data for secondary use which are set out in the EHDS Regulation, see Table 3 below for the fill list of categories.
Health data access body (HDAB)	A service that allows data users, such as researchers and policy-makers, to apply for access to health datasets to support research and innovation, education and training, policy-making, health service management and preparing national statistics.

Group	Description
Data permit	An administrative decision, made by a HDAB following a data access application by a data user, to process certain electronic health data specified in the data permit for specific secondary use purposes.
Data access application management system (DAAMS)	A system to receive, track and process applications and to issue permits.
Secure processing environment (SPE)	A highly-secure platform and isolated environment that allows all data processing activities to take place under supervised conditions.

2.2 Key initiatives to support the development of the EHDS

The foundations of the EHDS were laid through the EU joint action, 'Towards a European Health Data Space' (TEHDAS). This joint action aimed to help EU Member States and the European Commission to develop concepts and proposals to promote the secondary use of health data to benefit public health and health research and innovation in Europe.[6] The recommendations from the TEHDAS project were used by the European Commission to inform the development of a proposal for regulation of the EHDS in May 2022. The European Parliament formally approved the proposal for the establishment of the EHDS in April 2024 and it was adopted later that year. The Regulation was published in the Official Journal of the European Union on March 5th 2025 and entered into force twenty days later.[1, 7]

Following on from the work of the TEHDAS joint action, the HealthData@EU pilot set out to build a pilot version of the EHDS infrastructure for the secondary use of health data, referred to as HealthData@EU.[8] This project ran until December 2024 and developed a network infrastructure alongside services to support data users. It also provided guidelines for data standards, quality, security and transfers to support the EHDS infrastructure. In addition, a further EU joint action, TEHDAS2, commenced in 2024 with the aim of developing common guidelines and technical specifications to facilitate secure access to health data and strengthen European collaboration in using data efficiently.[9] These key initiatives are summarised in Table 2.

Table 2 Summary of relevant ongoing and completed EU projects

Project	Description
HealthData@IE	An EU-funded project, led by the Department of Health in collaboration with HIQA and the HRB, focussed on developing national infrastructures needed for data access, including data access infrastructure systems that have been identified by the EU Commission as being core Digital Business Capabilities for HDABs.
HealthData@EU Pilot (2022 – 2024)	Development of a pilot version of the EHDS infrastructure for the secondary use of health data, as well as services, and guidelines to support the EHDS infrastructure.
TEHDAS (2021 – 2023)	A joint action project which developed concepts and proposals for the secondary use of health data. Its recommendations informed the development of the proposal for the EHDS Regulation.
TEHDAS2 (2024 – 2026)	A second joint action, building on the work of TEHDAS. Aims to develop common guidelines and technical specifications for the European Commission to support the implementation of the EHDS Regulation.
QUANTUM (2024 – 2026)	An EU-funded project, focusing on developing a common label system for the EHDS that assesses and communicates the quality and utility of datasets and enables data users to identify high-quality data for research and decision-making.

2.3 Benefits of the EHDS

The EHDS will empower individuals to take control of their own health data and make it easier to access and exchange health data across EU Member States, both to support healthcare delivery (known as primary use of data) and to facilitate other uses of the data, including research and policy-making (known as secondary use of data). In relation to the secondary use of data, in particular, the potential benefits of the EHDS include:

- For citizens and patients: assurance that their data is being used to its full potential to drive improvements in population health and the provision of services, including new medicines, while being managed securely and transparently in a way that ensures their privacy and confidentiality is protected. Empowers individuals to access their data and make informed choices about the control and sharing of their health data.

- For data users, the broader workforce and the health service as a whole: access to a wide range of data and linked datasets, SPEs, leading to greater opportunities for research and innovation; a national contact point and a more streamlined, efficient system for accessing health data via the issuing of data permits; and greater capacity for evidence-based policy and decision-making.
- For data holders: support to make their datasets more readily available while maximising the utility and potential impact alongside training and guidance to promote the enhancement of the quality of their data.

Acknowledging that trust is fundamental to the success of the EHDS, the EU Commission has prioritised ensuring secure and trustworthy platforms for facilitating access to and processing of, health data. As such, the EHDS Regulation builds on the General Data Protection Regulation (GDPR), the Data Governance Act and the Data Act. In addition, among all Member States, there is need for legislative and operational preparations to ensure readiness to implement the EHDS.

2.4 Ireland's preparations for the EHDS Regulation

2.4.1 HealthData@IE 2023-2027

In respect of the secondary use of data, the EHDS Regulation places an obligation on Member States to establish a HDAB. A HDAB is a service connecting data users, such as researchers and policymakers, with anonymised health datasets for purposes including research, innovation, service oversight and patient safety. Access to datasets will be subject to a stringent and transparent decision-making process with legal, technical and ethical controls in place, in line with national requirements and those set out in the EHDS Regulation.

The DoH, in collaboration with the HIQA and the HRB, was awarded funding for the HealthData@IE project under the EU4Health programme to support the establishment of HDAB services in Ireland. Working with key stakeholders in the Health Service Executive (HSE) and across the health system, the HealthData@IE project will focus on the development of national infrastructures needed for data access, including data access infrastructure systems that have been identified by the European Commission.[10] These include a DAAMS to receive, track and process applications and to issue permits; a national health dataset catalogue to facilitate data discovery and contribute to an EU-wide catalogue, and SPEs to facilitate the secure processing of health data. The HealthData@IE project will also deliver important programmes of work centred on data quality enhancement, engagement and dissemination, and training and education for data users, data holders, HDAB staff and citizens.

2.4.2 Health Information Bill 2024

The Health Information Bill 2024 is part of a suite of planned legislative measures to give full effect to the EHDS Regulation. The Bill, which is a strategic enabler of Digital for Care – A Digital Health Framework for Ireland 2024-2030, will help create a fit for purpose digital-first health information system that enhances patient care and treatment as well as supporting better planning and delivery of health services into the future.[11]

The Bill provides a clear legal basis for the establishment of electronic health records by mandating the pulling together of prescribed categories of patient information from across all settings – public, private, and voluntary. This will enhance patient access to and control over their data, and provide health professionals with a more complete, holistic view of patients they are treating. In line with national digital strategy, the Bill provides for best practice use of Eircodes and PPSN to uniquely identify patients.

The Bill also provides for a robust legal basis for the sharing of personal health data by introducing a statutory duty for health services providers to share personal health data with other health services providers for the purposes of patient care and treatment, the sharing of health data at the patient's request, and the safeguarding of patient data in the event of service closure. In addition, the Bill strengthens the provision of health information to the HSE from bodies across the health services, including voluntary and private providers, for specified public-interest secondary-use purposes within the HSE's remit, including public health, service planning and performance management, and statistics.

National Standards for Information Management in Health and Social Care

In 2024, HIQA published National Standards for Information Management in Health and Social Care.[12] These national standards can be applied to both primary and secondary uses and aim to drive safer, better care by providing a roadmap for organisations and services to improve the management of their information. Presented under the four principles of a human rights-based approach, safety and wellbeing, responsiveness, and accountability, these national standards can also be used by data holders as a tool to assist with preparations for the implementation of the EHDS Regulation and the establishment of HDAB services in Ireland.

3. Secondary use of health data

3.1 What are secondary uses of data in the EHDS?

The EHDS Regulation will establish a common mechanism to access electronic health data for secondary use purposes across EU Member States.[1] This regulation will streamline the steps required for accessing health data, including a secure centralised platform hosting a national health dataset catalogue. Member States will be obliged to set up a HDAB service to enable data users, such as researchers and policy-makers, to apply for access to health data for various secondary use purposes, including:

- public health surveillance
- policy-making and regulatory activities
- education or training activities in health or care settings
- scientific research
- healthcare improvement.

A detailed explanation of the purposes for which health data can be processed for secondary use under the EHDS Regulation is set out in **Appendix 1**.
The EHDS will also make it possible to access data for these purposes on a cross border basis, including access to multi-country datasets.
There are three core groups for which the secondary use of health data, as set out under the regulation, relates to. These are data holders, data users and a health data access body, which are described in Table 1.

3.2 Opt-out for secondary use

Under the EHDS Regulation, individuals will have the right to opt out from the processing of their identifiable health data used for secondary purposes. Member States will create clear guidance regarding a user-friendly opt-out mechanism. Individuals may reverse their decision to opt-out at any time.

3.3 Who is a data holder in the EHDS?

The EHDS Regulation provides a specific definition for a data holder as follows:
"any natural or legal person, public authority, agency or other body in the healthcare or the care sectors, including reimbursement services where necessary, as well as any natural or legal person developing products or services intended for the health, healthcare or care sectors, developing or manufacturing wellness applications, performing research in relation to the healthcare or care sectors or acting as a mortality registry, as well as any Union institution, body, office or agency, that has either:

1. the right or obligation, in accordance with applicable Union or national law and in its capacity as a controller or joint controller, to process personal electronic health data for the provision of healthcare or care or for the purposes of public health, reimbursement, research, innovation, policy making, official statistics or patient safety or for regulatory purposes; or
2. the ability to make available non-personal electronic health data through the control of the technical design of a product and related services, including by registering, providing, restricting access to or exchanging such data;" [1]

The regulation provides a caveat to the obligation to make health data available for independent researchers and 'micro-enterprises'. A micro-enterprise under the European Commission's recommendation are those who employ fewer than 10 people and for whose annual turnover and/or balance sheet does not exceed € 2 million.[13]

Organisations must make available health data which they control and which falls under the categories of data, set out in Table 3. For example, if a provider of a patient management system is processing personal electronic health data on behalf of a hospital, they do not qualify as a health data holder in this instance, as the hospital and not the patient management system is considered to be the controller of the health data.

3.4 Which data will health data holders have to make available?

Chapter IV of the EHDS Regulation sets out the categories of data which will be required to be made available for secondary uses. See Table 3 for the full list of categories of data for secondary use under the EHDS Regulation.

> "Individuals, services, or organisations who process personal health data that falls into any one of these categories of data are considered data holders under the EHDS. Those who have the ability to make available non-personal data from any one of these categories, for example through control of a product or related service, are also considered data holders."

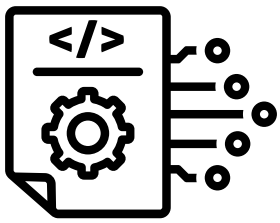
It is important to note that the majority of these categories of data must be made available for secondary use by 2029, four years from the date of entry into force of the regulation. For five categories of data, as indicated in Table 3 below, the regulation will come into effect in 2031, six years following the EHDS Regulation entering into force.

Table 3 EHDS categories of data for secondary use

A	Data from electronic health records (EHRs).
B	Data on factors impacting on health, including socio economic, environmental and behavioural determinants of health. For example, the Healthy Ireland dataset.*
C	Aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, and healthcare expenditure and financing. For example, the Patient Treatment Register (PTR) and HSE performance reports.
D	Data on pathogens that impact human health. For example, the Computerised Infectious Disease Reporting (CIDR) system.
E	Healthcare-related administrative data including on dispensations, reimbursement claims and reimbursements. For example, the Primary Care Reimbursement Service (PCRS).
F	Human genetic, epigenomic and genomic data.*
G	Other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data.*
H	Personal electronic health data automatically generated through medical devices.
I	Data from wellness applications.
J	Data on professional status; and on the specialisation and institution of health professionals involved in the treatment of a natural person. For example the Health Service Personnel Census.
K	Data from population-based health data registries such as public health registries. For example, the National Cancer Registry of Ireland (NCRI).
L	Data from medical registries and mortality registries. For example, the National Office of Clinical Audit (NOCA) datasets and the Irish National Rare Kidney Disease Registry.
M	Data from clinical trials, clinical studies, clinical investigations and performance studies.*
N	Other health data from medical devices.
O	Data from registries for medicinal products and medical devices.
P	Data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results. For example, the Irish Longitudinal Study on Ageing (TILDA)*.
Q	Health data from biobanks and associated databases.

* The inclusion of this category of data will come into effect in 2031, six years from the date of entry into force of the regulation.

3.5 Accessing data for secondary use purposes under the EHDS Regulation



Data discovery through a national metadata catalogue

As set out in the EHDS Regulation, when HDAB services are established in Member States, they will be responsible for the maintenance of national health dataset catalogues to facilitate data discovery. National health dataset catalogues will be integrated with an EU-wide catalogue. Defining the requirements and specifications for a national health dataset catalogue in Ireland, and developing and implementing the finalised digital catalogue to include all relevant datasets is a key programme of work under the HealthData@IE project. This national health dataset catalogue will be publicly-available and in a standardised machine-readable format.

Data holders will be required to provide a description of the datasets they will be making available to the HDAB for publication in the national health dataset catalogue. Data holders will be obliged under the regulation, to verify annually that information contained within the national health dataset catalogue is accurate and up-to-date. Guidelines on data description for data holders are currently in development at a European level, and it is anticipated that they will be published by the European Commission later in 2025.[14]

Through the HDAB website, data users will be able to browse the national health dataset catalogue and assess the suitability of available data sources for their specific needs.

By 2027, within two years of the EHDS Regulation coming into force, the Commission will publish, by way of implementing acts, the minimum metadata that data holders will need to make available through the HDAB. By making this information available, the aim is to create a standardised catalogue which facilitates accessibility and interoperability.[1]

Applying for data

When data users have identified suitable data sources, they can submit an application for data. For access to datasets located in a single Member State, applications will be submitted to the national HDAB in that Member State. For access to cross-border datasets and for access to multiple datasets from multiple Member States, additional information will be provided through the implementing acts. There will be two pathways for data users to request access to data.

- **Data request:** A data user applies for access to data in an anonymised, aggregated (non-individual-level) statistical format.
- **Data access application:** A data user applies for access to individual-level data in an anonymised or pseudonymised format. The data user will have safe and controlled access to data through a SPE.

As set out in the EHDS Regulation, HDABs must prioritise the protection of individual-level data by granting access to anonymised statistical data wherever possible. If anonymised individual-level data, aggregated data or statistical results, will meet the needs and objectives of a data user, the data request pathway should be taken by the data user. This, therefore, will be the default option for data applications.

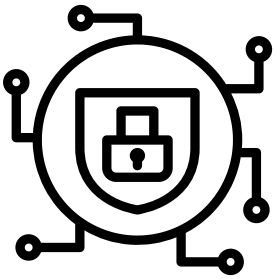
HDABs will only make pseudonymised individual-level data available if it is essential for the intended purpose. Data users will need to provide a clear argument in their data access application if pseudonymised data is required. Data users should select the data access application pathway only when individual-level data is necessary to achieve the objectives of the project and aggregated statistical results are insufficient to meet their needs.

In order to enable a future HDAB service to receive, process and reply to data users' applications, a DAAMS is being developed for Ireland as part of the HealthData@IE project.

Making data available

All data access applications will be assessed by the HDAB to ensure they comply with legal and ethical standards, with data users being notified of the decision within three months. If a decision is made to issue a data permit, a request will be sent to the relevant data holders who will have another three months to make the relevant data available to the HDAB. Subsequently, the dataset will be made available to the data user through a SPE in an anonymised or pseudonymised format. It should be noted that both data holders and the HDAB service can be involved in the pseudonymisation and anonymisation of health data, the EHDS Regulation recommends that the process occurs as early as possible in the process of making data available for secondary purposes. However, final responsibility for Pseudonymisation and anonymisation falls with the HDAB.

Standards, guidance and guidelines developed at a European level will support data holders to share their data with the HDAB in a standardised way. In order to support data holders in providing data to the HDAB service in Ireland, a national interoperability framework, aligned with European requirements will be developed by HIQA as part of the HealthData@IE project

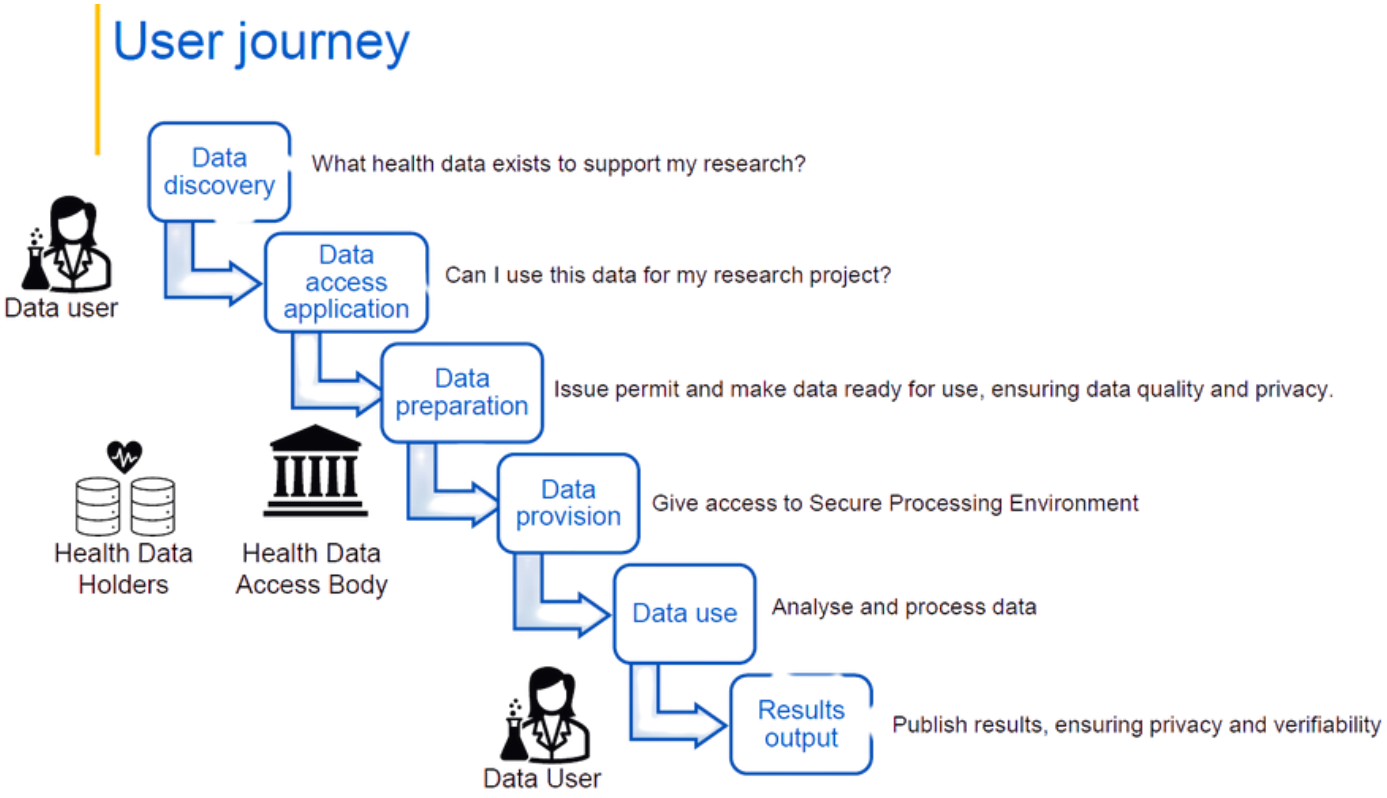


Accessing datasets

Once released, data users will have access to the datasets in a SPE, where data processing will take place. This highly secure and isolated environment will allow the HDAB control over how the data is accessed, used and processed. Defining the requirements and specifications for a SPE in Ireland, which are aligned with SPE in other EU Member States and based on high technical and security standards, is a programme of work under the HealthData@IE project. There will be a requirement for data holders to publish a report detailing their findings or output from the secondary use of the data.

The process for applying for and accessing data for secondary use purposes in the EHDS is summarised in Figure 1.

Figure 1 Summary of a data user's journey applying for and accessing health data for secondary use purposes under the EHDS



What does this mean for data holders?

Under the EHDS Regulation, data holders will be obliged to make health data available for secondary purposes through a HDAB service. They will also be required to provide a description of their datasets to the HDAB which will be published in a national health metadata catalogue. Data users will be able to browse this catalogue to discover and assess the suitability of available datasets. Access to datasets will be provided to data users on a permit basis and through SPE.

3.6 Unique personal identifiers and data linkage

The HDAB will create new potential for the linkage of individuals' health data from different sources safely and securely using established techniques. This will significantly enhance the potential and value of health data in Ireland by facilitating the effective secondary use of data from a range of sources, allowing for improved analysis and interpretation of the data.[15] As outlined in Section 2.4.2, the Health Information Bill will detail best practice methods and identifiers for data linkage. Under the EHDS, there will be a requirement for data holders to prepare datasets to facilitate linkage and ensure interoperability with other datasets. Recommendations have been made for data holders to implement data management procedures which allow for dataset linkage and persistent identification methods across datasets using unique identifiers.[16]

What does this mean for data holders?

The opportunity to link datasets will be a key feature of the EHDS. In order to facilitate this, the use of unique identifiers across datasets will be essential.

3.7 Compliance with the EHDS Regulation

Once established, HDAB services will have the power to monitor and enforce compliance with the EHDS Regulation for both data holders and data users. Where non-compliance is identified, the HDAB will have the power to place a fine on the data holder. The European Commission will publish guidelines for Member States and HDABs on enforcement measures.

What does this mean for data holders?

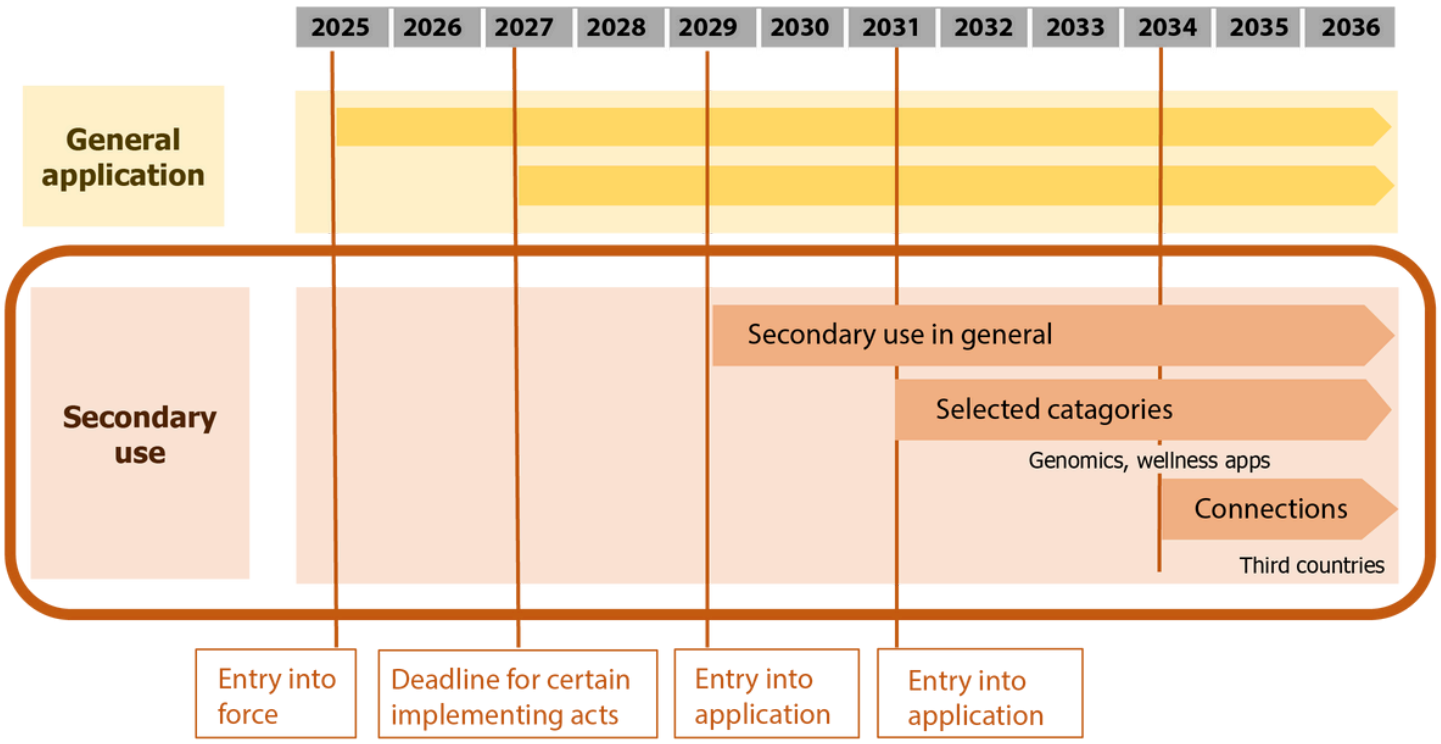
The opportunity to link datasets will be a key feature of the EHDS. In order to facilitate this, the use of one or more unique identifiers across datasets will be essential.

3.8 Important dates and timelines for data holders

The EHDS Regulation entered into force in March 2025. There will be a phased approach to the implementation of the regulation which relates to the secondary use of data. For the majority of categories of data, the regulation will come into force in March 2029, while for five categories of data, it will come into force in March 2031 (See Table 3 and Figure 2). This means that the majority of data holders will be required to be ready to submit their metadata and data to a HDAB service in 2029 to facilitate its use for various secondary purposes.

Data holders will be expected to submit descriptions of the datasets they hold which are relevant to the HDAB by either March 2029 or March 2031, depending on the implementation phase each dataset falls within. It is at this same time that data holders should be prepared to make available the datasets to the HDAB following a data permit being issued.

Figure 2. Overall timeline for implementation of the EHDS Regulation



4. Data quality and interoperability in the EHDS

Under the EHDS Regulation, data holders will have several responsibilities with regard to data quality. A recently developed data quality framework has made several recommendations to the European Commission and to Member States on data quality and utility in the EHDS. It sets out the main elements of data quality and documents data quality activities that are applicable to every stage of the data lifecycle, with a particular focus on the secondary use of data.[16, 17]

4.1 Data quality and utility label

The EHDS Regulation mandates the labelling of health datasets to demonstrate their quality and usefulness for data users and secondary use of health data. Under the EHDS Regulation, data holders will be required to apply a data quality and utility label to all datasets being made available through the HDAB. This label is currently under development and once finalised, this common labelling system will be available for use across Member States to report on the quality and utility of datasets so that data users can identify high-quality data for research and decision-making purposes.[20] The label aims to provide standardisation on the quality, structure and utility of data, and to enhance trust and usability of the data by providing clear, comparable information to data users. Further information will be provided on the data quality and utility label through implementing acts.

What does this mean for data holders?

To comply with the EHDS Regulation, data holders will need to apply a data quality and utility label to all their datasets. This label is currently under development and will be published by June 2026.

4.2 Standards for interoperability

Interoperability* refers to the ability of two or more systems to exchange information and use the information that has been exchanged. The EHDS Regulation sets out specific requirements to ensure interoperability between systems in order to facilitate seamless sharing and utilisation of data across Member States.Within the context of health data, interoperability facilitates the sharing of data between one system and another.[18]

* Interoperability in the EHDS Regulation is defined as 'the ability of organisations, as well as of software applications or devices from the same manufacturer or different manufacturers, to interact through the processes they support, involving the exchange of information and knowledge, without changing the content of the data, between those organisations, software applications or devices.'

It has been identified that interoperability standards will play a significant role in a number of stages of the data life cycle in particular, including in the data preparation process and in the publication of metadata. Standardisation will also be key to enabling data linkage and integration across systems. Recommendations have been made in relation to the use of standards at the various phases of the data lifecycle, including the following:

1. Standards for data discoverability (metadata standards)
2. Standards for semantic interoperability
3. Standards for interoperable communication (data exchange).[19]

These three types of standards will be summarised in the following section.

4.2.1 Standards for data discoverability

The DCAT application profile (DCAT-AP) is a specification used for sharing information about datasets in Europe. It is used widely across open data portals in Europe, including Ireland's Open Data Portal. The recently-developed HealthDCAT-AP is a health-related extension of DCAT-AP which introduces a set of descriptive terms to accommodate the unique requirements of electronic health data.[20] Data holders will be required to use the HealthDCAT-AP to share metadata describing their health-related datasets with the HDAB service.

4.2.2 Standards for semantic interoperability

Semantic interoperability refers to the ability to share data in a way that ensures mutual understanding of the meaning and interpretation of that data.[18] For the parties who are exchanging data, semantic interoperability makes data findable, understandable and communicable. In an assessment of standards for semantic interoperability, with a focus on secondary use purposes, SNOMED CT, LOINC and Orphanet codes were identified as the most appropriate systems for facilitating the sharing of information between data holders and a HDAB service.[19]

4.2.3 Standards for interoperable communication (data exchange)

Standards for interoperable communication, often referred to as messaging standards or data exchange standards, are commonly-accepted structures for electronic messages used to exchange information between systems. They specify how data elements (typically represented by standard vocabularies) should be arranged. Messaging standards outline the structure, content and data requirements of electronic messages to enable the effective and accurate sharing of information.[18] In this context, the term

'message' refers to a unit of information that is sent from one system to another, such as between a data holder and a HDAB service.[18] In an assessment of interoperability standards, HL7 FHIR and DICOM were identified as the most appropriate data exchange standards for the sharing of information between data holders and a HDAB service.[18]

What does this mean for data holders?

To ensure interoperability and to optimise the secondary use of data in the EHDS, data holders will be required to use certain standards. This includes the HealthDCAT-AP for sharing their metadata; SNOMED CT, LOINC and Orphanet codes for semantic interoperability; and HL7 FHIR and DICOM for exchanging information with the HDAB service.

4.3 Submitting metadata and data to a HDAB service

When HDAB services are established in Ireland, a variety of systems will be in place to enable data holders, including the submission of data from organisations like the HSE, to share their metadata and data with the service. This includes the manual submissions by the data holder; the pulling of data directly from data holders by the HDAB, or the pushing of data to the HDAB by data holders.[21]

- Manual submission of data and metadata from the data holder to the HDAB would involve the use of file uploads (e.g. CSV files) or a form-based user interface by the data holder.
- A 'pull' system would involve systems being in place to enable the HDAB service to harvest metadata and data from the data holder via an application programming interface.
- A 'push' system would involve data holders uploading metadata and data directly to the HDAB service via an application programming interface.

5. Glossary of terms

Term	Definition
Data access application management system (DAAMS)	A system to receive, track and process applications and to issue permits.
Data holder	"Any natural or legal person, public authority, agency or other body in the healthcare or the care sectors, including reimbursement services where necessary, as well as any natural or legal person developing products or services intended for the health, healthcare or care sectors; developing or manufacturing wellness applications; performing research in relation to the healthcare or care sectors; or acting as a mortality registry; as well as any Union institution, body, office or agency that has either: • the right or obligation, in accordance with applicable Union or national law and in its capacity as a controller or joint controller, to process personal electronic health data for the provision of healthcare or care; or for the purposes of public health, reimbursement, research, innovation, policy-making, official statistics; patient safety or for regulatory purposes; or • the ability to make available non-personal electronic health data through the control of the technical design of a product and related services, including by registering, providing, restricting access to or exchanging such data"[2]
Data permit	An administrative decision issued to a data user by a HDAB or data holder to process certain electronic health data specified in the data permit for specific secondary use purposes, based on the conditions set out in Chapter IV of the EHDS Regulation.[2]
Data quality	The degree to which characteristics of electronic health data are suitable for secondary use.[22]

Term	Definition
Dataset	A structured collection of electronic health data.[2]
Electronic Health Record (EHR)	'A system whereby the software, or a combination of the hardware and the software of that system, allows personal electronic health data that belong to the priority categories of personal electronic health data established under this Regulation to be stored, intermediated, exported, imported, converted, edited or viewed, and intended by the manufacturer to be used by healthcare providers when providing patient care or by patients when accessing their electronic health data'[1]
National health dataset catalogue	A collection of dataset descriptions, which is arranged in a systematic manner and consists of a user-oriented public element, where information concerning individual dataset parameters is accessible by electronic means through an online portal.[2]
Health data access body (HDAB)	A service that allows data users, such as researchers and policy-makers to apply for access to health datasets to support research and innovation, education and training, policy-making, health service management and preparing national statistics. Under the EHDS, each EU Member State will be required to establish one or more HDABs.[2]
HealthData@EU	An infrastructure connecting national contact points for secondary use of electronic health data and the central EU platform.[23]
HealthData@IE	An EU-funded project, led by the Department of Health (DoH) in collaboration with the Health Information and Quality Authority (HIQA) and the Health Research Board (HRB), focusing on developing national infrastructures needed for data access, including data access infrastructure systems that have been identified by the EU Commission as being core Digital Business Capabilities for HDABs.

Term	Definition
Interoperability	The ability of organisations, as well as software applications or devices from the same manufacturer or different manufacturers, to interact towards mutually-beneficial goals. It involves the exchange of information and knowledge without changing the content of the data.[18]
Metadata	Information that describes other data. It helps to explain what the data is, how it can be used and where to find it.[24]
Primary use of health data	The processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates; including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services.[12]
Pseudonymisation	The process of replacing and identifying characteristics of data with a pseudonym, a value which does not allow the data subject to be directly identified.[25]
Secondary use of health data	The processing of health data for purposes such as research, innovation, training and policy-making. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of secondary use.[12]
Secure processing environment (SPE)	The physical or virtual environment and organisational means to ensure compliance with European Union law; such as Regulation (EU) 2016/679, in particular with regard to data subjects' rights, intellectual property rights, commercial and statistical confidentiality, integrity and accessibility as well as with applicable national law; and to allow the entity providing the secure processing environment to determine and supervise all data processing actions including the display, storage, download and export of data, and the calculation of derivative data through computational algorithms.[2]

6. Appendices

Appendix 1. Secondary uses of data defined in the EHDS Regulation

"Health data access bodies shall only grant access to electronic health data referred to in Article 51 for secondary use to a health data user where the processing of the data by that health data user is necessary for one of the following purposes:

1. the public interest in the areas of public or occupational health, such as activities to protect against serious cross-border threats to health, public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices;
2. policy-making and regulatory activities to support public sector bodies or Union institutions, bodies, offices or agencies, including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;
3. statistics as defined in Article 3, point (1), of Regulation (EU) No 223/2009, such as national, multi-national and Union-level official statistics related to health or care sectors, or 215/329 EN education or teaching activities in health or care sectors at vocational or higher education level;
4. scientific research related to health or care sectors that contributes to public health or health technology assessments or ensures high levels of quality and safety of healthcare, of medicinal products or of medical devices with the aim of benefiting end-users such as patients, health professionals and health administrators, including:
    a. development and innovation activities for products or services;
    b. training, testing and evaluation of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health applications;
5. improvement of the delivery of care, optimisation of treatment and of the provision of healthcare based on the electronic health data of other natural persons."

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