



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

FREQUENTLY ASKED QUESTIONS

**WEBINAR: SECONDARY USE OF DATA UNDER THE EUROPEAN HEALTH DATA SPACE (EHDS) REGULATION -
What I need to know as a health data holder**



Có-mhaointhe ag an Aontas Eorpach

Co-funded by the European Union



An Roinn Sláinte
Department of Health



Acknowledgements

The Health Information and Quality Authority (HIQA) would like to thank all of the individuals and organisations who provided their time, advice and information in support of the webinar held on 19 November 2025, entitled, '*Secondary use of data under the EHS Regulation: what I need to know as a health data holder*'. Particular thanks are due to the webinar speakers:

- Dana (Iordana) Eleftheriadou, Senior Expert on Digital Health, European Commission
- Emer Doyle, Principal Officer, Health Information Policy Unit, Department of Health.

Thanks also to Bríd Burke, Programme Manager, Health Research Consent Declaration Committee, who provided advice in support of the writing of this document.

Members of the Health Information and Standards Directorate, HIQA

This work was led by staff in HIQA's Health Information and Standards Directorate. The following individuals contributed to the management, writing or dissemination of the webinar and this related document:

Rachel Flynn, Barbara Foley, Sarah Jane Flaherty, Suzanne Barror, Maria Ryan, Emma Burke, Joanne Fallon, Shauna Walsh, Adrian Nissen.

Table of contents

Acknowledgements	2
Introduction.....	4
European Health Data Space (EHDS) overview	4
HealthData@IE 2023-2027	4
Purpose of this document.....	5
About secondary use of electronic health data in the European Health Data Space (EHDS).....	6
1. How is the secondary use of health data defined under the EHDS Regulation?..	6
2. What types of electronic health data are available for secondary use under the EHDS Regulation?	7
3. Who is considered to be a health data holder under the EHDS Regulation?.....	8
4. What are the obligations of health data holders under the EHDS Regulation? ...	9
5. How does the European Health Data Space (EHDS) Regulation interact with existing legislation?	10
6 Who is a health data user?	10
7. What are the obligations of health data users under the EHDS Regulation?	10
8. Who is responsible for granting access to electronic health data under the EHDS Regulation?	11
9. What is a health data permit?	12
10. Will health data holders have any role in granting access to those requesting electronic health data for secondary uses?	12
About processing of electronic health data for secondary uses in the EHDS	13
11. What is a Secure Processing Environment (SPE)?	13
12. Will health data for secondary uses be anonymised or pseudonymised?	13
13. Once a health data permit has been approved, how does a health data user receive the health data?	14
Resources for further information.....	14
References	16

Introduction

European Health Data Space (EHDS) overview

The European Health Data Space (EHDS) is the first regulated European data space established under the European Data Strategy to promote secure and trustworthy health data use.¹ The EHDS is designed to benefit all EU citizens, including patients, healthcare professionals, researchers, policymakers, and innovators. The EHDS will improve data standards and increase data flow across the sector, thereby improving clinical care through better research, increased innovation, and greater evidence-based decision making.

The EHDS Regulation entered into force on 26 March 2025 and will be implemented on a phased basis between 2027 and 2031. Implementing Acts will further outline the implementation requirements including technical specifications and standards. The main Implementing Acts will be published by 2027. With regard to the secondary use of data, the EHDS Regulation places an obligation on individual Member States to establish one or more Health Data Access Bodies (HDABs). A HDAB will securely connect health data users, such as researchers and policymakers, with health datasets. Access to health datasets through HDAB services 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 majority of health datasets are to be made available through a HDAB by 2029. The remaining health datasets will be made available by 2031. Further information on the categories to be made available by each date is provided under Question 2.

HealthData@IE 2023-2027

The Department of Health, in collaboration with the Health Information and Quality Authority (HIQA) and the Health Research Board (HRB), was awarded funding under the EU4Health programme to support the establishment of health data access body (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 required for data access, such as a Data Access Application Management System (DAAMS), Secure Processing Environments (SPEs) and a National Health Dataset Catalogue (NHDsC). The HealthData@IE project will also deliver important programmes of work centred on data quality enhancement, engagement and dissemination, and training and education.

Purpose of this document

In order to build awareness of the EHDS among health data holders, HIQA hosted a webinar on 19 November 2025, entitled, '*Secondary use of data under the EHDS Regulation: what I need to know as a health data holder*'. The webinar aimed to:

- describe the key elements and timelines of the EHDS Regulation and the secondary use of health data from a health data holder's perspective
- outline who is considered a health data holder and clarify their obligations under the EHDS Regulation, and the steps they can take to fulfil the obligations
- support health data holders to understand the key elements of the National Health Dataset Catalogue and the data quality and utility label, as it applies to health data holders.

Time was allocated for a question and answers session at the end of the webinar. This document provides answers to the questions raised during this session by addressing key queries posed by webinar attendees. This document complements HIQA's *Guidance for data holders: Preparing for the establishment of a health data access body services in Ireland* document, published in 2025. Please see [here](#) for this guidance document.

About secondary use of electronic health data in the European Health Data Space (EHDS)

1. How is the secondary use of health data defined under the EHDS Regulation?

Under the EHDS Regulation, secondary use of electronic health data refers to the re-use of a person's electronic health data for purposes beyond their direct care.¹ Re-using a person's electronic health data can help to plan and manage health and social care services, guide policy-making and inform effective research and innovation.

Electronic health data may be used for the following secondary purposes, as set out in Article 53 of the EHDS Regulation:

- **Public interest:** Electronic health data may be used to protect against cross-border threats to health, to monitor public health and to ensure that healthcare, medicinal products or medical devices are safe for patients.
- **Policy-making and regulatory activities:** Electronic health data can be processed to support policy-makers and government bodies to carry out their official duties.
- **Statistics:** Electronic health data can be used as part of national, multinational or Union-level official statistics.
- **Education:** Electronic health data can be utilised in health and social care education at vocational or higher education level.
- **Research:** Electronic health data can be used in research related to health and social care sectors that contribute to public health or health technology assessment, to ensure quality and safety of healthcare.
- **Innovation:** Electronic health data can be used to inform development and innovation activities for products or services, and the testing or evaluation of medical devices, artificial intelligence (AI) systems and digital health applications.
- **Improving health and social care:** Electronic health data can be used to inform the improvement of health and social care, refinement of treatments and the provision of healthcare.

The use of electronic health data for the purposes of public interest, policy-making and regulatory activities, and statistics, is reserved for public bodies and their agents.

Electronic health data may only be processed when a health data user has official permission to do so. Electronic health data must be processed for the purpose specified on the data permit or approved health data request. Article 54 of the EHDS

Regulation outlines reasons for which the processing of electronic health data is not allowed:

- decisions about an individual or group of individuals that will cause them harm.
- decisions about an individual in relation to employment, offering them less favourable terms, on the basis of their health data.
- marketing or advertising activities.
- development of products or services that may cause harm to people on the basis of health data, such as illegal drugs.
- unethical activities in accordance with national ethical provisions.

2. What types of electronic health data are available for secondary use under the EHDS Regulation?

There are 17 categories of electronic health data to be made available for secondary use, as set out in Article 51 of the EHDS Regulation.¹ See Table 1 for the full list of electronic health data categories.

It is important to note that the majority of these categories of electronic health data must be made available for secondary use by 2029. For five categories of electronic health data, as indicated in blue in Table 1 and marked with an asterisk (*), the obligation to make them available will come into effect in 2031. The Regulation also states that individual Member States may provide, in their national law, that additional categories of electronic health data should be made available for secondary use.

Table 1. EHDS categories of electronic health data for secondary use

(a)	Data from electronic health records (EHRs).
(b)	Data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health.*
(c)	Aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, and healthcare expenditure and financing.
(d)	Data on pathogens that impact human health.
(e)	Healthcare-related administrative data including on dispensations, reimbursement claims and reimbursements.
(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.
(k)	Data from population-based health data registries such as public health registries.
(l)	Data from medical registries and mortality registries.
(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.*
(q)	Health data from biobanks and associated databases.

*The inclusion of this category of data will come into effect in 2031.

3. Who is considered to be a health data holder under the EHDS Regulation?

In order to be subject to the obligations referred to in this document, a body or person must first fall within the definition of a health data holder. Under the EHDS Regulation, a health data holder is any organisation, person or public body who collects, creates or manages health data.¹ This can include health and social care providers, public health bodies, national disease registries and drug payment schemes. Health data holders include:

- health and social care providers, such as hospitals, residential care homes, and disability support services
- public authorities or agencies involved in health and healthcare services
- health insurance companies and organisations managing care reimbursement systems
- developers of health-related products and services, including wellness applications
- research institutions and registries that manage or process health data
- EU institutions, bodies and agencies that manage or process health data.

Under the EHDS Regulation, health data holders must make electronic health data that they control available. If they do not have control over the electronic health

data, they cannot provide access. For example, if a manufacturer of a wellness application designs the application in such a way that electronic health data is only kept locally on the app user's device without a possibility for that manufacturer to access it, the manufacturer does not *hold* that electronic health data. This means that they are not considered the health data holder and would not be required to make such electronic health data available.

4. What are the obligations of health data holders under the EHDS Regulation?

Health data holders will have a number of relevant key responsibilities under the EHDS Regulation, including to:

- provide dataset descriptions to HDABs in line with required criteria and undertake annual review to ensure description is up to date
- report on their dataset quality in line with the EHDS data quality and utility label and provide documentation to the HDAB, to verify the label
- make relevant electronic health data, as outlined in Article 51 of the EHDS Regulation, available upon request to the HDAB, in accordance with a data permit and within three months of permit issue
- provide access to non-personal electronic health data through trusted open databases
- publish a report detailing their findings or outputs resulting from the secondary use of electronic health data.

These obligations are set out in Article 60 of the EHDS Regulation. It may also be useful for health data holders to refer to TEHDAS guidelines for further information on their role in making electronic health data available for secondary use under the EHDS Regulation.

Certain entities, such as individual researchers or a micro-enterprises (less than 10 employees and less than €2 million turnover) may be exempt from the mandatory obligations. Member States can further regulate these exemptions at a national level. For example, a healthcare provider that qualifies as a micro-enterprise may not have to make health data available, unless national legislation specifies that the obligations do not apply. Where an exemption applies, individual researchers and micro-enterprises will still be able to add their health dataset to the national dataset catalogue and allow access to data users to their health datasets, if they wish.

Organisations should continue to monitor their status and potential obligations, especially if their size or data holdings change over time.

5. How does the European Health Data Space (EHDS) Regulation interact with existing legislation?

The EHDS will build on and complement, existing legislation including General Data Protection Regulation (GDPR); Data Governance Act 2022; Data Act 2023 and the Network and Information Systems Directive 2016. Implementation of a comprehensive legislative framework, including the enactment of the Health Information Act 2026, and the EHDS Implementing Acts in 2027, will provide further guidance ahead of the Regulation's implementation. At a national level, the EHDS Regulation will interact with the Health Information Act 2026, the Health Research Regulations 2018, and the Data Protection Act 2018.

6 Who is a health data user?

Under the EHDS Regulation, a health data user is a natural or legal person, public authority, or other body responsible for making electronic health data available for secondary use through a data permit or approved data request. Health data users can use electronic health data in line with what is on their specific permit. See Question 2 for an overview of these uses.

7. What are the obligations of health data users under the EHDS Regulation?

According to Article 61 of the EHDS Regulation, health data users will have a number of duties, including:

- when processing health data for secondary use, health data users will not be permitted to share or provide access to third parties who have not been mentioned in the health data permit
- health data users will not be allowed to re-identify or attempt to re-identify individuals to whom the health data relates
- health data users will be obliged to make the results or outputs of secondary use of health data available to the public, within 18 months of completion of processing. These results or outputs must only contain anonymised data, meaning nobody can be identified from it. The HDAB may grant an extension to this timeline.
- health data users will have a duty to acknowledge the sources of the health data, and to confirm that it was obtained within the EHDS framework.

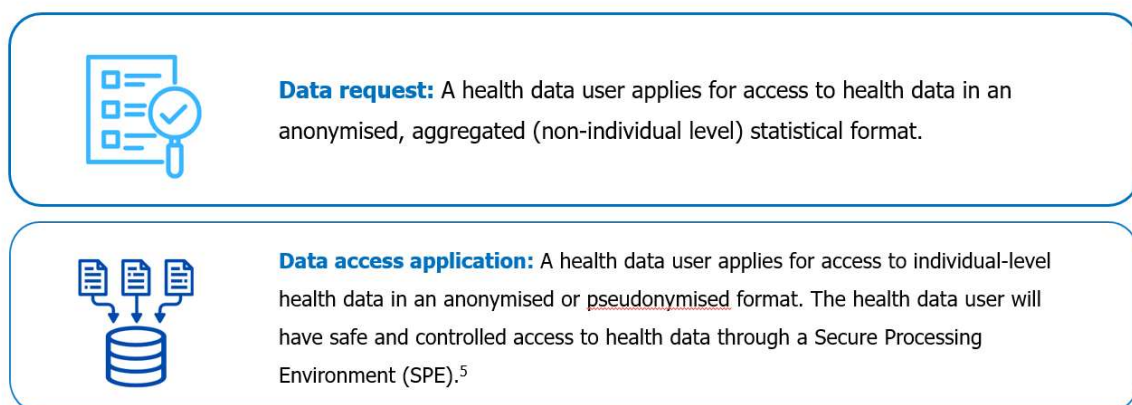
Under the EHDS Regulation, health data users will be encouraged to report any critical errors in a dataset to the HDAB, to help improve data quality.

8. Who is responsible for granting access to electronic health data under the EHDS Regulation?

As set out in the EHDS Regulation, HDABs are responsible for granting access to anonymised or pseudonymised health data. Due to the sensitive nature of electronic health data, data minimisation can help protect individuals' privacy. In the context of secondary use of health data under the EHDS Regulation, data minimisation must be applied throughout all stages of the data life cycle.

Under Article 67 of the EHDS Regulation, HDAB services in each Member State will process health data access applications. There will be two pathways for health data users to request access to health data, as outlined in Figure 2.

Figure 2. Health data for secondary use purposes access pathways



According to the Article 67 of the EHDS Regulation, a health data access application should include:

- the health data applicant's identity and a description of their professional functions and activities
- the intended purpose of the requested health data, and the expected benefit related to that purpose
- if requesting health data in a pseudonymised format, a justification as to why anonymised health data is insufficient must be provided
- details of any safeguarding processes that will be in place to prevent any misuse of the requested health data
- the length of time that the health data will be needed for.

It is important to note that process specifications around these pathways in Ireland are currently in development through the Data Access Application Management System (DAAMS) programme of work, as part of the HealthData@IE project.

Establishing a National Health Dataset Catalogue is also a key project currently being carried out as part of the HealthData@IE, and will facilitate data discovery for health data users. See [here](#) for more details on HealthData@IE.

9. What is a health data permit?

A health data permit is an administrative decision issued to a data user, by a HDAB service, to process certain electronic health data for specific secondary use purposes. A standardised process for issuing health data permits will be established in each Member State, in accordance with the EHDS Regulation. The information provided as part of a health data access application, must comply with the requirements of the Regulation, and a health data permit will only be issued where certain specified conditions have been met.

10. Will health data holders have any role in granting access to those requesting electronic health data for secondary uses?

In most cases, health data holders will not have a role in granting access to health data for secondary use. It will be the responsibility of the HDABs to decide on whether to grant or refuse access to electronic health data. HDABs will work closely with health data users during the application process on matters such as extraction criteria, cohort sizes and fees.

Trusted health data holders may have a role in assessing applications for granting access to health data. Trusted health data holders are health data holders who are appointed by HDABs based on their ability to provide a secure processing environment, expertise in health data management and meet specific guarantees in relation to the handling of health data. The EHDS Regulation creates the possibility for health data holders to be appointed as trusted health data holders. Trusted data holders will have permission to conduct assessments or applications to access electronic health data holder and make a recommendation to the HDAB on whether to grant or refuse access. Each Member State will decide whether to implement a process to apply to become a trusted health data holder.

About processing of electronic health data for secondary uses in the EHDS

11. What is a Secure Processing Environment (SPE)?

A Secure Processing Environment (SPE) is a secure environment where authorised health data users can process electronic health data in a very controlled manner. Within the context of the EHDS Regulation SPEs are an important part of the infrastructure which enables secondary use of electronic health data. Article 73 of the regulation specifies that SPEs must offer a high level of security and confidentiality when processing sensitive electronic health data.

An SPE must ensure data security by preventing unauthorised access to electronic health data and maintain confidentiality. It must allow only users with a valid data permit to process electronic health data within the permitted scope.

A SPE ensures data security by preventing unauthorised access, maintaining confidentiality, and ensuring the integrity of electronic health data that is being shared. Access is restricted so that users can process only the electronic health data covered by a valid data permit, and only within the scope of that permit.

Under Article 73 of the EHDS Regulation, a SPE will safeguard health data as it will:

- allow limited access to electronic health data, and only specific people with permission from the HDAB will be able to use pre-agreed electronic health data
- prevent the misuse of electronic health data, as the secure environment will reduce the risk of improper data usage
- track activities associated with electronic health data, such as keeping a detailed record of who accessed it, and these records must be kept for at least one year.

Defining the requirements and specifications for a SPE in Ireland, based on stringent technical and security standards and aligned with standards used in other EU Member States, is a key programme of work under the HealthData@IE project. Further information will be shared when available.

12. Will health data for secondary uses be anonymised or pseudonymised?

As set out in the EHDS Regulation, HDABs must prioritise the protection of personal electronic health data by granting access to anonymised statistical health data, wherever possible. If anonymised individual-level health data, aggregated health

data or statistical results, will meet the needs and objectives of a health data user, the HDAB will not grant access to pseudonymised data.

Pseudonymised individual-level health data will only be made available if it is essential for the intended purpose. Health data users will need to provide a clear rationale in their health data access application as to why pseudonymised health data is required.

Both health data holders and the HDAB service can be involved in the pseudonymisation and anonymisation of health data.

13. Once a health data permit has been approved, how does a health data user receive the health data?

Health data users will be notified of the HDAB's decision **within three months** of applying for access to health data. If a decision is made to issue a health data permit, a request will be sent to the relevant health data holders who will be **obligated to make the relevant health data available to the HDAB within three months**. Once health data has been released by the health data holder, the HDAB may complete further processing to prepare the electronic health data before the health data user has access. The HDAB is obliged to make the electronic health data available in the SPE to the health data user two months after receiving it from the health data holder. It may take up to five months in total for health data users to have access to the electronic health data, or more if extensions are granted, as set out in Article 68 of the EHDS Regulation.

Resources for further information

To support the implementation of the EHDS Regulation and its associated requirements for health data holders, resources are available on the HealthData@IE webpages on HIQA's website, at <https://www.hiqa.ie/areas-we-work/health-information/healthdataie>.

On these webpages, there is further information on the EHDS and the three programmes of work that HIQA is coordinating, as part of the HealthData@IE project.

HIQA has developed resources around engagement and education that may be useful for health data holders to review. These resources include information on the

changes to how health information will be collected, used and shared. These include:

- [International Review of Engagement, Education and Data Quality Enhancement in relation to health data access body services](#)
- [HealthData@IE Engagement and Education Strategic Plan 2024-2027](#)
- [HealthData@IE Training and Education Resources Portfolio.](#)

Another programme of work focuses on enhancing the quality of electronic health data that will be required to be made available through a HDAB. Health data holders can consider the practices their organisation currently have in place, in regard to electronic health data quality in preparation of EHDS implementation.

There are a number of other resources that health data holders can avail of, including:

- [Report on the findings of a readiness assessment of data holders in Ireland](#)
- [Readiness Assessment Protocol, Use Cases and Survey: Preparing for the establishment of HDAB services in Ireland under the EHDS](#)
- [Guidance for Data Holders: Preparing for the establishment of HDAB services in Ireland under the EHDS](#)
- [International review to inform the development of an interoperability framework.](#)

The European Commission has published a document which provides answers to other frequently asked questions regarding the EHDS Regulation and can be found [here](#).

The TEHDAS2 project develops concrete guidelines and technical specifications to make it easier to use health data in different countries. The aim of the joint action is to develop guidance to support health data authorities, health data holders and health data users during the implementation of the EHDS Regulation. More information on TEHDAS2 can be found [here](#).

References

1. Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance), Brussels: EU Commission; 2025. Available from: <https://eur-lex.europa.eu/eli/reg/2025/327/oj>. Accessed on: 27th January 2026
2. European Commission. *European Data Governance Act* [Online]. Available from: <https://digital-strategy.ec.europa.eu/en/policies/data-governance-act>. Accessed on: 11th February 2026
3. European Commission. *Data Act* [Online]. Available from: <https://digital-strategy.ec.europa.eu/en/policies/data-act>. Accessed on: 4th February 2026
4. Health Information Act 2026 [Online]. Available from: <https://data.oireachtas.ie/ie/oireachtas/act/2026/10/eng/enacted/a1026.pdf>. Accessed on: 12th May 2026
5. Health Information and Quality Authority. *Preparing for the establishment of a health data access body services in Ireland Guidance for data holders*. Dublin: 2025. Available from: [Health Information Readiness Assessment Guidance for Data Holders](#). Accessed on: 20th February 2026
6. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (Text with EEA relevance) (notified under document number C(2003) 1422), Brussels: EU Commission; 2003. Available from: [EUR-Lex - 32003H0361 - EN - EUR-Lex](#). Accessed on: 10th February 2026.



Published by the Health Information and Quality Authority (HIQA).

For further information, please contact:
Health Information and Quality Authority
George's Court
George's Lane
Smithfield
Dublin 7
D07 E98Y

+353 (0)1 814 7400
info@hiqa.ie
www.hiqa.ie

© Health Information and Quality Authority 2026