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

# Preparing for the establishment of health data access body services in Ireland under the European Health Data Space Regulation:

## Readiness Assessment Protocol

April 2025

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# 1 Background

## 1.1 The European Health Data Space

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.[1] 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.[2, 3] 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 to 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.[4]

The European Health Data Space (EHDS) is the first common data space to emerge from the European data strategy. 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.[5] The recommendations from the TEHDAS project were used by the European Commission to inform the development of a proposal for a regulation on the EHDS in May 2022. The European Parliament formally approved the proposal for the establishment of the EHDS in April 2024 and the regulation to enable the EHDS came into force in March.[6, 7]

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, and assurance that it is being managed securely in a way that ensures their privacy and confidentiality are protected.
- For data users, the broader workforce and the health service as a whole: Access to a wide range of data and linked datasets, through secure

processing environments (SPEs), leading to greater opportunities for research and innovation; a national contact point and a more streamlined and 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 and to maximise the utility and potential impact of these datasets; and training and guidance to promote the enhancement of the quality of their data.

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.[8] This HealthData@EU project developed a network infrastructure and services to support data users, defined as persons who have lawful access to personal or non-personal data for secondary use. It also provided guidelines for data standards, data quality, data security and data 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]

Acknowledging that trust is fundamental to the success of the EHDS, the European 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 EU Member States, there is a need for legislative and operational preparations to ensure readiness to implement the EHDS. In Ireland, the Health Information Bill 2024 is the first piece of legislation to support its preparations for the full implementation of the EHDS.[10]

## 1.2 HealthData@IE 2023-2027

In respect of the secondary use of data, the EHDS Regulation places an obligation on Member States to establish one or more Health Data Access Bodies (HDABs). A HDAB service securely connects data users, such as researchers and policy-makers, with anonymised and pseudonymised health datasets to support research and innovation, education and training, policy-making, health service management and preparation of national statistics.

The Department of Health, in collaboration with the Health Information and Quality Authority (HIQA) and the Health Research Board (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 as being core digital business capabilities for HDABs.[11] These include a national health dataset catalogue to facilitate data discovery, a data access application management system (DAAMS) to receive, track and process applications and to issue permits, and secure processing environments (SPEs) to ensure 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, as well as training and education for data users, data holders, HDAB staff and members of the public.

## 1.3 HealthData@IE Work Packages

The HealthData@IE project is comprised of eight Work Packages, three of which are coordinated by HIQA. See **Table 1** for a full outline.

**Table 1. HealthData@IE Work Packages**

| | Work package name | Lead beneficiary |
|---|---|---|
| **Work Package 1** | Management and Coordination | Department of Health |
| **Work Package 2** | Dissemination, Training and Support | HIQA |
| **Work Package 3** | Evaluation | Department of Health |
| **Work Package 4** | Sustainability | Department of Health |
| **Work Package 5** | Data Access Applications Management Solution | Department of Health |
| **Work Package 6** | National Dataset Catalogue for Health Data | HIQA |
| **Work Package 7** | Secure Processing Environment | Department of Health |
| **Work Package 8** | Health Data Quality Enhancement | HIQA |

The three work packages being coordinated by HIQA are described in more detail below.

### Work Package 2 - Dissemination, Training and Support

This comprises a programme of work centred on raising awareness of the HDAB function and responsibilities among the public, data holders and data users. An emphasis is placed on engaging effectively with members of the public, health and social care professionals and other relevant stakeholders on changes to how health information is collected, used and shared. Engagement will also comprise training and support initiatives for HDAB staff, data holders and data users.

### Work Package 6 - National Dataset Catalogue for Health Data

This programme of work sets out to develop a national health dataset catalogue (nHDsC) for the secondary use of data. This will enable the future HDAB service to provide data users with a way of browsing and assessing the suitability and utility of health datasets for various secondary use purposes.

### Work Package 8 – Health Data Quality Enhancement

This programme of work focuses on enhancing the quality of data that will be made available through the HDAB by developing guidance and tools for data holders to enhance the quality of their data, an interoperability framework, and a compliance assessment framework. An emphasis is placed on supporting data holders to prepare for the EHDS and the establishment of health data access body services in Ireland and ensuring they can meet their obligations relating to the secondary use of data. The first step is to undertake a readiness assessment.

## 1.4 Purpose of this readiness assessment

This readiness assessment is being undertaken by HIQA as part of the HealthData@IE project. To conduct it, three use cases have been selected in the areas of influenza, diabetes and colorectal cancer. By carrying out this readiness assessment, HIQA will explore if adequate structures are in place to enable the secondary use of data to further our understanding of influenza, diabetes, and colorectal cancer. The key data sources and the associated data holders for each use case will be identified and selected for inclusion in the various stages of the readiness assessment which comprises a desktop review of available evidence, a survey, focus groups and interviews.

The overarching aim of this readiness assessment is to obtain a baseline view of data holders' levels of preparedness for the establishment of HDAB services in Ireland across multiple areas, and to identify where gaps exist and what steps need to be taken to ensure Irish data holders' can meet future obligations under the European Health Data Space (EHDS) Regulation.

The specific objectives of the readiness assessment are:

1. To explore the feasibility of reusing and linking health and social care data from different sources for secondary use purposes in Ireland by assessing if potential linkage variables are present across datasets.

2. To identify whether there is capability and capacity among data holders to provide metadata and data in the necessary formats to a future HDAB service.

3. To determine the strengths and weaknesses of data holders' existing ICT systems interoperability and their ability to support discovery of their data, coding of data and the exchange of data with a future HDAB service.

4. To raise awareness among data holders about what their obligations will be under the EHDS, and explore perceived barriers and facilitators to the implementation of the EHDS and the establishment of HDAB services in Ireland.

5. To identify and prioritise data holders' data quality guidance and training needs.

6. To identify the steps required, and outline a pathway, to support data holders to make the required changes to ensure compliance with the EHDS Regulation.

The findings of this readiness assessment will inform many of the HealthData@IE deliverables, including the development of data quality guidance and training for data holders and a national interoperability framework as part of Work Package 8 and the development of a national health dataset catalogue (NHDsC) as part of Work Package 6.

# 2 Methodology

## 2.1 Selection of use cases

The topics of the three use cases were selected to align with those included in the HealthData@EU Pilot chosen by the European Commission, and the minimum categories of electronic data for secondary use, as outlined in the EHDS Regulation. The topics of the Data Access Sharing Storage Linkage (DASSL) project case studies were also taken into consideration.[12] See **Table 2** for an overview of the three use cases.

**Table 2. HealthData@IE use cases**

**Use case one: Influenza**
The aim of this use case is to demonstrate the feasibility of using available data to carry out surveillance of influenza and explore rates of influenza testing, vaccination and hospitalisation in vulnerable groups (for example older adults).

**Use case two: Diabetes**
The aim of this use case is to demonstrate the feasibility of using available data to enhance our understanding of diabetes (type 1 and type 2), to compare care pathways, measure clinical outcomes, costs of care, and enable better planning of services.

**Use case three: Colorectal Cancer**
The aim of this use case is to demonstrate the feasibility of linking clinical and genomic data to enhance our understanding of colorectal cancer, including incidence, risk factors (for example lifestyle, environment and genetic factors), aetiology, and long-term outcomes.

## 2.2 Identification of the relevant data sources and data holders

Through the process of developing each use case, the key datasets and data sources, as well as the associated data holders, will be identified and selected for inclusion in the various stages of the readiness assessment. Examples of the types of relevant datasets and data sources are outlined in **Table 3**.

**Table 3. Examples of sources of data for each use case**

| Use case | Influenza | Diabetes | Colorectal Cancer |
|---|---|---|---|
| **Data sources** | Hospital Inpatient Enquiry (HIPE)<br>Primary Care Reimbursement Service (PCRS)<br>Computerised Infectious Disease Reporting (CIDR)<br>COVAX: National COVID-19 Immunisation System<br>National Office for Clinical Audit (NOCA) datasets<br>The Irish Longitudinal Study on Ageing (TILDA)<br>Vital Statistics – Death Registration | Hospital Inpatient Enquiry (HIPE)<br>Primary Care Reimbursement Service (PCRS)<br>Chronic Disease Management Programme (CDMP)<br>Diabetic Retina Screen<br>Irish Childhood Diabetes National Register<br>MedLIS - The National Laboratory Information System<br>National Office for Clinical Audit (NOCA) datasets<br>Vital Statistics – Death Registration | Hospital Inpatient Enquiry (HIPE)<br>Primary Care Reimbursement Service (PCRS)<br>National Cancer Registry of Ireland<br>BowelScreen<br>National Cancer Information System (NCIS)<br>National Drug Treatment Reporting System<br>National Integrated Medical Imaging System (NIMIS)<br>Vital Statistics – Death Registration |

Once all datasets and data sources have been identified, they will be categorised according to the categories of data for secondary use which are outlined in the EHDS Regulation (see **Table 4**). Of note, the majority of these categories of data must be made available for secondary use by 2029, four years from the date into force of the EHDS Regulation. For five categories of data, the regulation will come into effect in the 2031, six years following the EHDS Regulation entering into force.

**Table 4. EHDS categories of data for secondary use**

1. Electronic health data from EHRs.
2. Data on factors impacting on health, including socio-economic, environmental and behavioural determinants of health.*
3. Aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing.
4. Data on pathogens that impact human health.
5. Healthcare-related administrative data, including dispensations, reimbursement claims and reimbursements.
6. Human genetic, epigenomic and genomic data.*
7. Other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other -omic data.*
8. Personal electronic health data automatically generated through medical devices.
9. Data from wellness applications.
10. Data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person.
11. Data from population-based health data registries such as public health registries.
12. Data from medical registries and mortality registries.
13. Data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council, Regulation (EU) 2017/745 and Regulation (EU) 2017/746.*
14. Other health data from medical devices.
15. Data from registries for medicinal products and medical devices.
16. Data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results.*
17. Health data from biobanks and associated databases.

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

## 2.3 Defining the readiness assessment methodology

This readiness assessment will comprise the following:

1. Desktop reviews to gather background information on the use cases and to identify the relevant data sources and data holders. As part of this, HIQA may also submit information requests to data holders in order to complete its assessment.

2. An online survey to gather information from data holders that have been identified as relevant to one or more of the use cases, on a range of topics, including general preparedness for the EHDS, use of identifier variables and de-identification techniques, use of standards for interoperability, current data quality practices, and data quality training and guidance needs.

3. Focus groups with data holders that have been identified as relevant to one or more of the use cases to get more in-depth information on the topics covered in the online survey, to further explore the three use cases and the barriers to secondary use of data in these contexts, and to discuss the perceived barriers and facilitators to the implementation of the EHDS and the establishment of HDAB services in Ireland.

4. Meetings and semi-structured interviews, as required, with data holders that have been identified as relevant to one or more of the use cases, as well as other key stakeholders, to gather additional information as required to complete the readiness assessment.

The readiness assessment methodology is summarised in **Table 5**.

**Table 5. Summary of readiness assessment methodology**

| | **Stage 1**<br>**Desktop review** | **Stage 2**<br>**Online survey** | **Stage 3**<br>**Focus groups** | **Stage 4**<br>**Meetings and semi-structured interviews** |
|---|---|---|---|---|
| **What will be assessed?** | ▪ Background information about each of the three use cases (incidence, current level of service provision etc.).<br>▪ Relevant data sources and data holders for each use case.<br>▪ Other key stakeholders and subject matter experts for each use case. | ▪ Availability of potential linkage variables.<br>▪ Use of standards for data discovery, semantic interoperability and data exchange.<br>▪ Capability and capacity to provide appropriately-coded metadata and data to a future HDAB service through secure standardised data exchange mechanisms.<br>▪ Current data quality practices and levels of maturity.<br>▪ Guidance and training needs. | ▪ Preparedness for the EHDS and the establishment of HDAB services, with a more in-depth focus on specific areas (based on survey responses)<br>▪ Experiences and the perceived barriers to the secondary use of data within the context of the three use cases.<br>▪ Perceived barriers and facilitators to the establishment of HDAB services in Ireland. | ▪ The views and perspectives of other key individuals and groups of relevance to one or more of the use cases. |
| **Who will be involved?** | | ▪ All data holders that have been identified as being relevant to one or more of the use cases. | ▪ Data holders that have been identified as being relevant to one or more of the use cases.<br>▪ Data users with experience of data linkage and or accessing data for secondary use purposes. | ▪ Other individuals or groups that have been identified as having experience or knowledge in the area of one of the use cases and or one of the areas of focus of the readiness assessment (e.g. data quality, data linkage, interoperability). |

Each of the four stages of the readiness assessment are described in more detail over the following sections (2.3.1 – 2.3.4).

### 2.3.1 Desktop review of available evidence

A review will be carried out to collect as much information as possible on the three use cases, including exploring key initiatives and ongoing work in the three topic areas, and identifying the relevant data sources and data holders. This will involve searching the websites of key organisations and reviewing relevant reports, key documents and publications.

### 2.3.2 Online survey

The readiness assessment survey will be purposefully-designed and consist of six sections. It will be administered online using Qualtrics (**Table 6**).

**Table 6. Outline of readiness assessment survey**

| Section | Scope of questions | Purpose |
|---|---|---|
| **1** | Details of the data holder and their dataset | To obtain an overview of the characteristics of the survey respondents. |
| **2** | General EHDS preparedness and information management maturity | To assess overall preparedness for the implementation of the EHDS and the establishment of HDAB services in Ireland, as well as information management maturity to support such practices. |
| **3** | Data linkage and anonymisation | To ascertain if potential linkage variables are present across datasets, and assess current practices with regard to data linkage and anonymisation methods. |
| **4** | Data quality | To explore current data quality practices and levels of data quality expertise among staff. |
| **5** | Standards | To explore readiness to support and implement data discovery standards, standards for semantic interoperability and data exchange standards. |
| **6** | Data quality training and guidance | To assess preferences and priorities for future data quality training and guidance. |

### 2.3.3 Focus groups

Focus groups will be undertaken to gain a deeper understanding of the topic and gather further information from selected data holders than that which can be collected through the survey. In particular, there will be a focus placed on exploring the differing views of data holders and their range of experiences with regard to the secondary use of data within the context of the three use cases, including experiences around data sharing and linkage. The questions asked during the focus groups will be informed by a number of the free-text questions in the survey. An overview of the number of focus groups to be conducted, and the planned topics and participants for each, is included in **Table 7**.

**Table 7**. **Focus groups**

| Number of focus groups | Topic of focus group | Participants | Areas covered |
|---|---|---|---|
| **2** | Influenza use case | Data holders | ▪ Experiences of linking their datasets with other datasets.<br>▪ Perceived barriers to the implementation of the EHDS and the establishment of HDAB services in Ireland.<br>▪ Perceived facilitators and steps required to achieve compliance with the EHDS Regulation. |
| **2** | Diabetes use case | | |
| **2** | Colorectal Cancer use case | | |

The focus groups will be undertaken in line with HIQA's standardised methodology, with a six to eight participants per group, as well as a facilitator and at least one note taker. A schedule of questions will be prepared, guiding the facilitator during each session. Participants will receive a guidance document in advance of the focus group detailing the background to the project and the requirements that the EHDS will place upon their organisation. The purpose of the readiness assessment will also be outlined to them. Each participant will be asked to provide informed consent, and their signed consent forms will be securely stored.

Focus groups will be held online to facilitate access for participants and each session will run for 60-90 minutes. As soon as possible after the session, coding will be carried out using the focus group notes as raw data. See Section 2.4 for further information on the data analysis plan.

### 2.3.4 Targeted engagement – meetings and semi-structured interviews

Meetings and semi-structured interviews will be undertaken as required to gather additional information to complete the readiness assessment. This will provide an opportunity to engage with, and obtain the views of, key stakeholders and subject matter experts who are not data holders but have experience, or hold views, in relation to one of more of the three use cases. The interviews will be semi-structured with an interview guide prepared prior to each interview outlining key questions to be asked of the participant. Interviews and meetings will last for approximately one hour and will take place online.

## 2.4 Data analysis plan

Responses to the dichotomous (yes/no), multiple choice, and Likert scale questions included in the survey will be analysed using descriptive statistics, with frequencies and percentages calculated for categorical variables and means and standard deviations calculated for continuous variables. Dependent on the number and diversity of survey respondents, a sub-group analysis may be conducted based on data holder category. Responses to the open-ended survey questions, as well as data collected during the focus groups and interviews, will be analysed using a content analysis approach.

## 2.5 Ethics

The work is being undertaken in line with HIQA's legislative remit under Section 8 of the Health Act 2007. Ethical standards will be adhered to at all stages of the project, particularly when engaging with data holders via the survey, focus groups and interviews. Data holders will be given comprehensive information at every stage of their involvement to ensure they know what the project is about, what their involvement entails, and how their information and responses to questions will be used.

## 2.6 Project oversight and governance

A project team has been convened, as well as a working group which comprises representatives from the Department of Health, the Health Research Board, various divisions of the Health Service Executive (Office of the Chief Clinical Officer, Office of the Chief Information Officer, Health Protection Surveillance Centre and the National Patient Forum), the Central Statistics Office, the National Cancer Registry Ireland, the National Office Clinical Audit, the Office of the Government Chief Information Officer, the Royal College of Surgeons in Ireland and the University of Limerick. The project will be monitored by HIQA's internal project oversight group which meets monthly. Updates on progress will be provided to the HealthData@IE Grant Consortium Steering Committee, chaired by the Department of Health, at its monthly meetings. Formal monitoring reports, including grant milestone and deliverable reports, as well as change requests as required, will be submitted by HIQA to the Department of Health, for submission to the EU.

## 2.7 Dissemination plan

Findings from this readiness assessment will be disseminated in a number of ways. Reports of the findings will be published on the HIQA website. Some findings may also be written up as one or more publications and submitted to peer-reviewed journals. The findings relating to interoperability will be written up as a report and submitted to the EU in line with the project deliverables, as set out in the grant agreement. Findings will also be disseminated at relevant seminars/webinars as presentations at various national and EU conferences. Summaries of the key findings will also be developed in an accessible format (for example, infographics) for sharing on social media (for example, Twitter/X and LinkedIn) and on the HIQA website.

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