An Roinn Sláinte
Department of Health

The EHDS Regulation & Health Information Bill 2024

- where are national ambitions align with our EU obligations!

Assistant Secretary Muiris O'Connor

R&D and Health Analytics Division

Department of Health

15th January 2025

An Roinn Sláinte
Department of Health

The European Health Data Space (EHDS)

The European Health Data Space (EHDS)

EHDS

- First sectoral European-wide data space, as part of European Data Strategy
- First of 14 planned common data spaces

Objectives of the EHDS

- The EHDS will provide a **common governance and infrastructure framework** for the **primary and secondary use** of electronic health data within the EU.
- This will be achieved by:

Facilitating the use of EU standardised and interoperable EHRs	Providing for EU cross-border exchange of electronic health data	Establishing fundamental patient rights for personal electronic health data

- Through **MyHealth@EU** – each person will have access to their personal health records for medical treatment (in Ireland & the EU).
- Through **HealthData@EU** – access to health datasets for public-interest uses.

New Authorities to be established under the EHDS

Digital Health Authority

- To monitor and support the implementation of **health data for primary use**
- To serve as the National Contact Point for **MyHealth@EU**

Health Data Access Body

- To provide guidance and support access to **health data for secondary use**
- To serve as the National Contact Point for **HealthData@EU**

Market Surveillance Authority

- To monitor **compliance of EHR systems** with EHDS Regulations

Accessing electronic health data for primary purposes

The EHDS will:

- Enable citizens to access and control their electronic health data
- Facilitate exchange of electronic health data for the delivery of healthcare across the EU
- Facilitated by standardised and interoperable EHR format on MyHealth@EU platform

What will be in the MyHealth@EU EHR? (Art 5)

- patient summaries*
- electronic prescriptions
- electronic dispensations
- medical images and related image reports
- laboratory results and related laboratory reports
- hospital discharge reports

Who will have access to and the ability to input/edit an EHR?

- healthcare professionals (Art 7a)
- natural persons (Art 8)
- a representative of a natural person (Art 8g)

EHDS/HIB Patient Summary

Items for Inclusion in the Patient Summary

1. Personal details

2. Contact information
   - DOB
   - Place of Birth
   - Sex
   - Nationality
   - Ethnicity
   - PPSN
   - IHI

3. Information on insurance

4. Allergies

5. Medical alerts

6. Vaccination/prophylaxis information, possibly in the form of a vaccination card

7. Current, resolved, closed or inactive problems

8. Textual information related to medical history

9. Medical device implants

10. Procedures

11. Functional status

12. Current and relevant past medicines

13. Social history observations related to health

14. Pregnancy history

15. Patient-provided data

16. Observation results pertaining to the health condition

17. Plan of care

18. Information on a rare disease such as details about the impact or characteristics of the disease

What does the EHDS look like for a patient by 2029?

Access
I can see my **Patient Summary, ePrescriptions** and **eDispensations** in my EHR (through an online portal or mobile app) and I can **download a copy** of my EHR. I can grant access to my EHR to an **authorised representative.**

Contents in the EHR
Where information is recorded in an electronic format (whher in private hospital or public sector), if it's in scope, it is **contained in my EHR.**

Awareness
I know who is my **Digital Health Authority** and how to use **MyHealth@IE**, including my cross-border access rights and all of my **rights under the EHDS**

The PATIENT

Edit/Restrict
I can easily **add electronic data** to my EHR (in a prescribed format). I can **restrict access** to my EHR and understand the **impact of this restriction**. I understand there is an **override** to this restriction and **my rights** in relation to its use.

Visibility
I can see **who has accessed my EHR** and control notifications about access. I can also see my **EHR system is EU certified**.

Portability
I can request access to my EHR when receiving **treatment in any EU MS** and **that HCP can add data** to my EHR during my treatment.

Consent
I can easily provide my consent for the **reuse of my data** for secondary purposes. I understand the **impacts of an opt-out**. I understand there is a potential **override** to this consent. I know who is my **HDAB.**

What does the EHDS look like for a healthcare practitioner by 2029?

Access
I have access to the **MyHealth@IE portal**, whether working in the public, private, or social care sector. I can **view and add information** relevant to my treatment to the patient's EHR.

Training and Supports
I know how to **access training** and supports required to understand **data quality and standards**, how **my EHR system works**, and my **legal obligations** under the EHDS.

The Healthcare Practitioner

Awareness
I know how to contact the **Digital Health Authority** and how to use **MyHealth@EU** for treating Irish and EU residents. I am aware of **my rights and obligations** as an HCP under the EHDS.

Visibility
I can see the **Patient Summary, ePrescriptions** and **eDispensations** when I login to a patient's EHR, unless access has been restricted by a patient.

Accessing electronic health data for Secondary Purposes
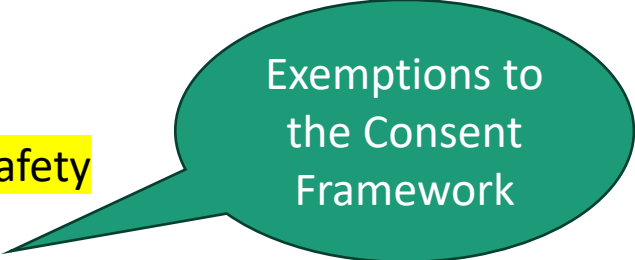
The EHDS will:

- Provide legal framework and facilitate reuse of electronic health data

- Facilitated by **HealthData@EU** infrastructure, governed by health data access body

What are some secondary purposes for which can data be accessed? (Art 34)

Examples include, but are not limited to:

- Public Health Interest, including Patient Safety

- Policy making and regulatory activities

- Developing statistics at national or multi-national levels

- Educational or teaching activities

- Scientific research

- Innovation contributing to health or social care (incl. medicinal products, medical devices or AI systems)

Exemptions to the Consent Framework

Electronic health datasets that can be accessed for Secondary Purposes

What datasets can be accessed under the EHDS? (Art 33)

17 categories of data with examples including:

- Data contained in **Electronic Health Records**

- Healthcare-related **administrative data** (insurance status or reimbursements)

- **Biobanks and databases**

- **Health survey-related data**

- **Wellness app generated data**

- **Genetic and genomic data**

- Other **human molecular data**

- **Registry data** (e.g. the National Cancer Registry)

- **Clinical trial data** (after completion)

- **Medical device-generated data**

- **Pathogen data**

Standards and the EHDS

Select references to standards in the EHDS Regulation

Primary Use

- In order to make electronic health data accessible and transmissible, such data should be accessed and transmitted in an **interoperable common European electronic health record exchange format.** *(Recital 19)*

- Member States should designate relevant digital health authorities for the **planning and implementation of standards** for electronic health data access and transmission *(Recital 22a)*

- Compliance with essential requirements on interoperability and security should be demonstrated by the **manufacturers of EHR systems** through the implementation of common specifications [...] regarding datasets, coding systems, technical specifications, **standards**, specifications and profiles for data exchange [...] *(Recital 33)*

An Roinn Sláinte
Department of Health

Standards and the EHDS

Select references to standards in the EHDS Regulation

<u>Secondary use</u>

- The **HDAB** should strive to expand the availability of additional health datasets, and **promote the development of common standards.** *(Recital 43)*

- A **data quality and utility label** for datasets would inform health data users about the quality and utility characteristics of a dataset and enable them to choose the datasets that best fit their needs […] Member States should raise awareness about the data quality and utility label through communication activities [and] The Commission could support those activities. *(Recital 59)*

- Existing health data infrastructures and registries can provide models that are useful for **defining and implementing data standards and interoperability** and should be leveraged to enable continuity and to build on existing expertise. *(Recital 61)*

An Roinn Sláinte
Department of Health

Roadmap of legislative measures to deliver on our health information policy

Health Information Bill (2024)

- Primary use and Digital Health Records

Statutory Instrument on the EHDS (2025)

- To give full effect to the EHDS Regulation in Ireland

Expansion of health information legislation (2026)

- To provide for health data access body (HDAB) and broader secondary use

European Health Data Space

Legal Translation → **Publication of the Regulation (Q1 2025)** → **Transposition of the Regulation into National Law** → **Appointment of Supervising Authorities and publication of the Implementing Acts (Q1 2027)**

↓

Full Compliance with EHDS Regulation (Q1 2031) ← **Initial Compliance with Regulation (Q1 2029) - initial access to platforms** ← **Participation in EU governance structures**
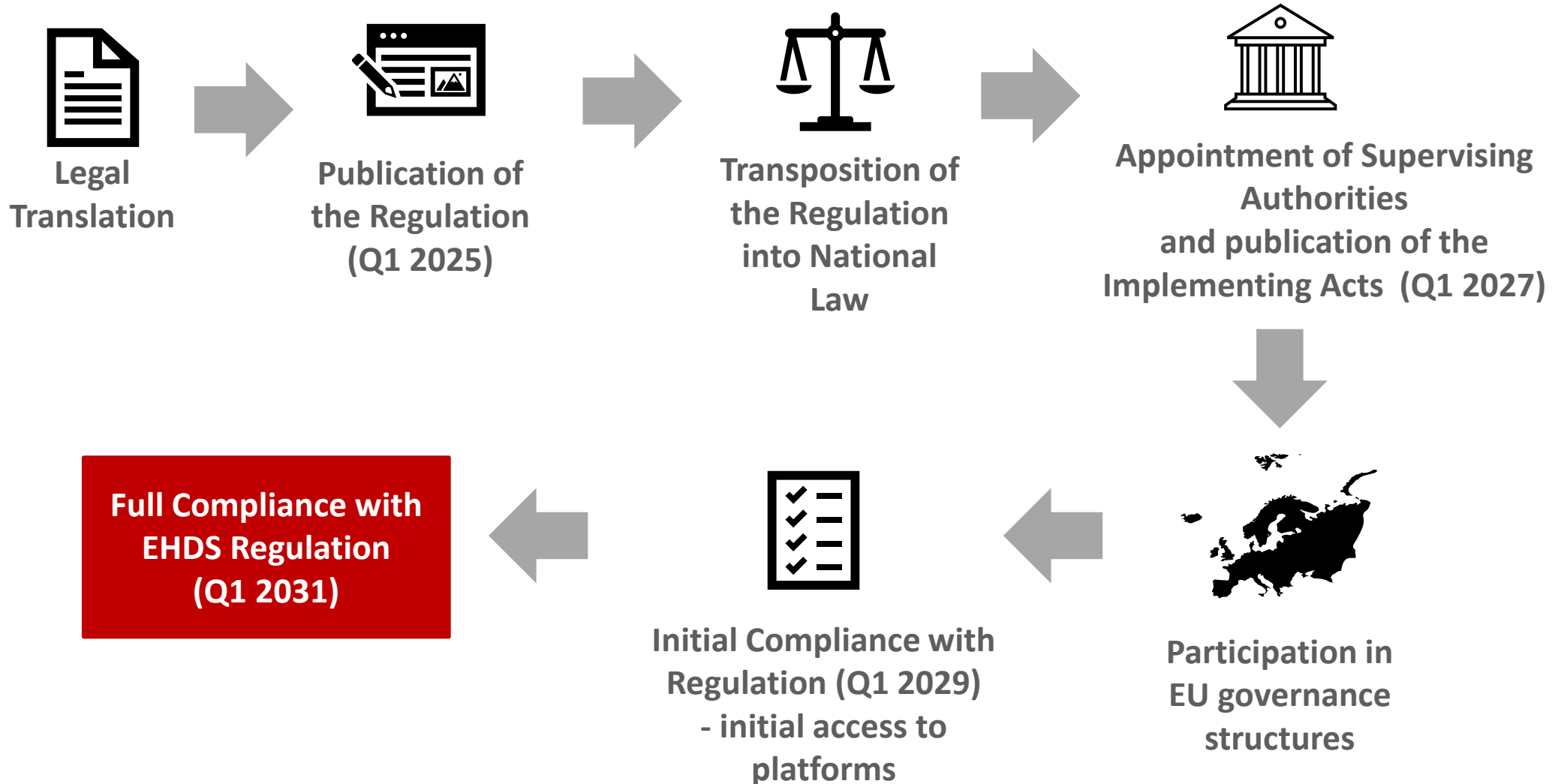
Health Information Bill (published 19 July 2024)

Foundational legislation: a key enabler of *Digital for Care: A Digital Health Framework for Ireland 2024-2030* and support for EHDS national implementation.

Part 1: Preliminary and General

Part 2: A **'duty to share'** health information for care and treatment, spanning public, private and voluntary settings.

Part 3: A legal framework for the development of **digital health records** in Ireland and **enhanced patient access** to their digital health records.

Part 4: **Enhanced provision of information to HSE for its secondary use.**

Legislative process

Each piece of legislation proceeds through the following steps:

Pre-Legislative

1 General Scheme published

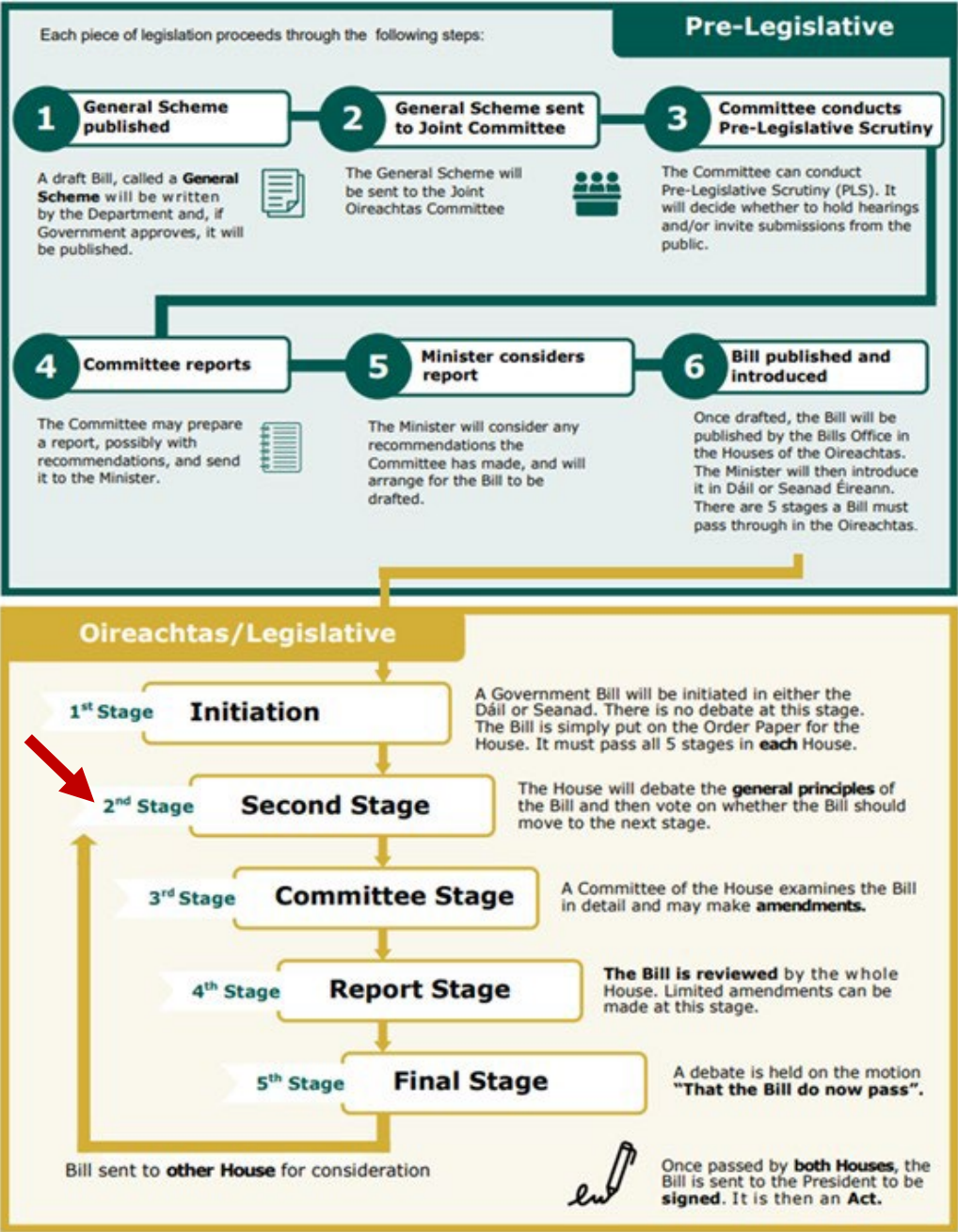A draft Bill, called a **General Scheme** will be written by the Department and, if Government approves, it will be published.

2 General Scheme sent to Joint Committee

The General Scheme will be sent to the Joint Oireachtas Committee

3 Committee conducts Pre-Legislative Scrutiny

The Committee can conduct Pre-Legislative Scrutiny (PLS). It will decide whether to hold hearings and/or invite submissions from the public.

4 Committee reports

The Committee may prepare a report, possibly with recommendations, and send it to the Minister.

5 Minister considers report

The Minister will consider any recommendations the Committee has made, and will arrange for the Bill to be drafted.

6 Bill published and introduced

Once drafted, the Bill will be published by the Bills Office in the Houses of the Oireachtas. The Minister will then introduce it in Dáil or Seanad Éireann. There are 5 stages a Bill must pass through in the Oireachtas.

Oireachtas/Legislative

1st Stage Initiation

A Government Bill will be initiated in either the Dáil or Seanad. There is no debate at this stage. The Bill is simply put on the Order Paper for the House. It must pass all 5 stages in **each** House.

2nd Stage Second Stage

The House will debate the **general principles** of the Bill and then vote on whether the Bill should move to the next stage.

3rd Stage Committee Stage

A Committee of the House examines the Bill in detail and may make **amendments**.

4th Stage Report Stage

The Bill is reviewed by the whole House. Limited amendments can be made at this stage.

5th Stage Final Stage

A debate is held on the motion "**That the Bill do now pass**".

Bill sent to **other House** for consideration

Once passed by **both Houses**, the Bill is sent to the President to be **signed**. It is then an **Act**.

Question –

Hi Muiris You mention PPS number can you clarify about legislation around this as there is a lot of mixed messages in relation to health professional allow or have obligations to get this from patient/service users

Robust identity management is fundamental to patient safety and the promotion of public health. The PPSN has been recognised as a key identifier for health services in Ireland, consistent with wider Government policy. The recording of PPSN in health is currently permitted under the Social Welfare Consolidation Act (SWCA) 2005, which lists the HSE and the voluntary hospitals as specified bodies permitted to collect and record the PPSN, and under the Health Identifiers Act 2014.   Many parts of the HSE currently collect the PPSN, for example Screening Services, Primary Care Reimbursement Service (PCRS) and Vaccinations.

The HSE is now moving to collect the PPSN in ALL health and social care interactions. In this regard, the HSE has completed a Data Protection Impact Assessment (DPIA) specifically on the wider collection of the PPSN. Additionally, the HSE has engaged with Patient Partners to hear their views on wider PPSN collection. The HSE will shortly issue guidelines, along with education and training material, for health professionals, frontline and support staff and introduce a standard practice of recording PPSN and including it on patient records. A dedicated HSE webpage for the public to access information on PPSN collection will also be available shortly.

The Health Information Bill, once enacted, will reinforce the existing legal basis for the collection and use of PPSN in healthcare by providing a basis for all health services providers – public, private, and voluntary – to collect PPSN for the purpose of digital health records for all patients.

For further information, please contact PPSNID@hse.ie