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

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Secondary use of data under the EHDS Regulation

what I need to know as a health data holder

19 November 2025

Có-mhaoinithe ag an Aontas Eorpach
Co-funded by the European Union

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

An Roinn Sláinte
Department of Health

HRB
An Bord Taighde Sláinte
Health Research Board

Learning Objectives

1. Describe the **key elements and timelines of the EHDS** Regulation and the secondary use of health data from a health data holder's perspective.
2. **Identify a health data holder and outline their obligations as per the EHDS Regulation** and the steps they need to take to fulfil their obligations.
3. Understand key elements of the **National Health Dataset Catalogue (NHDsC)** and the **data quality and utility label** as it applies to health data holders.

Today’s Speakers

Dr. Barbara Foley
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European Health Data Space

Secondary use of data – What I need to know as a health data holder'

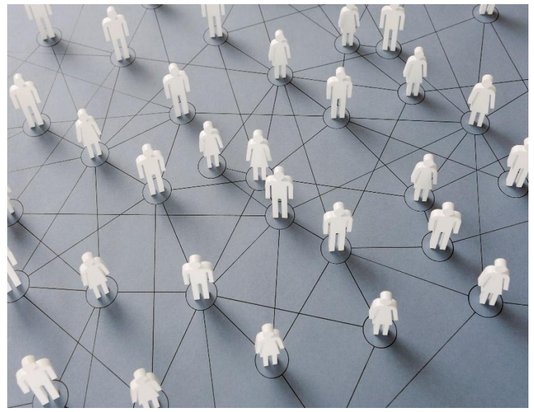
Dana Eleftheriadou

Policy expert, Digital Health
European Commission,
Directorate General SANTE – Digital Health

19/11/2025

The EHDS Regulation provides rules, common standards and practices, infrastructures and a governance framework for the of electronic health data for healthcare, research, innovation and policy making – creation of European Health Data Space (EHDS)

Empower individuals to access and control their personal health data + Ensuring seamless exchanges for continuity of healthcare.



Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities

Create a single market for electronic health records systems, supporting both primary and secondary use

EHDS in a Nutshell – what is it about?

Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space

1. Primary use of health data = use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare.

2. Secondary use of health data = use of data for research and public interest purposes
   - Making data available for research, policy-making, regulatory activiyities etc. in a safe and secure way.

3. Requirements for electronic health record (EHR) systems
   - Creating a single market for electronic health records systems, supporting both primary and secondary use.

EHDS in a Nutshell – Secondary Use of health data

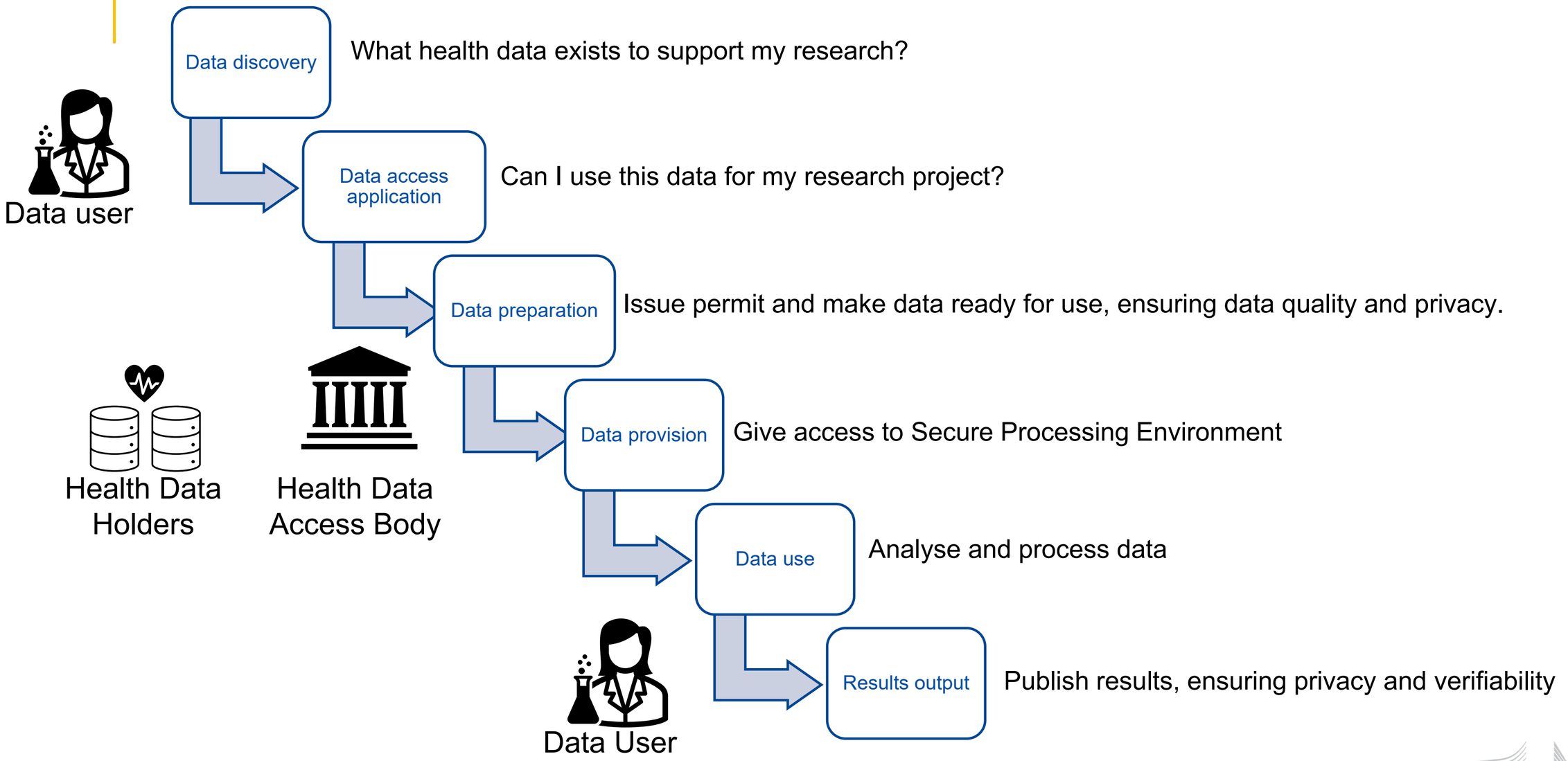
Use of health data for research and public interest purposes

- Making data available for research, policy-making, regulatory activities etc. in a safe and secure way

How?

- Common European rules on who has to make which data available for which purposes and under which conditions
- Common infrastructure HealthData@EU
- Health Data Access bodies
- Data catalogues of available datasets
- Permits for data use, common safeguards

User journey



Safeguards

Secure Processing Environment (SPE)

Data access only to **authorised users.**

State-of-the-art measures to prevent unauthorized data modification, access, or removal.

Download of personal data strictly prohibited.

Only aggregated results and fully anonymized data can be extracted.

Natural persons shall have the right to opt-out from the secondary use of their health data

at **any time** + **without stating reasons**

this right is reversible

through an easily accessible and understandable mechanism

*with the possibility for MS to have rules to ensure that for **selected purposes of public interest**, on **a case-by-case basis** and under **strict conditions**, also data of opted-out people may be made available*

Additional Safeguards

Allowed and prohibited purposes.

Legal and organizational measures to protect intellectual property and personal data.

Obligations to **inform individuals about data use** and their rights under data protection laws.

Public transparency on data processing activities and outcomes.

Data Minimization and Purpose Limitation

Access limited to data adequate, relevant, and necessary for specific, approved purposes.

Pseudonymized data provided unless anonymized data suffices, with strict controls on de-identification.

Data categories

electronic health data from **EHRs**;

healthcare-related **administrative data**, including dispensation, claims and **reimbursement** data

automatically generated personal electronic health data, through **medical devices**;

data from **wellness applications**;

other health data from medical devices.

population-based health data **registries** (public health registries);

data from medical registries and **mortality registries**;

data from registries for medicinal products and medical devices;

health data from **biobanks** and associated databases.

human **genetic, epigenomic and genomic** data;

other **human molecular** data such as proteomic transcriptomic, metabolomic, lipidomic and other omic data;

Data on factors impacting health, including **socio-economic, environmental and behavioural determinants** of health;

Aggregated data on **healthcare needs**, **resources** allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;

Pathogen data, impacting on human health

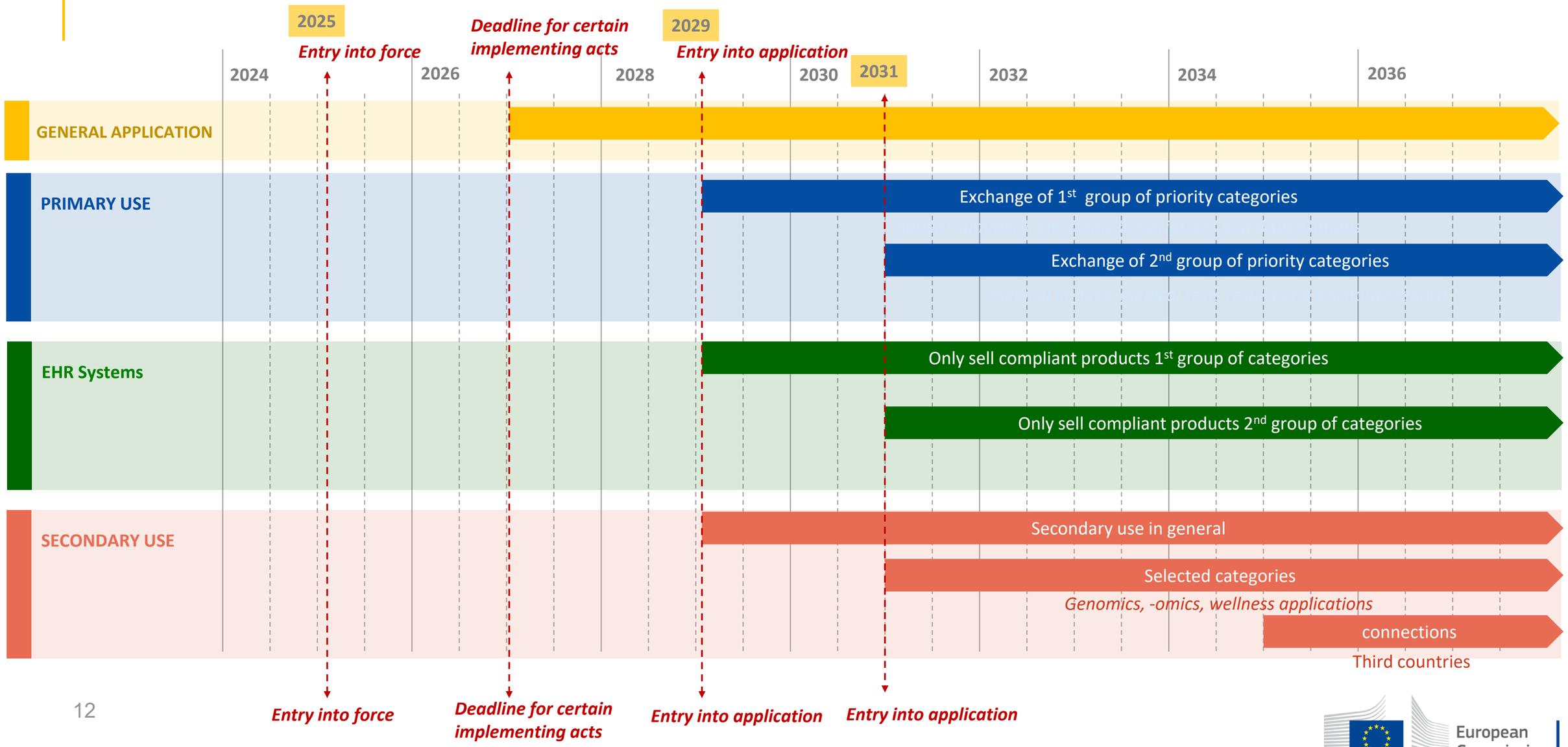
data from **clinical trials**, **clinical studies** and clinical investigations subject to Regulation (EU) 536/2014, Regulation [SOHO], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively;

data from **research cohorts, questionnaires** and surveys related to health, after the first publication of results

Implementation: What will happen when?

- EHDS Regulation published in the Official Journal on 5 March 2025.
- General entry into application on 26 March 2027 but most of the key provisions will enter into application on 26 March 2029.
- Several Implementing Acts to be adopted by March 2027. New EHDS Committee (Member States' representatives) set up for that purpose. First meeting of the EHDS Committee on 16 June 2025.
- Preparatory work ongoing: TEHDAS2, CoP of HDABs, QUANTUM etc.

EHDS – Overall timeline for application



European Commission

Implementation: Member States

- **Designate one or more HDABs** and set up all functions. By 26/03/2027 for designation, 26/03/2029 for receiving applications. Art. 70 implementing act on templates for HDABs.
- **Connect to HealthData@EU.** By 26/03/2029 for most Art. 51 categories, 26/03/2031 for remaining ones**.** Art. 75(12) implementing act on HealthData@EU specifications.
- **Ensure that HDABs can provide a Secure Processing Environment** to make data available in. By 26/03/2029. Art. 73(5) implementing act on SPE specifications.

Article 60

Duties of health data holders

- **Provide dataset descriptions to HDAB**, be ready to provide data pursuant to permit/request. By 26/03/2029 for most of Art. 51 categories, 26/03/2031 for the remaining ones. Art. 77(4) implementing act on minimum elements for dataset descriptions.
- **Make relevant electronic health data** (Article 51) **available** upon request to HDAB, in accordance with a data permit, within a reasonable time and no later then 3 months from the receipt of the request.
- Where a **data quality and utility label** accompanies the dataset the health data holder shall **provide sufficient documentation** to HDAB for that body to verify the accuracy of the label. 5.
- Provide access to **non-personal electronic health data** through **trusted open databases,** to be managed by a transparent and sustainable governance, to ensure unrestricted access for all users and data storage and preservation.

TEHDAS2 Joint Action

- Funded from EU4Health, May 2024 – December 2026
- 30 European countries, coordinated by Finnish Innovation Fund SITRA
- Common guidelines and technical specifications in the area of secondary use of health data
- Public consultations on each deliverable
- https://tehdas.eu/

Community of Practice of Health Data Access Bodies

- To foster collaboration and knowledge sharing among competent authorities and affiliated entities involved in establishing the HDABs and responsible for the secondary use in EU/EEA Member States.
- Set up in January 2024
- Governance: General Assembly, Steering Board and 6 Subgroups on
  - Data Access Application systems
  - Health Datasets Catalogue and Data Quality and Utility
  - Secure Processing Environments
  - Cross-border Gateways
  - Deployment and Operations
  - Stakeholders' engagement
- https://health.ec.europa.eu/ehealth-digital-health-and-care/ehds-action/projects-supporting-ehds/health-data-access-bodies-community-practice_en

QUANTUM: Data quality and utility label

Datasets may have a Union data quality and utility label (DQUL) applied by the health data holders. The Commission to adopt an implementing act on the DQUL specifications by 26/03/2027 (Art. 78)

Preparatory work = QUANTUM project

- **A common concept of the Quality and Utility of the Datasets** made available for secondary use → a technical specification → (label)
- **Piloting and implementing** the label in a controlled environment - QUANTUM data holders
- **Recommendations** out of the piloting experience that translate into guidance for the governance and sustainability of the label in real life

QUANTUM
THE HEALTH DATA QUALITY LABEL

European Commission

EHDS – IP Rights and Trade Secrets (Art. 52)

- Datasets protected by intellectual property rights/trade secrets **shall be made available for secondary use** in accordance with the rules laid down in the Regulation
- **Health data holders** shall **inform** the health data access body of any electronic health data containing content or information protected by intellectual property rights/trade secrets.
- **Health data access bodies (HDABs)** shall take all specific **appropriate and proportionate measures**, including of a legal, organisational and technical nature, they deem necessary to protect the intellectual property rights, trade secrets. HDABs are responsible for determining whether such measures are necessary and appropriate.
- HDABs **may** make the access to certain electronic health data **conditional on legal, organisational and technical measures**, which may include contractual arrangements between health data holders and health data users for the sharing of data. The **Commission shall** develop and recommend non-binding models of contractual terms for such arrangements.
- Where access to electronic health data for secondary use entails a serious risk which cannot be addressed in a satisfactory manner, the **HDAB shall refuse access** to the health data applicant to such data.

EHDS – IP Rights and Trade Secrets

- Further details/guidance to be provided on:
  - Which datasets will be concerned?
  - Which safeguards/measures may be taken by HDABs?
  - Which models of contract can the Commission provide and recommend?
  - In which cases should access be refused?

Relevant actions

- **TEHDAS 2** will organise a workshop with relevant stakeholders to foster discussions on relevant aspects related to IP rights and trade secrets (Q1 2026, TBC)

- A project funded under the IHI programme focused on "*Safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)*" will provide:
  - Recommendations to EHDS governance on "how to enable efficient data sharing to promote research and innovation in healthcare, and the need for maintaining a strong Intellectual Property (IP) system and preserving confidential information within health research data;
  - Recommendations and tools for enabling dialogues between health data holders (HDHs), health data users (HDUs) and health data access bodies (HDABs), **including comprehensive frameworks, processes, policies and guidelines, etc.**
  - **Link to IHI call text: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/HORIZON-JU-IHI-2025-10-02-two-stage**

An Roinn Sláinte
Department of Health

The EHDS Regulation

HIQA webinar
19 November 2025

Emer Doyle
Principal Officer
Health Information and Policy Unit
Department of Health
Ireland

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?

- 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
- natural persons
- a representative of a natural person

Governance & Infrastructure

Digital Health Authority

- To monitor and support the implementation of **health data for primary use**
- May serve as the National Contact Point for **MyHealth@EU**, which enables cross-border exchange of data for primary use.

Health Data Access Body

- To provide guidance and support access to **health data for secondary use**
- May serve as the National Contact Point for **HealthData@EU**, which enables cross-border exchange of data for secondary use.

Market Surveillance Authority

- To monitor **compliance of EHR systems** with EHDS Regulation.

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?

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)

Allowed & Prohibited Purposes

Art. 53 & 54

- **Public interest** in the area of public & occupational health, including public health surveillance and patient safety
- **Policy making** and **regulatory** activities
- Developing **statistics** at national or multi-national levels

[reserved for public sector bodies]

- **Educational or teaching activities** in health/care sectors
- **Scientific research** related to health or care, contributing to public health
- **Improvement of delivery of care**, optimisation of treatment, & providing healthcare, based on EHR data from other individuals

- Taking decisions **detrimental to individuals or groups** based on electronic health data (legal, social, or economic impacts)
- Making **employment-related decisions** based on health data, including discriminatory decisions affecting insurance, credit, or loans
- **Advertising or marketing** activities.
- **Developing products or services that could harm** individuals, public health, or society (e.g., illegal drugs, alcohol, tobacco, weaponry, or addictive products)
- Engaging in activities that **conflict with ethical standards** set by national law.

Health Data Access Body (HDAB)

Art. 55-59

- MS must appoint 1 or more HDABs
  - Union health data access service will be established for data held by Union institutions

- Some duties of the HDAB:
  - Publish national health data catalogue
  - Receive and decide on data access applications
  - Request data from health data holders (**not a data lake**)
  - Provide access to data in SPE
  - Monitor and enforce compliance
  - Provide public transparency
    - applications received and granted
    - measures related to non-compliance
    - results communicated by data users (e.g., research published)

Implementation of the EHDS Regulation

Legislative Landscape

The Health Information Bill (2024)

A Statutory Instrument on the EHDS (2025)

Expansion of health information legislation (2026)

Primary Health Data Landscape

Digital for Care: A Digital Health Framework for Ireland, 2024-2030

HSE Digital Roadmap

National Engagement on Digital Health & Social Care

MyHealth@EU & the eHealth Network

Secondary Health Data Landscape

HealthData@IE Direct Grant

EU Community of Practice

TEHDAS2

Quantum Joint Action

An Roinn Sláinte
Department of Health

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.

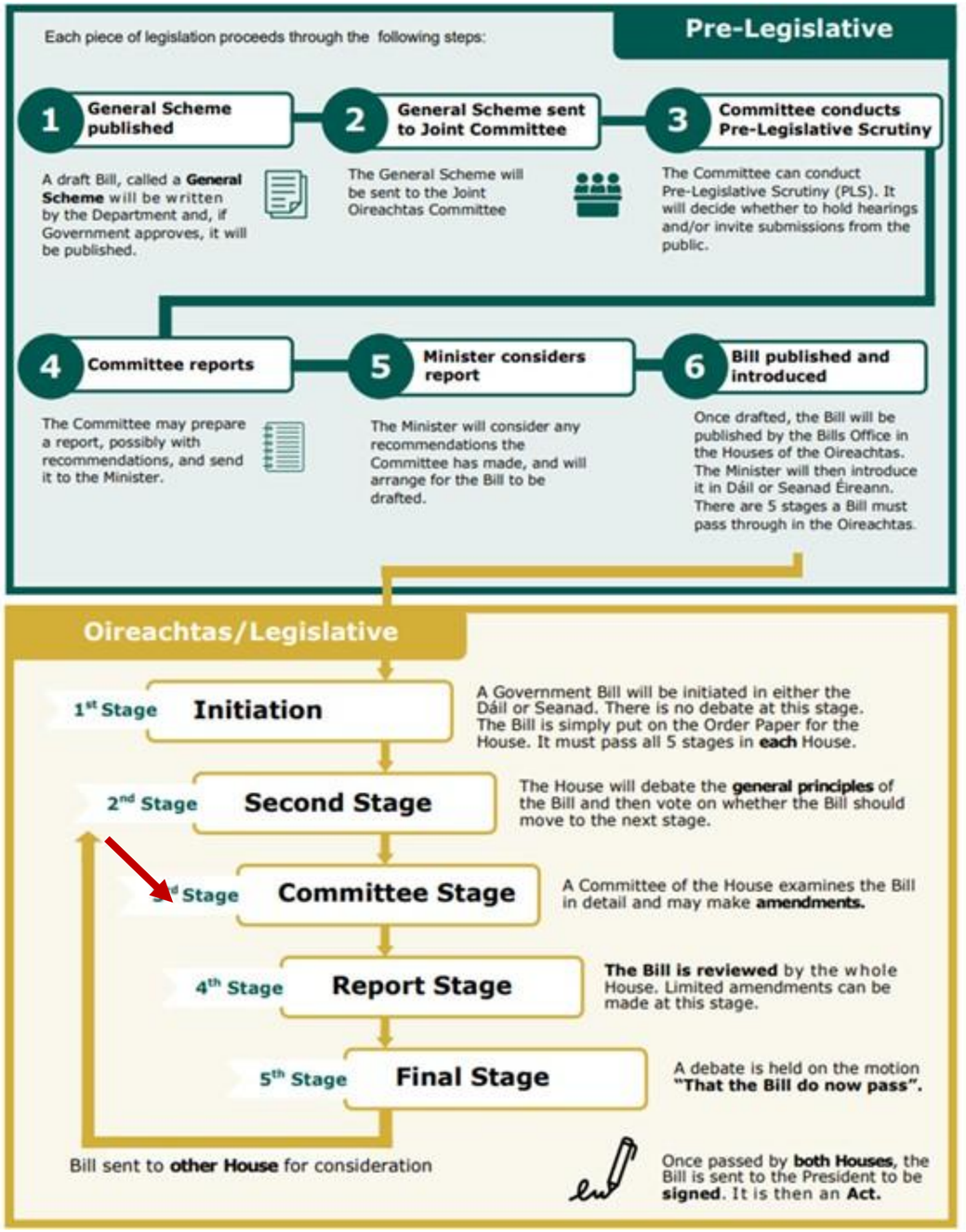
Part 1: Preliminary and General

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.**

Health Information Bill – awaiting Dáil Report Stage



National Health Dataset Catalogue (nHDsC)

Suzanne Barror
Programme Manager
Health Information Quality
and Assurance,
HIQA

HealthData@IE Overview

Funding from EU Commission to establish health data access services for Ireland

Collaborative approach - DoH, HIQA, HRB, HSE and key stakeholders

National Steering Committee - HealthData@IE

5 working groups established

Key areas for advancement

- **WP2** Programme of engagement, education and training
- **WP5** National data access application management system
- **WP6** National health dataset catalogue
- **WP7** Secure processing environments
- **WP8** Data quality enhancement

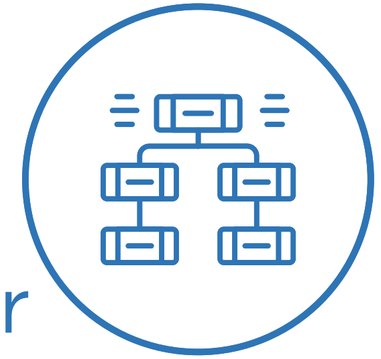
National Health Dataset Catalogue (nHDsC)

An nHDsC is a national centralised digital registry designed to support the discovery of health and related health datasets by facilitating the participation of both data users and data holders in a unified, transparent, and standardised metadata environment.

Its primary function is to make datasets held by data holders in Ireland discoverable and understandable, thereby supporting the use of health data for secondary purposes such as research, innovation, service planning, and policy development.

European Health Data Space

Categories of electronic data for secondary use



Categories to be made discoverable and available by March 2029

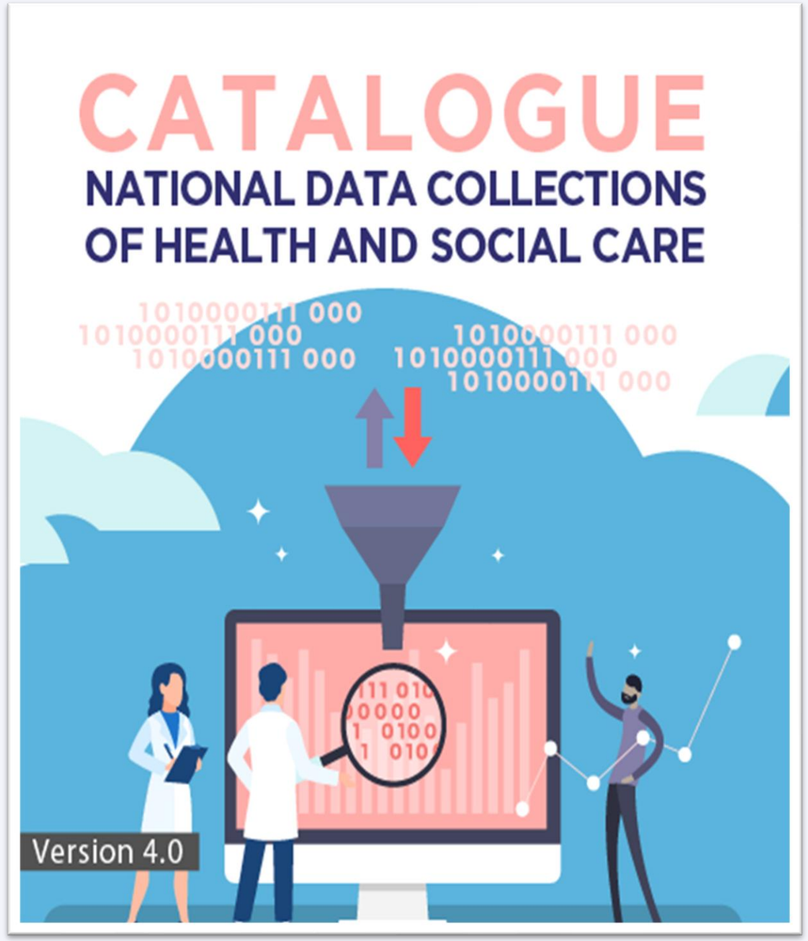
- Electronic Health Record (EHR) data
- Data on healthcare needs, resourcing, access, expenditure and financing
- Pathogen genomic data
- Healthcare-related administrative data
- Person-generated medical device data
- Other health data from medical devices
- Data from wellness applications
- Data on status, specialisation and institution of health professionals
- Population-based health data registries
- Data from medical and mortality registries
- Data from product and device registries
- Biobanks and associated databases

Categories to be made discoverable and available by March 2031

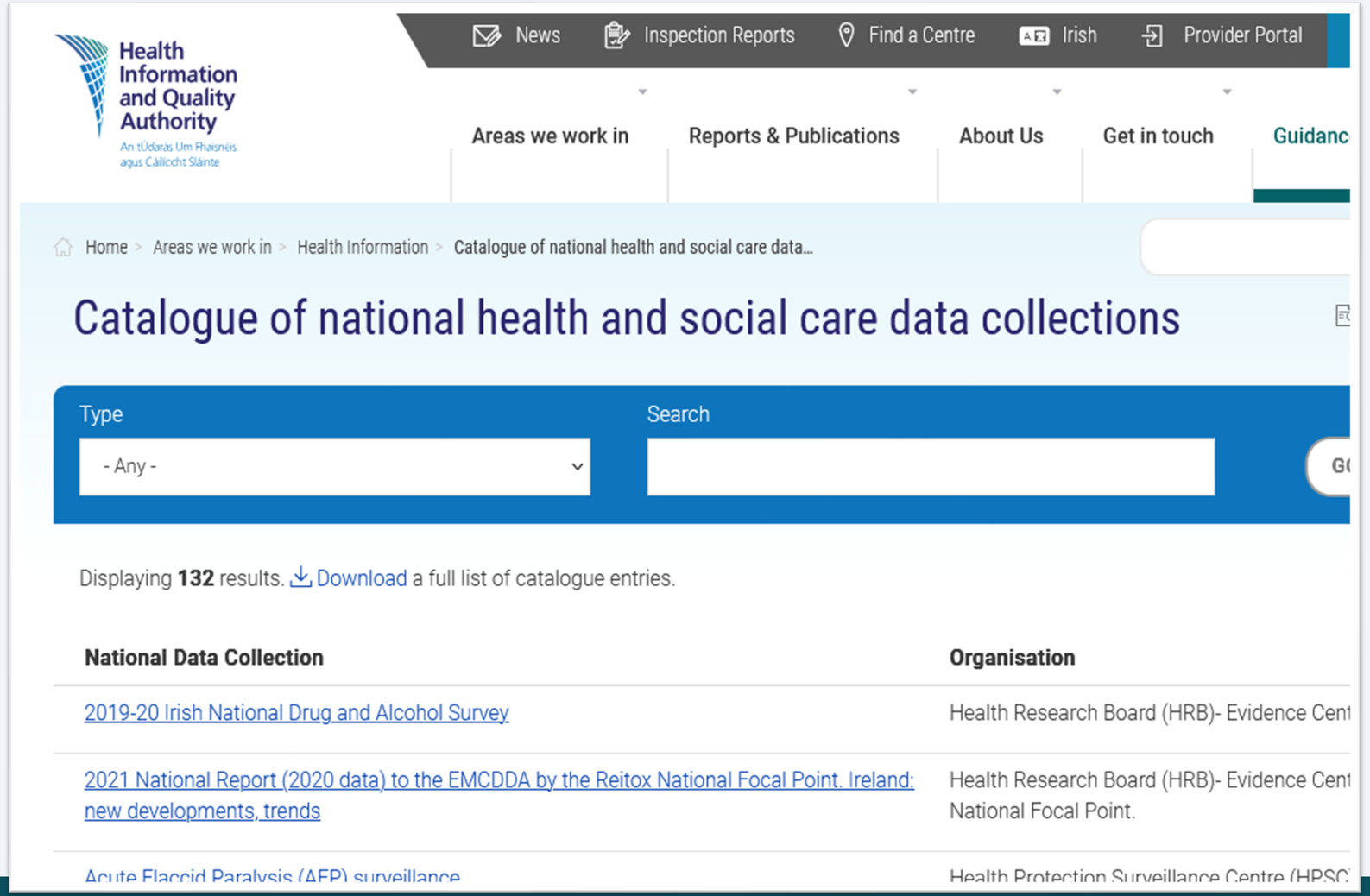
- Data impacting on health
- Human genetic and genomic data
- Other human molecular data
- Clinical trial data
- Health research cohorts/questionnaires/surveys

HIQA's Catalogue of National Health and Social Care Data Collections

Current catalogue maintained by HIQA –2022 Version 4.0



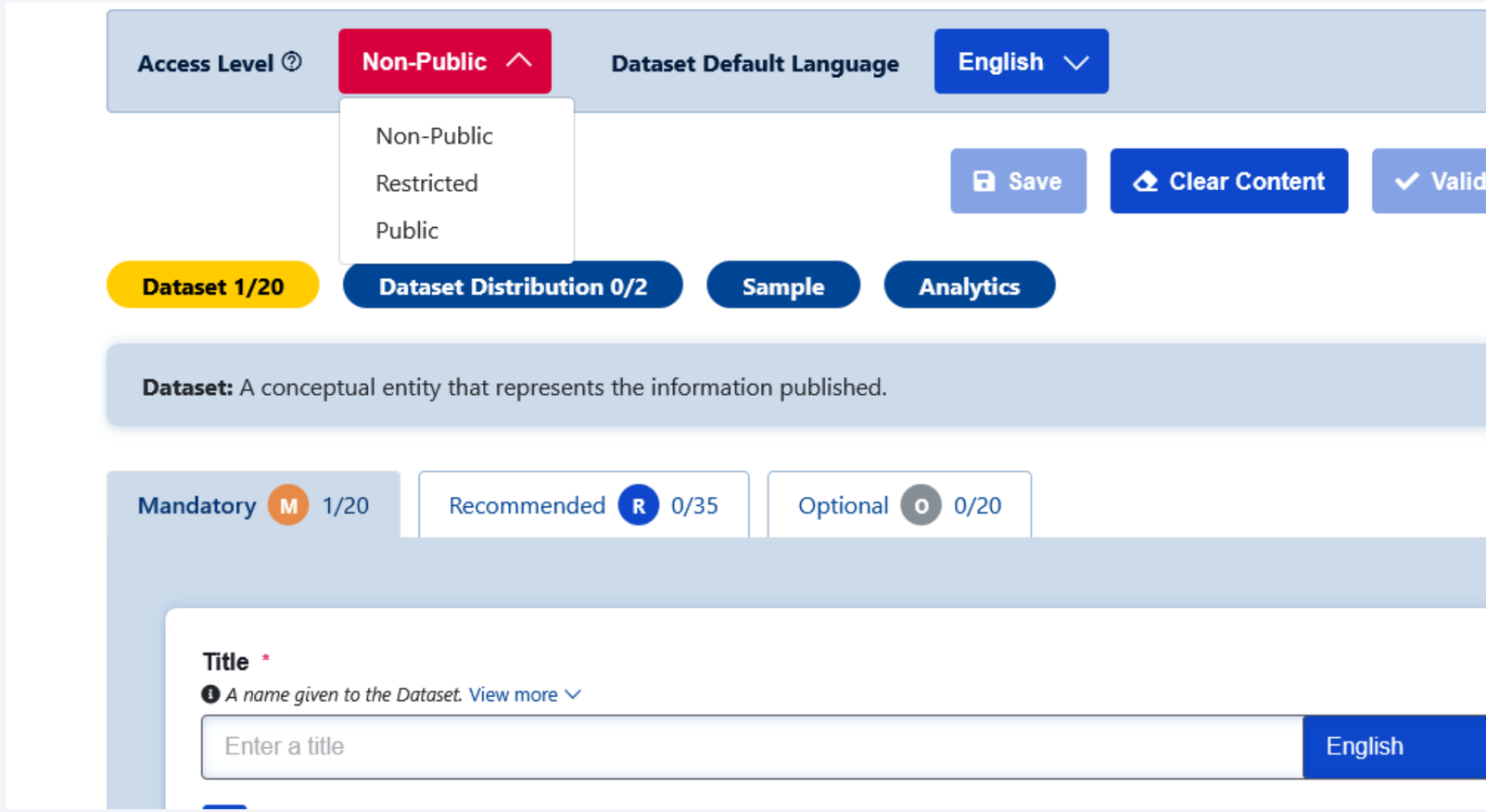
Online interactive version



Metadata Standards - HealthDCAT-AP

Health DCAT AP is a specialised extension of the European DCAT-AP standard. It was developed through HealthData@EU pilot and aims to standardise health metadata within the scope of the EHDS to facilitate better interoperability, findability and accessibility of electronic health data in Europe.

HealthDCAT-AP is designed to complement and coexist with standards such as HL7 FHIR, CDISC, and ISO/IEC 11179 (Metadata Registries), supporting cross-system data exchange while enabling a unified approach to metadata description.



HealthData@EU Central Platform Dataset Description Assistant

National Health Dataset Catalogue Project

Objectives, Milestones and Deliverables

Deliverables

Complete analysis and design of nHDsC

Month 24: Requirements and specifications report

Implement and pilot nHDsC

Month 36:
nHDsC pilot report

Deployment of operational solution for nHDsC

Month 48:
Operational services

2024 2025 2026 2027

Milestones

Month 24:
Draft requirements and specifications prototype

Month 30:
nHDsC: Minimum Viable Product (MVP)

Month 42:
nHDsC: Operational Product

National Health Dataset Catalogue Project

Objective 1: Key stages 2025

Working group convened (Jan 2025)

Technical team established

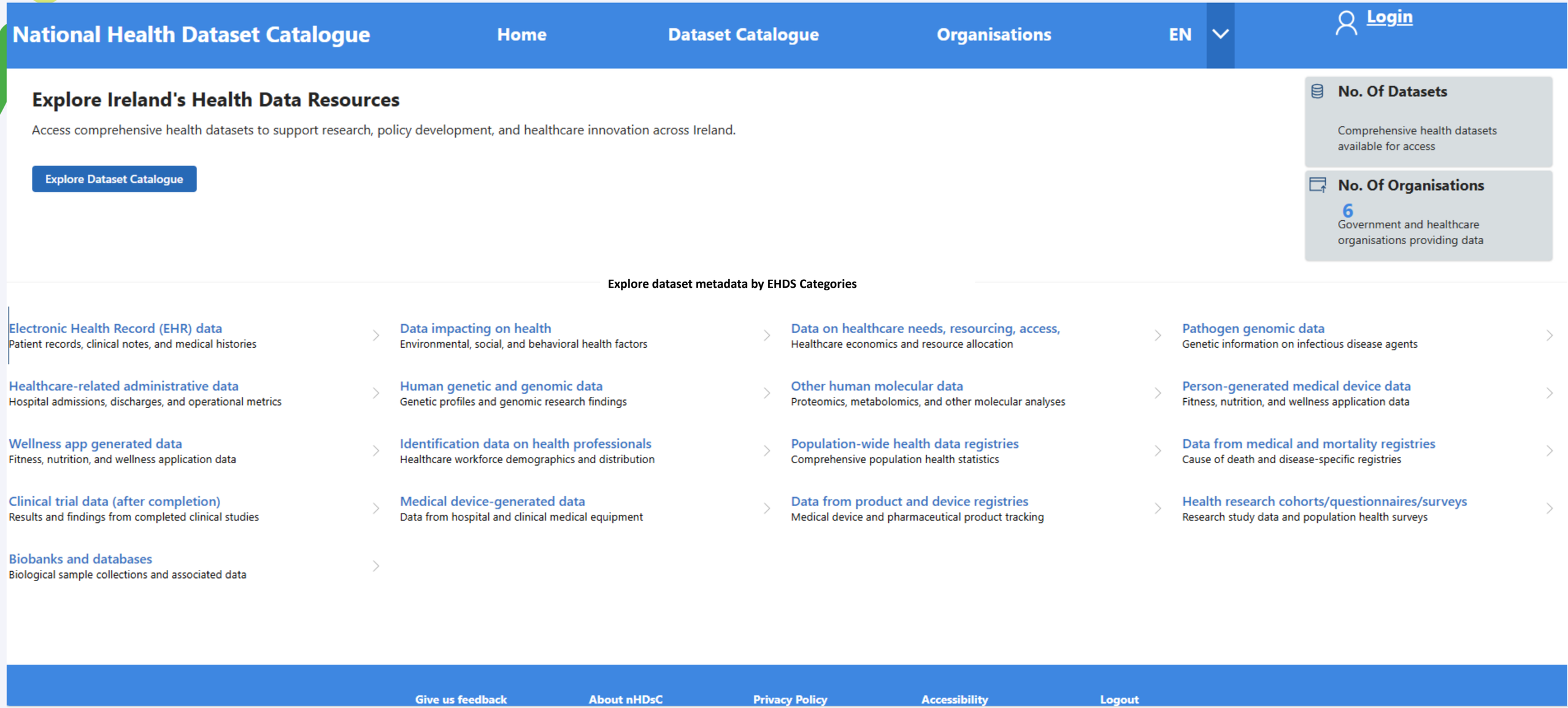
Review of European Initiatives and Irish Catalogues

Requirements and specifications drafted and updated based on feedback from stakeholders

Prototype developed and feedback sought from stakeholders

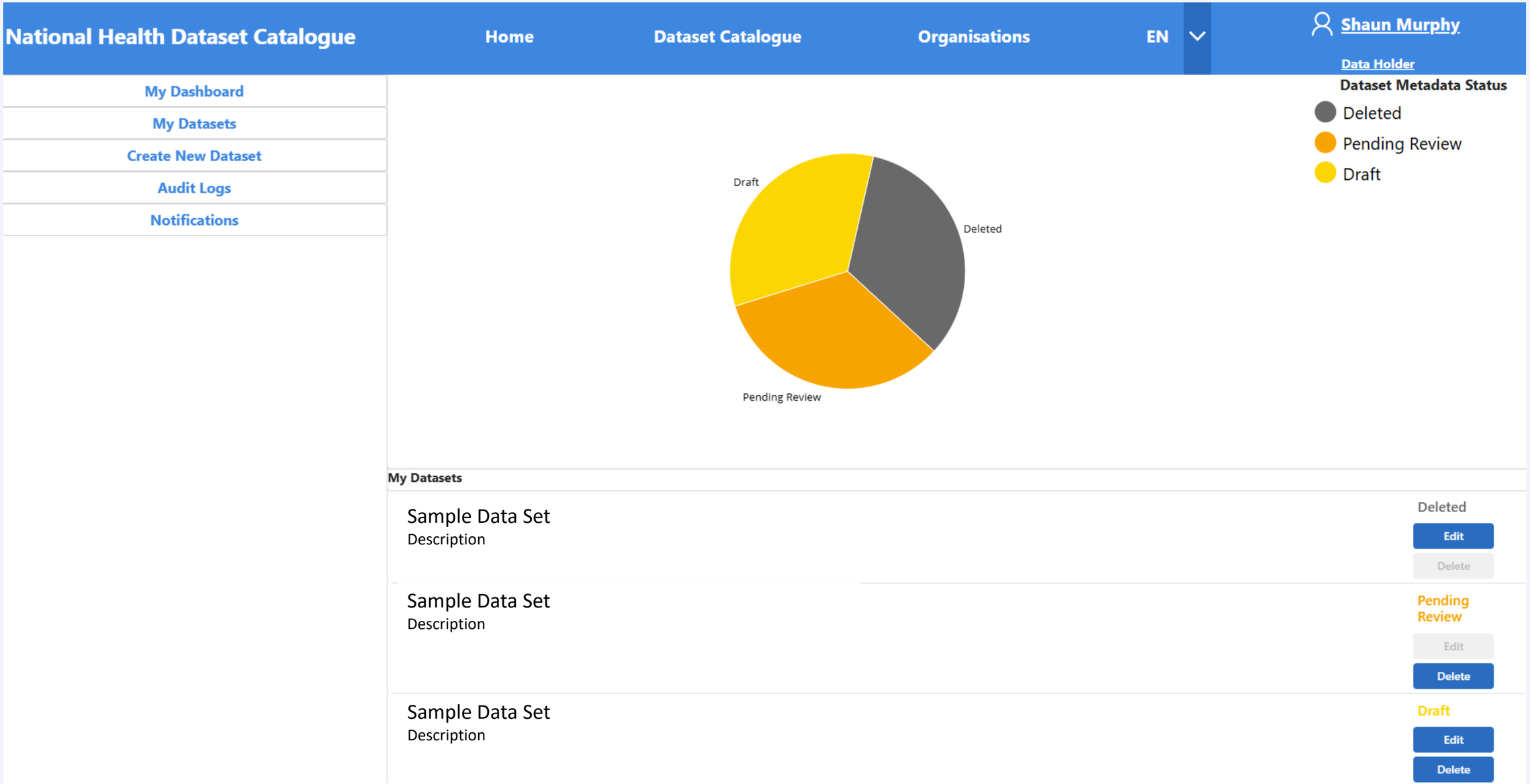
National Health Dataset Catalogue Prototype- sample page

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



National Health Dataset Catalogue Prototype- sample page

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



National Health Dataset Catalogue

Learn more

- TEHDAS2
  - D5.1 Guideline for data holders on their duties regarding data description
- HealthData@EU Platform
  - HealthDCAT-AP Release 5
  - Dataset Description Assistant

Data Quality and Utility Label

Dr. Maria Ryan
Programme Manager
Health Information Quality and Assurance,
HIQA

Data Quality and Utility Label

To meet the standards set by the **European Health Data Space (EHDS) Regulation**

Create a **common label system** that guarantees the quality and utlility of dataseta for **scientific and health innovation purposes.**

The label and its specifications are now the **standard for the secondary use of health data within the EHDS**

QUANTUM

Funded by the European Union

QUANTUM consortium

35 partners from 15 countries

- Health Data Access
- Bodies (HDABs)
- Data Holders (DHs)
- Data Users (DUs)

Stakeholder community

- HealthData@EU forum
- Projects forum
- Patients/citizens forum

SPAIN
IACS; Universitat Politécnica de Valencia

AUSTRIA
GöG; BBMRI

BELGIUM
i~HD; DIGITALEUROPE; EUHA; VIB; Sciensano

CROATIA
CIPH

FINLAND
HUS; THL

FRANCE
Health Data Hub; Hospices Lyon (AE); Hosp Toulouse (AE); CHU Bordeaux (AE); INSERM (AP); APHP; ECRIN; HAS (AP)

GERMANY
BFarm; edha gGmbH

GREECE
EKKE (AE)

IRELAND
HiQA

ITALY
UCSC; ISS

NORWAY
CESSDA; NDH; NIPH (AE)

PORTUGAL
SPMS; U.Porto

SLOVENIA
NIJZ

THE NETHERLANDS
Health-RI; KNAW (AE); Erasmus MC

UNITED KINGDOM
HDR UK (AP); U.ESSEX (AP)

AFFILIATED ENTITY (AP); ASSOCIATED PARTNER (AE)

QUANTUM

Funded by the European Union

Key stakeholders of the Data Quality and Utility Label

Data users

Data holders

Health Data Access Bodies (HDABs)

Primary Data Collectors

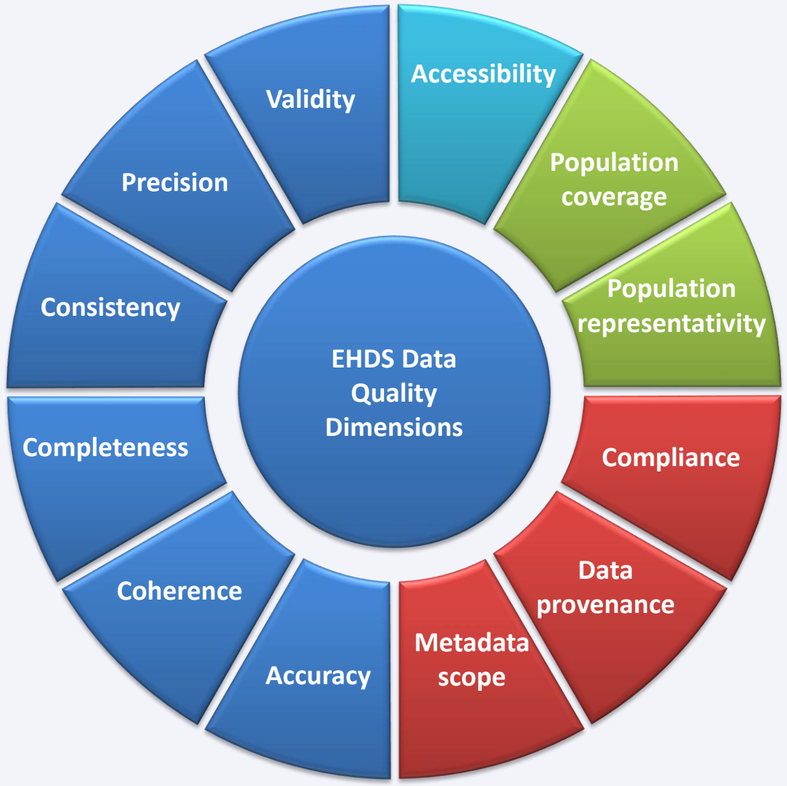
European Commission

General public (patients/citizens)

Data Quality and Utility Label content*

4 categories & 12 dimensions:

- Access and provision
- Coverage
- Data Documentation
- Technical quality



*__QUANTUM Deliverable 1.1__ - Specification of the data sets' quality and utility label

Example of the assessment of a data quality dimension*

Category: Access and Provision

Dimension: Accessibility

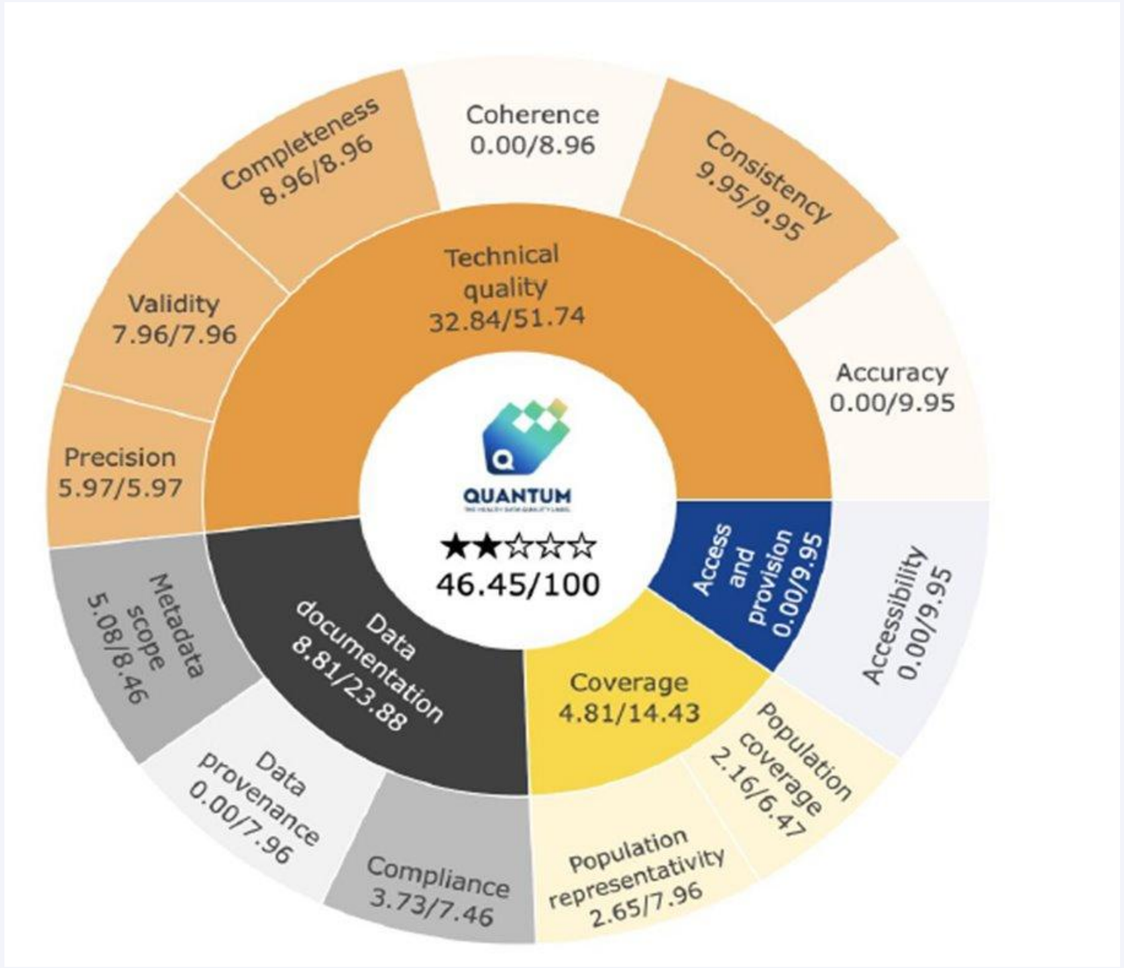
- **Definition:** Accessibility refers to the dataset being accompanied by clear and transparent access and usage conditions.

Measurement

- **Metric 1**: Availability of a data access & usage policy at the time of release of the dataset (No policy, Basic policy, Comprehensive policy)
- **Metric 2:** Average time from data access application to data release for a specific dataset (<1month, 1-3 months, 3-6 months, >6 months)

Note: the label is currently being piloted - draft shown for illustration purposes (details may change)

Data Quality and Utility Label output*



*Example from the mid-scale pilot

Q&A

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Dana (Iordana) Eleftheriadou
Senior Expert on Digital Health,
European Commission

Dr. Maria Ryan
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HIQA

Emer Doyle
Principal Officer,
Health Information Policy Unit,
Department of Health
Ireland

Thank you!

For more information:

HealthData@IE - HIQA