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

International review to inform the development of a national interoperability framework for secondary use health-related data exchange in Ireland

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Conflicts of Interest

None reported.

2 Glossary of key terms and acronyms

Table 1: A glossary of key terms and definitions for terms that are used throughout this review

Term	Definition
Data Holder	Services, or organisations who process personal health data that falls in to any one of the categories of data for secondary use, which are set out in the EHDS Regulation, see **Table 2** below for the full list of categories.
Data User	Any individual who has received a data permit (see below for definition) and thus has lawful access to personal or non-personal electronic health data for secondary use.
Health data access body (HDAB)	A service that allows data users, such as researchers and policymakers, to apply for access to health datasets to support research and innovation, education and training, policy-making, health service management and preparing national statistics.
Interoperability	'Interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support.
Metadata	Information that describes other data. It helps to explain what the data is, how it can be used and where to find it.
Ontology	Medical ontologies can be described as structured frameworks that categorise and represent knowledge in the medical domain, facilitating the organisation and analysis of clinical information and reasoning processes. They are developed to support the systematic understanding of clinical tasks and decision-making in healthcare.

Primary use of health data	The processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates; including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services.
Pseudo-anonymisation	The process of replacing and identifying characteristics of data with a pseudonym, a value which does not allow the data subject to be directly identified.
Semantic interoperability	Semantic interoperability refers to the ability to ensure that the precise meaning of exchanged information is unambiguously interpretable by any other system, service or user.
Secondary use of health data	The processing of health data for purposes such as research, innovation, training and policy-making. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of secondary use.
Secure processing environment (SPE)	The physical or virtual environment and organisational means to ensure compliance with European Union law; such as Regulation (EU) 2016/679, in particular with regard to data subjects' rights, intellectual property rights, commercial and statistical confidentiality, integrity and accessibility as well as with applicable national law; and to allow the entity providing the secure processing environment to determine and supervise all data processing actions including the display, storage, download and export of data, and the calculation of derivative data through computational algorithms.

Table 2: A glossary of key acronyms that are used throughout this review

Acronyms	Description
AI	artificial intelligence
BBMRI	the Biobanking and BioMolecular resources Research Infrastructure
CDISC	Clinical Data Interchange Standards Consortium
CDM	common data model
CEN-CENELEC	the European Committee for Electrotechnical Standardization
DCAT	data catalog vocabulary
DCAT-AP	DCAT Application profile for data portals in Europe
DGA	the Data Governance Act
DICOM	Digital Imaging and Communications in Medicine
EC	European Commission
EHDS	European Health Data Space
EHDS1	European Health Data Space for the primary use of data
EHDS2	European Health Data Space for the secondary use of data
EIF	European Interoperability Framework
ETL	Extract Transform Load (Data Transformation Software Tools)
EU	European Union
EUCAIM	European Federation for Cancer Images
FHIR	fast healthcare interoperability resource
GDPR	General Data Protection Regulation
HDABs	Health Data Access Bodies
IDERHA	Integration of Heterogeneous Data and Evidence towards Regulatory and HTA Acceptance
IEC	International Electrotechnical Commission
ISO	international organization for standardization
IVDR	In Vitro Diagnostics Regulation
JA	Joint Action
MDR	Medical Devices Regulation
OHDSI	Observational Health Data Sciences and Informatics
OMOP	Observational Medical Outcomes Partnership (creator the OMOP Common Data Model (CDM))
PGHD	Patient-Generated Health Data
ReEIF	Refinement of the eHealth European Interoperability Framework
SAREF	Smart Applications REFerence ontology
TEHDAS	Toward the European Health Data Space
W3C	World Wide Web Consortium
WHO	World Health Organization

3 Executive Summary

The digital transformation of health services in Ireland seeks to lead to greater availability of health information and improved efficiency with regard to how health-related data is collected, used and shared. Underpinned by national and EU legislation, including Ireland's Health Information Bill 2024[(1)] and the European Health Data Space (EHDS) Regulation[(2)], the Department of Health's Digital Health Framework (Digital for Care 2030)[(3)] and the HSE's Digital Health Strategic Implementation Roadmap[(4)], set out how Ireland's health service will be digitally transformed over the coming years. This framework and roadmap offer significant potential to drive improvements and increase efficiencies with regard to both the quality and quantity of health-related data collected within the Irish healthcare system over the coming years, thus helping to ensure that Ireland can meet its obligations with regard to the EHDS secondary use requirements.

The Department of Health's "Digital for Care — A Digital Health Framework for Ireland 2024-2030"[(3)] outlines clear objectives for the Irish health system by 2030. In the "Critical Success Factors" chapter of this report, there is a section dedicated to "Data, Standards and Interoperability", which highlights the key health data interoperability elements (such as data models and data standards) that should be in place in order to support achieving the report's objectives.

The EHDS Regulation will be a key driver of changes in the Irish eHealth system over the next five years (2025 - 2030) and preparations to meet this regulation's primary and secondary use requirements are underway. The HealthData@IE project[(5)] has been initiated by the Department of Health for the purpose of ensuring that Ireland can meet the EHDS Secondary Use requirements. This project is focused on laying the groundwork for the development of key elements for an Irish Health Data Access Body (HDAB) service. A HDAB service securely connects data users, such as researchers and policy-makers, with anonymised and pseudo-anonymised health datasets (sourced from data holders) to support research and innovation, education and training, policy-making, health service management and preparation of national statistics.

The Joint Action Towards a European Health Data Space (TEHDAS) has published a significant body of work in recent years, which provide rich detail on EHDS preparedness and health-related data secondary use prevalence across EU Member States. The TEHDAS outputs contain a large body of knowledge directly related to meeting EHDS Secondary Use (EHDS2) requirements and have been key pieces of evidence considered in this review.

Related to EHDS2 preparations, the EHDS2 interoperability framework[(6)] is an initiative to develop a toolkit[(7)] to address the challenges posed for EU Member States when implementing the EHDS Secondary Use requirements. This framework adopted the TEHDAS recommended health data interoperability standards for secondary use[(8)], including DCAT-AP for data discoverability, OMOP-CDM for semantic interoperability and for health data exchange, HL7 FHIR (health record data exchange) and DICOM (imaging data exchange).

Six jurisdictions

In light of these ongoing legislative and health system changes, this international review examined approaches to the exchange of health-related data for secondary use purposes in the following six EU jurisdictions:

- Finland
- The Netherlands
- Belgium
- France
- Sweden
- Greece

Finland, the Netherlands, Belgium, France and Sweden were selected as these jurisdictions were rated highly from a health data reuse perspective in multiple TEHDAS reports. Greece was selected as a number health data interoperability initiatives were introduced in the jurisdiction in recent years, starting at a similar point to the current Irish context.

Aim of this review

The aim of this review was to identify and synthesise available approaches in other jurisdictions (and non-jurisdiction relevant organisations) that facilitate the exchange of health-related data for secondary use purposes, in order to inform the development of a National Interoperability Framework (NIF) for HDAB services in Ireland. The NIF will support Irish data holders to exchange their health-related data with an Irish HDAB service.

More specifically, the key objectives of this review were:

- to conduct a desktop review of existing standards, national approaches and legislation, frameworks and tools from the six jurisdictions and non-jurisdictional organisations operating in this domain

- to identify SMEs in the six jurisdictions to validate findings from the desktop review and further understand experiences
- to consider the implications of the findings in the development of the NIF for HDAB services in Ireland.

Three major sources of evidence
The review covered three major areas of evidence including legislation, grey literature from key organisations and scoping meetings with relevant SMEs within the domain of health data interoperability and secondary use.

3.1 Overview of key findings

This review has explored six jurisdictions' approaches to health data interoperability and secondary use, as well as similar initiatives undertaken by international organisations within this domain.

The main findings relate to:

- commonly-used health data interoperability standards
- national approaches to health data interoperability and secondary use
- legislation that facilitates health data interoperability and secondary use
- interoperability frameworks that facilitate data reuse (not just health data)
- tools that enable health data interoperability
- challenges and barriers to health data interoperability

Summary of key findings and discussion points
A summary of the key findings and discussion points are summarised below.

Health data interoperability standards are key to ensuring health data is reusable

- Data discovery standards are a key enabler of health-related data reuse and national metadata standards and or models are being prioritised in most of the jurisdictions reviewed.

- Most of the jurisdictions reviewed are working to increase the adoption of SNOMED CT and HL7 FHIR at data collection, for the purpose of ensuring high quality and reusable health data is available in the future.
- Adoption of common data models such as OMOP CDM is growing in all the countries reviewed and is seen as a key enabler of secondary use of health data.

National Approaches to Health Data Interoperability are critical to supporting health data reuse

This review evaluated each jurisdiction for national initiatives that were designed to facilitate health data interoperability and secondary use, in order to extract key learnings that could inform the development of a NIF for HDAB services in Ireland. The key learnings from these national approaches included the following:

- National approaches to health data interoperability and secondary use were reviewed across the following five categories: Legal and Regulatory, Governance, Interoperability Standards, Data Sources and Catalogues and Data Access Processes.
- All of the jurisdictions reviewed are actively working to meet the EHDS Secondary Use requirements(9) and each of their approaches is tailored to the specific challenges / health data landscape.
- The Netherlands has created a number of initiatives(10, 11) to support the reuse of health data in a jurisdiction with a decentralised health data landscape.
- Belgium has also implemented some novel strategies to navigate their federal governance systems and federated health data ecosystem.

Health-related data reuse is more prevalent when the legislation is clearer

This review's findings highlight strong legislative foundations as a key enabler to secondary use of health-related data. In particular, Finland and Sweden both credit the historically high levels of health-related data reuse existing in both jurisdictions to a strong and clear legislative basis.

Of the national legislation reviewed (across the six jurisdictions) that facilitates the secondary use of health-related data, Finland stands out by having a dedicated secondary use of health and social data act, enacted in 2019.(12) Additionally, Belgium, Sweden, France, and the Netherlands all have strong legislative frameworks that underpin the reuse of health data.

EU legislation also plays a key role in facilitating secondary use of health-related data in the jurisdictions reviewed. The key elements relating to secondary use have been reviewed from the following EU legislation:

- The 2018 GDPR(13)
- The 2022 Data Governance Act (DGA) legislation(14)
- The EHDS (2)

Interoperability frameworks are essential for navigating the complexities of health-related data reuse

Eight interoperability frameworks were reviewed across five general levels of interoperability in healthcare, namely: Legal, Organisational, Process, Information and Technical.

- The EHDS2 Interoperability Framework(6) is an exciting development for Europe and has the potential to accelerate the level of health data reuse within EU Member States, as well as supporting compliance with EHDS Secondary Use requirements.
- The European Interoperability Framework (EIF)(15) , the New EIF(16) and Refined eHealth European Interoperability Framework (ReEIF)(17) are referenced in multiple TEHDAS reports as being key frameworks when considering health data interoperability in EU Member States.
- The Avoin Data Operating Model for Sharing Data(18) is a key framework for public sector data reuse in Finland.
- The MedMij framework(19) is used to standardise primary use health data at collection stage and it has resulted in high levels of SNOMED CT and HL7 FHIR compliance in the Netherlands and thus large quantities interoperable primary use data are available for reuse in the jurisdiction.

Tools that enable health data interoperability

Tools that enable health data interoperability and secondary use were evaluated under the following categories: semantic interoperability tools, metadata tools and data transformation tools.

- Semantic interoperability tools include using terminologies, shared lists of agreed terms as well as other tools to makes similar fields or variables in different datasets share a harmonised set of meanings (such as semantics).
- Metadata tools include software solutions to generate metadata for datasets (including automated generation, to reduce effort of manually generating metadata

for massive datasets) and validation tools to ensure that generated metadata complies with common metadata standards.
- Data transformation tools enable the "wrestling" of data from one format / structure to another, without risking data quality from time-consuming manual data manipulation.

Challenges & Barriers to health data interoperability and secondary use exist
This review identified multiple barriers to health data interoperability and secondary use in the six jurisdictions reviewed. While these barriers pose significant obstacles to efficient reuse of health-related data in each jurisdiction, a number of approaches designed to proactively overcome them exist. The key learnings from this finding is that barriers like these should be deliberately identified and planned for, so that possible solutions can be planned and implemented.

- This review has categorised these challenges into four broad categories: Legal & Organisational, Trust, Data Quality and Technical.
- The Netherlands has taken a proactive approach to these types of challenges and barriers by developing the "Dutch Trust Framework"[10] which includes a section dedicated to overcoming such barriers, titled "Obstacle Removal Trajectory".
- The EHDS Secondary Use requirements[9] are instigating preparatory efforts across the jurisdictions reviewed to address the challenges and barriers to secondary use of health-related data.

Key Discussion points
The key discussion points of this review are focused on the elements of the findings that have most significance to informing the development of the NIF for HDAB services in Ireland and include the following:
- The value of standardising health data upon collection was explored, using the Dutch MedMij framework to illustrate it.
- Exemplar cases of good practice were identified and included incorporating complex health data interoperability guidance materials in a user-friendly and accessible format; addressing the barriers of health data interoperability and secondary use; a dedicated interoperability framework to support meeting the EHDS2 requirements and an Interoperability Framework based on FAIR Principles.
- Elements to consider for the NIF include an outline of data discoverability and data model standards, as well as tools that have the potential to support data holders in Ireland to prepare and exchange data with a HDAB service.

3.2 Conclusion

Health data interoperability standards such as data discoverability standards are key enablers to secondary use in many of the jurisdictions reviewed. They provide the means for data holders to describe their data in detail so that it can then be published on public digital mediums such as national metadata catalogues and thus discoverable by data users.

Data model standards are another type of standard that facilitate secondary use of health-related data. The ODHSI organisation's OMOP CDM[20] is a widely-used data model which is a key enabler for secondary use as it allows data holders to structure their datasets in a structure that data users are familiar with and as a result, the process of interpreting a dataset (by a data user) is much easier.

This review has identified a number of tools that have the potential to support Irish data holders exchange health-related data with a HDAB service. Such tools are important for secondary use, particularly as making health data and or datasets interoperable often requires adding to or modifying the data. These types of tools include semantic interoperability tools, metadata tools and data transformation tools.

From the findings that have emerged in this review, there is much evidence to conclude that a NIF for HDAB services in Ireland should contain a combination of clearly communicated information on health data interoperability standards, as well as practical guidance and tools that can support Irish data holders through the process of preparing and exchanging datasets for secondary use, and thus meeting the EHDS secondary use requirements. Finally, there is a strong case that key elements of the NIF should comprise of:

- Accessible, clearly communicated and user-friendly guidance to make it possible for data holders to quickly understand the health data interoperability standards and specifications that are key for secondary use.
- Relevant best practices / examples from other jurisdictions in the EU that facilitate exchange of health-related data for secondary use.
- Summaries of key EU legislation that clearly signpost a data holder to the official texts, so that the process of understanding the legalities around preparing and exchanging data for reuse can be completed efficiently.
- Sufficient practical guidance on preparing a dataset for reuse including describing data, data provenance/versioning, dataset security, anonymisation and pseudo-anonymisation.
- Descriptions of the common challenges and barriers to secondary use and possible solutions to them, that are most relevant to Irish data holders.

4 Introduction

4.1 Background

The European Health Data Space

The European data strategy[21], 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. These data spaces will facilitate the reuse of data across different sectors of the economy and society. Two crucial pieces of legislation, namely, the EU 2022 Data Governance Act[22] and the 2023 Data Act[23], have been put in place to provide the legislative basis and regulatory framework for achieving the objectives of the strategy.[14, 21] The European Commission has also prioritised the development of the necessary technological systems and infrastructure to optimise data use and reuse across the EU and to drive innovation. The EU's Digital Decade policy programme[24], 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.

The European Health Data Space (EHDS)[2] 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.[25] 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 2025.[26, 27]

The EHDS seeks to 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.(28) 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.(29)

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.(30)

4.2 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). 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 focuses on developing the national infrastructure 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.(31) 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 is also delivering 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.

HealthData@IE Work Packages

The HealthData@IE project is comprised of 8 Work Packages, three of which are coordinated by HIQA. See **Table 3** for a full outline.

Table 3: Summary of the HealthData@IE Work Package names and lead beneficiaries.

	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, Health Research Board (HRB)
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

HIQA are coordinating three work packages - Engagement and education, National health dataset catalogue and Health Data Quality Enhancement. While HealthData@IE's Work Package 2 is dedicated to "Dissemination, Training and Support" and Work Package 6 is focused on a "National Dataset Catalogue for Health Data", this review has been undertaken as part of Work Package 8 – Health Data Quality Enhancement and specifically as part of task 4 of this work package namely "Work Package 8.4 - Development of a National Interoperability Framework (NIF) for the secondary use of health data".

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 HDAB services in Ireland and ensuring they can meet their obligations relating to the secondary use of data.

Work Package 8.4 - Development of a National Interoperability Framework for the secondary use of health data

The primary objective of Work Package 8.4 is to develop a NIF for the HDAB services in Ireland, by 13 October 2027.

Purpose and Scope of the National Interoperability Framework:

The scope and purpose of the NIF to support data holders in Ireland to provide data to the HDAB (as a result of successful data access request process), and thus enable reuse of this data by a data user, is the secondary use of health-related data exchange in Ireland (such as exchange of data from a data holder to the HDAB).

Throughout this review, the terms National Interoperability Framework and NIF are used interchangeably and refer to the description and scope just mentioned.

4.3 Aim of this review

The review aimed to identify and synthesise available approaches in other jurisdictions (and non-jurisdiction relevant organisations) that facilitate the exchange of health-related data for secondary use purposes, in order to inform the development of a NIF for HDAB services in Ireland. The NIF will support Irish data holders to exchange their health-related data with the Irish Health Data Access Body.

Key Objectives

The key objectives of this review were as follows:

- To provide an overview of the health data interoperability standards that facilitate health-related reuse
- To summarise the key aspects of national approaches to health data interoperability in other European jurisdictions
- To summarise and compare national legislation relevant to secondary use of health-related as well as EU legislation
- To review key Interoperability Frameworks that have the potential to inform the development of the NIF for HDAB services in Ireland
- To identify and describe the common barriers to health data interoperability and secondary use, and evidence on possible solutions to them
- To identify and describe key technological solutions that have the potential to support data holders to prepare health-related data for reuse

4.4 The Irish Context

The Department of Health's "Digital for Care — A Digital Health Framework for Ireland 2024-2030"[(3)] outlines clear objectives for the Irish health system by 2030. The "Data, Standards and Interoperability" within this framework's "Critical Success Factors" chapter highlights the key elements (such as data models and data standards) that should be in place in order to support achieving the framework's objectives. These include statements such as "data models must be implemented within the systems used to record, share, and consume this data. Interoperability standards are needed to ensure data 'flows' between digital health systems to enable the joining up of health and social care services" and "the need to ensure 'data follows the patient' is essential to achieving a joined-up health service where patients can safely transition between healthcare settings such as from acute to community and between public, voluntary, and private healthcare providers".

The EHDS will also be a key driver of changes in the Irish eHealth system over the next five years (2025 - 2030), and preparations to meet this regulation's primary and secondary use requirements are underway. Preparations to meet the EHDS secondary use requirements include the HealthData@IE project(5), which is laying the groundwork for the development of key elements for an Irish HDAB service.

This review was undertaken with the current and future Irish contexts (including the Irish eHealth and secondary use landscapes) firmly in mind, in order to ensure that the learnings from it would be conducive to informing the development of the NIF, and thus be a key resource to support data holders with health related data reuse in the coming years. The NIF will be developed as part of the HealthData@IE project and will be a key resource for data holders in Ireland in the preparation and exchange of datasets with a HDAB service, as part of a data access application initiated by a data user.

5 Methodology

In order to ensure a standardised approach, four distinct steps were taken when undertaking this review: defining the scope, search of relevant international sources, reviewing and extracting relevant information and summarising the findings.

5.1 Defining the scope

The following EU jurisdictions were selected for this review prior to the overall research question being confirmed:

- Finland
- The Netherlands
- Belgium
- France
- Sweden
- Greece

France, Belgium, Finland, Sweden and the Netherlands were selected, as these jurisdictions were showcased in TEHDAS reports (2022[(8)] and 2023[(29)]) as having well-established infrastructure which facilitates the exchange of health-related data for secondary use. Furthermore, France, Belgium and Finland were identified to have established organisations that play very similar roles to that of a Health Data Access Body. Greece was selected as it has recently introduced a number of health data interoperability initiatives[(32)], with these initiatives beginning at a similar point to the current Irish context. In addition, this review also evaluated approaches to health data interoperability and secondary use in non-jurisdictional (such as international organisations) organisations that publish healthcare interoperability standards and provide health research data infrastructure.

5.2 Search of relevant international sources

This review included three major areas of evidence including legislation, and grey literature (inclusive of guidance, specifications or frameworks) from key organisations. Scoping meetings with relevant SMEs from each jurisdiction within this review were held. Each aspect has been addressed below.

Legislation

This review considered legislation as potential sources of evidence. This included artefacts such as the EHDS Regulation[(2)], the EC's EHealth European Interoperability Framework[(33)], the EHN's Refined eHealth European Interoperability Framework (ReEIF)[(17)] and the Irish Health Information Bill 2024[(1)].

Grey literature from key organisations

Evidence of approaches (inclusive of guidance, specifications or frameworks) to the exchange of health-related data for secondary use purposes was gathered (via a grey literature search) from key organisations across the six European Union jurisdictions. Evidence was also gathered from international organisations which publish healthcare interoperability standards and organisations that provide health research data infrastructure, such as standards or tools that support the reuse of health-related data for research purposes.

Scoping meetings with subject matter experts

Scoping meetings were held with relevant health data interoperability SMEs from each of the six jurisdictions, who specialise in the secondary use of health-related data. These were carried out in order to validate our understanding of each jurisdiction's health data for secondary use landscape, explore the experience of SMEs in greater detail, and to obtain additional information that could not be acquired via the desktop research.

Eligibility Criteria

An initial search of evidence was undertaken to inform the eligibility criteria for this review and the following inclusion/exclusion criteria were established:

Inclusion criteria	1. National legislation, regulation, guidance, specifications and frameworks in current use that support the exchange of health-related data for secondary use purposes. 2. Information published in the English language or automatically translatable (via a tool like DeepL) to the English language. 3. Information published by organisations with a legal remit and or national mandate for developing guidance, specifications and frameworks for enabling the exchange of health-related data for secondary use purposes. 4. European context: relevant European Health Network Guidelines and EHDS requirements.
Exclusion criteria	1. Approaches that are focused solely on the exchange of primary use health data. 2. Published peer-reviewed academic literature.

5.3 Reviewing and extracting relevant information

Legislation and grey literature

A list of key national organisations relevant to health data interoperability and secondary use was developed for each jurisdiction and a Google Site Search[1] was undertaken. Relevant artefacts (such as documents, web pages) were identified using the above-mentioned eligibility criteria and information about these artefacts were stored in a MS Excel Spreadsheet. Relevant information on the following was then extracted from these artefacts:

- Legislation that has been published to facilitate the exchange of health-related data for secondary use purposes.
- Guidance, specifications and frameworks designed to enable the exchange of health-related data for secondary use purposes.
- Summaries from scoping meetings with SMEs who specialise in the secondary use of health-related data.

Key documents published in languages other than English were translated using the DeepL machine translation software.

[1] A Google Site Search can be described as directing Google's Search Algorithm to limit its search to just a single domain/website. The rationale for doing this is to leverage Google's powerful search algorithm in order to maximise the probability of finding all relevant artefacts.

Scoping meetings with subject matter experts

Scoping meetings were held with relevant health data interoperability SMEs who specialise in the secondary use of health-related data, to obtain additional information that was not obtainable via the desktop research. This was to validate our understanding of each jurisdiction's health data for secondary use landscape, and also to learn from and explore their experience in greater detail.

Where possible, SMEs with detailed knowledge of the health data for secondary use access and or transfer process were identified and contacted (SMEs engaged in roles in a service similar to that of a HDAB). Key high-level questions were circulated in advance of the meetings which ensured a repeatable structured format for each meeting. **Table 4** below outlines the organisation and role of each SME.

Table 4: Summary of the organisations and roles of the scoping meeting participants (SMEs).

Jurisdiction	Organisation	Role
Finland	Findata	Development Manager
The Netherlands	Health-RI / Lygature	Program Manager
Belgium	Health Data Agency (HDA)	EU Case Manager
France	Health Data Hub (HDH)	European Project Manager
Sweden	National Board of Health and Welfare (Socialstyrelson)	Head of E-health and Informatics, eHealth Strategist
Greece	Foundation for Research and Technology Hellas	Head of Center for eHealth Applications and Services (CeHA) / eHealth Strategist

5.4 Summarising the findings

Information on approaches inclusive of legislation, regulation, guidance, specifications, and frameworks; from other jurisdictions, and non-jurisdiction relevant organisations that facilitate the exchange of health-related data for secondary use purposes, was synthesised, while considering the Irish context. This information has been presented in the Findings section as a comparative review of identified commonalities and best practices. Tables, images or diagrams have been used, as appropriate, to summarise key points and findings.

6 Findings

This chapter provides an overview and summary of the six key findings of this review. These six findings have been generated from the evidence gathered, with an emphasis placed on information that has high potential to be useful in supporting an Irish data holder during the process of preparing or exchanging data with a HDAB service. Therefore, each finding has been written with Irish data holder's perspective in mind.

This chapter is structured in six sub sections: section 6.1 provides an overview of health data interoperability standards that are key to secondary use; section 6.2 outlines each of the six jurisdictions' approaches to health-related data reuse; section 6.3 discusses legislation and legislative approaches that facilitate the secondary use of health-related data; section 6.4 explores a number of key interoperability frameworks that are essential or navigate the complexities of health-related data reuse; section 6.5 provides an overview of tools that support health data interoperability and section 6.6 summarises the key barriers to health data interoperability and secondary use.

6.1 Commonly used health data interoperability standards

When health data adheres to standards that are used by other entities, the potential for reuse increases significantly as the effort involved in understanding and working with the data is reduced.[8] For example, the process of merging one health dataset with another becomes much less complex if both datasets follow the same health data standards.

Common health data interoperability standards can be grouped into the following categories[8, 34]:

- terminology and classification standards (SNOMED CT, ICD-10/11, LOINC)
- messaging standards (HL7 2.x, HL7, FHIR, DICOM)
- document standards for exchange of clinical documents (HL7 CDA)
- discovery standards (DCAT-AP, HealthDCAT-AP, ISO/IEC11179)
- data model standards (OMOP-CDM, CDISC STDM and CDASH).

Each of these standards will be explained in detail in the following sections and **Table 5** provides a summary of levels of adoption per jurisdiction reviewed.

6.1.1 Terminology and classification standards

Health data terminology and classification standards (or systems) enable the collection of health data in a standardised and structured manner (by following a commonly used standard) and therefore have a direct impact on secondary use. When these types of standards are in place where health data is being collected (such as when embedded into eHealth Systems used in clinical practice), there is a positive impact on data quality due to the data being stored in compliance with such standards (the data is stored in a highly detailed and structured manner).

Examples of terminology and classification standards (or systems) include ICD-10/11, SNOMED CT for clinical terms, LOINC for laboratory results and Orphanet Codes for rare diseases.

A terminology standard or system (often called reference terminologies) is a structured collection of descriptive terms for use in clinical practice. A reference terminology is defined as 'standardized terms and their synonyms which can be used to record patient findings, circumstances, events, and interventions with sufficient detail to support clinical care, decision support, outcomes research, and quality improvement; and can be efficiently mapped to broader aggregation terminologies for administrative, regulatory, oversight, and fiscal requirements.'[35]

When implemented, reference terminologies can facilitate the coding of clinical information (concepts) captured in an electronic health record or electronic patient record at the point of care. These systems assign a unique code or value to a specific disease or entity, are generally highly detailed, have predefined relationships between codes/concepts, and are fine grained. Terminology standards (or systems) define the meaning of all terms in a clinical domain unambiguously and independent of any specific purpose. International terminologies such as SNOMED CT and LOINC are widely used in clinical coding. Terminology-based coding at the point of care has been shown to significantly improve the overall quality of clinical data.[36]

An example of this is the SNOMED CT Concept Code for "Type 2 diabetes mellitus" is 44054006. SNOMED CT has extensive coverage of most health/medical concepts, making it a complete point of reference for health related concepts.

Classification systems (or standards), such as the World Health Organisation's ICD-10 and ICD-11, share similarities to terminology systems such as SNOMED CT, but differ primarily in how they are used. These types of standards group similar diseases and procedures based on pre-determined categories such as the cause of a disease. They are by far the most widely-used approaches to coding healthcare data in existence today.[36]

Health data that is coded (structured and stored) in compliance with a classification standard, is often used for secondary use purposes such as reimbursement, statistical and public health reporting, and operational/strategic planning, as well as quality of care measurements and other administrative functions.(36) For instance, the ICD-10/11 standards group related concepts together to satisfy a specified use case, such as cause of disease, in order to support the systematic reporting, analysis, interpretation and comparison of health data relating to mortality and morbidity. Examples of these use cases include using ICD-10 coded health data to support public health and policy-making initiatives such as population screening.

ICD-10 came into effect in 1993, is widely used internationally, and was superseded by ICD-11 in 2018. ICD-10 is a hierarchical system of codes that are used to structure and store health data related to cause of disease, for reporting purposes (rather than for the purpose of capturing detailed information to be stored in a patient's electronic health record). The 11th Revision of the ICD was released in 2018, as a replacement for ICD-10. This standard contains a number of improvements over its predecessor, including more meaningful clinical content, user-friendliness of implementation, technical features including the support of use in both online and offline environments, and a translation tool that ensures internationally consistent translations. Coding additions within ICD-11 include codes for antimicrobial resistance in line with international standards, specific coding for clinical stages of HIV, and codes for the classification of heart valve diseases and pulmonary hypertension, now matching current diagnostic and treatment capacity. In most jurisdictions reviewed, ICD-10 is well established within the respective eHealth landscapes and the migration to ICD-11 has not yet been completed.(37)

In order to enhance interoperability of health data coded using differing systems (SNOMED CT Vs ICD-10), a mapping exercise is usually undertaken where a set of codes/concepts from system are matched to the respective closest code/concept in the other system.(36)

6.1.2 Messaging standards

Messaging standards outline the structure, content and data requirements of electronic messages to enable the effective and accurate sharing of information. The term 'message' refers to a unit of information that is sent from one system to another, such as between a laboratory information system and a GP's clinical information system.(34) Types of messaging standards include HL7 Version 2.x (V2), HL7 FHIR, for clinical and administrative health data exchange, and DICOM for the exchange of medical images (radiology / x-ray images).

The HL7 Version 2.x (V2) is an older (first released in 1989), but still widely-used health data messaging standard that allows the exchange of clinical data between systems. This standard supports the use of messages in the XML data standard and is designed to support a central patient care system as well as a more distributed environment where data resides in departmental systems. Additionally HL7 2.x is also used in the exchange of health data between organisations, such as hospitals and primary care clinics.

The HL7 Version 3 (V3) was introduced to address the address the interoperability shortcomings of HL Version 2.x. V3 was based on a Reference Information Model (RIM), which is a universal mode for all information that needs representation within healthcare. A HL7 V3 RIM message is structured in the XML data standard format, is semantically interoperable and supports the embedding of code systems such as ICD and LOINC.(34)

HL7's Fast Healthcare Interoperability Resources (FHIR) is a messaging standard framework. FHIR combines the best features of HL7 V2, V3 and CDA (while also learning from these preceding standards' weaknesses), leveraging the latest web standards, with a strong emphasis on user friendliness for fast implementation. FHIR implementations are built from a set of components called "Resources". These resources align to common health data and or clinical concepts such as patient, practitioner, encounter, appointment and medication. FHIR is suitable for use in many different eHealth use cases, including mobile applications, EHR-based data sharing, and server communication in large institutional healthcare providers. FHIR offers improvements over the previous HL7 standards. These include faster and easier implementations which are enabled via open source specifications and implementation libraries which developers can leverage; and built-in interoperability and compatibility with the older HL7 messaging standards, as well as with common Web standards such as XML, JSON and OAuth. HL7 FHIR also has integrations to terminology and classification systems such as SNOMED CT and LOINC.(38, 39)

The Digital Imaging and Communications in Medicine (DICOM) was first published in 1993 and is an international messaging standard for the exchange medical image and related data. It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use. DICOM is widely used within medical domains such as radiology, cardiology, and radiotherapy (such as X-ray, CT, MRI, ultrasound), and also in other domains such as ophthalmology and dentistry. DICOM is recognised by the International Organization for Standardization as the ISO 12052 standard.(40)

Additionally, the 2022 TEHDAS Recommendations to enhance interoperability within the HealthData@EU report states that HL7 FHIR has been widely adopted in Denmark, France, Finland, Hungary, Portugal, the Czech Republic, and the Netherlands; and DICOM in all jurisdictions reviewed as part of the report, except Germany.(8)

6.1.3 Document standards

Document standards indicate the type of information included in a document and also the location of the information. HL7 Clinical Document Architecture (CDA) is one such standard, and HL7's most widely-adopted HL7 V3 standard. It provides both a standardised header containing metadata about the document, as well as the ability to represent a wide variety of clinical content arranged into various sections. The document content can be un-encoded, such as a PDF, through to a fully encoded HL7 v3 instance. This standard is often used for structuring documents such as discharge summaries and progress notes. CDA defines the following characteristics for all clinical documents: 1) Persistence, 2) Stewardship, 3) Potential for authentication, 4) Context, 5) Wholeness and 6) Human readability. Instances of CDA-based specifications include the document standard for a continuity of care document (HL7 CCD) and a discharge summary specification (HL7 DS).[34, 41]

6.1.4 Data discoverability standards

Data discovery standards relevant to health data interoperability and secondary use are primarily metadata standards. Metadata standards commonly used in health-related data include the DCAT application profile (DCAT-AP), ISO/IEC 11179 and FAIR Principles[42] relating to metadata.

DCAT-AP is a specification used for sharing descriptions of datasets through the use of web-based metadata catalogues. This metadata standard is used widely across open data portals and or catalogues in Europe, including Ireland's Open Data Portal. DCAT-AP was extended to create a health-specific version of the standard, named HealthDCAT-AP, which outlines a set of descriptive terms to accommodate the unique requirements of electronic health data. As part of the EHDS secondary use requirements, data holders will be required to use the HealthDCAT-AP standard when creating descriptions for their datasets, so that they can be published on a National Metadata Catalogue (EHDS requirement).[8, 43]

ISO/IEC 11179 is a standard used for metadata registries (MDRs), providing the schema and content of metadata and how to manage it. It provides a template for describing data elements, their concepts, meanings and relationships for the purpose of enhancing the understanding of a dataset to that it can be shared and reused.[8]

The "FAIR Guiding Principles for scientific data management and stewardship" include multiple principles that outline how metadata should be structured. Examples of these include mandating that metadata should be "assigned globally unique and persistent identifiers", so that that a metadata element cannot accidently be reassigned to other data, via the use of the same identifier. Another example of these principles is that metadata "are registered or indexed in a searchable resource", which means that the metadata is attached to a data element which is searchable and when the data element is retrieved from a search, the metadata is attached to it.[42]

6.1.5 Data model standards

A heath data model standard can be described as a pre-defined and documented structure for representation of health data. It creates a common framework that facilitates the exchange, organisation, analysis of disparate health datasets. For example, if multiple datasets containing similar data are using a pre-agreed or common data structure, merging the data together to conduct analysis becomes much more feasible. In addition, interpretation of the data becomes easier due to the predefined and documented structure that the data is in. This type of data model standard is often referred to as a Common Data Model (CDM).[8, 44]

The Observational Health Data Sciences and Informatics (OHDSI) organisation publishes and maintains one such model standard, which is named: Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). OMOP CDM is an open community data standard, created to harmonise the structure and content of observational data and to enable efficient analyses that can produce reliable evidence. A central component of the OMOP CDM is the OHDSI standardised vocabularies. These vocabularies are semantic interoperability tools that enable the standardisation of medical terms across various medical fields on the OMOP CDM and also support data analysis.[20] In most of the jurisdictions reviewed, OMOP CDM is used for structuring health-related data for secondary use[8], and Belgium is adopting this data model standard at a national level.

The Clinical Data Interchange Standards Consortium (CDISC) organisation publish and maintain a series of data model standards including their Study Tabulation Model (STDM), Analysis Data Model (ADaM), Clinical Data Acquisition Standards Harmonization (CDASH) and Operational Data Model (ODM).[45] The STDM standard is most similar to OMOP CDM as it defines a standardised structure for organising and formatting research study data, for the purpose of establishing consistency across multiple studies and supporting data exchange and analysis. The ADaM standard lays out principles for statistical analysis and reporting, through the incorporation of guidelines for structuring and data analysis for the purpose of generating meaningful results. The CDASH standard ensures that data collection during clinical research studies is consistent by providing guidelines for data collection, including variables, labels, definitions and code lists. The ODM standard is an XML-based data model that standardises the transfer of metadata and associated data for clinical trials. In the jurisdictions reviewed, levels of CDISC standard implementation and or use were very low, in the secondary use of health-related data.

A number of the jurisdictions reviewed have established national health information models which can then be implemented using terminology, messaging and document standards. In some cases, these types of models usually sit a level above the implementation standard, in order to be standard agnostic and or future-proofed, but not always. Examples of these types of national information models are Finland's Information Architecture, which specifies implantation standards such as SNOMED CT and ICD codes.(46) Sweden's National Information Structure (NIMs)(47) is an example of an implementation standard agnostic approach. A further example is that of the Dutch ZIBs, which involves creating "building blocks" of information in order to capture and store clinical concepts in a standardised manner and a key aim of the ZIBs initiative is to facilitate reuse of health data.(48)

6.1.6 Standards adoption by jurisdiction

Table 5: A summary of health data interoperability standards across the six jurisdictions reviewed

Jurisdiction	Terminology Standards	Messaging Standards	Document Standards	Discovery Standards	Data Model Standards	Summary
Finland	ICD-10, ATC, LOINC, SNOMED CT , Orphacode	FHIR widely used DICOM	CDA widely used	DCAT-AP, ISO/IEC 11179, FAIR Metadata	OMOP CDM widely used in secondary use, National Information Architecture	SNOMED CT and FHIR adoption increasing
The Netherlands	ICD-10, SNOMED CT LOINC, Orphacode	FHIR widely used DICOM	CDA being replaced by FHIR	DCAT-AP, FAIR Metadata	OMOP CDM widely used in secondary use, National information models - ZIBs	Widespread SNOMED CT, FHIR and OMOP adoption
Belgium	ICD-10, ATC, LOINC, SNOMED CT Orphacode	KMEHR, FHIR increasingly used DICOM	CDA limited use	DCAT-AP, ISO/IEC 11179	OMOP CDM widely used in secondary use	Migrating from KMEHR to FHIR, ICD-10 to SNOMED CT Mapped
France	ICD-10, CCAM, LOINC, SNOMED CT Orphacode	FHIR increasingly used, DICOM	CDA widely used	DCAT-AP, ISO/IEC 11179, FAIR Metadata	OMOP CDM somewhat used in secondary use	SNOMED CT adoption increasing
Sweden	ICD-10, ATC, LOINC, SNOMED CT, Orphacode	FHIR increasingly used DICOM	CDA minimal use	DCAT-AP, ISO/IEC 11179, FAIR Metadata	OMOP CDM somewhat used in secondary use National Information Models (NIMs)	Widespread SNOMED CT, FHIR adoption
Greece	ICD-10, ATC, LOINC, Limited SNOMED CT use	Limited FHIR use	CDA used in ePrescription and hospital systems	DCAT-AP planned	OMOP CDM somewhat used in secondary use	In early stage of standards adoption

6.1.7 Summary

Summary of commonly used health data interoperability standards

- This review has evaluated health data interoperability standards under the following categories:
  - Terminology standards (SNOMED CT, ICD-10/11, LOINC)
  - Messaging standards (HL7 2.x, FHIR, DICOM)
  - Document standards for exchange of clinical documents (HL7 CDA)
  - Discovery standards (DCAT-AP, HealthDCAT-AP, ISO/IEC11179)
  - Data model standards (OMOP-CDM, CDISC STDM and CDASH)
- Data discovery standards are a key enabler of health-related data reuse and national metadata standards and or models are being prioritised in most of the jurisdictions reviewed.
- HL7 FHIR is widely used in most of the jurisdictions reviewed and SNOMED CT adoption is increasing.

6.2 National approaches to health data interoperability

While each jurisdiction included in this review has a distinct approach to health data interoperability and secondary use, a number of similarities and patterns have emerged. Each jurisdiction is conducting preparatory activities for the upcoming EHDS secondary use requirements such as the publication of National Metadata standards and support mechanisms for data holders exchange data with data users, via a Health Data Access Body (HDAB) service.

Data collection that is in adherence with commonly used Health Data Interoperability Standards (HL7 FHIR, SNOMED CT, ICD10/11) is often a key enabler of the secondary use of this type of data and the aim of this section is to compare national strategies, standards, infrastructure and policies that support the implementation of these standards and how it impacts the reuse of health-related data in these jurisdictions.

An overview of each of these jurisdictional approaches are discussed in the sections that follow and **Table 6** provides a comparative summary of each.

6.2.1 Finland

Finland's 2019 Act on Secondary Use of Health and Social data(12) obliges data holders in Finland to make their health-related data available to share, provides guidelines for data reuse and a legal mandate to Findata, the Finnish data permit authority. Findata acts as the central intermediary service supporting both data holders and data users exchange datasets for secondary use purposes.

The largest source of health data available for secondary use in Finland is from the national eHealth infrastructure service, Kanta. Kanta is a centralised patient data platform and holds health, social and wellbeing data for each patient in Finland. Kanta is maintained by the Finnish Social Insurance Organisation, Kela who are also a large data holder of drug reimbursement, prescription and social welfare benefit data. Health Data is also held by many regional public sector organisations in disparate health systems.(49)

The Finnish Institute for Health and Welfare (THL) is responsible for publishing international and national standards and terminologies for eHealth. Multiple HL7 versions and ICD-10 are used for exchange of health data in hospitals and biobanks, the use of SNOMED CT is increasing and the OMOP Common Data Model (CDM) is widely used.(49)

Findata along with THL manage the national data catalogue and national metadata models. For example, Findata will routinely work with Finnish data holders to review their datasets and support them with the development of descriptions for these datasets, in a specific meta data standard/format (such as the HealthDCAT-AP standard) so that datasets can then be published on the national metadata catalogue.· In Finland, there is strong emphasis placed on ensuring that dataset descriptions follow the national metadata standard. However, there is not a national standard for common data models (to standardise dataset structures/formats) such as OMOP CDM or CDISC STDM and Findata doesn't conduct any data / dataset transformations of datasets into such standards/models. This type of work (loading data into an OMOP CDM) is always done at the data holder level.

The Findata organisation also manages the national data request process (DAAMS) and grants data permits to data users, publishes pricing of data requests (inclusive of Findata service charges, costs incurred by the data holders and Secure Processing Environment fees) and plays a key intermediary role between the applicant (data user) and the holders of the data requested (data often needs to pulled from multiple data holders and combined). For example, Findata reviews a data request with an applicant to ensure that the request is as clear as possible with regard to what data (such as list of variables) is being requested (from one or more data holder(s). Findata then distributes this request to the data holders so that they can extract the data. Another organisation, the Finnish IT Center for Science (CSC), provides the actual data transfer from the data holder(s) to one of the ten certified Secure Processing Environments (SPEs) in the jurisdiction.[49]

Findata often conduct operations on datasets, usually within the organisation's SPE, Kapseli. If a dataset contains individual level data (personal identifiable data (PII)), it is usually pseudo-anonymised and if the dataset contains aggregated data, it is usually anonymised. Similar to Sweden and Belgium, linkage is based on an individual's social security number (or the pseudo-anonymised equivalent).

There are high levels of trust reported among data holders in Finland with regard to the sharing of data for reuse and the Act on Secondary Use of Health and Social data clarifies this process by providing mandated timelines for data applications as well as broadly normalising the process.

Of the six jurisdictions reviewed, Finland is the most aligned with the EHDS secondary use requirements; having an established organisation that plays the role similar to that of a Health Data Access Body (the Findata organisation), an operational Data Access Application Management System, Metadata catalogue and multiple SPEs.[8, 49]

6.2.2 The Netherlands

The Netherlands does not have dedicated legislation for secondary use of health data, but the 2024 Electronic Data Exchange in Healthcare bill (WEGIZ) mandates the use of health data interoperability standards such as HL7 FHIR and SNOMED CT for the collection and exchange of primary use health data. Having data standardised when it is being collected means there is less work for a data user interpreting the data (if the data/dataset is coded/SNOMED CT compliant), or merging a dataset with another similar dataset.[50-52]

The Dutch health data landscape is federated, with most of the data being held by large academic research centres such as University Medical Center Groningen (UMCG), Maastricht University Medical Center (MUMC), Radboud University Medical Center, the Dutch Ministry of Health, Welfare and Sport (VWS) and other public sector bodies.

The Health-RI organisation plays a key role in the provision of integrated health data infrastructure to support secondary use purposes such as research, policy-making and innovation, offering many services that support this including guidance, software tools, onboarding to the National Metadata Catalogue (which Health-RI manages) and management of secure process environments for health data. The National Metadata Catalogue is an online web application and or portal containing descriptions of datasets which are discoverable and available for reuse. These descriptions include a dataset's creation date, the name(s) of the data holder(s) or the URL where the data can be accessed from. The datasets listed in the Catalogue come from various domains including medical imaging data, biobank samples, genomic data, clinical data and collections such as registries.[50, 53]

The Nictiz organisation publishes and maintains health information standards (National FHIR profiles, SNOMED CT Releases) and is dedicated to the digital information provision in the Dutch healthcare system. Nictiz are the primary driver nationally for maintaining high levels of data quality and standardisation when data is being collected, which the Health-RI services leverage to facilitate secondary use. In 2021, Nictiz published an information model called the Layer Framework (based on the EHN Refined eHealth Interoperability Framework (ReEIF)), which was designed to facilitate interoperable primary use health data exchange in the Netherlands. Within this framework, there is a section dedicated to terminology systems (SNOMED CT, ICD-10) and health data exchange standards (HL7 CDA, FHIR), and links to the Nictiz National Terminology Server and a number of other semantic interoperability resources. Common Data Models such as OMOP CDM are used widely for secondary use but they have not yet been adopted as a national standard by Nictiz.[48, 54-56]

The process of submitting a data access request is initiated through the National Metadata Catalogue, which includes information on how to access data such as the contact details of the data holder (of a dataset) or the URL where access can be requested. Dataset transformations and or modifications, such as pseudo-anonymisation, anonymisation or loading data into a common data model format, are all conducted at the data holder level, without a strict dataset model or specification that needs to be adhered to (at the dataset level). However, a dataset description must adhere to the national metadata standard (based on Health DCAT-AP), so that the dataset is discoverable in the National Metadata Catalogue.

The Netherlands has taken a proactive approach to overcoming the barriers to the sharing of health data and fostering trust among data subjects, data holders and data users. The 2021 Health-RI "Dutch national trust framework for secondary use of health data" details a list of known obstacles to sharing of health data for reuse, and suggested solutions to them.(10) Examples of trust-related obstacles mentioned in the framework included citizens not being well informed about the importance of reuse of health data, lack of clarity on who has control of health data and fear of lack of credit and or recognition by organisations generating health data. An implemented solution to one of these obstacles was a public awareness campaign titled "Data Saves Lives".(11) This campaign's aim was to stimulate a public debate on health data reuse and to generate awareness of the benefits to the public from it.(10)

In terms of alignment with the EHDS secondary use requirements, the Netherlands have an established National Metadata Catalogue, multiple SPEs and data holders are actively sharing health data for reuse. While there is not a centralised HDAB service like in Finland, Health-RI is responsible for the creation of a Dutch National HDAB service which will include a Data Access Application Management System and include the existing SPEs and National Metadata Catalogue.

6.2.3 Belgium

Similarly to Finland, the 2023 law establishing the Health Data Agency (HDA)(57), requires that Belgian data holders must make their health-related data available for secondary use, and gives the HDA a legal mandate to coordinate and support data exchange process between data holders and data users in Belgium.

Belgium has a mature health information system and a long history of routinely collecting population-level health data for reuse, however the data collection and storage is fragmented. Sciensano, Belgium's national public health institute, makes information on all registries available through the healthdata.be platform, which it manages. This platform is funded by the National Institute for Health and Disability

Insurance (RIZIV). RIZIV is another large data holder as are the Belgian Cancer Registry, the Intermutualist Agency or Common Sickness Funds Agency (AIM-IMA), the Federal Agency for Medicines and Health Products and Statistics Belgium (Statbel). The HDA has granted "trusted data holder" status to some of these large data holders in order to streamline the secondary use data access and transfer process by removing the number of entities involved.(58)

Sciensano has developed standards for primary use data collection and includes the SNOMED CT and ICD-10 international coding standards and a number of HL7 data exchange standards. In 2021, a National eHealth Action Plan was published and is key for EHDS preparations in Belgium.(59) The plan includes an integrated National Electronic Health Record (EHR), semantic interoperability standards including SNOMED CT and ICD-10, HL7 FHIR for primary use data exchange, Health DCAT-AP for dataset metadata and or data catalogues and OMOP CDM for secondary use. As part of this action plan, the Belgian Ministry of Health has developed a "Terminology Mapping Service" to assist with mapping from ICD-10 to SNOMED CT.

The HDA manages the Belgian National Metadata Catalogue. Part of this role includes assisting large Belgian data holders with onboarding onto the catalogue. This process is a collaborative exercise and often includes a "data maturity analysis", which involves assessing the required supports the data holder needs. Semantic resources have been developed to enhance the discoverability of datasets in the catalogue and are currently being integrated into it. To further support data holders add dataset descriptions to the National Metadata Catalogue, the HDA have created metadata collection and validation tools, while also providing training on the Health DCAT-AP metadata standard.

The data access process in Belgium is coordinated through the HDA's DAAMS Prior to implementing this system, the HDA undertook a testing exercise to identify potential issues with the data access process. A number of potential HDAB governance structures were selected and tested by use case. Findings from this exercise included that the dispersal of data requests to data holders was slow and complex when multiple entities were involved, resulting in challenges to meet the EHDS required data request timelines. As a result, the Belgian Ministry of Health decided that the data access process must be lean (as straightforward as possible) and this resulted in a data access request process that minimised the number of entities involved and that will contain a single coordinating HDAB service. The HDA does not conduct any manipulation of the data within a data request, such as pseudo-anonymisation, anonymisation or any other transformations. Loading of health data into common data models such as OMOP CDM, is typically completed by the data holder. However, the HDA do play a key "Health Data Intermediation

Service" role between data user and data holder, as referenced in the National eHealth Action Plan. This role involves the HDA facilitating communication and resolving challenges around the interpretation of data requests and datasets in general.

Data holder to data user trust levels are broadly high and the HDA's DAAMS process is transparent, however there have been reported trust issues on the side of the data holder when an application is submitted by a data user with strong commercial and or industrial objectives. When necessary, the HDA in its role as an intermediation service, helps to resolve trust issues between data holder and data user. Building and maintaining the trust of Belgian citizens in the reuse of their personal health data is a priority for the HDA and considered a key enabler for the secondary use of health data.

Belgium has much of the elements and entities required to meet the EHDS secondary use requirements, having a National Metadata catalogue, a live DAAMS, and multiple SPEs, with the National eHealth Action Plan deliverables designed to address these requirements.

6.2.4 France

France has two key pieces of legislation that support secondary use of health-related data, namely the 2016 Modernisation of the French System act [60] and the 2019 Ma Santé law.[61] The 2016 act provided a legal mandate to the Health Data Hub (HDH) to facilitate the reuse of French health data for research, policy-making and innovation purposes. The French data protection authority (CNIL) has a significant role in the authorisation of data processing for secondary use purposes, particularly when sensitive personal data is involved.[62] The HDH plays a similar role as the Belgian HDA and Finland's Findata and is responsible for the management of the national metadata catalogue[63] and data access request coordination, while also publishing health data interoperability guidelines and standards to support semantic harmonisation of health data in France.[64]

The largest holder of health data available for secondary use in France is from the French National Health Data System (SNDS), managed by both the National Health Insurance Fund (CNAM) and the HDH. The SNDS is a centralised data source of health insurance claims data and includes data from hospital medical records, GP visits, prescriptions and dispensations and cause of death information.[62, 65]

The HDH publishes specific guidance on health information standards to support French Data Holders to manage data in compliance with common health data interoperability standards such as HL7 FHIR, SNOMED CT, ICD-10 and OMOP CDM. The HDH also publishes similar guidance materials on more focused areas such as standards or protocols for working with biomedical or genomic data, alongside other materials in health informatics.[64]

The HDH hosts a metadata catalogue, which is a centralised searchable online portal containing dataset descriptions, contact details of the data holders and information about the legal basis for reuse of a dataset.[63] A number of other similar metadata catalogues exist in France, hosted by organisations including CNAM and SNDS. These catalogues contain similar dataset descriptions and data holder contact information as the HDH catalogue.

Applications to access data are made through the HDH DAAMS. Applications typically require a detailed research protocol, reviews by both an ethics and scientific committee, authorisation from the French data protection authority (CNIL) if personal data is being used, while a legal validation and data access agreement must also be signed.[62] The two independent committees that review applications are the Ethics and Scientific Committee for Research, Studies and Evaluations in the Health Sector (CESREES)[66], who must verify that the project is ethically relevant and in the public interest. The National Commission for Data Protection and Liberties (CNIL) is the second committee that reviews the application.[67] CNIL considers whether the request is acceptable in the context of data protection and individuals' rights. Once final approval is received, the HDH facilitates access to the data in a dedicated workspace within the HDH platform (in a Secure Processing or Operating Environment).[62] Key details of approved projects are listed on the HDH website.

There have been a number of initiatives in France in recent years to create the foundation that would underpin the reuse of health data in the jurisdiction, including establishing a legal mandate for the HDH via the 2016 Health Modernisation legislation[60], and by establishing the French Digital Health Agency (ANS) in 2009. There have also been efforts to build public awareness on the societal benefits for the sharing of personal health data for reuse including a campaign titled "Health Democracy for Health Data in France" for the purpose of providing patient associations with on-demand access to French national health system data indicators. This was a joint collaboration with the HDH and the French Patient Rights Organisation, Assos Santé. The output of this was a plan to facilitate simplified access to public health data, tailored to the needs of patient associations.[68]

In terms of alignment with the EHDS secondary use requirements, France has an operational DAAMS via the HDH platform, a number of metadata catalogues, an organisation with a role almost identical to a Health Data Access Body (the HDH), while HDH also hosts a secure processing or operating environment. However, the current data access process is complex and involves multiple organisations (including two committees), which may make the meeting of the EHDS data access applications challenging.

6.2.5 Sweden

Sweden has a long history of reusing health-related data for research, policy-making and innovation via registries, with data routinely and systematically collected at every point of contact with the healthcare system, and data linkage facilitated through the personal identity code. This data collection has a solid legislative foundation which includes the 2008 Patient Data Act, the 2022 Act on Personal Data for Health and Social Care Analysis, the 2023 Biobank Act and the 2018 Swedish Data Protection act (implementation of GDPR).[69-72]

The National Board for Health and Welfare (NBHW) is the largest health data holder in the jurisdiction and manages a total of sixteen national registries. The NBHW also has responsibility for over 100 healthcare quality registries, owned by the Swedish regions, for the purpose of learning, quality improvement and research. These are jointly funded by the Swedish Association of Local Authorities and Regions (SALAR) and the Swedish government. Statistics Sweden is the largest data holder of socio-demographic data; the national eHealth Agency holds prescription and medicinal product data, and there are also 200 biobanks across six regional biobank centres in the jurisdiction. Additionally there are a number of genomic data collections fragmented across Sweden, and a National Genomics Platform (NGP) run by the Genomic Medicine Sweden organisation. The NGP is an initiative to store, analyse and share genetic data securely and efficiently.[69]

The NBHW leads on terminology mapping and manages health information standards in the jurisdiction. Health data interoperability standards such as ICD-10 is widely used in Sweden and SNOMED CT is becoming increasingly used in registries. OMOP CDM is used in Sweden within health data reuse, but is not part of any national standards or initiatives. The NBHW has created a national information structure or National Information Models (NIMs), which are a set of health and social care information standards derived from relevant health data, data privacy laws and regulation. These models are at a level above actual common health data standards and are not standard specific (do not tie themselves to common standards like HL7 FHIR or SNOMED CT).[47]

Sweden does not currently have an official centralised/national metadata catalogue, although the Register Utiliser Tool (RUT) developed by the Swedish Research Council, resembles one. RUT is a metadata catalogue which provides information about Swedish registries and biobank sample collections. In addition, key organisations such as the NBHW host searchable catalogues of the data from the registries they hold. Sweden has mapped the RUT Catalogue and registry descriptions to the Health DCAT-AP standard.(69, 73)

Due to the fragmented nature of the Swedish Health Data landscape, data requests and access are typically completed directly between data user and data holder. Data holders charge a data user for the cost of processing and delivering the data, which depends on the size and complexity of the data requested. The major SPE in Sweden is MONA (Microdata Online Access) managed by Statistics Sweden.(69)

Swedish data holder to data user trust levels are high. A key reason for this is Sweden's long history of health and social care data exchange for reuse (via registries), which is underpinned by a strong legislative basis. Furthermore, data subject willingness to share personal data is also high due to the strict data privacy laws that are long-established in Sweden. This is illustrated by how seriously consent is considered and by the fact that a healthcare professional must ask a patient for consent to use their data for reuse during each visit. Another example of how personal health data is legally protected is how Swedish legislation mandated a major EHR vendor to make custom alterations to enable extremely granular access control to a patient's record (certain user roles are not allowed to view specific elements of an individual patient's record). This caused a delayed roll-out of the vendor's EHR platform in Sweden, but enhanced patient's trust with the eHealth System.(69)

While Sweden has operational instances of most of the elements in the EHDS secondary use requirements, the fragmented nature of the Swedish health data system means there may be a need for much coordination with regard to DAAMS and a National Metadata Catalogue. This may result in a multiple HDABs in the jurisdiction, with a single coordinating HDAB.

6.2.6 Greece

In preparation for the EHDS secondary use requirements, the establishment of a Health Data Access Body (HDAB) in Greece is in progress, although reuse of health data is currently low. The rules on the scientific reuse of personal data within the Greek implementation of GDPR, are the primary source legal guidance for the secondary use, in the jurisdiction.(74)

The Greek e-Government Center for Social Security Services (IDIKA) is also one of the largest data holders of health (including EHR data) and social care data in the jurisdiction; data is available for reuse, and data request applications must be filed with the Greek Ministry of Health. Another large data holder is the Greek National Organisation for Healthcare Services Provision (EPOYY). A large data source controlled by this organisation is the national e-prescription service and supports cross-border prescriptions by default.

The Greek Agency for Quality Assurance in Health (ODIPY) is responsible for data quality standards. The National Electronic Health Record (eHR) follows the OpenEHR model. There is a Greek node of the OMOP CDM network, however this is not part of any national health information standard.[32]

A central data catalogue does not currently exist in Greece, however, the planned HDAB infrastructure includes a national metadata catalogue (and DAAMS), which will be maintained by the Ministry of Health.

The current process of requesting data involves submitting an application to the Ministry of Health and following a period of time, an approval or denial is then communicated to the applicant. A centralised DAAMS is expected to be established and it is anticipated that applications will be managed by the Ministry of Health.

There are a number of trust-related challenges in Greece regarding the exchange of health-related data for secondary use. Similarly to Belgium, data holders tend to be reluctant to share their health data with commercially-focused projects. In addition, highly-specialised private clinics also tend to be hesitant to share health data for reuse.

EHDS preparations are well underway in Greece, with a HDAB in development, creation of a National Metadata Catalogue, DAAMS and SPE planned, and the roles for management of these key entities established. The HDAB data infrastructure and SPE will be maintained by IDIKA and the National Metadata Catalogue, and the DAAMS by the Ministry of Health.

6.2.7 Cross Jurisdiction Analysis

Table 6: Comparative summary of national approaches to health data interoperability (and secondary use):

Jurisdiction	Legal & Regulatory	Governance Model	Interoperability Standards	Data Sources & Catalogues	Data Access Process
Finland	Secondary Use Act 2019 Data Protection Act 2018	Centralised (Findata)	SNOMED CT, ICD-10, HL7 CDA, FHIR, DICOM, OMOP CDM	National Metadata Catalogue operational and managed by Findata. Kanta is largest data holder	Well established, transparent but not integrated to Metadata Catalogue
The Netherlands	WEGIZ 2024, WABVPZ 2020, Data Protection Act (UAVG) 2018	Decentralised (Federated among large Data Holders)	SNOMED CT, ICD-10, HL7 CDA, FHIR, DICOM, OMOP CDM	Federated data holding, HealthRI manage a National Metadata Catalogue	Well established, initiated from National Metadata Catalogue but not managed centrally
Belgium	Royal Decree 2023, Data Protection Act	Decentralised (HDA)	SNOMED CT, ICD-10, HL7 CDA, FHIR, DICOM, OMOP CDM	Federated data holding / trusted data holders, HDA Manage catalogue,	HDA manage process, efficient / exemplar approach to DAAMS
France	Ma Santé 2022, Data Protection Act	Centralised (HDH)	SNOMED CT, ICD-10, HL7 CDA, FHIR, DICOM, OMOP CDM	A number of large public body data holders, HDH manage catalogue, other catalogues	HDH manage process, multiple committees need to approve leading to slow timelines
Sweden	Patient Data Act 2008 Biobank Act 2023	Decentralised/Mixed	SNOMED CT, ICD-10, HL7 CDA, FHIR, DICOM, OMOP CDM	Fragmented data holding but lots of registries for reuse, no central national metadata catalogue	Access is directly with data holder and data user
Greece	Law 4624/2019	Decentralised	ICD-10, HL7 CDA, FHIR,	Fragmented across public and private sectors, no national catalogue yet.	Access through filing an application with Ministry

			DICOM, OMOP CDM		of Health, not fully transparent yet

6.2.8 Summary

Summary of key national approaches to health data interoperability

- This chapter details national approaches to health data interoperability and secondary use across five categories including Legal and Regulatory, Governance, Interoperability Standards, Data Sources and Catalogues and Data Access Processes.
- Strong legislative foundations are a key enabler of secondary use of health-related data in Finland and Sweden.
- All of the jurisdictions reviewed are actively working to meet the EHDS secondary use requirements.
- The Netherlands has created a number of initiatives to support the reuse of health data in a jurisdiction with a decentralised health data landscape. Furthermore, Belgium has implemented some novel strategies to navigate its federal governance systems.

6.3 Legislation that facilitates Health Data Interoperability

In each of the six jurisdictions included in this review, EU and Member State legislation is a key enabler to both health data interoperability and secondary use of health data. The relevant legislation is described in the following section.

Table 7: Summary of all EU and national legislation relevant to health data interoperability and secondary use

Jurisdiction	Year	Title
EU	2018	**General Data Protection Act** (GDPR)
EU	2022	**Data Governance Act** (DGA)
EU	2025	**European Health Data Space Regulation** (EHDS)
Finland	2018	**Finnish Data Protection Act**
Finland	2019	**Act on the Secondary Use of Health and Social Data**
Netherlands	2018	**Dutch Data Protection Act** (UAVG)
Netherlands	2024	**Electronic Data Exchange in Healthcare bill** (WEGIZ)
Netherlands	2023-4	**Amendments to UAVG**
Netherlands	2017	**WABVPZ Act** (including 2020 and 2025 Amendments)
Belgium	2023	**Royal Decree creating the Health Data Agency**
Belgium	2018	**Belgian Data Protection Act**
France	2016	**Health System Modernisation Act**
France	2016	**French Data Protection Act**
France	2019	**Ma Santé law**
Sweden	2008	**Patient Data Act**
Sweden	2018	**Data Protection Act**
Sweden	2023	**Biobank Act**
Greece	2019	**Law 4624/2019** (GDPR implementation)

6.3.1 EU legislation

The following three pieces of EU legislation are key enablers of secondary use of health data across the Union: The 2018 General Data Protection Regulation (GDPR), The 2022 Data Governance Act (DGA) and the 2025 EHDS Regulation 2025. All related pieces of EU legislation focused on data governance and protection, with the DGA and EHDS building upon and complementing the GDPR.

GDPR 2018

The GDPR came into force in 2018 with the primary purpose of transforming the way an EU citizen's personal data rights are protected by legally incentivising organisations to handles this type of data correctly. GDPR is considered the gold standard of personal data protection legislation internationally, with each EU jurisdiction having implemented it within a national law.

With regard to the secondary use of personal data (which often is included in health-related data), a number of GDPR key articles have relevance. Article 7 of GDPR describes the conditions necessary for consent to process personal data, including health data. Article 9 is concerned with the "processing of special categories of personal data" and Article 1 states that the processing of sensitive personal data concerning a natural person's ethnicity, religion, health or sexual orientation is prohibited. Article 35 mandates that Data Protection Impact Assessments (DPIAs) must be conducted when the processing of personal data (inclusive of personal health data) is likely to put an individual's rights or freedoms at high risk. Finally, Article 89 of GDPR is concerned with safeguards related to the processing of personal data for secondary use purposes (such as scientific research and historical research), and statistical purposes and outlines measures (such as pseudo-anonymisation or anonymisation), that should be put in place to protect a data subject's rights during large scale data collections.[13]

Data Governance Act 2022

The 2022 Data Governance Act (DGA) is EU legislation created specifically to enable the reuse (secondary use) of public sector data across EU member states by providing a framework that enhances trust in voluntary data sharing and thus facilitates the secure, lawful and ethical reuse of data. In doing so, the DGA lays the foundation for the establishment of common European data spaces in strategic domains, such as the European Health Data Space (EHDS).[22, 74]

Article 5 of the DGA is titled "Conditions for re-use" and consists of a series of rules that public sector bodies must adhere to when exchanging data for secondary use purposes. Articles 10-14 deal with data intermediation services that facilitate the sharing of health data between entities through technical interoperability and secure data exchange, stating that a data intermediary service must function as a neutral third party (Article 12). The provisions in these articles outline the services required for Health Data Access Bodies, which are covered in detail in the 2025 EHDS regulation.(22)

European Health Data Space 2025
The 2025 European Health Data Space regulation is the first common data space to emerge from the European data strategy. The foundations of the EHDS were laid through the previously mentioned DGA and the EU Joint Action, 'Towards a European Health Data Space'. Chapter IV of the EHDS is dedicated to Secondary Use of health data and articles 5–91 in this chapter are directly concerned with the secondary use of electronic health data.(2)

6.3.2 Finland - legislation

Of the six jurisdictions reviewed, Finland is the only jurisdiction that has implemented dedicated legislation for the secondary use of health-related data which fully enables GDPR Article 9.2 (reuse of personal data). The Finnish 'Act on the Secondary Use of Health and Social Data (552/2019)' legislation was enacted in 2019.(12)

This act established Findata, Finland's Social and Health Data Permit Authority and aims to support the efficient and secure processing of personal data collected from health and social care provision. It is aligned with Finland's implementation of GDPR, specifically on original purpose for storing personal data and allowed secondary uses.

By providing a legal mandate to Findata, the Finnish secondary use act aims to improve data access efficiency by promoting the elimination of overlapping administrative burden related to the processing of data access permits, facilitating the smoother collation of data from different registers and by establishing data access rights and the legislative basis for the national registers. Secure operating environment and associated infrastructure requirements, data security assessment and certification of a secure operating environment are also included in this act.(12)

6.3.3 The Netherlands - legislation

The Netherlands has a number of legislative initiatives designed to facilitate reuse of health data including the 2025 Data Processing by Partnerships Act, the 2024 Electronic Data Exchange in Healthcare bill (WEGIZ), 2020 WABVPZ act (including it's 2025 amendments), the 2018 Dutch GDPR implementation (UAVG) and the 2024 amendments to it.

The 2025 Data Processing by Partnerships Act focuses on inter-organisational personal data (including health data) exchange under strict conditions such as the public interest, anti-fraud and national security.(75)

The 2024 WEGIZ bill focuses mainly on primary use health data exchange and requires structured, standardised and high-quality data collection (health data collected must adhere to common health data interoperability standards such as HL7 FHIR). This has a direct consequence for secondary use because once the data is standardised at collection, it means that a data user will find it much easier to understand or analyse (once they are familiar with the health data standards that the data conforms to).(51, 52)

The 2017 WABVPZ act (including the 2020 and 2025 amendments)(76) stands for the Processing of Personal Data in Healthcare (Additional Provisions) Act. It supports reuse of health data for research, policy or statistics when data is pseudo-anonymised or anonymised or serves the public interest. This act requires national institutions to use national authentication standards for sharing of heath data, and reinforces data subject rights with regard to the reuse of their data. This practically means that citizens have the right to be informed about how their data may be used and also have the right to object to the reuse of their data. The WABVPZ also lists Trusted Research Environments (similar to Secure Processing Environments) as key infrastructure for reuse of health data, while the act also aligns with the MedMij(19) and Nictiz(54) frameworks, which support standardised and interoperable health data exchange.

The 2018 UAVG(77) is the national implementation of GDPR and allows for secondary use of personal data, once Article 89 safeguards are implemented. The 2023-4 amendments to the UAVG clarify how Data Protection Impact Assessments (DPIAs) apply to secondary use, conditions for pseudo-anonymisation and the role of Data Protection Officers (DPOs) in public health organisations. For example, these amendments clarify technical, legal and ethical safeguards that need to be in place when data is not pseudo-anonymised, and specify scenarios in which a DPIA must be conducted (for processing of sensitive data for research), including what it should cover (assessment of potential impact on data subjects' rights and mitigation strategies).

6.3.4 Belgium - legislation

In addition to the Belgian Data Protection Act(78) that was passed in 2018, the law that established the Belgian Health Data Agency (HDA) was passed in 2023. This law gives the organisation a mandate to facilitate the secondary use of health data and improve access to it by making the data access process more uniform, reliable, transparent and secure.(57)

As Belgium's governance and healthcare system is split into entities with either a regional or federal remit, the HDA was created as an inter-federal organisation so that it could operate and work with both of these types of data holder organisations. Furthermore this inter-federal structure allows the HDA to grant key organisations that hold large datasets the "Trusted Data Holder" status. This then allows the (trusted) data holder to interact directly with a data user in regard to a data access request.

A significant body of work has taken place in Belgium prior to the implementation of dedicated secondary use legislation. This work involved a heavy focus on establishing the roles and responsibilities of key organisations (such as large data holders) and how to harness existing processes and workflows, with regard to the sharing of health-related data. This dedicated legislation is planned to be enacted in 2026.

6.3.5 France - legislation

In addition to the 2018 French implementation of GDPR(79), France has two key pieces of legislation directly concerned with the secondary use of health-related data, namely, the 2019 Ma Santé law and the 2016 Health System Modernisation Act.

The 2019 Ma Santé 2022 law was designed to upgrade various elements of the French healthcare system such as hospital care, governance of healthcare organisations and tighter integration of healthcare services. By prioritising the digitisation of French healthcare, the law's aim is to enable the seamless and secure exchange of health data among patients and healthcare professionals within France and also across borders. It plans to achieve this by creating a "digital health space" for each patient through the use of electronic health records and other digital health technologies, thus making available a large, centralised pool of data for potential secondary use.(61)

The 2016 Health System Modernisation Act addresses management of and access to health data, including establishing a shared care record and open data provisions.

This act laid the foundation for the establishment of the French Health Data Hub (HDH), which was given a legal mandate in 2019 to enable easy access to health data for secondary use on a secure platform, in a compliant manner and safeguarding the individual's rights.(60)

As well as the above legislation, the French data protection authority, CNIL (Commission Nationale de l'Informatique et des Libertés), regularly publishes *deliberations* that outline specific interpretations and applications of data protection or privacy laws, such as pseudo-anonymisation versus anonymisation of health data.(80)

6.3.6 Sweden - legislation

Sweden has a long history of reusing health-related data for research, policy-making and innovation. This is backed by a solid legislative foundation which includes the 2008 Patient Data Act, the 2022 Act on Personal Data for Health and Social Care Analysis, the 2023 Biobank Act and the Swedish Data Protection Act (implementation of GDPR).

The 2008 Patient Data Act provides a legal basis for secondary use, especially by public institutions for statistics, research and quality assurance purposes. Key provisions of this act state that pseudo-anonymised data can be used without consent under strict conditions. Access is governed by both the National Board of Health and Welfare and the Ethics Review Authority.(71)

The 2022 Act on Personal Data for Health and Social Care Analysis regulates data exchange between government agencies for statistical and policy development and supports the reuse of personal health-related data by Swedish public institutions for research, planning and evaluation.(70)

The 2023 Biobank Act governs the collection of human biological data, permits secondary use for research purposes with appropriate ethical approval and consent mechanisms and has been modernised to reflect GDPR, EHDS and the requirement for increased national and cross border exchange of Swedish health-related data.(72)

The Swedish Data Protection Act clarifies how secondary use is permitted under GDPR articles 6 and 9 and states that secondary use must have a clear public interest basis or scientific purpose and Data Processing Impact Assessments (DPIAs) are often required. Furthermore there is a strong emphasis on data minimisation, anonymisation or pseudo-anonymisation and secure processing or operating environments.(69)

6.3.7 Greece - legislation

The 2019 Greek Data Protection Act (Greek implementation of GDPR) is the primary source legal and regulatory guidance for secondary use of health data and enables GDPR's standard rules on scientific reuse of personal data.[74]

Despite a lack of secondary use enabling legislation, the establishment of a Greek HDAB is underway and anecdotally, appropriate legislation is anticipated.

Summary of EU and national legislation

Summary of key elements of secondary-use relevant legislation

This review's findings highlight strong legislative foundations as a key enabler to secondary use of health-related data. In particular, Finland and Sweden both credit the historically high levels of health-related data reuse existing in both jurisdictions to a strong and clear legislative basis.[12]

The 2018 GDPR legislation provides strong protection for personal data and the 2022 DGA legislation is a dedicated act for the opening up of public sector data, which lays the foundation for the 2025 EHDS Regulation. The EHDS outlines clear secondary use requirements for each EU member state to create the mechanisms and infrastructure necessary to unlock the full societal value from health-related data, mandating that each Member State establish:

- A Health Data Access Body
- A publicly available national metadata catalogue
- Secure Processing Environments

Of the jurisdictions reviewed for legislation that facilitates the secondary use of health-related data, Finland is the most advanced, having a dedicated secondary use of health and social data act since 2019.

Belgium, Sweden, France, and the Netherlands all have strong legislative frameworks that underpin the reuse of health data in these jurisdictions.

In Greece, the 2019 Greek Data Protection Act (national implementation of GDPR) is the main legislative consideration for the secondary use of health data, in anticipation of specific legislation.

6.4 Interoperability Frameworks

Interoperability in healthcare can be broken down into a number of categories, and these are often referred to as *levels*. The 2010 European Interoperability Framework (EIF) version 2 (EIF version 1 was published in 2004) breaks interoperability into a four level model, namely: Legal, Organisational, Semantic and Technical.(15) The eHealth Network's 2015 Refined eHealth Interoperability Framework (ReEIF) builds upon the EIF's four levels to create a model for interoperability in healthcare which contains these six levels: Legal and Regulatory, Policy, Care Process, Information, Applications and IT Infrastructure. The ReEIF also maps and explains how the ReEIF maps to the EIF.(17)

In practice, the levels detailed in both the EIF and ReEIF typically cover the exchange of information within the areas such as:

Area	**EIF Level**	**ReEIF Level(s)**
Laws and agreements	Legal	Legal and Regulatory
Roles and governance	Organisational	Policy, Care Process
Clinical/Business processes	Organisational	Care Process
Shared meanings and terminologies	Semantic	Information
Information specifications/standards	Semantic	Information
APIs, infrastructure, security	Technical	Applications, IT Infrastructure

The above levels of interoperability have been incorporated into frameworks, often called *Interoperability Frameworks.* Examples of health-related interoperability frameworks include:

- The EC's European Interoperability Framework (EIF) (version 2)
- New European Interoperability Framework
- The eHealth Network's Refined eHealth Interoperability Framework (ReEIF)
- The Interoperability Framework of the European Health Data Space for the Secondary Use of Data
- The European Open Science Cloud (EOSC) Interoperability Framework
- Elixir Europe's FAIR Cookbook
- Finland's Avoin Data Operating Model for Data Sharing
- The Netherlands' MedMij Framework.

An overview of each of these frameworks is discussed in the sections that follow, while **Table 8** provides a comparative summary of each.

6.4.1 European Interoperability Framework (EIF)

The EIF version 2 was published by the European Commission (EC) in 2010 with the aim of facilitating easy and efficient cross-border public service data exchange among EU Member States. The EIF outlines a common approach for public service organisations to interact and share data with each other, thus enabling interoperability between disparate systems and institutions.(15)

The EIF version 2 focuses on four levels of interoperability, namely: legal, organisational, semantic and technical. While the EIF is not a dedicated health data interoperability framework, it establishes many of the foundational concepts (the four layers of interoperability) that have been subsequently built upon in later frameworks such as the ReEIF and the EOSC framework.(15)

6.4.2 New European Interoperability Framework

The New European Interoperability Framework was published by the EC in 2017. The purpose of the framework is to stimulate public service bodies across the EU to digitalise as much of their services as possible (digital by default), ensure their digital services are interoperable with other public services in other EU Member States (cross-border by default) and that these digital public services open; meaning that they support reuse, are accessible and transparent (open by default). This framework also aims to guide public service organisations in the design and updating of national interoperability frameworks and any other initiatives that promote interoperability. The final aim of this framework is to contribute to the creation of an EU digital single market through the enablement of cross-border and cross-sectoral interoperability within European public services.(16)

Many of the New European Interoperability Framework's principles are relevant to the secondary use of health-related data including "Underlying principle 4: reusability" which promotes the reuse of not only data but also technological solutions. Furthermore, "Underlying principles 5: technological neutrality and data portability" states that data should not be locked into specific technological solution (such as a specific eHealth System) and or do not impose "technological solutions on citizens". This is relevant to secondary use of health data as if data is not portable or is locked in a closed system, it reduces its usability.(16)

6.4.3 The Refined eHealth Interoperability Framework (ReEIF)

The Refined eHealth European Interoperability Framework (ReEIF) was published in 2015 by the eHealth Network. The eHealth Network is a voluntary network of national eHealth authorities and is focused on supporting interoperability in healthcare and digital health collaboration across the EU.

The ReEIF aims to establish a framework "for managing interoperability and standardisation challenges in the eHealth domain in Europe" through building upon the EIF and by outlining a new, six level model for interoperability in healthcare.

The ReEIF describes the plotting of the interoperability world into a six-level model, with actors and activities on each level. Secondly, a template for the uniform description of the use cases, and for their accompanying potential future scenarios, is given. These templates help in providing a consistent set of clinical problem descriptions, which effectively describes use cases. The third element of the ReEIF is a glossary of terms, for unifying 'language' and improving understandability. The EIF's Organisational level is split into the Policy and Care Process levels, as organisations often differ across the actors and responsibilities involved in the policy-making and care execution. A further instance of this is the EIF's technical level being split into Applications and IT Infrastructure, as typically the IT Infrastructure and software applications can be managed independently for the most part. (17)

6.4.4 EHDS2 interoperability framework

The EHDS2 interoperability framework is an initiative to develop a toolkit to address the challenges posed to EU Member States when implementing the EHDS secondary use requirements. The framework proposes to achieve its aims by developing an interactive toolkit informed by seven leading cancer research projects. The framework builds upon TEHDAS and the 2017 New European Interoperability Framework. A publication from April 2025 titled "Interoperability Framework of the European Health Data Space for the Secondary Use of Data: Interactive European Interoperability Framework–Based Standards Compliance Toolkit for AI-Driven Projects" (6,7) lists the key features of the framework / toolkit:

- User-friendly tools to support the development of interoperability frameworks to support EHDS secondary use implementation.
- Supports for projects with the implementation of EHDS secondary use recommended health data standards such as data discoverability standards and exchange standards.

- Facilitating knowledge sharing and collaboration between projects in order to share experiences and best practices in the implementation of health data interoperability standards, as well as navigating challenges.
- The framework's tools have been designed to consider the rapidly-evolving nature of EHDS secondary use requirements and regulatory landscape, such as the consequences of AI regulation and related standards.

This framework adopted the TEHDAS recommended health data interoperability standards for secondary use; including DCAT-AP for data discoverability, OMOP-CDM for semantic interoperability and for health data exchange, HL7 FHIR (health record data exchange) and DICOM (imaging data exchange). For data quality, Patient Generated Health Data (PGHD), AI reasoning, federated approaches, security, and privacy, appropriate ISO Standards were used.(6)

The EHDS2 interoperability framework includes an "Interoperability Framework Entry Module" which is user-friendly tool for the design and development of an interoperability framework through the completion of the following sections on standard web-based data entry user interface: (1) needs analysis, (2) selection of data and information, (3) processes and use cases, (4) interoperability standards and implementation guides, (5) risk analysis, (6) maintenance plan, (7) specification, design and planning of interoperability phases, (8) recommendations and future actions, and (9) implementation guide publication.(6, 7)

6.4.5 The European Open Science Cloud (EOSC) Interoperability Framework

The EOSC Interoperability Framework was published in 2021 by the European Open Science Cloud, an initiative aiming to create a secure, open environment where researchers can store, manage and analyse research data across various disciplines and borders. While this framework exists specifically for entities participating in the development and implementation of the EOSC, there is crossover with the activities of the EHDS as it is a dedicated framework for the reuse of European data, inclusive of health data.

The EOSC IF uses the EIF's four-level model of interoperability and for each of the levels includes a series of problems, needs, challenges and proposed high-level recommendations. Examples of these recommendations include: "every semantic artefact that is being maintained in EOSC must have sufficient associated documentation, with clear examples of usage and conceptual diagrams", or "Coarsegrained and fine-grained dataset (and other research object) search tools need to be made available".[81]

Specific to health data interoperability, the EOSC IF details a reference architecture framework which describes key components that an interoperability framework should contain, including semantic interoperability elements such as a metadata catalogue, a mapping repository and an identifier scheme. Additionally, the reference architecture framework contains a "Semantic Artefact Catalogue" which suggests multiple key semantic interoperability concepts including ontologies (Human Phenotype Ontology), terminologies (SNOMED CT) and controlled vocabularies (DDI Model of Collection and data models (OMOP CDM).[81]

6.4.6 Elixir Europe's FAIR Cookbook

The FAIR Cookbook was a developed as a key output of the Innovative Medicines Initiative (IMI) FAIRplus project which ran from 2019 to 2022, and is now part of the ELIXIR Europe ecosystem. It is an extremely comprehensive framework that contains detailed, hands-on and technical guidance for the implementation of FAIR data management. The Cookbook is designed for a wide audience including professionals that deal with data including researchers, data scientists, data managers, terminology experts and software developers. Furthermore, it is also a resource for policy makers such as funders and trainers, so that they can use it to incentivise FAIR Data management in the Life Sciences.[82]

Included in the Fair Cookbook is "The FAIRification Framework", which was developed to enable the translation of high-level principles into workable, "tried and tested" processes. It includes three key components:

- A repeatable "FAIRification Process", which outlines the main phases of a "FAIRification activity".
- A "FAIRification Template", which decomposes the main elements of the process into a series steps.
- "FAIRification Workplan layout", which provides a structure for the management of FAIR implementation activities, which can then be adapted for the needs of a particular project.

Compared to the majority of other interoperability frameworks reviewed, the FAIR Cookbook (inclusive of the FAIRification Framework) stands out because it offers health-related data holders a set of tools and practical strategies to unlock the potential of the data they hold, through guiding this group through the complex process of making data Findable, Accessible, Interoperable and Reusable (FAIR).[42, 82]

6.4.7 Finland's Avoin Data Operating Model for data sharing

The operating model for data sharing is a thorough framework model packaged as a website, for the opening of public sector data for reuse. This framework describes the many stages of data sharing, the obligations and recommendations to be considered when sharing data in Finland. The framework also includes useful detailed descriptions and links to relevant resources and materials for each step. The operating model contains a number of examples of data sharing and strategies used in Finnish organisations that have shared their data.[18]

6.4.8 The Netherlands' MedMij Framework

MedMij is an innovative Dutch framework for the secure exchange of health data between the citizen, healthcare providers and health professionals. MedMij operationalises the concept of "personal health environment" (PGO in Dutch) in the form of a website and or app in which one can keep track of information about their own health. It is significant for the secondary use of health data, as it clearly mandates health data interoperability standards that Dutch eHealth Systems must comply with, in order to become a certified MedMij compliant system. This means that by addressing the health data interoperability at source (at data collection), the reusability potential for this data increases due to it being standardised. This is illustrated by the fact that SNOMED CT and HL7 FHIR are key components of the MedMij information standards.[19]

6.4.9 Comparing Frameworks

Table 8: Level of detail that each interoperability framework goes into on the various levels of interoperability

Framework	Legal	Policy / Organisational	Process / Workflow	Semantic	Technical
EIF	High level of detail	High level of detail	Moderate level of detail	Low level of detail	Low level of detail
New EIF	High level of detail	High level of detail	Moderate level of detail	Moderate level of detail	Low level of detail
ReEIF	Low level of detail	Moderate level of detail	High level of detail	High level of detail	Moderate level of detail
EHDS2	Low level of detail	Moderate level of detail	High level of detail	High level of detail	High level of detail
EOSC	Moderate level of detail	Moderate level of detail	High level of detail	High level of detail	High level of detail
FAIR Cookbook	Low level of detail	Low level of detail	High level of detail	High level of detail	High level of detail
Avoin Data Operating Model for Sharing Data	Moderate level of detail	Moderate level of detail	Moderate level of detail	Moderate level of detail	Moderate level of detail
MedMij	Low level of detail	Moderate level of detail	Moderate level of detail	High level of detail	High level of detail

For the purposes of the summary in **Table 8** above, the High, Moderate and Low levels of details can be defined as follows:

- High level of detail: The framework contains detailed / granular information on a given level of interoperability.
  - the FAIR Cookbook has a **high** level of detail in the technical level and this is illustrated by providing detailed guides for data holders on how to implement data provenance as part of preparing it for reuse (as part of a data access request).
- Moderate level of detail: The framework contains high-level information on a given level of interoperability.
  - the Avoin Data Operating Model for Sharing Data is an example of an interoperability framework that covers levels of interoperability in **moderate** detail and this is illustrated by how it summarises the various stages involved in the sharing of public data for reuse, then signposts the reader to sources with more in depth detail, via hyperlinks.
- Low level of detail: The framework contains minimal or no amount of information on a given level of interoperability.
  - the FAIR Cookbook has a **low** level of detail at the legal level and this is illustrated by the framework not going into detail on how to interpret various data protection legislation.

6.4.10 Summary

Summary of the key interoperability frameworks that will inform the development of the NIF for HDAB services in Ireland

- Eight interoperability frameworks were reviewed across five general levels of interoperability in healthcare:
  - Laws and agreements (Legal)
  - Roles and governance (Policy/Organisational)
  - Clinical or business processes (Process/Workflow)
  - Shared meanings and terminologies (Semantic)
  - Information specifications or standards, APIs, infrastructure (Technical)
- The EIF, New EIF and ReEIF are referenced in multiple TEHDAS reports as being key frameworks when considering health data interoperability in EU Member States.
- The Avoin Data Operating Model for Sharing Data is a key framework for public sector data reuse in Finland.
- The MedMij framework is used to standardise primary use health data at collection stage and has resulted in high levels of SNOMED CT and HL7 FHIR compliance in the Netherlands; thus, large quantities of interoperable primary use data are available for reuse in the jurisdiction.
- The EHDS2 Interoperability Framework is an exciting development and has the potential to accelerate the level of health data reuse within EU Member States, as well as supporting compliance with EHDS secondary use requirements.

6.5 Tools that enable health data interoperability

While the two preceding Findings sections focused on "Interoperability Frameworks" and "Commonly used health data interoperability standards" respectively, this section is focused on practical digital solutions (tools) that support the secondary use of health-related data. These tools are often seen as key enablers to secondary use by providing the technological solutions to data holders during the preparation (modifying a dataset so that it is in compliance with an interoperability standard) and exchange of datasets for reuse (with a HDAB service as part of a data access request).

Tools that enable health data interoperability can be described as technological solutions that support the structuring of health data in a format compliant with a commonly-used health data interoperability standard. If the health data adheres to standards that are used by other entities, the potential for reuse increases significantly as the effort involved in understanding and working with the data is reduced. For example, the process of merging one health dataset with another dataset becomes much less complex if both datasets follow the same health data standards.

These types of tools are important for the secondary use of health-related data, as making health data and datasets interoperable often requires adding to or modifying the data. Examples of this include data transformation (reformatting the data), adding descriptions or more detail to the data (adding metadata, adding coding information) and validating the data (ensuring it complies with a standard).

This review has identified tools that enable the semantic interoperability, metadata generation and validation, and transformation of health-related data as key to supporting data holders to prepare and exchange data as part of data access requests. These are discussed in the following sections.

6.5.1 Semantic Interoperability Tools

Semantic interoperability tools are a key resource to make health data compliant with a standard and include terminology servers, vocabularies and reference datasets. These types of tools support data holders to code their data so that it adheres to common terminology standards (SNOMED CT, LOINC, ICD-10/11) and is therefore understandable to data users (it is semantically interoperable).

An example of such tools is that of Finland's Digital and Population Services Agency's Interoperability Platform.[83] This is a web-based portal that provides tools "defining interoperable data content" and comprises of the semantic resources needed (glossaries, code sets and data models) for data exchange and information management. This platform is intended for audiences in both the private and public sectors in Finland and is available free of charge. Core elements of the platform include a terminologies tool, reference data tool and data vocabularies tool. The terminologies tool is a web application that hosts multiple glossaries and concepts and includes many public sector concept lists (to enable all public sector data interoperability, not just health). The tool supports development and management of glossaries that contain concept definitions and other descriptive information. It also supports the process of defining the meaning of information, through use of the tool's glossaries and code sets, as well as using the concepts and terms already defined in the tool.

The reference data tool can be used to manage and publish code sets and their associated metadata. This tool supports the creation of hierarchical code sets, code set extensions and the publication of code set versions. Additionally, the definitions created in the terminologies tool can be used in the reference data tool. The data vocabularies tool enables the creation of data models that incorporate elements such as definitions of classes, their properties and the relationships between classifications. The tool is mainly used for the creation of logical data models (a blueprint for how data should be structured) and these models are exportable so that they can be shared and reused.

Other examples of semantic interoperability tools include HL7 FHIR Terminology Services and BioPortal. Similar to the previously mentioned Finnish Terminology tool, the HL7 FHIR Terminology Service enables the creation of terminology services.[84] This service builds on top of the following HL7 FHIR resources: CodeSystem, ValueSet and ConceptMap, so that healthcare applications make use of them.

BioPortal is the world's most comprehensive source of biomedical ontologies in one place and hosts ontologies on coding systems such as SNOMED CT, ICD, RXNORM (prescription medications), and LOINC. Additionally, BioPortal hosts other semantic resources including Classes and Mappings. Classes are placeholders for concepts or categories within an ontology. Classes contain attributes, known as properties, which contain all information included the class. An example of a class in a BioPortal ontology is that of the "Propranolol-containing product" SNOMED Concept and contains information about this concept, a visual representation of how it relates to other concepts and mappings to similar terms and or concepts in other ontologies. Mappings enable the connection or matching of similar terms from different terminologies or coding systems, which is a key enabler of health data interoperability. A concrete example of this is BioPortal's SNOMED CT to RXNORM mapping, where similar terms of both systems are mapped in a tabular format. This type of mapping supports interoperability (and reuse as a consequence) by making it possible to connect two datasets coded with different terminologies.[85]

6.5.2 Metadata tools

Detailed dataset descriptions written in a common metadata standard such as DCAT-AP and ideally in the health data specific version of this standard, Health DCAT-AP, is a key enabler of health data reuse. The primary reason for this is that it allows the description to be machine readable and integrated easily into a web-based metadata catalogue. This type of dataset description serves two primary purposes:

- findability of the data set making the dataset findable or discoverable due to its description existing in an online metadata catalogue
- reusability (there are detailed descriptions attached to the data, making interpretation of the dataset by a data (re)user possible).

However, generating this type of standardised metadata for a dataset can be challenging for a data holder who does not have extensive experience in this field, which is why tools to support the generation and validation of metadata are important. Examples of tools that support metadata generation and validation are the HealthDCAT-AP Literacy platform, 3DBIONOTES-WS and FAIRtracks.

HealthDCAT-AP Literacy platform

The HealthDCAT-AP Literacy platform, hosted by the Belgian Sciensano organisation, is a key resource for researchers, policy-makers, data holders, HDABs and technical experts for understanding the HealthDCAT-AP metadata standard and its role in the European Health Data Space (EHDS).[86] It contains documentation and guidance for the describing of health data in the HealthDCAT-AP standard and includes:

- HealthDCAT-AP Editor – for metadata generation
- HealthDCAT-AP Validator – for ensuring that metadata adheres to the standard
- A demo catalogue – a sample or sandbox metadata catalogue for experimentation
- HealthDCAT-AP API – to support exchange of metadata in machine-readable format for integration or sharing of data among health data platforms
- EHDS Dataset categories –a tool to identify the EHDS Article 51 category that a health dataset most closely aligns to, by submitting the dataset title and description.

The Belgian Health Data Agency has created metadata tools to support data holders. These tools include a metadata collection tool which is a simple excel tool streamlining the process of submitting dataset descriptions to the HDA, for the purpose of being published on the Belgian National Metadata Catalogue. The HDA has also created a metadata validation tool which checks a dataset description to ensure it is compliant with a metadata standard.

3DBIONOTES-WS

3DBIONOTES-WS is a bioinformatics tool used for embedding rich metadata to large datasets that automatically annotate biochemical and biomedical information onto structural and multi-omics data (genomic, metabolomics data). While is for a specialised field, it is powerful tool that facilitates reuse of this type of data by enabling the attachment of rich metadata at scale.[87]

FAIRtracks

FAIRtracks[88] is another bioinformatics tool that standardises genomic track metadata to support exchange, analysis and general reuse of this type of data. This tool is concerned only with genomic data whereas 3DBIONOTES-WS focuses on structural and multi-omics data (including genomics). FAIRtracks includes a metadata standard and an "ecosystem" of metadata services for genomic track data including:

- Metadata augmentation – automated generation of FAIRtracks compliant metadata
- Metadata validation – validates that metadata adhere to the FAIRtracks standard
- Metadata transformation – supports restructuring or "wrangling" metadata into the FAIRtracks standard
- Precision search – data discovery tool for searching genomic track metadata compliant with the FAIRtracks standard.

Avoin Data Operating Model for Sharing Data > Section 6

Finally, section 6 (Publication) of Finland's "AvoinData Operating Model for Sharing Data" illustrates how metadata guidance and tool resources can be embedded within an interoperability framework.[18]

6.5.3 Data transformation tools

Data transformation tools can be defined as a software solution that can convert or map data from one format to another, for purposes such as analysis, storage or integration and play a key role in making health-related data adhere to the FAIR Principles.[42] These types of tools can make data FAIR by converting it into standardised formats such as XML, CSV and JSON, assigning persistent identifiers (PIDs) to data in order to enhance the tracking and location of it (via unique PIDs). Data provenance tools provide an audit trail of transformations applied to data and therefore allow a data user to understand how data has changed over time.

Specific examples of these types of tools used with health data include Mirth Connect and OMOP on FHIR.

ETL tools
Additionally, generic Extract, Transform, Load (ETL) tools are often used in the transformation of health-related data. An ETL tool is software that makes it possible to extract data from one or multiple disparate sources (systems) and convert (Transform) it into a single format or structure, so that it is then possible to import (Load) the converted data into another system.

Mirth Connect
Mirth Connect is a health systems integration engine owned and maintained by the NextGen software company. It specialises in enabling agile and scalable integration of various eHealth systems. It has been in existence since 2006 and is one of the most popular tools to connect disparate eHealth systems. Mirth Connect has dedicated interoperability features including a HL7 integration engine which enables connection of multiple HL7-compliant systems and a Health Data Hub which supports the exchange, normalisation and aggregation of health data. Prior to exchanging a health dataset for reuse, a data holder must first prepare the data into a defined structure so that it can be understood, merged and analysed by a re-user of this data (a data user). Mirth Connect is a tool that can make this possible.(89)

OMOP-on-FHIR
In the previous Findings section, both the OMOP CDM data model standard and HL7 FHIR messaging standard were discussed. The following tool combines both of these standards, with particular implications for secondary use purposes. The "OMOP on FHIR" tool enables the conversion of HL7 FHIR data into the OMOP CDM structure, specifically for use cases such as research. This type of conversion (conversion of health data from HL7 FHIR to OMOP CDM) is typically done through the ETL processes embedded within the tool. OMOP-on-FHIR helps to bridge the gap between primary use and secondary use of health data. When primary use health data is stored in a HL7 FHIR compliant structure within an eHealth system, OMOP-on-FHIR is a powerful tool for making this type of data more reusable. OMOP-on-FHIR achieves this through enabling the mapping and importing of HL7 FHIR compliant data into OMOP CDM dataset structure. This makes the resulting dataset (in OMOP CDM) interoperable as it be easily understood / used by data users familiar with OMOP CDM. In addition, OMOP-on-FHIR will become more relevant in the near future, as more jurisdictions increase the levels of HL7 FHIR implementations in primary use eHealth Systems.(90)

6.5.4 Other tools

The Elixir Europe research data infrastructure organisation hosts a "Recommended Interoperability Resources" (RIRs).(91) RIRs are a set of tools and registries that have been endorsed by a panel of external reviewers as tools and resources that “facilitate the FAIR-supporting activities in scientific research”. Examples of such activities that these tools/resources can be used for include connecting or relating data resources, creating and exposing of metadata for data resources, creating infrastructure required to support integrated data collections, and use of interoperability resources to support the delivery of FAIR principles.[42]

The RIRs that have been reviewed and the most relevant tools to health data interoperability and secondary use have been outlined in **Table 9** below, along with the tools’ RIR description.

Table 9: A summary of Elixir Europe’s RIRs that are most relevant to secondary use

Tool	Description
BioImage Informatics Index	A bioimaging resource (tool/workflow) finder based on biological questions, methods and tools with linked literature of the resource.
Bgee Knowledge Graph	The Bgee database through its SPARQL endpoint provides access to gene expression patterns in multiple animal species, which result from the integration and harmonisation of several data sources.
BridgeDb	A combination of a software framework and an API for mapping identifiers for related objects in life sciences.
Data Stewardship Wizard (DSW)	Data Stewardship Wizard (DSW) is a service for data management planning, preparing data management plans.
DisGeNET RDF API	An RDF SPARQL Endpoint for DisGeNET, a knowledge platform on human disease genes and variants.
European Galaxy Server	Galaxy is an interoperable open-source platform for scientific data analysis and sharing, covering diverse research fields such as *omics, machine learning, and climate science.
g:Profiler	A gene-centric data integrator with web UI and API services.
Identifiers.org	Provider of persistent and compact identifiers for data objects in life sciences through a curated registry and associated resolver.
InterMine	Framework to integrate life sciences data based on an extensible data model, providing web interface and RESTful web services.
ISA Framework	The ISA (Investigation > Study > Assay) provides formats and tools to manage the experimental descriptions throughout the research life cycle, from collection, curation and deposition in public repositories, to analysis with existing tools and publication in data journals.
Jalview	Jalview is a Win/Mac/Linux/Web interactive graphical interface and command line tool for molecular sequence, alignment and 3D structure bioinformatics resource interoperability.
MOLGENIS	A flexible data integration platform to facilitate FAIR research data and accelerate scientific collaborations.
Omics Discovery Index (OmicsDI)	Provides a knowledge discovery framework across heterogeneous omics data (genomics, proteomics, transcriptomics and metabolomics).
Ontology Lookup Service	Repository for biomedical ontologies that aims to provide a single point of access to the latest ontology versions through web UI or RESTFUL API.
OpenEBench	OpenEBench is a platform to evaluate life sciences tools from two points of view: Scientific performance through community-based benchmarking and Quality through an Observatory of Software Quality.
PLAZA	Provides an integrative resource for functional, evolutionary, and comparative genomics in plants.
RDMkit	The RDMkit is an open-source, online toolkit for researchers and data stewards, providing Research Data Management (RDM) best practices in line with the FAIR principles.

6.5.5 Summary

Key tools that support the preparation of health-related data for reuse

- This review has identified tools that enable health data interoperability and secondary use and has focused on tools that support semantic interoperability, metadata generation and validation, and data transformation.
- Finland's Digital and Population Services Agency's Interoperability Platform provides a number of semantic interoperability tools to support data holders to make their data easier to reuse (by data users), through compliance with common terminologies and vocabularies.
- Belgium has a number of initiatives to support data holders with metadata including Sciensano's HealthDCAT-AP Literacy platform as well as a number of generation and validation tools published by the HDA.
- FAIRtracks and 3DBIONOTES-WS are examples of metadata tools that facilitate the automated generation, validation, transformation and search of metadata for large genomic and multi-omics datasets. These types of tools are relevant to data holders as they make it possible to automatically conduct the very labour and time intensive metadata work necessary so that a genomic or multi-omics dataset can be reused. Metadata tools include software solutions to generate metadata for datasets (including automated generation, to reduce effort of manually generating metadata for massive datasets) and validation tools to ensure that generated metadata complies with common metadata standards.
- Data transformation tools enable the "wrestling" of data from one format or structure to another, without risking data quality from time-consuming manual data manipulation.
- Specific examples of these types of tools used with health data include Mirth Connect and OMOP on FHIR. Additionally, generic Extract, Transform, Load (ETL) tools are often used in the transformation of health-related data. These types of tools allow data holders to efficiently prepare and standardise data as part of a data request, and are therefore key for secondary use.
- Elixir Europe's "Recommended Interoperability Resources" (RIRs) are a set of tools and registries that have been endorsed by a panel of external reviewers as tools and resources that "facilitate the FAIR-supporting activities in scientific

research”. The RIRs are a large list of digital tools that support the standardisation, integration, description and analysis of health-related data and therefore have the potential to support data holders with these activities as part of a data request process.

6.6 Barriers to health data interoperability

Barriers to health data interoperability and secondary use are abundant, often complex and exist within all levels of a healthcare system. This review has identified four core types of barriers which can be broadly categorised as legal and organisational, trust, data quality and technical. The 2022 TEHDAS report on "secondary use of health data through European case studies" outlines eleven key "barriers for the secondary use of health data"(92), most of which fall under the four key types that this review has identified, which are discussed below and in **Table 10** at the end of this section.

6.6.1 Legal and organisational barriers

Legal and organisational barriers exist between entities within jurisdictions and across borders, including challenges such as differing interpretations of legislation, lack of national secondary use legislation, complex data access approval processes and lack of clarity on what constitutes pseudo-anonymised versus anonymised data.(92)

Interpretation of data protection laws
Interpretations of data protection legislation (such as GDPR's legal basis for data processing) often differ, and as a result can hinder efforts to combine similar datasets from different sources together, for reuse. For example, GDPR is implemented differently in each EU Member State under national data protection acts, with some jurisdictions such as France and Belgium requiring strict Data Processing Impact Assessments (DPIAs) for pseudo-anonymised data exchange.(92) Another example is Finland's Secondary Use Act (which allows for reuse with clear conditions), while Sweden requires stricter justification and may deem more data identifiable.(92)

Dedicated legislation can be a key enabler for secondary use by providing a clear legislative basis for the processing of sensitive (personal) health data, and can be designed to overcome the obstacles that can occur in the absence of it, such as the lack of clear roles and responsibilities around the exchange of health-related data for reuse. Appropriate legislation can outline clear legal rules and conditions for a data holder and data user to follow when exchanging health-related data and thus avoid the need for these parties to rely on the more ambiguous secondary use wording present in many national GDPR implementations.(92)

Data governance, access and approval processes
Complex health data governance, data access and approval processes impact reuse of health-related data due to many reasons including multiple entities (data controllers/data holders) required to approve access to data, requirement for ethics approval and opaque approval process. This often leads to delays in access to data,

increased administrative burden or costs and can discourage an applicant (data user), as well as losing their trust in the process. For example in France, the process of applying for data from the Health Data Hub involves approval from multiple committees and often an ethics application.[62]. Conversely, in Belgium there has been an initiative to evaluate a number of different data access processes in order to identify barriers and challenges, which has resulted in the implementation of a streamlined data access process.

Anonymisation Vs Pseudo-anonymisation

Another legal and organisational barrier to health data interoperability and secondary use is disagreement over what constitutes pseudo-anonymised versus anonymised data. This can comprise of challenges such as conflict on the definition of "absolute" and "relative" anonymisation, lack of guidance for specific types of health data (medical images, genomic data, and rare diseases) and how to define the parameters for re-identification. The consequences of this can include risk-averse attitudes on the side of the data holder, often prompting over-anonymisation (anonymising an entire dataset to reduce risk) of data which can lead to a reduction in data quality, usability and reliability. Pseudo-anonymisation and the lack of a common European agreed definition of it, means that varying methods of it are used across EU Member States. Also, lack of consensus exists on the "degree of separation" required between the re-identification key and the data user, for the dataset to be deemed safely pseudo-anonymised.[62, 92]

6.6.2 Trust issues that inhibit secondary use

Lack of trust is a key barrier to the exchange of health data for secondary use and exists at three main levels, namely; citizen or data subject level, data holder level and data user level.

Citizen-level trust issues

Trust issues at a citizen or data subject level manifest in such cases as when a citizen does not feel willing to consent to the reuse of their personal health data. The reasons for this lack of willingness may vary, including one reason stated in the 2021 "Dutch national trust framework for secondary use of health data", described as "patients/citizens are not well informed about the importance of secondary use of health data". In addition, the Ministry of Health, Welfare and Sport (VWS) in the Netherlands implemented a solution to one of these obstacles by way of a public awareness campaign titled "Data Saves Lives". The aim of this campaign was to stimulate a public debate on health data reuse and to generate public awareness of its benefits. Conversely, in Finland and Sweden trust levels on the part of the data subject were reported as high, and health data reuse is well established in both of these jurisdictions.[10, 11]

Data holder trust issues
Data holder trust and willingness to share data for secondary use is another key inhibitor of secondary use and often stem from genuine fears such as potential legal liability and lack of recognition for their efforts in the generation of a health data dataset. Potential solutions to these challenges are detailed in the 2021 "Dutch national trust framework for secondary use of health data" and include assessing the aims of the data holder (and not just the data user) within the data request process, and a proposed platform for advisory or consultation services from a broad section of industry (start up to multinational).[10]

Another barrier to secondary use of health data was described in the 2022 TEHDAS report on "secondary use of health data through European case studies" and states that a "lack of standardised data sharing agreements for products developed by private sector providers using public health data" exists and is required to enable safe data sharing to protect public sector investment (investment in the generation and preparation of the public health data). This issue highlights distrust from the data user side and the report evidenced that data users believed a lack of common or standardised approach led to time-consuming and costly data application or request processing due to the need for custom data sharing agreements. From the data holder side, this barrier can lead to risk-averse approaches to data sharing. The TEHDAS report also outlines a number of potential solutions to this challenge including an EU-level framework, or standard policies designed for the exchange of health data between public and private sectors, and that EU Member States set national rules requiring that data collected using public funds be available for free at a given time after data collection.[92]

6.6.3 Data quality issues

Data quality issues are a significant challenge for the reuse of health-related data and occur across organisations, jurisdictions and borders.

Semantic interoperability issues
Semantic interoperability issues are a key data quality problem which can be defined as a disconnect between two or more datasets due to the data adhering (or not adhering) to different health data interoperability standards. The 2022 TEHDAS report states that the use of different interoperability standards makes the sharing and merging of datasets across EU Member States challenging. The use of varying and inconsistent levels of health data coding terminologies (SNOMED CT, ICD-10, LOINC, and Orphacode) can lead to challenges such as difficulty with the interpretation of datasets. Also mentioned is that the current SNOMED CT to Orphacode mapping (for rare disease coding) only has 85% coverage, meaning that there is an incomplete pathway for coding unknown diseases or flagging a disease as rare. A statement highlighted in the TEHDAS report was that "common models do

not work well with complex data that are not simply observational", which implies that common data models such as OMOP-CDM or CDISC STDM are not a universal solution for the exchange of health data for reuse. A number of possible solutions are suggested to the problems listed, including European Commission (EC) level adoption of a single interoperability standard for the EHDS. A further solution proposed is for the EC to recommend adoption of a defined list of common health data interoperability standards that would comprise of terminologies, ontologies and classification systems.(92)

Varying or inconsistent levels of adherence to common metadata standards

Varying or inconsistent levels of adherence to common metadata standards is another data quality challenge. Lack of standardised and detailed metadata is a strong barrier for the reuse of health-related data as it makes it difficult for a data user to interpret the data accurately without much hands-on help from the data holder, which is often not possible, practical or scalable. As well as making a dataset discoverable in a catalogue, detailed and standardised metadata plays a key role in transferring the data holder's tacit knowledge of the dataset to the data user. Furthermore, metadata has the ability to make dataset descriptions machine readable and to enable automated logic at the row or data element level, which can then be used to take specific actions. An example of this would be removing a data subject's data from a dataset if metadata exists that indicates that the data subject has opted out or not consented for their data to be processed for secondary use purposes.(92)

Metadata challenges

In the jurisdictions reviewed, challenges occur in the creation of metadata profiles for datasets, often due to a data holder's lack of familiarity with metadata standards such as DCAT. This can result in slow timeframes in adding a data holder's data to a National Metadata Catalogue so that the data they hold is findable. If a dataset is not findable within a metadata catalogue, it makes it difficult for a data user to understand what data is available, in order to facilitate their secondary use purpose. To address this challenge, the Belgian Health Data Agency has conducted a number of initiatives to support data holders to create metadata descriptions for their data. These include the creation of metadata generation and validation tools as well as providing onboarding for data holders in order to add their dataset descriptions to the Belgian National Metadata Catalogue.(92)

Other metadata-related challenges include use of varying metadata standards across different organisations. For example in Sweden, while there is a significant amount of health data registries (for the purpose of secondary use), there is not yet harmonisation of a common national metadata standard. Varying metadata standards across datasets means that publishing of these datasets into a metadata catalogue is not possible without significant efforts to map across standards. A number of the jurisdictions reviewed have either implemented or are in the process of implementing legally-mandated national metadata standards or models to solve this problem. For example in Finland, the act on secondary use of health and social care data includes metadata descriptions and the Netherlands manages a National release or version of the Health DCAT-AP, which is regularly updated for the purpose of improving and standardising the levels of metadata in Dutch health data.

6.6.4 Technical barriers

Technical challenges are primarily due to a lack of integration of electronic health data systems, such as hospital electronic health records (EHRs), GP Systems and lab management systems, among others.

These disparate systems are often difficult to integrate due to high costs. In almost all of the jurisdictions reviewed, there is no single eHealth system that contains or has access to all of a patient's health-related data in one place. Finland's Kanta, is a centralised platform containing all of a patient's health and social welfare data and as a result, Kanta is one of largest providers (data holders) of health-related data for reuse in Finland.[49] Similar platforms to Kanta exist in France (Mon Espace Sante), and Belgium (My health).

The Netherlands has overcome this challenge by using a different approach due to the federated or decentralised nature of eHealth systems within the jurisdiction. While there is a high level of eHealth system adoption in the Netherlands, there was a deliberate decision not to establish a centralised electronic patient data system due to the perceived data privacy risks of storing all citizen health data centrally, with a federated approach adopted as an alternative. In order to overcome the challenges of a federated landscape comprising of a large number of heterogeneous eHealth systems, MedMij was created. MedMij is described as the Dutch "national standard for the secure exchange of health data between care users and care providers". MedMij includes a framework to enable the exchange of health data between citizens and healthcare providers in the Netherlands, via an online portal or mobile application (called the PHE or personal health environment). It also publishes specifications and information standards for vendors/creators of eHealth systems, so that their system's data is compliant with the MedMij standard and thus accessible to patient and healthcare professional via the MedMij PHE.[19]

While MedMij is focused mainly on overcoming the primary use challenges created from disparate eHealth Systems, the Dutch Cumuluz project aims to create a centralised health data integration layer (and infrastructure) to connect eHealth data in the jurisdiction at scale and unlock its secondary use potential. MedMij has a direct impact on the Cumuluz project as integrating health data that adheres to the same standard (the MedMij mandated health data interoperability standards) means there is a standardised foundation to build upon.(93)

6.6.5 Barriers in relation to health data interoperability and evidence of solutions from the jurisdictions reviewed

Table 10: Summary of barriers and solutions identified from the evidence reviewed

Category	Barrier	Solutions
Legal / Organisational	Differing interpreations of data protection laws around purpose limitation (Legal/Org)	Dedicated Secondary Use legislation with clear rules on what purposes are allowed for reuse (Finland)
Legal / Organisational	Lack of dedicated Secondary Use Legislation (Legal/Org)	The Secondary Use of Public Health and Social Care Data (Finland)
Legal / Organisational	Disagreement around what constitutes pseudo-anonmymised / anonymised personal health data (Legal/Org)	Not yet identified
Legal / Organisational	Complex and time consuming data access request processes (Legal/Org)	Single point of contact data access request process in a federated / fragmented health data landscape and the Testing of multiple HDAB governance structures prior to implementing a DAAMS. (Belgium)
Trust	Lack of Public willingness to allow reuse of their health data (Trust)	Asking for Consent for Reuse by caregiver (at point of care / data collection) (Sweden) Dutch "Data Saves Lives" Public Awareness Campaign (The Netherlands)
Trust	Lack of Data Holder willingness to share data for commercial use cases / with industry (Trust)	Ad-hoc Intermediary Service, to mediate between Data Holder and Data User (Belgium)
Trust	Data Holders fear lack of recognition for data collection (Trust)	Dutch National Trust Framework for secondary use of health data (The Netherlands)
Trust	Lack of standardised data sharing agreements (Trust)	Not yet identified.
Data Quality	Varying levels of Health Data Coding exist in eHealth Systems (Data Quality)	National Information Structure/Models (NIMs) (Sweden) MedMij Framework (The Netherlands)

Data Quality	Use of different Health Data Coding Standards in use (Data Quality)	National Information Structure/Models (NIMs) (Sweden) MedMij Framework (The Netherlands)
Data Quality	Lack of a single EU Health Data Coding Standard (Data Quality)	Not yet identified.
Data Quality	Use of different Metadata Standards across organisations / jurisdictions (Data Quality)	National Health DCAT-AP Metadata Standard (The Netherlands)
Data Quality	Lack of Data Holder familiarity with Metadata Standards (Data Quality)	Training, Support and hands-on on boarding to the National Metadata Catalogue (Belgium)
Technical	Lack of integration between eHealth systems (data is silo'd) (Technical)	MedMij and Cumuluz (The Netherlands) Kanta Platform / Personal Health Environment (PHE) (Finland) Mon Espace Sante Personal Health Environment (PHE) (France)
Technical	Integration of eHealth Systems is time consuming and expensive due to complexity (Technical)	MedMij and Cumuluz (The Netherlands)
Technical	Data collection in eHealth Systems often not standardised (data is not coded at collection / retrofitting data later risks integrity of data) (Technical)	MedMij Framework (The Netherlands) National Information Structure/Models (NIMs) (Sweden)

6.6.6 Summary

Common barriers to health data reuse and possible solutions

- This review has categorised the challenges and barriers to health data interoperability and secondary use into four broad categories: Legal and Regulatory, Organisational, Trust, Data Quality and Technical.
- The challenges and barriers to health data interoperability (and secondary use) are many, but there is evidence from the jurisdictions reviewed that solutions are possible and have been successfully implemented in some cases.
- The Netherlands has taken a proactive approach to these types of challenges and barriers by developing the "Dutch Trust Framework" which includes a section dedicated to overcoming such barriers, titled "Obstacle Removal Trajectory".
- The EHDS secondary use requirements are prompting action across the jurisdictions reviewed to address the challenges and barriers to secondary use of health-related data.

7 Discussion

This review has explored six jurisdictional approaches to health data interoperability and secondary use, as well as similar initiatives undertaken by international organisations within this domain. As the scope of this review is to inform the development of a National Interoperability Framework for HDAB services in Ireland, this discussion is focused on the Irish context and elements of the key findings that are most relevant to it.

7.1 Informing a National Interoperability Framework for HDAB Services in Ireland

The findings of this review have been interpreted to identify key learnings that could inform the NIF, and thus support data holders to exchange health-related data with an Irish HDAB service. These learnings have been compiled from interoperability frameworks, national initiatives to enhance health data interoperability and secondary use, national approaches to the implementation of health data interoperability standards, and software tools that support data holders with the process of exchanging health-related data for reuse. The findings are presented in the context of exemplar cases of good practice and elements to consider in full in relation to the NIF for HDAB services in Ireland.

Implementing health data interoperability standards upon collection
One such learning that stands out is the **value of standardising health data upon collection** (ensuring that it is captured and stored in compliance with common health data interoperability standards) and its implications for making health data more reusable. This was evidenced in a number of the jurisdictions reviewed. One such example of this was the Dutch MedMij framework, which mandates that eHealth Systems must capture and store primary use health data in adherence with interoperability standards in order to receive the MedMij stamp of approval (it allows vendors of such eHealth systems to advertise their products with the MedMij logo on its marketing material), and thus be trusted by clinicians in the Netherlands' health system. A result of this, there is a high level of SNOMED CT and FHIR adoption within Dutch eHealth software platforms that capture primary use health data. This approach of incentivising vendors to implement these types of standards in their eHealth systems has been successful, as evidenced by the high levels of SNOMED CT and FHIR compliance and is an important consideration for Ireland as more and more eHealth solutions are rolled out.[19]

7.1.1 Exemplar cases of good practice

A number of exemplar cases of good practice were identified from the evidence reviewed and will be discussed accordingly.

Presenting complex information in a user-friendly way

Finland's Avoin Data Operating Model for Data Sharing is an interoperability framework published in a highly-structured and user-friendly website format. It describes the many stages of data sharing and the obligations and recommendations that should be taken into consideration when sharing data in Finland. The structure of the framework is extremely comprehensive and covers the many stages involved in data sharing including legal responsibilities, motivation for sharing of data, identifying and describing datasets, monitoring data use, supporting data users and even right through to the discontinuation of data sharing. Each stage is broken down into easy to follow detailed sub sections, which often include multiple links to relevant Finnish and international resources. An example that illustrates this is the "Datasets and demand" stage of the framework, which includes sub sections that deal with identification of datasets, data mapping methods, determining the value of and demand for datasets and also links to support materials. While this framework is designed for public sector data in general, and not specifically for health data, it is a comprehensive example of how to present a complex interoperability framework and relevant resources in a user-friendly and accessible medium.(18)

The Avoin Data Operating Model also illustrates how a large quantity of complex information or links to resources can be incorporated in a highly-structured and easy to follow format, and deserves consideration for input when the NIF for HDAB services in Ireland is being developed.

Addressing the challenges and barriers to sharing data

While the obstacles to the secondary use of health-related data are numerous and often complex, there is evidence of attempts to address them. One such example is the 2021 HealthRI "Dutch national trust framework for secondary use of health data". This is an initiative from the Netherlands which was created to anticipate and overcome the barriers to health data reuse in the jurisdiction. This is illustrated by a dedicated section of this framework titled "Obstacle Removal Trajectory", which describes many of the common barriers to secondary use of health data and proposed solutions to them. The previously mentioned Avoin Data Operating Model also anticipates and addresses potential challenges that are typically encountered when sharing data, in its section on "Data sharing ecosystems and cooperation networks". A similar theme is also evident in a 2022 TEHDAS report which outlines eleven key "barriers for the secondary use of health data" and suggested options to overcome them.(10)

It is fair to assume that while data holders in Ireland will face many challenges with regard to the preparation and exchange of health-related datasets for reuse, these two examples illustrate how they can be overcome. Additionally, they also highlight the importance of anticipating these types of barriers early and how proactive planning can support the design of solutions to address them.

A dedicated EHDS interoperability framework for secondary use

The EHDS2 interoperability framework is an initiative to develop a toolkit to address the challenges posed for EU Member States when implementing the EHDS secondary use requirements. This framework adopted the TEHDAS-recommended health data interoperability standards for secondary use(8), including DCAT-AP for data discoverability, OMOP-CDM for semantic interoperability and for health data exchange, HL7 FHIR (health record data exchange) and DICOM (imaging data exchange). The EHDS2 interoperability framework includes the web-based "Interoperability Framework Entry Module" which is a user-friendly tool for the design and development of an interoperability framework through the completion of a series of web form sections. This allows for the efficient development of interoperability frameworks in a standardised manner by automating the generation of the document layout and structure as well as the inclusion of key sections, such as health data interoperability standards.(6, 7)

The EHDS2 interoperability framework has the potential to support and accelerate the development of the NIF through the generation of the key structural elements considered essential for this type of framework. Furthermore, a possible consequence of using this approach could be that there are more resources available (due to the EHDS2 framework automating part of the development)(7) to embed tools and other key supports for supporting data holders in Ireland to prepare and exchange the data they host with the HDAB service.

An interoperability framework directly based on FAIR Principles

The FAIRCookbook is an in-depth framework that contains detailed, hands-on and technical guidance for the implementation of FAIR data management. The Cookbook is designed for a wide audience including professionals who deal with data including researchers, data scientists, data managers, terminology experts and software developers. This makes it very relevant to HDAB services and data holders that need to exchange data with this type of service. The framework includes a number of resources to support and manage the process of publishing and exchanging health-related data for reuse. Like the Avoin Data Operating Model, the FAIRCookbook is published in an easy-to-navigate website format and provides health-related data holders with a set of tools and practical strategies to unlock the potential of the data they hold, through guiding this group through the complex process of making data Findable, Accessible, Interoperable and Reusable (FAIR).(18, 82)

7.1.2 Elements to consider for the National Interoperability Framework for HDAB Services in Ireland

A number of key elements of the evidence reviewed have been highlighted for inclusion in the NIF and are discussed as follows:

Data Discoverability and Data Model standards

Health data model standards such as data discoverability standards are key enablers for secondary use in many of the jurisdictions reviewed, by providing the means for data holders to describe their data in detail so that it can then be published on public digital media such as national metadata catalogues, and thus be discoverable to data users. Detailed descriptions of datasets (through rich metadata) play a key role in aiding a data user to understand a dataset, thereby making it easier to reuse. However, the process of generating the metadata to describe a dataset is often challenging for data holders without expertise in metadata standards (DCAT-AP). Tools and initiatives to address these challenges exist in a number of the jurisdictions reviewed and include the Belgian Health Data Agency's development of metadata generation and validation tools, as well as their onboarding (supporting data holders with creating metadata descriptions of their data sets) of data holders to the National Metadata Catalogue through Health DCAT-AP training programmes.

Data model standards are another type of standard that facilitate secondary use of health data. The ODHSI organisation's OMOP CDM is a widely-used data model which is a key enabler for secondary use as it allows data holders to structure their datasets in a way that data users are familiar with; as a result the process of interpreting a dataset (by a data user) is much easier. CDISC is another publisher of common data models including the CDISC STDM model, which is most analogous to OMOP CDM. However in the jurisdictions reviewed, there is little evidence of CDISC model use and this indicates that CDISC models may need further investigation / evaluation before being selected for incorporation into the NIF.[20, 45]

Tools to support data holders

This review identified a number of tools that have the potential to support data holders to exchange health data with a HDAB service. These types of tools are important for secondary use, as making health data or datasets interoperable often requires adding to or modifying the data. Examples of this include data transformation (reformatting the data), adding descriptions or more detail to the data (adding metadata, adding coding information) and validating the data (ensuring it complies with a health data interoperability standard). Health data interoperability tools that facilitate reuse can be broadly categorised as: semantic interoperability tools, metadata tools and data transformation tools.

Semantic interoperability tools play a key role in the process of making health data compliant with terminology or classification standards such as SNOMED CT, LOINC in scenarios where the health data was not originally stored in adherence with these types of standards at collection.

Metadata tools support data holders with the process of adding rich metadata to their health-related data, so that their deep understanding can be embedded to support reuse. Metadata tools also play a key role in facilitating the generation of dataset descriptions that are then uploaded, imported and published on metadata catalogues (national metadata catalogues) so that a data holder's dataset(s) may be discoverable to data users.

Data transformation tools provide data holders with practical solutions to support the restructuring or reformatting of their data, which is often a key part of the data preparation process prior to reuse (prior to it being transferred to a data user as part of a data access application). These types of tools facilitate the process of making health-related data FAIR.[42] Transformations that these tools undertake include converting data into standardised formats such as XML, CSV and JSON. Even generic ETL tools have a role to play in this type of use case, by providing data holders with the ability to extract data from one or multiple disparate sources (systems) and convert (transform) it into a single format or structure so that it is then possible to import (load) the converted data into another system. A real example of this is the process of loading data into an OMOP CDM structure so that it is ready for reuse.

7.2 Conclusion

From this review's findings, there is much evidence to conclude that an interoperability framework for HDAB services in Ireland should contain a combination of clearly communicated health data interoperability standards, as well as practical guidance and tools that can support Irish data holders through the process of exchanging data with a HDAB service. There is also a strong case for the key learnings from the findings to be translated into the following elements of a National Interoperability Framework for HDAB services:

- Accessible, clearly communicated and user-friendly guidance to make it possible for data holders to quickly understand the health data interoperability standards and specifications that are key for secondary use.
- Relevant best practices and examples from other jurisdictions in the EU that facilitate exchange of health-related data for secondary use.
- Summaries of key EU legislation that clearly signpost a data holder to the official texts, so that the process of understanding the legalities around preparing and exchanging data for reuse can be completed efficiently.

- Sufficient practical guidance on preparing a dataset for reuse including describing data, data provenance and versioning, dataset security, anonymisation and pseudo-anonymisation.
- Descriptions of the common challenges and barriers to secondary use and possible solutions to them, that are most relevant to Irish data holders.

While the challenges and barriers for health data interoperability and secondary use are many, this review has outlined evidence of solutions to them. The findings also provide a foundation for the next steps of this project, such as informing the development of the NIF, with the above-mentioned elements at the core of it.

8 References

1. Department of Health. Health Information Bill Dublin: Houses of the Oireachtas; 2024. [Available from: https://data.oireachtas.ie/ie/oireachtas/bill/2024/61/eng/ver_a/b61a24d.pdf.
2. European Commission. European Health Data Space Regulation (EHDS) - European Commission. 2025.
3. Department of Health. Digital for Care: A Digital Health Framework for Ireland 2024-2030 [Online]. 2024 [Available from: https://assets.gov.ie/293780/5c6e1632-10ed-4bdc-8a98-51954a8da2d0.pdf.
4. Executive HS. Digital Health Strategic Implementation Roadmap. 2024.
5. Department of Health. HealthData@IE– National Project Implementing EHDS [Online]. [Available from: https://www.gov.ie/en/collection/87d0e-healthdataie-national-project-implementing-ehds/.
6. Hussein R, Gyrard A, Abedian S, Gribbon P, Martínez SA. Interoperability Framework of the European Health Data Space for the Secondary Use of Data: Interactive European Interoperability Framework–Based Standards Compliance Toolkit for AI-Driven Projects. Journal of Medical Internet Research. 2025;27(1):e69813.
7. R. Hussein AG, S. Abedian, P. Gribbon and S. A. Martínez,. EHDS2 Interoperability Framework - Toolkit 2025 [Available from: https://forms.fillout.com/t/juxLYSKmMwus.
8. Tehdas. Recommendations to enhance interoperability within HealthData@EU - a framework for semantic, technical and organisational interoperability. Finland; 2022.
9. European Commission. Reuse of health data [Available from: https://health.ec.europa.eu/ehealth-digital-health-and-care/reuse-health-data_en.
10. Health-RI. Dutch national trust framework for secondary use of health data. The Netherlands; 2021.
11. Data Saves Lives. Data Saves Lives 2025 [updated 2025/07/29/. Available from: https://datasaveslives.eu.
12. Act on the Secondary Use of Health and Social Data (552/2019), (2019).
13. Regulation - 2016/679 - EN - gdpr - EUR-Lex, (2016).
14. European Commission. European Data Governance Act [Online]. [Available from: https://digital-strategy.ec.europa.eu/en/policies/data-governance-act.
15. European Commission. European Interoperability Framework (EIF) for European public services. 2010.
16. European Commission. Directorate General for I. New European interoperability framework: promoting seamless services and data flows for European public administrations. LU: Publications Office; 2017 2017.
17. eHealth Network. Refined eHealth European Interoperability Framework. 2015.
18. Avoindata. Operating model for data sharing Finland2022 [Available from: https://www.avoindata.fi/en.
19. MedMij. MedMij Framework The Netherlands2025 [Available from: https://medmij.nl/en/medmij-framework/.
20. Observational Health Data Sciences and Informatics. Standardized Data: The OMOP Common Data Model: OHDSI; [Available from: https://www.ohdsi.org/data-standardization/.
21. European Commission. Data Act [Online]. [Available from: https://digital-strategy.ec.europa.eu/en/policies/data-act.
22. European Commission. Directorate General for H. European Data Governance Act [Online]. [Available from: https://digital-strategy.ec.europa.eu/en/policies/data-governance-act.
23. European Commission. Data Act [Online]. [Available from: https://digital-strategy.ec.europa.eu/en/policies/data-act.

24. European Commission. Europe's Digital Decade: digital targets for 2030 [Online]. [Available from: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/europes-digital-decade-digital-targets-2030_en.
25. Tehdas. TEHDAS2 Joint Action advances the cross border secondary use of health data in European to improve research, innovation and policymaking. Finland; 2024.
26. Regulation of the European Parliament and of the Council on the European Heath Data Space, (2022).
27. 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), (2025).
28. EHDS HealthData@EU Pilot. Health Data@EU Pilot: Piloting an infrastructure for the secondary use of health data [Online]. [Available from: https://ehds2pilot.eu/.
29. Kalliola M, Drakvik, E., Nurmi, M. (Ed.). Advancing Data Sharing to Improve Health for All in Europe. Finland; 2023.
30. Health Information Bill, (2024).
31. Department of Health. HealthData@IE– National Project Implementing EHDS [Online]. [Available from: https://www.gov.ie/en/collection/87d0e-healthdataie-national-project-implementing-ehds/.
32. Katehakis DG, Kouroubali A. A Framework for eHealth Interoperability Management.
33. European Commission. EHealth European Interoperability Framework. Publications Office of the European Union; 2013 2013. Report No.: 978-92-79-30389-0.
34. Health Information and Quality Authority. Overview of Interoperability Standards. 2013.
35. C Chute. Clinical Classification and Terminology: Some History and Current

Observations. 2000.
36. Health Information and Quality Authority. Guidance on Terminology Standards for Ireland. 2017.
37. World Health Organization. ICD–11 Fact Sheet. 2019.
38. Health Level Seven. Overview - FHIR v5.0.0: HL7; 2023 [Available from: https://hl7.org/fhir/overview.html.
39. Health Level Seven. Summary - FHIR v5.0.0: HL7; 2023 [Available from: https://hl7.org/fhir/overview.html.
40. National Electronic Manufacturers Association. Digital Imaging and Communications in Medicine 2013 [Available from: https://www.dicomstandard.org/about.
41. Health Information and Quality Authority. Guidance on Messaging Standards for Ireland. 2017.
42. Wilkinson M. Dumontier M. Aalbersberg I. et al. The FAIR Guiding Principles for scientific data management and stewardship,. Scientific Data,. 2016.
43. TEHDAS. M5.1 Draft guideline on data description. 2024 2024.
44. Tehdas. Identification of relevant standards and data models for semantic harmonization. Finland; 2022.
45. CDISC. Standards 2025 [Available from: https://www.cdisc.org/standards.
46. Finnish Institute for Health and Welfare. Information architecture 2024 [Available from: https://thl.fi/en/topics/information-management-in-social-welfare-and-health-care/information-architecture.
47. Swedish National Board of Health and Welfare. The mission of the National Board of Health and Welfare 2024.
48. Nictiz. Healthcare information building blocks The Netherlands2025 [Available from: https://nictiz.nl/wat-we-doen/activiteiten/zibs/.
49. TEHDAS. Country visit - Finland. 2022.
50. TEHDAS. Country visit - Netherlands. 2022.

51. Ministry of Health Welfare and Sport. Explanation of the Law The Netherlands2025 [Available from: https://www.datavoorgezondheid.nl/wegiz/uitleg-over-de-wet.
52. Wet elektronische gegevensuitwisseling in de zorg (Wegiz), (2023).
53. Health-RI. Datacatalogus | Health-RI Catalogue 2025 [Available from: https://catalogus.healthdata.nl/.
54. Nictiz. NICTIZ Layer Model 2021 [Available from: https://nictiz.nl/publicaties/toolkit-lagenmodel/.
55. Nictiz. NICTIZ Standards 2025 [Available from: https://nictiz.nl/standaarden/.
56. Nictiz. NICTIZ What we do. 2025.
57. 14 MARCH 2023. - Law relating to the establishment and organization of the Health (Care) Data Agency (1), (2023).
58. TEHDAS. Country visit - Belgium. 2022.
59. ésanté. eHealth action plan 2022-2024. Belgium; 2022.
60. LAW No. 2016-41 of January 26, 2016 on the modernization of our health system, (2016).
61. Dgs_Laetitia.B, Dgs_Pauline.J, Dgs_Laetitia.B, Dgs_Pauline.J. Ma santé 2022 : a collective commitment. Ministère du Travail, de la Santé, des Solidarités et des Familles.
62. TEHDAS. Compilation of perspectives on multi-country data access applications, mutual recognition and cross-border applications through a workshop approach. 2023.
63. Health Data Agency. Data Catalog | Health Data Hub.
64. Health Data Hub. Encouraging awareness of health data standards: HDH publishes a series of fact sheets | Health Data Hub France: HDH; 2025 [Available from: https://www.health-data-hub.fr/actualites/encourager-la-connaissance-sur-les-standards-de-donnees-de-sante.
65. Health Data Hub. Documentation kit for requesting access to a database in the SNDS Catalog 2025 [Available from: https://www.health-data-hub.fr/page/kit-documentaire-acces-base-de-donnees-catalogue-snds.
66. Health Data Hub. CESREES Calendar [Online]. [Available from: https://www.health-data-hub.fr/cesrees/.
67. Commission Nationale de l'Informatique et des Libertés. The CNIL's Missions: CNIL; 2025 [Available from: https://www.cnil.fr/en/cnil/cnils-missions.
68. Lopes D. Health democracy for health data in France. Data Saves Lives. 2025.
69. TEHDAS. Country visit - Sweden. 2022.
70. DLA Piper. Data protection laws in Sweden 2025 [Available from: https://www.dlapiperdataprotection.com/index.html?t=law&c=SE.
71. Patient Data Act (2008:355), (2008).
72. The Swedish Biobank Act, (2023).
73. Swedish Research Council. RUT - Register Utiliser Tool. 2025.
74. TEHDAS. Recommendations for European countries when planning national legislation on secondary use of health data. 2023.
75. Act of 19 June 2024 on rules regarding data processing by partnerships (Data Processing by Partnerships Act), (2024/06/28/, 2024).
76. Supplementary Provisions for the Processing of Personal Data in Healthcare Act, (2025).
77. Uitvoeringswet Algemene verordening gegevensbescherming (UAVG), (2018).
78. 30 JULY 2018 - Act on the protection of natural persons with regard to the processing of personal data, (2018).
79. LOI n° 2018-493 du 20 juin 2018 relative à la protection des données personnelles (2018).
80. Commission Nationale de l'Informatique et des Libertés. Les décisions de la CNIL: CNIL; 2025 [Available from: https://www.cnil.fr/fr/les-decisions-de-la-cnil.

81. European Commission: Directorate-General for Research and Innovation EEB, Corcho, O., Eriksson, M., Kurowski, K. et al., . EOSC interoperability framework – Report from the EOSC Executive Board Working Groups FAIR and Architecture. 2021.
82. Elixir Europe. FAIR Cookbook [Available from: https://fairplus.github.io/the-fair-cookbook/content/home.html.
83. Digital and Population Services Agency. Interoperability Platform Finland2025 [Available from: https://dvv.fi/en/interoperability-platform.
84. Health Level Seven. Terminology Service: HL7; 2023 [Available from: https://build.fhir.org/terminology-service.html.
85. National Center for Biomedical Ontology. BioPortal 2025 [Available from: https://bioportal.bioontology.org/.
86. Sciensano. Health Data Cataloging Literacy with HealthDCAT Belgium2025 [Available from: https://metadata.healthdataportal.eu/.
87. Biocomputing Unit at the National Center for Biotechnology. 3DBIONOTES-WS Spain2025 [Available from: https://3dbionotes.cnb.csic.es/ws/home.
88. FAIRtracks. FAIRtracks 2025 [Available from: https://fairtracks.net/.
89. NextGen Healthcare. Mirth® Connect by NextGen Healthcare 2024 [Available from: https://github.com/nextgenhealthcare/connect.
90. Elizabeth Shivers. OMOP on FHIR Server 2021 [Available from: https://github.com/omoponfhir.
91. ElixirEurope. Recommended Interoperability Resources: Elixir Europe; 2023 [Available from: https://elixir-europe.org/platforms/interoperability/rirs.
92. TEHDAS. Report on secondary use of health data through European case studies. 2022.
93. Cumuluz. Cross-sector data availability for better care The Netherlands2025 [Available from: https://www.cumuluz.org/.

9 Appendices

Appendix A: Steering Group Membership for HealthData@IE

Name	Organisation
Emer Doyle (Chair)	Health Information Policy, Department of Health
Dr Barbara Foley	Health Information & Quality Authority
Dr Kevin O'Carroll	Health Information & Quality Authority
Rachel Flynn	Health Information & Quality Authority
Bríd Burke	Health Research Consent Declaration Committee
Prof Markus Helfert	National University of Ireland, Maynooth
Denise Manton	National University of Ireland, Maynooth
Kerry Ryder	HSE
Kathryn Kissane	HSE
Richard Greene	HSE
Loretto Grogan	HSE
Ana Terres	HSE
Dr Teresa Maguire	Health Research Board
Anthony Macken	Central Statistics Office
Azul O'Flaherty	Health Information Policy, Department of Health
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Eoin Farrell	Health Information Policy, Department of Health
Brendan Brady	Health Information Policy, Department of Health
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Appendix B: Sub-Working Group for Work Package 8 Working Group

Name	Organisation
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Martin Troy	Office of the Government Chief Information Officer (OGCIO)
David Stratton	Primary Care Reimbursement Service (PCRS)
Patrick Marren	MyHealth@EU project, Health Service Executive (HSE)
Theresa Barry	SNOMED CT National Release Centre, Health Service Executive (HSE)
Sandra Lawler	Health Identifier Service (HIDS) Health Service Executive (HSE)
Brid Moran	National Office of Clinical Audit (NOCA)
Simon Wong	Irish Centre for High End Computing (ICHEC)
Ken Moore	Central Statistics Office (CSO)
Anthony Macken	Central Statistics Office (CSO)
Catherine McGovern	National Cancer Registry Ireland (NCRI)

Appendix C: Subject matter experts who contributed to this review

Jurisdiction	Name	Organisation
Finland	Maari Parkkinen	THL / Findata
The Netherlands	Jan-Willem Boiten	Lygature / Health-RI
Belgium	Inge Franki	Health Data Agency (HDA)
France	Emmanuel Barcy, Amelie Schafer	Health Data Hub (HDH)
Sweden	Anna Adelof Kragh, Niklas Eklof	National Board of Health and Welfare (Socialstyrelsen)
Greece	Dimitrios G. Katehakis	Foundation for Research and Technology – Hellas

Appendix D: Search strategy (from Methodology)

Key organisations in jurisdictions or non-jurisdiction relevant organisations that play a role in the facilitation of the exchange of health-related data for secondary were identified. A "Google Site Search" of each key organisation's website was performed to identify all relevant resources, including legislation, regulation, guidance, specifications and frameworks. This involved conducting a Google Search targeted on a specific website URL. This approach was chosen as it leverages Google's powerful search algorithm (as opposed to relying on a website's inbuilt search function) in order to ensure search consistency and accuracy (using the same search algorithm for each website).

The search included subject headings, keywords and associated synonyms. The search terms that were applied are set out below.

Term 1	Term 2	Term 3	Term 4
National health data interoperability framework	Secondary use of health data	Health data harmonisation	Common data model (CDM) for health
National healthcare interoperability framework	Secondary use of health information	Health data harmonization	Common data model (CDM) for healthcare
National Health data interoperability strategy	Secondary use of health-related data	Health information harmonisation	Common data model (CDM) for health data
National health data interoperability initiative	Secondary use of health-related information	Health information harmonization	Common data model (CDM) for health information
National health data interoperability strategy	Reuse of health data	Analysing disparate health data	Common model for health data
National health data interoperability toolkit	Reuse of health-related data	Analysing disparate health data	Common model for health information
National health data interoperability toolkit	Reuse of health information	Disparate health dataset analysis	
National health data interoperability model	Reuse of health-related information		

Appendix E: Scoping Meeting Questions / Template

Health Data Interoperability / Secondary use – Scoping Meeting Questions:

1. **National landscape/architecture and challenges/barriers**
    a. How is the exchange of health data for secondary use supported technically in your country (how are data holders supported to exchange data with a HDAB service)
    b. What are the biggest barriers / challenges to the exchange of health data for secondary use in your country?
        i. What are the legal challenges around reusing health data from EHR Systems, National Registries for example?
        ii. Is there any agent/mediator that provides legal support in a centralised or distributed manner, or is it done locally at each project/organisation?
    c. How does your country's HDAB service interpret and implement GDPR obligations, for secondary use.
        i. How is Patient Consent and Purpose/Limitation of data governed for secondary use (consent or purpose limitation, copyright issues)
    d. What are the typical barriers and blockers that slow down the Data Request Process? How manual/automated is this process?

2. **Legal and Regulatory**
    a. What legal grey areas do you encounter with access requests?
    b. How is trust maintained with data holders who submit datasets to your country's HDAB?
    c. At what stage and where is de-identification of dataset completed?

3. **Policy and Care Process**
    a. Do you have any policies or procedures defined in advance to encourage your community to work together and exchange information?
    b. Typically how is a Data Holder's tacit knowledge / deep understanding of a dataset *transferred* along with a dataset to your country's HDAB? (via data dictionary, rich metadata incorporated).

4. Information / Technical IOP questions

a. How do you validate datasets to ensure they adhere to common health data interoperability standards? Is there a preferred standard and why?
b. Is data published using any standards (W3C LinkedData standards such as RDF, SPARQL, and JSON-LD.? And also Deep MetaData Integration?)?
c. Are common data models such as OMOP CDM or CDISC STDM used?
d. Do you use ontologies/thesauri/terminologies/vocabularies in your community to achieve semantic interoperability? If yes, which ones?
e. In your experience, are the semantic resources available well suited for your community? If not, please elaborate.
f. Do any of your semantic resources have the potential to be reused/used by another community?

5. Beyond the Grey Literature

a. What frameworks or approaches exist in your country on this topic but are not well documented / in the public domain?
b. If you were tasked with drafting a new National IF for secondary use, what elements would place most emphasis on?

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