EIT Health Ireland-UK

Implementing the European Health Data Space in Ireland

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Executive summary

In 2020 the European Commission published the European Strategy for Data as part of Europe's Digital Decade policy programme. The strategy aims to create a single market for data and introduced plans to establish ten common European Data Spaces in areas such as health, mobility, and agriculture. These will bring together relevant data infrastructures and governance frameworks to facilitate data pooling and sharing across member states. Health is set to be the first common data space introduced and will allow for movement of electronic health information within the European Union (EU). The legislative proposal was adopted by the European Commission in May 2022 and is currently under negotiation in the European Parliament.

The European Health Data Space (EHDS) seeks to address key challenges facing healthcare systems in Europe resulting from lack of access to health data, and is designed to boost Europe's competitiveness on the global stage. If passed, individuals will have access to, and control over, their digital health data from anywhere within the EU. It will also make large, anonymised datasets available for research, innovation, and policymaking.

Anticipated benefits include:

- Access to personal health information places power in the hands of citizens, including when they travel in Europe. Through technologies such as sensors and mobile apps, they can monitor their own health and see how improvements in lifestyle impact health status
- Healthcare professionals can use data to create safe, personalised treatment plans, deliver more prompt diagnoses, and improve wait times across the system
- Secure exchange of health data across borders enables evidence-based research into diseases from diverse datasets, accelerating the pace of innovation into new, potentially life-saving, treatments
- Policymakers can access relevant health data to identify trends and patterns in health status for better and faster decision-making in public health

Successful implementation relies on the standardisation of electronic health record systems across Europe. MyHealth@EU is a new digital communication channel which facilitates the secure, electronic exchange of patients' health data, such as ePrescriptions and Patient Summaries, rapidly and efficiently across member states.

The HealthData@EU platform is being established to facilitate the cross-border use of health data for secondary purposes such as research, innovation, and policymaking. This will be managed via national health data access bodies. The HealthData@EU infrastructure is currently being piloted across five use cases, in nine countries, led by the Health Data Hub – France's health data access body.

In Ireland, health information policies are undergoing rapid change to develop a fit-for-purpose health system. The Health Information Bill, put forward by government in April 2023, provides for the creation of both summary care and shared care records, as well as the establishment of a National Health Information Authority. This will act as Ireland's health data access body.

Although the benefits of the EHDS could be far-reaching, major obstacles exist, with each country at a different stage of digital health record availability. In 2023, a pan-European steering committee, coordinated by EIT Health, and chaired by Dr Andrzej Rys, Principal Scientific Advisor at DG SANTE, European Commission, was established to assess member states' readiness for implementation of the EHDS. Eleven roundtables, as well as individual interviews with local key opinion leaders, took place across Europe with a view to publishing regional reports that assess preparedness and set recommendations for EHDS implementation for EU policymakers and national governments.

Research carried out for this report consisted of a national roundtable discussion in Ireland with eleven experts from the fields of healthcare, academia, consulting, clinical research, industry, and patient advocacy. Six additional stakeholders were interviewed from healthcare, medtech, and pharmaceuticals. The following report focuses predominantly on the secondary use of data for research and innovation, and makes recommendations across six dimensions of implementation, based on participant feedback.

For Ireland, a significant cultural change is required to move forward, transitioning from a focus on data protection to striking a balance between data protection and data sharing, to further research and drive innovation that enables improved care for patients. Investment in digital technologies will be required due to current reliance on paper records, as well as upskilling the healthcare workforce.

Despite anticipated challenges, this could be timely for Ireland, as lessons can be taken from European neighbours that are further ahead on health data standardisation and management. As a hub for medtech and pharmaceutical companies, with a highly educated workforce and renowned academic institutions, Ireland could become a leader in innovation utilising health data with sensors, nanotechnologies, genomics and artificial intelligence, enabling better treatments and patients' self-management of their conditions.

When compared to European countries such as Denmark, that has a similar-sized population, Ireland has traditionally had less access to health research funding. This coupled with a lack of integrated health data availability has meant that finding Irish patients to take part in clinical trials is difficult. By harnessing the value of health data, the EHDS has potential to enable better healthcare for patients, and improve the lives of the family teams that care for them. Ireland has a unique set of capabilities that can contribute to the vision of the EHDS and support the needs of patients, healthcare professionals, and others working on the frontline of healthcare at home and across Europe.

Six key areas have been identified to support successful implementation of the EHDS. Recommendations for both national and EU policymakers are set out.

Governance - Key recommendations

For EU policymakers

- Precisely define the data categories and data holders that will be subject to a sharing mandate in the final EHDS Regulation
- Clearly identify the authorised users, purposes, and modalities for access to data in the final EHDS Regulation
- Clarify definitions within the EHDS Regulation and ensure consistency across EU legislations e.g. GDPR, Data Act, AI Act
- Foster harmonised implementation through coordination between national health data access bodies and EU-level oversight by the EHDS Board

For national government

- Ensure patient and citizen representation in EHDS governance bodies including the National Health Information Authority
- Achieve cross-agency and cross-government (Department of Health, Department for Enterprise, Trade and Employment, Department of Further and Higher Education, Research, Innovation and Science, the Department for Public Expenditure and Reform and the Department of Environment, Climate and Communications) alignment on the path to implementation
- Review the communication and implementation of existing regulations which affect researchers, such as the Health Research Regulation 2018
- Update existing regulation, where necessary, to align with and enable data sharing provisions set out in the EHDS
- Broaden the National Health Information Authority’s mandate to encompass data standardisation, interoperability, and oversight of secondary use
- Build close links with health data initiatives and organisations in Europe, such as France’s Health Data Hub, to accelerate learning and bring best practice to health data activities in Ireland
- Ensure transparency across secondary use for data subjects

Capacity and skills - Key recommendations

For EU policymakers

- Allow a phased approach to data integration for data holders
- Provide greater investment and support to less digitally mature member states for capacity building within healthcare institutions and national health data access bodies to the vision of the EHDS

For national government

- Accelerate the rollout of EHRs across the health system
- Explore options for the introduction of centralised health data storage platforms such as Data Lakes including the possibility for shared infrastructures with other member states that are further ahead of Ireland
- Mobilise willing clinicians with industry to develop capacity and skills for the EHDS
- Develop graduate, postgraduate and micro-credential courses with academic institutions to train stakeholders in the health data ecosystem
- Leverage experiences from the HealthData@EU pilot to help Irish innovators position themselves at the forefront of AI development
- Focus on building strong cybersecurity into data storage and processing environments

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Resources and funding - Key recommendations

For EU policymakers

- Clearly define the compliance requirements and penalties for industry data holders, especially SMEs
- Define the return on investment and possible business models for industry data holders
- Leverage lessons learned from the implementation of similar legislation, such as the MDR, and provide adequate supports for countries to invest in infrastructure and resources

For national government

- Set a national strategy for health data, aligned to the Digital Healthcare Strategic Framework 2023-2030
- Allocate funds both to the national digital infrastructure, including a national EHR, and to upgrading local systems and networks
- Leverage EU funding for full-scale implementation of the EHDS including the infrastructure and capabilities training that would be required

Data quality -
Key recommendations

For EU policymakers

- Agree on healthcare data standards for Europe in line with international best practices
- Draw on the experience of fields like epidemiology and genetics in dealing with large datasets
- Encourage post-market publication of clinical trial data to avoid incentivising bias

For national government

- Adopt a coordinated strategy to educate clinicians on data standards to optimise the research potential of the data they record, and researchers on data collection and analysis applied to healthcare
- Leverage the standardisation potential of EHRs to embed data quality
- Move quickly to harmonise data standards country-wide to avoid future interoperability-associated costs
- Mandate the National Health Information Authority, or another equivalent agency, to regulate data collection standards

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Closing the loop: The relationship between primary and secondary use – Key recommendations

For EU policymakers

- Specify the characteristics for data from secondary use to be shared with healthcare

For national government

- Ensure traceability of data across primary and secondary use platforms
- Invest in connectivity between datasets and the healthcare setting in which they were generated, including a path to recontact patients via their healthcare team

Awareness, education and communication: Towards a data-driven culture in healthcare – Key recommendations

For EU policymakers

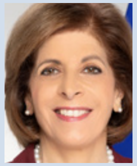
- Leverage lessons learnt from the HealthData@EU pilot to answer practical questions surrounding data governance and use
- Provide clear guidelines for industry on timelines for data-sharing and reassurances on the security of the data

For national government

- Raise awareness of the EHDS and its requirements to stakeholders through the National Health Information Authority and other communication channels
- Make guideline information and processes transparent and user-friendly, mindful of the variety of stakeholders and different knowledge levels of the communities that need to understand, interpret and implement the guidance
- Emphasise the life-saving potential of data sharing for citizens, while providing transparency around data collection, storage, use, and the privacy safeguards in place to protect citizens' data
- Empower citizens with digital tools to manage their own health and health data
- Adopt measures to enhance digital literacy among citizens

Introduction

On May 3 2022, the European Commission published its plans for the European Health Data Space (EHDS), a new framework intended to make it easier for individuals, doctors, clinicians, researchers, and regulators to access and use information about the health of millions of citizens across the European Union (EU). The legislation, which will require actions at the EU and national levels, aims to create a genuine single market for electronic health record (EHR) systems and patient health data—a key pillar of the European Health Union—following 'the EU's high data protection standards. In a statement to mark the launch of the plan, Stella Kyriakides, Commissioner for Health and Food Safety, said:



> ***"The European Health Data Space is a fundamental game changer for the digital transformation of healthcare in the EU. It places the citizens at its centre, empowering them with full control over their data to obtain better healthcare across the EU. This data, accessed under strong safeguards for security and privacy, will also be a treasure trove for scientists, researchers, innovators, and policymakers working on the next life-saving treatment. The EU is taking a truly historic step forward towards digital healthcare."***

The EHDS plan has three key objectives:

1. To give individuals better access to and control over their digital personal health data and to support free movement, by having health data accessible to citizens wherever they are across the EU.
2. To promote the data economy by fostering a single market for digital health services and products.
3. To set up strict rules for the use of an individual's non-identifiable health data for research, innovation, policymaking, and regulatory activities.

In its proposal, the Commission explains that while the EU health sector is rich in data, it is poor in making it work for people and science. The EHDS aims to harness the wealth of health data across the Union to help prevent, diagnose and treat diseases, support research, improve healthcare delivery, and speed up the development of new medical products and treatments — all while adhering to its strong principles of data privacy and control.

The Commission's EHDS plan covers the use of primary data, secondary data, common governance, and synergies with other health policy priorities. The primary use of data is the individual health record for a patient generated and recorded as part of their diagnosis and treatment during an episode of care. The EHDS aims to enable the millions of EU citizens access their own health data and make it available to a health professional of their choice, including when abroad, and to enable health professionals to update those records via the common myHealth@EU platform.

The secondary use of data is where summaries of health information across vast numbers of patients are used by policymakers, researchers and innovators to identify trends or new insights into diseases and their treatments. The EHDS aims to set out a common framework allowing for use of anonymised health data of EU citizens for research, innovation in public health, policymaking, regulatory activities, and personalised medicine. It will draw on the creation of a new and decentralised infrastructure for secondary use of health data, HealthData@EU, which will connect health data access bodies in all EU member states.

This infrastructure, piloted with five use cases under the leadership of the French Health Data Hub, includes plans for permits governing the access to anonymised health data and how it can be used, within closed, secure environments with clear standards for cybersecurity. It will be forbidden for the data to be used to make decisions that could be detrimental to individuals, to increase insurance premiums, to market health products toward health professionals or patients, or to design harmful products or services.

The EHDS Regulation also aims to reinforce the governance of health data at national and EU level. It will build on the current cooperation for primary use of data, within the eHealth Network which helped to build, in record time, two EU-wide infrastructures during the COVID-19 pandemic: the EU Digital

COVID Certificate and contact tracing and warning apps. This will include the creation of a new European Health Data Space Board to oversee the system, chaired by the Commission and staffed by representatives of digital health authorities and health data access bodies from the member states.

The proposed regulation is currently under negotiation within the European Parliament and the Council of Europe, whose final positions are expected in early 2024. If passed, the European Commission aims to have the EHDS in place by 2025.

How implementable is the EHDS? EIT Health assesses countries’ readiness for the legislation

How implementable is the EHDS? EIT Health assesses countries' readiness for the legislation

The purpose of this report is to assess the feasibility of implementing the EHDS in different EU regions and member states. EIT Health has conducted a pan-European, multi-stakeholder initiative focusing, in particular, on provisions relating to the secondary use of health data for research and innovation. The initiative aims to assess how the EHDS can be implemented in each country, rather than soliciting views on the legislation itself. EIT Health has gathered real-world insights from relevant health innovation ecosystem players on the realities and needs in individual countries for EHDS, and attempts to distil lessons learnt and best practices from previous experiences of health data sharing for secondary use. A series of roundtable discussions has been staged throughout Europe in 2023 to compare the ability across sectors and borders to put the regulation, as it is currently proposed, into practice. A European steering committee, coordinated by EIT Health, made up of experts from several member states, and chaired by Dr. Andrzej Rys, Principal Scientific Adviser at the European Commission's Directorate-General for Health and Food Safety, is overseeing the initiative.

In Ireland, EIT Health's approach was to survey views from senior stakeholders through formal and informal interviews and to conduct a national roundtable, held in collaboration with the Irish Medtech Association, during its Meeting of Minds event in Dublin on 30th May 2023. Meeting of Minds was held as part of the Ibec Digital Health Working Group's 'Where Digital Health Thrives' campaign which recognises the potential for Ireland to become a global hub for digital health. The roundtable was composed of two panels bringing together eleven experts from the fields of healthcare, academia, consulting, clinical research, medtech, and patient advocacy. Participants discussed Ireland's readiness for the EHDS under six dimensions of implementation: Governance; Capacity and skills; Resources and funding; Data quality; Closing the loop: The relationship between primary and secondary use; and Awareness, education and communication: Towards a data-driven culture in healthcare. Additional insights were obtained through individual interviews with stakeholders from the healthcare, pharmaceutical, medtech and digital health sectors.

About EIT Health

EIT Health is part of the European Institute of Innovation and Technology (EIT), a body of the European Union. EIT Health facilitates collaborative opportunities across industry, universities, and governments, leading to the development of new healthcare products and services for the benefit of patients in Europe.

In addition to providing pan-European training, public and private financing, mentorship programs, and consortium building, EIT Health hosts a Think Tank thought leadership forum. Subject matter experts collaborate across disciplines and borders to explore the most pressing topics impacting health and the adoption of innovation. The Think Tank generates knowledge and insight through research, expert roundtables, interviews, and publications.

Ireland context

Healthcare in Ireland is delivered through a mix of private health insurance, and a publicly funded national health service under a central Department for Health and Health Service Executive. Tertiary care is provided by 67 publicly funded hospitals and 19 private hospitals. Primary care is managed by independent general practitioners (GPs) and retail pharmacists where means-testing citizens and children under six are entitled to free primary care and reimbursement for medication. A network of Community Health Organisations provide community and mental health services.

Sláintecare is a multi-annual government strategic initiative to radically overhaul Ireland's healthcare system. Various reforms will be implemented including the regionalisation of hospital networks and linked community care; and a move away from the current two-tier private-public system to one which prioritises healthcare provision to those with the greatest need, rather than ability to pay. In July 2023, an implementation plan to restructure the health service into six regions was published. This plan includes a commitment to enhance data interoperability and data sharing within and across the new health regions.

Healthcare investment has traditionally focussed on ensuring patient access to care, with ICT investment curtailed. As a result, the technology and digital footprint across the Irish health system is low. A minority of hospitals, private and public, have full electronic health record systems, the rest rely on paper records. Data aggregation systems such as data warehouses are rare and transitions to Cloud Computing are in early phases. Primary and pharmacy care have more electronic systems but individualised to each location. Similarity, not-for-profit patient advocacy and research organisations have low digital footprints. This means that secondary use of health data for research and innovation has encountered challenges. Basic health information, such as numbers of patients with chronic disease like diabetes nationally, is not currently available in Ireland.

Six dimensions of implementation

1 Governance

The EHDS will include a common framework of governance, rules, and guidelines for data exchange in healthcare. This will be coordinated at national level by digital health authorities for primary use of patient data, and by health data access bodies for secondary use. The ability of different stakeholders in Europe's health ecosystems to apply the EHDS Regulation and engage in cross-border sharing of data will depend on: the existence and maturity of EHR systems in each participating country; legislative treatment of health data anonymisation privacy, authorised use purposes, and consent requirements under national interpretations of the General Data Protection Regulation (GDPR); existence of mature organisations for health data governance; and other potential scenarios, previously identified by EIT Health, such as different policies and practices surrounding the use of health data within individual organisations.

This section will review the governance structures, legislation, and formal processes for governing access to healthcare in Ireland. Recommendations on how they can be used or adapted for implementation of the EHDS are based on stakeholder feedback gathered.

1.1 How ready is Ireland?

1.1.1 Current landscape

Legislation
Patient's health information in Ireland is currently protected under GDPR and the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 , (referred to as 'Health Research Regulation 2018' throughout this paper).

In May 2023, Ireland's Department of Health published the Health Information Bill. This lays the foundations for the transformation of health data capture and use in Ireland and explicitly states its alignment with the objectives of the future EHDS: *"[...] the ideas and proposals in the proposed Regulation align with our own thinking on the role of health information in a modern integrated and innovative health service and they are, accordingly, reflected in the main elements of the Bill: namely, electronic patient summaries that can be accessed for care and treatment, wider use of health information for desirable health service and organisational developments that support the digitisation of health services."*

Agencies, committees and processes
In the current landscape in Ireland, no official agency responsible for health data has yet been established. The Health Information Bill provides for the creation of a National Health Information Authority, which will act as the national health data access body under HealthData@EU.

HIQA, the Health Information and Quality Authority, is an independent authority responsible for regulating health and social care services in Ireland. HIQA also has a specific legislative remit in relation to health information, with responsibility to set health information standards, assess compliance with standards, and make recommendations on the collection, use, and sharing of health information.

The National Office for Research Ethics Committees, set up in 2020, establishes National Research Ethics Committees (NRECs). These are responsible for reviewing research proposals in prescribed areas of health research, with the aim of providing single national ethics opinions that are respected nationally. They aim to protect the safety and dignity of health research participants.

The Health Research Consent Declaration Committee (HRCDC) was established as part of the Health Research Regulation 2018 as an enabler of health research where consent for the use of personal data for health research cannot be obtained. The HRCDC plays a decision-making role for health data access in certain limited situations, where patient consent is not possible and the public interest in conducting research significantly outweighs the need for explicit consent.

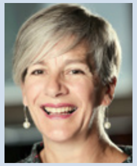
Despite these mechanisms, access to health data is challenging and, under the current fragmented landscape, data sharing is limited.

1.1.2 Challenges

A conservative regulatory landscape for health data
While effectively protecting health data, the current legislative framework is not designed to protect the patients who need that data to be used for their care and to give them access to clinical research and novel therapies.

General Data Protection Regulation (GDPR)
Ireland has one of the strictest interpretations of the GDPR in Europe. *"We forgot about the other side of the European regulation, which stipulates a duty to have the appropriate, most correct information on a patient and to share it in an appropriate way,"* said Prof. Richard Greene, Chief Clinical Information Officer of Ireland's Health Service Executive (HSE).

Even patients' access to information about themselves is strictly controlled: *"You actually have to sign off on a document to access your own data, and then the doctor also has to agree to their patient receiving the information,"* explained Greene. Patients also encounter difficulties navigating different healthcare providers' policies:



"When I looked for my data from the different providers I had visited seven years ago, it took 12 months. That's the last thing you want when you're going through a chronic illness. You want answers, you want to be able to access your information," Siobhán Freeney, Patient advocate, educator, and breast cancer survivor

Health Research Regulation 2018

The Health Research Regulation 2018 adds an additional layer of protection, which renders secondary use difficult. The Regulation sets out the governance of health data access through local and national Ethics Committees, and the rules for patient consent for research, and management of data collection during the research. This includes a requirement to anonymise, archive, or destroy patient personal data on the conclusion of the research project. The experience of researchers accessing and creating patient data for secondary use is that the process for approval can seem bureaucratic and time consuming, with the rules and requirements not well-understood.

One researcher explained that when participating in a clinical data project with European partners, the time for approval for data access in countries such as Belgium and Italy took eight weeks. The approval for Irish data had still not been received 12 months after submission request.

In many cases the requirement to anonymise personal patient data at completion of research has been interpreted as a requirement to destroy the data. This has impacted longitudinal knowledge of disease or therapeutic areas, especially when new information, innovations or other developments would benefit from comparison with older data. As an example, one researcher's source data on Multiple Sclerosis (MS) could not be accessed when later research showed potential increased cardiovascular events for MS patients.

Patient groups have expressed the wish for their data to be used for research to help future patients suffering from the same disease. The question of whether existing legislation will be amended as a result of the introduction of the EHDS remains open.

Inconsistent data-sharing practices across the healthcare ecosystem

Ireland's legal backdrop has often been used by various health ecosystem actors as a reason not to share data even in instances when it would be deemed legitimate. The Health Information Bill sets out a duty to share health information and describes the considerable reluctance to share information to date, even between the statutory bodies pursuing similar goals. It also refers to an information "black hole" on the private side of the health system, which accounts for over 1,000 hospital beds throughout the country, weakening attempts at policymaking or service planning based on health data.

"The fact that our medical records have been paper-based to date has significantly limited our ability to transfer data outside the hospital," Simon Moores, Chief Financial Officer, Bon Secours Hospital Dublin

Another participant cited an example of a medical student having to share diagnostic images by having a CD of a patient's MRI couriered from one hospital to another.

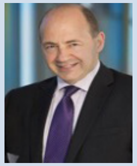
Additionally, health data sharing for research has stricter rules and requirements than sharing of patient data for clinical audit or service improvement. The definition of 'research' may become less clear in future, with technological advances for querying data becoming more ubiquitous and embedded in EHR systems for the delivery of care across the patient journey.

The revision of the Caldicott principles in the UK was cited as an example to follow: "An eighth principle was recently added stating that the duty to share is as important if not more so in some situations than the duty to protect data. We are very good at data protection, less so at data-sharing. We need to change that and empower patients through enhancing a rights-based approach to health information," said Barbara Foley, Health Information Quality Manager at HIQA.

There is also a lack of understanding of the rules for data sharing currently, with many advocating for better access to clear information about what is and is not appropriate. Additionally, the role and remit of Data Privacy Officers and Ethics Committees has led to confusion for stakeholders.

1.1.3 Opportunities

A favourable political climate
Limited possibilities to share and use health data have meant that a formal data governance framework has yet to be established in Ireland. However, experiences from the management of the COVID-19 pandemic and the large-scale cyber-attack on the HSE in 2021 have spurred political momentum for modernisation of the national approach to health information. In collaboration with the Department of Health, the HSE is currently in the process of overhauling its digital health strategy and producing an implementation plan.



> ***"What we need to do to achieve that is carved out for us in the EHDS. This is a powerful piece of regulation that will be very valuable to us because it is aligned with what we want, which is to make it patient-centred and enshrine the principle that data absolutely belongs to, and is used for the benefit of, the patient," Prof. Richard Greene, Chief Clinical Information Officer, HSE***

Furthermore, national strategies and priorities for health information have been established. The national digital strategy, Harnessing Digital – The Digital Ireland Framework, was published in February 2022 to drive and enable digital transition across the Irish economy and society. The goal to make Ireland one of the most digitally inclusive States in the EU is laid out in Ireland's Digital Inclusion Roadmap. The Health Information Bill will support these changes.

The Department of Health, the HSE and key agencies have begun actively preparing for the implementation of the EHDS, including development of the required cross-border infrastructure, participation in Joint Actions with other EU Member States and establishing national projects with direct grant funding from the EU4Health programme.

Opportune timing
The impetus coming from the EU as an external force may be well-timed to help overcome a level of inertia that has stalled the digital transformation of healthcare nationally in recent years.

> ***"We are somewhat behind the curve compared to our European partners, but this may also be an advantage in that we can learn from other jurisdictions and the EU in general," Prof. Seamas Donnelly, Professor of Medicine, Trinity College Dublin***

Irish initiatives in data governance for research may also provide valuable insights for national implementation of the EHDS. Examples include the Empower research programme funded by Science Foundation Ireland, and the "Proof-of-Concept: Technical Prototype for Data Access, Storage, Sharing and Linkage (DASSL) to support research and innovation in Ireland" from the Health Research Board.

Replicating models from other countries
The Health Data Hub, France's national data access body, has been established as a not-for-profit agency that sits outside the organisational structures of the health system. This example was cited as a potential model to replicate in Ireland via the National Health Information Authority.

1.2 Priorities for implementation

Cross-government buy-in
Political consensus around Ireland's strategy for digital health and health data will need to translate into alignment on a concrete path to implementation at the highest levels of the HSE, the Department of Health, other government departments and state agencies.

Due to the potential of the EHDS Regulation for improving healthcare, while supporting enterprise and driving next-generation skills, alignment and buy-in would be required across the Department of Health, the Department for Enterprise, Trade and Employment, the Department of Further and Higher Education, Research, Innovation and Science, the Department for Public Expenditure and Reform, and the Department of Environment, Climate and Communications (responsible for cybersecurity).

- Achieve cross-government, cross-agency alignment on the path to implementation

Adopt a holistic approach to governing health data

The role of the National Health Information Authority, as set out under the Health Information Bill, is deemed too narrow by several participants, limited to the achievement of a summary care record, and shared care record. They argued that this meets only basic requirements laid out in the EHDS for primary use of health data. A holistic approach to data governance should be adopted within the National Health Information Authority, with additional proposed mandates to include oversight of secondary use of health information, data standardisation and interoperability initiatives, and coordination of national data collections.

- Broaden the National Health Information Authority's mandate to encompass data standardisation, interoperability, and oversight of secondary use

Clear guidelines on data sharing

Secondary use for research and innovation vs. policymaking

Regarding the modalities of EHDS governance, the need to clearly define which datasets will need to be shared, who will be required to do so, and who will be eligible to gain access emerged as a top priority for both healthcare and industry representatives.

Private hospitals could be reluctant to release commercially sensitive operational data perceived to belong to the healthcare institution rather than the patient, such as utilisation rates of hospital beds, procedures, devices and medicines, average lengths of hospital stays etc., into the public domain given the potential market value. A mechanism to allow data holders to choose whom they share their datasets with could provide reassurances.

"The proposed legislation tries to combine data-sharing for policymaking with data use for research and innovation: our hospital would be open to providing data to the state for public health decision-making, and in fact we did during the COVID-19 pandemic, but why would we give our data away for free to pharmaceutical companies which could potentially build it into the price of new products?" Simon Moores

Industry concerns lie with the protection of the intellectual property (IP) rights on corporate datasets and a preference that only data from completed clinical trials should be eligible for sharing, with trial sponsors retaining a right to first access. Industry representatives advocated for legal recognition of the private sector's contributions to medical research and called for industry to be granted the same level of access to data as those from government-funded institutions. Data access within the EHDS should build on FAIR principles:

"Ensuring that data is findable, accessible, interoperable, and reusable will be key to promoting its constructive use for the benefit of patients," David Dowling, Health Systems Partner, Roche Products Ireland

- Precisely define the data categories and data holders that will be subject to a sharing mandate in the final EHDS Regulation
- Clearly identify the authorised users, purposes, and modalities for access to data in the final EHDS Regulation

Transparency on data usage
For patients and citizens, involvement of the public in designing the consent mechanisms by which individuals will be able to agree to or oppose the use of their data for secondary purposes will be important, along with the traceability of data access and use.

> ***"People see health data as part of their identity, and that applies equally to pseudonymised and anonymised data. As detailed in the 2021 report of our citizens' jury, patients in Ireland want their health data to be collected appropriately and securely, but also shared according to their wishes subject to certain conditions and red lines. They want to be able to follow where the data is going through audit trails, and to know who is accessing It, for what purposes, and who is protecting it." Derick Mitchell, CEO, Irish Platform for Patient Organisations, Science and Industry (IPPOSI)***

A recent public consultation by TEHDAS across EU countries on secondary use of data within the EHDS advocated for better traceability for patients of their health data usage, echoing IPPOSI's findings.

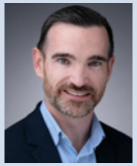
- Ensure transparency across secondary use for data subjects

Give patient and citizen voices prominence
Citizen or patient representation in EHDS governance bodies could serve to overcome historical objections to sharing data and antipathy between institutions and industry in this area, as set out by Mitchell.

- Ensure patient and citizen representation in EHDS governance bodies including the National Health Information Authority

Align relevant legislation
Efforts should be made at EU level to align the legal definitions and principles of the EHDS with existing and upcoming European legislation such as the GDPR, the Data Act, and the AI Act, as well as to ensure harmonisation of interpretation across the member states.

Pharmaceutical and medtech industry stakeholders noted that the EHDS proposal's definition of secondary data use itself is different from the language used in the GDPR, while the draft definition of a data holder was considered too broad.



> ***"For clinical trials conducted across multiple sites, for instance, it is unclear whether each site would be considered a data holder or whether there would be a single holder for all data from the same trial," John Coughlan, Government Affairs Partner, Roche Products Ireland (at the time of writing)***

- Clarify definitions within the EHDS Regulation and ensure consistency across EU legislations to improve legal predictability

Review existing legislation to strike a balance between data protection and data sharing
To create enabling rather than controlling governance of data, changes to legal and cultural approaches to health data are required. In addition to advocating for streamlining access to individual records, patients interviewed were positive about the use of their anonymised data for research in the hopes of helping other patients and to improve understanding of diseases. Access to health data by researchers and others should reflect this by reviewing the process for data collection and usage as set out in the Health Research Regulation 2018 and providing clearer communication on the potential use of consent declarations via the HRCDC.

- Review the communication and implementation of existing regulations which affect researchers, such as the Health Research Regulation 2018
- Update existing regulation, where necessary, to align with and enable data sharing provisions set out in the EHDS

Cross-border coordination across the EU

Coordination between national health data access bodies and oversight by EU-level EHDS governance bodies is required to facilitate harmonised implementation and prevent unnecessary red tape for data users seeking access across borders.

> ***"To prevent the EHDS from becoming a hurdle or an additional burden that stops innovation, Europe needs to ascertain that the interpretation of the EHDS does not increase the market fragmentation that currently risks keeping products developed in the EU out of the EU market," Louise Corcoran, Vice-President of Quality and Regulatory Affairs, FIRE1***

Public-private engagement is essential to the design of a workable and adaptable governance framework that could be implemented across Europe.

- Foster harmonised implementation through coordination between national health data access bodies and EU-level oversight by the EHDS Board
- Build close links with health data initiatives and organisations in Europe to accelerate learning and bring best practice to health data activities in Ireland

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1.3 Key recommendations

For EU policymakers

- Precisely define the data categories and data holders that will be subject to a sharing mandate in the final EHDS Regulation
- Clearly identify the authorised users, purposes, and modalities for access to data in the final EHDS Regulation
- Clarify definitions within the EHDS Regulation and ensure consistency across EU legislations
- Foster harmonised implementation through coordination between national health data access bodies and EU-level oversight by the EHDS Board

For national government

- Ensure patient and citizen representation in EHDS governance bodies including the National Health Information Authority
- Achieve cross-government, cross-agency alignment on the path to implementation
- Broaden the National Health Information Authority's mandate to encompass data standardisation, interoperability, and oversight of secondary use
- Review the communication and implementation of existing regulations which affect researchers, such as the Health Research Regulation 2018
- Update existing regulation, where necessary, to align with and enable data sharing provisions set out in the EHDS
- Build close links with health data initiatives and organisations in Europe to accelerate learning and bring best practice to health data activities in Ireland
- Ensure transparency across secondary use for data subjects

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2 Capacity and skills

Establishing and maintaining the collection, storage, protection, sharing, and secondary use of electronic health data requires supporting technology infrastructure and specific human resources and skills that are not always readily available. The National Health Information Authority will have various responsibilities that require skills-building in the management and execution of data access activities. Such responsibilities will include: examining requests and issuing permits, processing the relevant data in centralised pools and delivering access to it for users, and networking with its counterparts in other member states via the core platform HealthData@EU. Data holders such as hospitals, research organisations, and industry will also be required to standardise and make their health data available to users. This could be either via a national data server or by establishing secure processing environments in-house. This will require supporting technologies and skills, as well as providing guidance and communication to appropriate groups on ethics and data privacy.

The EHDS will bring about significant changes and new opportunities in the way users can interact with health data. For instance, the possibility to bring together large numbers of independent datasets for analysis or the potential to conduct studies on an unprecedented scale with millions of patients. New skills will emerge such as data governance and management for healthcare professionals and digital literacy for patients. Significant changes to existing practices of research communities, innovators, and policymakers will also take effect.

This section will assess the current capacity within healthcare institutions and identify the skills required to implement the EHDS, based on research conducted for this report.

2.1 How ready is Ireland?

2.1.1 Current landscape

Low availability

A vast amount of health data in the Irish system today is still on paper records. Ireland does not have a national EHR and out of 67 publicly funded hospitals, only five have implemented full electronic patient records. Digital maturity is still relatively low in several of the 19 private hospitals. The significance of this lack of digitisation is that health data does not exist in sufficient quantities to enable use for research and innovation in the manner anticipated by the EHDS. In the age of AI, which relies on large volumes of data for accuracy and usefulness, this low availability and fragmentation puts Ireland at a disadvantage for the adoption of next-generation technologies for patients and clinicians.

Capacity building has begun nationally

Progress has been made in recent years, with digital upgrades to clinical care pathways seen within healthcare institutions and efforts undertaken by the statutory bodies to build capacity for digital data collection and sharing. These have come in the form of the Sláintecare initiative and efforts to build a secure backbone for digital data within the HSE, and have included the successful rollout of the Individual Health Identifier (IHI) to 99.9% of the population in the course of the COVID-19 vaccination campaign. The IHI is used to uniquely identify each person engaging with the HSE and relevant social care agencies and allows records of patients from different systems to be linked together. *"A lot of work happened post-lockdown to create a unified patient record. We have exchanges of prescriptions and patient discharge summaries from hospitals to primary care settings already. These foundations put Ireland in a good position to be able to act on the EHDS,"* said Dowling.

2.1.2 Challenges

Poor interoperability of digital health data within legacy healthcare institutions

Where health data is present, systems are not interoperable and may encounter difficulties sharing data. Within single hospitals, it emerged that there could be 15 to 20 data systems running in parallel that are unable to communicate with one another. One notable exception is the National Integrated Medical Imaging System, which as of January 2022 connected 77 hospitals and imaging centres with almost 3,000 GP practices for the secure electronic sharing of diagnostic images.

Infrastructure for secondary use of data is lacking

Although nearly 130 national collections of health and care data have been catalogued in Ireland, ranging from disease registries to clinical care audits and national screening programmes, infrastructure for secondary use has yet to be developed. The fragmented nature of the data undermines decision-makers' ability to plan healthcare services effectively and efficiently. Notable information gaps are highlighted in the Health Information Bill, including the absence of incidence data on chronic illnesses and a lack of insight into the most prevalent reasons for emergency department visits.

> ***"We spend over €20 billion a year on health services in this country, but we do not have the ability to adequately assess return on investment of that money. That makes it very difficult to plan new services and to stop things that are ineffective, because we often can't show definitively whether or not they are working." Dr. Ronan Glynn, Health Sector Lead, EY, and former Deputy Chief Medical Officer, Department of Health***

Additionally, the lack of infrastructure for clinical research and the resulting difficulties of data capture can dissuade pharmaceutical and medtech companies, as well as clinical research organisations, from running clinical trials in Irish hospitals. This is a lost opportunity for patients to access new therapies.

Data curation and management within hospitals

Under the EHDS, several tasks will be incumbent on individual data holders, be they healthcare institutions, medtech or life science companies. These include the curation and standarW make them accessible, the publication of data catalogues to make them findable for secondary users and the production of metadata catalogues to ensure they are reusable for research purposes. Most healthcare institutions would lack the in-house capacity and skills to achieve this. *"The capabilities to manage these types of datasets are simply not there in hospitals. Even in large public hospitals there might be four people working with the EHR, but they don't have the capabilities to deliver a data platform, data governance, and data strategy. The highly specialised skillset required to manage and label massive amounts of data from the EHR for secondary use is going to be a major stumbling block,"* said Moores.

Skills shortage

Ireland's hospital system operates at 90% bed occupancy, the highest in the OECD. With a unique skillset required to implement and maintain the EHDS, a busy health service will be expected to implement a large-scale programme of upskilling its staff. "*The health service is maxed out since COVID. They rarely have the headspace to think 'what should I be doing?"* said David Wall, Chief Information Officer at Tallaght University Hospital. Skilled individuals with advanced digital capabilities typically opt for industry employment. *"How can a hospital compete with market rates for attracting these skillsets?"* added Wall.

2.1.3 Opportunities

A growing recognition of the power and potential of data to improve healthcare

The importance of digitally-enabled citizens across all aspects of society, including health is evidenced in several government developments published in recent years such as the 'Adult Literacy for Life for All' strategy and 'Digital for Good – Ireland's Digital Inclusion Roadmap'. Major technology platform implementations are planned across the health system. The potential of clinical research for patients and the Irish economy is being recognised with the major restructuring of research bodies and the pending appointment of a Chief Scientific Officer. These, and many more initiatives, mean that the introduction of the EHDS is timely and can help guide various digital, research and technology capacity building to enable health data to be a conduit for better research and world-leading innovation.

Digital upskilling

With a host of renowned academic institutions located in Ireland, and a highly educated workforce, there is an opportunity to rapidly upskill the health ecosystem through both traditional education and flexible modular learning for continuous professional development. Health ecosystem workers should be educated on the usefulness and value of data, its potential for innovation, and how to explain data to stakeholders of varying levels of digital literacy.

Upskilling opportunities would need to be made available in deeper skill subjects such as data management, data science, data engineering, and Lean or Agile workflow methodologies to drive improvements and innovation in patient care using health data.

The Irish Medtech Association and the Connected Health Skillnet published a digital health roadmap in 2023 for addressing skill needs for industry, with a view to address the skills gap by delivering training in advanced data analytics, information management, software development, and cybersecurity.

Irish medtech: a sector full of data opportunities

A wealth of digital data that could more readily be opened up to secondary use through the EHDS, is that generated by Ireland's life sciences industry and vibrant medtech sector. Ireland is the highest employer of medtech professionals, per capita, in Europe.

Datasets in this field are diverse, with novel types of datasets emerging as a cornerstone of innovation through products such as Abbott's cardioMEMS or Endotronix's Cordella. Sensors are embedded into traditional medical devices to gather clinical data such as blood pressure to optimise the management of cardiovascular disease.

Other data-gathering applications already in use include fall detectors and devices for patients to measure their blood glucose levels at home. In large volumes, this data could analyse and compare real-world outcomes from different interventions and patient self-management approaches that refine prediction and prevention models. This could ease the burden of chronic disease management for health systems and patients.

2.2 Priorities for implementation

Accelerate digitisation

Several participants involved in this study made it clear that building the foundational digital infrastructure and the human capabilities to manage the collection, storage, and movement of data within the EHDS will be the most challenging but also the most urgent task for Ireland. This will require a particular focus on accelerating digitisation and supporting data standardisation and interoperability measures within hospitals and other data holders across the legacy healthcare system.

- Accelerate the rollout of standardised EHRs across the public health system
- Explore options for the introduction of centralised health data storage platforms such as Data Lakes including the possibility for shared infrastructures with other member states that are further ahead of Ireland

Cybersecurity

In a context where data storage facilities and secure processing environments for secondary use will largely need to be built from scratch, industry, healthcare, and patient representatives alike highlighted the critical importance of ensuring strong cybersecurity to protect the large amounts of sensitive data which could go into circulation in a relatively short time.

- Focus on building strong cybersecurity into data storage and processing environments

Capacity-building

Ireland in effect has a dual challenge – firstly the need for investment to digitise health records, and then the investment in data infrastructures to analyse and interrogate data for secondary use. This means that Ireland is facing considerable investment over and above that of countries that already have a considerable digitised footprint of health records.

- Provide greater investment and support to less digitally mature member states for capacity building within healthcare institutions and national health data access bodies to the vision of the EHDS

A phased approach

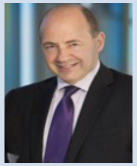
With the European Commission having set an ambitious goal for the EHDS to enter into force in 2025, a phased approach to data integration is required: *"Key datasets should be defined that we need to prepare for release into the public domain. 2025 is just around the corner and requiring us to make the entire EHR available in one go will be difficult,"* said Moores.

"The medtech industry has just recently experienced the transition to the MDR, which has been associated with significant challenges on the ground and ultimately required an extension of the transitional period because the infrastructure was not in place to support implementation. We appreciate the opportunities offered by the EHDS but we need to have the infrastructure, the capacity, and harmonisation across Europe when it comes into force." – Sinead Keogh, Head of Sectors & Director, Medtech & Engineering at the Irish Medtech Association.

- Allow a phased approach to data integration for data holders

An alliance of the willing

Capacity and skill-building efforts would need to focus on the ability of healthcare professionals and health innovators to interact effectively with the EHDS and reinvent processes in healthcare.



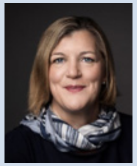
> *"This will not be achieved by the technical people alone. We need to involve the clinicians and the businesses in achieving digital health. The international evidence is very clear that you can't throw tools at people and expect them to work. If we take our old processes and throw digital at them, we won't improve things." Prof. Richard Greene*

Similarly, HIQA has published key considerations for policy on the collection, use and sharing of health information, highlighting the need for strategic engagement. HIQA is currently drafting an update to its 2017 National Standards for Information Management . These initiatives will guide organisations to develop robust information management practices by following data security, data quality and data standards requirements, which is fundamental to achieving information maturity at a systemwide-level.

- Mobilise willing clinicians with industry to develop capacity and skills for the EHDS

Training and education

A holistic approach should be adopted to promote a mindset of upskilling, by creating regular training opportunities for healthcare workers, senior executives and support staff so they can develop the digital expertise they need to implement the EHDS efficiently and effectively.



> *"Skills are needed at undergraduate and postgraduate level in addition to technical upskilling that can be offered through micro-credential courses across data governance, technical data skills and data management" Sinéad O'Connor, School of Medicine, Trinity College Dublin*

A flexible learning model could be made available for all types of data holders, including researchers and start-ups, at Ireland's academic institutions to providing training in areas such as how to anonymise health data. For future healthcare professionals, mandatory digital health training modules should be added to the undergraduate curriculum on data, including explaining data, how to use it, and how to interpret it.

- Develop graduate, postgraduate and micro-credential courses with academic institutions to train stakeholders in the health data ecosystem

Knowledge-sharing

There is an opportunity for Irish innovators to position themselves at the forefront of AI development by learning from the HealthData@EU pilot led by the French Health Data Hub. One of the pilot's use cases is dedicated to comparing care pathways for cardiometabolic diseases in European countries and building AI-based prediction models.

> *"The lessons learned from key projects in Europe focussed on data sharing and data spaces in health and beyond can help Irish researchers and innovators accelerate the overall process of producing real and practical data-driven solutions. However we also need to learn from our successes and failures in national projects as every country and even region in Europe has their own regulations and protocols" - Ricardo Simon Carbajo, Director of Innovation and Development, the Irish Centre for Applied Artificial Intelligence (CeADAR)*

- Leverage experiences from the HealthData@EU pilot to help Irish innovators position themselves at the forefront of AI development

Cybersecurity
In a context where data storage facilities and secure processing environments for secondary use will largely need to be built from scratch, industry, healthcare, and patient representatives alike highlighted the critical importance of ensuring strong cybersecurity to protect the large amounts of sensitive data which could go into circulation in a relatively short time.

- Focus on building strong cybersecurity into data storage and processing environments

2.3 Key recommendations

For EU policymakers

- Allow a phased approach to data integration for data holders
- Provide greater investment and support to less digitally mature member states for capacity building within healthcare institutions and national health data access bodies to the vision of the EHDS

For national government

- Accelerate the rollout of EHRs across the health system
- Explore options for the introduction of centralised health data storage platforms such as Data Lakes including the possibility for shared infrastructures with other member states that are further ahead of Ireland
- Mobilise willing clinicians with industry to develop capacity and skills for the EHDS
- Develop graduate, postgraduate and micro-credential courses with academic institutions to train stakeholders in the health data ecosystem
- Leverage experiences from the HealthData@EU pilot to help Irish innovators position themselves at the forefront of AI development
- Focus on building strong cybersecurity into data storage and processing environments

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3

Resources and Funding

Although health data access bodies and individual data holders will be entitled to charge access fees to users, these will likely recover only a small part of the total cost incurred to transform, pool their data, and make it accessible within the EHDS. The costs for organisations that do not have sophisticated data infrastructures in place will be higher than for those who have already implemented these technologies. The resources and technology tools available to extract data for EHDS requests will vary from one organisation to another and could in practice limit their ability to comply with the new requirements. In its position statement on the EHDS, EIT Health therefore called for support to ensure that the framework represents an opportunity rather than a challenge for stakeholders.

This section will focus on government policy to resource implementation effectively and outlines the needs of private data holders identified during this research.

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3.1 How ready is Ireland?

3.1.1 Current landscape

In the recently published Health Information Bill, a provision for a national health data access body, in this case the National Health Information Authority, is to be set up. Furthermore, the Digital Healthcare Strategic Framework 2023 – 2030, a successor to the government's 2013 eHealth Strategy for Ireland , is expected to be published later in 2023. This is designed to complement the Health Information Bill and is expected to provide clarity on the path forward for digitisation.

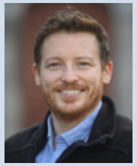
With a fragmented health service landscape for digital in Ireland at present, funding requirements for each stakeholder are set to vary. Areas expected to require sufficient investment to safeguard progress include setting up foundational digital infrastructures and large data platforms, as well as addressing the skills deficit.

Furthermore, there is currently a freeze on the recruitment of managers and administrators within the HSE. IT workers fall under this category, further impacting the ability of hospitals to attract much-needed skills.

3.1.2 Challenges

Many healthcare companies will struggle to resource the change

While mobilising the resources for compliance with the EHDS may be feasible for large pharmaceutical and medtech companies, Ireland's vast community of SMEs and start-ups would likely struggle to secure the funds to fulfil a potential obligation to provide access to their data.



> ***"These businesses are very sensitive to cost, so the downstream effect of a lot of regulation is that new therapies can be delayed in Europe. Many companies we work with in the Translational Medical Device Lab are already focused on moving to the US and delaying EU market entry, and there is a risk that additional requirements for the EHDS will accentuate that problem further," Martin O'Halloran, Director, Translational Medical Device Lab, University of Galway***

Without expected returns on the level of investment required to integrate with the EHDS, such efforts may not be considered a strategic imperative by hospitals, which need to prioritise patient care. *"We would need at least another five data scientists, a platform for all of this information, and the infrastructure. Mandatory or not, we currently do not have the money to invest or the capabilities to deliver what the EHDS requires, especially with no tangible return,"* Moores said.

Setting up the systems and processes to manage data and create secure processing environments in-house could open the door to additional possibilities to commoditise the data based on patient consent and raise funds required to support compliance within private hospitals.

Previously low government funding for technology investments

Throughout the public health system many of the digital upgrades needed to implement the EHDS will require funding at a national level, including to help healthcare institutions roll out EHR systems and make their data accessible in a secure way. As Coughlan reported, there has historically been concern about costs and implementation, and a lack of alignment between the Department of Health and the Department of Public Expenditure on this topic.

3.1.3 Opportunities

Prospects for funding increase

In 2019 the publication of the National Health Information Strategy marked a political paradigm shift which could unlock more comprehensive financial support in the future. *"This strategy was the first clear call for a whole-of-government joint approach to data. From that followed Harnessing Digital, The Digital Ireland Framework, which delineated the possibilities of digital transformation as a way of advancing services, including healthcare, in this country. These are important policy milestones because when something comes from the government as a whole, rather than just a health initiative in isolation, it does have an impact when you're looking for funding,"* said Glynn.

3.2 Priorities for implementation

A national strategy for health data

Mitchell stated that health data should be considered a national strategic asset and thus given the appropriate investment to maximise its potential value. With a national strategy for health data, as a follow on to the Digital Ireland Framework, sufficient resources would be allocated and clear short, medium, and long-term plans put forward. According to Grogan, a commitment of this nature would ensure the right executive sponsorship and buy-in from both the HSE and Department of Health, leading to effective resourcing being deployed.

- Set a national strategy for health data, aligned to the Digital Healthcare Strategic Framework 2023-2030

A commitment to full-scale implementation

At national level, the digital infrastructure for both primary and secondary use of health data is expected to require the majority of government funding. However numerous smaller investments will be needed to help primary care implement new systems and upgrade existing networks.
In this context, additional EU funding to support implementation of the EHDS should not be used solely for offsetting the basic commitments of governments, *"It would be important that any new European funding that becomes available is used to facilitate an ambitious approach to fully implementing the EHDS,"* said Coughlan.
EU funding should anticipate differences in existing digitally enabled infrastructures in health systems across countries, ensuring that the EHDS serves to reduce rather than increase the digital divide for Europe's citizens.

- Allocate funds both to the national digital infrastructure, including a national EHR, and to upgrading local systems and networks
- Leverage EU funding for full-scale implementation of the EHDS including the infrastructure and capabilities training that would be required

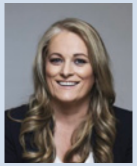
Define the compliance requirements for data holders

To facilitate the investments necessary to comply with the EHDS Regulation for non-government funded players, clarification is needed on the requirements they would be expected to meet, as well as clear communication regarding financial returns. *"As a start-up company in the digital health space, we are privately funded, and therefore need to show that there is going to be a return on the investments we make. It's important to understand the dynamics of investment and fundraising in this area,"* said Corcoran.

- Clearly define the compliance requirements and penalties for industry data holders, especially SMEs
- Define the return on investment and possible business models for industry data holders

Take lessons from the implementation of previous legislation

It is important to recognise the complexity of healthcare and the unintended consequences and costs that can arise from new legislation.



"We must learn from recent regulatory hurdles by bringing together policymakers with the stakeholders who will be directly affected, to ensure that we've the right infrastructure in place supported by effective Governance and the appropriate resources. The infrastructure is not currently in place to achieve the goals of the EHDS." Sinéad Keogh, Head of Sectors & Director, Ibec

- Leverage lessons learned from the implementation of similar legislation, such as the MDR, and provide adequate supports for countries to invest in infrastructure and resources

3.3 Key recommendations

For EU policymakers

- Clearly define the compliance requirements and penalties for industry data holders, especially SMEs
- Define the return on investment and possible business models for industry data holders
- Leverage lessons learned from the implementation of similar legislation, such as the MDR, and provide adequate supports for countries to invest in infrastructure and resources

For national government

- Set a national strategy for health data, aligned to the Digital Healthcare Strategic Framework 2023-2030
- Allocate public funds both to the national digital infrastructure, including a national EHR, and to upgrading local systems and networks
- Leverage EU funding for full-scale implementation of the EHDS including the infrastructure and capabilities training that would be required

4 Quality data

Collection, use, and storage of healthcare data varies between organisations and countries, making it difficult to compare data across different sources and across borders. A common framework is needed to ensure that the data being shared within the EHDS is reliable and meaningful to produce trustworthy and useful research results, yet standards and auditing requirements must be inclusive enough as to allow every member state to participate. In particular, the possibility to use data from EHRs or medical devices for secondary research purposes requires that the reliability of the relevant datasets be scientifically validated. This section will explore the interconnectedness of data, and set recommendations for data standardisation and management based on participant feedback.

4.1 How ready is Ireland?

4.1.1 Current landscape

Pockets of excellence in the system, but no shared learning or interconnectedness

HIQA has published a national catalogue of Ireland's 128 national data collections and has undertaken a review of national data collections to evaluate current practices in collection, sharing, and use of health information.

"Consistent with the results of a readiness assessment carried out by Joint Action TEHDAS, we found some instances of excellent practice, but challenges in relation to organisational governance, data quality and information governance. There was also a lack of consistency and harmonisation in the standards being applied by different data holders," - Barbara Foley, Health Information Quality Manager, HIQA

Extensive studies have been completed by HIQA setting out data quality improvements throughout the healthcare system. In addition to HIQA, the National Office of Clinical Audit (NOCA) and Cancer Trials Ireland were cited as points of reference on data quality for secondary use.

4.1.2 Challenges

Data quality management is not mature within health system institutions

The healthcare system's reliance on paper records means that data management and data quality have not been prioritised within Irish healthcare institutions. Even where digital systems are in place, data quality issues are common wherever the manual intervention of staff is required to input information. *"We have a performance team of five data analysts who manage data quality for our patient-level costing activities: for them, this means picking up on the fact that a person cannot possibly have spent six days in the operating theatre, going back to the nurse who discharged the patient to make sure they did so in due time and that this is reflected in the records,"* said Moores, who expected that quality management on the scale required to make an entire EHR suitable for sharing would pose significant challenges to hospitals' data teams.

The lack of interconnectedness of health data records due to the previous absence of a single patient identifier compounds data quality issues: "When going through my diagnosis, I had a BreastCheck patient identification number, a public number, and a private number. None of these numbers shared any level of connectivity," shared Freeney. This means that the richness of datasets that can be achieved across the full spectrum of care for a patient, including disease-specific registries and clinical trials, has not been available. This makes secondary use for research and innovation difficult.

Uncertain utility of medtech sector data

Although increasing amounts of health-related data are generated within medtech it must be cautioned against integrating large volumes of device-generated data in raw form. This is due to the difficulties its management would pose and its limited utility for generating meaningful insights.

Although aggregating sensor data on parameters like blood pressure could allow epidemiological studies to identify optimal blood pressure for reduced long-term mortality, the information collected by medtech manufacturers is likely much narrower than what would be typical in clinical research. *"If you only have data on blood pressure and stroke, without knowing anything else about those patients' diets, lifestyles, and history, that will have limited utility,"* said O'Halloran.

As data initially collected in commercial research is used to measure different, commercially driven endpoints there can be potential for bias to be introduced. *"Important metrics for commercial companies are readmission to acute care, because that is how their success is measured by their customers, the hospitals. It is a very different motivation to that of an epidemiologist who is looking for predictors of mortality,"* said O'Halloran.

4.1.3 Opportunities

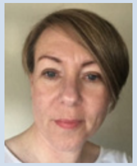
Assess current practices before digitisation begins
Due to the fragmented nature of Ireland's data infrastructure at present, and with relatively little health data available, there is an opportunity to invest in solid foundations for data collection, standardisation, and aggregation early in the digitisation process.
First, a digital maturity audit of Ireland's health service should be undertaken, so that a clear benchmark can be established before moving forward.

> ***"In order to put a realistic plan in place for the EHDS, we need to understand where we are starting from. We can then regionalise our research investment," - David Wall, Chief Information Officer, Tallaght University Hospital***

This audit benchmark, coupled with a clear set of standards, can enable major EHR and other health technologies to be implemented according to universal standards, and thus improve data quality for secondary use.

4.2 Priorities for implementation

Training on the importance of data standardisation
A key priority for Ireland will be to improve and standardise the quality of data collected within the country's healthcare institutions. Healthcare professionals should be educated on the importance of recording high-quality data with the potential for secondary use in mind, with clarity on the long-term benefits of what may seem like an extra set of tasks in their day.



> ***"Digital health is a team sport. Understanding the importance of data standardisation means we will be mindful of data going in, just as much as the data going out." - Loretto Grogan, National Chief Nursing and Midwifery Information Officer, National Digital Health Clinical Office, HSE***

For researchers interacting with health data on a daily basis, a holistic upskilling approach to data analysis is required. *"We have to educate clinicians and researchers on what AI actually is, how we use the data, how we can explain the model outcomes, how the AI systems we develop can be used as clinical support systems, and who is ultimately making the decisions,"* said Carbajo.

- Adopt a coordinated strategy to educate clinicians on data standards to optimise the research potential of the data they record, and researchers on data collection and analysis applied to healthcare

Move quickly to provide clarity on basic data collection
The implementation of robust, standardised EHR systems that define the metrics to be captured, and the creation of a standard automatic procedure for inputting data would be the most effective way of driving the correct behaviours over time. As providers such as Ireland's New Children's Hospital are already rolling out EHRs, the need to move quickly on setting core standards to future-proof practices must be addressed as a priority. This can avoid high costs other member states are currently facing in making their regionalised data interoperable. In the meantime, standardising the clinical documentation we do have before it moves into a digitised format is recommended.

- Leverage the standardisation potential of EHRs to embed data quality
- Move quickly to harmonise data standards country-wide to avoid future interoperability-associated costs

Mandate an independent external agency to monitor and enforce standards
At present, three national organisations have remits relating to the development and implementation of health information standards in Ireland: HIQA, the HSE, and the National Standards Authority of Ireland (NSAI). To optimise the implementation of the EHDS, new national governance structures will be needed, as well as collaboration between existing entities. The mandating of future standards should be considered along with assessing compliance with those standards. A national policy decision is required to define the roles and responsibilities of agencies in standardisation of health information.

Several hospitals would welcome clear guidelines on the basic data to be recorded, and in what structure, to ensure compliance. The National Health Information Authority could take on the role of independent regulator, taking inspiration from the UK's independent Quality Care Commission and National Institute for Health and Care Excellence (NICE). *"It must be given the appropriate authority, funding, and legislation,"* said Wall.

- Mandate the National Health Information Authority, or another equivalent agency, to regulate data collection standards

International best practice

The implementation of standards like the DIACOM format for X-rays in other areas of healthcare data is important to realise the potential of large-scale data aggregation through the EHDS. The field of genetics could be a role model in this area, with longstanding expertise and experience to be found within international initiatives such as the Global Alliance for Genomics and Health. Such standards must be agreed on at European level. To avoid creating its own standards, which could increase complexity and block innovation, the EU should look instead to international best practices.

- Agree on healthcare data standards for Europe in line with international best practices
- Draw on the experience of fields like epidemiology and genetics in dealing with large datasets

Avoid incentivising bias

Regarding the integration of data from the medtech and pharma industries into the EHDS, careful consideration should be given to biases that could be created by placing new requirements on businesses. *"Medtech companies are market-oriented, especially in early clinical trials. The data they gather affects their valuation and attractiveness to investors, so at times bias can be introduced to studies, by selecting the patients most likely to respond to treatment. Requiring them to make their results public before product commercialisation could accentuate this problem further,"* said O'Halloran.

- Encourage post-commercialisation publication of clinical trial data to avoid incentivising bias

4.3 Key recommendations

For EU policymakers

- Agree on healthcare data standards for Europe in line with international best practices
- Draw on the experience of fields like epidemiology and genetics in dealing with large datasets
- Encourage post-market publication of clinical trial data to avoid incentivising bias

For national government

- Adopt a coordinated strategy to educate clinicians on data standards to optimise the research potential of the data they record, and researchers on data collection and analysis applied to healthcare
- Leverage the standardisation potential of EHRs to embed data quality
- Move quickly to harmonise data standards country-wide to avoid future interoperability-associated costs
- Mandate the National Health Information Authority, or another equivalent agency, to regulate data collection standards

5

Closing the loop: The relationship between primary and secondary use

Secondary use of health data can positively impact the primary use in clinical care processes and accelerate the shift from treatment of illness to prediction and prevention in healthcare delivery. Conversely, effective secondary use depends on the quality of data collection in the primary use setting, as HealthData@EU will interface with MyHealth@EU and interoperable EHRs. The level of detail and choice of standards used when health data is documented during the delivery of patient care will determine whether it is reusable for secondary purposes at later stages. In general, a successful integration of data across the primary and secondary use ecosystems will require different actors within these ecosystems to play an active role beyond the interconnected technical infrastructure to be provided at EU level.

This section will examine the current health research ecosystem in Ireland, challenges researchers face, and the recommendations for data flow.

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5.1 How ready is Ireland?

5.1.1 Current landscape

Health research ecosystem

Health research is carried out across universities, industry, health research charities, and within the health service. Ireland's government makes significant investments each year into overall research and innovation activities, and EU funding instruments such as Horizon Europe provide considerable support to research activities.

Key players include the Health Research Board which is a State Agency under the Department of Health and oversees investment in health research activity each year. Other research agencies include Science Foundation Ireland which is the national foundation for investment in scientific and engineering research, and the Irish Research Council. Under 'Impact 2030: Ireland's Research and Innovation strategy,' published in 2022, both of these will merge to form a new research agency .

Over 450 medtech companies operate in Ireland. Four out of five of these companies are either start-ups or SMEs. Significant funding is available to the start-up community in Ireland under the Department of Enterprise, Trade and Employment' Disruptive Technologies Innovation Fund (DTIF) which is a challenge-based fund that aims to drive collaboration between Ireland's world-class research base and industry, building on research undertaken in Ireland and seeding a new wave of start-ups.

5.1.2 Challenges

Immature level of digitisation and regulatory hurdles

Despite favourable conditions in place for research with various funding available at both national and European level, researchers cited encountering challenges in accessing national health data due to perceived restrictions imposed by the Health Research Regulation 2018 and a lack of digital data available locally. Ireland-based researchers often resort to accessing clinical trial data from other markets such as Canada where large datasets are readily available, there is familiarity with the health system, and a shared language.

This lack of complete local datasets and fragmented data sources make informing Irish research challenging. Secondary use findings that flow back into primary use are either of lower quality and fragmented in nature if based on data collected in Ireland or are based on datasets from different population cohorts entirely. With a small population, the potential volume of health data is less than in larger countries putting Ireland's patients and researchers at a disadvantage, and somewhat excluded from the potential of AI and other innovations within the EHDS.

The development of personalised and precision medicine is limited by the inability to identify patients

An absence of connectivity between available datasets and the healthcare settings in which they were created limits their usefulness for research purposes and hampers the development of personalised and precision medicine. "The number one question we get asked by pharmaceutical companies planning clinical trials is, can you please find us the 16 individuals with this particular height, weight, or genetic mutation? We can't just enter that into a search box and look for all these different criteria across diseases and countries. For too long, we have expected pharmaceutical companies to go with what they had to develop medicines. As a result, we still have a lot of adverse drug reactions," said Joanne Hackett, Head of Genomic and Precision Medicine EMEA at IQVIA

Feeding data from secondary use back into healthcare

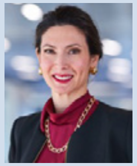
While there are many opportunities to close the loop between primary and secondary use of data by connecting new technologies such as home care services for the elderly with data on these patients during their visits to the hospital, healthcare institutions must also be ready to implement these connections. *"Collaborating with clinicians is difficult in itself, not because of their willingness, but rather because they face many hurdles both to access data and to get the ethical approval to work with researchers and innovators. Even when we achieve a way to collaborate, the prospects for then developing the AI system inside the hospital are poor because that requires buy-in from the management and expertise in medical device certification,"* said Carbajo.

Data ownership concerns

Questions of data ownership, management, and consent would have to be resolved once data begins flowing back and forth between primary and secondary use settings. Clinicians interviewed were optimistic about the Irish healthcare workforce's openness to using digital innovation for patient care but reported differences in individual physicians' willingness to share their own data and collaborate with industry on its development.

5.1.3 Opportunities

Starting with a blank slate
Ireland's relative infrastructural immaturity is an opportunity to invest in data connectivity from the outset, learning from other countries and organisations to anticipate the data requirements. Ireland's pharmacies could be potential enablers:



"The data sitting in pharmacies in this country is actually very standardised, which makes it some of the easiest data to gather and cleanse. Patients also have close relationships with their pharmacists, which makes these professionals uniquely qualified to fill gaps in the data, for example by noticing side-effects of medicines that patients had not necessarily identified," - Joanne Hackett, Head of Genomic and Precision Medicine EMEA, IQVIA

Potential process efficiencies
Fully digitalised health systems can inform industry on the healthcare needs within a given population, streamline how patients get access to trials through identification, and improve the measurement of real-world outcomes. However, a lot more work will be needed to implement digital systems, interoperability standards and data templates within healthcare before these processes can begin to be automated using AI and smart engines at scale.

5.2 Priorities for implementation

Connectivity between datasets
On the side of clinical research, a path to contacting individual patients through their healthcare team to obtain more information will be necessary. *"With a lot more dynamic consent happening today, patients have the ability to go back and change their consent, but conversely we need to be able to approach them to request an additional sample of blood, for example, which they can easily get drawn the next time they go in for a flu shot,"* said Hackett.

- Invest in connectivity between datasets and the healthcare setting in which they were generated, including a path to recontact patients via their healthcare team

Clear usage and reporting guidelines for research
A further safeguard to ensure the outputs of research are truly beneficial to healthcare processes would be to precisely define what types of data from secondary use should be released back into healthcare.

"Clinicians tell us that the worst thing we could do is to drown them in data and expect them to mine it for useful insights as yet another task they don't have time for in their busy workday," - Louise Corcoran

- Specify the characteristics for data from secondary use to be shared with healthcare

Traceability of data
The traceability of data across primary and secondary use would be an important vector of trust and acceptance towards new outputs and technologies being fed back into healthcare. *"The opportunity for innovation and new products to reach people faster is huge with the EHDS, but we need to have a good understanding of where the original primary data came from to ensure that whatever we learn can actually be used in a product to help patients,"* said Corcoran.

- Ensure traceability of data across primary and secondary use platforms

5.3 Key recommendations

For EU policymakers

- Specify the characteristics for data from secondary use to be shared with healthcare

For national government

- Ensure traceability of data across primary and secondary use platforms
- Invest in connectivity between datasets and the healthcare setting in which they were generated, including a path to recontact patients via their healthcare team

6

Awareness, education and communication: Towards a data-driven culture in healthcare

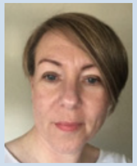
Achieving the full potential and benefits of secondary use of health data through the EHDS will require buy-in across all stakeholder groups, from clinicians, healthcare workers and payers, through the academic research community, pharmaceutical and health technology industries, all the way to patients, their carers and citizens at large. At present, perceptions and preparedness to participate differ across these groups and give rise to varying educational and communication needs, one of the most salient being the empowerment of individual citizens to exercise their rights in an informed manner. This will require strategic efforts to illustrate the life-changing benefits of secondary use of data, how it can optimise care, and dispel underlying concerns and distrust around the security and necessity of data-sharing.

This section will examine data culture, public trust, and set out the varied stakeholder positions.

6.1 How ready is Ireland?

6.1.1 Current landscape

Data culture



"We're in a digital-first society, but we don't have a digital-first health service," - Loretto Grogan

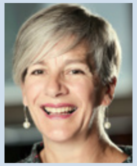
Data collection and storage practices are not yet embedded in Ireland's healthcare culture, due to the largely paper-based system across hospitals to date. The culture around health data in Ireland has traditionally been heavily focused on protecting the data itself, at times to the detriment of the individuals it concerns.

Public trust
According to a 2021 HIQA report on National Public Engagement on Health Information, 90% of participants surveyed trust GPs to keep their health information safe and secure, and to share only relevant information. 94% think it is important that health information is used to improve the quality of care provided to patients. 86% think it is important that all healthcare professionals involved in their care have access to their digital record.

6.1.2 Challenges

Opposing stakeholder positions

Patients and clinicians
Overall, there is enthusiasm among patients and clinicians on the potential of the EHDS for research and innovation.



"By sharing patient information we can gain access to clinical trials abroad. We're a little isolated at the moment and can't run clinical trials for all patient groups. Once we get involved in European data sharing we'll have access to endless possibilities," - Siobhán Freeney

Researchers
Researchers interviewed are sceptical about how the EHDS will work in practice, with many unanswered questions on consent and the mechanisms of data sharing. Research is currently restricted by a lack of data capture in Ireland, and the lack of large-scale clinical trials taking place. Many would like to see a clear path forward.

While the move towards open datasets within the EHDS would be welcomed by some research groups in the interest of good science, resistance is anticipated to come from the field of clinical research, where negative trial results are rarely published. According to O'Halloran, however, this is a problem that the EHDS could actually solve by mandating the release of all clinical trial data within a given timeframe.

Industry
Concerns were raised by industry on the data sharing aspect of the framework. Particularly for smaller companies, their data is their IP and reflects their valuation. There was a request for IP rights to be protected under the EHDS, and reassurance on the security of the data shared.

Healthcare system
Differing perceptions across public and private hospitals exist.
Public hospital management see the potential for healthcare systems to be managed more efficiently and effectively through greater use of health data.
Private hospitals have concerns over the ownership of certain types of data, such as operational data, and anticipated loss of control over this information. Conversely, value was attributed to these institutions gaining access to population health data as an avenue to conduct operational benchmarking using data obtained via the EHDS.

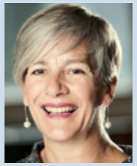
Awareness of the proposed regulation is low
Despite the momentous changes the EHDS would usher in throughout the healthcare ecosystem and the stated goal of having it enacted in 2025, awareness of the proposed legislation and its requirements to different stakeholders currently remains low in Ireland.

6.1.3 Opportunities

A cultural shift from data protection to data-sharing during the pandemic
A change in attitudes as the pandemic unfolded facilitated a rise in awareness of the potential of digitisation. Views in politics and across Irish society are now converging around the benefits of digital transformation and data-sharing in healthcare.

> ***"The single biggest issue we faced in trying to respond in the early months of the pandemic was our inability to understand what was happening with the virus because of the disconnected use of data across the system. What happened during COVID was not about technology. It was about the fact that people came together around a common problem with shared priorities and objectives." - Ronan Glynn***

Patients as the drivers of a cultural change in healthcare
Patient associations could be an enabling force for fostering trust and acceptance towards the EHDS in Ireland, driven by motivations that range from controlling their own health data, to improving access to clinical trials for underserved patient populations which could help better understanding of the disease.



> ***"Patients can help to deliver the message across the healthcare system and to the wider public that at some point in time, every citizen is going to want access to their health data for some very specific reasons," - Siobhan Freeney***

In a context where patient representatives are increasingly invited to join healthcare steering and decision-making committees in Ireland, their voices could carry far and wide on this topic.

6.2 Priorities for implementation

Awareness building by National Health Information Authority
There is a growing need to raise awareness of the EHDS and its implications for various stakeholders throughout the healthcare ecosystem, to help people and organisations prepare for its implementation. The proposed National Health Information Authority could lead this effort, taking lessons learned from the HealthData@EU pilot project to help answer practical questions and make the benefits tangible. Key issues on which clarification is needed include: Who will be able to access which datasets, for which specific purposes? Which entities and use purposes will be explicitly prohibited within the EHDS? What data will individual data holders be mandated to provide? By when will they have to provide it? Is it at the point of post-commercialisation? What will be the penalties for not doing so? What safeguards will be in place to protect commercially sensitive information?

- Raise awareness of the EHDS and its requirements to stakeholders through the National Health Information Authority and other communication channels
- Leverage lessons learnt from the HealthData@EU pilot to answer practical questions surrounding data governance and use
- Provide clear guidelines for industry on timelines for data-sharing and reassurances on the security of the data

- Make guideline information and processes transparent and user-friendly, mindful of the variety of stakeholders and different knowledge levels of the communities that need to understand, interpret and implement the guidance

Citizen and patient engagement to create transparency
Awareness campaigns should focus on creating transparency around where data is stored, who collects it, for what purposes it is used, and most importantly – the life-saving potential of data sharing. A coordinated and strategic approach to public engagement is key to building trust in the next phase of change. Patient advocates could be involved in delivering the message during the implementation phase as part of a large-scale public awareness campaign.

- Emphasise the life-saving potential of data sharing for citizens, while providing transparency around data collection, storage, use, and the privacy safeguards in place to protect citizens' data

Promote self-monitoring digital tools
Reassurance should be provided about data security protections that will be put in place so that people's data cannot be used inappropriately. *"People need to know, for example, that personal details will not be shared, but rather information to identify population cohorts who, for example, live near polluted sites. This information helps detect disease trends which can inform where targeted prevention and screening initiatives may be needed,"* said Hackett.

There is a need for digital tools to empower citizens to manage their own health and health data just as easily as they do their personal finances with online banking applications. This could be facilitated by adopting measures to enhance digital literacy among the general public, in line with the target of increasing the share of adults with at least basic digital skills to 80% by 2030, under the Digital Ireland Framework.

- Empower citizens with digital tools to manage their own health and health data
- Adopt measures to enhance digital literacy among citizens

6.3 Key recommendations

For EU policymakers

- Leverage lessons learnt from the HealthData@EU pilot to answer practical questions surrounding data governance and use
- Provide clear guidelines for industry on timelines for data-sharing and reassurances on the security of the data

For national government

- Raise awareness of the EHDS and its requirements to stakeholders through the National Health Information Authority and other communication channels
- Make guideline information and processes transparent and user-friendly, mindful of the variety of stakeholders and different knowledge levels of the communities that need to understand, interpret and implement the guidance
- Emphasise the life-saving potential of data sharing for citizens, while providing transparency around data collection, storage, use, and the privacy safeguards in place to protect citizens' data
- Empower citizens with digital tools to manage their own health and health data
- Adopt measures to enhance digital literacy among citizens

Conclusion

In the process of implementing the EHDS, Ireland will have many challenges to overcome, the biggest of which will certainly be the digitisation of 5 million citizens' health records. Infrastructure for secondary use of data will also need to be built almost entirely from scratch, and managed by people who are not yet on the payroll in most healthcare institutions and statutory bodies. Nonetheless, the dominant impression that emerged from these discussions is that the EHDS is coming at just the right time for the country as political consensus on the need for sustained investment into digital transformation converges with heightened public awareness and acceptance in the wake of the COVID-19 pandemic.

Although it is in many ways starting with a blank slate, Ireland has the opportunity to position itself as a leader in EHDS implementation without having to deal with the legacy issues that other countries face such as interoperability or public engagement. Among its competitive advantages, world-class scientists and an internationally leading health technology industry stand poised to revolutionise how data is used to advance knowledge and how healthcare is delivered in Ireland. Achieving this will require an enabling framework of data governance, where legal uncertainty is minimised, incentives are aligned towards contributing data of the best possible quality, and flexibility allows for future technological advances and new types of health data. It will also rely on the country's ability to mobilise sufficient funds, for everything from a national EHR and a health data access body capable of coordinating and enforcing data standardisation, interoperability, and access, all the way to education in data analytics and AI for healthcare professionals and researchers. Before any of this, however, awareness will need to be raised among key stakeholders—the healthcare system, patients, citizens—and support provided to help them prepare for the far-reaching changes ahead. Their engagement will in no small part determine Ireland's ability to make the leap from where it is today to full-scale implementation of the EHDS in 2025.

Participants

Drafting support provided by Alison Bouissou.

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Roundtable	
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Dr. Ronan Glynn	Health Sector Lead, EY Ireland. Former Deputy Chief Medical Officer, Department of Health
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Dr. Sinéad Keogh (PhD)	Head of Sectors, Director, BioPharmaChem Ireland, Ibec [Leading the Where Digital Health Thrives Campaign in Ibec]
Siobhán Freeney	Patient Educator, Advocate and Breast Cancer Survivor. Founder, Lobular Ireland
Louise Corcoran	VP Quality and Regulatory Affairs, FIRE1
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David Dowling	Healthcare Systems Partner, Roche Ireland
John Coughlan	former Government Affairs Partner, Roche Ireland

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