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

Deliverable 8.1

WORK PACKAGE 8
PROGRAMME PLAN 2024-2027

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1. Background

1.1 The European Health Data Space

The European data strategy, announced in February 2020, sets out to create common European Data Spaces in a number of strategic fields, including finance, agriculture and health, with the ultimate aim of creating a single market for data across all EU Member States.(1) These data spaces will facilitate the reuse of data across different sectors of the economy and society. Two crucial pieces of legislation, the Data Governance Act and the Data Act, have been put in place to provide the legislative basis and regulatory framework for achieving the objectives of the strategy.(2, 3) The EU Commission has also prioritised the development of the necessary technological systems and infrastructures to optimise data use and reuse across the EU and drive innovation. The EU's Digital Decade policy programme, launched in January 2023, sets out targets and objectives for 2030 in a number of key areas, including the digitalisation of public services and ensuring all citizens have access to their medical records online.(4)

The European Health Data Space (EHDS) is the first common data space to emerge from the European data strategy. The foundations of the EHDS were laid through the EU Joint Action, 'Towards a European Health Data Space' (TEHDAS). This Joint Action aimed to help EU Member States and the European Commission to develop concepts and proposals to promote the secondary use of health data to benefit public health and health research and innovation in Europe.(5) The recommendations from the TEHDAS project were used by the European Commission to inform the development of a proposal for a regulation on the EHDS in May 2022. The European Parliament formally approved the proposal for the establishment of the EHDS in April 2024, following which the EHDS regulation entered into force.(6-8)

The EHDS will empower individuals to take control of their own health data and make it easier to access and exchange health data across EU Member States, both to support healthcare delivery (known as primary use of data) and to facilitate other uses of the data, including research and policy-making (known as secondary use of data). In relation to the secondary use of data, in particular, the potential benefits of the EHDS include:

- For citizens and patients: Assurance that their data is being used to its full potential to drive improvements in population health and the provision of services, and is being managed securely in a way that ensures their privacy and confidentiality is protected
- For data users, the broader workforce and the health service as a whole: Access to a wide range of data and linked datasets, through secure

processing environments (SPEs), leading to greater opportunities for research and innovation; a national contact point and a more streamlined and efficient system for accessing health data via the issuing of data permits; and greater capacity for evidence-based policy and decision-making

- For data holders: Support to make their datasets more readily available and to maximise the utility and potential impact; and training and guidance to promote the enhancement of the quality of their data.

Following on from the work of the TEHDAS Joint Action, the HealthData@EU pilot set out to build a pilot version of the EHDS infrastructure for the secondary use of health data, referred to as HealthData@EU.(9) The project is developing a network infrastructure and developing services to support data users, defined as persons who have lawful access to personal or non-personal data for secondary use. It will also provide guidelines for data standards, data quality, data security and data transfers to support the EHDS infrastructure. In addition, a further EU Joint Action, TEHDAS2, commenced in 2024 with the aim of developing common guidelines and technical specifications to facilitate secure access to health data and strengthen European collaboration in using data efficiently.(10)

Acknowledging that trust is fundamental to the success of the EHDS, the EU Commission has prioritised ensuring secure and trustworthy platforms for facilitating access to, and processing of, health data. As such, the EHDS Regulation builds on the General Data Protection Regulation (GDPR), the Data Governance Act and the Data Act. In addition, among all Member States, there is need for legislative and operational preparations to ensure readiness to implement the EHDS. In Ireland, the Health Information Bill 2024 is the first piece of legislation to support its preparations for the full implementation of the EHDS.(11)

1.2 HealthData@IE 2023-2027

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

The Department of Health, in collaboration with the Health Information and Quality Authority (HIQA) and the Health Research Board (HRB), was awarded funding for the HealthData@IE project under the EU4Health programme to support the establishment of HDAB services in Ireland. Working with key stakeholders in the

Health Service Executive (HSE) and across the health system, the HealthData@IE project will focus on the development of national infrastructures needed for data access, including data access infrastructure systems that have been identified by the EU Commission as being core Digital Business Capabilities for HDABs.(12) These include a Data Access Application Management System (DAAMS) to receive, track and process applications and to issue permits; a national health metadata catalogue to facilitate data discovery, and SPEs to ensure the secure processing of health data. The HealthData@IE project will also deliver important programmes of work centred on data quality enhancement, engagement and dissemination, and training and education for data users, data holders, HDAB staff and citizens.

1.3 Overview of Work Package 8: Data quality enhancement

Work Package 8 of the HealthData@IE project, coordinated by HIQA, comprises a programme of work centred on enhancing the quality of data that will be made available through the HDAB and enabling data holders to improve and enhance the quality of their data. An emphasis will be placed on supporting data holders to prepare for the EHDS and the establishment of health data access services in Ireland, and ensuring they can meet their obligations relating to the secondary use of data.

The Data Quality Framework produced by the TEHDAS Joint Action made several recommendations to the European Commission and to Member States on data quality and utility in the EHDS. It sets out the main elements of data quality and documents data quality activities that are applicable to every stage of the data lifecycle, with a particular focus on the secondary use of data. Under the EHDS regualtion, data holders will have several responsibilities with regard to data quality. For example, they will be required to apply a data quality and utility label to their datasets before they can be made available through a HDAB. Such a label is currently being developed by the QUANTUM project. QUANTUM aims to create a common label system that can be used across Europe to report on the quality and utility of datasets so that data users can identify high-quality data for research and decision-making.(20) Under the EHDS regulation, there will also be requirements with regard to the use of standards and interoperability, and an obligation for organisations to assess levels of compliance among data holders with the various requirements under the EHDS.

A key focus of the Work Package 8 programme of work is to assess the level of preparedness of various data holders in Ireland for the establishment of HDAB services. Once this information is available and any gaps identified, it will inform the development of:

- A maturity framework for the *National Standards for Information Management in Health and Social Care* and an associated digital self-assessment tool for data holders to assess the quality of their data, in addition to a benchmarking tool that can be used to asses and compare data holders
- Guidance and training materials to support data holders in getting ready for the implementation of the EHDS and the establishment of HDAB services in Ireland, with a particular focus on ensuring they can meet requirements with regard to data quality
- A compliance assessment framework to inform the approach to undertaking thematic reviews of data quality in health and social care
- A national interoperability framework incorporating standards for data discovery, semantic interoperability and interoperable communication based on well-established interoperability standards to ensure data can be shared between data holders and future HDAB services.

The Project Team will ensure that all outputs are aligned with other relevant initiatives, including TEHDAS2, the HealthData@EU Pilot, and the QUANTUM project. Ongoing engagement with key stakeholders will be central to the entire programme of work and help ensure all outputs meet the needs of data holders.

1.4 Purpose of this Programme Plan

This Programme Plan sets out in detail HIQA's approach to delivering on the four tasks that fall under Work Package 8 and is the first grant deliverable for Work Package 8. Table 1 lists the four tasks and associated deliverables as set out in the HealthData@IE Grant Agreement. The full list of milestones and deliverables associated with Work Package 8 are listed in Appendix 1.

Table 1. Detail of tasks for Work Package 8

Task	Associated Deliverables, as set out in the HealthData@IE Grant Agreement
Task 8.1 Development of a digital self-assessment tool	8.1 – Programme Plan agreed by working group by December 2024 8.2 – Report on findings of pilot phase by January 2026 8.3 – Self-assessment tool available for use by October 2026 8.4 – Report on self-assessment tool completion for priority national data collections by October 2027
Task 8.2	8.5 – Publication of guidance materials by April 2026

Task	Associated Deliverables, as set out in the HealthData@IE Grant Agreement
Development of guidance and training materials	8.6 – Publication of training materials by February 2027 8.7 – Training delivered by October 2027 8.8 – Online peer support network established by October 2027
Task 8.3 Development of compliance assessment framework	8.9 – Compliance assessment framework piloted in two sites by April 2026 8.10 – Publication of compliance assessment framework by October 2027 8.11 – Publication of benchmarking tool by October 2027
Task 8.4 Development of a national interoperability framework	8.12 – Publication of readiness assessment by October 2025 8.13 – Interoperability assessment piloted in two sites by April 2027 8.14 – Publication of Interoperability Framework by October 2027

This plan has been developed by the HIQA project team, in collaboration with the Work Package 8 Working Group and HIQA's internal grant oversight group. It has been informed by the project milestones and deliverables, as set out in the HealthData@IE Grant Agreement and sets out the plan for the implementation of Work Package 8 of the HealthData@IE project in Ireland up to 2027.

1.5 Target Audience

The target audience for the resources developed as part of Work Package 8 is health data holders, who, under Article 2 of the EHDS regulation, are defined as persons, services or organisations that process, or have the ability to make available, electronic health data for the purpose of providing healthcare services or for various secondary use purposes.(8)

This includes holders of data that fall into one of the categories of data for secondary use which have been outlined in Article 51 of the EHDS regulation, such as holders of electronic health record (EHR) data, data from devices and wellness applications, administrative health data, clinical trial data, and registry data.

The full definition of data holders under the EHDS regulation and the full list of categories of data for secondary use are outlined in Appendix 2.

Within the context of the EHDS, data holders will be responsible for implementing measures to assess and report on the quality, utility, and maturity of their datasets. By delivering on Work Package 8, HIQA aims to develop a self-assessment tool, guidance and educational materials, a compliance assessment framework and a national interoperability framework specifically tailored to help data holders meet their obligations with regard to data quality under the EHDS regulation and to support them to enhance their data quality practices. A further specific aim of Work Package 8 is to support data holders in Ireland to implement, apply, and assess the data quality, utility and maturity label being developed by QUANTUM. In doing so, HIQA is supporting data holders to ensure that their datasets meet the standards required for secondary use of health data within the EHDS.

2. Objectives

The overall aims of Work Package 8, coordinated by HIQA, are to enhance the quality of electronic health data made available through a future HDAB service and to support data holders in enhancing the quality of their data. The specific objectives are summarised in Table 2.

Table 2. Work Package 8 objectives

Objective		Task*
1	**Undertake a readiness assessment** To undertake a readiness assessment in order to obtain a baseline view of data holders' levels of preparedness for the establishment of HDAB services in Ireland across multiple areas, including: data quality policies and processes; capacity for data linkage; capacity to share metadata and data; information technology systems and interoperability; and data quality guidance and training by December 2025.	8.2, 8.4
2	**Develop a maturity framework and digital self-assessment tool, and an associated benchmarking tool** To develop a maturity framework for the *National Standards for Information Management in Health and Social Care* and an associated digital self-assessment tool (SAT) for data holders to assess their levels of data and information management maturity, as well as a benchmarking tool that can be used to assess and compare data holders by October 2027.	8.1, 8.3
3	**Develop guidance for data holders** To develop guidance to support data holders to better understand their obligations with regard to data quality under the EHDS and to promote changes in practices that will lead to enhancements in data quality by October 2026.	8.2
4	**Develop and disseminate data quality training and educational materials** To develop and disseminate data quality training and educational materials for data holders, including adopting or adapting relevant resources produced by the QUANTUM project, and to host workshops and a national conference by October 2027.	8.2
5	**Develop an online peer support network** To develop an online peer support network for data holders to facilitate knowledge and information sharing in relation to data quality enhancement by October 2027.	8.2

Objective		Task*
6	**Develop a data quality compliance assessment framework** To develop a framework for conducting thematic reviews of data quality in health and social care, for use by HIQA reviewers when assessing compliance with the *National Standards for Information Management in Health and Social Care* by October 2027.	8.3
7	**Develop a national interoperability framework** To develop a national interoperability framework to set out interoperability guidelines in the form of common principles, recommendations, models and specifications for the provision of data from data holders to the HDAB by October 2027.	8.4

* As outlined in the HealthData@IE Grant Agreement

Objective 1: Undertake a readiness assessment

To undertake a readiness assessment in order to obtain a baseline view of data holders' levels of preparedness for the establishment of HDAB services in Ireland across multiple areas, including: data quality policies and processes; capacity for data linkage; capacity to share metadata and data; information technology systems and interoperability; and data quality guidance and training by December 2025.

By December 2025, HIQA will undertake a readiness assessment in order to obtain a baseline view of data holders' levels of preparedness for the implementation of the EHDS regulation and the establishment of HDAB services in Ireland across multiple areas, with a particular focus on data quality and interoperability. Holders of data from the EHDS categories of data for secondary use (see Appendix 2) will be eligible to participate in the readiness assessment, including holders of data from primary care systems, pharmacy systems, hospital and community healthcare systems, registries and other national data collections.

The overarching aim of the readiness assessment is to obtain a baseline view of data holders' levels of preparedness for the establishment of HDAB services in Ireland across multiple areas and identify where gaps exist with regard to data holders' future obligations under the EHDS regulation.

The specific objectives of the readiness assessment are:

1. To explore the **feasibility of reusing and linking** health and social care data from different sources for secondary use purposes in Ireland by assessing if potential linkage variables are present across datasets
2. To identify whether there is **capacity** among data holders to provide metadata and data in the necessary formats to a future HDAB service
3. To determine the strengths and weaknesses of data holders' existing ICT systems **interoperability** and their ability to support the exchange of data with a future HDAB service
4. To explore perceived **barriers and facilitators** to the implementation of the EHDS and the establishment of HDAB services in Ireland from the perspectives of data holders
5. To identify and prioritise data holders' **data quality guidance and training needs**.

The readiness assessment will include carrying out a desktop review of available evidence and undertaking a survey of data holders, followed up with focus groups and interviews as required. A purposefully-designed readiness assessment survey will be used to ensure it is appropriate and fit-for-purpose for evaluating how prepared Irish data holders are for the EHDS and the establishment of HDAB services in the areas of data linkage capacity, ICT systems and interoperability, and data quality guidance and training.

The findings of the readiness assessment and the key learnings will be written up to summarise the findings in relation to data linkage capacity, ICT systems and interoperability, and data quality guidance and training. These findings and key learnings will be used by the project team to inform all subsequent outputs, in particular the data quality guidance document (Objective 3), the data quality guidance and educational materials (Objective 4), the online peer support network (Objective 5), and the national interoperability framework (Objective 7).

Table 3. Objective 1 timelines

Stage	Action	Timeline
1.	Project planning and stakeholder mapping: ▪ Selection and development of three use cases and identification of the relevant data holders to be involved in the readiness assessment survey, focus groups and interviews ▪ Initial contact with the data holders that are included in the three use cases ▪ Identification and mapping of data holders to the 17 EHDS categories of data for secondary use ▪ Development of a protocol for the readiness assessment ▪ Development of the readiness assessment survey/tool and the focus group interview schedule/topic guide	October – December 2024
2.	▪ Finalise readiness assessment survey/tool ▪ Undertake planning for the focus groups and interviews ▪ Publish initial guidance and general information on the EHDS for data holders	January – February 2025
3.	Undertake the readiness assessment: ▪ Undertake desktop review of publicly available information	March – August 2025

Stage	Action	Timeline
	▪ Host online survey ▪ Run focus groups ▪ Hold interviews	
4.	Analyse and write up the findings and key learnings from the readiness assessment.	August – September 2025
5.	Publish the findings of the readiness assessment relating to interoperability.	October 2025
6.	Publish the key findings of the readiness assessment for each use case, as well as the findings relating to feasibility of data linkage and data quality training needs.	December 2025

Objective 2: Develop a maturity framework and digital self-assessment tool and an associated benchmarking tool

To develop a maturity framework for the *National Standards for Information Management in Health and Social Care* and an associated digital self-assessment tool (SAT) for data holders to assess their levels of data and information management maturity, as well as a benchmarking tool that can be used to assess and compare data holders by October 2027.

By October 2026, HIQA will develop and pilot a maturity framework for the *National Standards for Information Management in Health and Social Care* and an associated digital self-assessment tool (SAT) to enable data holders to self-assess their levels of data and information management maturity. By October 2027, HIQA will develop a benchmarking tool that is based on the maturity framework and digital self-assessment tool, and can be used to assess and compare data holders with regard to their data and information management maturity.

The *National Standards for Information Management in Health and Social Care* were published by HIQA in 2024 and aim to contribute to safer, better care by improving the management of health and social care information.(13) The development of a maturity framework and an associated digital SAT for these national standards will support their implementation and will help data holders to identify areas for improvement with regard to data and information management maturity. The benchmarking tool that is subsequently developed will be used by organisations, including future HDAB services, to make assessments and draw comparisons among data holders with regard to their data and information management maturity. By supporting the development of more mature data quality systems, data holders will be better prepared to ensure their compliance with the national standards and meet their future obligations under both the EHDS regulation and Ireland's Health Information Bill.

The development of this maturity framework, digital SAT and benchmarking tool, and the associated implementation and dissemination plan, will be carried out in consultation with key stakeholders within the Irish health and social care sector, including members of the Work Package 8 Working Group. In addition, HIQA will liaise with key individuals and organisations across Europe to ensure key learnings and recommendations from other ongoing projects, including QUANTUM, TEHDAS2 and the HealthData@EU Pilot, are incorporated as relevant.

Software designers will be engaged to design and develop the digital SAT. The tender for the software designers will form part of a broader tender package encompassing other requirements of the HealthData@IE project.

Table 4. Objective 2 timelines

Stage	Action	Timeline
1.	▪ Explore general maturity models, including the Capability Maturity Model, and how they might be applied to the *National Standards for Information Management in Health and Social Care*. ▪ Undertake a desktop review and engage with relevant stakeholders to identify and explore existing data, information and digital maturity models or frameworks and self-assessment tools. ▪ Conduct a mapping exercise to identify how the compliance levels for the *National Standards for Information Management in Health and Social Care* (as outlined in the Guide to the Assessment Judgment Framework) align with the maturity levels in the Capability Maturity Model.(14)	October – December 2024
2.	▪ Develop draft maturity framework for the national standards, collaborating with the Working Group to define the levels of maturity and the descriptors for each level. ▪ Convert the maturity framework into a format that data holders can use to self-assess their levels of maturity (for example MS Excel or Adobe). ▪ Prepare tender requirements for digital SAT and hosting platform. Identify and engage with software designers to start the tender process.	January – May 2025
3.	▪ Pilot the SAT with a representative group of data holders.	June – October 2025
4.	▪ Analyse data from the pilot of the digital SAT and publish a report of the findings.	November 2025 – January 2026
5.	▪ Revise and finalise the SAT based on the findings of the pilot, and incorporate key learnings and/or recommendations from QUANTUM, TEHDAS2 and the HealthData@EU Pilot. ▪ Engage with software designers to develop a digital version of the SAT. ▪ Define the scope, and commence development, of the benchmarking tool with the Working Group, incorporating key learnings and recommendations from the pilot of the digital SAT, as well as	January – October 2026

Stage	Action	Timeline
	outputs from QUANTUM, TEHADS2 and the HealthData@EU Pilot.	
6.	▪ Roll out the digital SAT to a representative group of data holders. ▪ Support these data holders to apply the SAT and provide recommendations on improvement opportunities. ▪ Pilot the benchmarking tool with selected data holders.	October 2026 – March 2027
7.	▪ Finalise the benchmarking tool based on findings of the pilot. ▪ Develop an implementation plan for the full roll-out of the digital SAT and the benchmarking tool to all data holders. ▪ Develop implementation support tools, for example, a webinar, a guidance document and an animation to raise awareness of the digital SAT and guide data holders on how to apply the tool to their datasets.	June – September 2027
8.	▪ Publish a report outlining the findings and key learnings from the initial roll-out of the digital SAT. ▪ Make the digital SAT and implementation support tools publicly available for use by all data holders. ▪ Publish the benchmarking tool.	October 2027

Objective 3: Develop guidance for data holders

To develop guidance to support data holders to better understand their obligations with regard to data quality under the EHDS and to promote changes in practices that will lead to enhancements in data quality by October 2026.

By October 2026, HIQA will develop resources for data holders to support them to prepare for the implementation of the EHDS and the establishment of HDAB services in Ireland. A particular focus will be placed on supporting data holders to better understand their obligations with regard to data quality under the EHDS regulation and to empower them to enhance their data quality practices and bring them in line with EHDS requirements. This will include the publication of initial guidance and general information on the EHDS for data holders in March 2025, prior to the readiness assessment being conducted, followed by a more detailed guidance document in October 2026, provisionally titled *Preparing for the EHDS and the establishment of health data access services: Guidance to enhance data quality and maximise the value of Ireland's health and social care data*.

These guidance documents will be developed through a process of ongoing engagement with data holders and will take into account their needs and priorities, as well as perceived barriers and facilitators to the successful implementation of the EHDS and the establishment of HDAB services in Ireland. Key learnings from QUANTUM, TEHDAS, TEHDAS2, and the work of the EHDS2 Capacity Building Team will also be incorporated as appropriate.(15) The more detailed guidance document will undergo a public consultation in 2026 in order to engage with, and gain the perspectives of, a wider audience than that which can be reached through targeted engagement methods. Examples of the types of topics to be addressed in both guidance documents include:

- What the EHDS means for the secondary use of data
- What the establishment of HDAB services in Ireland means for data holders
- Data quality requirements for data holders under the EHDS regulation
- Key data quality criteria and indicators
- Developing a data quality strategy for your organisation
- Developing a data quality improvement plan
- The Five Safes Framework
- The FAIR (Findable, Accessible, Interoperable, and Reusable) Principles.

Table 5. Objective 3 timelines

Stage	Action	Timeline
1.	▪ Develop initial guidance for data holders in advance of the readiness assessment being undertaken as part of the wider Work Package 8 programme of work (Objective 1).	November 2024 – March 2025
2.	▪ During the readiness assessment, engage with data holders to identify and prioritise key areas and topics for inclusion in the more detailed guidance document, and identity perceived barriers and facilitators to the implementation of the EHDS and the establishment of HDAB services in Ireland. ▪ Analyse and write up the findings and key learnings from the readiness assessment relating to data quality guidance and education needs.	January – October 2025
3.	▪ Develop draft document: *Preparing for the EHDS and the establishment of HDAB services: Guidance to enhance data quality and maximise the value of Ireland's health and social care data*, incorporating key learnings from the readiness assessment and collaborating with the Working Group. ▪ Prepare for the public consultation.	October 2025 – April 2026
4.	▪ Undertake a public consultation on the draft data quality guidance document.	May – June 2026
5.	▪ Revise and finalise the data quality guidance document based on the findings of the public consultation. ▪ Develop dissemination and communication plan for the guidance.	July – October 2026
6.	▪ Publish *Preparing for the EHDS and the establishment of HDAB services: Guidance to enhance data quality and maximise the value of Ireland's health and social care data*, and make publicly available for data holders to access.	October 2026

Objective 4: Develop and disseminate data quality training and educational materials

To develop and disseminate data quality training and educational materials for data holders, including adopting or adapting relevant resources produced by the QUANTUM project, and to host workshops and a national conference by October 2027.

Training and educational materials and online learning courses

By October 2027, HIQA will develop data quality training and educational materials and make these available online. The materials will be developed through a process of ongoing consultation with key data holders and will take into account their needs and priorities, as identified during the readiness assessment (Objective 1). They will also be informed by the data quality training and educational materials being developed by QUANTUM and TEHDAS2. Key learnings from the work of the EHDS2 Capacity Building Team will also be incorporated. For example, QUANTUM is developing an educational curriculum, referred to as the QUANTUM Academy, which comprises several modules, each focusing on a specific area of data quality. TEHDAS2 is developing guidelines and technical specifications to facilitate the implementation of the EHDS regulation and it is likely that there will be some outputs relating to data quality. Therefore, as part of Work Package 8, HIQA will disseminate information on both projects' outputs, and where necessary, will adapt available materials for the Irish context. In doing so, HIQA will support data holders in Ireland to implement, apply, and assess the data quality, utility and maturity label being developed by QUANTUM, and support them in working towards meeting the standards required for secondary use of health data within the EHDS.

All educational and other materials developed will be hosted on an online platform that is being developed as part of the wider HealthData@IE project.

Workshops

Throughout 2026 and 2027, a series of workshops for data holders will be hosted to promote the data quality guidance and training materials and to communicate and disseminate information on the work of the wider HealthData@IE project. The locations and format of these workshops (in-person or online) will be determined based on the needs and preferences of data holders and will be accessible to all relevant data holders.

Conference

A national conference on the theme of data quality will be hosted in 2027. The conference will include workshops and presentations from subject matter experts in the area of data quality. The timing of the conference will coincide with the completion of the HealthData@IE project and a key objective will be to engage with stakeholders from across the health sector and to deliver key messages with regard to Ireland's readiness for the implementation of the EHDS and the establishment of HDAB services.

Table 6. Objective 4 timelines

Stage	Action	Timeline
1.	▪ During the readiness assessment being undertaken as part of the wider Work Package 8 programme of work, engage with data holders to identify and prioritise their data quality training needs. ▪ Analyse and write up the findings and key learnings from the readiness assessment relating to data quality guidance and education needs.	January – October 2025
2.	▪ Develop data quality training and educational materials. ▪ Adapt, for the Irish context, data quality training materials, guidelines, templates and checklists for data holders developed by QUANTUM and TEHDAS2. ▪ Undertake user testing and piloting of online training courses and associated materials with data holders. ▪ Host workshops to promote the data quality guidance and training materials	October 2025 – October 2027
3.	▪ Host national conference for data holders.	April – October 2027

Objective 5: Develop an online peer support network

To develop an online peer support network for data holders to facilitate knowledge and information sharing in relation to data quality enhancement by October 2027.

By October 2027, HIQA will develop an online peer support network that facilitates knowledge sharing among data holders. This peer support network will be hosted on the online platform being developed as part of the wider HealthData@IE project and aligned to other developments taking place at an EU-level. This peer support network will provide a central point for data holders to connect and learn from each other, and share relevant information, including key learning materials and resources, as well as information on relevant events. The peer support network may also facilitate communication among data holders in Ireland by acting as a platform for hosting online meetings and discussion forums. To develop the peer support network, the project team will set out the requirements and specifications and undergo a public procurement process, prior to engaging with sub-contractors to develop the technical solution.

Table 7. Objective 5 timelines

Stage	Action	Timeline
1.	▪ During the readiness assessment being undertaken as part of the wider Work Package 8 programme of work, engage with data holders to obtain their views on the specifications of the online peer support network to ensure the platform meets their needs. ▪ Define requirements and specifications for an online peer support network to facilitate knowledge sharing among data holders. ▪ Complete tendering process for sub-contractors to deliver the online peer support network.	January – December 2025
2.	▪ Collaborate with software developers to design the online peer support network.	January – December 2026
3.	▪ Undertake user testing and share feedback with software developers to incorporate revisions.	January – May 2027
4.	▪ Launch the online peer support network to facilitate knowledge sharing among data holders.	October 2027

Objective 6: Develop a compliance assessment framework

To develop and pilot a framework for conducting thematic reviews of data quality in health and social care, for use by HIQA reviewers to assess compliance with the *National Standards for Information Management in Health and Social Care* by October 2027.

The EHDS Data Quality Framework, set out by TEHDAS, recommends the regular review of data holders with regard to their data and their quality assurance procedures.(16) By October 2027, HIQA will develop and pilot a framework to enable HIQA reviewers to conduct thematic reviews of data quality by assessing compliance with data quality elements of the *National Standards for Information Management in Health and Social Care* which were published in 2024. Thematic reviews focus on quality improvement in a specific aspect of a service or practice. The purpose of taking a themed approach to reviews is to promote improvements across practices as they relate to that theme. With regard to data quality, it is intended that thematic reviews of organisations and services that hold health and social care data will act to:

- focus data holders' efforts on improving data quality policies and processes
- incentivise data holders to reflect on their current approaches to data quality, share learnings and drive collective and individual improvements
- provide assurances to HIQA and the public with regard to the quality of available health and social care data.

To date, HIQA has undertaken five reviews of compliance with the *Information Management Standards for National Health and Social Care Data Collections*, which were published in 2017.(17-21) These reviews of information management practices were broad in nature, encompassing all of the standards, and had a particular focus on the governance, leadership and management arrangements of the managing organisations. In order to develop this framework for conducting thematic reviews of data quality, the project team will engage extensively with HIQA staff members who participated in those reviews, and key learnings and observations will be incorporated where relevant. This new compliance assessment framework for conducting thematic reviews of data quality will support HIQA's structured review programme for assessing compliance with the *National Standards for Information Management in Health and Social Care* (2024). The final version of the framework will incorporate key learnings or recommendations from QUANTUM, TEHDAS2 and the HealthData@EU Pilot, where relevant, in order to ensure it aligns with EHDS requirements relating to the assessment of compliance where possible.

Table 8. Objective 6 timelines

Stage	Action	Timeline
1.	▪ Identify key stakeholders to engage with about the development of the framework, including reviewers and inspectors from HIQA. ▪ Schedule interviews with key stakeholders.	November 2024 – January 2025
2.	▪ Engage with HIQA staff members about the proposed compliance assessment framework to discuss key learnings from previous HIQA reviews and identify perceived barriers and facilitators to conducting thematic reviews of data quality.	January – March 2025
3.	▪ Develop draft compliance assessment framework for carrying out thematic reviews of data quality in health and social care. ▪ Seek feedback on the draft framework from HIQA staff members who participated in the initial engagement (Stage 2). ▪ Identify data holders to participate in the pilot of the framework.	March – October 2025
4.	▪ Pilot the compliance assessment framework with data holders by carrying out two thematic reviews of data quality.	October 2025 – April 2026
5.	▪ Develop a summary of findings from the pilot of the compliance assessment framework.	April – December 2026
6.	▪ Revise and finalise the compliance assessment framework based on the findings of the pilot, and incorporating key learnings and or recommendations from QUANTUM, TEHDAS2 and the HealthData@EU Pilot. ▪ Develop dissemination and communication plan for the framework.	January – September 2027
7.	▪ Publish the compliance assessment framework and ensure the dissemination plan is fully implemented.	October 2027

Objective 7: Develop a national interoperability framework

To develop a national interoperability framework to set out interoperability guidelines in the form of common principles, recommendations, models and specifications for the data holders to provide data to a HDAB service by October 2027.

By October 2027, HIQA will develop a national interoperability framework that will incorporate standards for semantic interoperability and interoperable communication based on well-established interoperability standards. Such a framework will support data holders to provide data to a HDAB service.

The national interoperability framework will be informed by the findings of the readiness assessment (Objective 1), as well as the outputs of other ongoing projects, including technical specifications and guidelines being developed by TEHDAS2 and the HealthData@EU Pilot. Engagement with organisations in other countries who collect data for secondary use from data holders will also be undertaken.

The national interoperability framework will be developed in collaboration with key stakeholders from across the health and social care sector. A subgroup of the Work Package 8 Working Group will be convened, bringing together experts with knowledge and experience in semantic and data exchange standards to inform its development. This subgroup will report on its progress to the wider Work Package 8 Working Group.

The draft national interoperability framework will be piloted with key data holders and will undergo a public consultation in order to engage with, and gain the perspective of, a wider audience than that which can be reached through targeted engagement methods.

A dissemination plan will be developed and implemented to ensure the national interoperability framework is promoted effectively to data holders to support their preparations for the implementation of the EHDS and the establishment of HDAB services in Ireland.

Table 9. Objective 7 timelines

Stage	Action	Timeline
1.	Undertake and publish evidence syntheses to inform the development of a draft national interoperability framework, including: • Completing a desktop review of well-established interoperability frameworks used	February – Oct 2025

Stage	Action	Timeline
	internationally, such as the European Interoperability Framework and TEHDAS recommendations on standards for sematic and data exchange. • Reviewing the outputs of other ongoing projects, including technical specifications and guidelines developed by TEHDAS2 and the HealthData@EU Pilot. • Engaging with international organisations who collect data for secondary use from data holders. • Analysing the findings from the readiness assessment undertaken as part of the wider Work Package 8 programme of work (Objective 1).	
2.	▪ Convene National Interoperability Framework sub-group of the Work Package 8 Working Group to agree scope, process and stakeholder engagement plan for the framework.	September 2025
3.	▪ In conjunction with the National Interoperability Framework sub-group, develop a draft National Interoperability Framework and associated guidance.	October 2025 – October 2026
4.	▪ Undertake a public consultation on the draft national interoperability framework and associated guidance.	May – June 2026
5.	▪ Analyse findings from the public consultation and update the national interoperability framework and associated guidance accordingly.	October 2026
6.	▪ Pilot the national interoperability framework and associated guidance with two data holders.	October 2026 – April 2027
7.	▪ Revise the draft national interoperability framework and associated guidance based on the findings and key learnings from the pilot.	April – August 2027
8.	▪ Finalise dissemination plan for the national interoperability framework and associated guidance.	April 2027
9.	▪ Publish the national interoperability framework and associated guidance, and ensure the dissemination plan is fully implemented.	October 2027

3. Implementation of this programme plan

In order to inform the content and format of the resources being developed as part of Work Package 8, HIQA will carry out:

- an **international review of practices and available resources** in other jurisdictions
- development and testing of three **use cases**
- **extensive stakeholder engagement**, including the convening of a working group; targeted engagement with data holders via surveys, focus groups and interviews; piloting of tools and resources; and public consultations.

The team's use of these strategies is described in more detail in the following section.

3.1 International review

An international review was completed to identify examples of good practice and key learnings from jurisdictions with established HDABs (or similar organisations) in place. This included a desktop review, as well as semi-structured interviews with key individuals from each of the jurisdictions reviewed. The five jurisdictions reviewed were: Finland, Belgium, France, Northern Ireland and New South Wales, Australia. Details of the relevant organisations in each jurisdiction are provided in Table 10.

Table 10. Details of jurisdictions included in the international review

Jurisdiction	Relevant organisations
Finland	Findata
Belgium	Health Data Agency
France	Health Data Hub Directorate of Research, Studies, Evaluation and Statistics
Northern Ireland	Honest Broker Service Digital Health and Social Care Northern Ireland
New South Wales, Australia	Centre for Health Record Linkage The Population Health Research Network

A summary of the key findings relating to data quality, including other relevant projects and initiatives and examples of available guidance and educational resources for data holders, is provided below.

European initiatives

The EU Joint Action, **TEHDAS**, produced a number of recommendations relating to data quality and set out a Data Quality Framework for the EHDS. These recommendations highlighted the importance of data holders conducting regular self-assessments of data quality, maintaining strong data governance practices and publishing the results of these self-assessments to promote public confidence and demonstrate transparency.(16, 22-24) In addition, a specific recommendation was made for the need for data holders to use a data quality and utility label to inform data users about the quality and utility characteristics of their datasets, enabling users to select datasets that best fit their needs.(25) With regard to assessing compliance with data quality standards and regulations, TEHDAS recommendations included the following:

- Data quality should be assessed at institutional level and the EHDS nodes should be responsible for ensuring transparency, as well as the implementation of data quality assessment procedures.
- Processes for benchmarking and continuous improvement should be developed to assist with the measurement of data quality.(23, 26)

The TEHDAS Joint Action also produced guidance on the use of common data interoperability standards to enhance the use of health data for secondary purposes. Using national surveys and interviews, a working group consensus process, and an assessment framework, comparisons were made on the current use of standards for discoverability, semantic interoperability and interoperable communication between nodes.(27, 28) A report was produced which assessed and evaluated nineteen standards, and nine recommendations were drawn on how the standards should be implemented in the EHDS. These recommendations were a part of the TEHDAS Data Quality Framework.

The **TEHDAS2** Joint Action is continuing preparations to enable the secondary use of health data in the EHDS. This includes addressing the gaps in infrastructure and data access services by developing necessary guidelines, technical specifications and tools.(29) Guidelines will be produced for data holders and HDABs on technical specifications for national metadata catalogues and data enrichment capabilities.(30)

The **QUANTUM** project, underway until 2026, aims to create a common label system that can be used across Europe to report on the quality and utility of datasets. The data quality labelling system will enable data users to identify high-quality data for research and decision-making. QUANTUM is addressing Article 56 of the EHDS Regulation which mandates the use of a labelling system to demonstrate the quality and usefulness of data for being used for secondary purposes. This label system will enable researchers, policymakers, and healthcare professionals to identify high-quality data for research and decision-making. It will:

- Develop a common understanding across project stakeholders on how to access datasets' quality, utility and level of data holders maturity
- Design, develop, and test the label system with data holders
- Develop recommendations to support the implementation of the QUANTUM label.(31)

The **HealthData@EU Pilot** project is currently working across 17 countries to create a pilot version of the EHDS infrastructure for the secondary use of data. Five use cases are being used to illustrate the feasibility and the potential of reusing data from several European countries. The use cases encompass a range of research topics, including anti-microbial resistance, COVID-19, cardiometabolic diseases and colorectal cancer. In addition to the use cases, the HealthData@EU Pilot includes a number of other technical work packages, including one focused on metadata catalogues and metadata standards (Work Package 6), and one on data interoperability, quality and protection (Work Package 8). Reports outlining an EU metadata standard, based on an extension of the DCAT-AP (Data Catalogue Application profile for data portals in Europe) metadata standard,(32) as well as recommendations on standards for data interoperability, querying and exchange, are due to be published in 2024/2025. Furthermore, the EHDS2 Capacity Building Team are working to enable less digitally mature healthcare institutions to realise the vision of the EHDS.

Responsibility for data quality

While data quality assurance checks are generally carried out on data submitted to a HDAB service, across the jurisdictions included in this international review, responsibility for data quality remains with the data holders. This is underpinned in Finland through the use of a regulation which outlines requirements for data holders to prepare descriptions of the contents of their data collections.(33) This enables the suitability of the data for the uses referred to in Finland's Act on the Secondary Use of Health and Social Data to be assessed.(34) The purposes of the Regulation are outlined as follows:

- to ensure uniform and high-quality description of the data resources of the organisations referred to in Section 6 of the Act on the Secondary Use of Health and Social Data
- to allow safe and effective use of health and social data resources

- to ensure that Findata can perform its tasks and provide its customers with services in an effective and high-quality manner in accordance with the principles of good governance
- to promote the interoperability of data collections held by different organisations.

Similarly, the French Health Data Hub (HDH) developed a 'Data Controller Charter' which sets out the respective roles and responsibilities of data holders and the HDH. The Charter details that the responsibility for enhancing data quality sits with the data holders.(35)

Assessing data quality

A number of the HDAB services reviewed utilise a labelling system, or similar, to enable data users to explore the quality of available datasets. For example, researchers from Northern Ireland can view data collections available through the Health Data Research UK (HDRUK) Innovation Gateway webpage, using the HDRUK data utility framework.(36) This allows researchers to search the collections according to various data utility parameters. The framework contains five categories, separated across a range of dimensions, each of which is qualitatively evaluated to describe the characteristics of a dataset. Scores are assigned progressively along a four-level rating scale from Bronze to Platinum, with a definition for each level across the five categories. According to the Data Utility Framework report, use of the framework enables:

- data holders to communicate the utility of their dataset and any improvements made to it
- users to identify datasets that meet the minimum requirements for their specific purpose
- system leaders and funders to identify where to invest in data quality improvements and to evaluate what improvements have happened as a result of their investments.(36)

In France, the Agence du Numérique en Santé (Digital Health Agency) utilise a Convergence platform so that data holders can self-assess their compliance with its interoperability standards.(37) The results of these assessments can be made available to the public. The agency also supports data holders to develop improvement plans to improve their compliance.

Provision of support

The established HDABs included in this international review have implemented a range of guidance and support tools to promote data quality enhancement among data holders. For example, France’s Agence du Numérique en Santé has published a range of resources to support the enhancement of data quality across digital health data nationally. This includes a technical doctrine document which sets out the interoperability standards for health data.(37) In addition, the ‘La communauté d’entraide du Système National des Données de Santé’ (SNDS) operate a peer support forum which facilitates communication among members and the Health Data Hub on a range of heath data topics.(38) Members can post queries which are available for others to review, along with the responses. Links to a range of useful tools and resources are provided, including information on national and international data standards frameworks.

Provision of training and educational resources for data quality

The Belgian Health Data Agency provides online resources and courses through its ‘Health Data Academy’, an online platform which acts as a central location for hosting relevant information, including learning materials and initiatives and information on events, for data holders, data users and citizens.(39) Available courses for data holders cover topics such as analysing an organisation’s data maturity and how best to ensure data quality through controls and data quality process and standards. These resources include descriptions of data quality and metrics to ensure quality. The Health Data Agency provides supports to organisations during their data maturity analysis. Three options for support include end-to-end support, advice, and assistance through the data maturity analysis process. The French Health Data Hub hosts an online ‘meetup’ forum with over 3,000 members.(40) Through this forum, the Health Data Hub organises regular meetings to discuss current projects involving the wider Health Data Tools. Recordings of previous meetings are available for review at a later date. Over 100 events have been hosted to date.(40)

Maturity frameworks and self-assessment tools

Maturity frameworks describe how an organisation’s processes can progress from ad-hoc and chaotic to more mature and disciplined. With regard to data quality and information management, a maturity framework can provide a structured path for continuous improvement, enabling an organisation to self-assess their current strengths and weaknesses and guide improvement and the adoption of best practices.

Examples of published data maturity models include the Capability Maturity Model (CMM), which was originally designed to improve software development processes but has since been adapted for various domains.(41) Examples of the application of maturity models to digital health include the Digital Maturity Framework developed by

Health Data Research UK and the Digital Transformation Toolkit developed by the Government of South Australia.(42, 43) A data holders maturity model is being developed as part of the QUANTUM project, based on existing maturity models, including the CMM. As part of this task, levels of maturity for key dimensions affecting data management and data quality management are being proposed.

3.2 Use Cases

In planning for the readiness assessment of data holders (Objective 1), three 'use cases' have been selected in consultation with the HealthData@IE project Steering Committee and the Work Package 8 Working Group, to explore the feasibility of reusing and linking available data from different sources for secondary use purposes in Ireland. The topics of the three use cases were selected based on an analysis undertaken of the use cases included in the HealthData@EU Pilot which were chosen by the European Commission, as well as the minimum categories of electronic data for secondary use which have been outlined in the EHDS Regulation.(7, 9) The topics of the Data Access, Storage, Sharing and Linkage (DASSL) case studies were also taken into consideration.(44)

The three 'use cases' selected are as follows:

1. **Influenza:** exploring the feasibility of using and linking data from different sources to carry out surveillance of influenza and explore rates of testing, vaccination, and hospitalisation among vulnerable sub-groups of the population in Ireland
2. **Type-1 diabetes:** exploring the feasibility of using and linking data from different sources to compare care pathways, measure clinical outcomes and costs of care, and enable better planning of services for Type 1 diabetes in Ireland
3. **Colorectal cancer:** exploring the feasibility of using and linking data from different sources to gain a better understanding of risk factors, causes and long-term outcomes of colorectal cancer in Ireland.

Through the process of developing the three use cases, the key datasets and the associated data holders will be identified and selected for inclusion in the various stages of the readiness assessment. Examples of the types of relevant datasets are outlined in Table 11.

Table 11. Sources of data for each use case

Use case	Influenza	Type-1 diabetes	Colorectal cancer
Data sources	HIPE PCRS GP management systems CIDR COVAX system Hospital PAS NOCA	HIPE PCRS GP management systems CDMP PHIS NOCA	NCRI BowelScreen Genetic and genomic data (sources to be identified) PHIS

Key: CDMP, Chronic Disease Management Programme; CIDR, Computerised Infectious Disease Reporting; GP, General Practitioner; HIPE, Hospital Inpatient Enquiry; NCRI, National Cancer Registry Ireland; NOCA, National Office for Clinical Audit; PAS, Patient Administration System; PCRS, Primary Care Reimbursement Service; PHIS, Public Health Information System.

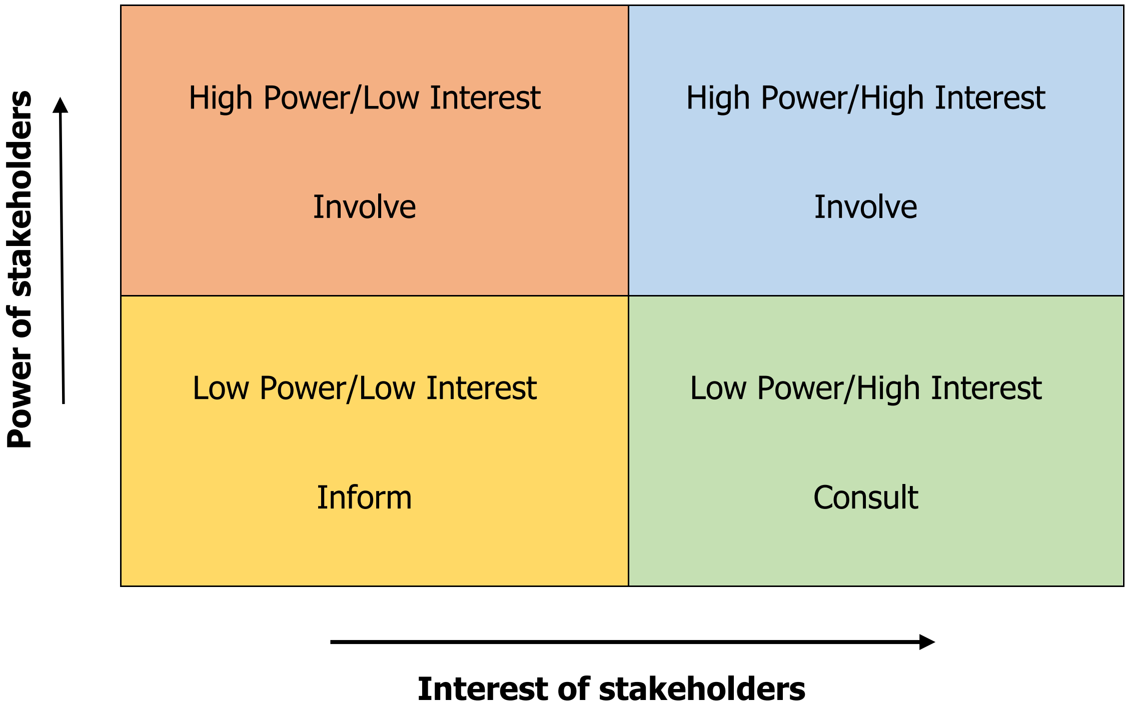
Through the process of carrying out the readiness assessment (Objective 1), HIQA will engage with the relevant data holders for each use case, as well as other interested parties via surveys, focus groups and interviews to explore key questions, particularly whether key linkage variables are present across datasets and whether there is capacity among the data holders to provide the data in the necessary format to allow such linkage to occur safely and securely. For each use case, HIQA will produce a summary report of the key findings.

3.3 Stakeholder engagement

To deliver on this programme of work, a Stakeholder Engagement Plan was developed. To ensure all relevant stakeholders have an opportunity to inform this work, the Project Team carried out a stakeholder mapping exercise to identify and prioritise a wide range of stakeholders. Given data holders are the primary audience for the tools and resources being developed as part of Work Package 8, they were the primary stakeholder group included in this exercise. To ensure alignment with the EHDS regulation, the team focused on ensuring that the stakeholder mapping exercise included representation from each of the 17 EHDS categories of data for secondary use (see Appendix 2). Other stakeholder groups included relevant government departments, representatives of various HSE divisions, data users with experience of accessing and linking data from different sources, and patient partners.

Using the Power/Interest matrix (Figure 1), stakeholders were categorised based on their level of influence and interest in the topic of data quality.(45) This enabled the project team to identify the most appropriate way of engaging with each group of stakeholders over the course of the project. For example, many of the stakeholders in the 'High Power/High Interest' quadrant were identified as having a significant influence and interest in the area of health data quality and being crucial players in the establishment of HDAB services in Ireland and were invited to sit on the working group; while those in the 'Low Power/High Interest' quadrant were identified as lacking significant power or influence but holding a strong interest in data quality so were deemed to be more suitable for engaging with through surveys, focus groups and interviews at various stages of the project. Details of the ways in which the project team will engage with the various stakeholders are set out in the following section. Stakeholders' levels of interest and influence will be monitored throughout the project to identify if their level of involvement should be revised.

Figure 1 Stakeholders Power/Interest matrix



High Power/Low Interest Involve	High Power/High Interest Involve
Low Power/Low Interest Inform	Low Power/High Interest Consult

Following the completion of the stakeholder mapping exercise, three main stakeholder engagement strategies are being utilised going forward:

- Close collaboration with a working group
- Targeted engagement with data holders through surveys, focus groups and interviews
- Undertaking public consultations.

An overview of the team's approach to utilising these three categories is outlined in more detail in the following section.

Working Group

A Working Group has been convened to actively contribute to the successful and timely completion of key project milestones and deliverables through providing expert advice, reviewing and providing feedback on all project outputs, and supporting stakeholder engagement at key stages. This group is comprised of representatives from the Health Service Executive (HSE), Department of Health, Central Statistics Office, Health Research Board, National Cancer Registry of Ireland, National Office of Clinical Audit, Office of the Government Chief Information Officer, University of Limerick, and the Royal College of Surgeons Ireland, as well as a patient partner, nominated to represent the HSE National Patient and Service User Forum.

The Working Group will meet regularly and actively contribute to the project in various ways including:

- reviewing and contributing to this Programme Plan
- providing input to the topics of the three proposed use cases
- actively participating in the development of all tools and resources, including the maturity framework and associated self-assessment tool and benchmarking tool; guidance and training materials; compliance assessment framework; readiness assessment and interoperability framework to enable data quality enhancement for data holders and provide feedback on draft versions at key stages
- providing their perspectives on priority areas and training needs of data holders
- assisting in the selection of data holders for piloting of all tools and resources
- assisting in planning for the promotion and dissemination of all tools and resources.

Targeted engagement with data holders

The Project Team will engage with data holders through online surveys, focus groups and interviews at various stages of the project to:

- identify the preparedness of various data holders in Ireland for the establishment of HDAB services

- understand the current data quality policies and processes among data holders and identify any gaps
- explore the feasibility of reusing and linking health and social care data from different sources for secondary use purposes
- identify their data quality guidance and training needs
- establish priority topics for inclusion in the guidance document and the training and educational materials
- explore preferences for the design, format and content of the online peer support network, self-assessment tool and compliance assessment framework
- test online training resources and tools to facilitate self-assessment of data maturity and compliance
- plan and identify preferences with regard the in-person workshops and the national conference
- determine the ability of data holders' existing information and communications technology (ICT) systems to enable the exchange of data with HDAB services (interoperability).

Public consultation

Key project outputs, including the guidance document, *Preparing for the EHDS and the establishment of health data access services: Guidance to enhance data quality and maximise the value of Ireland's health and social care data* (Objective 2) and the National Interoperability Framework (Objective 7) will undergo public consultations to ensure they are reviewed by wider audiences than can be reached through targeted engagement methods. The public consultations will be planned in collaboration with Working Group members and other key stakeholders. They will be held for six to eight weeks, following which responses will be collated and analysed for relevance and applicability. Based on the findings of the public consultations, the project team will incorporate appropriate revisions to the guidance document and the National Interoperability Framework prior to finalising and publishing them.

Piloting

At various stages of this project, tools and resources developed as part of this work package will be tested and piloted with a representative group of data holders in order to ensure they are usable, accessible and fit-for-purpose and to inform the development and implementation processes for each tool or resource. In particular, the following pilots will be conducted:

- Pilot of the **self-assessment tool** with a representative group of data holders to test the usability of the tool and identify any gaps or barriers to implementation
- Pilot of the **compliance assessment framework** by undertaking thematic reviews of data quality among two data holders
- Pilot of the **benchmarking tool** with a representative group of data holders to test the usability and applicability of the tool in various settings
- Pilot of the **national interoperability framework** with data holders to inform the development and implementation process

Feedback from these pilots will be incorporated into these tools and resources before they are disseminated to all data holders.

3.4 Monitoring

The implementation of this programme plan will be the responsibility of the Work Package 8 Project Team who will work in collaboration with the Work Package 8 Working Group (see Appendix 3). The entire Work Package 8 programme of work will be monitored and overseen by HIQA’s internal project oversight group which meets monthly (see Appendix 4). Updates on Work Package 8 activities, including progress on the implementation of this plan, will be provided to the HealthData@IE Grant Consortium Steering Committee at its monthly meetings. Formal monitoring reports will be submitted by HIQA to the Department of Health, as required, for submission to the EU.

4. Next steps

This Programme Plan will guide the development and piloting of all tools, resources and use cases developed as part of Work Package 8.

The readiness assessment, set out under Objective 1, will take place in 2025 and will provide a baseline view of data holders’ levels of preparedness for the establishment of HDAB services in Ireland across many areas. It includes the development and testing of three use cases to test the feasibility of linking health data from various sources and will provide invaluable information with regard to Ireland’s preparedness for the EHDS. The findings of this readiness assessment, due to be published in October 2025, will inform many of the other work package deliverables, including the guidance and training (Objectives 3, 4 and 5) and the national interoperability framework (Objective 7). Work on the development and piloting of the digital SAT (Objective 2) and the compliance assessment framework (Objective 6) will also commence in the coming months.

In order to ensure that all outputs from Work Package 8 are aligned with ongoing EU-wide initiatives, the project team will continue to actively participate in, and engage with, relevant groups, including the QUANTUM project and the EHDS2 Communities of Practice.

5. Appendices

Appendix 1. Work Package 8 milestones and deliverables

Milestones		**Deliverables**	
Task 8.1			
MS 17	Working Group established (M12 October 2024)	**D 8.1**	Programme plan agreed by WG (M14 December 2024)
MS 18	Pilot self-assessment tool (M24 October 2025)	**D 8.2**	Report findings of pilot phase (M27 January 2026)
MS 19	Digital self-assessment tool developed (M36 October 2026)	**D 8.3**	SAT available for use (M36 October 2026)
MS 20	Implementation - rollout high priority NDCs (M36-48 October 2026 - October 2027)	**D 8.4**	Report on SAT for priority NDCs (M48 October 2027)
Task 8.2			
MS 21	Guidance & education plan (M12 October 2024)	**-**	-
MS 22	Guidance materials developed (M30 April 2026)	**D 8.5**	Publication of guidance materials (M30 April 2026)
MS 23	Training materials developed (M40 February 2027)	**D 8.6**	Publication of training materials (M40 February 2027)
MS 24	Training delivered (regional workshops and conferences) (M48 October 2027)	**D 8.7**	Training delivered (regional workshops and conferences) (M24-48 October 2025 - October 2027)
MS 25	Online peer-support network established (M48 October 2027)	**D 8.8**	Online peer-support network established (M48 October 2027)

Task 8.3			
MS 26	Working Group established (M12 October 2024)	**-**	-
MS 27	Draft compliance assessment framework developed (M24 October 2025)	**-**	-
MS 28	Pilot of compliance assessment framework (M24-40 October 2025 - February 2027)	**D 8.9**	Compliance assessment framework piloted in two sites (M30 April 2026)
MS 29	Final compliance assessment framework developed (M42 April 2027)	**D 8.10**	Publication of compliance assessment framework (M48 October 2027)
MS 30	Benchmarking tool developed (M48 October 2027)	**D 8.11**	Publication of benchmarking tool (M48 October 2027)
Task 8.4			
MS 31	Working Group established (M12 October 2024)	**-**	-
MS 32	Undertake Readiness Assessment (M12-24 October 2024 - October 2025)	**D 8.12**	Publication of Readiness assessment (M24 October 2025)
MS 33	Develop draft Interoperability Framework (M18-36 April 2025 - October 2026)	**-**	-
MS 34	Pilot of Interoperability Framework (M36-42 October 2026 - April 2027)	**D 8.13**	Interoperability Framework piloted in two sites (M42 April 2027)
MS 35	Final Interoperability (M48 October 2027)	**D 8.14**	Publication of Interoperability Framework (M48 October 2027)

Appendix 2. EHDS data holders and categories of data for secondary use

Article 2 of the EHDS defines health data holders as:

> "any natural or legal person, public authority, agency or other body in the healthcare or the care sectors, including reimbursement services where necessary, as well as any natural or legal person developing products or services intended for the health, healthcare or care sectors, developing or manufacturing wellness applications, performing research in relation to the healthcare or care sectors or acting as a mortality registry, as well as any Union institution, body, office or agency, that has
>
> i. either the right or obligation, in accordance with applicable Union or national law and in its capacity as a controller or joint controller, to process personal electronic health data for the provision of healthcare or care or for the purposes of public health, reimbursement, research, innovation, policy making, official statistics or patient safety or for regulatory purposes;
>
> ii. or the ability to make available non-personal electronic health data through the control of the technical design of a product and related services, including by registering, providing, restricting access to or exchanging such data".(8)

Article 51 sets out the categories of data for secondary use as:

a) Electronic health data from EHRs
b) Data on factors impacting on health, including socio economic, environmental and behavioural determinants of health
c) Aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing
d) Data on pathogens that impact human health
e) Healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements
f) Human genetic, epigenomic and genomic data
g) Other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data
h) Personal electronic health data automatically generated through medical devices

i) Data from wellness applications
j) Data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person
k) Data from population-based health data registries such as public health registries
l) Data from medical registries and mortality registries
m) Data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council34, Regulation (EU) 2017/745 and Regulation (EU) 2017/746
n) Other health data from medical devices
o) Data from registries for medicinal products and medical devices
p) Data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results
q) Health data from biobanks and associated databases.(8)

Appendix 3. Work Package 8 Working Group members

Name	Organisation – Unit Title
Barbara Foley (Chair)	Health Information and Quality Authority – Health Information Quality & Assurance Deputy Director
Gabriela Avram	Health Service Executive – National Patient Forum Patient Partner
Brendan Brady	Department of Health – Health Information Policy Unit Data Officer
Leonard Browne	University of Limerick – School of Medicine Senior Research Fellow (Biostatistics)
Helen Conroy	Department of Health – Health Information Policy Unit
Sarah Craig	Health Research Board Head of National Health Information Systems
Louise Cullen	Health Service Executive – Health Protection Surveillance Centre Principal Epidemiologist
Loretto Grogan	Health Service Executive – Office of the Chief Clinical Officer Chief Information Officer – Nursing and Midwifery
Niall Halliday	Health Service Executive – Office of the Chief Clinical Officer Chief Information Officer – Health and Social Care Professionals
Fionnola Kelly	National Office for Clinical Audit Head of Data Analytics & Research
Jean Kelly	National Cancer Registry Ireland Data Quality Manager
Lorraine McNerney	Department of Public Expenditure, NDP Delivery and Reform – Office of the Government Chief Information Officer Head of Data Governance
Elaine Meehan	Health Information and Quality Authority – Health Information Quality & Assurance Acting Programme Manager, Work Package 8
Frank Moriarty	Royal College of Surgeons Ireland – School of Pharmacy and Bimolecular Sciences Senior Lecturer
Kevin O'Carroll	Health Information and Quality Authority – Health Information Standards Standards and Technology Manager
Sanela Smith	Central Statistics Office – Health & Social Cohesion Division Statistician
Patricia Wilson	Health Service Executive – Office of the Chief Information Officer ICT Project Manager – Shared Care Record

Appendix 4. HIQA internal project oversight group members

Name	**Role**
Rachel Flynn (Chair)	Director – Health Information & Standards
Suzanne Barror	Health Information Quality Manager (Work Package 6)
Deirdre Connolly	Acting Deputy Director – Health Information Standards
Barbara Foley	Deputy Director – Health Information Quality & Assurance
Marie Higgins	Acting Programme Manager (Work Package 2)
Elaine Meehan	Acting Programme Manager (Work Package 8)
Kevin O'Carroll	Standards and Technology Manager

Appendix 5. HIQA Work Package 8 Project Team members

Name	**Role**
Elaine Meehan	Acting Programme Manager
Shauna McCarthy	Senior Business Analyst
Lisa McSherry	Senior Business Analyst
Kevin O'Carroll	Standards and Technology Manager
Connie O'Regan	Research Officer
Alice Reetham	Senior Business Analyst

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