D6.1 Guideline for health data holders on making personal and non-personal electronic health data available for reuse

TEHDAS2 – Second Joint Action Towards the European Health Data Space

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0 Document info

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Contents

1 Executive summary

This guideline provides practical, high-level guidance to health data holders (HDHs) on their role in making personal and non-personal electronic health data available for secondary use under the European Health Data Space (EHDS) Regulation. It supports HDHs in understanding and navigating their obligations once a health data access body (HDAB) has issued a data permit (Art. 68) or approved a health data request (Art. 69).

HDHs comprise a wide and heterogeneous group of organisations, including healthcare providers, public authorities, research institutions, registries, insurers, and developers of health-related services and devices.

Under Article 60 of the EHDS Regulation, HDHs are legally required to:

- Make relevant electronic health data available to the HDAB in accordance with an issued data permit or an approved health data request, where the data fall within the minimum categories listed in Article 51.
- Provide the requested data within the prescribed time limits, namely within three months from receipt of the request by the HDAB, with a possible extension of up to three additional months in duly justified cases.
- Submit and maintain dataset descriptions (metadata) for inclusion in the national dataset catalogue and verify their accuracy at least once per year, in line with Articles 60(3) and 77.
- Ensure access to non-personal electronic health data through trusted open databases, where applicable, in accordance with Article 60(5).
- Cooperate with the HDAB for supervisory and enforcement purposes, including providing information necessary to verify compliance (Art. 63).

While HDHs are responsible for making data available, other tasks such as assessing access applications, deciding on access, and performing certain data preparation activities are assigned to HDABs or, where applicable, to trusted health data holders (THDH). For regular HDHs, mandatory involvement in the data provision process is primarily limited to extracting and supplying the data in line with the criteria set out in the data permit or request approval and complying with the applicable legal, organisational, and technical safeguards. Further involvement in data preparation may occur in practice, depending on national arrangements.

In addition to mandatory duties, this guideline describes recommended practices based on TEHDAS2 expert experience and common implementation patterns across Member States. These practices are not legally binding and do not create additional obligations but may support effective and proportionate implementation of the EHDS. Examples include organising internal workflows to manage timelines, performing basic feasibility and validation checks, maintaining clear communication with the HDAB, and, where appropriate, applying a part of data preparation measures close to the data source in line with national arrangements.

By following these recommendations, HDHs may strengthen their preparedness to comply with mandatory EHDS obligations and align with national governance structures, thereby

contributing to a harmonised and secure approach to the secondary use of health data across Europe.

In summary, this guideline focuses on and explains the mandatory duties of HDHs under the EHDS Regulation and on explaining the minimum process for making data available. It distinguishes clearly between mandatory requirements arising directly from the Regulation and recommended practices that reflect expert experience but are not legally binding. The document is intentionally positioned as an introductory connective guideline within the TEHDAS2 framework. It provides a structured overview of roles, responsibilities, and key process steps, while systematically referring to other TEHDAS2 guidelines for in-depth guidance on topics such as metadata and dataset description, data minimisation and anonymisation, opt-out implementation, application handling, and secure processing environments.

Abbreviations

Abbreviation	Description
AI	Artificial intelligence
DAAMS	Data access application management system
EHDS	European Health Data Space
EU	European Union
GDPR	General Data Protection Regulation (EU) 2016/679
HDAB	Health data access body
HDH	Health data holder
HDIE	Health data intermediation entity
IP	Intellectual property
LLM	Large language models
SPE	Secure processing environment
THDH	Trusted health data holder
TEHDAS2	The second Joint Action Towards the European Health Data Space
TTP	Trusted third party

2 Introduction

2.1 Advancing health data use in the European Health Union

As part of the European Health Union, the European Union (EU) is advancing the use of health data for secondary purposes, including research, innovation and policymaking. Smooth and secure access to data will drive the development of new treatments and medicines and optimise resource utilisation – all with the overarching goal of improving the health of citizens across Europe.

The EHDS introduces new roles, processes, and infrastructures at both EU and national level. Central to this framework are health data holders (HDHs), who hold or control electronic health data and are legally required, under defined conditions, to make such data available for secondary use. Given the wide diversity of HDHs, ranging from large public institutions to smaller organisations and private entities, the Regulation establishes common obligations while allowing Member States flexibility in how these obligations are operationalised.

TEHDAS2, the second joint action Towards the European Health Data Space, represents a significant step forward in this vision. The project will develop guidelines and technical specifications to facilitate smooth cross-border use of health data, and support data holders, data users and the new health data access bodies in fulfilling their responsibilities and obligations outlined in the European Health Data Space (EHDS) Regulation.

TEHDAS2 focuses on several critical aspects of health data use.

- **Data discover**y: findability and availability of health data, ensuring it is accessible for secondary purposes.
- **Data access**: developing harmonised access procedures and establishing standardised approaches for granting data access across Member States.
- **Secure processing environment:** defining technical specifications for environments where sensitive health data can be processed safely.
- **Citizen-centric obligations:** providing guidance on fulfilling obligations to citizens, such as communicating significant research findings that impact their health, informing them about research outcomes and ensuring transparency in how their data is used.
- **Collaboration models**: developing guidance on collaboration and guidelines on fees and penalties as well as third country and international access to data.

TEHDAS2 will contribute to harmonised implementation of the EHDS Regulation through the concrete guidelines and technical specifications. Some of these documents and resources will also provide input to implementing acts of the regulation. Hence, the joint action will increase the preparedness for the EHDS implementation and lead to better coordination of Member States' joint efforts towards the secondary use of health data, while also reducing fragmentation in policies and practices related to secondary use.

Within TEHDAS2, Work Package 6 focuses on access to electronic health data for secondary use. This deliverable D6.1, provides guidance to HDHs to help them meet their obligations when making both personal and non-personal electronic health data available for secondary use. It complements other TEHDAS2 deliverables that provide more detailed guidance for data users, HDABs, metadata catalogues, SPEs, and citizen-related obligations.

Deliverable D6.2 provides guidance for data users on good application practice for data access and requests. Deliverable D6.3 provides guidance for health data access bodies (HDABs) on procedures and formats for issuing data permits and decisions on data requests. Deliverable D6.4 establishes technical specifications and/or requirements for data access application management systems (DAAMS).

2.2 Scope and aim

This guideline supports the implementation of the EHDS Regulation by providing high-level, structured guidance to HDHs on how to fulfil their duties when making personal and non-personal electronic health data available for secondary use. It focuses on the phase after a data permit has been issued or a health data request has been approved by an HDAB, as set out in Chapter IV of the EHDS Regulation.

While the EHDS Regulation defines key roles and establishes core legal obligations, it does not comprehensively prescribe how all responsibilities are to be operationally allocated across the secondary-use process. Several aspects of implementation, such as the distribution of data preparation tasks, technical processing steps, and coordination mechanisms between actors are left to national legislation, governance arrangements, or organisational choices. Accordingly, this guideline does not attribute or reassign responsibilities beyond what is explicitly set out in the EHDS Regulation, nor does it override national implementation decisions.

For ease of reference, Annex 5 provides an overview of the relevant articles of the EHDS Regulation referred to throughout this guideline.

The guideline is grounded primarily in:

- **Article 60**, which defines the core duties of HDHs when making data available for secondary use; and
- **Article 63**, which describes the enforcement powers of HDABs with respect to HDHs.

Within this scope, the guideline aims to provide:

- An overview of HDHs role and core duties in the secondary-use pathway, as set out in the EHDS Regulation, together with operational tasks commonly involved in practice, some of which are subject to national implementation choices.
- Clarification of the mandatory minimum process for making data available, including how responsibilities are defined or commonly organised between HDHs, HDABs, and, where applicable, trusted health data holders (THDH) or Health Data Intermediation Entities (HDIE).

- A structured description of the minimum steps involved in data preparation and provision following the issuance of a data permit or approval of a data request, such as interpreting the permit or request, extracting data, and transferring relevant data to an SPE; and

- a set of recommended practices that may support implementation in practice, considering national choices and organisational capacity, including communication and procedural interactions and non-binding examples based on expert advice and experience.

To avoid duplication across TEHDAS2, this guideline focuses on the logistical, procedural, and organisational aspects of data preparation and provision. It does not provide detailed technical or procedural instructions on topics that are addressed in other deliverables. Guidance on the following topics is addressed in other TEHDAS2 deliverables and therefore not elaborated here:

- Dataset description (including metadata provision) and dataset catalogue obligations, addressed in M5.1.1 *Guideline on data description*, describing the 'data holders' duties regarding data description on data discovery.

- Opt-out management, citizen information and rights addressed in D8.1 Guideline for *health data access bodies on implementing opt-out from the secondary use of health data* and D8.2 Guideline for *health data access bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data*, and D8.3 Draft guideline for *health data access bodies on informing natural persons about the use of health data* – ("Citizen Information Point").

- Data anonymisation, pseudonymisation, data minimisation, purpose limitation, and linkage techniques addressed in M7.2 Guideline on *data minimisation, pseudonymisation, anonymisation and synthetic data*, and M7.5 Guideline for *health data access bodies on linkage of health datasets*.

- Intellectual property and trade secrets, and further specification on when to issue a data permit or a health data request is addressed in D6.3 *Guideline for health data access bodies on the procedures and formats for data access*.

For cross-references to other TEHDAS2 work packages, see Annex 3 (Health data holder resources). Where relevant, this guideline refers explicitly to these deliverables and positions itself as a connecting document that helps HDHs navigate the broader TEHDAS2 guidance landscape.

The overall aim of this Guideline is to:

- Support HDHs and Member States in preparing for EHDS implementation by clarifying HDHs' role and duties when making health data available for secondary use; and

- help HDHs assess their readiness and prepare accordingly, recognising that while the Regulation defines a common set of duties in Article 60, levels of preparedness and national implementation capacity will vary and require supporting governance structures and infrastructure at Member State level.

The methodology underpinning this guideline, as well as the results and processing of the public consultation, are further elaborated in Annexes 1 and 2.

2.3 Target audience/intended users

The primary target audience of this Guideline are 'health data holders' (HDHs), as defined in the EHDS Regulation (Art 2(2)(t)). HDHs are natural or legal persons, public authorities, agencies, or other bodies that operate in the healthcare or care sectors, or that develop products or services intended for those sectors, and that either:

- have the right or obligation, under Union or national law and in their capacity as a controller or joint controller, to process personal electronic health data for purposes such as healthcare or care provision, public health, reimbursement, research, innovation, policymaking, official statistics, patient safety, or regulatory activities; or
- have the ability to make non-personal electronic health data available through control over the technical design of a product or related services, including by registering, providing, restricting access to, or exchanging such data.

In practice, this definition covers a wide and heterogeneous range of entities, including, for example:

- healthcare providers (e.g., hospitals, clinics, and general practitioners);
- public authorities or agencies involved in health or care services;
- health insurances and organisations managing reimbursement systems;
- developers of health-related products and services, including wellness applications;
- research institutions and mortality registries; and
- EU institutions, bodies, and agencies that manage or process health data.

These entities may process personal and/or non-personal electronic health data and, where they qualify as HDHs under the EHDS Regulation, are subject to the duties set out in Chapter IV of the Regulation. This guideline supports HDHs in understanding their role and core duties in relation to the secondary use of health data and highlights key topics they need to be aware of to comply with those duties.

In addition to the HDHs, other stakeholders within the EHDS institutional landscape can benefit from these guidelines:

- HDABs: to support understanding of health data holders' mandated duties and recommended or optional tasks, and to prepare for interactions expected across all phases of the user journey. To facilitate these interactions, Member States may establish clear, secure, and traceable communication channels as part of the national EHDS infrastructure, in line with national governance arrangements.

- Member States and the European Commission: as contextual input for the design, establishment, and operation of national and EU-level EHDS governance structures and central services, in view of HDHs' mandated duties and recommended or optional tasks.

This document should be understood as an expert opinion and guidance document developed within the TEHDAS2 framework. It is not legally binding and does not constitute the formal guideline/technical specification under the EHDS Regulation. The binding and enforceable guidelines and technical specifications will be issued by the European Commission alongside the Implementing Acts, which will define the authoritative requirements for Member States and HDABs, as well as for HDHs and health data users.

3 Legal framework and mandatory process

3.1 Roles and responsibilities in the provision of health data for secondary use

The European Health Data Space (EHDS) Regulation establishes a framework for the secondary use of electronic health data that relies on the coordinated involvement of several actors, each assigned specific tasks and responsibilities. Rather than placing all obligations on a single entity, the Regulation defines a distributed model in which responsibilities related to data access, data provision, data preparation, supervision, and cross-border cooperation are allocated across different roles. These roles include health data access bodies (HDABs), health data holders (HDHs), trusted health data holders (THDHs), health data intermediation entities (HDIEs), and authorised participants in HealthData@EU.

Understanding the role of each actor and the responsibilities assigned to it under the EHDS Regulation is essential for the effective implementation of secondary use. Clear allocation of responsibilities supports legal certainty, helps organisations identify which obligations apply to them, and facilitates cooperation between actors involved in the data provision workflow. It also helps avoid overlaps, gaps, or misunderstandings regarding who is responsible for specific tasks, such as assessing data access applications, preparing data, or making data available through secure processing environments (SPEs).

This section is based exclusively on the provisions of the EHDS Regulation. Additional roles, responsibilities, procedures, or organisational structures may be introduced through implementing acts or as a result of national legislative choices when transposing and operationalising the Regulation. For instance, Member States and individual organisations may establish additional bodies, coordination mechanisms, or internal structures to support the practical implementation of secondary use. While such developments are expected and may significantly shape national EHDS ecosystems, the purpose of this section is to present and explain the core, foundational roles defined in the EHDS Regulation and their legally established responsibilities in the context of secondary use of electronic health data.

The table below (Table 1) provides a high-level comparative overview of the main actors involved in the provision of electronic health data for secondary use under the EHDS Regulation and their respective roles and legal responsibilities. It summarises how each role is established, the core responsibilities assigned by the Regulation, and key operational aspects of the data provision workflow, such as the assessment of data access applications, decision-making on access, data preparation, and the use of SPEs.

The purpose of this overview is to support a clear and comparable understanding of “who does what” in the EHDS secondary-use ecosystem. The table does not replace the detailed legal provisions of the Regulation but serves as an orientation tool for readers, particularly HDHs, to identify their own role and to understand how it relates to the responsibilities of other actors involved in data pro.

Table 1. *Overview of roles and responsibilities in the provision of electronic health data for secondary use under the EHDS Regulation*

	HDAB	HDH	THDH	HDIE	Authorised participant
How this role is established (eligibility)	Designated by Member States as one or more public sector bodies; One HDAB must act as national coordinator where several are designated	Falls under the definition of a HDH under the EHDS (Art. 2) and holds electronic health data referred to in Article 51	HDH designated by a Member State following an assessment by the HDAB, subject to periodic review and compliance with specific conditions	Legal person designated under national law to fulfil duties of certain categories of HDHs on their behalf	Health-related research or similar infrastructure operating under Union law and authorised to connect to HealthData@EU
Role description	Public authority responsible for managing access to electronic health data for secondary use, including decision-making, supervision, and coordination	Entity that holds electronic health data and is legally required to make them available for secondary use	HDH benefiting from a simplified access procedure and entrusted with additional assessment and provision tasks	Entity performing data holder duties for secondary use on behalf of one or more HDHs	Union or international infrastructure supporting cross-border secondary use of electronic health data
Key legal duties	• Metadata management • Application processing • Data permit issuance • Data preparation • Data provision to health data user • Documentation and reporting • Monitoring and supervision	• Dataset description and maintenance • Data provision to the HDAB	• Application assessment (simplified procedure) • Data preparation Data provision to health data user	• Execution of delegated data holder responsibilities • Data provision to the HDAB on behalf of HDHs	• Metadata management • Application processing • Access approval issuance Support of cross-border access workflows
Analyses data access applications or data requests	Yes, assesses health data access applications and health data requests	No	Yes, assesses applications and requests under simplified procedure	No	Yes, involved in cross-border handling of applications within their remit
Decision to grant or refuse access	Yes, issues or refuses data permits and approves or refuses health data requests	No	No, submits a proposal, but final decision remains with HDAB	No	Yes, issues access approvals for data within their remit
Responsible for data preparation (incl. pseudonymisation, anonymisation)	Yes, processes data including receiving, combining, preparing, compiling, and pseudonymisation or anonymisation	May compile and prepare data for provision to HDABs, including anonymisation and pseudonymisation	Yes, processes data including receiving, combining, preparing, compiling, and pseudonymisation or anonymisation	May compile and prepare data for provision to HDABs, when performing data holder duties on behalf of HDHs	Not specified in EHDS Regulation
Required to operate an SPE	Yes, when providing access to data, must do so through an SPE	No, not required to operate an SPE	Yes, must be able to provide access through an SPE	No	No
Able to charge fees	Yes, fees for assessing applications and costs related to the consolidation, preparation, pseudonymisation, anonymisation and provision of the electronic health data	Yes, indirectly, by providing an estimate of costs to the HDAB for compiling and preparing the electronic health data to be made available.	Yes, fees for assessing applications and costs related to the consolidation, preparation, pseudonymisation, anonymisation and provision of the electronic health data	Not specified in EHDS Regulation	Not specified in EHDS Regulation
Key legal basis (Articles)	Arts. 55, 57, 58, 59, 62, 63, 66, 68, 73, 77, 87	Arts. 50, 60, 62, 63, 68, 77 (Recital 72)	Arts. 62, 72, 73, 87; Recital 76	Art. 50; Recital 59	Arts. 68, 75

3.2 Who is considered a health data holder

Under the EHDS Regulation, an entity is subject to the obligations of Chapter IV only if it meets both of the following conditions:

- It qualifies as a HDH according to Article 2(2)(t) of the Regulation.
- It holds or processes electronic health data falling under one or more categories defined in Article 51, which outlines the types of data eligible for secondary use.

Understanding this “double condition” is critical for organisations to determine whether the Regulation applies to them. Article 2(2)(t) defines a HDH broadly to include:

1. Any natural or legal person, public authority, agency, or other body operating in the healthcare or care sectors, including entities managing reimbursement systems where relevant.
2. Any natural or legal person that:
    a. Develops products or services intended for health, healthcare, or care.
    b. Develops or manufactures wellness applications.
    c. Conducts research in relation to healthcare or care.
    d. Acts as a mortality registry or other specialised registry.
3. Any Union institution, body, office, or agency that:
    a. Processes personal electronic health data for healthcare, public health, reimbursement, research, innovation, policy making, statistics, patient safety, or regulatory purposes.
    b. Controls technical design of products or services to make non-personal electronic health data available, including registering, providing, restricting access to, or exchanging such data.

Importantly, the EHDS Regulation also establishes exemptions for certain entities, namely natural persons, including individual researchers and microenterprises, defined as legal persons with fewer than 10 employees and turnover or balance sheet total below €2 million. Member States may further regulate these exemptions at national level. Organisations should monitor their eligibility, especially if their size, business scope, or data holdings change over time.

3.2.1 Legal obligations of the health data holder

HDHs play a central role in enabling the secondary use of electronic health data under the EHDS Regulation. Their participation ensures that data can be accessed, analysed, and reused in a manner that is secure, consistent, and legally compliant across Member States. HDHs have a legal obligation related to three main areas:

Dataset description and maintenance: HDHs shall communicate to the HDAB a description of each dataset they hold that falls within the categories of electronic health data referred to

in Article 51 (see Section 3.4 on which data should be described). This description shall take the form of a metadata record, in accordance with Article 77, and must be checked at least once per year to ensure that the information in the national dataset catalogue is accurate and up to date. Where a dataset is accompanied by a data quality and utility label pursuant to Article 78, the HDAB shall verify the accuracy of the label. In the case of non-personal electronic health data, the HDH shall ensure access to the data through trusted open databases that implement robust, transparent, and sustainable governance and provide unrestricted access for all users, including data storage and preservation.

Data provision: HDHs shall make available, upon request by the HDAB and in accordance with a data permit issued pursuant to Article 68 or a health data request approved pursuant to Article 69, the relevant electronic health data referred to in Article 51 that they control. The requested data shall be placed at the disposal of the HDAB within a reasonable timeframe and no later than three months from the receipt of the request. In duly justified cases, the HDAB may extend this period by a maximum of three additional months. HDHs shall provide the data in an SPE stated in the data permit, ensuring that access is restricted to authorised users in accordance with the Regulation. These provisions establish the legal framework for the transfer of data and define the responsibilities of HDHs in enabling secure and compliant secondary use of electronic health data. Importantly, when established by national law, HDHs must implement and manage the opt-out mechanism for the data subjects whose data they hold, ensuring that restricted data is not shared for secondary use.

Opt-out secondary use: Where provided for by national law, HDHs are obliged to implement and manage the opt-out mechanism for the data subjects whose data they hold, ensuring that restricted data is not shared for secondary use unless an exception under Art. 71(4) applies.

3.2.2 Provision and compliance timelines for health data holders

Upon issuance of a data permit (Art. 68) or approval of a health data request (Art. 69) by the HDAB, HDHs are required to provide the requested data within a defined timeframe. Timely provision is critical for compliance.

According to Article 60(2) of the EHDS Regulation, HDHs shall provide the requested data within three months of receipt of the data permit or the approval of the health data request. This period may be extended once, for a further three months, in duly justified cases. Where unjustified delays occur, HDABs are empowered to impose enforcement measures, including periodic penalty payments and temporary or permanent restrictions on future data access activities by the non-compliant data holder.

While the EHDS Regulation sets specific deadlines for certain actors, the following timelines illustrate indicative end-to-end durations based on Articles 60, 62, 68–70, and 72:

- In a health data access application, the HDAB has up to three months to issue a data permit, and the HDH has three months to provide the data. In duly justified cases, the HDAB may extend the data provision period by a maximum of three months. The HDAB has another two months to make the data available in the SPE. The health data user then has the duration of access period specified in the data permit for analysis, followed by 18 months to publish results.

- In a health data request process, the HDAB has up to three months to assess the request and issue an approval. The HDH has three months to provide the data or aggregated statistical output. In duly justified cases, the HDAB may extend the data provision period by a maximum of three months. The HDAB then has three months to share the response with the health data user. The health data user then has 18 months to publish results.
- An accelerated review process may apply to public sector bodies and EU institutions with legal mandates in public health. In such cases, the HDAB shall decide within two months, though this period may be extended to three months where additional time is required.

3.2.3 Invoicing, fees and eligible costs

The EHDS Regulation acknowledges that preparing and transmitting data for secondary use may entail operational costs; accordingly, Article 62(2) allows HDHs to recover the costs incurred for compiling and preparing the data. These costs are part of the overall fee charged by the HDAB to the data user, and the relevant portion must be transferred to the HDH.

Cost estimates must be provided when requested by the HDAB as part of the total cost estimate that the HDAB must provide to the applicant in advance of the data provision. Eligible costs include data preparation and data provision activities, such as data extraction, formatting, and, where performed by the HDH, pseudonymisation-related expenses. Although Article 6 of the Data Governance Act (Regulation (EU) 2022/868) limits fees for reuse of public sector data, those limitations do not apply to cost recovery and fees under the EHDS Regulation framework for HDHs, including where the HDH is a public sector body. Cost recovery under Article 62 remains applicable. More detail on costing and invoicing can be found in TEHDAS2 M4.1.1 *Guideline on fees related to the EHDS Regulation.*

3.3 Special roles and delegation options for health data holders

The EHDS Regulation introduces additional considerations regarding the provision of health data for secondary use, recognising that different HDHs may face varying capacities, expertise, and resource constraints. These provisions are designed to accommodate two distinct scenarios. In the first, HDHs with the necessary capacity, expertise, and safeguards may assume additional responsibilities in the secondary use framework by becoming a THDH, allowing them to support the HDAB in assessing applications and providing data through a simplified pathway. In the second scenario, HDHs who prefer to delegate certain obligations under the secondary use framework may rely on HDIEs, which can act on their behalf to facilitate compliance while reducing the administrative and operational burden. Both cases are described in detail in the following sections.

3.3.1 Trusted health data holder (THDHs)

A THDH is a HDH designated by a Member State to perform additional tasks within the secondary use framework. The designation allows certain HDHs with appropriate capacity, expertise, and safeguards to support the HDAB by assessing health data access applications and health data requests for the datasets they control. THDHs operate under a simplified procedure intended to reduce the administrative burden on HDABs while maintaining legal compliance. Although THDHs may provide recommendations on data permits or approvals, the HDAB remains the sole authority responsible for issuing the final decision. THDHs are

required to provide access to data through an SPE in accordance with the Regulation and are listed in the national dataset catalogue once designated.

Designation process: Member States may establish procedures for HDHs to apply for designation as THDHs, provided they meet the following conditions: they must be able to provide access to health data through a compliant SPE; they must have the necessary expertise to assess health data access applications and requests; and they must provide guarantees to ensure compliance with the EHDS Regulation. Designation is granted following an assessment by the relevant HDAB and is subject to periodic review to confirm ongoing compliance with these conditions.

What changes from the role of HDH?

Beyond the standard responsibilities of a HDH, a THDH has the following additional tasks:

1. Assess health data access applications and health data requests submitted under the simplified procedure, based on their expertise in the datasets they hold.
2. Submit the assessment and a proposal for decision to the HDAB within two months of receiving the application or request.
3. Carry out specific data preparation and provision tasks once the HDAB issues a data permit or approves a health data request, including receiving, combining, preparing, compiling, and pseudonymising or anonymising datasets.
4. Provide access to the datasets through an SPE and ensure its proper operation according to the EHDS Regulation requirements.
5. Act in support of the HDAB to facilitate more efficient secondary use, while the HDAB retains the final authority to grant or refuse access.

3.3.2 Health data intermediation entities (HDIE)

HDIE is a legal person that may be designated under national law to carry out the duties of certain categories of HDHs. The purpose of HDIEs is to reduce administrative and operational burdens on individual HDHs, particularly those with limited resources or expertise in secondary use. While the EHDS Regulation provides the framework for their existence, the specific roles, responsibilities, and operational scope of HDIEs are determined by Member States in their national legislation. In practice, HDIEs may process, make available, register, provide, restrict access to, and exchange electronic health data for secondary use on behalf of HDHs.

Designation process: The EHDS Regulation allows Member States to establish HDIEs as a means for HDHs to delegate obligations under Chapter IV of the Regulation. When national law provides for the use of HDIEs, the data shared through these entities is still considered to be made available by the original HDHs. The EHDS text does not define the precise legal duties or operational procedures for HDIEs, leaving this to national implementation. HDIEs may support HDHs by interfacing with the HDAB, extracting data, submitting metadata, and providing access through an SPE if applicable.

Which health data holder tasks may be delegated to an HDIE?

HDHs may, in accordance with national law, delegate certain tasks associated with the provision of electronic health data for secondary use to an HDIE. These tasks may include, but are not limited to:

1. Preparing and processing datasets for provision to the HDAB.
2. Submitting dataset descriptions and metadata to the national dataset catalogue on behalf of the HDH.
3. Managing technical operations necessary to provide data through SPEs.
4. Facilitating access to electronic health data for HDHs in compliance with issued data permits or approved health data requests.

The exact scope and limits of these delegated tasks depend on national legislation and the agreements between the HDH and the HDIE. The HDIE acts as an operational extension of the HDH, but the legal responsibility for compliance with the EHDS Regulation ultimately remains with the original HDH.

3.4 What data needs to be provided?

3.4.1 What is health data for secondary use in the context of the EHDS Regulation?

The EHDS Regulation defines electronic health data, as personal or non-personal electronic health data (Art. 2(2c)). For secondary use, Article 51 sets out the minimum categories of electronic health data that HDHs must make available in according with Chapter IV, following a data permit or an approved health data request. These categories include, for example, data from EHRs, administrative and reimbursement-related data, registries, claims data, and data generated by wellness applications. M5.1 Guideline on Data Description provides further guidance on interpreting these categories and identifies typical HDHs for each category.

3.4.2 Dataset descriptions for national dataset catalogue

Under Article 60(3), HDHs must provide their HDAB with dataset descriptions for inclusion in the national dataset catalogue.

This description must be provided as metadata, including details on the source, scope, main characteristics, and conditions for data access (Art. 77). Dataset descriptions must be reviewed for accuracy at least annually. This information is essential for health data users to understand the nature and relevance of the available data for secondary use, supporting dataset discoverability and semantic interoperability. HealthDCAT-AP is an application profile based on DCAT and adapted within supportive actions preparing the implementation of EHDS, its use is expected to support implementation of the metadata obligations adopted via implementing acts under Article 77(4).

While the legal obligation to provide metadata applies to all relevant HDHs, the level of effort required may vary depending on data volume and complexity of data, existing metadata practices, and available expertise. Nevertheless, good-quality metadata can ease future data provision by improving alignment with data requests and enabling more efficient data extraction and preparation. It also helps applicants submit clearer applications and specify the data they seek, which in turns supports a more efficient response by the HDH.

Detailed recommendations and non-binding guidance on using HealthDCAT-AP for dataset description, together with further implementation considerations, are available in D5.1 Guideline for health data holders on data description, including data holder's duties on data description for data discovery.

Importantly, the HealthDCAT-AP common metadata model supports the categorisation of datasets into the different types of health data mentioned in the EHDS Regulation:

- **Personal health data** [sensitive data] – if a dataset contains personal electronic health data.
- **Non-personal electronic health data available as non-open data** [protected or restricted data] – if a dataset does not contain any personal electronic health data but is access-controlled.
- **Non-personal electronic health data available as open data** [open data] – if a dataset does not contain any personal electronic health data and is freely available to the public.

This categorisation is important because the three types of data lead to different access pathways under the EHDS framework: Personal health data access requires a data permit or approved data request; provided via the HDAB and data processing must be performed in an SPE.

1. Non-personal electronic health data – Open data must be made available via a public platform, in line with Article 60(5), with robust governance and sustainability.
2. Non-personal electronic health data (restricted/protected):
3. Provided on approval by the HDAB (data permit or request) and may involve additional safeguards (e.g. for commercially sensitive data).

Metadata should be complete, accurate and aligned with the actual technical and organisational capabilities of the HDH. Inaccurate or outdated metadata may result in non-compliance with Article 60(3) and Article 77(2). For further details on description of the data, see:

- D5.1 Guidelines for health data holders (HDHs) on data description
- D5.2 Guidelines for health data access bodies (HDAB) on minimum categories and limitations on the reuse of health data
- D5.3 Technical specification on the national metadata catalogue

Under Article 77(1), each HDAB is responsible for maintaining a national dataset catalogue in a publicly accessible and standardised machine-readable format, incorporating the metadata provided by HDHs. Under Article 79, these national catalogues are connected to form the EU-level dataset catalogue, which also integrates metadata from authorised participants in HealthData@EU.

Technical and operational requirements for the national dataset catalogue, including metadata management and HDAB responsibilities, are detailed in D5.3 Technical Specification on the National Metadata Catalogue.

Under Articles 60(2) and 60(3) of the EHDS Regulation, HDHs must make both personal and non-personal electronic health data available and provide corresponding metadata for inclusion in the national dataset catalogue, where the data falls within the minimum categories listed in Article 51.

3.5 Personal and non-personal data

Personal and non-personal data is defined in the EU law as follows:

- Personal data is defined in Article 4(1) of the GDPR as any information relating to an identified or identifiable natural person.
- Non-personal data is defined in Article 3(1) of Regulation (EU) 2018/1807 as data other than personal data as defined in the GDPR. (i.e. “data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679 (GDPR)”.

Non-personal data can have a wide range of characteristics and may, based on origin, be categorised into:

1. Non-personal data that was originally personal data (personal data rendered anonymous so that the data subject is not, or no longer, identifiable).
2. Non-personal data that has never been related to an identified or identifiable natural person.
3. Non-personal synthetic data.

The classification of a dataset affects how it is handled. However, obligations to describe datasets and, where applicable, to make electronic health data available apply across data types. The operational categories used in TEHDAS2 are provided for illustrative purposes and do not constitute legal definitions under the EHDS Regulation. Please note that, also in case of non-personal data, only data falling within the minimum categories set out in Article 51 is in scope. In addition, EHDS does not prescribe the precise data flows or technical modalities for provision of non-personal data. These aspects may be determined at implementation level by Member States.

Synthetic data

The primary rationale for synthetic data generation in the EHDS context is privacy protection. Synthetic data can be generated for a variety of reasons, including[1]:

- Preliminary data exploration: Enables recipients to explore dataset structure or identify required variables before accessing real data.

[1] Giuffrè, M., Shung, D.L. Harnessing the power of synthetic data in healthcare: innovation, application, and privacy. *npj Digit. Med.* **6**, 186 (2023). https://doi.org/10.1038/s41746-023-00927-3

- Code development: Enables development and testing without using actual personal data, by matching data structure (also known as "dummy data").
- Open science practices: Enables sharing code and synthetic datasets openly to support reproducibility and evaluation.
- Educational use: Enables training and teaching without sharing sensitive personal data, by providing synthetic examples.

Synthetic data can be generated to mimic personal or non-personal datasets. In the EHDS context, only synthetic data that no longer relates to an identifiable person is considered non-personal and falls under the provisions of Article 60(2). More detailed guidance on handling synthetic data in the preparation phase is provided in *MD7.2 Guideline on data minimisation, pseudonymisation, anonymisation and synthetic data.*

3.5.1 Intellectual property and trade secrets

Under the EHDS Regulation (Art. 52), HDHs are required to make electronic health data available for secondary use, even when such data encompasses protected intellectual property (IP) and trade secrets (Art. 52(1)). To allow for this, the HDH shall explicitly identify which data are covered by IP rights or other mentioned protected right or for which it deems necessary to protect IP or trade secrets. The HDHs must then communicate to the HDAB that their electronic health data contain information covered by IP rights or trade secrets (Art. 52(2)). They may do so when they submit the description of the electronic health data for inclusion in the data catalogue, or subsequently when a permit is issued on or a request approved for such data. In the former case, the use of the “Rights” property within the HealthDCAT-AP common metadata model may be useful to make explicit the presence of data covered by IP and trade secrets. In any case, the HDH is required to state the reasons that justify the need for specific protection measures of these data (Art. 52(2)), and the HDAB must assess whether the provided justification is valid (Art. 52(3)).

To facilitate the sharing of data protected by IP, it is crucial to develop a set of appropriate protection measures that ensure the protection of the rights of the HDH, while promoting access and use of the data by the data users. In the case of data permits, the HDAB may make the access to personal and non-personal data or pieces of data covered by IP or trade secrets conditional upon the implementation of these safeguarding measures (Art. 52(4)). Pursuant to Article 52(5), the HDAB may deny secondary use of data where a significant risk to IP rights or trade secrets remains, despite the implementation of safeguarding measures.

The safeguarding measures can be included in contractual arrangements between the HDH and the data user (Art. 52(4)), defining restrictions and permissions in proportion to the degree of protection that needs to be assigned to data covered by IP and trade secrets. Guidance is also provided in TEHDAS2 *D6.3 “Guideline for health data access bodies on the procedures and formats for data access”.*

3.6 Mandatory process for making data available

3.6.1 Data permit and data request processes

In Article 60, the EHDS Regulation mandates that HDHs make relevant electronic health data referred to in Article 51 available upon request to the HDAB, in accordance with a data permit issued pursuant to Article 68 (including individual-level data), or upon a health data request approved pursuant to Article 69 (resulting in anonymised statistical format). When issuing a data permit or approving a data request, the HDAB shall immediately request the extraction of the relevant data from the respective HDHs in accordance with Article 60 and Article 68(7) unless otherwise agreed with the health data user. The process following a data permit and a data request involves HDHs, respectively, but will differ in several aspects. Indicative schematic workflows for data preparation and provision are presented in Chapter 4.

For details on the HDAB duties for handling health data access applications and health data requests, issuing data permits and coordinating the exchange of electronic health data, see TEHDAS2 *D6.3 "Guideline for health data access bodies on the procedures and formats for data access".* This guideline includes annexes with the full templates for the data access application (Annex 5 of TEHDAS guideline D6.3) and the data request (Annex 6 of TEHDAS guideline D6.3), and details information regarding decisions on data permits and requests, including procedures for amendments or changes. Implementation acts including templates for the health data access application, the data permit and the health data request are expected to be adopted by March 2027.

Data permit

A data permit represents an administrative decision regarding data access, resulting from the processing of a data access application by a health data user. The HDAB issues permits for access to certain electronic health data for specific secondary use purposes based on conditions laid down in Chapter IV of the EHDS Regulation (Art. 2(2v)). Article 68(1) specifies the conditions for granting access and the information to be included in the permit. Article 68(1) specifies the conditions for granting access and the information to be included in the permit. The data permit states the general conditions for the health data user to comply with, including the details and specifications of data covered by the data permit, including sources and an indication of whether the electronic health data are to be accessed in a pseudonymised format in the secure processing environment. The information in the issued data permit is what the relevant HDHs is requested to act on by the HDAB.

Data request

A data request approval is an administrative decision document regarding access to non-personal data in an anonymised (aggregated) statistical format only, for the purposes referred to in Article 53 of the EHDS Regulation (Art. 69(1)). The HDAB processes and decides on data requests. Article 69 specifies the information to be included in a data request, such as detailed description of the requested health data, format, sources and statistical content. The information contained in a granted data request is the basis for the data request from HDHs and processing (preparation and provision) of data/results.

3.6.2 Data preparation

The issued data permit or approved data request is the starting point of a broader process, called data preparation, that includes transformation and organisation of electronic health data to comply with a data permit or a data request, and that will result in the relevant data delivery to the data user who asked for it. According to EHDS, the HDAB is responsible for processing electronic health data such as the combination, preparation and compilation of the necessary requested data from HDHs, and the pseudonymisation or anonymisation of the data (Art. 57(1)(b)). However, the responsibility for some steps of data preparation such as the management of opt-out is not assigned by the Regulation and will be defined in national laws.

Moreover, the EHDS defines the role of the THDH which is mandated to perform some of the data preparation steps (Art. 72(6)), and of the HDIE which can also be involved in the process. Therefore, the actual responsibility for each of the data preparation steps may vary on a case-by-case basis due to national designations and implementations of the EHDS.

In this part of the guideline, an overview of the entire data preparation process is provided, regardless of whether the responsibility is placed on the HDAB, on the HDH, or on the THDH. As many of the steps of data preparation are also covered by other TEHDAS2 guidelines and to avoid overlaps, here the focus is on clarifying the legal responsibilities for performing these tasks. More detailed technical instructions within TEHDAS2 guidelines are referenced in the text.

TEHDAS2 experts identify the following key steps of the data preparation process, which will be described in the following:

- Data minimisation and purpose limitation
- Data extraction
- Opt-out management
- Intellectual property and trade secrets and other protected rights management
- Pseudonymisation or anonymisation
- Data linkage
- Statistical aggregation in case of a data request

The following table (Table 2) summarises the legal obligations in data preparation, and describes which are the entities that are responsible.

Table 2. *Summary of key steps for data preparation*
HDH=Health data holder, HDAB=Health data access body, THDH=Trusted health data holder

Step	Responsibilities and obligations	Responsibility of	Relevant EHDS Articles	Actions to be carried out
Data minimisation and purpose limitation	Mandatory, final responsibility lies with the HDAB.	HDAB, THDH	66 (& art. 5 GDPR)	Ensure that only the relevant data is included in the permit/request.
Data extraction	The HDH is responsible for making data available upon request.	HDH, THDH	60	Select the relevant data based on permit/request.
Opt-out management	The EHDS Regulation allows Member States to assign the task of removing opt-outs to either the HDAB or the HDH.	To be defined in national laws	71	Remove individuals who opted out.
Intellectual property and trade secrets management	Mandatory, only if the HDAB has approved measures that need to be taken during data preparation.	HDAB,THDH	52	Apply protection measures.
Pseudonymisation or anonymisation	Mandatory, responsibility lies with the HDAB. However, process might be delegated to the data holder (optional).	HDAB, THDH	57, 66, 68	Apply pseudonymisation or anonymisation techniques.
Data linkage	Combination of datasets by different data holders is the responsibility of the HDAB. Linkage of internal datasets by the HDH is optional. This is not explicitly required by EHDS text, but it can be necessary if approved by the HDAB.	HDAB, THDH	57	Carry out data linkage of datasets.
Statistical aggregation in case of a data request	Mandatory, responsibility lies with the HDAB. However, process might be delegated to the HDH (optional).	HDAB, THDH	69	Carry out statistical aggregation of data.

Data minimisation and purpose limitation

Under Article 66, the EHDS Regulation requires that HDAB ensures that access is only provided to electronic health data that are adequate, relevant and limited to what is necessary in relation to the purpose of processing indicated in the health data access application by the

health data user. Data minimisation and purpose limitation measures apply to both personal and non-personal data.

Although in the EHDS Regulation this responsibility is placed on the HDAB, the HDH and all the actors involved in the process of making health data available must respect the data minimisation and purpose limitation principles, as mandated by the GDPR Regulation (Art. 5), to ensure that no more data is extracted and provided than what is strictly necessary based on the issued data permit or approved data request.

Further information can be found in TEHDAS2 *M7.2 Guideline on data minimisation, pseudonymisation, anonymisation and synthetic data*".

Data extraction

In general, a HDH may be requested to provide:

- a dataset as described in the national dataset catalogue
- a specified portion (subset) of the data in the catalogued dataset, which requires a data extraction process
- a combination of data contained in several datasets that the HDH controls, which requires data linkage to be performed

In the Data access application template and Data request template, the data user indicates from which database(s)/registry/registries the data will be extracted, lists the variables to be used in the data extraction, the inclusion criteria and exclusion criteria.

In case of a subset of the dataset is required, the HDH applies the selection to the fields indicated in the data access/data request approved application and the selections to the rows corresponding to the inclusion and exclusion criteria.

In case of a combination of data contained in several datasets is required, the EHDS Regulation establishes that responsibility for record linkage is assigned to HDAB or, if involved, to the THDH. However, according to expertise and capacity of HDH, this task can be delegated to HDH. Also in this scenario, appropriate selection on fields and rows are to be applied as indicated in the issued data access or approved data request.

Opt-out

The EHDS Regulation (Art. 71) provides Member States with the flexibility to determine the technical and operational implementation of the opt-out mechanism. The opt-out right is based on the EHDS Regulation, but its exercise must be carried out on a Member State-by-Member State basis (it does not extend to other Member States), and once natural persons have exercised the right to opt out, and where personal electronic health data relating to them can be identified in a dataset, personal electronic health data relating to those natural persons shall not be made available or otherwise processed pursuant to data permits issued under Article 68 or health data requests under Article 69 approved after the natural person has exercised the right to opt out (Art. 71(3). Within this, there may be centralised and decentralised solutions. The specific technical implementation methods for this (i.e. how the

data owner can possibly take this into account during data preparation, for example) will be worked out in the individual Member States in the near future.

As detailed in the TEHDAS2 D8.1 Guideline, this process may occur at different stages of the data flow, ensuring that restricted data is excluded before being made available in a secure processing environment.

Intellectual Property and trade secrets management

At the data preparation stage, it is assumed that the appropriate protection measures for information covered by IP rights or trade secrets, if any, have been established and applied by the HDAB.

More information on IP and trade secrets can be found in TEHDAS2 *D6.3 "Guideline for health data access bodies on the procedures and formats for data access".*

Pseudonymisation or anonymisation

Under the EHDS Regulation (Art. 66(2)), electronic health data shall be provided in an anonymised format by default, where the purpose of data processing can be achieved with such data. Where the data user has sufficiently justified that the purpose of data processing cannot be achieved with anonymised data (for example but not limited to, the need to identify repeated measurements over time from the same individuals), electronic health data shall be provided in a pseudonymised format (Art. 66(3), Art. 67(2)(e), 68(1)(c)). The final decision about the use of pseudonymised or anonymised data lies with the HDAB.

Article 57(1)(b) of the EHDS Regulation places responsibility for pseudonymisation or anonymisation on the HDAB. This duty might be formally delegated to the HDH, where it has the capacity and expertise to do so. In fact, it is good practice that personal electronic health data are pseudonymised or anonymised as close as possible to the data source, according to GDPR principles.

The process of pseudonymisation or anonymisation must be governed by clear procedural and technical guidelines. More detailed information can be found in TEHDAS2 *D7.2 "Guideline on data minimisation, pseudonymisation, anonymisation and synthetic data".*

Data linkage

Data linkage is the process of combining datasets from several sources on one topic or data subject. Article 57(1)(b) of the EHDS Regulation places responsibility of combining the data with the HDAB. Data linkage may be necessary for the HDH, especially when several datasets that the HDH controls need to be linked to comply with the request of the HDAB.

A detailed description of data linkage procedures can be found in TEHDAS2 *D7.5 "Guideline for health data access bodies on linkage of health datasets".*

Statistical aggregation in case of a data request

In case of a health data request, Articles 57(1)(b) and 69(1) of the EHDS Regulation place the responsibility for generating an anonymised statistical format on the HDAB. According to expertise and capacity of HDH, this operational task can be formally delegated to HDH. If not, HDH remains responsible for providing to HDAB the electronic health data which are

necessary to generate the anonymised statistical format required Article 72(6) sets out that if a data request covers electronic health data held by a THDH, the THDH shall carry out the tasks necessary to generate the anonymised statistical format.

A data request approval will contain a tabulation plan, and clear methodological definitions on how the anonymised statistical format should be calculated. TEHDAS2 *D6.3 "Guideline for health data access bodies on the procedures and formats for data access"* provides more details on the data request and associated data request form and assessment

3.6.3 Open data

HDHs with non-personal electronic health data that are publicly available should ensure that metadata for the data is included in the national dataset catalogue, including a link to the trusted open database where the data can be downloaded. As mentioned in the EHDS Regulation, trusted open public databases shall have in place robust, transparent and sustainable governance and a transparent model of user access (Art. 60(5)). Data users can access and download these open data directly from the original source – the EHDS Regulation does not require those data to be delivered to the HDAB.

4 How to navigate the EHDS landscape and infrastructure

4.1 Overview of the pathways for making data available

Up to this point, the guideline has outlined the legal obligations of HDHs under the EHDS Regulation and provided practical guidance for their implementation. The following sections describe the different pathways for making data available.

Under Article 60 of the EHDS Regulation, the procedures for making relevant electronic health data available may differ depending on the type of application and the national infrastructure in place. As described in Chapter 3.5.1 'Data permit and data request processes', the Regulation distinguishes between two application types: data permits under Article 68, which may involve access to individual-level data, and health data requests under Article 69, which result in aggregated or anonymised outputs.

Figure 1 illustrates the indicative pathway following the issuance of a data permit, while Figure 2 illustrates the indicative pathway following the approval of a health data request. Each figure provides a high-level view of the steps and decision points involved in making data available, reflecting differences related to the type of data, the application type, and the actors involved.

Across both pathways, the process of making data available follows a common sequence of actions by the HDH. This process begins once a data permit has been issued or a data request has been approved by the health data access body (HDAB), after which the HDH identifies the relevant data, prepares the corresponding electronic health data, and provides the data through the appropriate secure channel.

Subchapters 4.2 and 4.3 describe the detailed workflows and interactions specific to each pathway. These pathways are illustrated in figures 1 and 2.

- **Figure 1** provides a high-level conceptual illustration of the EHDS landscape and infrastructure for data permit, showing how data flows may differ depending on specific conditions.
- **Figure 2** provides a high-level conceptual illustration of the EHDS landscape and infrastructure for data request, showing how data flows may differ depending on specific conditions.

Figure 1 *Illustrative workflows for secondary use of electronic health data in the case of a data permit from a data holder's perspective.*

HDH=Health Data holder, HDIE=Health Data Intermediate entities, DU=Data User, Diamond=choices, Box=process, Oval=begin and end point, light blue box=non mandatory, expert advice process

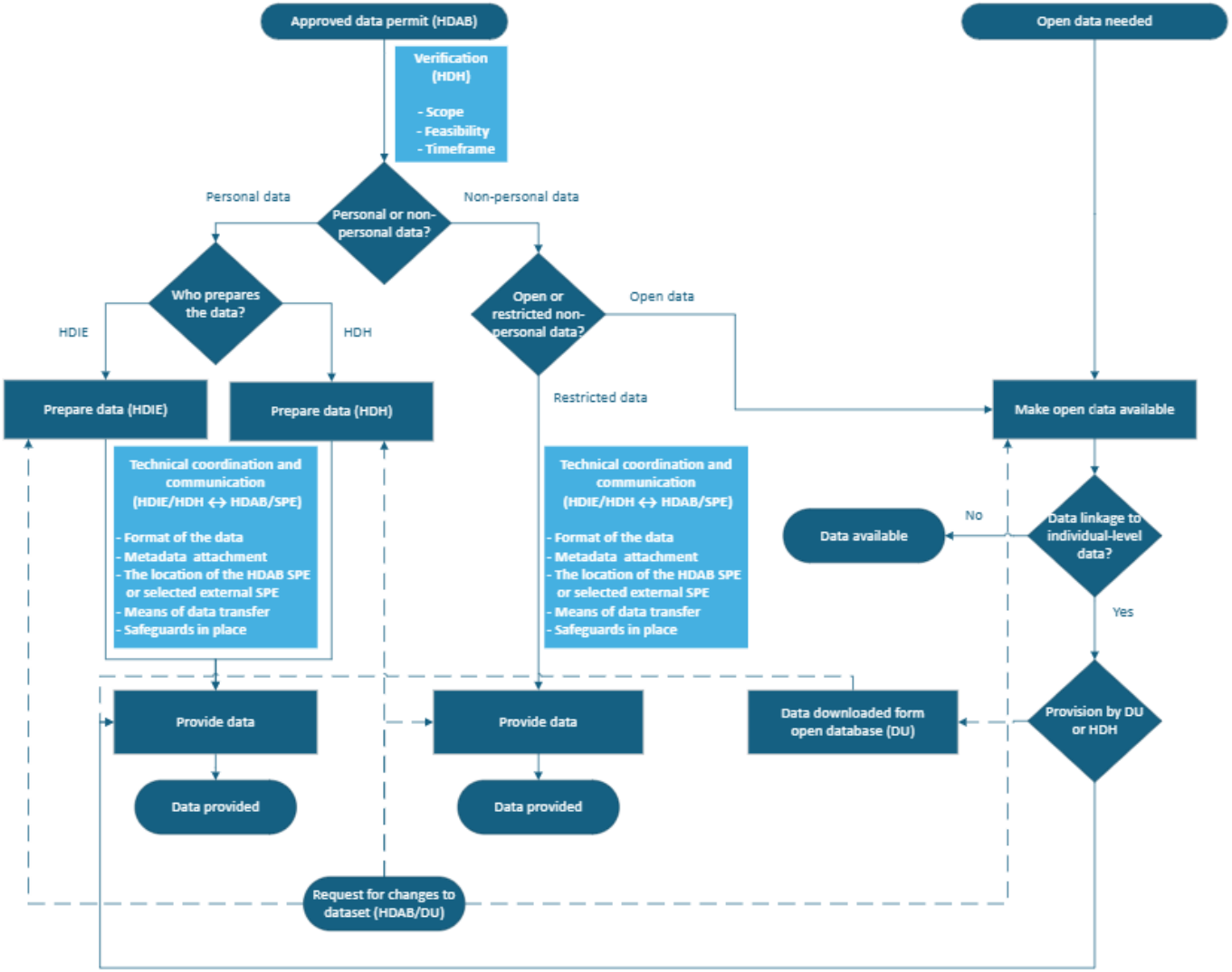
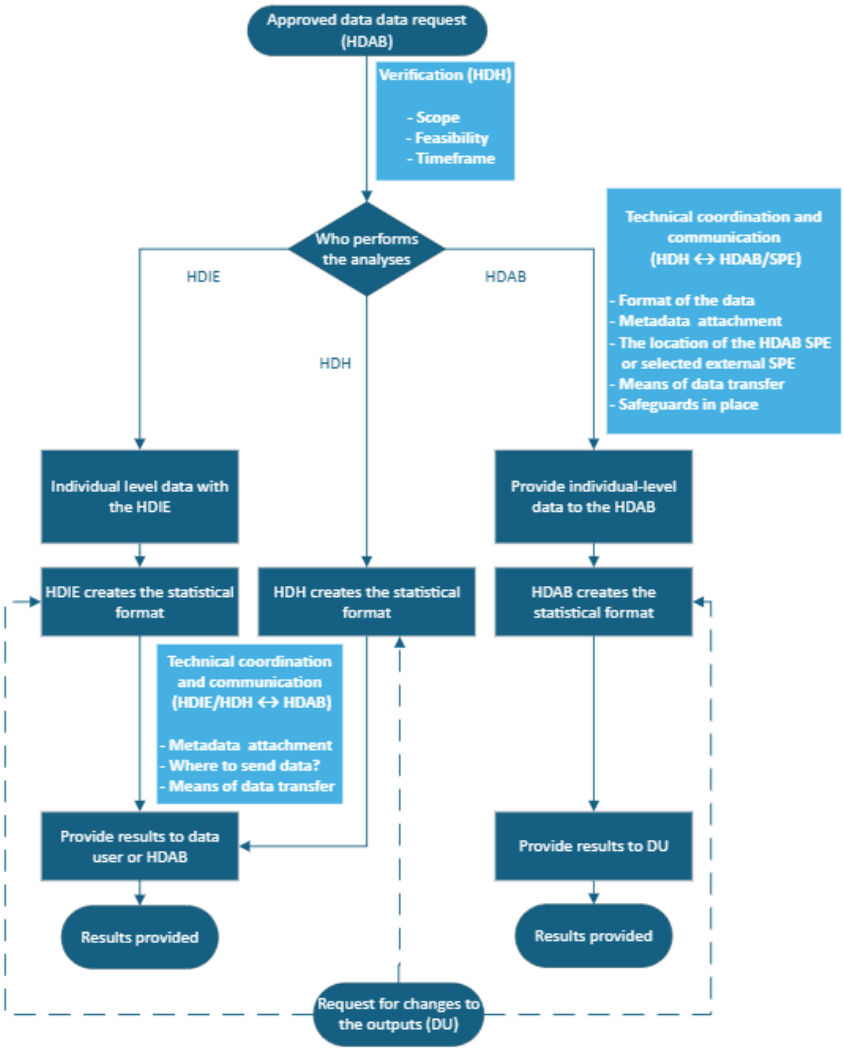


Figure 2 *Illustrative workflows for secondary use of electronic health data in case of an approved data request from a data holder's perspective.*

HDH=Health data holder, HDIE=Health data intermediate entities, DU=Data user, Diamond=choices, Box=process, Oval=begin and end point, Dashed box=non mandatory, expert advice process



4.1.1 Verification [Expert advice]

Expert advice — Verification of HDAB requests

TEHDAS2 experts recommend that HDHs verify key aspects of the HDAB's request before starting data extraction, preparation, and provision.

This verification applies to **both data permits and health data requests** and should focus on:

- the **scope** of the request
- the practical **feasibility**
- the **requested timeframe**

Although this verification step is not explicitly mandated by the EHDS Regulation, it reflects expert-recommended practice to support timely and compliant data provision. The purpose of this verification is to identify potential ambiguities, inconsistencies, or practical constraints at an early stage, thereby reducing the risk of delays, rework, or non-compliance later in the process.

The examples provided below are illustrative and highlight common situations in which clarification or adjustment may be needed. Other situations may arise in practice that similarly affect the scope, feasibility, or timing of data provision.

Scope of the request – *Is it clear which data should be provided and how?*

Examples of situations that may require clarification include:

- It is not clear whether data must be provided in an anonymised or pseudonymised format.
- The described method of selecting a population is unclear, contradictory or mutually exclusive.
- Tabulation plans needed for data preparation are not included.

Feasibility – *Is it practically possible to carry out the data extraction, preparation and provision in the way described?*

Examples include situations where:

- The population cannot be created using the specified method and/or variables listed in the data permit.
- The data is not structured in the way described by the HDAB.
- The described data provision to the HDAB would result in files that are too large for transferring to the selected secure processing environment (SPE).

Timeframe – *Can it be done and delivered within the requested timeframe?*

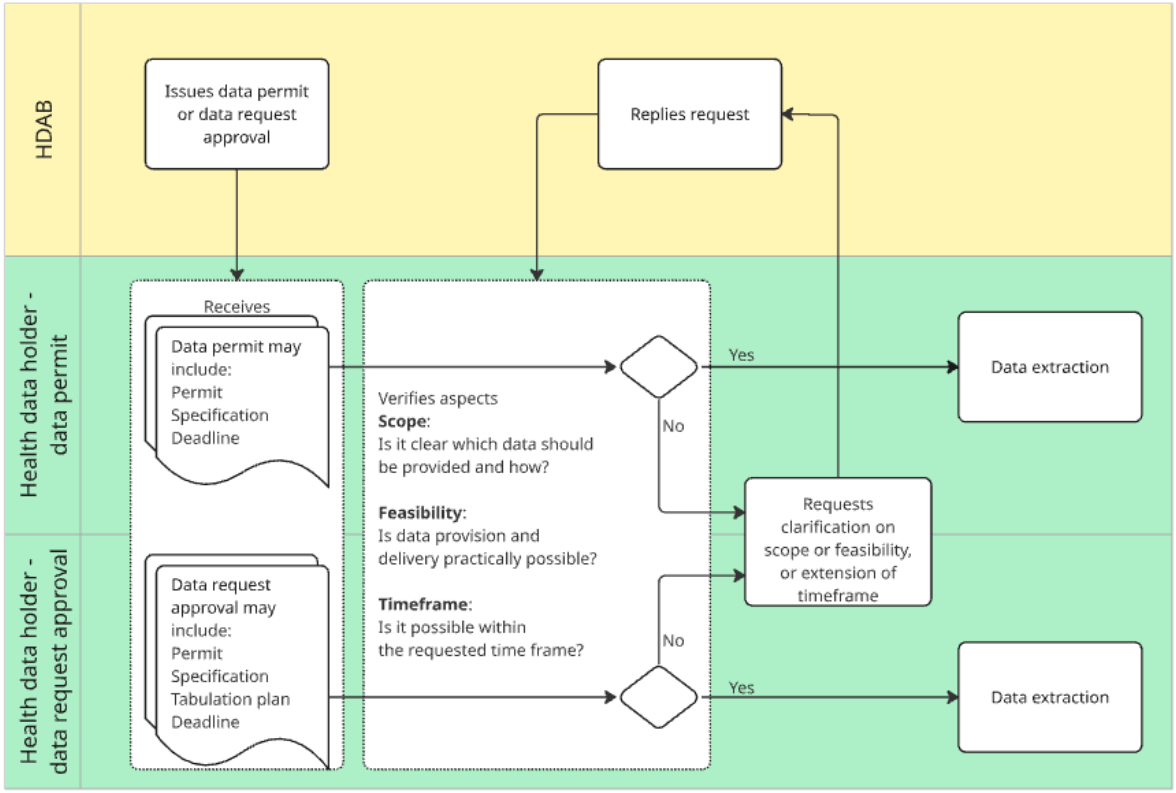
Example:

- The data extraction, preparation or provision has a high level of complexity that cannot be completed within the time frame.

It is recommended that HDHs are involved during the application assessment process. This will give the HDH the opportunity to see and comment the suggested data extraction description and prevent delays later in the process. However, experience shows that clarifications or extra information may be needed from the HDAB or the health data user after a permit has been issued or data request has been approved. After receiving a reply from the HDAB with clarifications or information on a potential extension of the timeframe, it is recommended that the HDH verifies these aspects again considering the new information.

Figure 3. *Illustrative flowchart of the recommended process of data verification and electronic health data subset creation by a health data holder after receiving a data permit or data request approval from a HDAB*.

HDAB=Health data access body.



4.2 Workflows for data provision

Article 60(1) of the EHDS prescribes that HDHs shall make relevant electronic health data referred to in Article 51 available, upon request to the HDAB. This section will briefly describe

what information the HDH will be provided with by the HDAB when it issues a data permit or approves a data request and the steps of the workflow for data provision for each of these application types.

Data provision refers to the process in which the requested data is provided to the designated recipient under the EHDS Regulation. Once the data have been extracted, and possibly prepared, by the HDH, the data is to be transferred to the HDAB (Art. 68(7)), typically via the SPE operated by the HDAB. When a Member State has designated/authorised one or more external SPE's the data may also be directly provided to such a secure environment (art. 73(2)).

The workflows for the data provision phase depends on several factors:

- The type of application (data permits and data request approval) i.e. the legal basis for the request.
- Type of data (personal or non-personal data), and
- the involvement of optional Member State assigned roles such as the THDH or the HDIE.

Depending on these factors, data holders will transfer data to the HDAB's SPE, a designated external SPE, or to an open database.

For cross-border data provision the data will first be provided to the HDAB coordination Member State HDAB, following the same provision process.

This section presents indicative schematic workflows for the two types of applications defined in the Regulation:

- Data permit under Article 68 (individual-level data); and
- health data request under Article 69 (resulting in aggregated outputs).

For more details on the HDAB duties for handling health data access applications and health data requests, issuing data permits and coordinating the exchange of electronic health data, see TEHDAS2 *D6.3 Guideline for health data access bodies on the procedures and formats for data access.* Additionally, the templates for the data access application, the data permit, and the data request are available in the HealthData@EU Central Platform. They are also presented in the annexes of the D6.3 guideline.

4.2.1 Workflow for data permit

The workflow for an HDH handling a request from an HDAB regarding a data permit begins when receiving the permit and ends when the data has been provided. The workflow is illustrated by Figure 1.

The HDAB will send the data permit decision to the HDH, together with a specification containing more detailed information of the data to be provided, and a deadline by which the data are to be delivered to the HDAB.

The data permit will provide information needed for the HDH to prepare the required data, including the following (as of the version annexed in the D6.3 guideline):

- In section 6.4 of the data permit, “Data to be disclosed on the basis of the data permit”, the HDH are listed, together with information on data sources and categories, as well as a short description of the data granted.
- In the same section, information can be found on whether the data are to be disclosed to the health data user in an anonymised or pseudonymised format.
- Section 6.5 of the data permit, “Preparing and disclosing of the data” together with corresponding parts of the specification (Appendix 1) is important for the HDH to understanding how the data should be prepared and disclosed.
- Appendix 1 of the data permit presents a detailed description of the data. The format of the specification may vary between Member States and/or HDABs.

After taking part of the information in the permit and potentially verifying its key aspects, as recommended in section 4.1.1 of this guideline, the data holder must perform the data preparation steps that fall under its responsibility and in accordance with the data permit. In Section 3.5.12, steps of the data preparation phase and responsibilities are described. Which steps that might be relevant will depend on the specific details of the permit.

Under Article 66, the EHDS Regulation requires that HDABs only make data available to the extent necessary for the approved purpose and, where appropriate, in anonymised or pseudonymised form.

It is considered good practice for anonymisation or pseudonymisation, where applicable, to be performed as close to the source as possible - for example, by the HDH before transmitting data to the HDAB or SPE. Therefore, TEHDAS2 experts recommend that, in the case of a data permit, already anonymised or pseudonymised individual-level electronic health data are provided to the HDAB or the selected SPE.

Communication:

When a data permit is issued by the HDAB, the HDAB coordinates with the HDH and designated SPE to organise the data transfer in accordance with the permit.

Expert advice — Technical coordination and communication

In order the coordinate the following information may be communicated:

- Format of the data
- Metadata to be added
- Dataset identifier
- The location of the HDAB, SPE or selected external SPE
- Means of data transfer.

The assigned SPE must meet the technical and legal conditions under Articles 73 and 74. The HDH may consult the HDAB to confirm that the appropriate safeguards are in place.

Metadata:

When providing data to the HDAB or SPE, good practice is to include metadata to the dataset, including at least the following information:

- Dataset Identifier.
- Versioning.
- Date and time of extraction.
- Date and time of the latest dataset update at the moment of the data extraction.

Data encryption:

Recital 4 of the EHDS Regulation highlights the sensitivity of personal electronic health data and the need for sufficient safeguards at both Union and national level to ensure a high degree of data protection, security, confidentiality and ethical use. To ensure safe and secure data provision, good practice is to encrypt the data before transferring it to the designated environment and to share the encryption key separately from the dataset. More details on data encryption can be found in TEHDAS2 *M7.2 Guideline on data minimisation, pseudonymisation, anonymisation and synthetic data*.

Data transfer:

As the EHDS mandates that data is provided safely and securely, TEHDAS2 experts recommend that the data transfer takes places via a secure channel, using the EHDS infrastructure. Examples of data transferral transactions include:

- Automatic transferral, for example:
    - Pull strategy – The target system initiates the data transfer by requesting or retrieving data from the source system.
    - Push strategy – The source system initiates the data transfer by send data to the target system.
    - Notified pull strategy – The source system sends a notification indicating that data is ready, after which the targets system initiates a pull to retrieve the data.
- Manual transferral, for example:
    - Drop transaction – The HDH copies their data and drops the copy into the target system.

After data provision the HDAB may check whether the provided data complies with the data permit. If the data is incorrect or not coherent with the data described in the data permit, the HDAB may notify the HDH that the data is incomplete, inconsistent and request a correction.

During this step, interaction is needed to clarify the change or addition needed. In case of a request for changes (modifications to the datasets) after data provision, the HDH would be referred to the steps of data preparation phase. After the changes have been made, the HDH will follow steps 1-4 of the data provision process again.

In some cases, the health data user may request clarifications or raise concerns through the HDAB. It is considered good practice for HDABs to relay such requests to the HDH where appropriate, particularly in relation to data quality or interpretation.

4.2.2 Workflow for data request

The workflow for a HDH handling a request from a HDAB regarding an approved data request begins when receiving the approval and ends when the data has been provided. The workflow is illustrated by Figure 2.

After approval, the HDAB will send the data request approval to the HDH, together with a specification of the required electronic health data, including scope, format, and intended use.

After taking part of the information in the data request approval and potentially verifying its key aspects, as outlined in section 4.1.1, the HDH must perform the data preparation steps that fall under its responsibility and in accordance with the approval. In Section 3.5.2 steps of the data preparation phase and responsibilities are described. Which steps that might be relevant will depend on the specific details of the approval. In order to derive anonymised, aggregated statistical outputs from personal or non-personal electronic health data, processing might be required by the HDH or an HDIE carrying out the HDHs duties and/or the HDAB.

In such cases where other entities than the HDAB creates the statistical format, one or more tabulation plans could be provided with the data request approval from the HDAB. Tabulation plans are vital to the HDH when preparing data in a statistical format as they contain information on the health data user's needs regarding how the data extraction and compilation of the statistics must be carried out. This includes information on data source(s), variables from each data source to be used, potential new variables to be constructed, linkage between datasets, the order of creating the statistics, and other factors that are of relevance when producing the requested statistics. (See section 3.5.2).

Depending on the nature of the data request, HDHs may need to provide individual-level personal data to the HDAB for further processing to achieve the statistical format. This could be the case for example, when the HDAB needs to combine data from two or more HDHs to produce the requested statistical format.

In case of a data request, two potential data provision options may apply for the HDH:

- **Option 1:** The individual-level electronic health data is provided to the HDAB. The provision of the data will follow the steps described in 4.2.1. The HDAB will then create the statistical format and provide this to the health data user.
- **Option 2:** The HDH creates the statistical format and provides the results to the HDAB or where applicable, directly to the health data user.

The EHDS Regulation does not prescribe which actor should perform the statistical aggregation. Depending on the request's complexity and the capacity of the HDH, the aggregation may be carried out by the HDH, an THDH, an HDIE, or the HDAB. Cross-border requests or complex linkages may require centralised processing by the HDAB.

A data request can only result in an anonymised statistical output which is non-personal data). The EHDS Regulation defines "non-personal electronic health data" as electronic health data that do not constitute personal data within the meaning of the GDPR (Art. 2(2)).

Workflow for option 1, where the HDAB creates the statistical format, is similar to that of a data permit (section 4.2.1). The HDH prepares the data and transfers them to the HDAB.

In the case of option 2 where the data holder creates the anonymised statistical format, the anonymised statistical output (i.e. results of the analyses) is transferred to the HDAB. In case of a trusted data holder, the results could be provided directly to the health data user. Figure 6 exemplifies the workflow in case of a data request when the (trusted) data holder performs the analysis.

To deliver the data to the HDAB or the data user, TEHDAS2 experts recommend taking the following steps.

Communication:

The HDH contacts the HDAB (or, where applicable, the relevant recipient) to confirm that the data have been prepared and are ready for transfer. The following information should be communicated:

- Where to send the data.
- Means of data transfer (technical).

Metadata attachment:

Good practice is to include metadata with the transferred dataset, including information on:

- Versioning (if applicable).
- date and time of data extraction.
- date and time of the latest dataset update at the moment of data extraction.

Data transfer:

It is recommended that data holder uses existing structures for the data transfer in case of anonymous statistical data (results). Anonymised data is not in scope of the GDPR (Art. 2(2)), and GDPR requirements do not apply to the transferred output. However, appropriate security and governance measures may still be required under the EHDS and national law.

4.3 Handling of non-personal data

The EHDS Regulation defines "non-personal electronic health data" as electronic data health data that fall outside the scope of the GDPR (Art. 2(2)). It does not, however, prescribe the provision of non-personal data. These are determined at implementation level by Member States. The recommendations provided in these sections are based on the advice of TEHDAS2 experts.

Depending on whether non-personal data are openly available or subject to use restrictions, different provision mechanisms may apply. The following subsections distinguish between:

1. Open non-personal electronic health data.
2. Restricted non-personal data provided via the HDAB, and
3. linkage scenarios involving both types.

Freely available non-personal data

HDHs with non-personal electronic health data that are publicly available should ensure that the data is listed in the national dataset catalogue, including a link to the open database where the data can be downloaded (Art. 60(5)). Examples of open data repositories can be found in the European Data Portal (EDP)[2].

When non-personal data is already available via an open public database, the EHDS Regulation does not require an additional delivery of those data to the HDAB. Health data users can access and download these open data directly from the original source. It is recommended to include the dataset catalogue metadata, a link to the database environment where the data are available for download.

Access-restricted non-personal data

Some non-personal data may be access-restricted, due to Intellectual Property (IP) rights or sensitivity reasons and will not be freely available to users in an open public database. Examples of such data are patient safety data per healthcare organisation or synthetic data. However, the EHDS Regulation (art. 60(5)) requires HDHs to make such data available for secondary users, if and when requested, and authorised through the relevant HDAB process.

For an HDH of access-restricted non-personal data to provide these to a user, the data provision steps are similar to provision of personal data, because of the safeguards needed to be in place. TEHDAS2 experts advise that the same steps can be expected in the data provision regarding communication, metadata information, data encryption and data transfer (via SPE). For more details per step, please read section 4.2.1 on Workflow for data permits and the visual representation in Figure 1.

Data Linkage with data in open data repositories

In case of approved access to individual level personal health data that needs to be linked to open data, the open data should be provided to the HDAB or external SPE for processing by the HDAB. For example, if a researcher wants to assess the correlation between air pollution and type of lung cancer, they can request lung cancer data from a cancer registry and link air pollution data to the individuals in the cancer registry via their postcode.

In case of linkage of individual level personal health data to be linked with non-personal data from an open data repository two options may apply:

- **Option 1**: The health data user can download the relevant open data and provide them to the HDAB / SPE. The HDH will transfer the relevant non-personal open data to the same SPE. HDHs that publish open data are primarily required to ensure that the data are made available via an open public dataset catalogue.

[2] Data.europa.eu; The official portal for European data. European Union). data.europa.eu

- **Option 2**: If open data are downloaded by the user and combined with personal health data by the health data user, this occurs within the SPE, under HDAB supervision (per Articles 73–74). The HDAB remains responsible for compliance with applicable security and governance requirements, and where personal data are processed, data protections requirements.

4.4 Interaction and communication within the national EHDS infrastructure

Interaction between HDHs and HDABs is an integral part of the secondary use process under the EHDS framework. Effective communication supports the timely, secure, and correct provision of electronic health data and contributes to their appropriate interpretation and reuse for secondary purposes such as research, innovation, policymaking, and public health activities.

Interaction occurs at multiple points throughout the data user journey. Some interactions arise directly from obligations set out in the EHDS Regulation, while others reflect recommended practices that support efficient workflows in practice. This section describes how interaction typically occurs across the main phases of data provision and highlights common interaction scenarios encountered by HDHs.

4.4.1 Means of communication

Facilitation of a communication channel between the HDAB(s) and HDHs is recommended, potentially within the SPE or an application portal.

Communication between HDABs and HDHs should follow a structured and transparent process to ensure efficiency and accountability. Upon receiving a health data access application or health data request, the HDAB is responsible for notifying the relevant HDH. In response, the HDH must confirm the feasibility of the request through the corresponding standardised form, which should include the expected timeframe for data delivery as well as an estimate of any justified costs related to data preparation. If the HDH requires additional clarification regarding the health data access application or health data request, they should initiate contact with the HDAB. See TEHDAS2 *D6.3 Guideline for health data access bodies on the procedures and formats for data access* for more details on HDAB responsibilities.

Furthermore, email or another mutually agreed communication channel should be used for correspondence that falls outside the scope of standardised forms, such as informal queries, coordination issues, or follow-up discussions. It is advised that communications are recorded in a traceable manner to ensure proper documentation and transparency, and to support fair appeal processes, if needed possible interactions across the data lifecycle

HDHs may interact with the HDAB and, in some cases, indirectly with health data users at different points throughout the data lifecycle. Some interactions are explicitly required under the EHDS Regulation, while others are recommended by experts to support efficient workflows, ensure data quality, and facilitate the correct interpretation of results.

Table 3 below provides a non-exhaustive and illustrative overview of possible interaction points between HDHs and HDABs across the different phases of the data lifecycle. Not all interactions will occur in every case, and the need for interaction depends on the specific context, the data requested, and national implementation arrangements.

Table 3. *Overview of possible interactions between health data holder(s) and HDABs across the data user journey*

Possible interaction	Phase of the process	Actors	Purpose of interaction	Nature of interaction
Clarification of dataset scope, availability, or metadata	Data discovery	HDH HDAB	To support accurate understanding of available datasets and prevent misaligned applications	Expert advice
Notification of intellectual property, trade secrets, or confidentiality constraints	Data discovery / Data preparation and provision	HDH HDAB	Notification of intellectual property, trade secrets, or regulatory confidentiality elements, with a request for appropriate safeguards	Mandatory Art. 52(2)
Verification of scope, feasibility, timeframe (see 4.1.1)	Data preparation and provision	HDH	To clarify scope, feasibility and timeframe before data preparation begins	Expert advice
Completeness of provided data	Data preparation and provision	HDH HDAB	To address incomplete or incorrect data prior to making data available	Expert advice
Technical coordination and communication (see 4.2.1)	Data preparation and provision	HDH	To support practical coordination on technical aspects of data preparation and provision, including formats, metadata, secure transmission, and safeguards	Expert advice
Clarification questions regarding data content or definition	Finalisation and follow-up	HDH HDAB	To support correct interpretation, analysis, and reuse of the data	Expert advice
Notification of significant findings	Finalisation and follow-up	DU HDAB	To enable the appropriate notification of significant findings to affected natural persons or treating professionals, while respecting individual preferences and national legal conditions	Mandatory Art. 58(3)
Audits of quality and utility labels	Across all phases	HDAB HDH	HDAB needs to verify the correctness of a formal label in the catalogue	Mandatory Art. 78(4)
Cooperation on data quality and usability	Across all phases	HDAB HDH	HDAB needs clarification about the data or metadata itself	Mandatory Art. 60(3), Art. 77

5 Implementation considerations

HDHs across Europe have a key role laying the foundation for health data use and reuse, for the potential benefit of individuals and society. The EHDS Regulation marks a significant initiative to make European health data more findable, accessible and useful for the intended secondary purposes. However, the realisation of this goal depends largely on the efforts of Member States and the HDHs, including assessment of their own ability and capacity not only to fulfil the mandated duties in the EHDS but also their broader commitment to foster data quality, to ensure effective data management and engage in communication with other stakeholders.

5.1 Considerations for health data holders on next steps towards the EHDS

While there is a set of defined duties and tasks for HDHs to comply with, it is evident that this draft guideline cannot go beyond the basic common elements of the requirements in relation to the preparation and provision of any health data for secondary use. To support these common elements, Annex 6 provides illustrative checklists for HDHs (6.1- 6.3) covering advice on, among others, preparation for EHDS readiness, subset creation, data preparation, and providing data, and offers a non-exhaustive overview of recommended preparatory steps based on expert advice. At the same time, detailed guidance for HDHs on how to proceed with initial assessment or what to consider in preparation would depend on multiple factors, including understanding of the individual business processes and needs in the different types of organisations and settings. Any natural or legal person as well as organisation that qualifies as a HDH according to the EHDS criteria will need to assess, in its specific context - their own ability and capacity to fulfil these duties. Dimensions to consider in relation to a HDHs ability and capacity concern the level of maturity and/or expertise regarding for example: data collection, data management and governance, infrastructure, data access procedures from a legal, ethical and technical perspective.

5.1.1 Maturity level at health data holder level

The sections regarding maturity levels within this chapter, provide a structured reference to assess the organisational and infrastructural maturity of HDHs and Member States in preparation for the application of Chapter IV of the EHDS Regulation, which becomes applicable from March 2029 for most data categories. The maturity guidance herein builds upon criteria developed in EU-funded initiatives, notably the QUANTUM project, the (first) TEHDAS Joint Action, and preparatory activities supported by the European Commission under the Digital Europe Programme. It reflects policy insights and practical readiness dimensions for secondary use of health data, aligned with Articles 50 to 78 of the EHDS Regulation and informed by practical implementation scenarios and use cases. The information supports the incremental development of national infrastructures, institutional capacities, and data governance systems that comply with the EHDS legal framework, while allowing for differentiated starting points and growth trajectories among Member States and HDHs. The maturity levels described in this chapter should be treated as illustrative examples.

In the national context, HDHs must assess their organisational maturity to determine their readiness to comply with the obligations established by the EHDS Regulation. This assessment should be aligned with structured maturity models, such as those developed by

the QUANTUM project, and reflect clear criteria across various levels, from initial or basic to advanced or optimised. A clear articulation of maturity levels helps distinguish between baseline compliance and advanced capabilities. A basic or entry-level maturity implies that an HDH has minimum capabilities to describe datasets (Art. 77), respond to data access requests (Art. 68), and ensure secure data sharing within prescribed timelines (Art. 60(2)). At the highest levels, organisations are able to provide automated data extraction, manage data across multiple domains, implement advanced privacy-preserving techniques (Art. 66), and proactively support data quality and utility labelling (Art. 78).

While both minimally and highly capable and equipped HDHs may comply with EHDS requirements, the ability to create meaningful subsets of data or extract specific variables from complex systems such as electronic health records represents a more advanced maturity. For example, two organisations may list "electronic health record data" in a data catalogue, but only one may be technically capable of isolating specific variables such as concrete disease, its stage, therapy, mortality or prescription history in the existing datasets for reuse. Higher capabilities enhance dataset granularity, facilitate reuse, and increase responsiveness to data permits (Art. 68). This should be acknowledged in maturity evaluations and labelling schemes. Advanced capabilities do not negate the compliance of less-equipped HDHs but indicate a higher performance tier.

Institutional maturity is also reflected in governance and risk management systems. Mature organisations have internal mechanisms to flag Intellectual Property (IP) or trade secret concerns early in the permit process (Art. 52), reducing processing delays and ensuring legal compliance. Institutions with robust policies are better positioned to support both primary governance functions and secondary use, including obligations tied to data altruism and public interest research under Articles 53 and 54.

Capacity plays a decisive role. Larger HDHs must ensure that their systems can scale appropriately to manage the increased volume and complexity of processing in line with EHDS requirements. Smaller entities, particularly those with microenterprise status exempted under Article 50 paragraph 1, may in some cases require support to fulfil their obligations efficiently. Depending on the national context and legal provisions, this support might be facilitated through the delegation of responsibilities to HDIEs, as envisaged under Article 50 paragraph 3. This approach allows Member States to accommodate a wide range of organisational capacities and capabilities of various data holders while maintaining coherence with the overall EHDS framework.

Steps toward readiness for beginner Health Data Holders

For HDHs at the beginning of their digital transformation in secondary use of health data, the pathway to EHDS readiness should be achievable through a set of foundational steps. These include:

1. *Definition of tasks and responsibilities* within the organisation/enterprise, allocation of staff and tools and (IT) technologies necessary for making health data available.

2. *Dataset identification and registration:* Clearly identify datasets relevant under Article 51 and ensure their registration with the Health data access body, including submission of dataset descriptions in line with Article 60 paragraph 3 and Article 77.

3. *Timely data provisioning:* Establish procedures to respond to data requests within three months, extendable once, as outlined in Article 60 paragraph 2.

4. *Governance structures:* Define internal responsibilities for data controllership and, where applicable, joint controllership in compliance with Article 60 paragraph 2.

5. *Secure data handling*: Develop basic capabilities for secure data transmission (Art. 60 (5)) and coordinate with the Health data access body for any required pseudonymisation or anonymisation under Article 66.

6. *Personnel training*: Ensure relevant staff are trained on their duties regarding access, opt-out mechanisms (Art. 71), secure processing environments (Art. 73), and interaction with the Health data access body.

These measures, while foundational, constitute the core of what is required to comply with the EHDS Regulation. Importantly, they provide a scalable basis upon which more advanced capabilities can be gradually developed. Beginners that establish sound data governance and cooperative procedures with national structures can meet their obligations effectively without having to implement complex technical systems from the outset.

The QUANTUM[3] maturity model and EHDS guidelines provide a shared reference framework that can support such incremental growth while ensuring alignment with European standards.

5.2 National considerations

Member States are obliged to ensure that legal, organisational, operational, semantic, technical, safety and cybersecurity measures are in place. Implementation will require several important choices affecting your place as an HDH within the EHDS legal and technical architecture. As a HDH, in preparation for the EHDS you need to be aware of the progress and choices made in the Member State in which the data is included in the national metadata catalogue (Art. 60(3), Art. 77(1)).

Based on emerging implementation discussions, at least four configurations of the EHDS-infrastructure may arise, based on the position of the coordinating Health Data Acces Body (HDAB) and the National Contact Point (NCP).

1. Member States with a single HDAB acting as the role of coordinating HDAB operating the HDAB Coordinator Portal and the NCP.

2. Member States with several distinct HDABs, and one HDAB acting both role of Coordinator HDAB and NCP operator.

3. Member States with a single HDAB acting as the coordinating HDAB, and another legally designated organisation operating as the NCP.

4. Member States with several distinct HDABs, one coordinating HDAB and another legally designated organisation operating NCP.

[3] QUANTUM Deliverable 1.2 Specification for the assessment of data holders´ maturity

Regarding secondary use, by 26 March 2029, HDABs must be ready to receive applications, as well as be connected to HealthData@EU. By 26 March 2031, the HDABs must also be ready to exercise their tasks regarding the final categories of data (Art. 51).

Although the EHDS Regulation is not specific on many topics, and several implementation acts are forthcoming, numerous choices that remain will be tackled by Member States. Besides the pattern of the infrastructure, these choices will have implications for the HDHs regarding the procedural pathways for data preparation, provision and interactions with HDAB and the other EHDS roles.

A minimum set of so-called digital business capabilities can be defined as a prerequisite for a Member State's participation in the EU HealthData@EU platform. These digital business capabilities result from the obligations enshrined in Chapter IV of the EHDS Regulation for the establishment of national HDABs in Member States and include:

- Data access application management system (DAAMS) – to streamline the process of requesting and granting data access.
- National dataset catalogue of health data – to provide a comprehensive and searchable listing of available health datasets.
- Secure processing environment – to ensure that health data is processed in a secure and compliant manner.
- Cross-border gateway for HealthData@EU – to facilitate the safe and efficient exchange of health data across borders.
- Health data quality enhancement – to improve the accuracy, completeness, and reliability of health data.
- Opt-out management system – mechanism to allow natural persons to opt-out from secondary use.
- HDAB transparency portal – to make publicly available information related to secondary use of health data (e.g. applications, permits, results).

Table 4 provides non-exhaustive, illustrative examples of Member State implementation choices that may affect the duties, responsibilities and operational processes of HDHs under Chapter IV of the EHDS Regulation.

Table 4. *Examples of choices made by Member States that will influence the data holders' duties, responsibilities, and processes.*

HDAB=Health data access body, THDH=Trusted health data holder, NCP= National contact point (NCP), DAAMS= Data access application management system

Category	Examples of choices made by Member States	EHDS Articles
Governance and the national authority responsible for EHDS implementation	Designation of coordinating HDAB, where applicable, and the NCP.	55(1), 75(1)
	Designation of one or multiple HDABs.	55(1)
	Assessment of required expertise and ensuring appropriate personnel are in place within the HDABs.	55(2)
	Potential extension of duties regarding micro-enterprises.	50(2)
	Member States may establish reduced fees for certain types of health data users	62(1)
	Potential additional categories of electronic health data (where permitted).	51(2)
Technical infrastructure and interoperability standards	Implementation of services such as a national dataset catalogue and the DAAMS.	57(1)(e), 57(1), point (j)(i)
	Designation of THDHs and HDIEs. (optional)	72(2), 50(3)
	Designating of national secure processing environment(s) used for the EHDS infrastructure (which may also be organised locally or regionally).	73(1)
Rules for accessing electronic health data, ensuring security and privacy	Setting up the national opt-out system for secondary use of health data (including responsibilities).	71(2), 58(2)
	Providing in national law for a mechanism to make data for which a right to opt out has been exercised available (under strict conditions).	
	Decision on permitted exceptions to the right to opt out (Art. 71(4)). (optional)	
	Decision on where to place responsibility for data security and privacy measures such as anonymisation	55(3)

	and pseudonymisation (also dependent on Member State organisation maturity).	
	Data access procedures: establish clear and transparent procedures for authorising and granting data access, including ethical and privacy considerations.	55(2), 67(2)(j), 68(1)(f)
	Stricter national measures and additional safeguards for sensitive data categories. Which may require additional approvals or further restrictions on access and use.	51(4)
	National law conditions for informing the natural person or health professional treating them in the event of "significant findings".	58(3)
Aligning EHDS implementation with existing national health data systems	Define technical infrastructure, interoperability standards, and requirements for national data-sharing frameworks.	
	Specify national standards to ensure data usability and reliability.	

Early clarification and communication of these national choices are critical for coordinated implementation.

In more mature systems, national authorities may offer support measures for HDHs:

- Centralised data services,
- Harmonised templates,
- Legal and technical guidance,
- Capacity-building initiatives.

To prepare as an HDH, it is essential to follow progress in your Member State and the choices made on these topics. The variability in national progress will directly impact how ready individual HDHs can be by 2029.

5.3 Concluding remarks

This guideline has provided high-level, structured guidance to HDHs on how to fulfil their duties when making personal and non-personal electronic health data available for secondary use, focusing on the phase after a data permit has been issued or a health data

request has been approved by an HDAB. Within this scope, it described the minimum steps involved in data preparation and provision and distinguished clearly between mandatory requirements arising directly from the EHDS Regulation and recommended practices based on TEHDAS2 expert advice. In summary, this guideline:

- Sets out the scope and boundaries of the document and its relationship to other TEHDAS2 deliverables (Chapter 2).
- Summarises the legal framework and mandatory minimum process for making data available (Chapter 3).
- Describes schematic workflows and recommended practices that may support effective and proportionate implementation in practice (Chapter 4).
- Highlights implementation considerations and next steps for HDHs, including maturity and national variability (Chapter 5).

This deliverable is an informative and non-binding document. It does not attribute or reassign responsibilities beyond what is explicitly set out in the EHDS Regulation, nor does it override national implementation decisions. It is intentionally positioned as an introductory and connecting guideline and does not function as a detailed technical or operational manual.

As part of TEHDAS2 Work Package 6, this guideline complements other TEHDAS2 deliverables that provide more detailed guidance on topics such as dataset description, data minimisation and anonymisation, opt-out implementation, application handling, and SPEs. It is important to note that the EHDS Regulation does not yet provide specific details on many topics. It will be supplemented by a number of delegated acts (implementation acts). Annex 3 (Heath data holder resources) provides an overview of relevant TEHDAS2 and other supporting materials; the most up-to-date versions can be found on the TEHDAS website[4]. In addition, other informative documents, such as the European Commission “Frequently Asked Questions on the European Health Data Space”[5], may support HDHs in their understanding of the EHDS.

[4] Draft guidelines and technical specifications of TEHDAS2, Public consultations - Tehdas. Accepted deliverables that are published: Results - Tehdas.
[5] Frequently Asked Questions on the European Health Data Space , European Commission 4dd47ec2-71dd-49fc-b036-ad7c14f6ed68_en

6 Annexes

Annex number	Annex title
1	Methodology
2	Public consultation summary
3	User journey and other HDH resources
4	Glossary
5	Links to the EHDS Regulation
6	Steps and illustrative checklist for health data holders

Annex 1 – Methodology

The contributors participated according to their promised commitments, ensuring a collaborative and thorough development process. See below the information about our structured work together.

- Desk research was performed by all contributors. During this process, relevant information was collected from expert organisations, related programmes and entities, such as the Community of Practice, QUANTUM, TEHDAS.
- Working meetings − We conducted regular working meetings to discuss and outline the key components and structure of the guideline, as well as address any unclarities in the regulation.
- Write-a-thons − Nine write-a-thons, lasting two to three hours, were held to collaboratively draft and refine the content. What was not written during the write-a-thon was finished offline by a designated contributor.
- Artificial intelligence (AI) tools were employed to support the development of this document, particularly OpenAI's ChatGPT. The enterprise environment of OpenAI was used, ensuring that no data entered was stored or used for training AI models. ChatGPT was used for summary and suggestive purposes. All output generated by ChatGPT was reviewed, edited, and finalised by the contributors. None of the text in the document was independently written by AI or LLM.
- Consultations with DG SANTE − Five meetings with representatives from DG SANTE were organised to ensure alignment with regulatory requirements and to gather expert feedback.
- Consultations with related TEHDAS2 tasks in which alignments between the guidelines was ensured.
- Public consultation results were analysed and processed with the whole workgroup and discussed during the working meetings. For further specification see Annex 2.

Annex 2 – Public consultation summary

A draft version of this document was in public consultation in November 2025. This document was commented in total for 99 times. The number of responses may contain some duplicates as there was no individual identification and verification required to respond to the surveys. Some respondents have also responded both from data holder's and data user's perspective. The responses came from 16 different countries from the EU countries and the European Economic Area countries. Responses from stakeholders based in Bulgaria (BG), Croatia (HR), Czech Republic (CZ), Estonia (EE), Greece (EL), Latvia (LV), Malta (MT), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI) and international organisations were largely missing. The respondents were primarily from three main types of organisations, listed in order of prevalence: public organisations, academic/research organisations, and private organisation.

A2.1 Main themes identified in the consultation feedback

Analysis of the consultation input revealed several recurring themes:

- **Scope, structure, and usability:**
  Many respondents perceived the draft guideline as lengthy and difficult to navigate. There were diverging expectations, with some stakeholders preferring a shorter, high-level document and others requesting more practical support.

- **Clarity on legal obligations versus recommendations:**
  A consistent concern was the need for clearer distinction between mandatory requirements under the EHDS Regulation and non-binding recommendations or expert advice, to avoid the perception that the guideline introduces additional obligations.

- **Feasibility, proportionality, and organisational diversity:**
  Respondents highlighted differences in maturity, resources, and technical capacity across HDHs, and stressed the importance of proportionality, particularly for smaller or less mature organisations.

- **Roles, responsibilities, and workflows:**
  Several comments requested clearer explanation of the roles of HDHs, HDABs, THDHs, and HDIEs, as well as clearer end-to-end workflows reflecting real-world practice.

- **Handling of non-personal data and interaction with other frameworks:**
  Respondents asked for clearer treatment of non-personal electronic health data and better signalling of how the guideline relates to other legal and technical frameworks, including other TEHDAS2 outputs.

A2.2. How the feedback was addressed in the revised guideline

In response to the consultation feedback, the task group revised the guideline with a focus on clarification, structure, and proportionality, rather than expanding scope.

1. **Clearer scoping and expectation management**
   The Introduction and Scope were revised to explicitly state that:

- the EHDS Regulation does not comprehensively prescribe all operational responsibilities;
- the guideline does not attribute or reassign responsibilities beyond what is defined in the Regulation; and
- several aspects of implementation depend on national legislation, governance arrangements, and organisational choices.

This clarification was introduced to manage expectations and to avoid interpretation of the guidelines as creating new or additional obligations.

2. **Restructuring of the document**
   The overall structure of the guideline was revised to improve readability and orientation. In particular:
   - mandatory duties and the minimum process derived from the EHDS Regulation are consolidated in a dedicated chapter (*Chapter 3: Legal framework and mandatory process*);
   - recommended practices, workflows, and expert advice are presented separately and explicitly framed as non-binding (*Chapter 4: How to navigate the EHDS landscape and infrastructure*); and
   - implementation considerations, including organisational maturity and national variability, are addressed in a concluding chapter *(Chapter 5: Implementation considerations)*.

   This restructuring was intended to help readers more easily distinguish between what is legally required and what is provided as supportive guidance.
3. **Revision of workflows without expansion of scope**
   Indicative workflows and figures were revised to improve clarity and consistency with the revised structure. No new workflows were introduced as a result of the consultation. The workflows are explicitly framed as illustrative and non-binding, reflecting expert experience rather than prescriptive process requirements.
4. **Increased use of cross-references to other TEHDAS2 deliverables**
   To address concerns about duplication and inconsistency, the revised guideline relies more explicitly on cross-referencing other TEHDAS2 deliverables for detailed technical or procedural guidance (for example on metadata, anonymisation, opt-out mechanisms, secure processing environments, and application handling), rather than restating or further elaborating those topics in D6.1.

To conclude, the public consultation confirmed broad support for the objectives of the guideline, alongside a clear request for improved clarity, usability, and proportionality. The revisions implemented in this version aim to reflect that feedback while maintaining alignment with the EHDS Regulation and the broader TEHDAS2 framework.

Annex 3 – User journey and other HDH resources

This Annex offers a curated selection of resources to support HDHs in preparing for and operating within the European Health Data Space (EHDS) Regulation framework for secondary use. It complements the main chapters of this guideline by referencing documents and initiatives offering additional technical detail, implementation support or process context.

The resources are grouped as follows:

A3.1 TEHDAS2 guidance: Overview of the TEHDAS2 guidelines and technical specifications relevant to the EHDS roles, including HDHs.

A3.2 HealthData@EU: Providing background information on the cross-border infrastructure supporting secondary use, including services that may shape future data provision workflows.

A3.3 QUANTUM: Providing background information on QUANTUM, an EU-funded initiative focusing on data quality and utility labelling.

A3.4 Data user journey: an overview of the phases in the secondary use process within the EHDS, provided to help HDHs situate their activities and touchpoints within the wider workflow.

A3.1 TEHDAS2 guidance

In the TEHDAS2 Joint action, many guidelines and specifications are provided for all roles in the EHDS Regulation of which the target audience usually include the HDHs. Many will provide useful information for data holders in their preparation for the EHDS. The release of TEHDAS2 outputs is an iterative process. For instance, as draft milestones for public consultation and later as final deliverables, document identifiers and titles may change over time. It is recommended that HDHs consult the TEHDAS website[6] for the most recent versions and references.

M(to be defined) Guideline for health data access bodies on enrichment of health datasets. This guideline helps (trusted) data holders in their data preparation phase by providing detailed information. Scheduled for consultation at the time of writing;

M4.1.1 Guideline on fees related to the EHDS Regulation. This guideline helps stakeholders to understand the fee structure in the EHDS;

M4.1.2 Guideline on penalties for non-compliance related to the EHDS Regulation. This guideline helps stakeholders to understand the penalties for non-compliance structure in the EHDS;

M4.3 Guideline for health data access bodies on international and third country access and transfer of personal and non-personal electronic health data. This guideline helps the data holder understand rules and infrastructure regarding international and third country access;

[6] Draft guidelines and technical specifications of TEHDAS2, Public consultations - Tehdas . Accepted deliverables that are published: Results - Tehdas.

D5.1 Guideline for data holders on data description. This guideline explains how to use HealthDCAT-AP to describe datasets and provides clear, practical steps to ensure metadata is accurate, interoperable, and compliant with legal requirements.

M5.2 Guideline for health data access bodies on minimum categories and limitations on the reuse of health data. This guideline helps data holders understand the different categories, which is important for determining whether they are a HDH under the EHDS Regulation and for selecting the correct category when submitting their metadata;

D5.3 Technical specification for health data access bodies on the national metadata Catalogue. This guideline provides technical guidance for HDABs, data holders and other stakeholders on how to implement and maintain a national metadata catalogue for datasets.

D6.2 Guideline for data users on good application and access practice. This guideline supports data users in navigating the EHDS data application process by offering detailed instructions on identifying relevant datasets, meeting regulatory requirements, and fulfilling access and usage condition.

D6.3 Guideline for health data access bodies on the procedures and formats for data access. This guideline helps (trusted) data holder in understanding their role in the application assessment process by providing detailed information;

D6.4 Technical specification for data access application management system (DAAMS) for health data access bodies (HDABs). This guideline provides the technical specifications required for HDABs in the European Union to develop and deploy a DAAMS. It includes functional and non-functional requirements, data models, process flows / business logic, and use cases.

D7.1 Guideline on how to use data in a secure processing environment. This guideline is designed to support data users, specifically reflecting their activities from the moment they gain access to the approved datasets within a secure processing environment (SPE).

M7.2 Guideline on data minimisation, pseudonymisation, anonymisation and synthetic data. This guideline helps the (trusted) data holder in their data preparation phase by providing detailed information;

M7.3 Technical specification for health data access bodies on the implementation of the common IT infrastructure. This specification helps the (trusted) data holder navigate the national and international IT-infrastructure;

M7.4 Technical, functional and security specifications of secure processing environments. This specification helps the (trusted) data holder understand the requirements for providing the data to the SPE;

M7.5 Guideline for health data access bodies on linkage of health datasets. This guideline helps the (trusted) data holder in their data preparation phase by providing detailed information;

D8.1 Guideline to health data access bodies "How to implement opt-out from secondary use of electronic health data". This guideline helps (trusted) data holder in their data preparation phase by providing detailed information;

D8.2 Guideline to health data access bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data. This guideline helps the data holder in understanding the potential interaction and processes regarding significant findings;

D8.3 Guideline for data users on handling research outcomes. This guideline provides guidance on regulatory, ethical and legal considerations.

A3.2 HealthData@EU

HealthData@EU is the cross-border infrastructure supporting secondary use under the EHDS.[7]

The platform presents a gateway to the HealthData@EU Infrastructure and (once fully developed) will provide relevant information and the key services required by the European Health Data Space Regulation (such as Dataset Catalogue, Data Application Forms).

It will provide a common application form that applicants can use to submit multi-country applications. The infrastructure will then forward the application to the relevant national contact points (who will then distribute it to the competent HDABs) or to the relevant authorised participant.

It will also provide tools for the cooperation among HDABs, for example to share information on penalties imposed.

It is composed of elements operated by different actors.

As per EHDS Regulation, in 2028 the HealthData@EU Central Platform will be fully operational. In the meanwhile, regular releases of the pre-deployment infrastructure are published and made available open source.

The HealthData@EU platform is useful for data holders in the preparation for the EHDS, as it provides detailed information on the future central service applications and most common infrastructure choices, which affects the data provision flows.

A3.3 QUANTUM

QUANTUM is an EU-funded project (2024-2026) that aims to create a common label system for Europe that guarantees the quality and utility of datasets for scientific and health innovation purposes[8]. This label system will enable researchers, policymakers, and healthcare professionals to identify high-quality data for research and decision making.

In the QUANTUM project:

A quality and utility label is created to specify the data holders' data quality maturity,

The label is tested with the data holders,

Sustainable recommendations are provided for the HealthData@EU infrastructure, and

[7] HealthData@EU Central Platform. acceptance.data.health.europa.eu public

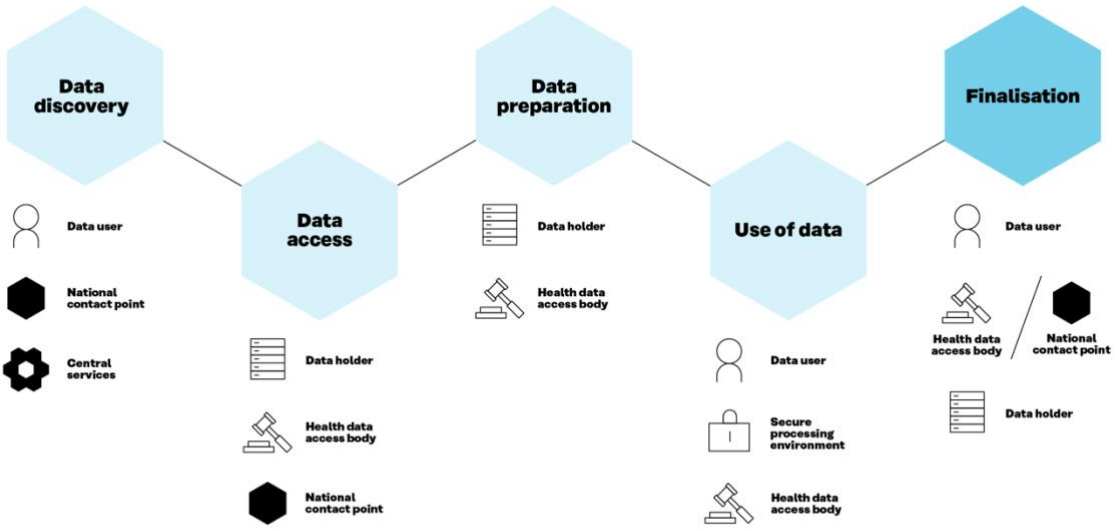
[8] Home - QUANTUM: The health data quality label

A learning program is developed, setting up a long-lasting data quality community of practice where data holders can attain necessary knowledge on improving their data quality.

A3.4 Data user journey

When a data user applies for electronic health data for secondary use purposes, such as research and innovation activities, education, and policy-making, within the European Health Data Space (EHDS), the user journey consists of several stages (see Figure 1). Access for certain purposes (public or occupational health, policy-making and regulatory activities, and statistics) is reserved for public sector bodies and Union institutions (see Chapter IV, Art. 53(1) and 53(2)).

Figure 1: EHDS user journey consists of five main phases: data discovery, data access, data preparation, use of data and finalisation.



Data discovery

Before being able to use the data, the user needs to investigate whether the data needed is available, and whether it is available in the necessary format for the secondary use purpose. This phase is called data discovery. Datasets available in the EU can be found in a metadata catalogue at https://qa.data.health.europa.eu/.Once the data discovery is completed, the user can begin the process of applying for the data.

Data access

In the data access phase, the user fills in and submits a dedicated and standardised data access application form or a data request to a health data access body (HDAB). The user must complete the information required in the form, upload necessary documents, and provide justifications as needed.

Data access application form is used when the user seeks to use personal level data. **Data request** is for cases when the user wants to apply for anonymised statistical data.

Data preparation

During this phase, the data holder(s) deliver(s) the necessary data to the HDAB, which starts to prepare the data for secondary use. Techniques for pseudonymisation, anonymisation, generalisation, suppression, and randomisation of personal data are employed. The data minimisation principle (as per the GDPR) must be respected to ensure privacy.

Use of data

In this phase, the user performs analyses based on the received data for the purpose defined in the application phase. Analysing personal level data must be performed in a secure processing environment. The duration of this phase is specified in the Regulation (Art 68(12)).

Finalisation

This last phase of the user journey concerns data user's duties regarding analysis outcomes derived from secondary use of data. Data user must publish the results of secondary use of health data within 18 months of the completion of the data processing in a secure processing environment or of receiving the requested health data. The results should be provided in an anonymous format. The data user must inform the health data access body of the results. In addition, the data user must mention in the output that the results have been obtained by using data in the framework of the EHDS.

Annex 4 – TEHDAS2 glossary

Key terminology in our guideline.

Term	Definition
Anonymisation	The process by which personal data is altered in such a way that a data subject can no longer be identified directly or indirectly. (Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information, Recital 52; EHDS Regulation, Recital 92)
Data controller	A data controller is a person or organisation that determines the purposes and essential means of the processing of personal data. The role of the data controller can be shared by several people or organisations. In that case, they are defined as joint controllers. The controller is accountable and responsible for establishing a lawful data processing workflow and observing the rights of data subjects. (GDPR Article 4(1)(7))
Data extraction	Data extraction is the process of retrieving data from its source dataset. Structured data extraction involves extracting data from datasets that are already organised in predefined formats. Unstructured data extraction pertains to extracting data from databases handling unstructured formats such as PDFs, images, or free text. There may be one or more different data sources from which data extraction may be required.
Data linkage	The process of combining **datasets** ”from several sources on one topic or data subject” (ISO 5127:2017, 3.1.11.12). This can be done using unique identifiers, probabilistic methods, or a combination of techniques.

Data minimisation	A principle mandating to only collect, store and process personal data in a manner that is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed. (GDPR Article 5(1)(c)) Access is only provided to electronic health data that is "adequate, relevant and limited to what is necessary in relation to the purpose of processing indicated in the health data access application by the health data user and in line with the data permit issues pursuant to Article 68." (EHDS Regulation, Article 66(1)) Data minimisation applies to all stages of the data lifecycle.
Data permit	An administrative decision issued to a health data user by a health data access body to process certain electronic health data specified in the data permit for specific secondary use purposes based on conditions laid down in Chapter IV of EHDS Regulation. (EHDS Regulation, Article 2(2) point (v))
Data preparation	Data preparation is the process in which an organisation (in this case the data holder or the health data access body) transforms and organises raw personal or non-personal health data into one or more datasets (either in individual-based or aggregated form), to comply with a data permit or a data request
Data processing	Any operation or set of operations which is performed on personal/non-personal data or on sets of personal/non-personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction. (Modified from the GDPR Article 4(2))
Data provision	The stage in the **EHDS user journey** where prepared health data is made accessible to authorised users for secondary purposes.
Data quality	Data quality means the degree to which the elements of electronic health data are suitable for their intended primary use and secondary use; (EHDS Article 2 (2)(z))
Data quality and utility label	Data quality and utility label means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset. (EHDS Article 2 (2)(aa))

Dataset	A structured collection of electronic health data. (EHDS Article 2(2)(w))
Dataset Catalogue	A collection of dataset descriptions, arranged in a systematic manner and including a user-oriented public part, in which information concerning individual dataset parameters is accessible by electronic means through an online portal. (EHDS Article 2(2) point (y)
Data Subset	Dataset subset contains only selected records, variables or elements from a larger dataset while maintaining its key characteristics and relationships.
Electronic health data	Personal or non-personal electronic health data (EHDS Article 2(2c)).
Health data access application	An application form used to seek access for personal-level electronic health data for secondary use in an anonymised or a pseudonymised format. (EHDS Article 67)
Health data access body (HDAB)	Member state-designated authority that facilitates the secondary use of electronic health data. HDABs assess the information provided by the health data applicant and decide on health data requests and access applications, authorise and issue data permits, obtain data from data holders and make data available in secure processing environments. HDABs systematically track the data request and data access applications received and the data permits issued. (EHDS Article 55 and Recital 52)
Health data applicant	A natural or legal person submitting a health data access application or a data request to a health data access body for the purposes referred to in Article 53 of EHDS Regulation.
Health data holder	Any person, organisation or public body involved in healthcare, care services, health-related products, wellness apps or health(care) research, that has the right to process data for health care provision or for public health purposes, reimbursement, research, policy making, official statistics or patient safety. This includes, for example, hospitals, insurers, research institutes and EU institutions. For a more detailed definition: EHDS Regulation, Article 2(2) point (t))

Health data request	A request to access data in an anonymised statistical format for the purposes referred to in EHDS Article 53. (EHDS Regulation, Article 69)
Health data user	A natural or legal person, including Union institutions, bodies, offices or agencies, which has been granted lawful access to electronic health data for secondary use pursuant to a data permit, a health data request approval or an access approval by an authorised participant in HealthData@EU
Intellectual property (IP)	(a) a trade mark; (b) a design; (c) a copyright or any related right as provided for by national or Union law; (d) a geographical indication; (e) a patent as provided for by national or Union law; (f) a supplementary protection certificate for medicinal products as provided for in Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (1); (g) a supplementary protection certificate for plant protection products as provided for in Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (2); (h) a Community plant variety right as provided for in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (3); (i) a plant variety right as provided for by national law; (j) a topography of semiconductor product as provided for by national or Union law; (k) a utility model in so far as it is protected as an intel lectual property right by national or Union law; (l) a trade name in so far as it is protected as an exclusive intellectual property right by national or Union law. (Regulation (EU) No 608/2013 concerning customs enforcement of intellectual property rights and repealing, Article 2(1))
Intermediation entity	A legal person that may be established by national law for the purpose of fulfilling the obligations of certain categories of health data holders and that is able to process, make available, register, provide, restrict access to and exchange electronic health data for secondary use provided by health data holders. (EHDS Regulation, Article 50 (3) and Recital 59)
Invoice	A legally binding commercial document, detailing the complete cost structure with breakdowns by services and data holders. It contains disaggregated cost elements

Non-compliance	Any failure to comply with any requirement under the Union harmonisation legislation.
Non-personal electronic health data	Electronic health data other than personal electronic health data, including both data that have been anonymised so that they no longer relate to an identified or identifiable natural person (the 'data subject') and data that have never related to a data subject. (EHDS Regulation, Article 2(2b))
Open data	Data in an open format that can be freely used, re-used and shared by anyone for any purpose. Open format means a file format that is platform-independent and made available to the public without any restriction that impedes the re-use of documents. (Directive (EU) 2019/1024 on open data, "Open Data Directive")
Open (data) database	Publicly accessible digital data that anyone can freely use, reuse, and redistribute for any purpose.
Personal electronic health data	Data concerning health and genetic data, relating to an identified or identifiable natural person, processed in an electronic form. (EHDS Regulation, Article 2(2a))
Pseudonymisation	The processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and
Purpose limitation	Personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes. (GDPR, Article 5(1b).
Secondary use	Processing of electronic health data for the purposes set out in Chapter IV of EHDS Regulation, other than the initial purposes for which they were collected or produced. (EHDS Regulation, Article 2(2) point (e))
Secure processing environment (SPE)	An environment in which access to electronic health data can be provided in following a data permit. A secure processing environment is subject to technical and organisational measures and security and interoperability requirements. Specifically allowing access to only those persons listed in the permit, as well as user authentication, authorisation, restricted data handling, logging and the compliance monitoring of respective security measures. (EHDS Regulation, Article 73)
Synthetic data	Data with potentially harmful effects in the event of disclosure (i.e., providing access to data to a third party) or misuse (ISO 5127:2017(en), 3.1.10.16)).

Tabular data	Data organised in a structured format of rows and columns, where each row represents a single record or entity, and each column represents a specific attribute or variable. This structure is commonly found in spreadsheets or relational databases, making it easy to store, query, and analyse. Tabular data is often used for structured datasets where relationships between variables are well-defined.
Trade secret(s)	Information which meets all of the following requirements: (a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) it has commercial value because it is secret; (c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret. (Trade Secret Directive (2016/943), Article 2(1))
Trusted health data holder	Member State designated health data holder for whom a simplified procedure can be followed for the issuance of data permits. Trusted health data holders leverage their expertise on the data they hold to assist the health data access body by providing assessments of data requests or access applications. Once data permits are authorised, these trusted data holders provide the data within a secure processing environment that they manage. (EHDS Regulation, Article 72 and Recital 76)
Trusted Third Party (TTP)	A **pseudonymisation entity** which is independent from the data user and data holder that processes identifiers into pseudonyms. (ENISA, Pseudonymisation techniques and best practices). The TTP needs only to know the identifiers of the data subjects on the basis of which it will compute the **pseudonyms**, and no other data. (EDPB Guideline 01/2025 Glossary, version adopted for public consultation)

Annex 5 – Links to the EHDS Regulation

Relevant EHDS Articles (for references)

In the EHDS Regulation, Health Data Holder (HDH) duties for making health data available are included in several Articles. Additionally, other Articles contain influence HDHs and their duties. Relevant Articles for this guideline are:

Main Articles:

Article 51 Minimum categories of electronic data for secondary use - Article 51 'Minimum categories of electronic data for secondary use' states the minimum categories of electronic data for secondary use of which the health data holders have to make the categories of electronic data available. These 17 categories are represented by a diverse set of data holders.

Article 60 Duties of health data holders - Article 60 describes the health data holder duties. This is a main Article covered by task 6.1.

Article 63 Enforcement by health data access bodies - Article 63 describes the enforcement by health data access bodies towards the health data holder.

Article 68 Data permit - Article 68 covers data permits and the time limits for providing the data.

Article 69 Health data request - Article 69 covers health data requests.

Additional Articles and topics related to task 6.1:

Article 52 Intellectual property rights and trade secrets - Article 52 describes how to handle intellectual property related to the EHDS data provision.

Article 57 Tasks of health data access bodies - Article 57 describes the tasks and duties of the health data access bodies. Some of those tasks relate to the communication with the health data holder.

Article 58 Obligations of health data access bodies towards natural persons - Article 58 describes obligations of HDABs towards natural persons. However, communication between HDAB and health data holder is included in sub-paragraph 3.

Article 61 Duties of health data users - Article 61 talks about duties of health data users. However, one sub-paragraph talks about communication towards the health data holder (via the HDAB).

Article 62 Fees - Article 42 talks about the fees related to a data access or permit request... This Article is relevant for task 6.1 because communication is needed between the HDAB and health data holder.

Article 66 Data minimisation and purpose limitation - Article 66 describes the enforcement by health data access bodies towards the health data holder.

Article 71 Right to opt-out from the processing of personal electronic health data for secondary use - Article 71 describes the Right to opt-out from the processing of personal

electronic health data for secondary use. This Article might be relevant in the communication between the HDAB and the health data holder and provision of the data, as an option must exist to provide data of patients that have opted out when relevant.

Article 72 Simplified procedure for access to electronic health data from a trusted health data holder - Article 72 describes the Simplified procedure for access to electronic health data from a trusted health data holder.

Article 73 Secure processing environment - Article 50 addresses the Secure processing environment (SPE). This is relevant to task 6.1 because this is the location that the data needs to be provided to. As there might be multiple SPEs, the correct location needs to be communicated. Relevant sub-Articles are presented here.

Article 74 Controllership - Article 74 provides guidance on controllership.

Article 75 HealthData@EU - Article 75 refers to HealthData@EU. It talks about cross-border access to data.

Article 78 Data quality and utility label - Article 78 covers the data quality and utility label. When a data request is approved and data is provided, a data quality and utility label can be attached to the data (health by the data holder). When this label might be inaccurate, this must be communicated from the HDAB to the data holder, and the label might have to be revoked.

Annex 6 – Steps and illustrative checklist for health data holders

The checklists in Annex 6 are illustrative and provide a non-exhaustive overview of mandatory and recommended steps based on expert advice. The checklists do not extend in any way the rights and obligations deriving from applicable legislation nor introduce any additional requirements.

A6.1 Checklist for EHDS Health Data Holders in preparation of the EHDS

Determine Eligibility

☐ Confirm whether your organisation qualifies as a *Health Data Holder* under the EHDS (based on roles and types of data processed).

☐ For companies in categories on the verge of the applicability of Chapter IV of the EHDS Regulation, check regularly at least once a year whether they meet the relevant requirements and/or whether changes in the scope or nature of the data held affect applicability.

Know Your Data Types and Categories

☐ Confirm that the datasets you hold fall within the minimum categories of electronic health data listed in Article 51 of the EHDS Regulation.

☐ Classify your data: personal, non-personal, anonymised, synthetic, or mixed.

☐ Analyse your existing health data from the viewpoint of health data categories for which there is obligation for making them available.

☐ Understand EHDS obligations for each type and category of health data.

Metadata & Dataset Description

☐ *Mandatory –* Prepare metadata using HealthDCAT-AP

☐ *Mandatory –* Submit and annually update dataset descriptions in your national dataset catalogue

Data Provision & Timelines

☐ *Mandatory –* Ensure that internal procedures support data provision within three months following issuance of a data permit or approval of a health data request, with the possibility of a justified extension where applicable.

☐ *Mandatory –* Be able to deliver data via the HDAB.

Internal Capacity & Readiness

☐ Assess your maturity level in data governance, quality, metadata management, and technical capability.

☐ Identify resource gaps and training needs.

Follow National Implementation Rules

☐ Monitor your Member State's EHDS-legal and technical architecture choices (e.g. opt-out system, HDAB setup, intermediation options).

☐ Be aware of relevant national legislation.

☐ Align with national legislation, procedures and exceptions.

☐ Identify which EHDS responsibilities are assigned to HDHs under national law (e.g. opt-out handling, delegation HDIEs).

Handle Intellectual Property & Trade Secrets
☐ Identify datasets containing Intellectual Property (IP)/trade secrets.
☐ *Mandatory* – Notify HDAB via metadata of the presence of trade secrets.

Opt-out management
☐ Determine whether responsibility for opt-out management is assigned to the health data holder under national law.
☐ *Mandatory* – If applicable implement procedures to exclude data of individuals who have exercised their right to opt out of secondary use.
☐ *Mandatory* – If applicable ensure opt-out exclusions are applied before data are made available for secondary use, unless an exception applies under the EHDS Regulation.

Trusted Data Holder Option
☐ Consider applying to become a trusted data holder if you meet technical and legal requirements.
☐ If aspiring to become a trusted data holder: Understand the additional duties for the trusted data holder (e.g. evaluating data requests).

Use of Intermediation Entities
☐ If relevant: Explore delegating duties (like data processing) to a HDIE, if allowed by national law.
☐ If relevant: Identify your Member State relevant HDIEs.

Communication & Interaction with HDAB
☐ Establish (secure) channels for formal and informal communications with the HDAB.

Cost Recovery & Invoicing
☐ Understand which preparation costs are reimbursable.
☐ Provide justifications and estimates to HDABs in advance.

Know where to find relevant information
☐ Stay Informed with EHDS & TEHDAS2 Guidelines
☐ Follow TEHDAS2 for updates and guidelines relevant for data holders
☐ Follo HealthData@EU for updates on infrastructure and application procedures.

A6.2 Checklist for making data available

Verification
☐ *Mandatory* – Verify whether you are responding to a data permit or a data request.
☐ *Mandatory* – Verify time limits for data preparation.
☐ *Recommended* – Verify the following aspects of the HDAB´s request:
- Scope
- Feasibility
- Timeframe

Data Extraction
☐ *Mandatory* – Include only electronic health records explicitly reported in the data permit/request (minimisation principle).

☐ *Mandatory –* Include only variables explicitly reported in the data permit/request (minimisation principle).
☐ *Mandatory –* Identify and remove data of natural persons who opted-out. National laws could assign this responsibility to the HDH, to the trusted data holder, or to HDAB.
☐ *Mandatory –* If requested by the HDAB, HDHs or THDH implement IP or trade secrets protection measures.
☐ *Mandatory –* In case of data permit, apply anonymisation or pseudonymisation according to data permit. This duty is a responsibility of HDAB (or of trusted data holder) but might be transferred to HDH.
☐ *Mandatory –* In case of data request, provide data in anonymised statistical format. This duty is responsibility of HDAB (or of trusted data holder) but might be transferred to HDH.
☐ *Recommended –* Validate dataset content and structure before delivery.

A6.3 Checklist for EHDS health data holders for providing data.

General Responsibilities

☐ *Mandatory –* Ensure data provision only follows an **approved data permit or request** specifying the purpose and access limitations.
☐ *Recommended –* Determine the correct data flow based on:
Type of application: **Data permit** or **Data request**
Type of data: **Personal**, **non-personal open**, or **non-personal restricted data**
Involvement of: **HDAB, SPE**, **data holder**, or **Intermediation Entity**

1. *Recommended* – Data Permit Provision Flow
Starting point is when data is prepared
☐ Identify the SPE (HDAB or external) to which the data will be provided
☐ Contact HDAB or SPE to discuss where and how to deliver your data
☐ *Mandatory in some cases –* Attach metadata and dataset identifier to your dataset
☐ Encrypt data before transfer
☐ Share encryption key through a separate channel
☐ Respond to Data User or HDAB request for clarification or changes (modifications to the dataset)
☐ Support interaction with HDAB or health data user if necessary

2. *Recommended* – Data Request Provision Flow (Two Options)
☐ Determine who creates the statistical format (this can be either the HDH, the HDIE or the HDAB)

Option 1: the HDAB or HDIE creates the statistical format
☐ Provide individual-level data to the HDAB or HDIE for anonymised, statistical processing
☐ Follow the same data transfer steps as for a data permit (see above)

Option 2: Data Holder creates the statistical format
☐ Identify the location where to provide the results to
☐ Create the statistical format resulting in anonymised, aggregated data

☐ Provide results to HDAB or directly to the data user
☐ Add relevant metadata and versioning when needed

Recommended – **Provision of Non-Personal Data**

☐ Determine whether you have open data (A) or restricted non-personal data (B)

A. Open Data

☐ Ensure your health data is findable in the national dataset catalogue.
☐ Make datasets accessible via a stable link to an open database

B. Restricted Access Non-Personal Data

☐ Ensure compliance with IP/sensitivity protections
☐ Add metadata and versioning
☐ Provide encrypted data using approved transfer method
☐ Share encryption key separately
☐ Respond to Data User or HDAB requests for clarifications or changes to the dataset if required