M8.2 Draft 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

TEHDAS2 – Second Joint Action Towards the European Health Data Space

7 September 2025

Co-funded by the European Union

0 Document info

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0.2 Keywords

Keywords	TEHDAS2, Joint Action, Health Data, European Health Data Space, Health Data Access Body, Significant findings

0.3 Document history

Date	Version	Editor	Change	Status
10-4-2025	0.1	Authors and Contributors	First draft	Draft
13-5-2025	0.2	Authors and Contributors	Revisions and additions	Draft
3-7-2025	0.3	Authors and Contributors	Submission for internal review	Draft
7-9-2025	0.4	EC review & Consortium review	Revised after internal review	Final
12-9-2025	1.0	Final version	Final version after PSG meeting	Final

Accepted in Project Steering Group on 12 September 2025.

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1 Abbreviations

Term	Abbreviation
Breast Cancer gene	BRCA
Charter of Fundamental Rights of the European Union	EU Charter
Computer Tomography	CT
Data Governance Act	DGA
Directorate-General for Health and Food Safety	DG SANTE
Electronic Health Record	EHR
European Convention on Human Rights	ECHR
European Group on Ethics in Science and New Technologies	EGE
European Health Data Space	EHDS
European Union	EU
European Union Agency for Cybersecurity	ENISA
General Data Protection Regulation	GDPR
Health Data Access Body	HDAB
HealthData@EU Central Platform	HD@EU CP
International Electrotechnical Commission	IEC
International Organization for Standardization	ISO
Joint Action	JA
Member State	MS
Milestone	M
Positron Emission Tomography	PET
Secure Processing Environment	SPE
Significant Finding	SF
Standard Operation Procedure	SOP
Trusted Third Party	TTP
Towards the European Health Data Space	TEHDAS
Work Package	WP

2 Executive summary

The European Health Data Space (EHDS) Regulation establishes a legal framework for the secondary use of electronic health data while safeguarding the rights of individuals whose data are involved. Within this framework, Task T8.1 of the TEHDAS2 project is dedicated to obligations towards natural persons, and within Task T8.1., this M.8.2. milestone provides practical guidance for Health Data Access Bodies (HDABs) concerning their obligations, when significant health-related findings are identified during the secondary use of identifiable electronic health data.

This guideline serves as an operational tool to help HDABs fulfil their obligations under Articles 58(3) and 61(5) of the EHDS Regulation. It focuses specifically on the procedures HDABs must implement when receiving reports of significant findings from data users and forwarding them to the appropriate health data holders. It clarifies the boundaries of their responsibilities, ensuring alignment with national implementation frameworks. While the guideline primarily targets HDABs, it may also offer value to data users and data holders, particularly in clarifying how their respective roles interact with HDAB processes.

Since the EHDS Regulation does not provide a formal definition of “significant findings”, the guideline offers a working interpretation supported by examples, focusing on the practical relevance of such findings in the context of secondary data use. It also presents the applicable legal framework under the EHDS and outlines the areas where Member States must introduce additional regulation, especially regarding the communication of findings to individuals.

The document describes the distinct roles of data users, HDABs, and data holders, making clear that HDABs are not responsible for clinically validating findings or directly informing individuals. It touches on privacy and data protection responsibilities, while noting that issues related to pseudonymisation, anonymisation, and technical safeguards are addressed in other parts of the TEHDAS2 project.

This guideline does not address the responsibilities of data users in deciding when and how to report significant findings to HDABs. These responsibilities are covered under Milestone M8.4. It also does not explain how national systems should be designed to govern the disclosure of findings to individuals, as this remains under the jurisdiction of Member States. Furthermore, the document does not provide guidance on how Member States should operationalise the individual's right not to be informed under Recital 67 and Article 58(3) of the EHDS Regulation. Likewise, technical and organisational measures to protect data during the transmission of findings fall outside the scope of this document and are addressed in separate workstreams.

In summary, within Task T8.1 this M.8.2. guideline is confined to describing the procedural role of HDABs when they receive a report of a significant finding from a data user and outlining how such findings should be forwarded to the relevant data holder in compliance with the EHDS Regulation. All matters related to national disclosure mechanisms, the responsibilities of data users, notification to individuals, privacy protection measures, and the exercise of the right not to be informed are explicitly excluded from the scope of this guideline. By clarifying this specific procedural responsibility, the document supports the readiness of HDABs and contributes to a harmonised and rights-respecting implementation of the EHDS across Member States.

3 Introduction

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.

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 electronic 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 electronic health data use.

- Data discovery: 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 electronic 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 electronic health data, while also reducing fragmentation in national policies and practices related to secondary use.

- The primary focus of the work performed in Task 8.1 is on providing guidance to fulfil obligations towards natural persons under the EHDS Regulation in the context of the secondary use of electronic health data. Task T8.1 addresses these obligations through two milestone documents: M8.1 Draft guideline for Health Data Access Bodies on implementing opt-out
- M8.2 Draft 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.

The present guideline focuses on equipping HDABs with the necessary procedures and defining requirements to fulfil their responsibilities for receiving significant findings from data users and forwarding them to the relevant health data holders in accordance with the EHDS Regulation. It recognises that any notification of natural person or health professional treating the natural person concerned lies exclusively with the health data holder and is determined by national law.

4 Scope and objective of the guideline

This guideline covers the implementation of the EHDS Regulation as regards significant findings from the secondary use of electronic health data related to the health of natural persons concerned.

The scope is limited to the relevant provisions of the EHDS Regulation, and only referring to the GDPR insofar as it has a direct impact on individuals' rights in respect of significant findings. This guideline does not attempt to interpret broader legal frameworks beyond what is necessary to implement the relevant provisions of the EHDS Regulation.

The Regulation leaves a number of issues relating to significant findings to the discretion of the Member States, in which regard this guideline makes some recommendations, but beyond that it does not affect regulatory issues falling within the competence of the Member States.

Technical specifications cannot be provided here, either, as the technical means to implement the obligations related to significant findings also fall in the competence of Member State.

The primary audience of this guideline are HDABs. It aims to provide HDABs with the necessary requirements and procedures to effectively implement their obligation concerning significant findings under the EHDS Regulation. Furthermore, the guideline may also be useful for data users and data holders as far as they are affected by legal obligations to manage significant findings.

This guideline is closely related to the guideline within milestone M8.4 for secondary electronic health data users presenting how to fulfil their duties regarding research. Advice for data users when to feedback significant findings to the HDABs will be covered by M8.4.

5 Explaining significant findings

5.1 Clarifying the terms “incidental findings” and “significant findings”

Incidental Findings refer to **unexpected** observations identified during a diagnostic test, medical examination, or research study that are **unrelated** to the primary reason for conducting the test. Such findings may be of varying clinical importance, ranging from benign anomalies to potentially serious conditions. In general, these findings are unanticipated, as they are discovered while investigating an unrelated condition and hence may or may not be clinically relevant, as some incidental findings require no action, while others may necessitate further evaluation or treatment. Regarding the ethical considerations related with incidental findings in medical practice and research which is out of scope of this document, guidelines are needed whether and how these incidental findings are disclosed to patients, balancing the potential benefits and risks of further investigation.

Clinically Significant Findings are observations that have **a direct impact on patient care, diagnosis, treatment, or prognosis**. These findings may play a crucial role in medical decision-making and could be relevant for guiding therapeutic interventions. A finding is considered clinically significant if it influences patient management, treatment options, or health outcomes. To be classified as clinically significant, findings must be relevant to the patient’s health (as may be determined later within the scope of decision-making in each Member State, in some context with the reason for the test or clinical evaluation) and of practical importance (have tangible effects on a patient's health and quality of life), having a direct impact on patient care (are directly related to the patient's condition and influence medical decisions, treatment plans, or prognostic evaluations). Such findings can be valuable research results, but must also be meaningful in a clinical context. It should be noted that new result from secondary use does not necessarily imply clinical significance. A result can be valuable without having meaningful clinical implications, and vice versa.

It is important to make a distinction between primary care significant findings and significant findings which are retrieved from secondary use of data. If the dataset is selected based on predefined conditions (e.g., BRCA1/BRCA2 mutation), the mere reconfirmation of those conditions does not constitute a significant finding. However, the emergence of new or previously unknown clinically relevant information may still qualify. For example, if analysis of a dataset originally collected for studying BRCA1/BRCA2 mutations reveals an unrelated but clinically important cardiovascular risk marker, this could be considered a significant finding. By contrast, if the sampling process is aimed at information about certain conditions (e.g., BRCA1/BRCA2 mutation or white blood cell count), then findings limited to those predefined variables are not considered significant, as they do not provide new or unexpected insights for the individual.

When data users such as researchers request data from the HDABs and through them from the data holders, they need to clarify some categories, which indicate the entry requirements of the samples. In these cases, the presence of a condition that has already been used as an indicator is not considered a significant finding. If not only the existence of these parameters is investigable during the secondary use of the data, and findings can aggravate or change the clinical judgement, they will be considered as significant findings.

To support ethical and responsible handling of such findings, Member States are recommended to establish clear processes and build capacity, as described in the chapter on issues to address at Member State level.

5.2 Typical examples of significant findings

It is not feasible to create a predefined list of all potential significant findings, due to the wide variety and complexity of health conditions and findings, as well as the rapid pace of research. The following non exhaustive examples are recommendations outlining what a significant finding could be across different types of results:

- **Genetic and Genomic Findings, Clinical Exome or Genome Sequencing:**
  Mutations in certain genes (for example BRCA1 and BRCA2) are clinically significant as they indicate a high risk for hereditary cancers and may lead to important medical actions such as genetic counselling, preventive measures, or enhanced surveillance. Other clinically relevant variants may also be detected through clinical exome or genome sequencing, including those related to increased cancer risk, cardiovascular conditions, or inherited metabolic disorders. Identifying such variants can enable early medical intervention and significantly improve health outcomes.
  These findings should always be handled with appropriate safeguards. National law may require that consent or other conditions be met before such findings are communicated. It is essential that genetic data be handled securely, and that any communication (by the data holder) to individuals (or their treating health professionals) must comply with the relevant national legal and ethical frameworks.

- **Laboratory Findings:**
  Diagnostic criteria for some conditions (for example preeclampsia), may be refined as medical knowledge advances. Furthermore, it may also happen that – in the course of research – new laboratory markers are recognized as clinically relevant in connection with the progression of the disease being studied. These require careful consideration, especially if they have clear implications for the health of the individual. If, during secondary use of electronic health data, a researcher detects a pathological laboratory parameter that is strongly linked to a condition such as preeclampsia and may carry direct clinical implications, this could constitute a significant finding. Its classification and any subsequent action should be evaluated by the competent health data holder or an appropriate healthcare professional.

- **Radiological Findings:**
  A lung nodule identified on a routine chest X-ray or CT scan may represent early-stage lung cancer and typically warrants further diagnostic testing, such as Biopsy or PET scan. Findings of this nature must be securely documented in the patient's electronic health record (EHR), followed by prompt referral to an oncologist and appropriate additional imaging. When interpreting significant findings in radiological image exchange research programmes under the EHDS Regulation, it is essential to recognise that such preliminary findings can include false positives or false negatives. While establishing feedback loops to manage these cases is important for patient safety and clinical accuracy, such processes fall outside the remit of Health Data Access Bodies and require coordination within clinical and research governance frameworks.

All examples are for illustration purposes only. Any decision to act upon a finding must be taken in accordance with national law and based on medical judgment.

5.3 Legal framework: The concept of significant findings under the EHDS Regulation

While the EHDS Regulation does not provide a formal legal definition of "significant findings," the term is generally understood, within the context of secondary use of electronic health data, to refer to new information that is relevant to an identifiable individual and may carry potential clinical importance for the individual. Such findings are typically considered noteworthy when they are novel, potentially actionable, and capable of informing diagnosis, treatment decisions, preventive strategies, or follow-up care. Examples may include early indicators of chronic conditions, genetic markers linked to disease risk, or serious abnormalities discovered incidentally. However, the interpretation and management of such findings remain subject to national frameworks and professional standards, particularly with regard to their scientific validity, clinical relevance, and the individual context.

The concept of significant findings under the EHDS Regulation is summarised in recital 67, as follows:

"Natural persons should be informed by the health data holders about significant findings related to their health made by health data users. Natural persons should have the right to request not to be informed of such findings. Member States could lay down conditions on the arrangements for the provision by the health data holders of such information to the natural persons concerned and on the exercise of the right not to be informed. Member States should be able, in accordance with Article 23(1), point (i), of Regulation (EU) 2016/679, to restrict the scope of the obligation to inform natural persons whenever necessary for their protection based on patient safety and ethics, by delaying the communication of their information until a health professional can communicate and explain to the natural persons concerned information that potentially can have an impact on their health."

Two important elements need to be highlighted from the above recital:

- The EHDS Regulation covers findings that are revealed by health data users during the secondary use of data.
- The condition that the individuals' data are included in a dataset implies that the rules on significant findings only apply if these individuals can be identified ultimately either directly (e.g. through personal identifiers) or indirectly (e.g. via pseudonymisation with a key).

The management of significant findings is based on Article 61 (5) of the EHDS Regulation (Duties of health data users) which states that health data users shall inform the health data access body of any significant finding related to the health of the natural person whose data are included in the dataset, without prejudice to the prohibition of providing access to data to third parties not mentioned in the data permit.

Article 58 of the EHDS Regulation establishes the procedural obligations of Health Data Access Bodies when significant health-related findings are discovered during the secondary use of electronic health data. Specifically, it clarifies the HDAB's responsibilities when a data user, such as a researcher, identifies a significant finding concerning an identifiable natural person. Upon receiving such a notification, the HDAB is mandated solely to transmit this information, securely and without delay, to the relevant health data holder. Importantly, the HDAB is not authorized to interpret, validate, or assess the clinical relevance of the finding, nor to directly inform the individual concerned. Its function is strictly functional and limited to

ensuring proper onward communication to an entity with clinical responsibility. The EHDS Regulation explicitly limits the HDAB's involvement at this stage, reinforcing the principle that the responsibility for any clinical follow-up or patient contact lies exclusively within the domain of the health data holder, in accordance with national legal and professional standards.

Once the health data holder receives the information, it becomes their duty, under the conditions laid down by national law, to ensure that the finding is communicated either to the natural person or to the health professional treating that person. The Regulation also provides that every natural person has the right to request not to be informed of such findings. The procedures for that right, as well as the practical conditions under which the communication to the individual takes place, are determined exclusively at Member State level in line with national legal and ethical frameworks. This provision underscores that the HDAB acts solely as an intermediary in the reporting chain for significant findings arising from secondary use. It has no clinical function and no direct relationship with the natural person; its duty is confined to relaying the information to the competent data holder in a secure and timely manner, in accordance with Articles 58(3) and 61(5) of the EHDS Regulation.

Furthermore, Article 94 (Tasks of the EHDS Board), para. 2 point (c) provides an overview of how the implementation of this process should be supported with the creation of guidelines related to secondary use by the EHDS Board to help health data users fulfil their obligation above, specifically: "creating, in consultation and cooperation with relevant stakeholders, including representatives of patients, health professionals and researchers, guidelines in order to help health data users to fulfil their duties under Article 61(5), and in particular to determine whether their findings are clinically significant".

Member States may define the criteria, categories, and procedures for identifying and managing significant findings at the national level, as described in the chapter on issues to be addressed on Member State level.

In line with the obligations set out in the EHDS Regulation, particularly the duty of health data users to ensure lawful and secure processing under Article 61, health data must be handled in a way that upholds data protection principles and ensures that clinically significant findings are appropriately managed while maintaining individual privacy.[1]

While ensuring that data are robust, interoperable, and reliable for secondary use, quality requirements should also allow data users to confirm the validity of clinically relevant findings. Criteria on completeness, consistency, and representativeness should be applied in a way that facilitates the identification of significant findings to researchers, to prove their result's validity, and subsequent communication by HDABs. For example, genomic datasets should retain sufficient detail (e.g., variant-level information rather than aggregated summaries) to enable the validation of pathogenic mutations, and laboratory datasets should maintain precision in measurement units and reference ranges so that abnormal values indicating conditions such as leukaemia can be reliably interpreted. Additionally, Recital 67 of the EHDS Regulation underscores the importance of processing health data in a secure and ethically responsible manner. While security requirements ensure the protection of personal data, it is primarily ethical considerations, such as the principles of proportionality, respect for autonomy, and the duty to avoid harm, that support a more precise definition of "significant findings." From an ethical standpoint, only findings that have substantial consequences for an individual's health or well-being should be classified as significant, to avoid overburdening individuals with uncertain, non-actionable, or potentially distressing information. This approach aligns with

[1] The final product of M8.4. which was based on Task 8.3 – Data users' duties regarding research outcomes conducted within the framework of WP8 Serving Citizens will address this topic in detail.

established bioethical frameworks, such as the Council of Europe's Convention (Article 10) and relevant opinions of the European Group on Ethics in Science and New Technologies (EGE), which underscores the ethical imperative to avoid burdening individuals with findings of uncertain or non-actionable relevance.

6 General aspects of the management of significant findings

The EHDS Regulation emphasizes data governance, ethical considerations, and secure data processing. Key Aspects for managing significant findings under the EHDS regulation include:

- **Identification and Assessment (Data Quality and Utility, EHDS Article 58, Recital 67):** Significant findings must be accurately identified during the processing of electronic health data. The high quality of data may support identifying significant findings.
- **Documentation (Secure Data Processing and Record-Keeping, EHDS Article 58, Article 61):** Significant findings must be clearly documented throughout the entire process related to them, ensuring that significant findings are handled according to data protection standards.
- **Communication (Patient Rights and Data Access, EHDS Article 58 and 61, Recital 67):** Under the EHDS Regulation, the rights of natural persons regarding their health data are strongly protected, particularly in situations involving significant findings uncovered through secondary use. According to Article 58(3), when a HDAB is informed by a data user of a significant health-related finding concerning an identifiable individual, its role is limited to securely transmitting that information to the relevant health data holder. Article 58(4) makes clear that the responsibility to decide whether, how, and when to inform the concerned individual or their treating health professional rests with the health data holder, following national laws and institutional protocols. Article 61 reinforces the importance of safeguarding patients' rights by requiring that data processing, including communication of significant findings, uphold the principles of data protection and medical confidentiality. As further emphasized in Recital 67, while the EHDS does not impose a uniform EU-wide approach to the return of findings, Member States are encouraged to ensure that, where such information is provided, it is communicated in a clear, compassionate, and timely manner, aligned with ethical and medical standards.
- **Follow-Up and Action (Secure Sharing of Data, EHDS Article 61):** Following the identification of significant findings, they should be transmitted and processed in compliance with the applicable security protocols, ensuring that patient confidentiality and data security are maintained.
- **Ethical and Legal Considerations (Compliance with Data Protection Regulations, EHDS Article 58, Article 61, Recital 67):** Full compliance with data protection legislation like GDPR must be ensured when managing significant findings. In practice, it is the healthcare providers and health data holders, such as hospitals or clinical institutions, who are responsible for safeguarding patient privacy and, where appropriate, for disclosing significant findings to individuals. While HDAB are required to transmit such findings to the relevant data holder, they do not engage in direct communication with patients. This division of responsibility reflects the legal framework of the EHDS Regulation and the operational reality across Member States, where the capacity and authority to interpret and communicate clinical information rests with those who have a direct care or institutional relationship with the individual.

Table 1: Key governance elements for managing significant findings under the EHDS Regulation. This table summarizes the key procedural and ethical elements involved in the handling of significant findings within the EHDS framework, indicating the division of responsibilities between EU-wide regulatory requirements and Member State-level discretion, supported by article and recital references.

Key aspect	EU-Level responsibility	National discretion	Legal basis (EHDS Article/Recital)
Identification	Datasets may have a Union data quality and utility label applied by the health data holders, which shall cover elements for e.g. assessment of technical quality and data quality management processes.	Define standards for clinical validity and significance in line with local healthcare practices.	Art. 78, Recital 84
Documentation	Require documentation of significant findings in compliance with secure processing and record-keeping standards.	Develop national documentation protocols and integrate with healthcare systems.	Art. 58, Art. 61
Communication	HDABs transmit findings to data holders; responsibility to inform the natural persons or health professionals treating the natural person concerned lies with data holders under national law.	Regulate how, when, and by whom patients are informed, respecting ethical and medical norms.	Art. 58(3), Art. 58(4), Art. 61, Recital 67
Follow-Up and action	Ensure secure transmission and processing of significant findings in line with confidentiality standards.	Develop secure data-sharing pathways and define procedures for clinical follow-up.	Art. 61
Ethical and legal considerations	Uphold GDPR and medical confidentiality; HDABs must transmit but not communicate directly with patients.	Establish mechanisms for return of findings, informed consent procedures, and cross-border coordination.	Art. 58, Art. 61, Recital 67

7 Responsibilities of the key actors

7.1 Process of notifying significant findings

Step 1. Identification of Significant Findings: When data users, e.g., researchers, identify results representing new findings that may influence the health status of individuals whose data are included in a dataset, it is the data user's obligation to report the potentially significant findings to the relevant HDAB. The way to assess if the findings can have potential impact on the individual's health, will be based on national legal or ethical rules and medical guidelines, as well as future guidance provided by the EHDS Board according to Art. 94, para (2) point (c) of the Regulation.

The condition that the individuals' data must be included in a dataset implies that these individuals are identifiable, including when the data is pseudonymised then the (trusted) data holder or the HDAB (depending on where the pseudonymisation was carried out) has the ability to link it to identifiers. In case re-identification of the individual is not possible, the obligations concerning significant findings cannot be applied. The logic of Article 11 of the GDPR also applies here which states that data controllers should not process additional personal data only so that they can comply with data subject rights.

The EHDS Board's tasks include, under Article 94 para. 2 point (c) of the EHDS Regulation, creating guidelines in order to help health data users to fulfil their duties, and in particular to determine whether their findings are clinically significant. Such guidelines should be adopted in consultation and cooperation with relevant stakeholders, including representatives of patients, health professionals and researchers.

Step 2. HDAB Responsibilities: The responsibility of HDABs begins when data users report significant findings to them. The core responsibilities of HDABs are outlined in detail in Chapter **4** below. While the EHDS Regulation does not assign HDABs any clinical role, Member States may, through national legislation, define additional procedural or administrative tasks, such as verifying that the notification meets formal criteria, before the HDAB transmits the findings to the relevant data holder. Under EHDS Regulation, HDABs are not responsible for assessing the clinical validity or medical relevance of the findings.

Step 3. Data Holder Responsibilities: The measures to be taken by data holders need to be determined at national level under Art. 58 para. 3 of the EHDS Regulation. Data holders should be responsible for communicating with those who makes direct clinical decisions about the significant findings, and later who can integrate the significant findings into the relevant health records or systems, **when possible and appropriate, recognising that not all datasets originate from or are linked to medical records.** Once informed by the HDAB, data holders should act within the scope of their role. It is also the data holders' responsibility, to decide on the extent to which of the significant findings they receive can change the care and perspective of patients, taking into account the individual characteristics of the patients and the capabilities of their institution. It is also their responsibility to finally assess the clinical significance of the findings on the patient's future care and perspectives and the need to communicate them to the natural person, involving the treating healthcare professional, if needed. It is the responsibility of the data holders – based on national legislation or ethical rules – to apply the appropriate method and timing to communicate these findings to the affected individuals, whilst ensuring that the information is conveyed in a sensitive and understandable manner. Communication to natural persons concerned may be delayed until a health professional can explain the information that potentially can have an impact on their health under the EHDS

Regulation, while Member States will address the guiding framework for and precise responsibilities of data holders in relation to this process.

Step 4. Notification of Individuals: Where permitted or required under national legislation, individuals should be informed by the relevant health data holder about significant findings related to their health data in a clear and understandable manner, unless the individual has explicitly opted not to receive such information. The process within the EHDS framework ends with the information obligation of the data holder to the natural person or the health professional treating the natural person. The further steps e.g., care provision fall outside the scope of the EHDS.

7.2 Communication between data user and HDAB, HDAB and data holder

Under the EHDS Regulation, the process for notifying significant findings involves a coordinated effort among data users, HDABs, data holders or health professionals, and individuals.

The outline of the process, as described in Articles 58 and 61 with a view to Recital 67 referred to above, is depicted in Figure 1.

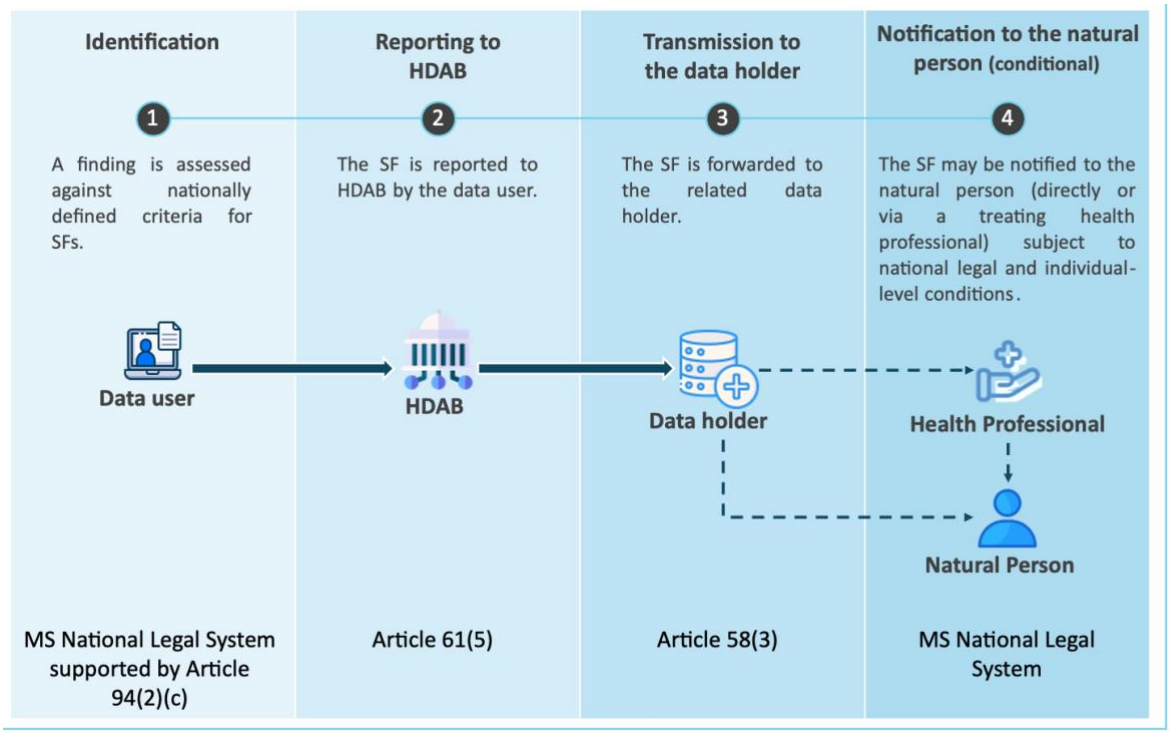
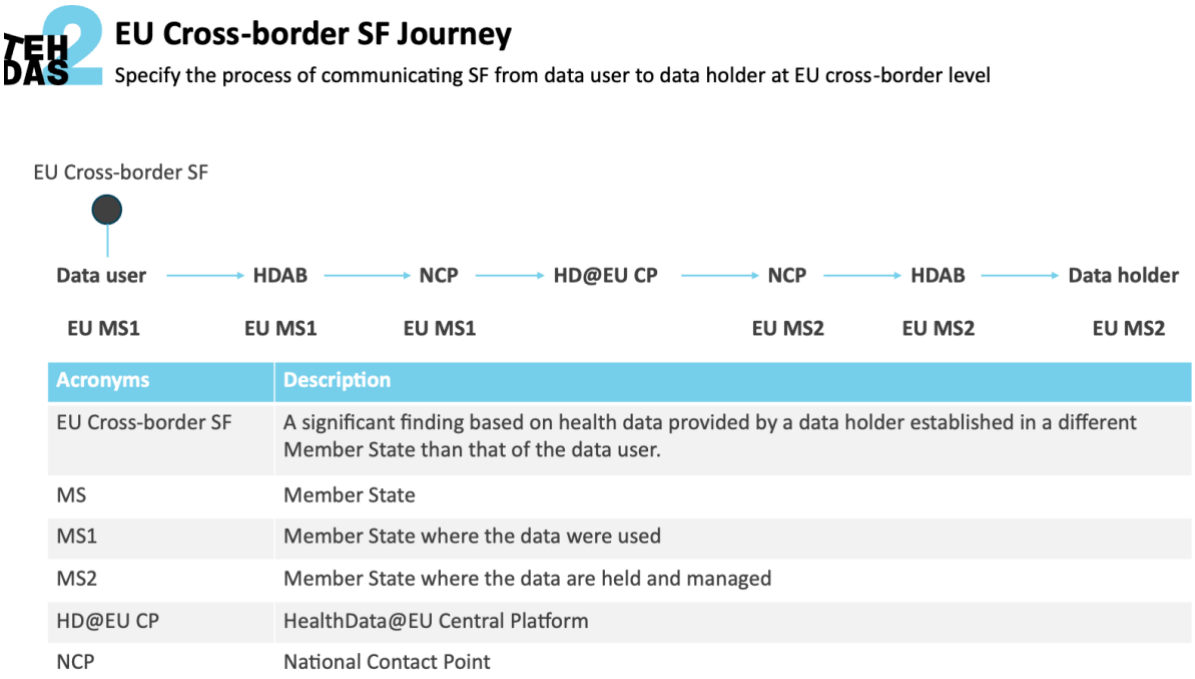


Figure 1: Overview of the EHDS2 significant finding journey, illustrating the procedural steps and responsible actors from identification by the data user to potential notification to the natural person, in accordance with Regulation (EU) 2025/327. Steps 2 and 3 are provisions of the EHDS Regulation (Articles 61(5) and 58(3)). Step 3 is addressed in this guideline under the remit of HDABs. Steps 1 and 4 fall under national responsibility: Step 1 is to be supported by the implementation of Article 94(2)(c), while Step 4 is to be governed by Member States in accordance with Recital 67. In the communication pathway, the dotted lines represent that any contact between the health data holder and the natural person (or their treating healthcare professional) is subject to Member State rules. These national rules determine whether the individual has exercised the right not to be informed and may require that any significant finding be first conveyed through the treating healthcare professional, as reflected in Recital 67.

Furthermore, it is also worth reviewing the scheme for the cross-border transmission of significant findings, as presented in Figure 2. The scheme illustrates a representative scenario in which a data user, operating under a multi-country data permit through the use of a Secure Processing Environment (SPE) based in one Member State (EU MS1), identifies a significant finding concerning a data subject from another Member State (EU MS2), while the relevant health data are held by a data holder located in EU MS2. The scheme brings to light the procedural and jurisdictional implications for notification workflows, as well as the cooperation mechanisms that may need to be established between the involved HDABs.



Acronyms	Description
EU Cross-border SF	A significant finding based on health data provided by a data holder established in a different Member State than that of the data user.
MS	Member State
MS1	Member State where the data were used
MS2	Member State where the data are held and managed
HD@EU CP	HealthData@EU Central Platform
NCP	National Contact Point

Figure 2: Diagram showing a proposed scheme for the cross-border transmission of a significant finding, where the data user operates under a multicountry data permit and uses a SPE of a particular Member State (EU MS1). The significant finding concerns a data subject from a different Member State (EU MS2) and the related health data are held by a data holder in EU MS2.

In line with the EHDS Regulation, it is recommended that communication on significant findings follows several overarching principles:

- Privacy must be protected by ensuring strict compliance with the data protection and confidentiality requirements set out in the applicable Regulations and in national implementing laws. This includes maintaining the integrity of personal and pseudonymised data when findings are transmitted between actors.
- Accountability requires that each actor in the chain: the health data user, the Health Data Access Body, and the health data holder, demonstrates compliance with the legal and ethical obligations defined at both Union and Member State level under the EHDS framework.
- Interoperability must be supported by using systems and procedures that are capable of working consistently across Member States, as envisaged in the EHDS Regulation, to enable secure and efficient national and cross-border data exchange.
- Transparency and data control are essential: natural persons should be able to obtain, where they request it, clear information on how their data is used under the EHDS and who has accessed it in the context of secondary use.

8 Guidance on the responsibilities of HDABs as regards significant findings

8.1 Measures in case of notification from data users

Data users are responsible for communicating significant findings to HDABs. When a potentially clinically significant finding is identified, the data user must notify the relevant HDAB in accordance with Article 61(5) of the EHDS Regulation. The responsibility of the HDAB begins when it receives such a notification. Under Article 58(3) of the EHDS Regulation, the HDAB must then transmit the finding to the appropriate health data holder. This transmission must take place in line with the conditions laid down in the Regulation and any applicable national rules. Throughout this process, the rights of natural persons must be safeguarded.

8.2 Measures to be taken towards data holders

The HDAB must collaborate with the original data holders, e.g., healthcare providers or institutions, to facilitate the appropriate transmission of the findings. Depending on national or local conditions, the HDAB may help to interpret and put the significant findings into context and, if the data holder requests it, the HDAB may participate in the re-identification process.

Where the HDAB has itself performed the pseudonymisation of the dataset, it may support the re-identification process. This role is strictly limited to cases where such support is necessary to enable the health data holder to fulfil its obligation to inform the natural person or their treating health professional. This is permitted under Article 58(3) of the EHDS Regulation, which defines the HDAB's duty to transmit significant findings to the data holder, and Article 67(3), which establishes that the linking information enabling reversal of pseudonymisation may be held by the HDAB or a trusted third party following national law. Any such re-identification support requires that national rules explicitly authorise the HDAB to access and use the linking keys for this purpose and must not extend beyond enabling the data holder to comply with their notification duties.

8.3 Individuals' preferences about disclosure of significant findings

The return of information to the individual is subject to their informed preferences, guided by consultation with a healthcare professional, and must comply with the applicable national laws and regulations, as described in the chapter on issues to be addressed at Member State level.

8.4 Register of natural persons' requests not to be informed of findings

Under the EHDS framework, individuals have the right to control the use of their electronic health data, including to request not to be informed of significant findings. The procedure and registration of such requests can be regulated at national level. Since data are primarily recorded by data holders, e.g., healthcare providers, it is most likely that natural persons' requests not to be informed of findings should be registered by data holders, too. Such requests may also be registered along with the informed consents about participation in research. National legislation should establish clear responsibilities and systems for recording and respecting such requests. In addition, data holders may also include custodians of national-level registers, such as hospital discharge registers, cancer registries, or other population-based databases. These entities should likewise establish mechanisms for recording and respecting individuals' requests not to be informed, ensuring that such preferences are consistently applied across both institutional and registry contexts.

8.5 Track record of notifications from/to data users/data holders

HDABs play a pivotal role in managing and overseeing the flow of health data between data users and data holders. A crucial aspect of their responsibilities includes maintaining comprehensive records of notifications on significant findings exchanged between these parties, including actions by HDABs and feedback from data holders, regulated on national level. The development of the track record of notifications should take into account obligations under the EHDS Regulation on reporting, the transparency portal, and statistics.

8.6 Privacy aspects

Individuals' rights including privacy are at the core of managing significant findings. When significant findings are identified, all actors in the process must adhere to GDPR's confidentiality requirements and ensure that any communication with affected individuals is done in a secure and privacy-respecting manner.

While the responsibility to uphold the rights of the individuals (data subjects) is shared across the entire data value chain – from the initial data collectors engaging directly with individuals to downstream data users – this responsibility must be clearly governed at the national level. Each Member State should define and enforce this governance through its own applicable laws, policies, and regulatory frameworks.

The other important privacy aspect is data anonymity or pseudonymisation, and the re-identification of the natural persons affected. According to EHDS Regulation recital 72: taking into account the specific purposes of the processing, personal electronic health data should be pseudonymised or anonymised as early as possible in the process of making data available for secondary use.

If the data holder performed the pseudonymisation then the HDAB must provide the data holder with the pseudonym so that the data holder proceeds with the re-identification and with what is provisioned for informing the natural person at national level. That is where the HDAB obligation ends. whether the data holder does the re-identification right seems to be out of scope for this deliverable (and must be addressed nationally).

In this case, the responsibility is on the data holder to re-identify the natural person correctly. Since the ultimate responsibility for proper pseudonymisation and anonymisation lies with the HDAB, if the data is pseudonymised and the holder is unable to link it to identifiers, but the HDAB can, the HDAB is responsible for re-identification. If personal data relating to a data subject is processed by multiple data controllers, the HDAB may be in the position and responsible to identify this person.

By analogy with opt-out rules, if neither the health data holder nor the HDAB can identify a natural person in a dataset, the obligations related to significant findings do not apply. If the data are anonymised instead of pseudonymisation, re-identification is not possible, and the significant findings cannot be communicated to the relevant individual, and conversely, pseudonymisation instead of anonymisation by the data holder may enable to identify and communicate significant findings. Depending on the flow of data, a data holder may be structurally distant from the patient and unable to directly re-identify or contact them. In such cases, it may be worth considering for Member States to adopt detailed rules within their regulatory scope, either by involving the HDABs or in other ways.

To protect the rights of individuals, the risks and benefits of data processing must be assessed in any case.

8.7 Issues to be addressed at Member State level

The following chapter summarises the issues raised in this document that should be regulated or otherwise addressed at national level and includes non-binding recommendations.

- To ensure the ethical and legally compliant handling of significant findings, Member States are encouraged to establish clear national processes and to build the necessary capacity within HDABs. These processes should define step-by-step Standard Operating Procedures (SOPs) for receiving, assessing, and transmitting significant findings in line with Article 58(3) and Article 61(5) of the EHDS Regulation. The roles and responsibilities of all actors involved (HDABs, data users, health data holders, and treating clinicians) should be clearly allocated, including specific protocols for managing complex or ethically sensitive cases.
- Member States are further encouraged to issue national guidance for HDABs and data users, developed in close cooperation with ethical bodies, legal experts, researchers, and representatives of citizens. Such national guidance should be tailored to the Member State's healthcare structure and ethical oversight framework and should also provide procedures for cases where significant findings arise in the context of cross-border secondary use of health data. In particular, it should address how HDABs are to cooperate when the data subject, the health data holder, and the HDAB receiving the significant finding notification are located in different Member States, as foreseen in Chapter IV of the EHDS Regulation (Section IV, Article 75–76) governing the HealthData@EU infrastructure and transnational data exchange.
- Member States may define the criteria, categories, and procedures for identifying and managing significant findings at the national level, taking into account local clinical practices, ethical standards, and healthcare system requirements. Multidisciplinary advisory bodies that include clinical, ethical, legal, and technical expertise to guide the development of context-specific definitions and protocols may be established. This process should consider local clinical practices, healthcare system capacities, and ethical standards, ensuring alignment with international guidelines where appropriate. National frameworks may include condition-specific criteria for actionability, standardized procedures for validation and communication of findings, and clear protocols for follow-up and integration into clinical care. Ethical oversight mechanisms should be in place to safeguard patient autonomy, privacy, and informed consent, while public engagement and transparency can help build trust and ensure that the approach reflects societal values. Integration into national health data infrastructures and coordination with EHDS mechanisms are essential to ensure consistency, interoperability, and responsible data use. The process and responsibilities about feedback of significant findings should be clarified in Member States' legislation.
- The detailed measures to be taken by data holders need to be determined at national level under Art. 58 para. 3 of the EHDS Regulation. Data holders should be responsible for integrating the significant findings into the relevant health records or systems, once informed by the HDAB. It is also the data holders' responsibility, to decide on the extent to which of the significant findings they receive can change the care and perspective of patients, taking into account the individual characteristics of the patients and the opportunities of their institution. It is also their responsibility, to finally assess the clinical significance of the findings on the patient's future care and perspectives and the need

to communicate them to the natural person, involving the treating healthcare professional, if needed. To ensure this obligation can be met in practice, data holders should maintain or have access to a reliable source of contact information for the natural person (or their treating professional), so that notification can be carried out effectively. It is the responsibility of the data holders – based on national legislation or ethical rules – to apply the appropriate method and timing to communicate these findings to the affected individuals, whilst ensuring that the information is conveyed in a sensitive and understandable manner. Individuals should be informed about the significant findings related to their health data in a clear and understandable manner, except when the individual requested not to be informed of such findings. This notification should include clear information about the findings and any recommended actions or follow-ups, under national law.

- It must be ensured that natural persons are appropriately informed by health data holders or health professionals of any significant individual findings that emerge from the secondary use of their health data. This notification should be delivered at the individual level under national rules, in a manner that is clear, timely, and understandable, respecting the right to be informed and ensuring transparency. Information shared should include the nature and clinical relevance of the finding, the potential health implications, and recommendations for follow-up actions such as further diagnostic evaluation or clinical consultation.
- Importantly, communication must comply with data protection laws such as the GDPR and uphold ethical standards. While explicit informed consent might be required for processing highly sensitive data, such as genetic data, the right not to be informed (an autonomous right distinct from data use consent) must also be respected. This right, grounded in the principles of autonomy and informational self-determination (such as Article 8 ECHR, Article 7 EU Charter), allows individuals to refuse receipt of certain findings such as genetic findings without affecting the lawful use of their data. Mechanisms must ensure individuals are informed of this right and can exercise it freely. Prior to disclosure, findings must be verified for accuracy and clinical validity, and communication should involve relevant healthcare professionals to provide counselling where medically justified. These measures align with the EHDS's objectives to promote trust, protect individual rights, and enable responsible health data use for research and care. Disclosure is a national competence but should be based on the individual's choice and ultimately the data holder's responsibility. Communication to natural persons concerned may be delayed until a health professional can explain the information that potentially can have an impact on their health, under the EHDS Regulation, while Member States will address the guiding framework for and precise responsibilities of data holders in relation to this process. The return of information to the individual is subject to their informed preferences, guided by consultation with a healthcare professional, and must comply with the applicable national laws and regulations. However, exemptions on Member State level might apply for specific cases, e.g., genetic results or severe health conditions.
- While the responsibility to uphold the rights of the individuals (data subjects) is shared across the entire data value chain – from the initial data collectors engaging directly with individuals to downstream data users – this responsibility must be clearly governed

at national level. Each Member State should define and enforce this governance through its own applicable laws, policies, and regulatory frameworks.

- Full compliance with data protection legislation like GDPR must be ensured when managing significant findings. It is the responsibility of the health data holders , HDABs, and health data users to ensure the privacy of patient data while also disclosing significant findings appropriately. From an ethical perspective, significant findings should also be considered when obtaining informed consent in a clinical study, including the request to be informed or not. It is an open issue for Member States to establish secure and trusted communication means for the communication of the significant findings.
- Quality Control and oversight, review and validation of significant findings (based on EHDS Article 58 and Recital 67): Robust review processes should be implemented to validate significant findings to maintain the accuracy and clinical relevance of health data. Responsibilities for overseeing the quality of health data should be defined, ensuring that significant findings are appropriately evaluated. In general, once significant findings have been identified one has to be able to categorise them based on their urgency. In all cases, data security must be granted and strict ethical guidelines for data sharing must be followed on national level. Member States should have procedures for the assessment of findings involving all partners in the chain.
- Under the EHDS framework, individuals have the right to control the use of their electronic health data, including to request not to be informed of significant findings. However, the request not to be informed may be expressed and recorded at different points in the process, depending on the characteristics of the type or the specific case of secondary data use. The procedure and registration of such requests can be regulated at national level. Since anonymisation and pseudonymisation are primarily carried out by data holders, e.g., healthcare providers, it is recommended that natural persons' requests not to be informed of findings should be registered by data holders, too. Such requests may also be registered along with the informed consents about participation in research. To ensure consistency, Member States should consider establishing a centralised or interoperable system for recording these requests, accessible by both data holders and HDABs. This would avoid duplication, reduce the risk of conflicting records, and guarantee that an individual's preference is respected across different datasets, institutions, and secondary use contexts.

Table 2: Responsibilities of HDABs under the EHDS: EU-mandated obligations vs. national discretion. This table presents the specific responsibilities assigned to HDABs under the European Health Data Space Regulation, as adopted at EU level. It distinguishes between obligations that are directly mandated by the Regulation and those aspects where Member States retain discretion in implementation. The table includes legal references to the relevant provisions of the final EHDS Regulation to clarify the legal basis for each task. The aim is to provide HDABs with a clear understanding of which duties stem from EU law and which depend on national legal or policy decisions.

Responsibility area	EU-mandated obligations	National discretion	Legal basis (EHDS Article/Recital)
1. Notification from data users	Receive significant findings from data users; forward to relevant data holder.	Define national protocols and ensure safeguards for data subject rights.	Art. 61(5), Art. 58(3), Recital 67
2. Measures toward data holders	Transmit findings; support re-identification only if HDAB pseudonymised the data.	Determine when and how HDAB supports data holders in re-identification.	Art. 58(3), Art. 67(3), Recital 72
3. Individuals' preferences about disclosure	Ensure respect for the individual's right not to be informed.	Establish procedures to record and act on such preferences.	Art. 61(5), Recital 67
4. Register of requests not to be informed	Guarantee right not to be informed; enable registration systems.	Define who registers preferences (e.g., data holders); integrate with consent.	Art. 58(3), Recital 67, Recital 72
5. Track record of notifications	Maintain notification records; support transparency and EHDS reporting.	Develop mechanisms for tracking exchanges and actions nationally.	Art. 58(3), Art. 61(5), Recital 67
6. Privacy and re-identification	Ensure pseudonymisation/anonymisation; only re-identify when authorised and necessary.	Determine linking key access rules; ensure national privacy safeguards.	Art. 67(3), Recital 72
7. Governance and SOPs	Apply EHDS principles for secure, ethical, and lawful data use.	Develop SOPs and national frameworks to manage significant findings.	Art. 58(3), Art. 61(5), Chapter V

Responsibility area	EU-mandated obligations	National discretion	Legal basis (EHDS Article/Recital)
8. Communication of findings	Enable transmission of significant findings without infringing privacy rights.	Regulate communication content, timing, and responsible actors.	Recital 67, Art. 58(3), Art. 61(5)
9. Quality control and validation	Ensure only clinically validated, accurate findings are transmitted.	Define national review mechanisms and urgency criteria.	Art. 58(3), Recital 67

9 Annexes

9.1 ANNEX I – Methodology

This milestone has been developed as a draft version of the guideline to HDABs on *implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data*. This was done through a structured process by incorporating initial input from the Task 8.1 group participants and regulatory analysis related to the significant findings. The contributors participated according to their commitments, ensuring a collaborative and thorough development process.

The structured work described below represents the first phase of delivering this draft guideline as a milestone under TEHDAS2 Task 8.1. It has been organised and implemented along the following main lines:

- Desk research was performed by all contributors. During this process, relevant information and best practices were collected from the participating Member States, organisations, and related projects such as TEHDAS1 and the EHDS2 Pilot.
- Working meetings − regular working meetings were conducted to discuss and outline the key components and structure of the guideline, address open questions, as well as issues falling within the competence of Member States.
- Drafting meetings – two drafting meetings were held by the major contributors in the last stage of the work to finalise the document.
- Consultations with DG SANTE − One meeting with representatives from DG SANTE was organised to ensure alignment with regulatory requirements and to receive expert feedback. The final draft was sent to the experts of DG SANTE for written comments.
- Alignment between the related TEHDAS2 guidelines is ensured, as the two related guidelines are also part of the present Task T8.1, and in this way the present guideline and the following guidelines are prepared in close collaboration:
    - the guideline for HDABs on the implementing of the opt-out in the secondary use of health data,
    - the guideline for data users on how to fulfil the duties regarding research outcomes.

For the next phase, this milestone will undergo a formal public consultation process in alignment with the TEHDAS2 Handbook to gather stakeholder feedback from HDABs. Although this guideline is not directly addressed to citizens or data users, HDABs may refer to it when structuring their information duties (as specified in Articles 58-59 of the EHDS Regulation).

The feedback obtained through consultations will be systematically analysed and integrated into the final guideline version ensuring the inclusion of legally robust and practically feasible recommendations within the defined scope of this guideline.

9.2 Annex II – Glossary

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)
Benefit (of data use)	Refers broadly to positive outcomes of data use. It can encompass social, health and environmental aspects, among others.
Central Platform	An interoperability platform established by the European Commission, providing services to support and facilitate the exchange of information between National Contact Points and authorised participants in HealthData@EU for secondary use of electronic health data. (EHDS Regulation, Article 75(8))
Data access	Processing by a data user of data that has been provided by a data holder, in accordance with specific technical, legal, or organisational requirements, without necessarily implying the transmission or downloading of such data. (DGA, Article 2(8)(9)(13))
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 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

TERM	DEFINITION
	permit for specific secondary use purposes based on conditions laid down in Chapter IV of EHDS Regulation. (EHDS Regulation, Article 2(2v))
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(2z))
Data quality & 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(2aa))
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(2y))
Dataset record	A catalogue A dataset record is a single, structured unit of data within a dataset, analogous to a row in a table or a record in a database. It contains specific information about a single entity or instance within the broader dataset.
Dataset subset	Dataset subset contains only selecte Dataset subset contains only selected records, variables or elements from a larger dataset while maintaining its key characteristics and relationships.
Dataset description	Health data access bodies shall, through a publicly available and standardised machine-readable dataset catalogue, provide a description in the form of metadata of the available datasets and their characteristics (EHDS Article (77(1))
Electronic health data	Personal or non-personal electronic health data (EHDS Article 2(2c)).
EU dataset catalogue	A dataset catalogue means 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 Regulation, Article 2(2y)) The EU dataset catalogue, the national dataset catalogues and the dataset catalogues of authorised participants in HealthData@EU shall be made publicly available. (EHDS Regulation, Article 79(1–2))
Health data access application	An application seeking to access 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

TERM	DEFINITION
	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. As per Article 58 of the EHDS, HDABs are required to publicly list information on 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(2t))
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. (EHDS Regulation, Article 2(2u))
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)
Interoperability	Ability of organisations, as well as of software applications or devices from the same manufacturer or different manufacturers, to interact through the processes they support, involving the exchange of information and knowledge, without changing the content of the data, between those organisations, software applications or devices. (EHDS Regulation, Article 2(2f))
Legal basis of data processing	The conditions under which personal data processing is considered lawful (GDPR, Article 6). Purposes for which the electronic health data can be processed for secondary use are laid down in EHDS Regulation, Article 53.
Metadata	A structured description of the contents or the use of data facilitating the discovery or use of that data. (Data Act, Article 2)

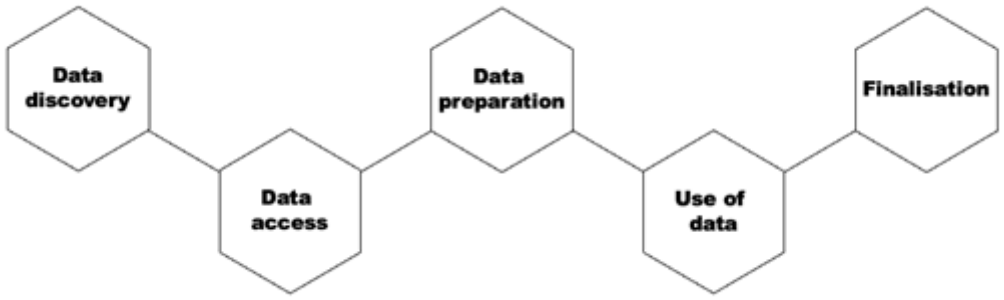
TERM	DEFINITION
National dataset catalogue	Making public, through electronic means: (i) a national dataset catalogue that includes details about the source and nature of electronic health data, in accordance with Articles 77, 78 and 80, and the conditions for making electronic health data available; (EHDS Article 57(1)(j)(i)).
National contact point (NPC)	A National Contact Point for secondary use is the organisational and technical gateway for making electronic health data available for secondary purposes, including research, innovation, policy-making, and public health. It plays a crucial role in connecting national data infrastructures to the HealthData@EU Central Platform, enabling secure and efficient data sharing across borders. (EHDS Regulation, Article 75(1))
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))
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 organisational measures to ensure non-attribution to an identified or identifiable person. (GDPR, Article 4(5))
Public value	Public value means a weighted composite of risks and benefits of the data use taking into account the sustainability of benefits, addressing future societal needs, distributing benefits fairly, evaluating potential harm, ensuring stable safeguards through risk assessment, and correcting any harms that may occur.
Re-identification risk	The risk of a successful re-identification attack (ISO/IEC 20889:2018(en), 3.33), which describes an action performed on de-identified data by an attacker with the purpose of re-identification (ISO/IEC 20889:2018(en), 3.32).
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(2e))
Secure Processing Environment (SPE)	An environment in which access to electronic health data can be provided in following a data permit. An SPE 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,

TERM	DEFINITION
	restricted data handling, logging and the compliance monitoring of respective security measures. (EHDS Regulation, Article 73)
Significant finding	The EHDS Regulation does not define this term. Recital 67 refers to significant findings as health-related results identified by data users during secondary use that may be relevant to a natural person. Their classification and clinical interpretation are subject to national frameworks and fall outside the remit of HDABs.
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)
Request for Payment	A formal request submitted to the data user for payment of the actual costs corresponding to work completed during a specific period. It follows the structure defined in the original invoice and refers to the relevant cost components outlined therein.

9.3 Annex III – EHDS User Journey

When a data user[i] 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)[ii]. 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)[iii] 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[iv]. 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.

[i] Data user = a person using electronic health data for a secondary use purpose
[ii] Health data access body (HDAB) = the authority responsible for assessing the information provided by the data user who applies for electronic health data for a secondary use purpose
[iii] Data holder = Any natural or legal person, public authority or other body in the healthcare or the care sectors that has the right or obligation to provide electronic health data for secondary use purposes or the ability to make such data available (see more EHDS Regulation Art. 2 (1t)).
[iv] Secure processing environment = an environment with strong technical and security safeguards in which the data user can process personal level electronic health data