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

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

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, T8.1 of the TEHDAS2 project is dedicated to obligations towards natural persons, and within T8.1., this D8.2 document 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 initial guiding tool to help HDABs fulfil their obligations under Articles 58(3) and 61(5) of the EHDS Regulation
- focuses specifically on the procedures HDABs must implement when receiving information regarding any significant findings related to the health of the natural person whose data are included in a dataset used by data users and forwarding them to the appropriate health data holders
- clarifies the boundaries of their responsibilities, ensuring alignment with national implementation frameworks.
- describes the distinct roles of data users, HDABs, and data holders
- provide guidance and clarification on how the Member States can support data holders in navigating the process of return of significant findings to the natural persons
- touches on privacy and data protection responsibilities, while noting that issues related to pseudonymisation, anonymisation, and technical safeguards are addressed in other guidelines of the TEHDAS2 project.

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.

For this guideline, it is important to clarify that significant findings may arise either incidentally or as a result of targeted analyses performed during the authorised secondary use of data. The EHDS Regulation does not impose an obligation on data users to actively search for clinically relevant findings beyond the scope of their authorised processing activities. The obligation applies only when such findings emerge within the permitted analytical context.

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 measures, especially regarding the communication of such findings to individuals.

One of the key operational messages of this guideline are that HDABs are not responsible for clinical validation or for direct communication with natural persons regarding any significant findings related to their health. From a liability perspective, HDABs function as procedural intermediaries, responsible for receiving and transmitting notifications of significant findings to the relevant health data holder. The assessment of clinical significance

remains subject to national clinical governance frameworks and applicable professional standards. Another important operational message is that significant findings may arise across diverse secondary-use contexts, including research, registries, advanced analytics, and artificial intelligence applications, and that cross-border scenarios require cooperation between HDABs and competent authorities, while notification responsibilities remain governed by national legal frameworks.

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 D8.4 (*Guideline for data users on handling research outcomes*). 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 to request not to be informed of such findings 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, such as specifications on implementation of Secure Processing Environment (SPE), or datils of data security and encryption, pseudonymisation or reidentification, cross-border infrastructure, logging and auditability, furthermore guidance on interoperability standards.

The effective implementation of the notification obligation will require HDABs to develop and maintain technical, organisational, clinical, and governance capacities. These include interoperable digital infrastructures, expert validation mechanisms, secure reidentification workflows, and sustainable institutional resources. While this guideline does not prescribe specific implementation models, it recognises that Member States will need to ensure long-term operational readiness of HDABs.

In summary, this 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 to request 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. The operational implementation of these obligations may require additional organisational and infrastructural arrangements at national level, which remain outside the scope of this guideline.

Additional background information on the development of the guideline, consultation activities, practical implementation examples and terminology is provided in Annexes 1–5.

2 Abbreviations

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

3 Introduction

3.1 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.

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 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 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.

This document should be understood as an expert opinion and guidance document developed within the TEHDAS2 framework, reflecting technical and expert input from the project partners. It is not legally binding and does not constitute a formal guideline or technical specification under the European Health Data Space.

This document does not represent the position of the European Commission.

3.2 Position of this guideline within the EHDS governance framework

This guideline serves as an initial step to support a consistent interpretation of the Regulation and to help Member States prepare for the implementation of Articles 58(3) and 61(5) of the EHDS Regulation. Further material, operational mechanisms, and detailed guidance will be developed by the EHDS Steering Board, which provides strategic direction, promotes

harmonisation, supports implementation, and addresses cross-border issues. These future elements will also contribute to the preparation of the implementing acts and will go through review of the relevant experts and authorities.

This guideline represents a first, foundational layer of the EHDS implementation, providing a harmonised high-level framework to support Member State preparedness, while recognising that more detailed operational guidance will emerge through future implementing acts, governance structures, and practical experience.

The introduction of obligations related to significant findings represents a functional expansion of HDAB responsibilities. HDABs will not only act as procedural intermediaries but may need to support complex workflows involving secure reidentification and communication mechanisms. These developments may require coordinated capacity-building across technical, legal, governance or clinical domains.

The cross-border nature of secondary use under the EHDS may introduce additional procedural considerations when significant findings involve actors or data subjects located in different Member States. This guideline aims to support consistent handling of such situations while respecting national legal responsibilities, acknowledging that the operationalisation of the EHDS is likely to generate novel or complex scenarios that may require iterative refinement through implementation practice, emerging evidence, and future regulatory or professional guidance.

The primary focus of the work performed in T8.1 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. T8.1 addresses these obligations through two documents:

- *D8.1 Guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data*
- *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*.

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.

This guideline clarifies procedural responsibilities for managing significant findings but does not establish uniform clinical or scientific criteria for determining when a research result qualifies as a significant finding. The assessment of clinical actionability, medical relevance, or risk thresholds remains subject to national clinical governance and professional standards. The guideline instead focuses on identifying the procedural pathway through which findings that meet such criteria, as defined at national or institutional level, are transmitted within the EHDS framework.

The emergence of large-scale data-intensive technologies, such as whole genome sequencing, artificial intelligence-assisted imaging analysis, and multi-omics approaches,

requires particular clarity regarding the interpretation of significant findings. In such contexts, findings may only become detectable through targeted analytical approaches and may not constitute incidental observations in the traditional clinical sense. This guideline therefore acknowledges the technological diversity of secondary data use scenarios.

Where this guideline uses explanatory terminology not explicitly defined in the EHDS Regulation, such terminology is intended to support interpretation and does not modify or limit the legal scope of the EHDS concept of significant findings.

The Glossary annexed to this guideline provides definitions of key terms used in this document. Where abbreviations are introduced, the full term is provided at first occurrence, followed by the abbreviation used throughout the document.

To facilitate practical implementation and interpretation of this guideline, a set of supporting annexes accompanies the main text. Annex 1 describes the methodology applied during the development of the guideline. Annex 2 summarises the outcomes of the public consultation process and stakeholder feedback. Annex 3 presents an illustrative user journey demonstrating possible procedural pathways for handling significant findings under the EHDS framework. Annex 4 contains a glossary of key concepts, definitions and terminology used throughout the document. Annex 5 provides an overview of the broader TEHDAS2 deliverables and explains how this guideline relates to other outputs supporting the implementation of the EHDS. Readers are encouraged to consult these annexes alongside the main text for additional context and practical guidance.

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.

This guideline is closely related to the guideline within D8.4 (*Guideline for data users on handling research outcomes*) for secondary electronic health data users presenting how to fulfil their duties regarding research.

While the primary focus of this guideline is to support HDABs in fulfilling their procedural responsibilities under the EHDS Regulation, the document also describes, at a general level, the interface between HDABs and health data holders. This reflects the role of health data holders as the actors responsible, under national legal frameworks, for assessing and communicating significant findings to natural persons. The guideline does not define or harmonise the specific responsibilities of health data holders in this process, which remain subject to national law and professional standards. Health data holders covered by the EHDS framework may include a broad range of entities, including healthcare providers with a direct care relationship with individuals, as well as public health authorities, population-based registries, and other entities processing health data under legal public-interest mandates, such as those under Article 9(2)(i) GDPR. This guideline acknowledges this diversity but does not define or harmonise the specific roles or notification responsibilities of different categories of data holders, which remain subject to national legal frameworks.

This guideline does not prescribe a specific technical, clinical, or organisational model for implementing the obligations related to significant findings, nor does it promote any single workflow such as a centralised validation pathway or a uniform national reidentification mechanism as a preferred approach. The EHDS Regulation requires Member States to ensure that significant findings identified during the authorised secondary use of electronic health data can be appropriately managed and communicated, while leaving the design of the underlying systems to national discretion. Member States may adopt centralised, decentralised, or hybrid arrangements, provided they comply with applicable data protection, information security, clinical governance, and confidentiality requirements. The existence of a notification mechanism should not be interpreted as requiring additional processing of personal data beyond what is strictly necessary for fulfilling the obligations set out in the Regulation. Member States and HDABs remain responsible for selecting implementation models that minimise security risks, avoid unnecessary concentration of sensitive information, and ensure that responsibilities are clearly allocated.

As a result, the management of significant findings may vary across national systems, and such differences may create challenges in cross-border scenarios, particularly when the data user, the health data holder, and/or the natural person are located in different Member States. These structural divergences reflect the balance struck by the Regulation between harmonisation and national responsibility. This guideline cannot resolve these differences but aims to make them transparent and to support coherent national implementation within the limits of the legal framework. Any further convergence will depend on future implementing acts and the work of the EHDS governance bodies.

This document is designed to be implementable in Member States with diverse levels of digital maturity and with existing national frameworks governing secondary use, clinical oversight, and patient communication. It does not require Member States to redesign national infrastructures or replace established statutory systems such as existing clinical governance structures, national data services, or long-standing legal obligations concerning patient notification. Instead, it identifies the EHDS-specific obligations and boundaries relevant to Articles 58 and 61, which must be integrated into, and where necessary aligned with, national frameworks. Existing mechanisms that already comply with the Regulation may remain in place and be further developed, provided that the obligations concerning significant findings are effectively supported within national implementation.

The framework described in this guideline offers an initial, concept- and principles-based contribution to support Member States in preparing for the implementation of Articles 58 and 61 of the EHDS Regulation. It is not intended to provide a final or exhaustive interpretation of the legal framework. As the European Commission develops the implementing acts foreseen under the Regulation, additional technical and procedural specifications will be issued. These may, where appropriate, be reviewed or co-created by and with experts such as but not limited to Medical Societies, the European Data Protection Board, and the competent national supervisory authorities.

Member States should therefore regard this document as a foundational reference that will evolve over time, ensuring that their national approaches remain aligned with forthcoming implementing acts, formal guidance from the European Data Protection Board, and oversight by their data protection authorities.

To avoid unnecessary repetition and to support consistent interpretation, all key concepts and legal distinctions relevant to significant findings, including the relationship between incidental findings and clinically significant findings are defined in the introductory chapters of this guideline. Annex 4 (Glossary) provides definitions of core terms used in this document. Subsequent chapters focus on responsibilities and procedures and do not restate definitions unless strictly necessary.

For clarity, references in this guideline to “significant findings” should be understood as referring to findings related to the health of an identifiable natural person within the meaning of the EHDS Regulation. No additional or separate category of findings is implied.

This guideline does not create an obligation for data users to actively search for clinically relevant findings outside the analytical scope authorised by the data permit. The obligation to notify applies only when a significant finding becomes apparent within the authorised analytical workflow and available methodological framework.

In cross-border scenarios, the responsibilities of data users, HDABs, and health data holders remain governed by the EHDS Regulation and applicable national frameworks. The role of the HDAB remains limited to procedural transmission of notifications to the relevant health data holder, irrespective of whether the data user and the natural person are located in different Member States.

5 Explaining significant findings

5.1 Terminological clarifications

Incidental findings are unexpected observations about an individual that arise during an examination, analysis, or research activity and are unrelated to the original purpose of that activity. Such findings may range from observations with no clinical relevance to findings that could warrant further assessment. While incidental findings can occasionally lead to important insights for the individual, the broader ethical and procedural questions surrounding their management or disclosure fall outside the scope of this document.

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. For the purposes of this guideline, findings may be regarded as clinically significant where, under applicable national clinical and professional frameworks, they are considered to have potential relevance for diagnosis, treatment, prognosis, or other health-related decision-making. Not all findings resulting from secondary use necessarily meet this threshold, and their assessment remains context-dependent.

It is important to distinguish findings arising in the context of direct care from significant findings emerging during 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.

In high-throughput data environments, such as whole genome sequencing or artificial intelligence-assisted image analysis, findings typically cannot be identified without predefined analytical criteria or targeted variant or feature screening. In such cases, a finding should not be considered “incidental” merely because it was not part of the original clinical purpose of data collection. The classification as a significant finding should instead depend on its novelty, clinical relevance, and potential actionability.

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 may alter the clinical assessment of the individual’s condition, 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.

Consistency in interpretation may be supported through national clinical governance frameworks, professional guidelines, and, where appropriate, collaboration and experience exchange between competent authorities and HDABs. While the EHDS Regulation leaves room for Member States to define the criteria for significant findings, excessive flexibility may lead to inconsistent interpretations and uneven protection for individuals. To support a more harmonised and evidence-based approach, Member States may draw, where relevant, on established professional guidelines and evidence-based classification frameworks in the relevant clinical domain. The use of such frameworks may support a more consistent and transparent identification of significant findings across jurisdictions, while preserving flexibility for scientific and clinical developments.

The criteria presented in this guideline are intentionally formulated at a high level to allow flexibility across different clinical domains, data types, and national healthcare systems. The EHDS Regulation does not harmonise medical decision-making criteria for determining clinical actionability or health risk thresholds.

The purpose of this guideline is therefore to support the identification of findings that may require procedural handling under the EHDS notification framework, while detailed clinical or medical decision support tools remain subject to national clinical governance, professional guidance, and specialised domain expertise.

The EHDS framework does not require data users to perform additional analyses solely for the purpose of identifying significant findings. Notification obligations arise only when such findings become apparent during the authorised analytical process. The notification obligation under Article 61(5) is triggered when a significant finding emerges in the course of lawful secondary use, not through a requirement to conduct systematic screening for unrelated conditions. Accordingly, the notification obligations set out in Article 61(5) and Article 58(3) of the EHDS Regulation apply when a significant finding emerges in the course of lawful secondary use as authorised, and not as a result of any expectation that data users proactively seek out all potentially relevant health information. The assessment of whether a finding is significant, and the conditions under which it should be reported, remain subject to national legal, ethical, and professional frameworks, as further reflected in guidance for data users developed under D8.4 (*Guideline for data users on handling research outcomes*).

5.2 Typical examples of significant findings

The interpretation of significant findings under the EHDS framework should be read in conjunction with guidance addressed to health data users under D8.4, which provides further considerations regarding the responsibilities of data users when such findings arise. This guideline does not replace national implementing measures or professional standards. While examples are provided to support a shared understanding at Union level, Member States remain responsible for specifying how the identification, assessment, and communication of significant findings are operationalised within their national legal and healthcare systems.

The examples presented in this section are illustrative and non-exhaustive and are intended solely to support a common understanding of the types of results that may constitute

significant findings in the context of secondary use of electronic health data. They do not establish binding criteria, notification thresholds, or uniform interpretation rules at Union level. In line with the EHDS Regulation, the determination of whether a finding is significant, and whether it should be reported, depends on the specific analytical context, the characteristics of the dataset, and the applicable national legal, ethical, and professional frameworks. These examples should therefore be read in conjunction with the guidance addressed to data users under D8.4 and with national implementing measures adopted by Member States.

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 illustrations 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 lay down specific conditions or safeguards for the communication of such findings. 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, in the course of research it may happen that new laboratory markers are recognised 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 which may carry direct clinical implications, this could constitute a significant finding. The classification of the finding 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. In the context of radiological image exchange research programmes under the EHDS Regulation 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.

The examples provided in this section apply across different data modalities, including high-throughput and large-scale datasets. Whether a finding can be identified depends on the analytical design, methodological choices, and data accessibility. The inclusion of such examples does not imply an obligation to conduct systematic or open-ended searches beyond the authorised processing purpose.

Significant findings are not limited to findings that are directly related to the primary research hypothesis. They may include, where identified in the course of lawful secondary use, unexpected safety-relevant signals or adverse events, as well as clinically relevant incidental findings. The inclusion of such categories does not imply an obligation for data users to actively screen for unrelated conditions; however, where such findings arise within the authorised analysis, the notification obligations under Articles 61(5) and 58(3) of EHDS apply.

Generally speaking, every findings may be important, further information on how to make feedback if you are a data user can be found in the following guideline: *D8.4 Guideline for data users on handling research outcomes*.

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

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 which may carry potential clinical importance for the individual. This should not be interpreted as a regulatory gap. Rather than establishing uniform EU-level clinical criteria or thresholds, the Regulation sets out a procedural framework for the handling of significant findings arising from secondary use, while leaving the substantive assessment of clinical relevance and actionability to national legal and professional frameworks. Under Article 61(5), health data users must notify the relevant HDAB when such a finding arises, and under Article 58(3), the HDAB must securely transmit that information to the relevant health data holder. The Regulation does not assign to Union law the task of defining uniform clinical thresholds or actionability criteria. These matters remain governed by national legal frameworks, professional standards, and ethical review systems.

While differences in interpretation may arise across Member States, such variation reflects the allocation of competences under the EHDS Regulation and the diversity of healthcare systems within the Union. Consistency is supported through procedural harmonisation at EU level and through further guidance developed under Article 94(2)(c), as well as through national implementing measures.

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)(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 the pseudonymisation key, which would allow re-identification of the natural person).

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.

Under Article 58(3), the HDAB shall transmit the information to the relevant health data holder in accordance with the procedural requirements set out in the Regulation. The Regulation does not assign to HDABs any role in determining whether a finding is clinically significant. Specifically, it clarifies the HDAB's responsibilities when a data user, such as a researcher, identifies a significant finding concerning the health of a natural person. While the Regulation does not explicitly define identifiability criteria, the notification chain presupposes that findings must be capable of being linked, directly or indirectly, to an individual in order for notification to be operationally meaningful. 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 authorised 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(2)(c) (Tasks of the EHDS Board) foresees that the EHDS Board may develop guidelines, in consultation and cooperation with relevant stakeholders, to support health data users in fulfilling their duties under Article 61(5). Such guidelines are intended to provide general guidance, including considerations for assessing whether findings may be clinically significant, without addressing individual cases.

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 could 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 is consistent with established bioethical frameworks, including Article 10 of the Oviedo Convention and relevant opinions of the European Group on Ethics.

While the EHDS Regulation necessarily leaves certain elements, such as the definition, validation, and communication of significant findings, to Member States, excessive flexibility in these core areas risks undermining the objective of a harmonised and predictable EHDS framework. If Member States diverge substantially in determining what constitutes a significant finding, how its clinical relevance is assessed, or how individuals are informed, the result may be a fragmented system in which individuals experience different levels of protection depending on jurisdiction. Greater convergence in interpretation may be supported over time through the exchange of practices, future guidance, and, where appropriate, the development of common approaches, while respecting Member State competence. Such developments may contribute to improved interoperability, legal certainty for HDABs, data users and data holders, and the overall coherence of the EHDS.

[1] The final product of D8.4. 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.

The processing of electronic health data under the EHDS framework remains subject to the General Data Protection Regulation, which applies horizontally. The EHDS Regulation establishes sector-specific obligations, such as notification of significant findings, without altering the fundamental principles of purpose limitation, data minimisation, and data subject rights under the GDPR. This guideline does not reinterpret GDPR requirements, nor does it introduce additional data protection obligations beyond those laid down in Union or national law.

6 General aspects of the management of significant findings

This chapter describes general governance and procedural principles relevant to the handling of significant findings under the EHDS Regulation. It does not establish clinical assessment criteria, notification thresholds, timelines, or technical implementation requirements. Nor does it define how Member States should organise national disclosure mechanisms or clinical follow-up. In line with the EHDS Regulation, these matters remain within national competence. The purpose of this chapter is therefore to clarify roles, responsibilities, and safeguards at a high level, without replacing national legal, ethical, or professional frameworks.

In order to support transparency and predictability for natural persons and stakeholders, Member States are encouraged to make publicly available information regarding national rights, obligations, and procedures related to the handling of significant findings under the EHDS framework. Where appropriate, such information may be published through the website of the relevant HDAB or other competent authorities. This promotes clarity without affecting the allocation of responsibilities established by the Regulation.

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 may arise during lawful secondary use of electronic health data. The EHDS Regulation does not impose an obligation to actively search for such findings but establishes duties that apply when a significant finding emerges in the context of authorised data processing. The characteristics and quality of the data may influence whether such findings can be identified, but do not in themselves create additional obligations for data users or HDABs.
- **Documentation (Secure data processing and record-keeping, EHDS Article 58, Article 61):** Where significant findings arise and are reported in accordance with the EHDS Regulation, relevant information may be documented in line with applicable data protection, confidentiality, and security requirements under Union and national frameworks. Such documentation may support accountability and traceability of the notification process but does not imply clinical validation or assessment by HDAB.
- **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 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. The responsibility to decide whether, how, and when to inform the concerned individual or their treating health professional rests with the health data holder, in accordance with national law, as reflected in Recital 67. Article 61 further reinforces the importance of safeguarding patients' rights by requiring that data processing, including communication of significant findings, comply with applicable data protection and confidentiality requirements. As emphasised in Recital 67, the EHDS does not impose a uniform EU-wide approach to the return of findings, and Member States may determine the conditions under which such information is communicated. In accordance with Recital 67 and Article 58(3),

natural persons may also exercise the right not to be informed about significant findings, where such a preference has been expressed or is recognised under national law.

- **Follow-up and action (Secure sharing of data, EHDS Article 61):** Following the identification of significant findings, any further processing or transmission of information must comply with applicable security and confidentiality safeguards. The EHDS Regulation does not regulate clinical follow-up or care pathways, which remain governed by national law and professional standards. Where a significant finding is identified, Articles 61(5) and 58(3) of the EHDS Regulation establish the procedural framework for notification and transmission between the health data user, the HDAB, and the relevant health data holder. Such transmission must comply with applicable data protection, confidentiality, and security requirements. The Regulation does not establish differentiated urgency thresholds based on clinical severity. Any prioritisation based on medical risk or urgency is determined under national legal and professional frameworks, as reflected in Recital 67.
- **Ethical and legal considerations (Compliance with Data Protection Regulations, EHDS Article 58, Article 61, Recital 67):** Full compliance with the GDPR and relevant national data protection rules must be ensured when managing significant findings. In practice, it is the healthcare providers and health data holders, such as hospitals or clinical institutions, are responsible for safeguarding patient privacy and, where appropriate, for communicating significant findings to individuals or their treating professionals. While HDABs are required to transmit such findings to the relevant data holder, they do not engage in direct communication with patients. This allocation of responsibility reflects the both the EHDS legal framework and the operational reality across Member States, where the authority to interpret and communicate clinically relevant information lies with actors who have a direct care or institutional relationship with the individual.
- **Reliability, trust and consistent implementation:** A clear distinction should be made between the reliability of the EHDS framework and the trust that citizens place in the actors responsible for its implementation. Reliability refers to the system's objective and predictable functioning: if the EHDS framework operates differently across Member States, or if procedures for managing significant findings vary substantially, the system's reliability is weakened because individuals cannot anticipate how their rights will be applied. Trust, by contrast, concerns citizens' beliefs about the commitment of implementers, such as HDABs and health data holders, to uphold the values embedded in the EHDS Regulation, including fairness and equal treatment. While reliability can be undermined solely by inconsistent system performance, trust is affected when citizens perceive that implementers may not be committed to treating them equally or applying the rules uniformly. At the same time, a less reliable framework can naturally erode trust, as inconsistent outcomes may lead individuals to doubt the intentions or competence of those responsible for carrying out the Regulation. Ensuring both reliability and trust therefore requires not only harmonised procedures across Member States but also transparent communication and demonstrable adherence to the principles of fairness and equal treatment.

The notification mechanism for significant findings is relevant only where the finding can ultimately be linked, directly or indirectly through authorised actors and lawful means, to the natural person concerned. Where no such identification is possible in practice, the obligation cannot be operationalised. This does not require additional processing of personal data beyond what is lawful and necessary under the EHDS and applicable data protection law.

Table 1: Key governance elements for managing significant findings under the EHDS Regulation. This table summarises 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 (5)
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 (5), 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 (5)

Key aspect	EU-level responsibility	National discretion	Legal basis (EHDS Article/Recital)
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 (5), 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 tasks and obligations of data users, as well as the procedures for these, are detailed in D8.4 (*Guideline for data users on handling research outcomes*). 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 Article 94(2) (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. Where the data used by the data user do not allow the identification of natural persons, the obligation related to significant findings may not be operational for the data user. However, under the EHDS framework, authorised actors such as health data holders may still be able to link the data to the relevant individual in accordance with national law and applicable data protection rules.

The EHDS Board's tasks include, under Article 94(2)(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. The EHDS Board supports the process in cases where the regulations are uncertain for the parties involved (e.g., cross-border, or secondary data use involving data from multiple countries, etc.). Such guidelines should be adopted in consultation and cooperation with relevant stakeholders, including representatives of patients, data protection authorities, 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 8 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. If the data comes from multiple data holders, sorting the information and communicating transparently with the data holders concerned is one of the tasks of the HDAB, in line with the national legal framework.

Step 3. Data Holder responsibilities: Once informed by the HDAB, the health data holder shall act under the conditions laid down by national law. The assessment of the relevance of the finding, the decision on whether and how to communicate it, and any involvement of the treating health professional remain subject to national legal, clinical, and organisational frameworks. Member States may consider supporting relevant actors through national guidance and training. It is important to reduce the administrative and evaluation burdens on healthcare providers, including in relation to significant findings.

Step 4. Notification of natural person: Where permitted or required under national legislation, the natural person 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 requested 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.

For sake of clarity, managing the re-identification of natural persons in the context of significant findings is one of the most sensitive operational steps for HDABs. It must be emphasised that the EHDS Regulation does not assign HDABs the role of re-identifying individuals themselves. Any re-identification necessary for forwarding a significant finding to the appropriate health data holder must occur exclusively within the secure, legally established frameworks of the Member State, and always under the responsibility of the data holder or through another authorised entity such as a Trusted Third Party (TTP). HDABs must ensure that any transmission of information enabling re-identification complies with GDPR principles, particularly data minimisation, purpose limitation, subsidiarity and security, and aligns with national rules governing pseudonymisation keys, linkage mechanisms, and access controls. Member States should therefore define clear, secure, and auditable re-identification pathways to prevent HDABs from inadvertently assuming clinical or data controller responsibilities that fall outside the EHDS framework.

An illustrative example of a notification pathway is presented in Annex 3 (User Journey).

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, potentially health professionals, and ultimately individuals.

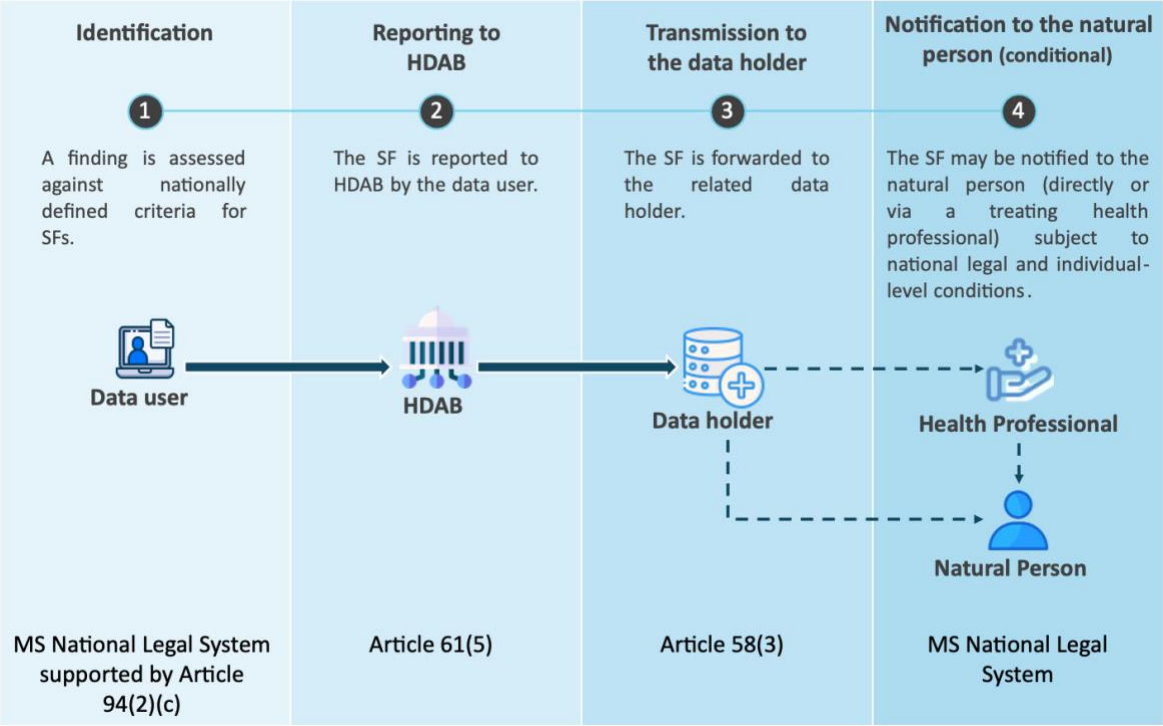
The outline of the process, as described in Articles 58 and 61 with a view to Recital 67 referred to above, is depicted in Figure 1. Steps 2 and 3 are provisions of the EHDS Regulation (Articles 61(5) and 58(3)). Step 3 is addressed in this guideline under the remit of HDABs. Steps 1 and 4 fall under 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. It is also the responsibility of Member States to determine how the communication chain should continue in cases where the primary data holder (who is in contact with the HDAB) does not have direct contact with the patients and/or the healthcare professionals whom treating them (e.g., national cancer registries). 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. Member States should also clarify how liability, conflict-of-interest situations, and data-quality uncertainties are to be managed when significant findings are reported.

In situations where significant findings are prompted by information, alerts, or signals originating outside the data user's own analysis or secondary-use activity, Member States should establish clear procedures for validation and allocation of responsibility. Such findings may arise, for example, where data-quality issues, misclassification, or algorithmic errors

(including false positives or false negatives) give rise to information that may be relevant to the health of a natural person. In such cases, the issue moves beyond data quality management and may fall within the scope of significant findings under the EHDS framework. Because these situations may also reveal past clinical oversights or misinterpretations, national frameworks should clarify how such findings are assessed and how responsibilities are allocated.

Relying solely on the original data holder to assess and disclose findings that may relate to their own prior error may create procedural conflicts, and Member States may wish to establish alternative or independent pathways for handling such sensitive cases. Clear national rules are essential to ensure professional confidence, protect individuals' rights, and support consistent cross-border implementation.

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 EHDS Regulation



In the context of the process illustrated in Figure 1, particular attention should be paid to the role of the health data holder following the transmission of a significant finding by the HDAB. Once informed by the HDAB, the health data holder acts under the conditions laid down by national law. The assessment of the relevance of the finding, the decision on whether and how to communicate it, and any involvement of the treating health professional remain subject to national legal, clinical, and organisational frameworks. 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

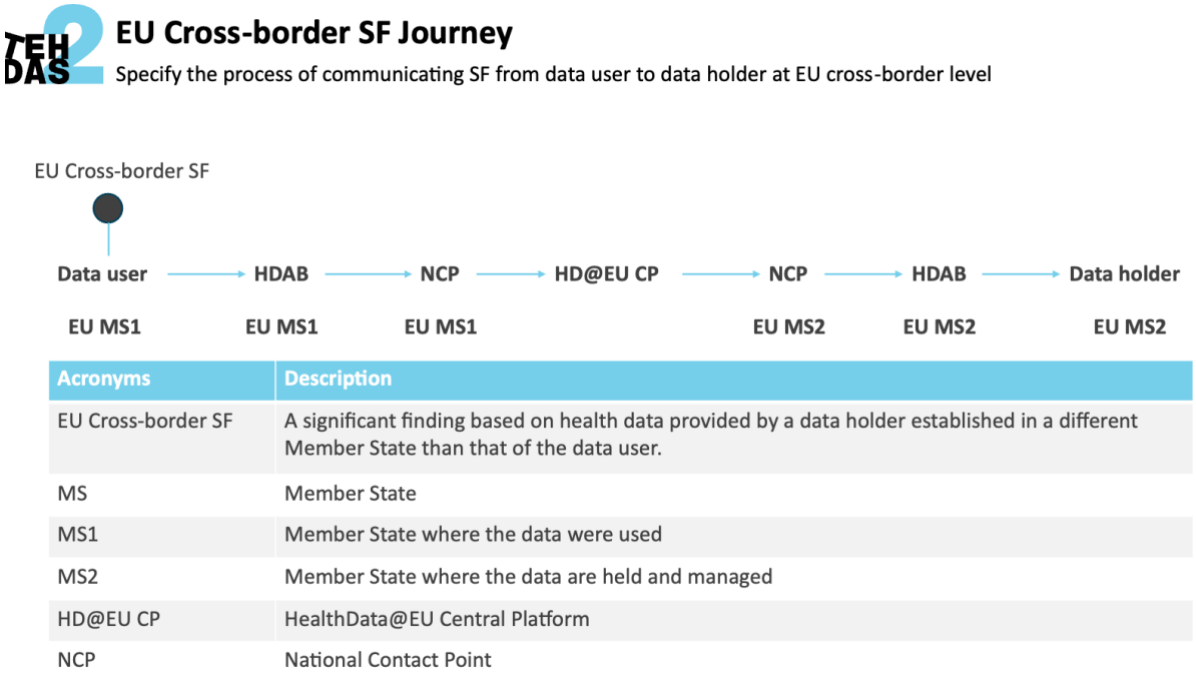
data holder located in EU MS2. The scheme brings to light the procedural and jurisdictional implications for notification workflows, as well as the cooperation mechanisms that may need to be established between the involved HDABs. These cases will certainly be subject to individual assessment following implementation, which is why transparent communication between Member States regarding the implementation is particularly important.

In cross-border or multi-national research contexts, differences in national approaches to defining and operationalising significant findings may arise. This guideline does not establish a hierarchy between national implementation approaches and does not prescribe a single method for reconciling differences between national lists or criteria.

Where such differences arise, coordination between relevant actors, including health data access bodies, national competent authorities and, where applicable, national contact points, may be necessary to determine the most appropriate approach in accordance with applicable legal frameworks and national implementation arrangements.

In the longer term, and as the EHDS governance and coordination structures mature, including through the work of the EHDS Board, further exchange of practices and development of common approaches may support greater consistency in the interpretation and handling of significant findings across Member States. This guideline does not establish such approaches and recognises that, at this stage, national implementation frameworks and case-by-case coordination remain the primary mechanisms for addressing cross-border differences.

Figure 2: Showing a proposed scheme for the cross-border transmission of a significant finding, where the data user operates under a multi-country 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.



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

In line with the EHDS Regulation, it is recommended that communications on significant findings follow these 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 can work 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.
- To support equitable and comprehensible communication across the Union, it would be ideal to establish a minimum EU-wide standard for the communication of significant findings. Such a standard should include the use of layered, plain-language information and integration with digital patient portals, while ensuring accessible alternatives for individuals who cannot rely on digital tools. These baseline requirements would promote clarity, consistency, and accessibility in all Member States, reducing the risk of unequal understanding or follow-up of significant findings.

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 clinically significant finding is identified, the data user must notify the relevant HDAB in accordance with Article 61(5) of the EHDS Regulation. The tasks and obligations of data users, as well as the procedures for these, are detailed in D8.4 (G*uideline for data users on how to fulfil the duties regarding research outcomes*). 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

In practice, the HDAB must collaborate with the original data holders, such as healthcare providers or institutions, to facilitate the appropriate transmission of significant findings. Depending on national or local conditions, the HDAB may facilitate the procedural transmission of the finding, may participate in the re-identification process. Where the identification of the natural person is possible through existing linking information or authorised mechanisms, such processes may be carried out in accordance with national law and applicable data protection requirements. This does not imply an obligation to process additional personal data for the sole purpose of identification. The EHDS Regulation does not prescribe which actor is responsible for such processes, which remain subject to national governance arrangements.

The HDAB's obligation under Article 58(3) of the EHDS Regulation is considered fulfilled once the significant finding has been securely transmitted to the relevant health data holder, in accordance with applicable legal and organisational arrangements. The HDAB is not responsible for assessing the clinical validity of the finding or for directly contacting the natural person. The subsequent obligation of the health data holder to inform the natural person or the treating health professional is governed by national law and the specific legal mandate of the data holder. It is recognised that certain health data holders, such as population-based registries or entities without a therapeutic relationship with the natural person, may be subject to specific national conditions or limitations regarding direct patient contact. In such contexts, the communication of the significant finding to the natural person may, where appropriate and subject to national law, involve a health professional, taking into account the considerations reflected in recital 67 of the EHDS Regulation regarding situations where information may have a significant impact on the natural person's health. The appropriate communication pathway remains dependent on national legal frameworks, the legal mandate of the data holder, and the specific circumstances of the case.

At the same time, it is essential to recognise that in some Member States data holders may process electronic health data without access to the underlying identifiers or clinical details of the individuals concerned. In such cases, the data holder must remain unaware of specific information, and providing additional identifying data could violate GDPR principles, including

purpose limitation and data minimisation. The EHDS framework does not require data holders to regain access to identifiers that have been removed during pseudonymisation, nor does it mandate the reversal of pseudonymisation where this would contradict national safeguards. Making data holders responsible for communicating with treating clinicians presupposes that a lawful and secure re-identification mechanism exists. Where identifiers have been removed or where no authorised re-identification pathway exists, the EHDS obligation cannot be operationalised. Member States must therefore define clear governance arrangements, potentially involving a TTP or another authorised entity, to ensure that re-identification, where permitted, occurs without undermining the protective purpose of pseudonymisation.

Where a significant finding emerges from the linkage of datasets originating from multiple health data holders, the identification of the “relevant health data holder” responsible for subsequent notification is determined in accordance with national law and applicable governance arrangements. In such situations, the determination of the most appropriate entity may depend on the specific context of the processing, including legal mandates, data governance arrangements, and the roles of the entities involved. This guideline does not establish a hierarchy between different types of data holders and does not prescribe a single method for making such determinations.

Where appropriate, and in accordance with national arrangements, relevant actors may consider factors such as the legal mandate of the entity, the ability to lawfully perform re-identification where permitted, or the existence of an established relationship with the natural person, taking into account the specific circumstances of the case.

8.3 Preferences of natural persons regarding the disclosure of significant findings

The return of information must respect the individual’s expressed preferences, including the right not to be informed, in accordance with national law.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.

Member States should clarify how the register documenting individuals’ choices not to be informed of significant findings is to be established, accessed, and used, particularly in situations where HDABs maintain the register but data holders are responsible for re-identification. To comply with data-minimisation principles, not all actors should have full visibility of individuals’ preferences; national rules should therefore specify which entities may consult the register, under what conditions, and through which privacy-preserving mechanisms. Clear allocation of responsibilities is essential to avoid situations in which HDABs inadvertently block notifications or data holders lack the information necessary to respect an individual’s choice.

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, may be recorded by data holders or, where appropriate, by health data access bodies or other authorised entities, in

accordance with national law. Such requests may also be recorded through mechanisms used in healthcare or research contexts, where appropriate under national law. National legislation should establish clear responsibilities and systems for recording and respecting such requests.

In cross-border scenarios, where a natural person's data may be included in datasets managed in more than one Member State, national frameworks should clarify the territorial scope and validity of a request not to be informed. The EHDS Regulation does not harmonise the cross-border recognition of such requests. Member States may therefore determine, in accordance with Union law and applicable national legislation, whether such preferences apply solely within their jurisdiction or are recognised through cross-border coordination mechanisms.

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 may include maintaining comprehensive records of notifications on significant findings exchanged between these parties, including actions by HDABs and feedback from data holders, as regulated on national level.

The maintenance of such records is intended to support transparency, traceability and administrative accountability in the exchange of notifications. It does not constitute monitoring of the subsequent assessment, clinical validation or follow-up actions taken by the health data holder. The responsibility for evaluating and acting upon a significant finding remains with the health data holder in accordance with national law and applicable professional standards.

Listing notifications may prevent duplication and overlap if a dataset was involved in several secondary data uses. The development of the track record of notifications should consider 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.

To ensure full compliance with the GDPR, the handling of significant findings must strictly adhere to the principles of purpose limitation, data minimisation, and confidentiality as set out in Article 5(1)(b), (c), and (f) GDPR. HDABs act solely as procedural intermediaries under Article 58(3) of the EHDS Regulation and must not access, interpret, or store any medical information contained in a notification beyond what is necessary to transmit it to the competent health data holder. Any part of the notification that contains clinical or health-related information should be protected through appropriate technical and organisational safeguards.

While the responsibility to uphold the rights of the individuals (data subjects, natural persons) 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: considering 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. In this case, the responsibility is on the data holder to re-identify the natural person correctly. Since the ultimate responsibility for ensuring proper pseudonymisation and anonymisation lies with the HDAB, even when it does not perform the technical process itself, situations may arise in which the data holder cannot link pseudonymised data back to identifiers, but the HDAB can. Where personal data relating to a data subject is processed by multiple data controllers, the HDAB may therefore be both uniquely positioned and obliged to identify the individual concerned.

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 as opposed to pseudonymised, re-identification is not possible, and the significant findings cannot be communicated to the relevant individual. Conversely, pseudonymisation by the data holder may enable them to identify the data subject 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.

Insofar the population-based registries, operating under Article 6(1)(e) and Article 9(2)(i) GDPR, such as cancer registries, must not be required to access, store, or process significant findings, as doing so would exceed their statutory mandate and introduce unnecessary data protection risks. Clear allocation of responsibilities between HDABs, data users, and data holders is therefore essential. Member States should ensure that lawful, secure, auditable, and encrypted communication channels are used for transmitting significant findings, preventing unauthorised access or retention of information beyond what is strictly necessary for the fulfilment of legal obligations.

Where a Trusted Third Party (TTP) is involved in the re-identification workflow, Member States should ensure that the repartition of responsibilities between the HDAB, the TTP, and the health data holder is clearly defined in accordance with the GDPR and the EHDS Regulation. Decisions on whether and when re-identification may be performed must rest exclusively with the legally competent actor, typically the health data holder or another entity designated under national law, and not with the HDAB or the TTP. This principle concerns the authority to decide on re-identification, not the technical ability to perform it. Trusted Third Parties may be capable of carrying out re-identification, but they have no legal mandate to determine when such processing is permitted. Although this rule does not appear verbatim

in the GDPR or the EHDS Regulation, it is an interpretive governance principle derived from both instruments, which require that only the legally competent actor, typically the health data holder or an entity designated under national law, may authorise re-identification. The TTP should therefore act solely as a technical service provider, performing re-identification only upon explicit and auditable instruction from the competent authority, without exercising independent discretion. This allocation of roles is essential to uphold GDPR principles such as purpose limitation and data minimisation, and to ensure that re-identification occurs only when legally justified and strictly necessary under Articles 58(3) and 61(5) of the EHDS Regulation. Member States should accordingly establish clear procedural rules and safeguards governing the initiation, authorisation, and documentation of any re-identification request involving a TTP.

For sake of clarity, Member States should ensure that procedures for managing significant findings take into account that data which appear anonymous to a data user may still be re-identifiable by other authorised actors, such as health data access bodies or data holders, depending on the technical and organisational context in which the dataset was created. For this reason, data users should notify the HDAB of significant findings even when working with datasets that are anonymous from their perspective, and HDABs should establish processes enabling data holders to determine whether re-identification is feasible and lawful under national frameworks. To support accurate identification of individuals and appropriate follow-up, insofar as this is compatible with national regulations, Member States may put in place structured channels for clear and timely information exchange between data users and data holders, facilitated by the HDAB, particularly in situations where the data user possesses relevant clinical or methodological expertise. This guideline should be read together with the broader guidance on data minimisation, pseudonymisation, anonymisation, and synthetic data (*D7.2 Guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data*), which provides the overarching framework for assessing identifiability and re-identification risk.

8.7 Checklist of national-level policy decisions

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

Governance, national frameworks, and allocation of responsibilities:

- ❑ **Member States should establish clear national processes and ensure that HDABs have the necessary capacity to handle significant findings in an ethical and legally compliant manner.** These processes could include step-by-step Policies, 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 defined, including specific protocols for managing complex or ethically sensitive cases.
- ❑ **Member States may consider defining the criteria, categories, and procedures for identifying and managing significant findings at the national level, considering local clinical practices, ethical standards, and healthcare system requirements**.

Multidisciplinary advisory bodies that include clinical, ethical, legal, and technical expertise may be established to guide the development of context-specific definitions and protocols. 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, standardised 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 of feedback of significant findings should be clarified in Member States' legislation.

- ❑ **Member States should establish clear national governance arrangements to ensure that the rights of individuals are upheld consistently across the entire data value chain.** While responsibility for protecting data subjects' rights is shared by all actors, from the initial data collectors who interact directly with individuals to downstream data users, this responsibility must be anchored in national law. Each Member State should therefore define and enforce the relevant governance structures through its own legislation, policies, and regulatory frameworks.
- ❑ **Member States may consider defining documentation, traceability and record-keeping approaches supporting transparency and accountability in the transmission of significant findings,** including how such records interact with national reporting obligations, transparency mechanisms, and statistical reporting under the EHDS framework.
- ❑ **Member States should develop national guidance for HDABs and data users in close cooperation with ethical bodies, legal experts, researchers, industry stakeholders, and representatives of citizens**. Involving a broad range of actors helps ensure that the resulting guidance is both ethically robust and practically implementable across diverse secondary use contexts.

Responsibilities of Data Holders and HDABs

- ❑ **Member States should establish clear national procedures to ensure that data holders can fulfil their responsibilities when a significant finding is transmitted to them.** The detailed measures to be taken by data holders need to be determined at national level under Article 58(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 the significant findings they receive can change the care and perspective of patients, considering 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.

- **Member States may consider defining the legal basis, controller responsibilities, and safeguards applicable to re-identification and communication of significant findings, ensuring consistency with both the EHDS Regulation and the GDPR.** This includes clarifying which actors are responsible for performing re identification, ensuring accuracy, managing individuals' preferences, and transmitting information through secure channels, as well as determining the lawful basis for processing when secondary use research leads to health relevant information. National frameworks should also address liability for misidentification or inappropriate re-identification or failure in providing information, and provide guidance for cross border scenarios where responsibilities may be shared across jurisdictions. Establishing these rules is essential to ensure lawful, proportionate, and accountable handling of significant findings.
- **Member States should establish clear rules on how data quality, data provenance, and the intended purpose of the original data source affect the interpretation of significant findings and the allocation of responsibilities**. Health data used for secondary purposes may originate from diverse systems whose coding practices, clinical validity, or structural design do not always reflect reliable clinical information. In cases where an apparent significant finding results from limitations in data structure, coding conventions, or the original purpose of the dataset rather than from a reliable characteristic of the individual, Member States should define which actors, such as the data user, the HDAB, the data holder, or the healthcare professional, bear responsibility for assessing validity and avoiding erroneous communication to individuals. National frameworks should therefore clarify liability boundaries, minimum data quality requirements for secondary use, and the safeguards needed to prevent misinterpretation of data that were never intended to support clinical inference. Establishing these rules is essential to ensure legal certainty, protect individuals from incorrect or misleading information, and support responsible secondary use across heterogeneous data environments.
- **Member States should establish national procedures and governance mechanisms to ensure that significant findings are properly reviewed, validated, and managed.** This includes putting in place quality-control and oversight processes, as required under Article 58 and Recital 67 of the EHDS Regulation. Robust review mechanisms should be implemented to validate significant findings and ensure their clinical relevance and accuracy. Responsibilities for overseeing the quality of health data must be clearly defined so that significant findings are appropriately evaluated. Once identified, findings should be categorised according to their urgency, and in all cases data security must be

ensured and strict ethical guidelines for data sharing must be followed at national level. Member States should also define procedures for the assessment of findings that involve all relevant actors in the chain.

Communication of significant findings to natural persons

- **Member States should ensure that national rules and procedures are harmonised and in place at the application of the EHDS Regulation, so that natural persons are appropriately informed by health data holders or treating health professionals of any significant individual findings that emerge from the secondary use of their health data.** This notification must 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. The information provided, consistent with national regulatory requirements, should include the nature and clinical relevance of the finding, its potential health implications, and any recommended follow-up actions, such as further diagnostic evaluation or clinical consultation.
- **Member States may consider determining how communication pathways** are organised where the relevant data holder does not have a therapeutic relationship with the natural person, including when and how communication may involve healthcare professionals, where appropriate and in accordance with national law.
- Importantly, communication should **comply with data protection laws such as the GDPR and uphold ethical standards and cultural sensitivities, ensuring that information is conveyed in a respectful, appropriate, and context-aware manner**. While in some countries 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, allows individuals to refuse receipt of certain 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. 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.
- **Member States should ensure that clear guidance is developed on accessible and plain language communication of significant findings, so that individuals can meaningfully understand the information provided and seek appropriate follow up care.** This includes establishing standards for readability, layered disclosures, and formats accessible to people with disabilities, as well as ensuring that digital patient

portals and alternative non digital channels are available for those with limited digital access or low digital literacy. Notification procedures for urgent or time sensitive significant findings should be explicitly defined to avoid delays in care.

- Particular attention is needed for populations with specific communication needs, such as individuals without reliable digital access, people with disabilities, and paediatric populations, who may require tailored, age appropriate, and population specific materials.

Right not to be known and preference management

- **Member States may consider establishing national procedures and mechanisms to ensure that individuals can exercise their right to request not to be informed of significant findings arising from the secondary use of their health data.** Under the EHDS framework, individuals have the right to control the use of their electronic health data, including the right to request not to be informed of significant findings. The procedure and registration of such requests can be regulated at national level. Since anonymisation and pseudonymisation are primarily carried out by data holders, it is appropriate that natural persons' requests not to be informed of findings are recorded at the level of the data holder responsible for the dataset. These preferences may also be registered alongside informed-consent procedures in research contexts. Because significant findings always relate to a specific dataset and therefore to a specific data holder, registering preferences at the data-holder level avoids conflicts even when an individual expresses different preferences with different institutions. To support coherence across institutions without undermining subsidiarity, Member States may, where appropriate, establish interoperable mechanisms that allow data holders to verify whether a preference has already been expressed, while ensuring that responsibility for recording and acting on such requests remains with the data holder directly involved in the secondary-use context.
- **Member States should clarify how the right of individuals to request not to receive significant findings is to be exercised, communicated, and respected within their national frameworks.** National law may restrict the right not to know in situations where withholding information could endanger the individual or undermine the provision of safe and appropriate healthcare. Clear national rules are needed on how individuals will be informed of their right to opt out, how their preferences will be recorded and verified, and how these preferences interact with re identification processes.
- **Member States may also define how the "right not to be informed" interacts with the notification of significant findings, including whether a general opt out from secondary use implies a refusal to receive such findings, or whether these preferences must be registered and checked separately.** Clear national rules on how HDABs and data holders must verify individuals' preferences, and whether re-identification is permissible when a person has opted not to be informed, are essential. Clear boundaries are likewise needed regarding the role of HDABs in any re-identification process, ensuring that HDABs act strictly as procedural intermediaries. Establishing a standardised, interoperable approach for managing patient preferences, including

updates over time, and implementing common safeguards across Member States would strengthen both compliance and public trust.

Data protection, legal compliance, and ethical safeguards

- ❑ Full compliance with the GDPR must be ensured in managing significant findings.
- ❑ Health data holders, HDABs, and data users are responsible for safeguarding privacy while disclosing significant findings appropriately.
- ❑ Significant findings should be considered when obtaining informed consent in clinical studies, including the option to request to be informed or not.
- ❑ Member States must establish secure and trusted communication means for transmitting significant findings.
- ❑ Member States must the applicable legal bases under Union and national law that enable re-identification and, where appropriate, re-contact of natural persons when significant findings arise, including situations where the initial processing did not include provisions for individual notification.
- ❑ In many national frameworks, re-contact for preventing serious harm may rely on protection of vital interests or performance of tasks carried out in the public interest, subject to national determination.
- ❑ Robust quality control, oversight, review, and validation processes should be implemented to ensure accuracy and clinical relevance.
- ❑ Significant findings should be categorised based on urgency.
- ❑ Data security must be guaranteed and strict ethical guidelines for data sharing followed at national level.
- ❑ Procedures for assessment of findings should involve all partners in the chain.

Cross-border and multi-country contexts

- ❑ **Member States should clarify how responsibilities are allocated where significant findings arise from the linkage or combined analysis** of datasets originating from multiple health data holders across one or more Member States. including how the “relevant health data holder” responsible for notification is designated in accordance with national law and governance arrangements.
- ❑ **Member States should clarify case by case how national approaches to defining and operationalising significant findings are applied in cross-border or multi-country research contexts,** including how differences between national implementation frameworks are managed in practice without establishing hierarchies between national approaches.
- ❑ **Member States should issue national guidance for HDABs and data users tailored to cross border secondary use,** including 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 governing the HealthData@EU infrastructure and transnational data exchange.
- ❑ HDABs should cooperate i**n cross-border secondary use scenarios** to ensure that notifications are transmitted to the appropriate health data holder capable of **managing communication with the natural person** in accordance with national law. Such

cooperation may include coordination regarding routing of notifications, identification of the competent health data holder, and ensuring that communication processes remain secure and traceable. Cross-border situations may require attention to differences in national communication practices, including language and documentation standards.

- ❑ **Member States should also address the risk of conflicting or overlapping national legislation concerning the obligation to inform individuals of significant findings.** Divergent national provisions may create uncertainty or contradictory duties, particularly in cross border secondary use scenarios. To ensure legal certainty and avoid contradictory obligations, Member States should align their national provisions with the EHDS framework, clarify the conditions under which the right not to be informed may be exercised or restricted, and establish interoperable procedures that allow HDABs to operate consistently across jurisdictions.

Contextual limitations and scope of the EHDS

- ❑ **Member States should establish clear national rules and guidance to distinguish EHDS-related obligations from those arising in clinical research, ensuring that responsibilities are not conflated across the two frameworks.** To avoid confusion between the EHDS framework and obligations arising within clinical research, it is important to emphasise that the EHDS Regulation applies exclusively to the secondary use of electronic health data, including data originating from clinical studies or trials, once such data are reused through a Health Data Access Body. Significant findings that arise during the conduct of a clinical study itself fall entirely outside the scope of the EHDS and must be managed under the applicable clinical research legislation, ethical review requirements, and study-specific informed-consent procedures. References to informed consent in this guideline should therefore not be interpreted as extending EHDS rights or obligations into the clinical research context. The EHDS right to be informed, or not to be informed, about significant findings applies only when data are accessed via an HDAB under a data permit.
- ❑ **Member States should define clear national rules that distinguish the responsibilities of data holders in routine healthcare and public-health settings from those in clinical research contexts.** The responsibilities described apply primarily to data holders operating within routine healthcare or public-health mandates. In certain contexts, such as clinical trials, data holders may not be able to integrate significant findings into trial databases or assume responsibility for modifying patient care. Clinical trial datasets are typically immutable, and the data holder may not be the treating healthcare professional. Member States should therefore distinguish between contexts where data holders can act on significant findings and those where their role is necessarily limited.

Equity, capacity, and public trust

- ❑ **Member States should ensure that the notification mechanism for significant findings is implemented in a way that protects individuals' privacy while also promoting fairness and consistency across different types of data users**. This

includes clarifying the technical and organisational measures required to safeguard privacy and defining how individuals can register preferences regarding notification.

- **Member States may consider addressing structural differences in the capacity of organisations to analyse data and meet notification obligations**. Unequal access to analytical tools, expertise, and infrastructure may lead to inconsistent compliance and uneven protection of individuals' rights. To mitigate this, Member States may consider providing clearer technical guidance, capacity building support, and proportionate requirements.
- **Member States should consider implementing transparent, publicly accessible audits and regularly published implementation reviews** to demonstrate consistent application, support mutual learning, and reinforce citizens' trust in equitable and accountable EHDS implementation.
- **Inconsistent notification practices across Member States risk undermining public trust in the EHDS framework.** Member States should consider implementing transparent, publicly accessible audits of how the notification obligations are applied in practice and regularly publish implementation reviews.
- **Member States should establish clear national criteria and guidance to ensure that data users report only those findings that meet the threshold of potential clinical relevance under the EHDS Regulation.** To prevent unnecessary burden on healthcare systems and avoid undue concern for individuals, data users should report findings only where they meet criteria of potential clinical relevance as interpreted under the EHDS Regulation and applicable national frameworks. Data users should report findings only where they meet criteria of potential clinical relevance under the EHDS Regulation and applicable national frameworks, to avoid unnecessary burden and undue concern.
- **Member States should provide clear technical guidance, capacity-building support, and proportionate national requirements to ensure consistent implementation across institutions and equitable protection of individuals' rights.** Providing technical guidance, capacity-building support, and proportionate requirements can prevent inequitable implementation and uneven protection of individuals' rights.

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)	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

Responsibility area	EU-mandated obligations	National discretion	Legal basis (EHDS Article/Recital)
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
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

Annex number	Annex title
1	Methodology
2	Public consultation summary
3	User journey
4	Glossary
5	An overview of deliverables in TEHDAS2

Annex 1 – Methodology

This document 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 the 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 document underwent 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 was 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.

Ensuring interoperability across national dataset catalogues requires that all Member States adopt a minimum set of technical and organisational capabilities. Achieving this level of harmonisation is essential for enabling seamless cross-border exchange of electronic health data for secondary use and for supporting a coherent European Health Data Space. The development of such capabilities cannot occur in isolation; it depends on structured collaboration and systematic feedback from stakeholders across all EU countries. For this

reason, the preparation of this guideline and any further guiding developments relies on iterative consultation with national experts, HDAB representatives, data holders, and other contributors from each Member State. Their input is critical to identifying practical constraints, aligning expectations, and ensuring that the recommended procedures can be implemented consistently across diverse national contexts.

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 47 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), Republic of Cyprus (CY), Czech Republic (CZ), Estonia (EE), Greece (EL), Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), 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 organisations.

I. Key gaps identified from public consultation:

1) Governance structure and responsibilities

Many respondents indicated that roles and responsibilities are not sufficiently clear, particularly regarding who is responsible for decision-making, notification, and oversight. Some comments referred to potential overlaps or gaps in accountability. In addition, several stakeholders noted that the decision-making processes could be described in a more transparent and structured manner.

2) Cross-border cooperation and coordination

A consistent concern was that guidance on cross-border situations is limited, particularly in relation to multi-country scenarios and shared datasets. Comments pointed to the need for clearer coordination mechanisms at EU level. Stakeholders indicated that more detailed procedures would support cooperation between data subjects, data holders, and HDABs located in different Member States, including through the HealthData@EU infrastructure.

3) Operational framework: timing, monitoring, and enforcement

Several respondents indicated that timelines and sequencing of actions are not sufficiently specified, creating uncertainty about when certain steps should take place and how processes should be coordinated. In addition, stakeholders noted that monitoring and oversight mechanisms are not clearly described, including how compliance would be assessed. Several comments therefore called for more structured timelines and clearer supervision arrangements to support effective implementation.

4) Methodology, accessibility, and continuous review

Many respondents indicated that the document uses overly legalistic language, making it difficult for non-legal stakeholders to interpret. Several comments noted the absence of clear evaluation and review mechanisms, leaving uncertainty about how effectiveness will be assessed. Stakeholders suggested including plain-language explanations and structured review cycles. Overall, respondents highlighted the need for clearer, more accessible language and defined evaluation processes.

II. 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) Governance structure and responsibilities

In response to comments requesting clearer allocation of roles and decision-making responsibilities, the guideline was revised to:

- More explicitly describe the governance framework and obligations set out in the EHDS Regulation.
- Clarify the high-level process leading up to the involvement of data holders.
- State clearly that detailed operational responsibilities and workflows depend on national implementation arrangements, which vary significantly across Member States.

Rather than prescribing uniform internal structures, the guideline now recommends that Member States ensure transparency by publicly describing their national governance setup, including roles, responsibilities, and decision-making processes. Non-binding examples are referenced to illustrate possible approaches, while respecting national competence and administrative diversity.

2) Cross-border cooperation and coordination

Stakeholders called for more detailed procedures for cross-border cases. In response, the guideline acknowledges that complex multi-country scenarios – particularly those involving shared datasets – will need to be addressed on a case-by-case basis once concrete situations arise.
The revised text clarifies that:

- The primary point of contact remains the Health Data Access Body (HDAB) that granted the data access permit.
- Cross-border questions may require coordination between relevant authorities depending on the specific circumstances.
- Practical arrangements will evolve with implementation of the EHDS framework, including through the HealthData@EU infrastructure.

The guideline therefore adopts a step-by-step and experience-based approach, recognising that it is not feasible to anticipate all possible cross-border configurations at this stage.

3) Operational framework: timing, monitoring and enforcement

In light of requests for clearer timelines and monitoring mechanisms, the guideline now explicitly clarifies that:

- The binding deadline for implementation is March 2029, when the relevant provisions of Member States and the infrastructure become applicable and the significant findings mechanism must be operational.
- No intermediate milestones are established at EU level.
- The detailed implementation method, internal sequencing, and supervision arrangements remain the responsibility of Member States.

The revised text emphasises the regulatory deadline while clarifying the distribution of responsibilities between EU-level obligations and national implementation.

4) Methodology, accessibility and continuous review

Regarding comments on legalistic language and evaluation mechanisms, the guideline clarifies its scope and target audience. It underlines that:

- The document is primarily addressed to Member States, HDABs, and data holders, who operate within a legal-regulatory context.
- The level of technical and legal terminology reflects the need for alignment with the EHDS Regulation.
- The guideline represents a first implementation layer under the broader EHDS framework and provides a general and harmonised structure.

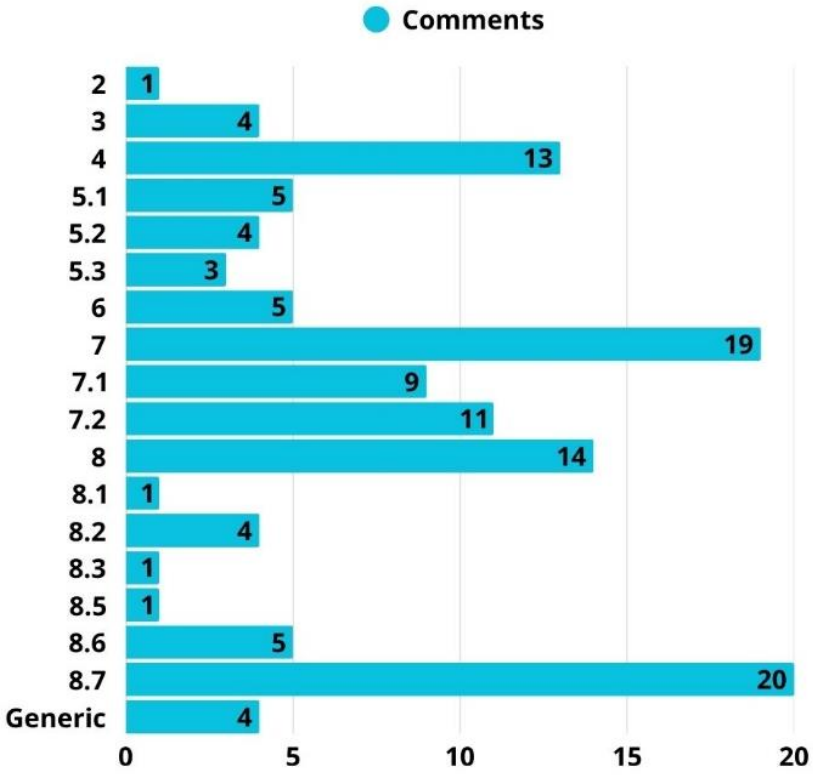
While the technical level is maintained, the document clarifies its role as a foundational instrument, acknowledging that further national-level communication and practical interpretation may be needed for different stakeholder groups.

III. Statistics of integrated comments:

During the processing of the consultation input, the 320 comments received were first allocated to the relevant chapters of the document. Where a single comment addressed multiple chapters, it was split accordingly and assigned new comment IDs. As a result, the total number of comment units increased to 356.

Subsequently, all comments were subjected to a triage process in which they were categorised as out of scope, not applicable, to be implemented, or requiring further discussion. This assessment resulted in 232 comments classified as not applicable or out of scope, representing 65.2% of the total, and 124 comments classified as to be implemented, representing 34.8%.

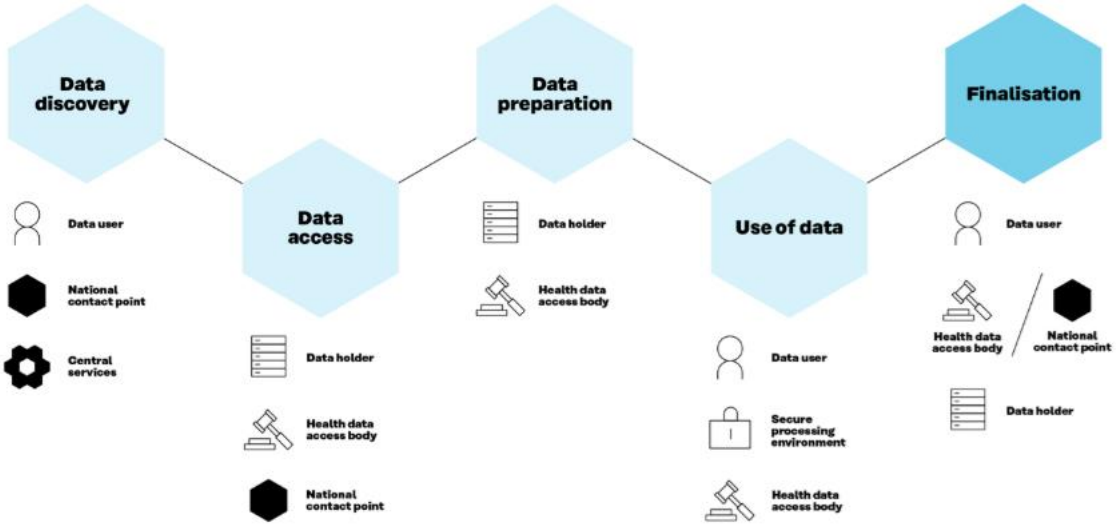
The comments marked for implementation were incorporated into the revised draft. The distribution of comments by chapter is presented below.



Annex 3 – User journey

When a data user[2] 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 3: 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)[3]. The user must complete the information required in the form, upload necessary documents, and provide justifications as needed.

[2] Data user = a person using electronic health data for a secondary use purpose
[3] 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

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)[4] 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[5]. 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.

[4] 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)).
[5] Secure processing environment = an environment with strong technical and security safeguards in which the data user can process personal level electronic health data

Annex 4 – 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	A phase in the EHDS user journey during which 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 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.

TERM	DEFINITION
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 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) point (z))
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(2) point (aa))
Dataset	A structured collection of electronic health data. (EHDS Article 2(2) point (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)
Dataset record	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 selected records, variables or elements from a larger dataset while maintaining its key characteristics and relationships. .
Dataset description	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(2) point (c)).

TERM	DEFINITION
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(2) point (y))
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. (EHDS Regulation, Article 2(2) point (u))

TERM	DEFINITION
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(2) point (f))
Legal basis of data processing	The criteria defined in EHDS Regulation Article 68 for health data access bodies to assess whether an applicant can be given a permit to process electronic health data. The conditions under which personal data processing is considered lawful are laid down in 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)
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))

TERM	DEFINITION
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	Identifier that is added to data during the **pseudonymising transformation** and set in such a way that it can be attributed to data subjects only using **additional information**. (EDPB Guideline 01/2025 Glossary, version adopted for public consultation)
Public value	For analytical or policy discussion purposes, public value could be understood as 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(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)
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.

TERM	DEFINITION
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.

Annex 5 – An overview of deliverables in TEHDAS2

D4.1 Guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation

This guideline creates guidelines for fees and penalties for non-compliance to facilitate organisational implementation of the EHDS for Health Data Access Bodies (HDABs) and data holders in the EU. The guideline aims to support the convergence of fees and penalties practices across the EU while also reflecting diverse perspectives of involved stakeholders.

D4.2 Guideline for Health Data Access Bodies on collaboration with other parties

This document outlines collaboration models for the EHDS secondary use framework, addressing ethical governance, intellectual property protection, and the role of research infrastructures across EU Member States.

D4.3 Guideline for Health Data Access Bodies on international and third country access and transfer of electronic health data

This guideline serves as a practical legal and operational guidance to Health Data Access Bodies and other stakeholders on how to interpret and implement the EHDS rules governing international access to and transfer of electronic health data by applicants established in third countries or international organisations.

D5.1 Guideline for data holders on data description

This guidance helps health data holders comply with the EHDS Regulation by clarifying which electronic health datasets must be made available for secondary use and providing practical instructions for describing them using the HealthDCAT-AP common metadata model.

D5.2 Guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data

This guideline reflects and do recommendations on allowed purposes and prohibited use according to EHDS.

D5.3 Technical specification for Health Data Access Bodies on the national metadata catalogue

The technical specification describes 4 main capabilities of the national Metadata catalogue Metadata input, Metadata management, Metadata output and Metadata access.

D5.4 Guideline for data enrichment for Health Data Access Bodies, data holder and data user

This guideline explains data enrichment approaches and best practices for consideration within the European Health Data Space framework.

D5.5 Guideline for data user navigating the catalogue

A user guide for discovering and evaluating health datasets available through the HealthData@EU Central Platform.

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

This guideline provides guidance for data holders on how to prepare, structure, and make electronic health data (personal and non-personal) available for secondary use in line with EHDS requirements.

D6.2 Guideline for data users on good application and access practice

This document defines best practices for data users on how to apply for and obtain access to health data, including completing applications and complying with legal, ethical, and procedural requirements.

D6.3 Guideline for Health Data Access Bodies on the procedures and formats for data access

This guideline specifies procedures and standardised formats for Health Data Access Bodies to manage health data access applications, health data requests, data permits, health data request approvals and data handling processes under the EHDS.

D6.4 Data Access Application Management System (DAAMS) - Technical specification for health data access bodies

This guidance defines technical specifications for the Data Access Application Management System (DAAMS) to support interoperable, efficient, and harmonised processing of data access requests across Europe.

D7.1 Guideline for data users on how to use data in a secure processing environment

This guideline aims at helping data users to inform on how to use data in a secure processing environment (SPE) under the EHDS.

D7.2 Guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data

This document helps HDABs manage data protection considerations and requirements under the EHDS, including hands-on examples.

D7.3 Technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure

These technical specifications provide a policy-level overview and technical guidance to help Member States and Health Data Access Bodies connect to the secure, cross-border HealthData@EU infrastructure for the secondary use of health data.

D7.4 Technical specification for Health Data Access Bodies on the implementation of secure processing environments

These specifications define the core functional and security requirements for SPEs to enable the safe secondary use of health data across the EU. It provides a harmonised framework for Member States to align their high-level design choices with the legal obligations of the EHDS.

D7.5 Guideline for Health Data Access Bodies on linkage of health datasets

This document helps HDABs on various aspects regarding data linkage under the EHDS.

D8.1 Guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data

This guideline helps HDABs establish practical and legally compliant procedures for implementing individuals' opt-out rights within the EHDS secondary use framework.

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

This guidance helps HDABs manage the assessment and communication of clinically significant findings arising from.

D8.3 Guideline for Health Data Access Bodies on informing natural persons about the use of health data - "Citizen Information Point"

This guideline instructs HDABs on what, how and when to inform natural persons and the general public about the secondary use of health data.

D8.4 Guideline for data users on handling research outcomes

This document provides practical and legal guidance for secondary data users on how to identify, assess, and appropriately manage research outcomes within the EHDS framework.