



M8.4 Draft guideline for data users on handling research outcomes

TEHDAS2 – Second Joint Action Towards the European Health Data Space

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0 Document info

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1 Executive summary

This document provides non-binding guidance on the duties and responsibilities of secondary data users in relation to outcomes derived from the secondary use of electronic health data under Regulation (EU) 2025/327 (EHDS). It focuses specifically on obligations arising after outcomes have been generated, including their reporting, dissemination, reuse, and related safeguards. In particular, it addresses:

- The accountability of secondary data users as controllers for processing carried out within the secure processing environment (Article 74)
- Transparency, reporting, and dissemination requirements for research, policy, regulatory, and commercially relevant outcomes (Articles 58 and 59)
- Conditions governing the export and reuse of outcomes, including anonymisation requirements (Article 73(2))
- The distinction between use of EHDS-accessed data and the subsequent use of knowledge or results derived from that data
- Responsibilities in collaborative contexts, ensuring that outcome handling remains within the scope and conditions of the authorised data permit

The document also integrates ethical considerations relevant to outcome handling, including proportionality, public interest, and responsible communication of results, without duplicating national ethics frameworks or GDPR requirements.

By using this guidance, secondary data users will be better equipped to comply with their legal obligations under the EHDS when generating, disseminating, reporting, and reusing outcomes. The guidance contributes to legal certainty, consistent interpretation of outcome-related duties, and responsible innovation within the European Health Data Space.

This document forms part of the broader TEHDAS2 work supporting Member State readiness and harmonised implementation of the EHDS, with a specific focus on ensuring that the benefits of secondary use are realised in a transparent, accountable, and legally compliant manner.

For the purpose of this document, “outcomes” refers to results, outputs, or knowledge derived from the secondary use of electronic health data.



2 Abbreviations

Term	Abbreviation
Data Protection Authorities	DPA
European Health Data Space	EHDS
European Union	EU
General Data Protection Regulation	GDPR
Health Data Access Body	HDAB
Intellectual Property	IP
Intellectual Property Rights	IPR
Lay Summaries	LS
Member State	MS
Milestone	M
Small and Medium-sized Enterprise	SME
Secure Processing Environment	SPE
Towards the European Health Data Space	TEHDAS
Work Package	WP



3 Introduction

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 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.

Within this broader framework, work package (WP) 8 focuses on obligations towards natural persons and the responsible handling of outcomes generated through secondary use. While Task T8.1 addresses opt-out rights and Task T8.2 provides guidance on clinically significant findings, Task T8.3 (Milestone 8.4) complements these by clarifying the duties and responsibilities of secondary data users once outcomes have been generated.



This guideline supports secondary data users in understanding and complying with their obligations under the EHDS Regulation in relation to:

- Reporting and transparency of research and innovation outcomes
- Dissemination of research, policy, and commercially relevant results
- Management of intellectual property and commercially relevant knowledge
- Collaboration and downstream use of outcomes
- Accountability and potential consequences of non-compliance

Unlike other deliverables addressing access procedures or citizen rights at the data-access stage, this document focuses specifically on obligations triggered by the generation, handling, dissemination, and reuse of outcomes derived from authorised secondary use of electronic health data.

By providing structured, legally aligned guidance to secondary data users, this document contributes to consistent and responsible implementation of the EHDS across Member States. It promotes transparency, accountability, and public trust while supporting innovation and societal benefit derived from the secondary use of electronic health data.

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.

Legally binding and enforceable requirements under the European Health Data Space are laid down in the EHDS Regulation and, where applicable, in Implementing Acts adopted by the European Commission, within the limits of the empowerments provided by the Regulation. The scope of this guideline is strictly limited to outcome-related obligations.



4 Scope and aim of the guideline

This guideline is strictly limited to the handling of research outcomes derived from authorised secondary use of electronic health data under the EHDS Regulation. It does not cover general operational, procedural, or access-related aspects of secondary use under the EHDS.

The scope is limited to the EHDS Regulation establishing the EHDS. References to the General Data Protection Regulation (GDPR) are made only where necessary to clarify how outcome-related responsibilities of secondary data users interact with existing data protection obligations. This guideline does not attempt to interpret broader legal frameworks beyond what is required to clarify duties triggered by the generation, dissemination, reporting, and downstream use of outcomes.

This document does not restate general conditions for accessing electronic health data, obtaining a data permit, or meeting procedural access requirements. Nor does it provide technical specifications for secure processing environments or anonymisation techniques. Such matters are addressed in the EHDS Regulation itself and in other TEHDAS2 deliverables. All subsequent sections should be interpreted in light of this scope limitation.

Instead, this guideline focuses on obligations that arise after results, outputs, or innovations have been generated, including:

- Reporting and transparency requirements
- Dissemination and publication of outcomes
- Export and reuse of outcomes
- Management of intellectual property and commercially relevant knowledge
- Accountability and consequences of non-compliance

4.1 Audience

The primary audience of this guideline is secondary data users, meaning entities or individuals who lawfully access electronic health data through EHDS-authorised channels for secondary purposes.

Health data users within the EHDS ecosystem represent a diverse community of organisations and actors who generate scientific, societal and economic value through the analysis of electronic health data.

These users may include:

Academic and clinical researchers, such as universities, research institutes and university hospitals conducting scientific or clinical studies;

Multinational research consortia, including cross-border collaborative projects funded under programmes such as Horizon Europe;



Public health authorities, using data for population health monitoring, epidemiological analyses and evidence-based policymaking;

Innovation-oriented small and medium-sized enterprises (SMEs) developing data-driven solutions, including artificial intelligence-based clinical decision support systems and digital health applications;

Research infrastructures and data support organisations, such as EUDAT, ELIXIR and other entities providing services for data access, management and analysis.

Recognising this diversity is important when designing governance mechanisms and guidance for secondary use of electronic health data under the EHDS framework.

The guideline may also be relevant to:

- Health Data Access Bodies (HDABs), insofar as they supervise compliance with outcome-related obligations
- Health data holders, in understanding the allocation of responsibilities once outcomes are generated
- Policymakers and oversight bodies seeking clarity on the governance of secondary-use results

This document is not intended to guide natural persons on the exercise of their rights, nor to provide operational instructions to HDABs on data access procedures. It does not define technical standards or procedural rules for obtaining a data permit. Its sole purpose is to clarify how secondary data users should handle outcomes in compliance with the EHDS framework.

4.2 Legal framework

The EHDS Regulation establishes a harmonised framework for secondary use of electronic health data, including governance mechanisms, secure processing environments, and structured data permits. Within this framework, different legal regimes apply depending on the stage of data use and the nature of the data involved.

4.2.1 Processing within the Secure Processing Environment (SPE)

Processing of electronic health data for secondary use takes place within a secure processing environment established under the EHDS framework. Where such processing involves personal electronic health data, the General Data Protection Regulation (GDPR) remains applicable.

The EHDS Regulation does not replace the GDPR but complements it in the context of secondary use of electronic health data. Where personal electronic health data are processed within the secure processing environment, the GDPR remains applicable, including requirements related to lawful basis under Articles 6 and 9 GDPR. The EHDS establishes the governance framework through which such processing is authorised and supervised.



In this context, the GDPR provides the legal basis and safeguards for the processing of personal data, including requirements related to lawful basis, data protection principles, and oversight by competent supervisory authorities. The EHDS complements this framework by establishing the governance mechanisms through which access to data is granted and monitored, including the role of HDABs, data permits, and secure processing environments.

4.2.2 Outputs and outcomes of secondary use

Once results are generated within the secure processing environment, their export is subject to strict output control requirements under the EHDS Regulation. In accordance with Article 73(2), only outputs that do not enable the identification of data subjects may be exported.

As a result, outputs of secondary use are, in principle, anonymised and do not constitute personal data. Consequently, their handling falls outside the scope of the GDPR and is governed primarily by the transparency, reporting, and accountability obligations established under the EHDS Regulation, in particular Articles 61, together with the transparency framework established in Articles 58 and 59.

This distinction is central to understanding the legal framework applicable to research outcomes under the EHDS: while the generation of results may involve processing of personal data within a controlled environment, the subsequent handling, dissemination, and reuse of outcomes is subject to EHDS-specific obligations relating to transparency and responsible use of anonymised outputs.

Relationship between lawful basis and outcome-related obligations

Outcome-related obligations under the EHDS, such as reporting, notification of clinically significant findings, transparency of results, and export restrictions, operate independently from the choice of lawful basis under the GDPR. Once secondary use is authorised through an EHDS data permit, secondary data users must comply with the specific outcome-related safeguards and transparency requirements laid down in the Regulation.

In conclusion:

- The GDPR provides the overarching legal framework for data protection in the EU
- The EHDS Regulation builds upon and specifies this framework in the health data context
- This guideline focuses exclusively on specific requirements that may apply once outcomes are generated



Table 1: Summary of the relationship between the GDPR and the EHDS Regulation in relation to outcome handling.

Aspect	GDPR	EHDS Regulation (EU) 2025/327
Legal role	Core legal framework for personal data protection in the EU	Sector-specific complement focused on electronic health data
Scope of regulation	Governs processing of personal data, including health data (Articles 6 and 9 GDPR)	Establishes structured governance for access, secondary use, and outcome-related obligations
Lawful basis for processing	Processing must rely on a lawful basis under Article 6 GDPR; health data require an additional condition under Article 9 GDPR	Secondary use is operationalised through data permits and HDAB governance, but lawful basis remains grounded in the GDPR
Role of controllers	Controllers are responsible for compliance with data protection principles and accountability (Article 5(2) GDPR)	Secondary data users are considered controllers for processing within the secure processing environment (Article 74 EHDS), including accountability for outcomes
Secondary use framework	Not specifically structured for health data; subject to general GDPR rules	Structured system for secondary use governed by HDABs, secure processing environments, and data permits (Chapter IV EHDS)
Transparency of results	No specific obligation to publish or report research outcomes	Results of secondary use must be made available under Article 58(1)(g), enabling HDAB reporting under Article 59
Clinically significant findings	No sector-specific notification pathway defined	Specific obligation to notify HDABs of clinically significant findings (Article 61(5)), with further handling under Article 58(3)
Export of processed data	GDPR applies to transfers of personal data	Export from secure processing environments limited to anonymised or non-personal data (Article 73(2))
Supervisory authorities	Data Protection Authorities monitor GDPR compliance	HDABs supervise secondary use compliance; DPAs remain competent for GDPR enforcement (Article 65 EHDS)
Relationship between frameworks	General, cross-sector data protection regime	Health-sector-specific governance that operationalises GDPR principles for electronic health data



Operational overview of outcome-triggered obligations

To support practical implementation, the following provides an overview of the key obligations that arise once outcomes are generated through authorised secondary use under the EHDS framework.

Under the EHDS Regulation, secondary data users are required to ensure that the results or outputs of their authorised secondary use activities are made available in accordance with the conditions of the data permit and the transparency framework established in Article 61(4), together with Articles 58 and 59.

These obligations apply irrespective of the type of outcome generated. Whether the outcome takes the form of a scientific publication, a policy-relevant analysis, or contributes to the development of a product or service, the same core requirements apply. Secondary data users must ensure that outcomes are reported to the HDAB and made available in a manner consistent with the EHDS transparency framework.

In addition, any outputs exported from the secure processing environment must comply with the output control requirements defined under Article 73(2), ensuring that they do not enable the identification of data subjects.

In collaborative contexts, each secondary data user remains responsible for fulfilling the obligations attached to their data permit, including reporting and transparency requirements. Internal coordination mechanisms may support consistent reporting but do not alter individual responsibilities.

Failure to comply with outcome-related obligations may lead to corrective measures or sanctions in accordance with the enforcement provisions of the EHDS Regulation and applicable national implementation.



5 Ethical and legal compliance

This section outlines the key legal and compliance considerations relevant to the handling, reporting, and dissemination of outcomes generated through authorised secondary use of electronic health data under the EHDS framework. Secondary data users are subject to specific obligations under the EHDS Regulation once outcomes are generated. In particular, they are required to ensure that results or outputs are reported and made available in accordance with Article 61(4), within the transparency framework established in Articles 58 and 59, and in line with the conditions of the data permit.

These obligations apply to the handling and dissemination of outcomes and are distinct from the legal requirements governing the processing of personal data within the secure processing environment. Once results are exported in compliance with the output control requirements defined under Article 73(2), they qualify as *non-personal electronic health data, including electronic health data in an anonymised statistical format*, and therefore fall outside the scope of the GDPR.

Secondary data users should ensure that outcomes are reported in a clear, accurate, and proportionate manner, enabling the HDAB to fulfil its transparency obligations. At the same time, reporting should be carried out in a manner that respects applicable legal protections, including intellectual property rights and confidentiality requirements. Failure to comply with the reporting and transparency obligations established under the EHDS framework may lead to corrective measures or sanctions in accordance with the applicable enforcement provisions and national implementation.

5.1 Accountability of secondary data users in the generation and dissemination of research outcomes

Under the EHDS secondary use framework, responsibility for the reporting and dissemination of outcomes generated through authorised secondary use rests with the secondary data user to whom the data permit has been granted.

Secondary data users are required to inform the health data access body from which the data permit was obtained about the results or outputs of their authorised use, in accordance with Article 61(4), and to assist the HDAB in making that information publicly available, in line with the conditions of the data permit.

In fulfilling these obligations, secondary data users must ensure that any results or outputs made available do not enable the identification of data subjects, in accordance with the output control requirements defined under Article 73(2) of the EHDS Regulation. Secondary data users are responsible for ensuring that outcomes generated through authorised secondary use are handled and reported in accordance with the conditions of the data permit and the applicable EHDS transparency framework.



In particular, secondary data users are required to:

- ensure that results or outputs reported to the Health Data Access Body (HDAB) comply with the reporting obligations established under Article 61(4), within the framework of Articles 58 and 59;
- ensure that any outputs exported from the secure processing environment comply with the output control requirements defined under Article 73(2), and do not enable the identification of data subjects;
- ensure that dissemination of outcomes remains within the scope of the authorised secondary use and complies with the conditions of the data permit.

Responsibility for compliance with these obligations rests with the secondary data user to whom the data permit has been granted. HDABs exercise supervisory and oversight functions under the EHDS Regulation but do not assume responsibility for the scientific interpretation or subsequent use of outcomes.

Accountability in this context relates to compliance with EHDS reporting and transparency obligations and does not extend to the actions of third parties once outputs have been lawfully disclosed.

5.2 Legal obligations relevant to the legitimacy and reporting of research outcomes

This section focuses on the legal obligations under the EHDS Regulation that directly affect the reporting and dissemination of research outcomes generated through authorised secondary use.

Processing of electronic health data for secondary use takes place within a secure processing environment. Export (download) of results from this environment is restricted. In accordance with Article 73(2), results may only be exported where they comply with the output control requirements of the secure processing environment and do not enable the identification of data subjects.

In cases where the secondary use takes the form of a data request resulting only in anonymised aggregated outputs pursuant to Article 69 EHDS, secondary data users must ensure that outputs comply with the EHDS output control requirements at the point of release, in accordance with Article 73(2), such that they do not enable the identification of data subjects.

Secondary data users must ensure that any research outputs intended for publication, dissemination or further use outside the secure processing environment comply with these export limitations and do not enable identification of data subjects.

Secondary data users are required to submit clear, accurate and complete information on the results or outputs of their authorised use to the Health Data Access Body within the timeframe specified in the data permit and no later than 18 months after the completion of the authorised processing, in accordance with Article 61(4) of the EHDS



Regulation. Such information must enable the HDAB to fulfil its transparency and reporting obligations pursuant to Article 59 of the EHDS Regulation.

The responsibility for accurate, complete and timely reporting of research outcomes rests with the secondary data user identified in the data permit, in accordance with the obligations established under the EHDS Regulation.

When relevant, secondary data users must also comply with any additional national legal or ethics-based obligations applicable to the reporting or dissemination of research outcomes.

Non-compliance with EHDS obligations may result in regulatory measures, including revocation of data permits or other sanctions provided under the EHDS framework.

5.3 Lawful bases for processing and accountability

The lawful basis for processing personal electronic health data applies to the generation of results within the secure processing environment and is governed by the applicable provisions of the GDPR, as clarified in Section 4.2.

Once research outcomes are generated, secondary data users must ensure that the use and dissemination of outcomes remain consistent with the purposes defined in the data access request and authorised in the data permit, in accordance with applicable GDPR requirements during the processing phase (Art. 6 and 9 GDPR).

The obligations relevant to outcomes are therefore those established under the EHDS Regulation, in particular the reporting and transparency requirements set out in Article 61(4), together with Articles 58 and 59. Secondary data users must verify, prior to dissemination of results outside the secure processing environment, whether applicable national law or conditions attached to the data permit impose additional restrictions on publication, especially in cases involving rare diseases, small populations or genetic data.

5.4 Ethical standards and research ethics oversight

Ethical considerations should inform decisions on validation, communication and dissemination of outcomes, particularly where findings may have clinical relevance or societal impact. Secondary data users should ensure that such considerations are reflected in research protocols and dissemination strategies, in line with applicable national ethics requirements. To operationalise these principles in the context of EHDS-compliant secondary use, secondary data users should ensure that ethical considerations are explicitly reflected in their research protocols, data access requests and dissemination plans. This may include documenting the anticipated societal impact of the research, assessing proportionality and potential risks, and demonstrating how the planned use of data aligns with recognised ethical standards and national research ethics requirements.



Where required under applicable national law, secondary data users must obtain approval from competent research ethics bodies before commencing processing. Even where formal ethics approval is not required, integrating recognised ethical principles into project design and reporting strengthens accountability and supports responsible handling of research outcomes.

5.5 Enforcement and overall compliance responsibility

Failure to comply with obligations relating to the handling of research outcomes may lead to enforcement measures by HDABs, including audits, suspension or revocation of data permits, and, where provided under national law, restrictions on future access to EHDS data. Administrative fines and other corrective measures may be imposed in accordance with the enforcement provisions of the EHDS Regulation, including Articles 63, 64 and 99, as applicable under national implementation law. HDABs retain supervisory powers under Article 57 of the EHDS Regulation, including the ability to verify compliance with the conditions attached to the data permit and with the obligations related to the handling, reporting and dissemination of outcomes generated through secondary use.

Secondary data users may establish internal governance, documentation, and reporting mechanisms to support compliance with the obligations arising under the EHDS framework. Such arrangements can facilitate the consistent handling and reporting of outcomes but do not constitute a requirement under the EHDS Regulation.

In summary, once research outcomes are generated within the EHDS secondary use framework, secondary data users are required to ensure that outcomes are reported and handled in accordance with the conditions of the data permit and the applicable transparency obligations under the EHDS Regulation. This includes ensuring that outputs do not enable the identification of data subjects, comply with output control requirements, and are reported to the HDAB in accordance with Article 61(4).

6 Managing Intellectual Property and Commercialisation

Secondary use of electronic health data may generate innovations and commercially relevant outcomes. This section clarifies how intellectual property generated from such outcomes may be managed within the EHDS framework.

The EHDS Regulation does not regulate the ownership, management, or commercialisation of intellectual property resulting from secondary use. These matters remain governed by applicable Union and national law, as well as by contractual arrangements between the parties involved.

Where relevant, specific conditions related to the protection of intellectual property rights or other protected interests may be included in the data permit or in agreements between data holders and secondary data users. Secondary data users must comply with such conditions where applicable.



6.1 Distinction between use of data and use of outcomes

A clear distinction must be made between:

- 1 Use of electronic health data under an EHDS data permit, which is strictly limited to the purpose, scope, and conditions authorised by the HDAB and carried out within a secure processing environment; and
- 2 Use of knowledge, insights, or results derived from that authorised use, including further research, innovation, or development activities informed by the outcomes of the research.

The EHDS Regulation governs access to and processing of electronic health data but does not regulate the subsequent use of knowledge or insights derived from authorised secondary use, provided that no further processing of the underlying electronic health data takes place outside the conditions of the data permit.

However, secondary data users remain subject to the transparency and reporting obligations established under the EHDS framework, in particular Article 61(4), and must ensure that any dissemination of outcomes complies with the conditions of the data permit and the applicable output control requirements.

6.2 Intellectual Property generated from secondary use

Secondary data users may seek protection for intellectual property generated from the outcomes of authorised secondary use, such as patents, or copyrights, in accordance with applicable Union and national law.

Access to electronic health data under the EHDS does not confer ownership rights over the underlying data to secondary data users. Responsibility for the original data remains with the health data holder, and the data may only be used in accordance with the conditions defined in the EHDS Regulation and in the specific data permit issued by the HDAB. In accordance with Article 52 of the EHDS Regulation, health data holders must inform the relevant Health Data Access Body when electronic health data made available for secondary use contain elements protected by intellectual property rights, trade secrets or regulatory data protection rights. Health data holders are expected to identify the relevant parts of the dataset concerned and justify the need for protection when providing the dataset description or when requested by the HDAB.

The EHDS Regulation explicitly recognises that electronic health data made available for secondary use may contain elements protected by intellectual property rights, trade secrets, or regulatory data protection rights, including those laid down in Directive



2001/83/EC¹ and Regulation (EC) No 726/2004². Article 52 clarifies that granting access to electronic health data for secondary use does not affect existing intellectual property rights, trade secret protection, or regulatory data protection rights. The framework therefore aims to enable lawful access while ensuring that protected rights are not infringed. Where datasets contain elements protected by such rights, health data holders are expected to identify and justify the need for protection, while HDABs may impose appropriate legal, organisational or technical safeguards to ensure that these rights are not undermined by the secondary use of the data.

In accordance with Article 52(4) of the EHDS Regulation, additional contractual arrangements may be required to safeguard intellectual property rights or trade secrets when granting access to electronic health data. Such arrangements, between health data holders and secondary data users governing the access to and use of protected data, may include confidentiality obligations, restrictions on use, or other safeguards necessary to ensure that protected information is not unlawfully disclosed or exploited. The European Commission may develop non-binding model contractual terms to facilitate such arrangements

Where risks to intellectual property, trade secrets or regulatory data protection cannot be adequately mitigated, access to specific elements of a dataset may be restricted or refused in accordance with Article 52 of the EHDS Regulation. Decisions concerning access must be duly justified and remain subject to the procedural safeguards established under the EHDS framework.

Within this framework, secondary data users remain responsible for ensuring that any intellectual property protection or commercial exploitation of outcomes derived from authorised secondary use remains compatible with the scope and conditions of the data permit and does not compromise the safeguards established by the EHDS Regulation.

In particular, where outcomes are developed using datasets that include elements protected by intellectual property rights or other legal protections, the resulting outputs may be subject to limitations arising from those pre-existing rights. While secondary data users may obtain intellectual property protection over their own contributions (for example, an algorithm or analytical model developed using the data), the use or further dissemination of such outputs may remain subject to the conditions of the data permit or to restrictions linked to the protected components of the underlying dataset.

For example, a secondary data user may develop a predictive model based on a dataset containing protected elements. While the model itself may qualify for

¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency



intellectual property protection, its use or further dissemination may remain subject to the conditions under which the original data were accessed.

Alignment between EHDS transparency and research funding rules

Secondary use projects are frequently conducted within multinational research consortia funded under EU programmes such as Horizon Europe. These projects are typically governed by grant agreements that regulate intellectual property ownership, confidentiality obligations and publication timelines. Secondary data users should ensure that dissemination obligations arising under the EHDS Regulation, including the requirement to make results publicly available under Article 61(4), are coordinated with the intellectual property and publication provisions applicable under their research funding agreements.

6.2.1 Ownership of Results and Innovations

The EHDS Regulation does not define or determine ownership of results or innovations derived from the secondary use of electronic health data. Ownership of such outcomes is governed by applicable Union and national intellectual property law, as well as by contractual arrangements between the parties involved.

Depending on the nature of the outcome, different intellectual property regimes may apply. For example, copyright may apply to certain outputs, while patents or trade secrets may be relevant in other cases. In some situations, outcomes may qualify as derivative works, and their use or protection may be subject to limitations arising from pre-existing rights.

Access to electronic health data under the EHDS does not confer ownership rights over the underlying data. Secondary data users may only use such data within the scope and conditions defined in the data permit, and any rights in resulting outputs remain subject to applicable legal frameworks.

6.2.2 Conditions and Limitations

The management of intellectual property should remain compatible with the transparency and reporting obligations established under the EHDS Regulation. The EHDS Regulation does not regulate intellectual property ownership, licensing models, or the commercialisation of outcomes derived from the secondary use of electronic health data. These matters remain governed by applicable Union and national law, as well as contractual arrangements between the parties involved.

However, secondary data users remain subject to the transparency and reporting obligations established under the EHDS framework. In particular, results or outputs of authorised secondary use must be made available in accordance with Article 61(4), within the transparency framework established in Articles 58 and 59, and in line with the conditions of the data permit.



These obligations apply irrespective of whether the outcomes are intended for further research, policy use, or commercial development. At the same time, reporting of outcomes should be carried out in a manner that respects the protection of intellectual property rights, confidential business information, and other legally protected interests.

Compliance with EHDS transparency obligations does not require the disclosure of proprietary methodologies, algorithms, or other protected elements, provided that sufficient information is made available to fulfil the reporting requirements under the EHDS framework.

6.2.3 Collaboration and Joint Ownership

When multiple entities collaborate on research projects involving secondary use of electronic health data under the EHDS, it is advisable to clarify contractual arrangements between the parties at an early stage. Such arrangements may address matters including the allocation of intellectual property rights in project results and the treatment of pre-existing intellectual property brought into the collaboration.

While the EHDS Regulation does not regulate intellectual property ownership or impose specific requirements regarding contractual IP arrangements, clear agreements between collaborating entities may help prevent disputes and facilitate the effective implementation of the data permit and related obligations.

6.2.4 Transparency and Public Benefit

The EHDS Regulation requires secondary data users to make the results or outputs of authorised secondary use available in accordance with Article 61(4), within the transparency framework established in Articles 58 and 59. This obligation applies irrespective of whether outcomes contribute to scientific research, policy development, or commercially relevant activities.

The requirement to report and make outcomes available supports transparency and accountability regarding the use of electronic health data within the EHDS framework. At the same time, this obligation must be implemented in a manner that respects the protection of intellectual property rights, confidential business information, and other legally protected interests.

The EHDS Regulation does not regulate intellectual property ownership or licensing models resulting from secondary use. Secondary data users remain responsible for ensuring that any dissemination of outcomes is consistent with both the transparency obligations under the EHDS and the applicable legal frameworks governing intellectual property and confidentiality.



7 Dissemination and reporting of research outcomes

Dissemination and reporting obligations for outcomes generated through EHDS secondary use derive primarily from Article 61(4) and the transparency framework established in Articles 58 and 59. Under this framework, secondary data users are required to make the results or outputs of their authorised secondary use activities available in accordance with the conditions of the data permit. These obligations apply irrespective of the type of outcome generated.

Secure processing environments introduce specific operational constraints for researchers. Because data cannot be exported from such environments and only approved outputs may leave the system, researchers may face challenges in documenting intermediate analytical steps, retaining methodological artefacts or securing intellectual property protection prior to publication. Secondary data users should therefore plan their research workflow carefully, ensuring that potential intellectual property elements are identified early and that publication timelines remain compatible with intellectual property protection strategies.

Under the EHDS Regulation, secondary data users are required to report and make publicly available the results or outputs of their authorized secondary use activities within the applicable timelines (Article 61(4)). These obligations apply independently of any intellectual property rights that may arise from the research. The existence of intellectual property protection does not exempt secondary data users from complying with the applicable transparency and reporting requirements under the EHDS framework.

Dissemination refers to the communication of outcomes generated through authorized secondary data use of electronic health data, in accordance with the transparency and reporting obligations established under the EHDS Regulation.

In practice, dissemination includes the provision of results or outputs to the Health Data Access Body (HDAB) that granted access, as required under Article 61(4), as well as any subsequent communication of outcomes through scientific publications, reports, or other channels. At a minimum, secondary data users should ensure that the outcomes of their authorised use are reported in a clear and accurate manner, enabling the HDAB to fulfil its transparency obligations under Articles 58 and 59.

These results must be reported within the timeframe specified in the data permit and, in any case, no later than the deadlines established under Article 61(4) of the EHDS Regulation.

All dissemination must comply with the conditions of the data permit and the output control requirements defined under Article 73(2), ensuring that no information is disclosed that could enable the identification of data subjects. Where intellectual property protection is sought, secondary data users should ensure that dissemination remains consistent with EHDS reporting obligations, while avoiding the disclosure of



confidential business information or protected proprietary elements. Dissemination does not require disclosure of detailed methodologies or proprietary elements where these are protected under applicable intellectual property or confidentiality rules.

7.1 Dissemination to the Health Data Access Body (HDAB)

Under the EHDS Regulation, HDABs are required to publish periodic reports including information on the outcomes of secondary use of electronic health data, in accordance with Article 59 of the EHDS Regulation, including the results generated through authorised data access and, where applicable, their contribution to research, innovation or product development.

To enable HDABs to fulfil these reporting obligations, secondary data users are required, under the conditions of their data permit, to provide the HDAB that granted access with information on the outcomes of their authorised secondary use activities. This includes a summary of the results or outputs generated and any relevant contextual information necessary for the HDAB's reporting obligations.

Where applicable, secondary data users should also indicate whether the authorised data use has resulted in publications, policy outputs or contributions to product or service development. This information supports the HDAB in complying with its obligations under the EHDS framework.

In cases where secondary data use is carried out by a consortium or involves multiple organisational entities within the same authorised project, internal coordination mechanisms should be established to ensure that reporting to the relevant HDAB is complete and consistent. This is a practical recommendation and does not alter the individual obligations arising from the data permit.

Information on the outcomes of secondary use may also be made available through the EHDS transparency framework managed by HDABs in accordance with Article 58 of the EHDS Regulation.

7.2 Dissemination to the scientific community

Scientific publication is one of the primary ways in which outcomes of authorised secondary use of electronic health data may be made publicly available. Publication supports transparency, enables scrutiny of methods and findings, and contributes to the broader body of scientific knowledge.

Under the EHDS framework, secondary data users are required to ensure that the results or outputs of authorised secondary use are made publicly available in anonymised form within the applicable timelines. Scientific publication is one possible means of fulfilling this transparency obligation, if it complies with the conditions of the data permit and applicable data protection requirements.

When disseminating findings within the scientific community, secondary data users should ensure that reporting is sufficiently clear and detailed to allow appropriate interpretation of the results. In the context of secondary data use, particular attention



should be given to the description of data sources and their provenance, as well as data quality and completeness. Where applicable, this should also include information on data linkage procedures, definitions of variables and outcomes, and any methodological limitations related to the reuse of data originally collected for other purposes¹.

Where appropriate, research findings may also be registered in scientific or institutional repositories, provided that such registration is consistent with EHDS reporting obligations and does not disclose personal data.

7.3 Reaching beyond the scientific community

In addition to reporting obligations towards the HDAB, secondary data users may communicate outcomes of authorised secondary use to broader audiences, including policymakers, healthcare professionals, patient organisations, and the public. Such communication should remain consistent with the transparency objectives of the EHDS framework and the conditions of the data permit. Where appropriate, outcomes may be presented in an accessible format to support understanding by non-specialist audiences.

Any communication beyond the scientific community must comply with the output control requirements defined under Article 73(2) of the EHDS Regulation, ensuring that no information is disclosed that could enable the identification of data subjects. The use of simplified or non-technical summaries (e.g. lay summaries) may be considered as a good practice to enhance accessibility of results, although this is not required under the EHDS framework.

7.4 Reporting of policy- and regulatory-relevant outcomes

Secondary use of electronic health data may generate outcomes that do not take the form of traditional scientific publications. These may include outcomes relevant for policy development, regulatory assessments, or the development of health-related products or services.

Examples may include analytical reports supporting policy formulation, technical assessments informing health system planning, regulatory evidence submissions, or innovations such as digital health tools, medical technologies, or decision-support systems informed by research conducted within the secure processing environment.

Although such outputs may not be disseminated through academic channels, they nevertheless constitute outcomes of secondary use under the EHDS framework. Their existence should therefore be communicated to the HDAB that granted the data permit, to support transparency and enable HDABs to fulfil their reporting obligations.

Providing this information enables HDABs to fulfil their transparency and reporting obligations under the EHDS Regulation. Article 61(4) establishes the obligation to make results or outputs publicly available, while Articles 58 and 59 provide the



transparency and reporting framework within which HDABs communicate information on secondary use.

Reporting such outcomes does not require disclosure of confidential business information and should be limited to the information necessary to fulfil transparency obligations under the EHDS framework. Rather, it ensures transparency regarding the types of impacts generated through the secondary use of electronic health data within the EHDS governance framework.

7.5 Reporting of product and service development

Authorised secondary use of electronic health data under the EHDS framework may contribute not only to scientific publications or policy-relevant outputs, but also to the development or improvement of health-related products and services. These may include medical devices, diagnostic tools, pharmaceuticals, digital health applications, or data-driven decision-support systems. Where such developments arise from authorised secondary data use, they form part of the results or outputs of the data use activity. As such, they fall within the transparency and reporting obligations applicable to secondary data users under Article 61(4) of the EHDS Regulation and the conditions of the data permit.

Secondary data users should therefore inform the relevant HDAB where authorised data access has contributed to the development, validation or improvement of a product or service. The information provided should be sufficient to enable the HDAB to fulfil its own reporting obligations under the EHDS framework. This clarification ensures that commercially relevant outcomes derived from authorised secondary use are appropriately captured within the EHDS transparency and accountability system, without affecting the protection of intellectual property or confidential business information.

8 Data Sharing and Collaboration

Where outcomes are generated through collaborative secondary use of electronic health data, each secondary data user remains individually responsible for fulfilling the transparency and reporting obligations associated with their data permit. In particular, each secondary data user is responsible for ensuring that outcomes derived from authorised secondary use are reported to the HDAB in accordance with Article 61(4) of the EHDS Regulation and the conditions of the data permit.

In collaborative projects, coordination mechanisms may be established to support consistent and efficient reporting of outcomes, including the designation of a lead entity to compile or submit results on behalf of the consortium. Such arrangements are part of internal project governance and do not modify the individual responsibilities of secondary data users under the EHDS framework.



Where outcomes are jointly generated, secondary data users should ensure that reporting is coherent, avoids duplication or inconsistencies, and provides sufficient information to enable the HDAB to fulfil its transparency obligations under Articles 58 and 59.

9 Conclusion

This guidance has clarified the key obligations that apply to secondary data users once outcomes are generated through authorised secondary use of electronic health data under the EHDS framework.

In particular, secondary data users are required to:

- Report outcomes to the HDAB that granted access, in accordance with Article 61(4) and the conditions of the data permit
- Ensure that reported outcomes are clear, accurate, and sufficiently informative to support the transparency obligations of the EHDS framework (Articles 58 and 59)
- Comply with output control requirements when exporting results from the secure processing environment, ensuring that no information is disclosed that could enable the identification of data subjects (Article 73(2))
- Ensure that dissemination of outcomes remains within the authorised scope of the data permit and does not disclose confidential or proprietary information beyond what is required for transparency

In collaborative contexts, each secondary data user remains individually responsible for fulfilling these obligations, regardless of any internal coordination arrangements.

By complying with these requirements, secondary data users contribute to the transparency, accountability, and consistent implementation of the EHDS framework, while ensuring that the outcomes of secondary use are handled in a legally compliant and responsible manner.



10 References

1. van den Akker O., Thibault R., Ioannidis J., Schorr S., Strech D. (2025). *Transparency in the secondary use of health data: assessing the status quo of guidance and best practices*. Royal Society Open Science, 12(3), 241364. <https://doi.org/10.1098/rsos.241364>

11 Annexes

Annex number	Annex title
1	User journey
2	Glossary

Annex 1 – EHDS User Journey – Reporting and Communication of Outcomes

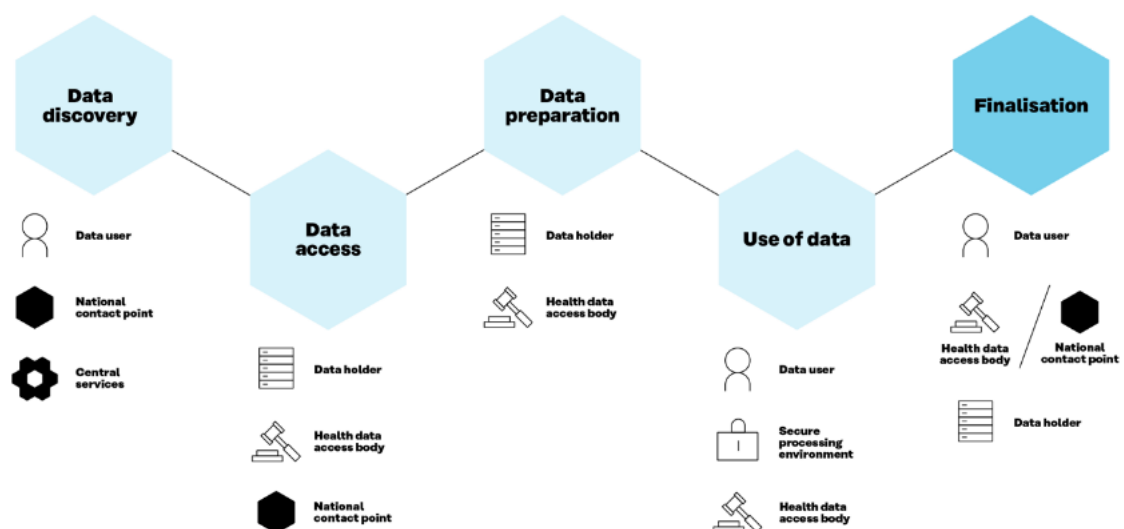
When a health data user applies for electronic health data for secondary use within the European Health Data Space (EHDS), the interaction with the EHDS governance framework follows several stages. These stages describe the lifecycle of a secondary use project from the identification of relevant datasets to the reporting and communication of outcomes generated through the use of the data.

The user journey reflects the responsibilities of health data users and Health Data Access Bodies (HDABs) throughout the secondary use process and highlights the stage at which outcomes of secondary use should be communicated in accordance with the transparency obligations of the EHDS Regulation.

To support understanding of how the reporting and communication of outcomes fits within the broader secondary use framework of the EHDS, this section presents a simplified user journey describing the lifecycle of a secondary use project. The user journey illustrates the main stages through which a health data user interacts with the EHDS governance framework, from identifying relevant datasets to the reporting of outcomes generated through the use of electronic health data.

While the earlier stages of the process, such as data discovery, access and preparation, are addressed in other TEHDAS2 guidance documents, the present milestone focuses particularly on the final stage of the process, where results and outcomes from secondary use activities are communicated. This phase is essential to support transparency, accountability and the visibility of the societal value generated through the secondary use of electronic health data.

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





Data discovery

Before requesting access to electronic health data, the data user identifies whether relevant datasets exist and whether they are suitable for the intended purpose.

This phase involves consulting dataset catalogues, metadata repositories, and other discovery tools made available through national dataset catalogues and the EU dataset catalogue connected to the HealthData@EU infrastructure. Through these tools, data users can assess dataset availability, structure, quality, and conditions for access.

Once suitable datasets have been identified, the data user may proceed to the data access phase.

Data access

In the data access phase, the data user submits a health data access application or a data request to the relevant HDAB.

The application must describe:

- the purpose of the secondary use,
- the datasets requested,
- the intended methodology,
- compliance with applicable safeguards and legal requirements.

The HDAB assesses the application and may issue a data permit or approve a data request if the conditions set out in Chapter IV of the EHDS Regulation are fulfilled.

Data preparation

Once access has been granted, the relevant health data holder(s) provide the requested datasets to the HDAB or the designated infrastructure responsible for preparing the data for secondary use.

During this phase, datasets may undergo technical and organisational preparation measures, including:

- pseudonymisation or anonymisation where appropriate,
- application of data minimisation principles,
- preparation of the dataset according to the conditions specified in the data permit.

These measures ensure that the data made available to the data user comply with the safeguards established by the EHDS Regulation.

Use of data

During this phase, the data user performs the authorised analysis using the electronic health data.



Where personal-level data are involved, the analysis must take place within a Secure Processing Environment (SPE) or another authorised processing environment.

The data user must conduct the analysis strictly in accordance with:

- the conditions of the data permit,
- the approved purpose of processing,
- the applicable data protection and security requirements.

Reporting and communication of outcomes

After completing the analysis, the data user is responsible for communicating the outcomes generated through the secondary use of electronic health data.

This phase may include several forms of outcomes, such as:

- scientific publications,
- research reports,
- policy-relevant analyses,
- regulatory evidence or technical assessments.

In accordance with the EHDS transparency framework, data users should:

- communicate the results of the secondary use project to the HDAB that granted the data permit;
- make the outcomes available in an appropriate form that ensures transparency regarding the use of electronic health data;
- ensure that published results do not allow the identification of natural persons.

The communication of outcomes contributes to the transparency obligations of the EHDS and supports the visibility of the societal value generated through the secondary use of electronic health data.



Annex 2 – Glossary

TERM	DEFINITION
Anonymised data	Data that do not relate to an identified or identifiable natural person or that have been rendered anonymous in such a manner that the data subject is not or no longer identifiable, as described in Recital 26 of the GDPR.
Clinically significant finding	A finding identified during authorised secondary use of electronic health data that may have relevance for the health of a natural person and must be notified to the Health Data Access Body in accordance with Article 61(5) of the EHDS Regulation.
Data permit	An authorisation issued by a Health Data Access Body allowing access to electronic health data for a specified secondary use purpose under defined conditions and safeguards, as provided for in the EHDS Regulation.
Health Data Access Body (HDAB)	A body designated by a Member State under the EHDS Regulation to assess applications for secondary use of electronic health data, issue data permits, and supervise compliance with the conditions governing such use.
Health data holder	A natural or legal person, public authority, agency, or other body responsible for making electronic health data available for secondary use under the EHDS framework, as defined in the EHDS Regulation.
Health data user	A natural or legal person who has been granted access to electronic health data for secondary use under the EHDS framework through a data permit or approved health data request, in accordance with Chapter IV of the EHDS Regulation.
Output control	Procedures applied within a secure processing environment to verify that results exported from the environment do not contain personal data or information



TERM	DEFINITION
	that could enable the identification of individuals.
Research outcome / output	Results or outputs generated through authorised secondary use of electronic health data, including scientific publications, analytical reports, policy-relevant outputs, or innovations derived from such use. This term is used operationally in this guidance.
Secondary use of electronic health data	Processing of electronic health data for purposes other than the provision of healthcare services to the natural person to whom the data relate, including research, innovation, policymaking, regulatory activities and public health.
Secure Processing Environment (SPE)	A secure technical and organisational environment in which electronic health data are made available for analysis by authorised health data users while preventing unauthorised access, identification of individuals, or unauthorised transfer of data.