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

Reflections and recommendations for HDABs on allowed purposes and prohibited use according to EHDS

TEHDAS2 – Second Joint Action Towards the European Health Data Space

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0 Document info

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Contents

1 Executive summary

This guideline supports how the European Health Data Space (EHDS) Regulation (EU) 2025/327 applies to the secondary use of electronic health data, clarifying the allowed purposes (Article 53), prohibited uses (Article 54) and the role of Article 52(3) where Intellectual Property Rights (IPR) and trade secrets may limit data availability. It is intended primarily for Health Data Access Bodies (HDABs) and is expert guidance from Second Joint Action Towards the European Health Data Space (TEHDAS2), not legally binding and not representing the European Commission.

The document scope supports Health Data Access Body (HDAB) assessments by verifying eligibility under Article 53, screening for risks under Article 54 and determining proportionate legal, organisational and technical safeguards required by Article 52(3), with pointers to related TEHDAS2 deliverables for coordinated implementation across member states.

The scope excludes detailed operational workflows (see Annex 7 for a summary of guideline D6.3), IPR/trade secret regimes beyond Article 52(3), opt-out rules under Article 71 except where relevant to Article 53(1)(b), and broader EHDS infrastructure topics unrelated to application management and permit issuing.

The methodology underpinning this guideline is described in Annex 1. Within TEHDAS2, a process of public consultation has been conducted prior to finalising the deliverable, with a summary and illustrative examples provided in Annex 2a and Annex 2b. In addition, the TEHDAS2 project has defined a User Journey to support practical implementation (see Annex 3).

Article 53 provides an exhaustive list of six allowed purposes: **(a) public or occupational health tasks; (b) policymaking and regulatory activities; (c) official statistics; (d) education in the health or care sectors; (e) scientific research** (broadly interpreted, including innovation and Artificial Intelligence (AI) when conducted with scientific rigour and public health relevance); and **(f) improvement of care delivery**. Purposes (a)–(c) are reserved for public bodies and Union institutions (including mandated third parties), and every application must show necessity, proportionality and appropriate safeguards.

Article 54 prohibits detrimental or discriminatory decisions, advertising or marketing, development of harmful or addictive products or services and activities conflicting with national ethical provisions.

Because Article 53 is exhaustive and Article 54 is not, any use outside Article 53 is not permitted even if not named in Article 54. HDABs should verify mandate (including on-behalf-of arrangements), confirm purpose, necessity and proportionality, check for indicators of prohibited use and impose IPR/trade secret safeguards.

Research applications should include a protocol, ethics approval where required and a data management plan (DMP), with binding commitments to refrain from misuse. Where protected elements are present, HDABs should use contractual measures, derived datasets or secure processing environments and may refuse access under Article 52(5) if adequate protection cannot be ensured.

Process notes include accelerated timelines for Article 53(1)(b) and narrowly defined Article 71(4) opt-out exceptions, with European Union (EU)-level convergence encouraged via the EHDS Board.

2 Abbreviations

Term	Abbreviation
Artificial Intelligence	AI
Data Management Plan	DMP
Directorate-General for Health and Food Safety	DG SANTÉ
European Medicine Agency	EMA
European Health Data Space	EHDS
European Union	EU
General Data Protection Regulation	GDPR
Health Data Access Body	HDAB
Health Technology Assessment	HTA
Intellectual Property Rights	IPR
Medical Device Regulation	MDR
Non-Interventional Study	NIS
Organisation for Economic Cooperation and Development	OECD
Post-Authorisation Safety Study	PASS
Secure Processing Environment	SPE
Towards the European Health Data Space	TEHDAS
World Health Organisation	WHO

3 Introduction

Advancing health data use in the European Health Union

As part of the European Health Union, the 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 EHDS, 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 (HDABs) 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.

3.1 Purpose and context of this guideline

This guideline provides interpretative support to HDABs when assessing applications for secondary use of electronic health data. It provides guidance on the understanding of:

- Article 53, setting out the allowed purposes for secondary use.
- Article 54, identifying prohibited secondary uses.
- Article 52(3), addressing limitations on data availability related to IPR and trade secrets.

The guideline explains how HDABs should analyse the intended use, assess mandate and eligibility, consider risks of prohibited use, and whether safeguards related to IPR and trade secrets are sufficient.

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

Legally binding and enforceable requirements under the EHDS are laid down in Regulation (EU) 2025/327 and, where applicable, in Implementing Acts adopted by the European Commission, within the limits of the empowerments provided by the Regulation.

3.1.1 Methodology

The methodology underpinning this guideline is described in Annex 1 and is based on a structured approach combining legal analysis and expert input, with validation through practical use cases.

Within TEHDAS2, a public consultation process has been conducted prior to finalising the deliverable, with a summary and examples provided in Annex 2a and Annex 2b.

In addition, the TEHDAS2 project has defined a User Journey to support practical implementation and alignment across Member States (see Annex 3).

3.2 Connections with other TEHDAS2 deliverables

This guideline is related to several other TEHDAS2 deliverables:

- D4.1 – Guideline for health data access bodies on fees and penalties for non-compliance related to the EHDS Regulation
- D4.2 – Guideline for health data access bodies on collaboration with other parties.
- D6.2 – Guideline for data users on good application and access practice requests
- D6.3 – Guideline for health data access bodies on the procedures and formats for data access

Together, these deliverables form a cohesive framework for consistent implementation of the EHDS Regulation across member states. (See Annex 7 for further information).

3.3 EHDS Regulation and secondary use

The EHDS Regulation provides a legal basis for processing electronic health data for secondary use, including the necessary safeguards under General Data Protection Regulation (GDPR) Articles 6 and 9[1].

Articles 53 and 54 define the boundaries of allowed purposes and prohibited secondary use.

Articles 67–69 specify the mandatory content of applications, HDAB obligations when issuing permits, and procedural requirements for handling data requests.

[1] Regulation (EU) 2016/679

Additional provisions address secure processing environments (SPEs), opt outs, monitoring, and data holder obligations.

3.4 Target audience

The guideline is primarily intended for HDABs responsible for assessing secondary use applications. It may also support health data holders, data applicants (including researchers, public authorities and private organisations), policymakers and IT implementers. Article 54 will affect data users, since the article targets the very use of health data (see further discussion in chapter 9).

3.5 Key terminology

See Annex 4 and Table 2 for a summary of concepts that are defined in legal acts of the EU.

The term health data applicant, data applicant(s) or data application(s) is used in this document as a general term that includes both health data requests and health data access applications, if not otherwise stated.

4 Scope

This guideline aims at supporting HDABs to interpret and apply the allowed purposes and understand the prohibited uses under Articles 53 and 54 in the EHDS Regulation, when assessing applications for secondary use of electronic health data. Further, the guideline addresses the implication of Article 52(3).

4.1 What the guideline covers

The guideline includes:

- Reflections and recommendations on Article 53 (allowed purposes for secondary use)
- Reflections and recommendations on Article 54 (prohibited secondary use)
- A general overview of Article 52(3) regarding limitations related to IPR and trade secrets
- Guidance on HDABs' assessment of applications in relation to these articles
- Alignment with related TEHDAS2 deliverables, related articles and recitals in the context of Articles 53 and 54

This guideline focuses on the interpretative aspects of Articles 52(3), 53 and 54. It does not replace detailed assessment procedures and further guidance is needed in several areas that are discussed in Chapter 9. Additional guidance may be required at national level to ensure consistency.

4.2 What the guideline does not cover

This guideline does not:

- prescribe operational or procedural workflows for handling applications (provided separately in D6.3 see Annex 7);
- address IPR or trade secret limitations beyond Article 52(3);
- address limitations linked to opt-out rights under Article 71 except where relevant for interpreting Article 53(1)(b);
- cover broader EHDS infrastructure topics unrelated to application management and permit issuing.

5 Articles 52(3), 53 and 54 in the context of application management by HDAB

The assessment of applications for secondary use of electronic health data is primarily set out in Articles 67–69 of the EHDS Regulation.

These articles specify:

- the mandatory information applicants must provide;
- requirements for common EU-wide application forms;
- obligations for HDABs when issuing permits;
- conditions for making decisions on data access;
- timelines, completeness checks, and procedural safeguards.

This chapter outlines the general assessment logic used by HDABs before the detailed interpretation of allowed purposes and prohibited use in later chapters. Guidance and recommended procedures for HDABs in the full processing of applications for issuing data permits and making decisions on health data requests can be found in TEHDAS2 D6.3 with operational guidance regarding interpretation of Articles 67-69, 72 and 73 (for short summary see Annex 7).

5.1 HDAB assessment considerations and requirements

The assessment carried out by the HDAB builds on several interconnected elements: the applicant's mandate to apply for a certain purpose, the declared purpose under Article 53, the potential presence of prohibited secondary uses under Article 54, and any limitations linked to IPR or trade secrets under Article 52(3). Together, these elements ensure that access to electronic health data is lawful, proportionate and aligned with the EHDS Regulation.

To clarify how this guideline fits into the broader HDAB assessment workflow, Figure 1 below illustrates the overall process. The highlighted area (red circle) shows where this document provides guidance — namely the interpretation and assessment of the allowed purposes and prohibited secondary uses.

Figure 1 Position of this guideline within the HDAB assessment process

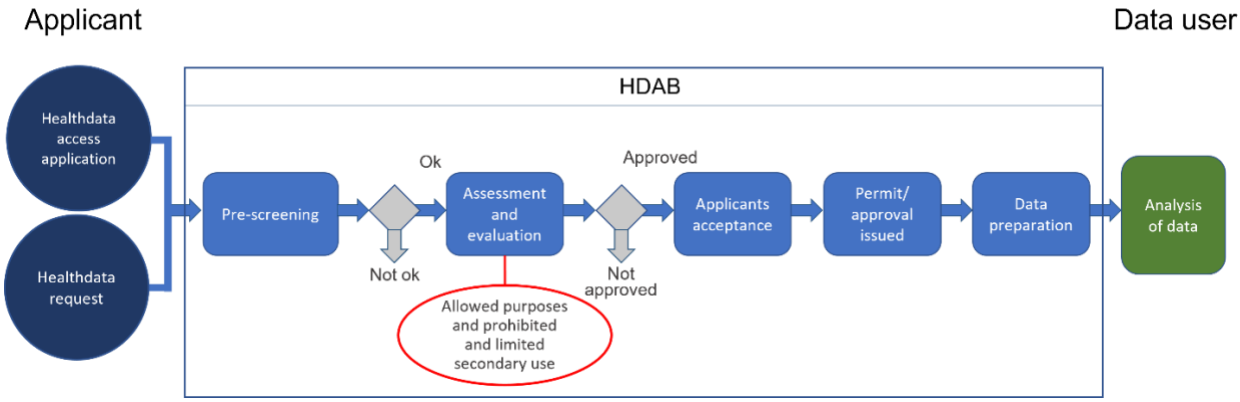


Figure 1 illustrates the phase of the HDAB assessment workflow in which the interpretation of Articles 52(3), 53 and 54 takes place. The highlighted section shows where this guideline provides support — namely the analysis of allowed purposes and prohibited secondary uses. This guideline does not cover all elements of the assessment and evaluation process, such as pre-screening technical validation or permit-issuing workflows; these are described in detail in D6.3 (see Annex 7).

Articles 67 and 69 specify the mandatory information that must be provided in health data access applications and health data requests. Article 68 defines the requirements for issuing data permits and the obligations HDABs must meet when granting access. Together, these provisions ensure that all applications include the necessary information to support a lawful and proportionate assessment.

The applicant's description of the intended use, the purpose selected under Article 53, the data requested and the relevant safeguards form the foundation of the HDAB's assessment.

5.2 Assessment of purpose of data use

HDABs must verify that the stated purpose of the application corresponds to one or more of the purposes listed in Article 53, and for reserved purposes under Article 53(2), HDABs must verify the legal status or mandate of the applicant. Further, HDABs need to assess that the application does not conflict with the prohibited uses outlined in Article 54.

Mixed-purpose applications may occur, and HDABs should assess whether each stated purpose is legitimate and whether the requested data are necessary and proportionate for the intended use. Additional procedural considerations may arise when IPR or trade-secret restrictions apply under Article 52(3).

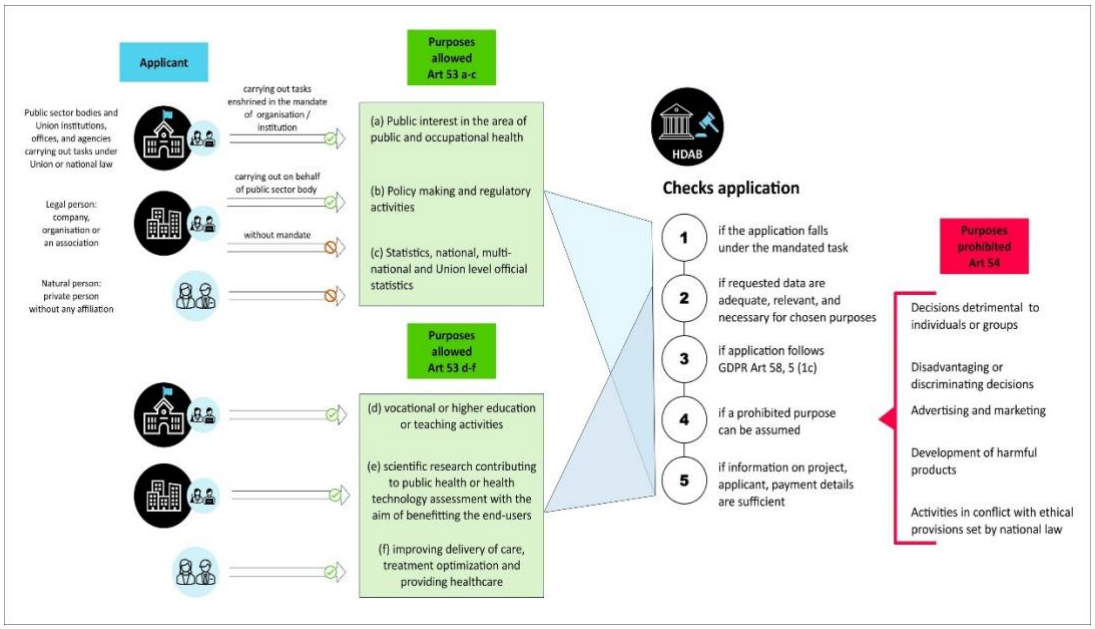
5.2.1 Overview of the assessment

An HDAB must ensure that:

- the declared purpose falls within Article 53,
- no aspect of the application indicates a risk of prohibited secondary use under Article 54,
- possible limitations under Article 52(3) are identified and addressed,
- the application contains sufficient information to support lawful processing,
- necessity, proportionality, and safeguards are documented.

The interaction between the applicant's mandate, the declared purpose and the risk of prohibited use is central to the assessment of a data application. The following figure visualises this relationship and illustrates how HDABs assess whether the applicant is entitled to invoke the chosen purpose, whether the purpose aligns with Article 53, and whether any indicators point towards risks under Article 54. More detailed interpretations and recommendations are presented in later chapters.

Figure 2. Overview of the applicant's mandate, declared purpose and potential prohibited uses. (See enlarged figure in Annex 5 with a suggested selection of questions to be asked initially for an assessment of Articles 53, 54 and 52(3)).



6 General recommendations

This section summarises general recommendations on what HDABs should consider and check for in the assessment process, both with regards to allowed purposes and the prohibited secondary use of electronic health data under Articles 53, 54 and 52(3) in the EHDS Regulation. Recommendations specific to allowed purposes or prohibited uses will be presented in the below sections (sections 6, 7, and 8).

When HDABs assess applications for access to electronic health data, Articles 53 and 54 should be read together. That is, an HDAB should conclude not only that the purposes described in a health data access application or health data request correspond to one or more of the purposes listed in Article 53(1) – as required when issuing a data permit or approving a data request (see Article 68(1)(a) and Article 69(2)(b)) – but also that nothing in the applications (or answers to questions following the application) indicates an infringement with the prohibited secondary uses in Article 54. In other words, the list of allowed purposes in Article 53 is exhaustive. This means that health data may be used only for the purposes explicitly listed in that Article. By contrast, the list of prohibited purposes in Article 54 is not exhaustive. Thus, any use that is not included in Article 53 is therefore prohibited, even if it is not specifically mentioned in Article 54.

Chapter IV in the EHDS Regulation, sets out the core legal conditions for secondary use. Any application processing must pursue a clearly defined and lawful purpose, be necessary for that purpose, be conducted within a secure processing environment, and comply with integrity, data minimisation and proportionality requirements; these principles apply irrespective of the specific purpose relied upon under Article 53 and thus guide HDAB's assessment of purpose and proportionality

In accordance with the respective roles in the application process, the following general recommendations apply to each role. Application requirements for Applicants / health data user.

6.1 Application requirements for applicants / health data user

The applicant must, in accordance with Article 67(2)(c) and (g) and Article 69(2)(b) and (e), provide a detailed explanation of how the intended use contributes to an allowed purpose, as well as identify potential risks and outline proportionate safeguards to prevent misuse, including any risk of serving a prohibited purpose under Article 54.

A clear explanation of how the declared purpose falls within the applicant's legal remit or delegated mission is required. The burden of proof lies with the applicant. HDABs are not required to investigate or confirm the mandate beyond the information provided.

6.2 Obligations and review steps for HDABs

- HDABs should ensure that the applicant's intended use of the requested health data is clearly described in the application and that at least one legal basis under GDPR Articles 6 and 9 applies.
- When assessing whether a data application falls under a given purpose, HDABs may need to request additional information or verifiable documentation from data applicants (e.g. a

research plan). In doing so, HDABs should ensure that the detail of any requested information is proportionate to the assessment needs and avoid unnecessary disclosure of material that could infringe on intellectual property or trade secret protections.

- HDABs should not make assumptions when assessing applications. Depending on the characteristics of the request, all necessary steps should be taken to clarify the application before deciding on access to electronic health data. These steps may include, for example:
    - Requesting additional information from the applicant until all questions are fully answered.
    - Discussing the application internally or, in multi-country applications and when needed, with other HDABs to identify missing information.
    - HDABs should verify that the described intended use and expected benefits are consistent with the purpose(s) chosen under Article 53.
    - HDABs should check that the applicant explicitly states the intended use and crossed the binding commitment that the data will be used exclusively for this purpose, and not for any prohibited secondary uses, such as for the ones listed in Article 54 (*i.e.,* advertising, marketing, discriminatory decision making, or the development of harmful or unethical products or services). These prohibited uses should be clearly reflected in HDAB guidelines and internal review procedures.
- If the information and documents in an application do not fully meet the criteria of the selected purpose, an HDAB, depending on applicable national laws regulating the HDAB in question, may have to consider whether the application fulfil an alternative permitted purpose and inform the applicant accordingly. If additional information is needed to fulfil the criteria for the alternative purpose the HDAB, shall, depending on the conditions of national legislation mentioned previously ask for that
- If not already required under national law, HDABs should document the assessment process, including all documents, communications, investigative steps (e.g., contacts with government agencies), and any other relevant information. This supports monitoring of compliance with the granted permit and provides a clear record of the basis for the assessment.
- It is further recommended that HDABs explicitly note—e.g., in a checklist—that Article 54 has been considered before granting a data permit or approval.

  To sum up, it is of utmost importance that member states, in an early stage, ensure that HDABs receive appropriate and coordinated support – ethical, legal, organisational, and technical – amongst others, to effectively assess electronic health data access applications in line with Articles 53 and 54. Clear procedures for seeking such support should be established. The operationalisation of these support mechanisms remains subject to further development and discussion. For more detail, see chapter 9.

  To avoid different assessments between member states it is important to establish a common EU level standard for the HDABs' assessment processes, for example regarding how detailed the investigations an HDAB must carry out should be, such as verifying the

health data user's company or entity name and understanding the business activities of the company or entity, including any subsidiaries. For further guidance on the assessment process please see Guideline for HDABs on the procedures and formats for data access (Annex 7, referring to D6.3).

7 Allowed purposes for secondary use

This section analyses the allowed purposes for secondary use of electronic health data under Article 53 of the EHDS Regulation. The purposes fall into two main groups: those reserved for public-sector bodies (public interest in the areas of public or occupational health, policymaking, and official statistics) and those available to all eligible applicants (education, scientific research, and improvement to healthcare delivery). It also clarifies certain concepts not previously defined in EU legal acts, addressing areas of uncertainty.

Recommendations for HDAB assessments regarding allowed purposes for secondary use of health data will be included.

It is crucial to be aware that, as clarified in Recital 52 of the EHDS Regulation, this regulation does not affect the initial processing of electronic health data by health data holders, such as for the delivery of healthcare. These activities do not involve making data available to others. Such uses, which fall within the original purpose for which the data were collected, remain outside the scope of the EHDS framework for secondary use and are not subject to data permit requirements. They may therefore continue in accordance with applicable data protection legislation, including the GDPR.

Some main concepts discussed in this chapter are healthcare, medicinal product, benefits of data use, AI system, health technology assessment (HTA), areas of public health, areas of occupational health, serious cross-border threats, public sector body and statistics, all of which are defined in Annex 4.

The definitions of conceptually complex terms are addressed within each corresponding section, namely Public Interest, Scientific Research, and Innovation.

7.1 Access to health data reserved for public sector bodies (Article 53(1) (a–c))

Three purposes listed in Article 53(1) (a–c) are restricted to public sector bodies as stipulated in Article 53(2) of the EHDS Regulation (see the full text of the article in Annex 6).

The definition of a ‘public sector body’ means the state, regional or local authorities, bodies governed by public law, or associations formed by one or several such authorities or one or several such bodies governed by public law as provided in Article 2(1)(c) of the EHDS Regulation, which refers to Article 2(17) of the Data Governance Act (Regulation (EU) 2022/868).

The activities of public sector bodies include amongst others the use of health data for tasks such as public health monitoring, planning and reporting, designing health policies, and ensuring patient safety, quality and sustainability. To fulfil their mandate, it may be necessary for them to regularly access electronic health data over a longer period. However, public sector bodies may carry out such research activities with the help of third parties, provided they retain oversight as described in Recital 61 (see the full text of the recital in Annex 6).

7.1.1 General reflections

Since a member state may mandate other entities to act on its behalf for a specific purpose in the same way as any other contractor, international organisations are not eligible by default and must act through or under a mandate from a public authority.

Because of this prerequisite of unconditional affiliation with a public sector body authorised for these application purposes it is not sufficient for an applicant to be a public sector body or to act on behalf of one — the mandate or delegation must also cover the specific purpose (a)(b) or (c) listed in Article 53(1). The HDAB should assess not only the status or affiliation, but also whether the delegated task explicitly relates to the stated purpose. This is essential to prevent overly broad interpretations of what constitutes public interest or eligibility for policymaking.

Therefore, affiliation with or contracting by a public authority is not sufficient unless the contract or delegation explicitly covers tasks relating to public health, policymaking or statistics.

In validating this requirement, HDABs must verify both

- the applicant's legal status or mandate, and
- that the scope of that mandate covers the stated purpose under Article 53(a–c).

For example: A national health research institute applies for access to conduct public health surveillance. It must provide the national law or governmental decree that legally establishes its role in public health monitoring. If acting under a ministry's mandate, it must provide proof of that.

7.1.2 Recommendations

To select data via the HealthData@EU Central Platform[2] and apply for access, prior registration or login via European Commission's user authentication[3] service is required, during which the affiliation should be checked. An automated check during the application process to determine whether the applicant belongs to a public sector body could support the HDABs. In this case, only in the case of a mandate, i.e., an application on behalf of a public sector body, would it be necessary to provide suitable evidence and check this manually.

The assessment of affiliation or mandate of the applicant is relevant not only for determining the admissibility of certain purposes, as set out under Article 53(2), but also because applications submitted by public sector bodies for the purposes set out in Article 53(1) points (a), (b), or (c) are subject to an accelerated procedure under Article 68(6) of the EHDS Regulation. According to Article 68(6), the EHDS Regulation allows an accelerated process for public sector bodies for the purposes established in Article 53(1), points (a), (b) and (c). In these cases, the HDAB must decide within two months rather than the usual three-month period. An extension into a third month is possible only where there are sufficiently justified

[2] https://acceptance.data.health.europa.eu/healthdata-central-platform?locale=en
[3] https://ecas.ec.europa.eu/cas/eim/external/register.cgi

grounds. Member states are responsible for putting in place and maintaining the necessary procedures within the HDAB.

- HDABs should verify both
  - the applicant's legal status or mandate, and
  - that the scope of that mandate covers the stated purpose under Article 53(a–c).
- HDABs are not required to investigate or confirm the mandate beyond what is submitted.
  - The burden of proof lies with the applicant. Applicants should provide documentation such as proof of legal status as a public sector body (e.g. statute, legal register).
  - In the case of delegated tasks: a formal contract, agreement, or letter of mandate clearly specifying the task and its relevance to the purpose cited. A clear explanation of how the declared purpose falls within the applicant's legal remit or delegated mission.

7.2 Access for purposes relating to public interest (Article 53(1) point (a))

The EHDS Regulation permits access to electronic health data when the stated purpose relates to the public interest in the areas of public or occupational health, such as activities to protect against serious cross-border threats to health, public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices under Article 53(1)(a).[4]

7.2.1 The concept of "public interest"

The term 'public interest' is of union law character. It is not defined precisely in any legal act, for instance in the GDPR. However, references to recitals in the EHDS Regulation and the GDPR may be useful as guidance for interpreting the provisions (see below). Linguistically, the concept of a matter of general interest can be assumed to refer to something that is of interest to or affects many people on a broader level, as opposed to a special interest or an individual interest.

It is a widely used and at the same time controversial term for which there is no clear and precise definition to date[5].

[4] See Annex 4 for definitions of public health and occupational health.
[5] See Annex 4.1 for a discussion of the term and its use in the EHDS Regulation.

The notion of 'public interest' must not be interpreted as a general justification. HDABs should require clear and well-documented evidence demonstrating how the intended purpose satisfies the criteria set out in Article 53(1)(a) and should verify that the applicant is duly entitled to act on this basis. Recital 54 of the EHDS Regulation specifies which facts are specifically to be assigned to the public interest:

"[…] strong link to the public interest, such as activities for protection against serious cross-border threats to health or scientific research for important reasons of public interest, […]"

Regarding the concept of public interest, Recital 46 of the GDPR states, inter alia:

"[…] humanitarian purposes, including for monitoring epidemics and their spread or in situations of humanitarian emergencies, in particular in situations of natural and man-made disasters. […]"

Furthermore Recital 52 of the GDPR states for example, that the prevention or control of communicable diseases and other serious threats to health is in the public interest.

7.2.2 General reflections

The EHDS Regulation treats public interest as both an enabling principle and a normative benchmark:

- **Enabling principle.** Public-interest purposes constitute the legal gateway for secondary use: only data processing that is necessary for clearly enumerated public-health objectives or for scientific research "for important reasons of public interest" may receive access to data from an HDAB. The necessity test, together with proportionality checks in Articles 68(1)(b), 69(2)(b) and 70, ensures that public interest is weighed against data-protection obligations rather than asserted abstractly.

- **Governance standard.** Bodies charged with implementation and oversight — the national digital health authorities, HDABs and the EHDS Board — must demonstrate independence and avoid conflicts of interest precisely to safeguard public-interest decision-making. This requirement institutionalises public interest as a criterion for administrative integrity.

- **Risk-mitigation trigger.** Market obligations (importer complaint channels, manufacturer disclosure after incidents) are explicitly linked to "public-interest protection". Thus, when a risk materialises, the duty to inform and to act is activated not only by private harm but also by broader public-interest considerations.

- **Procedural guarantee**. Individuals can rely on civil-society organisations with public-interest mandates to enforce their rights, which embeds public interest advocacy in the enforcement architecture.

In sum, the regulation operationalises public interest through concrete conditions of access, institutional duties of independence, and responsive obligations for economic operators. Public interest is therefore not a vague aspiration but a measurable legal test that guides data access decisions, shapes governance ethics and triggers protective measures throughout the EHDS.

The need for a more precise definition of 'public interest', particularly in relation to health research and innovation, has been emphasised above. It has also been noted that there is difficulty in distinguishing projects that genuinely contribute to surveillance or safety. Examples included AI for early sepsis detection and COVID-19 impact analysis. Medicines shortages were raised as a borderline case.

Concerns were expressed over subjective assessments and lack of standardisation. Furthermore, it is acknowledged that the public interest criterion under Article 53(1)(a) is vague, especially when intersecting with research and innovation projects. On the other hand, the wording of the law itself specifies the notion of public interest in the context of the EHDS by including the phrase "in the areas of public or occupational health." This clarification indicates that the provision does not refer to public interest in a broad sense—such as that which supports research, education, or even product innovation—but rather to the protection of public welfare and health, particularly within the context of workplace safety and occupational well-being.

Another aspect associated with the concept of public interest is 'ensuring high standards of quality and safety of health care' and its significance for scientific research and innovation. Here, too, the association can be made with the overarching goal of benefiting society. In individual cases, the degree and scope of 'high quality and safety' should be defined in as measurable terms as possible in order to facilitate assessment.

One of the main challenges with the concept of public interest is that it may be subjectively determined, making it difficult to standardise and ensure consistency as it is a broad concept which may include anything that serves a broader interest of the society. It could therefore enhance transparency for data applicants and benefit HDABs if member states ensured the integration of public institutions with standard-setting, policy-making, or regulatory authority into the governance structure of national HDABs.

While there is no clear definition of 'public interest' there has been an ongoing discussion specific to secondary use of health data between experts about the advantages of a broad or narrow interpretation of 'public interest' and the need to identify public interest a priori.[6]

Insofar as the more legal concept of public interest is also informed by what constitutes the 'common good', this expertise regarding the definition of public interest could or even should be informed by the public themselves, including citizens and patients, as their values should guide what constitutes the common good.[7]

7.2.3 Recommendations

This provision must be interpreted in light of its public governance focus: it applies to public health authorities or public sector bodies tasked with activities such as surveillance, monitoring, and protection of public health, not to general scientific research or private sector development activities.

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[6] Cervera De La Cruz, P., & Shabani, M. (2025). Conceptualizing fairness in the secondary use of health data for research: a scoping review. Accountability in Research, 32(3), 233–262.
[7] TEHDAS (2023). Qualitative Study to Assess Citizens' Perception of Sharing Health Data for Secondary Use and Recommendations on How to Engage Citizens in the EHDS.

HDABs should carefully assess:

- if the applicant is entitled to invoke this purpose (e.g., a public body with a health protection mandate, or a third party acting on its behalf), and
- if the project or activity genuinely falls within the scope of public health interest, and not another purpose such as research (Article 53(e)).

Relevant examples or use cases could include:

- Monitoring of antimicrobial resistance,
- Using large, longitudinal, multi-institutional datasets from intensive care units (ICU) to develop an AI-based sepsis early-warning system,
- Safety tracking of advanced medical therapies,
- Assessing the impact of COVID-19 on at-risk populations,
- Post-market evaluations of cardiac medical devices.
- Post authorisation safety studies (PASS) for pharmacovigilance and drug safety could be classified as research or public health measures in the public interest if there is a corresponding statutory transfer of tasks or a specific legal basis (e.g. pharmacovigilance obligations, EMA, specific research laws). Quality and transparency requirements for PASS/NIS (non-interventional studies) apply uniformly across the board; whether a party is a sponsor, co-sponsor or purely an 'implementing body' only determines which actor is responsible for which regulatory and data protection obligations.

There may be challenges in evaluating applications submitted by public sector bodies, particularly when access to data is needed to fulfil tasks outlined in their official mandates under Article 53(1). One example of a challenge that is likely to arise when assessing the purposes for which HDAB applies to use data could be the distinction from scientific research in the health or care sector that contributes to public health or the evaluation of health technologies, as referred to in Article 53(1)(e). There are public sector bodies that operate in the field of public health. On the other hand, scientific institutions such as universities also conduct research in the field of public health without being public sector bodies themselves. In such cases, the decision could be guided by the affiliation of the applicant institution or person and the associated mandate.

- HDABs should by following this determination have a clear investigative responsibility or obligation to determine what type of data access is being requested and by whom and for what purpose exactly.
    - A helpful question to identify “public interest” as a purpose for the application could be: “Is the data access application comparable to the examples given above?” and “Is the applicant by affiliation or proof eligible to apply?”.
- HDABs should take into account that projects involving technology development or clinical deployment, such as AI tools for diagnosis or treatment optimisation, when answering the questions and assessing the intended purpose specified by the applicant.
    - These typically do not fall under Article 53(a) unless they are part of a recognised public health programme or legal task. These are more appropriately assessed under Article 53(e) or (f).
- The HDAB should examine both the applicant and the exact purpose, as defined in the application form.
    - The mandate, institutional role and documented objective must be examined together. Whether the activity is in the public interest depends more on the desired outcome than the type of activity.

In ongoing discussions, concerns have been raised about how to clearly define the roles and responsibilities of national coordination entities within public sector bodies. These entities may operate under their own mandates, while also engaging in coordination tasks on behalf of the national system. Furthermore, public sector bodies often encompass multiple roles — including data holding, regulatory responsibilities, and research — which can lead to internal conflicts or prioritisation challenges.

As a result, challenges may arise in establishing a nationally consistent and fair approach to prioritising such applications. There may be a need for the development of standardised procedures or guidelines to ensure transparent and effective handling of these complex cases through all Member states.

7.3 Policymaking and regulatory activities (Article 53(1)(b))

The term ‘policymaking and regulatory activities’ in Article 53(1)(b) is referred to as follows:

“[…] policymaking and regulatory activities to support public sector bodies or Union institutions, bodies, offices or agencies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates; […]”

The aspects of policymaking and regulatory activities are not frequently addressed in the EHDS articles but are mentioned in the recitals:

- Electronic health data may also be collected and processed for policymaking or regulatory purposes and should be made available in accordance with the EHDS Regulation – Recital 6
- Policymaking and regulatory activities are core 'public interest' goal of the EHDS Regulation – Recital 110.

7.3.1 General reflections

Policymaking and regulatory activities are essential objectives of the EHDS, as reflected in Article 53(1)(b) and further supported by Recitals 6 and 110. National coordination measures alone have proved insufficient[8]. Because policymakers and regulators need comparable, cross-border evidence, the text of Recital 110 objectives cannot be met effectively by member states acting separately.

Article 53(1)(b) stipulates that access to health data may be granted for policymaking and regulatory activities in order to support public sector bodies or bodies of the Union in the performance of their tasks. The practical significance of this article is multifaceted:

- Evidence-based policy: Public authorities can access real-world data to assess the effectiveness of health systems, better plan resources, or increase patient safety.
- Privileged access: According to Article 53(2), this specific purpose is reserved exclusively for public sector bodies and Union bodies. This prevents private actors from using data for commercial interests under the guise of policy advice.
- Crisis response capability: In situations such as pandemics, Article 53(1)(b) enables rapid data analysis to guide effective policy responses and ensure high health standards.
- Regulatory support: Authorities such as the European Medicine Agency (EMA) can use this data to monitor the safety and efficacy of medicines or medical devices more efficiently.
- Restriction of opt-outs: Of particular practical relevance is the link to Article 71(4). Member states may stipulate by law that citizens' right to object shall be waived in exceptional cases where access for the purposes referred to in Article 53(1)(b) is imperative for a public authority and the data cannot be obtained by other means.

The result is an enabling infrastructure for data-driven legislation, standard-setting, market surveillance and public-health planning.

By invoking the principle of proportionality, Recital 110 affirms that the regulation introduces no greater obligations than necessary. In regulatory terms, this signals a calibrated approach: it balances individual data protection rights with the informational needs of competent authorities, thereby fostering "regulatory flexibility" while still guarding fundamental rights.

[8] https://health.ec.europa.eu/publications/study-supporting-evaluation-directive-201124eu-ensure-patients-rights-eu-cross-border-healthcare_en

7.3.2 Recommendations

Based on the considerations set out in the previous section, the following recommendations for the implementation of the application assessment process can be derived for the HDABs, as this purpose regulates privileged access for the fulfilment of public tasks.

1. Careful examination of application eligibility

   Access to data for policy-making and regulatory activities pursuant to Article 53(1)(b) is reserved exclusively for public bodies and Union institutions, bodies, offices and agencies. The establishment of a standardised procedure for verifying the status of the applicant body by the HDAB could increase the transparency and reliability of the assessment and relieve the burden on the assessing bodies. In this context, consideration should also be given to cases where a third party is acting on behalf of a public body. In such cases, the HDAB should check whether the requested data processing is explicitly carried out for the purpose of fulfilling the assigned public task.

2. Comparison with the legal mandate

   According to Art. 53(1)(b), data may only be granted to support public sector bodies in the performance of tasks specified in their mandate. The HDAB should require the applicant to provide a detailed explanation of how the requested data will contribute to the fulfilment of specific, legally established tasks. It should also be ensured that the data will not be used for prohibited purposes (such as measures to the detriment of natural persons).

3. Examination of opt-out exceptions (Article 71)

   The assessment is particularly critical if the applicant claims an exception to the citizens' right to object (opt-out). In this case, the HDAB must examine whether the data can be obtained in a timely and effective manner by other means under equivalent conditions. Since such access restricts the fundamental right to data protection, the HDAB must weigh the necessity for the public interest (e.g. scientific research of high public interest) particularly strictly against the rights of the data subjects.

- HDABs should develop mechanisms to enable the prioritisation of tasks, if there is sufficient justification for doing so.
- HDABs should retain the ability to ask clarifying questions in order to determine the specific role and intended outcome/purpose of the data applicant's request for health data.

7.4 Statistics (Article 53(1)(c))

The 'statistics' referred to in Article 53(1)(c) as a purpose of secondary use are narrowly defined to relate specifically to (inter)national statistical bodies, which are usually part of the institutional health care system. The regulation refers to:

"[…] statistics as defined in Article 3(1), of Regulation (EC) No 223/2009[9], such as national, multi-national and Union-level official statistics, related to health or care sectors; […]"

Under regulation (EC) No 223/2009 statistics is defined as "quantitative and qualitative, aggregated and representative information characterising a collective phenomenon in a given population".

Consequently, the term encompasses official statistical outputs that have undergone anonymisation and aggregation, thereby ensuring the description of groups rather than identifiable persons.

The term 'statistic' is supplemented with various additional aspects in the recitals and in Article 2 of the EHDS Regulation:

- Recital 1: Identifies "official statistics" as one of the societal purposes of secondary use.
- Recital 56: Notes that secondary use datasets can include data initially collected for statistics and other public interest tasks.
- Recital 87: Calls for harmonised templates for registries and datasets, explicitly mentioning statistics as an area where standardisation work is advanced.
- Article 2(2)(t): Counts organisations that process data for official statistics among the "health data holders" obliged to make data available.

7.4.1 General reflections

The defining characteristic of statistics, particularly national statistics, is not a specific quality or single use, but rather its broad and general purpose. National statistics function as part of an information infrastructure designed for widespread and varied use. They are not produced for a narrowly defined occasion or tailored to a specific user need. Instead, they consist of tabulations, calculated indicators, and other outputs intended to serve multiple purposes across many sectors.

[9] The European Statistical System (ESS) is the institutional network that produces and disseminates European official statistics. It comprises Eurostat, the national statistical institutes of all EU Member states, other national authorities that compile statistics, and the statistical services of EEA–EFTA countries, see https://ec.europa.eu/eurostat/web/european-statistical-system.

Taken together, these provisions show that Article 53(1)(c) is confined to national, multi-national and EU-level official statistics produced under the European Statistical System (ESS)[10]. The data concerned are:

- Aggregated and representative – they summarise phenomena at population level.
- Anonymised/confidential – micro-data remain protected under statistical-confidentiality rules in Regulation 223/2009[11].
- Health-or care-related – only statistics that describe health status, healthcare utilisation, health workforce, expenditure, etc., fall within the scope.

Since all analyses use statistics, this precise and strict definition is particularly important here, as it means that this purpose may only be used by public bodies. Entities not already subject to existing obligations to report data may still be involved in providing information for the production of statistics that extend beyond such obligations.

From a technical standpoint, it is generally clear what constitutes statistical data. However, the intended use of such data is often less straightforward.

The wording of the article implies that other types of public bodies that are not formally designated as statistical bodies are not covered by article 53(1)(c). Only entities legally mandated to produce official statistics under national or EU law can invoke Article 53(1)(c). Other public bodies conducting analytical work should apply under Article 53(1)(b) or (e).

- **Example (not covered by Article 53(1)(c)):** A regional health authority that is not designated as a statistical body calculates patient satisfaction scores for internal reporting. As the authority lacks a legal mandate to produce official statistics, this use does not fall under Article 53(1)(c) and should instead be assessed under Article 53(1)(f).

- **Example (not covered by Article 53(1)(c)):** A pharmaceutical company requests anonymised prescription data to analyse market trends. As this constitutes a commercial purpose, the request is prohibited under Article 54(c) and does not qualify as official statistics.

- **Example (covered by article 53(1)(c)):** The compilation and publication of official national statistics on hospital admissions, long-term care utilisation, and causes of death by a national statistical authority, in accordance with Regulation (EC) No 223/2009, for reporting to Eurostat and for EU-wide comparative analysis.

[10] The European Statistical System (ESS) is the institutional network that produces and disseminates European official statistics. It comprises Eurostat, the national statistical i nstitutes of all EU Member states, other national authorities that compile statistics, and the statistical services of EEA–EFTA countries, see https://ec.europa.eu/eurostat/web/european-statistical-system.

[11] REGULATION (EC) No 223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2009 on European statistics and repealing Regulation https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R0223

7.4.2 Recommendations

1. Clarification of Authorised Entities: Clarify which entities are authorised to rely on purpose 53(1)(c), particularly whether this includes only organisations with a formal mandate under national/EU law.

2. Scope limited to legally established statistical tasks: Purpose 53(1)(c) applies only to activities that fall within existing, legally defined statistical responsibilities and does not extend to general analytical or research uses.

3. Statistical mandate: Public authorities without a formal statistical mandate cannot invoke purpose 53(1)(c) and must instead rely on other purposes such as 53(1)(b) or 53(1)(e).

4. Distinguishing Statistics from General analytical work: Purpose 53(1)(c) should not be interpreted as covering general analytical work, even when performed by public-sector organisations.

These uncertainties make it difficult to assess the full scope of purpose 53(1)(c). While an application clearly referencing statistics may be understandable in its intent, it remains unclear who is authorised to apply under this purpose, and from which point in time — especially in relation to existing legal provisions and institutional roles.

Is purpose (c) intended to cover activities already established by law, or does it extend to additional or complementary statistical uses? Furthermore, does it allow non-designated public sector bodies to engage in statistical analyses for this purpose? It should be clarified that Article 53(1)(c) does not extend to general analytical or research uses, even by public authorities, unless they are acting within a recognised statistical mandate.

These questions have implications for the data catalogue, particularly for smaller health data holders, as they might not be prepared for the responsibilities or consequences associated with providing data for statistical purposes under purpose 53(1)(c).

If an authority is explicitly mandated to produce national statistics and seeks to use data for this purpose, such use can be considered legitimate within the framework of purpose (c), provided that the statistical processing aligns with the definition under Regulation (EC) No 223/2009 and that the applicant's institutional role is clearly documented.

- HDABs should have the ability to ask clarifying questions to determine the capacity in which the applicant is requesting access to the data. Recital 162 of the GDPR provides further relevant context for interpreting the notion of statistics

7.5 Education (Article 53(1)(d))

Article 53(1)(d) “education or teaching activities in health or care sectors at vocational or higher education level” allows electronic health data to be accessed for secondary use specifically for educational and teaching activities within the health or care sector. This provision applies to vocational and higher education levels, ensuring that data may only be used when necessary to support training and teaching that contributes to developing competencies in health care and care services.

When assessing applications for the secondary use of electronic health data for educational purposes, the HDAB must apply the principles and requirements of the EHDS Regulation. The Regulation’s recitals (6) and (61) state that such secondary use must serve broader societal interests, including research, innovation, the development of medical methods and improved health policy, with the overarching objective of promoting quality, safety and sustainability in healthcare; education in the health and care sectors is explicitly part of this societal benefit.

This means that HDAB may grant access when the requested processing is necessary to conduct formal education within the health or care sectors at vocational or higher education level. The decisive factor is that the activity has a primary pedagogical purpose, where data are used to support understanding, skills training, or methodological application within an accredited educational programme. This includes, for example, practical exercises in health informatics, clinical documentation, or epidemiology, provided that the amount of data is limited to what is required to achieve the learning objectives.

7.5.1 General reflections

This guideline does not cover educational activities that fall outside the scope of vocational or higher education, as only these are eligible under Article 53(1)(d). When considering educational activities under purpose (d), the focus should be on whether the activity involves training that necessitates access to sensitive health data on an individual level. This applies regardless of the underlying reason — whether legal, technological (AI), or otherwise. If such access is required to support the educational objectives, then purpose (d) should be a relevant reason for data access.

This provision refers to the purpose of the activity, rather than the status of the applicant. ‘Health and care sectors’ should be understood broadly, not limited to ‘medicine’ only. The activity must form part of a formal educational or training activity relevant to the health or care sectors (e.g. medicine, nursing, pharmacy, biomedical informatics, public health, or social care). It aims to support learning objectives or practical teaching (e.g., simulated case studies, classroom exercises) as well as improving healthcare professional training.

Regarding the classification of an application under this purpose, there will be some overlap with purpose (e), 'scientific research'.

Digital health tool training, for instance, includes wellness applications, AI training, and similar activities. However, training that involves tool development, evaluation, or general digital health literacy may not qualify under Article 53(1)(d) unless it is part of a formal curriculum. Instead, research and testing activities are more appropriately assigned to purpose (e), as they suggest rigorous testing of the application, including ethical review.

Therefore, HDABs should check which purpose best describes the issue. Contacting the applicant is also particularly important in this regard to make sure that the educational purpose is clearly stated in the application and supported by documentation such as course descriptions or training programme outlines.

7.5.2 Recommendations

- HDABs should distinguish education/training from scientific research. For instance, the use of health data in the context of a thesis or dissertation (e.g. Master or PhD project) may fall under either:
  - Article 53(1)(d), if the primary goal is educational (learning/training); and/or
  - Article 53(e), if the primary goal is scientific knowledge production or publication.
- In some member states, for example, a master's thesis is not considered to be scientific research, but rather an educational exercise.
- HDABs should assess the declared objective, supervision context, and methodology accordingly.
  - In practice, there would be concerns of a non-insignificant nature, such as data protection safeguards, confidentiality/secrecy issues, and ethical approval.
- While the EHDS Regulation does not require the applicant to be an educational institution or educator, the involvement of a recognised programme or supervisor may help demonstrate the legitimacy and structure of the educational purpose.

7.6 Scientific research (Article 53(1)(e))

Access to health data is allowed for scientific research purposes under Article 53(1)(e). The interpretation of this is meant broadly (aligning with the use of ‘scientific research’ in GDPR Recital 159), which is indicated by a non-exhaustive list of examples, such as development and innovation activities for products or AI development and algorithm training. Applications under this purpose must genuinely qualify as scientific research and show this by providing verifiable documentation (see. 6.6.3 for a list of examples). Projects without a clear scientific aim and without scientific methods do not qualify.

Furthermore, scientific research under Article 53(1)(e) must contribute to public health or health technology, assessments, or ensure high levels of quality and safety of healthcare, of medicinal products or of medical devices, with the aim of benefiting end-users, such as patients, health professionals and health administrators.

7.6.1 The concept of "scientific research"

Scientific research is not defined in any legal act, not even in the GDPR, although the concept appears in many different contexts, such as in the aforementioned legislation.

Scientific research is a heterogeneous activity, that encompasses a wide variety of methods, theories, and disciplines, and is a socially embedded practice that is shaped by institutional norms, funding structures, and political contexts[12]. Scientific research under purpose (e) of the EHDS is not limited to biomedical or clinical disciplines; it also encompasses many other research fields – including social sciences, humanities, statistics, and other empirical disciplines - when conducted according to recognised scientific methodology. Scientific research is usually characterised by a systematic approach, empirical grounding, transparency, and ethical conduct. It often begins with a clear research question or problem, aims to contribute to existing body of knowledge in a particular field, and may be theoretical or applied in nature. The Frascasti Manual emphasises the goal of acquiring new knowledge as an important characteristic of both applied and basic research[13]. Research findings are typically subject to peer review by experts in the field and/or published in academic journals or presented at conferences.

As indicated by Recital 159 of the GDPR, "the term processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research including privately funded research. In addition, it should consider the Union's objective under Article 179(1) TFEU of achieving a European Research Area. Scientific research purposes should also include studies conducted in the public interest in the area of public health" [14].

Recital 61 of the EHDS Regulation indicates an almost verbatim explanation of the concept:" The notion of scientific research purposes should be interpreted in a broad manner, including technological development and demonstration, fundamental research, applied research and privately funded research."

It also states:" Activities related to scientific research include innovation activities such as training of AI algorithms that could be used in healthcare or the care of natural persons, as

[12] Knorr-Cetina, Karin (1981). The manufacture of knowledge: an essay on the constructivist and contextual nature of science. New York: Pergamon Press.

[13] Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development

And the citation is proposed as: OECD (2015), Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing, Paris. DOI: http://dx.doi.org/10.1787/9789264239012-en

[14] See Guidelines 03/2020 of the EDPB from 21.4.2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, pages 5–6.

well as the evaluation and further development of existing algorithms and products for such purposes."

The Article 29 Working Party (Art. 29 WP) has pointed out that "the notion may not be stretched beyond its common meaning" and understands that "scientific research" in this context means a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice."[15]

Article 53(1)(e) allows access to health data for scientific research purposes and includes specific examples such as AI development and algorithm training, research conducted by public and private actors or applied or innovation-oriented research.

These examples are introduced by the word "including", which under EU legal drafting conventions indicates a non-exhaustive list. The purpose is to clarify that such activities can fall within the concept of scientific research, without limiting it to those cases.

Therefore, the inclusion of AI and algorithm training is meant to:

- Confirm that these emerging activities can qualify as scientific research.
- Prevent narrow interpretations that might exclude applied or technology-driven research.
- Ensure alignment with the broad interpretation of "scientific research" used in other EU laws, particularly the GDPR Recital 159, which explicitly recognises a wide range of actors and objectives under research.

The listed examples serve to clarify and broaden the interpretation of 'scientific research'. Consequently, it is not enough for a health data user simply to belong to a scientific institution (such as an academic organisation), nor is it sufficient that the stated purpose resembles a typical research activity. Instead, to allow for the broad interpretation, all data users, regardless of whether they come from academia or other sectors, must demonstrate that their intended use of the data genuinely qualifies as scientific research under this provision.

The fact that the final version of the EHDS Regulation no longer treats AI as a separate purpose means that the use of health data for the purpose of training, testing, and evaluation of algorithms and AI development more broadly is only permitted when it falls within the scope of scientific research. Therefore, it does not mean that all AI-related activities are automatically permitted under Article 53(1)(e). Training, testing and evaluation of algorithms is not a self-sufficient purpose but needs to serve the specific defined purpose of scientific research and its aims (e.g., ensuring high levels of quality and safety of medicinal products with the aim of benefiting end-users, as outlined above).

[15] See Guidelines on Consent under Regulation 2016/679 of the former Article 29 Working-Party from 10.04.2018, WP259 rev.01, 17EN, page 27 (endorsed by the EDPB). Available at https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051.

7.6.2 The concept of "innovation activities"

Regarding the concept of innovation, Recital 31 of Regulation (EU) 2021/695[16] states i.e., "[…] the concept of innovation should be used in accordance with the Oslo Manual[17] developed by the Organisation for Economic Cooperation and Development (OECD) and Eurostat, which follows a broad approach that covers social innovation and design."

According to the Oslo Manual" A business innovation is a new or improved product or business process (or combination thereof) that differs significantly from the firm's previous products or business processes and that has been introduced on the market or brought into use by the firm".

In the glossary of the European Statistical Office (Eurostat) innovation is the use of new ideas, products or methods where they have not been used before[18].

7.6.3 General reflections

This chapter includes general reflections on Article 53(1)(e) along some examples of data uses and a list of examples of verifiable documentation data users can provide.

- Both applied and basic research are included in purpose (e). While applied research often has practical and specific aims, basic research is exploratory or theoretical in nature and does not necessarily have direct benefits to end-users or patients but rather unfolds its societal benefits over a longer run (see Recital 61).
- The use of health data for training, testing and evaluating algorithms and AI development is only allowed when it falls within the scope of scientific research, since it is not its own separate purpose. The specific mention of AI under purpose (e) does not preclude the use of AI for activities under other purposes, provided that the intended use aligns with the objectives and safeguards of the EHDS. Examples under purpose (e) include activities such as the training of algorithms or the certification and post-market monitoring of medical devices or AI systems. To fall under purpose (e), such activities must demonstrate scientific rigor (see list of examples of verifiable documentation in Section 6.7.3). An example under purpose (f) would be the use of AI as a tool—such as employing a large language model—to improve a hospital workflow.
- Projects involving innovation activities can be eligible under purpose (e) as long as the project is based on scientific methods with clear hypotheses, or public interest aims. Commercial interest does not disqualify a project per se, but scientific rigor

[16] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013

[17] OECD/Eurostat (2018), Oslo Manual 2018: Guidelines for Collecting, Reporting and Using Data on Innovation, 4th Edition, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing, Paris/Eurostat, Luxembourg, page 68.

[18] OECD/Eurostat (2018), Oslo Manual 2018: Guidelines for Collecting, Reporting and Using Data on Innovation, 4th Edition, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing, Paris/Eurostat, Luxembourg. https://doi.org/10.1787/9789264304604-en.

must be demonstrated (see list below on providing verifiable documentation as well as chapter 7.2 and 7.3 for more clarity on the boundary between scientific research, market activities and product development).

- Research regarding fields, that might not be thought of as health or care sector related (e.g. cosmetic surgery with no medical indication), falls within purpose (e) if the aim of the research is related to health or care sectors and contributes to public health or health technology assessments, or ensures high levels of quality and safety of healthcare, of medicinal products or of medical devices, with the aim of benefiting end-users, such as patients, health professionals and health administrators. A concrete example would be to increase the safety of cosmetic surgery.

- Studies of the development of products that are not medical devices within the meaning of the Medical Device Regulation (MDR) or in vitro diagnostic regulation fall under purpose (e), as long as the research is intended to benefit patients. Such products may include hospital operation and management systems using artificial intelligence (AI), wellness or other digital health applications.

There is still a degree of uncertainty concerning what constitutes “scientific research”, which activities do not fall under this category and for what the data may be used. A borderline case might be a project focused primarily on training an existing AI system with minimal research that would gain or verify any new knowledge. However, the project must rely on a scientific basis to be eligible for purpose (e). Whether the intended data use falls under “scientific research”, should not just be based on a self-determined check box. HDABs should assess the scope, methodology and aims of the project against the stated purpose. At the same time, it remains unclear to what extent such an assessment can be carried out without being guided by the aspect of research quality. If needed the HDAB may use external scientific advisory boards to facilitate this assessment. Future EU-level guidelines or standards may further refine the understanding of what constitutes scientific research, and the interpretation of this concept may evolve over time as the regulatory framework develops.

HDABs are responsible for assessing whether the intended use qualifies as scientific research and should indicate which documentation data users have to provide under purpose (e). Following is a list of examples of verifiable documents that HDABs may rely on in their assessment (not all documents have to be provided, but a combination might help support the assessment):

- A scientific research protocol or study plan with a documented methodology grounded in recognised scientific standards
- Pre-registration of the study or protocol
- Source of research funding (e.g., a competitive grant or institutional funding)
- Academic or institutional supervision by qualified researchers
- Approval from a research ethics committee at regional, national, or EU level
- A data management plan (DMP) specifying handling, storage, access, and reuse
- Proof of peer-review processes (e.g., project evaluation in grant applications)

7.6.4 Recommendations

- The HDABs should retain their ability to ask clarifying questions in order to determine the specific role and intended outcome/purpose of the data applicant's request for health data.
- HDABs should check the obligatory additional verifiable documentation provided by the applicant for chosen purpose (e) (e.g., research plan, funding, ethics approval if needed).
- HDABs should specifically check the description of the aim, the described methods and the expected benefits when assessing if the purpose (e) is applicable.
    - These parts of the application should give the HDAB a picture of what evidence the applicant wants to create to contribute to public health or health technology assessments, or ensure high levels of quality and safety of healthcare.
- HDABs is strongly recommended to have access to adequate expertise in various scientific methods and study design/protocols to provide advice in assessment of applications involving new data uses or application of methods. If needed assign advisory board(s) to provide current and valid knowledge on accepted scientific protocols etc.

7.7 Improvement of healthcare (Article 53(1)(f))

Access to health data is allowed for the improvement of delivery of care, optimisation of treatment, and the provision of healthcare, based on electronic health data from other individuals.

This provision includes, but is not limited to:

- Personalised medicine, where treatments are tailored based on insights drawn from broader population-level data;
- System-level improvements, such as optimising workflows, resource planning, or evaluating care models.

Both categories are within scope, as well as other categories, provided that the data use is aimed at improving care and the project is grounded in a credible methodology suitable for the intended outcome[19].

[19] Answers from DG SANTE, dated 16.5.2025 to WP 5, task 5.2.1.

While any applicants can apply for data under purpose (f), they need to show that the purpose for the application aims not at general innovation, but at targeted care improvement. This can for example be shown by the applicant themselves being a healthcare provider or public health authority or having a direct link, by providing proof that project outputs will be directly integrated into care pathways, or by involvement of clinical staff in the study or implementation phase. If an applicant has no link to a healthcare provider, then the direct clinical utility has to be sufficiently documented in the application for the data use to fall under purpose (f). AI technology can be used as a tool in projects that fall under purpose (f), but the aim cannot be AI innovation.

Examples for clarification

Rare disease case comparison: A clinician orders data with the aim to improve the treatment of an individual patient with a very rare disease. The clinician wants to gather data from databases across Europe to find out if there are similar cases/images/reports. This would fall under (f).

Clinic benchmarking: If the head of a clinic wants to compare the treatment outcomes at their clinic to the outcomes of similar patients at other clinics, hoping to learn from these comparisons and the goal of this data use is to improve their own clinic's delivery of care, with no research protocol and no intention of publishing an article in a scientific journal, then this would fall under purpose (f) and not (e).

Updating prognostic tools: The applicant has a prognostic tool that was developed using data that the applicant got access to under (e), the development falls under scientific research. Then when the applicant has rolled out the product, under purpose (f), the applicant can apply for data to update the product´s prognostic factor. The applicant can do so by using the latest available data from other patients, the data available in the health care system, if the goal of the update is to improve healthcare delivery and it does not fall under a prohibited use (see Chapter 7.2 and 7.3 for more guidance).

7.7.1 Recommendations

- HDABs shall verify whether the project is methodologically credible and whether the intended data use is plausibly and directly aimed at improving healthcare delivery, treatment optimisation, or care provision, in line with Article 53(1)(f).
- HDABs should verify the applicant's organisational affiliation. While the EHDS Regulation does not require applicants to be clinicians or healthcare institutions, a plausible connection to healthcare delivery or planning may be inferred when the applicant is clearly linked to an organisation that provides clinical care (e.g., a hospital). In other cases, a connection could be demonstrated explicitly—for example, through documentation of clinical involvement, collaboration with healthcare providers, or an implementation plan showing how the proposed activity relates to healthcare practice

8 Prohibited secondary use of health data under Article 54

This chapter outlines five categories of prohibited secondary uses under Article 54: decisions detrimental to individuals or groups, discriminatory uses based on health data, advertising or marketing, development of harmful products or services, and processing that conflicts with ethical provisions in national law.

Analyses and reflections are given on what to consider in the assessment process regarding the provisions on prohibited secondary use of health data under Article 54 and the recommendations in this section are intended to complement the general recommendations set out in Chapter 6.

HDABs should monitor and supervise compliance by health data users and health data holders with the requirements laid down in the EHDS Regulation (Article 57(1)(a)(ii)). Where an HDAB finds that a health data user or health data holder does not comply with the requirements (for example by violating Article 54), the HDAB should, amongst others, immediately take appropriate measures. For example, HDABs are empowered to impose administrative fines to a health data user processing electronic health data obtained via a data permit for the uses referred to in Article 54 (Article 63(2) and 64(5)(a)). See further forthcoming deliverable in TEHDAS2, D4.1 (see Annex 7).

8.1 Decisions detrimental to individuals or groups and disadvantaging or discriminating decisions (Article 54(a–b))

Article 54 states that, seeking access to and processing electronic health data are prohibited for certain uses. Electronic health data obtained via a data permit (under Article 68) or a health data request approved (under Article 69) shall be prohibited for the following uses:

a) taking decisions detrimental to a natural person or a group of natural persons based on their electronic health data; to qualify as ‘decisions’ for the purposes of this point, they must produce legal, social or economic effects or similarly significantly affect those natural persons;

b) taking decisions in relation to a natural person or a group of natural persons in relation to job offers, offering less favourable terms in the provision of goods or services, including exclusion of such persons or groups from the benefit of an insurance or credit contract, the modification of their contributions and insurance premiums or conditions of loans, or taking any other decisions in relation to a natural person or a group of natural persons which result in discriminating against them on the basis of the health data obtained.

According to Recital 62, any attempt to use electronic health data for measures detrimental to natural persons should be prohibited. Examples of such detrimental decisions are to increase insurance premiums, to engage in activities potentially detrimental to natural persons related to employment, pensions or banking, including mortgaging of properties, and to automate individual decision-making.

8.1.1 The concept of "discrimination"

The EHDS Regulation does not say that Article 54(b) targets discrimination under Union law (compare for example the wording in Article 10.2(f) in the AI Act).[20] However, due to the context in which the concept is used, the authors find that it is the most reasonable way to understand it.

Under EU law, it is a fundamental right not to be discriminated against. Under the EU Charter of Fundamental Rights[21] (hereinafter "the Charter") any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited. Further, within the scope of application of the Treaties and without prejudice to any of their specific provisions, any discrimination on grounds of nationality shall be prohibited (Article 21 in EU Charter of Fundamental Rights the Charter).

EU directives regarding discrimination are adopted in certain areas in society, for instance working life. One form of discrimination is "direct discrimination", which is 'taken to occur where one person is treated less favourably than another is, has been or would be treated in a comparable situation on grounds of [a discrimination ground]'. Another form is "indirect discrimination", which 'shall be taken to occur where an apparently neutral provision, criterion or practice would put persons of a [discrimination ground] at a particular disadvantage compared to other persons. Most likely, these two forms of discrimination will be relevant for the HDABs to be aware of, when investigating applications. Further guidance on how the criteria, amongst others how less favourable treatment and causation to a discrimination ground, is to be understood can be found for instance in doctrine and judgements by the European Court of Justice.

The Commission has clarified that Article 54(b) in the EHDS Regulation, the discriminatory causation is "on the basis of the health data obtained".

Operational indicators that HDABs could pay attention to are for example use of data to segment individuals by health status in pricing models, service offers, or recruitment filters. Further guidance on how to understand Article 54(b) and the concept of discrimination is needed, which is discussed in Chapter 9.

8.1.2 General reflections

It might be difficult for an HDAB to figure out if a health data user is seeking access to and will process electronic health data for a prohibited secondary use under Article 54(a) or 54(b). In most cases it will not be stated in the application. Instead, an infringement might be discovered because of an HDAB's monitoring compliance under Article 57(1)(a)(ii)) or indications from an external actor (for example from the public or media). By then, the harm for the affected individuals or groups is already done. In order to trying to mitigate such a situation, perhaps HDABs could require applicants to provide a binding declaration that the

[20] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024.
[21] Charter of Fundamental Rights of the European Union (2016/C 202/02)

data will not be used for prohibited purposes under Article 54(a–b), including profiling, scoring or automated decision-making, that leads to exclusion or discrimination.

All kinds of decision-making, both “ordinary” (no machine involved), semi-automated and automated decision-making, are covered by Article 54(a–b). The emphasis is on the impact of the decision on the data subject. A case-by-case assessment must be made, based on the application and, where applicable, complementary information. Further operational clarification for HDABS could be developed by the EHDS Board, as referred to in Recital 95).

To be able to assess if a secondary use of electronic health data is contrary to the prohibition in Article 54(a) or 54(b), HDABs must have adequate competence or have access to relevant support for the task (for example technical and legal support, including competence on data protection under GDPR).

The Commission has clarified that although parallels can be drawn with Article 22 GDPR, the scope of Article 54(a) in the EHDS Regulation is broader. Under Article 22 GDPR, only decisions based solely on automated processing that produce significant effects are restricted. Article 54 prohibits the processing of electronic health data for any decisions detrimental to individuals or groups — whether automated, semi-automated, or manual — and is not limited to specific categories of personal data. These decisions may include, for example, exclusion from services or unfair prioritisation. HDABs should therefore not assume that compliance with GDPR Article 22 is sufficient to ensure compliance with Article 54(a).

8.1.3 Recommendations

- HDABs should emphasise the impact that the decision may have on the data subject. Therefore, HDABs should assess whether the stated use case indicates such risks. For instance, HDABs may pay attention to who the applicant is, what types of decisions the project entails and whether exclusionary impacts are foreseeable.
- HDABs should make sure that applicants provide sufficient details for HDABs to be able to assess whether the use may lead to harmful or discriminatory decision-making processes.
- Examples of red flags are:
    - Risk-scoring tools with individual-level consequences (for example exclusion from services, automated triage systems).
    - Automated profiling for eligibility in health insurance or access to services.
    - AI systems that produce binding clinical decisions without human oversight

8.2 Marketing activities (Article 54(c))

Access to and processing of electronic health data for carrying out advertising or marketing activities is prohibited under Article 54(c). Recital 62 clarifies this by stating that any attempt to use such data for measures detrimental to natural persons, such as to advertise products should be prohibited. This prohibition applies to all target audiences, not only health professionals or healthcare organisations, marking a broader scope compared to the original proposal. and it should be noted that the proposal has highlighted commercial advertising as example of prohibited data use.[22] Despite this, the prohibition does not target commercial activity as such, but specifically promotional and marketing uses.

In Article 2(a) of Directive 2006/114/EC, advertising is defined as "the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations". Recital (4) of Directive 2006/114/EC says that advertising, whether or not it induces a contract, affects the economic welfare of consumers and traders.[23] Marketing is often used as a broader umbrella term covering, alongside advertising, activities such as market analysis, branding, pricing strategies and customer engagement.

8.2.1 General reflections and practical boundary-setting

In practice, activities related to research, innovation, and product development may resemble marketing in terminology or methods, particularly in areas such as post-market surveillance, evidence generation or health campaigning. Such proximity does not in itself render these activities prohibited.

The decisive distinction lies in whether electronic health data are used to promote goods or services or to advance the commercial interests of a particular undertaking, or whether they are used to support scientific understanding, regulatory evaluation or public-interest objectives. Activities in the latter category do not constitute marketing merely because they involve communication, campaigns, or commercially relevant contexts. In practice, HDABs should focus on how the data will be used, rather than on the nature of the actor (public or private), the tools applied (advanced analytics or AI), or the possibility that research outcomes may later support commercial activities.

Example: A pharmaceutical company requests data on medications (e.g., ATC codes) prescribed by doctors in hospitals within a specific ICD-10 category, with the intention of marketing its products to doctors in hospitals where prescription rates are low. This is prohibited, as the data are used to identify targets and steer promotional strategies. By contrast, the same company may request the data to analyse treatment patterns and variability across healthcare systems, with the aim of improving or developing a new medicine. In this case, the data are not used for promotional outreach, and the immediate purpose of the analysis is scientific or developmental rather than promotional. Such use may

[22] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space COM/2022/197 final, page 19.
[23] Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (codified version)

fall within permitted secondary use under Article 53, provided that appropriate safeguards are in place and the data are not subsequently used for advertising or marketing purposes.

Prohibited activities (high signal)

The following uses of electronic health data are not permitted under Article 54(c), regardless of whether data are anonymised, aggregated or pseudonymised:

- Targeted advertising or profiling. *Example: Identifying healthcare professionals who frequently treat a specific patient group, to invite them to a sponsored event*.
- Product promotion disguised as research. *Example: An observational study is conducted using health data, but the main deliverables are marketing narratives, value propositions or sales decks rather than scientific publications or regulatory submissions.*
- Pricing or reimbursement strategy development. *Example: Using treatment and utilisation data primarily to test pricing scenarios or maximise commercial return, rather than to inform HTA or reimbursement decisions under public oversight.*
- Customer or market segmentation. *Example: Segmenting patient populations or care providers based on health data to focus marketing resources on the most commercially attractive segments.*
- Reuse beyond the scope of the permit. *Example: Data accessed for scientific research are later reused to inform marketing strategies, promotional targeting or sales planning.*

Any such use constitutes a breach of Article 54(c), even where the initial data access was granted for a permitted purpose.

Permissible neighbouring activities (often confused with marketing)

Certain activities may resemble marketing in terminology, methods or tools, but do not constitute marketing under Article 54(c).

For example, the following activities may be permissible;

- *Real-world evidence and medical research activities*, even where results may later inform product development or regulatory decisions. On the other hand, objectives such as “consumer insights”, “market positioning” or “user testing” without a clear scientific protocol or public-interest rationale should raise concerns.
- *Health economics and outcomes research* (HEOR);
- *Medical affairs and non-promotional medical education*, where secondary analyses of health data are used to generate and disseminate scientific or clinical knowledge, provided that dissemination is not designed to promote specific products or services.
- *Health technology assessment*, reimbursement and market access–related analyses, where health data are used to support public-interest evaluation of value, effectiveness or cost-effectiveness under regulatory or HTA frameworks, rather than to optimise commercial pricing or sales strategies.

- *Public-interest information and prevention campaigns*, where aggregated health data are used to identify population-level needs (e.g., regions or age groups with increased disease burden) in order to design targeted public health or harm-reduction interventions, provided that the data are not used for individual profiling or commercial promotion. Projects framed as quality improvement may become promotional if results are selectively communicated to enhance reputation or market position.
- *AI training and evaluation for scientific or healthcare innovation,* including model development, validation and bias testing, where electronic health data are not used to generate outputs for marketing, profiling, targeting or commercial optimisation.

Evaluating the purpose, focus, timing, and how the data are used helps the HDAB to determine whether the intended use is permitted or prohibited. Ultimately, the health data user bears the final responsibility for ensuring compliance.

8.2.2 Recommendations

- The immediate purpose of access shall not be advertising or marketing.
- Function of data use shall not be targeting, profiling, segmentation, or commercial optimisation.
- Outputs shall not include marketing materials, sales strategies, or pricing tools.
- Initially permitted accessed data shall not be reused later for advertising or marketing.
- Assessment shall focus on the actual use of the data, not (only) on the terminology, actor, methods (e.g., AI), or potential commercial benefits.

8.3 Developing harmful product or service (Article 54(d))

It is prohibited to apply for, grant access to, or process electronic health data for the purpose of developing products or services that may harm individuals, public health or society at large. Harmful products or services include, in particular, illicit drugs, alcoholic beverages, tobacco and nicotine products, weaponry, and products or services designed or modified in a manner that creates addiction, undermines public order or poses a risk to human health. The list is non-exhaustive and should be interpreted contextually in light of the intended use of the data.

Recital 62 further clarifies that any attempt to use electronic health data to develop harmful products should be prohibited.

Situations may arise where the declared purpose under Article 53 appears legitimate, yet the foreseeable downstream use of the data could conflict with Article 54(d). In such cases HDABs shall assess whether the stated purpose is specific, proportionate and consistent with the applicant's profile (Article 68(1)(a-b)), the context of the data use, purpose of the project, and the documentation of the application, as well as the foreseeable downstream use of the data.

8.3.1 General reflections

HDABs shall carefully scrutinise applications to ensure that electronic health data are not made available for purposes that may facilitate the development, optimisation or market expansion of a harmful product or service. In this assessment, HDABs should verify that the declared purpose is clear, specific, internally consistent and aligned with the applicant's profile and activities. As prohibited purposes of data use are unlikely to be explicitly stated, the assessment should consider the substance of the project, including methodology, expected outputs and practical effects. The assessment should determine whether the intended use, including any reasonably foreseeable downstream use of the data, could contribute to the development or strengthening of a harmful product or service.

Particular caution is required where the stated aim is to "improve" products that remain inherently addictive or harmful. Risk reduction that preserves core harmful characteristics may still fall within Article 54(d). HDABs shall determine whether the proposed use genuinely reduces harm or instead reinforces harmful markets.

Where necessary, additional documentation should be requested. HDABs should not rely solely on the applicant's declared purpose where risk indicators are present. If, after clarification, uncertainty remains, a precautionary approach should be applied. Any credible risk of supporting product design, refinement or market expansion of inherently addictive or harmful products or services may lead to a data permit refusal.

8.3.2 Examples under Article 54(d)

In practice, it may be difficult for an HDAB to distinguish, on the basis of the application, whether there is a risk that the data could be used for prohibited purposes. The examples below illustrate prohibited uses, borderline cases requiring strict scrutiny, and uses not constituting development of a harmful product or service.

Examples of prohibited uses

- *Tobacco product optimisation* - A tobacco manufacturer applies for access to electronic health data concerning smoking-related morbidity, cessation outcomes and patterns of nicotine dependence. The project is described as aiming to "improve product safety and consumer experience." The methodology includes behavioural segmentation, modelling of nicotine absorption patterns and analysis of user retention.

Although certain elements are framed as risk reduction, the expected outputs include refinements to nicotine delivery systems and product design features intended to sustain consumption and strengthen market competitiveness.

In substance, the project supports the optimisation of an inherently addictive tobacco product. The functional direction of the data use is product enhancement rather than public health improvement.

This constitutes development or optimisation of a harmful product within the meaning of Article 54(d).

- *Vaping product enhancement* - A vaping company requests access to respiratory health data and nicotine dependence profiles to redesign heating mechanisms and "reduce carcinogenic exposure." The project includes analysis of consumption intensity and user satisfaction metrics to improve sustained usage.

  Even if certain toxicological components are reduced, the product remains a commercially positioned addictive nicotine delivery device. The data are used to refine and strengthen the product's market viability and user retention.

  Reducing isolated risks while preserving core addictive characteristics does not remove the product from the scope of Article 54(d). The project contributes to strengthening an addictive market and falls within the prohibition.

- *Gambling service optimisation* - An online gambling operator applies for access to health data on mental health conditions, addiction indicators and behavioural risk patterns. The project proposes predictive modelling to "better understand user engagement and behavioural dynamics."

  The methodology includes vulnerability profiling, segmentation and modelling of engagement cycles. Although the application does not explicitly mention marketing or targeting, the outputs could enable optimisation of game mechanics, personalised engagement strategies and sustained user participation.

  Where the functional direction of the project is to refine or expand gambling services by leveraging behavioural vulnerabilities, the development concerns a service that may create addiction and public health harm. Such use falls within the scope of Article 54(d).

Examples of borderline case requiring strict scrutiny

- *Development of a ketamine-based treatment* - A pharmaceutical company applies for access to electronic health data to develop a ketamine-based treatment for severe, treatment-resistant depression. Ketamine is associated with abuse potential and risk of dependency, which may raise concerns under Article 54(d) in relation to products capable of creating addiction.

  The project is conducted under the Clinical Trials Regulation, with ethics approval and within the pharmaceutical regulatory framework. The objective is to obtain marketing authorisation for a prescription-only medicinal product, subject

to strict safety evaluation, controlled distribution and pharmacovigilance obligations.

HDABs should assess whether the data use genuinely supports regulated therapeutic development with appropriate safeguards to manage addiction risk, or whether it could facilitate the broader commercialisation or non-therapeutic expansion of a substance with dependency potential.

Where the activity clearly constitutes regulated medicinal product development aligned with public health objectives and includes safeguards addressing misuse and addiction risk, it does not amount to the development of a harmful product or service within the meaning of Article 54(d).

Examples of uses not constituting development of a harmful product or service

- *Public health smoking cessation programme* - A public hospital requests aggregated electronic health data to evaluate the effectiveness of smoking cessation interventions across demographic groups. The objective is to improve clinical protocols and allocate preventive resources more effectively.

  The project does not involve product design, nicotine optimisation or market expansion. The outputs consist of public health recommendations and revised treatment guidelines aimed at reducing tobacco use and associated morbidity.

  Because the purpose is to prevent and reduce harm, rather than to develop or enhance tobacco or nicotine products, the activity does not constitute development of a harmful product or service within the meaning of Article 54(d).

- *Regulated digital therapeutic for gambling addiction* - A company applies for access to electronic health data relating to gambling-related harm and addiction patterns. At first glance, the reference to behavioural modelling and engagement analysis may resemble optimisation techniques used by gambling platforms.

  However, the purpose is to develop a digital therapeutic qualifying as a medical device under Regulation (EU) 2017/745 for the treatment of gambling addiction. The project is subject to clinical evaluation, ethics approval and regulatory oversight, and must demonstrate safety, effectiveness and therapeutic benefit.

  Although behavioural modelling techniques are used, the functional direction of the data use is treatment and harm reduction. The project does not support the optimisation, expansion or strengthening of gambling services.

  Where the regulatory status and safeguards are clearly established, the activity does not constitute the development of a harmful product or service within the meaning of Article 54(d).

8.3.3 Recommendations

- HDABs should take into account the applicant's sector, core business and commercial context when assessing risks under Article 54(d). Enhanced scrutiny is warranted where the applicant operates in sectors associated with significant public-health risks, where its core activities involve inherently addictive or harmful products or services, or where the project is funded or strategically supported by actors active in such sectors. While the identity of the applicant alone is not determinative, it constitutes a relevant contextual risk indicator.
- HDABs should assess the purpose and functional direction of the project to determine whether, even if framed under an allowed purpose, it may lead to outcomes falling within Article 54(d). The assessment should examine whether the expected outputs and methodology support the design, refinement or market positioning of harmful products or services. Particular scrutiny is recommended where projects are presented as "harm reduction" or "product improvement" while addictive or harmful characteristics remain inherent to the product or service.
- HDABs should assess whether the proposed data use may reasonably enable downstream or indirect contributions to harmful product or service development beyond the immediate project scope. This includes examining whether the data could be repurposed within a corporate group, incorporated into broader product strategies, or used to generate insights transferable to harmful products or services.
- HDABs should recognise that certain projects may initially appear to fall within the scope of Article 54(d), particularly where they involve substances, technologies or behavioural mechanisms associated with addiction or public-health risks. However, where the development concerns a medicinal product or medical device carried out within a recognised regulatory framework, and is subject to ethics and clinical oversight with a demonstrated therapeutic objective and positive benefit–risk balance, the activity does not constitute the development of a harmful product or service.

  Similarly, projects aimed at preventing or reducing harm at population level—such as public health interventions targeting addiction or harmful consumption—fall outside Article 54(d) where they do not support product optimisation or market expansion.

8.4 Ethical provisions under national law (Article 54(e))

It is prohibited to seek access to and process electronic health data for purposes that conflict with ethical provisions laid down in national law. With the exception of ethical provisions relating to consent to the processing of personal data and provisions relating to the right to opt out since the EHDS Regulation takes precedence over the national law (Article 54(e) and Recital 62).

Before granting access to electronic health data, the HDAB must assess whether all applicable criteria are met. As part of the application, the applicant shall give information on any assessment of ethical aspects of the processing required under national law, which may serve to replace the health data applicant's own ethical assessment (Article 67(2)(j)). The HDAB must then assess whether this information complies with national law before issuing a data permit (Article 68(1)(f)).

For further guidance, see the Guideline for data users on good application and access practice (See D6.2 Annex 7) and Guideline for HDABs on the procedures and formats for data access (See D6.3 Annex 7).

According to Recital 73, an ethical assessment could be requested based on national law. In that case, it should be possible for existing ethics bodies to carry out such assessments for the HDAB. Existing ethics bodies of member states should make their expertise available to the HDABs for that purpose. Alternatively, member states should be able to provide for ethics bodies to be part of the HDAB.

Further, in Recital 83, it states that the authorisation process to gain access to personal electronic health data in different member states can be repetitive and complex for health data users. Whenever possible, synergies should be established to reduce the burden and barriers for health data users. One way to achieve that aim is to adhere to the 'single application' principle whereby, with one application, the health data user can obtain authorisation from multiple HDABs in different member states or authorised participants in HealthData@EU.

8.4.1 General reflections

Across the EU, there are significant differences in how ethical review is organised at national level and in whether ethical approval is required at all for secondary use of electronic health data. While there is broad agreement that medical research and invasive clinical testing require ethical approval by a medical ethics body, practices vary considerably for non-medical research, for example survey studies, which deal with sensitive questions or use of data (rare diseases, sensitive data etc.). Thus, whether an ethical review is needed differs substantially between member states and countries, and applicants' own ethical assessments cannot generally substitute for formal review where it is required by law. In other words, the applicant must comply with the requirements laid down in the national law and the HDAB must be able to assess whether these requirements have been obeyed. The same applies to multi-country applications, each national law needs to be obeyed.

So far, it has not been defined how the support to the HDABs should be organised across the member states, in order to tackle juridical or ethical problems. It has only been stated that, member states are required to ensure that each HDAB is provided with adequate human resources, along with the necessary expertise (55(2)). This should be seen as ensuring structured access to appropriate legal and ethical expertise for the HDABs who do not possess internally the required expertise. Such access enables HDABs to determine whether an ethical review is required under applicable national law and to substantively evaluate any information on ethical aspects of the processing provided by the applicant pursuant to Article 67(2)(j), in accordance with Article 68(1)(f). Access to legal and ethical expertise is particularly important in grey or borderline cases, where national requirements for ethical review are unclear, where no formal ethics review is legally required but ethical considerations remain relevant, or where applicant-provided ethical self-assessments, where included, raise potential concerns or red flags that need to be understood and taken into account as part of the overall assessment.

While the EHDS does not require applicants to submit an ethical self-assessment, applicants may voluntarily include ethical considerations as part of their project documentation, such as research plans or DMPs. Possessing or having access to ethical expertise allows HDABs to meaningfully evaluate such information as contextual input, supporting the assessment of safeguards, proportionality, and compliance with ethical provisions under national law, as well as the credibility of the claimed purpose under Article 53. Ethical expertise in this context does not replace ethics review required by national law, nor does it create a new obligation to conduct ethical assessments but supports informed and consistent decision-making within the limits of the EHDS framework.

Accordingly, while the EHDS does not harmonise ethical review requirements or mandate ethical assessments in all cases, HDABs should be able to identify and assess relevant ethical aspects where necessary to ensure that access to electronic health data does not conflict with ethical provisions laid down in national law.

In conclusion, whether an ethical review is needed, is based on the national law of the HDAB that receives the application. The EHDS does not harmonise the ethical review process or anything else relating to it. Thus, definitions, procedures etc. are based on national law and are not defined within this guideline. Furthermore, a single application for the ethical reviews in multi-country applications is not currently possible. On the other hand, the EHDS speaks on behalf of single application (Recital 83), and ways to execute a single application approach without harmonising national laws is possible. In any case, further guidance on when and how an applicant needs to apply for an ethical review in which country needs to be provided for the applicants on the EU level. These matters have raised a lot of comments during the public consultation and will be more thoroughly discussed in Chapter 9, Areas for further exploration.

8.4.2 Recommendations

- HDABs should be able to identify and take into account relevant ethical aspects as part of their overall assessment under Article 54(e), including evaluating any ethical self-assessment voluntarily provided by the applicant.
- When electronic health data are requested from multiple member states, the applicant must comply with the national law of each concerned member state, and each HDAB assesses the application in accordance with its own national legal framework.
- HDABs should have access to appropriate legal and ethical expertise, internally or via existing ethics bodies, to determine whether an ethical review is required under national law and to support decision-making in legally or ethically complex cases, including grey or borderline scenarios. Member states are encouraged to provide structured access to ethics bodies or advisory services to support both applicants and HDABs, especially in cases involving complex or non-medical studies.
- HDABs should ensure that clear, accessible information on national ethical assessment requirements is available to applicants, including for example, when an assessment is required, how to obtain it, required documentation, timelines, language and format rules, responsible authority and contact details, legal basis, appeal procedures, and interactions with other assessments (e.g. Data Protection Impact Assessments, DPIAs).
    - While member states are responsible for ensuring that this information exists, HDABs should provide or facilitate access to it before and during the application process.
- Where national law requires an ethics review, the applicant is responsible for obtaining it. The HDAB must ensure that the applicant provides proof that the approval is in place
- HDABs should be able to identify and take into account relevant ethical aspects as part of their overall assessment under Article 54(e), including evaluating any ethical self-assessment voluntarily provided by applicants.

8.5 Potential risk factors

Each application for access to health data must be assessed individually and proportionately, taking into account its specific context, safeguards, and demonstrated societal benefit, while avoiding systematic bias against particular applicant types or sectors.

The following list provides non-exhaustive examples of general "warning signs/red flags" that may indicate that further investigative measures would be advisable

- Applicant background and governance: known past violations, non-compliance, or involvement in unethical or harmful activities.
- Commercial incentives and research credibility: funders or commercial partners requiring access to raw data or exerting influence over analysis or outputs.
- Sensitive populations and high-risk data: processing involving sensitive or vulnerable populations without clearly demonstrated safeguards or proportionality.
- AI- and profiling-related risk: references to market testing, consumer insight, behavioural targeting, development of risk-scoring tools with individual-level consequences, automated profiling for eligibility, pricing, or access to insurance or services or AI system intended to produce binding or operational decisions without meaningful human oversight that could cause harm.

Anonymisation and re-identification risks: availability or additional datasets that could undermine claimed anonymisation or requests that increase the risk of re-identification through linkage or uniqueness of records."

9 Intellectual property rights and trade secrets (Article 52(3))

The provision in Article 52 in the EHDS Regulation targets the protection of IPR and trade secrets when electronic health data are made available under the EHDS Regulation. Further, Article 1(3) states that the EHDS Regulation is without prejudice to, amongst others, the Directive (EU) 2016/943 on undisclosed know-how and business information[24].

Article 52(3) does not concern the allowed purposes and prohibited secondary use in Articles 53 and 54, but rather the conditions and limitations under which data are made available. However, Directorate-General for Health and Food Safety (DG SANTÉ) has during the work with this guideline highlighted that HDABs are responsible for assessing applications and ensuring that data access is lawful, proportionate and secure, why it is important that HDABs are aware of how Article 52(3) may intersect with their role, in particular when:

- Evaluating whether specific data fields should be withheld or anonymised due to trade secrets;
- Ensuring that the data permit explicitly reflects any limitation imposed by the health data holder;
- Responding to health data users' questions about permitted reuse or the handling of sensitive commercial information.

Therefore, Article 52(3) is mentioned in this guideline.

The regulation states that HDABs shall take all specific appropriate and proportionate measures, including legal, organisational and technical measures, they deem necessary to protect the intellectual property rights, trade secrets or the regulatory data protection right laid down in Article 10(1) of Directive 2001/83/EC[25] or Article 14(11) of Regulation (EC) 726/2004[26]. HDABs shall remain responsible for determining whether such measures are necessary and appropriate (Article 52(3)).

Directive 2001/83/EC, Article 10(1), governs the re-use of toxicological and clinical trial data in the context of marketing authorisation for generics, with specific protection periods. These provisions serve as reference points for determining the regulatory data protection that HDABs must take into account under Article 52(3).

The reference to Article 14(11) of Regulation (EC) 726/2004 (dealing with authorisation and supervision of medicinal products for human use), defines the data and market protection periods for medicinal products authorised in accordance with that same regulation.

According to Recital 60 of the EHDS Regulation, electronic health data protected by intellectual property rights or trade secrets, including data on clinical trials, investigations and studies, can be very useful for secondary use and can foster innovation within the Union for

[24] Directive (EU) 2016/943 of the European Parliment and of the Council of 8 June 2016. On the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure

[25] Directive 2001/83/EC of the European Parliment and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use: Directive - 2001/83 - EN - EUR-Lex

[26] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures.

the benefit of Union patients. In order to incentivise continuous Union leadership in this domain, it is important to encourage the sharing of clinical trials and clinical investigations data through the EHDS for secondary use. Clinical trials and clinical investigations data should be made available to the extent possible, while taking all necessary measures to protect intellectual property rights and trade secrets. EHDS Regulation should not be used to reduce or circumvent such protection and should be consistent with the relevant transparency provisions laid down in Union law, including for clinical trials and clinical investigations data. HDABs should assess how to preserve such protection while enabling access to such data for health data users to the extent possible. If an HDAB is unable to provide access to such data, it should inform the health data user and explain why it is not possible to provide such access. Legal, organisational and technical measures to protect intellectual property rights or trade secrets could include common electronic health data access contractual arrangements, specific obligations within the data permit in relation to such rights, pre-processing the data to generate derived data that protect a trade secret but nonetheless have a utility for the health data user or configuration of the secure processing environment (SPE) so that such data are not accessible to the health data user.

Health data holders must notify the HDABs if their dataset contains information covered by IPR or trade secrets, either when submitting the dataset description for inclusion in the dataset catalogue or later when a permit or request for such data are issued (Article 52(2)).

HDABs are then responsible for ensuring that all necessary and adequate safeguards are imposed to preserve the confidentiality of IPR, under Article 52(3). Hence, the assessment also includes taking into account the relevant rights of both the health data holder and health data user (Article 57(1)(c)).

When it comes to IPR and trade secrets, it is important to read the whole of Article 52 in its entirety, in particular 52(3) and 52(4) need to be read together. However, only Article 52(3) is included in Task 5.2.1 scope.

9.1.1 General reflections

If HDABs conclude that there are insufficient safeguards to protect IPR or trade secrets, it may reject the permit application on these grounds (Article 52(5)).

The practical implementation of Article 52(3) by member states remains unclear, with few concrete examples available despite the efforts of this guideline. Workshop discussions did not yield additional examples beyond those already mentioned in Recital 60. To support implementation, further clarification and experience-sharing — particularly through continued exchanges between HDABs and health data holders — may be necessary to develop a library of viable practices. Further, operational clarification could be developed by the EHDS Board, as referred to in Recital 95.

9.1.2 Recommendations

- HDABs should always specifically consider if the data is limited according to Article 52(3) and whether measures are needed to protect IPR and trade secrets, before granting a data permit.
- HDABs should verify that the dataset description includes explicit notice from the health data holder if any data fields are covered by IPR or trade secrets, in accordance with Article 52(2).
    - For further guidance on the assessment, step by step, see Guideline for HDABs on the procedures and formats for data access. (See Annex 7 D6.3)
- HDAB should investigate the meaning of legal, organisational or technical protection measures in order to find applicable practical examples, as well as what are considered sufficient protective measures in terms of IPR and trade secrets.
- Develop a checklist that includes a summary of actions HDABs have to take when handling IPR and trade secrets.

10 Areas of further exploration

The following sections include questions and matters that still need further refinement in order to be used in practice as a recommendation. For instance, it includes processes, procedures and systems in need of clarification. The content of this section has not been an issue for the major contributor team but require further analytical consideration and are therefore explicitly flagged to the European Commission.

10.1 Continuous alignment between HDABs on the assessment

The work of this task regarding Articles 53, 54 and 52(3) should not end with the finalisation of this deliverable. A review needs to be done by the organisation responsible for revising the relevant information in the guideline, after the experiences received during the work with allowed purposes and prohibited secondary use. One example raised by the public consultation illustrates this need: the intentionally wide definition of "scientific research" (see Annex 6 Recital 61), where early EHDS implementation would benefit from continued alignment and exchange between HDABs on assessment practices, helping to translate this broad interpretation into more consistent and actionable procedures.

Further, it has emerged that it is difficult for member states to apply Article 52(3) in practice, above all there is a lack of clarification and examples regarding safeguards/what type of safeguards are sufficient based on different situations. EHDS Regulation does not give concrete information about this, apart from a few examples in Recital 60 (seeee Annex 6).

The question remains by whom this review should be done, e.g., the central HDAB, a cooperation between coordinating HDABs in each country, or a possible secondary use subgroup of the EHDS Board, and how it should be done. It is crucial that the information is updated and revised yearly to maintain its validity also in the future. Thus, it is a governance gap to be fixed.

10.2 Standard European procedure regarding the HDAB's assessment

Voluntary convergence on application assessment procedures across member states may begin through collaborative forums such as the HDABs Community of Practice, which is already mandated to promote best practices. Standard European procedures and corresponding guidelines for HDABs are not formally established at this stage, but practical alignment can be encouraged by developing shared examples, reference tools or informal "gold standards". The HDABs Community of Practice could serve as a starting point and valuable mechanism for this. The outcomes of the Community of Practice should be documented in written form, ideally as a guideline that is reviewed and updated annually by, for example, a potential secondary use subgroup of the EHDS Board, given that the Community of Practice is only a temporary structure. If such a subgroup is not established, or lacks the necessary resources or mandate, an alternative mechanism for regular review and adjustment will need to be put in place. As this review mechanism is not explicitly foreseen in the regulation, it constitutes a governance gap that should be addressed.

However, it should be acknowledged that no best practice can fully capture all scenarios, particularly given that each use case may raise unique risks of prohibited secondary uses.

Therefore, extreme clarity must be applied when articulating assessment expectations, procedures, and responsibilities.

10.3 Need for operational guidance on Article 52(3), IPR and trade secrets

Public consultation feedback clearly demonstrates that there is currently no harmonised or sufficiently operational framework to support HDABs in assessing and safeguarding IPR and trade secrets in accordance with Article 52(3). Respondents stressed that critical gaps prevent consistent and fair evaluations across member states, including:

- The absence of shared definitions for data types typically subject to IPR or trade secret protection;
- The lack of standardised methods for risk profiling, redaction, creation of derived datasets, and data minimisation relevant to trade secret protection;
- Insufficient clarity on minimum legal, organisational, and technical safeguards required in SPEs;
- Unclear criteria for determining when a dataset presents a 'serious risk' to protected rights under Article 52(5);
- Missing EU-level templates for IPR and/trade secrets declarations by data holders;
- Limited guidance on how HDABs should involve data holders or rights owners in the assessment process without creating additional exposure of sensitive information;
- A lack of harmonised mechanisms for dispute resolution when data holders challenge access decisions.

These challenges arise precisely in the context where Recital 60 envisions proportionate safeguards—contractual terms, pre-processing/derivation, and tightly configured SPEs — and where, if a serious risk remains after applying such measures, Article 52(5) requires refusal.

To ensure a balanced application of Article 52(3) that protects innovation while enabling secondary use of electronic health data, there is a clear need for the EHDS Board to develop EU-level standards, procedural guidance, and shared safeguards. These elements should be revised periodically and integrated into HDAB operational practice. While safeguards will always need to be tailored to the specifics of each case, it will be essential that forthcoming guidance provides clarity on the principles and assessment criteria HDABs should apply when determining whether the proposed protective measures are sufficient.

10.4 Arrangement of ethical and legal support in the HDABs assessment process

HDABs are expected, under the EHDS Regulation, to possess or have access to sufficient legal and technical expertise in-house to carry out their assessment tasks in accordance with Articles 53, 54 and 52(3) (see Article 55(2)). This includes the ability to identify when a request may trigger concerns regarding prohibited secondary use.

However, national law may impose ethical assessment obligations in specific cases. In line with Article 67(2)(j) and Recital 73, Member states retain full competence over ethics

provisions and are responsible for organising appropriate support mechanisms. These may include:

- ensuring HDABs have access to national ethics bodies, or
- embedding ethical expertise within the HDAB, with clear links to existing ethics review structures.

That said, not all aspects of Article 54 involve ethical considerations — some prohibited uses relate to discrimination, marketing or harmful products. Therefore, it should not be implied that ethics review alone can safeguard against all breaches of Article 54. Instead, HDABs must ensure that their legal assessment procedures are robust and clearly documented, and that roles and responsibilities are properly delineated.

In the longer term, it may merit discussion whether a centralised EU-wide ethics body would be beneficial. Such a body could be composed of ethics experts from each Member State and serve several important functions. It could act as an information hub, providing clear guidance to applicants on how ethical assessment is conducted in each country, what documentation is required, and how to comply with national procedures. Additionally, it could advise on country-specific ethical requirements, helping ensure that national rules are respected while streamlining the experience for applicants navigating a fragmented legal and ethical landscape.

Over time, the body could also evolve to take on a more operational role, carrying out ethical assessments itself. With representation from national experts, it would be well-positioned to offer country-specific evaluations, ultimately serving as a centralised, ‘single application’ solution for ethical review across the EU. Another possible approach would be for such a body to function as a central contact point between applicants and the relevant national bodies responsible for ethical review or approval, regardless of their institutional form. Through this model, applicants could submit ethical review requests for multiple countries via a single interface, with the body coordinating information exchange and correspondence with the competent national entities in each country.

However, while the idea of such an EU-level support service may merit discussion in the future, it goes beyond the current scope of the EHDS Regulation and this deliverable. Thus, instead of a recommendation this is a suggestion for future policy discussions.

For now, clarity is needed on how each country ensures that HDABs are equipped to deal with legal and ethical complexity in line with national frameworks. Furthermore, the Commission and/or the EHDS Board should be prepared for situations in which countries cannot adequately resource their HDABs due to financial or staffing constraints.

Given the current possibilities, a viable solution would be to map and compile national ethical requirements and make them publicly accessible via the EHDS Board or HealthData@EU. This would support transparency for data users and HDABs.

10.5 Automated decision-making and other decisions detrimental to individuals or groups

According to Article 54(a) and Recital 62, automated decision-making can be detrimental to or discriminatory against individuals and if so, seeking access to or processing of electronic health data for such uses are prohibited under the EHDS Regulation. Not only does this require HDABs to have relevant competence to make a correct assessment of such systems and uses; it also raises questions on how far an HDAB must go in its investigations to be able to assess a potential prohibited use.

Further, in situations involving AI and automated decision-making, it is not clear from the EHDS Regulation if HDABs are to demand transparency and other possible characteristics – depending on the nature of the AI system, innovation et cetera – from the health data user (Article 54 (a–b)). However, for AI systems suspected of being used in violation of Article 5 of the AI Act (Prohibited AI practices), HDABs ought to require satisfactory information to ensure that the data made available is not used to develop prohibited systems and practices. Therefore, in relevant situations, complementary checks can be made in the review process under Article 54(a). Information on how HDABs can act in their review process might be received if, as under Article 57(2)(c), the HDABs cooperate with national competent authorities under the AI Act. Further, operational clarification could perhaps be developed by the EHDS Board, as referred to in Recital 95.

10.6 Building a monitoring system for identifying possible misuse

Nationally this could be a separate part or a department of an HDAB that conducts random or systematic audits to ensure health data users have used health data only as permitted and not for prohibited purposes. In the case of multiple HDABs, this responsibility could be allocated, based on Article 55(1) of the EHDS Regulation to a single HDAB, not necessarily to the coordinator one, to avoid duplication of resources and to enhance the quality and consistency of the assessment.

Instead of assigning numerical scores, a voluntary, qualitative risk rating could be introduced based on monitoring outcomes, allowing HDABs to better assess potential risks while respecting transparency, proportionality, and data protection rights. Other HDABs could refer to an existing qualitative risk rating when evaluating the likelihood of prohibited data use under Article 54.

It should be considered that it is difficult for the HDABs to find misuse, and usually only significant or systematic violations can be identified. Experience from some Member states shows that restrictions on data use may be deliberately circumvented through formally compliant but substantively misleading applications. Illustrative examples include studies presented as research into the causes of cancer that were later found to be conducted by entities linked to the tobacco industry, or projects framed as “post-COVID” research with no genuine connection to COVID-19, primarily intended to gain access to restricted datasets. These examples highlight the limits of ex post detection and the importance of robust preventive and monitoring mechanisms.

By contrast, existing data access platforms demonstrate that layered safeguards can reduce the risk of inappropriate use. Such approaches include requiring a detailed research proposal with clearly defined questions and analysis plans, involving qualified statisticians in the review and execution of analyses, binding data use agreements that strictly define permitted uses, and public disclosure of approved analyses and outcomes. Together, these measures combine upfront scrutiny, contractual obligations, and transparency to strengthen accountability and reduce the risk of misuse.

Furthermore, the EHDS Regulation does not specify how long HDABs should have a monitoring function. The necessary monitoring timeframe may depend on the type of health data user (e.g., a cigarette company that might use the information to make its products less carcinogenic but still addictive, versus a university hospital posing lower risks), the nature of the health data, and the claimed usage.

Finally, the possibility of establishing a European-level follow-up mechanism is flagged as a suggestion for future policy discussions beyond the scope of the current EHDS Regulation. This could be considered either instead of, or in addition to the described national mechanism.

10.7 Considerations for the EHDS Board

Sections 9.1–9.6 describe a set of unresolved interpretative and procedural issues that are likely to lead to divergent practices among HDABs if addressed only at national level. Several of these matters fall outside the scope of this guideline; the suggestions below are therefore not recommendations within our mandate, but indicate areas where the EHDS Board may wish to consider further work in order to support the next steps in the implementation of secondary use under the EHDS.

In line with Articles 92–94 of the EHDS Regulation and Recital 95, the EHDS Board may consider:

- Supporting continuity of guidance, including mechanisms for regular review and updating of non-binding interpretative materials related to Articles 53, 54 and 52(3), for example to reflect implementation experience or recurring assessment challenges identified by HDABs.
- Facilitating convergence of interpretation, where recurring uncertainties emerge in HDAB assessments, for example through shared examples, indicators or reference materials addressing borderline cases such as innovation versus marketing, automated decision making or harmful product development.
- Consolidating emerging practices, by capturing lessons learned from Communities of Practice or similar forums and making them accessible in a durable form, such as periodic summaries of good practices or common assessment approaches.
- Improving transparency of supporting frameworks, in particular by enabling access to high level information on national ethical and legal requirements relevant to secondary use, especially in cross border or multi country application contexts.
- Providing a forum for reflection and learning, including experience sharing on monitoring, enforcement and potential misuse of health data, without presuming future policy or legislative action.

11 Annexes

Annex number	Annex title
1	Methodology
2a	Public consultation summary
2b	Examples from Public consultation
3	User journey
4	Glossary
5	Figure 1 enlarged with questions
6	Links to relevant EHDS articles and recitals
7	Short summary of deliverables or ongoing work in TEHDAS2

Annex 1 Methodology

The guideline is based on working group discussions (online meetings), individual desk research, expert interviews and results from discussions in three separate workshops with open participation from relevant stakeholders. The examples in this document are drawn from the work of the expert group, workshops, and public consultations.

Workshops and discussion

The workshop series was led by the major contributors in task 5.2.1, namely the Swedish e-health Agency (SEHA), the Swedish National Board of Health and Welfare (NBHW), the Danish Health Data Authority (DHDA), the Finnish Institute for Health and Welfare (THL), the Austrian National Public Health Institute (GÖG) and the Technology and Methods Platform for Networked Medical Research e.V. (TMF).

The TEHDAS2 community along with other stakeholders and external experts were invited for discussion. Professional representatives have included legal and technical expertise concerning health data infrastructure and health data policy from member states as well as non-member states. These include future key stakeholders such as health data holders, HDABs and health data users. In addition, international organisations such as the World Health Organisation (WHO), the European Commission, Eurostat, the Commission's Health and Digital Executive Agency and the OECD also participated. The countries that were represented in the workshops included Sweden, Austria, Denmark, Finland, Belgium, Spain, Croatia, Greece, Germany, The Netherlands, Italy, Iceland, Hungary, Ireland, France, Luxembourg, Ukraine, Latvia, Lithuania, Malta, Norway, Czech Republic and Slovenia. There were between 80 and 120 participants in each workshop.

The aim of the workshop series was to clarify, through discussion and shared experiences, the purposes for which health data can and cannot be used, as according to Articles 53, 54 and 52(3). The workshops focused on the role of HDABs in enabling the secondary use of electronic health data under EHDS. Discussions aimed at clarifying concepts and definitions, interpretation of allowed purposes and prohibited data use and exploring possible consequences for the assessment process of HDABs.

The thematic focus of Workshop 1 was on the interpretation of Article 53(a)–(d), covering public or occupational health, policymaking and regulatory activities, statistics, and education or teaching activities.

The thematic focus of Workshop 2 was on the interpretation of Article 53(e)–(f), focusing on scientific research and the improvement of the delivery of care.

The thematic focus of Workshop 3 was on the interpretation of Article 54, addressing prohibited uses of electronic health data for secondary purposes.

Each workshop was organised according to specific topics under Articles 53, 54 and 52(3) as summarised in the following Table 1.

Table 1 Workshops

Topic	Date	Articles
Workshop 1 Prohibited secondary use	250423	Article 54, Article 52(3)
Workshop 2 Purposes	250402	Article 53 e–f e) Scientific research f) Provision of care
Workshop 3 Purposes	250404	Article 53 a–d a) Public interest b) Policymaking c) Statistics d) Education

The information received in the workshops has been analysed and incorporated in the guideline.

Expert interviews

In addition, three expert interviews have been held with representatives from Vall d'Hebron Research Institute, Statistics Sweden and Finnish Social and Health Data Permit Authority (Findata) in order to acquire in-depth knowledge on certain topics.

Drafting and review process

The first draft of the Milestone has been developed by the major contributors of task 5.2.1 between April and June 2025. Each major contributor has been responsible for a section of the final report. In a weekly meeting upcoming questions and changes have been discussed. Collaborative tools and methodologies were used to draft the specification. This allowed for real-time input and revisions from all participants, ensuring a transparent and inclusive writing process. Desktop analysis of existing information has been performed.

Parts of the Milestone has been reviewed by the Review board of the work package, consisting of representatives from five countries, as well as the European Commission Directorate-General for Health and Food Safety (DG SANTÉ). DG SANTÉ has also provided input by giving guidance on questions concerning the interpretation of the regulation. The Milestone has furthermore been reviewed by Sitra, the members of the Project Steering Group of TEHDAS2 and DG SANTÉ before the public consultation. This Milestone will then in addition be reviewed through public consultation.

Method of processing the public consultation

During the consultation review, each Major contributor took charge of a defined set of questions and examined every comment through three lenses: first, if essential details were missing and therefore required additional clarification; second, if any part of the response was factually inaccurate and needed correction; and third, if the point raised fell outside the immediate scope and should instead be earmarked for future discussions. This triage — "Missing," "Incorrect," and "Future" — allowed the team to prioritise amendments, fill knowledge gaps and capture forward-looking ideas.

Annex 2a Public consultation summary

A draft version of this document was sent for public consultation from 1 October to 30 November 2025. This document was commented in total for 75 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 13 different countries in the EU and the European Economic Area countries. Responses from Easter and Southern European countries 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. Seven of the respondents represented an HDAB.

Respondents generally found the document clear and informative, appreciating its structure and comprehensive overview of EHDS secondary-use requirements. However, many noted that the text was legally and technically complex, which may challenge smaller organisations or those without regulatory expertise. Several respondents thought the document explained the requirements in the EHDS Regulation, but that it offered limited guidance on how the requirements should (or could) be implemented in practice.

Respondents therefore asked for more practical support, including examples, workflows, templates and checklists. The overall feasibility score reflected moderate concerns, as many Member states are still developing their national secondary-use infrastructures. Respondents highlighted the need for clearer instructions on cross-border processes, handling differing interpretations between HDABs, appeal procedures and documentation requirements, warning that without such clarity, national practices may diverge.

Open-text comments raised recurring themes. Many asked for clearer distinctions between different AI-related use cases and for AI-specific safeguards, including when SPE are required. There was also uncertainty about HDABs' operational responsibilities, such as mandate verification, consistency across countries and post-permit monitoring. Respondents requested more precise criteria to differentiate public-interest activities from commercial purposes and emphasised the importance of safeguarding intellectual property rights and trade secrets through, amongst others, standard clauses and harmonised SPE configurations.

Across all respondent groups, there were a strong call for practical tools and examples to support consistent assessment and decision-making. Overall, respondents regarded the document as well-aligned with objectives of the EHDS Regulation but stressed the need for more operational guidance to enable harmonised and effective implementation across Member states.

The comments received during the public consultation reflected a broad range of views, including several that touched on aspects outside the scope of or not in alignment with the EHDS, such as assumptions about the likelihood of successful data use or characteristics of data users having an impact on the assessment of data applications. Respondents felt more concrete examples and boundaries between allowed purposes and prohibited uses would be helpful. Examples mentioned in the course of the public consultation were included if they offered clear guidance. Additional examples and more detailed guidance on assessment

practices will only become possible once the first practical use cases are available. Although the definition of "scientific research" is intentionally wide (Recital 61), early EHDS implementation would benefit from continued alignment and exchange between HDABs on assessment practices, helping to translate this broad interpretation into more consistent and actionable procedures

Many stakeholders referred—often in a general or unspecific way—to ethical bodies or procedures as safeguards against prohibited or non–public-interest uses, while simultaneously highlighting that no clear or harmonised processes currently exist for assessing applicants' ethical self-evaluations in the absence of national requirements. Overall, the feedback underscored the need for more concrete direction on ethical oversight and public participation to support transparency and legitimacy.

The working party received several valuable comments, many of which have been incorporated where possible. However, many of the issues raised relate to interpretations of the EHDS Regulation that remain unresolved.

In chapter 9 in the deliverable most of the comments in the public consultation is addressed.

Annex 2b Examples from public consultation

In this annex there is a selection of examples from the public consultation that were important and relevant to save for future development. Many of the examples for the public consultation has been implemented in the deliverable and some has been discussed in chapter 9.

Article 53(e)

Feedback diverged on whether the guideline offers sufficient clarity, and on the requirement that AI-related activities must qualify as scientific research. Numerous comments argued that AI and algorithm training should constitute a standalone category, though the guideline's current formulation reflects alignment with the European Commission. Several contributors expressed concern that meeting purpose (e) might be too easily achievable and questioned how benefits to end-users can be ensured, pointing to a need for HDABs to manage this risk—potentially through the public-interest section or reporting-outcomes guidance. Respondents also called for more explicit guidance on ethical assessments—particularly regarding AI—along with greater emphasis on operational details and practical implications for HDABs.

Article 54 (a-b)

The respondents urged for more information on what red flags to look for, for example health data requests involving sensitive populations, variables commonly used for profiling or exclusion (e.g., genetic, behavioural, socioeconomic data), vague or commercially oriented objectives, unsupervised automated decisions and applicants operating in sectors where discriminatory decision-making is a known risk (e.g., insurance, employment screening, advertising technologies. Respondents also wanted clarification on how HDABs should assess the potential and less obvious prohibited uses, i.e. not only the declared use. One suggestion was to form examples of high-risk cases and a standardised EU-wide "detrimental use" checklist to improve consistency, protect vulnerable groups, and enhance legal certainty for both applicants and HDABs.

Further, others wanted to highlight that the potential discriminatory results should always be assessed and substantiated by the HDAB on a case-by-case basis, and must not be assumed solely based on the nature of the applying organisation. Care must be taken not to prohibit legitimate risk stratification tools used for care management, for example tools that identifies "high-risk patients" to offer them better care (e.g., a disease management program) discriminates in favour of the patient.

Respondents also raised the fact that discrimination may occur not only as a "part of the use" of the health data, but also from biased selection of data when training AI algorithms (e.g. models that systemically under- or over-represent certain groups).

To sum up, further guidance by the EHDS Board on the assessment process would be of great use to HDABs.

Examples from the public consultation, concerning Article 52(3)

Below, are five examples spanning clinical trials, genomics, medical and AI-enabled devices, pharmaceutical development, and post-market AI performance data — among the most frequently requested Article 51 data categories — and representing the areas where the toughest IPR and trade secret risk typically arise. (see Chapter 9.3 for further discussion on IPR/trade secrets).

1. Clinical trial data containing IPR-related protection or trade secrets

Clinical trial datasets may include proprietary endpoints, analytical strategies, or sensitive biomarker information protected under IPR or trade secrets. These elements require robust safeguards or, in some cases, may prevent data sharing when adequate protection cannot be guaranteed.

Example:

A Phase III clinical trial dataset at patient level contains much more than personal data: it embeds the sponsor's commercially confidential information (CCI)—such as trial design choices, proprietary endpoints and analysis strategies—and it sits within data protection and Clinical Trials Regulation/ EMA's Clinical Trials Information System transparency frameworks. Because these elements can be directly exploitable by competitors, any access must be configured to preserve the protection of IPR or trade secrets while enabling access only to the extent possible—typically by delivering derived or aggregated data in a SPE with no raw export, strict logging, and binding contract clauses (no reverse engineering, redistribution or competitive use) aligned to clinical trial transparency timing.

2. Medical device logs and algorithm parameters (risk of reverse engineering)

Device generated technical logs or algorithm related variables may reveal product design characteristics, calibration logic, or model behaviour. Such information can be reverse engineered, exposing protected IPR unless appropriate technical protections are applied within SPEs.

Example:

For AI enabled or software driven medical devices, raw logs, calibration values and algorithm parameters are frequently the vendor's core trade secrets: they can allow third parties to infer functional behaviour or re implement the model. Article 52(3) therefore points HDABs to require that data holders flag trade secret elements, replace raw logs with pre processed or derived telemetry, and confine access to an SPE configured with non exfiltration and output whitelists, supported by contractual bans on reverse engineering and functional cloning.

3. Genomic or biomarker datasets linked to patented diagnostic methods

High dimensional genomic data or biomarker panels may reveal patented analytical relationships or confidential developmental insights. Combinations of specific variables may risk unintended disclosure of protected diagnostic or analytical methodologies.

Example:

Genomic sequences and similar high dimensional datasets that are tied to a patented or patent pending method can reveal how that method actually works—even where individuals are anonymised—because the features, variable definitions or metadata can enable method

replication or model inversion. To respect Article 52(3), HDABs should require explicit IPR or trade secret clauses, role based access, and technical transformations (e.g., feature removal/partial extraction) so that the analysis remains scientifically useful but the protected technique cannot be reconstructed; all processing should occur inside an SPE with non exfiltration and controlled outputs.

4. Health economic models and other proprietary R&D datasets

Economic models used for health technology assessment, as well as upstream R&D datasets such as pre-clinical measurements or formulation variables, may contain proprietary pricing assumptions, market strategies, or proprietary algorithms. These components constitute trade secrets and require selective redaction, model isolation, or derived dataset generation when used for secondary purposes.

Example (drawn from parallel pharmaceutical-development risks):

Pre clinical measurements, formulation variables and related development metrics can be used to craft fast follower products outside clinical trial transparency regimes. To preserve protection while enabling access, HDABs should mandate redaction of formulation keys, time limited access that respects patent filing windows, competitive use prohibitions in the data permit, and (where appropriate) channel access via accredited public or academic bodies with conflict of interest controls.

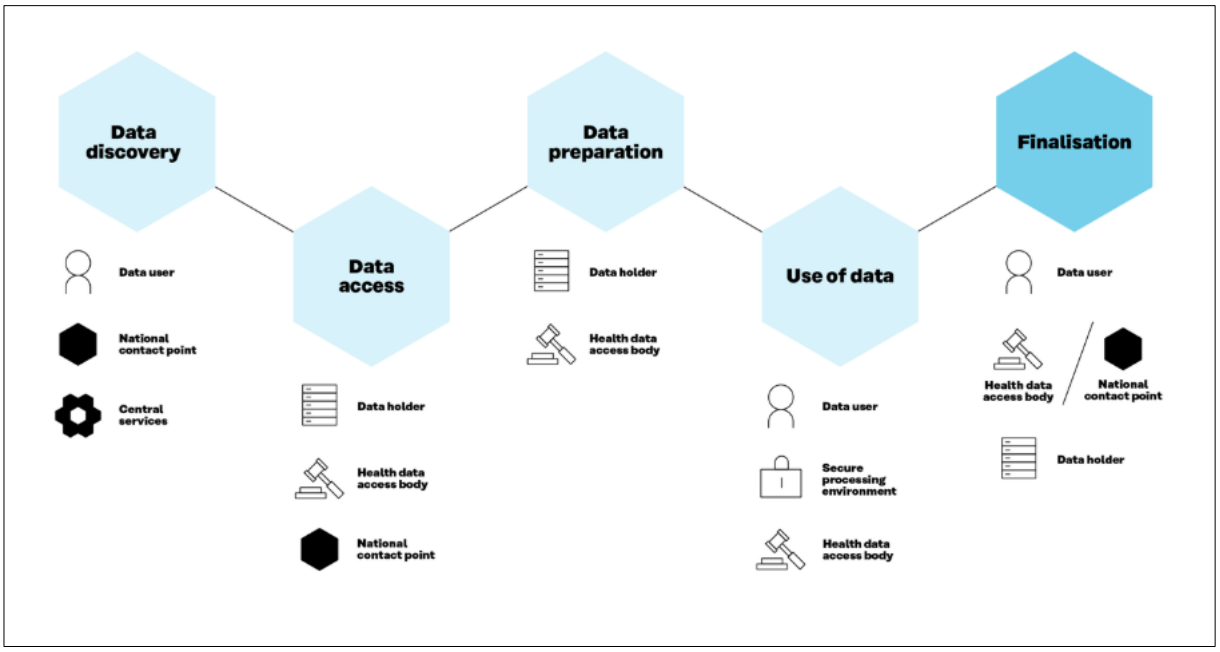
5. Post market performance data for AI enabled diagnostic devices

Even without parameters, performance and error patterns from post market surveillance can help a rival functionally clone a model. In line with Article 52(3) and Recital 60, HDABs should confine analysis to an SPE, limit toolsets to analytics only, allow aggregated or sanitised outputs (no artefacts that reveal model behaviour), and require no reverse engineering clauses and full audit trails.

Annex 3 User journey

When a data user[27] 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 HDAB[28]. The user must complete the

[27] Data user = a person using electronic health data for a secondary use purpose
[28] 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

information required in the form, upload necessary documents, and provide justifications as needed.

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

Data preparation

During this phase, the data holder(s)[29] 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[30]. 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 HDAB 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.

[29] 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)).
[30] 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

Below are the main concepts discussed in this guideline. There is a master glossary for TEHDAS2, that will be published later on.

Table 2 Concepts with a definition in a legal act of the EU

Concept	Definition	Directive /Regulation
AI system	A machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments.	AI Act – Regulation (EU) 2024/1689, Article 3(1)
Areas of occupational health	Areas of occupational health are the main disciplines concerned with protecting and promoting works health and safety in the workplace. It includes: • Occupational medicines: Prevention and management of work-related diseases, • Occupational hygiene: Identification and control of workplace hazards • Occupational safety: Prevention of accidents and injuries • Occupational health nursing: Workplace health services • Ergonomics: adapting work to fit the worker • Occupational psychology: Mental health and well-being at work • Environmental health: Control of environmental risks affecting workers A case of occupational disease is defined as a case recognised by the national authorities responsible for recognition of	Regulation (EU) 1338/2008, Annex V, (b) and WHO2, Article 3(c)

	occupational diseases. The data shall be collected for incident occupational diseases and deaths due to occupational disease Work-related health problems and illnesses are those health problems and illnesses which can be caused, worsened or jointly caused by working conditions. This includes physical and psychosocial health problems. A case of work-related health problem and illness does not necessarily refer to recognition by an authority and the related data shall be collected from existing population surveys such as the European Health Interview Survey (EHIS) or other social surveys.	
Areas of public health	'Public health' shall mean all elements related to health, namely health status, including morbidity and disability, the determinants having an effect on that health status, health care needs, resources allocated to health care, the provision of, and universal access to, health care as well as health care expenditure and financing, and the causes of mortality	Regulation (EU) 2021/2282, Article 2(5)
Benefits (of data use)	Refers broadly to positive outcomes of data use. It can encompass social, health and environmental aspects, among others. 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.	
Development activities	The concept 'Development activities' is not clearly defined in	Directive 2009/81/EC, Article 1(27)

	any legal act. However, there is a definition of the notion of research and development in Directive 2009/81/EC, Article 1(27): "'Research and development' mean all activities comprising fundamental research, applied research and experimental development, where the latter may include the realisation of technological demonstrators, i.e. devices that demonstrate the performance of a new concept or a new technology in a relevant or representative environment."	
Healthcare	'Healthcare' means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.	Directive 2011/24/EU, Article 3(a)
Health technology assessment	'Health technology assessment' or 'HTA' means a multidisciplinary process that summarises information about the medical, patient and social aspects and the economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner.	Regulation (EU) 2021/2282, Directive 2011/24/EU, Article 2(5)
Medicinal product	'Medicinal' product means any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying	Directive 2011/24/EU referring to Directive 2001/83/EC, Article 1(2)

	physiological functions in human beings are likewise considered a medicinal product.	
Medical device	'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: • diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, • diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, • investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, • providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: • devices for the control or support of conception;	Regulation (EU) 2017/745 and (EU) 2017/746, Article 2(1)

	products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.	
Public sector body	’Public sector body’ means the state, regional or local authorities, bodies governed by public law, or associations formed by one or several such authorities or one or several such bodies governed by public law.”	Regulation (EU) 2022/868, Data Governance Act, Article 2(17)
Serious cross-border threats	This Regulation shall apply to public health measures in relation to the following categories of serious cross-border threats to health: (a) threats of biological origin, consisting of: (i) communicable diseases, including those of zoonotic origin; (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (‘related special health issues’); (iii) biotoxins or other harmful biological agents not related to communicable diseases; (b) threats of chemical origin; (c) threats of environmental origin, including those due to the climate; (d) threats of unknown origin; and (e) events which may constitute public health emergencies of international concern under the International Health Regulations (IHR) (‘public	Regulation (EU) 2022/2371, Article 2(1)

	health emergencies of international concern'), provided that they fall under one of the categories of threats set out in (a–d).	
Statistics	Quantitative and qualitative, aggregated and representative information characterising a collective phenomenon in a considered population.	Regulation (EU) 223/2009, Article 3(1)

Analysis of the concept of public interest

The lack of a clear, generally applicable definition is countered in the EHDS Regulation, among others, by explicitly naming tasks or aspects that the legislator considers to be in the public interest. The notion of 'public interest' must not be interpreted as a general justification. HDABs should require clear and well-documented evidence demonstrating how the intended purpose satisfies the criteria set out in Article 53(1)(a), and should verify that the applicant is duly entitled to act on this basis

In the EHDS Regulation, public interest is often mentioned, notably in Recitals 19, 20, 52, 54, 95 and 100.

Recital 52 of the EHDS Regulation refers to the provisions in the GDPR:

"[...] This Regulation also assigns tasks in the public interest within the meaning of Article 6(1)(e), of Regulation (EU) 2016/679 to the health data access bodies and meets the requirements of Article 9(2) (g–j), as applicable, of that Regulation. […]"

Essentially, Article 6(1)(e) states that processing is lawful if it is 'necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller'. The specific task and its purpose must be based on Union or member state law, which must pursue a public interest objective and be proportionate. Examples include activities carried out by public authorities, registers, and other bodies with a public mandate, such as police tasks, population registers, certain health registers, and official statistics. For private institutions, Art. 6(1)(e) may apply if they have been entrusted with a public task by law, such as certain investigative bodies or entrusted companies.

Recital 61 of the EHDS Regulation describes the objectives to be achieved by enabling secondary use of the data. The overarching objective here is the following:

"[…] In particular, the secondary use of health data for research and development purposes should contribute to benefiting society in the form of new medicines, medical devices, and healthcare products and services at affordable and fair prices for Union citizens, as well as to enhancing access to and the availability of such products and services in all member states. […]"

Tasks and activities that serve these objectives or contribute to their fulfilment can therefore be understood as being in the public interest.

The references cited are almost identical to the cases provided for public interest in Recital 54 and Article 53(1)(c) of the EHDS Regulation.

Recital 54 of the EHDS Regulation specifies which facts are specifically to be assigned to the public interest:

"[…] strong link to the public interest, such as activities for protection against serious cross-border threats to health or scientific research for important reasons of public interest, […]"

Further, in Recital 54, other aspects are mentioned as being in the public interest:

"[…] Scientific research for important reasons of public interest could for example include research addressing unmet medical needs, including for rare diseases, or emerging health threats. […]"

These categorisations are taken up again in Article 53(1)(a) and explicitly named as permitted purposes.

Furthermore, Recital 54 and Article 71 of the EHDS Regulation allows that the member states may decide that they are authorised to access relevant data even if an opt-out is in place for the aforementioned circumstances, but the type of institutions authorised to access such data are precisely defined in Recital 54:

"[…] Such overrides should only be available to health data users that are public sector bodies, or relevant Union institutions, bodies, offices or agencies, entrusted with the performance of tasks in the area of public health, or to another entity entrusted with the performance of public tasks in the area of public health or acting on behalf of or commissioned by a public authority, […] and only where the data cannot be obtained by alternative means in a timely and effective manner. […]"

Table 3 shows a list of uses of the concept of public interest in the EHDS Regulation.

Table 3 Findings of public interest

Article	Title of article	Finding
1 (7)	Subject matter and scope	The EHDS Regulation does not override existing EU or national rules that already permit public authorities, EU institutions or authorised private entities to access and further process electronic health data when this is necessary to perform a public-interest task.
19 (4)	Digital health authorities	Digital health authorities — and all their staff — must remain independent, free from conflicts of interest, and act solely in the public interest.
32 (8)	Obligations of importers	Importers must ensure that publicly accessible complaint channels exist allowing users to submit complaints and to receive any communication concerning any risk related to their health and safety or to other aspects of public interest
44 (3)	Handling of risks posed by EHR systems and of serious incidents	If a market-surveillance authority determines that an EHR system has caused harm also in terms of certain aspects of public interest protection, the manufacturer must promptly supply the affected individuals, users, and any other impacted parties
53 (1)	Purposes for which electronic health data can be processed for secondary use	HDABs release electronic health data for secondary use only when the health data user needs them for public- or occupational-health purposes—such as tackling cross-border health threats, conducting public-health surveillance, or safeguarding the quality and safety of healthcare, medicines, and medical devices
55 (5)	Health data access bodies	Health data access bodies — and all their staff — must remain free of conflicts of interest, act independently and serve the public interest
71 (4)	Right to opt out from the processing of personal electronic health data for secondary use	A health-data request is admissible when it comes from a public-health authority (or an entity acting on its behalf) and the data are needed either for the specific public-health purposes listed in Article 53(1)(a–c) or for scientific research of significant public interest, even if an opt-out exists and the data cannot be obtained by alternative means and the health data applicant has provided the justification referred to in Article 68(1)(g), or in Article 69(2)(g) to fulfil purposes of public interest in the area of legitimate scientific and societal objectives.
92 (1)	European Health Data Space Board	Members of the EHDS Board shall undertake to act in the public interest and in an independent manner.
101	Representation of a natural person	Individuals who feel their rights under the EHDS Regulation have been violated may authorise a not-for-profit data-protection body having statutory public interest objectives to lodge a complaint or exercise the rights set out in Articles 21 and 81 on their behalf.

In the GDPR, the concept of public interest is used in a similar manner, as Article 6(1)(e) of the GDPR under the section titled “Lawfulness of processing”, states:

“[…] Processing shall be lawful only if and to the extent that at least one of the following applies: […] the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.”

Furthermore, Article 9(2) of the GDPR provides examples that are identical to those found in the EHDS Regulation (see references listed in Table 3). It also clarifies that the relevant protection must be ensured by the applicable Union or member state legislation in these cases:

“[…] processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or member state law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy; […]”

Annex 5 Figure 1 enlarged and consolidated operational checklist

Overview of the applicant's mandate and the assessment of allowed purposes and prohibited secondary use of health data. This annex provides a consolidated operational checklist to support HDABs in assessing data access applications under Articles 53 (allowed purposes), 54 (prohibited secondary uses), and 52(3) (measures regarding IPR and trade secrets) of the EHDS Regulation. Guidance and recommended procedures for HDABs in the full processing of applications for issuing data permits and making decisions on health data requests can be found in TEHDAS2 D6.3 (for short summary see Annex 7).

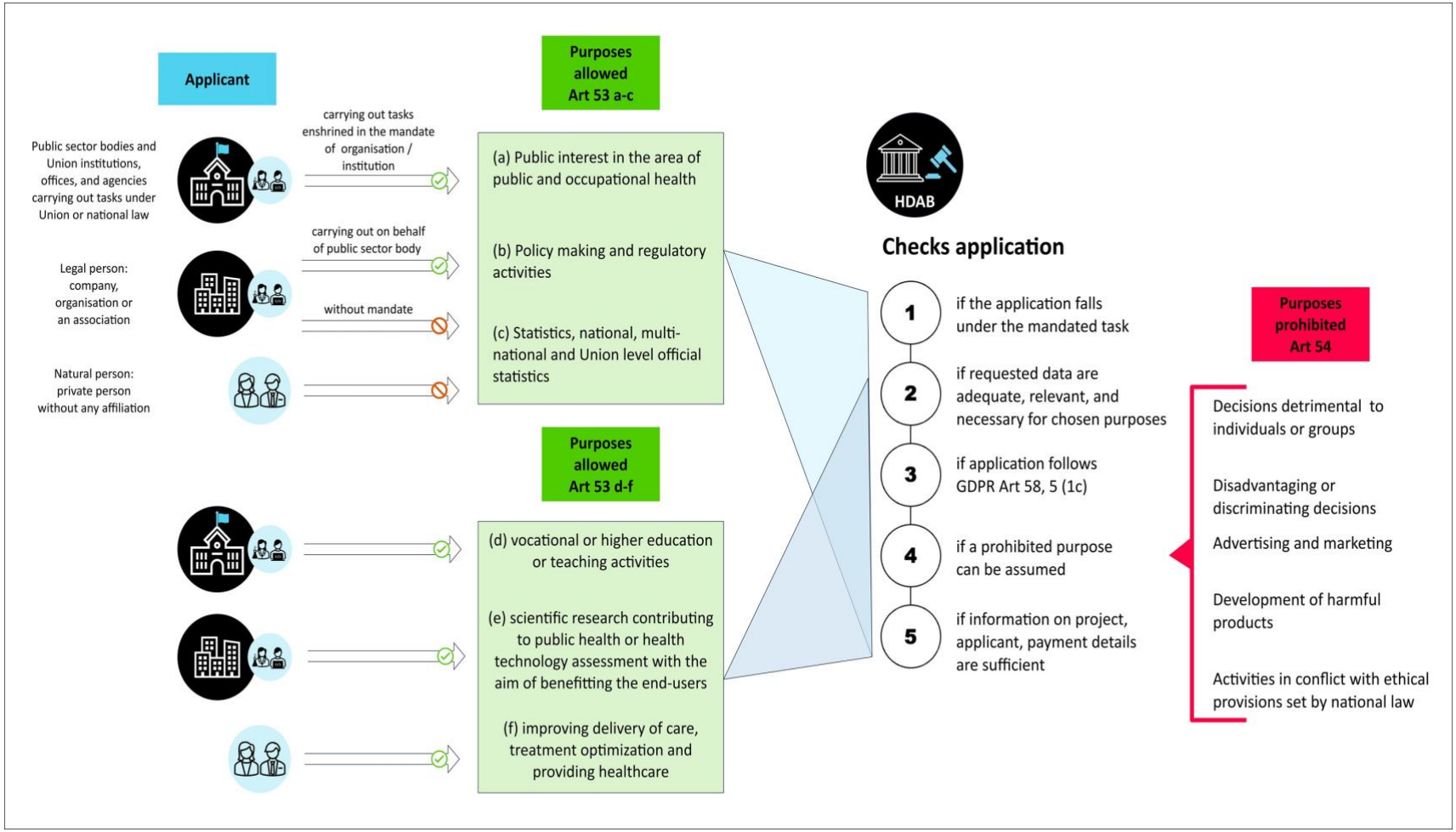


Table 4 Suggested selection of question to be asked in an assessment of Articles 53, 54 and 52(3)

Use the checklist provided in D6.3 as the starting point and then this checklist to more thoroughly evaluate/assess the purpose.	
Step/Article	**Key Questions**
53(a) Public/Occupational Health	• Is the applicant a public sector body or mandated entity?
	• Does the mandate cover surveillance, threats or quality/safety?
	• Is it clear this is not research or commercial activity?
53(b) Policymaking and Regulation	• Does the applicant have legal authority for policymaking/regulation?
	• Does the purpose support statutory tasks?
	• Is it clear that the purpose is not research or market analysis?
53(c) Official Statistics	• Is the applicant authorised to produce official statistics?
	• Will data be aggregated, anonymised and representative?
	• Is it clear that the purpose is not policy analysis or research?
53(d) Education	• Is the activity part of formal vocational or higher education?
	• Is the primary purpose clearly pedagogical?
	• Is it clear that is the purpose is not research or product development?
53(e) Scientific Research	• Are the described methods, the description of the aim, and the expected benefits in accordance with purpose (e)?
	• Can additional obligatory documentation provided by the data applicant be verified?
	• Does an application linked to innovation activities or testing, training and evaluation of algorithms clearly fall under purpose (e)?
53(f) Improvement of Healthcare	• Does the intended use directly improve care delivery or workflows?
	• Is there a clear clinical or implementation link?
54(a) Detrimental Decisions (Prohibited)	• Could the data be used in decision-making, causing legal, social or economic harm based on the health data?
54(b) Discrimination (Prohibited)	• Could the data lead to discriminating decision-making regarding, inter alia, employment, provision of goods and services (including insurance and credit), based on the health data?
54(c) Marketing (Prohibited)	• Could the data be used for advertising, promotion, segmentation or targeting?
	• Is there any indication of commercial market analysis?
54(d) Harmful Products/Services (Prohibited)	• Could the data contribute to developing harmful or addictive products?
	• Is there a downstream misuse risk?

54(e) Ethical Violations (Prohibited)	• Does the intended use comply with the ethical provisions laid down in your national law? Check whether the applicant's interpretation is correct and be extra careful in borderline cases. ◦ If documentation is required, has this been provided?
	• Has the applicant voluntarily provided an ethical self-assessment? If yes, that should be considered, but it cannot generally substitute for formal review where it is required by law
52(3) IPR and Trade Secrets	• Does the dataset include information protected by IPR or trade secrets?
	• Does the dataset include information protected by IPR or trade secrets?
	• Are suitable legal, organisational or technical safeguards in place?
	• Would insufficient safeguards require permit denial (Art. 52(5))?

Annex 6 Links to relevant EHDS articles and recitals

Articles 53, 54 and 52(3) of the EHDS Regulation[31], and their relevant recitals are found in Table 5 and presented in full version below.

Table 5 EHDS Regulation articles and their relevant recitals.

Articles	Recitals
Article 53	Recital 61
Article 54	Recital 62
Article 52(3)	Recital 60

Article 53 Purposes for which electronic health data can be processed for secondary use

1. Health data access bodies shall only grant access to electronic health data referred to in Article 51 for secondary use to a health data user where the processing of the data by that health data user is necessary for one of the following purposes:

    (a) the public interest in the areas of public or occupational health, such as activities to protect against serious cross-border threats to health, public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices;

    (b) policy-making and regulatory activities to support public sector bodies or Union institutions, bodies, offices or agencies, including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;

    (c) statistics as defined in Article 3(1) of Regulation (EU) No 223/2009, such as national, multi-national and Union-level official statistics, related to health or care sectors;

    (d) education or teaching activities in health or care sectors at vocational or higher education level;

    (e) scientific research related to health or care sectors that contributes to public health or health technology assessments, or ensures high levels of quality and safety of healthcare, of medicinal products or of medical devices, with the aim of benefiting end-users, such as patients, health professionals and health administrators, including:

[31] Regulation (EU) 2025/327 on EHDS, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL_202500327.

(i) development and innovation activities for products or services;

(ii) training, testing and evaluation of algorithms, including in medical devices,

(iii) in vitro diagnostic medical devices, AI systems and digital health applications;

(f) improvement of the delivery of care, of the optimisation of treatment and of the provision of healthcare, based on the electronic health data of other natural persons.

2. Access to electronic health data for the purposes referred to in paragraph 1(a-c), shall be reserved for public sector bodies and Union institutions, bodies, offices and agencies exercising the tasks conferred on them by Union or national law, including where processing of data for carrying out those tasks is done by a third party on behalf of that public sector body or of Union institutions, bodies, offices and agencies.

Article 54 Prohibited secondary use

Health data users shall only process electronic health data for secondary use on the basis of and in accordance with the purposes contained in a data permit issued pursuant to Article 68, health data requests approved pursuant to Article 69 or, in situations referred to in Article 67(3), an access approval from the relevant authorised participant in HealthData@EU referred to in Article 75.

In particular, seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 68 or a health data request approved pursuant to Article 69 for the following uses shall be prohibited:

(a) taking decisions detrimental to a natural person or a group of natural persons based on their electronic health data; in order to qualify as ‘decisions’ for the purposes of this point, they have to produce legal, social or economic effects or similarly significantly affect those natural persons;

(b) taking decisions in relation to a natural person or a group of natural persons in relation to job offers, offering less favourable terms in the provision of goods or services, including exclusion of such persons or groups from the benefit of an insurance or credit contract, the modification of their contributions and insurance premiums or conditions of loans, or taking any other decisions in relation to a natural person or a group of natural persons which result in discriminating against them on the basis of the health data obtained;

(c) carrying out advertising or marketing activities;

(d) developing products or services that may harm individuals, public health or society at large, such as illicit drugs, alcoholic beverages, tobacco and nicotine products, weaponry or products or services which are designed or modified in such a way that they create addiction, contravene public order or cause a risk for human health;

(e) carrying out activities in conflict with ethical provisions laid down in national law.

Article 52(3) Intellectual property rights and trade secrets

3. Health data access bodies shall take all specific appropriate and proportionate measures, including of a legal, organisational and technical nature, they deem necessary to protect the intellectual property rights, trade secrets or the regulatory data protection right laid down in Article 10(1) of Directive 2001/83/EC or Article 14(11) of Regulation (EC) 726/2004. Health data access bodies shall remain responsible for determining whether such measures are necessary and appropriate.

Recital 60

Electronic health data protected by intellectual property rights or trade secrets, including data on clinical trials, investigations and studies, can be very useful for secondary use and can foster innovation within the Union for the benefit of Union patients. In order to incentivise continuous Union leadership in this domain, it is important to encourage the sharing of clinical trials and clinical investigations data through the EHDS for secondary use. Clinical trials and clinical investigations data should be made available to the extent possible, while taking all necessary measures to protect intellectual property rights and trade secrets. This Regulation should not be used to reduce or circumvent such protection and should be consistent with the relevant transparency provisions laid down in Union law, including for clinical trials and clinical investigations data. Health data access bodies should assess how to preserve such protection while enabling access to such data for health data users to the extent possible. If a health data access body is unable to provide access to such data, it should inform the health data user and explain why it is not possible to provide such access. Legal, organisational and technical measures to protect intellectual property rights or trade secrets could include common electronic health data access contractual arrangements, specific obligations within the data permit in relation to such rights, pre-processing the data to generate derived data that protect a trade secret but nonetheless have a utility for the health data user or configuration of the secure processing environment so that such data are not accessible to the health data user.

Recital 61

The secondary use of health data under the EHDS should enable public, private and not-for-profit entities, as well as individual researchers, to have access to health data for research, innovation, policymaking, educational activities, patient safety, regulatory activities or personalised medicine, in line with the purposes as set out in this Regulation. Access to data for secondary use should contribute to the general interest of society. In particular, the secondary use of health data for research and development purposes should contribute to benefiting society in the form of new medicines, medical devices, and healthcare products and services at affordable and fair prices for Union citizens, as well as to enhancing access to and the availability of such products and services in all member states. Activities for which access in the context of this Regulation is lawful could include using the electronic health

data for tasks carried out by public sector bodies, such as the exercise of public duty, including public health surveillance, planning and reporting duties, health policymaking, and ensuring patient safety, quality of care and the sustainability of healthcare systems. Public sector bodies and Union institutions, bodies, offices and agencies might need to have regular access to electronic health data for an extended period of time, including in order to fulfil their mandate, as is provided for in this Regulation. Public sector bodies could carry out such research activities by using third parties, including sub-contractors, as long as the public sector body remains at all times the supervisor of those activities. The provision of the data should also support activities related to scientific research. The notion of scientific research purposes should be interpreted in a broad manner, including technological development and demonstration, fundamental research, applied research and privately funded research. Activities related to scientific research include innovation activities such as training of AI algorithms that could be used in healthcare or the care of natural persons, as well as the evaluation and further development of existing algorithms and products for such purposes. It is necessary that the EHDS also contribute to fundamental research, and, although its benefits to end-users and patients might be less direct, such fundamental research is crucial for societal benefits in the longer term. In some cases, the information of some natural persons, such as genomic information of natural persons with a certain disease, could contribute to the diagnosis or treatment of other natural persons. There is a need for public sector bodies to go beyond the scope of 'exceptional need' of Chapter V of Regulation (EU) 2023/2854. However, health data access bodies should be allowed to provide support to public sector bodies when processing or linking data. This Regulation provides for a channel for public sector bodies to obtain access to information that they require for fulfilling the tasks assigned to them by law, but does not extend the mandate of such public sector bodies.

Recital 62

Any attempt to use electronic health data for measures detrimental to natural persons, such as to increase insurance premiums, to engage in activities potentially detrimental to natural persons related to employment, pensions or banking, including mortgaging of properties, to advertise products or treatments, to automate individual decision-making, to re-identify natural persons or to develop harmful products should be prohibited. That prohibition should also apply to activities contrary to ethical provisions under national law, with the exception of ethical provisions relating to consent to the processing of personal data and ethical provisions relating to the right to opt out, since this Regulation takes precedence over national law in accordance with the general principle of the primacy of Union law. It should also be prohibited to provide access to, or otherwise make available, electronic health data to third parties not mentioned in the data permit. The identity of authorised persons, in particular the identity of the principal investigator, who will have the right pursuant to this Regulation to access electronic health data in the secure processing environment should be indicated in the data permit. The principal investigators are the main persons responsible for requesting access to the electronic health data and for processing the requested data within the secure processing environment on behalf of the health data user. Electronic health data protected by intellectual property rights or trade secrets, including data on clinical trials, investigations and studies, can be very useful for secondary use and can foster innovation within the Union for the benefit of Union patients. In order to incentivise continuous Union leadership in this domain, it is important to encourage the sharing of clinical trials and clinical investigations data through

the EHDS for secondary use. Clinical trials and clinical investigations data should be made available to the extent possible, while taking all necessary measures to protect intellectual property rights and trade secrets. This Regulation should not be used to reduce or circumvent such protection and should be consistent with the relevant transparency provisions laid down in Union law, including for clinical trials and clinical investigations data. HDABs should assess how to preserve such protection while enabling access to such data for health data users to the extent possible. If a HDAB is unable to provide access to such data, it should inform the health data user and explain why it is not possible to provide such access. Legal, organisational and technical measures to protect intellectual property rights or trade secrets could include common electronic health data access contractual arrangements, specific obligations within the data permit in relation to such rights, pre-processing the data to generate derived data that protect a trade secret but nonetheless have a utility for the health data user or configuration of the secure processing environment so that such data are not accessible to the health data user.

Procedures and formats for data access (D6.3)

This guidance supports HDABs in defining procedures for issuing data permits and decisions on data requests, based on receiving and handling data access applications for single-country and multi-country cases. It sets out common procedures for handling cross-border and multi-country data access requests, including the communication and steps required between HDABs and SPEs after a data permit has been granted. The guidance also includes common and standard forms or templates for data access applications, data permits, and electronic health data access contractual arrangements.

Annex 7 Short summary of deliverables or ongoing work in TEHDAS2

The related deliverables for this guideline are listed below. These deliverables will be available once they have been approved and can be found here: Results - Tehdas

Deliverables

D4.1 Guideline for Health Data Access Bodies on fees and penalties for non-compliance related to EHDS Regulation
This guidance provides an overview of fee structures for access to electronic health data under the EHDS and outlines the types of activities and cost elements that may be included in fees within the EHDS framework. It presents recommendations and options for policies on fees based on existing approaches and commonalities identified across member states. The guidance also sets out policies, terms and conditions for the application of penalties in situations where data users or data holders do not comply with the requirements of the EHDS Regulation. In line with the regulation, HDABs are responsible for monitoring and supervising compliance, and the guidance therefore addresses the definition of possible obligations for data holders, the verification of the correspondence between the health data requested and the data use carried out, and the notification process to data users in cases of non-compliance.

D4.2 Guideline for Health Data Access Bodies on collaboration with other parties
This guidance provides recommendations for HDABs on collaboration with other stakeholders involved in the implementation of the EHDS. It is based on knowledge gained through stakeholder engagement activities, including stakeholder forums and targeted workshops on IPR and trade secrets, collaboration and ethics. It sets out guidelines for cooperation between HDABs and other parties, including technical specifications for cross-border infrastructure, needs identified among relevant stakeholders, and existing mechanisms for decision-making and collaboration. The guidance includes recommendations developed from best practices and insights gathered across member states.

D6.2 Guideline for data users on good application and access practice
This guidance supports health data users in preparing applications for access to electronic health data under the EHDS. It describes the information that needs to be included in an application and outlines the requirements and obligations that apply during the application process, including the period of waiting for a permit. It also explains what happens once access is confirmed.

D6.3 Guideline for Health Data Access Bodies on the procedures and formats for data access
This guidance supports HDABs in defining procedures for issuing data permits and decisions on data requests, based on receiving and handling data access applications for single-country and multi-country cases. It sets out common procedures for handling cross-border and multi-country data access requests, including the communication and steps required between HDABs and SPEs after a data permit has been granted. The guidance also includes common and standard forms or templates for data access applications, data permits, and electronic health data access contractual arrangements.