



M4.2 Draft guideline on a framework for collaboration

TEHDAS2 – Second Joint Action Towards the European Health Data Space

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0 Document info

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1 Executive summary

This document presents a draft non-binding framework for collaboration in the context of the European Health Data Space (EHDS), developed under the TEHDAS2 Joint Action. It is intended to inform discussions at EU and Member State level in the development of sustainable, operationally and organisationally viable collaboration models for the EHDS secondary use framework, and to support the design of EU and national implementation efforts.

The document is structured around two complementary dimensions:

- Part I examines the conditions for collaboration across three thematic areas identified as particularly relevant for the EHDS secondary use framework: ethical governance (including alignment with applicable EU and national legal and ethical frameworks), collaboration models and coordination mechanisms, and the protection of intellectual property rights and trade secrets in line with applicable Union law. For each theme, the document draws on structured stakeholder engagement to identify the principal challenges, analyse their implications for the design of a collaboration framework, and formulate recommendations for consideration in EHDS implementation.
- Part II focuses on the role of research infrastructures, networks, and cross-border organisations in the emerging EHDS ecosystem. Drawing on a mapping of services and functions across the European health data landscape and structured engagement with representatives of these organisations, it analyses both where they can contribute concrete added value at each stage of the EHDS user journey, and how that contribution can be embedded in the framework in a systematic and sustainable way.

Together, the two parts aim to provide a grounded and actionable basis for the development of collaboration approaches. They reflect the operational realities of EHDS implementation and the diversity of actors whose engagement will be essential to the framework's long-term success.

2 Introduction

Advancing health data use in the European Health Union

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

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

TEHDAS2 focuses on several critical aspects of health data use.

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

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

This guideline aims to propose key elements of a collaboration framework for the secondary use of electronic health data under the EHDS. The Regulation establishes new roles, procedures, and cross-border mechanisms for data access and reuse across the European Union, but it does not specify how collaboration between the various actors should be organised in practice. Given the multi-actor and cross-border nature of the EHDS framework, effective implementation depends on coherent and workable collaboration models that ensure coordination, trust, and operational consistency across Member States.

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

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

Legally binding and enforceable requirements under the European Health Data Space are laid down in 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.

2.1 Purpose

The EHDS Regulation [1] establishes a new legal and operational framework for the secondary use of electronic health data in the European Union. It introduces defined roles, new procedures for data access and reuse, and mechanisms intended to facilitate cross-border data sharing at scale. While the Regulation sets out responsibilities for key actors, such as data holders, data users, Health Data Access Bodies (HDABs), and other entities including health data intermediation services or trusted data holders, it does not prescribe in detail how collaboration between these actors should be organised in practice. Given the multi-actor and cross-border nature of the EHDS, the effective functioning of secondary use depends not only on formal legal provisions, but also on workable and coherent collaboration models. Questions regarding coordination, alignment of responsibilities, and interaction formats between actors remain central to ensuring that the EHDS operates efficiently and consistently across Member States.

This guideline examines possible ways of establish a collaboration framework for EHDS secondary use through two complementary analytical dimensions: (i) a topic-based analysis of key cross-cutting issues affecting collaboration and (ii) a stakeholder-based analysis focusing on the roles and alignment of research infrastructures and networks within the EHDS governance and operational ecosystem. The topic-based dimension addresses specific steps in the EHDS user journey that present particular challenges for coordinated implementation, including ethical assessment procedures, the protection of intellectual property rights and trade secrets, and governance arrangements shaping interaction between actors. The stakeholder-based dimension explores how research infrastructures and related networks, many of which already provide services in the health data domain, may contribute to the EHDS framework, and what alignment considerations arise in this context. By combining these two perspectives, the guideline aims to provide structured recommendations for a collaboration model that supports consistent, trustworthy, and operationally effective secondary use across the Union.

2.2 Target Audience

The content of this guideline is primarily addressed to actors directly involved in the EHDS secondary use framework, including HDABs, data holders, data users, and other entities foreseen under the Regulation. At the same time, the considerations presented extend beyond the core EHDS actors and may be of relevance to a broader ecosystem of organisations operating in the European health data landscape. This includes research infrastructures (such as ERICs, EDICs and ESFRI-related initiatives), EU networks, European Reference Networks, EU-funded initiatives, non-governmental organisations, and other institutions engaged in health data governance, research, innovation, or public health activities.

Given the cross-sectoral and cross-border objectives of the EHDS, collaboration models necessarily involve actors with varying mandates and operational structures. This guideline therefore seeks to provide reflections and recommendations that are applicable across institutional contexts.

2.3 Scope

This document presents the outcomes of targeted stakeholder engagement activities carried out within the framework of this task. The analysis draws on:

- A series of thematic workshops addressing cross-cutting issues relevant to collaboration in EHDS secondary use, including ethical governance, collaboration models, and the protection of intellectual property rights and trade secrets;
- A mapping exercise, survey, and interviews focusing on the roles, services, and alignment needs of research infrastructures and related networks active in the health data domain.

The findings and recommendations presented in this draft are based on the synthesis of these engagement activities. They reflect identified challenges, stakeholder perspectives, and emerging alignment needs within the evolving EHDS governance architecture.

The present draft constitutes an intermediate milestone, developed on the basis of the stakeholder engagement activities described above. It is now submitted for public consultation, which will extend the feedback process to a broader range of stakeholders across the EU. The input gathered through this consultation will be used to further refine and consolidate the document towards the final guideline.

3 PART I – Topic-wise dimension: Conditions for Collaboration

This part of the guideline presents key perspectives from stakeholder engagement conducted across three thematic areas identified as particularly relevant to the development of a collaboration framework for the EHDS: ethical governance, collaboration models and coordination mechanisms, and the protection of intellectual property (IP) rights and trade secrets. These topics were selected on the basis of their direct relevance to the conditions under which cross-border collaboration in health data reuse can be established on a durable and trustworthy basis, and because they present questions that require deliberate consideration as EHDS implementation progresses. For each thematic area, a dedicated workshop was organised, bringing together relevant experts among others representatives from academia, industry and HDABs, as well as national representatives, clinicians, scientists and legal experts. Each workshop combined expert presentations with panel debates and open discussion, with the aim of surfacing a range of perspectives on the challenges and open questions associated with each topic. A detailed workshop report was prepared following each event [2, 3], documenting the key points raised during presentations and discussions. These reports have been published separately and are available as companion resources to this guideline.

For each of the three thematic areas, this section presents the key perspectives that emerged from stakeholder engagement, identifies the principal challenges and open questions raised, analyses their implications for the design of a collaboration framework, and draws out recommendations for consideration in the future implementation of the EHDS.

3.1 Ethical governance in the EHDS

3.1.1 Perspectives from stakeholders

Stakeholders highlighted several perspectives on ethical governance and access in the context of health data use. One perspective outlined a national approach to ethical review and data access for secondary use of health data, emphasising the role of centralised data access bodies, clear legal frameworks, and evaluation criteria such as data minimisation and compliance with applicable legal and ethical frameworks. The importance of transparency, public trust, and clearer communication with citizens was also underlined. Another contribution presented data solidarity as a possible analytical lens for ethical data governance, focusing on the equitable distribution of benefits and harms in digital health. This approach emphasised facilitating data uses that generate public value, preventing and mitigating risks, and ensuring that commercial gains are shared where public benefit is limited. Tools to support the assessment of societal value, including long-term, global, and environmental impacts, were also highlighted.

From a governance perspective, stakeholders pointed to the challenges of balancing EU-level harmonisation with national ethical oversight systems. Differences in national ethics procedures were identified as a potential barrier to cross-border research and multi-country secondary data use, suggesting that greater alignment of ethical review processes may be

needed to reduce fragmentation. Finally, the perspective of healthcare professionals emphasised the need to safeguard medical confidentiality, maintain patient trust, and uphold professional responsibilities in both primary and secondary data use. Strong ethical governance, the continued role of ethics committees, and sufficient flexibility at national level, particularly for smaller healthcare practices, were highlighted as important conditions for the effective and ethical implementation of the European Health Data Space.

3.1.2 Key challenges identified

Stakeholders outlined key challenges on ethical collaboration:

- **Fragmentation of national ethics procedures** - Ethical oversight remains a national competence, and the absence of commonly recognised approaches may slow cross-border secondary use of health data. Divergent national procedures risk becoming a bottleneck for multi-country research and data access under the EHDS. This fragmentation is further compounded by differences in scope, criteria, and timelines across national frameworks, generating uncertainty for data users who must navigate multiple and potentially conflicting requirements simultaneously. Stakeholders noted that maintaining fragmented systems also carries its own costs, and that the absence of coordinated action is not a neutral choice.
- **Unclear interaction between HDAB processes and national ethical oversight arrangements** - The EHDS Regulation requires data access applications to address ethical considerations, while ethical oversight itself remains governed by national law and institutional competence. How HDAB procedures should interact with ethical assessments required under national frameworks, and how such assessments should be reflected in access decisions, remains an open question that Member States will need to address in their implementation arrangements. Clear governance arrangements are needed to ensure appropriate coordination between HDABs and national ethics bodies, preserving the independence and transparency of both.
- **Uneven capacity and expertise across Member States** - Significant differences exist in the capacity, expertise, and resources available for ethical review. Some Member States and institutions may face challenges in conducting complex evaluations in a timely manner compatible with EHDS-related access processes. The scale and cross-border nature of secondary use under the EHDS, including increasing use of AI and more complex multi-country use cases, place additional demands on ethics bodies. These demands relate less to entirely new domains of expertise than to the need for greater coordination, consistency, and interdisciplinary capacity across Member States, which is not yet uniformly available.
- **Gaps in public trust and transparency** - Ensuring public confidence in the ethical and secure use of health data remains essential. Limited communication and transparency may lead to misunderstandings, increased opt-outs, or reluctance among patients and healthcare professionals. Trust depends not only on the robustness of governance arrangements but on their visibility and intelligibility, without clear communication on how

ethical review operates and what safeguards are applied, confidence may erode even where governance is substantively sound. Healthcare professionals were specifically identified as a group whose perceptions of confidentiality and professional responsibility have a significant bearing on the willingness of clinical institutions to engage with secondary use.

- **Lack of practical tools and shared resources** - The absence of common templates, operational guidance, and training may create uncertainty for ethics committees and data users, potentially leading to inefficiencies and inconsistent practices across Member States. Without a shared reference basis, the practical interpretation of principles such as public interest and societal benefit is left to individual discretion, risking divergent outcomes that complicate cross-border secondary use.

3.1.3 Recommendations for the collaboration framework

Achieving a trustworthy and ethically sound EHDS requires strategic alignment across Member States. While ethical guidance will remain a national competence, an alignment and shared understanding would support a coherent progress across the EU. The following recommendations address the principal dimensions of this challenge.

Recommendation 1: Promoting alignment in ethical governance across Member States

A trustworthy EHDS requires alignment across Member States while preserving national competence. The principle of data solidarity, which emphasises fair distribution of risks and benefits and an orientation toward public health and societal value, can serve as a shared ethical foundation. Harmonisation should prioritise non-binding common minimum reference criteria/principles that address public interest, societal benefit, proportionality, data minimisation and safeguards against re-identification. These standards can provide coherence without limiting national autonomy. A voluntary EU-level ethics reference framework can further support alignment by offering templates, guiding questions and case studies that help encourage consistent and outcome-focused assessments, as already suggested in other TEHDAS2 outcomes such as Guideline D5.2 *Guideline for common policies for Health Data Access Bodies on minimum categories of electronic data for secondary use purposes according to EHDS and on limitations in further processing of health data*. Additionally, documentation practices, transparency requirements and shared taxonomies of risks and safeguards should be aligned to support greater cross-border comparability over time. Finally, cross-country coordination should be part of EHDS governance to ensure that national diversity coexists with shared European principles.

Recommendation 2: Embedding trust, transparency and security in the EHDS

Public and professional trust must be actively cultivated as part of EHDS implementation, not treated as an incidental outcome of regulatory compliance. This requires making ethical governance visible and intelligible through publicly accessible summaries of approved data uses, clear communication on data security mechanisms and applied safeguards, and transparent articulation of the public interest rationale underpinning specific data uses. Healthcare professionals may be engaged as trusted intermediaries, informed about how

secondary use operates and how it relates to the quality of data generated in primary care. Citizen engagement should be inclusive and accessible to varying levels of digital literacy, designed to support informed participation rather than uninformed opt-outs. In the EHDS, opt-out is a rights-based mechanism designed to protect autonomy and choice, not a measure of public trust. Nonetheless, where significant variation across Member States is observed, this may usefully prompt reflection on whether communication and engagement strategies are reaching citizens effectively.

Recommendation 3: Strengthening capacity and expertise for ethical assessment

Effective EHDS governance depends on clarity about how HDAB procedures interact with ethical review arrangements under national law. Member States should clarify these interactions as part of their national implementation arrangements, ensuring appropriate coordination between HDABs and ethics bodies, and well-defined boundaries where HDABs simultaneously act as data holders. Transparent relationships between HDABs, ethics committees, data holders and data users should support coordinated, accountable and accessible ethical assessment processes. Member States need interdisciplinary expertise across ethics, data protection, informatics and legal frameworks, supported by organisational structures such as standard procedures, training programmes and shared assessment tools. EU-supported knowledge exchange, including networks, mentorship initiatives, workshops and shared digital resources, can help reduce capacity differences across countries. It is important to provide targeted support to less resourced systems in order to ensure equal access and maintain coherence across the EHDS as a whole.

3.2 Collaboration models and coordination mechanisms

The overall goal of the workshop on this topic was to discuss collaboration between HDABs, data users and data holders with a focus on the data discovery phase and multi-country applications under EHDS. Through presentations and discussions participants sought to identify what currently works, gaps and what needs to evolve for the EHDS secondary use framework.

3.2.1 Perspectives from stakeholders

Data discovery – key takeaways

Stakeholders highlighted that effective data discovery depends on early and structured engagement between data users and data holders to avoid misunderstandings and ensure feasible, high-quality data access requests. Stakeholders also emphasised the need for inclusive approaches, supporting data holders with guidance and standardised processes. Additionally, structured communication channels and traceable workflows during the discovery phase were identified as essential to prevent complications later in data preparation and provision. Data quality and interoperability were consistently raised as foundational requirements, with standardised coding systems, semantic harmonisation, and variable-level metadata documentation, where feasible, highlighted as critical enablers of

secondary use at scale. Participants also noted that already established research and industrial infrastructures for health data discovery and sharing should not be overlooked as the EHDS framework develops, given the operational experience and community networks they have accumulated.

Multi-country applications – key takeaways

Cross-border research benefits from federated models, shared standards and harmonised metadata, allowing collaboration without unnecessary data transfers. However, stakeholders emphasised that inconsistencies in national processes, maturity of catalogues, administrative burdens and fragmented governance structures make multi-country requests complex to navigate. Achieving transparency, aligning permit processes and creating predictable evaluation procedures are central to making multi-country applications functional and efficient within the EHDS framework. Specific operational challenges raised included heterogeneous catalogue coverage across countries, difficulties in tracking requests and avoiding duplicate records across jurisdictions, uncertainty around decision-making for cross-border or multi-country SPEs, and the practical burden of coordinating accountability and invoicing across multiple national bodies. Federated approaches enabling remote analysis without transferring patient-level data were seen as technically viable, but their scalability was considered dependent on harmonised governance and compatible technical standards. Practical collaboration among HDABs, data holders, and data users was broadly identified as the mechanism through which fragmentation is prevented, trust is built, and predictability for all actors is ensured, going beyond what legal and technical frameworks alone can achieve.

3.2.2 Key challenges identified

Stakeholders outlined key challenges for collaboration under the EHDS:

- **Fragmentation of national processes and uneven preparedness** - Member States are at significantly different stages of readiness for EHDS implementation, with variation in the maturity of metadata catalogues, governance structures, technical infrastructure, and institutional capacity. This unevenness means that multi-country applications must navigate divergent national requirements and timelines, creating administrative complexity for data users and risking unequal access to the EHDS ecosystem. Smaller or less-resourced data holders face particular difficulties in meeting the obligations the EHDS framework will place on them without targeted support.
- **Complexity of multi-country application processes** - Multi-country data access requests currently require applicants to navigate multiple national authorities with differing application procedures, evaluation criteria, and timelines. The absence of harmonised processes or a coordinated evaluation model means that parallel applications are often necessary, generating duplication of effort for both applicants and HDABs. Practical operational challenges, including tracking requests across jurisdictions, managing invoicing between multiple HDABs, avoiding duplicate patient records, and coordinating decisions on SPEs, add further layers of complexity that risk discouraging cross-border research.

- **Unclear governance roles and coordination arrangements** - The respective responsibilities of HDABs, HealthData@EU structures, data holders, and governance of infrastructures such as SPEs in the multi-country application process remain insufficiently defined in several key areas. Questions around how parallel applications should be coordinated, how a potential lead HDAB model would function in practice, and how accountability is maintained across jurisdictions have not yet been fully resolved. The absence of clear governance arrangements creates uncertainty for all actors and risks producing inconsistent or unpredictable outcomes for data users.
- **Operational and resource constraints** - The speed, cost, and scalability of data access processes were consistently identified as practical barriers. Infrastructure costs, particularly for SPEs, administrative delays, and workload pressures on HDABs and data holders risk making the EHDS secondary use framework slow and burdensome in practice. Without sufficient investment in operational capacity, automation tools, and streamlined workflows, the gap between the framework's ambitions and its practical functioning may widen as demand for data access grows.

3.2.3 Recommendations for the collaboration framework

The following recommendations address the principal conditions for effective collaboration between HDABs, data holders, and data users under the EHDS, drawing on the perspectives and challenges identified above.

Recommendation 1: Invest in data discovery infrastructure as a foundation for effective collaboration

Comprehensive, standardised, and interoperable metadata catalogues are a prerequisite for functional secondary use under the EHDS. Member States should invest in developing catalogues that are searchable, documented to the variable level, and aligned with common standards to support meaningful feasibility assessments by data users. Structured early engagement mechanisms, including expert feasibility meetings, clarification procedures, and iterative dialogue between data users and data holders during the discovery phase, should be formalised as standard components of the data access pathway. Building on existing national tools and approaches, rather than requiring parallel development from scratch, should be the default where feasible.

Recommendation 2: Establish structured and inclusive support for data holders

Data holders across the EHDS ecosystem vary significantly in size, resources, and technical capacity. Implementation guidance, standardised process templates, and targeted support should be developed to help a diverse range of data holders meet their obligations under the EHDS framework, with particular attention to smaller or less-resourced institutions. Clear allocation of responsibilities between HDABs and data holders, including roles in data quality assurance, metadata maintenance, and communication with data users, should be defined at national level as part of EHDS implementation planning. Structured feedback loops ensuring that data holders receive information about the research outputs generated from

their data should be developed to reinforce engagement and support data quality improvement over time.

Recommendation 3: Develop a coordinated model for multi-country applications

Cross-border data access applications will require separate decisions by each relevant HDAB under the EHDS framework. However, the mutual recognition provision under Article 68(5) of the EHDS Regulation offers a basis for streamlining this process and could be further developed through European-level guidance to reduce duplication and improve the efficiency and predictability of multi-country applications. Such guidance should address the practical conditions for mutual recognition, including criteria for determining which aspects of an evaluation can be recognised across jurisdictions, responsibilities for coordinating Secure Processing Environments, and mechanisms for managing accountability across national systems. Experience from analogous frameworks, such as the clinical trials regulation, may offer relevant operational lessons in this regard.

Recommendation 4: Clarify governance roles and establish cross-border coordination structures

Clear governance arrangements defining the respective responsibilities of HDABs, HealthData@EU structures, and data holders in multi-country processes should be established as a priority. Internal coordination structures should be set up to support consistent communication, shared dashboards and monitoring tools should be developed to support transparency and accountability in multi-country processes, and common guidelines and mutual agreements between HDABs should be established to ensure predictable and consistent handling of cross-border applications. Existing research and industrial infrastructures with experience in cross-border data collaboration should be engaged in the design of these coordination arrangements, given the operational knowledge they have accumulated.

Recommendation 5: Address operational constraints through investment and practical piloting

The speed, cost, and scalability of data access processes are practical determinants of whether the EHDS secondary use framework delivers on its objectives. Investment in automated tools, request tracking systems, and transparent cost estimation mechanisms should be prioritised to reduce administrative burdens on all actors. Practical use cases and pilots should be developed systematically to test and refine processes before full implementation, ensuring that guidelines and workflows are feasible and well-adapted to operational realities across Member States with different levels of preparedness. Demonstrating the tangible value of EHDS-enabled secondary use, for patients, healthcare systems, and researchers, should be treated as a sustained communication and governance priority, essential to maintaining engagement and investment over the long term.

3.3 Protection of IP rights and trade secrets

The overall goal of the workshop on this topic was to discuss how intellectual property (IP) rights and trade secrets can be protected while enabling secondary use of health data under the EHDS Regulation. Bringing together health data holders from industry and academia, HDABs, and health data users, the workshop aimed to clarify stakeholder needs and concerns throughout the entire secondary use workflow. Through presentations and interactive discussions structured around five key stages (metadata communication, HDAB assessment, data provision, analysis in secure processing environments, and result export), participants sought to identify current practices, key challenges, and practical solutions needed for effective and balanced EHDS implementation.

3.3.1 Perspectives from stakeholders

Stakeholders highlighted diverse perspectives on IP rights and trade secret protection in the context of secondary use of health data under the EHDS.

Industry stakeholders emphasized the critical importance of robust IP and trade secret safeguards to maintain competitive advantage and encourage ongoing investment in research and development. They highlighted that effective IP protection supports innovation while enabling data users and holders to operate within a secure and predictable framework. Key concerns included the handling of device-generated data and proprietary algorithms, as well as the risk of unintended exposure of sensitive clinical trial data that could compromise competitive positioning and patient confidentiality. Industry representatives proposed a framework based on three foundational principles: clarity to eliminate ambiguity, consistency to align practices across the EU, and certainty to provide a stable environment for all participants.

Academic stakeholders underscored a balanced approach between openness and protection, positioning IP and database rights as legitimate assets that merit recognition and protection. They highlighted that academic and hospital institutions invest substantially in structuring, curating, and annotating health data, embedding significant clinical know-how in registries and biobanks that constitute protected assets. From this perspective, secondary use must respect IP rights, database rights, and trade secrets while supporting recognition and attribution mechanisms that acknowledge the value of data stewardship. Academic stakeholders also emphasized that open science does not necessarily imply unrestricted reuse or loss of control over derivative outputs, and that proportionate governance agreements reflecting these interests can coexist with the goals of the EHDS.

HDAB representatives highlighted that IP safeguards form one component of a broader set of responsibilities, with significant operational challenges remaining regarding the practical identification and protection of protected datasets. They noted ongoing efforts to develop approaches through multi-stakeholder engagement, while pointing to the need for clearer operational frameworks, harmonized procedures across Member States, and strengthened capacity to assess IP protections effectively. HDABs emphasized the importance of

structured collaboration with data holders and data users to ensure appropriate coordination and mutual understanding of IP-related risks.

Data users acknowledged the importance of safeguarding IP rights while raising concerns about potential barriers to research, particularly for smaller research groups and academic institutions. They highlighted the need to ensure clarity and predictability regarding dataset accessibility and IP implications, while avoiding unnecessary complexity that could limit legitimate scientific research. Data users also noted the dual role of many institutions as both data holders and data users, which can create tensions between transparency and controlled access objectives.

3.3.2 Key challenges identified

Stakeholders outlined key challenges related to IP rights and trade secret protection in the EHDS:

1. **Identification and flagging of protected datasets** – While dataset discoverability is crucial for the functioning of the EHDS, identifying which datasets contain IP-protected elements or trade secrets remains challenging. Data holders face difficulties in isolating specific IP-protected elements within clinical datasets at the metadata stage, particularly when sensitive information may only become apparent after extensive analysis. The distinction between datasets warranting broader protection and those with isolated sensitive elements requires clearer guidance and practical tools. Additionally, the changing nature of IP protections over time, for instance, through patent expiry, implies a need for ongoing communication and notification mechanisms between data holders and HDABs.
2. **Balancing metadata transparency with confidentiality** – Metadata must be sufficiently informative to enable data users to identify relevant datasets and formulate access requests, yet detailed metadata can inadvertently reveal commercially sensitive information, trade secrets, or the identity of data holders. Even listing dataset variables may reveal proprietary knowledge. This tension between discoverability and confidentiality requires careful design of metadata standards that provide guidance without exposing sensitive competitive information or undermining the legitimate interests of data holders.
3. **Consistency and harmonization in data access assessments** – HDABs must assess IP and trade secret claims on a case-by-case basis, considering the type of data, its intended use, and the identity of the applicant. However, significant variation in capacity, expertise, and interpretation of legal concepts across Member States creates challenges for consistent decision-making, particularly in cross-border requests. The absence of common assessment criteria, shared tools, and aligned interpretations may lead to divergent outcomes and reduced trust in the system. Additionally, there is limited clarity on how to assess risks related to IP, trade secrets, and what constitutes a "serious risk" under the EHDS Regulation.

4. **HDAB capacity and expertise** – Assessing IP and trade secret protections requires multidisciplinary expertise spanning IP law, data protection, technical infrastructure, and sector-specific knowledge. Many Member States face challenges in attracting and retaining such expertise within HDABs, particularly when assessments involve complex cases or emerging areas such as AI-related intellectual property. This capacity gap is further compounded by the need to conduct assessments within compressed timelines while maintaining quality and consistency.
5. **Risk management throughout the data lifecycle** – IP and trade secret risks extend beyond initial data access decisions and must be managed at all stages of the secondary use workflow: metadata communication, access assessment, data preparation and transfer, analysis within SPEs, and export and disclosure of results. Ensuring that safeguards agreed during the assessment phase are correctly implemented in practice, and that results exported from secure processing environments do not inadvertently disclose sensitive information, requires robust governance and monitoring mechanisms. Uncertainty about technical safeguards within secure processing environments, particularly regarding cybersecurity protections and user monitoring, may limit trust among data holders and affect participation in the EHDS.
6. **Communication and trust between actors** – Structured dialogue between HDABs, data holders, and data users remains limited in many settings. Without early and effective communication about IP sensitivities and safeguard requirements, there is increased risk of misunderstandings, legal uncertainty, disputes, and reduced willingness to engage with the EHDS framework. Industry stakeholders in particular expressed concerns about institutional capacity to safeguard sensitive data, underscoring the need to demonstrate both technical robustness and institutional reliability.
7. **Role clarity and decision-making frameworks** – The division of responsibilities among data holders, HDABs, and data users regarding IP assessment and protection remains insufficiently defined. Unclear allocation of responsibilities may lead to disputes regarding who bears liability for breaches, and insufficient guidance on criteria for refusing access or imposing conditions. Additionally, the interaction between HDAB decisions and existing legal remedies, including complaint mechanisms and national court review, requires clearer articulation to support predictability and accountability.

3.3.3 Recommendations for the collaboration framework

Protecting IP rights and trade secrets while enabling secondary use of health data under the EHDS requires strategic coordination across Member States and among key stakeholders. The following recommendations aim to support the development of operational and sustainable approaches to IP protection:

Recommendation 1: Clarify governance roles and establish cross-border coordination structures

Member States may consider developing non-binding common minimum reference criteria and principles for assessing IP rights and trade secret claims, with a focus on transparency, proportionality, and evidence-based decision-making. A voluntary EU-level framework could offer templates, decision trees, checklists, and practical examples to support HDABs in conducting consistent assessments across Member States. Such guidance could address key scenarios, such as datasets containing rare disease information, device-generated data, clinical trial data, and research-enriched datasets, providing concrete examples of how protection mechanisms can be proportionately applied. Harmonized implementation may be further supported through the development of shared operational tools, including: common templates for data holder notifications and IP claim documentation; standardized formats for reporting safeguards in data permits; checklists for assessing different categories of IP-related risks; and decision-support tools (such as risk-triaging frameworks) to help HDABs prioritize assessments and allocate expertise appropriately. Capacity-building resources, including training programs, reference materials, and case study libraries, may help less-resourced HDABs develop expertise and apply common criteria. The development and maintenance of such resources could be coordinated at EU level through initiatives such as the EHDS Board or dedicated working groups, with regular updates to reflect emerging challenges, such as those related to artificial intelligence and novel data uses.

Recommendation 2: Strengthening structured collaboration and communication between all stakeholders

Effective IP protection relies on clear and timely communication between HDABs, data holders, and data users throughout the secondary use workflow. Member States may consider establishing structured dialogue mechanisms and early consultation procedures through which data holders can flag IP sensitivities and HDABs can clarify safeguard requirements before formal access assessments. Such mechanisms could include: data holder consultation phases integrated into the assessment process; accessible channels for data holders to document IP claims; and feedback mechanisms through which data holders are informed of relevant safeguards being applied. Beyond individual assessments, collaboration mechanisms such as sector-specific working groups or multi-stakeholder forums could facilitate knowledge exchange and collective problem-solving on recurring challenges. These could be supported by the EHDS Board, community of practice initiatives, or dedicated working groups bringing together representatives from HDABs, industry, academia, and research infrastructure organizations. Such structured engagement is particularly important for managing IP-related risks across the entire data lifecycle, from metadata communication through result export.

Recommendation 3: Clarifying metadata design and managing the discoverability-confidentiality balance

Member States may consider developing harmonized approaches to metadata design that serve the dual objectives of dataset discoverability and IP protection. This could include: standardized fields and flags to indicate IP-related constraints, allowing data holders to signal protected elements without revealing detailed information; guidance on what metadata elements can be appropriately disclosed while protecting commercially sensitive information; tiered metadata approaches, where initial discovery metadata is more restrictive but detailed

metadata is available to authorized users during assessment; and clear communication with data users about the implications of IP constraints for dataset usability. A shared metadata toolkit, building on Health DCAT-AP common metadata model, could provide practical guidance and examples across different data types and protection scenarios. Ensuring that metadata remains appropriately informative while protecting legitimate interests of data holders requires input from both data holders and data users, and may benefit from iterative refinement through practical implementation experience.

Recommendation 4: Enhancing HDAB capacity, expertise, and defining safeguards across the data lifecycle

Effective EHDS implementation depends on HDABs having access to multidisciplinary expertise spanning IP law, data protection, technical infrastructure, and sector-specific knowledge. Member States may consider: establishing or strengthening dedicated IP units or advisory roles within HDABs; developing formal training pathways and continuous professional development opportunities for HDAB staff; creating networks or communities of practice where IP specialists can exchange experience and develop common interpretations; and exploring options for specialized advisory support (such as reference centres or helpdesks) to assist with complex assessments. IP and trade secret protections must also be maintained throughout the secondary use workflow. Member States may consider developing harmonized approaches to: contractual safeguards, including model terms and conditions reflecting common minimum protections; technical measures within secure processing environments, with clear documentation of cybersecurity standards and user monitoring capabilities; monitoring and logging mechanisms to ensure accountability and traceability of data use; and output review and disclosure control procedures to prevent unintended revelation of sensitive information. Clear documentation of applied safeguards in data permits can provide transparency to all parties while ensuring that agreed protections are implemented consistently. EU-supported capacity-building initiatives, including mentorship programs and shared resources, can help address capacity differences across Member States, with particular attention to supporting less-resourced systems.

Recommendation 5: Promoting balanced and predictable frameworks that support both protection and usability

While robust IP and trade secret safeguards are essential, overly restrictive or unclear frameworks may discourage participation by both data holders and data users. Member States and the EHDS governance structures may consider ensuring that: assessment criteria and safeguard requirements are clearly articulated and predictable, reducing uncertainty; processes remain proportionate to the level of risk, avoiding unnecessary complexity for low-risk use cases; regular stakeholder consultation is conducted to assess the operational implications of IP protection approaches and refine frameworks to maintain the attractiveness of the EHDS; and clear appeals or dispute resolution mechanisms are available to address concerns regarding access decisions. This balanced approach recognizes that the success of the EHDS depends on sustained engagement from multiple stakeholder communities, each with legitimate interests in both data protection and data accessibility. Particular attention may be given to ensuring that the framework does not create disproportionate barriers for smaller research groups, academic institutions, or less-resourced Member

States, while still maintaining robust protection for legitimately sensitive data and intellectual property.

4 PART II - Stakeholder-wise dimension: Research Infrastructures and Networks in the EHDS

Complementing the topic-wise analysis, this section explores collaboration from a stakeholder perspective, focusing on research infrastructures and networks as potential enablers within the EHDS ecosystem.

4.1 EHDS framework and its implications for research infrastructures

Over the past years, a wide range of European research infrastructures such as ERICs, EDICs and EU-funded projects like the Genomic Data Infrastructure (GDI)¹, EUCAIM², EOSC4Cancer³ have developed advanced digital tools for research, healthcare and policy purposes for sharing, processing and analysing health data, creating strong domain-specific ecosystems particularly in genomics, cancer imaging, and neuroscience. These infrastructures are commonly organised around federated models in which a central coordinating platform provides guidelines, tools and services to national nodes, while data remains stored at Member State level, held and curated by national nodes in close relationship with data holders. Most of these initiatives were conceived before the adoption of the EHDS Regulation, and therefore operate under diverse governance, legal bases and access models.

The EHDS Regulation establishes a new horizontal legal and governance framework for the secondary use of health data across Europe, centred on national HDABs and the central HealthData@EU infrastructure. Its objective is to improve the findability, accessibility and secure reuse of health data across Member States, enabling dataset discovery at EU level, streamlined access authorisation and the conditions for cross-border data linkage for research, innovation, policy-making and regulatory purposes, where technically and legally feasible. The Regulation formally establishes roles that did not previously exist in the landscape (e.g. Health Data Access Bodies, Health Data Intermediation Entities, Trusted Data Holders, Authorised Participants in HealthData@EU, and Cross-Border Registries) and introduces binding procedural requirements for how data is requested, pseudonymised or anonymised, and made available exclusively within SPEs.

The EHDS addresses several structural challenges faced by existing infrastructures, notably EU-wide dataset discoverability and the streamlining of access authorisation, and in doing so it creates important opportunities for research infrastructures to extend their reach and visibility. At the same time, research infrastructures provide significant complementary value in areas that fall beyond the EHDS framework's design scope: data harmonisation and curation for research-grade reuse, the development and maintenance of domain-specific interoperability standards, support for time-sensitive research access needs, and the translation of data access into meaningful scientific and clinical outcomes.

The introduction of new roles and interaction models raises a set of important and practical questions for existing initiatives seeking to position themselves within or alongside the EHDS framework: which roles are realistic and desirable given their mandate and governance? What responsibilities and constraints does each role entail? Where do opportunities for synergy lie, and where are the limits? What adaptations (legal, operational or governance-related) may be needed to operate effectively within the EHDS legal framework? These questions constitute the alignment challenge that this section of the guideline addresses.

¹ [European Genomic Data Infrastructure \(GDI\) project](#)

² [Home - Cancer Image Europe](#)

³ [eos4Cancer - European Open Science Cloud for Cancer](#)

4.2 Stakeholder engagement methodology

This work aims to support a shared understanding and coherent interpretation of how research infrastructures, networks and EU-level initiatives can operate within the EHDS framework rather than alongside it. More specifically, the results are intended to feed into European-level guidelines and a reference framework illustrating how different EHDS roles may apply across infrastructures and use cases, supporting both policy implementation and operational decision-making by providing recommendations for alignment, governance and collaboration within the EHDS ecosystem.

The work combines two sequential levels of data collection. A survey was first administered to a broad population of target organisations, including ERICs, EDICs, EU-funded projects, ESFRI research infrastructures, European Reference Networks and other EU-level health data initiatives, providing a systematic landscape analysis of how these organisations currently operate and how they perceive their positioning in relation to the EHDS framework. Structured follow-up interviews were then conducted with a targeted subset of surveyed stakeholders, offering a deeper level of investigation into the issues surfaced by the survey. The interviews aimed to explore how infrastructures understand their potential roles under the EHDS, identify opportunities, challenges and risks from their perspective, understand which services they see as complementary to EHDS functions, and collect practical insights that can inform guidance.

The analysis presented in this chapter is structured in three parts. It begins with an examination of the services currently provided by research infrastructures and networks, assessing these functions and service offerings in light of the EHDS framework for secondary use and the opportunities for alignment and complementarity they present. This is followed by a description of the different roles that research infrastructures may take up within the EHDS framework, drawing on both the options established by the Regulation and the perspectives gathered through stakeholder engagement. The chapter concludes with a set of recommendations for the implementation roadmap, grounded in the practical insights and priorities expressed by research infrastructures and networks throughout the engagement process.

4.3 Mapping of services and functions by research infrastructures

This section analyses the responses to the survey section on services and functions provided by participating infrastructures. It examines the types of data held by these organisations, the breadth and nature of services they provide, and what this landscape reveals about the role research infrastructures currently play in enabling health data reuse and could play within the EHDS ecosystem.

4.3.1 Data holding and domain specialisation

The survey included 17 participating organisations. The landscape includes both data-holding infrastructures and service-oriented infrastructures that primarily facilitate access, harmonisation, or analysis without directly holding data. Results show that 65% of respondents hold data falling within the EHDS secondary-use categories defined under Article 51 of the Regulation, indicating that the majority manage datasets directly relevant to the secondary use framework being established. A further 6% hold data that falls outside the EHDS categories, while 29% do not hold data directly, operating instead as service or access facilitators across the ecosystem.

Data holding status across respondents

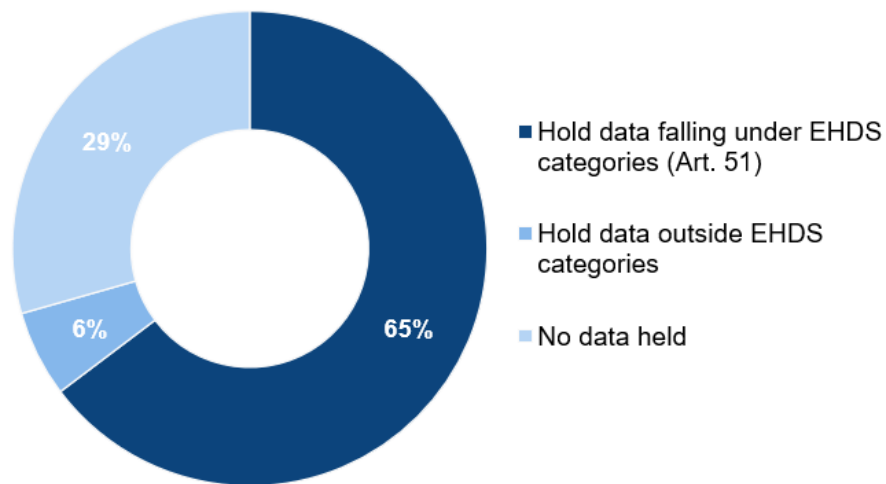


Figure 1: Graphic 1 - Data-holding capacity

Organisations holding data within the EHDS categories have, in many cases, developed dedicated collections of curated data, including disease-specific registries, longitudinal cohorts and biobank collections, often built over many years through sustained investment in data governance, quality control and community engagement. Others have established contractual arrangements with data providers such as hospitals, laboratories and clinical networks, creating structured pipelines for data contribution, preparation and sharing. In both cases, the result is a significant level of operational experience in the practices that the EHDS framework aims to support and make more consistent: data access governance, quality assurance, harmonisation, and the management of cross-institutional data flows. This expertise constitutes a significant asset for EHDS implementation.

Domain specialisation patterns

The distribution of data categories held by respondents reflects both the domain strengths of the European research infrastructure landscape and the areas where dedicated ecosystems have emerged ahead of the EHDS.

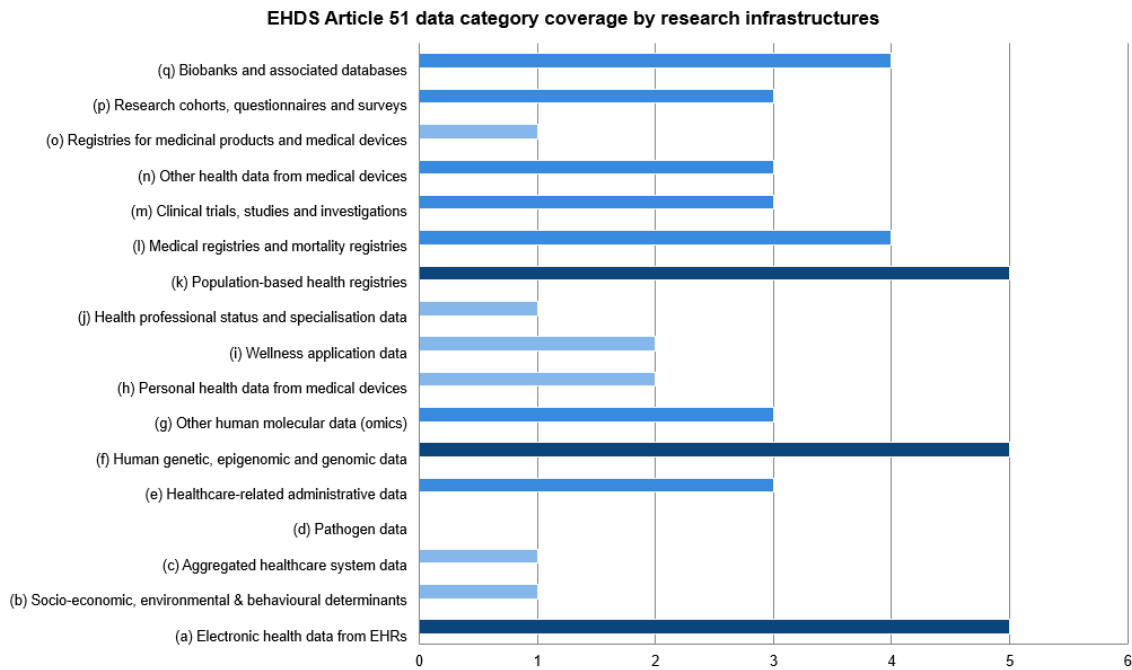


Figure 2: EHDS categories of data for secondary use held by research infrastructures

The highest coverage was reported for electronic health record data, human genetic and genomic data, and data from biobanks and associated databases, followed by population-based health registries and medical registries and mortality data. Data from clinical trials and studies, other molecular omics data, other medical device data, and research cohorts were each reported by three respondents. These patterns reflect years of domain-specific investment in data harmonisation, curation infrastructure and access governance in precisely those areas (genomics, biobanking, clinical research, population health) where structure secondary use has been most actively pursued. The implication is that for these data categories, the EHDS will encounter an existing ecosystem of expertise, tools and community practices that can be drawn upon and built upon, rather than developed from scratch. By contrast, lower representation was observed for socio-economic and behavioural determinants of health, aggregated healthcare system data, health professional data, and registries for medicinal products or medical devices. Notably, no respondent reported coverage of pathogen data. These gaps are relevant for EHDS implementation planning: they indicate data domains where the infrastructure of expertise and curated collections is less developed and where dedicated capacity-building effort may be needed to realise the secondary use potential the Regulation envisions.

4.3.2 Analysis of services and functions across the secondary use journey

Across the seven functional domains covered in the survey, respondents reported a remarkably broad portfolio of services, spanning the full journey of health data secondary use, from initial data discovery and access through to analysis, harmonisation, quality management, and user support. This section presents the reported services and functions provided by the infrastructures, examining how these are delivered across three modes:

internal provision, service provision to external users, or a combination of both. The analysis below examines them in terms of their distribution across the secondary use journey and their significance for the EHDS implementation context. A key observation cuts across all domains: many of these services are provided by multiple organisations working in different thematic fields, confirming their transversal relevance and demonstrating that operational solutions already exist at scale.

Data discovery, access, and governance

Discovery and access services are among the most widely deployed across the respondent landscape. The majority of respondents offer these externally or in a combined internal-external mode. Data access provision, support for contractual and legal arrangements, and eligibility review functions were each reported by the majority of respondents, typically in a mixed delivery mode. Data Access Committee support and multi-country access coordination, while less universal, were reported by six and eight respondents respectively. These findings demonstrate that the governance and procedural infrastructure for structured data access (e.g. the workflows, eligibility frameworks, legal support mechanisms, and multi-partner coordination processes that the EHDS will now formalise) are already operational across much of the research infrastructure landscape. Respondents have not only developed these capabilities internally but also have, in most cases, already extended them as services to external users and partner organisations.

Computational Infrastructure

The survey responses indicated that SPEs, now forming a cornerstone of the EHDS technical framework, are operated by several research infrastructures, predominantly for internal use or in a mixed mode. Containerised environments and data storage and archiving services were each reported by seven and eight respondents respectively, while monitoring and operational support was reported by seven. Federated analysis environments, a capability of strategic relevance given the federated architecture of many participating infrastructures, were reported by only four respondents, suggesting this remains a more specialised offering. The pattern here shows that the computational infrastructure tends to be deployed internally or in a mixed mode, rather than offered as a standalone service to external users. This reflects the resource-intensive nature of these environments and the tight coupling between infrastructure operation and domain-specific expertise. At the same time, the capacity that exists in this area, across SPEs, federated environments, and secure workspaces, is a directly relevant asset for the EHDS, which mandates SPE-based data access for secondary use.

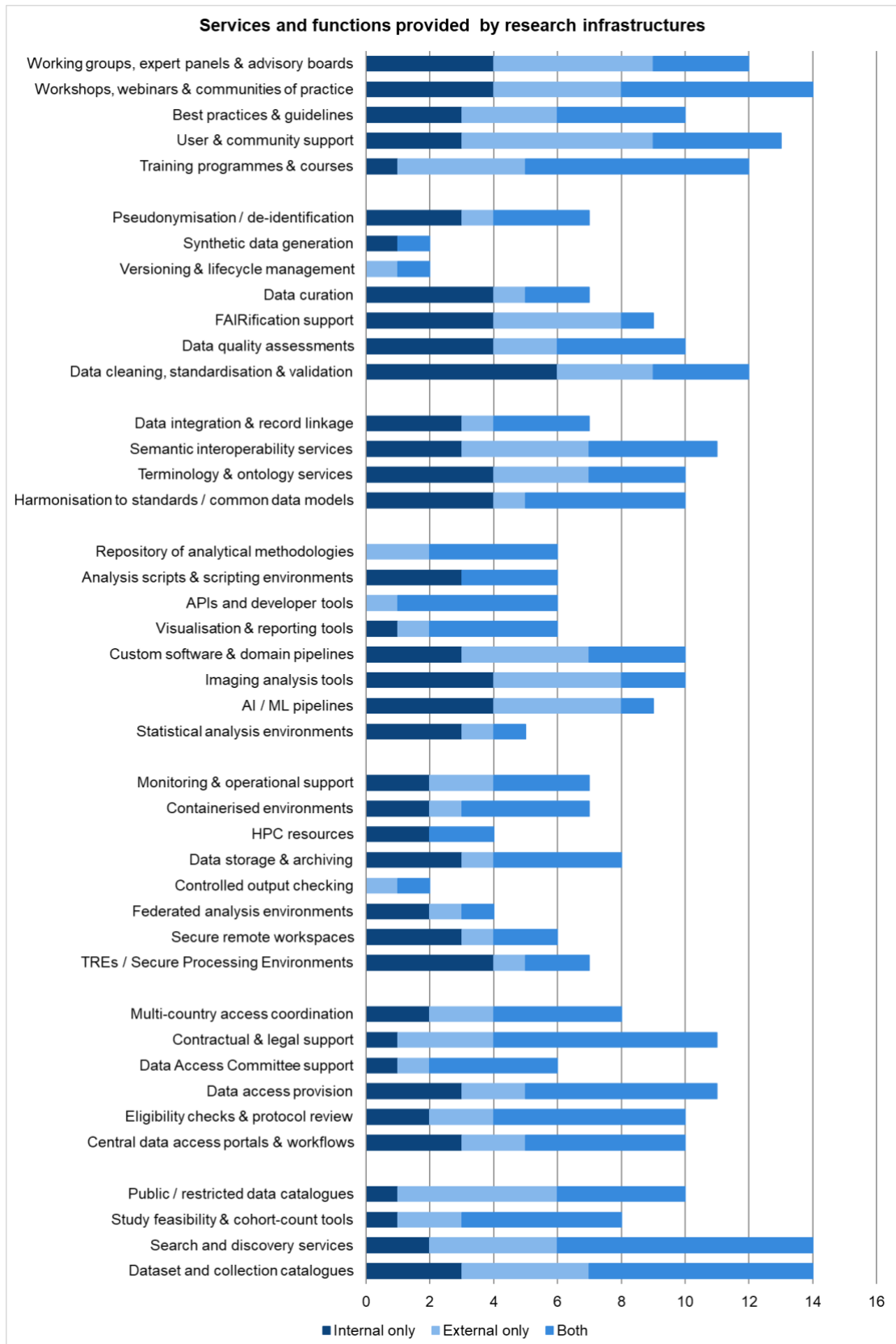


Figure 3: Services and functions provided by research infrastructures

Data analytics, harmonisation and quality

The analytical services layer reveals a rich and heterogeneous toolkit. AI and ML pipelines were reported by nine respondents, imaging analysis tools and custom domain-specific pipelines by ten each, the latter frequently offered externally or in mixed mode, reflecting the demand-driven nature of domain-specific analytical tool development. APIs and developer tools, reported by six respondents, are predominantly offered in both internal and external mode, pointing to a growing orientation towards programmatic interoperability.

In the harmonisation and interoperability domain, harmonisation to standards and common data models (OMOP, CDISC, FHIR) was reported by ten respondents, semantic interoperability services by eleven, and terminology and ontology services by ten. These high counts, distributed across organisations operating in different clinical and research domains, confirm that standards-based harmonisation is a transversal practice across the landscape, not confined to a single domain or infrastructure type.

Finally, data cleaning, standardisation and validation was the most widely reported data quality service, with data quality assessments and FAIRification support each reported by nine to ten. Data curation and pseudonymisation/de-identification services were reported by seven respondents each. These findings point to a mature, if unevenly distributed, culture of data quality management that the EHDS framework will need to engage with and build upon.

Training, capacity building and user support

The training and support domain showed the strongest and most externally oriented service provision of any area. Workshops, webinars and communities of practice were reported by 14 respondents, matching discovery services as the most widely deployed offering. Thematic working groups, expert panels and advisory boards (including ELSI functions) were reported by 12 respondents, as were training programmes and courses. User and community support was also reported by the majority respondents. This pattern is particularly significant, since training, capacity building, and community governance are not functions addressed or regulated by the EHDS framework, yet they are precisely the functions through which research infrastructures create the conditions for effective and responsible data reuse. The breadth and external orientation of these services reflects an embedded culture of community-building and knowledge transfer that is critical for EHDS operationalisation but is not systematically provided for within the Regulation itself.

4.3.3 Key insights for EHDS implementation roadmap

Taken together, the survey results reveal a service landscape of considerable breadth and operational maturity. A substantial share of the services currently provided by participating research infrastructures extend well beyond the minimum regulatory framework of the EHDS, particularly in the areas of capacity building, methodological development, domain-specific harmonisation, and community governance. Only a limited subset of these services, most notably dataset catalogues, data access management and SPEs, are explicitly addressed in the EHDS Regulation as technical capabilities with assigned responsible actors and defined obligations. What the survey makes visible is that research infrastructures are already active

at every stage of the secondary use journey. At the entry point, they provide data discovery, feasibility assessment and study design support that helps researchers navigate the data landscape before formal access requests are made. Further along, they offer data preparation pipelines, harmonisation services and quality assurance functions that transform accessible data into data that is actually usable for research purposes. They provide the analytical environments, domain-specific tools and interoperability standards that enable researchers to extract scientific value from the data once accessed. And throughout this journey, they offer training, user support, and community governance mechanisms that sustain the human and institutional infrastructure on which effective secondary use depends.

The EHDS framework regulates the access layer of this journey with precision and ambition. The survey findings invite a broader perspective: ensuring that the full value of the EHDS is realised will require engaging with the entire service ecosystem that surrounds and enables that access layer. This observation provides the analytical foundation for the role analysis and recommendations in the following sections.

4.4 Roles and Pathways for Research Infrastructures in EHDS

The EHDS Regulation establishes a set of defined roles through which organisations may participate in the secondary use framework, as authorised participants in HealthData@EU, specialised Health Data Access Bodies, health data intermediation entities, trusted health data holders, health data holders, or service providers. For research infrastructures and networks, each of these roles represents a distinct pathway for engaging with the EHDS ecosystem, carrying different responsibilities, governance requirements and operational implications. This section examines each role in turn, drawing on the provisions of the Regulation and their associated recitals, and considers their practical relevance for research infrastructures and cross-border networks in light of the landscape and service capabilities documented in section 4.3. The aim is not to prescribe which role any given infrastructure should pursue, but to support informed reflection on the options available and the conditions under which each may be appropriate.

4.4.1 Authorised Participants

According to Article 75(4), health-related research infrastructures or similar infrastructures whose functioning is based on Union law and which support the use of electronic health data for research, policymaking, statistical purposes, patient safety or regulatory activities may become authorised participants in HealthData@EU. These entities may therefore connect to the infrastructure and support the functioning of cross-border access to health data for secondary use. Authorised participants must obtain the necessary technical capabilities to connect to the infrastructure and comply with the operational and technical requirements necessary for participation in HealthData@EU (Article 75(6)).

The rationale for the participation of research infrastructures and similar entities is explained in Recital (80), which states that the cross-border infrastructure should support multi-country secondary use of health data while ensuring legal certainty, interoperability and strong safeguards for personal data. The recital explicitly refers to research infrastructures established under Union law, such as European Research Infrastructure Consortia (ERICs) or infrastructures under the ESFRI roadmap or federated under the European Open Science Cloud (EOSC), as potential authorised participants. According to recital (98) authorised participants should also be invited to steering groups to ensure proper day-to-day managements of cross-border infrastructure.

From the perspective of research infrastructures and cross-border research networks, this role is particularly relevant because many such infrastructures already coordinate multi-country health datasets, registries, or federated data resources. By becoming authorised participants in HealthData@EU, research infrastructures may support the discovery, access and coordinated use of these datasets across Member States. In practice, this may include providing services such as dataset cataloguing, metadata services, federated data analysis infrastructures, or coordination of cross-border data access requests within the EHDS ecosystem.

4.4.2 Specialised HDABs

Under Article 55(1) of the EHDS Regulation, Member States shall designate one or more Health Data Access Bodies (HDABs) responsible for carrying out the tasks set out in Articles 57, 58, 59, 63 and 64. These bodies are responsible for implementing the rules governing access to electronic health data for secondary use. If a Member State designates more than one HDAB, Article 55(1) allows the tasks described in Article 57 to be distributed between different health data access bodies. This creates the legal basis for specialised HDABs, where responsibilities may be divided according to, for example, types of data, specific data sources, sectors, expertise, or operational functions. In such cases, one of the HDABs must be designated as a coordinating HDAB, responsible for coordinating the tasks of the different HDABs at national level and cooperating with health data access bodies in other Member States. This requirement is set out in Article 55(1). The possibility of organisational diversity among HDABs is further explained in Recital (64) of the EHDS Regulation. The recital states that health data access bodies may vary in terms of organisation and size, ranging from a dedicated, fully established organisation to a unit or department within an existing organisation.

The tasks of HDABs, which may also form the basis for functional specialisation between different bodies, are defined in Article 57(1). These tasks include, among others, assessing health data access applications, issuing data permits, granting access to electronic health data through SPEs, monitoring compliance by health data users and health data holders, requesting electronic health data from health data holders, and preparing data for secondary use, including operations such as combining, compiling, pseudonymising or anonymising data.

From the perspective of research infrastructures and cross-border research networks, the possibility to establish specialised HDABs may be particularly relevant in cases where access requests concern highly specialised datasets or infrastructures that require domain-specific expertise. For example, infrastructures coordinating large-scale genomic data, clinical registries or imaging repositories may involve complex governance, technical standards or intellectual property considerations that benefit from specialised assessment expertise within the HDAB system. In practice, research infrastructures could therefore play a role as expert nodes or operational partners supporting specialised HDAB functions, for example by providing domain-specific expertise, supporting the preparation or harmonisation of datasets, or contributing to the technical implementation of secure processing environments and federated data access infrastructures. While the Regulation does not provide for research infrastructures to automatically act as HDABs, their expertise and operational capacities may support the functioning of specialised HDAB structures in Member States.

Although Member States may organise HDAB structures according to their national administrative systems, the Regulation establishes safeguards to prevent conflicts of interest. According to Article 55, Member States must ensure that conflicts of interest between organisational parts performing different HDAB tasks are avoided, for example through the segregation of functions related to the assessment of applications, preparation of datasets, and provision of data through secure processing environments. In addition, the staff of HDABs must act in the public interest and in an independent manner when carrying out their tasks.

Finally, Article 62 provides that health data access bodies may charge fees for making electronic health data available for secondary use, provided that such fees are proportionate to the costs of preparing and providing the data and that they do not restrict competition.

4.4.3 Health Data Intermediation Entities

The EHDS Regulation allows Member States to rely on health data intermediation entities to address situations where certain health data holders may face a disproportionate administrative burden in fulfilling the obligations established by the Regulation. Recital (59) explains that Member States may introduce arrangements that allow intermediary entities to carry out certain obligations related to making electronic health data available for secondary use.

This possibility is reflected in Article 50(3) of the EHDS Regulation, which provides that Member States may establish in their national law that the duties of certain categories of health data holders are to be fulfilled by health data intermediation entities. In such cases, even though the intermediary entity performs the relevant tasks, the data are still legally considered to be made available by the underlying health data holders. Article 50 also allows Member States, in their national legislation, to determine whether certain health data holders that would otherwise fall outside the scope of some EHDS obligations should nevertheless be required to comply with them. Where such obligations apply, the practical fulfilment of those duties may be carried out by health data intermediation entities on behalf of those data holders. Health data intermediation entities may therefore perform technical, organisational or operational tasks related to facilitating data sharing, interoperability or the management of infrastructures supporting the exchange of electronic health data within the EHDS ecosystem.

From the perspective of research infrastructures and cross-border research networks, this role may be particularly relevant where infrastructures coordinate complex or federated datasets originating from multiple data holders. In such cases, research infrastructures could potentially act as operational intermediaries supporting the preparation, harmonisation or technical management of datasets that are made available through the EHDS framework. This could include activities such as metadata management, interoperability support, dataset harmonisation, or the operation of technical platforms facilitating secure access to distributed data resources. However, the Regulation also establishes clear limits to this role. In particular, Recital (76) clarifies that health data intermediation entities should not be designated as trusted health data holders, ensuring that intermediary entities remain distinct from the governance role associated with trusted health data holders (THDH) in the simplified data access procedure established under Article 72.

Health data intermediation entities therefore act primarily as facilitators within the EHDS ecosystem, supporting the practical implementation of data sharing arrangements, but they do not have the authority to assess health data access applications or recommend decisions on data permits, which remain responsibilities of HDABs and, where applicable, THDHs.

4.4.4 Trusted Health Data Holders

The designation of THDHs is not automatic under the EHDS Regulation. Instead, Member States may establish in national law a procedure through which health data holders can apply to be designated as THDHs. According to Article 72(2), the designation requires that the health data holder has the ability to provide access to electronic health data through a SPE, the necessary expertise to assess health data access applications and requests, and the capacity to ensure compliance with the requirements of the Regulation. The fulfilment of these conditions is assessed by the HDAB. Member States must also establish procedures to regularly review whether the designated THDH continues to fulfil these requirements (Article 72(2)).

In the Recital 76 it is stated that “THDHs should be allowed to assess the health data access applications submitted under this simplified procedure, based on their expertise in dealing with the type of health data they are processing, and issue a recommendation regarding a data permit”. This reflects the logic of the simplified procedure, under which the expertise of the data holder in relation to the datasets concerned may be relied upon for the assessment, while the HDAB retains the final decision. The legal basis for the role of THDH is set out in Article 72, which introduces a simplified procedure for access to electronic health data. Under this procedure, when a health data access application concerns only data held by a THDH, the HDAB may forward the application to that THDH for assessment. The THDH evaluates the application and provides the HDAB with an assessment and a proposed decision. However, the final decision on issuing the data permit remains with the HDAB, which is not bound by the proposal submitted by the THDH (Article 72(5)).

The policy rationale for this role is explained in Recital (76) of the EHDS Regulation. The recital states that Member States should be able to designate THDHs so that the data permit issuing procedure can be carried out in a simplified manner. This mechanism is intended to reduce the administrative burden on HDABs when managing requests related to datasets processed by specialised data holders. THDHs may therefore assess health data access applications based on their expertise in the type of data they manage and provide a recommendation regarding a data permit. Nevertheless, the HDAB remains responsible for issuing the final data permit. The recital also clarifies that health data intermediation entities should not be designated as THDHs.

THDHs must also be able to provide access to electronic health data through a SPE. Recital (77) explains that access to health data for secondary use should take place through SPEs to ensure strong technical and organisational safeguards, minimise privacy risks and prevent the direct transmission of personal electronic health data to users. In practice, access to the data may therefore be provided either by the HDAB or, where relevant, by the THDH through such an environment. In addition, the Regulation establishes requirements regarding the location and processing of personal electronic health data. Article 87 provides that HDABs, THDHs and the Union health data access service must store and process personal electronic health data within the Union when performing pseudonymisation, anonymisation or other personal data processing operations related to the procedures described in Articles 67 to 72. These processing activities must take place through SPEs within the meaning of Article 73 and Article 75(9) or through HealthData@EU. This requirement also applies to any entity performing those tasks on behalf of these bodies or services.

Under Article 74, THDHs may act as controllers for certain processing activities related to making data available, and as processors on behalf of the health data user when providing access through an SPE. THDHs may also charge fees for making electronic health data available for secondary use, similarly to HDABs. This possibility is provided in Article 62, which allows fees to cover costs related to assessing access applications, preparing datasets and carrying out processes such as anonymisation or pseudonymisation. Under the simplified procedure, the THDH must submit its assessment and proposal for decision to the HDAB within two months of receiving the health data access application (Article 72(5)). Following the decision of the HDAB to issue a data permit or approve a health data request, the THDH may then carry out operational tasks related to providing access to the data in accordance with the Regulation. HDABs must also indicate the THDHs in the dataset catalogue referred to in Article 77, ensuring transparency regarding which entities perform this role.

From the perspective of research infrastructures and cross-border research networks, the role of THDH may be particularly relevant where infrastructures manage large-scale specialised datasets or federated data resources that require domain-specific expertise to assess data access requests. In such situations, research infrastructures that act as health data holders could potentially apply to be designated as THDHs under national procedures. Their expertise in managing specific types of health data, such as genomic data, clinical registries, imaging repositories or other specialised datasets, could support the simplified access procedure established under Article 72 while maintaining the overall governance responsibility of the HDAB.

Finally, the Regulation allows THDHs to be designated at Union level in certain situations. According to Article 72(7), the Union health data access service may designate Union institutions, bodies, offices or agencies as THDHs, provided that they fulfil the same conditions required for national designations.

4.4.5 Health Data Holders

According to Article 2(2)(t) a legal person, public authority, agency etc. performing, e.g., research in relation to the healthcare or care sectors is a data holder if it has either

- The right or obligation, as a data controller or joint controller, to processes electronic health data for purposes such as providing healthcare or related services, developing healthcare products or wellness applications, conducting healthcare research, fostering innovation, informing policy development, producing official statistics, ensuring patient safety, or fulfilling regulatory obligations; or
- The ability to make available non-personal electronic health data through the control of the technical design of a product and related services, including registering, providing, restricting access to or exchanging such data.

As health data holders, Research Institutions may be responsible for making certain electronic health datasets available for secondary use through the EHDS framework, in accordance with the requirements of the Regulation and national implementation rules. The data to be made available has been defined in Article 51(1) of the EHDS Regulation whereas based on Article 51(2) Member States may introduce additional data categories to be made available within their respective countries. Thus, this matter is dependent on the Member State where the research institution as a data holder is established. Where Member States establish rules for the reuse of dataset improvements generated under a data permit, research institutions may support the identification, documentation, and methodological validation of such improvements, including corrections, annotations, or enrichment of datasets (Article 51(3)).

Health data holders have legal obligations related to:

Dataset description and maintenance

- Communicate to the HDAB a description of each dataset they hold, in the form of a metadata record, in accordance with Article 77. The dataset descriptions need to be checked, at a minimum, on an annual basis that they are accurate and up to date (Article 60(3)).
 - The Commission shall adopt an implementing act regarding the minimum elements and characteristics for the datasets to be provided (Article 77(4)).
- Inform the HDAB if any data contains content or information protected by intellectual property rights or trade secrets. Identify which parts and justify the need for specific protection. This information needs to be provided when communicating the datasets to the HDAB, or the latest when receiving a request from the HDAB (Article 52).
 - Research institutions often/may have established expertise in managing intellectual property rights related to research data and methods, which may support the identification and documentation of protected elements within datasets. While the protection of IP rights and trade secrets is ultimately assessed and decided by the HDAB under the EHDS framework, research institutions acting as data holders may provide input and suggestions based on their existing practices. This collaborative approach allows data holders to flag IP sensitivities early, even though the HDAB retains final authority over what protections are applied and whether data can be shared while maintaining those protections. Research institutions acting as data holders may provide suggestions based on their existing practices, which could also inform broader approaches within the EHDS framework.
- Where a dataset carries a data quality and utility label under Article 78, supply sufficient documentation to enable the HDAB to verify the label's accuracy (Article 60(4)).
 - If the electronic data has been collected or processed with the support of Union or national public funding, it must have a data quality and utility label that covers elements mentioned in Article 78(3). Moreover, health data collected and processed with the support of Union or national public funding, should be made available to HDABs to maximise the impact of the investment (Recital 59).

Data provision

- Make available, upon request by the HDAB and in accordance with a valid data permit or approved health data request, the relevant electronic health data referred to in Article 51 that they control. The requested data shall be placed at the disposal of the HDAB no later than three months from receipt of the request (Article 60(1-2)).
- Where RIs act as health data holders of non-personal electronic health data, they may be required to make such data available through trusted open public databases with transparent governance and access models, in line with the EHDS requirements (Article 60(5)).

4.4.6 Cross-border registries and databases

The EHDS Regulation also addresses the situation of cross-border registries or databases, which may be particularly relevant for certain domain-specific European initiatives, such as disease registries or research infrastructures operating across several Member States. The legal basis for these arrangements is provided in Article 76 of the EHDS Regulation.

According to Article 76, registries or databases that operate in more than one Member State may organise themselves into a network at Union level in order to facilitate the provision of electronic health data for secondary use. This governance arrangement enables a coordinated approach to access decisions concerning datasets originating from multiple Member States. Where a coordinator has been designated, the Health Data Access Body of the Member State in which the coordinator is established becomes responsible for deciding on health data access applications relating to the electronic health data held within that cross-border registry network. This governance arrangement ensures that requests for data from cross-border registries can be handled through a single decision-making authority within the EHDS access system.

The provision is particularly relevant for European-level registries and collaborative data infrastructures, as it enables them to organise their data access processes in a coordinated manner while remaining integrated within the EHDS governance framework for secondary use. From the perspective of research infrastructures, this provision may be especially relevant for infrastructures that coordinate or host European-level registries or federated databases, such as rare disease registries, clinical research registries or other distributed data infrastructures operating across Member States. For example, European Reference Networks for Rare Diseases are mentioned as an example of such cross-border registries in the EHDS legislative context. In similar situations, a clinical research infrastructure or registry network could organise itself under the framework described in Article 76 and designate a coordinator responsible for interacting with the relevant Health Data Access Body.

This mechanism may therefore provide a governance model for cross-border data infrastructure used in research, allowing multi-country datasets to be accessed through a coordinated process within the EHDS system while maintaining compliance with the regulation's access procedures and safeguards.

4.4.7 Service providers

The EHDS Regulation does not define or specifically regulate “service providers.” Therefore, the examples and recommendations presented here are illustrative.

A service provider can be understood as an organisation that provides technical, methodological, or operational services to support actors, such as HDABs, health data holders and users, within the EHDS framework. Importantly, service providers do not make decisions on data access applications or data permits as described in Articles 67–69 of the EHDS Regulation. These responsibilities remain with the HDABs. Furthermore, service

providers cannot perform tasks that the Regulation explicitly assigns to other actors where those responsibilities cannot be delegated. Research institutions are well placed to act as service providers due to their experience in managing sensitive data, conducting scientific research, and operating secure data infrastructures.

Examples of services that research institutions could provide include:

- Operating or supporting secure processing environments (SPEs) compliant with EHDS technical, organisational, information security, confidentiality, data protection and interoperability requirements (Article 73 and implementing acts).
- Offer domain-specific analysis tools and software (e.g. imaging, genomics, AI tools)
- Support data holders, HDABs and data users operationally
- Providing statistical or methodological expertise to support scientifically sound analyses.
- Offering guidance and training on responsible use of health data.
- Preparing and managing datasets, including documentation, pseudonymisation, or anonymisation
- Supporting data linkage and interoperability between datasets or institutions.
- Supporting dataset improvements, such as identifying and documenting corrections, annotations, or enrichment of datasets generated during research activities, where the Member State has established rules for such processing under Article 68 of the EHDS Regulation.
- Supporting data holders in improving data quality and interoperability, for example by providing methodological guidelines, common tools, or data curation support.

When such arrangements are used:

- Existing expertise and infrastructures should be utilised where possible, particularly established research data platforms and analytical environments.
- Roles and responsibilities should be clearly defined to avoid overlap with the regulatory tasks assigned by the EHDS Regulation.
- Decision-making responsibilities related to data access, including the assessment of applications and issuance of data permits under Articles 67–69, must remain with the HDABs.
- Appropriate governance arrangements and safeguards should be ensured, including compliance with EHDS requirements on secure processing environments, data protection, and transparency.

Engaging research institutions in supporting roles may strengthen technical capacity, improve data quality, and facilitate the effective and responsible use of health data within the EHDS framework.

4.4.8 Perspectives on role allocation: key observations from stakeholder engagement

The stakeholder engagement process revealed that the question of EHDS role allocation remains, for the majority of participating research infrastructures and networks, an open and actively evolving one. Rather than articulating definitive role preferences, interviewees described a process of careful reflection on their existing service portfolios, close monitoring of regulatory and national implementation developments, and considered deliberation about how their operational profile might align with the role categories established by the Regulation. The analysis below identifies the principal dimensions of complexity that characterise this process.

1. **The regulatory framework continues to evolve, leaving significant operational parameters undefined:** While the EHDS Regulation establishes the framework and core obligations associated with each role, a number of implementing acts remain under development and national implementation choices have yet to be made, meaning that certain operational parameters and practical arrangements will be further specified as implementation progresses. In this context, participating organisations described a posture of informed observation rather than early commitment, emphasising that role allocation decisions carry significant operational and organisational implications that cannot yet be fully assessed. The prevailing view was that national and European-level implementation will produce varied outcomes, and that premature alignment with a specific role may not serve the long-term interests of individual infrastructures or the research communities they support.
2. **Organisations are approaching role alignment by reference to existing service provision:** In practice, research infrastructures are reasoning from the services and functions their organisations currently provide, asking how those activities could be positioned within or connected to the role framework established by the Regulation. This approach reflects the depth of existing operational investment and suggests that, for many organisations, the alignment process is primarily one of regulatory positioning of established capabilities rather than development of new ones. The mapping of existing services to EHDS roles is, however, complicated by the breadth of the service landscape documented in section 4.3 and by the fact that several roles involve functions, such as data access decision-making and regulatory oversight, that sit outside the primary operational mandate of research-oriented organisations.
3. **A structural distinction between regulatory authority and service provision functions requires careful consideration:** Several stakeholders highlighted the importance of maintaining a clear functional separation between the exercise of regulatory authority, comprising the assessment of access applications, the issuance of data permits and the oversight of compliance, and the provision of operational services oriented towards the needs of data users and data holders. The concern expressed is that organisations performing both functions simultaneously may face accountability tensions, since regulatory authority responds to governance mandates and public interest obligations, while service provision is primarily answerable to user needs and operational quality. For research infrastructures whose primary mandate is to serve scientific

communities, this distinction has practical implications for the roles they may most appropriately assume within the EHDS framework.

4. **The territorial logic of role allocation presents challenges for EU-wide organisations:** Several EHDS roles, including health data holders, trusted health data holders and Health Data Access Bodies, are allocated and governed at Member State level. For cross-border organisations such as ERICs and EDICs, which operate across multiple national jurisdictions and are constituted under EU law, this creates a structural tension between their organisational model and the territorial architecture of the Regulation. Questions regarding the applicable national authority, the allocation of obligations across Member States of operation, and the procedural arrangements governing cross-border organisation's interaction with national HDABs remain to be resolved. The resources available to cross-border organisations for EHDS role assumption will, moreover, depend significantly on the implementation choices and associated funding allocations made at Member State level, introducing a further dimension of national variability into the role alignment process.

5. **The accumulation of multiple roles is of interest to participating organisations but remains legally and operationally uncertain:** Several interviewees expressed interest in assuming more than one EHDS role simultaneously, for example, pairing authorised participant status with trusted health data holder functions, with the rationale that such combinations could allow infrastructures to offer more integrated services to their user communities and apply their domain expertise at multiple stages of the data access process. However, whether such combinations are permissible in any given national context, and how potential conflicts of interest and accountability obligations would be managed, will depend on the applicable legal framework and the governance arrangements established by Member States in their national implementation. These stakeholder perspectives may nonetheless provide useful input for future discussions on role design and implementation.

4.5 Recommendations for the Development of Collaboration Models in the EHDS Secondary Use Framework

This section draws on structured interviews and survey-based engagement with representatives of research infrastructures, networks, and EU-level initiatives to identify key barriers and opportunities for collaboration, and to translate these into actionable recommendations for the implementation of the EHDS collaboration framework.

4.5.1 Challenges and opportunities for the EHDS framework

The European health data ecosystem has, over the past years, generated a substantial body of expertise, tooling, and operational practice in the domain of health data reuse. This knowledge has been developed through a wide range of parallel efforts (e.g. domain-specific research infrastructures, EU-funded projects, collaborative networks, and community-driven

initiatives), each producing valuable contributions in areas such as data harmonisation, federated access architectures, quality curation pipelines, interoperability standards, and governance frameworks for responsible data sharing. The cumulative investment represented by this landscape is considerable. Yet, its defining structural characteristic is also the principal challenge reported in the stakeholder engagement: the knowledge, resources, tools, and communities remain distributed across a fragmented landscape of initiatives with varying mandates, funding cycles, and visibility. For research communities and health data users seeking to access and reuse health data across borders, this fragmentation translates into a dispersed resource environment, multiple and inconsistent entry points, and a significant burden of navigation that falls on individual users and organisations rather than being absorbed by a coherent common infrastructure.

The EHDS Regulation represents a structurally significant opportunity to address this fragmentation. For the first time, a binding common legal framework establishes shared obligations, reference standards, and governance architecture across Member States, providing a unifying context within which the distributed ecosystem of research infrastructures, data holders, health data access bodies, and data users can align their planning and operations. The EHDS has the potential to function as the integrating framework that brings existing communities, tools, and expertise into productive relationship, consolidating accumulated knowledge into a common reference base, providing a common governance architecture for cross-border data access, and establishing the conditions for a more coherent, user-oriented infrastructure for secondary use that individual projects and initiatives have not, by their nature, been able to deliver at scale.

The stakeholder engagement process further highlighted the relevance of the existing network of research infrastructures, collaborative initiatives, and domain-specific communities as a resource that the EHDS implementation process can draw upon. Over the course of preceding years, these organisations have developed working relationships across medical and scientific communities, established operational practices in data governance and quality management, and produced tools and frameworks that are actively used by research communities across several domains. Stakeholders pointed to the EHDS as an opportunity to bring this accumulated experience into closer relationship with the emerging governance architecture, connecting the framework to established user communities, drawing on tested methodological and technical resources, and building on the community engagement work that domain-specific initiatives have carried out over time. Whether and how this connection is realised will depend on the implementation choices made at national and European level. The opportunity, however, is widely identified as both significant and time-sensitive, given that implementation decisions currently being made will shape the architecture of the framework for years to come.

4.5.2 Actionable recommendations towards a collaboration framework

The following section is formulated with the specific aim of informing the development of sustainable collaboration models between health data research infrastructures, organisation and cross-border networks and initiatives, and the emerging EHDS governance architecture.

It addresses both near-term priorities in the current implementation phase and the structural conditions that will determine whether collaboration between research-oriented organisations and EHDS actors can be placed on a stable and durable foundation. It is addressed to the European Commission and Member States as the primary decision-making authorities shaping EHDS implementation, with reference to the role that research infrastructures and networks can play where relevant, and is intended to reflect operational realities and the evolving nature of the regulatory framework.

The section is structured around two interconnected dimensions of the collaboration challenge:

- **Where research infrastructures and organisations can concretely contribute** - identifying, at each stage of the EHDS user journey, the specific added value they bring, the opportunities for synergies with the emerging EHDS architecture, and the practical benefits this generates for the ecosystem as a whole.
- **How that contribution can be made systematic and durable** - addressing the governance, process, and structural conditions needed to embed collaboration on a sustainable footing within the EHDS framework.

1. Where research infrastructures and organisations can contribute to the EHDS

The EHDS establishes a legal framework for health data access and reuse, creating obligations around data discoverability, access procedures, and secure processing of data. Yet, the translation of this framework into a functional secondary use ecosystem depends on a wider set of conditions that the regulation itself does not fully cover: the quality and completeness of metadata, the usability of data for research, the availability of domain-appropriate analytical environments and tailored tools, and the capacity of diverse actor communities to navigate and interact with this new regulatory and operational system. Research infrastructures, networks, and cross-border organisations have developed substantial operational expertise across precisely these dimensions. The following analysis, based on the analysis gathered in Section 4.3.2, maps their potential contributions to each stage of the EHDS user journey, identifying both where structured integration would be most impactful and what concrete value it would generate for the EHDS ecosystem.

Data discovery

The EHDS user journey begins with the identification of relevant datasets through national metadata catalogues and the EU Dataset Catalogue. The quality of this first step is determinative: data users who cannot assess dataset characteristics in sufficient detail will either submit poorly calibrated access applications or fail to identify the data they need altogether. Research infrastructures could contribute here in two distinct ways. First, they can support data holders in producing richer and more complete metadata, providing domain-specific guidance and tooling for catalogue compliance that draws on deep familiarity with the characteristics, limitations, and contextual specifics of particular data types-knowledge

that is often not accessible through formal documentation alone and that generic EHDS metadata standards are not designed to capture at domain level. Second, they can support data users through structured study feasibility assessments prior to the submission of access applications, drawing on their expertise in research design, cohort definition, and dataset evaluation to help applicants identify the most appropriate datasets and formulate realistic, well-specified requests. The aggregate effect of both contributions would be significantly stronger catalogues and better-tailored applications, reducing the assessment burden on HDABs and increasing the likelihood that data access processes result in genuinely productive research.

Data access application

The EHDS introduces new and, in the case of multi-country applications, procedurally complex access mechanisms. Research infrastructures and cross-border networks have accumulated extensive operational experience in managing data access in multi-jurisdictional settings, including detailed knowledge of national legal frameworks, data governance cultures, and the practical requirements of data access committees, contractual arrangements, and ethics review processes across Member States. This accumulated experience, embodied in tested protocols, standard templates, and lessons learned from complex multi-country projects, represents a concrete resource that could inform EHDS implementation planning (as demonstrated in section 3.2.2). Its relevance is particularly significant at two moments: during the current design phase, where fundamental procedural questions around multi-country request coordination, HDAB cooperation, and permit assessment criteria remain open, and during the operational phase, where domain-specific applications, such as those involving genomic data, rare disease registries, or linked dataset analyses, will require expert input that extends beyond the administrative mandate of HDABs. Structured pathways for drawing on this expertise would enable HDABs to develop more robust and better-tested mechanisms from the outset and reduce the operational burden of complex case assessment once the framework is operational.

Data preparation

An important insight emerging from stakeholder engagement is the distinction between data accessibility and data usability. While the EHDS framework defines the conditions under which data can be accessed for secondary use, it does not cover the activities necessary to ensure that this data is ready for research and innovation. Tasks such as data curation, improvement of data quality at source, harmonisation to common data models, alignment of terminologies and ontologies, and the development of domain-specific interoperability standards are essential for making data usable in practice but fall outside the current HDAB mandates. These are precisely the areas where research infrastructures and domain-specific networks have built extensive expertise. Through sustained investment, they have developed methodological guidelines, common tools, and operational pipelines that have been validated across diverse national and institutional settings. Where this existing capacity is drawn upon, it could help ensure that available data is effectively reused for high-quality research and innovation. Efforts to enhance data usability alongside data availability would contribute significantly to the research and innovation outcomes the EHDS is designed to deliver.

Analysis in Secure Processing Environments

The EHDS mandates that all data access occurs through SPEs, establishing a technical architecture in which the quality, breadth, and domain-appropriateness of the analytical infrastructure available to data users will significantly shape what research is actually possible. As noted in Section 4.3.2, research infrastructures and domain-specific organisations already operate diverse secure analysis environments, federated architectures, high-performance computing resources, and containerised analytical platforms for health data. They have also developed extensive libraries of analytical methodologies, domain-specific pipelines, and AI/ML environments tailored to particular research domains, including genomics, imaging, and epidemiology. This operational capacity positions them as potential contributors to a scalable SPE ecosystem that provides genuine analytical depth rather than simply secure storage. Importantly, research involving complex data types (medical imaging or whole-genome sequencing) places demand on analytical infrastructure that differ substantially from those of tabular data analysis. Domain-tailored SPEs equipped with pre-configured tools and validated pipelines could allow data users to conduct research without rebuilding capabilities from scratch for each new project. The result would be a more attractive and efficient analytical ecosystem for EHDS data users, with direct implications for data uptake, research productivity, and the ability of the framework to support the full breadth of the European health research community.

Community support, training, and engagement

The EHDS introduces new roles, obligations, and procedures for a broad range of actors, many of whom have no prior experience with the framework's requirements. While the regulation places limited obligations on HDABs in this area, the scale of the onboarding challenge is considerable: data holders, data users, ethics committees, clinicians, and patient communities across Member States will need to understand and navigate a framework that is, in many respects, genuinely novel. Research infrastructures have extensive experience in capacity-building of this kind, having established working groups, expert panels, training programmes, communities of practice, and guidance materials tailored to specific actor communities. Beyond training, their established networks linking medical and research communities across Europe provide an existing channel through which EHDS awareness, adoption, and community engagement can be effectively fostered. This is an area where research infrastructures could provide significant added value to the EHDS secondary use framework, which ultimately depends on sustained participation from the communities it is designed to serve. Building that engagement is most effectively achieved through actors that already possess the relationships, domain credibility, and communication infrastructure to reach them.

2. How research infrastructures and organisations can integrate in the EHDS

Identifying where research infrastructures and organisations can contribute to the EHDS user journey is an important starting point for meaningful collaboration. Another fundamental question is how that contribution could be structured in a way that is durable and systematic,

supporting sustained engagement rather than relying solely on ad hoc arrangements or time-limited project relationships. Three interconnected dimensions of this challenge are addressed below.

Embedding domain expertise in governance from the outset

The stakeholder engagement process suggested that there is scope to draw more systematically on the operational knowledge accumulated across research infrastructures, registries, and domain-specific networks in EHDS governance and development processes. The knowledge in question is not only technical: it encompasses financial and organisational dimensions, including realistic assessments of what specific services cost to deliver sustainably, the administrative implications of different procedural choices for data holders, and the conditions under which data sharing generates genuine value for the clinical communities on whom data quality ultimately depends. The European Commission and Member States may wish to consider establishing advisory structures at national and EU level that create systematic and sustained pathways for this expertise to reach the governance bodies where implementation decisions are made. Such structures could encompass the full range of relevant actors (data holders, data users, research infrastructures, and service providers) ensuring that governance processes reflect a complete picture of the ecosystem. Where feasible, implementation frameworks and operational workflows should be developed through co-creation processes that bring together regulatory authorities, domain experts, and community representatives. This approach not only strengthens the quality of the outputs, but builds a sense of shared ownership over the framework that is itself a precondition for sustained engagement. Consideration of how such involvement could be supported on a sustained basis, beyond time-limited consultation exercises, may form a useful component of longer-term EHDS implementation planning.

Adopting an iterative, user-centred approach to technical implementation

The current phase of EHDS implementation has appropriately prioritised governance structures and legal frameworks. As implementation progresses toward the design and deployment of technical solutions, stakeholders highlighted the value of a user-centred and iterative approach, in which priorities for successive phases are defined in close dialogue with the communities that will use the system, and in which implementation experience is fed back into roadmap updates. This approach would allow for course correction as the framework matures, reducing the risk of misalignment between technical solutions and user needs. Member States and the European Commission may consider establishing sustained feedback mechanisms, including user panels, structured pilot evaluations, and systematic reporting channels, through which practical experience from data users, data holders, and supporting organisations can be incorporated into implementation planning on an ongoing basis. In this context, it would also be valuable to map the tools, methodologies, and operational practices relevant to each stage of the EHDS user journey already exists across research infrastructures, domain-specific initiatives, and networks. These resources, spanning data curation pipelines, harmonisation frameworks, federated access architectures,

analytical environments, and user support models, have been developed in response to the requirements of research and clinical communities, and their practical applicability has been validated through operational deployment. Identifying and assessing their potential relevance to EHDS technical development, rather than developing equivalent capabilities independently, could support coherence and efficiency in implementation.

Designing an integrated ecosystem with a sustainable value chain

The two dimensions addressed above are most fully realised within a broader structural consideration: the EHDS secondary use framework will most likely involve a wider range of actors than those formally defined by the Regulation. The EHDS Regulation establishes the governance and access architecture, yet several stages that are essential to making data not merely accessible but reusable for research, including work on domain-specific interoperability standards, data preparation and enrichment, and the development of analytical environments suited to specific data types and scientific questions, fall outside of HDAB mandates according to the regulation. . These are areas where research infrastructures, domain-specific networks, service providers, and other organisations have developed relevant expertise and operational capacity, as the mapping in the preceding section 4.3.2 illustrates. Developing a coherent model that recognises these contributions alongside those of formally defined EHDS actors could serve several practical purposes: providing clarity on which functions are most appropriately performed by which types of organisations, reducing the risk of duplication or gaps, and informing the design of incentive structures that support sustained participation and investment in quality across the value chain. Member States and the European Commission may wish to consider how such a model could be reflected in EHDS implementation guidance.

Sustained engagement from data holders will depend in part on their ability to observe meaningful returns from investment in data quality and secondary use workflows. Creating clearer pathways between data contribution and downstream outcomes, whether in research, clinical practice, or healthcare system performance, could support more durable engagement across the value chain. In this regard, Member States and the European Commission may wish to consider three practical directions as implementation progresses: developing a functional description of the secondary use value chain that clarifies how different categories of actors can contribute at different stages, consistent with the governance framework established by the Regulation. Identifying where existing service provision capabilities across the ecosystem could be mobilised to address functional needs at each stage and progressively developing incentive structures and sustainable participation models as implementation experience accumulates. Together, these steps could support a more coherent and inclusive ecosystem for EHDS secondary use, building on the investments already made across the European health data landscape. .

5 References

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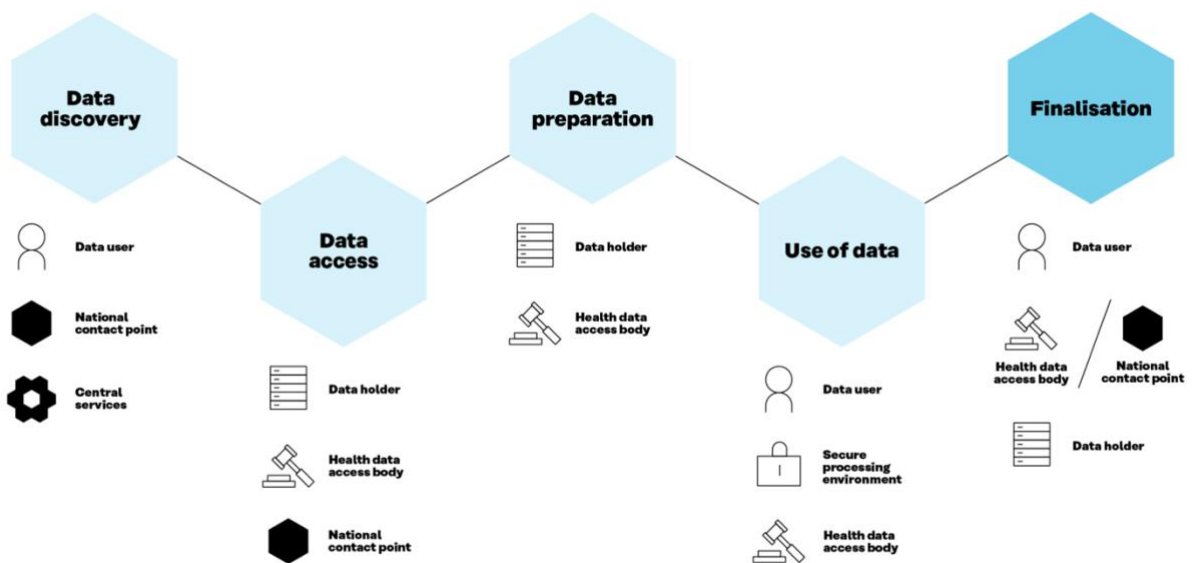
Annexes

Annex number	Annex title
1	User journey
2	Glossary
3	Stakeholder engagement activities

Annex 1 User journey

When a data user²¹ applies for electronic health data for secondary use purposes, such as research and innovation activities, education, and policy-making, within the European Health Data Space (EHDS), the user journey consists of several stages (see Figure 1). Access for certain purposes (public or occupational health, policy-making and regulatory activities, and statistics) is reserved for public sector bodies and Union institutions (see Chapter IV, Art. 53(1) and 53(2)).

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



Data discovery

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

Data access

In the data access phase, the user fills in and submits a dedicated and standardised data access application form or a data request to a health data access body (HDAB)²². The user must complete the information required in the form, upload necessary documents, and provide justifications as needed.

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

Data preparation

During this phase, the data holder(s)²³ 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 environment²⁴. The duration of this phase is specified in the Regulation (Art 68(12)).

Finalisation

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

Annex 2 Glossary

Term	Definition
Anonymisation	Anonymisation means the process by which personal data are transformed into data that do not relate to an identified or identifiable natural person, taking into account all means reasonably likely to be used, in accordance with Recital 26 of Regulation (EU) 2016/679 (GDPR).
Data controller	A data controller is a person or organisation that determines the purposes and essential means of the processing of personal data. The role of the data controller can be shared by several people or organisations. In that case, they are defined as joint controllers. The controller is accountable and responsible for establishing a lawful data processing workflow and observing the rights of data subjects. (GDPR Article 4(1)(7)).
Data extraction	Data extraction is the process of retrieving data from its source dataset.

	<p>Structured data extraction involves extracting data from datasets that are already organised in predefined formats.</p> <p>Unstructured data extraction pertains to extracting data from databases handling unstructured formats such as PDFs, images, or free text.</p> <p>There may be one or more different data sources from which data extraction may be required.</p>
Data linkage	<p>The process of combining <i>datasets</i> “from several sources on one topic or data subject” (ISO 5127:2017, 3.1.11.12.). This can be done using unique identifiers, probabilistic methods, or a combination of techniques.</p> <p>Access is only provided to electronic health data that is "adequate, relevant and limited to what is necessary in relation to the purpose of processing indicated in the health data access application by the health data user and in line with the data permit issues pursuant to Article 68." (EHDS Regulation, Article 66(1)).</p> <p>Data minimisation applies to all stages of the data lifecycle.</p>
Data minimisation	<p>A principle mandating organisation to only collect, store and process the minimum necessary amount of personal data for a specific purpose. This principle is fundamental under GDPR and relevant to the tasks outlined in EHDS. (GDPR Article 5(1)(c)).</p> <p>Access is only provided to electronic health data that is "adequate, relevant and limited to what is necessary in relation to the purpose of processing indicated in the health data access application by the health data user and in line with the data permit issues pursuant to Article 68." (EHDS Regulation, Article 66(1)).</p> <p>Data minimisation applies to all stages of the data lifecycle</p>
Data permit	<p>An administrative decision issued to a health data user by a Health Data Access Body to process certain electronic health data specified in the data permit for specific secondary use purposes based on conditions laid down in Chapter IV of the EHDS regulation (Art. 2(2v)).</p>
Data preparation	<p>Data preparation is the process in which an organisation (in this case the data holder) transforms and organises raw personal or non-personal health data into one or more datasets (either in individual-based or aggregated form), to comply with a data permit or a data request approval issued by a Data User and approved by the competent Health Data Access Body.</p>
Data Processing	<p>Any operation or set of operations which is performed on personal data or on sets of personal data, whether by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction. (GDPR Article 4(2))</p>
Data Provision	<p>The stage in the data user journey where prepared health data is made accessible to authorised users for secondary purposes.</p>
Data quality	<p>Data quality means the degree to which the elements of electronic health data are suitable for their intended primary use and secondary use; (EHDS Article 2(2)(z))</p>
Data quality and utility label	<p>Data quality and utility label means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset. (EHDS Article 2(2)(aa))</p>
Dataset	<p>A structured collection of electronic health data. (EHDS Article 2(2)(w))</p>
Dataset Catalogue	<p>A collection of dataset descriptions, arranged in a systematic manner and including a user-oriented public part, in which information concerning individual dataset parameters is accessible by electronic means through an online portal. (EHDS Article 2(2)(y))</p>
Data Subset creation	<p>Dataset subset contains only selected records, variables or elements from a larger dataset while maintaining its key characteristics and relationships.</p>

	Data subset creation refers to the process of extracting the specific portion of a larger database based on defined criteria, to support a particular analysis or creation of a statistical format. This evolves extraction of relevant observation and variables for the specified purpose.
Electronic health data	Personal or non-personal electronic health data (EHDS Article 2(2c)).
Health data access application	An application seeking to access personal-level electronic health data for secondary use in an anonymised or a pseudonymised format (EHDS Article 67).
Health Data Access Body	<p>Member State-designated authority that facilitates the secondary use of electronic health data. HDABs assess the information provided by the health data applicant and decide on health data requests and access applications, authorise and issue data permits, obtain data from data holders and make data available in SPE. HDABs systematically track the data request and data access applications received and the data permits issued. As per Article 58 of the EHDS regulation, HDABs are required to publicly list information on the data permits issued. (EHDS Article 55 and Recital 52)</p> <p>The HDAB duties include:</p> <ul style="list-style-type: none"> • Publishing the data dataset catalogue; • Evaluating health data access applications; • Maintaining records on data access applications and decisions; • Inform citizens on the use of data, the conditions under which data are made available and on how their rights are protected and safeguarded, respectively; • Receiving, preparing and compiling the requested datasets when requested, and properly anonymising or pseudonymising them; • Preserving the confidentiality of intellectual property rights and trade secrets; • providing access to electronic health data to health data users pursuant to a data permit in an SPE; • Supervising and enforcing the compliance of data holders and data users; • If a Member State has provided for the right to opt out pursuant to Article 71 to be exercised through the (coordinating) health data access bodies, the relevant health data access bodies shall provide public information about the procedure to opt out and facilitate the exercise of that right.
Health data applicant	A natural or legal person submitting a health data access application or a data request to a Health Data Access Body for the purposes referred to in Article 53 of EHDS.
Health data holder	Any person, organisation or public body involved in healthcare, care services, health-related products, wellness apps or health(care) research, that has the right to process data for health care provision or for public health purposes, reimbursement, research, policy making, official statistics or patient safety. This includes, for example, hospitals, insurers, research institutes and EU institutions. For a more detailed definition: EHDS regulation, Article 2(2)(t)).
Health data request	A request to access data in an anonymised statistical format for the purposes referred to in EHDS Article 53. (EHDS Regulation, Article 69)
Health data user	A natural or legal person, including Union institutions, bodies, offices or agencies, which has been granted lawful access to electronic health data for secondary use pursuant to a data permit, a health data request approval or an access approval by an authorised participant in HealthData@EU. (EHDS Article 2(2u))

	<p>The rights and responsibilities of health data users include:</p> <ul style="list-style-type: none"> ○ Accessing and processing electronic health data exclusively in accordance with an issued data permit, an approved health data request, or access approval from the relevant authorised participant within HealthData@EU. ○ Ensuring that electronic health data processed within secure processing environments is not shared or disclosed to third parties who are not explicitly identified in the data permit. ○ Refraining from re-identifying or attempting to re-identify natural persons from the electronic health data they have obtained, ○ Publicly disseminating results or outputs from secondary use within 18 months following either the completion of electronic health data processing in the secure processing environment or upon receipt of responses to health data requests, ○ Informing the health data access body of any significant finding related to the health of the natural person whose data are included in the dataset, ○ Cooperating fully with health data access bodies to facilitate the effective performance of their supervisory tasks.
Intellectual property (IP)	<p>(a) a trade mark; (b) a design; (c) a copyright or any related right as provided for by national or Union law; (d) a geographical indication; (e) a patent as provided for by national or Union law; (f) a supplementary protection certificate for medicinal products as provided for in Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (1); (g) a supplementary protection certificate for plant protection products as provided for in Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (2); (h) a Community plant variety right as provided for in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (3); (i) a plant variety right as provided for by national law; (j) a topography of semiconductor product as provided for by national or Union law; (k) a utility model in so far as it is protected as an intellectual property right by national or Union law; (l) a trade name in so far as it is protected as an exclusive intellectual property right by national or Union law. (Regulation (EU) No 608/2013 concerning customs enforcement of intellectual property rights and repealing, Article 2(1)).</p>
Metadata	<p>A structured description of the contents or the use of data facilitating the discovery or use of that data. (Data Act, Article 2)</p>
Non-compliance	<p>Any failure to comply with any requirement under the Union harmonisation legislation or under this Regulation; ((EC) No 765/2008 and (EU) No 305/2011)</p>
Non-personal electronic health data	<p>Electronic health data other than personal electronic health data, including both data that have been anonymised so that they no longer relate to an identified or identifiable natural person (the 'data subject') and data that have never related to a data subject. (EHDS Regulation, Article 2(2b))</p>
Open data	<p>Data in an open format that can be freely used, re-used and shared by anyone for any purpose. 'Open format' means a file format that is platform-independent and made available to the public without any restriction that impedes the re-use of documents; ((EU) 2019/1024 Open Data Directive)</p>
Personal electronic health data	<p>Data concerning health and genetic data, relating to an identified or identifiable natural person, processed in an electronic form. (EHDS Regulation, Article 2(2a))</p>

Pseudonymisation	The processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure non-attribution to an identified or identifiable person. (GDPR Article 4(5))
Secondary use	Processing of electronic health data for the purposes set out in Chapter IV of EHDS Regulation, other than the initial purposes for which they were collected or produced. (EHDS regulation, Article 2(2e))
Secure Processing Environment (SPE)	An environment in which access to electronic health data can be provided in following a data permit. An SPE is subject to technical and organisational measures and security and interoperability requirements. Specifically allowing access to only those persons listed in the permit, as well as user authentication, authorisation, restricted data handling, logging and the compliance monitoring of respective security measures. (EHDS regulation, Article 73)
Synthetic data	Synthetic data means artificially generated data created from an original dataset to reproduce its statistical properties, while not directly corresponding to real individuals. Synthetic data may constitute personal data where individuals remain identifiable, in accordance with Regulation (EU) 2016/679 (GDPR).

Annex 3 Stakeholder engagement activities

This document builds on an extensive programme of stakeholder engagement activities carried out throughout the development of the guideline. These activities were designed to gather perspectives from a wide range of actors involved in the European health data ecosystem, ensuring that the analysis and recommendations reflect practical experience, operational challenges, and emerging needs in the context of the EHDS.

1. Thematic workshops (Part I)

Three thematic workshops were organised to support the analysis presented in Part I of this document (Chapter 3). Each workshop focused on a key cross-cutting topic relevant to collaboration in the EHDS secondary use framework and brought together diverse stakeholder groups, including representatives from academia, public authorities, industry, research infrastructures, and patient organisations.

Workshop 1: Ethical dimensions of the EHDS

Held online on 23 June 2025, this workshop brought together 174 participants to explore how ethical considerations should be addressed in practice once the EHDS becomes operational. Discussions focused on what will change under the EHDS, potential concerns, and opportunities to strengthen trust, transparency, and accountability. The workshop featured four invited expert speakers, a panel debate, and three breakout discussion sessions. Speakers and moderators represented a broad range of perspectives, including public health, public policy, patient advocacy, medical ethics, research, and health informatics, at both national and EU levels. Discussions addressed key ethical challenges related to health data access in the EHDS context, including how overarching principles such as public interest, societal benefit, and legitimate interest can be translated into operational practice in a manner that is both coherent across Member States and sensitive to national and cultural contexts. Key themes included mutual recognition between ethics boards, the evolving role of Health Data Access Bodies (HDABs) in ethical governance, and the need to ensure that ethics remains a continuous, participatory process rather than a one-off compliance step. The workshop contributed to shaping a shared understanding of ethical governance under

the EHDS. The full workshop report is available at: [Workshop on the ethical dimensions of the European Health Data Space - Tehdas](#)

Workshop 2: Collaboration on data discovery and multi-country applications under the EHDS

This workshop brought together approximately 150 participants, both online and onsite in Paris on the 4th of November, to discuss challenges and opportunities related to collaboration between HDABs, data users, and data holders. The discussions focused on improving cooperation during the data discovery phase and in the context of multi-country applications, an area of increasing importance with the upcoming implementation of the EHDS Regulation. Expert presentations, grounded in practical experiences and use cases, provided the basis for interactive discussions. Participants examined current practices, identified gaps, and explored potential solutions and pathways for alignment. Particular attention was given to coordination mechanisms, process harmonisation, and the operational challenges associated with cross-border data access. The full workshop report is available at: [Workshop on collaboration on data discovery and multi-country applications under EHDS - Tehdas](#).

Workshop 3: Safeguarding IP rights and trade secrets in the EHDS

This workshop brought together 75 participants onsite and more than 150 participants online, including representatives from industry, academia, HDABs, and data users. The objective was to clarify stakeholder needs and concerns related to IP rights, trade secrets, and regulatory data protection in the context of secondary use under the EHDS. The workshop included a presentation on the legal framework by the European Commission, followed by a multi-stakeholder panel presenting perspectives from data holders, HDABs, and data users. These inputs informed a structured discussion session in which participants examined IP and trade secret considerations across five stages of the secondary use workflow: metadata communication, HDAB assessment of data access requests, data provision, analysis within SPEs, and export and disclosure of results. The workshop supported the development of a shared understanding of IP-related challenges and potential safeguards across the data lifecycle. The full report will be made available on the TEHDAS2 website.

2. Analysis of research infrastructures, networks and initiatives in the EHDS (Part II)

The analysis presented in Part II of this document is based on a combination of survey data and targeted stakeholder interviews, carried out in two complementary phases. First, a survey was conducted to provide a structured landscape analysis of research infrastructures, networks, and EU-level initiatives active in the health data domain. The survey collected information on organisational roles, services, and functions across the secondary use data lifecycle, as well as perspectives on potential alignment with the EHDS framework. This exercise enabled a systematic assessment of the current ecosystem and informed the analysis of role allocation and service provision within the EHDS. Building on the survey results, targeted interviews were conducted with selected stakeholders to gain deeper insights into operational experience, strategic positioning, and expectations regarding the EHDS framework. These interviews provided qualitative input that helped refine the analysis and supported the development of the recommendations presented in Section 4.5. The perspectives gathered through these interviews reflect contributions from individuals involved in the several organisations, initiatives, and networks. The table below provides an overview of the main organisations and initiatives from which stakeholder perspectives were gathered, including their type and core areas of expertise.

Organisation/Initiative	Type of organisation	Summary of activities/expertise
ECRIN (European Clinical Research Infrastructure Network)	European Research Infrastructure (ERIC)	Supports multinational clinical research by providing clinical operation services for study design, data management, and regulatory coordination across countries and data-related services (metadata repository and data sharing repository coupled to SPE).
UNCAN.eu	EU initiative/ Research Coordination Platform	Supports cancer research collaboration and federated access to cancer-related data and resources across Europe.
ERN eUROGEN	European Reference Network (ERN)	Focuses on rare and complex urogenital diseases, facilitating cross-border clinical collaboration and data sharing for specialised care and research.
Endo-ERN/ EuRREB	European Reference Network (ERN) / Registry Initiative	Endo-ERN focuses on providing knowledge and resources for diagnosis of rare endocrine conditions. EuRREB provides a centralised rare disease registry infrastructure supporting data collection, research, and patient registries in rare diseases.
Fraunhofer ISST (Fraunhofer Institute for Software and Systems Engineering)	Research Institute	Specialises in data spaces, data interoperability, and digital infrastructure, including governance and technical frameworks for secure data sharing.
1+MG/Genomic Data Infrastructure (GDI)	EU initiative/ Infrastructure Project	Supports cross-border access to genomic data and development of a federated infrastructure for genomics research and personalised medicine.
Euro-Biolmaging	European Research Infrastructure (ERIC)	Provides access to imaging technologies, data services, and expertise for biological and biomedical research, including imaging data management.
BBMRI-ERIC (Biobanking and Biomolecular Resources Research Infrastructure)	European Research Infrastructure (ERIC)	Facilitates access to biobanks and biomolecular resources, supporting data harmonisation, sample access, and research collaboration.
EHDEN (European Health Data and Evidence Network)/ DARWIN EU/OHDSI (Observational Health Data Sciences and Informatics)	Public-private partnership / EU network / research community	Focuses on real-world data, observational research, and common data models, enabling large-scale analytics and evidence generation across distributed datasets.

The diversity of organisations, initiatives, and networks represented, spanning multiple data domains such as genomics, clinical research, rare diseases, imaging, and real-world data, ensured a broad and multidisciplinary perspective on the issues addressed. The range of expertise, covering technical, organisational, legal, and scientific dimensions, allowed for a more comprehensive understanding of the challenges and opportunities associated with EHDS implementation. This diversity contributed to capturing cross-domain and transversal insights, supporting the development of recommendations that are applicable across different contexts within the European health data landscape.