

White Paper

EHDS2 Subnetworks as Operational Capability for Secondary Use

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From access to usability

Key message

EHDS2 creates a common framework for finding, requesting and securely using health data for secondary purposes. This is a necessary step for research, innovation, policymaking, patient safety and regulatory decision-making. However, access alone does not make data usable.

Recurring secondary-use cases require more than access to data. They require shared definitions, maintained metadata, data quality processes, domain expertise, governance and reusable workflows. As a result, EHDS2 will not become operational through a single “big bang” network, but partly through reusable, discoverable and use-case-specific operational capabilities: **EHDS2 subnetworks**. The prefix “sub” is intentional. A subnetwork is not an alternative or parallel network, but a specialized capability within the broader EHDS2 ecosystem.

The essence of this vision is simple: **HDU-led, HDH-enabled, HDAB-facilitated**.

The need originates with the Health Data User (HDU). The Health Data Holder (HDH) enables the capability. The Health Data Access Body (HDAB) facilitates and governs access, discoverability and monitoring, but does not determine whether a need for a subnetwork exists. Both HDU and HDH can be all kinds of organizations such as hospitals, research institutions, industry, and governmental organizations.



From access to usability: The operational EHDS2 challenge

EHDS2 establishes the legal and procedural framework for the secondary use of health data. It helps users find data, request access and use data securely. In doing so, it creates an important foundation for a European health data economy.

However, the implementation challenge goes much further. An HDU does not simply need access to datasets; they must be able to determine whether those datasets are suitable for their intended purpose. Are the required variables available? Are definitions comparable? Is the population representative? Is the quality sufficient? Are limitations understood? Can analyses be reproduced? Is sufficient domain expertise available to correctly interpret the results?

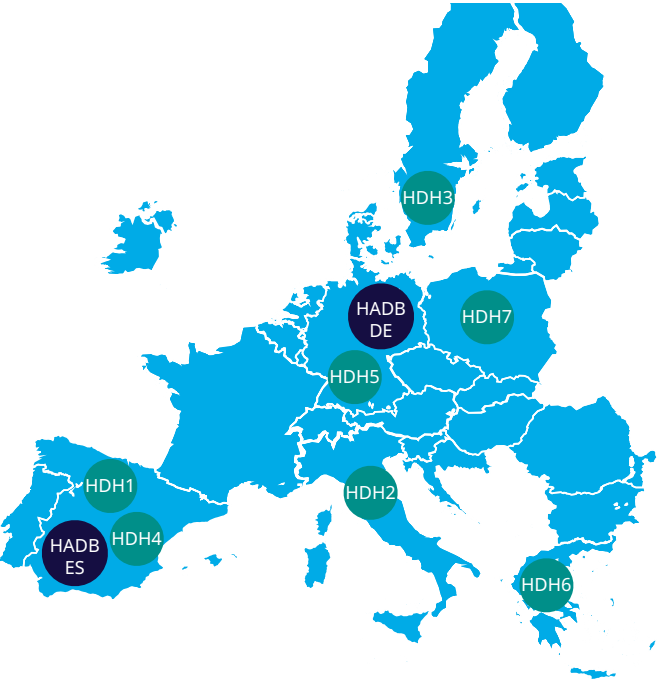
EHDS2 provides important building blocks such as catalogues, metadata, secure processing environments and a data quality and utility label. These building blocks make data easier to find and

assess. However, they do not automatically create the operational capability required for complex, recurring or cross-border secondary-use cases.

Interoperability is an essential part of that capability, but it is not the main topic. Interoperability is an essential part of that capability, but it is not the main topic. There is no universal interoperability stack- whether based on HL7 FHIR, SNOMED CT, OMOP, LOINC, OpenEHR, MedDRA, E2B(R3), DICOM, or other standards- that is suitable for all forms of secondary use. A drug prevalence study based on structured routine care data requires different standards and methods than safety signal detection from free text. An oncology outcomes study requires different capabilities.

Standards alone are therefore insufficient. Utility, feasibility, sustainability, governance, quality and community are at least as important as standards themselves. The central implementation question is not simply how access is granted, but who organizes the capability that transforms accessible data into reliable, usable and repeatable evidence.

Figure 1: Illustrative example than a rare disease registry, an AI training dataset or a public health surveillance use case



	DESIGNATED HDAB DE	DESIGNATED HDAB ES
	REGULATORY RWE SUBNETWORK	RARE DISEASE RESEARCH SUBNETWORK
HDH1		Member
HDH2		
HDH3	Member	
HDH4	Member	Member
HDH5	Member	
HDH6	Member	
HDH7		
Etc.		

Subnetworks as use-case-specific operational capability

An EHDS2 subnetwork is a voluntary, use-case-specific collaboration of HDHs, HDUs and, where relevant, intermediation capabilities, operating within the EHDS framework and maintaining a reusable interoperability stack, data quality framework, governance model and analytics workflow for a specific category of secondary use. A subnetwork does not exist alongside EHDS2; it exists within EHDS2. It builds on the same access infrastructure and governance principles while providing a common interoperability and operational framework through which diverse data sources can be made reusable for a specific secondary-use case.

Subnetworks are neither an alternative to EHDS2 nor closed data clubs. They are a practical mechanism for organizing operational capability around recurring secondary-use cases.

As figure one shows, HDHs may participate in multiple subnetworks, while subnetworks can span multiple countries and be supported by a designated HDAB responsible for assessment and monitoring of secondary use.

The demand determines the network. Subnetworks do not emerge because an authority decides they are needed. They emerge because future HDUs identify recurring needs that cannot be efficiently addressed through ad hoc dataset access alone[FM4.1][CVB4.2][FM4.3][CVB4.4]. Examples may include regulatory evidence generation, medicines safety, oncology outcomes, rare diseases, public health, or any domain where data quality, comparability and repeatable analytics are critical.

Subnetworks are therefore HDU-led. The HDU defines the question, the evidence need and the usability requirements. At the same time, they are HDH-enabled.

Without HDHs providing data, metadata, domain expertise, maintenance and operational capacity, the capability does not exist. The HDH therefore contributes not only data, but also the operational capability required to support the use case reliably.

Existing European initiatives demonstrate that elements of this thinking already exist in practice. BIGMSData illustrates how a disease-specific community can organize data, governance, expertise and infrastructure around a shared research objective. ELIXIR demonstrates how scientific communities organize standards and services around shared research needs. DigiCore shows how industry, researchers and data partners can collaborate around specific research questions, and how subnetworks can evolve over time by adapting established common data models to meet the changing needs of specific research use cases. These examples are not blueprints for EHDS2 subnetworks, but they demonstrate that federated collaboration, community-building, data quality and reusable analytical capability already work in practice. In principle, initiatives supporting similar use cases could even coexist within the same EHDS2 subnetwork, provided participating HDUs and HDHs see sufficient value in organizing a shared operational capability.

Importantly, subnetworks are not required for all forms of secondary use. For simple, one-off or local data requests, “standard” EHDS2 dataset-level access may be sufficient. Subnetworks become relevant when HDUs see enough value in jointly organizing capability, quality, governance and interoperability around a recurring use case. Subnetworks can emerge, grow, specialize, merge and disappear as needs evolve.

Design principles: Open, sustainable, verifiable and discoverable

Open, but not unconditional

A subnetwork should be open, but not unconditional. Open participation means that HDHs and HDUs can participate when they meet objective, use-case-specific requirements. It does not mean that every HDH or HDU can participate without conditions. Participation criteria are not intended to create exclusivity, but reliability. They should ensure that each participant possesses the capability, quality and maintenance discipline required to support the use case sustainably. Criteria may relate to capacity, capability, metadata maturity, data quality, maintenance processes, operational responsiveness, community contribution and fitness for the intended use case.

Not every HDH must actively contribute to governance, methodology or community leadership. Such a requirement would create unnecessary barriers. However, every participating HDH must take responsibility for the datasets made available through the subnetwork. This includes maintaining metadata, maintaining mappings, resolving data quality issues, documenting known limitations and periodically demonstrating that datasets remain fit for purpose and fit for use.

Participation in a subnetwork does not exempt a HDH from its broader EHDS2 obligations. A HDH participating in a subnetwork remains responsible for making relevant data available outside the context of that subnetwork whenever a legitimate request is made. A subnetwork creates an additional capability, not an exclusive access route.

Accessible to all applicants/HDUs, proportional to the use case

Subnetworks should remain accessible to both recurring and occasional HDUs. However, the level of support required to successfully execute a use case may vary significantly depending on the complexity of the request and the applicant's familiarity with

the supported use case. Participating HDHs should therefore be able to provide different levels of support, ranging from standard services to more intensive research-specific assistance where required. This flexibility helps ensure that subnetworks remain open and accessible while allowing scarce expertise and operational capacity to be used effectively.

Quality as a continuous process

The EHDS data quality and utility label can serve as an important starting point for quality assessment. It provides a foundation for describing datasets and helping users understand usability, quality and limitations.

However, the label should not be the endpoint. For a subnetwork, use-case-specific assessment is critical. A dataset may be well documented in general terms, yet still be unsuitable for a specific analysis, population, endpoint or study design.

Quality is therefore not a one-time checklist. It is a continuous process of maintenance, feedback, improvement and transparency.

Capability-level discoverability

EHDS2 will strengthen dataset-level discoverability. This is important: applicants must be able to identify which datasets exist, who manages them, which variables are available and under what conditions access may be granted.

Dataset-level discoverability shows what data exists. A subnetwork entry shows what use-case-ready capability exists. Such a capability entry could point to the relevant datasets, quality information, metadata, governance arrangements, supported use cases, analytical methods, contact points and maintenance processes.

The same principle applies to operational infrastructure. Not all secondary-use cases require identical processing environments, support models or security controls. A federated analytics use case that only shares aggregated results may require a different operational setup than a use case involving direct access to sensitive data. Subnetworks therefore

promote a fit-for-purpose approach in which operational arrangements, including secure processing environments, are tailored to the characteristics and risk profile of the supported use case while remaining fully compliant with EHDS2 requirements.

Sustainability through return of value

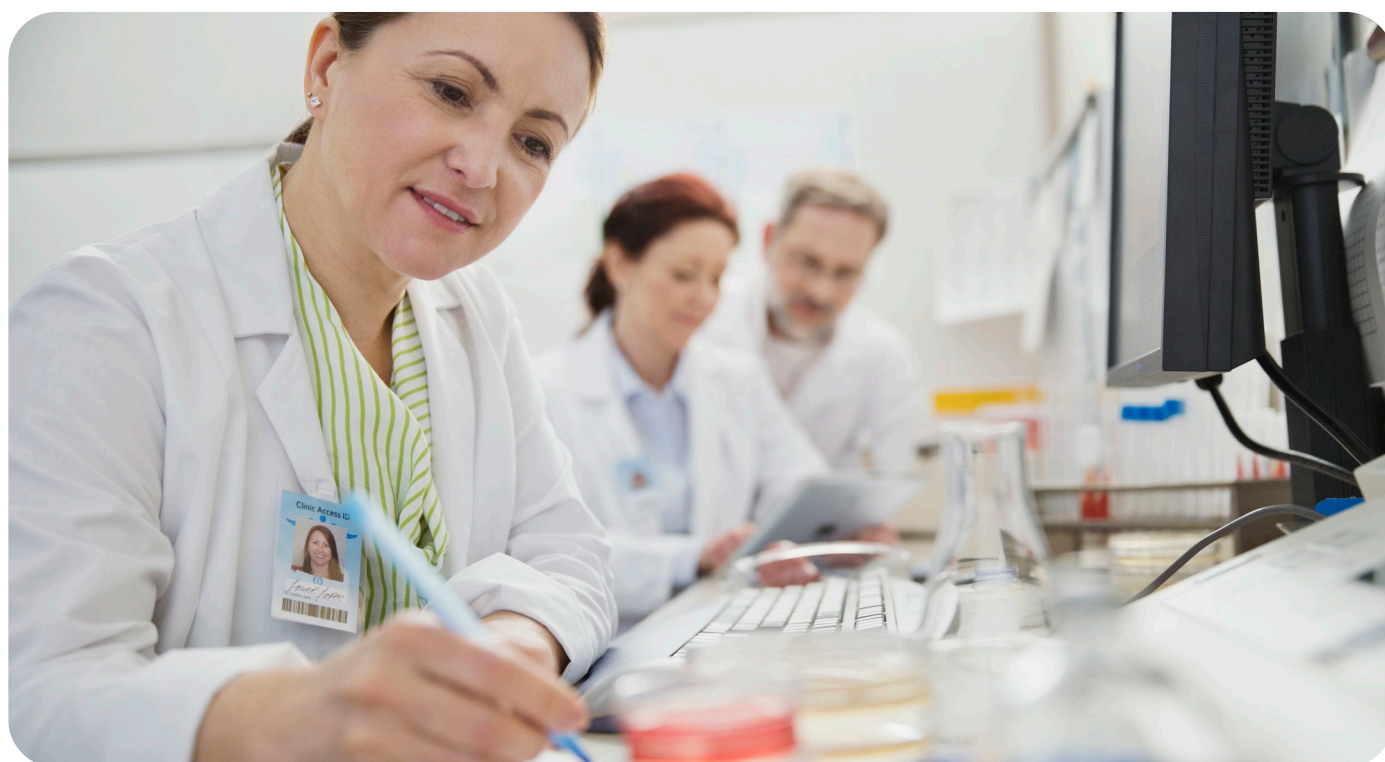
Subnetworks are sustainable only when participants receive value in return for participation. Many promising HDHs are also HDUs: academic centers, registries, research institutes, specialized healthcare networks, life sciences companies and existing research infrastructures. For these organizations, a natural loop-back mechanism emerges.

Investments in interoperability, metadata, data quality, governance and analytics workflows create value not only for external HDUs, but also for their own research programs, registries, quality initiatives, publications and European collaborations. For other HDHs, value may come through cost recovery, reputation, public mission, access to expertise or reduced ad hoc workload.

This loop-back mechanism is essential. A HDH will invest sustainably in quality, maintenance and interoperability only when a clear “return of value”

exists[FM6.1][CVB6.2], such as improved data quality, enhanced scientific output, improved patient outcome. Subnetworks make that value visible and reusable. Within a subnetwork, a HDH effectively becomes an active data service provider. Ultimately, the most valuable asset of a subnetwork is not the technology or the standard itself, but the community that maintains, applies and continuously improves it.

Participating HDHs are not merely custodians of data. Within a subnetwork they increasingly act as active data service providers, supporting metadata maintenance, interoperability, quality improvement, feasibility assessments, data preparation and, where relevant, study execution. The level of effort required may vary substantially between use cases and even between individual applications within the same use case. Subnetworks should therefore allow HDHs and HDUs to agree on fair, transparent and proportionate cost-based compensation that reflects the actual services provided. This flexibility is essential to ensure that operational support remains sustainable while maintaining trust and transparency for all participants.



Roles and policy choices: HDU-Led, HDH-Enabled, HDAB-Facilitated

Subnetworks originate from HDU needs. The HDU defines the question, the evidence need, the desired output and the data requirements. The HDH enables the capability by providing data, metadata, domain expertise, maintenance and quality. The HDAB facilitates discoverability, access legitimacy and monitoring, but is not constitutive for the creation or maintenance of a subnetwork.

A subnetwork therefore does not require prior HDAB approval to emerge. The initiative originates from user demand rather than administrative authorization. The formal interaction occurs when a subnetwork seeks recognition as a capability entry within national or European catalogues.

At that stage, a HDAB may assess whether minimum requirements are in place, including governance, metadata, quality processes, maintenance obligations, transparent participation criteria and periodic fit-for-purpose reviews. However, the HDAB should not determine whether the underlying scientific, public, regulatory or market need justifies the existence of the subnetwork. That need belongs to the HDUs.

HDABs are therefore facilitative rather than determinative. They are not required for the creation of a subnetwork but become relevant when the subnetwork becomes formally discoverable and when concrete secondary-use requests need to be assessed and monitored.

As a policy proposal, mature subnetworks should be supported by one or a limited number of designated HDABs responsible for substantive assessment and monitoring of secondary use[FM8.1][CVB8.2], regardless of the Member State from which the applicant originates. For example, a German applicant wishing to use a subnetwork for which a Dutch HDAB acts as the designated specialized reviewing body could submit their request through the regular national route, after which the substantive assessment and monitoring would be performed by the Dutch HDAB. This is explicitly a policy proposal. Its rationale is operational: specialization, consistency, reduced duplication, deeper understanding of the use case, and more predictable and consistent execution for both HDUs and HDHs.

Because subnetworks are use-case-specific, a specialized assessment and monitoring process can deliver higher quality than fragmented assessments where each authority has only limited familiarity with the data, capability, governance model and relevant quality criteria.

This model requires practical guidelines and tools. Establishing a subnetwork should not be perceived as a complex undertaking reserved for large institutions. Templates for governance, participation criteria, metadata, data quality review, fit-for-purpose assessment, fee principles, catalogue inclusion and community contribution can significantly lower the barrier to entry.

Conclusion

EHDS2 will make health data more accessible.

The next implementation challenge is organizing the operational capability required to support concrete secondary-use cases. EHDS2 subnetworks can fulfill that role: voluntary, use-case-specific and discoverable capabilities in which data, interoperability, quality, governance, expertise and analytics workflows are organized in advance.

Subnetworks are not a universal solution for all forms of secondary use. They become relevant where HDUs see sufficient value in jointly building and maintaining capability, and where HDHs receive value in return.

Subnetworks can emerge, grow, specialize, merge and disappear as needs evolve. The essence of the model is simple: HDU-led, HDH-enabled, HDAB-facilitated. EHDS2 provides access to health data; subnetworks organize the fit-for-purpose operational capability required to transform that data into usable, reliable and repeatable insights. By aligning governance, quality, interoperability, support services and operational infrastructure with the needs of a specific use case, subnetworks offer a pragmatic alternative to one-size-fits-all implementation approaches.

Do you share this vision? Or do you see a specific use case where an EHDS2 subnetwork could create value? Reach out to discuss how use-case-specific operational capability can be practically organized under EHDS2.

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