Understanding the European Health Data Space

& Secondary Use of Data Mandate

Challenges, Gaps and the Path Forward

What the European Health Data Space (EHDS) Secondary Use of Data (SUD) mandate means for data holders and how to prepare now

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Our Mission

Making responsible secondary use work in practice. Bridging data holders and users to unlock the value of health data for public benefit.

Independent European Non-Profit

Netherlands-based Stichting governing responsible health data sharing

Technical & Operations Solutions

Developing concrete operational frameworks and robust technical solutions for the secondary use of patient data at scale

Bridging Stakeholders Securely

Connecting relevant institutions, health data holders and users to securely access and use patient data

Q&A: Opportunity at the end of the webinar. Q&A document will be shared for any unanswered questions.

European Health Data Space Dual Mandate

An Unprecedented Ambition to Transform How Health Data Is Used for Care, Research, and Innovation across the European Union

Primary Use

Healthcare & Care Delivery

Patient access, healthcare delivery, and cross-border care across the European Union.

Data in scope: Patient health data used to support diagnosis, treatment and continuity of care.

Secondary Use

Reusing health data for public-interest purposes:

- Scientific Research & Innovation
- Public Health & Policymaking
- Regulatory Activities

Data in scope: Covers individual-level and aggregated electronic health data across clinical, research, genomic, registry & administrative sources..

EHDS Secondary Use of Data Pipeline

01

Data Holder

Organisations holding electronic health data and required to make data available under EHDS mandate.

02

Health Data Access Body

27 nationally appointed HDABs evaluate requests and authorise secure data access.

03

Secure Processing Env.

SPE ensures strict compliance with permitted use, protecting patient & data privacy.

04

Data User

Approved health data user who accesses data for research in line with permitted uses.

05

Outputs

Final research results and public benefit insights generated from the pipeline.

HealthData@EU: Enables cross-border data discovery and connects national HDAB infrastructures; it does not provide an operational coordination layer for data holders.

Takeaway: From direct data sharing → to a governed, multi-party European access pathway.

Why EHDS SUD Readiness Matters Now!

March 2025

EHDS Regulation entered into force.

March 2027

Deadline for key implementing acts.

March 2029

Key Secondary Use of Data (SUD) rules begin to apply.

(General Phase)

March 2031

SUD rules apply for all data categories including complex data types. (Specialised Phase)

Takeaway: 2029 is the critical operational milestone. Infrastructure and governance architectures must be fully operational by this date.

EHDS SUD: Key Requirements for Data Holders

What data holders will need to operationalise for secondary use compliance

PREPARE

01 Know Data & Scope

Identify relevant electronic health data (EHR, admin, clinical trials) that must be made available.

Q: Do we know which datasets are in scope, where they sit, and who owns them?

02 Make Datasets Findable

Prepare structured dataset descriptions and metadata to move toward a consistent, maintainable catalog.

Q: Can a HDAB discover our data assets without starting a bespoke internal exercise?

GOVERN

03 Respond to HDABs

Establish repeatable processes to receive, assess, and fulfill authorised access requests from Health Data Access Bodies.

Q: Who owns requests internally, and how does data move from request to secure delivery?

04 Prepare Approved Data

Minimise data to what is necessary and apply appropriate anonymisation or pseudonymisation techniques.

Q: Who performs data preparation, quality checks, and disclosure-risk reviews?

ENABLE

05 Secure Processing (SPE)

Ensure personal electronic health data is accessed only within controlled, secure environments, preventing downloads.

Q: How will our current secure-access setup interface with national HDAB infrastructure?

06 Governance & Controls

Maintain rigorous and repeatable governance around authorised use, quality, security, and auditing.

Q: Can we audit exactly what was shared, under what authority, and what purpose?

The Strategic Shift for Data Holders:

Move from responding to individual, ad-hoc data requests → to maintaining a compliant, EHDS-ready, and repeatable access capability.

Key Challenges for Data Holders

Many grey areas remain under the EHDS SUD Mandate for data holders who operate across the EU and not at a national EU member state level

01 Interpretation

Understanding which entities, datasets, obligations, and timelines fall within scope.

02 Fragmentation

Engaging with multiple national frameworks and HDABs, potentially facing different interpretations, processes, and expectations will be challenging for data holders and data users.

03 Operationalisation

Translating EHDS SUD obligations into scalable and sustainable governance, processes, technical capabilities, and resourcing across complex organisations.

EU-Wide Ambition, National-Level Solutions: European ambition implemented largely through national structures creates unique, unprecedented challenges for data holders operating at scale across Europe.

Interpretation Challenge

Which "EU Connection" creates obligation to comply with the EHDS SUD provisions?

Scope is framed around **"data held by health data holders,"** not just "EU citizens." Which connection brings a dataset into scope?

Data Holder Location in EU

Is the sponsor or global HQ based in the EU?

EU Participant Citizenship

Are EU citizens enrolled in a global study?

EU Sites

Are clinical trial sites located within the EU?

Data Location in the EU

Health data that is processed and controlled in the EU?

EU Regulatory Filing Link

Is the dataset linked to an EMA submission?

For global data holders, it is not always clear whether organisation establishment affiliates, trial sites, participants, data location/controller location or regulatory activity determines EHDS scope and therefore **who must comply, for what data, where and when**.

Additional Critical Scope Questions

- Are completed and legacy studies captured by the mandate?
- What technically counts as a trial having "ended"?
- How to handle old consent forms and historical contracts?

Fragmentation Challenge

For EU-wide data holders

EU-wide access, nationally delivered: Cross-border mechanisms are built into EHDS, but secondary use will be operationalised through national level Health Data Access Bodies (HDABs) and infrastructure. For global data holders, achieving a consistent and scalable approach remains a key challenge.

The Ideal

A clear, standardised interface with HDABs for receiving requests, understanding requirements and fulfilling approved access and providing data securely to researchers.

The Reality for Data Holders

- 27+ HDABs
- National approaches and access workflows.
- Managing diverse Secure Processing Environments (SPEs).
- HDABs provide the governance interface; data holders still need a scalable way to respond.

The Gap

No scalable operating model exists today to meet this distributed compliance burden for international data holders.

Operational Challenge

For data holders, the volume, coordination and ongoing resource burden required to fulfil EHDS SUD requirements at scale is a persistent capability gap.

What the Framework Requires

- **Dataset inventories:** Maintain metadata & catalogue entries
- **Access requests:** Receive and manage authorized requests
- **Data preparation:** Locate, extract, and prepare relevant data
- **Privacy:** Apply minimisation, anonymisation, pseudonymisation
- **SPE Delivery:** Support delivery into secure environments
- **Workflows:** Manage researcher-facing access workflows
- **Compliance:** Track conditions of use, monitoring & audit
- **Maintenance:** Retain reporting & process updates over time

The Target Operating Layer

Standardise • Coordinate • Execute • Evidence • Scale

- **Common Workflows:** Standardised and reusable processes
- **Central Coordination:** Unified request fulfillment hubs
- **Repeatable Prep:** Consistent metadata & data services
- **Secure Access:** Seamless processing environment enablement
- **Support:** Dedicated researcher & request-management
- **Auditability:** Continuous monitoring, audit & reporting

Takeaway: The burden is not simply understanding EHDS — it is creating the capacity to execute hundreds of operational activities consistently, repeatedly and at scale.

Vivli Europe: a neutral intermediary helping data holders operationalise EHDS SUD across Europe

From fragmented national responses to a coordinated, scalable European operating model for data holders.

1. Interpretation

As a neutral, non-profit representing holders and users, Vivli Europe provides a forum and raises practical implementation questions with relevant EHDS authorities and seeks clarity supporting responsible data reuse.

2. Fragmentation

We can coordinate common activities across multiple data holders to significantly reduce duplicated efforts, administrative burdens, and inconsistent approaches, especially for organisations operating in multiple EU Member States.

3. Operationalisation

We build scalable, sustainable workflows covering metadata, request management, governance, secure processing environments, researcher support, and continuous audit.

Vivli Europe helps turn EHDS SUD from a compliance burden into a coordinated, scalable operating model for responsible secondary use across the EU.

Join Vivli Europe’s EHDS Readiness Forum

Working together to shift from policy ambition to operational reality

Pharma Track

Pharma Readiness Forum

Collaborate with pharmaceutical industry peers to co-create practical operational blueprints.

Join the Pharma Forum

Academia Track

Academia Readiness Forum

Connect with academic researchers and institutions to align on EHDS data sharing requirements and challenges.

Join the Academia Forum

Email: **info@vivli.eu**

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Have follow-up inquiries or want to discover how to collaborate with pharmaceutical and academic peers?

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