DATASPACE 4HEALTH
LUXEMBOURG

Integration between Two Data Spaces

Document ID: DS4H_WP9_D9.2

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Date: 11/12/2025

Funding

This project has received funding from the Ministry of the Economy of Grand Duchy of Luxembourg under Grant agreement no 20230505RDI170010392869.

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Table of Versions

Version n°	Issue Date	Reason for change
0.0	05/11/2025	First draft.
0.1	11/11/2025	The internally reviewed version was distributed to all partners.
0.2	26/11/2025	The objective was refined, and the clinical dataflow in Figure 4 was updated to a generic representation.
1.0	26/11/2025	Final version has been sent to the coordinator.

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Glossary

Abbreviation	Expression
ATC	Anatomical Therapeutic Chemical Classification System
BBMRI-ERIC	Biobanking and BioMolecular Resources Research Infrastructure - European Research Infrastructure Consortium
CDM	Common Data Model
DAAF	Data Access Application Form
DAISY	Data Information System for accountability under GDPR
DCAT-AP	Data Catalogue Vocabulary - Application Profile
EHDS	European Health Data Space
EHDEN	European Health Data & Evidence Network
ELIXIR	European Life-Science Infrastructure for Biological Information
FHIR	Fast Healthcare Interoperability Resources
FLARE	Federated Learning and Analytics Research Environment
GDPR	General Data Protection Regulation
HDAB	Health Data Access Body
HL7	Health Level Seven
IAM	Identity and Access Management
IDERHA	Integration of Heterogeneous Data and Evidence Towards Regulatory and HTA Acceptance
LCSB	Luxembourg Centre for Systems Biomedicine
LOINC	Logical Observation Identifiers Names and Codes
MIABIS	Minimum Information About Biobank Sharing
OIDC	OpenID Connect
OMOP	Observational Medical Outcomes Partnership
REDCap	Research Electronic Data Capture
REMS	Resource Entitlement Management System
SNOMED CT	Systematised Nomenclature of Medicine – Clinical Terms
SPE	Secure Processing Environment
TEHDAS	Towards the European Health Data Space
WP	Work Package

1. INTRODUCTION

In recent years, federated healthcare networks have emerged among clinical, research, and registry data partners. The core concept of such networks is to retain data locally while enabling distributed analytics and privacy-preserving collaboration. With the advent of the European Health Data Space Regulation (EHDS), it has become increasingly important for these federated networks to align with a unified infrastructure, governance, metadata, and access framework that enables cross-border secondary use of health data in a trusted, interoperable, and lawful way.

As many existing federated networks predate the EHDS regime, the task of converting or upgrading these networks into EHDS-compatible ecosystems has become a pressing challenge. This alignment is critical for supporting European-scale research, innovation, and policymaking. In this context, this document outlines technical adjustments required for existing federated health-data networks to join in the EHDS. In particular, it draws from prior initiatives, presents our reference use case (Clinnova), details the gap analysis and concludes with recommendations for integrating the infrastructures into the EHDS ecosystem. Noted that the Clinnova project is currently in its early stages and aims to deploy a fully operational infrastructure by 2030. The underlying architecture presented in this document is conceptual, minor technical adjustments are anticipated during the implementation phase.

2. RELATED WORKS

Several established federated health-research networks in Europe are practically preparing for the EHDS era. Among numerous networks, this section introduces one of the corner stone project, managed by the European Health and Digital Executive Agency (HaDEA), brings cross-border data spaces together, while three federated networks how they are getting ready for the EHDS era.

2.1. HEALTHDATA@EU PILOT PROJECT

The HealthData@EU Pilot Project [1] served as a large-scale testbed for EHDS interoperability. Seventeen participants across Europe developed and evaluated a cross-border digital infrastructure over 27 months. It provided a concrete how federated health research networks can interoperate via shared metadata catalogues, standardised access workflows, and distributed analytics, while complying with the EHDS vision. Key deliverables included:

- Work package 4 covers practical guidance for establishing HDABs and harmonising access governance procedures across Member States.
- Work packages 5-8 are the technical deliverables including IT infrastructure (WP5), metadata standards (WP6), regulatory and legal compliance (WP7), and data interoperability, quality and protection (WP8).

These deliverables serve as the theoretical cornerstones and provide the baseline technical implementation and procedural specifications. For instance, WP5 build a first version of the European central platform [2], while WP6 developed the Health DCAT-AP extension [3] for describing metadata for the metadata interoperability, while WP7 proposed a common European data access application form [4].

2.2. IDERHA

The mission of the Integration of Heterogeneous Data and Evidence Towards Regulatory and HTA Acceptance (IDERHA) Project [5] aligns with EHDS for the secondary use of health data. IDERHA aims to create a federated data infrastructure for increase capability of caregivers by linking and analysing diverse health data sources such as omics, images, electronic health records, and wearables generated

data. IDERHA focuses on lung cancer, and it has gone beyond conceptual alignment. The manual for data standards and interoperability [24], as well as creating a harmonization toolkit are developed under the Luxembourg Centre for Systems Biomedicine (LCSB). The standards for the IDERHA align with the EHDS requirements as it covers standards for metadata, common data model, and data sharing.

2.3. EHDEN

The European Health Data & Evidence Network (EHDEN) is a large, federated network connecting more than 140 partners across Europe. EHDEN formally supports the EHDS regulation by joining the multi-stakeholder consensus response welcoming the EHDS proposal [6], which reflects its commitment to align with the emerging EHDS regulatory and interoperability framework.

EHDEN claims that it already aligns with one of the core pillars for EHDS interoperability. It enables distributed analytics while maintaining local data control by integrating observational medical outcomes partnership common data model (OMOP CDM).

2.4. BBMRI-ERIC

The Biobanking and BioMolecular Resources Research Infrastructure (BBMRI-ERIC) [7] provides federated access to biological samples and associated data across European biobanks. Using the MIABIS (Minimum Information About Biobank Sharing) standard, it enables harmonised metadata creation and discoverability of biobank datasets (BBMRI-ERIC, 2021).

BBMRI-ERIC utilized the MIABIS (Minimum Information About Biobank Sharing) [8] standard for metadata creation and enabled researchers to publish and discover biobank data. It demonstrated the use of the EHDS Catalogue concept for discoverability and has aligned its metadata with Health DCAT-AP.

3. CLINNOVA: A CANDIDATE FOR DATA SPACE INTEGRATION

The Clinnova initiative [9] represents a cross-border federated healthcare network involving more than 25 partners across Luxembourg, Germany, France, and Switzerland. It focuses on three immune-mediated diseases, including inflammatory bowel disease, rheumatoid disorders, and multiple sclerosis.

Its mission is to build a research environment by providing an operational testbed for federated data infrastructures. Clinnova's federated architecture ensures that data remain within institutional nodes, while metadata, governance mechanisms, and analytical results are exchanged through standardised interfaces. This approach is conceptually aligning with the principles in the EHDS Regulation (e.g., data sovereignty and privacy-by-design), however, many technical and practical aspects differ from the EHDS.

3.1. DS-PACK FOR FEDERATED DATA GOVERNANCE

Figure 1 [10] is the overview of technical components of the Clinnova project. These federated technical components are grouped into two functional layers, namely: federated analysis layer and federated data governance layer. The former one enables distributed computation without centralising data, while the latter introduces the mechanisms interconnecting partners by exchanging metadata and handling data access requests. This document focuses on the governance layer.

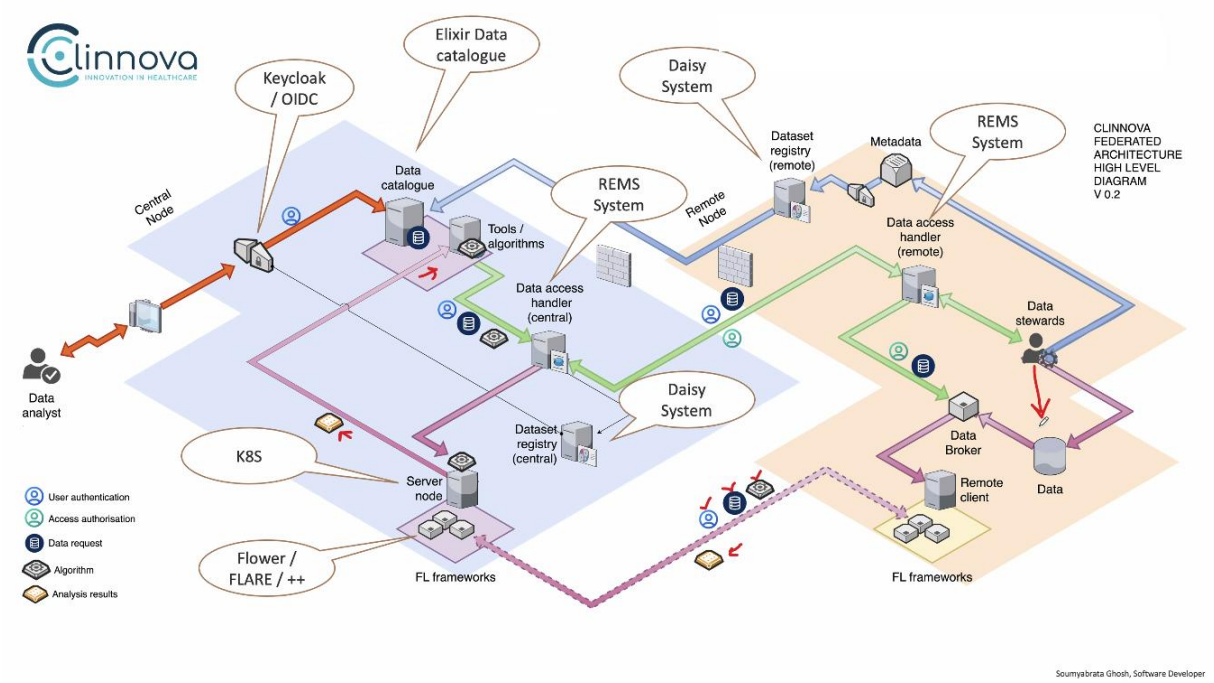

Figure 1. A high-level diagram of Clinnova federated architecture (version 0.2).

Clinnova adopt the DS-PACK assembly [11] providing an end-to-end framework for the controlled access and governance of sensitive biomedical data. This technical suite is aligned with the EHDS vision of interoperable, transparent, and accountable secondary data use. It is developed by ELIXIR Luxembourg and the Luxembourg Centre for Systems Biomedicine (LCSB), and it integrates four core components as shown in Figure 2 (left):

- DAISY (Data Information System) [12] is a data registry system supporting metadata creation, sensitivity classification, use-restriction documentation, and access-logging.
- REMS (Resource Entitlement Management System) [13] is a workflow engine that manages submission, review, and approval of data-access requests.
- Elixir Data Catalogue [14] is indexing and connecting distributed metadata.
- Keycloak [15] with OIDC (OpenID Connect) [16] is an identity and access management (IAM) service providing authentication and role-based authorisation across nodes.

Figure 2 (right) depicts the dynamic of numerous components and associated roles. It begins with data managers sharing the metadata of their datasets into the federated data catalogue. This enables a researcher (a data requester) to find the metadata entries in the data catalogue and checks the use restrictions before sends a data access request (DAR) to the relevant data stewards. Finally, data stewards either approve or reject the DAR, the final decision is informed to the researcher.

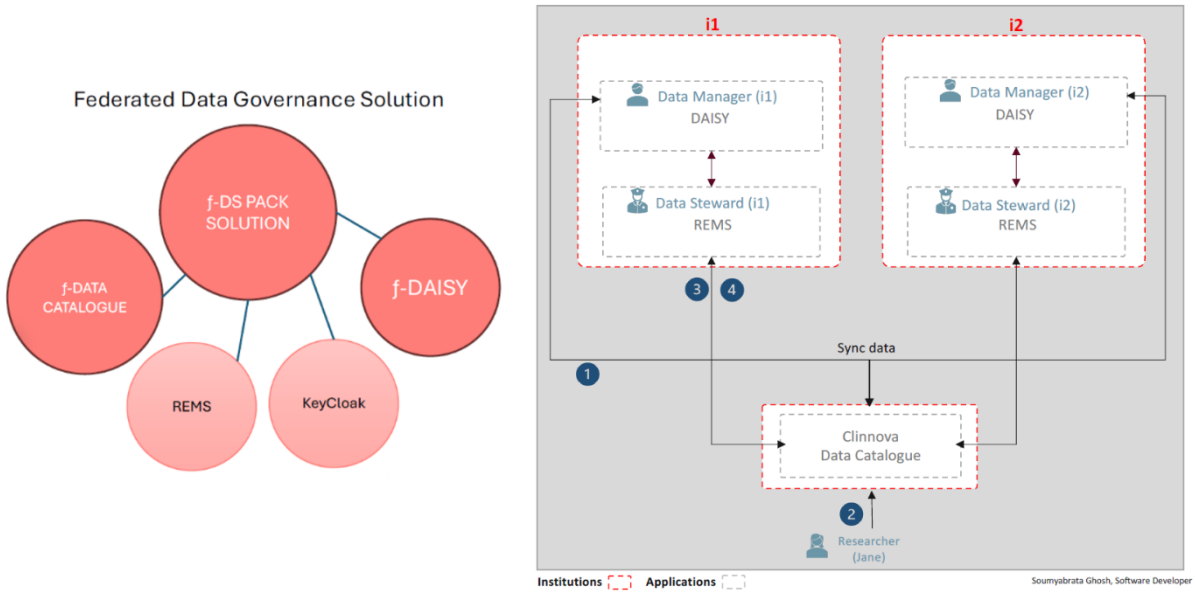

Figure 2. DS-PACK is a comprehensive federated data governance solution consisting of numerous tools (left). Dynamics of the DS-PACK components and associated roles for the Clinnova project (right) [10].

3.2. COMMON DATA MODEL

Clinnova harmonises data using REDCap and openEHR, enabling structured representation of clinical variables across sites. The overview of data pipeline for constructing CDM in Luxembourg is illustrated in Figure 3. Clinical data are generated, curated, and structured in a hospital, and then the cleaned and pseudonymized data are transferred to the Clinnova site in Luxembourg, Luxembourg Institute of Health (LIH).

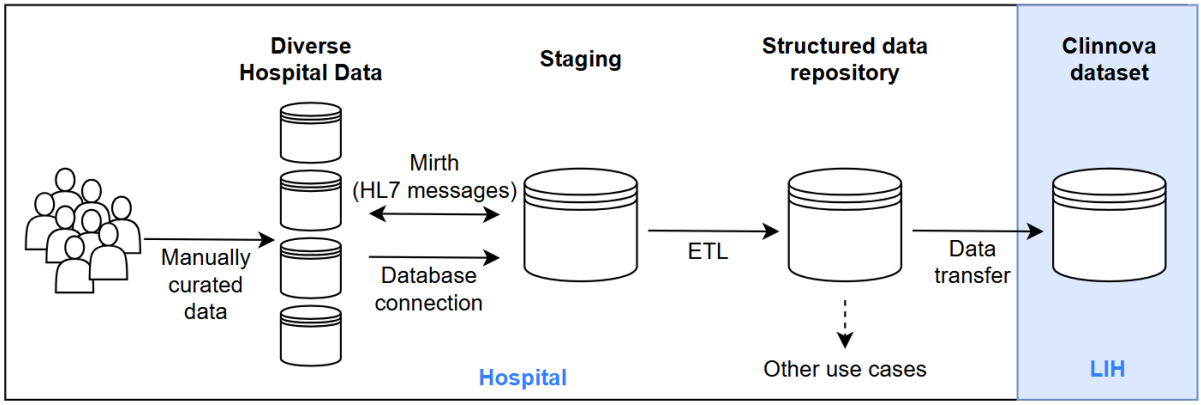

Figure 3. The Clinnova data pipeline in Luxembourg from a hospital to Luxembourg Institute of Health (LIH).

Heterogeneous data from electronic health records, biobank data, clinical-trial and registry data are harmonised for the semantic interoperability, which is a cornerstone of federated health-data collaboration. The harmonisation pipeline ensures that raw institutional data are transformed into interoperable formats through extract-transform-load (ETL) processes. This data structure alignment enables Clinnova sites to share analytical workflows and aggregate outcomes

4. ROADMAP TOWARD EHDS ALIGNMENT

This section outlines how the Clinnova federated networks can evolve into an EHDS-compliant data space based on five components: catalogue, data access application, secure processing environments, authentication and authorisation, and common data model. The first three are the core technical components of the HealthData@EU infrastructure defined in TEHDAS WP7 [21], while authentication and authorisation serve as the transversal layer underpinning these three core components. In contrast, the common data model is independent but a prerequisite for interconnecting data spaces.

4.1. CATALOGUES

The technical components of the Clinnova matching to the EHDS catalogues are DAISY and the Elixir Data Catalogue. DAISY ensures data holders to publish data with the relevant metadata (e.g., sensitivity levels, access restrictions, and update history), while the Elixir Catalogue enables cross-site indexing and findability. Both provide a solid basis for metadata documentation and discovery across its federated nodes.

However, to comply with EHDS, interoperability with the Health DCAT-AP standard is essential. The current metadata schema of Clinnova lacks mandatory descriptors such as dataset owner, versioning, update frequency, and data utility labels. Therefore, Clinnova needs to implement a mapping layer that translates the current metadata schema to Health DCAT-AP, while ensuring automated synchronisation with national Health Data Access Body (HDAB) catalogues. This will make Clinnova's datasets findable at the European level and ready for integration into the broader HealthData@EU infrastructure as shown in Figure 4 [17].

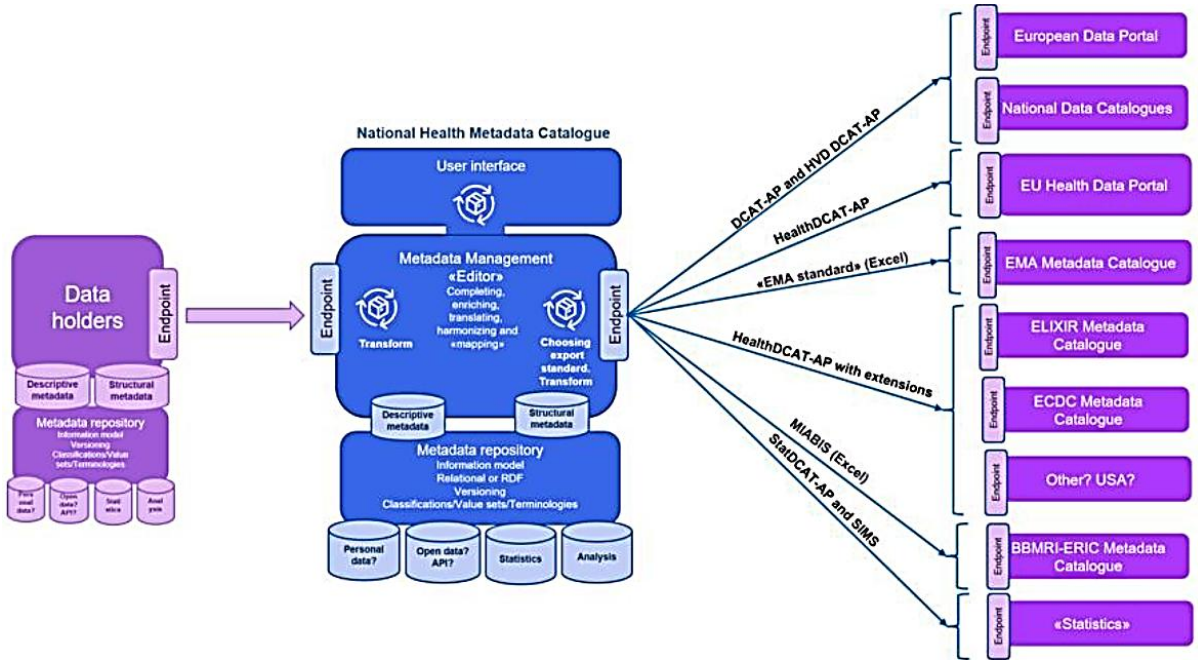

Figure 4. The metadata value chain from data holders, via the National Health Metadata Catalogue (Health Data Access Body) and to different dataset catalogues.

4.2. DATA ACCESS APPLICATION

REMS is the matching technical component for the data access application for managing DAR through structured workflows of submission, review, and approval. REMS provides a transparent and traceable process consistent with GDPR and institutional ethics policies.

In order to align with the EHDS provision, as defined under EHDS Article 67, an extension of REMS is required. The Clinnova's DAR needs to incorporate with the harmonising access templates based on

the Common European Data Access Application Form (DAAF) structure. Integrating API connections to national HDAB systems is also required. This extension will ensure that Clinnova's governance model not only remains compliant at the consortium level but also compliant at the EHDS level.

4.3. SECURE PROCESSING ENVIRONMENT

One of the three technical pillars of the EHDS is secure processing environment (SPE), defined under EHDS Article 73. It is a controlled and virtualized workspace that provides authorised researchers with access to data under strict governance and audit controls. Through the SPEs, data protection, reproducibility, and transparency of analytical operations are guaranteed. Developing its own SPE that supports EHDS-level auditing, version control and results validation might be technically complicated. Clinnova could subscribe to a SPE from an EHDS-certified provider, and collaborate with the SPE provider to deploy its solution for federated analysis across Clinnova partner sites.

4.4. AUTHENTICATION AND AUTHORISATION

The EHDS mandates that user authentication be compatible with eIDAS 2.0 [19] and the EU Digital Identity Wallet [20], enabling trusted cross-border authentication. It also requires the logs implementation for the authorisation and consent tokens for audit trail.

Currently, Clinnova plans to provide a secure authentication and role-based access control through Keycloak with OIDC only. To align with the EHDS, it needs to integrate Keycloak with eIDAS 2.0-compliant identity providers, allowing researchers from other member states to authenticate using their national digital credentials.

4.5.COMMON DATA MODEL

Interoperability at the semantic and structural levels is the key requirement for cross-border data exchange under the EHDS. TEHDAS deliverable 6.2 [22] and HealthData@EU Pilot deliverable [23] recommend using OMOP Common Data Model (CDM) and HL7 FHIR for semantic interoperability. In order Clinnova's CDM to align with the EHDS vision, mapping layer from REDCap and openEHR to OMOP and HL7 FHIR needs to be implemented. This activity will enforce standard terminologies and schema consistency, and get data ready to be interoperable in the EHDS era.

5. CONCLUSION

Clinnova and the EHDS vision share many commonalities conceptually and technically. Both aim decentralised data retention, federated access control, rich metadata documentation, and privacy-preserving governance. However, achieving interoperability within the EHDS ecosystem requires minor alignment. Integrating the Healthdata@EU infrastructure with core technical components such as harmonised metadata for catalogue, harmonised data access application form and its governance, secure processing environment in compliance with GDPR and EHDS obligations, and eIDAS & EU digital identity wallet is required.

This deliverable has outlined a pathway for evolving Clinnova into an EHDS-compliant data space, but not limited to the Clinnova project. It might serve as a blueprint how existing federated research networks can be bridged to other European health data spaces such as Dataspace4Health. Interconnecting data spaces will unlock the full potential of health data for research, innovation, and policy development across Europe.

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