



European Health Data Space for Secondary Use @CY - CY-EHDS-2ND

Proposal number: 101129405

D1.5 – Mid-term and final (overall) progress reports

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Abbreviations

COO	Coordination
CoP	Community of Practice
CY-EHDS-2ND	European Health Data Space for Secondary Use @CY
DAAMs	Data Access Applications Management solution
EC	European Commission
EHDS	European Health Data Space
EHDS2	European Health Data Space for the secondary use of health data
EHDS2 Pilot	European Health Data Space for Secondary use Pilot
EU	European Union
HD@EU CP	HealthData@EU Central Platform
LFA	Logical Framework Approach
LFM	Logical Framework Matrix
NeHA	Ethniki Archi elektronikis Igeias
nHDsC	National Health Dataset Catalogue
SIAMPI	Social Impact Assessment as a Measure of Productive Interactions
TEHDAS2	Second Joint Action Towards the European Health Data Space
SPE	Secure Processing Environment

SG	Subgroup
WP	Work Package
WPL	Work Package Leader

EXECUTIVE SUMMARY

This report provides an overview of the progress made in the European Health Data Space for Secondary Use @CY (CY-EHDS-2ND) project, emphasizing achievements in project management, coordination (COO), resource allocation, and dissemination activities. Milestones such as the submission of Deliverable D1.1 and D3.1 and participation in key events are highlighted. Core management structures and tools have been implemented to ensure efficient project execution and risk mitigation.

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1 INTRODUCTION

This deliverable outlines the project's mid-term and overall progress, showcasing the management efforts, key accomplishments, and forward-looking strategies necessary for achieving the project's objectives. It reflects on the processes established to support the European Health Data Space (EHDS) regulation and the delivery of high-quality outcomes. Below, you will find updates regarding the different Work Packages (WPs). Delays are anticipated in preparing the first deliverable of the WPs 5–9 about the Requirements and Specifications, as proper alignment with the HealthData@EU Central Platform (HD@EU CP) release 3 must be ensured. This release is expected to be shared with the EHDS2 Community of Practice (CoP) in March of 2025. Consequently, an extension request for the deadline for the related project deliverables was submitted and approved.

2 PROGRESS REPORTS

2.1 WP1 – Management and Coordination

Effective management and coordination mechanisms have been established to ensure the CY-EHDS-2ND project is successfully executed. Weekly coordination meetings provide a structured platform to address ongoing tasks, resolve issues, and align objectives across all WPs. These meetings foster clear communication and proactive decision-making. Significant progress has been made, marked by the submission of deliverable D1.1, which details governance management and the participation report, and deliverable D3.2, presenting the overall evaluation report, including Action Level Indicators (ALIs).

The project is supported by a robust management framework encompassing several key areas. Project management ensures progress, adherence to timelines, and alignment with objectives. Risk management involves a proactive approach to anticipate, assess, and mitigate potential challenges. Quality management enforces standards to guarantee consistency and high-quality outcomes. To streamline processes, standardized templates for documentation and deliverables have been developed, along with essential tools for documentation management, enabling efficient task execution and record-keeping.

A comprehensive risk management structure identifies and addresses potential challenges while continuous monitoring mechanisms provide real-time assessments and necessary adjustments to maintain progress. Deliverable templates ensure uniformity and compliance with European Union (EU) requirements, and a resource monitoring system has been implemented for efficient tracking and optimization of resource use throughout the project lifecycle.

Financial and operational management has been effectively handled to ensure resources are available for all activities. The documentation system has been established using SharePoint, while communication frameworks and reporting structures facilitate seamless collaboration among project participants and support efficient execution. This integrated management approach keeps the project on track, maintains high standards, and aligns with the EHDS vision to achieve its objectives.

2.2 WP2 – Dissemination, training and support

The dissemination, training, and education plan aims to establish clear goals for communicating CY-EHDS-2ND activities and outcomes. It focuses on identifying and engaging stakeholders effectively, crafting targeted communication strategies, and utilizing appropriate channels and tools to maximize impact. Outreach activities will focus on providing the audience with a clear overview of the EHDS, highlighting its goal of effectively utilizing health data for secondary purposes.

The project logo was developed at the outset of the project and is utilized in all communications and public documents associated with the project. Guided by CY-EHDS-2ND graphic charter, the logo ensures

consistency and uniformity across all forms of communication, both external and internal. This cohesive approach builds a strong and recognizable image, enhancing the project's visibility and reinforcing its presence in the public's mind.

Standardized templates for presentations and documents were created to ensure alignment with the project's visual identity and branding guidelines, enhancing clarity and coherence. By providing a uniform structure, these templates streamline content creation, promote brand recognition, and support effective communication among stakeholders, while preserving the project's professional image.

The targeted communication channels for the CY-EHDS-2ND project aim to enhance visibility, engagement, and information sharing. An official website (<https://www.cy-ehds-2nd.eu/>) has been developed to provide detailed updates on the progress that Cyprus has made in the development of the basic components of the secondary use of health data national infrastructure through the implementation of the project CY-EHDS-2ND, including milestones and objectives. Press releases will highlight key achievements, partnerships, and developments, with specific outreach targets already defined. Social media platforms, including a newly created LinkedIn account, will share updates, infographics, and news while fostering stakeholder engagement. Stakeholder events such as webinars, workshops, and meetings will disseminate information and gather feedback with target values already established. Regular newsletters are being prepared to inform stakeholders about the project progress and upcoming activities, with work on the first edition underway. Collaboration with journalists and media outlets will further promote understanding of the EHDS and Cyprus contributions to health data management, supported by defined engagement targets.

A repository has been created to map relevant stakeholders, including organizations and associations related to data holders. This repository will support the evaluation of individual deliverables and will be updated throughout the project, ensuring alignment with the needs of the CY-EHDS-2ND. These stakeholders will form the core audience for targeted communication efforts.

Key dissemination activities include the project's in-person kick-off meeting at the University of Cyprus, which fostered collaboration and established a solid foundation for future actions. Additionally, the project was presented during Athens Digital Health Week 2024¹, gaining visibility among stakeholders and highlighting its alignment with the overarching goals of the EHDS regulation.

2.3 WP3 – Evaluation

Under WP3 an evaluation plan was developed to ensure successful project management and sustainability. The evaluation team, working closely with Work Package Leaders (WPL), collected and validated ALIs across 9 packages WPs. Several indicators were pre-approved by the European Commission (EC), ensuring alignment with the project's goals. The coordination team supports the validation and quality control of ALIs, promoting collaboration. WP3 leads ongoing monitoring, using ALIs to track progress and guide decision-making. The evaluation plan ensures transparency, accountability, and continuous improvement throughout the project.

Evaluation objectives serve interconnected purposes. Identifying successes and areas for improvement enhances strategies, supports evidence-based decisions, and informs policies. Monitoring progress and managing risks ensures quality and alignment with goals. Open communication fosters engagement and drives development. Verification of adherence to guidelines builds stakeholder confidence and public acceptance. Formative evaluations provide ongoing feedback to improve outcomes, while summative evaluations assess effectiveness post-completion, offering insights for future planning. Both approaches support robust, informed decision-making.

¹ <https://www.athensdigitalhealth.eu/>

The Logical Framework Approach (LFA) and Logical Framework Matrix (LFM) are applied to articulate the theory of change, supporting the formative assessment approach. Drawing from the Social Impact Assessment as a Measure of Productive Interactions (SIAMPI) framework and pay-back frameworks, productive interactions guide the collection of empirical evidence, further aiding formative evaluation. For summative assessments, the intervention logic model focuses on process, output, and outcome dimensions.

2.4 WP4 – Sustainability

A draft version of the deliverable D4.1 has been prepared to address the project's sustainability. NeHA is dedicated to ensuring the continuation and enhancement of the project's outcome beyond the grant period. Efforts will focus on developing a robust national eHealth ecosystem aligned with the EHDS regulation, building on the progress achieved under HealthData@EU. To this end, government funding will be utilized where applicable, while additional grants will be sought to support and expand capabilities. Furthermore, harmonization efforts and stronger integration with other MS will contribute to a unified European eHealth ecosystem.

2.5 Work Packages WP5 – WP9

In this period, the primary objective of the WP5 – WP9 was twofold: first, to review the existing information and resources related to secondary use health data infrastructures compliant with the EHDS legislation, and second, to design the architecture of the CY-EHDS-2ND infrastructure. Based on this architectural framework, we started working on the requirements for each distinct component of the CY-EHDS-2ND infrastructure, ensuring full alignment with the EHDS law. Given that Cyprus currently lacks any established national infrastructure for the secondary use of health data, every component must be designed and developed from the ground up.

This challenge prompted us to exploit information and resources provided by related EU-funded joint action projects, such as the European Health Data Space for Secondary use Pilot (EHDS2 Pilot²) and Second Joint Action Towards the European Health Data Space (TEHDAS³). However, of paramount importance was the adoption of knowledge and tools made available through the HD@EU CP and its services for the secondary use of health data. To this end, we conducted a thorough review of the work carried out under the EU HD@EU CP, as supported by the EC. This review included an in-depth study of the proposed architecture designed for the European Health Dataset Catalogue and the European Data Access Application management system. The analysis focused on workflows, technologies, metadata standards, and implementation parameters that shape these systems.

As a result of this review, the concept of a national platform serving as the foundation for the CY-EHDS-2ND infrastructure emerged. This platform was envisioned as a centralized hub providing services applicable to all components of the CY-EHDS-2ND system, supporting the secondary use of health data. It also aimed to connect and harmonize these components through a unified control point, facilitating centralized management and monitoring.

Building on this vision, the CY-EHDS-2ND infrastructure was designed and developed to ensure that each distinct component will be engineered to maximize the services and support of the central platform. This architecture fosters an integrated system where all components operate synergistically, benefiting from centralized functionalities to achieve efficient and harmonized implementation.

Priority was placed on WPs 5, 6, and 8, as detailed information concerning these WPs became available early on the project. This availability facilitated the consolidation of relevant material and enabled the drafting of the initial chapters of the corresponding deliverables. The primary task across all technical WPs has been the creation and documentation of sections within their respective deliverables pertain to the requirements, specifications, and prototypes, providing a detailed account of the work carried out for each WPs up to this point. The following outlines the specific actions undertaken for each technical WP.

² <https://ehds2pilot.eu/>

³ <https://tehdas.eu/>

2.5.1 WP5 – Data Access Applications Management solution

A review was conducted of the material provided by the EHDS2 Pilot, particularly under WP7 - Regulatory and Legal Compliance, focusing on the deliverable *D7.1 Common Data Access Application Form and Accompanying Report*.

Concurrently, active participation in the meetings and workshops organized by the Community of Practice (CoP) subgroup (SG)1 - *Data Access Application Systems [HDAB CoP]* provided invaluable insights. These interactions enabled access to shared knowledge and practical experiences from other member states, offering an in-depth understanding of the design, implementation, advantages, and limitations of different sub-components of Data Access Applications Management solution (DAAMs). The knowledge acquired from these engagements, combined with interactions with the HD@EU CP⁴ and information shared during the presentation of its releases and the related presentations during the EHDS2 Pilot Final General Assembly, significantly contributed to the development of the CY-EHDS-2ND DAAMs. Specifically, part of the text describing the functional and non-functional requirements of the system were informed by these learnings. Functional requirements were addressed systematically, focusing on use cases such as “Creation of a New Application,” “Management of Existing Applications,” and “Deletion of an Application.” Additionally, the structure of the applications was thoroughly discussed, linking it to specific provisions outlined in the EHDS provisional agreement. Requirements were further refined by analysing how datasets are defined within the application process.

Moreover, common and distinct sections required for data permit applications and data requests were identified and recorded. This structured approach ensured that the system’s design would align with regulatory standards while accommodating practical implementation considerations. The work done so far for WP5 is documented in the deliverable “*D5.1 – DAAMs Requirements, Specifications and Prototype*”.

2.5.2 WP6 – National Dataset Catalogue for health data

The initial action undertaken for WP6 was the identification of relevant actors and associated use cases pertaining to the national Health Dataset Catalogue (nHDsC). The key actors were identified, and a thorough review of the material provided by the HD@EU CP regarding the European Health Dataset Catalogue was conducted. This review enabled the development of workflows related to the use case of searching and discovering one or more health datasets using the nHDsC.

Based on interactions with HD@EU CP, an initial set of functional requirements was documented. These included the catalogue’s structure, parameters describing the catalogue and the metadata records, usability features, and other non-functional attributes. Following recommendations from the EHDS2 Pilot and HD@EU CP, the metadata standard HealthDCAT-AP was selected to describe the health datasets’ metadata records. A comprehensive study of this standard was initiated to deepen our understanding and ensure its effective adoption.

In parallel, a landscape analysis for WP6 was conducted, focusing on Findata⁵ implementation of a nHDsC. Findata, with five years of experience in the secondary use of health data at a national level, has developed a robust infrastructure, including a functioning nHDsC. Their open-source tools for editing⁶ and publishing⁷ the national catalogue was reviewed to assess their potential as a foundation for developing corresponding tools in Cyprus. During this process, it was also noted that the European Health Dataset Catalogue used by HD@EU CP is built on the Piveau⁸ platform. A comparison between the Finnish solutions and Piveau revealed that Piveau offers enhanced capabilities and greater adaptability for a national implementation. Building on this, a comparative study between the EHDS2 Pilot metadata editor⁹ and the Piveau editor for creating and updating metadata records is currently underway. Additionally, an approach involving the storage of metadata records in a FAIR Data Point, with subsequent transformation into the HealthDCAT-AP format for harvesting by Piveau, is being explored. For validating the created

⁴ <https://acceptance.data.health.europa.eu/>

⁵ <https://findata.fi/en/>

⁶ <https://aineistoeditori.fi/login?returnUrl=%2Feditor%2Fstudies>

⁷ <https://aineistokatalogi.fi/catalog>

⁸ <https://www.piveau.de/en/>

⁹ <http://healthdataportal.eu/editor/>

or received metadata records, we are considering utilising the HealthDCAT-AP Validator¹⁰ provided by the HealthData@EU Dataset Catalogue which is expected to be released by January 2025, enabling its review and subsequent adoption as the final solution

All the efforts undertaken within WP6 were further supported by insights gained through participation in the CoP SG2 - *Datasets Catalogue & Quality of Data [HDAB CoP]* meetings while the progress made thus far for WP6 has been documented in the deliverable “D6.1 – nHDS Requirements, Specifications and Prototype.”

2.5.3 WP7 – Secure Processing Environment for Health Data

To deepen our understanding of the Secure Processing Environment (SPE) concept, definitions provided by the EHDS regulation and other related sources were gathered and documented. This compilation served as a foundational guide for the required work to be undertaken in subsequent stages. Additional definitions published by the CoP SG3 - *Secure Processing Environments [HDAB CoP]* SG were also incorporated into the documentation.

Due to limited material available from the EHDS2 Pilot, TEHDAS, or HD@EU CP regarding SPEs, a preliminary analysis of the relevant articles in the EHDS proposal was conducted. This analysis offered insights into the functionality and constraints of SPEs as defined by the regulation.

Simultaneously, through participation in the CoP SG3 - *Secure Processing Environments [HDAB CoP]* and its landscape analysis survey, it became evident that Finland possesses the most established and functional SPE, supported by a national legal framework. In this context, a detailed description of Finland's SPE, Kapseli¹¹, provided by Findata, was documented.

Further material regarding SPEs was identified under the Capacity Building section, which included a list of tools and trainings¹². This material is currently under review to extract additional requirements, ensuring alignment with EHDS provisions for the CY-EHDS-2ND infrastructure.

The progress made for WP7 has been documented in the deliverable “D7.1 – SPE: Requirements, Specifications and Prototype.”

2.5.4 WP8 – Cross-border gateway to connect with the HealthData@EU infrastructure

The work carried out under the EHDS2 Pilot WP5 has been reviewed and documented, focusing on the *IT infrastructure Proof of Concept*¹³. Specifically, two workflows were recorded: the data discovery workflow for updating the EU dataset catalogue and the data access workflow. For both workflows, all steps were outlined concisely, including the roles of all actors, such as the HDAB Cross-Border Engine, the NCP National Connector, and the EU Connector.

The concept of eDelivery as a technology is currently under review to identify the requirements it introduces. More detailed requirements are expected to be drafted following the release of HD@EU Release 3 and the completion of the deliverable for EHDS2 Pilot WP5.

In the interim, any relevant information or definitions identified through participation in the CoP SG4 - *Cross-Border Gateway [HDAB CoP]* SG are being documented. The progress achieved so far for WP8 has been recorded in the deliverable “D8.1 – National Connector for Cross-Border Gateway: Requirements, Specifications and Prototype.”

2.5.5 WP9 – Health data quality enhancement

Limited effort has been directed toward this WP, as it provided the least material for analysis and development of CY-EHDS-2ND requirements in alignment with the EHDS. However, progress and updates from Project Quantum¹⁴ are being closely monitored to guide efforts toward quality enhancement.

¹⁰ <https://health-data-itb-rdf-validator.acceptance.data.health.europa.eu/shacl/ehds/upload>

¹¹ <https://findata.fi/en/kapseli/>

¹² <https://webgate.ec.europa.eu/fpfis/wikis/display/EHDS/Inventories+of+trainings+and+tools>

¹³ https://ehds2pilot.eu/available_results/poc-communication-wp5/

¹⁴ <https://quantumproject.eu/>

Simultaneously, our investigation into the use of the FAIR Data Point for storing health dataset metadata records aims to improve the quality of metadata. Additional work is anticipated following the review of tools and training materials provided by the CoP under the Capacity Building section. These efforts will be further refined based on outputs from EHDS2 Pilot WP8, relevant guidelines published by TEHDAS2, and advancements from Project Quantum as well as support given by the CoP *SG2 - Datasets Catalogue & Quality of Data [HDAB CoP]*.

3 CONCLUSIONS AND NEXT STEPS

In conclusion, the efforts undertaken during this period have started laying a strong foundation for the infrastructure for the project CY-EHDS-2ND. By leveraging insights from EU-funded projects and from the HD@EU CP, significant progress has been made towards defining the architecture and requirements for a national system supporting the secondary use of health data. This comprehensive approach is ensuring alignment with the EHDS regulation and enables the design of a unified platform to support the harmonised functioning of the core components of the national infrastructure for the secondary use of health data.

Moving forward, the next steps will focus on finalizing the requirements and specifications while it is the foundation for the development and testing of the platform. Collaborative engagements with the relevant stakeholders will be the key to achieving a fully operational and compliant infrastructure. This approach will ensure that the project CY-EHDS-2ND establishes a robust, scalable and efficient system for the secondary use of health data while the focus will remain on maintaining high-quality outputs, fostering collaboration, and adapting best practices to meet emerging needs.