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

Proposal number: 101129405

D1.6 – Mid-term and final (overall) progress reports

(Co-)Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

Author(s)

Name	Surname	Country	Organisation	Role of the Organisation
Antonis	Stylianides	Cyprus	National eHealth Authority (NeHA)	Coordination (COO)
Maria	Papaioannou	Cyprus	University of Cyprus (UCY)	Affiliated Entity (AE)

Reviewed by

Andreas	Neocleous	Cyprus	NeHA	COO
Nicoletta	Prentza	Cyprus	UCY	AE
Constantinos	Pattichis	Cyprus	NeHA	COO
Christos N.	Schizas	Cyprus	NeHA	COO

Abbreviations

AE	Affiliated entity
ALI	Action level indicators
CING	Cyprus Institute of Neurology & Genetics
COO	Coordination
CoP	Community of Practice
CP	Central Platform
CY-EHDS-2nd	European Health Data Space for Secondary Use @CY
CyFPA	Cyprus Federation of Patients' Associations
CyMA	Cyprus Medical Association
DAAMs	Data Access Applications Management solution
EC	European Commission
EHDS	European Health Data Space
EHR	Electronic Health Record
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
Gen2EHR	Integrating Genomics into the Electronic Health Record
HD@EU CP	HealthData@EU Central Platform
HDAB	Health Data Access Body
HealthDCAT-AP	Health Data Catalogue Application Profile
HL7	Health level seven
KIOS CoE	KIOS Research and Innovation Center of Excellence
LFA	Logical Framework Approach
LFM	Logical Framework Matrix
NeHA	National eHealth Authority
nHDsC	National Health Dataset Catalogue
PDF	Portable Document Format
SG	Subgroup
SIAMPI	Social Impact Assessment as a Measure of Productive Interactions
SPE	Secure Processing Environment

TEHDAS2	Second Joint Action Towards the European Health Data Space
UCY	University of Cyprus
WP	Work Package
WPL	Work Package Leader

EXECUTIVE SUMMARY

This report presents the midterm progress of the CY-EHDS-2nd project during the second year of implementation, covering the period Month 13 (December 2024) to Month 24 (November 2025). The period marks a decisive shift from preparatory phases to full-scale specification and early implementation of Cyprus national infrastructure for the secondary use of health data, in alignment with the European Health Data Space (EHDS) Regulation (EU) 2025/327 and the evolving HealthData@EU Central Platform (HD@EU CP) releases.

During this period, the project:

- Finalised the requirements and specifications for all five technical components (DAAMs, nHDsC, SPE, Cross-border Connector, Data Quality Toolbox – WPs 5–9), anchored in the EHDS Regulation and HD@EU CP documentation (notably Release 3 and scale-up guidance).
- Delivered a unified architecture annex to support integration, compliance and cross-WP consistency.
- Initiated pilot implementation across DAAMs (WP5), nHDsC (WP6), and SPE (WP7), guided by HD@EU CP open-source components and implementation trajectories.
- Advanced cross-border readiness through alignment with the Interoperability Test Bed framework and acquisition of access credentials (WP8);
- Consolidated the specification for the Dataset Quality and Utility Label, readying it for piloting once catalogue onboarding stabilises (WP9).
- Work Package 1 maintained robust management and coordination mechanisms, ensuring progress tracking, risk mitigation and structured communication across all partners.
- Dissemination and stakeholder activities under WP2 intensified, with targeted outreach sessions engaging data holders, patient groups, health professionals and research infrastructures. These engagements yielded the first metadata authoring actions for the national dataset catalogue and laid the groundwork for quality labelling.
- The evaluation framework (WP3) matured with continuous monitoring of Action-Level Indicators (ALIs), reinforcing evidence-based planning and adaptive implementation.
- WP4 remained dormant in this cycle, as sustainability actions are scheduled for later stages following the technical pilots.

By the end of Month 24, the CY-EHDS-2nd project has moved from concept to implementation. It now operates on a coherent legal, architectural and procedural baseline, actively integrating European guidance from TEHDAS2, QUANTUM and the Community of Practice. The upcoming phase will finalise national pilots, expand catalogue content, initiate labelling, and prepare the infrastructure for full-scale operational deployment.

TABLE OF CONTENTS

1 INTRODUCTION

This document serves as the Midterm and Progress Report for the CY-EHDS-2nd project, covering the period from Month 13 (December 2024) to Month 24 (November 2025). It provides a comprehensive overview of the project's implementation status at its halfway point, including progress across Work Packages (WPs), achievements against deliverables and milestones, and alignment with the European Health Data Space (EHDS) Regulation (EU) 2025/327 and the evolving HealthData@EU Central Platform (HD@EU CP).

CY-EHDS-2nd aims to design and deploy a national infrastructure for the secondary use of health data in the Republic of Cyprus. The project is structured around nine interdependent WPs, with WPs 5-9 focused on the technical implementation of key EHDS components (DAAMs, nHDsC, SPE, Cross-Border Connector, and Quality Label Toolbox), and WPs 1-4 ensuring management, dissemination, evaluation and sustainability.

During the first reporting period (M1–M12), the project focused on governance setup, stakeholder mapping, dissemination planning and defining the performance evaluation framework. In the current reporting period, the project shifted to specification-driven execution, resulting in the submission of the full set of technical requirements and specifications (Deliverables D5.1-D9.1), initiation of pilot implementation activities, and active participation in the EHDS ecosystem, including TEHDAS2 and the HealthData@EU Community of Practice (CoP).

This report describes the progress made across all WPs, structured as follows:

- Section 2 provides detailed WP-level progress reports, including technical achievements, stakeholder engagement activities and coordination actions.
- Section 3 outlines key conclusions and next steps, focusing on the transition to full implementation and operational readiness.

The report is submitted in accordance with the Grant Agreement obligations and contributes to the overall monitoring and evaluation of the project by the European Commission and HaDEA. It is also intended to support alignment with the broader European Health Data Space objectives, ensuring that the Cyprus implementation remains interoperable, lawful and future-ready.

2 PROGRESS REPORTS

2.1 WP1 – Management and Coordination

Effective management and coordination mechanisms continue to guide the successful execution of the CY-EHDS-2nd project. Weekly coordination meetings remain a key practice, providing a structured forum for monitoring progress, addressing challenges and maintaining alignment across all WPs. These meetings have further strengthened communication and supported timely, informed decision-making. Since the first reporting period, the project's management framework has matured, demonstrating steady progress. Building upon the foundations set with the submission of deliverables D1.1 (Governance Management and Participation Report) and D3.2 (Overall Evaluation Report including ALIs), the coordination team has maintained consistency in project oversight and documentation practices.

The established project management structure continues to support adherence to timelines and objectives, while the risk and quality management processes have evolved through continuous monitoring and refinement. Standardized deliverable templates and documentation tools, introduced earlier in the project, are now routinely applied across all WPs, enhancing uniformity and compliance with European Union (EU) requirements.

The SharePoint-based documentation and communication system remains central to collaboration and reporting, now fully embedded in the daily operations of partners. Resource and financial management processes have been systematically maintained, enabling efficient allocation and use of funds throughout the project lifecycle. Overall, the management framework has transitioned from initial setup to a stable and operational phase, ensuring coordinated progress, transparency and quality outputs that align with the overarching objectives of the EHDS regulation.

2.2 WP2 – Dissemination, training and support

The dissemination, training and education plan has progressed steadily, further refining its goals for communicating the CY-EHDS-2nd project's activities and outcomes. Efforts have focused on maintaining targeted stakeholder engagement, implementing tailored communication strategies and expanding the use of effective channels and tools to maximise outreach and visibility. The project's communication activities continue to highlight the objectives of the EHDS, particularly the value of health data for secondary use.

The project's visual identity, established early with the creation of the CY-EHDS-2nd logo and graphic charter, remains consistently applied across all communication materials. This has contributed to strong brand recognition and coherence across internal and external outputs. Standardised templates for presentations and documents, developed in the first reporting period, are now routinely used, ensuring visual consistency and reinforcing the project's professional image.

The official project website (https://www.cy-ehds-2nd.eu/) continues to serve as a central communication platform, regularly updated with information on progress and national developments related to the secondary use of health data. Social media engagement through the LinkedIn account has increased, with posts sharing updates and event highlights. Press releases have also advanced.

Stakeholder engagement has deepened through ongoing outreach events, including workshops and meetings designed to disseminate results and collect feedback. The stakeholder repository, initially created to map relevant organizations and data holders, is being continuously updated to reflect new collaborations and maintain alignment with project needs.

To mobilize data holders and end-users for the nHDsC (WP6) and the quality/utility label (WP9), we organized three targeted group meetings:

(i) The Cyprus Federation of Patients' Associations (CyFPA) and the Cyprus Medical Association (CyMA) – 25th of September 2025
(ii) Services of the Ministry of Health – 26th of September 2025
(iii) Research centres and biobanks – 6th of October 2025

Each session included a thorough project briefing, Q&A, and open discussion on roles, data flows and expected contributions.

We also held separate working meetings with the Cyprus Institute of Neurology & Genetics (CING) and the KIOS Research and Innovation Center of Excellence (KIOS CoE). In these sessions, we demonstrated the HD@EU CP Health Data Catalogue Application Profile (HealthDCAT-AP) editor and began the process of drafting dataset descriptions to seed the initial national catalogue sample and prepare for label authoring under WP9.

A follow-up workshop/lab with national stakeholders was scheduled for 25 November 2025 to review Second Joint Action Towards the European Health Data Space (TEHDAS2) milestones and define concrete stakeholder contributions to the national infrastructure. Additional meetings and hands-on labs will be planned to maintain momentum and broaden participation across data holders and user communities.

Additionally a workshop was held named “Integrating Genomics into the Electronic Health Record " (Gen2EHR) at 29-30 of September 2025 at CING which was organized by NeHA, CING and University of Cyprus (UCY) The invitation was open to all stakeholders involved in the primary and secondary use of health data. The Gen2EHR workshop established the foundations for integrating genomics into Electronic Health Record (EHR) systems using shared standards and ontologies. Consensus was reached to extend existing eHealth Network laboratory exchange models to support HL7 (Health Level Seven) FHIR (Fast Healthcare Interoperability Resources) Genomics Reporting. Laboratories must eventually transition from static Portable Document Format (PDF) reports to structured, computable formats, linking variants, phenotypes and diagnoses using standardized codes. A national-to-EU implementation pathway was agreed, starting with a pilot in Cyprus, followed by validation, submission to the eHealth Network and adoption EU-wide via the EHDS. The approach prioritized structured data first before technical deployment and supported learning EHR systems where genomic data continuously informed clinical decision support, research and public health initiatives.

2.3 WP3 – Evaluation

During the current reporting period, WP3 advanced its core objective of evaluating the project’s performance and impact by operationalising the methodology and Action-Level Indicators (ALIs) defined in D3.1 and D3.2. The evaluation team, led by NeHA and supported by UCY, maintained a structured approach to monitor implementation fidelity, operational effectiveness, stakeholder engagement, and alignment with the EHDS Regulation.

Throughout M13–M24, WP3 focused on:

- Consolidating ALI data from all Work Packages via regular inputs from Work Package Leaders (WPLs);
- Validating progress against defined targets using measurable and time-bound indicators;
- Supporting WP1 with performance evidence for project coordination and decision-making;
- Updating the ALI matrix with current values (as of M24) to provide a clear status snapshot across all categories: governance, dissemination, data infrastructure, and cross-border readiness.

The team held multiple check-ins with WPLs to verify indicator values, particularly for infrastructure-related WPs (WP5–WP9), and to address early risks or delays. This work has reinforced transparency, accountability, and responsiveness, contributing to the project’s overall quality assurance strategy.

The updated indicators are presented in Chapter 3 of this deliverable. They reflect a high level of completion across the board, confirming that project implementation remains on track with its intended outcomes and timeline.

2.4 WP4 – Sustainability

Progress under WP4 has been limited at this stage, as the related activities are scheduled for later phases of the project. The draft version of deliverable D4.1, which focuses on sustainability planning, has not yet been developed, since it depends on the completion of key technical and operational outputs in other WPs. Consequently, no substantial work has been carried out under WP4 during this period, as it is too early to effectively address long-term sustainability aspects.

2.5 Work Packages WP5 – WP9

During this period, we finalised the system architecture and design, using the final EHDS Regulation (entered into force March 2025) as the legal anchor for secondary-use operations (Chapter IV) and cross-border interoperability. This enabled a last legal/technical pass and the freeze of the requirements and specifications across WP5–WP9. In parallel, we grounded our designs in the HD@EU CP material, first the

December 2024 scale-up guidance, then the Open-source Release 3 documentation (Objectives/Business Requirements/Use Cases; Architecture & Technical Specification) and mapped the Health Data Access Body (HDAB) Digital Business Capabilities into our national blueprint. On this basis, we produced and submitted D5.1–D9.1 (Requirements & Specifications), accompanied by a comprehensive Architecture Annex (in D5.1) that describes the national platform and the coordination layer that brokers identity, workflows and messages between DAAMs (WP5), nHDsC (WP6), SPE (WP7), and the Cross-Border Gateway (WP8), and hosts data quality labelling services (WP9). These five deliverables followed a single, shared method: common actors and terminology, legal traceability to EHDS, alignment to Central Platform (CP) R3 interfaces, and explicit inter-WP dependencies via the CP layer.

After submission, we moved into pilot implementation for all five WPs, with emphasis on WP5 (DAAMs), WP6 (nHDsC), and WP7 (SPE). Because WP5 and WP6 are tightly coupled to HealthData@EU, their pilots track each new CP release: we customized the HD@EU CP open-source solution to meet the national user interface requirements and configured the national dataset catalogue component. In parallel, we reviewed TEHDAS2 wave-1 and wave-2 outputs to anticipate implementing-act details and continued active participation across all Community of Practice (CoP) sub-groups (SG1–SG6) to align on best practices, shared challenges and converging patterns with other Member States.

2.5.1 WP5 – Data Access Applications Management solution

DAAMs function as the core procedural layer through which applications for secondary use are submitted, assessed, permitted and routed. The operating assumptions were consistently reconciled with the EHDS Regulation so that national workflows, roles and artefacts remain compliant and interoperable.

In this period, we adopted the HD@EU CP DAAMs solution as the base reference and used the CP documentation to complete the Cypriot DAAMs requirements and specifications. The analysis covered Release 3 materials (Objectives, Business Requirements and Use Cases; Architecture and Technical Specification) and the Scale-Up documentation provided in December 2024. The specification work also produced the overall infrastructure architecture of CY-EHDS-2nd, integrating identity, messaging, logging and cross-component interactions. This architecture was included as an annex to D5.1 to ensure a coherent system view that coordinates DAAMs with the nHDsC, SPE, Cross-Border Connector and the Data Quality and Utility components.

Following completion of D5.1, we initiated the pilot implementation. The pilot uses the HD@EU CP DAAMs code as the baseline and adapts it to the Cypriot legal, procedural and operational requirements captured in D5.1. During Ms 13-24 we aligned the implementation path with CP Release 4 and the subsequent R5 so that form schemas, message profiles and decision artefacts remain consistent with the evolving EU reference.

In parallel, we reviewed TEHDAS2 milestones and deliverables (M6.3[1], M6.4[2], M7.3[3]) to identify additional actions required for DAAMs development. This review was used to refine our application content, evidence capture and review workflows and to align terminology and role responsibilities with emerging EU guidance.

2.5.2 WP6 – National Dataset Catalogue for health data

The nHDsC constitutes the national entry point for structured, searchable descriptions of health datasets that are eligible for secondary use. In alignment with the EHDS Regulation, its mission is twofold: enable domestic discovery and selection by applicants and support federation toward HealthData@EU CP. This

[1] TEHDAS2, M6.3 DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON THE PROCEDURES AND FORMATS FOR DATA ACCESS

[2] TEHDAS2, M6.4 DATA ACCESS APPLICATION MANAGEMENT SYSTEM – DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES

[3] TEHDAS2, M7.3 DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES ON THE IMPLEMENTATION OF THE COMMON IT INFRASTRUCTURE

mandate presupposes the adoption of a harmonized metadata profile and the ability to exchange catalogue records across borders under the CP's governance.

During Ms 13-24 we consolidated requirements and specifications using the HD@EU CP documentation available to the project in D6.1. The specification covers the end-to-end onboarding pipeline (authoring, validation, publication) and the interfaces toward DAAMs for pre-fill and toward the National Connector for federation. This work is consistent with the CP's catalogue and preserves traceability to the legal articles and to the shared architecture annex delivered under WP5.

During Ms 13-24 we initiated the nHDsC pilot by adopting the CP code and tooling available up to Release 5 as our baseline, with a standing plan to adjust the implementation path as subsequent releases are issued by the Commission. In this reporting period we advanced by activating data-holder engagement to seed the first Cypriot catalogue entries. Specifically, we onboarded priority holders into authoring sessions using the HealthData@EU CP HealthDCAT-AP editor line of work from the R5 stream to begin creating compliant dataset descriptions. This will allow us to validate the authoring and validation stages, produce a small but representative sample of national records and exercise the pre-fill interface toward DAAMs.

We also reviewed TEHDAS2 milestones and deliverables to align metadata practices and onboarding legal and technical guidance (D5.1[4], D5.3[5], M6.1[6], M7.3[4]).

2.5.3 WP7 – Secure Processing Environment for Health Data

The SPE constitutes the controlled setting where authorized users analyze permitted datasets for secondary use, in line with EHDS Chapter IV and Article 73 on secure processing environments. It is designed as a two-tier model operated by NeHA (Internal SPE for ingest/prepare and External SPE for user analysis), with strong authentication, audited workflows and reviewed output.

In the last 12 months we have finalized the SPE requirements and specifications. Our approach combined (i) a structured review of operational SPEs in other Member States, with particular attention to Findata's Kapseli operating model and controls, and (ii) selective use of the EC Scale-Up documentation where applicable to SPE governance and interfaces. The resulting D7.1 fixes the two-tier architecture, roles, functional and non-functional requirements and technical controls (identity, access, logging, monitored tooling, output vetting). We reviewed the TEHDAS2 guidance provided through milestones M7.2[7] and M7.4[8] to align our approach with emerging EU expectations and we used it to shape the SPE build plan. We are now in the process of defining the provisioning flow, baseline tool catalogue, security parameters and export-control checks and are ready to stand up the SPE in a testing environment to tune configurations before the formal pilot.

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

WP8 establishes the national connection with the HealthData@EU CP, enabling cross-border catalogue updates and the receipt of applications through the eDelivery four-corner model.

In this period, we finalized the requirements and specifications for the National Connector by aligning with the CP architecture and message choreography and fixing the integration points with DAAMs and the nHDsC resulting the deliverable D8.1.

[4] TEHDAS2, D5.1 GUIDELINE FOR HEALTH DATA HOLDERS ON THEIR DUTIES REGARDING DATA DESCRIPTION

[5] TEHDAS2, D5.3 TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES ON THE NATIONAL METADATA CATALOGUE

[6] TEHDAS2, M6.1 DRAFT GUIDELINE FOR HEALTH DATA HOLDERS ON MAKING PERSONAL AND NON-PERSONAL ELECTRONIC HEALTH DATA AVAILABLE FOR REUSE

[7] TEHDAS2, M7.2 DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON DATA MINIMISATION, PSEUDONYMISATION, ANONYMISATION AND SYNTHETIC DATA

[8] TEHDAS2, M7.4 DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES ON THE IMPLEMENTATION OF SECURE PROCESSING ENVIRONMENTS

Further to that, we reviewed the Commission's "Open-source Release 5" Test Framework[9] for the exchanges between the national dispatcher and the HD@EU CP to be aligned with the current onboarding, connectivity and conformance expectations. In this direction, we obtained access credentials for the HealthData@EU Interoperability Test Bed and outlined our next steps following the framework's prescribed sequence (onboarding details, connectivity checks and conformance suites).

2.5.5 WP9 – Health data quality enhancement

The objective is to operationalize the EHDS requirement for transparent dataset quality and utility information, so that applicants and reviewers can assess fitness for secondary use. During this period, we completed the requirements and specifications by reviewing the final EHDS Regulation, the Commission's scale-up documentation where applicable and related TEHDAS2 deliverable D5.1[10]. All these were consolidated into the deliverable D9.1 which fixes:

- the label structure and required evidence fields
- the author-review-publish workflow under HDAB oversight

These choices ensure that the label can be created and validated onboarding, displayed to data users and governed with auditable updates. The pilot has not started within the reporting window. Our work in M13-M24 focused on consolidating the specification and aligning it with EU guidance, so that pilot activities can begin once the catalogue onboarding flow stabilizes and the first dataset descriptions are available. This staging reflects the dependency on WP6 for label attachment and display.

3 CONCLUSIONS AND NEXT STEPS

The progress achieved during Ms 13–24 substantiates the transition from preparatory organisation to specification-driven execution. The definition of requirements and specifications across WP5 - WP9, accompanied by a unifying architecture annex, established the project as a "system of systems" wherein DAAMs, the nHDcS, the SPE, the cross-border connector and the data quality & utility toolbox interoperate under one governance and audit framework. Stakeholder engagement evolved from general awareness to activation, enabling initial metadata authoring and practical preparation for labelling. Technically and legally, the work remained anchored to the EHDS Regulation, most notably Chapter IV on secondary use and on the HealthData@EU infraastructure aligned with the CP releases utilized during the period. Consequently, the project now stands on a coherent baseline with pilot activity initiated where dependencies allowed and with cross-border testing readiness evidenced by Interoperability Test Bed credentials.

In the forthcoming period, the project will conclude the pilot implementation across the national platform and prepare and submit the associated project deliverables. Stakeholder engagement will continue as a core activity: we will maintain structured dialogues with data holders, patient and professional bodies and research infrastructures to expand catalogue coverage, improve application content and prepare for quality and utility labelling.

Concurrently, we will sustain a rolling alignment with the European baseline. The solution will be reviewed against subsequent releases of the HD@EU CP and adjusted where necessary, while incorporating guidance emerging from TEHDAS2 and the QUANTUM initiative.

[9] European Commission: Directorate-General for Health and Food Safety, HD@EU CP – Open-source release 5 – Test framework for end-to-end tests between national contact point for secondary use and HD@EU CP, Publications Office of the European Union, 2025, https://data.europa.eu/doi/10.2875/1895551

[10] TEHDAS2, D5.1 GUIDELINE FOR HEALTH DATA HOLDERS ON THEIR DUTIES REGARDING DATA DESCRIPTION