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

Proposal number: 101129405

D1.2: Governance management and Participation Report

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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

Name	Surname	Country	Organisation	Role of the Organisation
Nicoletta	Prentza	Cyprus	UCY	AE
Andreas	Neocleous	Cyprus	NeHA	COO
Constantinos	Pattichis	Cyprus	NeHA	COO
Christos N.	Schizas	Cyprus	NeHA	COO

Abbreviations

AE	Affiliated Entity
ALI	Action-level Indicator
CA	Competent Authority
CING	Cyprus Institute of Neurology and Genetics
COO	Coordinator
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
EHR	Electronic Health Record
EHR	Electronic Health Record
Gen2EHR	Integrating Genomics into the Electronic Health Record
HDAB	Health Data Access Body
LEAR	Legal Entity Appointed Representative
M	Month
NeHA	National eHealth Authority
nHDsC	National Dataset Catalogue for health data
RM	Risk Management
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 document is the second Governance Management and Participation Report of the European Health Data Space for Secondary Use @CY (CY-EHDS-2nd), covering Months M13 to M24 (December 2024 – November 2025). It confirms the continuity of the governance model established in the D1.1 Governance management and Participation Report and summarises the main coordination, monitoring and oversight activities conducted during this period.

The project continued to support Cyprus in developing its national Health Data Access Body in line with the European Health Data Space regulation and the HealthData@EU. NeHA, acting as the national HDAB. Progress during this year focused on advancing the national infrastructure for the secondary use of health data to support research, innovation, policy development, public health and education. This report summarises meetings and participation activities, the status of Action-Level Indicators and the key risk and quality management operations. All risks remained valid, with one downgraded from medium to low due to improved communication with data holders. Quality processes proceeded as expected and all scheduled deliverables for this period were submitted and accepted on time. Overall, Months M13–M24 demonstrated stable governance, consistent procedures and effective coordination across the CY-EHDS-2nd project.

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1 INTRODUCTION

The CY-EHDS-2nd project continues to align with the European Commission (EC)'s vision for a "Europe fit for the digital age" and contributes to the objectives of the EU4Health Programme by advancing the digital transformation of health systems. The project focuses on establishing and developing the infrastructure required for the national Health Data Access Body (HDAB) in Cyprus and preparing the framework for the secondary use of health data in alignment with the European Health Data Space (EHDS) Regulation.

During this reporting period, the project has concentrated on management activities, coordination mechanisms and the preparation of technical specifications for the upcoming implementation phases. These actions have laid the groundwork for the systematic development of the national infrastructure that will support the secondary use of health data in Cyprus and its integration into the broader European ecosystem.

1.1 Objective of the Deliverable

The objective of this deliverable is to report how governance management and participation mechanisms have been operated during Months M13 (December 2024) – M24 (November 2025) and to present measured Action-Level Indicators (ALIs).

1.2 Connection with other Work Packages

The Project Management and Coordination Work Package (WP1) has maintained close collaboration with all other WPs to integrate work plans, monitor resources, allocate personnel and manage funding effectively. Through continuous coordination and communication, WP1 has supported alignment across activities, contributing to the coherent advancement of the CY-EHDS-2nd project toward its overall objectives.

2 CY-EHDS-2ND MANAGEMENT STRUCTURE

During the first year of the CY-EHDS-2nd project, the collaboration between NeHA, acting as the Competent Authority (CA) and its Affiliated Entity (AE) UCY has been strengthened. The joint efforts of both partners have focused on establishing a solid foundation for the project's implementation and reinforcing NeHA's role as the national HDAB. Throughout this period, NeHA continued to mainly lead coordination and governance activities, while UCY contributed with technical and research expertise, supporting progress across all WPs in alignment with the project's objectives.

2.1 CY-EHDS-2ND Coordination

2.1.1 Project Management

Governance methods have been maintained to support the production of high-quality outputs and consistent progress reporting throughout the second year of the CY-EHDS-2nd project. A structured quality control process continues to apply to all deliverables, while progress across WPs is monitored through regular coordination meetings and standardized reporting by WP leaders. During this reporting period, no significant changes have been identified.

2.1.2 Risk Management

Unplanned events with potential impact on the project's scope, timeline, cost, quality, risks or stakeholder satisfaction continue to be managed according to their severity. No major issues were detected during this reporting period. Deliverables undergo internal review led by the WP1 Quality Review Team (QRT) which evaluates structure, content and alignment before submission to the AC for final validation. Risk Management (RM) activities have progressed in line with the established framework.

2.2 Project Management Team

NeHA plays a key role within the CY-EHDS-2nd by coordinating and aligning activities across all WPs. Comprising all WP leaders, co-leaders and task leaders, NeHA maintains continuous oversight of inputs and results to promote collaboration and project coherence. The authority supports communication through regular meetings, the SharePoint platform, emails, physical meetings and video conferences when required. Its role also includes close cooperation with risk and quality management teams. WP leaders and co-leaders remain responsible for guiding their respective areas in alignment with the project's overall objectives.

3 MONITORING

3.1 Implementation Progress

The project's specific objectives are pursued through the following categories for ALIs:

1. Set up a functional HDAB with the necessary services to manage data requests, provide metadata catalogues, and offer Secure Processing Environments.
2. Create a digital gateway for the HDAB to join the HealthData@EU cross-border infrastructure, connecting with authorized entities and central services.
3. Support data holders in improving health data quality to ensure interoperability between the HDAB and data holders.

By addressing these specific objectives and utilizing the list of ALIs shown in Table 1, the project aims to lay the foundation for a robust and interoperable health data ecosystem, fostering improved access, quality and cross-border collaboration in the secondary use of health data. The category represents the broader classification under which specific indicators are grouped. The indicator defines a measurable element that tracks progress toward the project's objectives. The baseline reflects the initial status of the indicator before any intervention or implementation and thus, it establishes a reference point for comparison. The indicator status captures the current progress of the indicator, for example "Not yet" means "not started" and "In progress" means "partially implemented". Finally, the target value defines the expected outcome or goal for the indicator once the implementation is complete (e.g. "Yes" for full implementation or a specific numerical target).

Table 1: list of ALIs

Category	Indicator	Baseline	Indicator Status @M12	Indicator Status @M24	Target value
1. National services and infrastructures	HDAB implemented as health data repository for secondary use as a service given by the NeHA	NO	Not yet	In progress	YES and with the common business capabilities implemented

	Is the NeHA-HDAB able to receive, process and reply to national data access applications, and to issue data permits	NO	Not yet	In progress	YES
	Number of data access applications that the NeHA-HDAB can receive, process and reply per M	Nil	None yet	None yet	Not limited
	Average time to process a data access application	Cyprus	None	None	< 2 M
	Is there a health dataset catalogue available?	NO	Not yet	In progress	YES and publicly available
	Number of datasets published in the dataset catalogue	NO	None yet	None yet	Not limited
	Do the datasets contain a description of the contents?	NO	Not yet	In progress	YES and in a common format
	Is NeHA-HDAB able to provide a Secure Processing Environment (SPE) to data users?	NO	Not yet	In progress	YES
	Average time to set up an SPE	Nil	None	None	< 1 M
2. Cross-border services and infrastructures	Is the NeHA-HDAB connected to the HealthData@EU infrastructure?	NO	Not yet	In progress	YES
	Is the NeHA-HDAB able to receive, process and reply to cross-border data access applications, and to issue data permits	NO	Not yet	Not yet	YES and to multi-country requests too
	Number of cross-border health data access applications that the NeHA-HDAB can receive, process and reply per M	Nil	None	None	10 at lunch [targeting to increase]

3. Enhancing data quality	List of tools available for enhancing data quality	NO	None	In progress	Compliance with Model-View-Controller + Fast Healthcare Interoperability Resources PROFILING + International Patient Summary + eHealth Bioar + National Implementation Guide
	Are the datasets semantically and technically interoperable?	NO	Not yet	In progress	YES also cross-border and following a common format

3.2 MEETINGS AND WORKSHOP MANAGEMENT

The management of meetings within the CY-EHDS-2nd governance structure has been effectively organized to support collaboration and strategic alignment. These meetings continue to play a central role in facilitating decision-making and coordination across the project as seen in Table 2. Over the past year, all scheduled meetings were successfully held as planned, allowing discussions to remain productive and outcomes to progress in line with the project's objectives.

Table 2: Important meetings

Meeting type	Frequency	Organizations
Technical solution	Every week	UCY
Coordination meeting	Every other week	NeHA, UCY
Consortium Strategy Alignment Workshop	Once (10/12/2024)	NeHA, UCY
Stakeholder meetings	Once (25/09/2025)	NeHA, UCY, Ministry of Health of Cyprus
	Once (25/09/2025)	NeHA, UCY, Cyprus Federation of Patients' Associations, Cyprus Medical Association
	Once (06/10/2025)	NeHA, UCY, Bank of Cyprus Oncology Centre, CYENS Centre of Excellence, Centre of Excellence in Biobanking and Biomedical Research, German Oncology Centre, Cyprus Institute of Neurology and Genetics (CING), KOIOS Centre of Excellence for Research and Innovation

3.2.1 Organisation of workshops

Workshops within the CY-EHDS-2nd project continue to be organized in both face-to-face and hybrid formats, supporting collaboration and progress across WPs. Their preparation follows a structured approach, with agendas and materials shared in advance to promote effective participation. Depending on the topic, external experts or facilitators may be invited to contribute. Workshops serve as productive working sessions focused on achieving defined objectives while also fostering team interaction and collaboration. Below we present the Integrating Genomics into the Electronic Health Record (Gen2EHR) workshop and the stakeholder's workshop.

3.2.1.1 GEN2EHR

The workshop "Integrating Genomics into the EHR – Gen2EHR Implementation Guidelines Workshop" was organized and funded by NeHA in collaboration with the CING and the UCY. The event took place on 29–30 September 2025 at the Auditorium of CING in Nicosia.

Held within the framework of the EHDS Regulation, the workshop aimed to define the prototype design for integrating genomic data into citizens' Electronic Health Records (EHRs). The discussions focused on enabling the secondary use of health data to enhance healthcare delivery, support scientific research and guide health policy development.

The workshop brought together healthcare professionals, researchers, policymakers and domain experts from Cyprus and abroad. It featured presentations, discussions and collaborative sessions across two days. The first day included open sessions while the second day was dedicated to focused working meetings for invited participants concluding with a final open session to present the workshop's results.

3.2.1.2 Stakeholders workshop

On 25 November 2025, NeHA organised a one-day, in-person stakeholder workshop in Nicosia to advance Cyprus' participation in the EHDS. The forum provided participants with an overview of the EHDS framework for secondary use, presented NeHA's digital capabilities as the national HDAB, and highlighted the components being implemented through the CY-EHDS-2nd project. The workshop also served as a collaborative platform for co-developing Cyprus contributions to the 11 milestones of the Second Joint Action Towards the European Health Data Space (TEHDAS2), which were under public consultation at the time. The outcome included the finalised responses of Cypriot stakeholders to the TEHDAS2 public consultation survey, structured by milestone.

3.3 RESOURCE MONITORING

The financial management of the CY-EHDS-2nd during the period December 2024 to November 2025 progressed as planned under the responsibility of NeHA, which handled fund disbursement in alignment with the grant agreement.

The COO coordinated the collection of regular cost statements, acting as the link between the project and NeHA Financial Department, where the Legal Entity Appointed Representative (LEAR) and Financial Signatory oversaw all financial matters.

Budget execution per WP followed the structure set out in the project plan. NeHA led WP1 to WP4, covering coordination, dissemination, evaluation and sustainability, supported by UCY, external experts and subcontracted entities. UCY led WP5 to WP9, which focused on solution development and integration activities with contributions from NeHA.

Throughout the year, NeHA prepared reporting templates, collected and analysed financial data from all partners and maintained ongoing budget monitoring. This collaborative structure supported transparent and effective financial governance for the CY-EHDS-2nd while upholding accountability and adherence to established procedures.

4 TIMELINE/ GANTT CHART

The project schedule outlines a series of deliverables and milestones across multiple WPs over the 48Ms duration of the CY-EHDS-2nd project, running from 1 December 2023 to 30 November 2027. WPs 1- 4 led by NeHA, focus on preparing and monitoring progress reports, implementing dissemination activities, designing and delivering training and support, performing evaluation and planning for sustainability. WPs 5-9 led by the UCY are focused on the requirements' recording, implementation and running of the Data Access Applications Management solution (DAAMs), the National Dataset Catalogue for health data (nHDsC), the SPE, the cross-border gateway to connect with the HealthData@EU infrastructure and the health data quality enhancement.

This schedule provides a systematic and collaborative framework to advance the project's objectives. The Gantt Chart of the CY-EHDS-2nd is presented in Figure 1 highlighting D1.2 Governance management and Participation report.

WP	30 Nov 2024	28 Feb 2025	31 Mar 2025	**30 Nov 2025**	31 Jul 2026	31 Aug 2026	30 Nov 2026	28 Feb 2027	31 Jul 2027	31 Aug 2027	30 Oct 2027	30 Nov 2027
WP1: Management and Coordination	D1.1: Governance management and Participation report											
	D1.2: Governance management and Participation Report											
	D1.3: Governance management and Participation Report											
	D1.4: Governance management and Participation Report											
	D1.5: Mid-term and final (overall) progress reports											
	D1.6: Mid-term and final (overall) progress reports											
	D1.7: Mid-term and final (overall) progress reports											
	D1.8: Mid-term and final (overall) progress reports											
WP2: Dissemination, training and support	D2.1: Dissemination, training and education plan											
	D2.2: Dissemination, Education and Training - Portal											
	D2.3: Dissemination, Education and Training monitoring report											
	D2.4: Dissemination, Education and Training Monitoring Report											

	D2.5: MS Service Desk Plan										
WP3: Evaluation	D3.1: Report on the performance monitoring indicators framework										
	D3.2: Overall evaluation report, including the action-level indicators										
	D3.3: Overall evaluation report, including the action-level indicators										
	D3.4: Overall evaluation report, including the action-level indicators										
	D3.5: Overall evaluation report, including the action-level indicators										
WP4: Sustainability	D4.1: Sustainability Plan										
	D4.2: Business Continuity Plan										
WP5: Data Access Applications management solution	D5.1 DAAMs: Requirements, Specifications and Prototype										
	D5.2 DAAMs: Pilot Report										
	5.3 DAAMs: Operational Service										
WP6: National Dataset Catalogue for health data	D6.1 nHDsC: Requirements and Specifications										
	D6.2 nHDsC: Pilot report										
	D6.3 nHDsC: Operational Service										
WP7: Secure Processing Environment for Health Data	D7.1 SPE: Requirements and Specifications										
	D7.2 SPE: Pilot										
	D7.3 SPE: Operational Service										
WP8: Cross-border gateway to connect with the HealthData@EUinfrastructure	D8.1: National Connector for Cross-border gateway: Requirements and Specifications										
	D8.2: Cross-border gateway: Pilot										
	D8.3 Cross-border gateway: Operational Service										
WP9: Health data quality enhancement	D9.1: Health data quality enhancement toolbox: Requirements and Specifications										
	D9.2: Health data quality enhancement toolbox: Pilot										
	D9.3: Health data quality enhancement toolbox: Operational Service										

Figure 1: Gantt Chart of the CY-EHDS-2nd

5 DOCUMENTATION MANAGEMENT

Since the previous reporting period, the SharePoint platform has continued to serve as the central repository for all project documentation, supporting effective coordination and management of the CY-EHDS-2nd project. Team members have consistently used the platform to access, share and update documents, which has strengthened collaborative efficiency and maintained a structured approach to project record-keeping.

The SharePoint folder structure remains organized at the root directory, containing seven main folders and two Excel files. The "Mailing list" file continues to provide up to date contact information for all participating project partners while the “Workplan” file includes the current project schedule and deliverable deadlines updated in the form of Gantt Chart (Table 1) to reflect recent progress and planning adjustments.

6 CY-EHDS-2ND CONTACTS

The email distribution lists continue to facilitate communication across the CY-EHDS-2nd project, covering administrative matters for each WP individually (WP1–WP9). Task-specific lists remain established in coordination with the Work Package Leaders (WPLs). Comprehensive contact information for all project participants and their mailing list affiliations is maintained in the “Mailing List” Excel file, which is accessible on the Collaborative Platform.

Management of these lists remains active, with the project’s members being able to request the addition or removal of members by contacting the project management team. Requests must include the member's name, email and the relevant lists. When a member leaves the project, their removal from the Collaborative Platform is carried out by the coordination team.

7 DELIVERABLES

7.1 Quality Management

During the second year of the CY-EHDS-2nd, quality management processes continued to strengthen the delivery of reliable and timely project outputs. Effective deliverable management remained a critical component of coordination activities, reinforcing structured planning, consistent documentation and systematic review cycles across all WPs. Building upon the practices introduced during the first year, WPLs maintained close supervision of workflows, supporting alignment with the project’s goals and the evolving EHDS framework. The use of standardised templates, periodic internal checks and clear communication channels contributed to improved coherence across deliverables. This coordinated approach to preparation, review and submission sustained progress toward the project’s milestones and supported advancements in the secondary use of health data.

7.2 Quality Management Reporting

Across the reporting period from December 2024 to November 2025, all deliverables due for submission within this timeframe were accepted following the first review round, highlighting the project’s strong internal coordination. Seven deliverables were completed during this period, each benefiting from a consistent review cycle that typically involved two rounds of internal assessment prior to submission. No major or minor revisions were requested, reflecting the careful preparation, structured documentation and effective collaboration across the contributing WPs.

The deliverables accepted during this reporting period began with two submissions in March 2025:

- D2.1: Dissemination, training and education plan
- D3.1: Report on the performance monitoring indicators framework.

Five more deliverables were finalised and accepted on schedule in May 2025:

- D5.1: DAAMs – Requirements, Specifications and Prototype
- D6.1: nHDsC – Requirements and Specifications
- D7.1: SPE – Requirements and Specifications
- D8.1: National Connector for Cross-border Gateway – Requirements and Specifications
- D9.1: Health Data Quality Enhancement Toolbox – Requirements and Specifications.

The timely submission and acceptance of all scheduled deliverables during this phase reflect the maturity of the project's quality management approach. Continued collaboration, structured review processes and clear communication channels supported consistent progress and upheld the quality standards of the CY-EHDS-2nd, contributing meaningfully to the project's overall advancement.

8 RISK MANAGEMENT

All identified project risks remain valid for the current reporting period and continue to be considered throughout the implementation of the project. Only one adjustment has been made regarding the risk related to irregular and inconsistent interaction between data users, data holders and HDABs as seen in Table 3. This risk has been reclassified from medium to low, as communication channels with data holders have now been effectively established. Three data holders' engagement meetings have already taken place, as well as a dedicated workshop and preparation for subsequent steps is actively underway. These developments have significantly strengthened the predictability and stability of interactions. All other risks remain unchanged and are systematically monitored and addressed as part of the project's ongoing activities.

Table 3: Project risks

Risk	Likelihood	Impact	Mitigation Strategy
Inappropriate connection to national infrastructures and frameworks (technical, semantic, organisational)	Low	Medium	Ensuring appropriate participation of national entities and partners in the project to facilitate connections
Difficulties amending national legislation to enable the access to health data by data users and availability of datasets	Low	High	Implement measures to facilitate legal convergence with the upcoming EHDS regulation.
Multiple health datasets catalogues exist but are not linked	Medium	Low	Harmonise standards and practices and federate existing dataset catalogues
National dataset catalogues descriptions are not publicly available	Low	Medium	Establish appropriate frameworks and procedures for the submission, approval and maintenance of datasets descriptions in a publicly available data catalogue

Poor data discovery and data user knowledge of the existence of the infrastructure	Medium	Medium	Ensure proper training, promotion and communication activities of the project work to allow data users to find suitable data
Burdensome and complicated submission of data access applications	Low	Medium	Streamline and harmonise the application process with other countries, including the use of shared portals for data discovery and application submission and follow up
Burdensome and inefficient handling of data access applications (national and EU level) and issuance of data permits to data users/authorisation of data requests	Low	Medium	Foster automation, standardisation and convergence in the processing of data access applications
Irregular and inconsistent interaction between data users, data holders and HDABs	Low	Medium	Increase availability of services by health data access bodies to data holders and data users, and promote them through proper training, promotion and communication activities
HDAB faces difficulties in setting up SPEs	Low	Medium	Liaise with other health data access bodies where these services are already available and engage in capacity building initiatives
Difficulties in (up)loading data into the SPE by the data holders	Medium	Medium	Follow guidelines and security checks, cybersecurity rules on appropriate secure environments
HDAB does not ensure smooth extraction and access to requested electronic health data indicated in the data access application by the data user and in line with the data permit granted	Low	High	Liaise with other health data access bodies where these services are already available and engage in capacity building initiatives
Disrespect of privacy of natural persons and incorrect anonymisation of electronic health data	Low	High	Establish a privacy-by-design culture among the HDAB staff and run recurrent internal (automated) controls and compliance checking audits.
Risk of re-identification of natural persons from the dataset provided	Low	High	Establish a privacy-by-design culture among the HDAB staff and run recurrent internal (automated)

			controls and compliance checking audits.
Risk of storage of electronic health data for a longer period of time exceeding the initial 5 years allowed by data permits	High	Low	Establish a privacy-by-design culture among the HDAB staff and run recurrent internal (automated) controls and compliance checking audits.
Risk of the unauthorised reading, copying, modification or removal of electronic health data hosted in the SPE through state-of-the-art technological means	Low	High	Establish a privacy-by-design culture among the HDAB staff and run recurrent internal (automated) controls and compliance checking audits.
Inability to travel for F2F meetings due to force majeure.	Low	Low	Organize virtual meetings and redirect travel budget to cover the cost of technologies that minimize participant impact.

9 COMPLIANCE AND ALIGNMENT

Throughout the reporting period, governance activities remained fully aligned with national HDAB responsibilities and the secondary-use processes set out in the EHDS regulation. This alignment supported coherent implementation across all WPs and reinforced the national framework for secure and structured data reuse. The technical work progressed in alignment with the HealthData@EU Central Platform, with each release informing updates and refinements to national components to maintain interoperability and compliance.

Since 2019, the national eHealth Law has governed digital health operations in Cyprus. With the adoption of the EHDS Regulation, an amendment to the national law became necessary to provide a clear legal basis for secondary use of health data and to formally establish the HDAB. To support this process, a public procurement procedure was launched during the reporting period for conducting a regulatory impact assessment of the EHDS Regulation. The resulting contract was signed in November 2025, initiating a five-month implementation period. These combined efforts contribute directly to the CY-EHDS-2nd project's regulatory alignment and technical preparedness.