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

Proposal number: 101129405

D1.1: Governance management and Participation Report

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Abbreviations

AE	Affiliated Entity
ADHW	Athens Digital Health Week
AGB	Appropriate Governance Body
BEN	Beneficiary
BIG	Business Implementation Group
BM	Business Manager
CAG	Consortium Agreement
CA	Competent Authority
COO	Coordinator
DD	Draft Deliverable
DAAMs	Data Access Applications Management solution
EC	European Commission
EHR	Electronic Health Record
EHDS	European Health Data Space
EHDS2	European Health Data Space for the secondary use of health data
EHU	European Health Union
EU	European Union
F2F	Face to Face
GA	Grant Agreement
ITH	Interoperability Technical Helpdesk
HDAB	Health Data Access Body
KPI	Key Performance Indicators

LEAR	Legal Entity Appointed Representative
NCP	National Contact Point
NeHA	Ethniki Archi Ilektronikis Igeias
nHDsC	National Dataset Catalogue for health data National dataset catalogue
PCT	Project Core Team
PMT	Project Management Team
PM	Project Manager
PO	Project Owner
PST	Project Support Team
QRT	Quality Review Team
RM	Risk Management
SP	Solution Provider
SPE	Secure Processing Environment
UCY	University of Cyprus
WP	Work Package
WPL	Work Package Leader

EXECUTIVE SUMMARY

Background:

The primary aim of this project is to support Cyprus efforts to implement the national Health Data Access Body (HDAB) as envisaged in the proposed European Health Data Space (EHDS) regulation, thus becoming part of the European secure peer-to-peer infrastructure to foster secondary use of health data. The National eHealth Authority (NeHA) will serve as the sole HDAB of Cyprus. In parallel, in accordance with the provisions of the national eHealth law (N.59 (I)/2019) [1], NeHA functions as both a data controller and a National Contact Point (NCP). As a data controller, it oversees the regulation and management of the Single EHR (Electronic Health Record) Data Bank, which centrally manages and stores citizens' health data for the national EHR system. As the NCP, NeHA is responsible for providing cross-border health services at European level. Within CY-EHDS-2ND NeHA will be expanding its digital business capabilities, establishing its connection with HealthData@EU and related services for the development of the EHDS for secondary use of health data. In this respect, Cyprus through NeHA and the partners will design and implement the national infrastructure in alignment with the EHDS provisions for the secondary use of health data. The primary objective of this infrastructure is to create enhanced opportunities both in quantity and quality for conducting studies supporting innovation, policy making, academic research, public health monitoring and education purposes. The goal, both at the national and European levels, should be for citizens to benefit from the outcomes and products derived from the secondary use of health data. This aims to optimize their health status by tailoring care to their individual environments and personal profiles, ultimately advancing the vision of personalized medicine.

Purpose of the Deliverable:

The main purpose of this document is to establish the appropriate national management structure to enable the cross-border use of health data for research, innovation, policy making, educational activities, patient safety, regulatory activities and personalised medicine, in line with the purposes set out in the EHDS regulation proposal. Additionally, to monitor the overall progress of the different tasks of the project and finally, to participate in the European HealthData@EU temporary governance body and procedures.

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1 INTRODUCTION

The CY-EHDS-2ND aligns with the European Commission (EC)'s commitment to a "Europe fit for the digital age" and advances the objectives of the EU4Health Programme by strengthening health systems. This project aims to enable Cyprus to:

- Establish and deploy services for its HDAB, including its minimum business capabilities, and
- Provide cross-border connections for the large-scale deployment of HealthData@EU, to facilitate the EHDS regulation's implementation.

The CY-EHDS-2ND also supports the establishment, capabilities enlargement, and alignment with European Union (EU) standards of national HDABs and related services and infrastructures across the EU. The action will also consider requirements of specific areas of health data, including those linked to quality of health data and for statistical purposes, as part of the data and infrastructure ecosystem of the EHDS2.

Key Benefits of the CY-EHDS-2ND, the creation of:

- Data Access Application Management solution (DAAMs) to record and process data access applications and issue data permits, data requests or record replies to data access applications.
- National Dataset Catalogue for health data (nHDsC) publicly available to register and facilitate the discovery of health datasets available for secondary use.
- A Secure Processing Environment (SPE) infrastructure to provide a secure, privacy - preserving processing environment as a service to data users.
- A digital gateway to connect with other authorised participants and with the federation services in the EHDS2 infrastructure.
- A health data quality enhancement toolbox for data holders, allowing them to assess the quality of their datasets while enabling data users to understand the quality features of a dataset.

The CY-EHDS-2ND Project Governance Management and Participation Report sets the foundation for successful implementation of high-quality deliverables of the project. By addressing the complexities of the secondary use of data, the CY-EHDS-2ND aims to provide support with the goal of facilitating the realization of the EHDS.

The CY-EHDS-2ND will achieve its objectives by:

- Adopting the HealthDCAT-AP [2] as the core metadata standard for data holders to describe their available health datasets.
- Establishing secure and efficient communication channels between data holders and the HDAB for the provision of the health datasets metadata records.

- Setting up a nHDsC which will collect, validate and publish the metadata records of the health datasets for secondary use in the form of a national health datasets catalogue. The nHDsC will be searchable and accessible to potential data users using metadata descriptors

- Providing the ability to the data user to search and discover one or more datasets by using the nHDsC.

- Providing the data user the ability to apply for access to the discovered datasets. In this regard, NeHA, as the HDAB, will establish a DAAMs which will be used by the data users to create an application requesting access to specific health datasets either in the form of a data permit or data request. DAAMs will also be utilised to track the status of applications throughout their lifecycle covering key phases such as the examination of the application, negotiation, any emerging amendments, and finally the application's approval or rejection.

- Establishing a SPE for every authorised data user based on the corresponding data permit. The SPE will offer the data user an environment for securely accessing the permitted datasets along with tools and means for the analysis and processing of the accessed health data.

- Establishing a framework for the data users to report the final important outcomes and findings resulting from the accessed health data analysis and processing.

- Building the national cross-border gateway to connect with the HealhtData@EU infrastructure to enable cross-border workflows for secondary use of electronic health.

- Providing support to the data holders regarding the enhancement of the quality of their health datasets. In this direction, a health data quality enhancement toolbox will be developed and provided to the data holders.

CY-EHDS-2ND will support NeHA in its role as the sole national HDAB of Cyprus orchestrating the operational and technical framework for the establishment of the national ecosystem for the secondary use of health data under the EHDS.

1.1 Objective of the Deliverable

The objective of the deliverable is to establish the appropriate national management structure to enable the national and cross-border use of health data for secondary use such as research, innovation, policy making, educational activities, patient safety, regulatory activities and personalized medicine, in line with the purposes set out in the EHDS regulation proposal. Additionally, to monitor the overall progress of the different tasks of the project and to participate in the European HealthData@EU temporary governance body and procedures.

1.2 Connection with other Work Packages

The Project Management and Coordination Work Package (WP) 1 collaborates closely with other WPs to integrate work plans, monitor resources, allocate personnel, and manage funding effectively. By facilitating communication and aligning strategies, the Project Management and Coordination WP ensures that the overall objectives of the CY-EHDS-2ND are met through a cohesive and well-coordinated effort across all WPs.

2 CY-EHDS-2ND MANAGEMENT STRUCTURE

The CY-EHDS-2ND consortium is composed of the appointed Competent Authority (CA) (NeHA), its Affiliated Entity (AE) University of Cyprus (UCY). This joint work will enable the Beneficiary (BEN) to work towards strengthening the establishment of the NeHA in its role as the national HDAB while being complemented by its partners' expertise to ensure the necessary competence and capacity to deliver the expected outcomes. As the authority mandated by Cyprus legislation to implement the eHealth Law, NeHA is recognized as the CA for eHealth. Therefore, NeHA will be the main entity responsible for the establishment of the functions of the HDAB.

The workplan (Figure 1) emphasises the proper implementation of the new regulation for the EHDS.
It comprises two main groups of work packages:

1. Work Packages 1-4 (Horizontal application):

- WP1: Management and Coordination
- WP2: Dissemination, training and support
- WP3: Evaluation
- WP4: Sustainability

2. Work Packages 5-9 (Specific Requirements and Technical Specifications):

- WP5: Data Access Applications management solution
- WP6: National Dataset Catalogue for health data
- WP7: Secure Processing Environment for Health Data
- WP8: Cross-border gateway to connect with the HealthData@EU infrastructure
- WP9: Health data quality enhancement

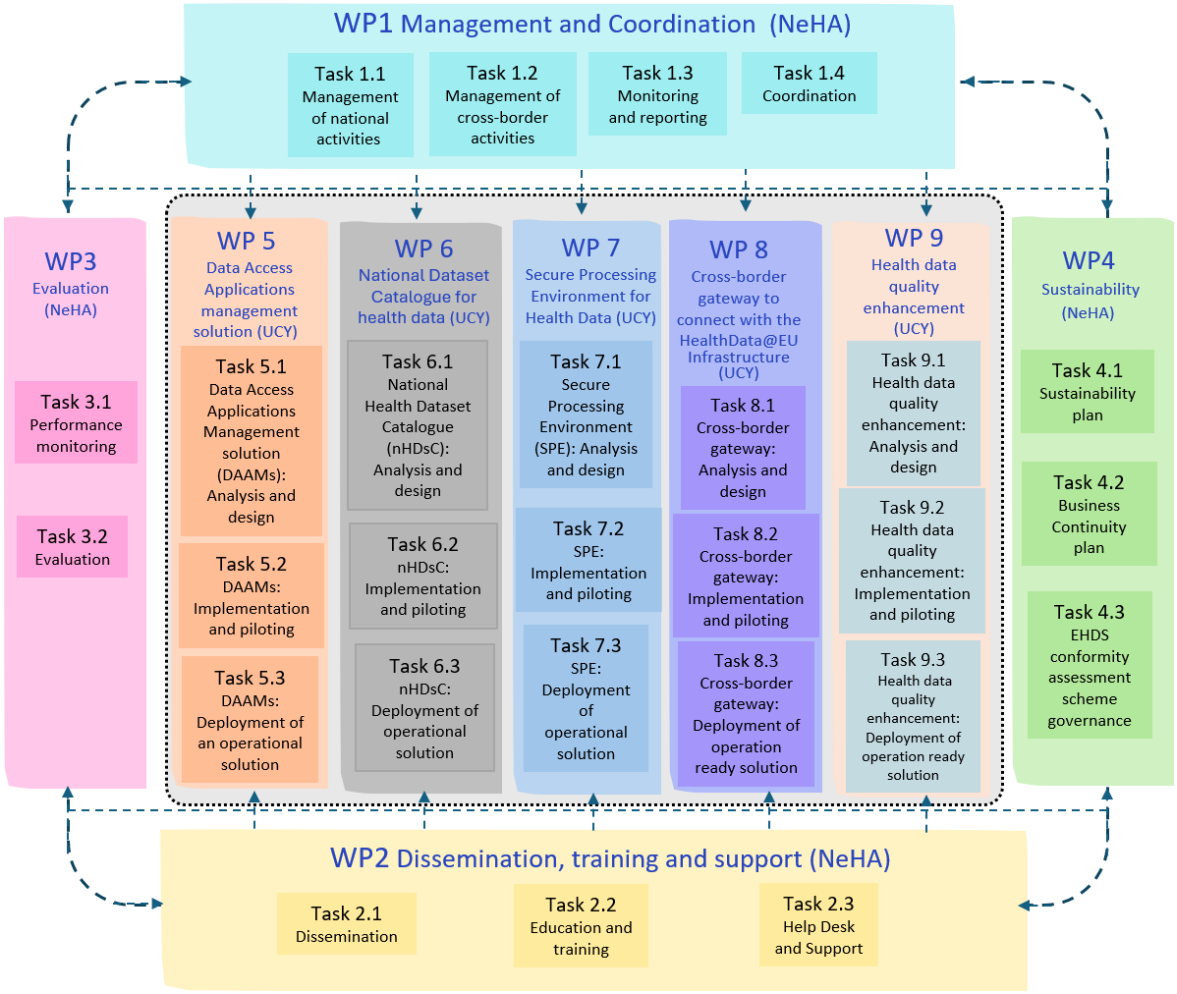

Figure 1: The overall governance structure of the CY-EHDS-2ND

2.1 CY-EHDS-2ND Coordinator

2.1.1 Project Management

Governance methods are in place to ensure high-quality outputs and consistent progress reporting. In this direction, a stringent quality control will cover all deliverables. The project will produce a specific number of deliverables, using milestones, to ensure the timely completion of key aspects of the project and deliverables. WP1 will closely monitor each WP through regular meetings where standard progress reports will be required from the WP leaders. Change management for major changes involving those related to the Grant Agreement (GA), Consortium Agreement (CAG) or the project's deliverables is done centrally within the WP1. Minor changes in the project, which do not have an impact on the deliverables are managed within the respective WPs. The coordination through the WP1 will also keep track of the project's risks and provide guidance during meetings as needed.

2.1.2 Risk Management (RM)

Unplanned events that might have an impact on the project's scope, time, cost, quality, risk, or stakeholders' satisfaction are managed according to their severity. Major issues are taken to the AC. Major issues and the decisions taken to address them will be logged into the issue management log. Each major issue will have a dedicated issue number and can therefore be traced and referred to through multiple meetings and documents.

Prior to submission, each deliverable will undergo an internal review led by the WP1 Quality Review Team (QRT). The WP leader will submit a Draft Deliverable (DD) to the internal QRT. The QRT will perform a quality review assessing content presentation, structure, format, language and coherence with other outputs. The modified DD will be submitted to the AC which will either "Accept", "Accept with minor changes", "Request major changes", or "Reject" the DD. The Coordinator (COO) and Work Package Leaders (WPLs) will be assisted by a pool of international experts, via the Interoperability Technical Helpdesk (ITH), to ensure quality assurance of technical deliverables. A co-funding mechanism between BENs will be established and documented in the CAG to properly fund the ITH in support of the resources provided by the COO.

Within the CY-EHDS-2ND, a systematic approach is employed for the identification, assessment, planning, and implementation of mitigation measures for risks. This well-defined process is overseen by the RM team, whose primary responsibility is to ensure the efficacy of the risk assessment process. The RM plays an important role in monitoring and managing risks at all levels throughout the project lifecycle. This delineation of roles ensures a clear and effective RM strategy, contributing to the overall success and resilience of the CY-EHDS-2ND project (Figure 2).

2.1.3 Quality management

The Quality Management (QM), appointed by NeHA, assumes the responsibility of establishing and adhering to a robust quality assurance process for deliverables. This process is designed to ensure a systematic approach in crafting the project's deliverables, emphasizing thorough reviews before documents are deemed final. By focusing on structured quality assurance procedures, the QM contributes to the overall reliability and excellence of the deliverables, aligning with the high standards set forth by the CY-EHDS-2ND project. For the verification of the work, especially from the technical WPs 5 – 9, stakeholders outside of the project may be invited to review and comment on DDs throughout the project duration (Figure 2).

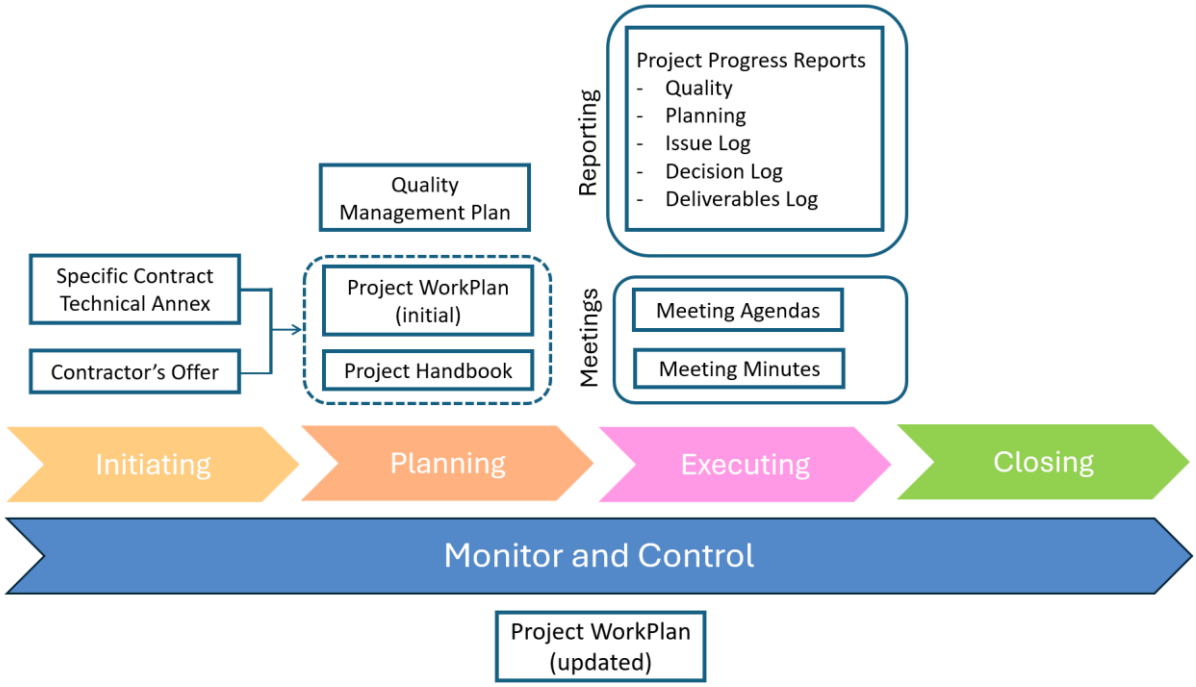

Figure 2: Project management, quality assurance and monitoring and evaluation strategy

2.2 Project Management Team (PMT)

NeHA takes on a crucial role within the CY-EHDS-2ND, ensuring effective coordination and alignment of ongoing activities across all WPs. Comprising all WPLs, co-leaders and task leaders, NeHA conducts a continuous assessment of inputs and emerging results, fostering a collaborative environment that enhances the overall effectiveness of the project. NeHA, is not only responsible for maintaining regular communication through regular meetings, but also for exercising project management through the utilisation of the SharePoint site, emails, physical meetings and video conferences as needed. NeHA's responsibilities extend beyond decision-making to close collaboration with RM and QM. The WPLs and co-leaders themselves bear the responsibility for steering their respective WPs and tasks, aligning them with the overall objectives of the project.

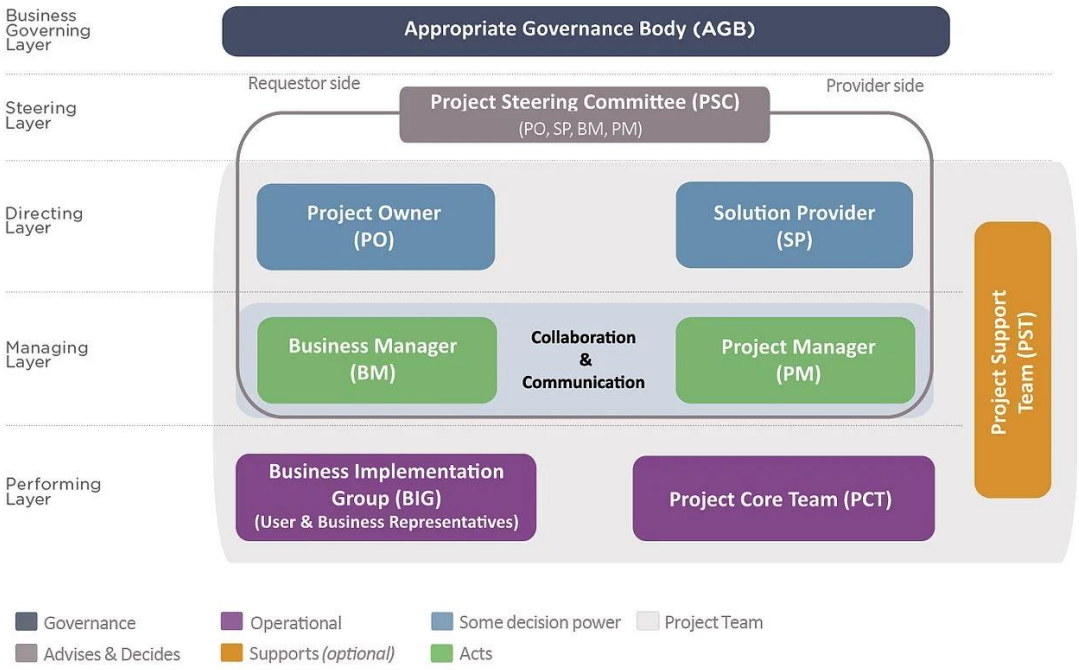

Figure 3: Project organization and roles

2.3 Business Governing Layer

The Business Governing Layer determines the vision and strategy for the entire organization. It consists of one management committee operating at the director's level, where priorities are defined, investment decisions are made, and resources are allocated by the Appropriate Governance Body (AGB).

2.3.1 Appropriate Governance Body

The AGB is the key decision-making entity responsible for strategic planning and portfolio management, setting objectives and releasing funds. The AGB defines corporate strategy, implements portfolio management, monitors performance and optimizes resources and benefits.

2.4 Steering Layer

The Steering Layer provides general project direction and guidance, keeping the project focused on its objectives. It reports to the AGB. The Steering Layer is composed of the roles defined in the Directing and Management Layers explained below.

2.4.1 Directing Layer

The Directing Layer champions the project and owns its Business Case. It mobilizes the necessary resources and monitors the project's performance to realize the project's objectives. The Directing Layer comprises the roles of Project Owner (PO) meaning the coordinator of the project and Solution Provider (SP), who is responsible for executing the project and delivering the outcomes requested by the PO. The SP holds full responsibility for project deliverables and advocates for the interests of those involved in designing, managing, and executing (or outsourcing) the project's deliverables.

2.4.2 Managing Layer

The Managing Layer focuses on day-to-day project operations by organizing, monitoring, and controlling work to produce the intended deliverables and implement them in the business organization. Members of the Managing Layer report to the Directing Layer. The Managing Layer comprises the roles of Business Manager (BM) and Project Manager (PM).

The PM is responsible for managing all phases of the project, from initiation to closing, ensuring the project stays on track and meets its goals. The role requires not only technical project management skills but also interpersonal abilities like communication, leadership, negotiation and problem-solving. PMs would be required to understand the project's business context and organizational policies.

The BM shares many of the same competencies as the PM, focusing on aligning the project with organizational strategies and ensuring it delivers values. Both roles require a mix of people skills, strategic thinking, and knowledge of organizational structures, with BMs having a stronger emphasis on business alignment and governance [4].

It is of utmost importance for the success of the project that there is close collaboration and communication between the BM and the PM.

2.5 Performing Layer

The Performing Layer carries out the project work, producing the deliverables and implementing them in the business organization. Members of the Performing Layer report to the Managing Layer. The Performing Layer comprises the roles of the Business Implementation Group (BIG) and the Project Core Team (PCT).

2.5.1 Business Implementation Group

The BIG is coordinated by the BM. It is responsible for planning and implementing the necessary business changes to effectively integrate project deliverables during daily operation. Key tasks include analysing the project's impact on ongoing operations and existing processes, participating in process design and preparing the business area for changes.

2.5.2 Project Core Team

The PCT consists of specialists responsible for creating project deliverables, with its structure defined by the PM based on the project. Coordinated by the PM, the PCT participates in planning activities, executes tasks, produces deliverables and provides progress updates to the PM. PCT also participate in meetings and help resolve issues when arise.

2.6 Project Support Team

The Project Support Team (PST) is an optional group responsible for providing support to the project, with its composition tailored to project needs. Typically consisting of representatives from various horizontal services or units, the PST's responsibilities include offering administrative support, defining reporting and communication requirements, managing meeting and related reports, assisting the PM in planning and

monitoring, advising on project management tools and administrative services and managing project documentation, including versioning and archiving (Figure 3) [3].

2.7 The Interoperability Technical Helpdesk

The ITH within the CY-EHDS-2ND assumes a crucial role in supporting the COO and WPL by providing access to a pool of international experts who will ensure the highest standards of quality assurance for technical deliverables. To secure the necessary funding for the ITH, a co-financing mechanism among the BENs will be established, with the details outlined in the CAG, thereby supplementing the resources provided by the COO.

3 MEETINGS MANAGEMENT

The meetings management within the governance structure of the CY-EHDS-2ND is carefully organized to promote collaboration and strategic alignment. Meetings play significant roles in decision-making and coordination. NeHA will follow each WP through regular meetings where standard progress reports will be required from each WP leader.

4 TIMELINE/ GANTT CHART

The project schedule encompasses a series of deliverables and milestones across various WPs. The duration of the project is 48 months and is running between the 1st of December 2023 and the 30th of November 2027. In WP1, led by NeHA, the deliverable "D1.1 - Governance management and Participation Report" is set to be a public report due in 12 months. WPs 1- 4 led by NeHA, are focused on the writing and monitoring of progress reports, implementing dissemination activities, designing and providing training opportunities and support, performing evaluation and sustainability. WPs 5-9 led by the UCY are focused on the requirements' recording, implementation and running of the DAAMs, the nHDsC, the SPE, the cross-border gateway to connect with the HealthData@EU infrastructure and the health data quality enhancement.

The governance management structure and participation report is outlined to ensure high-quality outputs and participation reporting. Major milestones include:

- The establishment of a national governance and management structure (WP1)
- The Dissemination campaign and Training and education material (WP2)
- The overall evaluation report (WP3) scheduled at different intervals throughout the 48-month project timeline.
- The draft versions of all the deliverables (including the requirements and specifications, the pilot and operational service) scheduled for the technical work packages WP5-WP9.

This comprehensive schedule outlines a systematic and collaborative approach towards achieving the project objectives. The Gantt Chart of the CY-EHDS-2ND is presented in Table **1**.

Table 1: Gantt Chart of the CY-EHDS-2ND

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										

5 RESOURCE MONITORING

The financial management of the CY-EHDS-2ND falls under the purview of NeHA, which holds the responsibility to disburse funds, in alignment with the GA and CAGs. The COO ensures the collection of regular cost statements and audit certificates, if required. In this capacity, the COO serves as the link between the CY-EHDS-2ND and the Financial Department of NeHA, where the NeHA Legal Entity Appointed Representative (LEAR) and Financial Signatory oversee financial matters. The ongoing overall financial management and the establishment of a continuous reporting mechanism for associated partners are managed by NeHA's project officers.

In terms of budget allocation per WP, NeHA will lead WP1-WP4, work packages that relate to coordination, dissemination, evaluation, and sustainability, respectively, aided by UCY, experts, and subcontracting entities. The remaining scientific and technical WPs that concern the solution implementation, integrating different components and services, will be led UCY, assisted by NeHA, while exploiting the unique and combined expertise brought on by subcontracting entities and domain experts.

NeHA is responsible for creating reporting templates, collecting, analysing, and evaluating data from all project partners, and maintaining continuous budget planning and monitoring. Any deviations or significant financial issues will be identified early based on the activities and financial reports and will be discussed at a project management level. A mitigation strategy will be proposed, which might include which will further propose reallocation of funds if deemed necessary. NeHA implements appropriate solutions in adherence to the rules outlined in the GA and CAG. This collaborative approach ensures transparent and effective financial governance within the CY-EHDS-2ND, promoting accountability and adherence to established protocols.

6 FUNDING

The BEN is responsible for its AEs in terms of ensuring that the foreseen work is carried out. EC funding is 80% of the total eligible costs, while partners, as well as AEs, are responsible for co-funding the remaining 20%.

7 DOCUMENTATION MANAGEMENT

In support of the streamlined coordination and proficient management of the project, all pertinent documents are consolidated within the SharePoint management tool. This platform serves as a centralized repository, fostering enhanced accessibility and collaborative efficiency among team members. Through the strategic utilisation of SharePoint, the project benefits from a comprehensive and organized approach to document storage, ensuring that essential information is readily available to facilitate optimal coordination and successful project management.

The structure of the SharePoint folders is demonstrated below. At the root directory, there are seven folders and two Excel files. The initial Excel file "Mailing list" encompasses the contact information of the project's participating partners. The second Excel file "Workplan" comprises the project workplan and deliverable deadlines, presented in the form of a Gantt Chart (Table **1**).

Within the first folder, essential documents such as the proposal and CAG are stored as presented in Figure **4Error! Reference source not found.**. The second folder houses 9 sub-folders - one dedicated to each WP and one extra folder that will include the work impacting all technical work packages (WP5-WP9) horizontally (Figure **5**). Within each WP-specific subfolder, there are five further subfolders, categorizing material related to tasks, deliverables, milestones, meetings, and presentations.

This careful folder organization ensures systematic arrangement of project-related documents, facilitating efficient retrieval and collaboration among team members. Each subfolder's distinct focus streamlines access specific information, enhancing overall project management and coordination.

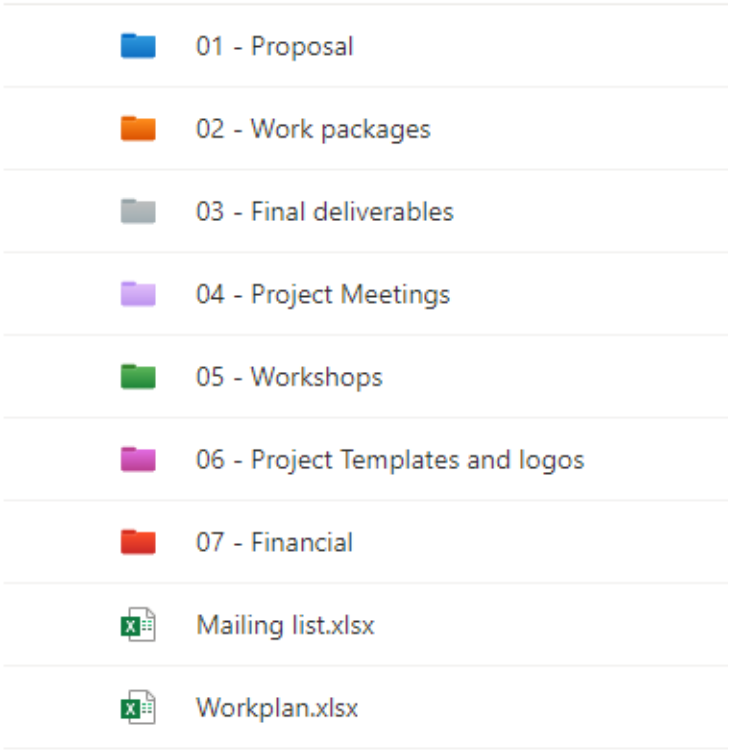

Figure 4: Main Directory on the SharePoint Platform.

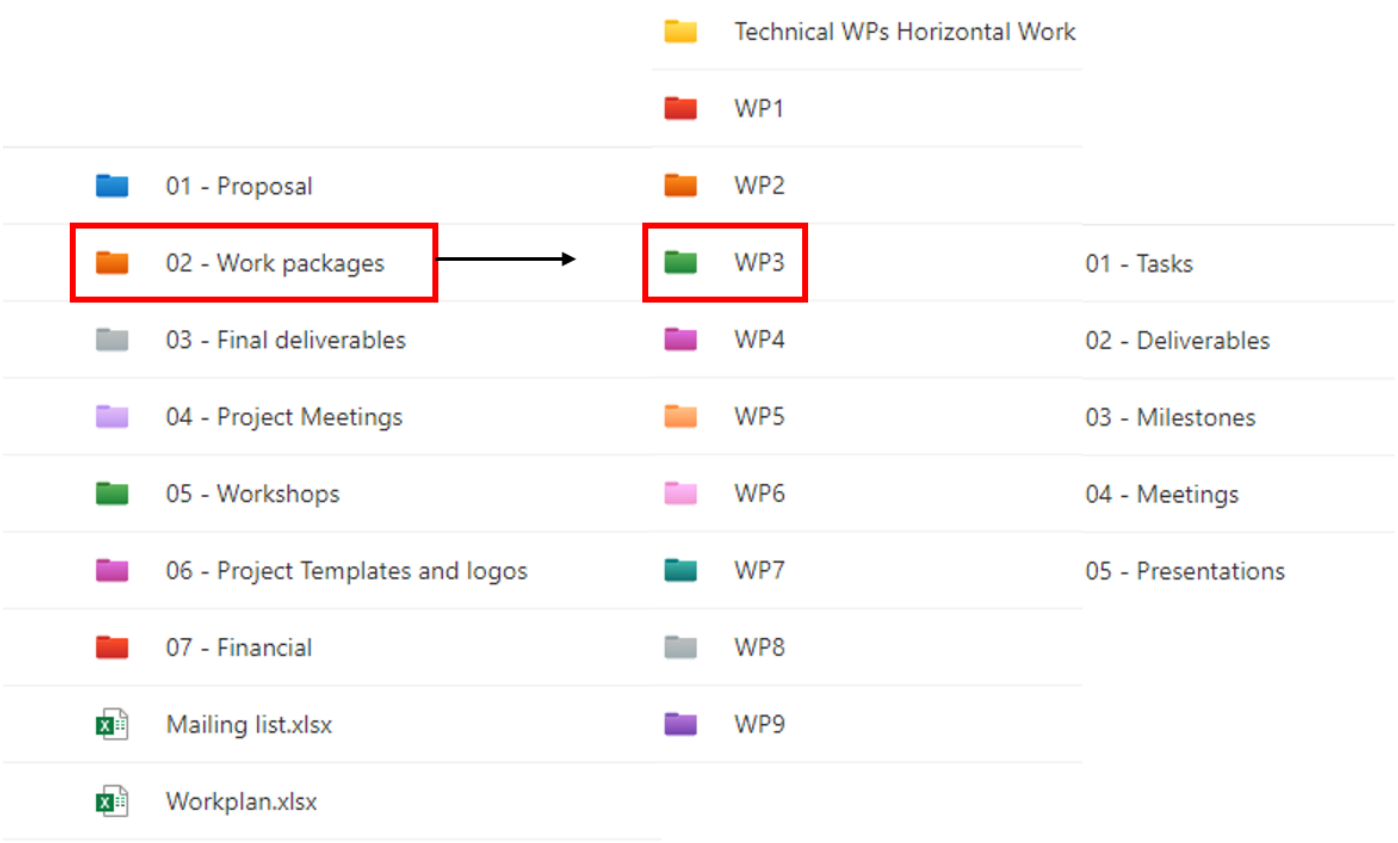

Figure 5: Detailed structure of WP Folders in the SharePoint Platform.

8 CY-EHDS-2ND CONTACTS

The creation of email distribution lists aims to facilitate communication for various aspects of the project, including administrative matters, for the SC, QM and each WP individually (WP1 – WP9). Additionally, task-specific lists are established in alignment with the WPL's. The comprehensive contact information of project participants and their corresponding mailing list affiliations is documented in the "Mailing list" Excel file accessible on the Collaborative Platform.

To manage the membership of these lists, any partner or AE can request the addition or removal of a member by contacting the PMT. The request should include the member's name, email, and specify the relevant email lists. In the event of a member departing the project, their removal from the Collaborative Platform is automatically carried out. All requests for modifications should be accompanied by a justification for the proposed changes.

9 WORKSHOPS AND F2F MEETINGS

Workshops and face-to-face (F2F) meetings play an important role in the CY-EHDS-2ND, serving as crucial forums for collaboration, innovation, and knowledge exchange. In this context, workshops serve as invaluable opportunities for direct interaction, facilitating immediate reactions, and sustained interest in complex topics. They are more than mere discussion forums; rather, they are structured working meetings aimed at achieving tangible goals, such as drafting deliverable chapters and proposing solutions for critical components.

With a structured approach to organization, including detailed agendas and materials sent in advance, workshops ensure participants are well-prepared to make meaningful contributions.

These sessions address specific needs through various types of workshops, including consolidation workshops for consensus, ideation workshops for strategic initiatives, and activation workshops for initiative implementation urgency. Importantly, in EU-funded projects, workshops drive progress while also disseminating knowledge, promoting cross-border collaboration, and advancing collective goals in improving healthcare services through eHealth solutions.

9.1 Organisation of workshops

The organization of workshops within the CY-EHDS-2ND entails both F2F and hybrid formats, with logistics including budgeting, catering, venue selection, and booking being managed by the respective organizers. Typically, this responsibility falls under a specific WP, such as WP2, in collaboration with WP1. To ensure a workshop is productive, several key considerations should be considered. This includes sending out essential communications in advance: a "save the date" email and identification of key invitees two months prior, followed by a preliminary version of the agenda, any necessary survey, or questions one month ahead, and a final version of the agenda along with all pertinent written materials one week before the workshop to foster adequate preparation. Additionally, a document outlining the scope and a summary of the main goals and expected outputs should accompany the agenda. In cases requiring external expertise, the WPL or co-leader, in collaboration with coordination (WP1), should identify stakeholders and experts to be invited at least two months in advance. If feasible, the identification and appointment of one or more facilitators to guide the workshop are recommended.

Each workshop should be accompanied by a detailed plan, not limited to a timetable, but also inclusive of itemised goals, concrete steps, and methodologies. Lastly, the social dimension is emphasised, urging the capture of group photos during the event, as the integration of social gatherings with intellectual engagement is deemed crucial for the collaborative success of the CY-EHDS-2ND. The template for the presentations is found in APPENDIX II - The template of the presentations.

In the following paragraphs we present some completed workshops and known planned workshops, including the kick-off and closing meetings. However, other workshops may be organised, as the need arises.

9.2 Athens Digital Health Week 2024 - (Athens, 15 – 19 January 2024)

During the Athens Digital Health Week (ADHW) the purpose of the project was introduced presenting NeHA as the sole HDAB of Cyprus. The connection with HealtData@EU was emphasized, along with the legal and technical frameworks. Additionally, the project's WPs deliverables and use cases related to secondary use of data were presented.

9.3 University of Cyprus (Nicosia, May 2024)

A kick off meeting was held, featuring a presentation on the project's objectives. The discussion emphasized the national services and infrastructure, with a particular focus on the interaction between HDAB, data holders and data users. Representatives from both NeHA and UCY attended the meeting. The meeting concluded with an overview of the different WPs and their specific purposes.

9.4 National eHealth Authority (Nicosia, March or April 2026)

A mid-term event will be held, featuring a comprehensive update on the project's progress. The discussion will highlight key achievements and challenges, focusing on the integration of national services and infrastructure. Special attention will be given to the ongoing collaboration between HDAB, data holders, and data users. Representatives from both NeHA and UCY will attend. The event will conclude with a review of the work packages' progress and necessary adjustments to ensure alignment with project goals for the remainder of the term.

9.5 National eHealth Authority (Nicosia, during 2025-27)

In addition to the above planned events, we are considering organizing joint events with other Member States who received similar direct funding for exchanging experiences and developing pilot studies for testing exchanges of data for secondary use. In this respect we are in communication with Greece, Finland and Austria.

9.6 Closing event in - (November 2027)

The final event of the CY-EHDS-2ND project in Cyprus is set to be a significant occasion, uniting the project partners, experts and stakeholders to commemorate the projects successful completion. This event will not only celebrate the project's achievements but also serve as a key moment to reflect on advancements in the secondary use of health data, marking the dawn of a new era in digital healthcare. Our aim is to support the EU's collective efforts towards building a stronger European Health Union (EHU) by implementing the EHDS regulation across Europe.

10 DELIVERABLES

Effective deliverable management is crucial for the success of the CY-EHDS-2ND, ensuring the timely and high-quality completion of key project outputs. Led by a coordinated effort from WPLs, the deliverable

management process involves meticulous planning, execution, and monitoring of tasks related to each project deliverable.

WPLs play a crucial role in overseeing the preparation and presentation of deliverables, aligning them with project goals and EHDS regulations.

The establishment of templates for different deliverable categories (see APPENDIX I - The template of the deliverables), periodic reviews, and clear documentation of technical annexes within WPs contribute to streamlined and efficient deliverable management. This approach ensures that the CY-EHDS-2ND project stays on track to achieve its milestones and produces valuable outcomes aligned with the overarching goal of establishing secondary use of health data in the national and EHDS. The deliverable management process in the CY-EHDS-2ND project is carefully structured to ensure a smooth and timely submission of high-quality outputs. WPLs, along with the coordination team, adhere to a well-defined timeline for deliverable submission. Three months prior to the deadline, a rough draft, encompassing all major sections and an introductory paragraph, is submitted to the COO. This initial submission serves as the foundation for subsequent refinements. One month and a half (six weeks) before the deadline, a near-complete (~80%) draft is shared with the coordination team, allowing for a two-week feedback and comments period. In the following two weeks, the deliverable will address the feedback and comments raised and agreed upon. The final draft, representing a 100% completion, is submitted to the COO two weeks before the deadline. During the two subsequent weeks, the WP leader and coordination team conduct a thorough review, addressing any final comments from relevant partners. Emphasising the importance of punctuality, the CY-EHDS-2ND project enforces a commitment to submitting deliverables on time, ensuring a consistent and effective progression toward project milestones.

The procedure described above applies to the external deliverables, to be submitted to the EC HaDEA via the online Portal (SyGMa). The same approach could be followed for the internal deliverables (not to be submitted to HaDEA; in that case, however, this procedure should not be considered mandatory.

11 RISK MANAGEMENT

The project recognizes and addresses several potential risks which are outlined in Table **2**.

Table 2: CY-EHDS-2nd potential 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	Medium	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.

11.1 Monitoring

This section underscores the utilisation of Key Performance Indicators (KPIs) as an integral tool for continuous oversight and evaluation. KPIs provide measurable metrics that enable the project team to systematically track and assess the effectiveness of risk mitigation strategies. Here, we emphasise the importance of referring to the dedicated output document on KPIs, which serves as a comprehensive guide detailing the selected indicators, their definitions, and the associated monitoring processes. The incorporation of KPIs in the monitoring process enhances the project's ability to detect potential issues early on, enabling timely interventions and contributing to the overall success of the RM strategy. The current version of KPIs related to WP1 are listed below.

11.1.1 Implementation Progress

Definition: The percentage completion of key project milestones and deliverables and their acceptance by the EC following the review process.

Importance: Monitoring the progress of implementation against the project plan ensures that the project stays on track and meets its objectives within the defined timeline. This KPI can be tracked for each of the outlined activities, providing a comprehensive view of overall project advancement.

Use/Explanation: The percentage completion of key project milestones and deliverables and their acceptance by the EC following the review process.

Target Value: 100% for each deliverable and milestone of the project.

11.1.2 Meeting Participation and Engagement

Definition: It measures the level of involvement and active contribution of project partners and stakeholders in project meetings, workshops, and other collaborative sessions. It assesses the extent to which participants are actively engaged, providing valuable input, sharing insights, and contributing to decision-making processes during these gatherings.

Importance: This KPI is vital for assessing the effectiveness of communication and collaboration among project partners and stakeholders. It indicates the level of commitment, alignment of goals, and active contribution to decision-making processes, leading to informed decisions and successful project outcomes. Monitoring meeting participation and engagement enables PMs to foster inclusivity, enhance knowledge

sharing, and address any issues early on, ensuring smooth project implementation and stakeholder satisfaction.

Use/Explanation: It measures the level of involvement and active contribution of project partners and stakeholders in project meetings, workshops, and other collaborative sessions. It assesses the extent to which participants are actively engaged, providing valuable input, sharing insights, and contributing to decision-making processes during these gatherings.

Target Value: 80% participation rate in meetings and collaborative sessions.

11.1.3 Financial Resources

Definition: The Financial Resources tracks the allocation, utilization, and availability of financial resources within the project. It encompasses monitoring budget allocations, expenditure, cost management practices, funding sources, and financial sustainability to ensure that financial resources are effectively managed and aligned with project objectives.

Importance: Monitoring financial resources helps maintain transparency, accountability, and compliance with funding requirements, fostering trust among project stakeholders and funding agencies. Additionally, it facilitates strategic planning, resource optimization, and the identification of opportunities for securing additional funding or reallocating resources to meet evolving project needs. Overall, effective management of financial resources is critical for the successful implementation and long-term viability of the project.

Use/Explanation: The Financial Resources tracks the allocation, utilization, and availability of financial resources within the project. It encompasses monitoring budget allocations, expenditure, cost management practices, funding sources, and financial sustainability to ensure that financial resources are effectively managed and aligned with project objectives.

Target Value: 100% of financial resources are monitored.

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APPENDIX I - The template of the deliverables

DX.Y Deliverable's Name

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

Proposal number: 101129405

[Number and TITLE of the deliverable]

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APPENDIX II - The template of the presentations

Table Example #1

Col A	Col B	...	...	...
Text	Text	Text	Text	Text
Text				

- Text
  - Test
    - Test
      - Text
        - Can you share the email to request for login here in the chat?


European Health Data Space for Secondary Use @CY
CY@ EHDS secondary use
Thank you!
This is a thank you slide to thank everyone and present contact info if desired.
NATIONAL eHEALTH AUTHORITY
Πανεπιστήμιο Κύπρου
Ερευνητικό Κέντρο Βιοϊατρικής Μηχανικής - ΕΚΒΜ
eHealth Lab