Project acronym: HealthData@PT

Project full title: Setting up a Health Data Access Body in Portugal and laying the national foundations for EHDS2

WP3 – Evaluation

D3.1– Report on the performance monitoring indicators framework

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Executive Summary

The HealthData@PT - *Setting up a Health Data Access Body in Portugal and laying the national foundations for EHDS2*, is a European Union's EU4Health (2021-2027) programme co-funded action that will perform the groundwork necessary to establish the national infrastructure, network, and the fundamental components required to offer secure access to high-quality health data for research, medical innovation, and health policymaking purposes (secondary uses of health data) in Portugal. Such groundwork will drive the technical implementation of the Portuguese health data access body (HDAB), posing a crucial landmark to advance the secondary use of health data in Portugal, to ultimately improve citizens' healthcare and outcomes and strengthening the national health system. This action is led by the Shared Services of the Ministry of Health, Portugal (SPMS).

Aiming at the technical implementation of the Portuguese HDAB as anticipated in the European Health Data Space regulation proposal, HealthData@PT technical work packages (work packages 5 - 9) entail the design, development, and implementation of five digital business capabilities: i) a data access application management system operational by the end of the action, ii) a national datasets catalogue publicly available by the end of the action, iii) the groundwork necessary for the future deployment of a secure processing environment, iv) the minimum viable product for the cross border gateway and v) data quality enhancement.

The present document – D3.1. performance monitoring indicators framework– contains the plan that will guide continuous monitoring, and the evaluation of the activities related to the implementation of the business capabilities of the Portuguese HDAB. Therefore, the framework presented in this document focuses on HealthData@PT´s WPs 5-9. The D3.1 pertains to WP 3 – Evaluation, more specifically to task 3.1, which entails the establishment of a performance monitoring plan to assess the implementation of the digital business capabilities and the execution of continuous monitoring activities.

In the performance monitoring framework herein presented, SMART (S- specific, M – measurable, A- achievable, R – realistic, T – time-bound) key performance indicators (KPIs) were devised, to guide continuous evaluation activities and provide metrics for continuously monitoring the implementation of the business capabilities of the Portuguese HDAB. Action overall KPIs and WP-specific KPIs are supplied, the last to ensure a level of specificity for driven evaluation processes. This document also includes information about the monitoring roles and responsibilities, the evaluation timeline, the tools that will be utilized to carry out monitoring activities, and details regarding the operationalization of the evaluation activities.

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Terms and Abbreviations

D	Deliverable	
DAAMs	Data Access Application Management System	
DBC	Digital Business Capability	
EC	European Commission	
EHDS	European Health Data Space	
EU	European Union	
GA	Grant Agreement	
HDAB	Health Data Access Body	
KPIs	Key Performance Indicators	
M	Month	
MS	Member State	
MSx	Milestone	
MVP	Minimum Viable Product	
nHDsC	National Health Dataset Catalogue	
NSDGRI	Global Digital Health and International Affairs	
O.x.	Objective	
OS	Operation and Security Unit	
SMART	S- specific, M – measurable, A- achievable, R – realistic, T – time-bound	
SPE	Secure Processing Environment	
SPMS	Shared Services of the Ministry of Health, Portugal	
UCS	Cybersecurity Unit	
UIA	Advanced Analytics, Artificial Intelligence and Robotics Unit	
UID	Digital Innovation Unit	
UPACE	Planning, Architecture, Compliance and Engineering Unit	
WP	Work Package	

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1. Introduction

1.1. Background

HealthData@PT is a 4-years EU co-funded action coordinated by the Shared Services of the Ministry of Health, Portugal (SPMS), that envisions to advance the secondary use of health data in Portugal, by performing the groundwork necessary for the technical implementation of the national health data access body (HDAB). Secondary use of health data refers to the use of high-quality health data by researchers, innovators, policymakers, regulators, public institutions, or industry aiming at developing better treatments, vaccines or medical devices, improving healthcare and disease management, and strengthening the health systems [1]. According to the European Health Data Space (EHDS) regulation proposal, the secondary use of health data at national and cross-border levels requires the establishment of a "*legal and governance framework and structure*" in every member state (MS) of the European Union. This structure, entitled HDAB, will be responsible for granting data users with access to health data for secondary use in a streamlined, secure, trusted, and efficient way [2]. According to the EHDS regulation proposal, every MS must have at least one HDAB established, although several HDABs may be set per MS. In the last case, one must be designated as the coordinator.

According to article 37, and further supported by articles 44, 46, 50, 52, 53 and 55 of the EHDS regulation proposal, an HDAB must, among other functions (Figure 1):

- Maintain a data access management system to process and record data access applications, data requests and the issued permits;
- Analyse and decide on data access applications, issue data permits for accessing electronic health data in case of approved requests;
- Provide data users with access to electronic health data, for requests aligned with the purposes stated in article 34 of the EHDS regulation proposal (scientific research, teaching activities, medical innovation, development of public health/social relevant medical solutions, etc.);
- Provide data users with access to anonymised health data. Pseudonymised health data can be provided under specific circumstances when the purpose of data use cannot be accomplished with anonymized data;
- Provide access to health data for secondary uses in a secure processing environment;
- Made publicly available a national dataset catalogue;
- Enable cross-border access to electronic health data for secondary use purposes held in other MS through HealthData@EU.
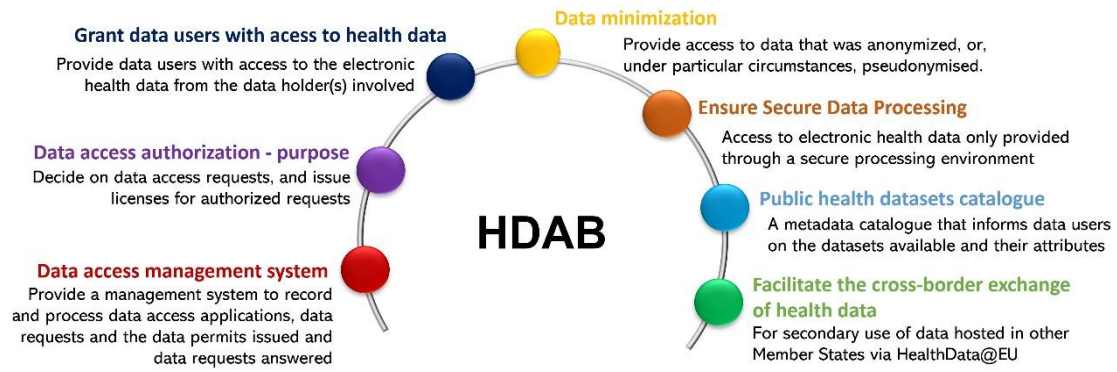
Figure 1. Some of the duties and functions of a HDAB, as anticipated in the EHDS regulation proposal.

Towards fulfilling these tasks, a legal, organizational, and technical infrastructure that ensures these functions is required.

Portugal has made remarkable advances in the context of the primary use of health data with the development of a national interoperability platform and technical and semantic standards, and a well-established and operational infrastructure for the exchange of health data for primary use purposes.

However, currently, Portugal does not have a HDAB or framework as specified in the EHDS regulation proposal for secondary use of health data. A Transparency Portal, which compiles data from several national health entities (ACSS, INSA, DGS, IPST, INFARMED, INEM) has been deployed to provide data users with data and metrics on a wide range of health topics (e.g. number of electronic prescriptions over the years, morbidity and mortality per health institution, etc.). However, access requests to health data for secondary use are yet performed by e-mail.

Hence, the development of services and infrastructures at national level and for cross-border exchange, as well as the improvement of data quality are required to deploy a HDAB with the services and the framework anticipated in the EHDS regulation proposal for the secondary use of health data.

In this scope, the HealthData@PT action, which started in November 2023, aims at the development of the key digital business capabilities (DBCs) required to deploy a HDAB in Portugal with the minimum operational requirements, enabling the processing and management of health data access applications, future connection with the HealthData@EU for the cross-border exchange of health data, and equipped with the services needed for the implementation of the EHDS for the secondary use of health data.

Therefore, the general objectives of HealthData@PT are:

1) To establish, design, deploy and prepare future services for a Portuguese HDAB, which encompass 5 DBCs (Figure 2):

- Data Access Application Management System (DAAMs)
- National Dataset Catalogue
- Secure Processing Environment (SPE)
- Cross Border Gateway
- Data Quality enhancement

2) To establish the cross-border gateway for linking the national infrastructure with the EU secure infrastructure for the cross-border exchange of health data for secondary use, the HealthData@EU.

Figure 2. The digital business capabilities (DBCs) under development during HealthData@PT.

To fulfil these goals, HealthData@PT is composed by 5 technical work packages (WPs), WPs 5-9, each focused on the development of one of the abovementioned DBCs (Table 1). WP 5 comprises all the activities necessary to deploy an operational data access applications management system, capable to receive, process and reply to data access applications in less than 2 months for non-complex requests, during HealthData@PT's lifecycle. Likewise, WP6 entails the work necessary to make publicly available a national datasets catalogue. During WP7, an implementation plan for the national secure processing environment (SPE) will be outlined, and a continuous assessment will be performed to explore opportunities for advancing the development of the national SPE. WP8 is dedicated to all the activities required to implement a minimum viable cross-border gateway product, capable to connect the national infrastructure with the HealthData@EU. Finally, WP9 aims at improving the quality of the data made accessible though HealthData@PT by evaluating data quality and by offering data holders with guidelines and recommendations to support them enhancing the quality of their data.

These 5 technical WPs are supported by 4 horizontal WPs, WPs 1-4, which are dedicated to project management and coordination (WP1), dissemination, training, and support activities (WP2), evaluation (WP3) and sustainability (WP4) (Table 1).

Table 1. Overview of HealthData@PT work packages (WPs).

WP	WP Title	WP Description
1	Management and Coordination	This WPs entails i) establishing a governance and management framework to set the national governance model for HealthData@PT, ii) engaging with HealthData@EU-related initiatives and bodies to ensure national and EU alignment and iii) coordination activities to ensure successful execution of the action.
2	Dissemination, training and support	In this WP, dissemination and training initiatives will be organized, and educational materials will be made available to share information on the HDAB functions and structure, and on EHDS2-related topics.
3	Evaluation	WP3 entails the set of a monitoring framework and continuous monitoring activities to assess the progress of the implementation of the five DBCs.
4	Sustainability	WP4 activities aim at establishing a sustainability and business continuity plan to ensure the continuity of the implemented DBCs beyond the duration of this action.
5	National data access application management system	WP5 comprises all the activities - defining the requirements and specifications, designing, implementing and piloting - necessary to deploy an operational data access applications management system, capable to receive, process and reply to data access applications.
6	National dataset catalogue	In this WP, all the work necessary to make publicly available a national health datasets catalogue will be performed. This comprises defining the requirements and specifications, design, implementation, and piloting operations.
7	Secure processing environments	During this WP, the requirements and specifications for the national SPE will be outlined, and a plan for its implementation will be set. A continuous assessment of opportunities will be performed to further advance the deployment of the national SPE.
8	Cross-border gateway	This WP aims at performing the work necessary to implement and test at a pilot scale the minimum viable product capable to connect the national infrastructure with HealthData@EU. This WP encompasses setting requirements and specifications, implementing and piloting activities.
9	Data quality enhancement	WP9 will dedicate itself to assessing data quality and elaborating guidelines and recommendations to support data holders improving the quality of their health data.

To accomplish the objectives of these WPs, an internal team and structure were assembled in SPMS. HealthData@PT action is coordinated by Cátia Pinto, from the Global Digital Health and International Affairs (NSDGRI) team. The NSDGRI team is responsible for overall project management and the ultimate responsible party for the fulfilment of HealthData@PT deliverables/objectives. Nevertheless, due to the technical nature of WPs 5-9, pertaining to the development of the DBCs, several SPMS units, composed by experts in the work envisioned in these WPs, were assigned to these WPs. One SPMS unit per WP (for WPs 5-9) was assigned as main responsible for tasks'

completion and deliverables/milestones' fulfilment. From this assignment, performed in the M1 of HealthData@PT, the following resulted:

- **WPs 1-4**: under the responsibility of the NSDGRI team.
- **WP 5**: the main responsibility for the tasks' completion in this WP was attributed to the *Advanced Analytics, Artificial Intelligence and Robotics* (UIA) SPMS unit. In this WP, the *Planning, Architecture, Compliance and Engineering unit (UPACE)* and the *Digital Innovation Unit* (UID) also participate.
- **WP6**: the responsibility for this WP was attributed to UIA. UPACE also participates in this WP.
- **WP7**: the responsibility for this WP was attributed to the Operation and Security Unit (OS). UPACE and the SPMS *cybersecurity unit* (UCS) were assigned as co-responsible units. UIA and UID also participate in this WP.
- **WP8**: the responsibility for this WP was attributed to UPACE.
- **WP9:** the responsibility for this WP was attributed to UIA. UPACE also participates in this WP.

The designated unit manager of each SPMS unit assigned as WP-responsible and the NSDGRI team will collaborate closely to track progress and quality, coordinate work within tasks, and submit reports/deliverables to the project coordination. The governance structure of HealthData@PT is fully described in the grant agreement (GA). A brief overview will be provided in section 2.4 for context.

1.2. Purpose and scope of a key performance indicators framework

To ensure that the endeavours in the scope of HealthData@PT are progressing towards the fulfilment of its general goals, the establishment of a monitoring framework is required. This framework enables to assess whether HealthData@PT is being implemented and progressing as planned, and to track the successful and timely accomplishment of HealthData@PT's planned objectives.

Therefore, a key performance indicators (KPIs) framework was outlined in the first months of the project, aiming at serving as a roadmap to guide evaluation and continuous monitoring activities in WP3 (Evaluation). This framework provides a streamlined approach to assess if the implementation of the DBCs of HealthData@PT is progressing as expected, to allow the early detection of any deviations that may compromise HealthData@PT general objectives. Therefore, this is a crucial tool for outlining correction plans or measures whenever the need arises, and to drive HealthData@PT towards success.

This key performance indicators framework, as described in the GA, is dedicated to monitoring the progress of the DBCs of the HDAB. Therefore, in this document, a detailed

framework for evaluating the progress of WPs 5, 6, 7, 8 and 9 was outlined, as it will be further detailed in the next section.

2. Key performance indicators framework

2.1. Context

The WP3 of HealthData@PT will conduct evaluation activities, to assess if the project is being implemented towards accomplishing the proposed goals presented in section 1.1. To guide evaluation activities, a framework based on key performance indicators (KPIs) was outlined to provide metrics for monitoring activities. The rationale followed for devising this framework will be detailed in this section of this document. The proposed framework outlines i) the procedures that will be implemented for continuous evaluation of the progress of the DBCs under development during HealthData@PT, ii) the metrics that must be considered in specific timepoints for assessing the successful progress of HealthData@PT endeavours, iii) the roles and responsibilities assigned for evaluation activities and iv) evaluation timeline.

2.2. Designing the key performance indicators monitoring framework

HealthData@PT KPIs monitoring framework was built by first defining the action overall KPIs, and, subsequently, by breaking down the overall action KPIs into WP-specific KPIs to feature continuous monitoring at a more detailed level. Both overall and WP-specific KPIs were drafted following a SMART (S- specific, M – measurable, A- achievable, R – realistic, T – time-bound) approach, providing indicators that specifically define what is expected to be accomplished, in which extension (quantifiable metric) and when (deadline) along with the actions needed and the person/unit responsible for goal fulfilment (Figure 3).

Figure 3. SMART approach, that was followed to draft HealthData@PT KPIs.

The HealthData@PT GA outlines the action **specific objectives**: objective 1 (O.1.) refers to national services and infrastructures for the national HDAB, objective 2 (O.2.). to the cross-border services and infrastructures, and objective 3 (O.3.). to enhancing data quality (Figure 4).
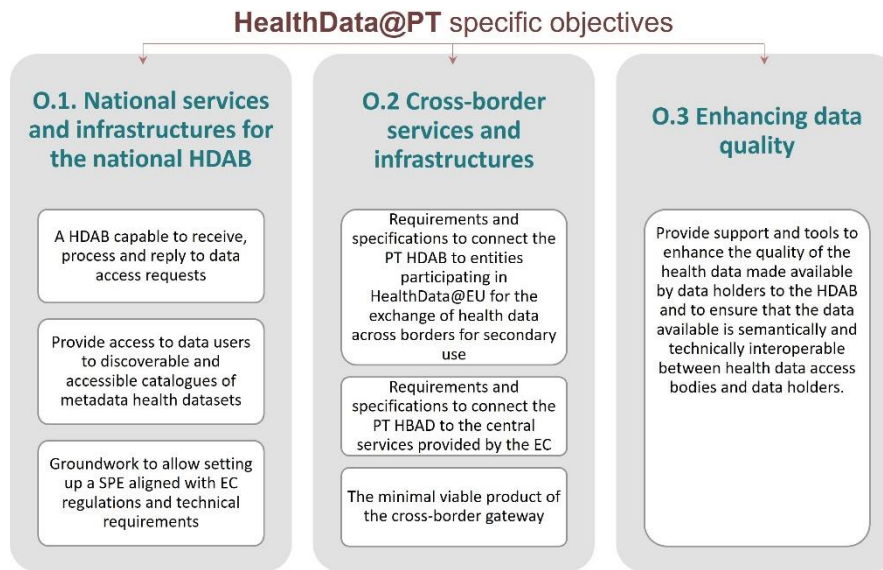
HealthData@PT specific objectives

Figure 4. The specific objectives of the HealthData@PT action.

A list of specific indicators and targets were provided in the GA for each of these objectives, albeit without using a SMART approach. Considering the indicators and targets mentioned in the GA for each specific objective of HealthData@PT, along with the objectives of each technical WPs (WPs 5-9), the overall action KPIs were outlined, as presented in **Table 2** of section 2.3.1. This posed the **step 1** of designing the HealthData@PT framework. Subsequently, the specific goals of each WP were delineated, considering the steps necessary to achieve the HealthData@PT overall KPIs and the descriptions of the tasks comprised in each WP (**step 2**). Different SPMS units participate in the technical WPs of HealthData@PT. When initiating the project, a coordination group meeting, involving all the SPMS units participating in the HealthData@PT was conducted. In this meeting, the responsibility of each technical WP was allocated to a specific SPMS unit/team (see section 1.1 for details), which is henceforth responsible for the execution of the technical work and for managing the work within the assigned WP towards the fulfilment of HealthData@PT specific goals. Units responsible for part of the technical work envisioned in a WP that are not leading the WP itself, were also defined. The assigned teams´ responsibilities and participation in HealthData@PT WPs were registered in the meeting minutes and sent to all HealthData@PT involved collaborators for registry and approval. Thus, for the elaboration of the KPIs framework, responsibilities were attributed for each WP specific objectives based on the SPMS units involved in that WP (**step 3**). Both main responsible unit and participating units were held as responsible.

Subsequently, for each WP-specific goal, a set of indicators—*measurable variables that enable tracking the degree of progress toward an objective*—were established (**step 4**). Target values for each indicator were devised (**step 5**) to provide a quantifiable means

for evaluation purposes. The month of completion was specified along with each target value.

The next step comprised the establishment of a source of verification (**step 6**), that will be used to confirm the timely fulfilment of the set target values. Finally, reporting periods were established (further details in section 2.4) for each KPI, to assure the continuous monitoring of activities progress and early identification of any risks/delays/constraints (**step 7**). Whenever a link or dependency between one KPI and another KPI or activity was found, such connection/dependency was indicated, to support the early identification of any potential risk/constraint (**step 8**). The overall workflow to set the HealthData@PT KPIs monitoring framework is summarized in Figure 5.
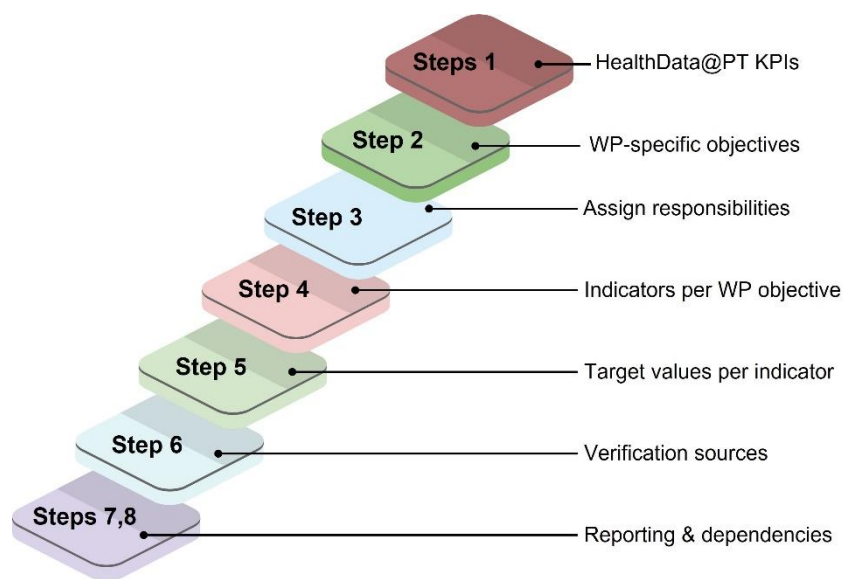
Figure 5. The rational followed for drafting HealthData@PT´s KPIs monitoring framework.

2.3. HealthData@PT key performance indicators framework

2.3.1. HealthData@PT overall KPIs

To establish a KPIs monitoring framework as envisioned in the deliverable 3.1 (D3.1) of WP3, the overall KPIs of HealthData@PT action were outlined (step 1). In fact, even though the GA included a list of indicators related to the action-specific objectives (Figure 4), these indicators were not presented using a SMART methodology, which is necessary for efficient and clear-cut evaluation processes. Therefore, HealthData@PT overall KPIs were outlined, resulting in **a list of 13 KPIs (Table 2)**. Each KPI is provided along with a short description, and an indication of target values, WP holding the main responsibility for fulfilment and specific sources of verification.

KPIs 1-8 pertain to O.1. KPI #1 was outlined based on the indicator 1 present in the GA, which covers i) the operational DAAMs, ii) the national health dataset catalogue (nHDsC) publicly available, and iii) the plan outlined for implementing the future PT SPE. As these points result from WPs 5, 6 and 7, respectively, these 3 WPs were mapped as responsible for the fulfilment of this KPI (Table 2). The outlined KPI #2 also refers to the indicator 1 of the GA, and refers to the establishment of the HDAB governance framework. This KPI was defined, as it is an indicator set in GA for the HealthData@PT action. However, it should be highlighted that this KPI is not directly related with the development of the DBCs, and therefore does not fall into the purview of the D3.1 KPIs monitoring framework. Therefore, this KPI will not relate with the WP-specific KPIs that will be addressed in the section 2.3.2. of this document.

The KPI #3 was outlined combining the indicators 2 and 3 set in the GA, which refer to an operational DAAMs capable to receive, manage, evaluate and answer to data requests in less than 2 months for non-complex requests. Likewise, KPI #4,5 and 6 refer to the indicators 4, 5 and 6 set in the GA, which refer to a publicly available national health datasets catalogue (nHDsC), with datasets description in a common format, and composed by different datasets. The indicator 7 of the GA was described by 2 KPIs, KPIs #7 and 8, which refer to the groundwork necessary to set the national SPE, namely the definition of the specifications and requirements (KPI #7) and the drafting of an implementation plan (KPI #8).

Regarding O.2., 3 KPIs were outlined. KPI #9 refers to the indicator 8 of the GA, pertaining to defining the specifications and requirements for the future setup of the gateway to connect with the HealthData@EU infrastructure. The indicator 9 was divided into KPIs #10 and #11, which refer to the implementation plan and to the deployment of the operational version, respectively, of the minimum viable product (MVP) to connect the national infrastructure (HDAB) with the HealthData@EU.

Finally, for the O.3., the indicators 10 and 11 of the GA were contemplated in the KPIs #12 and #13. These refer to making available guidelines and recommendations to support data holders improving the quality of dataset descriptors (metadata) and raw data (data) and on developing datasets according to EHDS future regulation recommendations.

Table 2 fully describes the 13 HealthData@PT overall KPIs, offering a clear roadmap for evaluating the progress of the DBCs development, as intended by D3.1. However, to track the project's development over time and ascertain whether these KPIs are being met, a more thorough methodology is needed. As a result, the objectives of each WP were carefully examined to decompose each KPI into more manageable, time-bound variables that could be tracked, as will be explained in the next section.

Table 2. HealthData@PT overall KPIs per specific action objective.

Action specific objective	KPI #	Associated KPIs	Targets	Main WP responsible	Verification source
O.1. National services and infrastructures for the national HDAB	1	One HDAB established, with >2 DBCs deployed (DAAMs, nHDsC, MVP), one governance model defined, and with an outlined plan for implementing an SPE.	1 (M48)	WP 5 - 7	D5.3, D6.3, D7.1, D7.2, D8.3
	2	A governance framework is defined according to the EHDS regulation proposal and national legislation.	1 (M36)	WP1	D1.5
	3	One DAAMs that is capable to receive, manage, evaluate and answer to data requests in less than 2 months for non-complex requests.	1 (M48)	WP5	D5.3
	4	One nHDsC is publicly available.	1 (M48)	WP6	D6.3
	5	Datasets are published in the public nHDsC.	25 (M48)	WP6	D6.3
	6	The public nHDsC containing a description of the contents – metadata records - in a common format and according to the EU established standard, health DCAT-AP.	1 (M48)	WP6	D6.3
	7	One report outlining the specifications and requirements defined for the future setup of an SPE.	1 (M48)	WP7	D7.1
	8	One implementation plan for the future setup of the national SPE.	1 (M48)	WP7	D7.2
O.2. Cross-border services and infrastructures	9	One list of specifications and requirements for the future setup of the gateway to connect with the HealthData@EU infrastructure.	1 (M46)	WP8	D8.1
	10	A plan for implementing the MVP to connect the national infrastructure with the HealthData@EU.	1 (M48)	WP8	D8.2
	11	An MVP prepared for the cross-border gateway, to connect the national HDAB with the HealthData@EU infrastructure.	1 (M48)	WP8	D8.3
O.3. Enhancing data quality	12	A report providing guidelines and recommendations to be made available to support data holders in improving the quality of dataset descriptors (metadata) and raw data (data).	1 (M48)	WP9	D9.1
	13	Datasets developed according to EHDS future regulation recommendations.	1 (M48)	WP9	D6.3

2.3.2. HealthData@PT WPs´ objectives, KPIs and verification sources

To break down the action overall KPIs into smaller variables that are adequate for continuous monitoring, and whose accomplishment is explicitly allocated to WP-responsible units, the WP-specific objectives of HealthData@PT technical WPs were defined (step 2).

Table 3. WP-specific objectives for the technical WPs (WPs 5-9).

	WP-associated specific objectives
WP 5	O5.1. DAAMs: Analysis and design
	O5.2. DAAMs: Implementation and piloting study
	O5.3. DAAMs: Deployment of operation ready solution
WP 6	O6.1. Analysis and design of the nHDsC
	O6.2. Implementation and piloting of the nHDsC
	O6.3. Maintaining and updating the nHDsC
WP 7	O7.1. Design of an SPE
	O7.2. Production of an SPE implementation plan
	O7.3. SPE Market Assessment
WP 8	O8.1. Analysis and design of the cross-border gateway
	O8.2. Cross-border gateway implementation plan
	O8.3. Implementation and piloting of the cross-border gateway
	O8.4. Development continuity of the cross-border gateway
WP 9	O9.1. Production of health data quality guidelines

Then, a set of KPIs was devised for each WP-specific objective, considering the tasks' descriptions as well as the anticipated deliverables and milestones described in the GA. These aim to feature an appropriate evaluation strategy for monitoring the project progress. These indicators in general comprise i) the reports of the deliverables envisioned in the work plan, ii) the drafts of preliminary versions of the reports (e.g. milestone 11), iii) reports on particular aspects, to be included as chapters in some of the project´s reports (e.g.in O6.3), iv) links to the operational DBCs (e.g. link for the operational DAAMs platform website is an indicator of O5.3). Each indicator was provided along with a concise statement outlining indicator´s main objective and impact (Figure 6). A target value and a source of verification was defined for every indicator. This last consists mainly in links to reports/reports´ chapters or operational DBCs. Each target value was provided along with a month of completion, to provide the time-bound parameter of SMART KPIs. The reporting period for each indicator is also indicated. As some of the deliverables imply a 3 to 4-years work, it was defined to perform continuous progress checks on interim versions, as it will be further detailed in section 2.4. Thus, this rational resulted in a WP-specific KPI evaluation framework for each work package, with the overall structure as presented in Figure 6 for WP9. Whenever there are relationships or dependencies between indicators, these are also indicated.

KPIs monitoring framework for the WP9 of HealthData@PT

WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
O9.1. Production of health data quality guidelines	T9.1. leader (UIA)	One report on the evaluations and assessments of the data quality performed	One report describing the major findings from conducting data quality assessment and evaluation. This will provide guidance for data holders' recommendations on improving data quality.	1 (M48)	A chapter outlining the gathered insights and conclusions to be part of Project deliverable D9.1 (Health Data quality Enhancements requirements) Report	Report Status, including the link to the D9.1. report	M1-M12 M13-M24 M25-M36 M37-M46	
		Elaborate a report with guidelines and recommendations to support data holders in enhancing data quality.	Produce guidelines and recommendations to be made available to support data holders in improving the quality of dataset descriptors (metadata) and raw data (data).	1 (M48)	Project deliverable D9.1 (Health Data quality Enhancements requirements) Report	Report Status, including the link to the D9.1. report	M1-M12 M13-M24 M25-M36 M37-M46	

Examples of indicators for O9.1	How much of each indicator? And when?	How to verify conclusion?	Periods for verification

Figure 6. Example of the overall structure of the monitoring framework outlined for HealthData@PT WP-specific KPIs.

The complete HealthData@PT KPIs monitoring framework for WPs 5, 6, 7, 8 and 9 can be consulted in Annexes I-V of this document. This framework will be a crucial tool to guide evaluation activities throughout HealthData@PT lifecycle, as it will be further discussed in the sub-section 2.4, along with operationalization details.

2.4. HealthData@PT KPIs monitoring framework: roles and responsibilities, operationalization of evaluation activities, and timeline

HealhData@PT is coordinated by Dr. Cátia Pinto, which leads the NSDGRI team at SPMS. The NSDGRI team is responsible for the WPs 1-4, and for overseeing the progress of all WPs (Figure 7). Considering HealthData@PT governance structure and the roles and responsibilities attributed internally, it is the NSDGRI team responsibility to perform evaluation activities entailed in WP3, including i) the elaboration of the KPIs monitoring framework herein presented for the WPs related with the development of the DBCs, ii) continuous assessment of the activities to implement the DBCs and iii) preparation and submission of the overall project evaluation report.
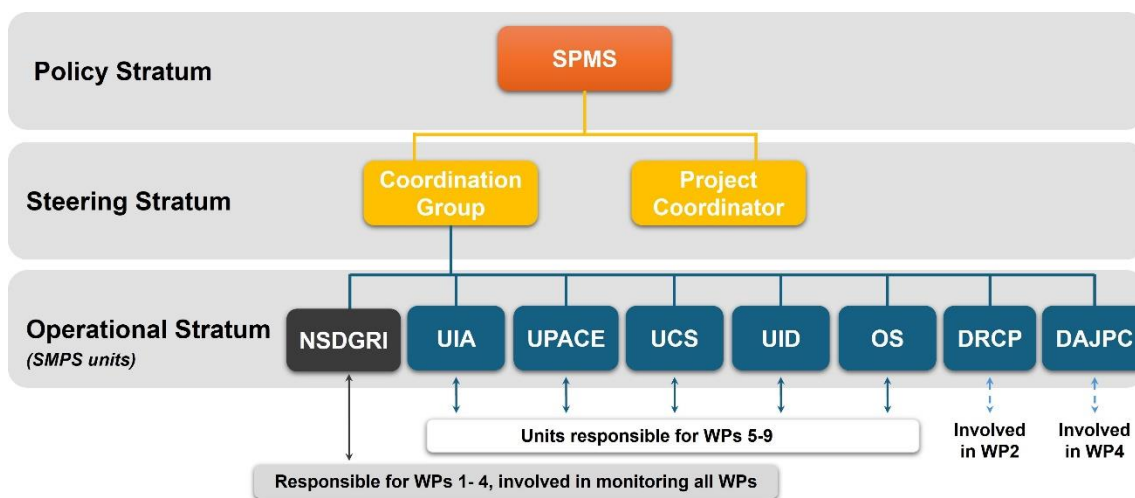
Figure 7. HealthData@PT governance structure.

The NSDGRI team will implement the KPIs monitoring framework outlined in this document throughout HealthData@PT action, working closely with the SPMS units in charge of WPs 5-9 toward KPIs monitoring.

Project managers from the SPMS units in charge of each WP and project managers from NSGRI will meet on a regular basis in focused groups to gather brief updates on the status of the tasks as part of a continuous assessment of project´s progress. These meetings will guide risk management activities (performed in the scope of WP1), ensure continuous monitoring efforts, and will also serve for decision-making purposes. Similarly, coordination group meetings involving all units/staff members taking part in HealthData@PT WPs will be held.

Regarding the evaluation activities entailed in WP3, KPIs will be monitored WP by WP by the NSDGRI team, using the framework presented in this document (Annexes I-V).

Four reporting periods for evaluation activities were established (Figure 8):

- **Reporting period 1:** from month 1 to 12 (M1-M12, corresponding to November 2023 - October 2024)
- **Reporting period 2:** from month 13 to 24 (M13-M24, corresponding to November 2024 - October 2025)
- **Reporting period 3:** from month 25 to 36 (M25-M36, corresponding November 2025 - October 2026)
- **Reporting period 4:** from month 37 to 46 (M37-M46, corresponding November 2026 – August 2027)

At the end of each of these report periods, SPMS units will formally report on deliverables´ progress (**report status**). **Four timepoints for report status, towards evaluation activities, were established**: the first report status will occur in M13, the second in M25, the third in M37, and the final report status at the end of M46. The last

reporting period was set shorter in comparison with the previous ones, to guarantee the gathering of data and the timely completion of the final overall evaluation report, which is due in M47.

The report status will consist of the completion of data by SPMS teams regarding the status of the deliverables, milestones, and DBCs implementation progress in a standardized form that will be made accessible on a collaborative platform (Confluence™). In this form (HealthData@PT *KPIs log*), the units must provide the link to the verification source outlined for each indicator (Annexes I-V). The content of the interim and final versions of the reports/DBCs will be the basis of NSDGRI team evaluation activities, which will be supported by the set internal quality procedure (detailed in the project handbook, developed in WP1).

For example, in accordance with this scheme, a report whose development began in month 1 and whose completion is scheduled for month 46 will have four report statuses: in the first three, links to the report's interim version must be provided within the designated timepoint in the form (HealthData@PT *KPIs log*), for monitoring progress aims; in the fourth report status , a link to the report's final version must be provided.
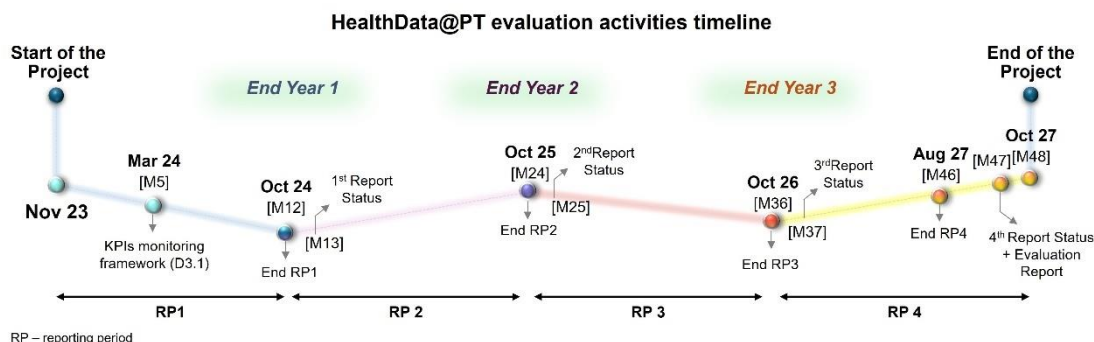

Figure 8. Timeline of HealthData@PT evaluation activities.

3. Concluding remarks

This deliverable entails the overarching KPIs monitoring framework that will be used during HealthData@PT lifecycle to monitor the progress of the WPs associated with the implementation of Portugues HDAB DBCs: WPs 5-9. Both the overall (Table 2) and the WP-specific KPIs (Annexes I-V) are provided, with the last serving to guarantee the level of specificity necessary to guide streamlined and well oriented evaluation operations. The KPIs established in the framework proposed in this deliverable cover the indicators specified in the grant agreement of HealthData@PT action, which were delineated in accordance with the action-level indicators of the EU4H-2022-DGA-MS-IBA-4 call and considering Portugal´s national context.

Details regarding the evaluation activities, the monitoring roles and responsibilities, the evaluation timeline, and the tools that will be used to carry monitoring activities were also outlined in this document.

This document, along with the internal quality procedure and risk management plan, these two comprised in the project handbook (WP1), provide the tools to efficiently track whether project objectives are being accomplished on time, enabling informed decision-making to enhance performance whenever needed.

It is important to refer that, despite this KPIs monitoring framework only pertains to WPs 5-9 monitoring, the final evaluation report will also focus on the accomplishment of the goals established for the horizontal WPs 1-4, to which monitoring framework is disclosed in project´s handbook.

References

[1] European Commission, "European Health Union: A European Health Data Space for people and science," 3 May 2022. [Online]. Available: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2711. [Accessed 12 March 2024].

[2] European Comission., "Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space," 3 May 2022. [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197. [Accessed 13 March 2024].

Annex I – WP5 KPIs monitoring framework

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period(s)	Connection / dependencies
A DAAMs capable to record and process data access requests, partially issue data permits, and reply to data access applications made by data users	O5.1. DAAMs: Analysis and design	T5.1. leader (UIA); participating unit: UID	Elaborate one preliminary version of the report concerning the DAAMs: requirements and specifications	Draft of the requirements and specifications necessary to set up the access application management system, as well as the rules for data request, processes and flows of data access management. This will feed D5.1.	1 (M33)	Project MS11 - Draft for the D5.1 (Data Access Applications management: requirements and specifications) Report	Link to the report versions	M1-M12 M13-M24 M25-M36	
			Elaborate one report concerning DAAMs requirements and specifications, to be publicly available	This report will describe the requirements and specifications necessary to the design of the DAAMs, and will define the rules for data request, processes, and order management flows. This will impact management system design and piloting (T5.2 and D5.2).	1 (M35)	Project deliverable D5.1 (Data Access Applications management: requirements and specifications) Report	Link to the final report	M25-M36	

Figure 9. Excerpt from WP5-specific evaluation plan: O5.1.

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period(s)	Connection / dependencies
	O5.2. DAAMs: Implementation and Piloting Study	T5.2. leader (UIA); participating unit: UID	Elaborate one report outlining the DAAMs technical design	Report describing the technical design of the DAAMs, the definition of the test rules, and the platform monitoring. This will outline the final refinements towards the operational platform (D5.3).	1 (M48)	Project deliverable D5.2.(Data access application management: design) Report	Link to the final report (D5.2)	M37-M46	WP5- T5.1

Figure 10. Excerpt from WP5-specific evaluation plan (cont.): O5.2.

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period(s)	Connection / dependencies
	O5.3.DAAMs: Deployment of operation ready solution	T5.3. leader (UIA); participating unit: UID	Deployment of a publicly available operational data access application management platform	Deployment of a publicly available operational DAAMs platform (website) capable to record and process data access requests, partially issue data permits, and reply to data access applications made by data users.	1 (M48)	Project deliverable D5.3. Data access application management: Operational Service	Link for the operational DAAMs platform (website)	M37-M46	WP5- T5.1 and T5.2
			Version of the software of the deployed operational data access application management platform	A link for the software version of the deployed operational DAAMs website (e.g. link for GitHub).	1 (M48)	A link to be included as part of the D5.3. Data access application management: Operational Service	Link to the final report (D5.3)	M37-M46	WP5- T5.1 and T5.2
			A software manual of the deployed operational data access application management platform	A software manual pertaining to the deployed operational DAAMs website.	1 (M48)	A software manual to be included as part of the D5.3. Data access application management: Operational Service	Link to the final report (D5.3)	M37-M46	WP5- T5.1 and T5.2

Figure 11. Excerpt from WP5-specific evaluation plan (cont.): O5.3.

Annex II – WP6 KPIs monitoring framework

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
A publicly available catalogue composed by different datasets, including tools and descriptions (metadata records using HealthDCAT-AP) to facilitate their discovery and use for secondary use	O6.1. Analysis and design of the National Health Dataset Catalogue (nHDsC)	T6.1. leader (UIA); participating unit: UID	Elaborate one report describing the requirements and specifications outlined for the National dataset catalogue	This report will describe the analysis performed, and the defined requirements and specifications for the nHDsC. This report should include an evaluation of metadata needs, the definition of dataset, their sources (data holders) and the respective variables, the use of structured data, international standards and a harmonized technical sheet. This will be crucial for the design (D6.2) and implementation (T6.2) of the nHDsC.	1 (M48)	Project deliverable D6.1 (National dataset catalogue requirements and specifications) Report	Link to the report versions	M1-M12 M13-M24 M25-M36 M37-M46	WP6 - T6.2
			Elaborate one report describing the technical design of the National dataset catalogue	This report will describe the design of the nHDsC, taking into account the requirements and specifications set in D6.1. This will be crucial for the implementation (T6.2) and piloting of the nHDsC, as these two activities may influence the technical design in an iterative way.	1 (M48)	Project deliverable D6.2 (National Dataset catalogue design) Report	Link to the report versions	M13-M24 M25-M36 M37-M46	WP6 - T6.2

Figure 12. Excerpt from WP6-specific evaluation plan: O6.1.

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
	O6.2. Implementation and piloting of the nHDsC	T6.2. leader (UIA); participating unit: UID	Elaborate one report describing the implementation status of the nHDsC	This report will describe the implementation progress of the nHDsC (the status of building the software, integrating the different components, and if the performance is aligned with the set requirements). This will be crucial to fine-tune the technical design of the nHDsC (T6.1) and for the piloting stage (D6.3).	1 (M37)	A chapter (MS12) to be included in the Project deliverable D1.3 (Periodic Technical-Financial Report: RP2)	Link to the versions of the D1.3 report	M25-M36 M37-M46	WP6 - T6.1
			Elaborate one report describing the pilot phase of nHDsC	The overall results of the pilot phase and the actions conducted (testing environment, nHDsC iterative improvement throughout piloting, overall performance of stable version, etc.) will be covered in this report.	1 (M48)	Project deliverable D6.3 (National Dataset catalogue implementation) Report	Link to the D6.3 report versions	M25-M36 M37-M46	WP6 - T6.1
	O6.3. Mantaining and updating the nHDsC	T6.3. leader (UIA); participating unit: UID	Elaborate one report concerning the requirement to maintain and update the nHDsC	Definition of the requirements (automation procedures, maintenance rules) needed to maintain and update the datasets on the platform.	1 (M48)	A chapter to be included into project deliverable D6.3 (National Dataset catalogue implementation) Report	Link to the D6.3 final report	M37-M46	WP6 - T6.2

Figure 13. Excerpt from WP6-specific evaluation plan (cont.): O6.2 and O6.3.

Annex III – WP7 KPIs monitoring framework

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
Requirements and specifications for an SPE infrastructure to provide a secure, privacy-preserving processing environment as a service to data users	O7.1. Design of a SPE	T7.1. leader: OS; co-responsible units: UPACE and UCS; participating units: UID and UIA	Elaborate one report concerning the activities performed on analysis and SPE design.	One preliminary version of the report concerning the analysis and design activities undertaken to define SPE requirements and specifications. The outputs from these analysis and design activities will feed the definition of the SPE requirements and specifications (D7.1).	1 (M33)	Project milestone MS13: preliminary version of the Project deliverable D7.1 (SPE: Requirements and Specifications) Report	Link to the report versions	M13-M24 M25-M36	
			Elaborate one report concerning the SPE requirements and specifications	One report on the requirements and specifications for the national SPE, resulting from analysis and design activities (MS13). These will consider recommendations from EHDS2-related initiatives (e.g. TEHDAS, TEHDAS 2, EHDS2 pilot), as well as EHDS regulation and future recommendations within this scope. This will be crucial for setting up a SPE implementation plan (D7.2).	1 (M35)	Project deliverable D7.1 (SPE: Requirements and Specifications) Report	Link to the final D7.1. report	M25-M36	

Figure 14. Excerpt from WP7-specific evaluation plan: O7.1.

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
	O7.2. Production of an SPE implementation plan	T7.2. leader: OS; co-responsible units: UPACE and UCS; participating units: UID and UIA	Elaborate one report concerning the SPE implementation plan	One report describing the outputs from validating the functional and technical requirements produced in task 7.1, and outlining the implementation plan for a national SPE aligned with EHDS2 requirements. This will impact further possible developments along T7.3.	1 (M48)	Project deliverable D7.2 (SPE: Implementation plan) Report	Link to the D7.2. report versions	M25-M36 M37-M46	WP 7- T7.1
	O7.3. SPE Market Assessment	T7.3. leader: OS; co-responsible units: UPACE and UCS; participating units: UID and UIA	Elaborate one report on resources, opportunities and activities that can promote SPE further progress.	One report compiling the insights gathered from continuously assessing the new resources and opportunities (e.g. open-source software made available, formal EC requirements for SPEs, co-creation of solutions with other MS and the EC, and other funding sources) that may appear during HealthData@PT timeline and that may lead to SPE progress/construction beyond the projections.	1 (M48)	A chapter outlining the gathered outputs to be part of project deliverable D7.2 (SPE: Implementation plan) Report	Link to the report versions (D7.2)	M1-M12 M13-M24 M25-M36 M37-M46	WP 7- T7.1 and T7.2

Figure 15. Excerpt from WP7-specific evaluation plan (cont.): O7.2 and O7.3.

Annex IV – WP8 KPIs monitoring framework

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
Requirements and specifications for a digital gateway able to connect with other authorised participants and with the core services of the EHDS infrastructure for secondary uses of health data (HealthData@EU)	O8.1. Analysis and design of the cross-border gateway	T8.1. leader (UPACE)	Elaborate one report on the specifications and requirements for the cross-border gateway	One report concerning the activities of analysing requirements, specifications and specific solutions and the subsequent design of the minimum viable product to successfully connect with HealthData@EU. The activities performed under this scope will consider the EHDS2 pilot outcomes. This report will be crucial for designing the implementation plan (T8.2).	1 (M46)	Project deliverable D8.1 (Report on the specifications and requirements for the cross-border gateway)	Link to the D8.1. report versions	M1-M12 M13-M24 M25-M36 M37-M46	

Figure 16. Excerpt from WP8-specific evaluation plan: O8.1.

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
	O8.2. Cross-border gateway implementation plan	T8.2. leader (UPACE)	An outlined plan for the cross-border gateway implementation	One report on the validation of the functional and technical specifications produced in T8.1, and outlining an implementation plan for the cross-border gateway. This will be crucial for the implementation and piloting stages (T8.3).	1 (M24)	Project deliverable D8.2 (Cross-border gateway: Implementation plan) Report	Link to the D8.2. report versions	M1-M12 M13-M24	WP 8- T8.1

Figure 17. Excerpt from WP8-specific evaluation plan (cont.): O8.2.

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
	O8.3. Implementation and piloting of the cross-border gateway	T8.3. leader (UPACE)	A minimum viable product for the cross-border gateway deployed	A report (MS14), to be included as a chapter of D8.3 describing the features of the early version of the minimum viable product for the cross-border gateway, that will be tested by early users (pilot) to provide feedback for future refining and improving the development of the cross-border gateway (T8.4).	1 (M48)	Project milestone MS14, which is part (one chapter) of the content of project deliverable D8.3	Link to the D8.3. report versions, and/or to this chapter particularly	M13-M24 M25-M36 M37-M46	WP 8- T8.1 and T8.2
			Elaborate one report on the implementation and piloting of the cross-border gateway minimum viable product	Report documenting the implementation of the cross-border gateway minimum viable product and the outcomes from its connection to HealthData@EU under a controlled environment and for specific use cases (piloting). This will be crucial for fine-tuning the technical development, to further advance the cross-border gateway in the future (T8.4).	1 (M48)	Project deliverable D8.3 (Cross-border gateway: implementation and pilot) Report	Link to the D8.3. report versions	M13-M24 M25-M36 M37-M46	WP 8- T8.1 and T8.2

Figure 18. Excerpt from WP8-specific evaluation plan (cont.): O8.3.

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
	O8.4. Development continuity of the cross-border gateway	T8.4. leader (UPACE)	Elaborate one report on resources, opportunities and activities that can promote the further progress of the cross-border gateway minimum viable product.	One report compiling the insights gathered from continuously assessing new resources and opportunities (e.g. formal EC requirements for cross-border gateways, co-creation solutions with other MS and the EC) that may appear during HealthData@PT timeline and that may lead to a cross-border gateway progress beyond the initially projected.	1 (M48)	A chapter outlining the gathered insights to be part of Project deliverable D8.3 (Cross-border gateway: implementation and pilot) Report	Link to the D8.3. report versions, and/or to this particular chapter	M1-M12 M13-M24 M25-M36 M37-M46	WP 8- T8.1, T8.2 and T8.3

Figure 19. Excerpt from WP8-specific evaluation plan (cont.): O8.4.

Annex V – WP9 KPIs monitoring framework

HData@PT Specific Objectives	WP specific objectives	Task/ Responsibility	Indicators	Indicator description	Target value	Source of verification	Method for evaluation monitoring in WP3	Reporting Period	Connection / dependencies
Initiatives to enhance the quality of electronic health data made available through the HealthData @PT	O9.1. Production of health data quality guidelines	T9.1. leader (UIA)	One report on the evaluations and assessments of the data quality performed	One report describing the major findings from conducting data quality assessment and evaluation. This will provide guidance for data holders' recommendations on improving data quality.	1 (M48)	A chapter outlining the gathered insights and conclusions to be part of project deliverable D9.1 (Health Data quality Enhancements requirements) Report	Link to the D9.1. report versions	M1-M12 M13-M24 M25-M36 M37-M46	
			Elaborate a report with guidelines and recommendations to support data holders in enhancing data quality	Produce guidelines and recommendations to be made available to support data holders in improving the quality of dataset descriptors (metadata) and raw data (data).	1 (M48)	Project deliverable D9.1 (Health Data quality Enhancements requirements) Report	Link to the D9.1. report versions	M1-M12 M13-M24 M25-M36 M37-M46	

Figure 20. Excerpt from WP9-specific evaluation plan: O9.1.

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