



D1.1 – (D1.1.1) XpanDH project Handbook

WP1 – Coordination

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Authors:

Name	Organisation	Name	Organisation
Anderson Carmo	ISCTE		
Henrique Martins	ISCTE		

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What did this document aim to achieve?	The aim of this document is to present to the consortium partners the basic concepts and rules that will be implemented on the project.	
Present the main methodological approaches in bullet point format		
What were the main findings or take-away messages? What implications does it have for the XpanDH project?		
Which project stakeholder group would benefit the most from the document and why?	Healthcare Professional	
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List of abbreviations

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Executive summary

The project XpanDH aims at mobilizing and building capacity in individuals and organisations to create, adapt and explore purposeful use of interoperable digital health solutions based on the shared adoption of the European Electronic Health Records Exchange format (EEHRxF) across Europe.

The Project handbook has the main goal of define the project concepts that will be developed along of the 24 months of the project and present the project infrastructure and the best practices that should be followed by all partners.

This document includes descriptions about the project boards, coordination, quality management, amendments, meetings, voting process, communication, production of deliverables, reporting, and the main concepts developed in XpanDH in order to guide the project members to achieve the high-quality outcomes proposed.

The project handbook should also be consulted with the deliverable 'D1.3 – (D1.2)–QRC plan' to guide the members on the development of their activities towards the expected high-quality level proposed by XpanDH.

1 Introduction

1.1 Background

The project XpanDH aims at mobilizing and building capacity in individuals and organisations to create, adapt and explore purposeful use of interoperable digital health solutions based on a shared adoption of the European Electronic Health Records Exchange format (EEHRxF) across Europe.

To achieve this main goal, the project is considering the outputs and outcomes of past projects, such as X-eHealth, to develop the specifications to be used on the adoption domains, and further feasibility evaluation, implementation and testing among the project partners and stakeholders.

1.2 Scope and objectives

This document intends to bring to the project the basis of concepts and standards to be used as a guidance by the partners develop their activities.

The goal of the Project handbook is to define the project concepts that will be developed during the 24 months of the project and present the project infrastructure and the best practices that should be followed by all partners.

The XpanDH Handbook aims to ensure the standardisation of the routine procedures to guarantee a smooth project development, through a strong communication between the coordination and WP leaders, as well with the project managers that should allow the development of the project vision.

2 Governance Framework

This chapter presents the general governance framework of XpanDH, including the description of the main actors on the project and their respective role on the development of the action.

On the Figure 1 is possible to see the overall XpanDH governance structure.

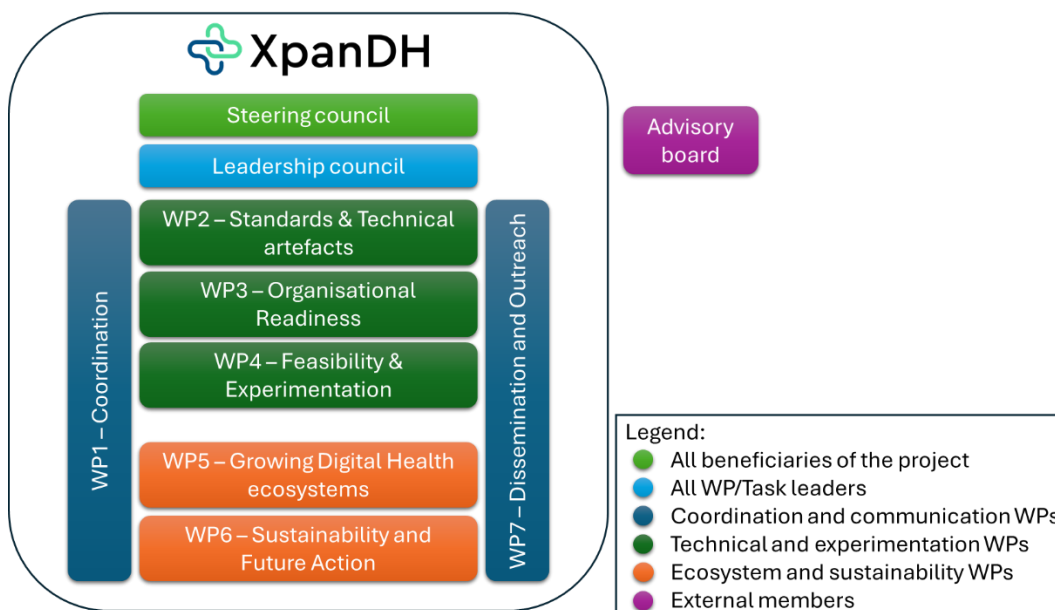


Figure 1 – XpanDH governance structure

2.1 Coordination

The coordinator is responsible to coordinate, organise and control all the project development. The coordinator shall ensure the management and communication approaches that guarantee the efficient and smooth development of the project in line with all project members (beneficiaries, associated and stakeholders).

The coordination team is composed of the project coordinator, project managers and financial controller that develop their work within the WP1 but ensure the strict cooperation with the WP7 for dissemination and communication and the other WPs regarding the project development.

The responsibility to monitor and guide the project activities, technical and financial reports, quality management and progress lies with WP1 and the project coordinator.

2.2 Leaders (Work Package & Tasks)

During the proposal phase, the attribution of the Work Package Leader and Task Leader was agreed between the partners of the project during the preparation of the Description of Action (DoA). Each Work Package (WP) has one leader and co-leader, and each Task has a Leader.

The leaders are responsible for the WP coordination including the tasks. The responsibility of the task's development lies also with the Task leaders. They shall monitor the work progress of the WP/Task activities, being the bridge between the coordination and the WP/Task partners. The Leaders shall support on the project decisions, organisation of events and the dissemination activities.

2.3 Leadership council

The leadership council (see Figure 1) is constituted by the coordinator, project manager and the WP leaders and co-leaders of XpanDH. It is responsible for the coordination, ensuring the project alignment and monitoring of the project execution and development. It can also rely on the Steering Council and Advisory Board for recommendations regarding project decisions.

The Leadership council is the highest council on XpanDH and responsible for the decisions that don't require the Steering Council. Complex decisions that are out of the scope of this group should be prepared by the Leadership Council and proposed to be deliberated by the Steering Council.

The project coordinator is the chair of this group that also present the WP leaders and co-leaders. The Leadership council shall meet monthly at online meetings and in person during the other project meetings or events

The decision procedure is a simple voting with the majority, to achieve a consensus of the decision. For that, each WP and Task leader has one vote only.

2.4 Steering Council

This is the group designed to be highest decision-making group on the XpanDH (see Figure 1). It is constituted by all partners of the project, in order to take decisions on the project on the strategic level.

This group is composed of the coordinator (that is also the chair of the group) and one representative for each partner. It is responsible for monitoring all project issues and activities and decision-making processes, in other words, all decisions that significantly affect the project shall be made in this group. Such as: amendments to GA, resources reallocation, financial or administrative decisions and etc.

The Steering Board shall meet every 3 months, at online meetings, and occasionally face to face (in the beginning and end of the project). However, if there is any situation that requires a voting process an extraordinary meeting can be setup, see Decision Taking Process for more details. Each partner has the right of 1 vote per decision, and follow the simple voting procedure, with the majoritarian votes of two-thirds of the partners and more than 50% of votes rights attendance. For example, if a vote process end with the same number of votes (12 vs 12), this voting process needs to be repeated.

2.5 Advisory board

The Advisory board (AB) (see Figure 1) is an external structured and collaborative group that was created to support the leadership board with subjects related to the

technical/scientific expertise regarding the domains discussed on the project, such as adoption domains, interoperability, networks, planning and testing scenarios.

This group is composed of expert representatives from international agencies and organisations that compose the body constituted by strategic advisors with deep experience on the domains referred above and has interest and experience on the EEHRx. The role of this group within XpanDH is to support, with high-quality advice to the coordination/direction of the project, provide, when required, operational guidance and follow up the project development and effectiveness of their actions towards the proposed goals.

The advisory board will have a subgroup of advisors who also will be called occasionally to provide ethical advice and will be chosen according to that capacity and the adoption domains to be determined in the early stages of the project. If an overall appreciation of ethical and data processing issues may be required, it will be dealt with on a case-by-case analysis, involving the ethical subgroup of the advisory board, WP1 and eventually DPOs from participating institutions.

The advisory board group should meet at least once a year in online meetings. This group has no voting rights on the project decisions.

The selection of the advisory board will involve between 11 and 13 organisations and individuals to be invited (e.g., Ministry of Health, Universities, MEDCON, ESMO, etc.). This AB will include a subgroup of advisors who will also be called to provide ethical advice and will be chosen according to that capacity and the adoption domains to be finally defined in the early stages of the project.

3 Quality management

All the knowledge generated on the project will be documented through the deliverables. For that purpose, XpanDH has a process to revise and ensure the high quality of the deliverables produced by all the WPs.

The quality manager is responsible for ensuring that the deliverable production process is made by a defined approach, in order to follow the required standards to be apt to handover to the European Commission. However, the responsibility of technical/scientific quality of the deliverables lies with the WP/Task leaders of the project.

Below is described the revision and submission of the deliverables:

1. Before the quality assurance of the deliverable, the WP/Task leader shall circulate the deliverable for comments with the task members and key internal project revisors.

2. At least 3 weeks before the deadline for the submission of the deliverable, the WP/Task leader will send the deliverable to the coordination to proceed the quality assurance of the deliverable
3. The deliverable will be evaluated regarding the structure, style, and content before being sent to the European Commission
4. If there is any issue with the deliverable, it will be sent back to the WP/Task leader for improvements before the submission.
5. The deliverable revised can be submitted to the EC portal and inform the Project Officer by email.
6. The project coordinator is responsible to proceed the final revision on the document and upload it on the EC portal. Aligned with this action, the project coordinator will send the deliverable by email to the Project Officer.

If any delay on the production of the deliverables is identified, the WP/Task leaders shall communicate it with the coordination in order to mitigate any possible issue regarding this delay.

4 Risk Management

All projects present risks that shall be identified and monitored to avoid it from arising, in any case the risks must be mitigated. During the proposal phase, a series of risks were identified for the project that were to be monitored during all its execution. In addition, new risks could be identified and monitored during the project. The risk management is based on a stepwise approach that supports risk identification and mitigation. Below we outline this 3-stages risks management approach:

1. Identify all the potential risks

- The WP leaders shall analyse their work, based on the objectives and responsibilities. This simple exercise makes clear all the roles of the project and can facilitate the identification of the risks.
- The identified risks must be deeply analysed in order to identify their potential causes, the probability to happen and the impact on the project (low, medium, high).

2. Elaborate the mitigation plan

- Based on the initial analysis, the assess risk initiate to evaluate their degree, connection with other potential risks, and the prioritisation, in case that multiple risks emerge at the same time.
- With all details related to an identified risk, the plan starts by the consideration of all details related to the risk. The plan is structured in order to avoid the risk from arising and also provide strategies to mitigate it as well as prioritisation criteria.

3. Project control (outputs/outcomes) and project development

- The strategy of risk mitigation is implemented through a series of procedures that will ensure their correct management.
- The risks are constantly monitored in XpanDH, with registration of any occurrence and procedures of mitigation, if there is a need.

The risk manager shall have close contact with all project boards in order to monitor the risks and apply mitigation strategies as soon a risk arises. It is their role to identify, categorise them and provide mitigation actions, for more details, please consult XpanDH D1.3 – (D1.2)–QRC plan.

5 Project Amendments

An amendment is a legal act that intends to modify the Grant Agreement (GA) with the objective to propose the change some commitments previously stated on this document, resulting in the creation of new rights and responsibilities of the parties. It is allowed to modify the GA within the project lifetime.

Any modification on the content of the Description of the Action (DoA) or on the administrative data of the XpanDH shall be accepted by EC on an amendment process. The amendments must be prepared by the coordinator of the project by writing procedure. The coordinator will contact the Project Officer on behalf of the consortium to formalise the submission of the document.

The project shall pay attention on the small modifications that can be done without an amendment, accordingly the GA description.

6 Decision Taking Process

For decisions that are considered crucial to the project, a voting process will take place during a Steering council meeting. The responsibilities and roles of the consortium members about voting rules, quorum and veto rights are already defined in the project Consortium Agreement.

Each consortium member present on the meeting must have one vote. The minimum quorum valid is if $\frac{2}{3}$ (two-thirds) of the members are present/represented. If the quorum does not reach this number ($\frac{23}{35}$) after 30 mins of the starting meeting, the quorum is considered to exist with at least, 50% of bodies. For example: in a meeting with the participation of 25 project entities, there is enough quorum for voting. However, in a meeting with 22 project participants there is no quorum and the decision need to be made in another meeting or by written procedure.

Decisions can be postponed, if there is a need, for an offline procedure that is based on the statement of a clear information and also providing 2–5 workdays to receive the responses.

All decisions shall be taken with a 2/3 majority, otherwise the consensus is not possible. It also must comply with the EC obligations.

If there is any aspect or process important to decision taking, it can be solved by a decision of the Steering Council under the indication of the coordinator.

6.1 Decisions by Written Procedure

Decisions that need to be done without a meeting should follow the process below:

Any decision may also be taken without a meeting if:

- a) the coordinator or project manager circulates to all Members of the Steering Council a suggested decision with a deadline for responses of at least 10 calendar days after receipt by a Party the written decision, if agree or not and
- b) the written decision is agreed by 51 % of all Parties (18/35).

The Coordinator shall inform all the Parties of the outcome of the vote.

A veto according to Section 6.2.4 of the Consortium Agreement may be submitted up to 15 calendar days after receipt of this information.

The decision will be binding after the Coordinator sends a notification to all Members. The Coordinator will keep records of the votes and make them available to the Parties on request.

6.2 Meetings

The consortium will meet with regularity to discuss the project activities and progress, as well exchange of relevant information and results.

The kick-off meeting of XpanDH project was organised in the first month of the project, via teleconference, with the presence of all members representatives.

The Leadership council meeting is scheduled monthly with the presence of all WP leaders and coordinator, where each WP is designated to summarise their achievements and ongoing work, being fundamental that difficulty and barriers be reported in order to find solutions and define the upcoming steps.

Biweekly meetings are also schedule between the coordinator and other WPs to ensure the flux of information and strengthen the flux of the interdependencies within the project.

Each WP leader will also schedule WP specific meetings in order to develop their work and ensure the continuity of the action.

It is the function of the meeting chair to announce all meetings and guarantee the proper information to all participants. Due to the nature of the European consortium, almost all meetings will be held online.

All meetings shall be registered by minutes (OneNote on Teams) or recorded (with general consent) for follow-up and monitoring purposes. It will ensure that the discussed information is shared with the non-present representatives.

6.2.1 Meeting Minutes

The XpanDH meetings information, as well the discussed points, further actions required, documents and the decisions taken shall be registered properly on the standardized minutes that shall be available for all the project members.

The project tool election for this purpose is the 'OneNote' hosted on the XpanDH Microsoft Teams tool. The Figure 2 shows the meeting minutes location on top functions of the Microsoft Teams XpanDH group, and it gives access to all minutes produced on the project accordingly the following division:

- General meetings

It hosts the full project meetings, such as the Leadership Council, Steering Council and consortium meetings.

- Cross WPs meetings

It hosts the meetings dedicated to the short discussions about the project's information flows and the WP interdependencies.

- WPs meetings

It hosts the specific WP meetings of the project. Where is discussed the development of the tasks and deliverables for each WP.

- Workshops

It hosts the Workshops meetings and their outcomes.

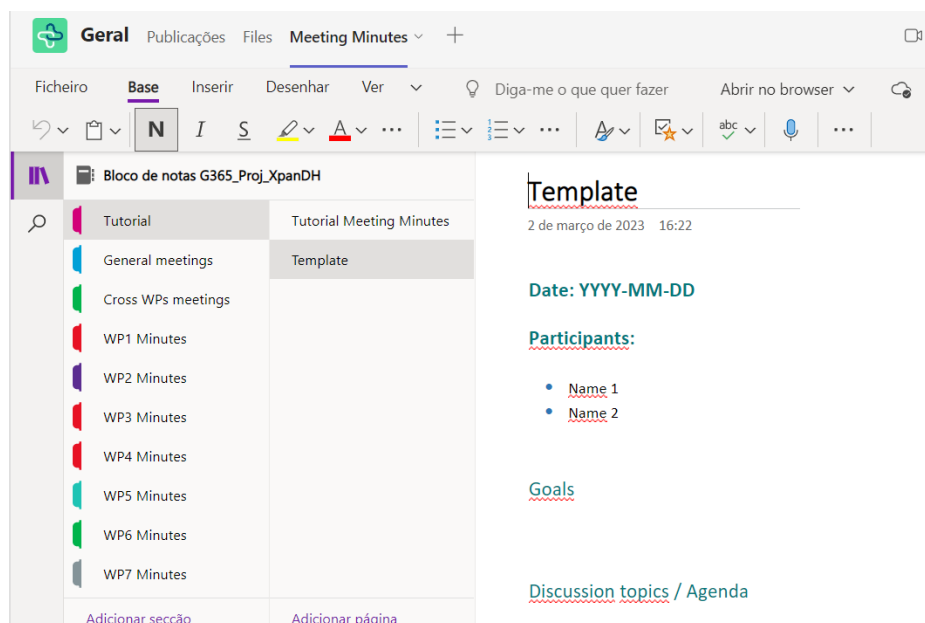


Figure 2 – General view of the XpanDH Meeting Minutes

The Minutes shall be generated accordingly the tutorial, by the copy and paste of the minutes template under 'Tutorial' indication. All the meetings shall be registered following a common name description on chronologic dates. The name description shall contain: date (YYYYMMDD) followed by '_' and the task/deliverable meeting subject:

Example: **'20230322_D1.4'** – 'meeting held on 22 March 2023 about the Deliverable 1.4'

Additional information can be included on the 'meeting subject' such as: 'del development, kick-off, etc.

Example: **'20230322_D1.4_Kick-off'** – 'meeting held on 22 March 2023 about the kick-off of the Deliverable 1.4'

Additional information shall be included on the minutes such as the link to the presentation, recording of the meeting, additional documentation (that shall be saved on the specific WP folder following the above nomenclature rules).

This process intends to ensure full access of the project meeting information for all the members and provide access to the material used on the meetings.

6.3 Communications

The XpanDH consortium will use, at least, 3 communications systems along of the project lifetime:

1. Email – is the formal communication system of the project, it will be used to share communications, documents, and all-important information required among the partners.
2. Microsoft Teams – is the document repository of the project, where specific folders for all WPs and transversal themes can be found. Quick information can also be exchanged on it by chat. It is also the main teleconference tool of the project.
3. Website – it plays an important role on the main dissemination of the project, as well aligned with the social media (Twitter, LinkedIn). All reports and documents produced on the project, (non-confidential) will be hosted on the website (after EC approval).

7 Project structure

The XpanDH project has a duration of 24 months and had its official start date on 01/01/2023, with the end foreseen for the 31/12/2024.

XpanDH counts 24 beneficiaries and 10 associated partners distributed among 12 countries and has an overall budget of 1 972 311.25 €, 100% financed by HaDEA.

The detailed budget can be seen on the grant agreement.

Below, you can find some information regarding the project structure and deliverables elaboration.

7.1 Work Packages and Tasks

The project XpanDH has 7 Work Packages (WPs) designed to coordinate and orient the flux of work. The Table 1 below presents the WPs and Tasks designed to support this action. The detailed description of the WPs and tasks are on the DoA and GA.

Table 1 –XpanDH WPs & Ts

WP/T	LEADER	TOTAL EFFORT	START MONTH	END MONTH
WP1 – COORDINATION	ISCTE	36.10	1	24
TASK 1.1 – ADMINISTRATIVE AND OPERATIONAL MANAGEMENT	ISCTE		1	24
TASK 1.2 – QUALITY ASSURANCE, RISK MANAGEMENT AND CONTINGENCY	ISCTE		1	24
TASK 1.3 – PROJECT EVALUATION AND IMPACT ASSESSMENT	ISCTE		1	24
TASK 1.4 – DEFINITION OF EEHRXF ADOPTION DOMAINS	ISCTE		1	4
TASK 1.5 – LEGAL, ETHICAL, CYBER SECURITY ISSUES	ISCTE		4	24

TASK 1.6 – POLICY DIALOGUE	NCZI		4	24
WP2 – STANDARDS & TECHNICAL ARTEFACTS	HL7	26.7	1	24
T2.1. X-BUNDLE TECHNICAL SPECS BASED ON HL7 FHIR REST API FOR EHRXF	HL7		1	24
T2.2. CREATION OF AN ONLY RESOURCE TO HARBOUR X-BUNDLE ASSETS, SUCCESS STORIES, AND ONLINE EEHRXF CO-CREATION AND SUPPORT COMMUNITIES	HL7		1	24
T2.3. TECHNICAL REQUIREMENTS FOR QUALITY LABELLING OF CONSUMER HEALTH PRODUCTS AND EHR SYSTEMS	CEN/TH		1	18
WP3 – ORGANISATIONAL READINESS	IHE-EUR	40.7	1	24
TASK 3.1: DEFINE THE X-BUNDLE READINESS MODEL	IHE-EUR		1	20
TASK 3.2: DEVELOP THE READINESS MODEL EVALUATION PROCESS FEEDBACK LOOP	OKFO		6	13
TASK 3.3: X-BUNDLE READINESS STEPPINGSTONE GUIDES AND CAPACITATION	CHUP		11	24
WP4 – FEASIBILITY & EXPERIMENTATION	UNINOVA	58.2	1	24
TASK 4.1 – PREPARING THE EXPERIMENTATION BUBBLES	UNINOVA		1	20
TASK 4.2 – EHRXF-BASED INFRASTRUCTURE	UNINOVA		6	21
TASK 4.3 – INTEGRATE LESSONS LEARNT FROM FEASIBILITY AND EXPERIMENTATION	EMP		18	24
WP5 – GROWING DIGITAL HEALTH ECOSYSTEMS	EMP	39.6	1	24
TASK 5.1 – EXPANDING THE NETWORKS AROUND XPANDH ADOPTION DOMAINS AND BEYOND	EMP		4	24
TASK 5.2 – SHARING DRIVERS AND BENEFITS OF INTEROPERABILITY	I~HD		1	24
TASK 5.3 – SETTING UP A COMMUNITY OF DOERS AND CO-CREATORS	GNOMON		3	24
WP6 – SUSTAINABILITY AND FUTURE ACTION	I~HD	17.3	1	24
TASK 6.1 – PROMOTING AND SUSTAINING THE XPANDH ASSET BUNDLES	I~HD		1	24
TASK 6.2 – EEHRXF NEW ADOPTION DOMAINS: CONSUMER USE CASES FOR REMOTE VISIT, TELEHEALTH, AND TELEMONTORING	ISCTE		6	24
TASK 6.3 RECOMMENDATIONS TO MEMBER STATES AND THE EUROPEAN COMMISSION	ISCTE		6	24
WP7 – DISSEMINATION AND OUTREACH	ECHA	16.3	1	24

TASK 7.1 – COMMUNICATION AND DISSEMINATION	ECHA	1	24
TASK 7.2 – OUTREACH AND STAKEHOLDER ENGAGEMENT	ECHA	1	24
TASK 7.3 – CONCERTATION ACTIVITIES	EMP	1	24

The WPs present a leader designated by their entity, (s)he is responsible for the management of the WP, including technical and financial aspects, and share the responsibilities with each task leader. Figure 3 presents the relationship of the WPs and tasks on XpanDH.

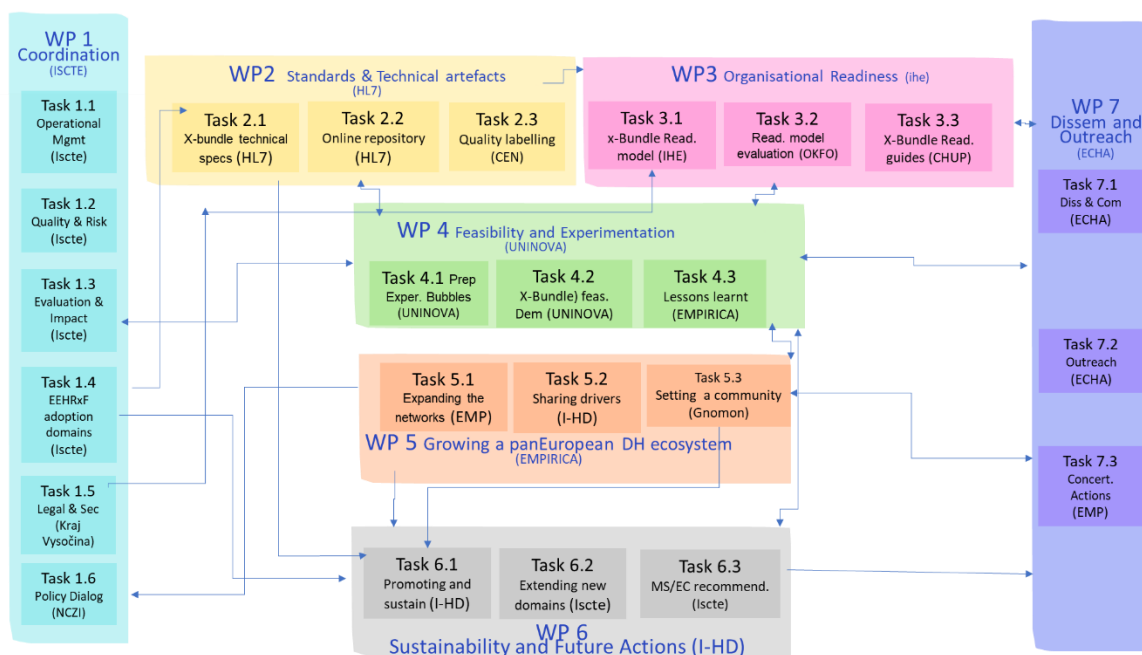


Figure 3 – XpanDH Impact / interrelationship structure

7.2 Deliverables

In order to provide high quality information produced on the project, the deliverables were designed to contain all the important and key information for the reader. On the Table 2 is possible to see all the deliverables and their respective responsible, as well the foreseen submission dates.

Table 2 –XpanDH Deliverables

del #	Deliverable name	WP	Lead	Delivery Month
D1.1	D1.1.1 – XpanDH project Handbook	1	Iscte	M4
D1.2	D1.1.2 – Technical and Financial Reports	1	Iscte	M12
D1.3	D1.2 – QRC Plan	1	Iscte	M4
D1.4	D1.3 – Evaluation and Impact Assessment	1	Iscte	M13

D1.5	D1.4 – Definition of the EEHRxF adoption domains Report	1	Iscte	M4
D1.6	D1.5.1 – Ethics and Data Management Plan	1	Iscte	M6
D1.7	D1.5.2 – EEHRxF legal, cybersecurity & trust issues Report	1	Iscte	M6
D1.9	D1.5.3– Updated Ethics and Data Management Plan	1	Iscte	M18
D1.8	D1.6 – Report on Policy Dialogue activities and achievements	1	NCZI	M23
D2.1	D2.1 – Digital health compass for the application of EHRxF	2	HL7	M9
D2.2	D2.2– EHRxF FHIR IG and repository of supporting materials	2	HL7	M12
D2.3	D2.3 – Report on for quality labelling of EHRs	2	CEN/TH	M10
D3.1	D3.1.1 – First version of the X-Bundle Readiness model	3	IHE-EUR	M9
D3.2	D3.1.2 – Final version of the X-Bundle Readiness model	3	IHE-EUR	M18
D3.3	D3.2.1 – Intermediate readiness model evaluation process 1.0	3	OKFO	M12
D3.4	D3.2.2 – Readiness model evaluation process Report	3	OKFO	M13
D3.5	D3.3 – X-Bundle Readiness steppingstone guides	3	CHUP	M12
D4.1	D4.1.1 – XpanDH Adoption Domains	4	UNINOVA	M6
D4.2	D4.1.2 – Adoption opportunities, challenges and barriers	4	UNINOVA	M21
D4.3	D4.2 – XpanDH feasibility demonstrators	4	UNINOVA	M12
D4.4	D4.3 – X-Bundle refinement report	4	EMP	M24
D5.1	D5.1 – XpanDH Ecosystem Report	5	EMP	M22
D5.2	D5.2 – Interoperability Enabler Report	5	I~HD	M18
D5.3	D5.3 – X-Bundle open source community of the doers	5	Gnomon	M24
D6.1	D6.1.1 – Governance & operating model for asset bundles & Exploitation Plan	6	I~HD	M18
D6.2	D6.1.2 – Published library of documented asset bundles	6	I~HD	M24
D6.3	D6.2 – Report on EEHRxF new adoption domains	6	Iscte	M24
D6.4	D6.3 – Recommendations for MS & EC	6	Iscte	M24
D7.1	D7.1 – XpanDH DC, Outreach and Exploitation Plan	7	ECHA	M6
D7.2	D7.2 – XpanDH DC and Outreach Report	7	ECHA	M12
D7.3	D7.3 – Concertation Activities Report	7	EMPIRICA	M12
D7.4	D7.4 – XpanDH website	8	ECHA	M6

7.2.1 Evaluation and submission of deliverables

The deliverables identified on the Grant Agreement and in Table 2 must be submitted within the indicated deadlines. All deliverables must be submitted to the EC by electronic means, through the Participant Portal.

The task leaders and the WP leaders are the responsible for the quality of the document (technical and format). A quality process will take place in order to ensure the quality of all deliverables. The process of deliverable revision is accordingly described in the chapter Quality management.

If there is any kind of delay on the production of the deliverable, it should be communicated to the project coordinator, in this case, the needed actions will be taken. The Project Officer will also be informed by email.

A mitigation procedure will be taken 6 weeks before the deliverable deadline. The project coordination will contact the WP/Task leader in this time in order to verify if the deliverable will be submitted according to the plan or, if there is any unexpected issue identified, that it may reach a substantial delay.

8 Reporting

Below the procedures and contents of each XpanDH report to the EC are explained.

8.1 EC periodic reports

The process of monitorisation of the implementation of the project is an ongoing task that takes place during the lifetime of the project, active period and afterwards. To ensure this monitoring process, there are some contractual tasks that are designated to this, such as the RP and the payments.

There are some kinds of reports to the EC, focusing on the technical and financial aspects of the project. The reports Periodic and Final are obligated by contract. In line with the GA, the obligated reports to the EC are described as following:

1. **Deliverables** – as described on the DoA and on this document.
2. **Periodic Reports** – it should be done within 60 days after the reporting period
 - a. Periodic financial report
 - b. Periodic technical report
3. **Final Report** – in complement to the periodic report and counts with a summary of all publications and financial certificates
 - a. Final financial report
 - b. Final technical report

4. **Payments Report** – it is designed to prove the transference of the budget to the partners

8.2 Content of the Periodic Reports

Below is described all the obligatory items for the periodic reports:

1. **Periodic Technical Report**
 - The presentation/explanation of the work developed
 - An overview of the project achievements, highlighting the milestones, deliverables, any deviations and dissemination actions
 - The summary of all publications
 - Present the issues on the project and also a socio-economic impact
2. **Periodic Financial Reports**
 - An individual financial statement from each beneficiary
 - The justification of the resources consumed by the project and the specification of any subcontracting and potential contributions for third parts (if applicable)
 - A summary statement of the period of report, which is generated automatically by the electronic exchange platform system, it consolidates the financial statement for the period of the report and request for the interim payment

8.3 Content of the Final Report

When the project finishes, one Final Report must be elaborated and submitted in addition to the periodic reports for the previous period. Below there is a short description of the content of the Final Report:

1. **Final Technical Report**
 - A publishable document report containing an executive summary, the objectives, a description of the project and the presentation of the main results achieved, the impact of the project and the dissemination activities and exploitation
 - The project conclusions
 - The socio-economic impact analysis
2. **Final Financial Reports**
 - The final summary financial statement, which is generated automatically by the electronic exchange platform system, it consolidates the individual financial statement for all project report periods, including payment information.
 - A Certificate on the Financial Statements for each beneficiary, if it requests a total contribution of more than 430,000.00 €, also

reimbursement of all actual unit costs that are calculated, that is based on its usual cost account practices.

8.4 Report on the Distribution of the Payments

With the final payment received from the EC, the coordinator must submit a report containing the distribution of the EU financial contribution among all beneficiaries within 30 days after receiving the final payment.

9 Payment

Article 22 of the GA establishes the payments to be made from the EC to the Coordinator, and from the Coordinator to the rest of the Consortium Partners.

The pre-financing payment amount is EUR 1 577 808.40 € (one million five hundred seventy-seven thousand eight hundred eight EURO and 40 cents). The pre-financing was received by the coordinator in the first month of the project's official start and was transferred to all beneficiaries.

The amount of 98 613.04 € (ninety-eight thousand six hundred thirteen EURO and four cents), that's corresponding to 5% of the maximum grant amount is retained by the CE from the pre-financing payment and transferred into the Mutual Insurance Mechanism (MIM).

The eligible costs regarding the implementation of the project will be reimbursed by interim payments during the corresponding reports periods (RPs). From here, the payments are subject to the approbation of the related periodic report.

There will be up to 3 more payments to the coordinator that will be transferred to the beneficiaries, it corresponds to:

1. Initial payment: received on Month 1 (January 2023)
2. Interim payment of RP2: estimated around Month 12 (December 2023)
3. Final payment: estimated in Month 24 (December 2024)

The cumulative paid amount will never be over 90% of the beneficiary's contribution before the final payment.

All the beneficiaries must keep the records, the originals and other supporting documents for a period of 5 years after the end of the project.

10 XpanDH main concepts

The XpanDH project comes with a number of concepts that will form the basis for developing the partners' activities. These concepts were created during the project

proposal and have been refined during the project through meetings and intense communication between the partners.

The concepts of ‘Adoption domain’, ‘X-Bundles’, ‘X-Bubbles’ and ‘X-Nets’ present on the proposal will be further explored in this chapter.

10.1 EEHRxF Adoption domain

An **adoption domain** specifies the application of a use case to one or more particular care pathways and patient groups, (or clinical/organisational/inter-organisational workflows), for which the digital solutions implementing the use case are expected to deliver value. It therefore provides focus to the use case.

As such, an **EEHRxF adoption domain** can be considered **an instantiation of a specific use case within a health system or clinical setting**. It involves clear requirements for implementation, which can be simple if it uses one EEHRxF priority category or complex if it uses multiple categories. These requirements satisfy all the necessary conditions for users to be ready to exchange data according to EEHRxF guidelines and specifications.

This is also in line with End-to-End software testing¹ approaches that serve to verify the applicability of a software product or interconnection effort from start-to-finish taking not only technical interoperability but also other aspects into consideration.

10.2 X-Bundles

An **X-Bundle** consists of a group of well-defined interoperability assets that align with the six dimensions of the Refined eHealth European Interoperability Framework (ReEIF): Legal, Organizational, Semantic, Technical, Cybersecurity, and Person-readiness/Digital capabilities. This ensures that a simple or composite adoption domain can be implemented across two or more connected ends of an EEHRxF-compatible health data sharing connection.

For example, an X-Bundle includes the:

- Necessary semantic specifications (data sets, values, coding systems, nomenclature)
- Technical definitions (e.g., FHIR Implementation Guide – IG)
- Legal and organizational arrangements
- Individuals' capacity to use and understand shared health data

¹ **End-to-end testing** verifies that all components of a system can run under real-world scenarios, on the XpanDH context, the adoption domains with the proper set of actors and transactions involved.

- Cybersecurity and information security safeguards mutually recognized by entities exchanging health data (e.g., between two hospitals, or between hospitals and payers)

The terms **interoperability asset collection** and **X-Bundle** are used to denote the collection of interoperability assets that need to be used in order to achieve the required interoperability and may include additional helpful resources such as requirements specifications and adoption guidance. For organizational readiness assessment XpanDH has to develop an **European EHR Exchange Format Readiness Model** (see Deliverables D3.1 – (D3.1.1)– First version of the X-Bundle Readiness model; D3.2 – (D3.1.2) – Final version of the X-Bundle Readiness model from WP3– Organisational Readiness).

10.3 X-Bubbles

The ‘Experimentation bubbles’ or X-Bubbles are collections of organisations that agreed to experiment with using the EEHRxF in a certain adoption domain and under the X-Bundle-defined conditions, mostly on their own budget, or using other projects budgets, or pro-bono, but in effective articulation with XpanDH. The experimentation bubbles can be further extended to include other third-party organisations, and European or EU-funded initiatives and projects, and can benefit from insights of organized groups of stakeholders.

10.4 X-Nets

XpanDH develops key activities through the XpanDH X-Nets. They are networks of organized groups of stakeholders (EU or MS organisations) that, linked by similar interests, form the existing pan-European (Digital) Health space and can potentially use or benefit from the widest adoption of the EEHRxF. Ten of these networks will be promoted throughout the CSA, inspired by the Hospitals-on-FHIR initiative set out in March 2022 to network all Hospitals and Healthcare Providers (HCP) across Europe. The following 10 XpanDH X-Nets have been established in the proposal stage, engaging already and just in a few days, around 20 organisations (local, regional, or national in nature) in total, out of 461 invited, and will be further enlarged and nurtured by the X-Net Agitators, throughout and beyond the project duration.