XpanDH

Expanding Digital Health through a pan-European EHRxF-based Ecosystem

D1.3 – (D1.2) QRC Plan

WP1 – Coordination

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What did this document aim to achieve?	This deliverable aims to ensure that all members of the Consortium participate in all steps and analysis of the main elements of the data management policy regarding all the quality, risks and datasets generated by the project. This is also an internal communication instrument about how the Consortium sees their work and outputs.
Present the main methodological approaches in bullet point format	• Revision on literature about the Quality and Risks management • Elaborate a general Quality and risk management for XpanDH
What were the main findings or take-away messages? What implications does it have for the XpanDH project?	Describe in clear and direct way all the quality and risk management process adopted by XpanDH project.
Which project stakeholder group would benefit the most from the document and why?	
List any relevant organizations or social media accounts for wider visibility	

Healthcare Professional	No
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Patient/Caregiver	No
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Public Authority or Policymaker	No
Regulatory body	No
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List of abbreviations

Acronym	Description
EC	European Commission
EU	European Union
QRC	Quality and risk management
WP	Work Package

Executive summary

This document is meant to guide the XpanDH project members through the standards adopted related to the data and quality management that shall be used by all members to ensure the high quality on the outputs produced and define the risk management procedures.

The QRC plan should also be consulted with the deliverable *D1.1 – XpanDH project Handbook* to guide the member on the development of their activities towards the expected high-quality level proposed by XpanDH.

1 Introduction

XpanDH is a project that goes beyond state of art to promote the use and specification for the EEHRxF. It must count on a proper management of the quality, risks and data generated and processes in the project:

1. Overall quality and data management of the project outputs
2. Overall risk management and mitigation process of the project

This deliverable aims to ensure that all members of the Consortium participate in all steps and analysis of the main elements of the data management policy regarding all the quality, risks and datasets generated by the project. This is also an internal communication instrument about how the Consortium sees their work and outputs, and be able to avoid some common risks, such as:

1. Risk of missing the objectives of the project (i.e., not achieving high quality proposed).
2. Risk of ethical and legal issues that may result from the mismanagement and lack of alignment of the Work Packages (WPs) and Tasks.
3. Risk of data breaches and data loss due to information security (including cyber security) problems arising.
4. Also, there are risks of lack of scientific alignment with other projects due to poor interoperability, or future scientific exploitation of XpanDH outcomes by the eHealth ecosystem.

The data worked will be identified on the project and find the best quality formats to represent them on the deliverables and other outcomes. The project will assess which processes and tools will be used to collect, organize and share the results. The standards will be highlighted to be used. All these aspects contribute to the XpanDH Quality and Risk Management Plan.

1.1 Scope and objectives

This document is meant to be a guideline and reference to the project partners to enable a collaborative work to achieve the project objectives and goals. It establishes procedures for Quality Assurance Control, Risk Management and data collection.

It will provide information regarding the following activities:

- Liaise with the Project coordination about the quality of the project outputs
- Define the quality procedures for XpanDH and provide guidelines for the production and evaluation
- Support the WPs activities on the document's elaboration

- Support the coordination and risk management team to monitor the outputs quality.

2 Data Types and sources

The general purpose of documents, data generation and collection in the XpanDH project is to obtain quantitative and qualitative data and ensure the quality of all outputs generated to reach the project objectives. The data generation and collection will comply with the European Union (EU) ethics and legal requirements.

XpanDH project integrates clinical, computer science, interoperability standards, as well as social sciences.

The quality management, risk management and data collection in the XpanDH project will concern scientific and technical literature of interest, data from standards and international data sets and data from inquiries to evaluate the socio-economic impact. Data will be generated from experimental and computational work, and interactions with the eHealth ecosystem thought the X-nets and other approaches.

XpanDH Project has several types and formats of data along of their WPs that will be used, as described in Table 1.

Table 1- Types and formats of data generated and collected during the XpanDH Project.

Data Type	Data Format Generated
Text data, presentations, tabular, image	pdf, docx, pptx, xlsx, csv, JPEG (.jpeg, .jpg, .jp2), GIF (.gif), TIFF (.tif, .tiff), RAW image format (.raw), Photoshop files (.psd), BMP (.bmp), PNG (.png), Adobe Portable Document Format (PDF/A, PDF) (.pdf), Hypertext Markup Language (html), JavaScript Object Notation (json), Extensible Markup Language (xml).

All re-used data will be referenced according to the owner's terms and conditions. These data are essential for comparative analysis of results, preparing successful pipelines, and studies involving modelling.

There are two main origins of the data generated and collected during the XpanDH project:

1. New data generated during project development / experimentation;
2. Data obtained through ecosystem analysis.

The produced data will be useful to the XpanDH Consortium partners, and to dissemination, communication, and exploitation activities. Within XpanDH, data will be collected or generated for different purposes:

- To calculate the project indicators and thus monitor the impact of the project;
- To address transparency requirements;
- To foster stakeholder awareness;
- To foster citizen (predominantly patients and caregivers) participation;
- To extrapolate produced data to clinical practice.
- To develop the Adoption Domains, X-bundles and X-bubbles

Open formats, such as CVS, JSON and XML are strongly recommended but it is impossible to exclude that closed formats like XLS or PDF might be used for legacy reasons.

Data will be captured by different means. Additionally, health professionals and project partners may collect data using forms (including paper forms if needed). Documents and data from other projects will also be used, e.g., to provide the baseline for inputs or indicators.

3 Quality assurance plan and activities

Ensuring the quality of the work developed on XpanDH is a fundamental activity to keep the high standards of the project outputs as proposed.

Below the plan and all related aspects related to the quality assurance in XpanDH project is described.

3.1 Roles, procedures and tools

The quality assurance activities of the XpanDH project shall include key members on the process of documents evaluation. The Leadership council, Steering council, the project Coordination, and WP and Task leaders shall assume responsibilities among the quality management, with focus on the completion of tasks, deliverables and milestones.

These groups have different functions on the project and are described below:

- **Work Package Leaders**
  - Ensure timely and high qualitative production of all WP deliverables and results (e.g., adoption domains, X-bundles specifications, deployments, tests, demos, etc.).
- **Task Leaders**
  - Coordinate quality control of the activities related to their task.
- **Coordinator**
  - Quality control and overall risk and deadlines management
  - Collaborate with the WP/Task leaders to ensure deliverable quality of the documents

The quality assurance of the XpanDH must follow some principles and criteria in order to ensure the overall quality of the project's outputs. Below the list of criteria that shall be followed by the quality assurance team is presented:

- Respect the timeline of submission of deliverables to the Commission
- Monitor the work regularly of the work
- Define methodologies and preparation for experimentation
- Monitor ecosystem and report to the project
- Monitor the stakeholder needs
- Monitor regulatory frameworks and European Commission (EC) policy groups
- Monitor the scientific quality of the documents
- Monitor the communication quality

The project uses the templates for all the text communications, that shall be used by all project partners. Those templates are available on the XpanDH SharePoint folder for all participants. Below the templates are described:

- Deliverable - (Microsoft Word, when applicable[1])
- Presentation - (Microsoft PowerPoint)
- Simple documents - (Microsoft Word)

The project visual identity is also available to all the partners, and some elements are common to all documents. All the specifications about format of the text are available on the templates.

All the Word and PowerPoint files produced on XpanDH will be identified with the following elements:

- YYYYMMDD_ [Date of the last update]
- XpanDH_
- Topic: Report, Deliverable (if deliverable, only the abbreviation D.X.X should be included), Presentation on date (date to be included), Data file (.csv, .jpeg, .jpg)
- Version (v0.1, v0.2, …. Vx.n)

For example, a deliverable produced on the 30 of March 2023 is saved as:

20230330_XpanDH_D1.2_v0.3

The deliverables and other documents produced on XpanDH project must follow the template specifications. Also, the cover page must be fulfilled accordingly to provide

[1] Most of the de XpanDH are text documents, however some deliverables require different formats, such as 'D7.4 - XpanDH website' that is 'DEC —Websites, patent filings, videos, etc'.

all the basic information for the readers and other participants, including the revision history.

To keep the control of the production of the project outputs, all the information shall be stored on the XpanDH SharePoint. Each WP has one specific folder to develop their work and each of these folders there will be following sub-folders:

a. Meetings (referrer to regular meetings of the WPs)
b. Deliverables (each deliverable shall have their specific folder)
c. Activities (workshops, and other activities)
d. Documents (supportive documents not produced by the project)
e. Others

The material relative to the communication, such as pics and materials, should be stored on the WP7.

After the handover of the deliverable, the coordination must store it in two versions: Microsoft Word and PDF. The PDF version is also submitted to the EC portal within the deadline. If there is any delay foreseen, it must be communicated with the EC as soon as possible.

3.2 Quality timeline

The coordinator and the WP/Task leaders shall inspect the quality for this project according to the proposed timeline. They need to ensure the completion of the tasks and deliverables within the timeline and approve the documents produced for submission to the EC.

Below the revision and submission of the deliverables is described:

1. Before the quality assurance of the deliverable, the WP/T 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 leader will send the deliverable for 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 EC
4. If there is any issue with the deliverable, it will be sent back to the WP/T leader for improvements before the submission.
5. The revised deliverable can be submitted to the EC portal and the Project Officer will be informed by email.

4 Risk management

All projects present some risks that shall be identified and monitored to avoid them from arising, in any case the risks must be mitigated. The risk management is based on a stepwise approach that support the risk identification and mitigation.

The risk assessment with a deep analysis of all potential risks and a close monitorisation strategy with a mitigation plan is a crucial point on the coordination role. This importance goes beyond achieving the XpanDH project objectives within the proposed timeline, it also intends to reach the highest alignment with the eHealth ecosystem and other related actions.

A 'risk' can be defined as an event that somehow delay or make impossible the achievement of the objectives of a specific task or tasks. The risk management involves a detailed process to estimate the probability of occurrence of a specific risk event, also identifies the consequences of this risk and the mitigation procedures to be adopted.

This key activity aims to support the project to achieve their objectives by the identification of potential risks and take some procedures to avoid that the risk happens. The coordination team in line with the WP/Task leaders will monitor the risks already defined on the proposal and identify new risks that arise. Following this recurrent revision of the risk's identification and registration, the coordination will update the risks, including the mitigation procedures and other risk related information.

The monitorisation of the risks is a parallel activity performed with the quality assurance. The definition of clear procedures, including timelines for deliverable production, revision and submission, the quality and risk management, will ensure the low probability to risk and high quality of all produced work.

From the risks already identified on the proposed project phase, new risks can be identified and included in the risk management table, including their mitigation actions. Each 6 months, the risks will be evaluated by the project WP/Task leaders in order to identify if any risk identified has arisen and identification of the new ones. If a risk has happed, it will be reported including their mitigation action and the result, in order to ensure the completion of the project.

Additionally, the recommendations from the EC periodic revisions will be included as risks and addressed on the following review reporting period.

Below, in Table 2 shows the initial risks identified as well as their mitigation actions proposed.

Table 2 – XpanDH identified risks and mitigation measures

Risk number	Description	Risks Level	WPs evolved	Mitigation measures
1	Difficulties in implementation within the budget	L, M	WP1	Continuous interim monitoring to detect at an early stage any unpredicted obstacles and apply proper mitigation measures.
2	Discrepancies between the plan and the implementation, progress	L, M	WP1	Regular interim WP meetings, progress reports, and internal communication will keep the Project Coordinator informed to act upon.
3	Disagreements between partners or about the assigned tasks in a large consortium	L, M	All	Work assignment and related questions will be decided in internal meetings. Cases of disagreement will be discussed in internal meetings, with final decision from the Coordinator
4	Proper standards & technical artefacts available in time for all interrelated activities	L, M	WP2	Regular WP meetings, progress reports, and internal communication will mitigate this risk and the WP will make intermediate data available for the proper needs.
5	Delay in gathering necessary legal and technical requirements	M	WP3	Preliminary content to be shared by M3 and joint meetings of WP1, 2 and 3 will anticipate potential delays and act upon.
6	Low interoperability literacy, difficulty in stakeholders' engagement	M, L	WP3, WP7	WP3, WP7 Communication / dissemination and outreach activities with targeted stakeholders will be reinforced with the help of WP5, WP6 and WP7
7	Difficulties in the implementation activities in the experimentation bubbles	L, M	WP4	Coordination of the actions will be prepared well in advance to ensure all involved stakeholders allocate enough time to contribute to the joint preparation of the different actions
8	Maturity level in the early adopters is insufficient	L, M	WP4	Support actions will be developed to prepare the bubbles and make sure involved stakeholders fulfil necessary requirements
9	Low engagement in the X-Networks	L, M	WP5	Early involvement of key stakeholders leveraging of the vast consortium networks; meticulous engagement of X-Nets.

10	Dependency on activities performed by external partners without allocated budget	M	WP5, WP6	Pinpoint win-win situations for external partners to enhance motivation; promote their visibility through dissemination; offer to contribute to partner's endeavours in return
11	Disagreement between organisations on the sustainability strategy	L, M	WP6, WP7	Careful stakeholder consultation; investment in early common definitions of sustainability; seeking guidance from the EC

* Risk level: L-Low; M-Medium; H-High.

5 Data Management

5.1 Data location

XpanDH data will be shared between partners to ensure the smooth development of the actions and experimentation. All the data will be stored in files that have a common template for all partners in the project – Reports, presentations, short communications, etc. To enhance the search of the required files, documents must follow a specific naming and contain:

- Standard data format
- A list of abbreviations used in the specific WP;
- A list of keywords;
- A list of the references used in the WP.

Previous files from the work will not be deleted, just saved in a folder identified as "backup" on their respective SharePoint folder.

XpanDH open data will be deposited in the EC open access repository and the public documents on the XpanDH website (https://xpandh-project.iscte-iul.pt). The documents tagged as 'SEN – Sensitive' are restricted to the commission and the project partners.

All the deliverables produced by the project will include a list of keywords regarding data and publications:

> *Interoperability; surgery; adoption domain; X-nets; X-bundles; X-bubbles; cloud-based health care platform; XpanDH; etc.*

The version numbers are provided in the file name. Draft versions will not be deleted and will be stored in the respective "backup" folder, as explained in chapter 3.1.

Metadata will include a collection of information to describe the document, namely the title, author, deliverable/milestone number, description, type, publication date, keywords, access rights, license, related identifiers, and grant reference.

The identification of data will be tackled by adopting a naming convention for datasets. To be able to distinguish and identify the datasets, each dataset/database are assigned with a univocal name. This name can also be used as the identifier of the datasets. Each dataset name consists of four different parts separated with a "." character:

- Project Name:
  - Constant for all datasets: XpanDH
- Participating Centres:
  - One of the hospitals: CHUPorto; etc…

- Dataset Name:
  - The full name of the dataset.
- Version:
  - Version number

An example of a dataset's name could be the following:

XpanDH.CHUPorto.Listofsemanticassets.InterimExport.1

5.2 Data accessibility

The data produced and/or used in the XpanDH project will be revised and approved by the Consortium partners before making it openly available.

All data published in scientific journals, presented orally or as poster in scientific conferences, used to produce communication material, or used to elaborate questionnaires and interview questions will agrees with the HORIZON EUROPE guidelines and made available in open access through the XpanDH website. The Consortium may decide that some data should not be made openly available before IPR protection or access is clarified.

Data shared among the XpanDH Consortium partners is made accessible through a dedicated cloud service, Microsoft SharePoint/Teams, available only for project members and allocated at the ISCTE infrastructure. Documentation on how to access, deposit, and search for data in the project's SharePoint is available to all project members.

All processed data produced during the project will be available to the Consortium through the dedicated cloud service. Other data related with the project, agreed to be openly available, will be deposited in the current openly available on XpanDH website.

Scientific publications resulting from project scientific achievements will be published as open access by default and deposited in the XpanDH website.

5.3 Making data interoperable

The data produced in XpanDH project will be interoperable between project members. This will be achieved by always using open or globally used data formats for data exchange, also using the recommended international standards for eHealth, following the eHN and MyHealth@EU recommendations. During the project, the use of open software is recommended, although for certain tasks licensed software may be used when needed. The final data will always be available in open format.

Interoperability will be granted by the usage of standard formats such as XML, JSON, CSV. Standard data and service access protocols. To ensure the interoperability

among the instruments applied to the data processing, it is necessary to adhere to the common data management implementation technologies. In this way, the implementation of the data management, processing, and visualization in specific domain and for specific scenarios may be re-used across X-bundles and X-bubbles.

5.4 Making data reusable

The definition of the license(s) to be used when publishing data is still to be discussed internally to the project.

About possible limitations to the re-usage of data, at the moment we do not foresee the need of any embargo policy, or any other limit, also temporal, to the reusability also by third parties of the data that will be made publicly available.

5.5 Post project data management

All the produced data on XpanDH will be stored on the ISCTE server for at least 2 years. The public data will be available on the XpanDH website.

Access to sensitive data is granted only for project members dedicated each particular task/aspect of the project, with usage of secure passwords and encoding of the folders and files within cloud storage.

6 Allocation of Resources

The project partners have allocated resources to cover costs associated with open access publications and other goods, works and services. Partners will also use Open Access Publishing Platforms namely the Open Research Europe platform.

The costs for data storage, during and after project is finished, is the responsibility of the Coordinator partner for internal data, and each Consortium partner for open data.

The project coordinator (in the person of Henrique Martins) acts as responsible for data management in the project.

7 Data Security

Access to sensitive data is granted only for project members dedicated each particular WP/Task of the project, with usage of secure passwords and encoding of the folders and files within cloud storage. Data transfer is secured via HTTPS protocol.

The following security measures will be implemented: 1) storage of redundancy to assure full data recovery; 2) external data access/transfer accessible only to project partners; 3) access to the back-office, backend and frontend server(s) will only be allowed inside ISCTE's private network.

The coordinator will use mostly Microsoft SharePoint/Teams for sharing of documents, reports and deliverables; this platform implements well described security protocols and policies.

XpanDH internal data security, recovery and storage will be maintained for 2 years after the project finishes. Open data will be stored in XpanDH website for long term preservation.

8 Conclusions

The quality & risk management plan (QRC), is meant to cover the procedures to be adopted by the project participants, control the measurements and operate good practices that aims to ensure that all XpanDH activities can be performed in a high-quality standard level. It is also aligned with the project handbook (D1.1).

This work is fundamental to the project development and it is in line with the Consortium and Grant Agreements, that should be consulted together.