



XpanDH

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

D1.6 – (D1.5.1) Ethics and Data Management Plan

WP1 – Coordination

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Present the main methodological approaches in bullet point format		
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List of abbreviations

Acronym	Description
DOI	Digital Object Identifier
EEHRxF	Electronic Health Records Exchange format
FAIR	Findable, Accessible, Interoperable, Re-usable
GDPR	General Data Protection Regulation
REC	Research Ethics Committee

Executive summary

This document sets out the Data Management Plan XpanDH project. XpanDH is a Coordination and support action that 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 (EEHRx^F) across Europe.

The Data Management Plan is divided into three main sections. Following the first introduction section, the second section sets out the legal requirements of **processing of personal data** in accordance with the General Data Protection Regulation – GDPR (Regulation (EU)2016/679)¹. The third section set out the requirements to be met to ensure that data generated by the project that may be lawfully re-used by other are researchers **Findable, Accessible, Interoperable and Re-usable (FAIR)** as required Horizon Europe Data Management Plan guidance.

The section on **Processing Personal Data** is divided into three parts. It looks first at the legal and ethical requirements of processing of personal data of project partners in the context of project work. It then considers the legal and ethical requirements of processing of personal data collected in the context of the project from people who engage with the project at webinars, events and through newsletters and similar tools, but who are not signatories to the Grant Agreement and therefore have no contractual relationship with the project consortium. Finally, this section looks at the legal and ethical aspect of collecting and processing sensitive personal data, such as health related data. This has only limited relevance to XpanDH, but is included for completeness.

Section three, under the heading of **Ethical and FAIR data processing** considers briefly requirements of processing data in the context of any experimentation and testing and ensuring they can be re-used where appropriate. This is set out according to the Horizon Europe data Management Plan Template.

This Data Management Plan is a live document, it will be updated as needed and as the data processing activities of the project partners become clearer. It is designed to support both the project centrally, as well as individual partners in their data processing activities.

¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance) available at: <https://eur-lex.europa.eu/eli/reg/2016/679/oj>

1. Introduction

1.1. Background

XpanDH is a Coordination and Support Action designed to build capacity in individuals and organisations to be ready to use the European Electronic Health Records Exchange Format (EEHRx). It seeks to create, adapt, and explore purposeful use of interoperable digital health solutions through an EEHRx Network of Networks. The Network is built up among stakeholder and experts in the field and seeks to support them with tailored guidance and real examples to help them advance in the use of EEHRx-embedded digital health solutions. Its overall objective is to ensure that using EEHRx based solutions adds value to health and care and promote Personal and European Health Data Spaces.

A key aspect of this is to build the X-bundles, which are an aggregation of interoperability assets that support the connections and interconnectivity between health systems based on the specifications of the EEHRx. The X-Bundles are developed through X-Bubbles, which bring together key stakeholders from across the healthcare continuum and across EU Member States experiment with using the EEHRx.

As part of this work the project partners must work together, therefore exchanging non-personal information (e.g., technical and semantical specification, data fields, etc.). The ideas and concepts they develop will be shared and tested with healthcare system stakeholders outside the project to gather input and experience, therefore without collecting and processing personal and non-personal data. And finally, to be successful in meeting the objective of increasing uptake of the EEHRx-embedded digital health solutions, the project partners will engage in a wide range of outreach activities which will include webinars, meetings, conferences and dissemination of newsletters, which will require the data of participants and recipients to be collected.

Although the XpanDH project is concerned with developing and testing interoperability solutions, all testing will be done either with dummy data or anonymised data. All data collected to align and prepare the experimentations will be mock-up data and/or data that have been stripped of any means of identification and are classifiable as anonymous in the terms of GDPR Recital 26 “namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable”.

Any patient level data exchange will always take place in the scope of normal operation of each bubble partner (hospitals, health authorities and organisations) and, in this regard, safeguarded by the privacy and security measures in place, and subject to the authorisation of the data protection officer or officers at each health facility. Where trials are done in the context of everyday work any real patient data

that may be involved will be under the auspices of the organisation engaging in any form of trial. It will fall outside the project, if there is a need, any patient data reported from such partners into the project will be fully anonymised. In other words, the patient data will not be used, exchanged or shared among the project.

From a data governance perspective therefore, the project has minimal demands, which are limited to ensuring that the personal information of project partners is processed in accordance with their reasonable expectation under the terms of the Grant Agreement; and that personal data are collected from individuals who are not party to the Grant Agreement are processed lawfully, as set out below.

1.2. Scope and objectives

The scope and objective of the Data Management Plan is to address the legal and ethical requirements of the project. It has been prepared to enable appropriate interpretation and application of ethical and data protection principles throughout the project's life cycle and beyond.

The Data Management Plan addresses four elements falling into two broad categories: **processing of personal data in accordance with the legal requirements of the General Data Protection Regulation** (Regulation (EU)2016/679); and **Ensuring that data generated by the project that may be lawfully used by other are Findable, Accessible, Interoperable and Re-usable (FAIR)** as required by the Horizon Europe Data Management Plan guidance.

This Data Management Plan is a live document, it will be updated as needed and as the data processing activities of the project partners become clearer. It is designed to support both the project centrally, as well as individual partners in their data processing activities. Where data are collected and stored by a project partner, each partner is legally responsible for compliance with data protection legislation in the country in which the organisation is legally established. Where data are processed by the project co-ordinator for the project as a whole, the legal responsibility for its appropriate processing and storage is with Iscte-CVTT in Lisbon. Primary data will be stored in institutional infrastructures and will be preserved for at least 10 years. Additional security measures will be applied for personal and sensitive data. Primary data that can be reused, and data underpinning a scientific publication will be deposited in Iscte community in Zenodo (<https://zenodo.org/communities/iscte/>), where a Digital Object Identifier (DOI) is issued for every published record, in line with the FAIR (Findable, Accessible, Interoperable, Reusable) principles.

2. Data Summary, 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 through 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	CSS, GLSL, 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 XpanDH project expects to generate about

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. Processing of Personal Data

In the context of the project personal data are generated from two types of sources: the project consortium in the context of the partners work on the project, and personal data collected in the context of the project from people who engage with the project at webinars, events and through newsletters and similar tools, but are not member of the consortium.

Data generated from both types of source must be processed in accordance with requirements of the General Data Protection Regulation (Regulation (EU)2016/679), generally known as the GDPR. However, the legal basis on which they may be processed will not be the same.

In the first group the relationship between the partners is based on a contract to which they are all party, the Grant Agreement, data are therefore processed on the basis of fulfilling the obligations under the contract and do not require any further consent or explanation. However, only data relevant to the execution of the contract may be collected and processed. In the second group no contractual relationship exists between the parties, so another legal basis must be established. This will usually be consent. The concept of legal bases for data processing comes from the GDPR which is outlined below.

The GDPR was enacted in 2016, building on the previous Data Protection Directive of 1995. The new law is a Regulation, not a Directive, meaning that it is directly applicable in every Member State and does not have to be transposed into national legislation.

3.1. General Data Protection Regulation (GDPR)

The GDPR creates duties for data controllers and give rights to data subjects. **Deliverable 1.5.2 on the Legal Framework of Digital Health** gives a thorough explanation of the GDPR, a short summary is provided in the table below, showing how the key requirements impact XpanDH

Table 2: GDPR in XpanDH

GDPR	Summary	Impact on XpanDH
Scope and Applicability	The GDPR applies to all organizations that process personal data of individuals within the EU, regardless of the	Applies to all the organisations that are partners in XpanDH and applies to the individual

	<p>organization's location. It also applies to organizations outside the EU that offer goods or services to people in the EU.</p> <p>It applies to personal identifiable data. Special rules apply to sensitive personal data, such as health data.</p>	<p>behaviour of the people working in the project, although liability for their behaviour will apply to the organisations that are their legal employers,</p>
Rights of Individuals:	<p>The GDPR grants individuals rights regarding their personal data. These rights include the right to access their data, rectify inaccurate information, erase data (the "right to be forgotten"), restrict processing, data portability, and object to processing for certain purposes.</p>	<p>XpanDH partners must be able to provide access to data if they have collected it, and to portability of such data if it was collected on the basis of consent.</p>
Duties of Data Controllers:	<p>The legal and natural persons who are responsible for how data are processed (whether by themselves or an entity or person employed by them to process data on their behalf) are data controllers. They have to ensure that they can meet the rights of the individuals whose data they process and that they have a legal right to process that data.</p> <p>If a data breach occurs, the data controller must notify this to the national authority and data subjects.</p>	<p>Each XpanDH partner must know who is responsible for compliance with GDPR in their organisation and ensure they have the approval of the responsible person to process data.</p> <p>Data must be stored securely.</p>
Legal Bases for data processing:	<p>The legal bases available are:</p> <ul style="list-style-type: none"> • Consent • Contractual necessity • Legal obligation • Vital interests • Public tasks • Legitimate interest 	<p>In XpanDH if data are collected from project partners or from event participants.</p> <p>For project partners' data the legal basis is likely to be the contractual</p>

	<p>When the data are sensitive data, such as health data, a further legal basis must exist, this must be one of the following:</p> <ul style="list-style-type: none"> • Explicit consent • Legal obligation • Vital interests • Legitimate interest • Data made public by data subject • Legal claims • Public interest • Healthcare • Public health • Public interest <p>Legal basis for processing data in the context of healthcare is usually based on the legal obligation of the data controller (a healthcare provider, to collect data in order to treat a patient properly.</p>	<p>relationship between the partners based on the Grant Agreement.</p> <p>For data from people outside the project attending events and other connections, consent is likely to be necessary. This requires that an information notice must be provided that tells data subject detailing what data will be collected, for what purpose and how long it will be kept (inter alia).</p> <p>It is unlikely that the project will process any sensitive data collected specifically for the project at project level. If such data are collected in the routine work of project partners and re-used in the project, the data will be anonymised and will fall outside the GDPR.</p>
<p>Data Transfer</p>	<p>Restrictions on transferring personal data outside the EU to countries that do not provide an adequate level of data protection. Organizations can use various mechanisms, such as standard contractual clauses or binding corporate rules, to ensure adequate safeguards for such transfers.</p>	<p>Any person identifiable data XpanDH partners collect should not be sent outside the EU</p>

The table above provides a very minimised overview of GDPR, some of the implications on the project will be discussed in more detail in the sections below.

3.2. Processing project partners' personal data

The conduct of a project necessarily entails the generation of a great deal of data about the consortium partners and the work they conduct. The consortium partners have a duty towards each other to ensure that such communications and data are treated respectfully, and in compliance with GDPR.

In terms of GDPR compliance the legal basis lies in the contractual relationship between the partners. This means however that the data collected relate to the execution of the contract, it cannot be used to justify collection of data that are not needed for completing the work of the project.

The data collected will generally include personal data when work tasks are reported, notably within time reporting, but it also includes significant amount of email traffic, report drafting and other creation of data trails. It will involve collection of personal data from consortium members during virtual meetings conducted over Teams or other platforms, e.g., recordings, pictures or field notes. This means the following data will be recorded about project partners:

- name and registration details provided
- image, if a camera is used at any time during virtual meetings
- voice, if a question is asked or comments are made orally
- any text provided in a chat function.

The project communication operates on the basis of Microsoft Teams and Microsoft SharePoint and email communication. All reports, deliverables, minutes and other text-based material is stored within the Microsoft Teams environment and hosted on the secure servers of Iscte – University institute of Lisbon which operates the log-in process for access to the Teams site. Microsoft Teams is built on the Microsoft 365 and Office 365 hyper-scale, enterprise-grade cloud, delivering advanced security and compliance capabilities. The data controller for this type of information is Iscte who undertakes to keep such data safe.

3.3. Processing non-project partners personal data

A key focus of the XpanDH project is building capacity and engagement on the use of the eHRx. This will involve consortium partners working with external partners who will typically provide the project with their names, affiliation, contact details, and may also share professional background data as well as their experiences and opinions.

Where personal data from participants are collected, these data are collected on the basis of informed consent. A standardised informed consent template form and information notice will be developed by the consortium team for use by all partners. Each partner is responsible for ensuring that informed consent is

obtained. The final iteration of the DMP will include an annex of the consent forms used.

The data collected on the basis of informed consent will be used only for the purposes stated (this will usually be to provide further project related information) and will be stored in a specifically designated folder with access restricted solely to the team directly involved in XpanDH management.

In the case of a personal data breach, the project partner who has data controller responsibility for the data will without undue delay and, where feasible, not later than 72 hours after having become aware of it, notify the personal data breach to the national supervisory authority. Where the notification to the supervisory authority is not made within 72 hours, it will be accompanied by reasons for the delay. The processor will notify the controller without undue delay after becoming aware of a person data breach.

In the case that any personal identifiable data have been transferred to the project co-ordination team and stored as part of the project material, the project co-ordinator's organisation will be data controller of such data and will comply with GDPR requirements for safe storage and will report any data breach that might arise as outlined above.

3.4. Processing sensitive personal data

The GDPR classifies some data as sensitive personal data. This data which reveals any of the following:

- Racial or Ethnic Origin
- Political Opinions
- Religious or Philosophical Beliefs
- Trade Union Membership
- Biometric Data:
- Sex Life or Sexual Orientation
- **Genetic Data: Data concerning the inherited or acquired genetic characteristics of an individual, which can be derived from analysis of their biological samples.**
- **Health Data: Data that pertains to an individual's physical or mental health, including medical conditions, treatments, and health services received.**

Processing of sensitive personal data is generally prohibited under the GDPR unless certain conditions or exceptions apply. However, there are specific circumstances where the processing of such data is allowed, such as explicit consent from the data subject, obligations related to employment or social security, **processing for the provision of healthcare**, as well as the other legal bases set out in the table above.

2.3.1 Sensitive personal data in XpanDH

It is not anticipated that any sensitive personal data will be collected for the purposes of the tasks in XpanDH. At this stage therefore, no ethical review process for collecting sensitive personal data from any trial participants or patients. Although it is possible that in the context of taking part in trials or experiments project partners involved in the X-Bubbles may use some patient data, this will be done under the auspices of their everyday work. Any such data collection and processing will take place outside the project remit and will be conducted under the supervision and approval of the data protection office of the relevant project partner. Should any information be provided to the project it will be fully anonymised. As anonymised data are not covered by the GDPR there are no further EU level legal requirements to address. However, national level legislation may exist which must be addressed by the relevant project partner.

If at a later stage in the project it becomes clear that sensitive data will be collected and used within the remit of the project, the relevant ethical and legal procedure will be set up. This will include the provision of a template for a privacy information notice and support in obtaining ethical compliance from a Research Ethics Committee or other relevant approval body.

4.FAIR data

4.1. Making data findable

The project will not create significant amount of primary data. Results from surveys or focus groups will be available in public deliverables.

To be compliant with FAIR (findable, accessible, interoperable and reusable), data must be associated with the described information in the form of metadata. The primary data that could be reused, and data underpinning a scientific publication will be deposited in Iscte community in Zenodo², where a DOI is issued for every published record, in line with the FAIR principles.

Zenodo's metadata is compliant with DataCite's Metadata Schema³ minimum and recommended terms, with a few additional enrichments. One of the mandatory terms in Zenodo's metadata is the 'license' in line with the Grant Agreement obligations.

In order to make the XpanDH bundles FAIR the project will develop data tags to support data integration, analysis, storage and sharing. If appropriate tools such as

² <https://zenodo.org/communities/iscte/>

³ <https://schema.datacite.org/>

data dictionaries may be designed and developed during the project to make data from the project more findable. Further detail will be provided in a later iteration of this deliverable.

A naming convention has been adopted for documents that includes a standardised naming format for all documents and datasets and a series of Unique Identifiers: ensuring that each document and or data set is referenced by a unique identifier to ensure effective version control. Zenodo repository, DOI will be used as the standard unique identifier in line with ISO 26324.

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 documents 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

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.

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

An example of a dataset's name could be the following:
XpanDH.CHUdSA.Listofsemanticassets.InterimExport.1

4.2. Making data accessible

The consortium is committed to making results from the project available at the appropriate time-points, has included provision for open access publications within the budget for this purpose, and data will follow the principle "as open as possible, as closed as necessary".

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 agree with the HORIZON EUROPE guidelines will be deposited in open access in Zenodo repository and made available in through the XpanDH website using the persistent identifiers. 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 Zenodo repository.

4.3. Making data interoperable

A core objective of the project is to promote interoperability solutions for digital health. Accordingly, the project will be focussed also on ensure that the information it generates is interoperable across different actors and stakeholders.

The data produced in XpanDH project will be interoperable between project members and for outsiders after approbation by the commission (where it is applicable). 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 PDF, XML, JSON, CSV. Data will be acquired, processed and stored using one of these open formats as described on Chapter 2 'Data Summary, types and sources'. 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.

4.4. Increase data re-use

The projects' overall commitment to interoperability and FAIR data will ensure that the data models, labels, nomenclatures and conventions developed in XpanDH support the re-use of XpanDH Bundles and data where this may be done in accordance with GDPR and other applicable legislation. In addition, XpanDH project will provide all required documentation to validate the data analysis in order to facilitate its re-use, such as by tutorial files (read.me), with the description of the methodology, analysis, definitions, etc.

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. Intellectual Property Rights

The lawful use intellectual property either brought to the project by partners (background IP) or generated by the project (foreground IP) is detailed in the Project

Consortium Agreement. Annex 1 of the Consortium Agreement details all the Background information brought by each partner.

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 personal identifiable data is granted only for project members dedicated to 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 10 years after the project finishes. Open data will be deposited and accessible through the Zenodo Repository for long term preservation. The citation will include the persistent identifier (DOI) and will be available in XpanDH website.