Platform for Innovation of Procurement
and Procurement of Innovation

D1.9 Data Management Plan

PiPPi

GA No 826157

May 30th 2019
Updated
May 31st 2020 & Q4 2020
Resubmitted 15 Jan 2021

Table of content

History of changes

Change	Date/Beneficiary	Explanation
Revisions made based on reviewers' comments with tracked changes	December/Jan 2020/2021 / SLL	First draft of revisions according to the mid-project review
Revised Word and PDF versions uploaded	May 2020	Updated version uploaded to portal
Revised Word and PDF versions uploaded with response to the review	Jan 2021 / SLL	Uploaded to portal

Comments from the review

The relevant section of the DMP did not convincingly address the ethics requirements as laid down in WP8 and the DoA (Part B, Section 5). The consortium is requested to clarify the situation and plan to address ethics in its DMP as soon as possible, as this requirement was due at an early stage of the project.
Response: Please see page 17 and chapter 11 for information on the ethics requirements.

The Project hasn't satisfied yet the ethics requirements listed in the DoA through the two deliverables submitted. In addition, in the related work of WP2 and WP1, there are no evidences justifying that the Beneficiaries have adopted norms for future involvement of patients in Innovation Procurement and for management of POPD. It is understood that the risk and innovation management has to cope with the changed situation after the outbreak of the COVID-19 pandemic, and to adequately take into account the related future challenges and issues that will come in the next months.
Response: Please see page 10-11 and chapter 7 for information on patient interaction.

The Plan (Data Management plan) is addressing in a generic level the relevant issues for the management of data, policy for anonymization/ pseudonymization of data and security without specifying a set of procedures per stakeholder case, and furthermore fails to describe in a concrete way how the project will address the issues highlighted by the ethics evaluation and described in the WP8 deliverables. There is no substantial update of the initial Data Management Plan presented in the proposal. The Plan is addressing in a generic level the relevant issues for the management of data, policy for anonymization/ pseudonymization of data and security without specifying a set of procedures per stakeholder case, and furthermore fails to describe in a concrete as well as in Section 5 of the DoA.
Response: Please see page 11 and chapter 7 for information on stakeholder engagement.

1. Purpose of document

The following document contains the Data Management Plan for the Platform for Innovation of Procurement and Procurement of Innovation (PIPPI) project. It is based on the template offered by the Economic and Social Research Council (ESRC) and includes (as suggested[1]) information on:

- ✓ the handling of data during & after the end of the project
- ✓ what data will be collected, processed and/or generated
- ✓ which methodology & standards which will be applied
- ✓ whether data will be shared/made open access and
- ✓ how data will be curated & preserved (including after the end of the project).

In addition, elements from the "TEMPLATE HORIZON 2020 DATA MANAGEMENT PLAN (DMP)" have been added complementing the original template. N.B The document is a living document and will thus be continuously developed as the project progresses.

2. Data Management in PIPPI

The PIPPI project does not call for the creation or management of research data or "primary data" regarding patients and/or other sensitive information. However, due to the nature of the activities, for example interviews with stakeholders and contact with patient groups, sensitive data might still be collected and managed within the project. In addition, the type of data handled requires a need for understanding and creation of procedures for future joint procurement activities among the partners. The Data Management Plan for the PIPPI project (DMP) will therefore offer important information and clarifications that will allow the partners to identify necessary improvements in data procedures.

Data Management in the various WPs

Task 1.3 in WP1 (Project Management) will focus on the compliance of the project to national and Horizon 2020 ethics requirements, including ensuring that any data collected is managed according to relevant regulations and directives. It will also involve open access management of the collected data. The Data Management Plan describes how data generated by the project will be handled as well as the procedures for full anonymization of any healthcare-derived datasets that may be applied in the activities of WP5. Work will include keeping up-to-date documentation of processing activities and appointing a project-specific data officer, who in-turn will maintain communication with each project partner. Work will also include the implementation of measures to meet the principles of data protection by design and by default, as well as appropriate technical and organizational measures (policies and procedures) to ensure and demonstrate compliance. The task will ensure that any need for conducting a data protection impact assessment (DPIA) will be identified and performed. The work could cover responsibilities such as:

- ✓ Data officer in collaboration with all partners summarizes core principles and regulations regarding data management for the project and collects ethics documentation if applicable for data used in and generated by the project.
- ✓ Data officer defines governance and communication processes for continuous data management issues/activities and an overall data management plan.
- ✓ Introduction training on data management principles, project governance processes and escalation steps, and specifically addressing WP and task specific responsibilities when applicable

[1] http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm

as defined in the data management plan.
- ✓ Monitoring of defined data management governance processes and responsibilities

In addition, data management will predominately concern:
WP2 Stakeholder identification, engagement and enrolment
WP3 Development and establishment of the CoP - task 3.1
WP4 PIPPI platform development and validation - task 4.2 and 4.4
WP5 Preparation for execution of a cross border PCP -
WP6 Development of the business model, business plan and operating model -
WP7 Dissemination and Communication – Tasks 7.2, 7.3, 7.4

3. Data Management in PIPPI – Introduction

The aim of the PiPPi project in terms of data collection is to attract and enroll already identified, as well as new stakeholders within all relevant stakeholder groups. The aim is to create an active stakeholder network which can be scaled beyond the project scope and duration, establishing a sustainable and successful open innovation ecosystem centered on the CoP vision. To ensure this the beneficiaries have identified a number of key stakeholder types:

1. Industry
2. Healthcare providers / Hospitals
3. Research & Innovation community
4. Citizens / patient associations
5. Enablers: venture capital
6. Payers
7. Policy makers

A temporary registration form has been made available through PIPPI webpage with the collaboration of WP7. This registration form can be found at: https://pippi.meduniwien.ac.at/general-information/community-of-practice/ . The registration form asks for the following info:

1. Partners site / Event registered participant
2. Name and Surname
3. Organization
4. Role
5. Working country
6. Stakeholder cluster
7. Type of stakeholder: internal: contacts inside partners organizations / external: contacts from non-partners organizations
8. Status:
   - *Active*: have been actively participated in survey and workshops during last 12
   - *Involved*: have been participating events, workshop and surveys.
   - *Communicated**: have been informed of PIPPI project.
9. PIPPI registration form - Consent

Consent
I consent to the processing of my personal data and having my contact details stored in the PIPPI contacts directory. I also agree to being contacted by representatives of the PIPPI project as regards PIPPI activities, news and events. *
I accept

Furthermore, I consent that the data obtained during events and workshop(s) being used, stored and processed by the PIPPI project and its consortium parties, particularly in order to further the PIPPI knowledge base. *
I accept
I am aware that later on a new registration process may be needed due to adaptation to new technological platform *
I am aware

** Please note that the Communicated status include stakeholders registered to PIPPI newsletter, and registered members of the CoP that have not been involved in surveys and workshops. The type of data collected from the stakeholders mainly concern contact info to the stakeholder representative. Only in the case of patient stakeholders is it therefore expected that additional type of data can be collected and thus requiring additional measures (please see section 7 and Annex 1 for more information on how this data is collected and consent ensured). In tables 3.1 & 3.2 the data types and its uses are summarized:*

Table 3.1 – Currently type of data collected

Analysis of dataset: definition of data and standards applied	
What is the purpose of the data collection/generation and its relation to the objectives of the project?	The data will be collected for both industry and health care to determine best practice for public procurement.
What kinds of data and formats will be collected or generated to perform the research?	• Text docs (DOC, ODF, PDF, TXT, etc.) • Pictures/images (JPG, GIF, SVG, PNG, TIFF) • Videos and films (MPEG, aVI, WMV, MP4) • Audio recordings (MP3, WAV, AIFF, OGG, etc.) • Structured data (HTML, JSON, TEX, XML, RDF) • Tabs (CSV, ODS, TSV, XLS, SAS, Stata, SPSS portable) • Source code (C, CSS, JavaScript, Java, etc.)
What is the origin of the data?	Data is produced and collected by Project members through workshops, stakeholder interactions, literature studies.
Will you re-use any existing data and how?	No historical data will be added to the system but references to external documentation will be part of the information stored.
What is the expected size of the data?	During the PIPPI project, data is likely to be less than one terabyte.
How are you going to store data and metadata?	Data will primarily be stored in Microsoft Teams as individual files. An email host will probably be contracted to facilitate a common CoP email domain/address and it will store incoming and possibly outgoing emails.
To whom might it be useful ('data utility')?	Partners within the Community of Practice.

Table (*Table 3.2*) below describes the data set and the purpose of the data collection/generation in relation to the objectives of the project. Additionally, it shows the data utility to clarify to whom the data might be useful.

Table 3.2 - description of data set and purpose of collection

Data Type	Description & Purpose	Utility
Stakeholder contacts	**Description:** Data containing information about stakeholders and associated contacts. Includes Policy makes, caregivers, industry, researchers, patient organizations, **Purpose:** The collection is used for dissemination of the project, invites to events, participants in workshops, as reference groups, participants to surveys and connecting interested in collaborations.	Useful for the project as reference group, a source of interested participants and for gauging interest. Also useful for stakeholders looking for collaboration partners. Provides a starting point for the CoP.
Survey Data	**Description** Quantitative data collected from stakeholders in surveys conducted during for example workshops or events or mailing list derived from the collection of contacts. **Purpose** Provide feedback on events, workshops or ideas and provide a way to submit ideas.	Feedback to the project group on how events and workshops are perceived by the invited stakeholders.
Collection of unmet needs	**Description** A collection of unmet needs collected from participating organizations by the project participants. **Purpose** A collection of real examples of unmet needs that can be used as examples, as a source of experiences and a potential candidates for a pilot case.	Used by the project to gain understanding on how unmet needs are managed today, as examples to test proposed CoP processes and as candidates to the pilot. The collection could also be useful as a starting point for the CoP's collection of unmet needs.
Workshops data	**Description** Data consist of protocols, notes, summaries and output from workshops organized to elicit business processes associated with innovative procurements from the participating organizations. **Purpose** The data is used to understand how innovative procurement is done today and as an input to constructing the future CoP processes. Data is also used as input into the PiPPi platform development	Primarily for the project to build new processes but also as a repository for the CoP
Procurement examples	**Description** A collection of innovation procurements that has been done and the results of these, initially collected from consortium partners. **Purpose** To serve as examples that can be used as reference and source to draw on other experiences.	Useful for the project, CoP members, stakeholders and other interested parties as a source of examples.

4. Procedures for Quality Assurance

Data Quality
The quality assurance of the data will be taken care of by the creation of a repository of good quality with metadata and unique identifiers. The data shall be accessible via internet with strong authentication. The enrolment of users will be done via the project. And the idea is to encourage the partners to describe their solutions using international standard nomenclature with the purpose the of future opportunities for interoperability.

Informed Consent
The working policy for the PiPPi project is that local procedures are used at first and then if consent is given locally the stakeholder is transferred to PiPPi registration and consent forms. Forms and written information regarding informed consent is validated by the local organizations legal department as this needs to be written in local language and conform to local law. Currently (Q1 2021) the main organisations handling stakeholder interactions include:

Karolinska University Hospital
As further explained below, the principle of public access to information applies for Karolinska (being a Swedish entity). Therefore, considering that national legal variations might exist, when data is shared, each party must determine if the data is confidential. If the answer is yes, those parties are responsible for the data encryption, and that a two-factor authentication is used. For detailed information, see:

https://www.sll.se/globalassets/6.-om-landstinget/styrande-dokument/2-verksamhetsstod/sakerhet-och-beredskap-informationssakerhet/riktlinjer-for-informationssakerhet.pdf

Medical University of Vienna (MUW)
MUW is the beneficiary responsible for WP7 Communication & Dissemination. To ensure and monitor procedures for data quality assurance and to fulfil the requirements from the GDPR, the MUW has appointed a data management officer and operates a repository with processes, metadata and unique identifiers for all types of data which are processed, analysed and/or stored at the MUW. Data that leave the MUW need to be reviewed by an internal data clearing committee. The MUW currently explores open data strategies.

Vall d'Hebron University Hospital (HUVH), Catalan Institute of Health (ICS)
They are in charge of WP2 and WP6 where interactions with stakeholders are present. Deliverables 2.4 explain in detail how the interaction with patients are managed.

5. Backup and security of data

Currently, the project uses a Karolinska University instance of Microsoft Teams, this is mainly a cloud-based collaboration tool which also has some on-premise storage areas for sensitive information. All data, such as meeting notes, presentations, studies etc. produced during the project activities is stored and shared in that environment. The service provides an authentication function.

Each party is responsible for local backup and security of data according to international standards regarding information security: ISO 27000, ISO 27001 and ISO 27002.

With regard to the PIPPI project and its status as a collaboration project with EU partners, the objective is to follow international standard regarding information security. The project will use ISO 27000, ISO 27001 and ISO 27002.

During the course of the project, a technical platform will be developed that will replace Teams and will be in-line with the aforementioned ISO standards. It will be defined during the development and deployment of the technical platform in WP4 (for more information see deliverables 4.1-4.5).

Confidentiality, data integrity and availability
The need for confidentiality is high as data is expected to be of all types of confidentiality, ranging from personal data (eg contact person) subject to GDPR regulation, confidential proprietary information (company/organizational, IPR etc) to public information.

The need for data Integrity is low/medium as information is used mostly for guidance and orientation. The need for data availability is in turn also considered low/medium as data is for information only and mostly for guidance.

6. Management and curation of data

Karolinska University Hospital
Due to its role as partner and owner of task 1.3 in the PIPPI project, it is important to note that Karolinska University Hospital, along with all other public authorities in Sweden, is governed by the so called ”Offentlighetsprincipen” (“Principle of public access to official records”). The principle of public access to official records gives the general public the right to read official documents submitted to or drawn up by public authorities. This means that documents sent to an authority are registered. All documents received, dispatched letters, decisions and reports are then in principle considered public documents and must be made available for anyone to read. The principle entails a right for everyone to gain insight into the activities of the authorities, for example by taking part in public documents. Personal data in public documents can thus be requested and disclosed according to this principle - regardless of the purpose for which the personal data were originally collected and/or processed. The right to access public documents does not apply, however, if the documents contain information that is confidential according to the Public Access to Information and Secrecy Act (as allowed by GDPR Art 86).

However, personal data may only be collected and processed for specific purposes, which must be based on legal grounds. As a general point of departure, consent from the individual is required in order to be able to process personal data. Each party (healthcare provider) is responsible for ensuring that the personal data is handled correctly. Identifying the type of data collected and then treating it in-line with both Swedish and EU law is thus an important task of the organisation. Which in turn means that there are strong procedures in place to manage collected data.

With regard to the PIPPI project and its status as a collaboration project with EU partners, the objective is to follow international standards regarding information security. The project will use ISO 27000, ISO 27001 and ISO 27002. WP4 will determine this further during the development and deployment of the technical platform.

GDPR Requirement Fulfilment
The bulk of data collected and produced by PiPPi consist of non-sensitive data related to processes, requirements, activities performed etc. the only sensitive data to date is the stakeholder contact list that holds contact information such as name, email and organization. These contacts are collected locally but collated to a central list that hold the contacts for all stakeholders involved with PiPPi. This list is managed by WP2 and access to it is only available to PiPPi project members and according to the consent given by the contacts. Contacts can request to have their data amended, access it or have it deleted, etc. as per GDPR requirements by contacting the PiPPi project using the projects email address. Managing the list and GDPR requirements is done manually at this point and likely throughout the PiPPi project but that is not expected to be a problem due to the limited amount of data. Project emails to stakeholders will be managed and sent using MailChimp and the Erasmus Medical Center congress management system. Both are GDPR-compliant and maintained by project partner Erasmus.

7. Consent, anonymization and strategies to enable further re-use of data

PIPPI project
Stakeholders involved in the presentation, business and operating model workshops sign an informed consent validated by local legal departments. Business and operating model workshop were virtual, so participants where contacted and required to submit a signed informed consent by email.

New stakeholders have the opportunity to sign up to join the CoP and/or to receive information directly through the website or through registration forms. New registrants will be informed before registration with the proceeding of their personal data and privacy. All registered members will be informed of their right to access, limitation, and deletion of their personal data using the PIPPI project email address. Registration of new stakeholders will be managed using MailChimp.

Any data collected for scientific research reasons not included in the included use of PIPPI platform will be strictly through informed consent and all appropriate ethical and/or data protection regulations and processes will be followed as indicated.

Anonymization of data
The CoP will not handle sensitive patient information other than when it is already publicly available in reports or as aggregated data. Data collected trough for example polls with stakeholders is presented in aggregated form and thus anonymized by design.

Stakeholder type and associated procedures to ensure engagement and assurance of consent

Patients
As stated in D2.4 The engagement of patients and citizens is needed throughout the PiPPi project since they play an essential role as stakeholders at the point of service of the delivery of care. Patient involvement is central to the pursuit of sustainable allocation of financial resources in healthcare, as patients who know how to navigate through the healthcare system tend to use more efficiently resources available. Engaging patients both through the patient/citizen advisory group and other forms of participation enables for a better assessment of patients' needs, envisioned outcomes and expectations, all of which are key at different stages of the innovation procurement process. Doing so ensures that resources are allocated where it matters most to patients and improve acceptance of the innovation, in line with the highlights of the 2017 OECD report on tackling wasteful spending on health (OECD, 2017).

The engagement of patients will follow a dynamic process according to the stage of the CoP and the profile of patients (see Table 1). For this purpose, different levels of patient engagement are defined, following the classification proposed by the International Association for Public Participation (IAP2) Patient Participation Spectrum (International Association for Public Participation, 2014). Three different levels of engagement are considered relevant for our context.

1. Inform: patients will receive information to assist them in understanding problems, opportunities and/or solutions for unmet needs. Patients for example may receive the

information through newsletters or the webpage. This is the lowest level of engagement in the project.
2. Participate: patients will provide specific feedback on analysis, alternatives and/or decisions related to unmet needs. Patient input may be obtained through quantitative or qualitative methods (such as focus groups or surveys).
3. Collaborate: patients will provide data and resources to obtain feedback as consultants in specific stages of the project through participative techniques such as working groups. Collaboration is the highest level of engagement.

Ethical principles will be guaranteed in accordance with national, Union and international legislations, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Particular attention will be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.

Voluntary participation. Participation throughout the course of the PIPPI project is strictly voluntary and can be terminated at any point upon notification. The termination of the participation will be possible without any consequence for the participants. All participants will be informed about their voluntary participation in the informed consent to participate.

Contact with patients/citizen. First contact with patients or citizens will always be carried out by a designated gatekeeper of the association, the partner institution (personnel from a hospital's customer service unit or clinicians) or by the PCAG. All participants will be informed about project objectives, implications and their obligations and responsibilities.

Prior informed consent. Patients will be informed and asked for their consent upon first contact. Consent forms will be adapted for each nation's legal framework and each specific activity by a team of legal experts and at least will include the following items:

- Consent to have your contact details stored in the PIPPI CoP contacts directory
- Consent to be contacted with regards to specific activities of the PIPPI Project
- Consent to be informed of news, activities and events regarding the PIPPI Project
- Consent to have any anonymously collected data be used for the purposes of the PIPPI Project.

Participants will receive an informed consent form and a detailed information sheet in their national language. Annex 1 contains a preliminary template of the informed consent form.

Privacy, data protection and management. Data related with the health status of participants will not be asked, used or stored at any point of the project. PIPPI members will not have information regarding patient health status, as gatekeepers will be the ones contacting patients and citizens and for the open call this information will not be asked. The team of PIPPI project (as described in deliverable 1.9) will guarantee the compliance of national and Horizon 2020 ethics

requirements, ensuring that any data collected is managed according to regulations and directives. The PCAG personal data will be protected in accordance to the General Data Protection Regulation (GDPR). All partner institutions involved in patient identification and selection will appoint a Data Protection Officer (DPO), the details of whom will be made available to all data subjects involved in any activities that require data process.

With regards to the other stakeholder types identified the situation is considered similar in that only contact details are expected to be collected:

Industry
Only contact details for the representative of the organisation is collected and requiring consideration with regards to data management. Commercially sensitive info is managed via NDAs and/or existing internal procedures for interaction with the PiPPi beneficiaries and the organisation in question.

Enablers
Only contact details for the representative of the organisation is collected and requiring consideration with regards to data management.

Payers
Only contact details for the representative of the organisation is collected and requiring consideration with regards to data management.

Hospitals/Healthcare providers
Only contact details for the representative of the organisation is collected and requiring consideration with regards to data management.

Policy makers
Only contact details for the representative of the organisation is collected and requiring consideration with regards to data management.

Research & innovation Community
Only contact details for the representative of the organisation is collected and requiring consideration with regards to data management.

Future Procurement Projects
In addition, PIPPI will abide by any and all confidentiality requirements as laid down in each country's specific public procurement legislation.

It is expected that data collected during the PiPPi project will be transferred to the CoP once it is established and operational and form an initial base for the CoP to build upon. This will, however, be subject to renewed consent from each stakeholder engaged in PiPPi regarding the engagement in the final cop format

FAIR Data
Table 7.1 below shows the confidentiality level of different types of data. Confidential data cannot be readily shared. Data that is not confidential can be shared but this does not necessarily mean it will be publicly published as the project does not have the tools or resources to make everything publicly available in a suitable format.

Table 7.1 - Data type and level confidentiality

Data Type	Confidential	Justification
Stakeholder contacts	Yes	Information collected is for professional contacts but due to potential misuse by automated spam programs we cannot publish them, data can however be shared upon request from credible organizations if this conforms with given consent.
Survey Data	No	Aggregated survey data can be published as long as individual respondents cannot be identified.
Collection of unmet needs	Partly	Unmet needs can be published if they are not subject to a procurement process and associated confidentiality
Workshops data	No	Aggregated data from workshops can be published if individuals cannot be identified.
Procurements examples	No	These are made available explicitly to share and learn from and should only contain non confidential information.

Making data findable

A core challenge for the PiPPi CoP is that most data collected is of qualitative type and often unstructured. For the foreseeable future this will likely be the case even after the PiPPi project. How to make this data accessible and reusable so that experiences and lessons learned can be retained in an effective manner is a challenge that will not be solved by the project but will be a continuous activity in the CoP and needs to be supported by the PiPPi platform.

8. Copyright and intellectual property ownership

Within the PIPPI project, all rights such as copyright and intellectual property ownership of results such as novel technology, processes, databases and trademarks shall be agreed upon between the parties within the PIPPI Consortium/Partner Agreement.

When information is shared between PIPPI parties and third parties, individual agreements or non-disclosure agreements shall be established governing potential copyright and intellectual property concerns.

The PIPPI name and logo may be considered to be protected by trademark, this is to be decided by the PIPPI consortium. Projects ensuing from the PIPPI collaboration, such as procurement projects, will establish its own regimen as regards IPR's in accordance with any and all applicable IPR legislation.

9. Project data responsibilities

The project uses Microsoft Teams, a mix of on premises and cloud-based collaboration tool. All data, such as meeting notes, presentations, studies etc. produced during the project activities will be stored and shared in that environment. The service provides an authentication function. However, this is not a strong authentication (two-factor) and the service cannot therefore be used for confidential and primary information. Due to the nature and scope of the PIPPI project, where limited sensitive data is expected to be produced (WP2), the solution is considered adequate for now. Any and all ensuring challenges in this area will be resolved by the relevant WP.

In addition, the intention is to setup a dedicated email domain for the CoP that can be used for communication with stakeholders. A third-party email host will probably be contracted for this purpose as the CoP should be independent.

Karolinska University Hospital has a Chief Information Security Officer, CISO, who has the responsibility for and is appointed to the role of Karolinska Data Protection Officer (DPO) in the project. Each other party will appoint their own DPO for the management of their own data.

If the project needs to share confidential data, it must be encrypted, with an emphasis on the privacy of the originator and recipient identities.

In addition, all individual participants from the project partners will give their consent that the project stores data about them, all in accordance with GDPR. Furthermore, specific to WP7, project emails to stakeholders are managed and sent using MailChimp and the Erasmus Medical Center congress management system. Both are GDPR-compliant and maintained by project partner Erasmus. Current stakeholder emails have been collected with explicit consent through the WP2-coordinated workshops. Furthermore, new stakeholders will have the opportunity to sign up to join the CoP and/or to receive information directly through the website or through registration forms. Any data collected for scientific research reasons will be strictly through informed consent and all appropriate ethical and/or data protection regulations and processes will be followed as indicated.

10. Allocation of resources and data security

Estimated costs of resources for making the appropriate project data open access* and the potential value of long-term data preservation, such as procedures for data backup and recovery, transfer of sensitive data, and secure storage in repositories for long-term preservation and curation, will be determined during the development and deployment of the technical platform (WP4).

* The question regarding “open access project data” will be further addressed after a thorough analysis of how stakeholder interaction will be conducted during and after the PIPPI project.

11. Explanation/description of requirements from the ethics review

Although no sensitive data is expected to be produced or handled during the project, the DMP, as stated in the GA, include an explanation/description that/how:

- ✓ All of the data which are processed in the PIPPI project is relevant and limited to the purposes of this specific project (in accordance with the 'data minimisation 'principle).
- ✓ The technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects involved as stakeholder/advisor patients.
- ✓ Anonymisation/ pseudonymisation techniques that will be implemented.
- ✓ In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary/partner has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects.

N.B With the document being considered a live document, answers to the above matters will be addressed during the course of the PIPPI project.

2.1. The procedures and criteria that will be used to identify/recruit patient stakeholders involved in the projects will be clarified and submitted as a separate deliverable.
Response: this is part of the revised Deliverable 2. 4.

2.3. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) will be kept on file.
Response: Please see Annex 1 for an example of the consent form used and which will be kept on file.

2.4. The applicant must clarify whether children and/or adults unable to give informed consent will be involved and, if so, justification for their participation must be submitted as a deliverable.
Response: No children or adults unable to give informed consent will be involved.

2.5. In case children and/or adults unable to give informed consent are involved, details on how the consent of the legal representatives (and assent, when applicable) will be acquired must be submitted as a deliverable.
Response: See answer to 2.4.

4.2 The host institution can confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research.
Response: All subjects are informed about who to contact. In case they are requesting their data to be changed or deleted, in accordance with the GDPR regulation. However, the title of this contact person might vary depending on the beneficiary and in some cases involve someone not only in charge of the project but rather the organization as a whole.

4.4 An explanation will be added of how all of the data intended to be processed is relevant and limited to the purposes of the research project (in accordance with the 'data minimisation 'principle). This will be specified in the Data Management Plan to be submitted at M06 (T1.4). (Deliverable 1.9). The information will include results and work conducted in WP2 and WP4 (under the responsibility of the respective WP leader).
Response: As mentioned the only data collected in the PiPPi project involves contact details to the representatives of each stakeholder organisation.

4.6 A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects involved as stakeholder/advisor patients will be specified in the Data Management Plan to be submitted at M06 (T1.4) (Deliverable 1.9). The information will include results and work conducted in WP2 and WP4 (under the responsibility under the responsibility of the respective WP leader).
Response: Everyone contacted by PiPPi have been informed on where to turn in case they want to remove or change their data. This process will also be managed in WP2.

4.8 Description of the anonymisation/pseudonymisation techniques that will be implemented will be specified in the Data Management Plan to be submitted at M06 (T1.4). (Deliverable 1.9). The information will include results and work conducted in WP2 and WP4 (under the responsibility under the responsibility of the respective WP leader).
Response: Besides from the contact list being compiled, only aggregated or public data (already anonymised) is collected. Thus, no such technique is needed for now.

4.15 In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects will be specified in the Data Management Plan to be submitted at M06 (T1.4). (Deliverable 1.9). The information will include results and work conducted in WP2 and WP4 (under the responsibility under the responsibility of the respective WP leader).
Response: As outlined in chapter 7 procedures for stakeholder contact is in place and managed in WP2. The data collected involve contact data for most stakeholder groups but an additional process step is in place when involving patients (see also Annex 1).

4.16 The beneficiary will evaluate the ethics risks related to the data processing activities of the project. This includes also an opinion if data protection impact assessment should be conducted under art.35 General Data Protection Regulation 2016/679. The risk evaluation and the opinion will be submitted as a deliverable. (Deliverable 1.9). The information will include results and work conducted in WP2 and WP4 (under the responsibility under the responsibility of the respective WP leader).
Response: Due to the type of data collected, the analysis for period 1 indicated that this risk is considered minimal. The management of sensitive data will be managed according to existing legislation relevant to each beneficiary (please see our response to 4.15). However, the need for such an assessment might arise in period 2 and on a case-by-case basis, within the regular project work. This will be monitored & discussed during the status meetings and full team events. If such a need arises, it will be executed within the respective WP.

Annex 1 - Patient Citizen informed consent

Prior informed consent for the H2020-PIPPI Patient Citizen participation

Project: H2020 PIPPI (GA Nº826157)

Aims

We request your participation in the project, which main goal is to develop a better way to work together on the digital transformation of healthcare, by incorporating patient participation. It is important to incorporate your opinion through the project, for example identifying and verifying new areas of improvement or studying the best way to contact and train patients with punctual participation during the project. Your participation in the project will involve your attendance to meetings to debate and interviews, but in any case it will not imply medical visits nor usage of medical data.

If you accept to participate in the project, you will be part of the patient advisory group of the H2020-PIPPI. You will have the opportunity to actively participate in meetings and other events to guarantee the success of the project. If you give your consent you will be part of a multidisciplinary team working in an European project to develop the hospitals of the future.

Benefits

It is possible that your participation in the project does not lead to direct benefits. However, patient involvement is central to enable better assessment of patients' needs, envisioned outcomes and expectations, all of which are key at different stages of the innovation process. Therefore, your participation will help to find adequate and better solutions to patient needs

Personal data protection

According to the European and national personal data protection law, personal data obtained will be the necessary for the purpose of the project. We inform you that the Foundation Hospital Universitari Vall d'Hebron -Institut de Recerca (VHIR), with NIF G-60594009, Barcelona -08035- Passeig Vall d'Hebron 119-129, Edifici Mediterrània, 2a floor, it is responsible for the personal data and will process it in a transparent and loyal manner.

The purpose of the processing of the data is being able to participate in the project entitled: H2020-PIPPI.

The recipient of your data is VHIR, or other authorized personnel, and they will have to keep the confidentiality of the information according to the law. In any case your personal data will be transferred without your previous consent, with the exception of legal obligation according to (UE) 2016/679 to the people who can demand it. International transfers are not foreseen, however in some cases it could be done.

Personal information will be kept under secure conditions by: TBD[3]

The legal basis of the processing is your given consent, which can be revoked at any time. However, if you do not give your consent for process your data, you will not be able to participate in the project. Automatic decisions regarding personal data will not be taken, including profiling. Personal data will be processed during the time that they are useful and necessary for the purpose they have been taken, or until you revoke your consent or you ask for its suppression.

but personal data can be kept for legitimate reasons or in the exercise or defense of possible claims.

[3]TBD: to be determined

In any case you will be able to exert your right of access, modification, opposition, limitation, portability and suppression or cancelation of your consent.
According to the regulation (UE) 2016/679, VHIR has designed a delegate for data protection: dpd@ticsalutsocial.cat.

The legal unit of the Foundation we will solve all the doubts, complaints, clarifications, suggestions and we will attend to the exercise of the data subject's rights, through the electronic mail: lopd@vhir.org.
You can also do a claim to the Control Authority in data protection.

Voluntary participation and revoke right of the consent
Your participation in this project is voluntary and you can change your decision and revoke the consent any time.

If you need further information regarding this project contact with: TBD
Telephone: TBD

Informed consent

Title of the project: H2020-PIPPI.

I _____ (name and surname of the participant)

I read the information gived by the professional that signs this consent regarding:

- ☐ The project
- ☐ Where personal data will be obtained, stored and processed,
- ☐ My participation in the project is voluntary
- ☐ I can revoke my consent in any moment, request the erasure of the persona, data and withdraw from the project without explanation.
- ☐ I have the right to access, rectify, restriction, portability and erasure of personal data.
- ☐ I understood the information and I have asked all questions that I considered to TBD

With my signature I confirm that:

- ☐ I give my consent that I will be able to revoke my consent in any moment, and I accept to participate in the project.
- ☐ I give my consent to the responsible of the project to contact me in the futur for specific activities regarding PIPPI project.
- ☐ I give my consent to the processing of my personal data according with the information read in the personal data protection section
- ☐ I give consent to have my contact details stored in the PIPPI CoP contacts directory.
- ☐ I give consent to be informed regarding news, activities and events related with PIPPI project.

Barcelona, _____de _____de 20_____

Participant:

Name of the participant (over 14 years old): _____

DNI: _____

Signature: _____

Tutor o legal representative _____

Name of the legal representative:_____

Identification number.: _____Relation: _____

Signature of the authorized person:_____

Declaration of the person who has informed to the participant:

Name of the authorized person: _____

Identification number: _____

Signature: _____