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Deliverable Summary

This Data Management Plan in its M6-version provides a framework that covers matters, rules and procedures in the project for ensuring appropriate quality assurance of the project implementation and sustainability of results beyond the project. During the Invest4Health project needs of data collection and management will be considered from four main perspectives with data from the latter three identified in detail early in the project; project management perspective, business management perspective, and Use-cases and regional test-bed perspective.

In addition to this report the project plan includes *an Updated Data Management Plan*, updated after review of concluded project activities with a particular focus on data management in modelling (financial, business), intervention analysis and outcomes, collaboration platform, and general governance of collaborative initiatives.

During the project review at RP1 the project did receive comments from the experts involved on the Data Management Plan (D1.2). The project was requested to update the Data Management Plan accordingly, which has been the main reason for a version 1.1.

This updated version of the Data Management Plan is planned as D1.3 and includes insights fain during Report Period 2 (M19 - M36).

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Table of Contents

DISCLAIMER 2
Deliverable Summary 3
List of Authors 4
Document (Data Management Plan) History 4
1 Introduction 6
1.1 Open access to research and guiding principles 7
1.2 Invest4Health and GDPR 8
1.3 Proceeding from D1.2 Data Management Plan 9
2 Invest4Health perspectives on data management 10
2.1 Main perspectives on data management in I4H project 10
2.2 Invest4Health testbeds – organization and governance 11
2.2.1 Informed consent 13
2.2.2 Data management aspects in relation to design of the digital collaborative platform 14
2.3 International data transfers and non-EEA countries 15
2.4 Complementary information at RP1 16
2.4.1 Main purpose of I4H data management 16
2.4.2 I4H data management principles and processes 16

1 Introduction

The starting point of Invest4Health is that European health systems are unsustainable and not fit for purpose. Certainly, for the last 30 years the focus has been on short-term easing of pressures due to continuing financial instabilities while the dominant care model embedded patterns of demand that locked funds into increasingly costly treatment and care. While hospitals retain political and emotional capital – with the hospital-centric model consolidated across Europe in the 80's and 90's – they have failed to meet the needs and challenges of increasing inequalities, the burden of chronic diseases and mental ill health. The complexity of health in modern societies and the increasing scarcity of resources to address them, we need more creative ways to maximise public sector assets. *The project focus is on stakeholders in health ecosystems working together to plan and finance health promotion and disease prevention (including future pandemic readiness) at population, community and individual levels.* **This shifts us from hospital-centred to community-based, people-centred and integrated services enabled by relevant social and technological innovations. The anchoring concept for this project is smart capacitating investment. This means that the stakeholders share risks and resources to invest at scale across multiple levels within health ecosystems, generating sustainable returns and localised benefits.**

Understanding and implementing smart capacitating investment depends on generating and integrating knowledge stemming from both social science and humanities disciplines and non-SSH (Special Sciences and Humanities) disciplines. How this will happen, is evident across the three workstreams and 8 work packages of Invest4Health and in the consortium composition. In this sense, Invest4Health is transdisciplinary. It draws together theories and approaches to form a shared conceptual and analytical framework for smart capacitating investment – producing an integrated story. The contextual knowledge consists of a range of components, such as (i) knowledge of relevant actors and stakeholders in the localized intervention ecosystem, (ii) pain points and triggers relevant for the localized intervention, (iii) comprehensive data sets, primarily at a system level, forming the basis of design, implementation and evaluation of the defined interventions. In the context of this Data Management Plan (iii) is most applicable to be discussed, but also how access to a broad set of relevant data can incentivise stakeholders, with reference to (i), to become engaged in collaborative initiatives.

As referred to in the ethics annex of the INVEST4HEALTH original proposal;

> Interventions are demonstrated as part of WP6 activities (testbeds), involved stakeholders and groups will be identified as part of the design of the collaborative platform (WP3). Objectives of the activities are not about study of vulnerable populations. Citizen panels will be supported in line with relevant ethical principles and protocols on the pilot testbeds. The citizen panels have been structured to ensure ethical compliance in the sense of co-creation and co-design, referring to the PFMD (Patient Focus (Medicine) Development) frameworks and the 7 principles of patient engagement that are in use for different areas of the project cycle. This means the testbeds do contain aspects of both of the above, i.e. relevant and appropriate patient involvement in throughout the development process. The patient engagement approach will vary depending on context and situation, and will be unified under the evaluation framework feeding into WP8.
>
> Project activities are designed to avoid negative environmental impact, regarding particular social groups, adverse financial consequences, etc. In the context of WP8 CSR and environmental impact are taken into account as well as the need for representation of underrepresented groups, minority communities and diversity.

About this version

As discussed in Section 1.3, during the project review process at RP1 (M18) the project got a request to update the Data Management Plan and in particular section 2, which resulted in a version 1.1, The version 1.1 included updates reflecting on initial learnings from the project testbed activities on the data management perspective.

The updates in this version of the Data Management Plan (version 2.0) have thus the objective to include insights and experiences gained during Reporting Period 2. The specific focus of this deliverable, see section 2.2.2, has thus been on the experiences from "the design of the collaborative platform" as reported by WP3 in D3.1

1.1 Open access to research and guiding principles

The Invest4Health Open research data policy will follow the EC open science – research data guidelines, applicable in Horizon (2020 and Europe) funded projects[1] , under the responsibility of Work Packages 1 and 8, and the researcher(s) developing content for publication. Open access (OA) refers to the practice of providing online access to scientific information that is reusable and free of charge to the end-user.

[1] https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/our-digital-future/open-science_en

The EU offers Open Data Platforms, for presenting research data and making it accessible. Relevant data generated by the Invest4Health project will also be accessible through these platforms. There are no limitations to the data to be stored, other than that the data must comply to General Data Protection Regulation (GDPR).

1.2 Invest4Health and GDPR

General Data Protection Regulation (GDPR) is the current legislation for data protection, processing and protecting personal data in the EU. Invest4Health is focused on developing and testing investment, business and governance models for smart capacitating investment in health promotion and disease prevention with decision-makers and citizen panels in four regional test-beds. During this testing and validating process, there will be research components where personal information is processed, controlled and managed within the project. By adhering to GDPR, we ensure that personal information processing is conducted lawfully, fairly, and transparently in the project. This document describes the purposes of data management, the different types of categories of data which may be applicable, and general procedures on a project management level for the appropriate collection, management, and access to that data.

One of the cornerstones of GDPR is the identification and definition of distinct categories of data, which can then be collected, accessed, managed, stored, and archived according to general rules and guidelines. Importantly, particular attention is paid to 'special categories of data' (such as personal health data) to ensure appropriate management of such data. In relation to the Invest4Health project the testbeds and local interventions will for their specific objectives access and manage special categories of data such as personal health data. However, it is important to note that from the Invest4Heath project perspective and objectives these special categories of personal data sets are unlikely to be managed by the Invest4Health project team, but more likely by the activities within the localized testbeds that are related but not fully integrated into the project. The Invest4Health project objectives are more focused on exploring anonymized data at population or at group level, and data sets at system level.

As discussed below in section 2, several types of data falling outside of the definition of special category-data are likely to be collected and managed by the project (such as public records/deliverables, project management data, and data collected through interviews). The data will be managed appropriately according to context and type, including consent management, when applicable.

Project partners, including universities, research organizations, and others, will comply with their ethical research guidelines or research ethics policies, which encompass GDPR rules. However, we highlight the following points for consideration that are the most relevant to I4H.

Lawful Basis for Data Processing *(Article 6 - Lawfulness of processing)*	We will ensure that if personal data is processed, it will be based on a valid legal basis, such as obtaining consent, fulfilling a contract, or meeting a legal obligation.
Data Minimization and Purpose Limitation *(Articles 5 - Principles relating to processing*	We will collect and use only the necessary, minimum amount personal data if required, ensuring that it is used solely for the stated research purposes.

of personal data, 6 - Lawfulness of processing)	
Informed Consent for the Participants *(Articles 6 - Lawfulness of processing, 7 - Conditions for consent, 13 - Information to be provided where personal data are collected from the data subject, 14 - Information to be provided where personal data have not been obtained from the data subject)*	If required for the research, we will obtain explicit and informed consent from participants for data processing, providing them with understandable information about the research purpose, data processing, and their rights. We will ensure participants understand the research's purpose, risks, why it benefits them and how we will use their data.
Data Security *(Article 32 - Security of processing)*	We will use security measures to keep personal data safe. This can include: using encryption; controlling who has access to the data, and; regularly checking for any security risks. Accordingly, we protect the data from unauthorized access or loss.
Data Subject Rights *(Articles 15 - Right of access by the data subject, 16 - Right to rectification, 17 - Right to erasure (or "right to be forgotten"), 18 - Right to restriction of processing, 21: Right to object)*	We will respect people's rights to access, correct, delete, limit, and object to their data. We will ensure individuals have control over their personal information and can decide how it's used.
Data Retention and Deletion *(Articles 5 - Principles relating to processing of personal data, 17 - Right to erasure ('right to be forgotten)*	If collected, we will retain personal data only for the necessary research period and will have procedures in place for the secure deletion or anonymization of the data.
Data Processing Agreement *(Article 28 - Processor)*	If we share personal information with others, like third-party service providers or collaborators, we will make sure they follow the rules too. We will have a special agreement that outlines their responsibilities and ensures they comply with GDPR requirements. This way, if any personal data is shared or transferred, it will be done in a safe and legal way, with the right protections in place.
Record of Processing Activities *(Article 30 - Records of processing activities)*	We will keep a record of how we handle data, including why we use it, who the data is about, if it's shared with anyone, and how long we keep it. This helps us stay organized and accountable for our data processing activities.
Data Protection Officer *(Article 37 - Designation of the data protection officer)*	If our project may involve large-scale regular and systematic monitoring of individuals or processing of sensitive data, we consider appointing a Data Protection Officer.

Table 1 I4H GDPR specifications

1.3 Proceeding from D1.2 Data Management Plan

The Data Management Plan is a project deliverable to be submitted to EC by month 6 of the project. We recognize that for all project activities (and testbed interventions) designs for the appropriate collection, access control, security measures and overall management of data are yet to be outlined and implemented. This means that for the project consortium and activities the submitted D1.2 at month 6 of the project intends to serve as a framework upon which specific, detailed activities and measures can be developed (and implemented). As part of the concluding project activities an

Updated Data Management Plan (D1.3) is to be published by Month 40, adding and incorporating data management efforts, considerations and lessons learned throughout the project. To ensure a quality focus on data management, draft versions of the M40-version will be regularly updated during the continuation of the project.

During the project review at RP1 the project did receive comments from the experts involved on the Data Management Plan (D1.2). The project was requested to update the Data Management Plan accordingly, which has been the main reason for this version 1.1. Most of the additional information requested by the experts are given in section 2.3 Complementary information at RP1. The information added in version 1.1 could be seen as a first contribution to the month 40 deliverable (D1.3).

2 Invest4Health perspectives on data management

2.1 Main perspectives on data management in I4H project

During the Invest4Health project needs of data collection and management will be considered from four main perspectives with data from the latter two identified in detail early in the project:

1. **Project management** - Data management necessary for securing quality and efficient implementation of project activities, such as collection of data for purposes of internal communication through mailing lists and Teams, KPI tracking, project meeting logistics, qualitative and quantitative financial management.
2. **Business and stakeholder management** - Data management for exploring and developing secure long-term sustainability of project results, with the purpose of developing appropriate business models for target environments, and collaborative multi-actor ecosystems. The collaborative platform explored and implemented as part of WP3 activities will be an important component for the purposes of storing, giving access to, and management of relevant data sets.
3. **Use-cases and regional testbeds** - The project methodology will, through identified use case environments and test beds, develop and demonstrate scenarios with high potential for adaptable and improved financing models for "sustainable" health initiatives. For these environments to be fully explored, data from several sources will be appropriate to retrieve, such as (but not limited to) demographic data, socio-economic (at population level as well as at group level), infrastructure, public health-related data. From a general point of view testbed-related data can be split into two distinct sets of data:
    a. Individual data. These may be special category of data, such as personal health data, or other types of data such as from collected in interviews in relation to the specific testbed activities. Principally these data subsets (on an individual level) remain accessible only to the local testbed actor(s)

   b. Aggregated data of interest to the Invest4Health project team, such as relating to the validation and assessment of the testbed financing model, population or group data, data reflecting outcomes and impact at a system level.

4. **Stakeholder interviews and questionnaires** – Several WPs will conduct interviews with or administer questionnaires to experts and stakeholders involved in SCI beyond the test-beds. These stakeholders include investors, citizens, national and subnational governments, formal and informal health and social care providers etc. The data collected through the interviews and questionnaires pertain to the investment models, finance models, business models and governance models used for SCI and the importance of certain outcome measures and decision criteria.

The project adheres to a general approach towards data management guided by the general principles of data management, being

- Collection of data shall be fit-for-purpose and determined to be of value for project implementation of appropriate reporting of its activities (and results).
- Collection of data shall adhere to the principle of data minimization, meaning the extent and scope of which data is collected shall be limited to what is necessary (for the purposes of the project)
- The management and storage of data shall adhere to the principle of storage minimization, meaning the extent and scope of stored data shall be limited to what is necessary (for the purposes of the project) whilst adhering to applicable archiving regulations.

Regardless of data type, origin and purpose any project activity will be conducted in accordance with EU's General Data Protection Regulation 2016/679 (GDPR), The European Code of Conduct for Research Integrity, EU's Charter of Fundamental Rights, and the guiding principle of the Declaration of Helsinki. Moreover, in the implementation of GDPR in national legislation, procedures and policies, project activities in general and the localized testbed intervention in particular will comply with any national legislation, policies and procedures governing the localized testbeds (and actors, relatedly).

2.2 Invest4Health testbeds – organization and governance

Organisation and governance from the ethics and data management perspectives will fully comply with the legislation mentioned above. To ensure compliance each testbed of the 4 localised testbeds will for each local intervention and testbed assign an Ethics & Data Protection Officer (EDPO) for assisting in local interventions requiring ethics and data protection measures. The EDPO will collaborate with the test manager/coordinator for each intervention/test bed site, and the project ethics responsible. As the relation management to the testbeds are part of Work Package 6 the following image can be found for illustrating the organization of data and ethics management in relation to the testbeds.

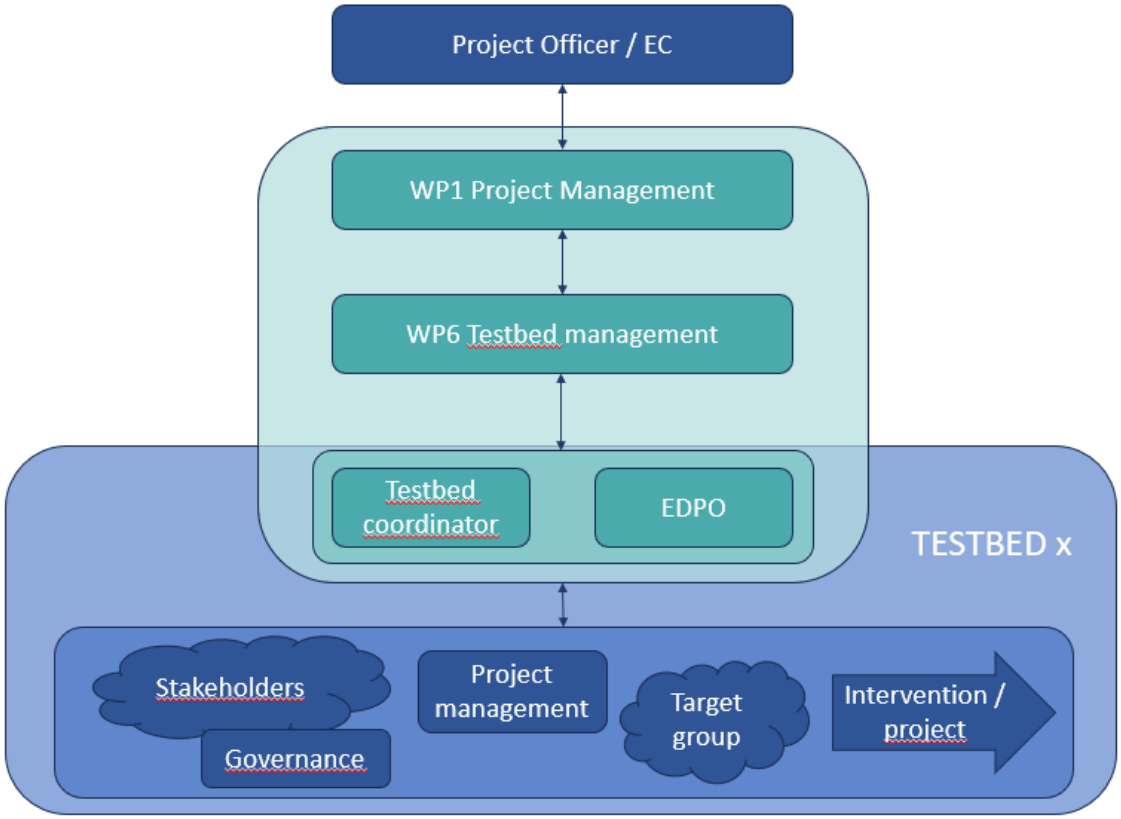

Figure 1 Organisation of testbeds roles; data and ethics

Referring to the overall categories of data listed in the introduction of this chapter, specifically type 3 *testbed data;* For each of the 4 local testbeds the following data sub-categories might be of interest, as the interventions and their relation to the research conducted in Invest4Health have been defined more precisely:

a) Personal data/health data
b) Quality registry data
   Data made available from historically collected data, typically from registration in various diagnosis-specific data archives, for research purposes. The scope of the collected data (in terms of data categories) vary from registry to registry, and are reliant upon regionally or nationally agreed upon data structures (including format and terminology). Typically, the data collection is based upon the principle of data minimisation. The relevance of the data is likely to be highly dependent on the type of research service provided by the specific supplier(s) awarded for Phase 3 field testing. Research involving this type of data is unlikely (by itself) to be considered a clinical trial, this does not mean that clinical approval will not be required for using specific data types for the research purposes in the Invest4Health project. Handled by procedure below.
c) Pseudonymised data
   Data that has through technology or a set procedure fully or partially removed the direct link to an individual, for example by using keys, or table of identifiers linking a fictional ID to the individual. While pseudonymisation can provide individual data subjects with a degree of protection and anonymity, *pseudonymised data still fall within the scope of personal data because it is possible to re-identify the data subject.* Applicable types of data

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may be internally available to IT dept´s of Healthcare organisations for the purpose of developing maintaining internal system for healthcare management, patient logistics, process logistics, healthcare staff, or other, purposes. The relevance of the data is likely to be highly dependent on the type of research service provided by the specific supplier(s) awarded for Phase 3 field testing.

d) Anonymised, synthetic or similar data
Data which might be similar in structure and format to the types mentioned above but fully and irreversibly anonymised. These are exempt from (GDPR) requirements.
e) Aggregated data sets, such as data sets related to the evaluation and validation of the testbed financing model, population or group level data sets, data sets reflecting outcomes and impact at a system level
f) Qualitative data from interviews with experts and stakeholders within and beyond the testbeds.

Whilst it is expected that the data collected related to the Invest4Health project by each individual testbeds will rarely be personal special category data, since the project is more focused and concerned by exploring the business case of the intervention, the allocated EDPO will ensure that ethics considerations have been adequately explored, prepared and procedures followed.
All collected, managed and shared data are subject to classification in terms of sensitivity and handled accordingly. It is expected that while most data related to project management will be of non-special category type[2], data related to data platform(s) and personal data (related to the testbeds) may include the collection and management of special category data, such as;

a) Population Health data, socio-economic data
b) Data related to evaluation and validation of intervention outcomes and impact,
c) Results classified as foreground, IPR. The ownership of and access to such data is described and agreed upon by the consortium in the Consortium Agreement.

Related to (a) and to some extent (b) this is data generated in, or in relation to the intervention planned in the 4 localised project testbeds[3]. From the Invest4Heath project perspective special categories of data are unlikely to be managed within the project, or the testbeds relation to the project, as the project purposes are more focused on exploring anonymized data at population or group-level (as described in 1.2 Invest4Health and GDPR)

2.2.1 Informed consent

For data collection upon which the legal basis Informed consent is to be used, the procedure and the role of the testbed EDPO outlined above will ensure that locally applicable templates of the informed consent forms and information sheets (in language and terms intelligible to the participants) in regard to patient involvement and data processing are complied with.

Interested stakeholders and research participants will be asked to opt-in for research activities and to receive project communications. Consent will be informed and will be asked and tailored for each purpose and for each activity separately. Therefore, for example, research participants will be asked for a separate, specific consent to process their personal data in the context of the specific activity planned for each demonstration activity, in each buyers group location.

[2] Formerly known as 'sensitive data'
[3] A 2nd trache of testbeds will be implemented in the latter part of the project, procedures related to this report are expected to be similar as for the original testbeds.

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According to the general data types described in 2.2 the necessity of consent management is applicable in the case of case (a-c) personal, individual data. For appropriate and relevant consent to be able to be collected target groups will be provided with (i) instructions and relevant, easily understood background information on the given consent, and (ii) and form for providing their consent. When the specific characteristics of individual testbed (related to the project), the identified actors, and intended end-users have been defined appropriate documentation can be developed and provided.

2.2.2 Data management aspects in relation to design of the digital collaborative platform

In a parallel task to this update, WP3 has worked on a design guide for the digital collaborate platform. The results of that task are reported in D3.1 Technical guide on collaborative platform design, in where the principles of the Data Management Plan are applied and put into practice. The data perspective of the digital collaborative platform is described in “Section 4 Data” of the report D3.1.

By working on concrete use cases from the 4+4 testbeds available in the project, it has been verified that data management principles and processes, including the relevant data types, as specified below in section 2.4.2 are applicable and valid.

In the development of the design guideless, WP3 has provided examples of different types of structural data

> “The prototype relies on **structured data** representing users, programs, key performance indicators (KPIs), feedback, decisions, navigation, and testbeds, implemented with common primitive and composite data types”

thar can be mapped into the data types presented in the table in section 2.4.2. Examples on how these structural data set are modelled are given and detailed, which further strengthen the validity of the data types coved in the I4H Data Management Plan.

For example, the data type “business and stakeholder management” is further modelled as

> **“KPI data** are expressed as mixed-type fields, combining numeric and string values (counts, percentages, scores), optional units and colours, and categorical change directions, reflecting the heterogeneous nature of dashboard metrics.”

Abd the feasibility and applicability of the synthetic data type are detailed and further elaborated on as

> “To generate **synthetic data** for this prototype, a combination of rule-based and probabilistic algorithms can be applied. Rule-based generators handle the structural backbone — constructing consistent categorical fields and enumerations (roles, statuses, change directions) and enforcing business constraints such as valid route–role mappings, coherent program timelines, and allowable date ranges.”

The design guidelines do also touch upon and exemplifies principles for AI-based features:

> "In the prototype, **AI** can be described as a recommendation layer that operates on structured feedback, KPI, and program data and could be realized with a combination of natural language processing, predictive modelling, and ranking algorithms"

With these examples, it is argued that the WP3 activities on the digital collaborative platform have shown the applicability of the I4H Data Management Plan in real-world settings. An update of the principles and processes specified in section 2.4.2 are at his stage of the project not necessary, but it is recommended to revisit and further specify the information in the table in section 2.4.2 in case of each real-world setting.

2.3 International data transfers and non-EEA countries

Although no data of special category, used in the context of the testbeds, are expected to be shared outside of each local testbed, it can be noted that as part of the INVEST4HEALTH consortium there are partners from non-EU members (UK, Norway) which *may* represent a risk of data processed in the project being transferred to non-EU countries. However, EU data protection rules apply to the European Economic Area (EEA), which includes all EU countries and non-EU countries Iceland, Liechtenstein and Norway. In the context of the testbeds it is noteworthy that the testbed prepared in Wales is not governed by this.

When personal data is transferred outside the European Economic Area, special safeguards are foreseen to ensure that the protection travels with the data.

A risk identification and management procedure has indicated the risk of transfers of 'Special categories of personal data' between organisations in EU member states (or EEA) and actors from outside of the EEA. The European Commission's instrument for assessing these risks are Adequacy decisions; How the EU determines if a non-EU country has an adequate level of data protection. During the project duration, and after project conclusion, the management of those categories of data are expected to be in relation to the preparations of and research conducted in relation to the localized testbeds, for which it is described that any type of special category of data collected, processed and stored data is only expected to be accessible and processed locally (for the benefit of the local demonstrator site), meaning that transfer of personal (special category) data is unlikely. From the Invest4Heath project perspective special categories of data are unlikely to be managed within the project, or the testbeds relation to the project, as the project purposes are more focused on exploring anonymized data on population or group-level (as described in 1.2 Invest4Health and GDPR). In case research (such as efforts related to WP4) require access to particular types of data from local testbeds the data and procedure will be designed to comply with the procedure described above. Local ethics data protection officers (EDPO´s, as presented in 2.1) will ensure appropriate management of procedures and data processing at each demonstrator site.

2.4 Complementary information at RP1

2.4.1 Main purpose of I4H data management

The main purpose of data management in the I4H project is to provide data sets necessary for gaining insights and for the implementation and evaluation of the SCI concept in the context of the four regional testbeds. Most of these data sets are representing conditions and characteristics at a system level.

2.4.2 I4H data management principles and processes

To be able to deliver on this purpose, the project has to implement quality-assured data management principles and processes applied to the four main perspectives introduced in section 2.1. Each of the perspectives will require that the data management principles are understood and applied, and that effective process are defined and implemented within the project.

The data management principles and processes have to adhere to e.g.

- Who will own the data sets and take responsibility for principles and processes?
- How will the data sets be stored?
- How will access to data be controlled and managed?
- How to ensure that the general principles for data management are quality-assured over time and for the duration of the project

The common understand of the data management perspectives at the time of RP1 review is summarised in the table that follows. The table will be revised as the data management process are implemented by the respective WP being responsible for each of the four perspectives. An addition, architectural topics, such as how/where certain data sets will be stored, have not yet been decided.

Type of data		Owner	Storage	Access		EU/UK regulations
				Who	How	
Project management		WP1, WP8	I4H Teams file structure	I4H Partners,	Through CA agreement	respected
				selected individuals (e.g. CPAG and SAB Members)	Request to I4H Project Management	
Business and stakeholder management		WP3/WP6	tbd	I4H Partners, stakeholders through respective collaborative platform	Defined inI4H data management processes (common for I4H and per testbed)	Respected, transfer might be applicable for I4H
Individual health data	**Personal**	<local registry centre in testbed's context>	EHR system within testbed's context	Authorised personnel in testbed's context	Local processes	Respected (transfer not applicable for I4H)
	Pseudonymised		EHR system within testbed's context	Authorised personnel in testbed context	Local processes	Respected (transfer not applicable for I4H)
	Anonymised, synthetic	<local registry centre in testbed's context> and/or WP3/WP6	tbd	I4H Partners	I4H data management processes	Respected, transfer might be applicable for I4H
	Aggregated health data at group/population level		tbd	I4H Partners, stakeholders through collaborative platform	I4H data management processes	Respected, transfer might be applicable for I4H
	Quality registry	Quality registry centre	Held by Quality registry centre	On request, provides by QR centre	QR-specific process	QR-specific process
Research interview data		WP4	I4H Teams file structure	I4H Partners	Through CA agreement	Respected. transfer might be applicable for I4H