Citizen-centred EU-EHR exchange for personalised health

Smart4Health
Building today a healthier tomorrow

WP1: Citizen- and Professional-User participation: user requirements and performance criteria

D1.2: Report on the methodological design of the co-creation environment

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Short Abstract

Deliverable D1.2 provides the methodological design of the co-creation environment putting citizens centre-stage in the research, development and design processes of an interoperable prototype for electronic health record exchange. It outlines the co-creation processes as well as the considerations to be taken into account in designing and running the co-creation environment throughout the project.

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History

Versions	Description
D0.1	Draft version of the “Report on the methodological design of the co-creation environment” by UNIVIE produced on the basis of extensive input from consortium partners.
R0.1	Preparing a revised version after reviewer feedback from HPIHS and UNINOVA.
F1.0	Final version written by UNIVIE addressing the reviewer’s comments.

Contributors	Description
UNIVIE	Literature review on co-creation and previous projects, conducting partner workshops and interviews, analysis of the entire partner input, preparation and design of the co-creation environment.
UKA, UNINOVA, ZS-UG	Provision of CUC storylines to the consortium (March 2019).
HPI, D4L, HPIHS, UNIVIE	Workshop and group discussions on the 4HP scenario and CUC storylines (March 2019) facilitated by UNIVIE.
ZS-UG, UKA, ITTM, SHD, UNIVIE	Workshops and interviews on the 4HP scenario and CUC storylines (March 2019) prepared and conducted by UNIVIE.
EFN	Focus groups with representatives of nurses discussing different scenarios on how health care providers may access and use citizen's health data (April 2019).
UNINOVA, KBZ, UNIVIE	Group discussion on the 4HP scenario and CUC5 and CUC8 storylines (July 2019) prepared and conducted by UNIVIE.
OSR, UMC+, ELIXIR-LU, EFN, GovMad, UNIVIE	Remote interviews on the exploration of the 4HP scenario, delineation of user groups (and potential participants for USEEs) and of further collaboration (June - September 2019) prepared and conducted by UNIVIE.
ISMMS, UKA, ZS-UG, UNINOVA, SHD, UNIVIE	Brainstorming exercises on anticipated interactions of potential users in each CUC with the 4HP (July - August 2019) structured by UNIVIE.
HPIHS, D4L, HPI, UNINOVA, KBZ, UNIVIE	Several rounds of User Story Mapping workshop meetings, f2f and remote (May - August 2019).
All consortium partners	Co-creation workshop at the GA meeting on aligning work of CUC- and tech-partners (September 2019) organised by UNIVIE.

Further Information

www.smart4health.eu

Disclaimer

Executive Summary

The objective of Deliverable 1.2 is to outline the methodological design of the co-creation environment for the Smart4Health project. The central aim of Smart4Health is to develop a health data infrastructure to empower citizens as future users to manage their own health. In doing so, the project puts European citizens centre stage – conceptually and methodologically.

Producing an appropriate solution for a portable, interoperable citizen health data platform prototype will therefore proceed in a process of co-creation, involving citizens as well as diverse health-care professionals throughout the process of development, design and implementation. Through this approach, potential future users are put in the position of (1) playing a central role in identifying needs, but also problems; (2) expressing values and concerns; (3) proposing requirements to be met, and (4) being involved in the testing and assessing when gradually building the Smart4Health prototype.

Proposing a co-creation approach to building the Smart4Health Health Platform (4HP) and its services testifies to the consortium's awareness how important it is to build this platform in a way that meets the needs and concerns of future users, both citizen- and professional users. Not doing so might increase the risk that people refuse to adopt, build and make use of such an infrastructure or that they abandon it soon after initially inscribing to it. Furthermore, it is important to ensure the 4HP and its operational use guarantees unobtrusiveness and avoids attention theft. To reach this goal, we will have to understand and reflect on the impact the infrastructure and its services will and should take in future users' lives, as well as citizen's divergent capacities to engage with a health data infrastructure in the first place and, with this, a difference in attention requirements needs to be tackled.

The introduction to the deliverable (**chapter 2**) briefly sketches the reasons why we engage in co-creation. We underline that it is of key importance to bring different parties together in order to jointly produce a mutually valued outcome. Successful value co-creation will only be achieved if the 4HP and the connected services meet the user requirements and is best suited to user's health-related data practices. Furthermore, users should be able to perceive tangible benefits as this is an important motivational factor for long-term engagement. This also means building trust relations, as this is a key issue to ensure sustainable relations between (future) users of the 4HP and those running the 4HP.

In order to prepare the co-creation environment, in **chapter 3** the report presents current debates on co-creation, lessons learned from past and current EU projects as well as a number of key-concerns to be considered during the co-creation process. We will mainly use elements from three different understandings of co-creation: technology co-design and experienced-based co-design (EBD) are the two most central approaches, with elements of the value co-creation also coming to matter. The main points to highlight from this chapter are the attention to user recruitment, which needs to be broad and diverse, and to support users to articulate their needs and concerns. When it comes to the process itself, transparency about the scope and the limits of co-creation is essential and so is the justification of final design choices made. Furthermore, the importance of facilitating choice and keeping explorations open for as long as possible are highlighted. Taking these elements together points to the importance of appropriate facilitation all along the process.

In **chapter 4**, the report gives a detailed explanation of our general approach to co-creation (4.1) and describes the set of methodologies which will be used in different combinations along the whole process (4.2). The project speaks of a “co-creation environment” (4.3) in order to point to the fact that the co-creation will be happening all along the process of development, design and implementation and will consist of many different settings in which co-creation happens in parallel. At different instances of the project we will use different methods to engage with users, we will address different problem areas from the technical to the social. At different points in time (in 4 co-creation waves of 6-9 months) different parts of the consortium will be involved. We will go to different places – where the Citizen Use Cases (CUCs) happen – thus moving into different institutional environments (hospitals, factories, offices, leisure environments) as well as encountering different cultural settings and engaging with different sets of users. All along the process, partners involved in the CUCs, the technical partners as well as the social science partners will closely work together, the latter playing the role of broker between users and the Smart4Health consortium members. This chapter thus outlines the choreography, the timeline as well as processes, practices and methods of the co-creation environment. Yet, it also addresses ethical issues (4.4) related to the different decisions that users make when they register to the 4HP but also when they make important choices, e.g. to donate their data for research or to share data with a trusted person.

Chapter 5, finally outlines the user groups and roles we will engage with in the co-creation process and the CUCs participating in the “co-creation environment”. This clearly points to the size and complexity of the health data infrastructure to be used across different national/cultural contexts and to integrate different types of health data. But it also testifies to the multiple sites in which the consortium can engage with potential (future) users.

The deliverable concludes with a summary and final considerations (**chapter 6**). In essence, it reminds the reader why Smart4Health is engaging in a co-creation approach and did not venture in a top-down defined health data infrastructure. It points to the strong link that the practices of co-creation have with the sensitivities that were outlined in D1.1 and in particular what it means to think of the 4HP from a Responsible Research and Innovation (RRI) angle. This means to be attentive to giving voice to a diverse range of citizen-users and to carefully consider which societal values get embedded into and are realized through such a health data platform. The co-creation approach, however, also means that there will be a lot of interaction between the partners of the consortium in collectively working together with citizen-users towards a jointly produced and a mutually valued health data infrastructure. This is a strength of the Smart4Health project.

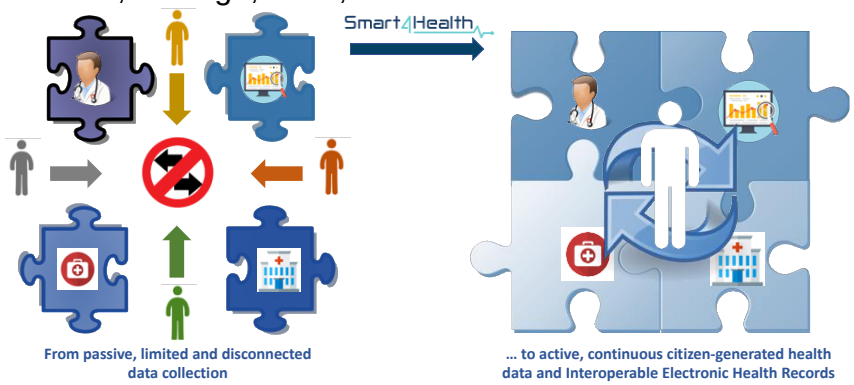
Table of Contents

1 Document Summary

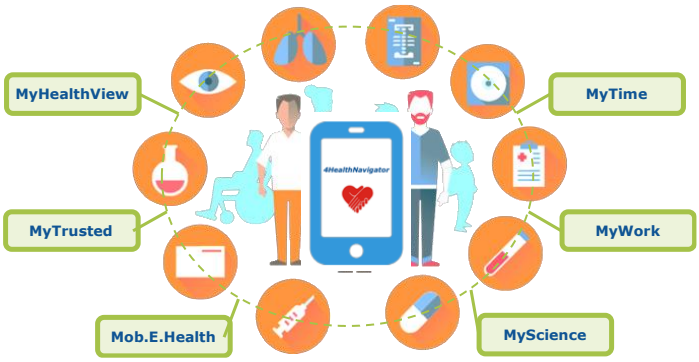
1.1 Smart4Health Project Overview

Smart4Health: Building today a better tomorrow

Smart4Health aims at empowering EU Citizens with an interoperable and exchangeable European Electronic Health Record (EHR) that will allow EU citizens to be active participants in managing their own health. The key objective of Smart4Health is to place **the citizen** in the centre of the decision of citizen health care. The citizen will be empowered with the possibility of sharing health data with different clinicians, medical centres, local and international societal and for research activities as well as to cooperate directly with health care providers. The 4HealthPlatform will allow citizens to collect, manage, store, access and share own health and health care data, through an easy-to-use, secure, constantly accessible and portable health data and services prototype within the EU and beyond. The 4HealthPlatform data layer connects with the 4HealthNavigator portal for services and applications to provide advanced personalised health services accessible whenever and wherever. Citizens will be able to upload data (from EHR, over self-collected data, to work-health related data) through the interfaces MyHealthView, MyTime and MyWork.



Also, they will be able to share data with persons of trust as well as with health care professionals in situations when reliable health information is essential to assure efficient health care (MyTrusted, Mob.E.Health). Finally, citizens willing to support research, can donate their data to the scientific community (MyScience).



The technological elements will be developed in a co-creation process using eight Citizen Use Cases. These cases cover all aspects of citizens' active role in using the 4HealthNavigator to access the 4HealthPlatform and to increase positive user experience and system usability. Citizens from different national, cultural and institutional health-related contexts will be able to interact with and test the different steps of health data management at home, at work, while traveling, or during leisure and sport activities. Smart4Health is based on a truly multidisciplinary approach with a project team constituted by eighteen beneficiaries from eight different European Union member states and the United States of America, including ICT developers, hospitals, social sciences researchers, physiotherapists, nurses, informal caregivers, regional government, research centres, universities and SMEs.

Smart4Health will contribute for a positive impact on EU citizens health and wellbeing, for building today a healthier tomorrow.

1.2 Deliverable Purpose and scope

The objective of D1.2 is to delineate the co-creation environment of Smart4Health and the iterative and collaborative processes therein as well as the methodologies that will be used. It, thus, substantially shapes the future work in T1.3, T1.4 and T1.6.

1.3 Impact and target audiences

This deliverable is meant for both project internal as well as external audiences. Building such a complex health data infrastructure to be used across different national/cultural contexts and which integrates different types of health data is a unique project in size and complexity. Therefore, it is essential for those working within the project to ensure that the citizen-users are integrated into the technical development – along the whole process and in the different sites where the 4HP is tested. By being very specific on the choreography of co-creation, D1.2 serves as a roadmap for the work to be performed. To the outside world, this report should demonstrate the consortium's awareness of the need for a co-creation approach and the exact procedure of its implementation.

1.4 Deliverable methodology

The report on the co-creation environment was produced as a first draft by UNIVIE. The report is (1) based on a thorough literature review of current debates co-creation as well as (2) on lessons learned from past and current EU projects. (3) Numerous discussions, workshops and interviews with the consortium partners doing technical developments as well as with those involved in the CUCs delivered further details for the co-creation environment. (4) We used the sensitive points identified in D1.1, which need closer consideration and reflection during the process of co-creation. (5) Finally, interviews with experts in co-creation - specifically also with those who deal with health and big data issues - gave additional input to the co-creation environment.

The feedback from consortium members was integrated in the revised version of the report.

1.5 Document Structure

The document is structured in five chapters. After an introduction to the report which clarifies the notion of "co-creation environment" (chapter 2), the report presents a focused review of the literature on co-creation, a number of lessons learned from previous other EU projects as well as a number of key-concerns to be considered during the co-creation process (chapter 3). In chapter 4, the report gives a detailed explanation of the processes essential to the co-creation environment and describes the set of methodologies which will be used in different combinations along the whole process. Chapter 5 outlines the user groups we will engage with in the co-creation process and the Citizen Uses Cases participating in the "co-creation environment". The report ends with a summary and some final considerations (chapter 6).

1.6 Document status

This is the final version of D1.2 outlining the co-creation environment of Smart4Health. No further updates are expected.

1.7 Ethics

This deliverable relates to questions on ethics in two ways. First, we describe in section 4.3 the ways in which we will consider ethical issues in our co-creation work with citizen and professional users. We outline the informed consent (IC) procedures for those participating in the different forms of engagement exercises that will happen.

Second, part of the co-creation process will be specifically devoted to the procedures of consenting (to using the 4HP as well as sharing and donating data), how citizens and professional users are informed and how basic values such as privacy and security will be ensured.

1.8 Dependencies and supporting documents

This document is directly related to D1.1 – "Social Sciences and Humanities Framework" which outlines the main considerations for developing the 4HP. Furthermore, it connects to D1.4 – "1st Citizen/User Consent Language Report" and to D8.1 – "H - Requirement No. 1" when it comes to developing and testing IC documents.

1.9 Main results

The main result of this deliverable is the establishment and delineation of the Smart4Health co-creation environment. This includes the detailed description of the four waves of co-creation that the consortium and (potential) citizen and professional users will engage in, the methods toolbox that will be employed in a situated manner all along the process of co-creation, the different user groups that we will be working with, and a detailed description of the CUCs as the specific empirical settings of the co-creation environment and what can be created, tested and evaluated therein.

1.10 Future Work

This report on the methodological design of the co-creation environment in Smart4Health will substantially shape the work in Task 1.3 and, thus the Deliverables D1.3 - "1st Specification of user requirements and performance criteria" (M12), D1.5 - "2nd Specification of user requirements and performance criteria" (M24), D1.6 "3rd Specification of user requirements and performance criteria (M32) and D1.7 - "Final Report on User Requirements and Performance Criteria" (M40). Given that the Use Design Cases are being elaborated through the iterative co-creation process of T1.3 – "Citizen/user co-creation: user requirements, performance criteria, implementation", D1.2 also is linked with D1.8 - "Description of the Use Design Cases from the citizen/user perspective" (M42) and D1.10 "Validation Report" (M50).

1.11 Remarks and considerations

If updates/changes to the co-creation approach presented in this deliverable are made, they will be reported in the project periodic reports.

2 Introduction

The central aim of Smart4Health is to develop a health data infrastructure to empower citizens as future users to manage their own health. In doing so, the project puts EU citizens centre stage – conceptually and methodologically. Producing an appropriate solution for a portable, interoperable citizen health data platform prototype will therefore proceed in a process of co-creation involving citizens as well as diverse health-care professionals. Through this approach, potential future users are put in the position of (1) playing a central role in identifying needs, problems, and potentially also solutions; (2) expressing values and concerns; (3) proposing requirements to be met, and (4) being involved in the testing while gradually building the prototype system. This is in line with several studies which looked into the (non)use of personal electronic health records, stressing how important it is to "align [this new health infrastructure] closely with people's attitudes, self-management practices, identified information needs, and the wider care package (including organisational routines and incentive structures for clinicians)" (Greenhalgh et al., 2010) and thus engage in user-centred design methods. Not doing so might increase the risk of either abandonment even after initially inscribing or non-adoption by users.

Using a co-creation approach, as will be outlined in this deliverable, will enable citizen- as well as professional-users to make creative contributions in the formulation of future needs and to be engaged in design choices, bringing their expectations, knowledge and experiences to the table. **Co-creation thus aims at bringing different parties together in order to jointly produce a mutually valued outcome.** Successful value co-creation will only be achieved, if future users are able to experience the using of the 4HP and the connected services in ways that fit their respective health-related data practices (including self-care practices). It also means to be particularly attentive to developing the 4HP and its services as **unobtrusive** as possible and to **avoid attention theft**. In the process of co-creation, we thus have

(1) to carefully reflect the impact that the new health data infrastructure and its connected services will/should take in citizens' lives,
(2) to be aware that citizens' capacities to engage with a health data infrastructure vary considerably and therefore what they find suitable or challenging is also quite different and
(3) to reflect how the value provided by the new health data infrastructure is commensurate with the attention it asks of users.

In short, future users need to perceive tangible benefits as this is an important motivational factor for longer term engagement.

Beyond this, we also have to consider citizens' core concerns (e.g. privacy, data security, transparency), as well as how to best build trust relations. Trust will be a key issue in building sustainable relations between (future) users of the 4HP and those being the trustees (those running the 4HP). This is of particular importance as the working of data infrastructures is often hard to understand for many users, but might have potential impact on their lives (e.g. data breaches). Trust in this understanding means that throughout the co-creation process we will also have to create a data environment in which (future) users are ready "to be vulnerable […] based on the expectation that the [trustee] will perform a particular action [e.g. assure data security and privacy] important to the trustor, irrespective of the ability to monitor or control" (Mayer, Davis & Schoorman, p. 712).

In order to achieve citizen-centeredness, the development process will concretely engage with users in 8 so-called "**Citizen Use Cases (CUCs)**" (see section 5.2) and around 6 **"Use Design Cases" (UDCs)**. The latter cover the safe ingestion of different kinds of health data (EHR data, work-related health data and data collected in everyday life) into the citizen's data space as well as the sharing of data with different actors (from health care professionals to trusted persons and the donation for research). The CUCs will involve citizen-users, professional users and other stakeholders (e.g. hospitals, national providers of EHRs, national and regional policy makers and legal advisors) in different countries and diverse empirical settings. They will cover a broad range of settings where health care professionals (e.g. general practitioners (GP), physiotherapists, hospital workforce, nurses, mobile caregivers) interact with citizens. The CUCs revolve around the core concern of backpain problems, as they are very widespread among the population (specific professional groups being highly affected) and have a detrimental socioeconomic impact (e.g. sick leave, work loss, early retirement).

The deliverable at hand will describe **the choreography, the timeline as well as processes, practices and methods of the co-creation environment in the Smart4Health project**. Furthermore, it will give insights into the user groups we will be working with as well as describe the functionalities we will be able to engage with in each CUC. Within these environments continuous mutual engagement and learning will happen. These processes will take place along the whole project duration and will create open spaces for engagement and interaction between future users (citizen and professional users), the 4HP as well as its developers. This will allow for responsiveness and adaptation towards the emerging needs, issues and concerns. In different formats, we will collectively identify and prioritize the issues and concerns that different user groups have and formalize them as user requirements in terms of desired elements and functionalities. In a number of iterations this will shape the UDCs and ultimately the overall functioning – including the governance structures and the information provision before and during the use of the 4HP (both Citizen Health Data Platform (CHDP) and Research Platform (RP)) and its services.

The following report on the methodological design of the co-creation environment has profited from our conversations and reflections with a number of experts in the fields of co-creation, digital health and big data. Tariq Osman Andersen (Co-constructing IT and Healthcare; SCAUT), Robert Braun & Johannes Starkbaum (New HoRRIzon; RiConfigure), André Martinuzzi (Living Innovation), Anneli Roose, Nini Gigani & Thomas Blanchet (HubIT) and Hilda Tellioğlu (TOPIC) had been ready to share their knowledge, reports or experiences. Additionally, we were able to draw substantially from our workshop (organized for D1.1) with Klaus Høyer, Barbara Prainsack, Tamar Sharon and Sally Wyatt, four SSH experts in the fields of digital cultures, digital health and data governance, especially of big data. This allowed us to carefully think through and delineate the complex multi-sited co-creation processes in the development of a large-scale health data infrastructure.

Before entering the methodological design of the co-creation environment, we want to underline that it is important to reflect our own role as actors in the project, as we know from experiences with public participation exercises in the medical field and beyond. This means that we have to be aware of our role in creating space for mutual engagement and the responsibility that comes with it. For example, we participate in shaping who gets a voice and who does not (Braun & Schultz, 2009; Felt & Fochler, 2010) and we are responsible for ensuring that our practices and methods are "well

equipped to account for contestation, conflict and power" (Braun & Könninger, 2018, p. 675).

In the chapters that follow, we will in chapter 3 outline current debates on co-creation based on both a literature review and interviews with experts in the domain (3.1), describe the key-lessons learned (3.2) and identify key-concerns for the Smart4Health context (3.3). In chapter 4, our general approach to co-creation is described (4.1), the toolbox with the different methods to facilitate co-creation will be presented (4.2) as well as the co-creation environment and the processes and practices involved (4.3). Furthermore, the ways in which we address ethical issues in the project will be outlined (4.4). Chapter 5 will then describe our work in the field, specifying the user groups we will engage with in the co-creation process as well as the CUCs participating in the "co-creation environment".

3 Preparing the co-creation environment

3.1 Current debates on co-design

Co-creation is a concept for the ways in which knowledge production should be performed for growth and innovation and the benefit of the collective that has gained traction in public policy in recent years. As William Voorberg and colleagues for instance point out:

> *"Policy makers and politicians consider co-creation/co-production with citizens as a **necessary condition** to create innovative public services that **actually meet the needs of citizens**, given a number of societal challenges, like ageing and urban regeneration, and all of this within the context of austerity." (Voorberg, Bekkers, & Tummers, 2015, our emphasis)*

In Horizon2020, the EC drew strongly on the idea of co-creation as the way to tackle societal challenges through responsible research and innovation. In the H2020 work programme of 2016-2017, for instance, co-creation featured prominently with the call "Co-creation for growth and inclusion" (EC, 2017). Here, the argument to foster co-creative processes goes as follows: while the EU is stable, diverse but unified, and shows great competitive strength due to its people, its industrial base and trade position, there still are obstacles to and untapped resources of growth and employment. In order for the EU to "progress at socio-economic, political, educational and cultural levels", co-creation is key. Co-creation encourages creativity and collaboration between "engaging citizens, users, academia, social partners, public authorities, businesses including SMEs, creative sectors and social entrepreneurs in processes that span from identifying problems to delivering solutions". Co-creation here has a clear function: to enable growth and better public services, and in addition, to establish more "legitimacy of public policy-making" through involving and engaging citizens.

It can be expected that co-creation will play a similar role in the next framework programme, as can be seen in the orientations document towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe that was put out for public consultation in mid-2019:

> *"Engaging and involving citizens, civil society organisations and end-users in co-design and co-creation processes and promoting responsible research and innovation will improve **trust between science and society**, and the **uptake** of scientific **evidence-based public policies** and **innovative solutions**."(our emphasis)* (EC, 2019).

Thus, co-creation is expected to enrol citizens in processes of creating knowledge and innovations, and thereby establish relations that build on trust. If participation enhances engagement, **co-creation supports ownership of innovations** that potentially change our lives.

If we look more closely into what co-creation means for the development of technologies, systems, products and/or services, we see that it promises shared responsibilities, inclusive processes and multivocal and diverse participation, sustainable products that better serve the needs of future users, and many more. In the health care area, the involvement of a wide range of future end-users in the development of health care systems means to change the top-down approach of developing with (and for) lead clinicians and managers, and promises to offer a significant role to health care professionals such as nurses, midwives etc. as well as

patients (Farrington, 2016). In short, co-creation has become a term that many people can agree upon is a good approach to follow.

3.1.1 Four ways of understanding co-creation

Looking more closely, though, we see that one of the reasons so many people can agree on the usefulness of the approach might be related to it comprising a number of different means at different scope towards differing ends. Thus, the concept is not very clearly defined and **practices may vary considerably**.

Trisha Greenhalgh and colleagues (2016) understand co-creation as a conceptual approach in which knowledge is produced by a variety of actors, i.e. academic researchers and stakeholders from other areas (Greenhalgh et al., 2016, p. 393). Knowledge production, thus, is conceptualized as a shared endeavour and goes beyond the mere translation of knowledge from academic fields of production to practitioners, citizens or other actors and stakeholders who are located on the outside.

By reviewing different models of co-creation that come to relevance in the field of community-based health services, they were able to identify **four distinct ways of understanding co-creation**:

(1) value co-creation,
(2) community-based participatory research,
(3) experience-based co-design and
(4) technology co-design.

These four models differ in disciplinary groundings and epistemological foundations as well as in goals and key stakeholders to be involved in the co-creation process. For Smart4Health it is thus helpful to engage with these differences and reflect the understanding of co-creation that the consortium wants to engage in.

(1) Value co-creation

… is grounded in the field of business and management, has as its focus the creation of value (Prahalad & Ramaswamy, 2004). It is based on the idea that "people are naturally creative and seek to generate value for themselves and others" (Greenhalgh et al., 2016, p. 398). Co-creation, here, means the joint creation of value by a company and its customer, whereby customers are involved in the definition of the problem as well as finding a solution and are brought in the situation of co-constructing their personalized experiences (Prahalad & Ramaswamy, 2004, p. 8). Corporations provide platforms on which stakeholders can interact and share their experiences, generating subjective value for them (Greenhalgh et al., 2016, p. 398). The aim is to increase creativity, productivity and growth, and to develop long-term relationships between stakeholders including "customers, staff, suppliers, government, partner organizations, funders, end-users, citizens" (ibid., p. 398).

(2) Community-based participatory research

… has its foundation in developmental studies (Greenhalgh et al., 2016) and "emphasizes 'equitable' engagement of partners throughout the research process, from problem definition, through data collection and analysis, to dissemination and use of findings to help effect change" (Cacari-Stone, Wallerstein, Garcia, & Minkler, 2014, p. 1615). The goal of community-based participatory research is to facilitate more local forms of learning and sustainable change regarding health disparities,

which enables a reduction of inequalities, and which is only possible in more longstanding collaborations based on mutual trust (Greenhalgh et al., 2016, p. 398).

(3) Experience-based co-design (EBD)

… is a co-creation approach in the field of health care services development, with an interdisciplinary foundation drawing from phenomenology, design science and management. This approach **starts from the patient experience in order to redesign a health service** and can mean a collaboration between patients and health care providers (ibid., p. 398). The starting point of EBD is the observation that patient involvement in health service improvement had strongly been focused on an evaluatory approach to their attitudes and had not taken their experience into account, thus, largely missing out on unique and invaluable input (Bate & Robert, 2006). The approach does not merely aim for a higher degree of patient-centeredness or patient participation, but "goes much further than this, placing the experience goals of patients and users at the centre of the design process and on the same footing as process and clinical goals" (Bate & Robert, 2006, p. 308). EBD as a user-focused design process aims to make patient/user experience accessible to designers (ibid., p. 308). Methodologically, EBD disregards focus groups in which patients/users merely get to evaluate health services and privileges collaborative work in which "users and professionals [work] together over a period and throughout the change process as the co-designers of a service" (ibid., p. 309). Experience, however, is inherently internal, subjective and difficult to study directly. It can only be accessed via language, stories being the "repository of experience." Thus, storytelling plays an important role.

(4) Technology co-design

… has its foundation in early computer science and management studies (Greenhalgh et al. 2016, p. 405). Its driving principle is to develop technologies starting from future users' needs, their capabilities and "what matters to them" (ibid., p. 399). The idea was that technologies are not to be separated from the (work) practices they are to be embedded in. Therefore, it was stipulated to co-design technologies and work-practices and to do so in participatory work on the ground. As Greenhalgh and colleagues point out, we can learn from the early work on technology co-design in the interdisciplinary field of Computer-Supported Cooperative Work (CSCW). These studies did focus on people living and working with technology and the workarounds they develop along the way (ibid., p. 405). Since the beginning, researchers in the domain of CSCW had been interested in and engaged with health care-related areas (Fitzpatrick & Ellingsen, 2013, p. 613) aiming to design together with future users "systems that may support the collaborative practices in healthcare" (ibid., p. 615).

For **our establishment of a co-creation environment, technology co-design and experienced-based co-design (EBD) are the two most central approaches, with elements of the value co-creation also mattering.** While the relevance of technology co-design is quite straightforward (Smart4Health aims to develop a large-scale health(care) data infrastructure that delivers benefits for citizens and health care professionals), EBD's focus on narrative and storytelling and its methodological implications are specifically important to us. Stories are "our way of organizing,

interpreting, and creating meaning from our experiences while maintaining a sense of continuity" (Atkinson 2001). Storytelling is a central social practice, which we will foster in our co-creation environment, in particular in our open and card-based discussion groups in different empirical settings (see section 4.2 and 4.3). Finally, value co-creation will support a focus on what is valued by different actors and how they perform (e)valuation and will keep us alert that valuation (the estimation of something's worth) and evaluation (the assessment thereof) are intimately intertwined, in particular, but not only, in the testing and validation part of our co-creation environment. We will therefore be attentive to the devices and methods users employ to value and evaluate a health data platform like Smart4Health.[1]

3.1.2 Attention to power relations and inequalities

In the co-creation literature we find frequent references to the fact that not sufficient attention is paid to issues of power or to grasping the power dimensions in work and health related practices (Bratteteig & Wagner, 2016, p. 430; see also D1.1 – "Social Sciences and Humanities Framework"). The tradition of Participatory Design (PD), on the other hand, had power issues inscribed into its program since its beginning. The early Scandinavian tradition of PD came out of the engagement between designers/engineers and workers unions and a critique of how computer systems were introduced into the workplace and their effects on workers' everyday work lives. Its proponents adhered to the following values: "(1) democracy and quality of work life, (2) workers acquiring control of computer systems and their use at work and (3) designing computer support for skilled workers" (Andersen, et al., 2015, p. 252). To bring those who are developing technologies and those "living with its consequences" together in a co-creation process, was seen as democratizing technology development by sharing responsibility and accountability for what is being developed throughout the whole process (Kensing & Blomberg, 1998).

As we have outlined in D1.1, we aim at paying particular attention to the **power relations** that come into play in the process of realizing an innovation such as Smart4Health is aiming to develop. It is crucial to do so in a way that sufficiently considers societal needs and concerns, and the values of citizen-users. This requires taking into consideration already existing power relationships, social and cultural disparities as well as inequalities deeply rooted in existing structures (Erikainen et al., 2019), and how the new digital health infrastructure might generate new ones or reify existing ones. Infrastructures build on **already existing (information) infra-structures** and relations, on their strengths and vulnerabilities. Infrastructures incorporate specific concerns, values and visions and their development testifies to power relations in who gets to articulate the initial justification and who gets to participate further. We therefore have to carefully attend to the question of who can gain a voice in shaping an infrastructure and from what positions of power they arise. This helps us to understand and – potentially – intervene in who frames the ways in which this emerging new everyday health data world is taking shape.

In general, participatory approaches aim to enable a collectivization of the definition and elaboration of problems and solutions, and with this a form of mutual learning, whereby technology developers learn about users' ways of thinking (Bratteteig & Wagner, 2016) and their frames of reference. Participation of future potential users in

[1] Zuiderent-Jerak and Van Egmond (2015) use a valuation studies approach to look into the disappearance of the value of solidarity in a Health Care Market.

research and technical development can thus be understood as an attempt to distribute the responsibility for developing technology and society, to facilitate the elaboration of shared visions of the collective good, and the building of infrastructures integrating these visions. Next to the democratic stance on involving participating users in all aspect of design, there is also a more pragmatic element to it: "it is not only about social democracy but also about the systems that stand more chance of a success when the users are able to have a stake in their development" (Martin et al. 2009, cit. in Bratteteig & Wagner 2016, p. 426). Participatory approaches allow for diversity in users' voices, concerns, positions and contexts of use (Andersen et al. 2015).

While the values of PD may be articulated quite well, in referring to a review study done by Halskov & Hansen (2015), Andersen and colleagues (2015) conclude that the meaning of participation in the notion Participatory Design is notoriously underdefined. They argue that instead of looking at participation as isolated instances that happen in single design events such as workshops or interviews, it is much more helpful to look at participation as a "productive matter of concern throughout the full range of project activities in specific design projects" (Andersen et al., 2015, p. 253) a suggestion that our development of a co-creation *environment* in Smart4Health speaks to.

In a similar manner, Bratteteig and Wagner investigate what it is that users participate in in PD, what is their contribution to the outcome, how they do contribute and how they will know what they have contributed; in doing so, they specifically focus on power and decision making (Bratteteig & Wagner, 2016, p. 425). Design, as they outline, faces ill-defined and ill-structured problems, whose understanding and resolution cannot be held separate. These so-called wicked problems, in our case, are closely linked to the **complex relationship between doctors, health care professionals, patients and other stakeholders** (Farrington, 2016, p. 368), but also to users relation to their bodies and health. The character of these problems leads to the requirement for open-ended, exploratory and highly complex design processes, that bring with them the challenge of

> *"**expand[ing] the design space, creating a multiplicity of design options, and not closing it too early** (…) An important part of the practice of design is to support the possibility to make choices that can be unmade." (Bratteteig & Wagner, 2016, p. 428; our emphasis)*

As they point out, not all design choices that make sense to participants will ultimately be pursued; some will be represented and explored, others will be discarded and not followed up on (ibid., p. 439). They invite us **to analyse choice formation** and for that matter suggest **a distinction between creating choices, selecting a choice, concretizing a choice** and, subsequently, **seeing and evaluating the result of said choice** (Bratteteig & Wagner, 2016, p. 438). Tracing choices and using the practices of choice formation as analytic lens promises to be fruitful in understanding limitations in participatory process and to better grasp and, thus, potentially tackle power relations in the design and development setting.

3.2 Lessons learned

As we have seen from this overview, co-creation can not only mean a number of different things with overlapping ideas, but there already is ample material available to draw lessons from practice. For instance, Conor Farrington (2016) identifies a number of potential barriers to successful co-design practices in the field of developing health

care systems, which – if not taken seriously – could significantly hamper the potential success of the co-design process. Farrington underlines the need for rigorous evaluation procedures that are "capable of capturing the complexity and diversity of impact" and that are implemented from the beginning onwards. Also, he stresses the importance of avoiding bias and exclusion by **broad and diverse recruitment procedures** instead of self-selection and involving pre-existing groups who already have participated in design endeavours before (Farrington, 2016, p. 396). Another consequential problem area refers to the actual position and potential for participation by those involved in co-creation practices. In order to avoid disappointment and disillusionment it needs to be **clearly communicated what the scope and limits of participation actually are and what concrete temporal dimensions the participation entails**:

> *"Unless stakeholders can continue their involvement over the extended time-periods required for innovation, implementation, evaluation and redesign of services, they may feel exploited – i.e. they may feel that they have been involved in co-design processes merely to access their valuable personal experience, which is then taken over and operationalized by 'the professionals'." (Farrington, 2016, p. 396)*

When it comes to EU projects involving co-creation approaches, we can also learn from their experiences. We will shortly look into three such EU projects: eStandards, HubIT and SISCode and point to some of the aspects relevant to the co-creation in Smart4Health.

As already outlined in Smart4Health D1.1, **eStandards** was a H2020 project, with an explicit **co-creation approach** (eStandards, 2015). Its aim was to strengthen eHealth standardization and interoperability in Europe by bringing together "stakeholders in Europe and globally to build consensus on eHealth standards, accelerate knowledge-sharing, and promote wide adoption of standards" and to develop a roadmap for alignment, consolidation and acceptance that is supported by standards developing organizations, the eHealth Network, providers and industry (CORDIS). The development of the eStandards Roadmap followed a methodology that should specifically allow for "collaborative and sustainable roadmap development" and is based on three core concepts: (1) the eStandards Compass of perspectives, (2) the eStandards Roadmap Components of standardised artefacts, and (3) the Co-creation-Governance-Alignment Model for the identification and coordination of actions in the development, deployment and maintenance of eStandards." (eStandards, 2017[2]).

While the compass approach in eStandards treated citizens/patients, health system, market and the health care professional workforce somewhat symmetrical, ***Smart4Health is clearly centering citizen users*** *– from the outset onwards, methodologically and conceptually. This, however, does not mean that in the Smart4Health project health care professionals will not be engaged in the process of co-creation. They will enter as important players to give feedback, evaluate development and design directions, participate in "reality-checks" and participate in the gradual (re)formulation of user requirements all along the process. This is essential for turning Smart4Health into a powerful and supportive instrument in improving both*

[2] It would have been important for the co-creation approach to get more practical insights into the "how" of the co-creation process and the practical working of the compass approach. Yet, so far no publication on that aspect of the project could be found.

the interaction of health care professionals and citizen-patients as well as citizen's own capacity to care for their health.

HubIT is a Coordination and Support Action within the H2020 framework, offering co-creation and RRI approaches for ICT (HubIT, 2017a). It aims to ensure that funded ICT innovation is done in responsible and inclusive ways, reversing and not reifying inequalities (CORDIS). HubIT addresses challenges in ICT-related developments and aims to bring together ICT and Social Sciences and Humanities (SSH) communities by facilitating interactions between ICT developers, SSH researchers and other stakeholders. While HubIT aims to provide engagement of stakeholders (e.g. through thematic workshops, networking events, or policy workshops), facilitate collaborations and experimental activities (e.g. hackathons, interactive ICT labs) and to establish an evidence base for research and innovation policies that are measured by key success indicators, they also provide a European Framework Model for Responsible ICT innovation (HubIT, 2017b). Based on the continuous work on the Framework, HubIT published a list of 10 tips for implementing RRI in ICT projects through interdisciplinary collaborations – the target audience being ICT developers and researchers (HubIT, 2017c):

- *Rely on expertise from **social sciences and humanities** to co-create and cooperate*
- *Have a **user-centered** approach by defining your target audience*
- *Understand the **cultural context** while analysing your potential market*
- *Implement **responsible concepts** and **principles***
- ***Reflect on the purposes** of a given product or service*
- *Think of **possibilities** and potential **risks***
- *Be **transparent***
- *Hear from **different stakeholders***
- ***Test** the product on the users*
- ***Review** your own innovation process (HubIT, 2017c).*

Interviews with three experts from the HubIT consortium did flow into this report and it is planned throughout the co-creation process to relate to some of their expertise and experiences.

SISCODE (Society in Innovation and Science through CODEsign, 2018-2021) is a Horizon2020 project focusing on the development of best practices around co-creation in RRI (SISCODE, 2018a). The aim is to understand what co-creation can actually mean and what would be favourable conditions that support its introduction, scalability and replication (CORDIS). The consortium defines co-creation as "a non-linear process that involves multiple actors and stakeholders in the ideation, implementation and assessment of products, services, policies and systems with the aim of improving their efficiency and effectiveness, and the satisfaction of those who take part in the process" (SISCODE D1.3, p. 11) (SISCODE, 2018b).

In the SISCODE D1.1 (SISCODE, 2018c) the consortium offers a review of the current RRI research landscape and outlines a number of lessons learned on co-creation that stem from previous EU-funded RRI projects:

- Stakeholders have **great aspirations** for what can be achieved with co-creation, which is expected to have the "potential to bring science and society closer together and avoid future controversies", to bring about "better

democracy, better accountability and more effective policy decisions" and to support transparent processes (SISCODE, 2018c, p. 11).

- It is important to be clear about the **objectives of co-creation and participation exercises** – for engagement to function well, it is important to have **full transparency** regarding "the rationale, purpose, and method of the activity; the roles and relationship of the actors involved; dealing with expected results and how the results are used; and intended impact" as well as regarding the actual impact of participation, regarding "what was used, why and how" (p. 13).
- The review of RRI projects also showed that citizens and researchers need **support for participating in co-creation activities**, which highlights the requirement for spaces that enable the bi-directional flow of information from citizens to researchers and vice versa as well as the availability of carefully produced, accurate, adequate and trusted briefing material and general information that is being provided to participants prior to an engagement exercise (p. 15).
- Another lesson learned was that **ways need to be found to put citizens in the position of an equal actor** in the process and instead of assigning them the role of a non-expert. A key approach here is to **frame co-creation activities around issues of actual concern to citizens** and by using these concerns to have them participate in agenda-setting exercises or to seek their contributions for designing research agendas and thereby co-shape visions of the future (p. 16).
- Co-creation sessions need to be **well-facilitated**, which means to assign roles of mediation, that are not filled by researchers or industry actors (p. 17).
- The engagement in co-creation processes and events need to be **incentivized** (for citizens) and **institutionalized** in organizational culture (for researchers) (p. 18) and **not be expected to be of such intrinsic value that individuals freely participate in**.

Over the course of the project, SISCODE will run 10 experiments in co-creation taking place in 10 co-creation labs across Europe (SISCODE, 2018d). SISCODE defines 4 phases of the iterative co-creation process to be performed in these labs, as outlined in their toolbox (SISCODE, 2018e):

1) Analyse the context
2) Reframe the problem
3) Envision alternatives
4) Prototype and experiment (to be done in at least two iterations)

Each of these phases is supported by a so-called phases canvas, which shall support the definition of the co-creation procedure, its different phases and the input needed (SISCODE Toolbox, p. 8), as well as an activities canvas, that in more detail defines the activities to be realized. The phase canvas supports deliberation on the planned activities, the stakeholders involved in them and their respective roles, as well as the expected outcomes of the phase (p. 9). The activity canvas tracks the objectives of the activity, lists and describes the tools used to achieve the objectives, outlines the desired outcomes and the expected time for reaching the objective (p. 11). As soon as the phases and activities have been defined, so-called synthesis tools can be brought in to support the work in the different phases (e.g. stakeholder engagement and dissemination plan for the context analysis, frameboards for reframing the

problem, idea cards for envisioning alternatives, personas or stakeholder journeys for prototyping and experimentation) as well as to illustrate accomplishments and document the outcomes of the process (p. 6).

While the Smart4Health co-creation environment will not proceed in the way SISCODE defines the phases, the different canvases may provide additional input for refining parts of our toolbox and that we may draw on in the reflection phases between the waves (see section 4.2 and 4.3).

3.3 Four areas of concern to be considered

After having sketched four models of co-creation in the area of health care, services and technology development and implications for the co-creation environment in Smart4Health as well as having given an outline of co-creation approaches in previous EU projects, we will now lay down four areas of concern that we see crucial and that will require attention and care in the establishment and running of the Smart4Health co-creation environment.

In the literature, we find many examples of co-creation processes done in limited form (e.g. by co-creating with a limited group of people, developing a specific technical system for a defined condition), yet how do we engage in the citizen-centred co-creation of an infrastructure that upscales this complexity and that aims at a very large user-base? Gabriele Bammer (2019) points out that the literature on co-creation in research mostly describes approaches to tackle problems that are clearly defined and that can be treated as solvable. Yet, oftentimes we have to deal with problems that are complex, that is they are difficult to delimit, contested in their definition, defined by multiple uncertainties and unresolvable unknowns, and experience constraints and solutions that are always partial and temporary (Bammer, 2019, p. 424). In their review of 25 years CSCW Research in Healthcare, Geraldine Fitzpatrick and Gunnar Ellingsen raise the issue that the majority of contributions they reviewed were workplace studies and the design prototypes aimed at small-scale interventions (Fitzpatrick & Ellingsen 2012, p. 2).

For Smart4Health this means asking:

What difference does it make for co-creation, when the problems that should be solved are complex and the scale is large? How can we facilitate co-creation processes in the development of a ***complex, large-scale and transnational infrastructure*** *such as Smart4Health?*

This ties in with issues Tariq Osman Andersen has outlined in a recent paper: while the changes that digital health brings to our health care systems are expected to be large, and there already exist promising prototypes and communication infrastructures to connect patients and health care providers, the actual use in practice is seldomly realized (Andersen, 2019). Andersen locates this diffusion problem in the trajectories of how project-based design and development function and particularly in the discontinuation of design after implementation: “Too little time and effort is spent on configuring the systems and adapting the clinical practices and the day-to-day activities of patients (not) using the new systems” (ibid., p. 74). Co-creation in the way it oftentimes is practiced means to involve future users in workshops and prototyping sessions in a timeframe before the implementation of a system. This, then has the effect of robbing oneself of the important lessons that have so far received little attention and that one can only learn in ‘use time’, that is, “when new technologies are put to use as part of actual healthcare practices” (ibid., p. 74). Andersen reports from

the research project SCAUT, that runs a long-term large-scale living lab, enabling collaborative practices of users, engineers, designers, researchers and other relevant stakeholders that go beyond the limited timeframes and user bases one normally works with. Their approach facilitates timely small-scale testing and learning with the possibility to quickly upscale participation. Furthermore, patients can participate for a longer period of time, offering insights into longer durations of use (ibid., p. 75). The long-term large-scale living lab approach brought together the lived worlds of patients with clinicians' practices and opened up a space for reflection and insight into the question of what ideas are still considered good, once they have left the site of a workshop and have been deployed.

For Smart4Health this means asking:

*How can we ensure a trajectory that enables **learning** from **implementation**? What kinds of spaces do we have to open **during project-time** in order to understand the configuration and adaptation work that is crucial for an infrastructure to be made workable/meaningful? Where do we need to go empirically and what do we have to do and observe there? And, crucially, how can learning continue after the **project** has **ended**?*

Co-creation means to actively involve (potential) end-users in the production process of goods and services (Voorberg et al. 2014, p. 3) and in the development of infrastructures. In the private sector, this involvement means two things that are beneficial for a company doing so: first, future end-users/customers are integrated into the production chain and perform some activities as co-producers; second, they become co-creators, as their experiences with a certain product or service provides added value for the company (p. 2). Those benefiting here are the company and their customers – the ones co-creating not necessarily have to benefit but they can as long as they become/remain customers themselves. In the public sector, however, the entity to benefit from co-creation endeavours is the larger collective and, thus, in an ideal version also those who participate in co-creation – the citizens.

For Smart4Health this means asking:

*What difference does it make for the meaning of the 4HP and the implications of choice, if in the public sector the end-users are citizens and what they are supposed to be co-creating is part of their own future (public?) health care infrastructure? What are then the conditions for **citizen** co-creation and how can we facilitate them?*

Finally, we want to outline questions that emerged from our engagement with Bratteteig and Wagner's work on participation and power in participatory design. What design does is to continuously move further and close some choices while at the same time opening others (Bratteteig & Wagner 2016, p. 434). Grasping how certain choices are opened up or closed down, how explicit this is, who gets to participate in them, who decides on their relevance and on what bases are important questions for co-creation practices, in particular when it comes to the development of a large-scale infrastructure such as the one envisioned in Smart4Health.

For Smart4Health this means asking:

*How to navigate **openness** and **closure**? How to facilitate **choice** and **open exploration of experiences**? How do we deal with asymmetries, hierarchies and power relations in the health care field itself and, thus, in our empirical settings but also between future potential users and technical developers?*

4 The Smart4Health co-creation environment

The previous chapter has been preparing the ground for elaborating the co-creation environment to be developed and used in Smart4Health. So far, the deliverable elaborated on the main lines of discussion in the field of co-creation, pointed to experiences made and lessons learned from previous and current projects, and identified areas of concerns to be considered. We now want to **outline our approach to co-creation used in the Smart4Health project**. As explained in the introduction, Smart4Health aims at developing an EU-wide health data infrastructure with an exceptionally large and diverse potential user-base, spanning different national health care systems with their respective approaches to digital health, and a variety of rather different cultural settings.

As the title of this report already indicates, the aim is to provide a lively co-creation environment, which accompanies the whole design, development and implementation process of Smart4Health. We call it a **"co-creation environment"** in order to point to the fact that the co-creation will be happening all along the process of development and design and will consist of many different settings in which co-creation happens in parallel. At different instances of the project we will use different methods to engage with users, and will address different problem areas from the technical to the social. At different points in time different parts of the consortium will be involved and different temporal and spatial aspects will come to matter. We will go to different places – where the CUCs happen – thus moving into different institutional environments (hospitals, factories, leisure environments) as well as encountering different cultural settings and engaging with different sets of users.

What a project like Smart4Health thus needs, is a multi-faceted, responsive and well-structured co-creation environment in order to develop the 4HP and the services it will offer in a co-creative manner. In order to outline the co-creation environment in all its dimensions we will proceed in four steps.

- First, we will give a description of our general approach to co-creation.
- Second, we will provide an overview of the methods toolbox we have assembled and outline in an exemplary manner which methods will be used how, involving whom and for what purpose.
- Third, we will outline the structure of the co-creation environment and the different processes and waves we have planned.
- Fourth, we will address ethics questions such as appropriate information practices as well as informed consent (IC) procedures.

4.1 Description of our general approach to co-creation

As already outlined in D1.1 chapter 3, we proceed in a cyclical innovation process in which stage 3 "Engaging in processes of co-creation: defining and refining requirements" plays a central role (see Figure 1) and its relation to the other stages is in the focus of this report.

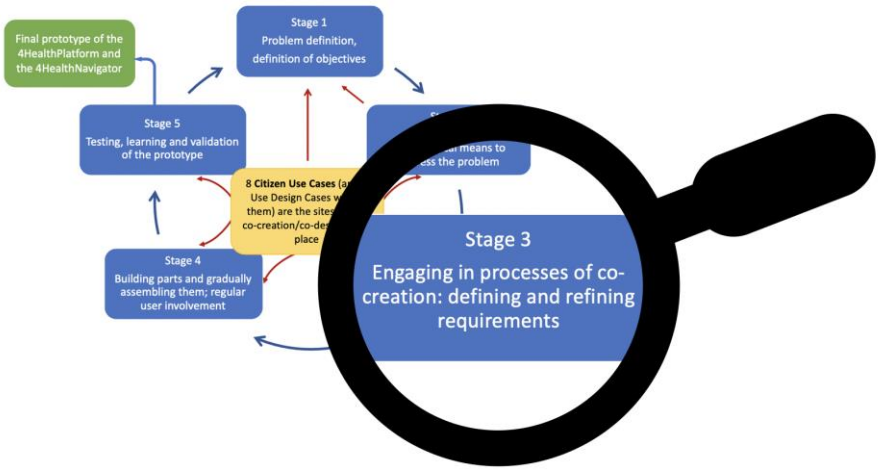


Figure 1 - A cyclical process of co-creation (see D1.1, Figure 2)

In unfolding the cyclical process described in D1.1 we will proceed in an iterative process organized in four waves of engagement with users (both citizens and professionals) and those responsible for the technical developments as captured in Figure 2.

However, before entering into a detailed description of the "co-creation environment" it seems essential to revisit shortly some of the elements we have identified in D1.1 as key to consider in the development of the 4HP and its services.

As the concept of **Responsible Research and Innovation** was put at the core, the four dimensions — inclusiveness, anticipation, reflexivity, and responsiveness — are central to the co-creation process. Across all chapters of the Social Sciences and Humanities Framework Report we have described important facets to be considered. Most of them can be subsumed under the four dimensions.

Inclusiveness means

- Integrate users from the start of developing and designing the project;
- Embrace the different values that are essential to future users;
- Be attentive to the differences between and within user groups (cultural differences, situations within the health care system, digital/health literacy, gender, different phases of life) and thus be attentive to diversity and its meaning in the health(care) context;
- Consider user non-adoption and abandonment of personal electronic health records;
- Reflect these differences not only in the technical set-up of the 4HP and its services, but in particular when it comes to information provision and IC language and procedures

Anticipation means

- Consider the future impact of using this health data infrastructure and how this might impact people in very different ways (e.g. infrastructural exclusion)
- Carefully think about potential future users and uses
- Reflect on the stabilisation of long-term trust relations
- Think about privacy by design solutions in order to avoid any future problems

Reflexivity means

- Question assumptions and commitments of those designing the 4HP
- Make transparent the choices that were made along the design and implementation process
- Carefully develop the realistic expectations users can have towards the 4HP and its services
- For whom does the new health infrastructure bring benefits and for whom not
- Which potential users were neglected or got less attention and way

Responsiveness means

- Ensure that the gradual development and design remains sufficiently open for new inputs as we advance in the co-creation process
- React to the ways in which the debates around the GDPR evolve and adapt accordingly
- Be open to cultural differences or identification on new user groups or use situations and develop the necessary adaptations

To summarize, the issues opened up in D1.1 will guide the co-creation process.

Within the co-creation environment, mutual engagement and learning will happen throughout the lifetime of the project. It will occur between the researchers/ developers/designers of the 4HP and the (potential) users – **social scientists become brokers between user communities and technological developers/ designers.** In different formats, we collectively identify and prioritize the issues and concerns different user groups have, and we formalize them as **user requirements in terms of desired elements and functionalities of the 4HP.** A number of collaborative iterations will then shape the 6 UDCs, i.e. how future users will be able to collect/upload and share health-related data. **Questions of in- and exclusion**, so who can shape the future 4HP, will be **an essential element in our reflection**. We also need to be aware that the format of engagement will be more inviting to some citizen-users than for others, and it will be essential to consider this very carefully.

4.2 Methods toolbox and recruitment process

The main conclusion we draw from the current debates on co-creation and the areas of concern that we have outlined in the previous section is that the requirement to construct a co-creation *environment* that is variable and flexible, yet durable and allows for situated depth as well as for longitudinal practices of (re-)engagement. This environment will spatially and temporally span the 8 different CUCs and, partly, even go beyond it. As will be outlined in section 4.3, we will adapt the empirical process and align the co-creation approach with the temporal needs and situated capacities of the CUCs – in particular regarding the recruitment of different citizen-/professional-user groups at different times, as well as the availability of specific functionalities of the 4HP that already may be stabilized, while others are only present in mock-up stage. One central feature of Smart4Health is that it allows for longitudinal practices due to the 4-year framework, i.e. to engage with citizens in a specific phase of the project and to re-engage them again at a later point in time, when their experience with use or non-use of the 4HP has solidified and can be understood. In this way we will be able to learn from development as well as implementation, understand configuration and adaptation work, the becoming of a (non-)user, to facilitate the open exploration of experiences, and trace choices opened and closed.

In running the co-creation environment, we will draw on a toolbox of different methods that we can combine, thus allowing for various participatory co-creative practices at different times.

4.2.1 Method toolbox

In what follows, we will outline the methods our toolbox contains and give a brief overview of the key parameters for their implementation.

Method toolbox for the co-creation environment	
1	**Discussion settings with diverse user groups** The centrepiece of the co-creation environment are discussion groups (Felt et al. 2014; Felt et al. 2018) of different formats – open, card-based and application-centred – that enable the collective exploration of the prototype development in open as well as more structured phases. Working with small groups of users and fostering a combination of individual and more collective reflections on their visions, preferences and concerns will be key.
1a	**Co-Creation Workshops (CCWs)** The Co-Creation Workshops with citizens who are not involved in the CUCs explore broader questions and *potential* concrete situations of interaction. At the point in time of the CCWs, no prototype is in place and the exploration of the situations is speculative. **The workshop participants are recruited from the general public.** The CCWs mainly use a card-based discussion method. The discussion starts with a broader exercise asking participants for their more general position towards digital health infrastructures (e.g. national or regional EHRs). We then walk them through the whole process of using the imagined platform. For this purpose, we structured the process of use in "situations" where users would have to act or take a decision – such as subscribing to the future 4HP, collecting personal health data, sharing data with the doctor/a loved one, donating data for research, being re-contacted after data-donation. Technical partners provide us with some mock-ups to create a clearer vision of potential future interfaces. We end with a discussion on the key-values that are essential in the citizens' views when developing and implementing the 4HP. This allows to gain a broader vision of how citizen users position the overall idea of a citizen-centred health data platform, how they assess specific situations of choice and which values they see as key. CCWs will also be **devoted to IC** procedures regarding the structure and social acceptability of IC forms and processes and provide input for D1.5 – "1st User Consent Language Report".
	Details **Participants**: 6-8 per CCW **Type**: general citizens; diversity as selection criterion **Interaction**: group, f2f **Duration**: approx. 4 hours (or 2 hours when focusing on specific questions such as IC) **Aim**: collect different points of view and encourage reflection and debate; explore concerns, expectations or opinions around particular moments in the process of using the 4HP and its services

	Support: cards that support engagement with specific aspects, issues or processes **Documentation**: audio recording (after IC), transcription, bottom-up approach to data analysis through open and focused coding (see Charmaz 2014)
1b	**User Engagement Exercises (USEEs)** The User Engagement Exercises will focus on the articulation of problems and needs with regard to the 4HP development, and the proposition, testing and validation of user requirements. **The USEE participants will be recruited from CUC participants.** Depending on the phase of the project and the availability of the 4HP prototype, the USEEs will follow a process of open phases of discussing specific issues and concerns, and structured phases of concretely working with situation cards, mock-ups and/or the 4HP prototype itself. Some of the USEEs will also have a more experimental character. Users will collaboratively work on identifying potential solutions to some of the problem zones identified either by them or by other user groups. In doing so, we will be attentive to cultural differences. The recruitment processes will also need to be adapted to the specific setting of the CUC in which the USEEs will take place. Potential exercises depending on the CUC, the technical advancement of the prototype and the user groups might include elements frequently used in co-design practices such as story mapping and scenario building, prioritizing/card sorting exercises, "rose-bud-thorn" exercises (what works well, areas of opportunities to be elaborated, elements not working) or other feedback exercises (I like… /I wish… /I wonder…). At different points in time, specific USEEs will be devoted to IC procedures regarding the structure and social acceptability of IC forms and processes and provide input for D1.9 – "2nd User Consent Language Report".
	Details **Participants**: 8-12 per USEE (depending on the issues, relation to the 4HP) **Type**: citizen or professional users in CUCs (diversity as selection criterium) **Interaction**: group, f2f **Duration**: approx. 4 hours **Aim**: collect different points of view and encourage reflection and debate; explore concerns, expectations or opinions around particular moments in the process of using the Smart4Health prototype; the CUC-specific environment will be in focus **Support**: cards that channel engagement into a specific group of aspects, issues or processes or open focus groups type of interaction generating people's questions, frames, priorities and concepts (Kitzinger 2005); use cards to collect ideas and to describe processes of using (parts of) the prototype **Documentation and analysis**: audio recording (after IC), transcription and analysis with a bottom-up approach (i.e. open coding) or with more issue-focused coding; observation protocols
1c	**Longitudinal accompanying user groups (LAUG)**

	Through our work in the CUCs we aim at recruiting a number of users who agree to collaborate with us along the project, spanning more than one wave. By accompanying them over a longer period of time and across different stages of the project and, thus, potential for use and non-use, we will be able to learn what it means to become and to be a (non-)user. We will repeatedly conduct discussion rounds with them and/or qualitative interviews (see 3).
	Details **Participants in a LAUG**: 6-12 per LAUG (depending on the CUC environment) **Type**: citizen or professional users in CUCs (diversity as selection criterion) **Interaction:** group, f2f, continues across several meetings **Duration**: approx. 4 hours **Aim**: get in-depth understanding if solutions are seen as responding to specific requirements made; engage with overall requirements expressed across all participants in a specific CUC and perform assessment and validation **Support**: cards or hands-on experiences which allow engaging with specific requirement-solution packages; do prioritizing exercises when it comes to realising specific values based on cards; use cards to collect ideas and to describe processes of using (parts of) the Smart4Health prototype. **Documentation and analysis:** audio recording (after IC), transcription and analysis with mainly issue-focused coding; observation protocols focusing on engagement across time
2	**Walkshops – mobile ethnography**
	Not everything can be understood in the setting of a group discussion, even if it is card-based and hands-on. For that matter we will engage in so-called walk-shops, that will be adaptive per CUC and situation, and that draw on interview strategies from the *Ethnographic Interview* (Spradley, 2002). We will be on-site with CUC participants and physically walk through different everyday situations (e.g. ICU nurses at work, formal carers at work, citizens using wearables) with them, observe what they do and how they (inter)act and ask them practice-based questions. The idea here is to understand the context and practices of their everyday (work) lives and the situations into which the 4HP needs to be integrated.
	Details **Participants**: single users **Type:** citizen or professional users in CUCs **Interaction:** f2f **Duration**: approx. 1-2 hours **Aim**: get a clearer vision of the hands-on use contexts and what visions, values and concerns participants express in these situations **Support:** - **Documentation and analysis**: observation protocols, ethnographic fieldnotes, photos and/or video recordings (after IC)
3	**Qualitative interviews**

	Occasionally, we will conduct f2f qualitative interviews (Atkinson 2001; Czarniawska 2004) with citizens and professional users who are involved in the CUCs. These interviews can be conducted to support the observations from the walk-shops, to facilitate an in depth-evaluation of specific functionalities, or can be repeated in order to gain deeper insights into the development of the 4HP users' (dis-)engagement.
	Details **Participants**: single users **Type**: citizen or professional users in CUCs selected either from group engagements or citizen/professional users in settings where it will prove difficult to have group engagements; researchers **Interaction**: f2f **Duration**: approx. 1 hour **Aim**: deepen and specify reflections, values and concerns opened up in focus groups or develop individual vision of the 4HP and its services (depending on the interviewee); discuss relevant aspects of health data donation with researchers **Support**: interview guideline **Documentation and analysis**: audio recording (after IC), transcription and analysis with a bottom-up approach (i.e. open coding) or with more issue-focused coding; will deliver input for further co-creation activities
4	**Questionnaires** For feedback and validation of specific and well-delineated aspects of the 4HP we will also make use of quantitative survey questionnaires among specific user groups as well as across them. These will play a role in assessing and validating certain features of the 4HP.
	Details **Participants**: larger groups of users (size depending on the CUC) **Type**: citizen or professional users in CUCs **Interaction**: depending on setting (e.g. f2f, online) **Duration**: between 10-20 minutes **Aim**: feedback on and assessment of specific issues **Support**: online questionnaire incl. multiple choice options **Documentation and analysis**: quantitative assessments of user experiences; satisfaction with realisation of specific requirements
5	**Reflection workshops** After each wave, we will conduct a reflection workshop with our consortium partners. In these half- to one-day workshops we will engage in scenario work, discuss and evaluate the evolving user requirements and performance criteria, and prepare the upcoming USEEs.
	Details **Participants**: consortium members **Interaction**: f2f; smaller groups and plenary exchanges **Duration**: 4-6 hours

	Aim: update and feedback from the whole consortium; identify specific issues to be taken up in the respective next wave of co-creation **Support**: presentation of observations and advancement of user requirements; at moments when needed the data will be structured around themes to allow different groups of participants to work on different theme areas; cards and panels to expose ideas for further developments **Documentation and analysis**: recording (after IC); if applicable, we will make use of select synthesis tools (SISCODE) outlined in section 3.2.

Practical considerations

USEEs will be mainly half day events taking place 2-3 times in each of the CUCs, over the lifespan of the project. The recommended number of participants would be about 8 to max. 12 participants in each of the sessions. The other methods used will then be decided according to the co-creation wave we are in and what kinds of input/feedback is needed. This decision will, as outlined in 4.3.1, be made in the initial phase (first month) of each wave, in which we will develop an outline of our co-creation activities in the respective wave.

We will develop materials describing how we specifically design and conduct each of the interactions (incl. recruitment processes), develop specific IC sheets and outline how we document the outcomes emerging from the interactions with users. This will provide the necessary consistency across the different project sites.

The waves of the interaction moments will follow an evolutionary path from baseline conceptualisations, to problem definition, needs refinement and gathering to testing prototypes. Via iterative feedback loops, solutions will be co-created with the identified user communities.

In order to sustain user engagement, we will have to consider that different types of users have different motivations and are drawn to specific co-creation activities. As mentioned in the introduction to this report, it is essential to understand the individual values-based motivation (Wright et al., 2015) of participants in the co-creation process. However, it is also clear, that not all those volunteering has such a value-based motivation. Therefore, we will have to identify groups with a similar motivational situation and tailor messages that resonate with their situation. Furthermore, in the process of recruiting, it will be key to not create misleading expectations. If expectations do not align with what happens, both during and after the engagement, participants might get disappointed which might impact their readiness to further engage with the Smart4Health prototype and abandon it. Finally, it will be essential to identify incentives that can be offered, to reflect on their effects and/or the barriers need to be broken down.

All these reflections will also have to flow into our selection and recruitment processes of users for the co-creation activities.

4.2.2 Recruitment process

In order to engage with users – both citizen- and professional users – we will follow CUC-specific **recruitment processes** as the CUCs run in different settings. We will aim at maximising the diversity of users involved, specifically differentiating according

to gender, age, education, digital literacy, and other specific features (e.g. when it comes to involve researchers or health care professionals). Both the number of interviews we will conduct with citizen/professional users as well as the group size of citizens/professional users engaged in each CUC will depend on kinds of issues that are to be elaborated, the development of the Smart4Health prototype as well as the composition of the user groups involved in the respective CUCs.

Therefore, it will be essential to start by a detailed **mapping of user groups** – both citizens and professionals – **within each CUC** involved in the Smart4Health project. This will allow us to understand the "**ecosystem of users**" and, thus, ensure consistency of methods across sites as well as the possibility for the diverse user groups to get their voice heard in the co-creation process. An ecosystem of potential (citizen and professional) users demands a careful mapping of potential users in each CUC and reflecting how they might relate differently to the Smart4Health prototype. It also needs to consider the social contexts (e.g. at work, in private environments, …) in which the 4HP will be encountered/used. Furthermore, features such as potential inter-/disruptions, the preconditions of use (e.g. digital literacy) and time investments have to be featured in this map of the user ecosystem.

Once the **ecosystem of users has been appropriately mapped by the partners – CUC partners together with the social science partners** – the number and kinds of users we are planning to engage with, the concrete blend of methods we will be using and a good timing for the co-creation exercises can be decided upon. Only then a suitable recruiting strategy can be developed and put in place. CUC-specific information flyers for the recruitment of participants to specific activities will be developed. While we will start with an initial group of users, the exact final number of users to engage with will be defined in the process. In qualitative research, to which co-creation methods also belong, the exact number of users to engage will also depend on the point where saturation is reached, i.e. where no fundamentally new perspectives arise in the engagement (Charmaz 2014).

Researchers are also an important professional user group in Smart4Health, as they will be able to use data donated to the Smart4Health RP. Therefore, interviews with researchers will be used to specifically explore the data donation interface in order to understand what kind of data donation options might make sense from a scientist's point of view. This will be essential to consider when engaging in-depth with citizens around the concrete question of data donation as well as IC for it.

4.3 Outline of the co-creation environment and the related processes

4.3.1 The 4 waves of co-creation

In Smart4Health the co-creation process will be organized in 4 waves.

Each wave will mean multiple engagements with different user groups in the different CUCs using a context-specific blend of methods. As citizens are our primary users, they will thus be in the centre of our attention. However, in order to make full use of the digital 4HP, we also have to engage with professional users such as health care professionals or researchers, as they play an important role in using health data, whether in the context of treatments or medical research. The outcomes of each wave will lead to the formulation and refinement of a set of user requirements and respective performance criteria, which will be documented in Deliverables D1.3 and D1.5 – 1.7 that are due in months 12, 24, 32 and 40 of the project. Towards the end of each wave

we will also organize a workshop with all consortium partners in order to share the respective insights and to get feedback. This will then also flow into the technical development process.

From the timeline in Figure 2, it is visible that the first two waves will each cover a longer period (approx. 9 months) as many more design and development decisions concerning the basic structure and the features of the 4HP need to be made during these two phases. Wave 3 and 4 will then each cover a period of about 6 months. In-between the waves time will be devoted to bringing together the diverse observations in the CUCs and distilling main observations and take-aways that are essential to feed back to the technical partners and for preparing the next wave.

Initially, the project proposal had planned to devote each wave only to a selected number of CUCs and elaborate the UDCs in this context. However, during the first months of the Smart4Health project it became clear that the CUCs all work at different pace as they face different situated challenges. To smoothly advance in the development process, we decided to not proceed CUC by CUC over the development of the Smart4Health prototype. This is not only much more flexible, but above all it allows to revisit the different CUC sites and engage with users at different stages of the project.

1st wave of co-creation
This wave has started early in the project and is still in process as we write this report. The following activities (for the methodological details see chapter 4.2) were performed to achieve first steps in this co-creation process. • While it had been initially planned to conduct one **Assumption Persona workshop** (Pruitt & Adlin, 2006) with all our project partners, we instead conducted (1) smaller workshops with parts of CUC leaders and members of the consortium; and (2) open-ended interviews with the other CUC leaders and consortium members, in order to identify users and user-groups they imagine and the scenarios they see relevant either in their specific CUC or for the 4HP more widely speaking. From the material generated in the workshops and interviews, personas are being elaborated. This approach allowed for more space to individually explore the different expectations partners have towards the 4HP and, thus, to reflect in more detail the differences between the use scenarios and imagined users in the CUCs. • Based on these workshops and interviews we engaged with the technical partners responsible for building the 4HP and for data ingestion procedures in several rounds of **user story mapping** (Patton 2014) exercises (see section 4.3.2). • **Co-creation workshops** (CCWs) with citizens who are not involved in any of the CUCs were done in order to further explore details of a first set of requirements. These groups were carried out in September-October 2019 and participants were recruited from the general public by an open call. A card-based discussion method (Felt et al., 2014) was used. It started with a broader exercise asking people for their more general position towards eHealth and in particular digital health data infrastructures (national EHRs). We then walked them through the whole process of using the 4HP. For this purpose, we structured the process in “situations” where users would have to act or take a decision – such as subscribing to the future 4HP, collecting health data, sharing data with the

doctor/a loved one, donating data for research, being re-contacted after data-donation. Technical partners provided us with some mock-ups to create a clearer vision of potential future interfaces. We ended with a discussion on the key-values that are essential in the citizens' views when developing and implementing the 4HP. This allowed us to extract specific scenarios of use, allowed to identify major concerns citizens voice more generally and in specific situations, but also more broadly speaking the values they would want to see respected and to learn what would be essential to them.

- The work on user story maps has been expanded by including **input by CUC leaders via brainstorming exercises** about how users in each use case might interact with the 4HP, as if it were already up and running.
- In several steps, the insights from the co-creation engagements were input to **user story mapping exercises with our technical partners**. The aim was to gain first insights into the personas and to identify first sets of requirements which were taken up by the partners responsible for the technological development. The final round of user story mapping of the 1st wave will take place in November 2019.
- EFN organised (April 2019) **focus groups with representatives of nurses** discussing different scenarios on how health care providers may access and use citizen's health data. From there some general requirements were formulated by nurses from their professional perspective.
- We also organized a **co-creation workshop with all partners** involved in the Smart4Health project during our General Assembly Meeting in Lisbon (September 2019). The aim of this CCW was to foster engagement between the different partners concerned with technical developments and those doing the CUCs.
- During this first phase we will also perform a co-creation workshop with citizens (November 2019) in order to engage with the IC document for access to the 4HP, which had been developed in WP8 – "Ethics requirements". We will specifically discuss IC procedures regarding the structure and social acceptability of IC forms and processes and provide input for D1.4. – "1st Citizen/User Consent Language Report".

Taken together, these diverse activities will then collectively contribute to user requirements to be outlined in D1.3 - "1st Specification of user requirements and performance criteria" (M12). This diversity of co-creative activities is essential to capture as many perspectives as possible. The **social sciences then work as brokers to translate the information gathered as well as visions and values expressed into user requirements**.

This first wave had two aims: to start the co-creation process; and, second, to allow to define and refine the overall co-creation process for Smart4Health as captured by Figure 2 and as outlined further in detail (waves 2-4).

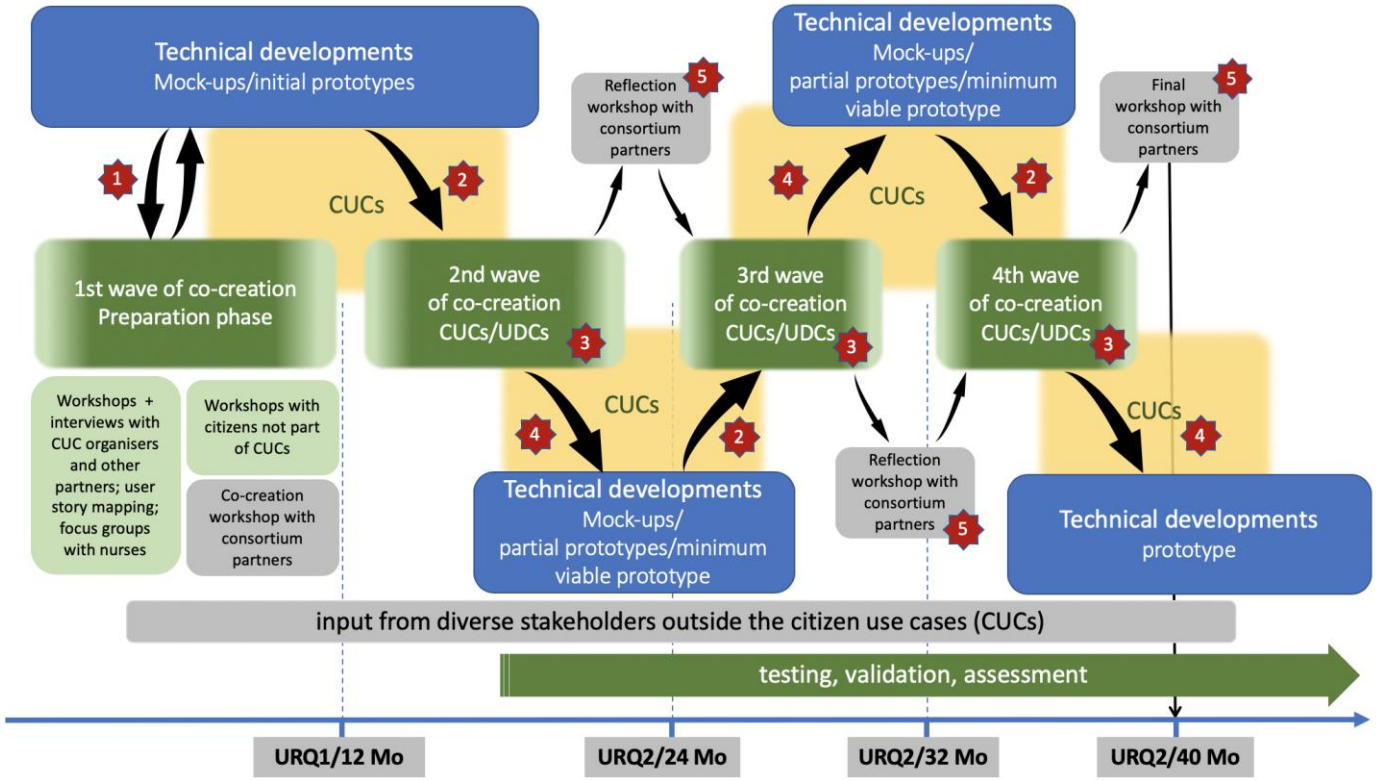


Figure 2 - The co-creation process

1. Iterative process between social science partners and technical partners based on the workshops & interviews; development of first mock-ups for the Co-creation Workshops (CCWs) with citizens; user story mapping
2. Input from the technical partners for the co-creation activities; this can be in form of mock-ups or initial/partial proto-type elements (e.g. testing the inscription process or the uploading of data)
3. Co-creation activities (user engagements) within the CUCs; these will depend on the concrete questions we will be working on and be composed of a mix of the methods described in chapter 4.2.
4. The outcomes of the user engagements will be transferred to the technical partners. These will then further adapt the technological solutions found so far or create new ones.
5. Workshop with the whole consortium in order to report developments and get feedback.

2nd Wave of co-creation

In the second wave of co-creation activities we will work in close collaboration with those involved in the CUCs and the technical partners, both those developing the 4HP and those working on data ingestion procedures.

To do so, in the initial phase (first month) of each wave we will develop an outline of our co-creation activities for each CUC within this wave. The structure and process, but also the number of and kinds of users involved in the planned co-creation activities will depend on

(1) the availability of mock-ups and initial prototypes,
(2) the status of activities in the CUC and
(3) which UDCs can best be tested in a specific CUC.

We also define for each wave **how we will recruit users, the sampling of user groups as well as how many users we plan to recruit**. To be able to do so in a CUC-specific manner, the CUC partners will be asked to develop (in interaction with the social scientists) a **detailed description of "the ecosystem of users"** (see section 4.2.2).

This means that not all CUCs will be involved in the same intensity in all waves. This will be discussed and agreed upon with the partners leading and supporting each CUC as well as with the technical partners. The result will be **a wave-specific roadmap that entails a tailor-made set of co-creation activities per CUC, showing how users will be engaged in the processes of development and design and what kind of specific issues and questions will be addressed.**

The insights produced by these activities will then – step by step – allow the development and refinement of personas and use scenarios which are then **transformed into user story maps together with our technical partners**. This will allow advances in the design of the 4HP and its services. It also permits to further identify and iterate requirements and respective performance criteria.

Besides the user engagement concerning the 4HP, in this wave we will also start to explore the interface between the CHDP and the RP. This means engaging specifically with the process of **health data donation** with citizen users as well as with researchers as data donation and its modalities will strongly affect both groups.

A reflection workshop with the whole consortium will ensure the flow of knowledge and allow for feedback and refinement/extension of the requirements.

In wave 2 we will also start to recruit citizen users from different settings who would be ready to engage on a more long-term basis with the development of the project (see section 4.2.1, method 1c), as well as plan engagements with professional users. Furthermore, we will start to prepare the testing and validation phase (T1.6, starting month 18). Finally, we will also develop procedures how to feedback to engaged users about how requirements got realised.

Taken together, these diverse activities will then collectively contribute to user requirements to be outlined in D1.5 – "2nd Specification of user requirements and performance criteria" (M24).

3rd Wave of co-creation
The third wave will proceed in a similar manner as wave 2, but shorter (6 months). We will again develop a first outline of our co-creation activities for each CUC in wave 3. The detailed outline will again depend on (1) the availability of mock-ups, partial prototypes/minimal viable prototype, (2) the status of activities in the CUC and (3) which UDCs can best be tested in this wave in the respective CUC. A reassessment of the user ecology will be performed, considering that early perceptions on user(group)s and roles might not have matched with the user(group)s in the CUC realities. The outline will be discussed and agreed upon with the partners leading and supporting each CUC as well as with the technical partners. The result will be a wave-specific roadmap that entails a tailor-made set of co-creation activities per CUC, showing how users will be engaged in the processes of development and design. However, as we here are in the third year of the project, we will already have more concrete elements of the 4HP to be experimented with and we will have to use a blend of the co-creation methods previously described. Given that we get closer to a minimum viable prototype, we will also use this wave to explore further **questions of information provision and IC language with users**. Feedback to the technical partners as well as a reflection workshop with the whole consortium will again be core activities. Taken together these diverse activities will then collectively contribute to user requirements to be outlined in D1.6 – "3rd Specification of user requirements and performance criteria" (M32).
4th Wave of co-creation
The fourth wave will proceed in a similar manner as wave 3. We will again develop a first outline of our co-creation activities for each CUC in wave 4. The detailed outline will again depend on (1) the availability of mock-ups, partial prototypes/minimal viable prototype, (2) the status of activities in the CUC and (3) which UDCs can best be tested in this wave in the respective CUC. Also, a reassessment of the user ecology will be performed, in order to discuss and agree upon with the partners leading and supporting each CUC as well as with the technical partners. The result will again be a wave-specific roadmap that entails a tailor-made set of co-creation activities per CUC, showing how users will be engaged in the processes of development and design. At the time of wave 4 we will be at the end of year 3 and beginning of year 4. Therefore, our core activities will be devoted to testing and refinement.

From month 18 onwards also **processes for testing and validation will be designed and prepared**. Testing and validation will be carried out once specific features of the 4HP are available and feedback will be provided to the respective partners up until month 50.

Along the process of co-creation in the 4 waves a set of interviews with diverse stakeholders outside the CUCs, such as national providers of EHRs, national and regional policy makers and legal advisors will be carried out.

4.3.2 Translating user requirements — User Story Mapping (USM)

User Story Mapping (Patton 2014), as a method from software development and thus suggested by our technical partners developing the 4HP prototype, **serves as an interface between those realising the technical developments in the consortium and citizen/professional users as well as other consortium members**. UNIVIE as social scientific partner has agreed to use this method of outlining linear stories about the 4HP usage from a user perspective to translate and track user requirements along the process of co-creation. However, the method also served to summarize and integrate first assumptions about user interactions with the 4HP by consortium partners, particularly by those leading and supporting CUCs and in development. As such, user story maps also aim at creating a common shared understanding of potential interactions as well as issues, concerns, and thus challenges that need to be considered in the iterative process of engaging with users and finding technical solutions. Thereby User Story Maps are embedded in a cyclical process of being shaped by conversations and discussions with citizen-/professional-users and, simultaneously, serve as a repository of solutions, procedures, ideas and issues to be engaged with in the USEEs. They track issues and decisions and enable a reflection of identified issues with citizen- and professional-users.

The procedure involves a hands-on approach by using post-it-notes to jot down steps of **a narrative flow through anticipated interactions with the 4HP**. These are laid out in a **matrix-like overview**, in order to re-arrange the steps in it while discussing them, as show in Figure 3.

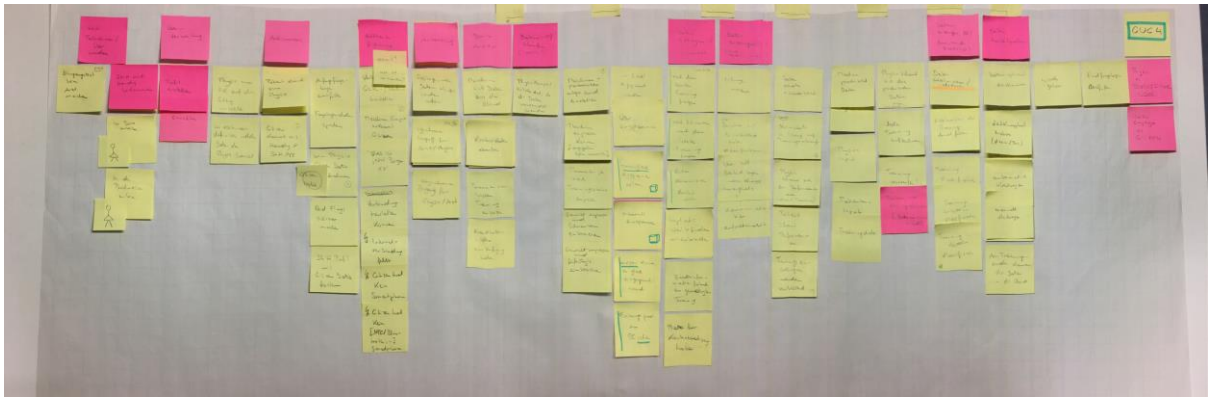


Figure 3 - Initial User Story Map of 4HP

On the highest level, we identified use(r) activities/actions such as registering to the 4HP. This receives a dedicated post-it, which together with other such key-actions form the “backbone” of the collective user story map. Below each step, further notes can be placed for detailed tasks related to each key-action followed by the varied issues and concerns users raised (e.g. “what to do when forgetting my password”, or “what information do I want to have before registering”). These latter can then also be prioritized if needed.

While the methodology tends to create a linearized and somewhat stabilized visualisation of the overall process, it is important to keep in mind that in practice single future users might have different visions of the overall process and develop their own

use patterns or not find a match with the proposed structure and related possibilities. Drawing on the Social Sciences and Humanities Framework (D1.1) it is thus essential to consider that users might in the end not follow the script that has been built into the 4HP on the basis of these user story mapping exercises. Therefore, it is important to use the time of the project **to follow use practices and reflect on how they match with the initial user story mapping outcomes – and adapt features accordingly.**

To give an idea of the user story mapping exercise as developed so far, we shortly describe in Table 1 the collective activities up until M10 of year 1 of the project:

Table 1 - User Story Mapping

Topic	Activities of UNIVIE	With partners
User Story Mapping workshop	Host a workshop on USM methodology by HPIHS to get a shared understanding on requirements elicitation and communication	HPIHS, D4L, HPI; f2f workshop (Vienna, May 8, 2019)
USM on 4HP	Produce first USM on the 4HP scenario focused on CUC 4, based on partner interviews	(May-June 2019)
	Walk-through of first USM and identify open questions, plan upcoming workshop	HPIHS, HPI; TelCo (June 5, 2019)
	Present the USM to partners and translate it collectively to a condensed working version for D4L and HPIHS, identify open questions	HPIHS, D4L, HPI; f2f workshop (Potsdam, June 11, 2019)
	Clarify questions regarding CUC4 work procedures that arose through the USM workshop	ZS-UG; email (June 12, 2019)
	Present updated USM, feedback on first UDC brainstorming by HPI, HPIHS, D4L	HPI, D4L; TelCo (June 27, 2019)
USM on 4HN portal	Kick off the portal USM to focus on possible interactions with the 4HN interface, as well as registration process	HPIHS, D4L, HPI, UNINOVA, KBZ; f2f workshop (Vienna, July 11, 2019)
	Present extended portal USM, identify open questions and issues	HPIHS, D4L, HPI; TelCo (July 25, 2019)
	Present extended portal USM, identify open questions and issues	HPIHS, D4L, HPI, UNINOVA; TelCo (Aug 29, 2019)
Brainstorming of CUC partners on portal interactions	Diversification of the input to the portal USM by including the CUC partners. The input from partners was analyzed by UNIVIE and included in the portal USM	All CUC leads: ISMMS, UKA, ZS-UG, UNINOVA, GovMad, SHD; email (Aug 7 – Sept 11, 2019)

4.4 Ethics-related issues

Within the co-creation environment, we will address questions of ethics on two levels: (1) we will consider the different IC procedures needed within the 4HP; and (2) we will be looking at IC and other relevant questions in terms of ethics as test cases in the co-creation environment.

First, we will have to consider IC procedures that are tailored to the empirical co-creation work in the different CUCs. The CUCs comprise different institutional settings; the co-creation work is being performed e.g. with citizens as part of the workforce in the production industry, in the hospital or in home-care settings. We will therefore have to pay specific attention to the recruitment procedures and the implications and requirements for consent under the different circumstances (D8.1 – "H – Requirement No. 1" (M12)).

The IC procedures will have three elements:

1. The first element is the IC regarding the citizen/professional users' participation in the co-creation workshop/user engagement exercises. This IC applies to all waves of the co-creation environment, as it does not require citizens/ professionals to be 4HP users.
2. As soon as the CHDP is operative, citizens will be able to register, upload, access and share health and health-related data. If the use, testing and validation of CHDP functionalities is part of the USEE and citizens engage directly with the 4HP, an additional informed consent (IC-CHDP) is to be signed.
3. As soon as the RP is operative, citizens will be able to donate their data to research. If the use, testing and validation of RP functionalities is part of the USEE, an additional informed consent (IC-RP) is to be signed.

Not all three elements will be relevant in all phases of the development of the 4HP prototype, yet all three need to be in place for the co-creation environment to be performed in an ethically appropriate way.

Second, throughout the project ethical considerations and practices of IC will become an explicit focus of deliberation in the process of co-creation itself. At different points in time, one dedicated Co-creation Workshop and several USEEs will specifically investigate IC procedures regarding the structure and social acceptability of IC forms and processes. Thereby, **questions of what being informed means, and questions of choice, benefit, justice and risk on multiple levels (e.g. data security or privacy) will be explicitly addressed.** The results of these investigations will substantially shape the development of the citizen/user consent language (D1.4 – "1st Citizen/User Consent Language Report" (M12) and D1.9 – "2nd Citizen/User Consent Language Report" (M46) respectively).

5 Working with the Citizen Use Cases (CUCs)

5.1 Citizen-centred co-creation: user roles in the CUCs

Through the various valuable discussions UNIVIE could have with partners leading and supporting the CUCs, as well as those responsible for the technical developments, it became apparent that it was necessary to specify more clearly the central user-category of Smart4Health - 'the citizen.' Indeed, one and the same person can hold **very different roles**. When specifying user requirements, we thus have to be attentive to these differentiations.

For example, if a nurse were to receive access to a patient's Smart4Health account in order to assess the patient's health status, medication, etc., he/she would act as a **professional user** (caring for a citizen user as patient). If, however, the nurse is uploading data from e.g. wearable sensors like a vest that monitors his/her posture throughout the workday, he/she would act as a **citizen at work**. Were the uploaded wearable data collected outside of the work environment in leisure time, e.g. from a smartwatch used to record a running workout, he/she would act as a **citizen in leisure time**. If the same nurse though partakes in a back-training program as a prescribed treatment after which data is uploaded to his/her Smart4Health account, he/she would act as a **citizen as patient** him-/herself.

5.1.1 Users

Overall, we identified the following users/user roles within the CUCs of Smart4Health, to whom partners can provide access during our waves of co-creation.

Citizens at work

- Nurses in the ICU (UKA)
- Nurses as mobile caregivers and office staff (SHD)
- Blue/white collar workers in industry (UNINOVA, ZS-UG) and in public administration (GovMad, UNINOVA)

Citizens as (potential) patients

- Patients organized in patient groups (OSR)
- Patients in therapy (ZS-UG)
- Patients at hospitals (UKA, ISMMS)

Citizens in their leisure time

- Tourists in Madeira (GovMad, UNINOVA)
- Workers in everyday life outside of work (UNINOVA)
- Citizens outside the CUCs (diverse groups)

Professional users

- Physios (access to be provided by SHD, ZS-UG, GovMad/UNINOVA)
- Doctors (access to be provided by OSR, UKA, Govmad/UNINOVA; potentially also UMC+)
- Nurses/caregivers (access to be provided by EFN, OSR, GovMad/UNINOVA, SHD)
- Researchers (ELIXIR-LU, ISMMS, UMC+)

In order to become a meaningful platform for citizens that also improves the care relation with various health care professionals, it has to be meaningful and suitable for both citizen and professional users. Hence, the inclusion of professional users clearly serves the citizen-centredness of the project and does so in the following way. In contrast to former EU-projects, which either centred around health care professionals and health policy actors or which treated citizens/patients, health system, market and health care professional workforce somewhat symmetrically, **Smart4Health is clearly centring citizens – from the outset onwards, methodologically and conceptually**. Yet, in Smart4Health, health care professionals are nevertheless engaged in the process of co-creation by giving feedback, evaluating development and design directions, participating in "reality-checks" and in the gradual (re)formulation of user requirements along the process. This is essential for turning Smart4Health into a powerful and supportive instrument in improving both the interaction of health care professionals and citizen-patients as well as citizen's capacity to care for their health and health-related data.

As emphasized in Smart4Health D1.1, the Social Sciences and Humanities Framework Report, and despite this further differentiation, such user categories and types previous mentioned still cannot be understood as clear-cut and homogeneous categories, as the diversity and potential inequalities (e.g. because of varying data literacy) need to be reflected across them and not be taken for granted. Otherwise we would run the risk of flattening these groups regarding the articulation of needs, values, and in essence their requirements with regard to the 4HP and what it should be able to do in health- and data-related futures.

5.1.2 Considering non-users

To understand the usage of the 4HP and its requirements from multiple user perspectives and situations, we need to be particularly attentive to **when and why it is not being used (anymore)** – whether temporarily or for good – but also what might lead back to usage again after not using it. This, furthermore, needs to be considered case by case and account for the specific settings of each CUC (e.g. being in a work environment), its cultural embedding and the types of data and users involved (or not).

As we referred to in D1.1, Wyatt and co-authors (2002) have argued in the case of internet (non)use that it is important to distinguish at least four groups of non-users: **the resisters (not using it at all), the rejecters (not using it anymore), the socially or technologically excluded (who have no access) or the expelled (who were using it at one point, but can no longer do so, e.g. afford it)**. Or as Greenhalgh and co-authors (2010) differentiate actions of user **adoption, non-adoption, or of abandonment** when it comes to personal electronic health records.

A first step of addressing non-users has been the very first round of co-creation workshops with heterogeneous groups of citizens in Vienna, which by design could not have been users at that point in time, as the 4HP was not up and running yet, but nevertheless included via visual mock-ups. Some of the participating citizens had even opted out of the Austrian national electronic health record (ELGA). This allowed to retrieve critical input, e.g. about privacy issues, of people who would fall into the resisters' category, and gain insights that are of great value for the project. While these groups were also intended as a workaround of not having actual users in the CUC contexts yet, the approach proved useful to also repeat it in another round with citizens in Germany, which, in contrast to Austria, does not have a national EHR available.

In the course of developing the 4HP it will be vital to not only establish access to users but to also keep communication channels open as long and easily as possible, in order to keep contact also with those who might have stopped using the 4HP. Thereby, non-users can be considered in a longitudinal sense, which also entails the possibility of becoming users again. For our planning of the co-creation environment this means that we have to establish a communication strategy with partners that makes CUC participants feel involved in the project, even though they might not use the 4HP as often as hoped for or not anymore. Thus, the collective work in the CUCs needs to ensure the consideration and, were possible, also the involvement of non-users too.

The close relation of users and non-users, however, also underlines that in order for people to establish trust regarding the 4HP and use it sustainably, it is necessary to explicate from the outset on the possibility of becoming a non-user, how to do so, and what this entails (this was clearly voiced by citizens in the discussion groups). Thus, **before becoming a user, the means and ends of becoming a non-user need to be clarified and communicated**, which is reflected in the collective work on the project's IC under WP8.

5.1.3 Stakeholders

Besides involving citizen-users and professional users, the CUCs also consider stakeholders (e.g. hospitals, companies at which citizens work) in different countries and empirical settings. In regard to the CUCs within the Smart4Health project, stakeholders are defined as follows:

Groups of persons or organizations that will interact with the 4HP and will be involved in the CUC Storyline in order to achieve and facilitate the CUC objectives. Stakeholders can be Smart4Health partners or be external to the Smart4Health project. Stakeholders will have interest and rights with respect to the actions in the CUC that will meet their needs and expectations. Stakeholders can be different between different CUCs (but this is not mandatory).

Hence, stakeholders in the CUCs have the double function of both facilitating its progress, and benefitting from it meeting its objectives. Details of who the stakeholders are or can become in each CUC throughout the project, are outlined by each CUC leader in their respective CUC handbook and kept up to date as these are living documents (we will draw on this resource when preparing for the co-creation waves).

In the Smart4Health project as a whole, however, an even wider understanding of stakeholders is required in order to live up to the argument that involving citizens and stakeholders into processes of innovation is essential to "obtain relevant knowledge" on the potential outcomes of innovations, and for effectively assessing "both outcomes and options in terms of societal needs and moral values" (von Schomberg 2011, p. 9). Accordingly, the work under WP1 also includes the valuable input from stakeholders outside the CUCs, such as experts in the fields of health data and related issues, or co-creation processes and challenges. The involvement of stakeholders also on project level aims at according to the premises of RRI, to ensure that **both the process and outcome of research and innovation are acceptable and socially desirable**, particularly in a citizen-centred project like Smart4Health.

5.2 Citizen Use Cases

In order to design the co-creation environment, it is essential to know where USEEs can be conducted and how interactions with the 4HP are to be expected in each CUC. This key interest thus also includes knowing who the users are – according to the

previous finer differentiation of citizen- and professional-users – and what kinds of data are ported to/from the 4HP.

Hence, getting this understanding is relevant for the work within the consortium as it aligns it in a threefold way: between technical partners, developing the 4HP and/or the implementation of wearable devices, the partners leading and supporting the CUCs, and of the WP1 lead responsible for the user engagements, all of which however also feeds back into the consortium throughout and at the end of the prototype development process.

The work of WP1 needs to focus on concrete interactions of citizen users and professional users with the 4HP via the portal and components pairing to it (e.g. for wearables or physio machines) in each of the CUCs also considering the 6 UDCs. The UDCs assemble and integrate desired elements and functionalities of the 4HP, each linking citizen, data and potentially other actors in specific ways, and enabling citizens to act on and relate to their own data in new ways. Three UDCs – "MyHealthView", "MyTime" and "MyWork" – will be devoted to developing and designing the specific views and functions for the citizens. Three further UDCs will then each focus on specific functionalities for allowing citizens to give access to their personal health data ("MyTrusted", "Mob.E.Health") or to donate their data to research ("MyScience"). Whereas it remains important to think the CUCs together with the UDCs, at this stage of planning the co-creation environment it is necessary and beneficial to focus on the concrete health data practices that citizens are expected to do in each CUC.

Our approach of planning/designing the co-creation environment starts by looking into each CUC identifying where it takes place, what users and data are involved, and what interactions with the 4HP can be expected. The further concretization of and relation to the UDCs will be specifically addressed in the dedicated task T1.4, which runs along and beyond the iterative user/citizen co-creation process.

The 8 CUCs have been divided in three groups, each having a specific relation and making a specific contribution to the 4HP development (see Figure 4). Hence, the tables 2-4 also follow this grouping by: (1) **Testing infrastructure,** (2) **Collecting citizen-generated health data,** and (3) **Considering citizen diversity and mobility**. Moreover, the tables include the following kinds of partner input:

- outcomes of the f2f co-creation workshop of all consortium members held at the GA meeting September 2019 in Lisbon and
- follow-up email correspondences of WP1 lead UNIVIE with CUC partners to clarify (further) questions
- previous work by CUC leaders in filling out handbooks for each (addressing involved users, data, sites, stakeholders, and storylines)
- outcomes of a brainstorming workshop by WP2 an WP3 partners about relating the UDCs to concrete interactions with and functionalities of the 4HP.

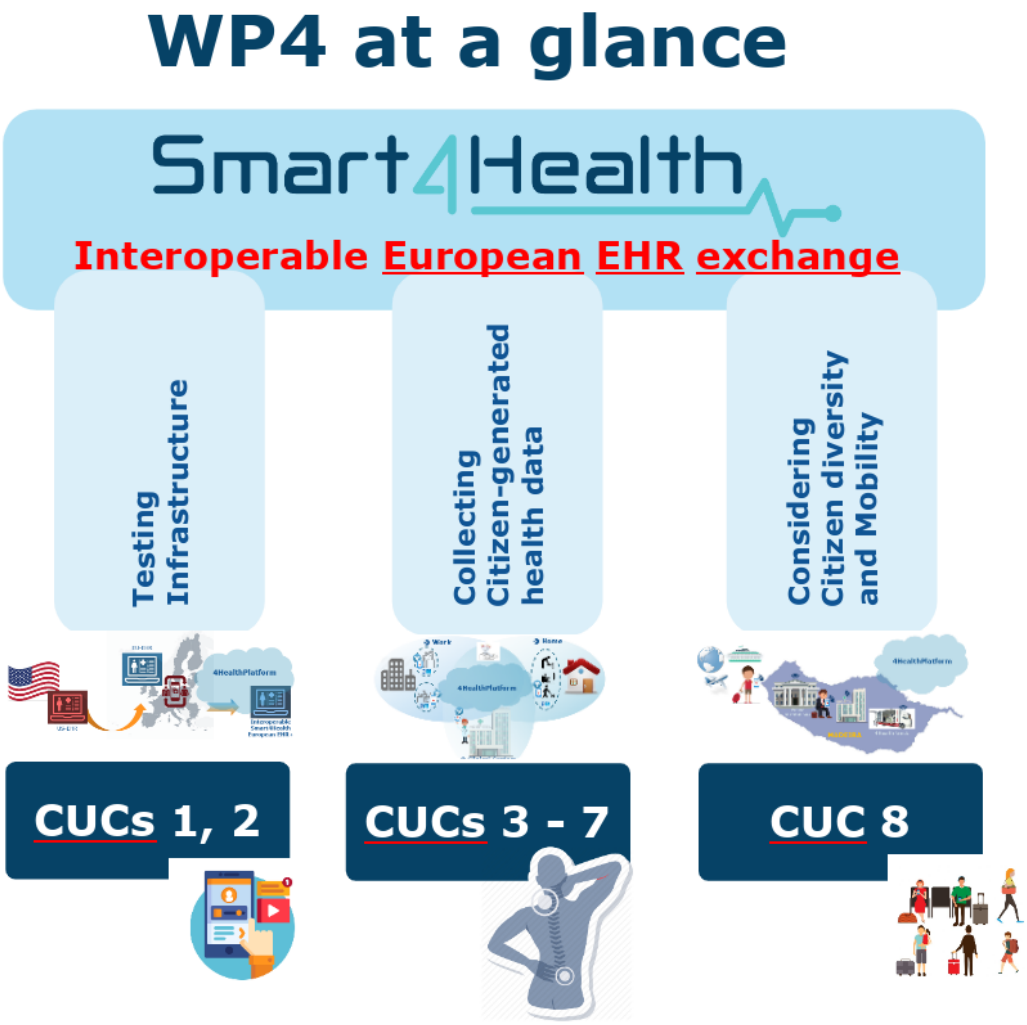


Figure 4 - Grouped overview of the CUCs in Smart4Health[3]

[3] This grouping of CUCs was developed in WP4.

Whereas CUC 1 and 2 include data donation, this interaction and feature remains present across all other CUCs as an option that the citizens themselves can trigger. While, however, other CUCs do not focus on data donation as such, it is still a testable interaction with the 4HP. What this functionality should be able to offer (or not) is nevertheless considered in the work of WP1 in all USEEs, enabled through the use of mock-ups and story cards that outline and balance potential issues and benefits of this specific use scenario, as previous explained. Furthermore, data donation has already been the topic of co-creation workshops in form of citizen discussion groups independent of the CUCs.

Table 2 - Testing the infrastructure

Testing infrastructure				
CUC number and title	**Place (of user access)**	**User types (citizen/ professional users)**	**Data types**	**Interactions with the 4HP**
CUC1: Full US EHR+, ePrescription-eDispensation, full clinical hospital cases	n/a, implementation across platform (Partners in: New York, Aachen, Potsdam, Maastricht, and Milan)	- Citizens as patients (at Mount Sinai, UKA, UMC+, OSR) - Professionals (researchers, HCP)	US EHR at Mount Sinai HealthSystem Mount Sinai de-identified EHR	Develop models for the RP, inform citizen data & RP development, data access (only for internal S4H researchers), collaborate with EU hospitals to reconcile data element differences across countries
CUC2: EU EHR, Patient summary+, ePrescription-eDispensation, full hospital cases	n/a as tied to CUC1 for 2020, from 2021 onwards: University hospital Aachen, DE	- Citizens as patients (in ICU as data donors, access to Fallakte+ patients only) - Professionals (researchers, HCP)	de-identified ICU patient records (for year 2020), patient records from Fallakte+ (for year 2021 onwards)	Data ingestion to the CHDP and donation to the RP, researcher access; Registering and consenting to the 4HP, accessing, uploading, managing and sharing health data with HCP at hospitals across Europe

The means of collecting and generating citizen health data vary, but always involve technological devices being used throughout the CUCs 3 to 8. Three types of technologies are integrated: First, the back-training machine MedX, which is used in CUCs 3 to 8. When using the MedX back training machines, data in form of training reports and questionnaires that the physiotherapist asks the participant, are uploaded to the citizen users' account. For this to happen, the specifically adapted software running on the physio machine, the 4Health Monitor (4HM) needs to connect to the 4HP in a **pairing** process, which then becomes one of the interaction points with the 4HP.

Second, unique to CUC7, ICU nurses will be supported by single robot arms to aid the lifting and turning of patients. The robot-supported ICU nurses will moreover be wearing vests with integrated sensors that monitor and track the posture, and which produce data to be ingested to the 4HP.

Hence, third, wearables that monitor and track the posture are involved in CUCs 5, 6, 7, and 8. The citizens at work are thus situated in different work environments and cultures, e.g. an office worker sitting at a desk, industry workers doing heavy duty tasks, or nurses caring for patients.

Whereas the objective of a CUC might be to ideally relieve workers from the stress that their demanding work can have on their backs, for the project's objective of developing an interoperable health data platform prototype it is of interest how that generated data can be ingested to the 4HP, and thus into a citizen account, how it can and should be represented to the citizen, what options citizens can and want to choose from therein in order handle their own data in new ways, etc.

Table 3 - Collecting citizen-generated health data

Collecting citizen-generated health data				
CUC number and title	**Place (of user access)**	**User types (citizen/ professional users)**	**Data types**	**Interactions with the 4HP**
CUC3: Back pain and muscular-skeletal disease treatment	Aachen, DE, „back centre“ practice at ZS-UG	- Citizens as patients (in therapy) - Professionals (MD, physios)	Training reports/questionnaires, clinical/medical documents (e.g. referral letter)	Registering and consenting to 4HP, accessing, uploading, managing and sharing data with HCP, pairing with 4Health Monitor (4HM)
CUC4: Back pain and muscular-skeletal prevention	Aachen region, DE, company workplaces	- Citizens at work (white and blue collar) - Professionals (physios, sports scientists, health managers)	Training reports/questionnaires, wearables sensor data/reports	Registering and consenting to 4HP, accessing, uploading, managing and sharing data with HCP, pairing with 4HM
CUC5: Life and workplace, back pain prevention	Minho, PT, industry workplaces	- Citizens at work (white and blue collar) - Citizens in leisure (workers) - Professionals (physios)	Training reports/questionnaires, wearables sensor data/reports	Registering and consenting to 4HP, accessing, uploading, managing and sharing data with HCP, pairing with the Citizen Hub and 4HM
CUC6: Caregivers‘ workplace, back pain prevention	Luxemburg, LU, SHD and outbound	- Citizens at work (caregivers in-/formal, office staff) - Professionals (GP/MD, physios)	Wearables sensor data/reports, Training reports/questionnaires	Registering and consenting to 4HP, accessing, uploading, managing and sharing with HCP, pairing with the Citizen Hub and 4HM
CUC7: Hospital workplace, back pain prevention	Aachen, DE, UKA hospital	- Citizens at work (ICU nurses), - Professionals (MD)	Wearables sensor data/reports (Smart-vest, posture-sensor) Training reports/questionnaires	Registering and consenting to 4HP, accessing, uploading, managing and sharing data with MD, pairing with the Citizen Hub and 4HM

CUC8 is specific by design in several ways. It encompasses users from three user groups, which also CUC5 does, but is the only one that specifically addresses tourists as citizens in their leisure time and thereby the topics of citizen diversity and cross-border mobility. Next to involving two types of citizen generated health data (reports from MedX trainings and wearables), so too are clinical/medical data. By also including professional users CUC8 offers broad access to users, which is potentially widened even more in (the unfortunate) case that a tourist might also interact with the 4HP in the role of a citizen as patient.

Table 4 - Considering Citizen diversity and mobility

Considering Citizen diversity and mobility				
CUC number and title	**Place (of user access)**	**User types (citizen/ professional users)**	**Data types**	**Interactions with the 4HP**
CUC8: Regional health, tourists, preparedness, back pain prevention	Madeira, PT, street events, regional government and hotels	- Citizens in leisure (tourists, locals), - Citizens at work (office staff), - Professionals (nurses, MD, physios)	Wearables sensor data/reports (Smartwatches), Training reports/questionnaires, clinical/medical data	Registering and consenting to 4HP, accessing, uploading, managing and sharing data with HCP, pairing with the Citizen Hub and 4HM

While in Tables 2-4 the first three columns are rather straightforward, the fourth column outlines the expected interactions with the 4HP in each CUC. Whereas these can and should overlap in order to reflect and validate in USEEs on certain interactions with the 4HP in specific situations of everyday life, they should not be understood as being exhaustive. Instead, it is imperative in following a citizen-centred approach to remain open to new types of interactions that have not been anticipated by the consortium. This openness ties back to the toolbox of methods with which citizens can be addressed in the most fitting ways (e.g. in interviews, walkshops), whether in group settings or individually, to account for variations in the capacity and willingness of engaging in a co-creation environment.

Hence, the mentioned interactions with the 4HP, as complex as they might be in practice, are merely **a first basis that needs to be expanded but also questioned and reflected on throughout the project** regarding its implementation and its ability to meet RRI criteria. Other interactions than those previous mentioned (donating and pairing), are the following:

Depending on the CUC, a first interaction is likely one of **registering and consenting** to use of the 4HP, which requires communicating the project and formulating an IC, which is developed and tested regarding its language, intelligibility and acceptability along the project in T1.5.

Accessing entails seeing an overview of one's own health (related) data in the user portal of the 4HP. This in turn is closely linked to **managing** one's own health data, e.g. to search, filter, group and tag data, as well as seeing and **managing/editing** one's emergency information and/or Smart4Health profile/account.

Uploading encompasses the ingestion of citizen generated health data gathered via wearables through the so-called Citizen Hub component, which pairs with the 4HP and/or can have professional users like a physiotherapist upload a training report, or a medical doctor upload medical reports to the CHDP, i.e. the account of a citizen user.

Which uploaded data one can and might want to be **sharing** and with whom varies again by the involved users of the CUC. That interaction thereby links to the previous mentioned interactions of what data has been uploaded already, how it is represented and manageable, but also goes beyond such technical functionalities, e.g. by also addressing issues of trust – on who to give access and share data with but also if and how for example professional users trust certain data.

This first exploration of the basis thus already gives a glimpse at the complexities that the interactions with the 4HP can mean and need to be considered in engagements with (potential) users.

6 Summary and final considerations

The objective of Deliverable 1.2 is to outline the methodological design of the co-creation environment for the Smart4Health project. The central aim of Smart4Health is to develop a health data infrastructure to empower citizens as future users to manage their own health (data). In doing so, the project puts European citizens centre stage – conceptually and methodologically. Producing an appropriate solution for a portable, interoperable citizen health data platform prototype will therefore proceed in a process of co-creation, involving citizens as well as diverse health-care professionals throughout the whole process of development, design and implementation. This approach puts potential future users in the position of (1) playing a central role in identifying needs and problems, but also in finding solutions; (2) expressing values and concerns; (3) proposing requirements to be met, and (4) being involved in the testing and assessing when gradually building the Smart4Health prototype.

Proposing a co-creation approach to building the 4HP and its services testifies to the consortium's awareness that the final prototype must meet the needs and concerns of future users, both citizen- and professional users. Bringing different parties together and creating space for exchange will lead to jointly produce a mutually valued outcome. Successful value co-creation will only be achieved if the 4HP and the connected services meet the user requirements and is best suited to user's health-related data practices. Furthermore, users should be able to perceive tangible benefits as this is an important motivational factor for long-term engagement. This also means building trust relations, as this is a key issue to ensure sustainable relations between (future) users of the 4HP and those running the 4HP. Not doing so might increase the risk that people refuse to adopt, build and make use of such an infrastructure, or that they abandon it soon after initially inscribing to it.

The deliverable also points to the strong link that the practices of co-creation have with the sensitivities that were outlined in D1.1. and in particular what it means to think of the 4HP from a Responsible Research and Innovation (RRI) angle. This means engaging with the four core values of inclusiveness, anticipation, reflexivity and responsiveness which were spelled out in detail.

Co-creation is not a new concept and therefore Smart4Health can learn both from international experiences in doing co-creation and in particular from European projects. After presenting the four different understandings of co-creation, we decided that for Smart4Health *technology co-design* and *experienced-based co-design (EBD)* are the two most central approaches. Yet, also elements of the value co-creation will need to be considered. Overall, from past experiences we learn about the centrality of user recruitment, which needs to be open, broad and diverse, and about the importance of proactive user support so that they can articulate as clear as possible their needs and concerns. When it comes to the process of co-creation itself, transparency about the scope and the limits of co-creation is essential and so is the justification of final design choices made. Finally, it will be key to keep the development and design process open as long as possible, so that iterative learning will be possible all along the project. Taking these elements together points to the importance of appropriate facilitation throughout the entire process.

The project speaks of a "co-creation *environment*" in order to point to the fact that the co-creation will be happening all along the process of development, design and implementation and will consist of many different settings in which co-creation

happens in parallel. We will work in 4 waves, each refining the user requirements through user engagement. At different instances of the project we will use a blend of different methods to engage with users, we will address different problem areas from the technical to the social realm. As the CUCs are located in different regions of Europe, therefore we will encounter different cultural settings and different users, who will also take us to different institutional environments (e.g. hospitals, factories, leisure environments). This will allow to carve out cultural differences, engage with language issues and to encounter users in work, leisure or health related setting.

We also need to address ethics in and of the health data infrastructure prototype. The **ethics in the making of the infrastructure** points to the different moments where IC is needed during the co-creation process and it calls for attention to the recruitment processes in order to not exclude important user groups. **Ethics of the health data infrastructure prototype** points to potential consequences for users. Furthermore, we will also use the co-creation process to develop IC processes which are satisfactory from a user perspective.

Overall, what makes the strength of Smart4Health is that through the co-creation process there will be dense and very regular interaction between the partners of the consortium and jointly producing a mutually valued health data infrastructure.

References

Andersen, L. B., Danholt, P., Halskov, K., Hansen, N. B., & Lauritsen, P. (2015). Participation as a matter of concern in participatory design. *CoDesign, 11*(3-4), 250-261. doi:10.1080/15710882.2015.1081246

Andersen, T. O. (2019). Large-scale and long-term co-design of digital health. *Interactions, 5*(August 2019), 74-77.

Atkinson, R. (2001). The Life Story Interview. In J. F. Gubrium & J. A. Holstein (Eds.), Handbook of Interview Research. Context & Method (pp. 121-140). Thousand Oaks/London/New Delhi: SAGE Publications.

Bammer, G. (2019). Key issues in co-creation with stakeholders when research problems are complex. *Evidence & Policy: A Journal of Research, Debate and Practice, 15*(3), 423-435. doi:10.1332/174426419X15532579188099

Bate, P., & Robert, G. (2006). Experience-based design: from redesigning the system around the patient to co-designing services with the patient. *Quality & safety in health care, 15*(5), 307-310. doi:10.1136/qshc.2005.016527

Bratteteig, T., & Wagner, I. (2016). Unpacking the Notion of Participation in Participatory Design. *Computer Supported Cooperative Work (CSCW), 25*(6), 425-475. doi:10.1007/s10606-016-9259-4

Braun, K., & Schultz, S. (2009). "... a certain amount of engineering involved": Constructing the public in participatory governance arrangements. Public Understanding of Science, 19(4), 403-419. doi:10.1177/0963662509347814

Braun, K., & Könninger, S. (2018). From experiments to ecosystems? Reviewing public participation, scientific governance and the systemic turn. *Public Understanding of Science, 27*(6), 674-689.

Cacari-Stone, L., Wallerstein, N., Garcia, A. P., & Minkler, M. (2014). The promise of community-based participatory research for health equity: a conceptual model for bridging evidence with policy. *American journal of public health, 104*(9), 1615-1623. doi:10.2105/AJPH.2014.301961

Charmaz, K. (2014). Constructing Grounded Theory. 2nd Edition. London: SAGE Publications. Clarke, A.E. (2005). Situational Analysis. Grounded Theory After the Postmodern Turn. Thousand Oaks: SAGE Publications.

Czarniawska, B. (2004). *Narratives in Social Science Research*. London: Sage Publications.

Erikainen, S., Pickersgill, M., Cunningham-Burley, S. & Chan, S. (2019). Patienthood and participation in the digital era. Digital Health 5, 1-10. doi:10.1177/2055207619845546

EC (2019). Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe, Co-design via web page consultation. [online] Available at: https://ec.europa.eu/research/pdf/horizon-europe/ec_rtd_orientations-towards-the-strategic-planning.pdf [Accessed 12 October 2019].

EC (2017). HORIZON 2020 - Work Programme 2016 – 2017, Europe in a changing world – Inclusive, innovative and reflective societies. [online] Available at: https://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-societies_en.pdf [Accessed 12 October 2019].

eStandards (2015). eHealth Standards and Profiles in Action for Europe and Beyond. [online] Available at: http://www.estandards-project.eu/ [Accessed 25 October 2019].

eStandards (2017). Deliverable 3.5: Roadmap for collaborative and sustainable standards development: Recommendations for a globally competitive Europe.

[online] Available at: http://www.estandards-project.eu/eSTANDARDS/assets/File/deliverables/eStandards-D3_5-Roadmap_v1_2a.pdf [Accessed 25 October 2019].

Farrington, C. J. (2016). Co-designing healthcare systems: between transformation and tokenism. *Journal of the Royal Society of Medicine, 109*(10), 368-371. doi:10.1177/0141076816658789

Felt, U. and Fochler, M. (2010). Machineries for Making Publics: Inscribing and De-scribing Publics in Public Engagement. *Minerva* 48(3), 219-238.

Felt, U., Fochler, M., & Sigl, L.(2018). IMAGINE RRI. A card-based method for reflecting on responsibility in life science research. *Journal of Responsible Innovation*, *5*(2), 201-224. doi.org/10.1080/23299460.2018.1457402

Felt, U., Schumann, S., Schwarz, C. G., & Strassnig, M. (2014). Technology of imagination: a card-based public engagement method for debating emerging technologies. *Qualitative Research, 14*(2), 233-251. doi:10.1177/1468794112468468

Fitzpatrick, G., & Ellingsen, G. (2013). A Review of 25 Years of CSCW Research in Healthcare: Contributions, Challenges and Future Agendas. *Computer Supported Cooperative Work, 22*(4-6), 609-665. doi:10.1007/s10606-012-9168-0

Greenhalgh, T., Stramer, K., Bratan, T., et al. (2010b). Adoption and non-adoption of a shared electronic summary record in England: a mixed-method case study. *BMJ, 340*, c3111. doi:10.1136/bmj.c3111

Greenhalgh, T., Jackson, C., Shaw, S., & Janamian, T. (2016). Achieving Research Impact Through Co-creation in Community-Based Health Services: Literature Review and Case Study. *The Milbank quarterly, 94*(2), 392-429. doi:10.1111/1468-0009.12197

HubIT (2017a). The HUB for boosting the Responsibility and inclusiveness of ICT enabled Research and Innovation through constructive interactions with SSH research. [online] Available at: https://www.hubit-project.eu/ [Accessed 25 October 2019].

HubIT (2017b). About project. [online] Available at: https://www.hubit-project.eu/about-project [Accessed 25 October 2019].

HubIT (2017c). Guidelines: 10 tips for how to implement RRI through interdisciplinary collaboration in ICT projects. [online] Available at: https://www.hubit-project.eu/guidelines/download/HubIT_10%20tips_guidelines.pdf [Accessed 25 October 2019].

Halskov, K., & Hansen, N. B. (2015). The diversity of participatory design research practice at PDC 2002–2012. *International Journal of Human-Computer Studies, 74*, 81-92. doi:https://doi.org/10.1016/j.ijhcs.2014.09.003

Kensing, F., & Blomberg, J. (1998). Participatory Design: Issues and Concerns. *Computer Supported Cooperative Work (CSCW), 7*(3), 167-185. doi:10.1023/A:1008689307411

Kitzinger, J. (2005). Focus group research: using group dynamics to explore perceptions, experiences and understandings. In Holloway I. (Ed.), *Qualitative Research in Health Care*. Maidenhead: Open University Press.

Mayer, R.C., Davis, J.H. & Schoorman, F.D. (1995). An integrative model of organizational trust, *Acad. Manag. Rev.* 20 (3), 709–734.

Patton, J. (2014). *User Story Mapping*. Sewastopol: O'Reilly.

Prahalad, C. K., & Ramaswamy, V. (2004). Co-creation experiences: The next practice in value creation. *Journal of Interactive Marketing, 18*(3), 5-14. doi:https://doi.org/10.1002/dir.20015

Pruitt, J. & Adlin, T. (2006). The Persona Lifecycle: Keeping People in Mind Throughout Product Design. Amsterdam/Boston: Elsevier.

von Schomberg, R. (2011). Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields. Brussels: European Commission.

Spradley, J. (2002). Interviews. In Mark E. Pogrebin (Ed.), Qualitative Approaches to Criminal Justice. Perspectives from the Field (pp. 44-53). London: SAGE Publications.

SISCODE (2018a). Deliverable 1.3: Theoretical framework and tools for understanding co-creation in contexts. [online] Available at: https://siscodeproject.eu/wp-content/uploads/2018/11/Theoretical-Framework-and-Tools-for-Understanding-Co-Creation-in-Contexts_D1.3.pdf [Accessed 25 October 2019].

SISCODE (2018b). Society in Innovation and Science through CODEsign. [online] Available at: https://siscodeproject.eu/ [Accessed 25 October 2019].

SISCODE (2018c). Deliverable 1.1: RRI research landscape. [online] Available at: https://siscodeproject.eu/wp-content/uploads/2018/11/RRI-Research-Landscape_D1.1.pdf [Accessed 25 October 2019].

SISCODE (2018d). Deliverable 3.2: Co-creation labs: Solutions and policies. [online] Available at: https://siscodeproject.eu/wp-content/uploads/2019/08/Co-creation-labs-solutions-and-policies_compressed.pdf [Accessed 25 October 2019].

SISCODE (2018e). SISCODE toolbox for co-creation journeys. [online] Available at: https://siscodeproject.eu/wp-content/uploads/2019/09/toolkit-27092019-1.pdf [Accessed 25 October 2019].

Voorberg, W. H., Bekkers, V. J. J. M., & Tummers, L. G. (2015). A Systematic Review of Co-Creation and Co-Production: Embarking on the social innovation journey. *Public Management Review, 17*(9), 1333-1357. doi:10.1080/14719037.2014.930505

Wright, D. R., Underhill, L. G., Keene, M., & Knight, A. T. (2015). Understanding the motivations and satisfactions of volunteers to improve the effectiveness of citizen science programs. *Society & Natural Resources*, 28(9), 1013-1029.

Wyatt, S., Thomas, G. and Terranova, T. (2002). They came, they surfed, they went back to the beach: Conceptualising use and non-use of the Internet. In Woolgar, S. ed., Virtual Society? Technology, Cyberbole, Reality. Oxford: Oxford University Press, 23-40.

Zuiderent-Jerak, T., & Van Egmond, S. (2015). Ineffable Cultures or Material Devices: What Valuation Studies can Learn from the Disappearance of Ensured Solidarity in a Health Care Market. *Valuation Studies, 3*(1), 45-73. doi:10.3384/vs.2001-559.153145

List of Acronyms/Abbreviations

Acronym/ Abbreviation	Description
4HP	4Health Platform
4HM	4Health Monitor
4HN	4Health Navigator
CCW	Co-Creation workshop
CHDP	Citizen Health Data Platform
CORDIS	Community Research and Development Information Service (of the EU)
CSCW	Computer-Supported Cooperative Work
CUC	Citizen Use Case
D	Deliverable
D4L	data4life gGmbH
DE	Deutschland/Germany
EBD	Experience-based co-design
EFN	European Federation of Nurses
EHR	Electronic Health Record
ELGA	Elektronische Gesundheitsakte (EHR in Austria)
ELIXIR-LU	ELIXIR Luxembourg
EU	European Union
f2f	Face-to-face
GA	General Assembly
GDPR	General Data Protection Regulation
GovMad	Government of Madeira
GP	General Practitioner
H2020	Horizon2020 EU research and innovation programme
HCP	Health Care Professional
HPI	Hasso-Plattner-Institute for Digital Engineering gGmbH
HPIHS	HPIHS GmbH
HubIT	Research project on activating interactions between ICT developers, SSH researchers and stakeholders
IC	Informed Consent
ICT	Information and Communication Technologies

Acronym/ Abbreviation	Description
ICU	Intensive Care Unit (at hospital)
ISMMS	Icahn School of Medicine at Mount Sinai
ITTM	Information Technology for Translational Medicine
KBZ	KnowledgeBiz
LAUG	Longitudinal accompanying user group
LU	Luxembourg
NewHoRRIzon	Research project: Excellence in science and innovation for Europe by adopting the concept of Responsible Research and Innovation
MD	Medical Doctor
OSR	Ospedale San Raffaele
PD	Participatory design
PT	Portugal
RiConfigure	Research project: Reconfiguring Research and Innovation Constellations
RP	Research Platform
RRI	Responsible Research and Innovation
SCAUT	Research project: Self-, Collaborative- and AUTo-detection of signs and symptoms of deterioration
SHD	Stëftung Hëllef Doheem
SISCODE	Research project: Co-design for Society in Innovation and Science
SMEs	Small and Medium-sized Enterprises
SSH	Social Sciences and Humanities
S4H	Smart4Health
TelCo	Teleconference
TOPIC	Research project: The Online Platform for Informal Caregivers
UDC	Use Design Case
UKA	Universitaetsklinikum Aachen
UMC+	Maastricht University Medical Center
UNINOVA	Instituto de Desenvolvimento de Novas Tecnologias
UNIVIE	University of Vienna
URQs	User Requirements
US	United States
USEE	User Engagement Exercise

Acronym/ Abbreviation	Description
USM	User Story Map
WP	Work Package
ZS-UG	ZS Unternehmen Gesundheit

List of Tables

List of Figures