Citizen-centred EU-EHR exchange for personalised health

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

D1.3: 1st Specification of user requirements and performance criteria

Deliverable Leader: UNIVIE

Due Date: M12

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Short Abstract

Deliverable D1.3 provides the first specification of user requirements and, accordingly, the identification of related performance criteria. The report provides insights into the main considerations, the methodological approach and in the co-creation activities that were performed with future users. Based on these latter a 1st set of user requirements is identified and an approach to define and track performances is presented.

Document Status

Deliverable Leader	UNIVIE (Ulrike Felt, Susanne Öchsner, Robin Rae)
Internal Reviewer 1	D4L
Internal Reviewer 2	KBZ
Type	Report
Work Package	WP1: Citizen- and Professional-User participation: user requirements and performance criteria
Deliverable	D1.3: 1st Specification of user requirements and performance criteria
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History

Versions	Description
D0.1	First draft version written by UNIVIE, sent out to WP1 partners for early feedback
D0.2	Feedback from partners (EFN, D4L, HPI, ISMMS, I-VLab); a new version was prepared by UNIVIE, revising and extending parts of the report
R0.1	Revised version after review by KBZ and D4L
F1.0	Final version ready for submission prepared by UNIVIE

Contributors	Description
UNIVIE	Organize and conduct two rounds of partner workshops and interviews including their transcription; analyse received partner input; creation of actor maps to outline visions and concerns; formulation of first assumed user requirements; input to and participation in user story mapping (USM) workshops; continuous work on USMs e.g. by analysis and integration of further partner input; formulation of assumption personas; conducting five citizen co-creation workshops; elicitation and communication of a first specification of user requirements and development of approach to identify and monitor performance criteria
D4L, HM, HPI, ITTM, SHD, UKA, ZS-UG	Participation in workshops and interviews (face-to-face) organized by UNIVIE with technical and CUC partners - to explore platform scenarios and larger narratives of the project, CUC storylines, involved actors, and assumptions on users and the development. All of this fed into early work on assumption personas and user requirements (03/2019)

GovMad, KBZ, UNINOVA, UNIVIE	Organization of a two-day communication event with citizens and tourists of Funchal, Madeira, including the development and utilization of digital questionnaires about health- and wellbeing-data management as well as mobile device usage (05/2019)
D4L, HM, HPI, UNIVIE, ZS-UG	Participation in work on the platform USM, face-to-face and remote to explore a first user journey of a citizen in a CUC and identify points of consideration in the development (05-06/2019)
ELIXIR-LU, GovMad, OSR, UKA, UMC+, EFN	Participation in remote interviews with UNIVIE to explore platform scenarios, current institutional procedures and standards, potential user groups and access, and further modes of collaboration (06-07/2019)
D4L, HM, HPI, KBZ, UNINOVA, UNIVIE	Participation in work on the portal USM, face-to-face and remote to identify possible interactions with the interface of the platform, which also serve as points for discussion in first citizen co-creation workshops (07-08/2019)
GovMad, ISMMS, SHD, UKA, UNINOVA, ZS-UG	Conducting brainstorming exercises sent out by UNIVIE to diversify the input to the portal USM (08-09/2019)
All partners in the General Assembly	Co-creation workshop with all partners at the General Assembly (09/2019)
D4L, HPI	Provision of mock-ups, i.e. visual input, for situation cards developed and used for citizen co-creation workshops conducted by UNIVIE (09-10/2019)

Further Information

www.smart4health.eu

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Executive Summary

The objective of Deliverable 1.3 is to present the first specification of user requirements and, accordingly, the identification of related performance criteria. Smart4Health aims to develop a health-data infrastructure that shall support citizens in taking control of their own health data. No infrastructure starts *de novo*, but always builds on pre-existing ones. In the case of Smart4Health, there are pre-existing health data infrastructures in different national health-care systems, diverse visions of e-health and how citizens should profit from such approach, as well as varying degrees of implementation of ICT infrastructures and ICT literate citizens. Furthermore, some of the functionalities of the prototype to be developed in Smart4Health (e.g. what data can/should be uploaded, how data can be shared, the provision of data for research) were already defined in advance in the course of preparing the project proposal. Finally, contemporary societies already have several systems handling sensitive data in place (e.g. the banking system); thus, there are sets of standards of how to build such infrastructures as well as regulatory systems governing these infrastructures.

While this is our starting point when working with future users on their requirements, we engage in a co-creation process, which means that we put citizen-users in the centre stage of the development of user requirements and performance criteria and the articulation of areas of concern, as the detailed key-features of the platform are still open to be developed following the requirements formulated by citizens.

The deliverable starts out with an introduction (chapter 2) into the relevance of specifying user requirements and performance criteria and offers an overview of the structure of the deliverable.

Chapter 3 explains the **overall approach** to developing user requirements and performance criteria and outlines an iterative process of five steps: (1) Defining key features of the health-data platform and its services, (2) Gathering user requirements and classifying them, (3) Evaluation and prioritization of user requirements, (4) Developing performance criteria and (5) Integration and validation.

Chapter 4 starts out (4.1) with a detailed description of the **methods and collaborative procedures** that were employed to **develop the first set of user requirements**, namely partner interviews and workshops, user story mapping workshops and the development of assumption personas. The chapter then (4.2) offers an outline of the **recruitment procedures** and **methodological approach** of the first four co-creation workshops (CCW) in Vienna with citizens, to explore broader questions and potential concrete situations of interaction with the health-data platform. The CCW participants were recruited from the general public; the groups were diversified according to gender, age, educational background, current job and whether they had opted out of the national electronic health record or not. The **CCWs** used a **card-based discussion method** (Felt et al., 2018), adapted to allow citizens to explore issues related to a potential use of a future health-data platform and making use of mock-ups. Furthermore, this section describes the set-up and process of three focus groups with nurses conducted by EFN. In section 4.3 we present a **first set of user requirements** that relate to specific interactions with the 4HealthPlatform (4HP) to be explored, tested and validated in the different Citizen Use Cases (CUCs). It has to be noted that the elaboration of user requirement follows an **iterative process** and that the first set is based on workshops with potential users of the Smart4Health platform outside the CUCs. They are a first input and point to possible directions into

which the development and feature set of the 4HP can evolve. Therefore, they have to be seen as a first approach to citizens' expectations and concerns, and not as a fixed list of requirements to be realised by the technical partners. In the further course of WP1 we will continue to work with citizen users and professional users and continually refine, classify and prioritize both the user requirements and the performance criteria.

The user requirements are structured according to 16 situations of use, detailing 16 specific scenarios with a number of open questions. The user requirements that relate to these situations are formulated from the perspective of a citizen user and contain the requirement itself and the citizen's motivation. Chapter 4 ends with a **first set of requirements by representatives of nurses.** These requirements were translated into two challenges, and they were formulated from the perspective of a nurse and included - in parallel to the formulation of the citizen user requirements - the nurse's motivation.

Closely linked to this, chapter 5 elaborates on the **performance criteria** and on a procedure of integrating a careful monitoring of how these performance criteria are met all along the process of development and design. It offers a **first tentative list** that spells out examples of performance criteria for selected user requirements. Furthermore, chapter 5 presents a **monitoring tool** for an assessment if and how user requirements have been implemented.

Finally, chapter 6 offers a **conclusion** that **summarizes** the main points of the deliverable and provides an **outlook** into future work on user requirements and performance criteria.

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1   Document Summary

1.1   Smart4Health Project Overview

Smart4Health: Building today a healthier 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 healthcare providers. The 4HealthPlatform will allow citizens to collect, manage, store, access and share own health and healthcare data, through

From passive, limited and disconnected data collection

... to active, continuous citizen-generated health data and Interoperable Electronic Health Records
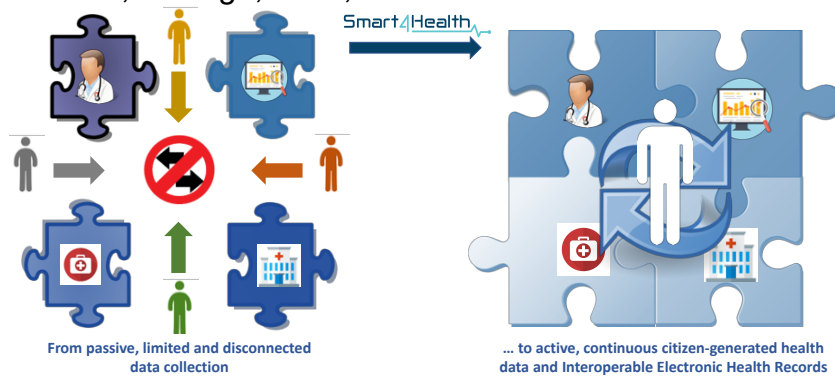
an easy-to-use, secure, constantly accessible and portable health data and services prototype within the EU and beyond. The 4HealthPlatform data layer connects with the 4HealthNavigator

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 science, 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 D1.3 *1st Specification of user requirements and performance criteria* is to deliver a first set of user requirements as well as to define corresponding performance criteria. It, thus, substantially shapes the future work in WP2 and WP3. This is a "living document" and it will be updated in form of 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).

1.3 Impact and target audiences

This deliverable is meant for both project internal as well as external audiences (e.g. potential users). Building such a complex health data infrastructure to be used across different European 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 requirements of citizen-users are integrated into the technical development – along the whole process and in the different sites where the platform is tested.

1.4 Deliverable methodology

The report on the 1st specification on user requirements and performance criteria was produced as a first draft by UNIVIE. The report is based on partner workshops and interviews with most of our project partners, which fed into early work on assumption personas, platform scenarios and user requirements, user story mapping with our technical partners and clarifying resulting questions by Citizen Use Case (CUC) partners, co-creation workshops with citizens, brainstorming exercises by CUC leads, focus groups with nurses and a co-creation workshop with all partners. We also strongly drew on D1.1 *Social Sciences and Humanities Framework* and D1.2 *Report on the methodological design of the co-creation environment* where the Social Sciences and Humanities Framework as well as the co-creation approach were respectively spelled out.

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

1.5 Document Structure

After an introduction, which clarifies the aim of this report (chapter 2), the report summarizes relevant key-aspects identified in D1.1 and D1.2 (chapter 3). In chapter 4, the report gives a detailed account on the processes and the outcomes of a first set of citizen and professional user requirements. Chapter 5 addresses the process of identifying performance criteria, describes the creation of a living document to be accountable for addressing the performance criteria and spells out a first exemplary set of performance criteria. The report ends with a summary and some final considerations (chapter 6).

1.6 Document status

After having received and integrated the feedback from our reviewers, this is the final version of D1.3. Upcoming results will be reported in D1.5, D1.6 and D1.7.

1.7 Ethics

This deliverable relates to questions on ethics in three ways. First, in chapter 3 we bring to mind how we will consider ethical issues in our co-creation work with citizen and professional users. Second, we outline the informed consent (IC) procedures for

those participating in the different forms of engagement exercises that happened. Third, the IC process for the platform and data provision for research itself is addressed in this report.

1.8   Dependencies and supporting documents

This document is directly related to D1.1 which outlines the main considerations for developing the health data platform. Furthermore, it connects to D1.4 *1st Citizen/User Consent Language Report* (M12) and to D8.1 *H - Requirement No. 1* (M12) when it comes to developing and testing IC documents.

1.9   Main results

The main result of this deliverable is a first set of user requirements, a methodology to outline corresponding performance criteria and a first set of examples of performance criteria. Furthermore, this deliverable is a living document to follow the realisation of requirements and performance criteria along the development, design and implementation process.

1.10 Future Work

This report is related to Deliverables D1.5, D1.6 and D1.7. 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* and will be shaped by user requirements, D1.3 also is linked with D1.8 *Description of the Use Design Cases from the citizen/user perspective* (M42) and D1.10 *Validation Report* (M50). Furthermore, our results will feed into the technological development processes and thus into deliverables D2.1 *Prototype Plan and Requirements Specification Report* (M12) and D3.1 *4HealthNavigator portal detailed engineering requirements and software architecture report* (M12).

1.11 Remarks and considerations

This report is a "living document" and will be updated on a regular basis throughout the project.

2 Introduction

This report focuses on both the process of specifying a first set of user requirements and identifying the related performance criteria. When a system, such as the Smart4Health health-data platform and its services, is being created, identifying user requirements is a central tool for ensuring that it will perform in ways that meet the needs and expectations of future users while also respecting their core values and concerns. To carefully document such requirements is an essential part of the process of validating the Smart4Health platform.

User requirements generally come in the form of functional and non-functional requirements. Functional requirements describe "the services that the system should provide, including the behaviour of the system in particular situations" (dos Santos Soares et al. 2011). The non-functional requirements "are related to emergent system properties such as safety, reliability" and many more (see chapter 4 of this report). The development of user requirements in Smart4Health requires particular attention as the health data to be uploaded, stored and shared on the 4HealthPlatform (4HP) is sensitive data and data subjects could potentially become vulnerable in case of data breaches.

In this first report specifying user requirements (three further reports will follow in M24, M32 and M40) we will proceed in three steps. In the next chapter (Chapter 3) we will shortly describe the general approach of defining user requirements and summarize some of the key-points to be considered when doing so. This means describing the general approach to developing a first set of user requirements and performance criteria while highlighting some of the concerns already raised in D1.1 as well as in D1.2.

Chapter 4 will be the first of the two core chapters of this report. It spells out the processes and methods by which first user requirements (URs) were achieved. For this purpose, first partner interviews and a workshop were drawn upon, several iterations of user story mapping exercises with consortium partners took place and first assumption personas were developed. In a second step, the chapter outlines early face-to-face co-creation activities with citizens (independent of CUCs). Finally, it also describes discussions with representatives of nurses as potential professional users carried out by EFN. Based on all these inputs and processes, we will present a first set of user requirements mainly for citizen-users, but also for nurses as professional users.

Developing the performance criteria along with user requirements will then be elaborated in chapter 5. We will present the approach used to define performance criteria as well as a monitoring tool to oversee how requirements and performance criteria are integrated into the design, development and implementation process of the health-data platform and its services. This should ensure a close collaboration between the social scientists engaged with different users and the technical partners and allow an oversight on the development steps.

The conclusions summarize the main points and give an outlook on the trajectory to follow in the further elicitation and elaboration of user requirements and performance criteria.

Before entering the report, it is essential to clarify the use of the notion of "user" in this report. As the title of the project "Citizen-centred EU-EHR exchange for personalised health" indicates, **the users at the centre of the design, development and implementation process of the 4HP and its services are citizens.** Smart4Health aims at enabling "citizens to manage and bridge their own health data throughout the

EU and beyond, advancing own and societal health and wellbeing"[1]. Professional users in the meaning of the grant agreement are then either "professionals as citizens" (e.g. nurses in their workplace suffering from backpain and wanting to use the 4HP) – in D1.2 we summarized them under the notion of citizens at work – or "professional users as health care professionals" who would give feedback when it comes to citizens providing them access to their health data through the 4HP. Therefore, at this stage of the process user requirements will be formulated on the basis of co-creation activities of citizens.

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[1] Taken from the Grant Agreement of Smart4Health.

3   General approach

Before spelling out the 1st set of user requirements and performance criteria, it is important to outline the overall approach. As outlined in Figure 1, we will use an integrative approach that covers six steps from defining the key-features of the health data platform to the integration and validation. As already outlined in D1.1, infrastructures never start *de novo*, but always build on pre-existing ones. In the case of Smart4Health, there are:

(1) pre-existing health data infrastructures in different national health care systems;

(2) diverse visions of e-health and how citizens should profit from such an approach;

(3) varying degrees of implementation of ICT infrastructures and ICT literate citizens.

Furthermore, the project had, in its proposal stage, already defined some of the key-features as well as some of the technical functionalities that the prototype to be developed in Smart4Health should have (e.g. what data can/should be uploaded, how data can be shared, an early version of the research platform). Finally, contemporary societies already have a number of systems handling sensitive data in place (e.g. the banking system); thus, there are sets of standards of how to build such infrastructures as well as regulatory systems governing these infrastructures.

Together, this is our starting point when working with future users on their requirements. However, as we are engaged in a co-creation process, the detailed key-features of the platform are still open to be developed following the requirements formulated by citizens.

Based on these structural key-features, we started to **elicit, gather and classify** first **user requirements.** The elaboration of user requirements will be an **iterative process**, gradually engaging with larger and more diversified user groups to deliver a solid input to the prototype development and implementation. The different methods to be used (e.g. group discussions, workshops, qualitative interviews, questionnaires, reflection workshops) during this elicitation and gathering process have been spelled out at length in D1.2.

This iterative process as outlined in Figure 1, goes through 5 steps, with regular feedback loops between them.

(1) In a **first step** it will be essential **to reflect on the problem the health data infrastructure is addressing.** This involves identifying **who needs to be involved in deciding on requirements** and **who will be affected** by both the way the problem gets framed and which solutions get sought for. We will engage with these users and user groups when developing user requirements. As already outlined in D1.1, it will be essential to strive for diversity in considering future users and to carefully reflect potential exclusions, due to the design of the co-creation process and to the ways in which the CUCs implicitly pre-select specific users/user groups. But we also need to consider non-users (i.e. people either refusing to use digital infrastructures or citizens hardly having access to such infrastructures) and what potentially can change their position towards embracing the use of a health-data platform.

(2) In **step 2**, once the requirements are gathered, it will be essential to classify them in groups of requirements, which address specific functionalities of the infrastructure to be built, as well as to condense and refine them over the course of the project.

(3) In a next step, **step 3**, the requirements voiced by users will be **evaluated** for functionality and feasibility – both through assessment by the technical partners, through feedback from consortium members as well as, where needed, through involving further user groups in a next loop of the co-creation process. Also, in this step, decisions will be made whether certain user requirements can be realized and which developments to prioritize. At this stage we will also need to reflect on the **emergent (partly unintended) system properties** and how they (might not) match user expectations.

(4) Along with spelling out user requirements, in **step 4**, also performance criteria get defined. The following is an example: As will be shown in chapter 4, users express a need for easily understandable information before deciding on certain choices during their journey into and through the health data platform. We will therefore have to develop a performance criterion "accessibility of information". Some of the performance criteria will be quantifiable, other will need more qualitative assessments by users (e.g. through questionnaires.)

(5) Finally, **step 5**, the process of specifying user requirement and performance criteria "ends" with their integration into the design, development and implementation process. This will be **monitored in a "living document"** in order to oversee the achievements along the project.
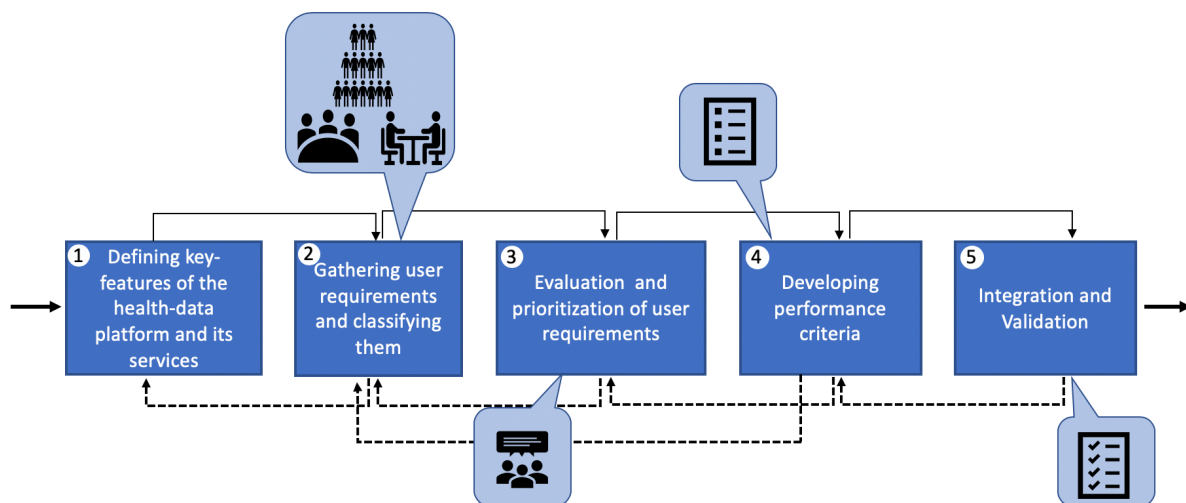

Figure 1 – Iterative process of eliciting user requirements and developing performance criteria

Throughout the process of gathering user requirements we will be attentive to inclusiveness to ensure the diversity of users to engage with as well as the geographic regions covered by the CUCs working with actual users present in the consortium

(Germany, Luxemburg, Portugal). Furthermore, each information gathering activity will use a situation- and context-specific IC form, which explains the purpose and format of the information gathering, states that we wish to record and transcribe the conversations (both interviews and discussion groups) for closer analysis, outlines the fact that we will use data only in a pseudonymized form, that data is stored on a password protected server at the University of Vienna and that only the group producing the data will have access.

4 User requirements specification

4.1 User requirement elicitation procedures

This first formulation of user requirements is, in essence, based on workshops and interviews (individually and in groups) with different consortium partners and citizens (independent of CUCs). Besides this, EFN organised focus groups to discuss the perspectives and expectations of representatives of nurses. As Smart4Health is a citizen-centred project, we will focus, as outlined in the introduction, mainly on the work with citizens.

A two-stage process has been central to eliciting and formulating user requirements:

(1) The start of the user story mapping (USM) work that presumes: a citizen with back pain, not further specified (yet), travels through the platform interface. The task is to thereby formulate user requirements for different possible interaction points with the platform, from which we developed so-called situations to stimulate/trigger face-to-face discussions with groups of citizens (see 4.2.1).

(2) Extraction of assumption personas in the CUCs, through which we will then bridge the CUC storylines to user journeys/stories with the platform prototype – in particular with its frontend/interface, the portal, to proliferate the stories and thus the user requirements.

The procedures of developing the first specification of user requirements draws on what we have outlined in D1.2 regarding our first wave of co-creation. The box below is reproduced from D1.2 (pp. 27-28) and shows the different steps taken and the methodological approaches used to create input for the first user requirements.

1st wave of co-creation

This wave has started early in the project and the following activities were performed to achieve first results 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 Smart4Health platform, more widely speaking.
  From the material generated in the workshops and interviews, personas were elaborated. This approach allows for more space to individually explore the different expectations partners have towards the platform 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 platform and for data ingestion procedures in several rounds of **user story mapping** exercises (Patton 2014).
- **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 09-10/2019 with participants

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recruited from the general public by an open call, and a card-based discussion method applied (Felt et al., 2018).

- 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 Smart4Health platform, 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 for the 1st wave has taken place in 11/2019 with technical partners and those responsible for CUC3.
- EFN organised (04/2019) **focus groups with representatives of nurses** discussing generic[2] scenarios on how health care professionals (HCP) may access and use citizen's health data. From there, some general comments and usability challenges were formulated by representatives of nurses across Europe against their professional and national EHR background.
- We also organized a **co-creation workshop with all partners** involved in the Smart4Health project during our General Assembly Meeting in Lisbon (09/2019). The aim of this CCW was to foster engagement between the different partners concerned with technical developments and those doing the CUCs, which also led to the above CUC3 user story mapping workshop.
- During this first phase, we also performed **a further co-creation workshop with citizens** (11/2019) to engage with the IC document for access to the platform, which had been developed in WP8. We will specifically discuss IC procedures regarding the structure and social acceptability of IC forms and processes in D1.4 *1st Citizen/User Consent Language Report*.

Taken together, these diverse engagements with consortium partners and citizen users collectively contributed to the user requirements presented in this deliverable. This diversity of co-creative activities is essential to capture as many perspectives as possible. The **social sciences thus work as brokers to translate the information gathered as well as visions and values expressed into user requirements**.

In a nutshell, the first set of citizen and professional user requirements (see 4.3) came into being in an iterative process of conducting **(1) partner interviews and workshops, (2) user story mapping workshops with consortium partners**, as well as **(3) co-creation workshops with citizens** (see Figure 2)**.** Outcomes from the focus groups with nurse representatives were integrated when addressing citizen-user requirements. While (1) and (3) were planned and performed by UNIVIE, (2) was carried out together with technical partners and CUC representatives. The focus groups with nurse representatives were done by EFN, which on one hand was a more general input on expectations that frontline general care nurses would have as professional users towards a health-data platform. On the other hand, they served the nursing leaders to outline how current EHRs in 13 EU member states consider data relevant to nurses and comment on how to improve the resulting challenges. While

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2 The defined usage scenarios are "generic", in the sense that they do not refer to a specific local context (e.g. specific country, hospital, health care professional, legacy system). Also, the reference to specific clinical conditions of the patients is just an exemplification, intended to be representative of many other situations that may involve citizens/patients with different pathologies (co-morbidity), but requires similar interactions with the developed IT/device eco-systems.

they delivered insights into the expectations of nurses towards the 4HP, only the parts relevant to user-requirements formulation and related performance criteria will be part of this report.
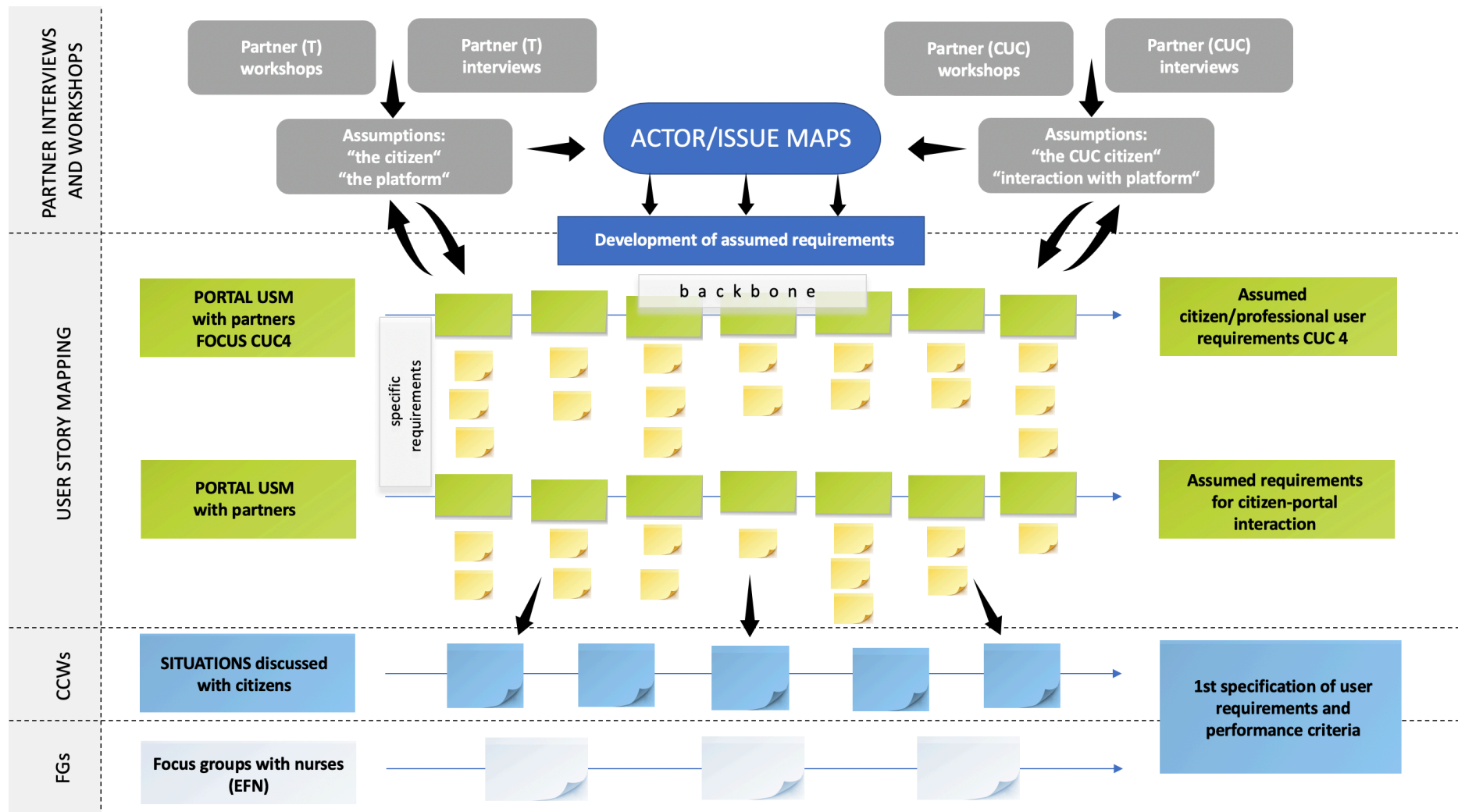
Figure 2 – Process of developing 1st specification of user requirements and performance criteria (until M10)

In what follows, we will briefly describe our methodological approach. The partner interviews and workshops together with user story mapping activities and citizen co-creation workshops led to formulating **assumption personas**, i.e. personas based on visions of imagined users that are held by members of the consortium. This was essential and highly relevant for making underlying assumptions explicit and improving shared understandings about who the target users are and might be like and how they will interact with the platform. In the following three sub-chapters we will therefore describe the outcomes of the first two (4.1.1 and 4.1.2) methods and processes by giving visual examples (such as iterations of user story maps), which went into the development of assumption personas and the development of situations of user interaction with the 4HP; the process of which is then described in 4.1.3. The latter two methods (co-creation workshops with citizens and EFN discussion groups) are ways of engaging with participants not actively involved in the project – neither as consortium partners nor as users – and are followed up in chapter 4.2.

4.1.1 Partner interviews and workshops

Assumptions expressed in technical partner workshops and interviews as well as in CUC partner workshops and interviews were used to develop so-called actor and issue maps (see Figure 3). Concretely, this approach allowed us to identify and map key actors in the CUCs, actions and data flows as well as to identify crucial issues that need to be considered for the platform to respond to user needs and concerns. Such an approach would be one of the starting points in an effort to develop a socially and technically sustainable version of the 4HP.
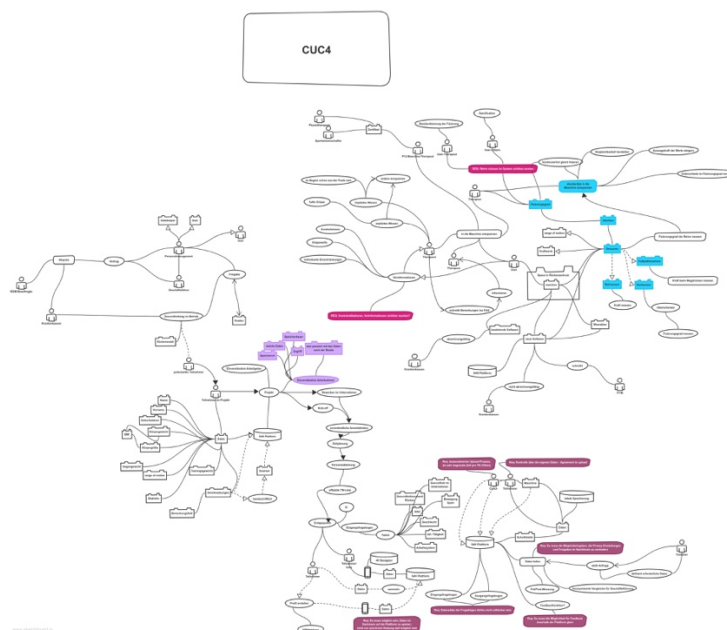

Figure 3 – A first actor and issue map as result of and input for further partner interviews

The very first set of requirements regarding the citizen/platform interaction that we derived from this work with assumptions was presented in the Requirements Working Group (RWG) remote meeting (TelCo, 18/04/2019). We drew on the data practices outlined in the Grant Agreement (i.e., data access, portability, control, sharing and provision) and broke them down into a number of first concrete interactions

(registration, collecting data, uploading data, accessing data). Based on these and on the interviews/workshops with partners, we outlined potential first requirements as well as potential issues (transparency and infrastructural security).

After that meeting, technical partners suggested to continue our exchange by engaging together in "user story mapping" (e.g. Patton 2014) as a procedure to spell out and communicate the user requirements identified in workshops and interviews to them as well as to the consortium.

The outcome of these meetings did not only serve the development of user requirements, but also fed into our work of **developing a first set of personas** based on the retrieved assumptions on interactions of future potential users with the platform and its portal. Given that a user story map offers a simplified version of a user's journey through the platform, it was important to develop personas with diverse attitudes, aptitudes and motivations (see 4.1.3) in order to enable variations in the user stories we tell and, thus, in the platform development.

It is essential to underline that these personas were developed on the basis of input of Smart4Health consortium participants and are thus drawn from specific sets of experiences and expectations, which will need to be and will be widened when working with citizen-users in the CUCs in wave 2 of the co-creation process.

4.1.2 User Story Mapping workshops

As outlined in D1.2, *user story mapping* (Patton 2014), as a method used in software development, was suggested by our technical partners to stimulate productive exchange between the work of social scientists with users and the technical development team. The method thus **serves as an interface between citizen users and those realising the technical development in the consortium, with the social scientists being brokers.**

Any user story map outlines user stories, by arranging them in two dimensions (see Figure 2, the segment on user story mapping).

The horizontal dimension – the **backbone** (green sticky notes in Figure 2) – identifies key-steps in the overall user activities in the health-data system whose prototype Smart4Health is developing (e.g., subscribe, upload health data, organise data, give access to health data, …). Together they aim at capturing the way in which users interact with the platform, i.e. it is a simplified (linearized) version of a user journey.

However, user stories also develop in a **vertical direction** describing more **specific tasks** (yellow sticky notes in Figure 2) a user may want to be able or be required to take. Generally, these vertical elements are then **prioritized**, in order to see which features are central to consider in a first step of development and which features could be added at a later stage of development (also referred to as **slicing** in the language of user story mapping). This prioritizing allows to keep specific requirements on file, ready to be revisited at a later stage of the project development. This process will allow to collectively identify what is of central importance for a first minimum viable prototype of the 4HP. Developing a more mature version of the platform and its services will then engage gradually with other vertical layers of the user story map.

Finally, in order to create a prototype that provides **meaningful and relevant experiences to users**, research on and analysis of relevant information about future users is essential. This means understanding why citizens use the 4HP and its

services and what they expect from it. This will also include gaining insight into what health data information systems citizens use so far, as this will be "the competing product" to what Smart4Health can offer. However, we also will have to carefully identify the situations where citizens see a need to access their health data. Here it will also be important to engage with health care professionals who can assess the need of information access from their side and inform in which ways access would be supportive to receive better treatment.

The research on users will allow to create **citizen-user personas**, i.e. idealized fictional representations of future users (user groups), capturing who such future users are, and how they might like to interact with the 4HP and its services.

Documenting these steps, i.e. the information which formed the basis of development and the choices made, will also help UNIVIE in communicating with users once first parts of a minimum viable prototype are available. In short, this will make the process of producing the Smart4Health prototype more transparent.

To summarize, the method so far served to stabilize and integrate first assumptions about user interactions with the platform that consortium partners formulated, particularly those leading and supporting the CUCs and those engaged in technical development. As such, user story maps also aim at creating a common shared understanding between the partners 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 users and professional users and, simultaneously, serve as a repository of solutions, procedures, ideas and issues to be engaged with in the User Engagement Exercises (USEEs).

The procedure of user story mapping involves a hands-on approach by using sticky notes to jot down steps of **a narrative flow through anticipated interactions with the platform**. The sticky notes are laid out in a **matrix-like overview**, in order to re-arrange the steps in it while discussing them. 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 SSH Framework (D1.1) it is thus essential to consider users who might not follow the script that has been built into the platform on the basis of these USM 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 or not – and adapt features accordingly.**

In this deliverable, however, we provide in the following exemplary images to outline the activities regarding the USM development and involvement of partners in terms of the first two kinds of USMs developed. First, a USM focused on the platform through the lens of a CUC storyline (CUC4), and second, a USM on possible interactions with the interface/front-end of the 4HP, its portal.

> *It is important to underline that for the user story maps presented below we did not yet engage with future users. The input came from the partners responsible for the CUCs as well as from our technical partners and includes visions of future users and does not give voice to the users themselves. We documented the process of user story mapping to show the interactive ways in which they take shape. Their outcome was*

important to identify the "situations" we discussed with potential citizen-users in the co-creation workshops described in 4.2.1.

4.1.2.1 **4HealthPlatform – Platform USM (focus on CUC4)**

In a first workshop hosted by UNIVIE (08/05/2019), HM (with HPI and D4L present) introduced the USM methodology in order to get and agree on a shared understanding of the user requirements elicitation and communication, via the process of mapping user stories. Thereafter, UNIVIE started to produce and explore a first USM on a platform scenario focused on CUC4, based on the input from previous partner interviews and workshops (ZS-UG and ITTM). CUC4 will engage citizens working in companies in Germany to join a training program to prevent back pain issues. Over the course of four months the participants will engage in training exercises on a backpain treatment/prevention training machine (MedX machine) and, optionally, use wearables. Citizens will be able to test the 4HP by registering and consenting to the 4HP, accessing, uploading, managing and sharing data with the HCP (training data produced from the MedX machine as well as potential reports generated by third-party applications that collect well-being data from wearables). The reason for starting out with CUC4 was its broad scope in terms of Use Design Cases (UDCs) to be elaborated and its similarity to CUC5, CUC6 and CUC8 in terms of using the MedX machine and wearables.
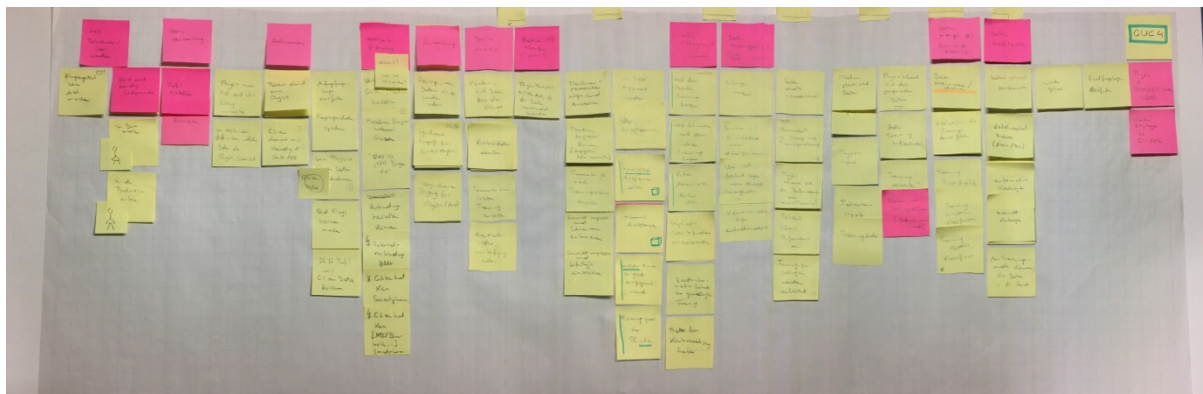

Figure 4 – USM1 done by UNIVIE based on partner input (ZS-UG and ITTM)

After laying out **potential steps in a user story** horizontally, we identified on the highest level (in pink) main use(r) activities/actions, e.g. registering to Smart4Health, authentication, arriving at the MedX training facilities, generating data, uploading data, etc. This receives a dedicated sticky note, which together with other such key-actions form the so-called "backbone" of the USM. Below each step (in yellow), further notes can be placed for detailed tasks as well as various issues and concerns related to the step (e.g. "what to do when forgetting my password", or "what information do I want to have before registering"). The latter can then also be prioritized if needed.

A first walk-through and presentation of this USM was then held remotely with HM and HPI (05/06/2019), followed by a next face-to-face meeting in Potsdam attended by D4L, HM, HPI and UNIVIE (11/06/2019). There, the above version (Figure 4) was discussed more closely in order to translate it collectively into a **condensed working**

version (Figure 5) for D4L and HM in which actions and steps have been further grouped.
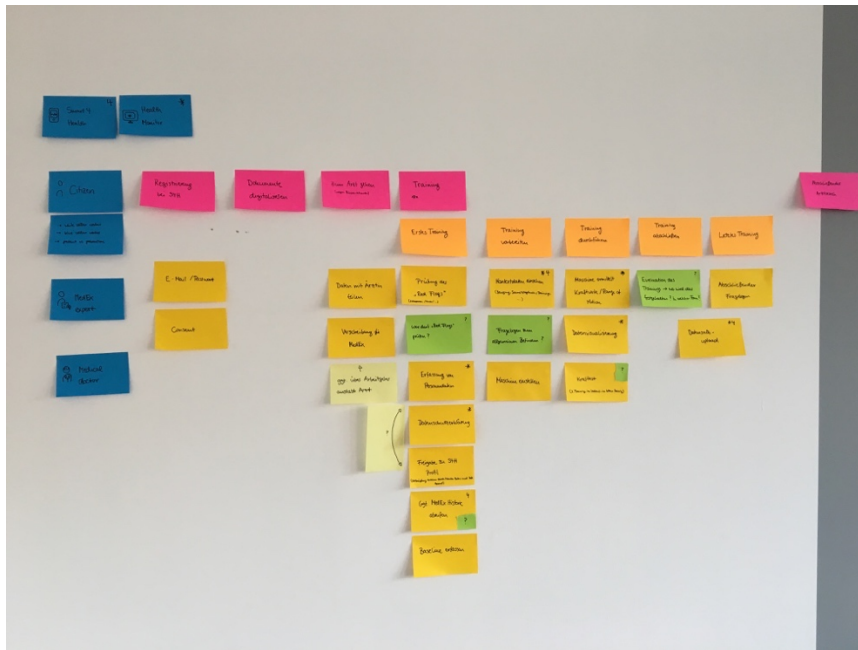

Figure 5 – Condensed version of USM1, produced in Potsdam (D4L, HPI, HM, UNIVIE)

This process, however, also served to identify open questions regarding CUC4 work procedures that arose through walking through the USM1 (e.g. who checks for red-flags/contra-indications for doing back training). Open questions were quickly clarified by ZS-UG in email conversations with UNIVIE and integrated into the USM1, as well as communicated to HPI who were in the process of transforming the USM1 into a digitized version for their internally used Jira system (see Figure 6). Meanwhile, the USM1 with addressed questions was presented to two of the involved partners (HPI, D4L) in a remote meeting (27/06/2019).
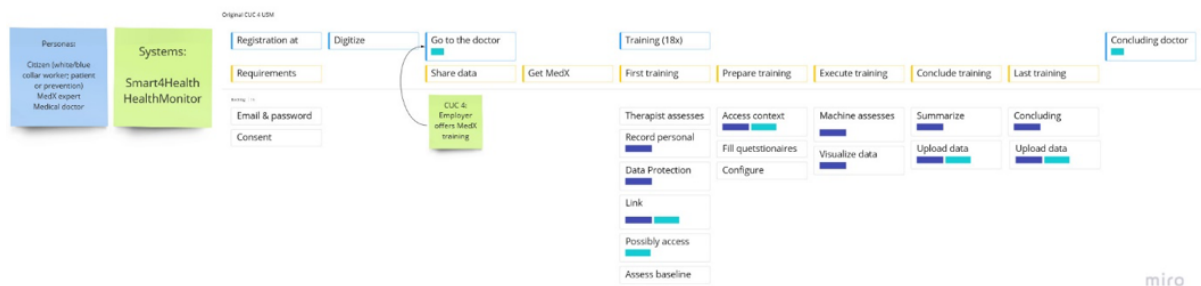

Figure 6 – Transferred USM1 in Jira (HPI)

Starting out from the USM1 in Jira, HPI pre-formulated examples of user requirements in order to present them at the General Assembly in Lisbon (09/2019). These served as examples for how user requirements can be formulated in a user story format (see Figure 7).
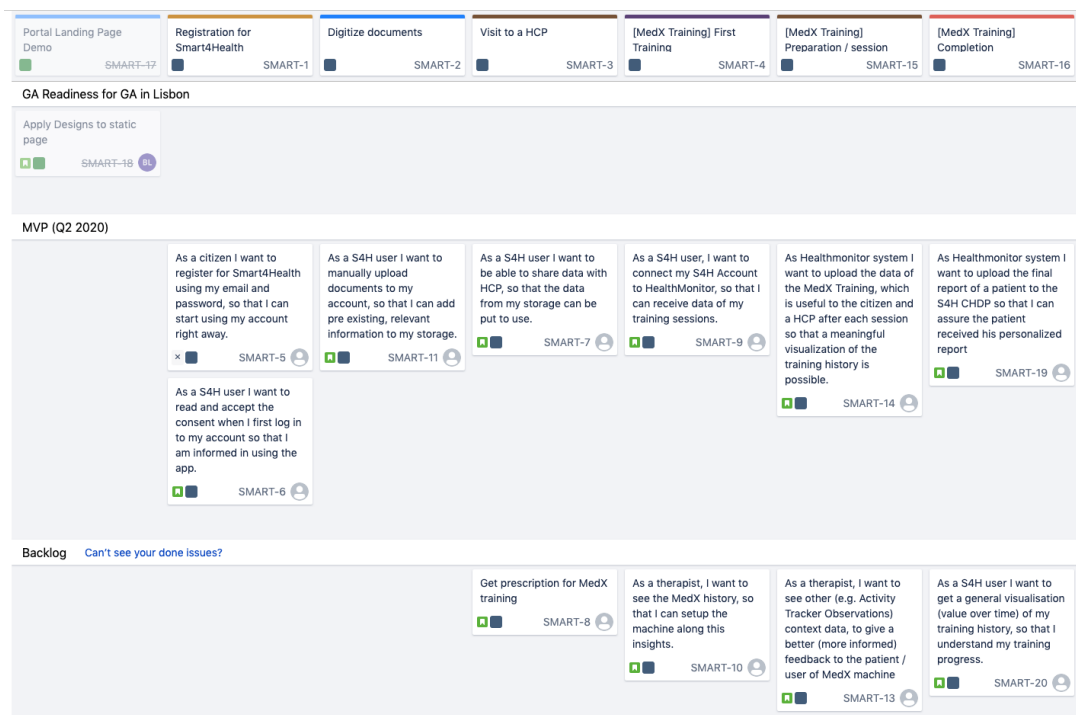
Figure 7 – Pre-formulation of user requirements based on USM1 in Jira (HPI)

The platform USM described in this section already touched on potential interactions of citizens with the 4HP (e.g. registering, uploading data). Following this, we focused even more on citizen/platform interaction by developing the portal USM, i.e. a story map for the **4HealthNavigator** app, which we will describe in the following section.

4.1.2.2 4HealthNavigator – Portal USM

To think through **potential user interactions with the interface/front-end of the 4HP**, the so-called portal of the 4HealthNavigator app, work on the portal USM was kicked-off in a first face-to-face workshop in Vienna, attended by members of D4L, HM, HPI, KBZ, UNINOVA, and UNIVIE (11/07/2019). One of the main goals of the USM was to explore how the very first functional version should look like, thus what functionality should be offered first. The portal USM focused on an **assumed user journey through the interface of the 4HealthNavigator app** and drew on interpretations of what a user would want to or should encounter. Hence, also this USM work is based on first collective assumptions about the steps and their details, e.g. what a user should see the first time after opening the app.

Figure 8 – USM2 started in workshop in Vienna (D4L, HPI, UNINOVA, KBZ, UNIVIE; July 2019), continued work by UNIVIE

In contrast to the platform USM, which was also based on a number of partner interviews and workshops that UNIVIE could bring in as input, the portal USM at that early stage included only the work and assumptions of the above five partners. This was then slightly extended by UNIVIE on the basis of early partner interviews and workshops (see Figure 8). It was presented remotely (25/07/2019) to identify open questions and issues with D4L, HM and HPI. Furthermore, in order to diversify the input to the portal USM, all CUC leads were contacted via email and invited to conduct a specific brainstorming exercise set up by WP1 lead UNIVIE in collaboration with UKA as lead of WP4 responsible for the CUCs. In that brainstorming exercise, the CUC leads were asked to do the following:

Exercise description
Please reserve yourself a time slot of one hour or more, and ideally do this together with at least one other colleague of yours. Have some form of note taking available - whether pen and paper, sticky notes, etc. or digital options for jotting down notes quickly.
Imagine the following:
The CUC is up and running, and a first version of the 4HealthNavigator app is available. A participant of your CUC has heard about S4H already and is willing to start using the app for the first time. Stick to that one participant. What happens next? What might she/he want to do first, and what in the following steps?

Some food for thought (you do not need to answer each, as it is about initiating the brainstorming):
What happens before she/he gets to see the app portal/interface for the first time? In which situation/context might she/he get to see the app interface? What could or should she/he then see on the interface and be able to do (or not) and how? Which other functionalities might be missing?

Depending on your CUC and storyline, please feel free to think about the breadth of functionalities of the app and platform, or only specific ones that particularly (come to) matter for that one participant in your brainstorming.

After you feel done with the exercise (no new ideas come up and existing ones are ordered) please send it in a readable format to us at UNIVIE. This can be a picture of notes, a text file, sketch, etc.
As the whole exercise should not take too much time, we ask you to have it ready by next Wednesday, August 14th EOB.

The feedback received from CUC partners then allowed UNIVIE to expand the portal USM (see Figure 9) on the basis of the assumptions coming directly from partners leading the CUCs in which future users will interact with the 4HP (ISMMS, GovMad, SHD, UKA, UNINOVA, ZS-UG).

Figure 9 – USM2 transferred post-its and extended with partner brainstorming input (all CUC leads), integrated by UNIVIE (Sept 2019)

To facilitate collaboration in expanding and reworking USMs, HPI proposed to use the web application Miro (08/2019). While Jira was used internally by HPI and D4L, Miro allowed for more openness, as multiple partners could virtually and collaboratively work on the different elements for the USM. The portal USM was transformed into the virtual board by HPI (see Figure 10), and the further extended portal USM was remotely presented by UNIVIE (29/08/2019) to the partners of the first face-to-face workshop (D4L, HM, HPI, KBZ, UNINOVA).
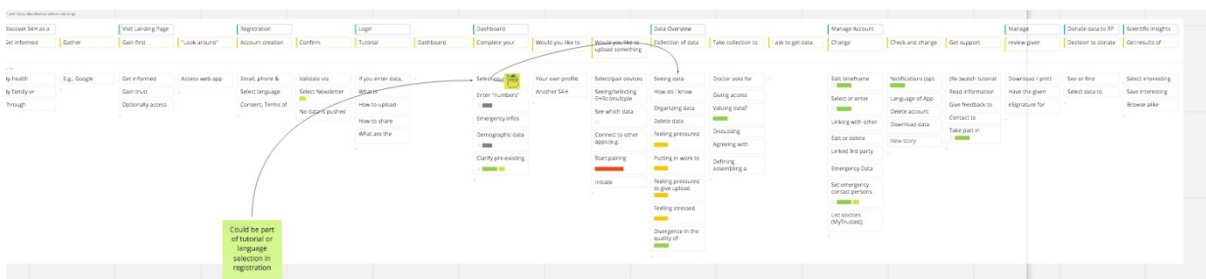

Figure 10 – USM2 transferred to Miro (HPI), before producing a more compact version

As in the process regarding the platform USM, also the portal USM was walked and thought through in order to collectively group cards together, raise questions and issues and in the end have a more compact or cleaned version of it, without, however, omitting any raised concerns (see Figure 11).
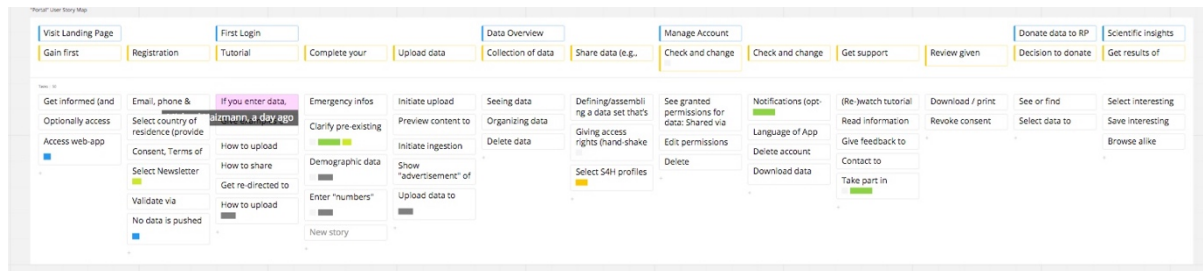
Figure 11 – USM2 in Miro (HPI), more compact version

After having outlined the past processes of these two USMs – the platform and portal USM – a broad group of partners (D4L, HM, HPI, ITTM, KBZ, UNINOVA, UNIVIE, ZS-UG) started at a recent face-to-face USM workshop in Berlin (11/2019) with a third USM focussing on the platform scenario of CUC3. The USMs will then help to get transparency of the possible user journeys and the existing solution provided by developers and will be used to collectively decide on the next implementation steps by slicing, i.e. vertically prioritizing, them.

The collective work and discussions about potential user interactions with the portal USM, together with the previous work done on platform storylines (developed, explained and refined by CUC partners) helped UNIVIE to develop a set of so-called situation cards. See Annex I: Situation Cards for the full set of 15 situation cards (in German).

These sets of cards, with textual and visual input, were used in the citizen co-creation workshops (CCWs) held in Vienna, as a basis and trigger for discussing the above situations and questions around them (see 4.2.1). Taken together, the work that went into the USMs (partner interviews and workshops) and the CCWs also fed into the development and refinement of assumption personas.

4.1.3 Assumption persona development

"Personas are not real people, but they represent them throughout the design process. They are **hypothetical archetypes of actual users**. Although they are imaginary, they are defined with significant rigor and precision." (Pruitt & Adlin 2006; highlight by authors)

As outlined in D1.2, it is necessary to precisely differentiate not only between different user types, i.e. citizen users and professional users, but also in terms of the role one and the same person might have in a given Citizen Use Case (CUC), and thus in which of these we engage with that very person. In order to consider this variety and breadth of users implied with the notion of 'the citizen', the persona-method is used as it is able to "represent them throughout the design process" (Cooper et al. 2007, p. 75). According to Cooper and colleagues, personas "provide us with a precise way of thinking and communicating about how users behave, how they think, what they wish to accomplish, and why." (Cooper et al. 2007, p. 75).

At this stage and as stated in the DoA, however, we are working with assumptions. As Cooper et al. outline, though, "personas are derived from patterns observed during interviews with and observations of users and potential users (and sometimes customers) of a product" (Cooper et al. 2007, p. 97). Our personas are derived from

patterns observed during interviews and workshops, but for the time being with technical partners, CUC partners and stakeholders about imagined users and scenarios with them. Our assumption personas, thus, follow what Cooper et al. term a "persona hypothesis", that is a "first cut at defining the different kinds of users (and sometimes customers) for a product" (p. 60), or for services. **A persona hypothesis aims to address three questions:**

- "What different sorts of people might use this product?
- How might their needs and behaviours vary?
- What ranges of behaviour and types of environments need to be explored?" (p. 60)

Regarding the first question, of what different sorts of people might use this product, work has been done in our outline of the groups and roles of users in the project (see D1.2, p. 35), which delivered a first answer to that question.

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, UMC+, OSR)

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+)

While the first three groups of users will be at the core of the co-creation process (i.e. highlighting the project's citizen-centeredness), also professional users matter as they will have to engage with the information citizen-users provide them with in case of health-care or prevention-oriented interactions. Input provided by professionals, e.g. about how and which data should be displayed, thus, further ensures building a health data platform prototype that will be valuable for citizens and their interactions in the realm of health care.

While this grouping of users follows the straightforward logic of roles users have, Cooper et al. (2007) underline that ultimately user roles oftentimes are not the most relevant structuring principle for developing personas for a product or service but that it is more important to look at attitudes and aptitudes of potential users. They point out that **it can be useful here to draw on demographic variables for recruitment of interview/discussion participants** in order to differentiate and engage a diversity of respondents, which should enable the identification of behaviour patterns (p. 62).

Thus, next to the user roles, **the development of personas requires a differentiation between users that is based on their behaviours[3] and needs.** For the time being, in this report we outlined personas in a speculative way based on assumptions from different consortium partners. This will need careful tracing over the further course of the empirical engagements with (potential) users in co-creation activities - accordingly, personas will be updated. This will be done on a regular basis with (re)formulating and refining user requirements explicitly traced in three further deliverables (D1.5, M24, D1.6, M32 and D1.7, M40).

The behaviour patterns Cooper and colleagues outline are structured according to the following variables. While we will not use them to pre-structure our personas, they supported the way we engage in persona development:

- *Activities - What the user does; frequency and volume*
- *Attitudes - How the user thinks about the product domain and technology*
- *Aptitudes - What education and training the user has; capability to learn*
- *Motivations - Why the user is engaged in the product domain*
- *Skills - User capabilities related to the product domain and technology* (Cooper et al. 2007, p. 98)

In our case, the behavioural variables (in terms of needs, motivations, and behaviours) have been stabilized at this point in time as:

- ✓ Activities: Time and attention available (in users' everyday lives)
- ✓ Attitudes: Engagement with electronic health record and health care data
- ✓ Aptitudes/Skills: Data literacy and technical proficiency
- ✓ Motivations: Responsibility for health care/data

Additionally, Cooper et al. also suggest environmental considerations, which will be of high relevance for Smart4Health given its scope (different cultural regions across Europe) and different use contexts in the CUCs. They offer a number of environmental variables which we will adapt accordingly: e.g. company size, location, industry/sector, IT presence, security level. In the context of Smart4Health we will have to consider, for example, the wider cultural context when it comes to health-related issues, the work environments different CUCs will be part of, the technical and data literacy of participants, the wider trust structures and concerns voiced towards digital health

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[3] Behaviour distinctions are related to the expertise a future user has. Cooper et al. here distinguish between domain and technical expertise, that shapes the functionalities appropriate for different users. In D1.1. Social Sciences and Humanities Framework we also point to the importance of carefully investigating the whole spectrum between users and non-users as very different kinds of in- and exclusions might occur with the introduction of health data management practices through a health data platform like the one Smart4Health is working towards.

developments in a national context, the use intensity of digital health services[4] before encountering Smart4Health, and many more. To identify these environmental dimensions which matter for Smart4Health will be at the heart of the fieldwork to be done in the framework of WP1 and WP4. These environmental considerations (regarding the context of implementation and use) shape how the product or service can be integrated into the life worlds and practices of users.

For developing the first set of assumption personas, the material from interviews and workshops as well as work done with UNINOVA in developing a first questionnaire for CUC8 led us to consider the following dimensions: user role, gender, age, education, collaboration at work (formal/informal), work time (full-/part-time or none), computer/mobile device usage, and health data record usage (manual, electronic, for oneself and/or others). Being a first set implies that these are neither exhaustive nor set in stone but subject of ongoing refinement, particularly through field work done in the CUCs with actual users.

While personas are commonly developed around the 'neediest' users (Pruitt & Adlin 2010, p. 184), it can also be fruitful to look at the most demanding users, those being most vocal, and thus use them to complement each other. Hence, **we can think about the full spectrum from digital literates and digital non-literates.** However, the so-called needy persona creates a bigger gap between the current state (e.g. manually managing health records, if at all) and the future state as anticipated with a fully functional platform that is being used to manage health data also by those who have not before. In that sense, it is a bigger challenge and therefore benefit for the platform development to first think with needy personas along the various possible storylines. After all, the target users are EU citizens with either existing back pain or a prevalence for it (which has been argued is basically every adult) and not a specific audience, e.g. a fitness enthusiast using a training app.

In this following first set, the assumption personas overall are assumed to not be waiting for the S4H solution and its potential benefits; this means that there is a broad gap between the current status and shall-be status of using the platform sustainably. As these can be understood of currently not knowing that they 'need' something like the 4HP, we might also call them 'challenging' instead of 'needy'. It is thus not about convincing them through promoting potential benefits, but how the platform needs to be to specifically address these challenging personas through practices of experiencing it.

With the citizen being at the centre of Smart4Health, the primary persona, accordingly, is the citizen. Supporting this citizen-centredness of the platform prototype

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[4] From the Eurobarometer survey 460 on "Attitudes towards the impact of digitisation and automation on daily life" (EB 2017) we already have some indication how big the differences are between nation states. "In the part on "digital health and care", we learn that, on average, about 80% of European citizens (with Germany as one of the countries represented in our Citizen Use Cases scoring over 90%) have never used any electronic health service. Not unexpectedly, age and education matter, rising age lowers the chance of engagement, while higher education raises it. About 50% of the respondents, however, expressed their wish "to have online access to [their] medical or health records (health data, prescriptions and medical records about [them] allowing [them] to consult them at any time wherever [they] are", with a significant difference between age groups and level of formal education. Here, we find that "respondents are much more willing to share their health and wellbeing data with doctors and health care professionals (65%) than with public authorities or public sector companies (21%) or with private sector companies (14%) – even if anonymised and for research purposes". (D1.1, p. 31)

development, however, are also professional users such as HCPs, which then become our secondary personas with the function of helping to further specify citizen requirements. Both are currently present and have already been presented at the last USM workshop (during wave 1 of the co-creation process) with technical and CUC partners held in Berlin 11/2019 in order to receive early feedback. Although the above approach might have one think that highly data-literate users (i.e. digital natives) are non-personas, they too are important to consider in our further development, as also supported by the partner feedback received at the above USM workshop.

While the following assumption personas are preliminary, they have been reworked slightly already and will be further adjusted.

Assumption personas

Citizen at work1, mobile nurse
female, age 40-45, mother, married – mobile use at work, but barely outside it

Dalia is 42 and works full-time as a mobile nurse. She has been doing this work for many years and has been caring for patients from various backgrounds. Integral to her daily work is the use of a PDA to see her tasks and check them off throughout the day, ideally in specific timeframes. If she does not meet her tight schedule, her breaks have to be shorter. Using and having this device with her all day makes her use her own mobile device less frequently. When she does use her smartphone, it is mostly to briefly communicate with her child and husband. Her work is stressful on a mental and physical level, as her care work not only involves the turning and lifting of patients, but also dealing with their painful experiences and the effects on their life and on the lives of their relatives. As she is taking care of the health-related situation of others at work, she tries to keep health-related engagement in private life to a minimum. In her case, this includes storing health records manually for each family member in a folder. In essence, her work is quite exhausting, which is why she does not find the time or energy to do some training after work, although she is aware of the benefits to her (back) health and thus work. Instead she recuperates by trying to do nothing too stressful on the weekends, like going for walks.

Citizen at work2, student in part-time office job
male, 20-25, single – familiar with apps but not into health or fitness at all

Dave is 22 and lives his student life between sitting in lecture halls, at home studying, and in his part-time job in a call-centre. He commutes frequently to/from University and work, and meets up with friends on the weekend to study for exams or at night for a drink. He uses his smartphone mostly for social media and news while commuting, and to message his friends and family. Although he sits a lot and is not active in a sporty sense, he has no issues with his health despite not caring specifically for it. Similarly, he also does not invest much thought and time in keeping his health records, because, luckily, he did not have any impactful health issues yet. He is aware though that he has some of his health records also electronically in his national EHR, into which, however, he has never logged in. Another reason that keeps him from using his EHR proactively, is hearing in the news about data breaches of cloud services generally. Yet he has not signed out

either, which is also rooted in his uncertainty if that would decrease the quality of his health service in the long run.

Citizen as patient and on travel (first time)
male, age 45-50, single, unemployed – with health issues (back and legs)

Frank is 46, unemployed, single, and has health issues related to his overweight and his previous job in the steel industry. Having had back issues and heavy feeling legs then already made him one of the first affected by job cuts. Additionally, his education is very job specific and low, making it hard for him to find a new job. Meanwhile though, he is in physio treatment for his back pain, but progress is slow, as he cannot perform the exercises as easily and lacks overall motivation. With his income always having been low, he has never been abroad, but is curious to, despite only speaking his native language. He has been using an aging smartphone with a limited data plan for years, which limits his scope of use. Because of his previous and ongoing treatment, he has gathered quite some health data and has them all at home – somewhere, somehow, as he does not want to be reminded of his bad health status also in that way. Besides trying to take care of his own health, he visits his mother in a retirement home, where also all her health records are managed. He thus neither manages his own health records, at least not systematically, nor does he have to manage those of his mother.

Professional user (as HCP persona who supports the citizen-centredness by feeding into our development of citizen user requirements from the side of the HCP - hence, it is not about his/her own health and health data management as a citizen.)

Professional user, physiotherapist
female, age 30-35, in relation – used to internal health information system (HIS)

Veronika is 34 and works as a physiotherapist full-time, treating patients with various backgrounds and health issues. She speaks multiple languages to ensure communication with them. In order for patients to get the most suitable treatment she needs to learn about their medical history before the treatment starts. Furthermore, before each treatment session she asks them about their wellbeing. Thereby she gets some context information and can decide on adapting the training intensity (to raise or lower it, or not), to best align treatment for the patient. In order for the patient to get the most out of the training even on a bad day, she also motivates them verbally. At the end of each session, she asks the patients for feedback, to ensure that the treatment advances within the scope of the patient's capabilities. With the agreement of the patient, she notes down any updates and changes in electronic form. This facilitates documentation as well as communication with colleagues. Through their internal health information system, which tracks every access, also her colleagues can read into those files and do the next treatment, e.g. with the right amount of weights. This assures patients that they will receive a consistent training throughout the whole duration of the treatment and get a full picture of their progress, including a pre-/post-analysis.

4.2 Early co-creation with potential citizen users and first reflections from professional users

The input from 4.1 was used to fuel a card-based discussion method, which is also guided by questions raised in D1.1. The aim was to elicit user requirements at the very early stage of the project when design and development choices are still open. This meant, however, that we had to create actively a setting in which potential users could imagine a future health-data platform and formulate a first set of relatively fine-grained requirements. The requirements formulated in this first round will address the features the future health-data platform should have and from there which functional requirements each of these features should have.

4.2.1 Citizen co-creation workshops

Four Co-Creation Workshops (CCWs) with citizens who are not involved in the CUCs were held in Vienna to explore broader questions and *potential* concrete situations of interaction with the health-data platform. At the point in time of the citizen CCWs, no prototype is in place yet and the exploration of the situations is thus speculative. This approach of involving citizens independent of CUCs was chosen in order to retrieve a first set of user requirements from potential users to facilitate the platform development and bridge the time until we will be able to work with users involved in the CUCs. For the time being, and in contrast to the USEEs that will then be conducted within the CUCs, **the CCW participants were recruited from the general public, i.e. citizens.**

As also outlined in D1.4 (1st citizen/user consent language report) the recruitment of citizens was done by an open call sent out by bulk mail to households in Vienna, were WP1 lead UNIVIE is located. The four groups were conducted at the premises of UNIVIE, the Department of Science and Technology Studies at the University of Vienna, from September to October 2019 (Sept 13/14/21, Oct 5). The CCWs took place in a face to face setting with a duration of four hours with a break. An exception has been the CCW focused on the IC form and procedures, which had a two-hour timeframe. While participation was voluntary, participants received a compensation of 10 Euros per hour[5].

In recruiting, diversity was paramount. We aimed at heterogeneous discussion groups in regard to the following dimensions: gender, age, educational background, current job, and having opted out of the Austrian national electronic health record (ELGA) or not. As there have been public debates about electronic health records in the Austrian context, of its (potential) pros and cons, we identified this as ideal to explore visions of citizens towards the making of a citizen-centred health data platform. Thus, the national context and embedding of the discussions was taken into consideration from the very start. Regarding age, persons under 18 years were excluded, as also the Smart4Health project does not address or include them. For details on the recruitment flyer distributed to households see Annex II: Recruitment Flyer.

The citizen responses allowed us to assemble diverse groups regarding the above categories and reach the aimed group size of 4 to 6 participants in each (similar to focus groups). This ensures ongoing and in-depth discussions between participants and allows for following the discussion dynamics. Slightly more participants would still

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[5] This compensation is meant to allow people to use transportation means such as a cab if they have difficulties to take public transportation or to finance childcare during the discussion – to give but two examples.

be possible, with ten participants being the upper limit as this bears the methodological risk of getting only very brief statements, without detailed engagement.

The **overall composition of the four citizen CCW groups** regarding the categories in the recruiting survey is as follows:

- Gender: Two of the groups were gender balanced, the others had either mainly female or male participants. There is no clear difference in the discussion dynamics due to gender.
- Age: In three of the groups all four age categories (18-30, 31-45, 46-60, >61) were present, whereas group 4 was equally split between two age ranges (18-30 and 46-60).
- Educational background: From the five possible options, we had not managed to attract participants who only had compulsory schooling (until 15/16 years); participants who had finished an apprenticeship were present twice (group 1 and 3). Hence, the majority had at least a high-school level of education. Those remaining on that level (including students, employees as well as retirees) were present in each group and with those having a professional education amounted to about the half of the cohort. Participants with professional education were present in all but one group (group 4). Meaning, the other half of the cohort had a college degree or similar.
- Current job: With this category having an open answer field, the responses reflect the achieved diversity ranging from retired, jobs in various fields (food service industry, marketing, office in general, as well as two nurses), to housewife, student, and unemployed. Missing, however, for example, were doctors, civil servants, or workers in physically demanding areas (e.g. industry).
- National EHR opt-out: From all respondents two citizens had opted-out of the Austrian EHR, about a third did not know, and the majority responded with not having opted out.

All in all, we have quite detailed and engaged accounts from a broad variety of citizens. While some of them were missing from our groups, such as physical workers, we will be able to engage with representatives from that group in the framework of CUCs, as they facilitate access to them.

The CCWs use a card-based discussion method (Felt et al., 2014), which has been specifically adapted to allow citizens the exploration of issues related to a potential use of a future health-data platform (see Figure 12). A set of basic features of the health data platform had been already specified in the project proposal writing phase, such as what data could be uploaded (*MyHealthView* to upload personal health data) and which kinds of interfaces were foreseen to give access to data (e.g. *MyTrusted* to allow data access to other people such as loved ones or health professionals). Yet, participants were invited to engage with the concept of a digital health data platform more generally, to do an imagined user journey through the platform and to spell out the key values that would be most important for them to be attentive to when designing, developing and implementing the platform.

After the welcome, all participants were asked to read and sign an IC form specific to the University of Vienna, with the time and possibility of asking any occurring questions. This ensured their voluntary participation and their right to withdraw at any moment without giving a reason. The IC form explained how data (audio files and transcripts thereof) are stored following the GDPR and who has access to the data (they are stored at the University of Vienna on a password-protected server, only

accessible by members of the WP1 lead UNIVIE). Finally, we underlined that we will pseudonymize the data and their names will not appear in any reporting. A co-signed copy of the IC form remained with each participant. See also D8.1 for more details on IC procedures.

We then started the workshop with a short video, briefly explaining Smart4Health. We described the scope of the discussion and explained the three steps of the discussion.

Step 1: The discussion started with a broader exercise inviting participants to outline their more general position towards eHealth infrastructures (e.g. national or regional EHRs).

Step 2: We then walked them through the whole process of using the imagined platform. For this purpose, we structured the discussion of the process of inscribing and using the health-data platform along a number of concrete "**situations**". Each situation describes a specific moment/setting where users potentially have to act or take a decision – such as subscribing to the future "Smart4Health" health-data platform, collecting personal health data, sharing data with other people such as the doctor or a loved one, providing data for research, being re-contacted after data-donation and many more. The 15 situations and the requirements that were a result of our discussion with potential users are described in detail in chapter 4.3.2.

Technical partners provided us with some visual mock-ups to create an imagination of potential future interfaces. According to Carleton and Cockayne (2009) the creation of mock-ups can contribute to the process of designing user interfaces, as they help to make collective ideas tangible, iterate them at low cost and quickly, and thereby to establish a common ground and language of the prototype and its functionalities. In context of these CCWs, however, mock-ups served to stimulate the discussion; the aim was not to validate them with participants.

Step 3: We ended with a discussion on the key-values that are essential in citizens' views when developing and implementing the platform.
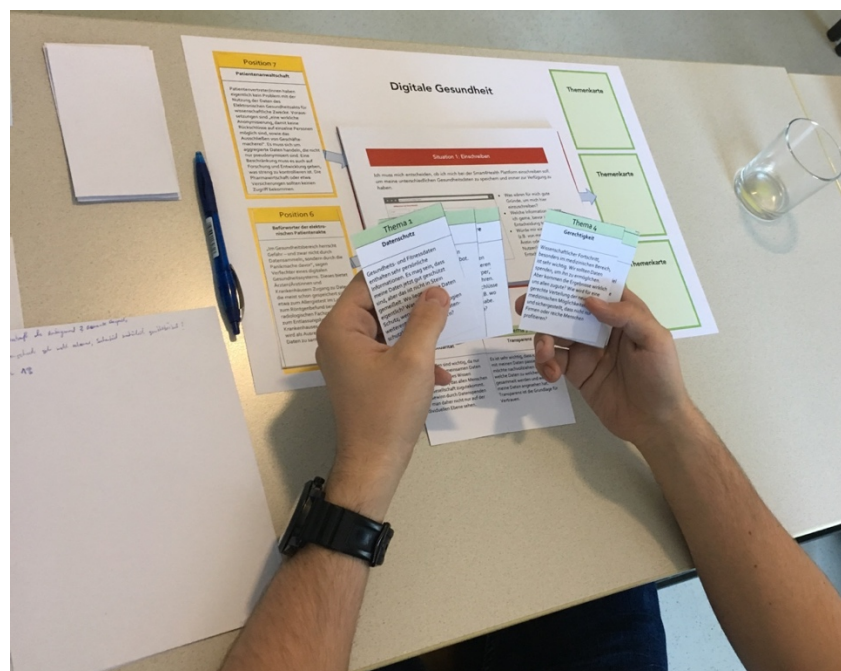

Figure 12 – Pad and selection of cards used in the card-based method (CCWs)

This allowed us to extract specific scenarios of use, to identify major concerns citizens voice more generally and in specific situations, to learn what is and would be essential to them, but also more broadly speaking the values they would want to see respected.

Following a bottom-up approach, the qualitative data analysis (QDA) of the pseudonymized transcripts, which usually amount to 160+ pages for each group, has been done through open and focused coding (see Charmaz 2014) with the QDA software ATLAS.ti.

At the time of writing, also another type of CCW has been conducted, which has been **specifically devoted to IC procedures,** regarding the structure and social acceptability of the IC forms and processes, to provide input for our deliverable D1.4 *1st User Consent Language Report* as well as to WP8 on ethics.

4.2.2   Focus groups with nurses

This following section outlines the procedures of the discussion groups conducted by EFN on 11-12/04/2019. EFN provided a report of the groups on 31/08/2019. As UNIVIE as work package leader of the co-creation activities was informed about them only after their realization, their planning and conducting was solely done by EFN and did not follow a similar logic than other CCWs. The number of participants mentioned exceeds those recommended in the methodological literature for doing focus groups, which usually ranges from 4 to 12 (e.g. Barbour & Flick 2009, Morgan & Krueger 1998) in order to allow an in-depth discussion between participants. We nevertheless refer here to the terminology of 'focus groups' used in the EFN report. While the report does give insights into the experiences and visions of representatives of nurses, for writing the report on user requirements at this point in time the input has only be partially considered. The input from health care professionals concerning the access citizen-user might give to them, will be essential at later stages of the development. We nevertheless document the organisation of the focus groups.

Setting-Up the EFN focus groups

The EFN members meet on a regulator basis to discuss and decide on EU policies, especially with the context of the EU legislation linked to the European Pillar of Social Rights. These are the EFN General Assemblies.

When EFN members met on April 11-12, 2019 in Brussels, focus groups were set up and EFN members were free to join these 3 group sessions of 4 hours depending on their resources and availability. However, EFN members delegations, often 3 nursing leaders (often operating in daily practice) per country joined each focus group. Prior the EFN General Assembly, EFN members got written information and were also asked to give written input, which led to an overview of how EHR (whether in single institutions or on the national/regional level) is used in the different European countries. The Focus Groups had a lead (a member of the EFN EXCOM) and got support by the EFN policy officers. Both individuals informed the participants on the content, the process and the expected outcomes.

The main goal in doing these focus groups was ensuring that representatives of nurses get to know the process of building Smart4Health and can express their visions and expectations when it comes to the development of the Smart4Health platform. The EFN Focus groups were composed of 63 participants (92% women), equally divided

over 3 Focus groups, making sure all Members States are covered in all 3 Focus Groups. Participating nurses were described in the EFN report as mainly working in a professional organisation, in a union, in educational setting, in regulatory sector and in hospitals. None of these nurses were involved in the daily activities of the project. They participated anonymously. When national delegations had less than 3 participants, EFN members were allocated to a group to reach equal number of participants for each focus group.

Participants of the focus groups were eased into three generic scenarios[6] that could be covered by the Smart4Health UDCs and CUCs for data use and donation within the platform and were asked for their input and comments on user requirements characteristics. Two of them involve access by authorized people in a country to the health data of patients from other countries, the third access to research data.

Outcomes of the three groups for example addressed how EHR datasets of citizens should look like for nurses to do their jobs properly, e.g. covering which information in which detail (group 1), what an emergency dataset may contain (group 2), and how to share health data with authorised nursing researchers (group 3).

In chapter 4.3.3 we will outline in an exemplary manner two challenges formulated by nurse representatives as outcomes of the discussion and formulate corresponding requirements from nurses.

4.3 First specification of user requirements

In what follows, we present a first set of user requirements. These are based on the (collective) assumption personas (and thus on the interviews, group discussions and USM workshops with partners), and the citizen co-creation workshops (independent of CUCs). As already underlined, these first specifications of user requirements are based on potential users outside the CUCs. They provide initial input and point to possible directions into which the development and feature set of the 4HP can evolve. As outlined in chapter 3 (Figure 1), the elaboration of user requirements will follow an iterative process. The citizen-user requirements formulated below have to be seen as a first approach to citizens expectations and concerns, and not as a fixed list of requirements to be realised by the technical partners. UNIVIE will further engage with larger and more diversified user groups such as in the CUCs, as well as classify, prioritize, further analyse and also validate the elicited user requirements. For further details on the cyclical approach, the waves of USEEs and feedback loops within the consortium, see also D1.2.

With regard to the focus groups carried out by EFN, the outcomes from the discussions with representatives of nurses will only be touched on rather shortly, as their input is less about what citizen-users would need from their work perspective, but much rather

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[6] Scenario 1: „a citizen and a healthcare professional (HCP) exchange health data using their devices using a local link and not using internet nor a cloud storage" with the questions what data the respective nurse would need to do properly their job.

Scenario 2: "on how HCPs may access citizen's health data in emergency situations" with the question what an emergency data set would need to contain.

Scenario 3: "how to share health data, owned by EU citizens, with authorised nursing researchers (ENRF nursing research network)" with the question on the data needed to develop evidence-based EU policies in the nursing domain.

(Information taken from the EFN Report)

about what nurses would need from the Smart4Health prototype. Given the citizen-centredness of the development process and the aim of this first user requirement specification report, we will only shortly touch on the focus groups.

4.3.1   Methodology

In this section we present a first set of citizen user requirements that relate to specific interactions with the 4HP to be explored, tested and validated in the different CUCs. These interactions relate to citizen action as the counterpart to what will be presented in section 4.3.3, i.e. the first set of professional user requirements derived from focus groups with representatives of nurses (organized by EFN). In the first wave of the co-creation environment we so far have conducted four co-creation workshops with citizens (M9-M10) as well as one co-creation workshop with citizens that was specifically focused on IC (M11). While the latter was conducted as part of Task 1.5 (citizen/user consent language), it will also feed into this deliverable (D1.3).

In D1.2 we have presented three tables grouping the CUCs into (1) **Testing infrastructure,** (2) **Collecting citizen-generated health data,** and (3) **Considering citizen diversity and mobility** (pp. 39-42). These three tables each contained a column in which we outlined the expected user interactions with the 4HP for each CUC. It is important to note that this first version should not be interpreted as being exhaustive but can be expected to be shaped over the further course of empirical work and user engagement exercises. We therefore have to remain open to new types of interactions that have not been anticipated. Hence, the following interactions with the 4HP are **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.

As outlined in D1.2, d*epending on the CUC, a first user interaction is likely one of* ***registering and consenting*** *to the use of the 4HP, which requires communicating the project description and formulating an IC, which is developed and tested regarding its language, intelligibility and social 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, seeing and* ***managing/editing*** *one's emergency information and/or Smart4Health profile/account* as well as **deleting data** and/or one's account.

Collecting and ***uploading*** *encompasses the ingestion of citizen-generated health-related data gathered via wearables through the so-called Citizen Hub, 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.* The differentiation here is to be made in terms of who initiates the uploading – the citizen via the citizen hub or the healthcare professional via e.g. the 4Health Monitor.

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.*

Data can not only be shared with HCPs or loved ones, it can also be **provided** for research, which raises its own set of questions regarding consent and appropriate language, infrastructure legibility as well as pseudonymization and de-identification. We follow up on points regarding citizen/user consent language in D1.4.

4.3.2   1st set of citizen user requirements

As the CUCs are not yet in place, this first specification of user requirements is not based on engagement with actual users in Smart4Health, but with citizens as potential users of the 4HP. As CUCs are about to start, we will be able to work on the further elaboration and refinement of these first specification of user requirements by including and analysing the input and feedback of actual users enrolled in the project.

In what follows, we always first describe the way we elicited requirements from citizens and then point to the user requirements based on citizen formulations. The core of the elicitation process was guided by 15 situations (S1-S15), followed by another situation (S16) that emerged out of the discussions. The elicitation cards were essential as many potential future users have little to no experience with electronic health records and thus need some input in order to be able to express their concerns, expectations and thus elaborate on their requirements. See Annex I: Situation Cards for the original cards set used – in German and with visual stimuli in form of some mock-ups. The situations which are described below are a translation of the situation cards slightly amended including elements from the analysis of the CCWs. The situations described below, include further specifications to the situation made in the discussion and therefore give a more precise description of the scenario on which the requirements formulated are based.

While this is only a first step, in the following months we will continue to work with citizen users and professional users and continually refine, classify and prioritize both the user requirements and the performance criteria. This further research with users through deploying a set of different social-scientific methods (see methods toolbox in D1.2) will thus be an ongoing process to identify unmet needs and challenges. This will allow technical partners to develop potential solutions, which in return will be put up again for discussion and validation with users. Below is thus a first approach at an early stage of the project.

Situation 1 (S1): Registering for the 4HealthPlatform
Description of the scenario
I have heard about Smart4Health and have found it online. Now I am in the situation where I have to decide if I want to register for the Smart4Health platform so that I can save all my health and health-related[7] data and have them available at all times.
• What would be a good reason for me to register for such a platform?

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[7] Health-related data in this report is used as higher order term that comprises what has been referred to as fitness data, well-being data, wellness data, lifestyle data. They are thus not medical data in the classical sense. Using a wider notion of health, citizen see these data connected to their overall health-status. We therefore will use this notion in the context of this report on user requirements.

- What kind of information would I need to have available, in order to form my decision?
- Would a recommendation help me with this kind of decision? If so, by whom (e.g. from my GP, MD, or other users)?

User Requirements

UR1.1: As a citizen contemplating registering to Smart4Health, I want to know beforehand who will have access to my uploaded data, in order to value its trustworthiness.

UR1.2: As a citizen contemplating registering to Smart4Health, I want to know how I can de-register before registering and what that means for my uploaded data, in order to avoid having to register and check if and how de-registering is possible.

UR1.3: As a citizen contemplating registering to Smart4Health, I want to know who pays for this infrastructure, in order to come to a first assessment in terms of costs and benefits or interests behind such an infrastructure and to form my decision to register or not.

Situation 2 (S2): Consenting to platform use

Description of the scenario

I have taken the decision to have a look at what Smart4Health can offer me and to start using it. I am now in the process of registration and I have entered my basic information. In this process, I get the declaration of consent displayed. This is a longer document describing what I can do on this platform and how my data will be protected. I must read it and then give my IC. I can also retrieve and view the declaration of consent afterwards.

- What information is important to me so that I can give my consent to the use of the platform?
- How exactly should I read the document, or can I trust the site?
- What if I do not understand everything? Who would I want to turn to?
- What choices do I want to have available?

User Requirements

UR2.1: As a citizen registering for Smart4Health I want the IC Form to be phrased in short sentences and understandable terminology in order to make an informed decision that does not take too long.

UR2.2: As a citizen registering for Smart4Health, I need to have a good understanding of the risks and benefits in order to make an informed decision.

UR2.3: As a citizen registering for Smart4Health, I want to have access to a hotline or the possibility to chat with a real person whom I can ask specific questions and get specific answers, in order to be taken seriously and not have to deal with a chatbot or general Q&A.

UR2.4: As a citizen registering for Smart4Health, I need to have a good understanding of who might economically benefit from my participation, in order to not provide data to somebody who makes money from it as this would make me feel exploited.

Situation 3 (S3): Collecting Health Data

Description of the scenario

In my life I have been to many doctors and also to hospitals. Now I should collect and upload as much data as possible, so that my data collection is as complete as possible. Therefore, I need to ensure that every HCP makes available and uploads collected and stored health data. And I should ask the doctor to add the findings to my personal Smart4Health data area every time I visit him/her, and the same should happen each time I have to go to the hospital.

- How much time would I be willing to or could I spend collecting and uploading past health data?
- How much time would I be willing to or could I spend to keep my data up to date?
- Is there any health data that I want to have available in digital form at all times?
- What support would I need to keep my data up to date?

User Requirements

UR3.1: As a citizen wanting to collect my data on the 4HP, I want the interfaces to be intuitive and easy to understand even for someone not highly digitally literate, in order to spend as little time as possible uploading information.

UR3.2: As a citizen, I want my HCP to be able to upload my previously collected health data, in order to not make any mistakes, as I don't know how that should work.

UR3.3: As a citizen wanting to collect my data on the 4HP, I want the HCP to easily access my account in order to ensure that he/she will make use of it now and in the future so that I have an accurate and complete dataset.

UR3.4: As a citizen I want to have my health data uploaded by my HCPs in order to save time and to have it all complete (assumption: HCPs have it all digitally collected anyway). As a citizen I want to have the possibility that another HCP can upload old health data in order to be able to add to my history.

UR3.5: As a citizen I want to have the option to select/deselect which data my HCP uploads to my Smart4Health account and thus exclude e.g. certain sets of medications that I don't want anyone ever to know about, in order to have control over the data collected.

Situation 4 (S4): Place of use

Description of the scenario

One can access the Smart4Health data platform either from home via one's own computer or on the road via the smartphone.

- Would you rather use the platform from home?
- Or would you prefer mobile use via your smartphone?
- What difference does it make which data is being handled? In what way?

User Requirements

So far, no explicit user requirements have been formulated.

Situation 5 (S5): Uploading health-related data (via Citizen Hub)

Description of the scenario

I have had a watch that counts my steps, measures my pulse, tracks my sleeping patterns and my heart rate and other things for quite some time now. While this data is not medical data as such, it still might provide interesting insights to my HCP. I could now upload this data to the platform and add it to my collection of health data.

- What will be my benefit, if I do this?
- Would I want such data to be used by my doctor in combination with other health data?
- Are there any specific data that I do not want to collect and make available to my HCP?

User Requirements

UR5.1: As a citizen uploading my health-related data from personal devices to the 4HP, I want to be able to exclude specific fields, e.g. on eating or drinking habits, or location, in order to control what could be possibly seen when giving access.

UR5.2: As a citizen, I want to be assured and be able to control where data and metadata travels to in order to be sure that none of my health-related data ends up with insurance companies.

UR5.3: As a citizen uploading my health-related data coming from my personal devices to Smart4Health, I want to keep them clearly separate from my health data, in order not to create a mixed set of data that might reduce its quality and usefulness for HCPs, and thus my health.

UR5.4: As a citizen ready to upload my health-related data, I want my HCPs, whom I give access, still taking care of diagnostics, in order to not become responsible for this myself.

Situation 6 (S6): Workplace and health data

Description of the scenario

Employees in my company again and again have health problems, such as back pain. Now my boss has made the offer that we could participate in a training program during our working hours to improve our health. For example, I can wear a special t-shirt, and then one can measure whether I am sitting or standing in the right way and if I could do it better. I could also upload this data to my health data on the platform.

- What would I see as my benefit if I go along with it?
- Who should be able to see my data: only me, the company doctor or also my employer?
- Would I upload this data to the platform?

User Requirements

UR6.1: As a citizen at work, I want to be able to limit access to work-related health data to a medical professional, in order to have my health data never communicated to my employer (except in aggregated and anonymous form).

Situation 7 (S7): Sharing data with the HCP

Description of the scenario

I have registered for Smart4Health, have had some HCPs upload previously collected data and I have uploaded self-collected data. Now I am sitting at the doctor's office and my doctor says that they would like to see my data.

- Is there data that I would like to share with my doctor? All or only specific data?
- What do I expect from my doctor having access to all data, including my self-generated health-related data? What should they do with it?

User Requirements

UR7.1: As a citizen, I want to have the option of giving my HCP full access to all my data if needed, in order to provide him/her a broad basis for making decisions affecting my health.

UR 7.2: As a citizen giving access to my HCP, I want to have a selection of options, in order to make a fine-grained choice regarding access to which part of my data.

UR7.3: As a citizen sharing data with my HCP I want to be able to define a time limit to access, in order to stay in control of my personal data and not inadvertently continue to grant data access.

UR7.4: As a citizen sharing data with my HCP, I want to be able to select between read or write/upload only or both, in order to stay in control of my personal data and be able to adapt the rights to the situation and my relation with the HCP.

Situation 8 (S8): Sharing data with a trusted person

Description of the scenario

I have registered for the Smart4Health platform. My partner and I are contemplating if it would be good to have access to my health data and vice versa. I might also want to share my collected health data with a nurse providing mobile care - now that I am still healthy this does not quite apply yet, but at a later point in time this may be relevant and useful.

- Would I give a trusted person such as my partner or a nurse providing mobile care access to my health data?
- Under what circumstances would I do this?
- Are there situations in which I would never do this?

User Requirements

UR8.1: As a citizen making available my data collected on Smart4Health to my partner, I want to be assured that they cannot save/download my data, in order to feel in control over who has my data.

UR8.2: As a citizen making available my data collected on Smart4Health to my partner, I want to have a selection of options so that I can control which parts of my data are visible to that partner.

UR8.3: As a citizen making available my data collected on Smart4Health to my partner, I want that the app sends/displays her/him an information about not being liable for my health, in order to assure her/him that the responsibility for my health still lies with me.

UR8.4: As a citizen contemplating access for my partner, I want to be able to link this to my advance healthcare directive, in order to be able to assure that my choices are respected.

Situation 9 (S9): Revoking access

Description of the scenario

I have given my doctor access to all data, including my self-collected data and I have given my partner access to all my data, including my health care data. After having thought about this for a while, I'd rather undo this or at least restrict the data access a bit, so that my doctor only sees my health care data and my partner only sees my self-collected data.

- How can I decide for myself which data I want to share and which I do not want to share?
- How can I revoke access to my data without jeopardizing the relationship of trust?

User Requirements

UR9.1: As a citizen making available my data collected on Smart4Health to my partner, I want to be able to revoke these rights in order to keep control over my data and to protect me and my data in case our relation changes.

UR9.2: As a citizen making available my data collected on Smart4Health to my partner or HCP, I want the process of revoking access to be easy and clear (a de-selection interface) so that I can ensure that I share the right elements with them and correct mistakes quickly.

UR9.3: As a citizen having revoked access rights, I want to be informed about the point in time when the access is no longer granted, in order to feel in control of my health data.

Situation 10 (S10): Making data available for research

Description of the scenario

I am considering making my collected health data available for research purposes. This can comprise scientific research being conducted by researchers in public academic institution or by researchers in third parties, e.g. in industry. In the process of donating my data, the data is de-identified, that means that my name and other person-specific information will be removed.

- What do I want to know in detail before I donate my health data?
- Whom would I donate my data to?
- Would I donate my entire data set, or would I want to be able to make a selection?
- What aspects would play a role in selecting which data to donate and who could help me with this?

User Requirements

UR10.1: As a citizen considering providing my data for research, I want to know for which kind of research (purpose, domain) my data is used, in order to exclude that data is used for purposes I do not condone.

UR10.2: As a citizen considering providing my data for research, I want to know where the data will go (e.g. outside Europe), in order to exclude data transfer to locations I do not condone.

UR10.3: As a citizen considering providing my data for research, I want to be able to exclude industrial research, i.e. pharma, in order to feel in control of my data and provide it to academic research only.

UR10.4: As a citizen considering providing my data for research, I want to be able to choose a donation for the time after my passing, in order to keep my data privacy during lifetime while still contributing to research.

UR10.5: As a citizen considering providing my data for research, I want to be sure that the data will never be sold in order to sustain the character of data for the public good.

UR10.6: As a citizen considering providing my data for research, I want to know about direct or indirect benefits for myself, i.e. incentives, in order to decide whether my gesture is worth it.

Situation 11 (S11): Being re-contacted after providing data for research

Description of the scenario

I have decided to provide data for research. In this process I have agreed to be re-contacted. In this way, I can find out what research is being done with my data, scientists can ask additional questions if they need more information, and I could also find out about results that are relevant to my health. Yet, this also means that the data I have donated stays linked to me.

- What benefits and risks do I expect of the possibility of being re-contacted after a data donation?
- What happens, if the information is not relevant to me, but rather frightens me?
- If one can associate the donation with me, what can one indirectly find out about my family?

User Requirements

UR11.1: As a citizen being re-contacted, I want to be able to talk to a qualified person who can explain everything to me, in order to not be alone with interpreting information obtained and/or potential risks.

Situation 12 (S12): Defining emergency information

Description of the scenario

I like traveling and go abroad regularly, also to countries where I do not speak the local language. In my Smart4Health profile, I have created a specific list of emergency information, that doctors can access in case of an emergency. For instance, if I am on vacation and unfortunately have to go to the hospital, the doctor there can have access to this specific part of my health data in the local language. Or I could have had an accident and may no longer be able to act and decide for myself. Doctors could access this emergency information without my active collaboration.

- What information would I want to give to the doctor? Or to any other person who can access this emergency information?
- Which data is really important to me?
- Is there any kind of data that is too sensitive for me?

- What do I need to know in order to be able to trust that I will be treated correctly if this emergency information is displayed in a language I don't know?

User Requirements

UR12.1: As a citizen defining my emergency information, I want to have different options of data fields, in order to adapt the information to my individual situation and receive treatment adequate to my health condition.

UR12.2: As a citizen defining my emergency information, I want to be assured that what I have defined is adequately speaking to my health status when I no longer can. Therefore, I need the possibility of consultation in order not to omit something that is relevant just because I am not an expert.

UR12.3: As a citizen defining my emergency information, I want to make available all possible health data, in order not to omit something that is relevant just because I am not an expert.

Situation 13 (S13): Giving access to a doctor while being abroad

Description of the scenario

I am on vacation in a resort and unfortunately have to go to the hospital. I can give the doctor access to a specific part of my health data in the local language.

- What do I need to know in order to be able to trust that I will be treated correctly?
- Who should be responsible if I am treated incorrectly due to an erroneous automatic translation?

User Requirements

So far, no explicit user requirements have been formulated.

Situation 14 (S14): Transparency with regard to access

Description of the scenario

I have so far compiled a broad collection of health-related data and given several doctors access to my health and self-generated health-related data. I have also donated some of my data for research.

- Should I or would I like to be able to trace which data my doctor or a trusted person has accessed and when?
- As far as the use of my data in research is concerned, would it be important for me to know for which larger research area these data are used or am I not interested?

User Requirements

UR14.1: As a citizen who has uploaded data to the 4HP, I want to see who has accessed them and when, in order to have an overview and feel supported by the app.

UR14.2: As a citizen who has uploaded data to the 4HP, I want anyone (even with permission) accessing my data to know that I can see this, in order to discourage inconsiderate access.

Situation 15 (S15): De-registering

Description of the scenario

After having tried it out for a while, I have come to the decision that Smart4Health is not for me after all. Therefore, I would like to de-register.

- Which were the main reasons for me to come to this decision?
- What happens to my data when I de-register from the platform?
- Where could my data have left traces despite de-registering?

User Requirements

UR15.1: As a citizen having used the 4HP and not wanting to do so anymore, I want to be able to deactivate and reactivate my account, in order to pause its usage, reflect calmly about this, but not have to lose all my data, should I ever want to resume using it at a later point in time.

UR15.2: As a citizen having used the 4HP and not wanting to do so anymore, I want to be able to easily delete my profile and with it all my data that were stored on the platform (CHDP) in order to have all my traces cleared.

UR15.3: As a citizen having used the 4HP and not wanting to do so anymore, I want to be informed by the platform provider that my profile and all my data have been deleted so that I rest assured that all traces of myself have been removed through the deletion request.

Situation 16 (S16): Deleting data

Description of the scenario

I now have been using Smart4Health for a while. I have uploaded previously collected health care data and self-generated health-related data and have had my HCP upload newly produced health care data to Smart4Health and thereby have amassed a substantial collection. Still, it contains some elements, that I'd rather not have there if I think about it.

- Can I delete everything I have collected?
- Is there a backup if I inadvertently delete something I actually want to keep?

User Requirements

UR16.1: As a citizen I want to selectively decide which data I keep and share and which data I want to delete, in order to stay in control of my health data.

UR16.2: As a citizen, I want to be the only person who has the right to delete my data (unless specified otherwise in my advance healthcare directive) in order to be protected against potential misuse.

4.3.3   1st set of requirements by representatives of nurses

The output produced in the focus groups done by EFN in April 2019 (UNIVIE having neither been involved in the carrying out nor in the planning) had remained mostly very broad, while at times moving to a very specific level. They did not follow the structure used in the citizen groups and therefore the user requirements that can be formulated on the basis of the report are less detailed and specific to the platform. It will need engagements with citizen- and professional-users in the CUCs to explore how details such as data fields used in EHRs will be demanded and matter (e.g. in therapy or in a hospital abroad).

However, taken together, the general comments and abstract objectives made about the platform allowed to formulate first preliminary professional user requirements, which, however, will also need exploration and evaluation with citizen- and professional-users in the CUCs. Hence, in the following are these two types of input and preliminary professional user requirements based on it.

First, a number of objectives on what the platform should be able to offer have been retrieved. EFN has reported that ideally, the data access, portability, control, sharing, exchange and provision for citizens and HCPs is:

- helpful for users,
- easy to manage,
- informative,
- used in unplanned situation,
- allows checking health data backwards in a timescale (days/weeks),
- can generate statistics and graphs.

The ease of use, particularly in collaboration with HCPs, has also been addressed by citizens, as formulated in above citizen user requirements under situation 3 (e.g. UR3.1 and UR3.3). As the involvement of professional users in Smart4Health serves to solidify the citizen-centredness of the platform prototype, we see the needs addressed by these respective early user requirements also supported from a professional user perspective.

Second, in the EFN focus groups general comments have been voiced that outline the challenges or pain-points to be addressed by the 4HP, if citizens want to use the 4HP to support their interaction with health care professionals. Overall, the representatives of nurses expressed their **usability challenges underlining what kind of health data they would want to see in patients' health data and what would be needed for them to easily upload data**. As the examples of challenges 1 and 2 show, we

describe two such challenges from a professional perspective. However, as the **citizen-users are at the centre of Smart4Health**, it will be the citizen users who can decide which data to present and to whom and their expectations and concerns will be centrally driving the development. However, the perspective of professional users will be important when supporting and refining needs expressed by citizen users.

Therefore, for the time being we documented two of the challenges formulated and expressed them in form of requirements voiced by nurse representatives. However, given the citizen-centredness of the design process, requirements by professional users, as explained above, will only enter the design and development process at this stage if they support and refine the usability of the 4HP for citizens.

Challenge 1 (C1): Interface use
Description
• Information display: EHRs displays information in confusing ways as the logic way of using data is not in line with the workflow of the end-user, often the nurse. • Difficult data entry: challenges here often cause delays for orders and lead to nurses to not trust the system. • System feedback: EHRs may not communicate that an action has been taken, such as when a patient has already received a medication.
Professional User Requirements (Nurses)
PUR1.1: As a nurse, I want to be able to enter/upload data easily, in order to not cause delays and lose trust in the system. PUR1.2: As a nurse, I want to see if a patient-/citizen-action has been taken, such as when a medication has been received already, in order to get feedback by the system.

Challenge 2 (C2): Data availability and migration
Description
• Workflow support: problems may arise when doctors and nurses share information or tasks. A study in Lille highlighted this communication challenge. • Interoperability stays a main challenge as the healthcare settings are a competitive world for industry. Communication between systems remains a challenge. Nurses face the uphill task of making different facets of their practice share a similar digital language. Interoperability requirements are key. • Data migration is a challenge, especially when moving from other digital systems or paper-based forms to another format (D4L). Data loss is a huge risk factor (e.g., buy a new mobile phone and see what data are lost) Ensuring data exportation to a newly EHR system needs attention, to support the end-user.
Professional User Requirements (Nurses)
PUR2.1: As a nurse, I want to be sure that the data I get to see from patients/citizens is relevant for my tasks and does not interfere with the work of others.

> PUR2.2: As a nurse, I want to be able to seamlessly upload existing health care data from the current health information system or EHR into the 4HP, in order to ensure a safe data migration and citizen support.

Nurses also underlined the importance of their role in fostering citizens' use of such health data platforms. It will therefore be important for Smart4Health to get their support in communication activities.

5 Performance criteria

As we are only in a very early phase of user engagement and the requirements are a first step and their development will be continuing, it is challenging to formulate a well-delimited set of performance criteria.

In what follows, we will therefore present a first tentative list of performance criteria, or better to say, **a procedure of building citizen-oriented performativity in from the very beginning of the development and design process**. This means that both requirements and performance criteria will be refined and adapted all along the Smart4Health project. Explicit stock taking will happen in deliverables D1.5 (M24), D1.6 (M32) and D1.7 (M40).

At this stage of the project, one way to define performance criteria is to take each of the requirements formulated above and define how this translates into **socio-technical requirements**. Using the notion of socio-technical means that part of the performance must respond to "social" concerns such as the information needed and the other part to the "technical" which means that access is working smoothly and the platform has the expected functionalities.

Taking **a citizen-centred approach to defining performance criteria**, we will proceed as follows:

- We will use each user requirement, formulated as a user story, i.e. "as a citizen I want to … in order to …", to identify and **write a matching card for the performance criteria attached to it**. Thus, WP1 specifically looks into how users define their needs, analyses how they can be formulated into user requirements and how then their quality of performance can be assessed. Reminder: as outlined above user requirements formulated by citizens will need to be grouped, evaluated and prioritized together with the technical and CUC partners. Only then will they be gradually transformed into technical performance criteria in the context of WP2 and WP3.
- We will establish **performance accountability and ownership** for all those involved in a user story, which means **documenting the user requirements** (including prioritization)**, performance criteria and the fulfilment of both in a living document** that is shared by all those participating in the process of developing, designing and implementing the prototype.
- A requirement can thus only be regarded as achieved when the corresponding performance criteria are fulfilled.
- This will be closely connected with the processes of testing, validation and assessment, which will start gradually in Task 1.6 with month 18 of the project.

As we are still in the process of developing user requirements and performance criteria, we will give here only some first examples. The full documentation of user requirements will follow a structure outlined in Table 1. The following three examples illustrate the definition of first performance criteria related to specific user requirements. The achievements of requirements can then be tested and validated along the process of design, development and implementation.

Example 1

UR1.1: As a citizen contemplating registering to Smart4Health, I want to know beforehand who will have access to my uploaded data, in order to value its trustworthiness.

PC1.2.1 The question of who has access needs to be explicitly addressed before a user has started the registration process.

PC1.2.2 The access possibilities need to be explained in a clear manner and be easy to understand.

PC1.2.3 If doubts arise, users have to have the possibility to ask questions before starting to register.

Example 2

UR 7.2: As a citizen when giving access to my HCP, I want to have a selection of options, in order to make a fine-grained choice regarding access to which part of my data.

PC7.2.1: Options for selecting parts of data to be read by medical professionals or loved ones are available.

PC7.2.2: Options are clearly communicated.

PC7.2.3: Options are easy to select and deselect.

PC7.2.4: Options remain in place for a specific amount of time (e.g. for a year, a month, …) which can be chosen by the user.

Example 3

UR 10.1: As a citizen considering providing my data for research, I want to know for which kind of research (purpose, domain) my data is used, in order to exclude that data is used for purposes I do not condone.

PC10.1.1: Options to donate data for specific research purposes should be provided.

PC10.1.2: Options to donate data for specific research purposes must be clearly communicated.

PC10.1.3: Options must be easy to select.

In order to accompany the process of design, development and implementation and establish performance accountability, we will document the user requirements, performance criteria and the fulfilment of both in a living document which is structured in the following way.

Table 1 – User requirements and performance accountability table (living document)

User requirements	Performance criteria	Integration into the prototype	Validation
UR1.1: As a citizen contemplating registering to Smart4Health, I want to know beforehand who will have access to my uploaded data, in order to value its trustworthiness.	**PC1.1.1** The question of who has access needs to be explicitly addressed before a user has started the registration process.		
	PC1.1.2 The access possibilities need to be explained in a clear manner and be easy to understand.		
	PC1.1.3 If doubts arise, users need to have the possibility to ask questions before starting to register.		
UR10.1: As a citizen considering providing my data for research, I want to know for which kind of research (purpose, domain) my data is used in order to exclude that data is used for purposes I do not condone.	**PC10.1.1** Options to donate data for specific research purposes should be provided.		
	PC10.1.2 Options to donate data for specific research purposes must be clearly communicated.		
	PC10.1.3 Options must be easy to select.		

6 Conclusions and further work

Our objective in this deliverable has been to specify a first set of user requirements and, accordingly, the identification of related performance criteria and to outline our methodological approach in developing them. We first discussed the relevance of specifying user requirements and performance criteria. This was followed by an explanation of our **general approach** to developing them. This approach contains five steps: (1) Defining key features of the health-data platform and its services, (2) Gathering user requirements and classifying them, (3) Evaluation and prioritization of user requirements, (4) Developing performance criteria and (5) Integration and validation. All along this process we have to be attentive to inclusiveness. This means ensuring that we engage with a diverse set of users and that we consider the specificities of different geographic regions/cultural contexts covered by the CUCs (Germany, Luxemburg, Portugal). The latter will be essential when aiming to expand the use of the Smart4Health prototype across all European regions.

We have then described in detail the methods **and collaborative procedures** that were employed to **develop the first set of user requirements**, namely partner interviews and workshops, user story mapping workshops and the development of assumption personas. We have also outlined the **recruitment procedures** and **methodological approach** of the **first four co-creation workshops** (CCW) in Vienna with citizens to explore broader questions and potential concrete situations of interaction with the health-data platform. Furthermore, we have described the set-up and process of three **focus groups with nurses** conducted by EFN.

The main part of the deliverable contained a **first set of user requirements** that relate to specific interactions with the 4HP to be explored, tested and validated in the different CUCs. The elaboration of user requirement throughout the project follows an **iterative process**. The first set of requirements was based on workshops with potential users of the Smart4Health platform outside the CUCs. The requirements are to be understood as a first input and they point to possible directions into which the development of the 4HP may evolve in the further course of the work in Smart4Health. Therefore, they have to be seen as a first approach to citizens expectations and concerns, and not as a fixed list of requirements to be straightforwardly realised by the technical partners.

The deliverable also elaborated on the **performance criteria** and a **monitoring tool** for continuous assessment if the user requirements have been implemented. In this way, performance criteria are present from the very beginning of the development and design process. Both, user requirements and performance criteria will be refined and adapted all along the course of the project. In the further course of WP1 we will continue to work with citizen users and professional users and continually refine, classify and prioritize both the user requirements and the performance criteria. These will then be delivered in form of further reports on user requirements and performance criteria in Mo 24, 32 and 40.

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List of Acronyms/Abbreviations

Acronym/ Abbreviation	Description
4HP	4HealthPlatform
CCW	Co-creation workshop
CHDP	Citizen Health Data Platform
CUC	Citizen Use Case
D	Deliverable
D4L	Data4Life gGmbH
DoA	Description of Action
EB	Eurobarometer
EC	European Commission
EFN	European Federation of Nurses
EHR	Electronic Health Record
ELGA	Elektronische Gesundheitsakte (Austrian EHR)
ELIXIR-LU	European infrastructure for life science information – Luxembourg node
EU	European Union
EWG	Ethics Work Group
FP7	EU Research and Innovation funding programme 2007-2013
GDPR	General Data Protection Regulation
GovMad	Government of Madeira
GP	General Practitioner
H2020	EU Research and Innovation funding programme 2014-2020, Horizon 2020
HCP	Health Care Professional
HIS	Health Information System
HPI	Hasso-Plattner-Institute for Digital Engineering gGmbH
HM	Healthmetrix GmbH
IC	Informed Consent
ICT	Information and Communication Technology
ITTM	Information Technology for Translational Medicine
ISMMS	Icahn School of Medicine at Mount Sinai

I-VLab	Laboratoire Virtuel Européen dans le Domaine de l'interoperabilite des Entreprises AISBL
KBZ	Knowledge Biz
M	Month
MD	Medical doctor
OSR	Ospedale San Raffaele
PC	Performance Criteria
PDA	Personal Digital Assistant
PUR	Professional User Requirement
QDA	Qualitative Data Analysis
RP	Research Platform
RRI	Responsible Research and Innovation
RWG	Requirements Working Group
S4H	Smart4Health
SHD	Stëftung Hëllef Doheem
Smart4Health	Citizen-centred EU-EHR exchange for personalised health
SME	Small and medium enterprise
T	Task
TelCo	Telephone Conference
UDC	Use Design Case
UKA	Universitaetsklinikum Aachen
UMC+	University Medical Center Maastricht
UNINOVA	Instituto de Desenvolvimento de Novas Tecnologias
UNIVIE	University of Vienna
UR	User Requirement
USEE	User Engagement Exercise
USM	User Story Map
WP	Work Package
ZS-UG	ZS Unternehmen Gesundheit

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Annexes

Annex I: Situation Cards

Disclaimer: This set of situation cards has been developed by UNIVIE. The images of the mock-ups have been produced by D4L/HPI. The cards may not be re-used without reference to

Ulrike Felt, Susanne Öchsner, Robin Rae, Card-based citizen co-creation workshops,

https://sts.univie.ac.at/en/research/current-research-projects/smart4health/.

Situation 1: Einschreiben

Ich muss mich entscheiden, ob ich mich bei der Smart4Health Plattform einschreiben soll, um meine unterschiedlichen Gesundheitsdaten zu speichern und immer zur Verfügung zu haben.

- Was wären für mich gute Gründe, um mich hier einzuschreiben?
- Welche Informationen hätte ich gerne, bevor ich meine Entscheidung treffe?
- Würde mir eine Empfehlung (z.B. von meinem Arzt/meiner Ärztin oder durch andere Nutzer/innen) bei der Entscheidung helfen?

Situation 2: Einverständniserklärung

Ich schreibe mich gerade ein und habe meine Basisinformationen eingetragen. Nun bekomme ich eine Einverständniserklärung angezeigt. Das ist ein längeres Dokument, in dem beschrieben wird, was ich alles auf dieser Plattform tun kann und wie meine Daten geschützt werden. Das muss ich lesen und dann mein Einverständnis geben. Die Einverständniserklärung kann ich auch im Nachhinein wieder abrufen und anschauen.
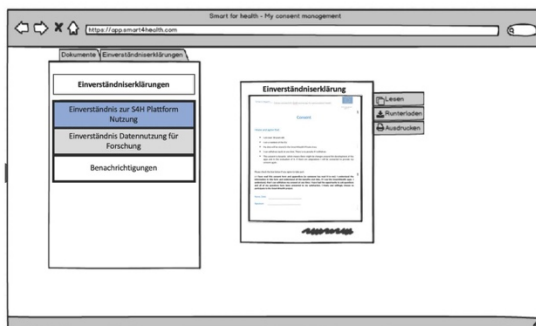
- Welche Informationen sind mir wichtig, damit ich mein Einverständnis zur Plattformnutzung geben kann?
- Wie genau sollte ich das Dokument lesen, oder kann ich der Seite ohnehin vertrauen?
- Was tun, wenn ich nicht alles genau verstehe? An wen würde mich wenden wollen?
- Welche Wahlmöglichkeiten sollten für mich vorhanden sein?

Situation 3: Gesundheitsdaten sammeln

Ich war in meinem Leben schon bei vielen Ärzten/Ärztinnen und auch im Spital. Jetzt sollte ich so viele Daten wie möglich sammeln und hochladen. Und ich sollte bei jedem Arztbesuch gleich den/die Doktor/in bitten, die Befunde meinem persönlichen Smart4Health-Datenbereich hinzuzufügen.

- Wieviel Zeit würde oder kann ich aufwenden, um zurückliegende Gesundheitsdaten zu sammeln und hochzuladen?
- Wieviel Zeit würde oder kann ich aufwenden, um meine Daten auf dem letzten Stand zu halten?
- Gibt es Gesundheitsdaten, die ich unbedingt in digitaler Form jederzeit verfügbar haben möchte?
- Welche Unterstützung würde ich benötigen, um meine Daten immer am neuesten Stand zu halten?

Situation 4: Verwendungsorte

Auf die Smart4Health Datenplattform kann man entweder von zuhause über den eigenen Computer zugreifen oder auch unterwegs über das Smartphone.

- Würden Sie die Plattform eher von zuhause aus benutzen?
- Oder wäre für Sie die mobile Nutzung über das Smartphone eine bessere Wahl?
- Macht es hier einen Unterschied, um welche Daten es sich handelt? Inwiefern?

Situation 5: Eigene Daten sammeln

Ich habe seit einiger Zeit eine Uhr, die meine Schritte zählt und die auch meinen Puls und andere Dinge misst. Diese Daten könnte ich jetzt auch zu meinen Gesundheitsdaten auf die Plattform hochladen.

- Was habe ich davon, wenn ich das mache?
- Würde ich wollen, dass solche Daten von meinem Arzt/meiner Ärztin in Kombination mit anderen Gesundheitsdaten verwendet werden?
- Gibt es bestimmte Daten, die ich nicht zentral sammeln möchte?

Situation 6: Arbeitsplatz und Gesundheitsdaten

Mitarbeiter/innen in meiner Firma haben immer wieder Probleme, wie etwa Rückenschmerzen. Jetzt hat mein/e Chef/in das Angebot gemacht, dass wir während der Arbeitszeit an einem Trainingsprogramm teilnehmen können, das unsere Gesundheit verbessert. Ich kann zum Beispiel ein spezielles T-Shirt tragen, und dann kann man messen ob ich richtig sitze oder stehe und ich könnte es besser machen. Auch diese Daten könnte ich jetzt zu meinen Gesundheitsdaten auf die Plattform hochladen.

- Was habe ich davon, wenn ich da mitmache?
- Wer dürfte meine Daten sehen: nur ich, der Betriebsarzt/die Betriebsärztin oder auch mein Arbeitgeber?
- Würde ich diese Daten auf die Plattform hochladen?

Situation 7: Daten mit dem Arzt/der Ärztin teilen

Ich habe mich in Smart4Health eingeschrieben und mein Arzt/meine Ärztin sagt, er/sie würde gerne meine Daten einsehen.
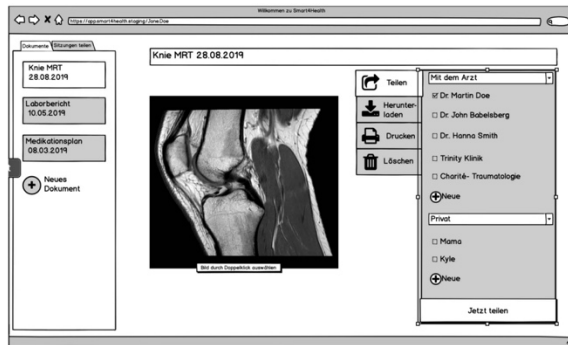
- Gibt es Daten, die ich mit meinem Arzt/meiner Ärztin teilen würde? Alle oder nur bestimmte?
- Was erwarte ich mir davon, dass er/sie nun Zugang zu allen Daten hat, inklusive meiner Fitnessdaten? Was soll er/sie damit tun?

Situation 8: Daten mit vertrauten Personen teilen

Ich habe mich bei der Plattform angemeldet. Mein/e Partner/in und ich denken darüber nach, dass es gut wäre, wenn er/sie auch Zugang zu meinen Gesundheitsdaten hätte. Auch später möchte eventuell Pflegepersonal Zugang haben.
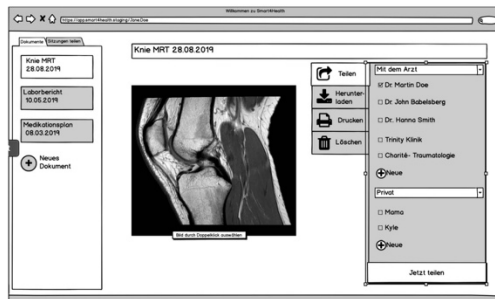
- Würde ich einer vertrauten Person, etwa meinem/meiner Partner/in, Zugang zu meinen Gesundheitsdaten geben?
- Unter welchen Umständen würde ich dies tun?
- Gibt es vielleicht Situationen, in denen ich das niemals tun würde?
- Kann ich für jede Person, mit der ich Daten teilen möchte, aussuchen, welche Daten er/sie genau einsehen kann?

Situation 9: Daten nicht mehr teilen

Ich habe meinem Arzt/meiner Ärztin Zugang zu allen Daten gegeben – inklusive meiner Fitnessdaten –, aber auch meinem/meiner Partner/in. Jetzt würde ich das aber lieber wieder rückgängig machen oder zumindest etwas einschränken.
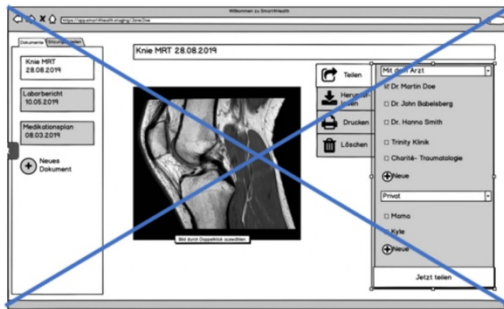
- Wie kann ich selbst entscheiden, welche Daten ich teilen möchte und welche nicht?
- Wie kann ich den Zugang zu meinen Daten jemandem entziehen, ohne das Vertrauens-verhältnis zu gefährden?

## Situation 10: Datenspende für die Forschung

Ich überlege, meine gesammelten Daten der Forschung oder für die Nutzung durch Dritte wie etwa Pharmafirmen zu spenden. Dabei werden meine Daten de-identifiziert, also mein Name und andere personenspezifischen Informationen werden entfernt.
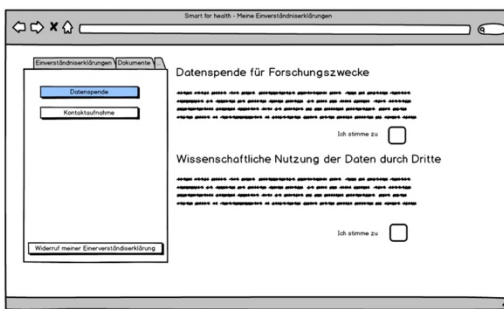
- Was möchte ich genau wissen, bevor ich Daten spende?
- Wem würde ich Daten spenden?
- Würde ich alles spenden, oder würde ich eine Auswahl treffen wollen?
- Welche Gesichtspunkte würden bei dieser Auswahl eine Rolle spielen und wer könnte mir dabei helfen?

Situation 11: Kontaktaufnahme nach Datenspende

Ich habe mich bereit erklärt, dass man mich nach der Datenspende wieder kontaktieren darf. So kann ich erfahren, welche Forschung mit meinen Daten gemacht wird, Wissenschaftler/innen können zusätzliche Fragen stellen, wenn sie noch weitere Informationen benötigen, und ich könnte auch erfahren, wenn es Ergebnisse gibt, die für meine Gesundheit relevant sind. Dadurch sind meine gespendeten Daten aber weiterhin mit mir verknüpft.
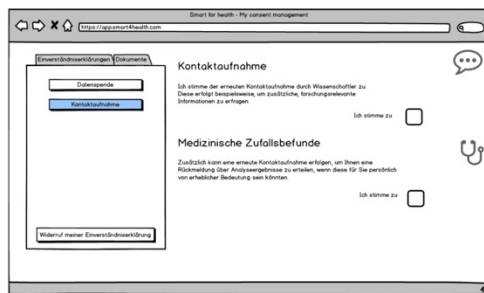
- Was erwarte ich für Vorteile und Risiken von der Möglichkeit der Kontaktaufnahme nach einer Datenspende?
- Was ist, wenn die Informationen für mich dann gar nicht relevant sind, sondern mir eher Angst machen?
- Wenn man die Spende mir zuordnen kann, was kann man dann indirekt auch über meine Familie herausfinden?

Situation 12: Notfallinformation

Ich bin auf Urlaub in einem Ferienort und muss leider ins Krankenhaus. Ich habe einen Zugang zu Notfallinformationen angelegt für den Fall, dass ich nicht mehr selbst handeln und entscheiden kann.

- Welche Daten würde ich dem Arzt/der Ärztin geben wollen? Oder jeder anderen Person, die diese Notfallinformation abrufen kann?
- Welche Daten sind mir wirklich wichtig?
- Gibt es Daten, die mir zu sensibel sind?

Situation 13: Arzt/Ärztin im Ausland Zugang geben

Ich bin auf Urlaub in einem Ferienort und muss leider ins Krankenhaus. Ich kann dem Arzt/der Ärztin in der jeweiligen Landessprache Zugriff auf einen spezifischen Teil meiner Gesundheitsdaten geben.

- Was muss ich hier wissen, um darauf vertrauen zu können, dass ich richtig behandelt werde?
- Wer wäre verantwortlich, wenn ich aufgrund einer fehlerhaften, automatischen Übersetzung falsch behandelt werde?

## Situation 14: Transparenter Zugang

Ich habe mittlerweile eine breite Sammlung gesundheitsrelevanter Daten angelegt und habe mehreren Ärzten und Ärztinnen Zugang zu meinen Gesundheits- und Fitnessdaten gegeben. Einen Teil meiner Daten habe ich auch für die Forschung gespendet.

- Sollte ich oder möchte ich nachvollziehen können, wann und auf welche Daten von meinem Arzt/meiner Ärztin oder von einer vertrauten Person zugegriffen wurde?
- Was die Verwendung meiner Daten in der Forschung betrifft, wäre es da wichtig, dass ich weiß, für welchen größeren Forschungs-bereich diese benutzt werden oder interessiert mich das nicht?

Situation 15: Abmelden

Ich entscheide mich, dass Smart4Health doch nichts für mich ist und möchte mich wieder abmelden.
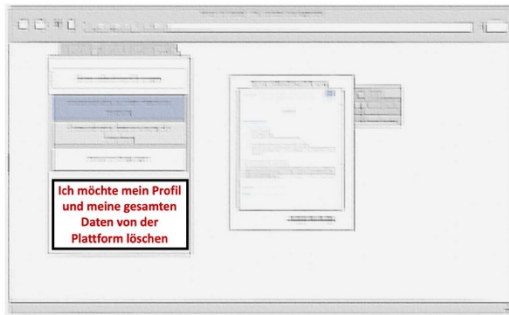
- Welche Gründe waren für mich besonders ausschlaggebend, um zu dieser Entscheidung zu kommen?
- Was passiert mit meinen Daten, wenn ich mich wieder von der Plattform abmelde?
- Wo könnten meine Daten trotz Abmeldung noch Spuren hinterlassen haben?

Annex II: Recruitment Flyer

Recruitment flyers for Citizen Co-Creation Workshops (09-11/2019, UNIVIE)

Bitte falten!

Porto zahlt
Empfänger

ANTWORTSENDUNG

Institut für Wissenschafts- und
Technikforschung, Universität Wien
Universitätsstraße 7, Stiege II/6. Stock
1010 Wien

Postentgelt bar bezahlt

Teilnehmer/innen für Diskussionsrunde gesucht!

Wir, das Institut für Wissenschafts- und Technikforschung (Universität Wien), suchen im Rahmen des EU-Projekts *Smart4Health* Interessierte, die sich an einer Bürger/innendiskussion zum Thema **Gesundheitsdaten** beteiligen möchten.

Durch die neuen Europäische Datenschutzgrundverordnung (Mai 2018) haben Bürger/innen mehr Rechte in Bezug auf ihre Daten. Damit Sie diese Rechte wahrnehmen können, hat das Projekt *Smart4Health* zum Ziel, eine digitale Plattform zu entwickeln, auf der Bürger/innen **ihre gesundheitsrelevanten Daten speichern, jederzeit verfügbar** haben und **teilen** können.

Damit diese Entwicklung **den Bedürfnissen von zukünftigen Nutzer/innen gerecht wird,** veranstalten wir **in verschiedenen Ländern Diskussionen mit Bürger/innen.**

Vorwissen ist nicht erforderlich**.** Wir erwarten von Ihnen **eine rege Teilnahme an der Diskussion und Freude an der Auseinandersetzung** mit anderen Meinungen.

Wenn Sie an einer Teilnahme interessiert sind, füllen Sie bitte den Fragebogen im Inneren des Flyers so rasch wie möglich aus und schicken Sie ihn uns zurück.

Smart4Health wird von der
Europäischen Kommisssion finanziert

Kurzfragebogen

Wir ersuchen Sie höflich, den folgenden Kurzfragebogen auszufüllen. Dieser dient dazu, eine ausgewogene, möglichst vielfältige Diskussionsgruppe zusammenzustellen. Ihre persönlichen Daten werden vertraulich behandelt, auf einem passwortgeschützen Server der Universität Wien abgelegt und nicht an Dritte weitergegeben. Unmittelbar nach den Diskussionsrunden werden die Kurzfragebögen gelöscht bzw. vernichtet.

Vorname: Nachname:

Adresse:

Telefonnr.:

Erreichbarkeit: ☐ vormittags ☐ nachmittags ☐ abends

E-Mail:

Geschlecht: ◯ weiblich ◯ männlich ◯ k.A.

Alter: ◯ 18-30 ◯ 31-45 ◯ 46-60 ◯ >61

Beruf:

Höchster Bildungsabschluss: ◯ Pflichtschule ◯ Lehre

◯ Matura ◯ Fachausbildung ◯ FH / Universität

Ich habe mich von ELGA abgemeldet:
◯ Ja. ◯ Nein. ◯ Ich weiß es nicht.

Die Diskussionsrunden finden im September und Oktober 2019 an der Universität Wien statt. Bitte kreuzen Sie an, an welcher Diskussionsveranstaltung Sie teilnehmen möchten (mehrere Optionen möglich):

☐ **Freitag, 13.09.2019, von 14-18 Uhr**

☐ **Samstag, 14.09.2019, von 10-14 Uhr**

☐ **Samstag, 21.09.2019, von 10-14 Uhr**

☐ **Samstag, 05.10.2019, von 10-14 Uhr**

Jede Diskussionsrunde dauert ca. **vier Stunden** und es nehmen jeweils 8-10 Personen teil. Sie erhalten eine **Aufwandsentschädigung von 40 Euro.**

Smart4Health wird von der Europäischen Kommission im Horizon 2020 Programm für Forschung und Innovation finanziert (Grant Agreement Nr. 826117). Für weitere Informationen kontaktieren Sie uns bitte.

Kontakt:
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Tel.: 01/ 4277-49616 (Robin Rae)
Email: smart4health.sts@univie.ac.at
Web: https://sts.univie.ac.at/forschung/laufende-projekte/smart4health/

Anmeldung:
Per Post: Bitte den Bogen falten, zukleben und an die umseitig stehende Adresse schicken.
Postgebühr bezahlt der Empfänger.

Per E-Mail: Bitte diese Seite scannen oder auf unserer Website herunterladen, elektronisch ausfüllen und an folgende Adresse schicken:
smart4health.sts@univie.ac.at