



**Citizen-centred EU-EHR exchange for
personalised health**

Smart4Health

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

**D1.5: 2nd Specification of user requirements and
performance criteria**

Deliverable Leader: UNIVIE

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Short Abstract

Deliverable D1.5 provides the second specification of citizen and professional user requirements and, accordingly, the identification of performance criteria and outlines the process in which they were developed and traced. The report provides insights into the main considerations, the methodological approach and the co-creation activities that were performed, including an outline of the mitigation strategies due to COVID-19 and the establishment and collaborative work with the Performance Accountability Table (PAccT).

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R0.1	Revised version from internal reviewers.
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Contributors	Description
UNIVIE	Organized and conducted co-creation activities with consortium partners, citizens related to CUCs, and citizens independent of CUCs; adapted the methodological approach to remote settings; developed performance criteria from the first set of user requirements; formulated a second set of user requirements and further performance criteria; developed the performance accountability table (PAcCT) as a collaborative workspace.
UNINOVA	Provided input regarding data sharing functionality, on the basis of which UNIVIE formulated questions for HCP partners. Participated in discussions on the PAcCT regarding the validation space. Recruited participants for co-creation engagements out of CUC 5 contexts.
HPI	Participated in discussions on performance criteria developed in Y2; provided input to the PAcCT regarding the requirement, integration, and validation space.
D4L	Provided mock-ups for the co-creation workshop at the GA in Potsdam, and the Go-Live version of the CHDP for co-creation engagements conducted by UNIVIE. Provided input regarding data sharing functionality, on the basis of which UNIVIE formulated questions for HCP partners. Participated in discussions on performance criteria developed in Y2; provided input to the PAcCT regarding the requirement, integration, and validation space.



Contributors	Description
HM	Provided a first version of the MyScience research application for co-creation engagements conducted by UNIVIE.
UKA	Provided input on current everyday practices of sharing data between citizens and HCPs in the respective health care environments.
UMC+	Provided input on current everyday practices of sharing data between citizens and HCPs in the respective health care environments. Participated in HCP one-on-one engagements conducted by UNIVIE.
ITTM	Provided input regarding HCP interactions with the CHDP via the HealthMonitor application.
ISMMS	Provided input on current everyday practices of sharing data between citizens and HCPs in the respective health care environments.
ZS-UG	Provided input on current everyday practices of sharing data between citizens and HCPs in the respective health care environments. Participated in HCP one-on-one engagements conducted by UNIVIE. Recruited participants for co-creation engagements out of CUC 3 contexts.
OSR	Provided input on current everyday practices of sharing data between citizens and HCPs in the respective health care environments.
EFN	Provided input on current everyday practices of sharing data between citizens and HCPs in the respective health care environments. Provided input to the PAccT regarding policy documents and requirements related to the performance criteria of user requirements. Participated in HCP one-on-one engagements conducted by UNIVIE.
I-VLab	Participated in discussions on the PAccT regarding the validation space.
EASPD	Provided input on current everyday practices of sharing data between citizens and HCPs in the respective health care environments. Provided input to the PAccT regarding policy documents and requirements related to the performance criteria of user requirements.
All	Participated in co-creation workshops conducted by UNIVIE at the General Assembly Meeting 3 in Potsdam (January 21-23, 2020) to identify the user ecosystem and align on this year's wave 2 of co-creation activities and provided further general inputs.

Further Information

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Executive Summary

This deliverable focuses on the process of specifying a second set of user requirements and identifying the related performance criteria. It is a “living document” as it builds on the first set of user requirements specified in M12 (D1.3) and will have two follow up reports in M32 and M40.

The report consists of, next to the introduction, five substantive chapters describing the processes and methodologies used to identify citizen and professional user requirements and detailing them.

The first chapter describes our work towards developing the second set of user requirements (i.e. chapter 3). We start with outlining our five-step approach to make the process of co-creation that we followed transparent. We then offer a description of the co-creation workshop we did with all partners of the consortium. In this workshop we collectively identified the ecosystem of users we aim to address in this second wave, identified the input we will get from the technical partners, defined the methodological approaches we will take to the specific Citizen Use Cases (CUCs) and identified the timelines to follow. The outcome was a stabilised timeline for the second wave of co-creation. Finally, we outline in detail the methodological and procedural adaptations we had to undertake due to COVID-19, which meant that the face-to-face interactions with users largely had to be transferred to the virtual space.

Chapter 4 attends to Performance Accountability by elaborating in detail how we will trace and document the process from eliciting user requirements to the decisions taken to either implement a user requirement, to post-pone it or to not realise it. For the purpose of tracing user requirements and their (non)realisation we have put in place a Performance Accountability Table (PAccT) which has four spaces each devoted to a specific way of addressing user requirements: requirement, integration, validation and documentation space. The chapter thus describes how Smart4Health ensures a transparent handling of user requirements, allowing to follow how they were (not/not yet) integrated into the final prototype. We also describe in this chapter how we use the PAccT in practice.

The following two chapters, chapter 5 and 6, then address in detail the elicitation of the second set of user requirements by citizen and professional users (health care professionals). Chapter 5 (citizen user engagement) is organised along “situations” such as registration, informed consent, authentication and many more. We thus simulate how users navigate through the platform and identify what requirements they voiced step by step. For each situation we present the card that was used to stimulate the discussion followed by a short formulation of the user requirements drawn from the discussion. In order to better capture the explanations users would give for any specific requirement, each set of user requirements is followed by broader insights from the user engagements. This allows the reader to better grasp the argumentative environment from which we extracted the user requirement and allows to better evaluate whether or not and when a requirement should actually be implemented. Eleven such situations were explored with citizen users (some of them are drawn together).

Chapter 6 then specifically looks into the everyday practices of sharing data by professional users and we elicited user requirements through one-on-one engagements



with HCP and hospital partners. This is essential as the quality of the platform prototype will depend on how both citizens and professional users can work with it. The chapter has three parts and starts with summarizing responses received by HCP partners to a set of questions we asked them about current practices of sharing data between citizens and HCPs in the respective health care environment of the partner. This delivers a first set of insights how data exchange matters in real-life situations. We then, in the second part, provide a list of the professional user requirements focusing mainly on the different aspects of sharing health data. This brought up important aspects concerning access, reliability of data, document classifications and many more. Finally, the last part of the chapter briefly summarizes main insights from the one-on-one engagements with HCP/hospital partners pointing to a number of problem areas that they identified with regard to data collection and sharing. We could identify here the importance of differentiating between different groups of health care professionals and what they need with regard to data sharing. These will get our attention in the further course of the project.

In chapter 7, we then move from user requirements to formulating the Performance Criteria (PC) from the first and second wave of co-creation. We first provide a list of PC that were established on the basis of the user requirements reported at the end of M12 (D1.3). This is done on the basis of a careful analysis of the arguments brought forward when formulating user requirements. The PC will allow us to assess the degree to which a user requirement has been implemented. The chapter then continues with an overview showing the status quo of PC development for the user requirements reported at the end of year 2, i.e. in this report. They will be elaborated in more detail based on the documentation of the user engagement exercises and the interviews in the first part of year 3.

Chapter 8 then closes this report with a short summary of the different parts and an outlook to next year's work on user requirements. We underline, that the interface to the research platform will be one specific focus during the third wave of developing user requirements.



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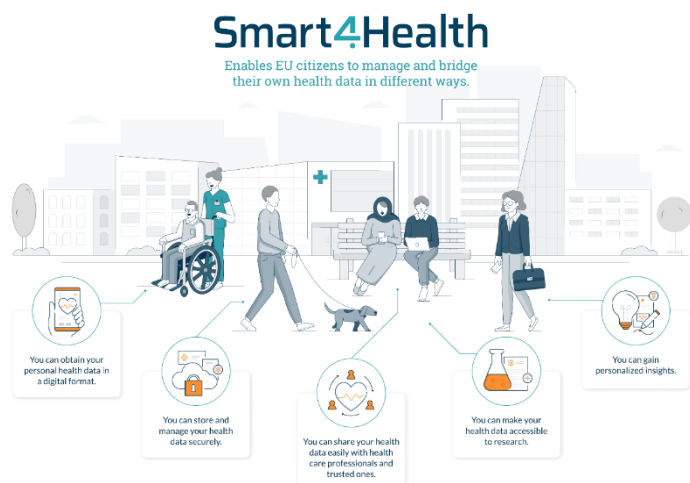


1 Document Summary

1.1 Smart4Health Project Overview

Smart4Health: Building today a healthier tomorrow

Smart4Health aims at empowering EU Citizens with an interoperable European Electronic Health Record (EHR) exchange that supports 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 decisions with regard to their own healthcare by enabling the possibility of sharing health data with different clinicians, medical centres, local and international societies, for research activities as well as to engage directly with healthcare providers. The 4HealthPlatform allows citizens to collect, store, manage, access and share their own health and healthcare data, through an easy-to-use, secure, constantly accessible and portable health data and services prototype within the EU and beyond. The 4HealthPlatform data layer connects with the 4HealthNavigator portal for services and applications to provide advanced personalised health services that are



accessible anytime and anywhere. Citizens are able to upload data (from EHRs over self-collected data to work-health related data) in the use design cases MyHealthView, MyTime and MyWork. Also, they are able to share data with health care professionals in situations when reliable health information is essential to ensure efficient health care as well as with other persons of trust such as family

members (MyTrusted, Mob.E.Health). Finally, citizens willing to support science can provide their data to the scientific community (MyScience). The technological elements are developed in a co-creation process drawing on eight Citizen Use Cases. These cases cover all aspects of citizens' active role in using the 4HealthNavigator to access the 4HealthPlatform. Citizen and professional user engagement aims to understand and align user needs for a mutually valuable solution and to ensure positive user experience and system usability. Citizens from different national, cultural and institutional health-related contexts are 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 follows 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 to a positive impact on EU citizens' health and wellbeing, for building today a healthier tomorrow.



1.2 Deliverable Purpose and scope

The objective of D1.5 *2nd Specification of user requirements and performance criteria* is to deliver a second set of user requirements as well as to define performance criteria, to be addressed and implemented in WP2 and WP3, thus, substantially shaping the development of the 4Health Platform and the 4HealthNavigator. This is a “living document”: it is the continuation of work reported in D1.3 *1st Specification of user requirements and performance criteria* (M12) and it will be updated in form of D1.6 *3rd Specification of user requirements and performance criteria* (M34) 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 2nd specification on user requirements and performance criteria was produced by UNIVIE with input provided by the HCP partners. The report is based on a consortium-wide co-creation workshop to define and structure the second wave of identifying user requirements, remote User Engagement Exercises with participants recruited by UNINOVA and ZS-UG, one-on-one face-to-face engagements with citizens recruited in Vienna and one-on-one remote engagements with the HCP partners; the consortium-wide engagement with the Performance Accountability Table (PAcCT; conceptualized by UNIVIE, developed further in close collaboration with EASPD and EFN through the integration of policy requirements into the process and the PAcCT itself, and with HPI by implementing the PAcCT into Jira) and input by the HCP partners on the process of sharing data (in the form of the description of their current practices of sharing data between citizens and HCPs).

1.5 Document Structure

After an introduction, which clarifies the aim of this report (chapter 2), the report summarizes the general approach of defining user requirements, including the description of the partner workshop to define the structure of the second wave of co-creation, and the methodological adaptations that were necessary to mitigate the effects of COVID-19 (chapter 3). In chapter 4, the report describes the Performance Accountability Table, which traces the entire process from eliciting user requirements to the decisions taken with regard to their implementation. Chapter 5 gives a detailed account of the elicitation of the second set of citizen user requirements by citizens, based on the processes and the outcomes of a first set of citizen and professional user requirements.

1.6 Document status

After having received and integrated the feedback from our reviewers, this is the final version of D1.5. Upcoming results regarding the elicitation of user requirements and the development of performance criteria will be reported in D1.6 (M34) and D1.7 (M40).



1.7 Ethics

This deliverable relates to questions on ethics in the following three ways. First, in chapter 3 we spell out how we use situation- and context specific informed consent forms in the iterative process of eliciting user requirements and performance criteria. Second, in chapter 3.3 we outline how informed consent procedures were applied in the different types of user engagements that could take place. Third, both the consenting process as well as the content of the informed consent for the citizen health data platform as well as the research platform have been a topic in user engagements and are thus addressed in the report in chapter 5.

1.8 Dependencies and supporting documents

This document draws on D1.1 *Social Sciences and Humanities Framework* which outlines the main considerations for developing the health data platform prototype by emphasizing responsible research and innovation and diversity. D1.2 *Report on the methodological design of the co-creation environment* is referred to as it spells out the overall co-creation approach. It builds on the first specification of user requirements outlined in D1.3 *1st Specification of user requirements and performance criteria* (M12). Furthermore, it connects to D1.4 *1st Citizen/User Consent Language Report* (M12), to D8.1 *H - Requirement No. 1* (M24) when it comes to discussing with citizens the informed consent and the functionalities, the Use Design Cases (UDCs), of the platform, and to D8.2 *POPD - Requirement No. 2* (M24), where the procedures for the protection of data in the empirical work is described. Finally, our latest results feed into the technological development processes and thus into deliverables D2.2 *4HealthPlatform Citizen Health Data Platform Implementation* (M24) and D3.3 *4HealthNavigator portal dynamic consent, access rights management: report on functionalities, features, and implementation* (M24).

1.9 Main results

The main results of this deliverable are:

- a methodology for user engagement exercises that has been adapted to remote settings in order to proceed despite COVID-19 restrictions,
- the establishment of a process to achieve performance accountability,
- a second specification of user requirements, elicited with (potential) citizen and professional users,
- a full specification of performance criteria based on the first specification of user requirements,
- already further performance criteria based on the second specification of user requirements.

1.10 Future Work

Directly related to this report are the upcoming deliverables D1.6 (M34) and D1.7 (M40), respectively for the third and the final specification/report of user requirements and performance criteria. Given that the UDCs, as functionalities of the platform, are also elaborated through the iterative co-creation process of T1.3 *Citizen/user co-creation: user requirements, performance criteria, implementation* and will be shaped by the elicited user requirements, D1.5 is linked with D1.8 *Description of the Use Design Cases from the citizen/user perspective* (M42) and D1.10 *Validation Report* (M50).



1.11 Remarks and considerations

This deliverable is a “living document” to follow the realisation of user requirements and performance criteria along the processes of development, design and implementation, as well as the validation and assessment thereof. Thus, it will be updated throughout the project with further achievements reported in the follow-up deliverables.

1.12 COVID-19 impact and mitigation measures

The COVID-19 pandemic which took its start in early March 2020, had a number of effects on the User Engagement Exercises (USEEs) that were planned for Year 2 of the project. UNIVIE should have been able to recruit participants for the co-creation activities from CUC participants and platform users in different national environments.

The COVID-19 situation in Germany, Portugal and Luxembourg meant that the CUCs could not start as planned in March 2020. As a consequence, even though the platform prototype went live at the end of March, there were no platform users from the CUCs since then. This, in turn, had effects on the recruitment strategies UNIVIE could follow for the co-creation activities.

Furthermore, the COVID-19 restrictions put constraints on the general methodological approach to co-creation, which demand face-to-face qualitative engagement, and on the formation of groups of patients or nurses in the care context (e.g. CUC6). Additional details about the COVID-19 impact and its mitigations measures are available in chapter 3.



2 Introduction

This report focuses on both the process of specifying a second set of user requirements and identifying the related performance criteria. Two further reports will follow in M32 and M40. We will proceed in five steps. In the next chapter (Chapter 3) we will start with describing our general approach of defining user requirements. This is then followed by a description of the co-creation workshop we did with all partners of the consortium to define and structure the second wave of identifying user requirements. Finally, we will outline in detail the methodological and procedural adaptations we had to undertake due to COVID-19.

Chapter 4 is then devoted to the Performance Accountability Tables (PACcT) which is meant to document the process from eliciting user requirements to the decisions taken to either implement a user requirement, to post-pone it or to not realise it. For the purpose of tracing user requirements and their (non)realisation we have put in place four spaces each devoted to a specific way of addressing user requirements: requirement, integration, validation and documentation space. We also describe in this chapter how we use the PACcT in practice.

The following two chapters, chapter 5 and 6, are then devoted to describing in detail the elicitation of the second set of user requirements by citizen and professional users (health care professionals). Chapter 5 is organised along what we call “situations” such as registration, informed consent, authentication and many more. Each time we present the card that started the discussion followed by a short formulation of the user requirements drawn from the discussion. Each set of user requirements is followed by insights from the user engagements in order to contextualise and further explain the reasons behind the specific user requirements. This allows the reader to better grasp the argumentative environment from which we extracted the user requirement. Ten such situations were explored with citizen users.

Chapter 6 then engages with the everyday practices of sharing data by professional users and we elicited user requirements through one-on-one engagements with HCP and hospital partners. The chapter starts with summarizing responses received by HCP partners to a set of questions about current practices of sharing data between citizens and HCPs in the respective health care environment of the partner. In a second step, the chapter provides a list of the professional user requirements. Finally, the chapter gives a brief summary of the main insights from the one-on-one engagements pointing to a number of problem areas that the HCP and hospital partners identified with regard to data collection and sharing. These will get our attention in the further course of the project.

In chapter 7 we then offer the Performance Criteria (PC) from the first and second wave of co-creation. We provide a list of PC that were established on the basis of the user requirements reported at the end of last year (D1.3) as well as an overview showing the status quo of PC developed for the user requirements reported at the end of year 2, i.e. in this report. They will be elaborated in more detail in the first part of year 3.

Chapter 8 then closes this report with a short summary of the different parts and an outlook to next year’s work on user requirements.



3 General approach and methods in times of COVID-19

3.1 General approach

Despite already having outlined it in detail in D1.3, we want to briefly describe our overall approach to co-creation. As Figure 1 shows, the co-creation approach of Smart4Health uses an integrative approach that covers five steps from defining the key-features of the health data platform to the integration and validation. 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.

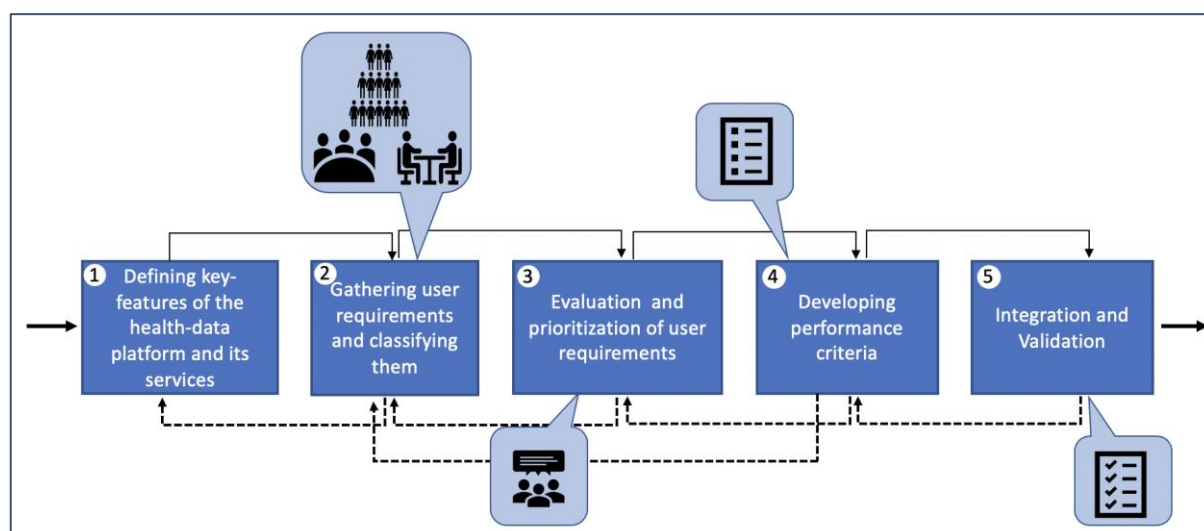


Figure 1 – Iterative process of eliciting user requirements and developing performance criteria.

Furthermore, the Smart4Health 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 should have. Finally, contemporary societies have already 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 (e.g. GDPR). While these are the starting points for the co-creation process, the detailed key-features of the platform are still open to be defined, developed and refined following the requirements expressed by citizens and professional users.

Based on these structural key-features, we started to **elicit, gather and classify user requirements (URs) and to further develop URs that had been reported in D1.3**. The elaboration of user requirements is an iterative process. We gradually engage with larger and more diversified user groups to deliver a solid input to the prototype development and implementation – and to ensure the long-term sustainability of this solution. As already outlined in D1.1 it will neither be sufficient to achieve interoperability on the technological level, but we also have to aim for socio-cultural interoperability, i.e. to consider the different health related cultures future users are

part of. The different methods that are being used during this elicitation and gathering of user requirements have been spelled out at length in D1.2 (e.g. group discussions, workshops, qualitative interviews, questionnaires, reflection workshops).

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 **‘the problem’ to which health data infrastructures are ‘the solution’**. 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 Citizen Use Cases (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 are **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 (PC) emerge out of a fine-grained analysis of ethnographic observations, justifications and argumentations of citizens as well as other context relevant information which we produced through our qualitative approach. The PC first serve as guiding principle for implementation of the UR (i.e. what has to be provided for the UR to be fulfilled) and second as a means to assess if a specific UR has been implemented and to which degree (e.g. if all PC have been fulfilled or only some, or if a PC has been entirely fulfilled or only partially). The definition of PC in step 4 might lead to the need of refining a UR and, thus, a loop back to step 2.
- (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 the Performance Accountability Table (PAcCT) available in Excel and Jira (see chapters 4 and 7)** in order to trace the decisions, and achievements along the project.

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 **informed consent** (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 are stored on a password protected server at the University of Vienna and that only the group producing the data will have access. These restrictions are there to assure participants that what they share with us will be treated with the highest standards of confidentiality. This is essential as participants might see our interaction as potentially intervening in their interaction with the HCP or with their employer (in case of work-related CUCs).

3.2 Co-Creation workshops to establish the time plan for Y2

As outlined in D1.2, an

“ecosystem of potential (citizen and professional) users demands a **careful mapping of potential users** in each Citizen Use Case (CUC) and **reflecting how they might relate differently** to the Smart4Health prototype. It also needs to consider the **social contexts** (e.g. at work, in private environments, ...) in which the data platform will be encountered/used. Furthermore, features such as **potential inter-/disruptions**, the **preconditions of use** (e.g. digital literacy) and **time investments** have to be featured in this map of the user ecosystem.”

In line with this, UNIVIE facilitated at the 3rd General Assembly in Potsdam (January 2020) three parallel co-creation workshops to plan in detail the Wave 2 (Feb-Aug 2020) of user engagements in 6 of the CUCs (CUC3-8)¹. The members of the consortium were divided into **three groups**, developing together the timeline and the formats of engagement for the second year of co-creation. The groups were formed according to CUCs. Group 1 combined CUC2 and CUC8, group 2 combined CUC6 and CUC7 and group 3 combined CUC3 and CUC4. UNIVIE as WP1 lead acted as moderators in all three groups.

We started the workshop with a collaborative identification of the **user ecosystem**. For each CUC, we discussed the different **user groups** relevant in the specific CUC as well as **wider user groups to be considered**. User groups were described in some detail, specifying their role in Smart4Health and we identified elements that needed closer consideration (e.g. language, data literacy, social situation, ...). Furthermore, we agreed on procedures of **recruitment** in order to understand where and when we could meet these groups.

The outcome was a detailed description of potential participants, their characteristics, knowledge, experiences etc. and an outline of the recruitment procedures (including actors involved in recruitment), incentives, access, space, vulnerabilities and ethical issues.

¹ As CUC1 and CUC2 will not have enrolled any “citizen users”, they were not taken into account in the workshop setting.



For this process UNIVIE provided participants with user cards (see Figure 2) to map the user ecosystem and describe the user groups in detail, their relevance for the CUC and potential issues with regard to recruitment procedures.

User Group: _____		<input type="radio"/> Citizen at work <input type="radio"/> Citizen as patient <input type="radio"/> Citizen in leisure <input type="radio"/> Professional user
Description of the user group		Relevance for the CUC 0-----5-----10
<u>Age group</u> <input type="radio"/> 18-30 <input type="radio"/> 31-45 <input type="radio"/> 46-60 <input type="radio"/> >61	<u>Language</u>	Relevance for Smart4Health 0-----5-----10
<u>Gender</u> <input type="radio"/> F <input type="radio"/> M <input type="radio"/> other	<u>Place of interaction</u>	Estimated digital literacy 0-----5-----10
Recruitment: Approach, where to meet them, hurdles, ethical issues (e.g. vulnerability)		
Comments: Limitations, experiences, knowledge they have, space and mobility,		

Figure 2 - User card for mapping the user ecosystem.

Then we turned to the stabilization of a timeline for the user engagements in the individual CUCs. The timeline for co-creation in wave 2 outlined when user groups can be encountered and clarified their availability in terms of time. Our aim was to have a clear **timeline** in terms of **user recruitment** (how accessible are they in principle, when will we be able to access them?), to agree on a prioritization and to identify potential challenges.

The workshop participants were asked to arrange the user cards on a paper-based timeline (provided by UNIVIE, see Figure 3) and, if applicable, to prioritize the user groups by ordering the user cards on the timeline, in order to define, which groups will be accessed in the beginning and which ones at a later point.



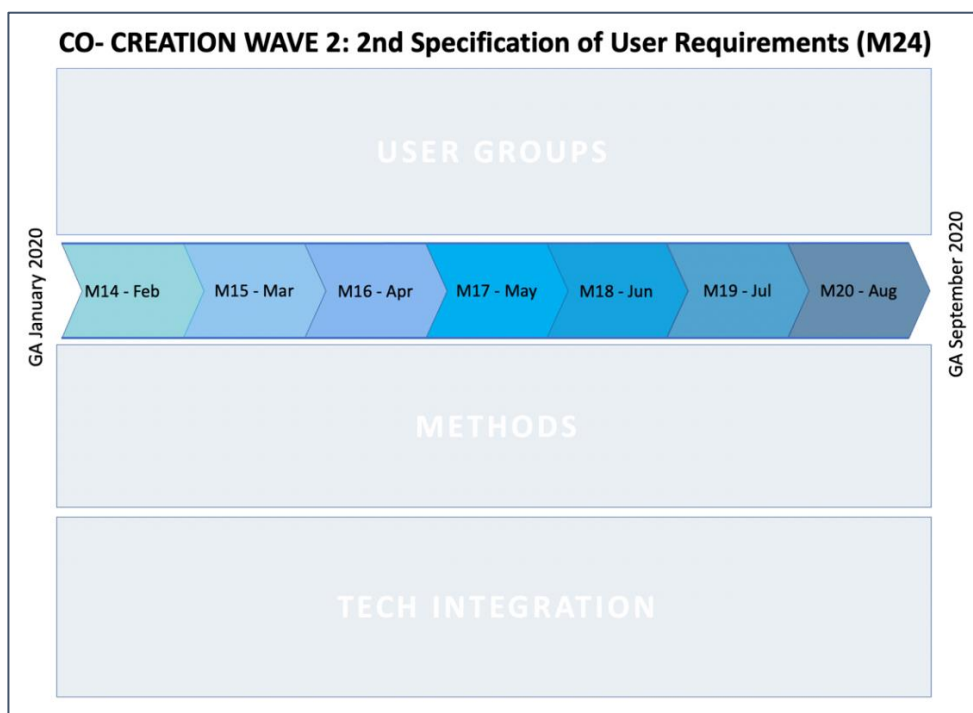


Figure 3 - Timeline for planning the user ecosystem in the co-creation workshop.

After a short break we turned to defining the methods to be used for each CUC and identifying technical developments which would be important to consider when making a timeline. The latter would indicate which technical developments will be ready for exploration and testing in wave 2. We walked through each CUC in order to understand which methods are best used in the specific CUC and for which groups of users, what would be the best order in which we address different user groups and what elements of the Smart4Health platform can be tested specifically (platform prototype, mock-ups, ...). Our aim was to arrive at an integrated timeline that aligns users, methods and technical developments to be used and tested in the empirical settings.

UNIVIE provided the workshop participants with a method handout as well as with a set of method cards (see Figure 4) that represented and sketched these different methods.



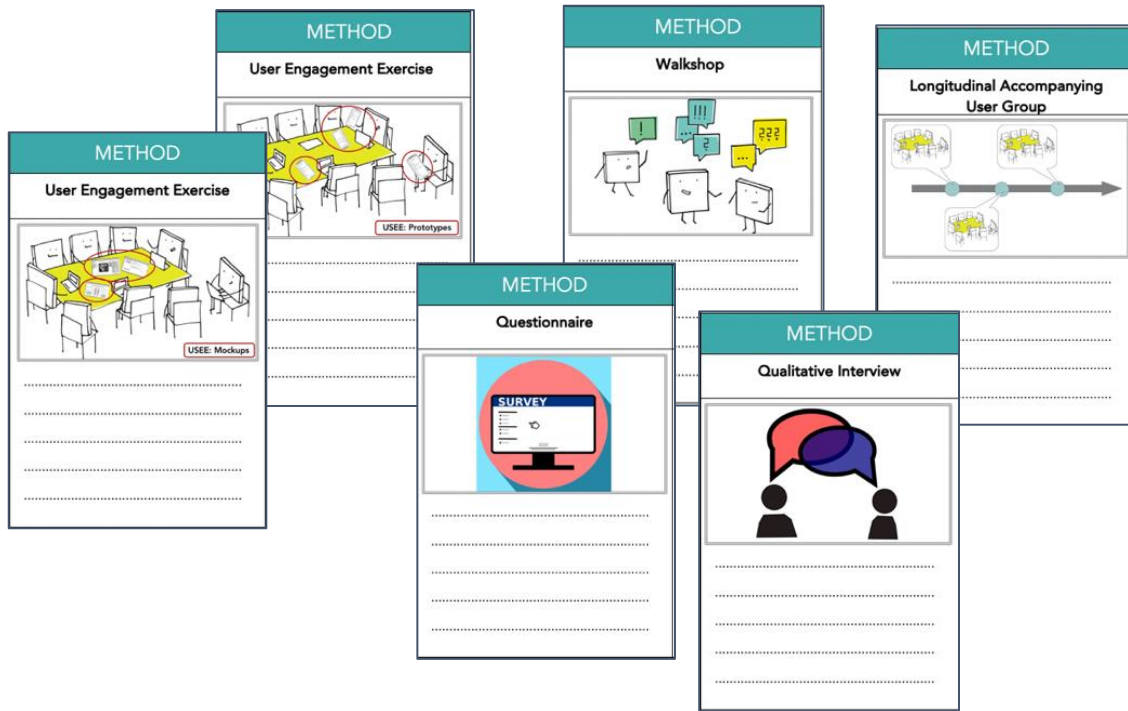


Figure 4 - Set of method cards for defining the methods used in Wave 2 of co-creation.

Furthermore, D4L provided cards representing platform functionalities that were planned to be available in year 2 of the project (see Figure 5). We then arranged the method cards and the functionality cards on the timeline.

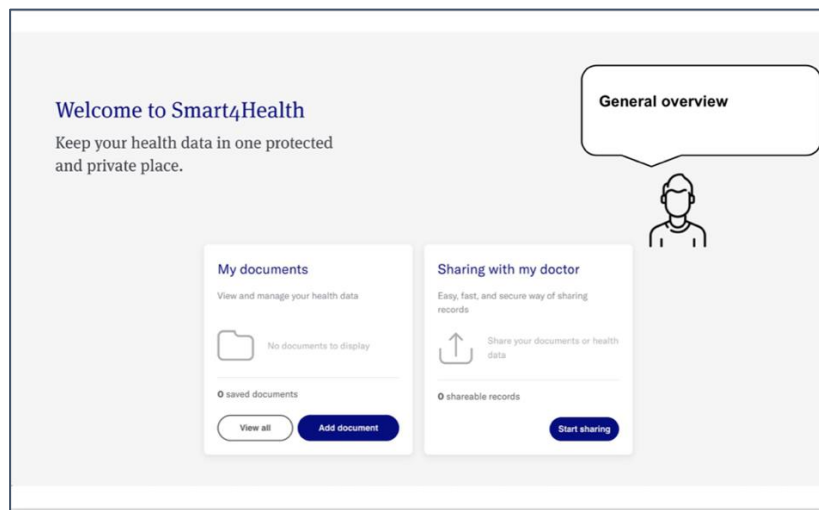


Figure 5 - Example of mock-up provided by D4L.

We ended the workshop with a brief wrap-up and validation session in which we walked through each CUC timeline and everything that has been arranged on them (see an example of one such timeline in Figure 6), and saw how it fit with the engagement method and tech elements to be tested and summarized the common understanding of the process in wave 2, the commitment of the CUC partners and what UNIVIE would do in terms of co-creation work.



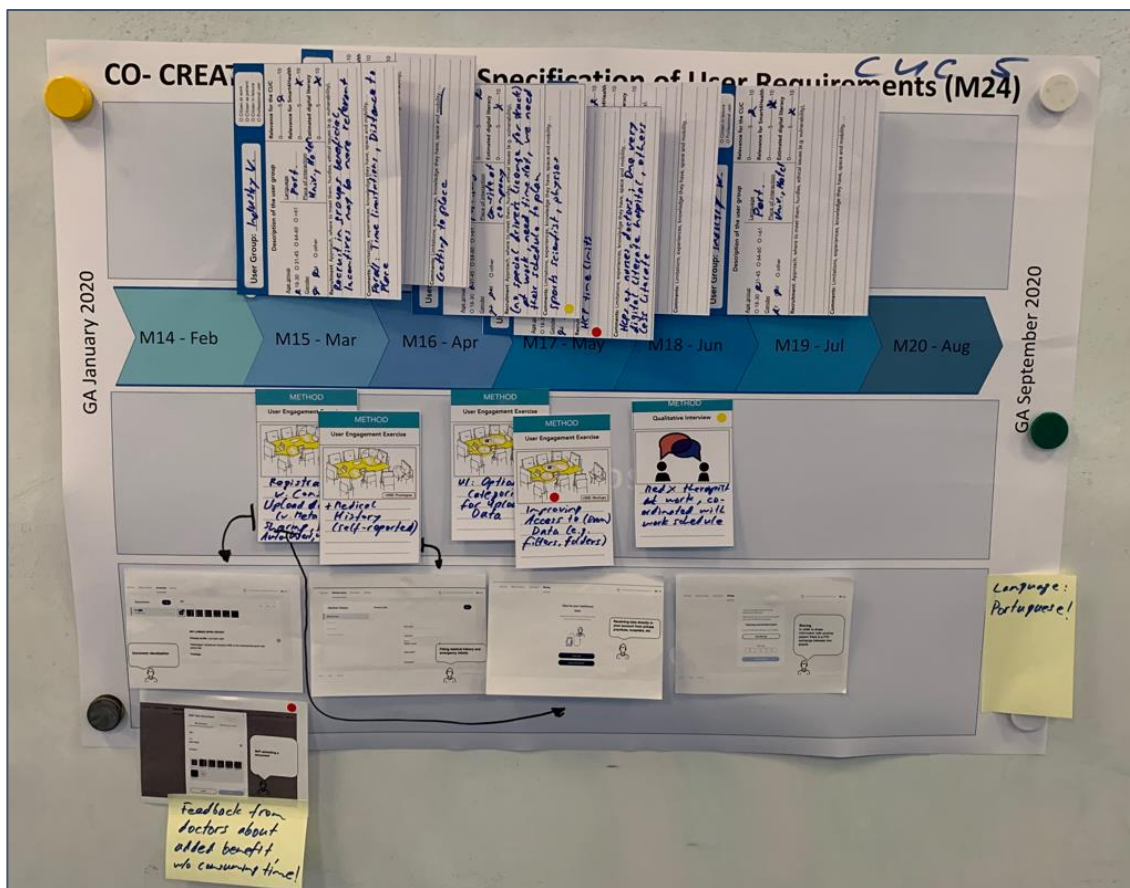


Figure 6 - Example of one finalized timeline from one Co-creation Workshop.

The definition of user ecosystems, timelines, engagement methods and integration of technical developments all came together in Figure 7.

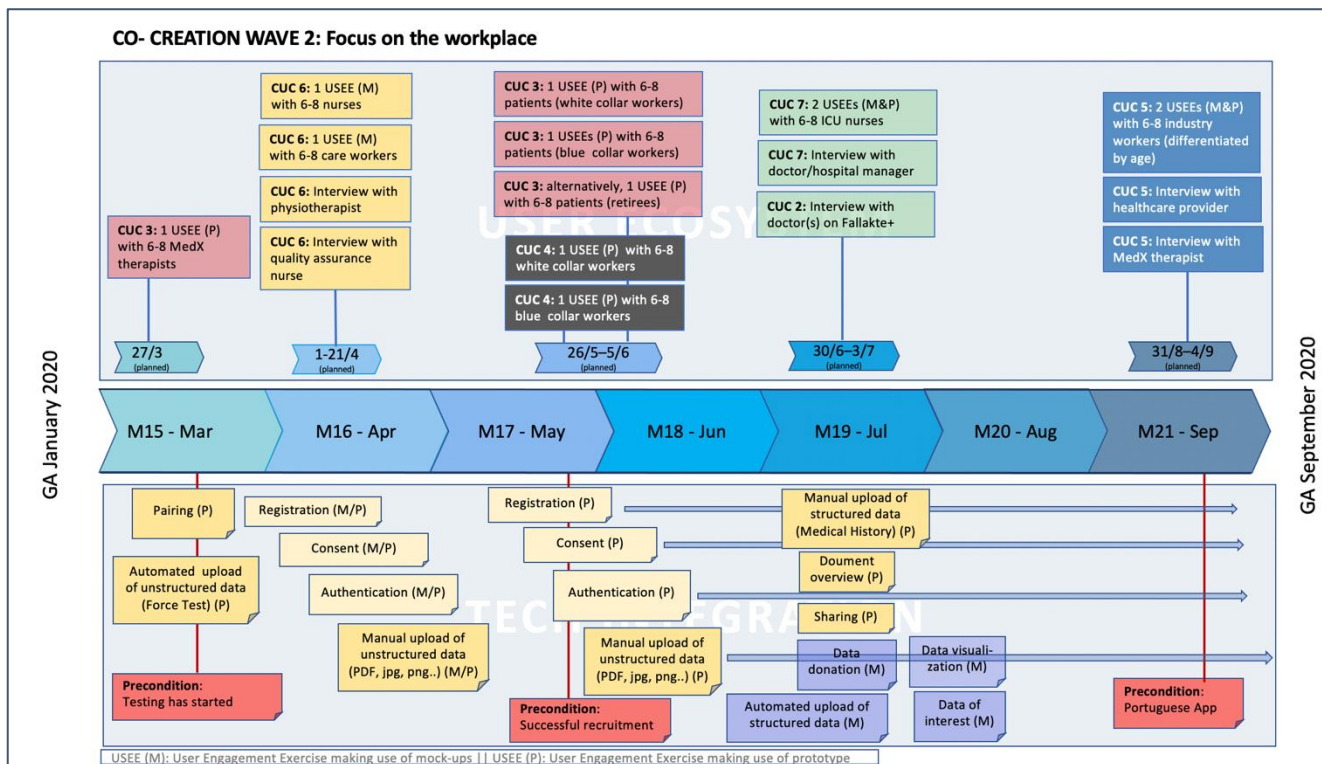


Figure 7 - Stabilized timeline for the second Wave of co-creation.

3.3 Methodological approach, adapted for COVID-19 situation

The COVID-19 pandemic which took its start in early March 2020, had a number of effects on the User Engagement Exercises (USEEs) that were planned for Year 2 of the project. UNIVIE should have been able to recruit participants for the co-creation activities from CUC participants and platform users in different national environments as described in section 3.2. CUC participants are crucial since in this early phase the use of the platform is linked to participation in one of the CUCs. The COVID-19 situation in Germany, Portugal and Luxembourg meant that the CUCs could not start as planned in March 2020. As a consequence, even though the platform prototype went live at the end of March, there were no platform users from the CUCs since then. This, in turn, had effects on the recruitment strategies UNIVIE could follow for the co-creation activities.

Furthermore, the COVID-19 restrictions put constraints on the general methodological approach to co-creation, which demand face-to-face qualitative engagement, and on the formation of groups of patients or nurses in the care context (e.g. CUC6). As in other parts of Europe, there was a lockdown in effect in Austria from March to May 2020, so the project team was not able to travel and conduct face-to-face meetings. Given the delay of the CUCs due to COVID-19 and the severe travel restrictions, we had to find mitigation measures to deal with the risks for the co-creation work in WP1 – an essential input for the tech development in the project.

We had the choice of postponing, restructuring or cancelling some activities we had outlined in our detailed planning of the second wave made in January 2020 (see section 3.2). **Postponing** the activity would mean to shift it to the months that had been foreseen for analysis and not deliver input for the tech partners. The second possibility was to **cancel** specific USEEs and shift their completion to the next wave (engagement in CUC6 for instance had to be cancelled for this wave, as the prospective participants could neither come together in person nor be recruited for individual remote interviews due to the ethics votum not having come through). Finally, **restructuring** the settings would mean that we would, for instance, work with individuals, instead of groups, or to go remote where at all possible, or to outsource single tasks of empirical engagement to the CUC partners, supporting them remotely. In general, we felt the need to be creative and pragmatic in the approach but not to sacrifice methodological rigor and the care to be as inclusive as possible when delivering together with users input for the development and design process.

We opted for a **redesigning of the user engagements for use in a digital environment** where possible (CUC3/4 and CUC5), thus developing what we call **remote User Engagement Exercises (rUSEEs)**. The main issue for us was how to meet the challenge of getting as close as possible to people's expectations, values and concerns, while staying physically distanced, in order to produce and provide qualitative insights that are valuable for our partners in the development of a sustainable European health data infrastructure.

Conducting qualitative social science research remotely poses a challenge, however, as the virtual space shows some limitations. Interview settings and, in particular, group settings strongly rely on the interpersonal relation that can be established between research participants and researchers and on the rapport that can be built. This building of trust relations opens up reflections essential to better understand users' expectations. At the same time, we are addressing health data platforms which demand



a certain kind of digital literacy. Moving this engagement to the digital space thus could potentially create a double exclusion. While we are confident that the results provide valuable insights, it needs to be noted that qualitative research functions best when done in a face-to-face manner, when the social scientists are in the field with the participants and not on the computer in a teleconference.

Also, one of the strengths of the card-based method we had planned to use in the user engagement exercises of the second wave is exactly the tangible aspect of participants “having something in their hand”, of being able to investigate a complex topic by engaging with material objects, the cards and their content. As we know from numerous engagement exercises that use cards to support the expression of values and concerns, the ability to work with cards and to see others also do so as well as the fact of being able to physically touch and sort the cards, supports participants in articulating values and concerns and helps the deliberation we want to achieve.

In what follows we will outline how we transformed our methods to adapt them to the virtual setting while staying true to the methodology and our epistemological interests of producing a meaningful and sustainable citizen-centred health data platform.

3.3.1 Transforming User Engagement Exercises (USEEs) to remote User Engagement Exercises (rUSEEs)

As outlined in D1.2,

“the centrepiece of the co-creation environment are discussion groups (Felt et al. 2014; Felt et al. 2018) of different formats – open, card-based and application-centred – that enable the collective exploration of the prototype development in open as well as more structured phases. Working with small groups of users and fostering a combination of individual and more collective reflections on their visions, preferences and concerns will be key.”

Given the situation with COVID-19, we moved from face-to-face meetings to a remote setting and conducted the engagement exercises using the GoTo Meeting software. Instead of conducting one card-based group discussion with 6-8 participants, we reduced the number of participants per rUSEE and asked our partners to recruit 3-4 participants per rUSEE, which they thankfully did. This group size was deemed large enough so that discussion among participants would happen, and at the same time small enough that overactive participants could be gently slowed down, and that more quiet or introverted participants could be encouraged. We also adapted the time structure and distributed each rUSEE over 1 week. We met with the participants remotely 2 times for 2 hours instead of 4 hours in one go. Concretely this meant that we would have 3-4 individual sessions with the participants on separate days, and then one meeting bringing together these 3-4 participants. This allowed us to have both individual exchanges and collective debates which often added important specific details and we could observe the collective assessments of certain problems and solutions.

<p>Participants: 3-4 participants per rUSEE</p> <p>Type: citizen or professional users related to the CUCs (diversity as selection criterion)</p> <p>Interaction: group and individual interaction in different phases of the engagement</p> <p>Duration: the envisioned time of 4 hours was reduced to 2 times 2 hours (2 hours per individual remote interview and 2 hours per remote group setting)</p>
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Aim: collect different points of view and encourage reflection and debate; explore concerns, expectations or opinions around particular moments in the process of using the Smart4Health prototype get an understanding if these are met by Smart4Health with the focus on specific situation (according to the tech integration space in the timeline)

Support: cards that channel engagement into a specific group of aspects, issues or processes or open focus groups type of interaction generating people's questions, frames, priorities and concepts (Kitzinger 2005); use cards to collect ideas and to describe processes of using (parts of) the prototype

Documentation and analysis: audio recording (after IC), transcription and qualitative data analysis (QDA), following a bottom-up approach that comprises iterations of open and focused coding (see Charmaz 2014) and network building, using the QDA software ATLAS.ti

Between April 21 and May 8, 2020, we conducted **two rUSEEs** with participants associated with CUC3 (in German) and CUC5 (in English), working with three participants each. We started by conducting individual remote interviews with the participants. In these interviews we opened with a card-based discussion of digital health and health data and positions taken therein. Then we turned to three specific situations – registration, consenting and authentication – which we discussed with the participants using “situation cards” as input. In the next part of the interview, we asked participants to access the Smart4Health platform (app.smart4health.eu), share their screen with us and go through the registration flow while “thinking aloud”, a method borrowed from usability engineering. The authentication process was explored thereafter via mock-ups. We ended the interviews with a short reflection and outlook to our next meeting.

In the second meeting we brought the participants together in a remote group setting. Drawing on our reflection of the individual interviews, we had developed so-called “**experience cards**”. These cards contained issues and questions from the individual interviews, in order to build a bridge between individual and collective deliberation. These were rather concrete issues such as issues around the recovery key, but also fairly broad issues such as the platform identity or questions of responsibility. In the second step of the group discussion we again drew on “situation cards” we provided and explored together three situations – collecting health data, uploading self-generated data as well as data in the workplace. We ended the group meeting with a broader reflection of the process.

A **third rUSEE** was conducted between July 21 and July 27, with participants associated with CUC5 (in Portuguese). The individual sessions also opened with a card-based discussion on positions taken towards digital health and health data. Then, however, we did not engage in prototype testing but invited them to think through projected situations of use as presented on situation cards that we shared with the participants on the screen. We discussed collecting health and self-generated health-related data, collecting data in the workplace, sharing data with a doctor and with other trusted actors.

In the group setting we first again drew on a reflection of the individual interviews and open issues and questions that we had outlined on “experience cards”, which were



specific to the group. These comprised issues such as responsibility, citizen empowerment and exploitation. We then moved towards data provision for research and discussed the situation of considering data provision for research, being re-contacted after data provision and ended with an exploration of the question of which data should be provided for research.

In all three rUSEEs we worked with a group of three participants each. This means, in total we conducted 9 individual interviews, one group interview (as one participant had to excuse himself immediately before the group discussion, leaving us only with two participants, hence the group interview situation) and two group discussions. With each of these 12 sessions lasting approximately 2 hours, this amounts to 24 hours of in-depth discussions with the participants. The individual interviews and group settings were, after participants had given their IC, digitally recorded, subsequently transcribed and analysed. While we are confident that the results provide very valuable insights, there are some limitations. Remote user engagements that draw on online interactions via a teleconferencing software, on practices of screen sharing require participants not only to have access to infrastructure that facilitates this (a quiet room, a relatively fast computer, broadband internet access etc.) but also to be digitally literate enough to participate in the first place, excluding those whose concerns, values and expectations are just as important. Furthermore, we experienced divergences in the access to participants in our engagement exercises. For instance, we were not able to recruit nurses and caregivers from CUC6 due to them not being able meet for more than 1 hour, thus excluding highly relevant perspectives on data collection in the workplace. The rUSEEs, thus, serve as a workaround with all the limitations that this brings along, which need to be kept in mind and balanced out, as soon as broad recruitment for face-to-face engagements will again be possible.

3.3.2 One-on-one engagements with citizens

As an additional mitigation measure, in September and October 2020, UNIVIE recruited eight citizens to participate in COVID-19-safe **one-on-one engagements**. These engagements were conducted **face-to-face** to explore and test specific functionalities of the health data platform and form the backbone of this preliminary input to WP2 and WP3. The participants were recruited from members of the University of Vienna via snowballing. Involving members of the University of Vienna meant that we could work with them directly in their well-known environment ensuring all COVID-19-related security measures. In that sense, no individuals from outside had to be invited to the university facilities in a time of having to reduce face-to-face contacts.

Participants: 8 participants in individual settings

Type: citizens not related to the CUCs (diversity as selection criterion) in order to be able to conduct face-to-face engagements during the COVID-19 pandemic

Interaction: individual interaction

Duration: 30-90mins each (with the majority of sessions exceeding 60mins)

Aim: explore and discuss specific functionalities of the platform that already had been implemented; refine existing user requirements and establish new ones

Support: Android-based tablet



Documentation and analysis: audio recording (after IC), transcription and qualitative data analysis (QDA), following a bottom-up approach that comprises iterations of open and focused coding (see Charmaz 2014) and network building, using the QDA software ATLAS.ti

In each one-on-one engagement, strict precautionary measures were taken for the protection of participants and researchers alike: by disinfecting tablet, table, chair and pen (i.e. every item that the participants and researchers would touch) before and after the session, providing and using hand disinfectant, wearing masks at all times, keeping a safe distance and regularly airing the room or leaving the windows wide open altogether. While at the point in time of finalizing this deliverable eight such engagements have been conducted and analysed, seven one-on-one engagements had still been planned. However, the new lockdown measures that entered in effect in Austria on November 2, 2020 and were intensified on November 17, 2020 stopped this endeavour, forcing us to postpone the additional face-to-face engagements to Q1 of 2021 at the earliest.

In the eight one-on-one engagement sessions we conducted, we provided the participants with an Android-based tablet and asked them to access the Smart4Health web app. They were asked to log-in with the credentials of a test user that we had created for them. In the **first four sessions (1-4)**, the participants initially were given a moment to investigate the platform a little, to find their way through it and familiarize themselves with the documents and files we had collected for them, while talking out loud. Then we asked them first to walk through the **sharing process with a trusted person** (whom we impersonated) and second, through the flow of **providing data for research**. In the **second set of four sessions (5-8)**, we again started out with an exploration of the platform but then we asked them to first walk through the manual **uploading process**, asking them to upload health data (x-rays, lab results) that we had stored on the tablet, before turning to the sharing process with a trusted person, in the same manner as in the first four sessions.

While the participants were thinking aloud during their testing of the functionalities and flows of the platform, this engagement triggered in-depth discussions of choice, control, responsibility, distribution of agency that the platform enables, relations with the HCP that might get changed etc. The sessions lasted between 30 and 90 minutes (with all but one significantly exceeding 60 minutes) and they were (after giving IC) digitally recorded, subsequently transcribed and analysed.

3.3.3 Engagements with HCP/hospital partners

In the process of developing the Use Design Case narratives (T1.4), the WP1 discussion of the UDC narrative of MyTrusted (with the focus on processes of sharing data in healthcare settings) brought forward a great number of questions addressing the HCP/hospital partners. UNIVIE distributed a template containing these questions and more, asking the HCP and hospital partners to describe the everyday practices in their institution (or those that they represent), healthcare environment, or healthcare context with regard to data sharing between citizens and HCPs/healthcare institutions. The task was to describe a chronological rundown (or, if needed, several), starting at the first communication with the citizen, which may precede any meeting or visiting the healthcare environment, and ending the rundown wherever they see fit, briefly explaining why.



In addition to this, a number of HCP and hospital partners met with UNIVIE per TelCo in one-on-one remote workshop settings to discuss the sharing process from the HCP perspective, as the one-on-one engagements with citizens in September and October brought up additional questions on the sharing process from the side of HCP. In the meetings, thus, we went through the sharing process in detail and specifically focused on the HCP side of the flow, exploring the sharing of unstructured data and the sharing of the medical history as citizen-reported structured data. This input, combined with the HCP input on the data sharing processes and input on classification needs from the side of HCPs (particularly nurses), served the continuation of the development of Professional User Requirements (PURs).



4 Performance Accountability: From the elicitation of requirements to the documentation of decisions

4.1 The process of working with the Performance Accountability Table

In what follows, we describe the process of eliciting, implementing, assessing/validating and documenting User Requirements (URs) and Performance Criteria (PC) facilitated by the so-called Performance Accountability Table (PACt). The PACt has been conceptualized, developed and established in Smart4Health and ties together the work done under WP1 for user participation, WP2 and WP3 for the technical implementation, and WP4 for CUCs. For accountability and transparency to be ensured in the development of our platform prototype, this process (see Figure 8) accompanies the iterative development down to the documentation of decisions taken with regard to the implementation or non-implementation of URs/PC.

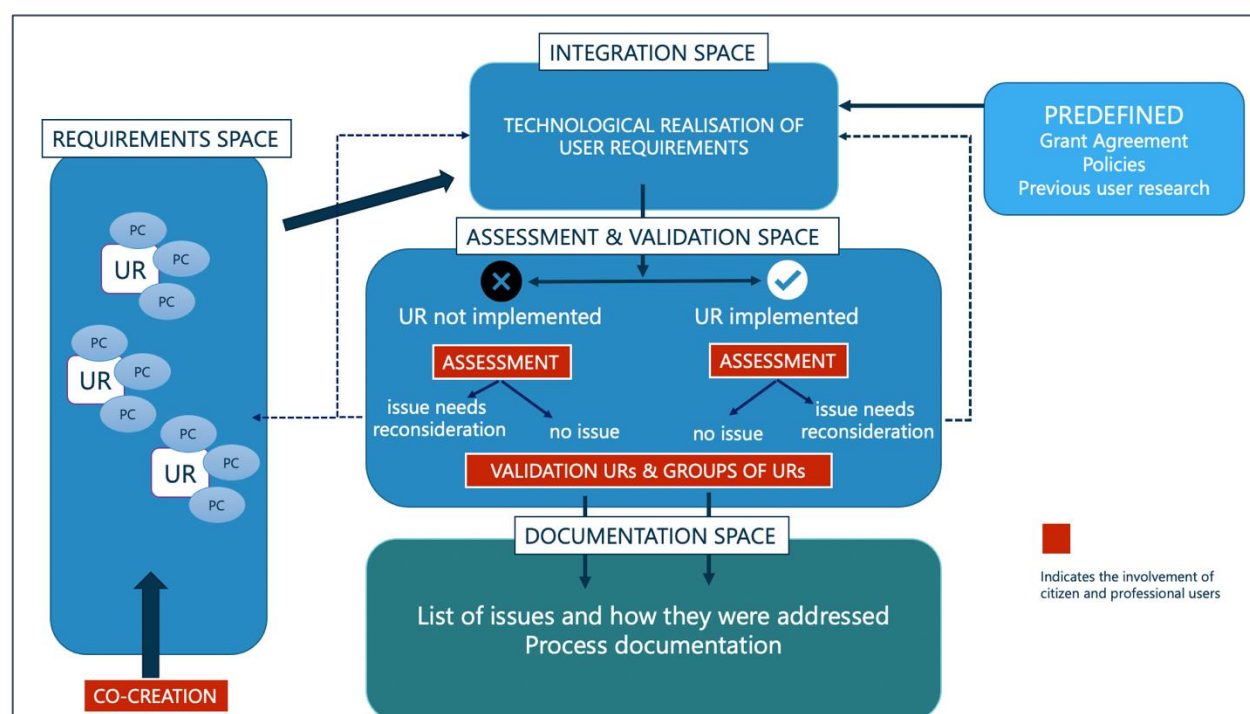


Figure 8 - The PACt process ensuring accountability and transparency.

The PACt is a living document, thus its content changes, it is updated and refined. It is maintained in form of a table and an online work environment in Jira, both of which are explained below. For both, however, the **collaborative work across work packages (WPs)** evolves along the **following steps**:

- Elicitation of URs through user engagements, based on which PC are developed (WP1).
- Evaluation of UR/PC feasibility and their prioritization (WP1 and WP2/WP3)
 - Responding to open questions that specific URs/PC raised.
 - Entering into a process of “scoping” with justifications of feasibility and prioritization.
- Implementation of URs into the prototype with PC as guiding principles (WP2/3).
- Assessment and Validation of URs by drawing on PC (WP1/WP4).

These steps are carried out in what we call the **four spaces of the PAcCT**, for requirements, integration, validation, and documentation. In the following exemplary overview of the PAcCT as spreadsheet table, each space is outlined by a coloured heading (see Figure 9).

Performance accountability table		Requirement Space				Integration Space				Validation Space		Documentation Space				
Situation	Process	User UR # requirement	Performance PC # criteria	Policy relations	Effects	Questions this opens	Response to the questions	Status of Implementation	Reformulation as Technical Requirement	Ranking (low to high / best to worst)	Questions this opens	Response to the questions	Validation Area	Assessment Area	Closure No.	Issue No.
1. Registering for the HealthPlatform	Registering	LEAD: WP1	LEAD: WP1	Policy relations	Effects	LEAD: WP1	LEAD: WP2/3	LEAD: WP2/3			LEAD: WP2/3	LEAD: WP1/4	LEAD: WP1/4	LEAD: WP1/4		

Figure 9 - The PAcCT in Excel.

4.1.1 Requirements space

The starting point of the (iterative) process of co-creation is the establishment of User Requirements (URs) and Performance Criteria (PC) through citizen co-creation workshops (CCWs), user engagement exercises (USEEs) and input by consortium partners (HCP and hospital partners). This is detailed in the so-called REQUIREMENTS SPACE. This requirements space is a series of dedicated columns in the PAcCT Excel file, which also exists a specified area online in Jira.

In what follows, we describe the process according to the logic of building the PAcCT Excel file (see Figure 9). The requirements space consists of altogether five columns. We start from the “situations”, e.g. registration, IC, authentication, and group related **URs in the first column of our excel table**. Once the URs are listed, we add a **second column to define the PC** related to each UR (see also chapter 7.1). With the support of EASPD and EFN, we then identified how some of these PC clearly **relate to policy documents** and discussions (e.g. to specific articles of the GDPR) and documented these relations in a **third column** next to the PC. In a last step, we identify **effects that these policy relations** may have **on the prioritization** of URs and PC, and thus on their further iterative elicitation and development process and list them in a **fourth column**. To classify the relevant policy environments, EASPD suggested the following three categories:

Tier 1 - Legal documents

- 1.1 EU Regulations: binding legislative act to be applied in its entirety across the EU. Example: GDPR
- 1.2 EU Directives: legislative act that sets out a goal that all EU countries must achieve but Member States decide (through national legislation) how to achieve these goals. Example: EAA

Tier 2 - Policy documents

- Not legislative act but policy documents which indicate the EU's priorities and goals Examples: Strategies (e.g. Data, Disability), Funding instruments (e.g. Horizon Europe), EU Recommendations or Opinions, etc.

Tier 3 - Standards

- Guidelines and recommendations to achieve or evaluate desired criteria, (e.g. WCAG 2.0)

Given that they more closely describe/define specific PC, they also are assigned to specific PC in Jira. This allows to have a filter with an immediate overview of all PC that



are more directly affected by policy, and also to select by Tier category, e.g. to view all PC with Tier 1.1 policy relations.

The fifth and last column, is dedicated to open questions that emerged within the requirements space, as well as questions that relate to the implementation and thus ask the technical partners to respond within the integration space.

4.1.2 Integration space

The URs and PC are then related to the technical developments, which means that the technical partners work on them and report this in the integration space. The task for the technical partners in the integration space is to develop a solution that responds to the URs/PC and provide information on the status of implementation of the URs/PC into the platform prototype. Here they also provide answers to questions that have emerged in the requirements space and pose new ones.

There is a second pathway for requirements to enter the solution developed in the integration space. The platform development does not start entirely from scratch but builds on an installed base. There are predefined frameworks in place that have that come from e.g. the Grant Agreement, user research performed by D4L beforehand, regulations, technical feasibilities etc.

Once a specific requirement has been realized, the UR/PC is pushed to the ASSESSMENT and VALIDATION SPACE for the solution that has been found to the problems the URs/PC articulate to be assessed and, if appropriate, to be validated.

4.1.3 Assessment and validation space

The first activity in this space is the assessment of the solution that has been provided as a response to the URs/PC by citizen and professional users in different engagement settings (e.g. in User Engagement Exercises with groups of citizen or professional users, qualitative interviews, etc. For a specification of the entire methods toolbox see D1.2 *Report on the methodological design of the co-creation environment*). If the solution is assessed as appropriate, it is being validated more broadly in a second step (see Figure 8) by both qualitative and quantitative means.

The outcome of the assessment may be that the solutions have to be adapted as the URs/PC have not been sufficiently implemented. Another possibility is that the implementation of specific URs/PC by themselves was assessed and validated positively, but in combination with other requirements the solution is not acceptable. These outcomes would mean that the solution moves back into the integration space for adaptation.

At the point of writing this report, the validation and assessment process is in its initial stages, as there are no CUC users yet with whom the platform prototype can systematically be assessed and validated over a longer period of time and the platform prototype development is ongoing. What we are in the process of doing, though, is the assessment of the implementation of specific URs/PC. While we are now assessing the implementation of single URs/PC (as indicated in chapter 5) the assessment and validation process will become more complex in the two waves to come as the potential interplay of URs may lead to unexpected effects.

- If the UR/PC **has been implemented**, then its implementation will be assessed. In Jira, this means that the UR/PC first moves into the assessment area of the



assessment and validation space and is then, if assessed positively, validated more broadly. If we come to the conclusion that there is **no more issue** with the implementation, i.e. that the UR has been fulfilled and that the PC have been sufficiently covered, the UR can be closed. This status needs to be documented, which happens in a closure list which is part of the DOCUMENTATION SPACE. However, if the process lets us conclude that there **has been an issue** with the implementation (e.g. that one or more PC have not been taken into account), the UR/PC is moved back to the integration space.

- If the technical partners inform us that a UR/PC **has not been/will not be implemented**, for which an explanation is being provided, an assessment of the decision will follow. In Jira, this means that the UR/PC will move into the assessment area of the validation space. There are three possible outcomes of the assessment of open issues. The result of the assessment can be that the UR/PC themselves were not clear enough and need to be refined. This calls for more work with citizen and/or professional users with the potential effects of a refinement of the UR/PC under discussion or the formulation of additional URs/PC. This means, the UR/PC move back into the REQUIREMENTS SPACE for further work and, thus, for another iteration. The result can also be, that actually there is no issue – we decide to stay with the decision to not implement a specific feature – and that no further work is needed. This decision is documented (giving a reason) within the DOCUMENTATION SPACE in the closure list. The result can also be that this is an important requirement seen from user side, and that therefore additional work on the UR/PC and its implementation should be undertaken. The UR is moved back into the INTEGRATION SPACE. All these decisions are documented within the DOCUMENTATION SPACE in the issue list.

4.1.4 Documentation space

The documentation space consists of a separate document, which traces the decisions that were taken in the process of implementing or non-implementing UR and PC. The documentation space can also be found in Jira, where the URs/PC will be moved to, once they have been **closed** (for whichever reason, see the two options sketched below).

- For one, we will keep a **closure (CL) list** that **documents the closure of URs/PC** after they have been implemented. Each closure in this list will have its own number (i.e. CL.1, CL.2, ...) that gets added to a dedicated column in the PAccT. The closure list contains a brief statement on the implementation of an UR and its PC. In addition to this, it can also comprise the following:
 - It may be the case, that a UR itself is considered closed, but one or more PC that are assigned to it are not, which is justified here as well.
 - If, in the assessment process (section 4.1.3), we come to the conclusion that what we initially may have identified as issue actually is a non-issue, this is explained and justified in this list. The closure list, thus, tracks when issues have been redefined as non-issue within the assessment process.
- We will also keep an **issue (IS) list** that documents the decisions that were taken if URs/PC are not implemented, and a justification for not doing so (e.g. out of scope and why, feasibility, etc.). The issue list also allows for disagreement and



offers a space for differences in positions that were taken in the process of deciding for or against the implementation. In the same manner as for the closure list, each UR/PC decision will have its own number (i.e. IS.1, IS.2, ...) that will be reported in a column in the PAcT. While these issues as suggested here mainly emerge out of the PAcT, and specifically the discussion of open questions regarding user requirements and performance criteria in Jira, issues can also surface from discussions in workshops, emails or other settings.

4.2 The PAcT in practice

The Performance Accountability Table (PAcT) is being worked on and with, in two distinct environments: (1) in an Excel sheet (see section 4.1), where UNIVIE as WP1 lead keeps track of all user requirements and performance criteria and which contains the different spaces, the policy relations, questions that come up in one setting (e.g. the requirements space) and are addressed in another (e.g. in the integration space); (2) in an online Jira board set up by HPI, which is organized following the four spaces of the PAcT (see Figure 10).

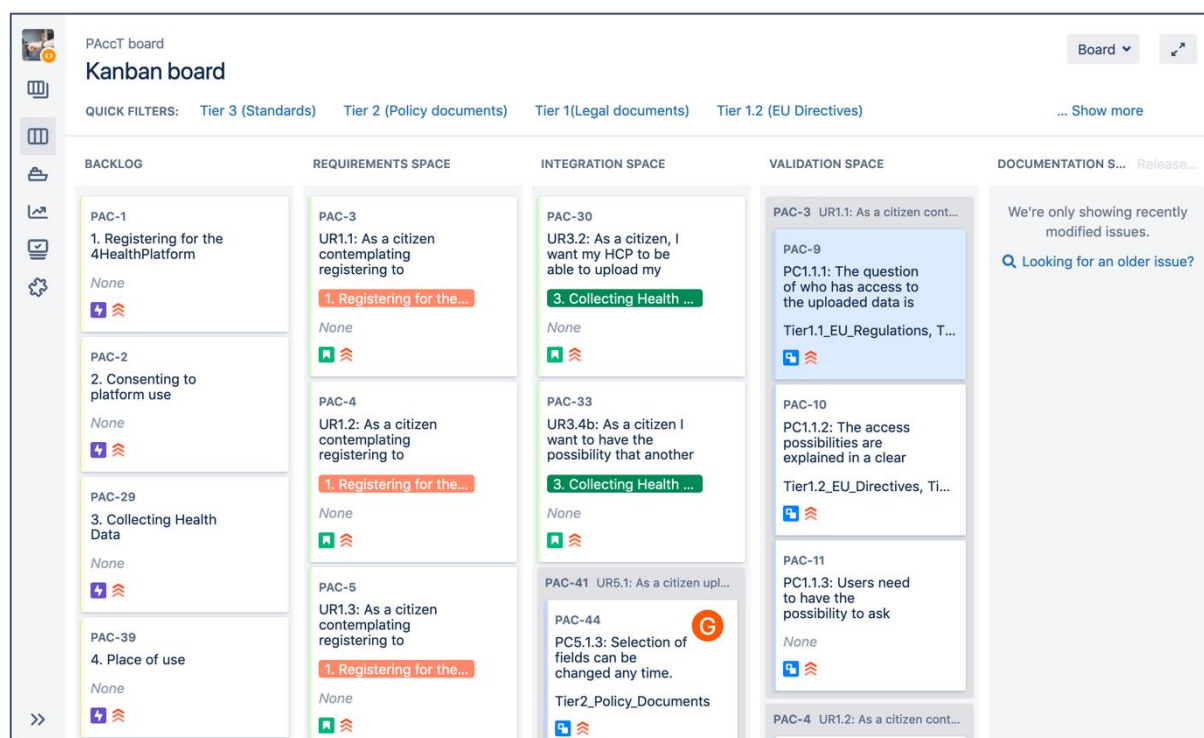


Figure 10 - The PAcT in Jira.

In the Jira board, all URs and PC as well as the policy relations are represented on “cards”, which can be assigned to project partners by name, can be moved between the spaces, and whose status, content and further procedure can be discussed in a designated comment area. In this way, PAcT not only allows for broad participation and ownership, but also for shared responsibility and transparency.



5 Second set of user requirements by situations

Working within iterations means at different points in time different practices of engagement with the platform prototype are possible.

What unifies the engagement is that in all settings we discussed and tested the processes delineated in the situations that are found in the upcoming sections. However, while we for instance drew on situation cards to discuss the sharing process with the participants in the first two rUSEEs and had them test the registration, consenting and authentication process in a hands-on way, in the one-on-one citizen engagement settings we explored the sharing situation and providing data for research by directly walking through the respective processes. The URs reported here were developed in a process that relied on projection and testing practices, drawing either projection (e.g. rUSEE CUC5_2) or prototype testing (e.g. one-on-one engagements with citizens) in the foreground or a fair combination thereof (rUSEE CUC5_1, rUSEE CUC5_2).

The resulting **wealth of new URs then also speaks to already existing URs and technical implementations**. These, however, can also have taken place without having had a user requirement formulated, as parts of the platform prototype are based on what D4L has brought into the project. To present this new set of URs in the most fruitful way, thus, also means to introduce its relation to the first set of URs and inherently also some complexity.

To easily navigate and understand this second set of URs, we color-coded them according to their relation to existing URs and technical implementations, which also addresses the validation of URs and their saturation. As we are in year 2 of a dynamic process of prototype development, we decided to closely document the formulation of URs in order to not only point to new requirements, but to also show recurrent demands of users or report some first validating comments of implementations already done. In what follows we will thus use a color code to point to the different status of the **URs formulated in this second wave**:

- **completely new URs that were formulated (PURPLE)** – they were not related to previously defined URs or to any implementation made by the tech partners
- **new URs which have no relation to a previous user requirement, but speak to an implementation made by the tech partners (BLUE)**
- **URs that were re-formulated (formulation connected to a previous UR) by users in the second wave and have been already implemented (TURQUOISE)** – this indicates an assessment and first validation and points to the importance of a specific UR²)
- **URs that were re-formulated (formulation connected to a previous UR) by users in the second wave but have not been yet implemented (GOLD)** – this indicates the importance of a specific UR

The color legend above should guide the reader in understanding this new set of URs. In the following situations, on which the formulated URs are based, the order follows a

² The connections with previous URs are continuously documented and reported in the PAcCT



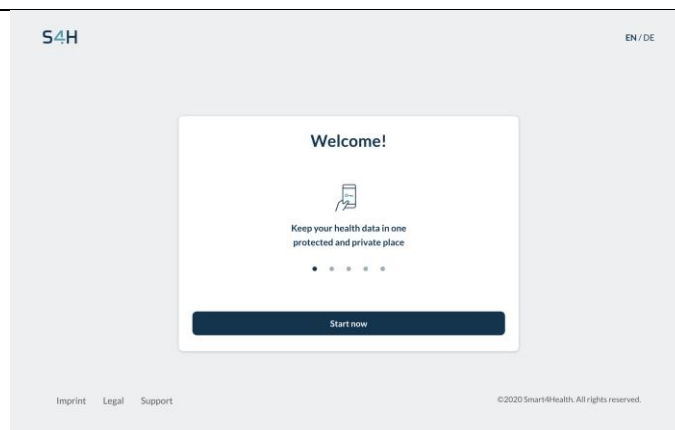
chronological logic within each specific situation, thus with the colors underlying that logic.



5.1 Registering

Situation 1: Registration

I have heard about Smart4Health and have found the app online. Now I am in the situation of deciding, if I want to register for the Smart4Health platform, so that I can save all my health and health-related data and have them available at all times.



As a citizen **contemplating registering** for the platform, I want

- ... first to be informed about the benefits of the platform in order to know what I will be using.
- ... the platform to be visibly associated with trustworthy institutions to consider using it and entrust them with my data.
- ... the platform to be associated with and promoted by the national healthcare system in order for me to feel safe and be ensured that my privacy is protected (as they have that data already anyway).

As a citizen **registering** for the platform, I want

- ... to have clear visual indications of actionable items on the website and how to navigate them (mouse, arrow keys), in order to easily explore the content.
- ... to get only those functionalities presented that I will be able to actually use after registering at this point in time.
- ... to make a cookie selection once and for all and not be asked again, in order to feel my choice being taken seriously.
- ... text only be presented in the language I selected at the start, in order to fully understand all features of the platform (imprint, feature description, privacy policy recovery key).
- ... to clearly understand the reason for each step to assure me and build trust.

... to have direct support during the registration process without leaving the page I am on.

... to be able to contact someone and receive a timely reply, so that I have my questions answered.

As a citizen having **lost my password and registration key**, I want to be able to

... have a reliable separate identification procedure in place for regaining access to my account.

... access my account in some way, even if I forget my password and lose my recovery key (shared responsibility for recovery of data); otherwise I cannot upload sensitive health data to it.

5.1.1 Insights on the registration process from the rUSEEs (CUC5 April/CUC3 May)

First, the following two sub-sections refer to the current registration flow, which highlighted an incoherence regarding the user role. As the current registration flow is more aimed at new users registering, participants who wanted to log in as existing (test) users had to start as if they were about to register. Besides this one flow not being able to lead both **new and recurring users** to their desired entry point (e.g. direct log-in), the language pre-selection and current limitation to English and German raised concerns.

Second, the two sub-sections thereafter address a particular point of irritation that was caused by the **recovery key**, which follows the **password creation** page, but thereby also highlights an in-coherence between the two: While the former is abstract (letters, numbers, special characters), chosen by the user, and able to be recovered by help of the system, the latter is the opposite. With it being a row of pre-defined, intelligible yet random English words, which when lost denies access to the account, made it difficult for citizens to grasp both its content and process.

5.1.1.1 Log-in process

Having to enter through the start/carousel page again

With participants being told to have a (test) account already made some wondered why they have to enter and encounter the start page with the carousel again.

- It was deemed as not relevant anymore after having registered, as the carousel addresses newcomers to the platform.
- However, statements in the carousel were also read closely and relied upon to come up, which is problematic if they do not, e.g. you can scan documents, or not yet fully, e.g. control in sharing (as only entire documents/folders can be shared).
→ The carousel text thus should be aligned with the current state of the app and updated along the development of functionalities, to not risk trust.
- When just wanting to log in, it appeared to be an unnecessary step that needs to be (over-)taken, i.e. clicked on 'let's get started' again, which has been done already.



Prominent registration button

There were some difficulties of finding the log-in button – the registration button seemed to be more visible, given that they had not themselves signed up. One participant specifically was wondering why the registration button would be so much more prominent than the log-in. While it is clear that the prominence of the registration button supports novices of the platform, the difference maybe could be slightly attenuated.

Imprint

One test participant³ was puzzled about what the notion imprint would signify. After seeing the content, she suggests renaming the section “About us”.

5.1.1.2 The start page

It goes to note first that all of the participants have been introduced to the project and its aims already. Therefore, they enter that start page pre-informed and are not informed via the web-application and its visual representation. Yet, as we will see, also pre-informed people will have uncertainties and questions, which might be of even greater concern for people who did not get the project introduced by its members.

- Even though participants usually stated that they would go directly to the Start Button, they spoke out about things they noticed before doing so. For instance, the attention of participants was first drawn to the cookie bar up top. One participant would have expected to not only have the option to accept or deny cookies, but also have the commonly used third option of only necessary cookies. At the moment the necessary cookies are accepted nonetheless, which the user learns only after rejecting cookies. He rejected cookies, and was surprised that the bar re-appeared on the next page nevertheless, as well as later on again (after clicking on the confirmation link sent via email). He would thus ignore the bar, as he could not trust it to disappear despite his previous actions of denying cookies. The rejection of cookies should be accepted, and the question should not reappear on the next page as this undermines trust.
- Despite this user’s reaction, the cookie bar also meant for other participants that they did not see the bottom row of links before doing some action with it, or scrolling down first. In that row of links at the bottom another participant would have expected to see a contact option, just in case (even though she knew about the project and platform), and although this might be in the imprint section somewhere. The bar containing question regarding the cookie policy should not have the effect of making the imprint, legal and support buttons invisible by pushing them out of the frame. The start page should be entirely visible.

³ While one could argue that an observation by one participant is not as relevant, we want to draw attention to the fact that our assessment of the relevance of an utterance is always based on multiple related observations in other settings. Participants might be intrigued but do not verbalize it as explicitly or in the exact same manner as the ones we refer to.



- The language selection up top on the right was appreciated throughout, but also raised questions regarding the already chosen language displayed on the start page, and what other languages would come later. These led a participant to question what the website does in the background, e.g. locate the country or see the browser or system language, and what seeing that page in English would mean for people who cannot speak that language well, and thought it would lead them away. The participant raised the idea to have a screen for language selection as very first page.
- A significant misconception by all of the participants was the box – the benefit carousel – in the middle. In the short time span before clicking on the Start button, they perceived it as representing the progress of registration. As the row of dots had the first in blue and the following in grey, it was expected to get to the next screen when clicking Start and go to the next page in the registration flow. Hence, no one clicked in the box and on the dots, which could again depend on being pre-informed, but their small size was mentioned as reason to not bother to try clicking on them. As one participant said, arrows might work better, and to navigate through the box also via the keyboard's arrow keys. In order for citizens to engage with it, its symbolism needs to be reworked.

5.1.1.3 Password generation

While the password itself and the process associated with its definition were not surprising for most of the participants (i.e. the flow worked well, the combination of letters, numbers, symbols and caps was understandable and acceptable), but the **colour and contrast** lead to some substantial problems. One participant had significant difficulties with the formulation of an appropriate password that covered all the requirements, because he simply was **unable to properly read those requirements**. Another participant (of younger age) recognized that criteria had to be met only by typing into the password field, and thereafter seeing them appear only by having turned green.

Two other participants who did not have problems seeing the criteria (in their greyed-out state) remarked that it would be helpful to also have a red colour used to indicate criteria that are not met yet. Additionally, one of them suggested to have symbols displayed according to the state of the criterion, like an X next to it when red, or also a check-symbol when having turned green. Although the participant did not explicate it, this clearly addresses people with colour blindness or other visual impairments.

- Accessibility is key here – the colour combination, contrast, and visualization (e.g. symbols) need to be adapted accordingly.

5.1.1.4 Recovery key

All participants had difficulties in the flow of understanding, downloading and saving the recovery key and there were a number of concerns that they voiced:

- The explanation of what the recovery key is was not clear to all of them, especially the two first paragraphs were difficult to understand with regard to how they differ. In the first paragraph, there is a reference to “the **following**



recovery key” – however, there is a red paragraph in-between, that does not contain the key. In their expectation of “following key” they were looking for something in the red paragraph that they could not find there.

- The **colour red** that is used to underline the importance of the text had the effect, that two of the participants thought that they **had done something wrong** and that they would now have to recover their password and for that matter download the recovery key. One clicked back to check if he accidentally clicked on a link to recover the password or similar. It is important to have consistency in colour use and what action a specific colour within a process (such as the registration) communicates, e.g. to use of red on the password page or to highlight an important section.
- The participants did not immediately understand **what the key was**; to a certain degree, this has to do with the expectations they had regarding what a key normally is or should be – some of them expected a longer and abstract combination of letters, symbols and numbers, more in the direction of a password. The prior experience of trying to find a password that meets the various criteria (upper- and lower-case letters, numbers, etc.), was given as reason for the expectation to see something along these lines and more complex than a row of words; which was deemed to be safe nevertheless. They did not immediately understand that the combination of random words (some interesting combinations came up such as “dirt hole” in one instance) would actually be the key. By starting to read and trying to understand the line of words as sentence, they also started to question their own English skills.
- In terms of language, some expectations were not met. The fact that the words that the key consists of were **English** words while they were using the **German** version of the platform was surprising to them – they had expected the language to coherently adapt. One participant also questioned the effect that line of words has for users who do not speak English well, who might think that they need to understand it.
- The two **checkboxes** at the end did not entirely fit with the inscribed flow, given that the participants had to agree with that they had understood what the recovery key was (most did not entirely) and that they had stored it in a safe place (something most found troublesome and not appropriate, see below). It was not entirely clear to them what functions the checkboxes had, whom they should protect and what they should ensure. The download of the recovery key is not mandatory (which would come with its own set of problems) and the checkboxes therefore could be ticked no matter what the users had done before. Some people get into a certain kind of box-ticking-mode and proceed very quickly, yet as soon as one has left that page after not downloading but ticking the boxes without detailed reading, there is no way to go back and retrieve the key.
- As the key is so important in its current implementation, a user would have hoped for **more activity by the app** when **proceeding without having clicked** on the **download** button, e.g. to get a message displayed reminding that the recovery key was not downloaded. Another user got slightly upset by the checkboxes: as the first is to confirm understanding the process with the key; but if one does not, there is no other option than continue regardless or quit. An option to **get help** and/or **ask questions** throughout the process would have been appreciated (see more below). And that the wording of the second checkbox should also cover the



possibility of saving the key without downloading it (e.g. writing it down, printing it), in case one cannot trust to download it to the currently used device.

- Furthermore, the participants were concerned about the process associated with the recovery key itself; they did not find it to be trust-inducing but much rather worrisome. Most of them were **convinced that there must be some other way of getting or resetting the password again**, that it cannot just be the recovery key that is involved in this process. Imagined means of doing so ranged from sending it via postal mail (e.g. in two letters), email, calling by phone, to attending somewhere in person, using one's national health card or some other form of ID. There are a number of issues associated here:
- literacy/skills:
 - While some users will be able to clearly define and later remember where the recovery key will be stored, not everybody will be able to do so. This holds true for the management of downloads on a computer but even more so for the management, retrieval and storage of downloaded documents on a smartphone. Recovering the password should not be possible only for highly data literate users, quite on the contrary.
 - The participants in CUC5 pointed out different practices in dealing with data and passwords that are related to users' data (infrastructure) literacy. While they positioned themselves as experienced and well organized, they delineated a potential user group who are less educated, who do not use computers every day, who are less experienced and also unorganized. This group does not know where the files are on their machines, they download and distribute them all over their systems, sometimes print and store them physically and will then not have them at their disposal when they need them.
- mobility: Another concern here was the question of how mobility and the recovery key as single passage can be aligned with the mobility aspect of the platform, ensuring the accessibility of health data when one is on the go, nationally and internationally. If one is mobile, one might not access the platform from the place and with the device that one has signed up with and therefore cannot access the recovery key. Needing instant access to one's health data, having forgotten one's password (e.g. because one has not accessed the platform for a while, or the password criteria are manifold) and not having the registration key at one's disposal, subverts the purpose of mobile access to health data. As one participant said, for a user that would be "stupid".
- security: The participants voiced the concern of losing the key by having one's computer or smartphone stolen or losing them. In general, the recovery key as the only passage to one's data in case of password loss was seen as troublesome – especially if one has put a lot of effort into one's data collection.
- bank comparison: In a number of places, the participants drew on online banking applications to discuss means of accessing one's data in the platform and security mechanisms in this regard, also to be able to contact someone here, to prove one's identity. One participant put it succinctly, when he argued for the importance of having another possibility to regain access when the recovery key is not downloaded or otherwise stored or if it is lost: *"You can have a bank account and if I lose my username and password, I'm not going to lose my money."*



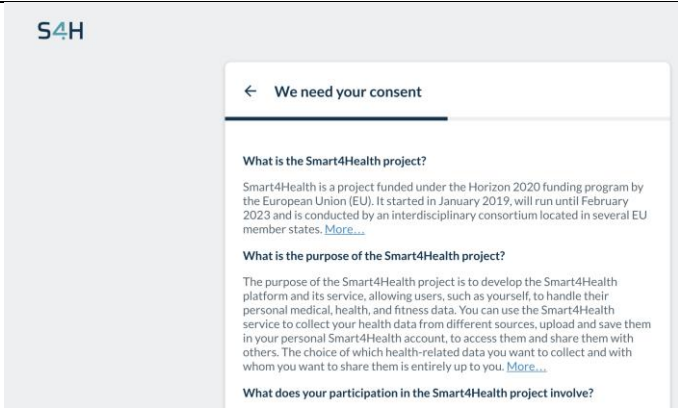
- responsibility: Some participants felt the need to underline that the loss of the recovery key can happen inadvertently, without the user being at fault. This was expressed by pointing not to the user doing something (i.e. forgetting or losing the key by negligence), but by the infrastructure itself breaking down (e.g. the hard disk, upon which the recovery key is stored breaking, not functioning any longer, being destroyed). Losing access to one's data in this way would, as one participant put it, not be fair.



5.2 Informed Consent

Situation 2: Consent

I have taken the decision of registering to Smart4Health to look at what can it offer, and have entered my basic information. In this process, I get the declaration of consent displayed. This text describes what I can do on this platform and how my data will be protected. I have to read it and then give my informed consent. I can also retrieve and view the declaration of consent afterwards.



As a citizen **going through the informed consent procedure**, I want to be

- ... able to expand the risks and benefits in order to read them more closely.
- ... able to read it on my phone and thus want the text to be adapted to the device, so that it is still accessible and not overwhelming.
- ... guided by having a visual structure, in order to not miss any critical information and feel well informed without investing much time.
- ... able to read legal terms and abbreviations without needing to invest time to look things up myself, in order to feel supported and well informed.

5.2.1 Insights on the consenting process from rUSEEs (CUC5 April/CUC3 May)

The informed consent (IC) was quickly noticed as not another terms of use or privacy policy, as the risks and benefits made clear that using a health data platform affects oneself.

Engagements with the IC showed reading rhythms, as in how much time and energy should be invested when moving through the IC, and with which kind of available help, e.g. visual elements or support.

Engaging with the IC also led to considerations about the use contexts, in which language and on which device, as well as to a broader embedding of the platform on EU level.



Without exception, all participants in the rUSEEs so far had a pronounced position regarding the IC process, showing in discussing the consent procedures of the Smart4Health platform that this was something they could relate to in their everyday life and where they already had practices implemented as routines.

5.2.1.1 Time and effort

Interestingly enough, in discussing IC procedures in theory and going through them in practice both showed, that the participants strongly drew on their experiences with terms of use and privacy policies which are ubiquitous in our digitized platform realities. And while they claimed that “no one reads these disclaimers”, we saw that they did in fact have rhythms of reading and practices of engagement in place, that showed that it does indeed matter what the IC contains (despite the widespread statement of not reading this document). We learned that it is particularly the section on benefits and on risks that called for attention – and once the attention is captured, this may lead to closer reading.

IP3_CUC5_1⁴: *“It takes a lot of energy, so people won’t read it. I would not read it, it’s a laziness, (...) but I think if you can change the approach not to put people reading. (...) In physics, it takes a lot of energy to start moving something, but if you only use a little bit of energy, something more visual, something more that is more captive, I think people would, understand better.”*

- A recurring complaint about ICs in general is that in they are too **long**, take too much **time** to read and are too complex and contain sentences, notions or elements that are not **understandable**, which is a cause of **frustration**. For instance, in one of the interviews, we had the case of our Portuguese interview partner not being able to judge what kind of an entity D4L is. They were well aware that there are companies involved in the platform development, but they were unaware of the status of D4L as a non-profit entity, which is signified by the German abbreviation gGmbH. Given the importance of being able to judge the platform identity in terms of public/private status of an entity that is involved in the collection and processing of personal health data, the **burden of proof** should lie with Smart4Health and the effort should not be outsourced to the citizens. It is important that the **language is coherent** and that all notions are adapted accordingly.
- ICs should be **concise, on point, and accessible** – complex procedures need to be well explained and broken down, using comparatively simple explanations, for instance facilitated by visuals. The respondents linked the accessibility to the literacy and level of education of potential users, making a case for **equity** – the understandability and accessibility for all needs to be ensured by having adaptable levels of detail and simplicity in explanation in place, not leaving anyone behind (while at the same time clearly positioning themselves as literate and delineating themselves from a less data [infrastructure] literate other).

⁴ IP stands for Interview Participant, an abbreviation used for discussion, interview and test participants alike. It is followed by the participant number and the abbreviation of the engagement setting (e.g. CUC3) as well as its number if multiple engagements were done in this period (e.g. CUC5_1).



- In general, anything that gives **structure** and **visual guidance** (such as headlines) was highly appreciated, especially if one skims the content for familiar hooks or reads them diagonally, as one of our interview partners put it. We received positive feedback also for the **questions** that were guiding the IC as well as in particular the **expansion** possibility via the “more...”-link.
- In addition to this, the information the IC contains must be accessible and readable for everyone in the same manner, their technical equipment notwithstanding, which is an **issue of justice**. The availability of technical infrastructure is unequally distributed; our interview partners pointed out that while most people do have smartphones and with this will be able to participate in the data practices of platform use, they may not have a computer at their disposal. The IC (as well as the terms of use and privacy policy) has to be well **structured** and **adapted to smartphones** in a way that testifies to the requirements of the sociotechnical environment, helping the gaze, making up for the limited space. If deeper engagement and, thus, deeper understanding of what is at stake, of risks and benefits is not facilitated, they were concerned about potential disadvantages in the possibility of being informed and, thus, of understanding as the prerequisite for choice.

5.2.1.2 Information and trust

What came out clearly is that the **IC process** is embedded in **relations**. The way one learns about the platform, the direction through which one arrives to it already positions the platform, initially shapes the trust that it receives and the responsibilities that are expected of those developing and/or running the platform to live up to.

IP1_CUC5_1 *“My expectation is, this will be a national thing or a European thing. (...) People like me that agree (...) with those kinds of platforms, we need to be safe. And for us, or for me, to be safe this to have something not private but national. European or local.”*

- In a number of moments our interview partners told us that they do not have to go very deep into the IC as they already know about the platform, as they already know us, as they already know the project, as they already know the consortium partners who have recruited them. Getting a first impression of the platform in sociotechnical network form - of what it is, of the **network of relations** that it is embedded in and that to a certain degree defines its **trustworthiness** – had an effect on the effort that the respondents deemed necessary to judge the platform identity.
- To have a clear identity as a **public platform** requires less trust-building in the first place. Knowing that the platform is “a national thing” or “a European thing” as our interview partner put it, an entity that it is associated with national healthcare institutions or with EU institutions, that is a public and not a private entity would enhance the feeling of safety and trust.
- The information on the existence of the platform comes via a **credible source**, e.g. a doctor, a department head in a workplace, national health services etc.

5.2.1.3 Contact and questions

While exploring the registration flow, our respondents voiced the wish to be able to contact someone in a number of ways; with (1) questions and concerns during the



process of registration and consent as well as with (2) problems and issues, for instance with regard to the loss of the recovery key. They also suggested different means of support and contact.

- In discussing the IC process (as well as referring to the terms of use and the privacy policy), our respondents said they wanted to be able to have a **point of contact** they could address, if they have notions, sentences or sections, they do not understand. While they clearly saw the benefits of this point of contact being virtual and they were also open for **asynchronous communication**, it was underlined as significant that the response would be **timely**, as otherwise they would lose interest and move on. Although the IC section was appreciated for its being compact enough and having the option to see more, particularly the IC section also triggered the idea and wish to be able to get into contact somehow. While one imagined means were **information boxes** placed next to demanding words or sections, a common imagination to get into contact was a chat window that could be opened up and ask questions in real-time, also if this means to queue up and wait. The reason stated was to be able to talk to someone in person, when having individual questions. Also, because all participants stated that they would talk also with friends, family or colleagues about registering for Smart4Health, they imagined that a chat option would cater to those who have not but would like to exchange about making that decision.

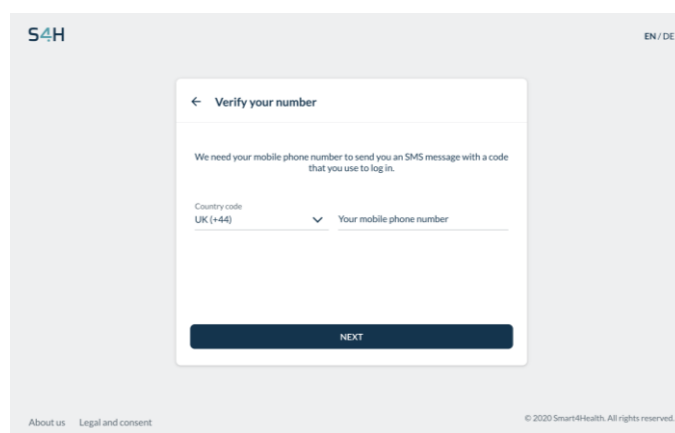
As already outlined before, on the sequences on the recovery key, our respondents voiced the importance of being able to **recover the password** even if the recovery key is lost. They suggested to draw on official mechanisms of **identification** (e.g. through a national ID card) in order to regain access to a dataset they had put work and effort in, and that they located in the public domain, being associated with public institutions (cf. “public platform”). One way to do so could also be to get in contact with a physical institution, in order to **prove one’s identity**.



5.3 Authentication

Situation 3: Authentication

I have given my informed consent for using the platform. But before I can access my account on the platform, I have to first confirm that I actually want to have an account created and that it is really me. Therefore, I am asked to enter a phone number to which a PIN will be sent, which I then have to enter in the web-interface one time.



As a citizen **authenticating my device**, I want to

... have the country codes shown in a way that makes it easy for me to find mine.

... be able to directly put in my country code so that I don't have to scroll through a long list.

... be brought to the exact step in the process where I am supposed to take an action (e.g. enter my log-in credentials), in order to feel supported.

As a citizen **with an active Smart4Health account**, I want to

... login as directly as possible and not have to read/click through content meant for new registrants, in order to not waste my time.

5.3.1 Insights on the authentication process from the rUSEEs (CUC5 April/CUC3 May)

The two-factor authentication was regarded as a meaningful measure, which reminded about the seriousness of a health data platform. However, more support by the platform was expected in directing the user to the asked action (e.g. log-in, country code selection) and explaining the effects of a checkbox.

The two-factor-authentication process of the sign-up was interpreted as appropriate for a platform with the security requirements such as Smart4Health. In discussing this, one of our Portuguese interview partners explained that he appreciates having to be



more attentive in this process if this is a platform that is of importance for his life. In that sense, the requirement of more human attention by a process of repeated authentication indicates that this is a secure platform. However, in terms of the flow, there were a number of issues:




- When receiving the email with the confirmation, basically all participants would click right away on the confirm link. One participant though wondered why the webpage before did not state to also check the spam folder, in order to ensure a quick follow-up. Also, other participants expected to receive that email quickly, as waiting too long for it might let them lose interest to continue. However, after clicking the confirm-link all of them would have expected to then be **re-directed to a log-in page where they can actually enter email and password, not again to the start page**, or even be logging in already as one had hoped for. Some were annoyed to be confronted with the start page as they had run through the whole process already before (and for instance denied cookies). Thus, even though already the next page allows entering email and password, seeing the start page reminded them about the entire process.
- After logging in and then seeing the authentication page, some **positive confirmation was desired**, as one participant expected to see a message that the registration was successful. When seeing the need for authentication on the follow-up page, a similar reaction to the recovery page occurred for some: the thought of having done something wrong. Two of them suggested independently of another **a statement that clarifies the reasoning for the (two-factor) authentication** and that it is for safety/security reasons only, which would be calming.
- When having to enter the phone number many expected to be able to enter the country code themselves (and see the entry in the list selected), as they know it already anyway. When scrolling down the country code list, they usually looked for the first letter of the country in the language they use the web-app, i.e. “D” instead of “G” when using the German language version, as they expected them to correspond to another. Again, the language used needs to be consistent across the platform and its functions.
- But having to enter one’s phone number was seen critical by all the German participants and one Portuguese participant, who interpreted the phone number as a very private information, despite seeing the security benefits here. While one was generally not comfortable to state the phone number in registration processes, the other two questioned why only a PIN via SMS is used and no other option like email. For one, the dependency on the phone and the limitation to it was seen very critical, and expect to be informed about having to enter the phone number already when “downloading” the app.
- A point of uncertainty for basically all participants was the functionality of the checkbox “remember this device”. If it were checked, it was unclear if a PIN would have to be entered from this device the next time, and this step could be skipped next time, if one would get a notification if one logs in from another device, and if the device or the phone number is remembered. This function was confusing and needs clarification.



5.4 Collecting health data

Situation 4: Collecting health data

After having registered for the Smart4Health platform, I am now in my account. There I see the option of collecting my health data. I can upload files that I already have at home (e.g. previous doctor's letters, x-rays, lab results etc.), or I can ask my doctors and other health care professionals to upload health data they generate while I am in their care.

As a citizen **uploading health data** to the platform, I want to

- ... immediately understand how the document I want to upload should be classified, in order not to upload it as the wrong document type (my document vs medical document).
- ... have some clearly visible indication on the data type, maximum file size etc. in order to know what I can upload.
- ... be able to easily interact with the attachments through gestures and well-sized buttons in order to be able to check them after they have been uploaded.
- ... have my health data automatically uploaded by my HCP in order to have as little work with it as possible.
- ... to be able to link national platforms and Smart4Health, in order not to be entirely responsible for keeping my health data up to date.

As a citizen **collecting, viewing and sharing** health data, I need

- ... the terminology for folders/documents/attachments to intuitively relate to the action and processes I am supposed to engage in, in order to feel in control.

As a citizen **viewing my documents**, I want to

- ... have a visual indication as to how the documents are ordered, to find my way once I have more data.
- ... be able to define and change how the documents are ordered myself, so that I can choose an overview that is suitable to my preferences.



5.4.1 Insights on collecting health data from the one-on-one engagements (Citizens in Vienna – September/October)

Overall, participants needed explanations to feel sufficiently supported. Particularly with regard to what the **differentiation of document type – My Document and Medical Document** – means, why, when, and how it matters for whom, as well as which limitations may apply in the upload process (e.g. file size, number of files) but are not made explicit.

In creating a document, it was also unclear how to best name it, as participants **hoped for some guidance**, also with regards to the above of not knowing how this can matter to whom.

Another point of confusion was the **terminology of a document with attachments**, as participants only understood the latter as documents and the overall entity (currently the document) **as a folder that contains documents**.

Exaggerating this confusion was the realization that not what they perceived as documents – the single attachments – but **only the entire folder/document can be shared**. This is problematic as it led to reconsidering what to upload at all, what to delete before sharing, and potentially re-upload after sharing, and thus **working towards the app, not the other way around**.

In interacting with the uploaded files/attachments it was expected to have clearer visual indications of **what can be done and how**, e.g. zoom in/out. On the level of file/attachment and of folder/document, there was the **need to being able to edit more**, such as renaming the file/attachment, and especially adding meta data/descriptions/notes that were deemed as being valuable for others.

Support

The uploading process needs to be better explained.

- IP7_1on1 for instance expected some kind of intro guide within the platform regarding the medical information that one fills out oneself. In this way the app could ensure that she has information in her account that is of value.
- The need of support also relates to the point of differentiation between My Document and Medical Document, which was unclear to the participants.

Differentiation in My Document and Medical Document

This differentiation was unclear to all participants testing the upload process. This is exacerbated by the fact that the notion “My Document(s)” is used twice, once on the home screen with the choice of upload or sharing and one within the upload process, differentiated in My Document and Medical Document.

- While the participants tried it out extensively, they did not arrive at a point where they were clear about what the difference was and, accordingly, the benefit of having both. If the differentiation is retained, it needs to be made much clearer, also explaining the actions and processes that follow from it.
- IP8_1on1 for instance initially interpreted Medical Documents to be documents that are uploaded by an HCP and then, after understanding that this is not the case, that the Medical Documents simply are given the priority.



Creating a Medical Document

One participant (IP8_1on1) pointed to a number of questions pertaining to this process, that would warrant further exploration.

- Regarding the mandatory field for discipline/Fachrichtung it is not clear to her, what the purpose is for whom. An information box to explain the purpose of that field (e.g. who gets to see it when) might help.
- Upon adding several files to the document, IP8_1on1 wondered how many could be added here as maximum. Her rationale here is that because it is called a document – she compares it to a report which only spans some pages – she would expect some kind of limitation here.
- Upon clicking the upload button, initially nothing seems to happen and she is missing feedback regarding what is happening, e.g. a progress bar, to communicate that the app is responding and doing something). While the process worked just fine, her imagined mitigation measure of uploading the documents anew left her wondering about duplicates.

Not uploading and re-uploading

Some participants started to rethink which files to actually upload into a document, after getting to see that only entire documents/folders can be shared.

Some also thought about deleting attachment/files they do not want to share, only to reupload them afterwards again, in order to have the files with them.

Transition from upload to document view

This is an element that needs a different conceptualization and testing of different options.

- From the perspective of IP8_1on1, to **arrive at the detail view of the first file** gives a somewhat unprofessional impression. Instead, she would have expected to see all files in that doc in an overview, and be able to control the view e.g. switching between a list view and one in tiles.

Terminology and control

The differentiation in documents and attachments was unclear to the participants, which is of particular relevance for the sharing process. This then also had effects on the accessibility of the selection process and the degree to which the participants felt they were in control of it. Depending on how documents/attachments or folders/documents/files are conceptualized, expectations of what can be done with them differ.

- While the notion **document** refers to what the participants understood to be a **folder containing several items**, the system refers to these items as **attachments**, which is what the participants perceived as **documents**.
- One participant (IP1) was in the middle of the sharing process when he realized that he may well be **in control of the documents** and which of those to select, there was no way for him at that point to **deselect an item (i.e. an attachment)**.



Interpreting the documents as “folders”, he expressed the wish for another drop-down menu to select what he wants to share and being able to edit exactly what he shares. (see above entry page and carousel statements/promises)

- When creating a document, the empty title field left participants wonder how to best name a document, and expected some guidance on where that will matter elsewhere in the app (e.g. in sharing, data provision), and/or see a default value in it (e.g. date), in order to be assured that what they create is of benefit in use.

Preview

Attachments/files can only be viewed after the upload which runs counter to the desire of ensuring that it is the correct file (IP6_1on1). Viewing uploaded files/attachments triggered the desire to interact with it, but did not indicate how exactly.

- Only trial and error showed that it is not possible to zoom in with swipe gestures like pinching (IP5_1on1).
- Symbols that indicate to zoom in/out or also to close were difficult to discern (although all participants were rather young and not visually impaired).
- When in the enlarged view (by pressing +) IP6_1on1 wanted to scroll down to ensure she does not oversee an upper or lower section of the uploaded (unstructured) file. But the swipe down resulted in closing the large view instead of zooming it.
- Only the preview made apparent the lack of any information/metadata about the file/attachment.
- While looking into a document that has multiple files/attachments and viewing them in large/detail view, IP6_1on1 would have expected to be able to swipe between them, but the app does not allow so, only closing this and opening another it seems.

Metadata/descriptor

There are no descriptions to the attachments.

- Some participants (IP7_1on1, IP6_1on1, IP5_1on1) were **wondering about the absence of any additional data or descriptors** of the attachments, e.g. date, title, who created it and where, etc. that also cannot be added by the user themselves.
- Participants expected to see the file title somewhere (again).
- IP8_1on1 pointed out that from her perspective it is unclear what the **document date** actually pertains to, e.g. when the file was created, uploaded here, and who is the addressee of this information.
- IP8_1on1 voiced that she missed a **field to add notes**, on both document and file/attachment level. This would add significant value for her, particularly because the app shall be usable when mobile, but also when at the doctor. For her, it might also be valuable for insurance reasons, e.g. being able to make notes to a doc and/or files that pertain to an accident, as well as for her medication and intolerances (which she then could/would like to make notes about in a doc and file/attachment – it would give her control).

Editing documents

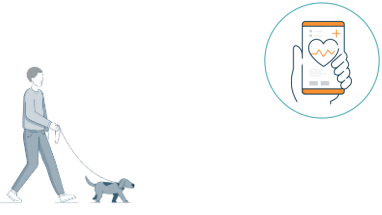


- Editing a document produces a tag that is added to the document in a similar manner as the information that a document has newly been added (“new”). In German, this is called “Aktualisiert am” which would require a date. The date, however does not change.

This brought up the question of the implementation logic and the process at its base. In the case of (automatically) adding attachments to a document (e.g. during the 18 sessions with the MedX machine) it makes sense, given that users would be alerted to the fact that a document has been changed or adapted. In case of users themselves adding something, i.e. changing the name of a document, the benefit and value of this functionality is less clear. Therefore, it needs to be further investigated under which circumstances citizen users would want to have this feature, what process/what use practices it would support and what additional information it would need to provide (e.g. a date of having changed something, who has made the change – if an automated adaptation is at all possible in the first place).



5.5 Collecting health-related data

Situation 5: Collecting self-generated health-related data	
<p><i>Next to uploading health data myself or having it uploaded by HCPs, I can now also upload health-related data into my Smart4Health account – e.g. from a watch that counts my steps or measures my pulse, a t-shirt that tracks my posture or a pain diary that I keep. With this I can complement my collection of health data, if I want. While this data is not medical data as such, it might provide interesting insights if I share them with people of my choosing.</i></p>	
	<p>As a citizen collecting health-related data on the platform, I want</p> <ul style="list-style-type: none"> ... the collection of health-related data to happen automatically so that the data collection is more reliable. ... to be able to hide specific data/files in order to not inadvertently share something I do not want to share.

5.5.1 Insights on collecting self-generated health-related data from remote group discussion (CUC5 April, July)

Automatic collection and reliability

Both groups of participants in the CUC5 engagement settings saw a clear benefit in the collection of health-related data alongside health data, with relatively little effort: The collection happens automatically without the user changing the data, which leads to a higher reliability of the data. Given that health-related data can be collected for a long period of time and, thus, expands the timeframe of examination, the participants expected a holistic perspective on the body to better understand health problems. For instance, this could mean to bring together posture data with data on nutrition and sleep. As IP1_CUC5_2 pointed out, data could be counterchecked, broadening the scope and integrating data that is specifically posture-related as well as data that newly becomes posture-relevant. This monitoring in real-time, thus, can be understood as an intervention with the objective of prevention, as it seems possible to get to the bottom of the actual cause of health problems as the result of cumulative action over time.

Hiding specific data


One participant was thinking about how he could prevent the inadvertently sharing of health-related data that he had collected and came up with the idea to hide or to block specific files.



5.6 Workplace and health data

Situation 6: Workplace and collecting data

Wearable devices can also generate health-related data in the work context. For instance, at our company we as employees can partake in a training program to improve our health and prevent back pain from doing manual work. For this, I can wear a special t-shirt that measures whether I am sitting or standing in the right way and if I could do it better. I could also upload this generated data to my account on the platform, if I want.



As a citizen at work, I want

... to be able to deselect any kind of notification about my posture or progress, in order to follow my everyday practices without interruption.

5.6.1 Insights on workplace and collecting data from remote group discussions (CUC3 and CUC5, April/May)

Collecting health-related data in the workplace

While some easily extended the benefit narrative of continuous monitoring to see the actual problem to the workplace as regular space through which individuals move. Their expectations here included being able to assess the stress employees have in their work life, enable better workplaces and prevent injuries and in general to gain a better understanding of a worker’s performance together with their quality of life. In that context, one participant in CUC5_2 expected health-related data that can be collected in the workplace to contribute to workplace studies. There was broad agreement that this data collection should only happen voluntarily and data sharing in the workplace was seen as appropriate only with health-care professionals and not employers.

Agency of the wearable device, instead of the app

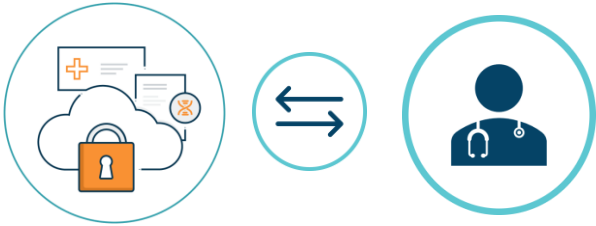

The reactions were based on the visual input on the card, which (in the first sessions) had a depiction of a smart T-shirt, and how it might integrate in everyday life, rather than on the interaction with the platform.



- IP3_CUC3 imagined that someone might feel pressured to be active when wearing such a device/shirt, but also that someone who is actually doing well might get told by the shirt that he is not doing enough and then feels bad about it.
- Similarly, IP1_CUC3 also thought about how the actions such a shirt demands from the wearer could hinder its application in a work setting, e.g. a dentist who has to bend down and over patients might feel obliged to do what the device demands, but also stressed out if not able to.



5.7 Sharing data

Situation 7 & 8: Sharing data with a doctor/trusted person	
<p><i>I have had back pain for quite some time now and want to get to the bottom of it. I have had a number of physiotherapy sessions, have done X-rays, have tracked my posture in my free time and at work via a wearable shirt and have kept a pain diary. I have registered for Smart4Health, have added previously collected health data and I have also uploaded self-generated health-related data. Now I am sitting at my doctor's office and my doctor says that s/he would like to see my data.</i></p>	<p><i>I have registered for the Smart4Health platform and now I am thinking about for whom my data could be interesting. It could be good for my partner to have access – maybe already now but also for the worst case in which I may no longer be able to voice my health-related wishes. I might also want to share it with a mobile care person - now that I am healthy this does not apply, but at a later point in time this may be relevant and useful. There might also be persons from self-help groups or even my work colleagues, with whom it could be interesting to share and compare data.</i></p>
	
<p>As a citizen contemplating sharing my data, I want</p> <ul style="list-style-type: none"> ... to have options of sharing all of my data or only parts of it, which includes a selection option at attachment level, in order not to inadvertently share something I did not want to. ... to be able to share only specific sections of my medical history so that I do not share something I do not want to share. ... to opt into sharing documents and not the other way around, in order not to be pressured into sharing everything. ... to see which of my documents that I selected will now be shared, in order to be in control of the process. ... to be made explicitly aware of the inability to revoke shared documents before sharing them, in order to be able to reconsider or confirm my choice. ... be asked to confirm what I am about to share in order to be sure that these are the right documents. 	



... get signaled clearly which of my actions in the app actually starts the sharing of which documents, in order to feel safe and in control.

As a citizen **sharing my data**, I want

... to have an easy possibility of stopping the sharing process, in order to remain in control until when my data can be accessed.

As a citizen **sharing my data with the HCP**, I want

... the URL to be simple, in order to cause as little extra work as possible.

... to be informed beforehand about a timer that stops me from sharing, in order to not having to go through the entire process with the HCP again.

... to remain in the sharing session as long as I am actively doing something, in order not to disturb my interaction with the HCP.

... to be informed if one of my documents is downloaded, in order to know who has my documents.

As a citizen **sharing my data with my trusted**, I need

... to explicitly agree to downloading my data, in order to control who can potentially keep my documents beyond the moment of sharing.

As a citizen **stopping the sharing of my health data**, I want

... to have the option to actively do so for both parties, in order to feel in control of my data and remedy potential mistakes.

... a clear indication with whom I currently have an active sharing session open, in order to not end the wrong session.

... to have a confirmation of the session being terminated, in order to be assured that it has happened.

... to be prompted to the log-out section in order not to have to look for it.

As a citizen **having shared** my health data, I want

... to have an overview of my sharing activities, in order to feel in control.

5.7.1 Insights on data sharing from remote group discussion (CUC5, Aug)

Narrations about sharing mostly referred to existing health-care relations, and thus focused on **sharing with HCPs**. Other potential data recipients were existing groups of citizens, e.g. with similar health conditions, or in work relation, but sharing with others (e.g. family or friends) was not imagined as particularly beneficial.



Participants voiced **expected changes of the citizen-HCP-relation**, by having more rights and agency regarding their data, e.g. to easier ask for a second HCP opinion or to make (e)valuations of health care provision. This made them aware of **needing full transparency as citizens** in the first place, **to actually become the main beneficiaries** instead of some health care institutions as now already, and to thereby make the platform a success.

Not being physically co-present with an HCP highlighted the anticipated agency of the platform, which **should enable transparency for citizens** towards others, but should **also act as a controllable shield towards research access**.

Sharing data with real-world groups

What became clear from the discussion was that the participants did not see any major benefits in sharing specific health data with anyone else than an HCP or a healthcare institution – as individuals, as exemplified in the following quote.

IP2_CUC5_2: “I would not share with anyone who is not a doctor or a health institution related with the health care system, because, in my view, that does not make much sense.”

However, they did see benefits if there already are groups in place, with whom data sharing aligns with/contributes to furthering a specific relation, i.e. with people who also suffer from a specific condition (e.g. backpain), people who also work and with whom one may want to enter into a playful competition.

IP3_CUC5_2: “One can look at health from a sporty point of view, and from a sporty perspective it would be important and interesting to share.”

Family members or other trusted individuals were not seen as an appropriate recipient due to them not having medical expertise. If there exist real-world groups, they might see a benefit. If there are none, the participants were skeptical regarding benefits. These real-world groups do not constitute themselves via the means of the platform. Turned the other way around, the participants also were skeptical about becoming recipients of someone else’s data, as this would only make sense to them if they were in the position of supporting them. Support could mean being an HCP oneself (which they were not), as in offering support through medical expertise, but it could also mean experiential support in the sense of supporting someone else who shares a condition with one’s own experiential expertise, as the following quote shows:

IP1_CUC5_2: “When I have back problems and (...) someone with back problems wants to share data with me, so that also I share in some way my experience, that could, in my opinion, make sense.”

This support was seen as beneficial if reciprocal – both, the one who shares the data and the one with whom the data is shared have a benefit and can learn from each other’s experiences, based on the shared data.

Changes in the relationship between citizens and HCP: Individual control, transparency, rights



The participants in the group discussion noted the expected change of no longer being dependent on the doctor and private healthcare providers for health data in the same way as before to be something positive. Drawing on the scenario of making data mobile between institutions (e.g. different hospitals within the same national setting), IP1_CUC5_2 underlines that from his perspective the platform will have positive effects on the rights and agency of patients with regard to their data, which was supported by IP3_CUC5_2, in terms of citizens being better able to take matters into their own hands (i.e. supporting the individual control of data). There were a number of instances in this group discussion where the participants referred to heightened individual control through being able to make data mobile and, thus, a disturbance of a healthcare business they perceived as problematic.

IP2_CUC5_2: "Basically, health is one of the most profitable businesses that currently exist, and tends to get always bigger. One of the attitudes, particularly from private institutions, is to bind customers to them and basically force them to use their services within their network of service providers."

In this quote IP2_CUC5_2 sketches the point of departure: The healthcare industry is a profitable endeavor, which to a certain degree is based on data remaining with those having produce them. In their expectation, having a platform such as the one developed in Smart4Health helps citizens to make their health data mobile and, thus, to become independent from healthcare industry actors' economic interests. Talking of the Portuguese setting, where patients of public hospitals have to redo exams when changing to another hospital that also belongs the national health care network and mentioning also private hospitals, the medical data is something that is available for every doctor within that system (of value), doctors from within can consult the results, but it is restricted to doctors from the outside. So medical data is bound up within a logic of profit, something that is the result of production/ownership, not within a logic of providing care, medical data as a different kind of "product"/result, something that should not be owned. The platform, in their agreement, could enable greater individual control with regard to their healthcare.

IP1_CUC5_2: "I thus think very clearly that we here have the opportunity to not be dependent from an institution or a person or a particular doctor."

One such instance of discussing individual control came up when IP3_CUC5_2 articulated the greater ease by which a second opinion of an HCP could be looked for.

IP3_CUC5_2: "[I think] that this enables the citizen to have all this information always with him/her, and to be able to choose the health service that he wants to and where he wants to, in here and out there, right."

This includes the patient user as knowledgeable entity who can judge if it is necessary to do so. What we find here is an understanding of the patient (in need of care) more as a customer (with rights), that is someone who is well informed, well capable of making comparisons and informed choices and of getting their needs taken care of. IP2_CUC5_2 added to this configuration by speculating about the platform enabling the (e)valuation of health provision through citizens, e.g. by producing a ranking of healthcare institutions so that citizens would know what kind of treatment they receive, in that sense pushing the customer-patient configuration further.



IP2_CUC5_2: “The people can be better informed about the kind of treatment that they currently receive, and if it really is (...) the best treatment, which they currently receive, and if it is the most suitable for their problem, and they can also find out if that institution is the best place for doing this treatment.”

In response to this, IP1_CUC5_2 introduced the term transparency as key notion, that supports citizens in the engagement with institutions and specialists, going against what he perceived as conflict of interests in the of area healthcare due to the foregrounding of economic benefits:

IP1_CUC5_2: “I just wanted to substantiate that this effectively brings transparency into the relation between patients, institutions and specialists, and that in the mid- to long-run, (...) it will educate the population differently, and this will eradicate the existing conflict of interest in the business (...), which has to take care of health.”

Transparency, in his expectation, changes the relation between the involved actors in the area of healthcare, “bringing a little humanity into this business” (IP1_CUC5_2), that works against “being a number” (IP3_CUC5_2) and against “business interests that are limiting” (IP1_CUC5_2) citizens in their healthcare decisions. Citizens are changed as well, as the possibility to have transparency will change their scope of action. In that sense, the platform becomes an actor that supports patient-customers, that facilitates the relationship between patients and doctors, that shifts the power position by offering rankings, transparency, and a new patient-configuration that is characterized by less dependency and more individual control. In this way, HCP can be made to care, profit-making moves into the background. The issue of transparency was taken up in the closing statement of IP3_CUC5_2 who linked it to the sharing process and transformed it into a prerequisite of the platform prototype becoming a success.

IP3_CUC5_2: “The question of transparency and how this collective use will be put into practice, will be one of the cornerstones or the most important stepping stones for the success of the project.”

Interestingly enough the above-mentioned formulation of “not being a number” resurfaced in the context of the question of who should have access to data provided for research. Underlining the importance of respect and “not treating someone as a number” (IP1_CUC5_2) was articulated in combination with the importance of transparency, that could work against this. He problematized the relationship between researchers and data subjects and effects on feelings of responsibility through doing research on data and not with patients.

IP1_CUC5_2: “It is one thing to have a patient in front of oneself, it is another to receive data.”

This quote, thus, is to be seen in response to the expected responsibility that researchers may feel for data subjects, i.e. the citizens that have provided the data to them. In another sequence of the group discussion, namely while talking about the effects the platform may have on the relationship between HCP and patients, IP2_CUC5_2 was optimistic in this regard, expecting patient and doctor to move closer and to be better aligned. In addition to this, he saw the absence of the necessity of co-presence for exchanging information between doctor and patient as beneficial – underlining the benefit of saving time, a classical move:



IP2_CUC5_2: "But I think, that it makes this information exchange with our doctor easier and it will be more comfortable, it will not be necessary to drive to a place, to show our examinations, which nowadays is great for all, if we can save some time."

However, in the doctor-patient relationship, physical distance and letting data speak for oneself by means of the platform did not seem to have the same expected effects.

From the perspective of these three participants, the platform shows agency in two directions: 1) from citizens towards other actors (within the healthcare system as well as towards researcher), in that it enables/should enable transparency (this is an expectation as much as a normative stance). 2) From researchers towards citizens, in that it acts as a shield which citizens can control. In addition to this, the platform was perceived as a disinterested actor, promising to contain and distribute information that is reliable and not manipulated (IP2_CUC5_2). IP1_CUC5_2 drew on his professional background in summarizing why he strongly supports the platform and the practices he expects to come into being:

IP1_CUC5_2: "I am very happy that this project takes place, because it is a bit ironic that, coming from the area of mechanical engineering and knowing that this is done with machines already, why we do not also do this with humans. All this real-time control and telemetry is essential for a preventive service of the machines, why is this not also applied for the preventive maintenance of all humans' health?"

5.7.2 Insights on data sharing from the one-on-one engagements (Citizens in Vienna – September/October)

As **multiple start points** exist to initiate data sharing (the home/start page, the document view, the share tab/page), it was unclear if and **what difference this makes**, e.g. which documents are (pre-)selected for sharing.

Generally, there was a need to **receive communication by the app**, e.g. reassurance on what will be done if the user proceeds. However, agency was wanted in the critical step of selecting documents for sharing, instead of having all pre-selected. As above, **confusion about the document terminology** appeared, as well as the surprise of **being able to only share entire documents** (as folders).

A big point of concern and frustration was the **encounter with timers running in the background** and getting to know about them only when coming into effect, e.g. by forcing to re-login, or to exchange a PIN for another sharing session. To follow the asked-for actions, e.g. to log-out, **guidance and activity by the app** was expected and needed but missing.

While the **PIN sharing worked technically**, **getting to share caused problems**, e.g. by the description who has to do what when, because it involved **switching to face-to-face interaction**, although being a cloud-based service; or by not knowing how long the PIN is valid.

Thus, **more transparency was needed before sharing**, e.g. not being able to revoke shared documents, **as well as after the sharing** by seeing an overview of past sharing sessions in form of a sharing history. Getting to such a section was imagined as an **actual closure of sharing**, instead of being redirected to the share screen again.



Selection of documents

Our participants arrived at the sharing process via two paths. First, they arrived from the overview page by clicking “start sharing” within the field “sharing with my doctor”.

- One participant (IP8_1on1) was concerned that clicking on the document sign (that she interpreted as uploading) on the home screen could have the effect of her already starting some kind of upload process that she does not know about. In this regard she would hope to receive info-boxes/messages that ask her for instance “Do you really want to ...”, to not initiate something by accident.
- It was a general pattern in a number of engagements that participants were hoping for an additional step before taking a consequential action, such as sharing. This additional step would enable them to check the documents/attachments that they are about to share and, thus, to be reassured that they do not inadvertently share something they would rather keep to themselves.
- Most participants wondered about the default being that all documents are pre-selected for sharing. Instead, they would have expected that none are, but they decide what to share and thus actively do the selection, and not have to deselect the already ticked documents.
→ For IP5_1on1 it was a case of “simplicity takes away my control”.

Second, if they already were within the “Documents” section they could click “share”.

- The expectation was that **sharing from within the document** (at attachment level) **would enable to share the attachment only**. This is supported by the following process: Upon clicking share on attachment level, the user is being led directly to the page prompting them to initiate the PIN-sharing process, yet without having to confirm what part of the document (i.e. which attachment) they want to select. However, the HCP sees the entire document with all attachments and not the attachment that the user started the sharing process from.
- One participant (IP1_1on1) expected it to be easy to **deselect** what one has already selected and he was content with how it was implemented. However, when he then walked through the process, he realized that he can only share what he interpreted as “**folders**” (i.e. the documents) but not what he interpreted as “**documents**” within them (i.e. the **attachments**). The terminology of the containers and the effects it has on the expectations and experiences of the associated processes (see separate item) should be reviewed.
- Also, visual guidance was expected, such as seeing the number of attachments of a document in the selection overview, or being able to preview them also from the sharing screen, to better know what the document comprises, as this matters in that moment.
- Another participant (IP7_1on1) expected to be able to **move files/attachments from one document to another**, conceptualizing documents as folders. This expectation was voiced in the context of ensuring to **not share sensitive information** which she actually does not want to share. The first idea here was to not upload them at all, but thinking it further brought here to wanting to prevent



sharing too many files or critical ones by moving them to another document, before the sharing process. In this way IP7_1on1 devised a work-around for things that the app currently does not provide, e.g. deselecting file/attachments or hiding them from the sharing functionality, like by marking them as critical do-not-share files).

- Because a document implied for participants a file like a report or image, it was unintuitive to not be able to upload such a file directly, but only after creating or going into a document.
- One participant (IP8_1on1) expected the **differentiation of My Documents and Medical Documents** (at document level) to be represented in the sharing process as well, namely for personal and medical documents. Here, however, it is missing entirely, which makes her wonder again why she was asked to make that differentiation when creating a document to upload files into.

Log-out for sharing after 10 minutes

The process should be improved:

- All participants who met this issue did not understand the reason why this would be the case. Thinking through concrete scenarios of users dealing with the scarcity of time in a doctor's practice (e.g. through preparing the access to the platform already in the waiting room, logging in already so that they do not have to go through the process) this **timeframe did not seem feasible**.
- Also, the fact that the **information** of having to log-out and log-in only came **at this point in time** (at the point in time when the problem occurred but not as a warning beforehand so that they could avert it).
- They showed some confusion about the fact that it was simply communicated to them that they have to log-out **without the process being initiated system-wise** (e.g. by pointing them to the log-out button).

Confusion about activity and sharing timer

There was confusion about the sharing timer **only being applicable for the sharing process** but not for other processes, e.g. accessing the documents.

- Several participants had expected an **activity timer** to prompt them to re-login, pointing out that they had shown activity now in the past 10 minutes. Upon realizing that the sharing timer is a different one (given that they had indeed shown activity) they pointed out that it was unclear to them why the sharing process had its own timer and, thus, was treated separately, as it was still possible to access e.g. the documents, the upload function and even the sharing functionality, albeit without being able to complete it. The two timers (activity and sharing) should not be in conflict.
- An **indication of the activity timer could be beneficial**. One participant specifically asked if something like this was in place (IP8_1on1), another participant (IP7_1on1) showed frustration when getting the time-out error message without prior warning, which stopped her from continuing with the upload process. IP7_1on1 clearly expected a message warning her about the timeout coming into effect, which basically locks her out (and nevertheless asks her to do an action, logging out and in again).



- IP5_1on1 would have expected to have a function/button through which he can avoid having to go through the logout and login procedure, as this caused trouble in itself.

Log-out was not intuitive

In line with the issue regarding the 10-minute timer, the log-out process that had to follow from not being able to share was perceived as difficult. The participants did not immediately find the log-out button but had to look for it.

- Given that this is a mandatory action if one wants to share something and that it also could be a cause of stress in a situation of wanting to share with an HCP in their practice, the users should be supported better. Log-out should either be **easily findable**/be more visible or users should be **prompted/led to log-out** directly from the error message.
- One participant (IP8_1on1) was unsure if this message had now stopped the process or if something has been shared after all.
- Several participants tried **reloading the page**, in the expectation that this action would bring them to the log-in page, as they assumed to be logged out from all functionalities, as they were asked to log out and in again. They were surprised when they realized that they could still e.g. upload data despite the error message that they interpreted as affecting the entire platform (e.g. IP8_1on1).
- When the log-out was done, it caused confusion why they are directed to the start page with the carousel not the login page, and why on the (next) login page the visual emphasis on the larger 'create account' button instead of the smaller login button, although the app asked to do that action.

Account management

In line with the difficulty of finding the logout button to re-login after being locked out of the sharing process, the area of account management was not easily found.

- When looking around and clicking on the Menu icon, IP8_1on1 for instance would have expected to see more clearly a section for "My Account" or at least one where the icon is bigger – after all she is in charge to control and manage it (and not someone else for her).

Documents were ordered differently after re-logging in

After the documents had been re-ordered upon re-log-in, several participants started to wonder how they had been ordered beforehand, kicking off a discussion on ordering principles and preferred ways of the documents being ordered.

- There needs to be a clear way of **communicating how the documents are ordered** – it needs to be immediately obvious how they are ordered.
- Also, the participants wanted to be able to **define themselves how the documents are ordered**, e.g. alphabetically by name, chronologically by date, or by type – this needs to be investigated further, depending also on the different possibilities we will have. IP3_1on1 for instance voiced that it would be important for her to see the ordering logic and she, personally, would like to have them ordered according to date of upload, chronologically. In principle an



ordering mechanism that can be changed by the user themselves would be good, not the app defines it for whatever reason (that is unclear).

PIN for data sharing

Functionally, the pin exchange worked well, and our participants appreciated that the PIN process would also enable a sharing process where both parties are not co-present. Still, it took all our participants quite some moments to understand who needs to be sharing what with whom. The text that describes the action to be taken needs to be simplified and adapted to the practices (e.g. “scan the QR code displayed on his computer” would imply that the patient sees the HCP’s screen. This is not always the case). There are a number of reasons for this:

- The **direction of the information flow**, which the sharing process is based on, was unclear. It took the participants some time to understand who has to set which action, and who has to make someone else do something, especially in a situation with an HCP that they all defined as being pressed for time. IP8_1on1, for instance, initially interpreted the process as her having to ask the HCP to register. In IP3_1on1’s interpretation of the flow, the participant would provide the URL to the HCP and with this give their verbal consent for viewing and accessing patient data. This implies that IP3_1on1 assumed sharing process to be a simple one-way flow: the patient gives something – i.e. shares something – with the HCP. However, the flow entails a loop: the patient gives something to the HCP (the URL), the HCP gives something back to the citizen (the PIN), and the patient, again, gives something else to the HCP (the access to the selected health data). This process seemed counterintuitive due to the misalignment of expectation and implementation and was not immediately grasped.
- Another issue that came up was the question of **how this PIN sharing will be realized in practice** from the side of the HCP, on what device, with what kind of URL – that can actually be put in, as the link now is rather complicated. Several participants were already now thinking about workarounds (such as asking if one could not also send the HCP an email in order to avoid having to spell out the URL or showing the URL to the HCP on their phone), as the length of the URL was cause for concern. They had difficulty imagining sitting in an HCP practice and telling their HCP to access an URL, also because they were worried about typos, misspellings and – most importantly – the limited time that is available in public health care settings for one patient and that might be lost in this process. IP7_1on1 for instance was skeptical of asking the HCP to do an extra action.
- This links to another issue with this process, namely the **bridging** that citizens and HCPs are expected to do **outside of the app** (i.e. that HCPs have to be informed of and have to type in an URL on their own device), while the expectation was that the link is to be facilitated by the platform and the web app. Several participants were confused about what they felt was leaving the flow they are engaged with in the app, making their HCP do something, and again entering the flow in the app.
- IP7_1on1 (and IP5_1on1) for instance, was puzzled about having to **switch from the digital environment to a face-to-face interaction** and **depend on it to complete** what she is supposed to do with the app only, to **share digital data**. As the app implies the digital realm, having to leave baffled her. What would the



analogy to an online banking app be – relying on co-presence with the one who receives a payment? Why does it then need the app?

- The QR-code option caused confusion for all participants the, as it was not apparent that it, first, would appear on the HCP's device, and second, that they were supposed to scan it from the co-present device of the HCP.
- PIN temporality: Returning to the sharing screen after logging in again due to the time-out error, IP5_1on1 thought that the PIN he got told before the message appeared would still work. It was not clear how long the PIN would be valid and if there is a timer running on that too. The time-out error thus seemed to trigger such thoughts about what is running in the background but not visible to the user.

Revocation of documents

As they realized that the HCP might see this e.g. on their mobile device, some participants got concerned about security issues.

- While they assumed there to be rules in place upon **what devices HCPs are allowed to display/download medical data**, they were still worried that they may have to ensure that these rules are not bent, out of momentary convenience.
- After they realized that there is **no way for them to revoke the document** several participants expressed concerns about the whole sharing process itself. They expressed the clear need to be explicitly **notified of this** at some point before starting the sharing of documents.
- IP5_1on1 realized for instance only after sharing that it was the whole document with all attachments (x-ray images), although he wanted to share only one.
- IP8_1on1, for instance, pointed out that during the sharing she would like to have a revoke access screen at her disposal.

Sharing history

One clear expectation that was voiced by all participants so far was that there is a sharing history in place, so that users can at a later point inform themselves of what they have shared with whom and when.

- In general, they wanted to have **control over and reassurance of the sharing process** functioning as expected. They wanted to be able to check that they will indeed share the right documents before actually doing so, that they actually have shared the right documents, and that they have done so with the right persons/actors.
- One participant (IP3_1on1) She thinks this has to be a functionality for sure, because if the app does not show what has been done with the data, and it does not record any interaction with the data, it will feel as if the data disappears in a void ("im Nirgendwo"), however, if they have shared it with the doctor, the HCP will have saved it somewhere. The data being "**somewhere**" but having the feeling that they are "**nowhere**" does not match, impacting how the sharing process is seen.
- In the context of a missing sharing history, IP3_1on1 also voiced skepticism regarding the **anonymous and informal character** of the sharing process and, thus, sharing health data with a doctor. She wanted to be able to **record the**



doctor's name and practice, given that the doctor now would have the data as well – pointing to a form of reciprocity in the data flow: “It's not an anonymous doctor after all.”

- IP8_1on1 pointed out she would **expect to be notified** when the other one, the HCP, **downloads the shared document**, which she compares to a function in the app snapchat.
- Also, the option of seeing in that history clearly who actually downloaded which document or attachment was deemed important. For IP6_1on1, for example, it would otherwise remain unclear where to her data actually went.

Closure

For several participants, the sharing process remained somewhat open and the field informing about the success did not close the sharing process enough.


- One participant (IP3_1on1) for instance would ask the HCP if the sharing has worked, as for her the process was not concluded.
- Another participant (IP8_1on1) addressed the need to have a list (sharing history) where she can see with whom something was shared. Ideally this should be the page to which she is directed after ending the sharing session, and not to the share now page again. Seeing that share page again does not provide closure but gives her a feeling of unfinished business.
- Some voiced the expectation that they would be able to see a screen in-between (in terms of “do you really want to share these documents”) selecting documents and sharing them. Others expected to have a screen after the sharing process informing them of the documents that they have shared.
- More communication by the app in the critical moment of initiating the sharing upon PIN confirmation was requested. A message was expected that tells/shows the user (again) which data is now going to be shared and asks if s/he really wishes to do so with another button press.
- After entering the PIN, the user is taken back to the generic share screen, which some found awkward, as it gave the impression to just share more or again.
- IP6_1on1 expected to see a log about when what has been shared with whom, and thus be directed to a sharing history.
- For IP8_1on1 it was unclear if the access (to the HCP) remains open for longer. Thus, she would need and want to be informed beforehand about the sharing duration. More precisely, she would expect to see and be reminded about it at two specific points: before starting the sharing session (e.g. when reading about the process), and again before clicking on the PIN code confirm button, which initiates the actual sharing.

The sharing process, thus, can be improved and some steps could be added that ensure **transparency** with regard to what will be shared and to what has been shared and **closure** with regard to the fact that the process is now finished.



5.8 Making data available for research

The new set of URs presented in the following three sections continues the first set of URs that was established the first wave of co-creation in year 1. In the first wave citizens discussed provision of data for research in CCWs, thinking through different situations described on cards. The URs presented in what follows stem on the one hand from participants discussing in rUSEEs their potential future practices of data provision for research. On the other hand, we were also able to do first tests of an early version of connecting the citizen health data platform (CHDP) to the research platform (RP) and walk with potential future users through the dynamic consent process for providing data for research. Our in-depth investigation of providing data for research, thus, has only started and will be in focus of the co-creation work in wave 3 (year 3 of the project), which will lead to a further elaboration and expansion of the URs.

Situation 9: Considering data provision for research	
	<p><i>I am interested in making my data available for research and have learned that in the process of providing my data to the research platform the data is pseudonymized. This means that all data that could identify me (such as my name, date of birth, address etc.) is replaced by a combination of characters (a pseudonym). My personal data is stored separately from the health data I provide for research and remains under the control of a neutral institution. Researchers working with my data do not know my name and other person-specific information.</i></p>
<p>As a citizen contemplating to provide my data for research, I want to know</p> <ul style="list-style-type: none"> ... which of my data previously uploaded into the CHDP are eligible/useful for being provided for research, in order to continue. ... where my data will go, in order to assess the trustworthiness of potential recipients and local legal regulations. ... what the consequences of revoking my consent are on research that made use of my data, in order to know where my data might remain even if I revoke my consent. ... about the specific/concrete value my contribution could have instead of a generic narrative of helping (unspecified) others, in order to continue. ... how long my consent will be valid and if and when I will be asked to re-consent, in order continue the registration. ... know up front about the choices I have, in order to be able to decide quickly if I want to continue. <p>As a citizen reading the RP IC, I want</p> <ul style="list-style-type: none"> ... to be informed how long my consent will be valid and if and when I will be asked to re-consent, in order continue the registration. 	



... the compact view of sections to cover all important points and not see new ones appear under “more”, in order to feel well informed and trust the app.

As a citizen **consenting to using the RP**, I want to

... have visual clues that indicate clearly how far in the process I am, in order to feel guided and continue without frustration.

... have clearly indicated which selections are optional and which are mandatory, in order to build trust.

... be able to adapt my initial choices also after having consented to using the app, in order to make an experience-based decision.

Situation 10: Being re-contacted after data provision



When I gave my informed consent to provide my data for research, I also allowed to be re-contacted by Smart4Health. In this way I could be informed about broader scientific results of research studies or about incidental findings that are relevant for my personal health. I could also be re-contacted if researchers need additional information for their studies or to let me know about research projects/studies I may want to participate in.

As a citizen **providing my data for research**, I expect to be

... informed by the app about outcomes of the research that my data contributed to, in order to get potential direct benefits and to feel involved and valued.

... able to see how often it was actually used for research, in order to know I made a valuable contribution and stay motivated for doing so again.

Situation 11: Providing which data for research



I have been using the Smart4Health platform for a while and have collected quite a bit of data. There is a description of my conditions, which currently are being monitored, my current and past medications as well as a documentation of allergies and intolerances. In addition to the current conditions, I have also collected information on previous illnesses that I have had and have collected diagnostic results (lab results, X-rays and MRT images) including a genetic test. Also, I have uploaded some data I have generated myself through a wearable that tracks my posture as well as a pain diary that I have kept. I am now about to make my collected health data available for research purposes.



As a citizen **already having a Smart4Health/CHDP account**, I want

... the research app to show the same view on my documents, in order to select those, I want to provide and to feel that my efforts of organizing my data was worthwhile (also) for data provision.

As a citizen **providing my data for research**, I want to be able to

... select which of my documents I provide, in order to feel in control and satisfied with my contribution.

... to exclude sections/parts of my data that I do not want to provide, in order to continue with the provision of that data.

5.8.1 Insights on providing data for research from remote group discussion (CUC5, Aug)

Providing data for research was imagined as beneficial on a collective and individual level. However, preconditions were voiced **to consider actually providing data and getting imagined benefits**, e.g. incidental findings. For participants it was crucial to know and understand in a fully transparent manner:

- when and how anonymization and pseudonymization apply,
- how the research platform is governed,
- and what value their data has for whom and for which research purpose.

In principle, the participants agreed that there are benefits to be expected of providing data for research such as developing medications and making treatments better – however, only under the condition that they would be able to remain anonymous. These benefits could be collective, as well as individual, e.g. through the recommunication of incidental findings.

IP1_CUC5_2: „If something is not ok with us, it would be interesting to have a warning, and we (should) also get to know about this warning, (but), the institution does not know, that IP1_CUC5_2 or IP3_CUC5_2 struggles with any kind of problem, so that anonymity stays preserved.“

While it was clear that an information flow between researchers and individual users is difficult to realize while upholding the principle of anonymity, the platform could act as facilitator of anonymity; while they saw it as enabling the relation, they also saw it as providing a buffer, an extra layer of protection between citizens and researchers, to protect citizen's anonymity. So, while the platform enables the data flow between citizens and other actors in the health care and research areas, in their reading it also puts in place a protective shield (IP3_CUC5_2: “the platform as element of security in data exchange”).

IP3_CUC5_2 pointed out that the platform needs to have a robust structure and process for those wanting access to the data (IP3_CUC5_2). Platform governance and its accessible explanation was seen as crucial for data provision for research. Transparency, again, was a crucial term here, meaning that the process of pseudonymization/anonymization is made clear and understandable. While IP1_CUC5_2 for instance showed understanding for the need to have access to



additional data (e.g. age, region, ...) in order to better interpret medical data, this again should be possible by going through a formal process of application, again speaking to platform governance.

For these participants, information was crucial and transparency the way to go towards motivating people to provide their data for research. They all agreed on the importance of informing citizens about the importance and relevance of data for medical research and treatments and that this will make it obvious that providing data for research is a good thing.

IP3_CUC5_2: "I think the secret lies in the information and informing the user, because it is that, if a person may not want to share the access to the data, but it turns out that the data are important and relevant, then I think that the person will change its mind."

The participants did want to have specific information, though. They wanted to be informed about the research purpose, what the data will be used for and what kinds of institutions would be allowed to use the data they have provided.

IP2_CUC5_2: "I think, the most important thing of the app will be that people are always well informed and well instructed, what information will be used for, for which kind of research, for which kind of purposes and for which institutions. I think, if people are well informed, there will only be few who do not want to share their data."

5.8.2 Insights on providing data for research from the one-on-one engagements (Citizens in Vienna – September/October)

Whereas **encountering visual clues** was appreciated, they did not meet the anticipated functionality or outcome, e.g. dots as indicators for the upcoming steps in the consent flow, or being able to write in the signature field directly (without having to first click a button).

Similarly, **having compact and expandable sections** of the consent was appreciated, but caused surprise if the latter contained significantly more content than the compact view.

A core topic and ultimately a precondition voiced for considering provision of data for research, was **being able to decide what data is shared to whom and for which purpose**. Within the consent process it was also crucial to identify quickly which options are mandatory and which optional.

Participants voiced a central **discrepancy to the CHDP in choice**, as it provides plenty and requires activity in creating, ordering, managing health data, all of which seem absent in the app for providing data for research.

In testing the synching of the platforms, **more feedback/transparency by the research app** was required before the process starts, to know which data will be synched, as well as receive information on what has been synched or not. Also, the **consequences of revoking consent** still remained unclear.



Imaginations of providing data for research were often related to the **potential benefits** that might return to citizens. These implied that they as providers of data are also kept in the loop regarding how the data actually got valuable.

Finally, the place of using an app for such a sensitive topic like providing own health data for research was imagined to not happen on the go but rather at home, and thus implies also **using other devices than a mobile device**.

Separate App

It first needed explanation that it requires a switch out of the browser to a dedicated mobile app, although the provision of data for research is a functionality of the Smart4Health platform. As the current go-live version of the user portal does not yet have a section or menu in which this functionality is visible, it required verbal communication and guidance to the app (on the tablet's home screen).

Dots

While it was appreciated that the dots indicated how long the consent process would last (which the participants assumed to be the case), they were also cause for frustration especially when the expected process based on four dots and the actual process do not align.

- Several participants voiced the expectation (and voiced appreciation) that the **four dots would represent four steps**. The frustration came when they found the process to contain more steps than four and when they were not even able to distinguish four categories with additional subsections.
- For IP4_1on1 the dots also gave the impression of being able to swipe to the next page(s). Only the unresponsiveness to the gestures gave way that this action is not possible.
- As the overall lengthiness was only apparent in the process, it was expected to be made aware of it upfront and be shown throughout how much remains to be read.

Extended view

Our participants were content that there was a compact and an extended view and they happily clicked on “More” to learn more. However, upon extending the compact view most of them were startled when they saw the amount of text.

- The amounts of text in the extended and compact version need have an **appropriate ratio**. The compact texts should not be devoid of meaning or be too vague, just because they are short.
- The **text** of the extended and compact version itself should be **aligned well** content-wise. The extended text should actually an **expansion**, not an **addition**, i.e. it should not introduce entirely new aspects that were not addressed in the compact version. The short version should give an indication on what will be communicated in the long one.



- Some also wondered about the amount of blank space around the long version, as the screen's real estate was not made use of.

Signature

- Several participants tried unsuccessfully to sign the consent directly on the page where the signature function is initially presented.

Choice

Having a choice for the participants meant to have the opportunity to select and deselect data for provision for research.

- IP1_1on1 voiced the expectation of having a consistent choice regarding what to share, similar to the process within the sharing functionality of the CHDP. From this participant's perspective, specific things, should be deselected (preexisting condition, family history, citizenship, personal data, ... things that are not necessarily health data) and he would expect options to decide what to share. While in the case of sharing with an HCP the selection process should be more detailed in principle, in case of providing data for research he wanted the process to be more streamlined albeit with the option of detail.
- IP3_1on1 saw a **discrepancy** regarding the **specificity of choice** that is inscribed in the CHDP as opposed to the RP. While in the CHDP the user has great choice in terms of what to upload and what to share, there seems to be no choice in the RP, but the implication is that everything has to be shared.
- Interestingly enough, IP3 pointed out that she would then already in filling the CHDP decide what could be shared later and limit what she uploads or leaves on the platform, in order to **control what gets provided for research** and what does not. This means that at some point in time, choice will be enacted – if it cannot be done in the provision process, then it will be done beforehand.
- IP4_1on1 realized only at the very end of the entire flow/process, when syncing to her CHDP account, that it is not possible to select the files for being synced, which simply amazed her.
- Not having such choices of de-/selecting data for provision for research also raised concerns of the scope of citizen participation, of what citizens can actively contribute and thereby feel involved. Otherwise this could lead to an impression voiced by IP2_1on1 that one is only needed to say 'Yes' to the data provision.

Having a choice was also associated strongly with being able to select the research purpose.

- IP4_1on1 did not understand why she was not offered a choice, which is not what she thought it would be. For her it is clear that this non-optional should be mentioned upfront, and not on some page down in the process.
- A comparison made in this regard is "shooting data in the cloud", in the sense of not knowing where data will go to.



Being presented with choice required to also know which decisions are mandatory or optional to make, and have the app present this clearly/transparently.

- When IP4_1on1 saw for the first time that it was mandatory to press/slide a certain button to even proceed to the next page, she instinctively repeated that action on the next page with the same button layout, although it was an optional decision yet not a trivial one.
- The clear expectation was voiced that the app should indicate which selections are mandatory, and which optional, whether through different layouts or additional signifiers (e.g. asterisk).

Recipients

An information asked about was who will have access to the data that is going to be provided (in theory).

- This information about who can and cannot access provided data was said to be crucial for even just considering the option of data provision for research.
- Also explaining the principle of researchers accessing the RP with regard to a specific research topic did not alleviate this issue.
- What is then still needed is information about who will not be granted access, e.g. MA or BA students, as well as companies in general (without further specification).

Provision

It was difficult for participants to understand why some documents were not shared and not others and, crucially, which ones they were.

- They were **missing feedback** as well as something of an **error message** that would inform them of why some documents did not go through and point them in the right direction if they wanted to solve the issue (i.e. to explain what could be done, if they could try again, if someone could be contacted, ...).
- For IP1_1on1, **closure** of the process was explicitly **missing** the participant felt stuck half-way through.

Receiving benefits

Providing health data for research was often associated with receiving individual benefits and questioning what that could mean within a frame that emphasizes the participation and empowerment of citizens. The situation of being re-contacted after data provision for instance triggered imaginations of learning about the outcomes of studies that used the provided data, and thereby how that provision became of actual value. This, however, was already based on two assumptions. First, that citizens are able to decide, and thus know, into which areas of research their provided data will concretely flow to, and second that their health condition is related to that research topic. As a participant summarized in comparison to another cloud service:



IP2_1on1: “Just to say ‘take my drobox and data, and look what things you can find’ is not enough for me to feel good after it [the data provision].”

In case of IP2_1on1, also an empowering effect of such returning study outcomes was imagined by being then able to talk to her general practitioner in a different way, based on the gained knowledge that her doctor might not even have yet. The imagined reciprocity and empowering effect thus were based on being able to decide which data can flow where. This form of control was also appreciated in the imagination of being able to just say ‘No’, if requests for additional data might return.

Generally, the overall promise of being able to contribute to research implied for citizens that they are kept in the loop somehow, whether through outcomes of research studies or some feedback by the app on how their data provision actually got valuable.

Research App and seeing the life through the frame of health

IP3_1on1 questioned the app being the right tool for what should be accomplished and drew on her own experience in using apps.

- Her association of app points to the expectation of it being used while being mobile, on the move.
- Given that she understands dealing with personal health data as a **serious business**, deciding on providing data for research is not something she would quickly decide while being on the move. Instead, she would rather do that in a **safe space at home**, where she has **time to read** through it properly. For her this would make more sense to be **done on the computer** – not quickly (‘schnell einmal’).
- ‘Data and health’ also is a specific topic, which she does not want to have to engage with it all the time. She deals with health issues if something comes up, but **does not want to constantly look at her life through the frame of health**.

Duration of provision

An information needed in advance, before signing up, is what the consequences of withdrawing consent would actually be, which was entirely unclear.



6 Professional user requirements

As outlined in section 3.3.3. we collected input from partners on the sharing process and conducted remote one-on-one engagements with HCP and hospital partners in order to formulate a set of professional user requirements (PURs), covering doctors and medical professional bodies.

In what follows we will first present a table that summarizes the responses received by HCP partners to a set of questions (each inserted in the section's heading) about current everyday practices of sharing data between citizens and HCPs in the respective health care environment of the partner (or of members it represents). UNIVIE ordered and condensed parts of the received input for readability of the overview, which has been approved by the respective partners.

Whereas the respondents are HCP partners, the set of questions stems from collective discussions in the MyTrusted UDC team (in task T1.4) pertaining to the sharing functionality – whether with HCPs or other trusted persons. Following these discussions, UNIVIE initiated a feedback loop amongst the UDC team members on the narrative description of this UDC/functionality, to collect points that were deemed needing clarification. Particularly on the basis of such input received by D4L and UNINOVA, UNIVIE formulated the set of questions for HCP partners as guide to collect responses out of their practice and experience, before any Smart4Health implementations.

The resulting better understanding of current sharing practices by citizens and HCPs in different contexts then not only contributed to the UDC progress, but also to preparations by UNIVIE for the engagements with HCP partners and the following formulation of PURs.

In a second step, we will provide with a list of the PURs that were formulated.

We will end this section with a brief summary of the main insights from our one-on-one outlining a number of problem areas that the HCP and hospital partners identified with regard to data collection and sharing, which need more attention in the further course of the project.



6.1 HCP perspective on sharing practices (without Smart4Health)

Table 1 - HCP partner Q&A on sharing practices.

HCP partner Q&A on sharing practices (before Smart4Health)	
HCP partner responses	1. How does a citizen find out what data to bring? What happens if data are incomplete or missing? What do you ask citizens to do? What clinical data do you/does your institution usually collect yourself anyway?
EASPD Member organization	<p>At start of a vocational training in “MARGARITA”, a member organization of EASPD, written consent is required by the citizen/beneficial for sharing his/her medical history with the institution.</p> <p>Another form of medical history, the “Health Summary Sheet” needs to be filled in, which asks for full name, date of birth, weight, special diet, and chronic health problems (e.g. allergies, mental disorders, etc.).</p> <p>If information is missing, the beneficial and caregiver is contacted about required data. The Health Summary Sheet needs to be updated at the training start.</p> <p>Throughout the training, record is kept on: every drug that was given (when, to whom, dosage, reason), and absences related to symptoms compatible with COVID-19 (e.g. start of symptoms, date of return).</p> <p>The psychiatrist–scientific director keeps detailed record of every session, together with other medical data of the beneficiary - all are kept in written form, in accordance with the regulations governing medical confidentiality in the Code of Medical Ethics</p>
EFN	<p>Not EFN but frontline nurses are using/collecting health data, and tell/ask patients to bring data required for planning the care process.</p> <p>Also sensitive data is collected, depending on the care context, and patient’s health status and needs. Sensitive data as in the eNursing Summary Content, e.g. allergies & vaccinations, devices used, diet, etc.</p>
ISMMS	<p>When a patient is new to Mount Sinai, they first sign the Mount Sinai Notice of Privacy Practices, which delineates all aspects of data privacy. An EHR is created for the patient and they may create a patient portal account to access their EHR information.</p> <p>The patient can supply existing health records to Mount Sinai via PDF or paper (e.g. a vaccine history), additional information that may be needed is asked by the patient at time of visit.</p>
OSR	<p>The citizen brings all paper files regarding medical history and usually the most recent imaging examinations. The doctor writes a past anamnesis with a synthesis of all the medical history of the patient, and may also copy the most relevant paper of the medical history.</p>



UKA	<p>Citizens bring their data, saved on their health insurance card (demographic data, partly medical history, e.g. medication) Citizens sign an informed consent sheet on current and future data Clinical data collected depends on the reason of medical treatment/check and is stored in the so-called “FallAkte Plus” – for secure doctor-to-doctor communication Files stored in FallAkte Plus are e.g.: admission letter, redundancy letter, and medication plan.</p>
UMC+	<p>Patients are asked to bring referral letter, medication list and, if the first encounter, an ID. All other information is asked later. If incomplete, the patient or referral physician is asked to complete. In an emergency, data from the ambulance is collected. At inpatient intake, the medication is collected in LSP (laboratory specific tool). Patients can log into their account at the hospital, to consult personal medical data, lab results, investigation results, correspondence documents and appointments via a DigID</p>
ZS-UG	<p>At the orthopedic the patient receives a treatment plan for the therapy, and a prescription to bring to the HCP. If data is incomplete, the HCP gets in touch with the orthopedic (in the same building). At the HCP, the patient needs to fill out the general data protection protocol of the HCP and hand out the prescription. At the MedX machine, data is collected to conduct the training (gender, name, date of birth, weight, height, pre-existing conditions) During training on the machine, data is stored in its software, and the test is printed out for the patient, to bring to the next appointment with the orthopedic to discuss next steps like suitability of the training</p>
<p>2. How does a citizen share a medical history when arriving at an HCP they are not yet a patient of? In which formats?</p>	
EASPD Member organization	<p>The nurse and psychiatrist–scientific director have access to all the above data. These are shared only if necessary with the “MARGARITA” scientific and educational personnel (educators, psychologist, social workers, occupational therapist) who interact directly with the beneficiaries, only for matters concerned to their work.</p>
EFN	<p>There is no common format of sharing health care history, hence the need for interoperability.</p>
ISMMS	<p>If a patient has multiple physicians at Mount Sinai, they may choose to share additional health information to that doctor by sending them a secure direct message in the patient portal (MyChart) with an attachment and/or written note. The doctor may add this information to the patient’s full EHR if deemed useful, through a clinical note (unstructured data).</p>
OSR	<p>The patient usually brings paper records. If he/she has performed imaging studies he/she also brings CDs with the imaging examination or radiograms accompanied with the paper, with the report.</p>
UKA	<p>Other hospitals besides UKA cannot access FallAkte Plus without permission. In select cases, regional partner hospitals can register to retrieve access (shared data agreement).</p>



UMC+	Done in non-acute situations, using paper print, fax, pdf, TIPP, from referring doctor, further information is shared via scanned/printed files – both are attached to EHR in pdf. Larger files are shared on CD/DVD from referring doctor. Images come also via EVOCS (online system), or systems used with hospitals or family doctors.
ZS-UG	The patient shares with HCP the medical history if the orthopedic provides a document, otherwise tells about the back problems/issues. The HCP collects only name and phone number when the patient registers.
	3. How does a citizen share data that is relevant to a particular medical specialist, e.g. an oncologist or gynecologist? Are there discipline-specific patterns of what is desired in each field, which could be used to suggest the user what to share?
EASPD Member organization	In the case a beneficial requires further medical evaluation (e.g. due to the presence of a symptom), the beneficial’s judicial supporter is informed, upon his consent, via phone by the nurse, the psychiatrist, or the social worker.
EFN	Discipline specific sharing is mostly covered by the eNursing Summary Content, advance care nurses might ask for more specific health data re co-morbidities
ISMMS	Specialists may focus on certain elements of the EHR, but they would be able to access any data points in the entirety of the EHR. Generally, all doctors in the health system have the same access to all of data.
OSR	Actually there is not a discipline-specific pattern of what is desired in each field, in fact usually every patient shares his/her medical history bringing papers of digital supports for imaging studies.
UKA	Patients can access their personal health data via the so-called HITSSafe App or UKASafe App. So far, they cannot share data with another HCP at UKA.
UMC+	Generally, this is done on paper from the referring specialist. More specifically, each specialism or case can differ
ZS-UG	The HCP cannot share the test with any medical specialists, like the orthopedic, and only print it for the patient
	4. What are best practices for sharing data with others, in a way that doesn’t affect relatives (cf. genomics data)?
EFN	Patient IC, to abide to the GDPR principles, and to only share the needed data for each occasion
ISMMS	Under HIPAA, it is required that practitioners/medical professionals only access patient data when/if they need to (e.g., they should not look up a patient that is not <i>their</i> patient, unless requested by another medical professional for advice/second opinion, etc.)



OSR	Genomic data or other sensitive data are shared with the patient through papers, which reports the examinations results. Only in the case of hospitalization and only if the patient requests, the medical reports can be obtained in a digital format (CD).
UKA	FallAkte Plus is a TÜV-tested electronic collaboration platform for secure doctor-to-doctor communication with certified data protection and supports the IHE-compliant specification EFA 2.0
UMC+	No best practices in hospital (perspective IT, and ICU). Raw genomics are not often shared, when necessary on DVD, interpreted genomics data (report) on paper print or PDF from referring doctor. Raw datasets are shared only with one other hospital.
	5. What regulations do exist that specify how to share data among two parties, e.g. in terms of duration of the sharing relationship, right of the recipient to make copies (“download”) the shared information, technical restrictions, etc.?
EFN	While the GDPR does not specify how to share, it regulates the way data may be exchanged, collected, used, donated, and, in case of a general care nurse, that only the needed data would be shared between patient and nurse and kept for a minimum of time.
ISMMS	It is the patient’s responsibility to choose who to share the data with (e.g. with a family member). If chosen to share the EHR with someone outside the Mount Sinai system for a limited time, one may do so via MyChart. This enables them to write clinical notes (but not add/change the existing record data). A physician or clinical professional who can access the data is not allowed to download it to a personal device or misuse the data – it must stay behind Mount Sinai firewalls, etc. in order to maintain HIPAA compliance.
OSR	By law the hospital should keep clinical information of patients at least for 10 years in paper format (in a repository under limited and controlled access). The same information is usually kept in the digital cloud of the hospital, available for consultation by all hospital doctors, through the hospital medical management software. By law when admitted to the hospital the patient can request to keep his clinical information secret and available for consultation only by few doctors who are in charge of his/her healthcare management. Of course in general by law a doctor is not allowed to share medical information of a patient to third parties unless the doctor is in charge of the patient healthcare and he/she needs another doctor’s consultation.
UMC+	Regulations are not general, but evaluated case-by-case if and how data are transferred – the goal is important, decisions are taken by the director’s board.
	6. What are the regulations for sharing data with the Medical Officer / Company Medical Officer (German: Betriebsarzt) in an employee/employer relationship?
ISMMS	Regarding sharing data with the employer, it is up to the employee to choose to do this.
OSR	For a doctor, every data regarding a patient should not by law be shared with other people different from doctors who are in charge of the patient’s healthcare and unless this is done for a necessary consultation.



UMC+	Company Medical Officer gets indication to contact an employee and asks for medical details in the encounter – no medical data exchange between the hospital and the Company Medical Officer
ZS-UG	None of the data from the citizen is shared with the CEO, who, however, gets an anonymized overall evaluation regarding training effects/back health



6.2 Professional User Requirements⁵

6.2.1 Collecting health data

As a researcher working with data, I want citizens to be asked only to self-report on items they really have knowledge of, in order for data to be reliable.

As an HCP, I want to know where the medical history came from/how it was assembled (self-assembled or professionally assembled) so I can trust the quality and the value of the information.

6.2.2 Sharing health data

Accessing data

As an HCP wanting to access a patient's data, I want to put in a simplified web address, in to order not lose time that I have available for my patient.

Reliability of data that is shared

As an HCP, I want to be sure that the data I am being shared with has not been edited by the citizen in order to be able to take responsibility for my diagnosis.

As an HCP receiving the medical history, I want to know if and which data are citizen-reported in order to treat them accordingly.

Medical history

As a doctor, I do not want to be put in the situation of having to support patients in filling in their medical history, in order to keep focused on what I see as the core of my work.

As a doctor accessing a patient's medical history, I want to view only medical diagnoses and doctors' letters and not patient-reported diagnoses, in order to work with reliable health data.

Document View / HCP side

As an HCP looking at the medical history (on a computer screen), I want the information to be organized in an accessible, well-structured way in order not to spend too much time looking for data.

As a physiotherapist accessing my patient's medical history, I want to know when the diagnosis was received for the first time and if it is still acute.

As an HCP looking at data, I want to see metadata that adds information to the document and to the attachment, e.g. the date of examination, upload date, institution etc., as I want to know where people have been and when in order to interpret the data.

⁵ While nurses are included in the category and PURs of HCPs, there are some PURs specific to nurses that are formulated as such.



As a doctor looking into a patient's document, I want to have a well-structured preview and order of shared files and their meta data, in order to quickly assess their content and work effectively.

Naming of Documents/Attachments

As an HCP having data shared with me, I need the documents to be named in an understandable way so that I can immediately recognize what it is that I am looking for.

As an HCP accessing a patient's documents, I want the document titles to be translated into my selected language as well, in order for me to understand what they refer to/what they contain.

Engaging with documents

As a nurse looking at a patient's health data, I want to have filtering options so that I can quickly find the data that is relevant for the care situation and do not have to go through the entire set.

As a nurse using the platform on a tablet, I want the picture to maximize by default when I click on full screen so that I can see it as large as possible and do not have to spend time on zooming in.

As an HCP I want to be able to select attachments within a document for download, in order to only download citizen data that I really need.

As an HCP looking at data with my patient, I want the data to be displayed in a similar manner as on the patient's device so that we can point to specific issues. (patient interaction)

As an HCP I want the citizen to be able to select specific documents/attachments to share with me, so that they only share with me what I need in order to not waste too much time going through too many documents/attachments. (patient interaction)

As an HCP I want the citizen to be able to select a timeframe for the documents to be shared, so that I only get the selection necessary for an assessment of the current situation.

As a nurse telling the citizen what data I need, the citizen needs to be able to straightforwardly be able to identify the data that need to be provided. (patient interaction/need for simplified categories)

Log-out timer

As a doctor accessing my patient's documents, I do not want the sharing process to be interrupted by a (citizen-facing) timer any earlier than after 20 minutes, in order to not be stopped during working with the documents.

As a doctor accessing my patient's documents, I do not want to be dealing with (prolonging) a timer, as I do not want to work under anyone/anything else's time constraints/in order to take the time with the patient the way I see fit.



6.3 General insights from HCP/hospital partner engagement

The main issue as it appeared in the engagements with the HCP partners so far is the assessment of and working with citizen-generated and collected data. This seems to stand in tension with the data practices prevalent and the requirements for the quality of the data to be provided to HCPs in the situation of interaction in the practice setting and beyond. Citizen-generated data refers to the data that citizens manually upload (documents and attachments), generate through their own descriptions and classifications (medical history) and manage in different areas of the platform. It includes the upload of unstructured data into what is called documents, whereby multiple attachments can be uploaded into one document. It also includes the generation of structured data by filling in different sections of the medical history (personal data, conditions, risk factors). This citizen-generated data can then be shared with the HCP and, if applicable, provided for research.

At this stage, the upload and data generation processes include that citizens manually provide specific descriptors of the data – either through open fields or through the selection of predefined categories.

- Documents (My document; Medical document)
 - *Open fields*: Title, Doctor's first name, Doctor's last name
 - *Predefined category to select*: Document category (e.g. doctor's letter, lab report, ...), doctor's specialty (e.g. Adult Mental Illness, Clinical Immunology, ...), date
- Attachments (unstructured data)
 - The system uses the file name of the attachment as it was named by the citizen outside of the Smart4Health platform. This means, that if the citizens download a lab report from somewhere that is named following the lab's naming convention or if they scan it with their own scanner, the attachment will carry that given name also in the platform and will be shown to everyone it is shared with (in their preview via mouseover and when they download it).
- Medical history (structured data)
 - *Open fields*: First name, last name, occupation,
 - *Predefined category to select*: Gender, blood type, blood type RH factor, Conditions (e.g. Abdominal and pelvic pain, Abnormal findings in cerebrospinal fluid, Acute myocarditis, ... plus date of diagnosis), date of birth
 - *Other*: Weight & height (produces BMI), risk factors (Y/N)

6.3.1 Time

The role of time appeared in all conversations about the sharing process we had with the HCPs. When they saw the data that had been shared with them, the question about **filtering** possibilities appeared right away. Nurses, for instance need less detailed information, but they need it very fast – filtering the data, here, is perceived as essential.



For the case that citizens have shared a great number of documents, it needs to be possible to filter and arrive at only those that are relevant for providing care and not having to go through all of them, losing precious time. One crucial filter possibility/share function was according to specific body parts.

The **document view** on the HCP side needs to be well-structured, so that one knows immediately what is to be found where and does not invest valuable time in searching. For instance, the preview should be more strongly structured, differentiating better between document level and attachment level, underlining the entity of the document on the one side and the coherence of the thumbnail of the attachment and its preview. The incoherence of the attachment names that is shown via mouseover was identified as problematic, adding to a difficulty of grasping what has been combined into a document. As the attachment's name when downloaded is important, one idea was to not keep the name that the user assigned, but automatically assign a new one. This will be explored in more detail.

Finally, all conversation partners identified the function not being able to share documents beyond **10 minutes after log-in** as problematic. There are a number of reasons for this: there can be delays and the patient needs to wait, as the HCP needs to briefly leave and attend to an emergency, sometimes there is a back and forth looking at different documents at different points in time or something additional comes up, so the patient is supposed to provide another document. A time of 20 minutes was seen as more adequate to cover most document-based engagements.

6.3.2 Medical history

The anamnesis should be seen as a conversation starter. The self-filled questionnaire of **risk factors** could be supportive here, but the questions need to be simplified so that citizens can actually answer them, such as “Do you have family members that have cancer?” Or “Do you have family members that have died from cancer?” In the status quo, the questions are posed in a way that doctors could answer them if they had the results already, but the citizens might not be able to provide the appropriate answer (such as the question “Have you ever had high levels of blood glucose?” in the *Risk factors* of the Medical history) and might thus produce structured data that is flawed. We thus will have to reflect if the expectations (of HCPs) change when the anamnesis is done in digital form as opposed to the paper a prospective patient fills in when going to a new doctor.

The **list of conditions** that citizen can choose from themselves should be substantially simplified. The drop-down list of existing conditions was perceived as too difficult for citizens as it uses medical terms that most citizens do not understand and also the purpose and audience (Medical? Scientific?) of the information was not clear. The categories need to be simple for the citizens to choose from, valuable for the HCP and for researchers alike. We need to look into ways of facilitating citizen's choice to define what their conditions actually are without providing them with too much detail. The imagined user here is a citizen-patient who is capable of accurately representing their diagnosis by choosing the right category and by recognizing/remembering it at a later point in time. We find a divergence between citizens expecting the HCP to articulate the correct diagnosis and treatment, while the expectation is that citizens should fill this in by themselves, which may result in a condition list that is not workable. While it was seen as very positive that a search function has been implemented within the condition



list, citizens need to be supported differently in their articulation of their condition, because otherwise they will require the support of the HCP in completing and validating their medical history, a role that one of our conversation partners clearly refuted.

For one of our conversation partners in particular, the assumed **role of the citizen-generated condition list** was unclear. He constructed the anamnesis as a shared endeavor between HCP and patient, whereby the HCP poses questions to the patient and the patient responds, drawing on the patient's lived and embodied experience, conveying concerns and fears. The HCP draws on their professional experience in working with patients' verbalizations and leading the patient in specific directions through further questions. Through this interaction, they arrive at a point where the HCP can then ask for specific prior diagnoses, results etc., which would be the starting point for the sharing process. In this sequence, there was no space for citizen-generated conditions. To summarize, the relevance of the condition list for HCPs was questioned, since the completion seemed too complex for citizens and doubts were raised that it would produce something that is usable without HCP assistance as the conditions are not connected with results.

6.3.3 Data categorization

One main point was that the HCP has to immediately understand what has been shared with them. The **title of the documents** was perceived as a potential problem in this context. Given that citizens name documents themselves when they upload unstructured data and the HCP sees a list of documents, the question came up how the HCP would be able to quickly identify what a document actually contains. While in a consultation situation it may be possible to obtain this information by asking the citizen, the titles should already carry the information of what the documents contain, especially in a situation where an HCP needs to go through the data faster.

A very important issue here is the appropriate **categorization of data**. HCP voiced the concern that citizens will find many different ways of organizing their self-uploaded data. In order to make this data valuable and usable, the ordering principles the platform invites the citizen to perform need to be clear and it needs to be assessed what effects this will have at the other end for those, who the data are being shared with. In the case of citizens uploading unstructured data or filling in conditions within their medical history, the categories that are offered to them need to be simple enough so that they can be understood. At the same time, they need to be inclusive and broad enough. If categories are too specific, there is the risk that the HCP may ask to receive data on a specific topic, but might miss information, as the categorization was not done in an adequate manner.

Thus, the available categorizations need to **make sense on both ends**: categories need to be meaningful and recognizable for citizens and HCPs alike. If uploaded data has been categorized appropriately and intelligibly and the HCP asks the citizen for specific data, the citizen will be able to tell if they are available and start the sharing process. If the categories used by the HCP and citizen do not match, this communication will not work. Categorization, here, serves as a crucial means of communication, however this would also mean that more categories are visible on the HCP side and that the data can be searched for specific categories.



The differentiation in *My document* and *Medical document* needs to be clarified. One initial association one HCPs was that *My documents* would refer to health-related data, while *Medical documents* were to contain self-uploaded health data. Clarification, thus, was required especially in terms of **document categorization** (i.e. document type such as doctor’s letter, lab report etc.) which, at the moment, overlaps and positions both document types in the medical realm. The date shown in the document view was perceived as unclear in terms of the point in time it refers to (e.g. the source date of a document, the upload date, automatically assigned, or the last time it was edited, which in itself was perceived as problematic).

6.3.3.1 Nursing Minimum Data Set (NMDS)

Following a discussion on potential ways of categorizing data so that it is useful for nurses in providing care, ENF provided an outline of a nursing minimum data set (NMDS) that could be integrated into Smart4Health. The outline of the dataset, was assembled by the ENF, taking into account the following:

- THE European Committee for Standardization
- ISO – Health Informatics
- International Patient Summary
- Health Level 7
- International Classification for Nursing Practice – ICNP

Table 2 - Nursing Data included in EU EHR to boost the continuity of care – e-Nursing Summary Content.

Category	Details
Personal information	<ul style="list-style-type: none"> • Full name • Date of birth • Gender • Primary language spoken
Blood group	
Allergy Alerts	<ul style="list-style-type: none"> • Transfusion related reactions intolerance
Vaccinations	
Resuscitation Code Status	
Admission	<ul style="list-style-type: none"> • Diagnosis • Complications <ul style="list-style-type: none"> ○ Active Problems ○ Main Complaint • Main Chronic Conditions • Lifestyle factors • Special needs
Autonomy	<ul style="list-style-type: none"> • Activity (ADL) • Invalidity • Fall risk Assessment



Category	Details
	<ul style="list-style-type: none"> • Cognitive abilities • Level of Consciousness
Health Assessment on Admission	<ul style="list-style-type: none"> • Vital Signs <ul style="list-style-type: none"> ○ weight (kg) ○ height (cm) ○ blood pressure (mmHg) ○ resting heart rate (bpm) ○ peripheral oedema • Lab values • Latest EKG
Pain Scale Assessment	
Wound Assessment	
Medication Summary	<ul style="list-style-type: none"> • List of current medicines • Oxygen Treatment Plan • Pain management
Devices Medical Devices and implants	
Nutrition	<ul style="list-style-type: none"> • Diet • Fluid Management
Procedure and Interventions	<ul style="list-style-type: none"> • Nursing care interventions • Isolation Procedures • Wound care management

This dataset is a valuable indication of how nurses collect and use patient data and an example for the potential classifications of data. It will serve as a starting point for future co-creation engagements between HCP/hospital and technical partners in the next wave of co-creation.



7 Performance criteria from the first and second wave of co-creation

7.1 List of PC established on the basis of the URs reported in D1.3

The following table presents in the left two columns the URs specified in Y1, for which during Y2 PC have been elaborated (two columns on the right) after having collectively evaluated and prioritized the elicited user requirements. It needs to be noted, that the URs and PC are embedded in the iterative PAcT process whereby the URs/PC move between requirements, integration, assessment & validation and documentation space.

As explained in section 3.1, PC emerge out of a fine-grained analysis of ethnographic observations, justifications and argumentations of citizens as well as other context relevant information which we produced through our qualitative approach. The PC first serve as guiding principle for implementation of the UR (i.e. what has to be provided for the UR to be fulfilled) and second as a means to assess if a specific UR has been implemented and to which degree (e.g. if all PC have been fulfilled or only some, or if a PC has been entirely fulfilled or only partially). Some of the performance criteria will be quantifiable, other will need more qualitative assessments by users (see also D1.3)

The PC captured in the following table, represent our starting point which will be refined in the process of the platform co-creation activities, development and testing. Some of the PC are marked in green to reflect their current status of being either partially (light green) or fully (dark green) implemented from a technical point of view. This, however, does not mean that the corresponding PC and UR is closed, but that an existing implementation speaks to the PC. Like other PC, they are part of the iterative co-creation process, in which citizen- and professional user input further shapes their content and implementation, and thus the platform prototype. Also feeding into this process are engagements for the validation and assessment of implemented PC.

Table 3 - PC based on Y1 URs.

UR No.	User Requirement	PC No.	Performance Criterion
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 to the uploaded data is explicitly addressed before a user has started the registration process.
		PC1.1.2	The access possibilities are explained in a clear manner and are easy to understand.
		PC1.1.3	Users need to have the possibility to ask questions before starting to register, in case doubts arise.
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	PC1.2.1	The procedures for deregistration are explained before registration has been completed.
		PC1.2.2	The consequences of deregistering for the uploaded data is explained.



UR No.	User Requirement	PC No.	Performance Criterion
	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.	PC1.3.1	Citizens can easily understand the scope of the project.
		PC1.3.2	Citizens can easily find a list of who is involved in the development of Smart4Health (linked, max. 1 click from IC/startpage)
		PC1.3.3	Citizens can easily determine who is funding the development of the platform (linked, max. 1 click from IC/startpage)
UR2.1	As a citizen registering for Smart4Health I want the Informed Consent Form to be phrased in short sentences and understandable terminology in order to make an informed decision that does not take too long.	PC2.1.1	The sentences and sections in the IC are kept as short as possible.
		PC2.1.2	The language in the IC has been cleaned of jargon.
		PC2.1.3	The IC has been translated to Simple English/Leichter Lesen.
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.	PC2.2.1	The risks of enrolling in and using the platform have been thoroughly explained.
		PC2.2.2	Strategies for risk mitigation have been thoroughly explained.
		PC2.2.3	The benefits have been thoroughly explained.
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.	PC2.3.1	Citizens can get in contact with the project consortium via an e-mail address that is monitored.
		PC2.3.2	Citizens can get in contact with the project consortium via a phone number that is monitored.
		PC2.3.3	Contact options via email and phone are provided in multiple languages.
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.	PC3.1.1	The flow of the upload process can be immediately understood: the start- and endpoint of the flow is clear as well as the (number of) steps to get there.
		PC3.1.2	There is textual and/or visual support information available at key moments of the process.



UR No.	User Requirement	PC No.	Performance Criterion
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.	PC3.2.1	HCPs have the possibility to upload previously collected data to the platform.
UR3.4a	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, with no scanning needed).		
UR3.4b	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.		
UR3.3	As a citizen wanting to collect my data on the 4HP, I want the HCP to easily upload data to 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 ⁶ .	PC3.3.1	The platform procedures fit with the workflow of the HCP, and ideally make it faster.
		PC3.3.2	With permission of the user, the HCP can upload data into the users's account without asking every time.
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.	PC3.5.1	Data coming from the HCP can be selectively accepted.
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	PC5.1.1	Option of selecting specific fields of structured data for upload is provided.
		PC5.1.2	Selection of specific fields for upload is remembered.
		PC5.1.3	Selection of fields can be changed any time.

⁶ Adapted for better motivation of the UR. Considering that Smart4Health constructs a health data platform for citizens, the process is conceptualized as such, that HCPs do not have their own account but that they can easily access the data the citizen shares with them as well as upload data to the CHDP.



UR No.	User Requirement	PC No.	Performance Criterion
	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.	PC5.2.1	Only the citizen user can enter the PIN from the sharing page into the app, and thus decide with whom to share.
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.	PC5.3.1	Option of having different areas for health data and health-related data is provided and can be selected.
UR5.4	As a citizen ready to upload my health-related data, I want my HCPs, whom I give access, to still take care of diagnostics, in order to not become responsible for this myself.	PC5.4.1	The presentation (e.g. visualization, location,...) of health-related data shall not give the citizen the impression of representing a diagnosis that replaces consulting an HCP.
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).	PC6.1.1	The citizen user can add meta data about a file's origin/context, to have it then be displayed to her/him in a way that highlights its confidentiality.
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 with a broad basis for making decisions affecting my health.	PC7.1.1	Users have the option to grant HCPs access to all data at once.
UR7.2	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.	PC7.2.1	There are fine-grained options available for granting data access to HCPs.
UR7.3	As a citizen sharing data with my HCP, I want to be able to define a time limit to access, in	PC7.3.1	Users are provided with different options to define a time limit of access.



UR No.	User Requirement	PC No.	Performance Criterion
	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.	PC7.4.1	There are different options available for access by HCPs.
		PC7.4.2	Citizens themselves define the access rights an HCP has.
		PC7.4.3	Citizens can check and adapt the access rights after having granted them.
UR8.1	As a citizen making available my data collected on the platform (previously: 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.	PC8.1.1	A read-only sharing access is implemented, i.e. data download to another device is not officially supported.
		PC8.1.2	A watermark (e.g. "read-only") is displayed temporarily across any document, if the user chooses the read-only option.
UR8.2	As a citizen making available my data collected on the platform (previously: 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.	PC8.2.1	Users are provided with options to select which documents they can share with someone else.
		PC8.2.2	Users are provided with options to select which data fields they can share with someone else.
UR8.3	As a citizen making available my data collected on the platform (previously: 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.	PC8.3.1	The PIN-sharing site/link informs the receiving end about no added implications than in the current relation of sharer and the person with whom data are shared.
UR8.4	Has been moved to S12 "Defining Emergency Information"		
UR9.1	As a citizen making available my data collected on the platform (previously: Smart4Health) to my partner, I want to be able to revoke these rights in order to	PC9.1.1	Citizens can see and immediately understand to whom they have granted access.
		PC9.1.2	Access granted can be revoked at any time before it expires.



UR No.	User Requirement	PC No.	Performance Criterion
	keep control over my data and to protect me and my data in case our relation changes.	PC9.1.3	Citizens can see and immediately understand for how long the granted access is valid.
UR9.2	As a citizen making available my data collected on the platform (previously: Smart4Health) to my partner or HCP, I want the process of revoking access to be easy and clear so that I can ensure that I share the right elements with them and correct mistakes quickly.	PC9.2.1	An option to deselect/revoke access is implemented.
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.	PC9.3.1	Citizens receive feedback/confirmation after having revoked data access.
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 provide data for specific research purposes are provided.
		PC10.1.2	Options to provide data for specific research purposes are clearly communicated/displayed.
		PC10.1.3	Different options for data provision must be easy to select.
		PC10.1.4	Data can be excluded from specific research purposes.
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.	PC10.2.1	Option to include data transfers to different locations is provided.
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.	PC10.3.1	Option to include industrial research as a data recipient is provided.
		PC10.3.2	Option to include academic research as a data recipient is provided.
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 life time	PC10.4.1	Option to provide data after citizen's death is provided.



UR No.	User Requirement	PC No.	Performance Criterion
	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.	PC10.5.1	Commitment of understanding of the non-alienability of health data is displayed in an introductory statement.
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.	PC10.6.1	Direct benefits of a specific data provision are outlined
		PC10.6.2	Indirect benefits of a specific data provision are outlined.
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.	PC11.1.1	When health-relevant research results are communicated, also a consultation by a qualified person is facilitated.
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.	PC12.1.1	Different data fields are provided for input of emergency information.
		PC12.1.2	A selection of data fields by the citizen is possible.
		PC12.1.3	Only some data fields are mandatory, others are optional.
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.	PC12.2.1	Option for consultation and to ask questions is provided.
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.	PC12.3.1	Option to select all health data is provided.



UR No.	User Requirement	PC No.	Performance Criterion
UR8.4	As a citizen contemplating access for my partner, I want to be able to link my account and my advance healthcare directive, in order to ensure that my choices outlined in the healthcare directive are respected and are not overruled by my partner. (reformulated for clarity)	PC8.4.1	Alignment with healthcare directive has been enabled.
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.	PC14.1.1	Access of others to data (via sharing) is logged.
		PC14.1.2	Access log is displayed for the citizen in a dedicated place.
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.	PC14.2.1	Those accessing data receive information that their access is logged.
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.	PC15.1.1	Deactivation of the account has been implemented.
		PC15.1.2	The collected data is kept when account is deactivated.
		PC15.1.3	Reactivation of the account has been implemented.
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 account (previously: profile) and with it all my data that were stored on the platform (CHDP) in order to have all my traces cleared.	PC15.2.1	Deletion of the account has been implemented.
		PC15.2.2	Deletion of all collected data (in the CHDP) has been implemented.
		PC15.2.3	Before deletion, all the collected data (in the CHDP) can be transferred/downloaded by the user from the platform in a structured, commonly used and machine-readable format.
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 account (previously: profile)	PC15.3.1	Before deleting the account, the citizen is informed about receiving a final confirmation (e.g. email, sms) when the deletion has been successfully done.



UR No.	User Requirement	PC No.	Performance Criterion
	and all my data have been deleted so that I rest assured that all traces of myself have been removed through the deletion request.	PC15.3.2	After deleting the account, the citizen receives a final confirmation, that the deletion has been successfully done.
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.	PC16.1.1	Implementation of options for selecting which data shall be deleted.
		PC16.1.2	The user has to confirm her/his decision for deleting 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.	PC16.2.1	Data deletion rights have been assigned only to account owner.
		PC16.2.2	Alignment with advance healthcare directive has been enabled.

7.2 Status quo of PC from this year’s co-creation activities

The development of performance criteria follows the five-step iterative process as outlined above (see Figure 1). Therein, the elicitation of user requirements is followed by a collective evaluation and prioritization in step three, such as in consortium workshops. Only thereafter, the full-fledged development of performance criteria for the new UR can begin in the fourth step, which is then followed by moving into the spaces for integration and validation. Therefore, the main activities in this year regarding the development of performance criteria is reflected above in chapter 7.1.

Thus, the performance criteria listed below are first preliminary formulations for selected user requirements elicited in this year’s co-creation activities with citizens and health care professionals.

Table 4 - New user requirements with performance criteria examples.

Situation 1 - Registration	
User requirements	Performance criteria examples
As a citizen registering for the platform, I want:	
... text only be presented in the language I selected at the start, in order to fully understand all features of the platform.	The language selection is prominent at the start before displaying content (e.g. carousel).
... to clearly understand the reason for each step to assure me and build trust.	On each step’s page it is explained why it is required and is of benefit for the citizen (e.g. two-factor authentication).



	Signaling colors are used coherently (e.g. red to indicate only missing or failed actions, not to also highlight text).
	Successful interactions with the backend are highlighted throughout the process in word and color in an affirmative genuine manner (e.g. for setting password, consenting, logging in, having created the account).
... to have direct support during the registration process without leaving the page I am on.	More detailed information on critical terms, phrases or topics is easily at hand for citizens when registering.
	Direct contact options are provided without having to leave the current page.
	Checkbox options for not understanding or agreeing to a point or process are implemented, which lead to support or alternative paths in the registration.
As a citizen having lost my password and registration key, I want:	
... to be able to access my account in some way, even if I forget my password and lose my recovery key (shared responsibility for recovery of data), otherwise I cannot upload sensitive health data to it.	The importance of the recovery key is underlined by further technical functionality than a checkbox only.
	Alternatives to a recovery key are offered and implemented.

As with the development of performance criteria for citizen user requirements, also professional user requirements (see 6.2) will follow the iterative process with an upcoming evaluation and prioritization step, particularly with HCP partners and their representatives in the consortium. This, accordingly, will ensure a solid foundation, based on which performance criteria for this year’s professional user requirements will be further developed.

Table 5 - New professional user requirement with performance criteria examples.

Situation: Engaging with documents	
Professional user requirement	Performance criteria examples
As an HCP I want the citizen to be able to select a timeframe for the documents to be shared, so that I only get the selection necessary for an assessment of the current situation.	Option to indicate and filter data type is implemented.
	Selecting a timeframe to filter files is implemented.
	Giving access to a batch of selected/filtered files is implemented.



8 Summary and final considerations

The objective in this deliverable has been to specify a second set of user requirements, to report how they were developed in different user engagement settings and to outline the process of following up the realisation of requirements through the performance accountability process.

In **chapter 3**, we first revisited our general approach to co-creation and, thus, our iterative process of developing of user requirements and performance criteria. This also pointed to the regular feedback loops needed to ensure a sustainable solution which does not only respond to technical requirements but is also socioculturally interoperable. We presented the process and result of a co-creation workshop with all consortium partners to collectively define a detailed timeline for the second wave of co-creation, in which the focus was on digital health in the workplace. For six of the eight CUCs we identified the user ecosystem and defined the methods to be used, as well as the technical developments to consider. Chapter 3 ended with a detailed description of our adaptations of the methodological approach due to the COVID-19 pandemic. We here outlined our user engagements in this wave of co-creation, i.e., remote User Engagements with potential CUC participants, one-on-one face-to-face engagements with citizens recruited in Vienna as well as remote one-on-one engagements with HCP and hospital partners from within the consortium.

Chapter 4 described the process of eliciting, implementing, validating and documenting User Requirements (URs) and Performance Criteria (PC) that we follow to ensure transparency and performance accountability. Here, we introduce the Performance Accountability Table (PAcCT) which we developed and employed in order to trace decisions and achievements along the project. This is essential to keep an overview of how outcomes of engagement exercises find their way into the design and development process.

In **chapter 5**, we present the second set of **citizen user requirements** and the insights that led to them. The citizen URs relate to specific interactions with the 4HealthPlatform (4HP): Registration, informed consent, authentication, collecting health data, collecting health-related data, workplace and health data, sharing data, making data available for research, being recontacted and data provision for research and choice. The URs were developed in engagement processes which either invited participants to develop visions how they would use the platform prototype once developed (projecting) or to test specific features of the platform prototype or a combination of both. The second set of URs contains **new URs** as well as URs which are connected to or reconfirm previously identified URs (in the first wave of co-creation, reported in D1.3).

Additionally, in **chapter 6** we outlined a set of **professional user requirements** with a strong focus on practices of sharing data, described our process of eliciting these requirements and presented insights that led to their formulation.

In **chapter 7**, we provided a list of performance criteria that were established on the basis of the empirical work performed in wave 2. We also provided some exemplary performance criteria for new user requirements that are based on this year's co-creation activities and that yet need to be evaluated and prioritized in an iterative process as outlined in chapter 2.



In the further course of WP1 we will continue to work with citizen users and professional users. However, in doing so, we will be able to work increasingly with the emerging prototype of the health data platform. This will allow us to continually refine existing user requirements and the performance criteria, to identify new ones as the technological development of the prototype advances and engage with our partners to prioritize URs and integrate them into the further development process. We will also see through the validation processes which start in parallel, which of the requirements can be seen as fulfilled. In addition to this, providing data for research will be in our focus in the course of the next year. These demands both engagement with researchers in order to better understand their needs when it comes to health-related data, while at the same time meeting the requirements formulated by those who provide their data for research. These will then be presented in form of further reports on user requirements and performance criteria in respective deliverables in M32 and 40.

Aspects of language translation, especially diagnoses and pharmaceuticals, will be addressed in WP1 in detail and user requirements will be specified during the upcoming reporting period(s), when users will have structured data ingested/uploaded to their accounts, e.g. by an HCP.

Additionally, the specification of additional requirements (e.g., aiming at permitting a citizen to retrieve the whole list of his/her health data, in compliance to the Article 20 of the GDPR (data portability)), will be also the focus in the next reporting period(s).



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List of Acronyms/Abbreviations

Acronym/ Abbreviation	Description
1on1	One-on-one
4HP	4Health Platform
App	Application
BA	Bachelor
BMI	Body Mass Index
CCW	Co-creation Workshop
CD	Compact Disc
CEO	Chief Executive Officer
CHDP	Citizen Health Data Platform
CL	Closure
COVID-19	Corona Virus Disease 2019
CUC	Citizen Use Case
D	Deliverable
D4L	Data4Life gGmbH
DoA	Description of Action
DVD	Digital Video Disc
EAA	European Accessibility Act
EASPD	European Association of Service Providers for Persons with Disabilities
EC	European Commission
EFA	Elektronische Fallakte
EFN	Federation Europeenne des Associations Infirmieres AISBL
EHR	Electronic Health Record
EKG	Electrocardiogram
ELIXIR-LU	Universite du Luxembourg
EU	European Union



Acronym/ Abbreviation	Description
GA	General Assembly
GDPR	General Data Protection Regulation
gGmbH	Gemeinnützige Gesellschaft mit beschränkter Haftung
GovMad	Secretaria Regional do Turismo e Cultura
H2020	EU Research and Innovation funding programme 2014-2020, Horizon 2020
HCP	Health Care Provider
HIPAA	Health Insurance Portability and Accountability Act
HM	Healthmetrix GmbH
HPI	Hasso-Plattner-Institute for Digital Engineering gGmbH
IC	Informed Consent
ICT	Information and Communication Technology
ICU	Intensive Care Unit
ID	Identification
IHE	Integrating the Healthcare Enterprise
IP	Interview Participant
IS	Issue
ISMMS	Icahn School of Medicine at Mount Sinai
IT	Information Technology
ITTM	Information Technology for Translational Medicine
I-VLab	Laboratoire Virtuel Europeen dans le Domaine de l'interoperabilite des Entreprises
KBZ	KnowledgeBiz Consulting - Sociedade de Consultoria em Gestao Lda
LSP	Laboratory Specific Tool
M	Month
MA	Master
NMDS	Nursing Minimum Data Set
OSR	Ospedale San Raffaele SRL



Acronym/ Abbreviation	Description
PAccT	Performance Accountability Table
PC	Performance Criteria
PDF	Portable Document Format
PIN	Personal Identification Number
PUR	Professional User Requirement
Q	Quarter
QDA	Qualitative Data Analysis
QR	Quick Response
RH	Rhesus
RP	Research Platform
RRI	Responsible Research and Innovation
rUSEE	Remote User Engagement Exercise
SHD	Stiftung Hëllef Doheem
Smart4Health	Citizen-centred EU-EHR exchange for personalised health
SME	Small and Medium-sized Enterprise
SMS	Short Message Service
T	Task
TelCo	Telephone Conference
TIPP	Translation Interoperability Protocol Package
TÜV	Technischer Überwachungsverein
UDC	Use Design Case
UKA	Universitaetsklinikum Aachen
UMC+	Universitaetsklinikum Aachen
UNINOVA	Academisch Ziekenhuis Maastricht
UNIVIE	Universitat Wien
UR	User Requirement
URL	Uniform Resource Locator



Acronym/ Abbreviation	Description
USEE	User Engagement Exercise
WCAG	Web Content Accessibility Guidelines
WP	Work Package
Y	Year
ZS-UG	ZS Unternehmen Gesundheit GmbH & CoKG



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