Citizen-centred EU-EHR exchange for personalised health

Smart4Health

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

D1.6: 3rd Specification of user requirements and performance criteria

Deliverable Leader: UNIVIE

Due Date: M34

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Short Abstract

Deliverable D1.6 provides the third specification of citizen and professional user requirements and their respective performance criteria. The report delivers insights into the methodological approach for conducting co-creation engagements with citizen and professional users, in and after COVID-19 lockdowns. It shows how the collective work environment for user rquirements and performance criteria – the Performance Accountability Table (PAccT) – has been re-structured to further improve productivity and accountability. The report finally outlines the main challenges of the platform infrastructure based on the analysis of engagements with users and their needs.

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Document Status

Deliverable Leader	UNIVIE (Ulrike Felt, Susanne Öchsner, Robin Rae)
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History

Versions	Description
D0.1	Draft version written by UNIVIE with input from UNINOVA, HPI, D4L, HM, and EFN
R0.1	Revised version from internal reviewers.
R0.2	Revised version with reviewer feedback integrated by UNIVIE.
F1.0	Final version ready for EC submission.

Contributors	Description
UNIVIE	Organized and conducted co-creation engagements with citizen and professional users (in health care and research), and with citizens independent of CUCs; refined the methodological approach for remote settings; elicited new user requirements (URs) and consolidated them with previous URs; formulated performance criteria for the set of consolidated URs; and re-structured the Performance Accountability Table (PAccT) as a collaborative workspace
UNINOVA	Provided input on section 3.4 regarding engagements with policy actors; recruited support personnel from CUCs for CUC-internal qualitative engagements with citizens conducted by UNIVIE
HPI	Provided a description of implementations of user requirements (wave 1-3) for section 4.4; provided input on section 3.4 regarding engagements with policy actors; provided input to the PAccT regarding the requirement, integration, validation, and documentation space allocations; commented on version D0.1.
D4L	Provided a description of implementations of user requirements (wave 1-3) for section 4.4; provided input to the PAccT regarding the requirement, integration, validation, and documentation space; provided researcher access to the research platform and created a mock data set
HM	Provided a description of implementations of user requirements (wave 1-3) for section 4.4

Contributors	Description
ITTM	Co-developed with UNIVIE, ITTM provided a data protection compliant technical solution for UNIVIE to distribute and manage online questionnaires
ELIXIR-LU	Recruited researchers as professional users for qualitative interviews conducted by UNIVIE
ISMMS	Recruited researchers as professional users for qualitative interviews conducted by UNIVIE
ZS-UG	Participation in CUC-internal qualitative engagements with health care professionals conducted by UNIVIE
OSR	Recruited researchers as professional users for qualitative interviews conducted by UNIVIE
EFN	Provided input to the PAccT regarding policy documents and requirements related to the performance criteria of user requirements; provided input on section 3.4 regarding engagements with policy actors
GovMad	Recruited support personnel from CUC8 for CUC-internal qualitative engagements with citizens and health care professionals conducted by UNIVIE
EASPD	Provided input to the PAccT regarding policy documents and requirements related to the performance criteria of user requirements

Further Information

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Disclaimer

Executive Summary

The objective of Deliverable 1.6 is to specify a third set of user requirements (URs) and identify the related performance criteria (PC). It builds on the first (D1.3, M12) and the second set of URs and PC (D1.5, M24).

After the Document Summary (Chapter 1) and the Introduction (Chapter 2), in Chapter 3, we discuss our methodological approach and what it meant to conduct empirical social science research in and after the COVID-19 lockdowns. In this chapter, we first revisit the general approach to co-creation before we offer some reflections on our methodological toolbox, which we established and reported on in the first year of the project. Then, we continue with a detailed description of our third-wave engagements with citizen and professional users. This comprises a description of (1) user engagements with citizens and researchers, in which we focused on data provision for research, and (2) our work of tracing platform interactions by collecting frictions that occurred when becoming and remaining a user by talking to citizens and health care professionals. After presenting the newly established tool *Friction Input and Story Collector* (FISC), we briefly reflect on the reusability of our methodology, which we will devote more space to in the Final Report on User Requirements and Performance Criteria (D1.7) that concludes Task T1.3 (M40). Chapter 3 closes with a section on the project's engagements with policy actors, which is grounded in the need to raise awareness and engage with policy actors as a mean to better perceive the benefits, risks, and constraints of developing a citizen-centred health data platform.

Chapter 4 gives an updated outline of how Smart4Health proceeds to ensure performance accountability. Central to the Smart4Health project is its citizen-centeredness regarding both the goal of developing an interoperable EU-EHR prototype, and the means of achieving it through its dedication to co-creation. The input retrieved and generated from engagements with (potential) users needs to be taken up with great care in the development process throughout the project. It is important to remain transparent about where and how user input has been incorporated, and thus enable accountability for how the development performs under the project's propositions of citizen-centeredness and co-creation. Chapter 4 starts with a recapitulation of the process of working with the Performance Accountability Table (PAccT) and its four spaces, through which URs can move: the Requirements space, Integration space, Assessment and Validation space, and the Documentation space. Then, we discuss in detail the process of restructuring the PAccT and the URs and PC it contains. The restructuration was done according to the six broader functionalities of the platform – the Use Design Cases (UCDs) MyHealthView, MyTrusted, MyScience, MyTime, MyWork and Mob.E.Health. Furthermore, the restructuration process meant that all URs of the first three waves of co-creation were reviewed, in order to ascertain potentials for aligning new with previous URs, and in effect achieve a refined and consolidated specification of URs and PC across the waves. The Chapter ends with an overview of the technical implementation of the URs so far.

Chapter 5 describes the main challenges of the platform infrastructure, which resulted from the qualitative analysis done for the consolidation of URs across waves. In this chapter, we summarize the overarching needs that the specific functionalities of the platform should be able to address. The objective is to provide high-level insights from

an assessment of user-based articulations of needs regarding the Smart4Health platform infrastructure in-the-making, in a narrative manner of describing the main lines. Chapter 5 starts with a brief explanation of this approach and offers a list with key points. We then move through the UDCs MyHealthView (the functionality of overviewing, managing and navigating data), MyTrusted (the functionality of sharing data with trusted actors) and MyScience (the functionality of providing data for research) and summarize the key challenges that need to be taken into account for the platform prototype to be functional, meaningful, and sustainable from a user perspective. The list of URs and PC (spanning wave 1-3 of co-creation), that these analyses are based on, is ordered according to the UDCs and can be found in the Annex.

Chapter 6 ends the report with a summary, some final considerations for our future work in the fourth and final wave of co-creation.

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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 health care 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 health care providers. The 4HealthPlatform allows citizens to collect, store, manage, access and share their own health and health care data, through an easy-to-use, secure, constantly accessible and portable health data and services prototype within the EU and beyond. The 4HealthPlatform data layer connects with the 4HealthNavigator portal for services and applications to provide advanced personalised health services 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 D1.6 *3rd Specification of user requirements and performance criteria* is to deliver a third set of user requirements and related performance criteria, to be addressed and implemented in WP2 and WP3, thus, substantially shaping the development of the entire platform infrastructure. 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 in D1.5 *2nd Specification of user requirements and performance criteria (M24)*, and it will be updated in form of 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. Thus, it is crucial for the project consortium to ensure that the requirements from both citizen and professional users (in health care and research) are well represented and aligned, and moreover integrated into the technical development – along the whole process and in the different sites where the platform is discussed and tested. The third set of user requirements and performance criteria delivers a further set of crucial input from co-creation engagements and provides a means of orientation in the development process.

1.4 Deliverable methodology

The report on the 3rd specification on user requirements and performance criteria was produced by UNIVIE with input received throughout the recent empirical wave by:

- partners responsible for the technical implementation and reporting on its current status (HPI, HM, D4L),
- partners who engaged with policy actors (EFN, UNINOVA, HPI) and/or reported about policy relations of performance criteria (EFN, EASPD),
- partners who recruited participants for co-creation engagements or provided access to them (UNINOVA, ZS-UG, ISMMS, ELIXIR-LU, OSR, GovMad),
- partners who contributed by providing tools for engagements (ITTM) or feedback on the elicited user requirements and performance criteria in the PAccT (HPI, D4L).

1.5 Document structure

The introduction will detail the aim and scope of the report (chapter 2). It continues with the general approach and methods used in and after COVID-19 lockdowns in chapter 3, which provides a methodological reflection on the co-creation engagements, and an overview of the types of engagements and participants, including citizens, professionals, and policy actors. Chapter 4 focuses then on the PAccT as collective work environment, how it has been re-structured by Use Design Cases (UDCs) to incorporate all newly and previously elicited user requirements (URs) and their performance criteria (PC), and how the current status of implementations is able to address URs. In chapter 5 we outline articulations of the main challenges of the platform infrastructure, based on user engagements and the analysis thereof. Its sections follow along the main functionalities that have been in focus in this empirical wave, and provide high-level insights of the related URs. While the report concludes with the summary and final considerations, the Annex is of particular importance as it

provides the major achievement of the entire list of user requirements and the respective performance criteria developed so far, as well as their current space allocation in the PAccT, reporting on the degree of their realization in the development.

1.6 Document status

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

1.7 Ethics

This deliverable continues to be related to ethics through the topic of informed consent (IC) in the following ways. In our general approach in section 3.1 we explicate how we use situation- and context-specific IC forms for co-creation engagements and reflect in section 3.2 how remote engagements are suited for evaluations of IC content. In this recent wave an advanced version of the IC for the Research Platform (RP) was a topic for such engagements, as we detail in section 3.3.1, with insights being reported in section 5.4. The IC for the Citizen Health Data Platform (CHDP) continues to be a topic to provide feedback on, but now through CUC partners who will report on observed frictions in the registration process of or for citizen users via a specific template (see section 3.3.2).

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 and establishes a methodological toolbox that was drawn from and developed further. It builds on the first specification of user requirements outlined in D1.3 *1st Specification of user requirements and performance criteria* (M12) as well as on the second specification of user requirements and performance criteria outlined in D1.5 *2nd Specification of user requirements and performance criteria* (M24). Furthermore, it connects to D1.4 *1st Citizen/User Consent Language Report* (M12) regarding what needs to be taken into account when addressing informed consent in health-data related domains, to D8.1 *H - Requirement No. 1* (M24), where the procedures of recruitment and the process of obtaining informed consent are detailed, and to D8.2 *POPD – Requirement No. 2* (M24), where the procedures for the protection of data in the empirical work is described.

The work that is cumulatively reported in this deliverable covers all three completed waves of co-creation. Thus, finally, it has fed into the technical development processes and has thus contributed to the deliverables:

- D2.1 *4HealthPlatform detailed prototype plan and specifications requirements report* (M12), D2.2 *4HealthPlatform Citizen Health Data Platform Implementation* (M24),
- D2.3 *4HealthPlatform De-identified Research Platform Implementation with analytics, connectivity and access control, de- identification/pseudonymization, data integration/harmonization* (M30),

- D3.1 *4HealthNavigator portal detailed engineering requirements and software architecture report* (M12),
- D3.2 *4HealthNavigator Portal user sign-up, login and record deletion* (M18),
- D3.3 *4HealthNavigator portal dynamic consent, access rights management* (M24) and
- D3.4 *4HealthNavigator User Portal (M32).*

1.9 Main results

The main results of this deliverable are:

- a further refined co-creation approach through methodological reflection,
- the description of conducted user engagements with citizens and professionals (in health care and research),
- the re-structuration of the PAccT by the UDCs as high-level ordering principle,
- the establishment of a third set of URs ranging from Y1 to Y3 of the project,
- a full specification of formulated PC for the third set of URs where applicable,
- and a narrative analysis of UR categories and relations thereof in the UDCs MyHealthView, MyTrusted and MyScience.

1.10 Future work

Directly related to this report is the upcoming D1.7 (M40), the final specification/report of user requirements and performance criteria. Also linked to this deliverable is D1.8 *Description of the Use Design Cases from the citizen/user perspective* (M42) because:

- the Use Design Cases represent the major functionalities of the platform,
- they are introduced here as high-level ordering principle,
- they are also elaborated through the iterative co-creation process of task T1.3 (*Citizen/user co-creation: user requirements, performance criteria, implementation),*
- and will be (further) shaped by the elicited user requirements.

Moreover, D1.6 will be related to D1.10 *Validation Report* (M50), as it sets the technical implementations in close relation with URs and their PC, which serve as guiding principle for implementations.

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 final follow-up deliverable D1.7, and will also contribute to the related deliverable D1.10.

1.12 COVID-19 impact and mitigation measures

The COVID-19 pandemic situation continued to pose challenges with regards to conducting face-to face citizen/user engagements. These, however, could be continued through successful mitigation measures like remote engagements with citizens and professionals, and returning to face-to-face engagements under strict safety measures when local situations allowed for it. For details see Chapter 3 on the general approach and methods in and after COVID-19 lockdowns.

2 Introduction

This report focuses on the process of specifying a third set of user requirements that describe the functionalities of the platform, identifying the related performance criteria and of organizing the accumulated set of requirements from waves 1-3 of co-creation according to the platform functionalities. One final report will follow in M40.

The report is organized in the following way:

In Chapter 3, we discuss our methodological approach, in particular in and after the COVID-19 lockdowns. We first revisit the general approach to co-creation and offer some reflections on our methodological toolbox, in particular in times of COVID-19. Then, we provide a detailed delineation of our third-wave engagements with citizen and professional users and offer a description of an important methodological addition. Chapter 3 ends with an account of the project's engagements with policy actors.

Chapter 4 provides an update on Smart4Health's approach to ensure performance accountability, which is grounded in the need of remaining transparent about where and how user input has been incorporated, and thus enable accountability for how the development performs under the project's propositions of citizen-centeredness and co-creation. The chapter starts with a recapitulation of the work with the project-internal Performance Accountability Table (PAccT), moving to a description of the restructuration of the PAccT and the user requirements therein. This happened according to the six broader functionalities of the platform – the Use Design Cases (UCDs) MyHealthView, MyTrusted, MyScience, MyTime, MyWork and Mob.E.Health – and involved also a refinement and consolidated specification of the URs and PC. The Chapter ends with an overview of the technical implementation of the URs so far.

Chapter 5 describes the main challenges of the platform infrastructure, which resulted from the qualitative analysis done for the consolidation of URs across waves. First, it gives a brief explanation of our approach and summarizes the insights in a number of key points to consider. The analysis follows the UDCs MyHealthView (the functionality of overviewing, managing and navigating data), MyTrusted (the functionality of sharing data with trusted actors) and MyScience (the functionality of providing data for research) and summarizes the key challenges that need to be considered for the platform prototype to be functional, meaningful, and sustainable from a user perspective. The updated, consolidated and restructured list of URs and PC (spanning wave 1-3 of co-creation) can be found in the Annex.

Chapter 6 concludes the report with a summary and some final considerations for our future work until the end of Task 1.3 to be reported in D1.7 (M40).

3 General approach and methods in and after COVID-19 lockdowns

3.1 General approach

Before we offer some methodological reflections on our empirical engagements in wave 1-3 of co-creation and describe our concrete empirical approach in wave 3, let us briefly revisit our general approach to co-creation (text adapted from D1.5). As Figure 1 shows, the iterative co-creation approach of Smart4Health covers five steps from defining the key features of the health data platform to the integration and validation. We want to point out that infrastructures never start *de novo*, but always build on pre-existing ones. Some structural key features and technical functionalities, which the prototype to be developed should have, already were in place at the proposal stage. Also, there are sets of standards of how to build such infrastructures as well as regulatory systems governing these infrastructures (e.g., GDPR). This means, that there were specific starting points for processes of co-creation, while the detailed key-features of the platform were still open to be defined, developed and refined following the requirements expressed by citizens and professional users.

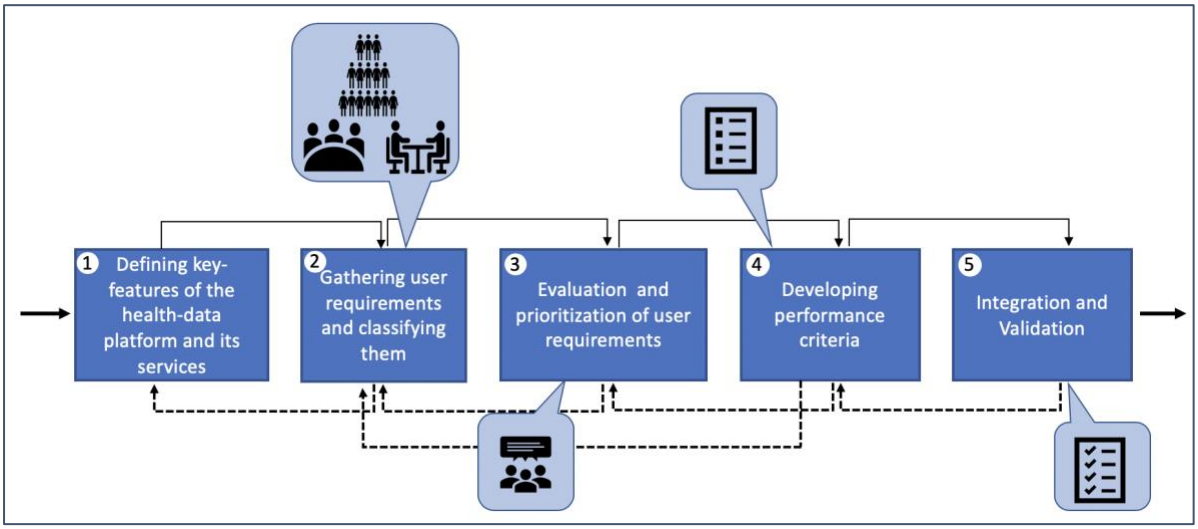

Figure 1 - Iterative process of eliciting user requirements and developing performance criteria.

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

(1) In a **first step** it is 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 are deemed appropriate.

(2) In **step 2**, once the user requirements (URs) are gathered, they are classified into groups of requirements, which address specific functionalities of the infrastructure to be built, as well as condensed and refined over the course of the project.

(3) In a next step, **step 3**, the elicited URs 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 are made whether certain user requirements can be realized

and which developments to prioritize. At this stage one also needs to reflect on the **emergent (partly unintended) system properties** and how they (might not) match user expectations.

(4) Along with spelling out URs, 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.

(5) Finally, **step 5**, the process of specifying URs and PC "ends" with their integration into the design, development and implementation process. This is continuously being **monitored in the Performance Accountability Table (PAccT)** in order to trace the decisions, and achievements along the project.

Throughout the process of gathering URs, we are 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 uses 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 Methodological reflection

As reported in D1.2, our co-creation work started out from the "requirement to construct a co-creation environment that is variable and flexible, yet durable and allows for situated depth as well as for longitudinal practices of (re-)engagement" (D1.2). In the first year of the project we thus developed a methodological toolbox, from which we would draw in assembling the most appropriate method for a particular group of participants, a specific set of questions, a particular point in time etc. The toolbox contained a variety of methodological approaches with a broad scope to account for the anticipated diverse demands of different empirical situations (see D1.2, p. 20-23). It comprised the following methods:

- **discussion settings** with diverse user groups (non-/potential users, citizen users, professional users) such as Co-creation Workshops (CCWs), User Engagement Exercises (USEEs) and Longitudinal accompanying user groups (LAUG)
- face-to-face **qualitative interviews**
- **walkshops and other forms of ethnographic observations,** to understand potential users' context and practices of work and the situations of (potential) platform use
- **questionnaires** for feedback on and validation of specific features or aspects of the platform prototype
- **reflection workshops** within the consortium.

Apart from the questionnaire, the methods in our toolbox are qualitative research methods. We want to underline that we do not see our qualitative engagements as precursor to quantitative methods, which then more broadly investigate the results yielded by the qualitative engagements. Instead, in our work we see quantitative questionnaires as an addition to our methodology that supports and triggers the expressions of issues, challenges and concerns within a testing situation, leading the analytic view of the interviewer as well as the participant. In wave 3 of co-creation, we have used a questionnaire in combination with ethnographic observations and conversations, which contextualize the answers given and give us insights into how people value what Smart4Health aims to offer and how they justify why they make a choice and tick a specific box in a questionnaire. This adds empirical depth to the singular selection of an answer category.

The methodological toolbox was crucial for the continuation of the citizen-centred co-creation approach, as we were able to adapt, develop and add methods in a flexible way (e.g., FISC, see section 3.3.2). Before we go into the methodological details (in section 3.3), we first want to take a moment to **reflect on the effects of ensuring co-creation in the times of COVID-19** that were generally characterized by remote engagements.

When the pandemic started early in 2020, at the beginning of our second wave of co-creation (i.e. when the stage of USEEs with CUC participants was expected to begin), the breadth of the methodological approaches available and the flexibility we had inscribed into the establishment of the co-creation environment helped us in finding mitigation measures. As reported in D1.5, we adapted the USEE method towards three rounds of remote User Engagement Exercises (rUSEEs). The observations of testing situations were performed in Vienna, due to pandemic-related travel restrictions. Face-to-face qualitative interviews were substituted by remote interviews. In year 3,

however, first face-to-face observations of platform use could be conducted in Madeira and will be continued broadly in wave 4, as most of the CUCs are now running.

There are two issues we want to address with regard to co-creation in times of COVID-19, where a lot of the co-creation work had to be conducted in remote settings.

First, there is the issue of **linear communication** in online discussion groups. In the rUSEEs of wave 2 of co-creation as well as in the remote interviews with potential citizen users we saw the predominance of a perspective on linear processes. We have to be aware that such a change in the social setting of discussions, even if carefully methodologically designed, potentially limits our possibilities to observe certain aspects essential to co-creation (Law 2009).

For instance, the co-creation workshops of the first year generated rich material on how citizens feel about providing data for research. The participants offered insights into the complex and intricate ways of valuing the possibilities of data provision for research and into the favourable circumstances in which they would provide their data for research. The setting was face-to-face and the group was assembled around a table. They were all able to see each other, interact interpersonally with the others to whom they set themselves in relation, respond to what was being expressed verbally and non-verbally, to what was being shown, to the tone of voice of the others, their gestures and body position.

These processes of expressing their values regarding the provision of data for research were complex, associative, multi-layered, and highly interactive. For instance, one participant would voice something, another one would push the point forward, and a third one would only use one notion from the first participant and develop a separate but related narrative. These exchanges and dynamics allowed us to gain insights into the value orders of participants, but also into certain flexibilities, where positions could be negotiated and changed. Turn taking was done routinely, and aside from rare confrontational or heated moments in the discussion it largely seemed to be clear to the participants – as competent communicators – when to speak and when to let others speak.

In our adaptation of the User Engagement Exercises to a remote setting, we reflected on the intricacies of turn-taking and on the difficulties due to the limitation of non-verbal communication on digital platforms. By carefully selecting the situations of potential platform interactions, by reading out their descriptions and by posing concise yet open questions, we could ensure giving the participants enough time for contemplation, in particular as we were unable to read the non-verbal signs of understanding quite as well through a monitor. However, the remote setting, from our experience, not only draws from but also brings into being a linear form of investigation. Participants tended to not engage with each other around an issue raised, but rather respond one after the other to a question posed. This was clearly visible when discussing with co-creation partners in the consortium and, crucially, with the citizens. The exception was a setting, in which the participants were physically in one room and knew each other, while the moderation team was remote. In this case, the discussion happened in a similar manner as when face-to-face.

The linearity, however, was quite appropriate for the straightforward assessment and evaluation of the research consent and catered well to the needs we had here. This

observation makes the case for a combination of remote and face-to-face approaches. However, it is important to underline that this exercise also expected from participants certain capacities: while we aimed to adapt our card-based approach (Felt et al. 2014; Felt et al. 2018) in digital form (as it supports discussants), the engagements on informed consent was a relatively text-heavy exercise, privileging experienced readers, who can read, process and understand text relatively quickly, in order to formulate their judgement.

Second, with such a remote approach it was unavoidable to run into **infrastructural exclusions**. More specifically, by shifting our face-to-face engagements to digital form, we inevitably reproduced pre-existing "digital exclusions", as remote co-creation requires citizens to have their own technical setup and bring a certain degree of digital literacy. Not all citizens were able to do so, given the unequal distribution of fast computer systems, laptops with high quality cameras and microphones, connection to high-speed internet, with a data plan that allows for screen sharing, camera use and 2 hours of engagement.

There was one situation where a potential participant, who previously had participated in a co-creation workshop, showed great interest in the assessment and evaluation of the consent for data provision for research. However, he neither had the proper equipment to participate nor the financial means to keep up to date technically. In other situations, the participants' technical system was not very good and there were substantial difficulties in mutual understanding. These difficulties, however, that could have caused a discontinuation were bridged by our previous research relation (as also this person had been a co-creation workshop participant before), and by the participants' generosity and patience. It thus needs to be critically reflected what it means for justice in co-creation, if the tools for participation are outsourced to participants – from our perspective, using digital engagements can be a mitigation measure, but does not fully allow for just and sustainable co-creation practices.

3.3 Engagements with citizen and professional users

Due to the ongoing COVID-19 restrictions, the 5th General Assembly (January 2021) did not happen in person, but in a remote setting. As the user ecosystems had already been defined in the co-creation workshops at the 3rd General Assembly in Potsdam (January 2020), they merely required adaptations and expansions, which is something that is being done on a regular basis, taking into account the developments in the Citizen Use Cases (CUCs).

For that matter, we collectively stabilized the timeline in the beginning of wave 3 in the WP1 TelCos. We established a choreography that was flexible enough to be adapted with regard to the availability of interview partners and workshop participants in the CUCs, but defined enough to hold the partners accountable. Figure 2 depicts from top to bottom a schematic[1] overview of:

- the types of users (researchers, citizens, and HCPs) and the topics to be explored,
- the timeline for user engagements with related input requests for technical deliverables,
- which partners can provide access and/or recruit which user types when,
- and the platform functionalities that were to be explored and tested in wave 3.

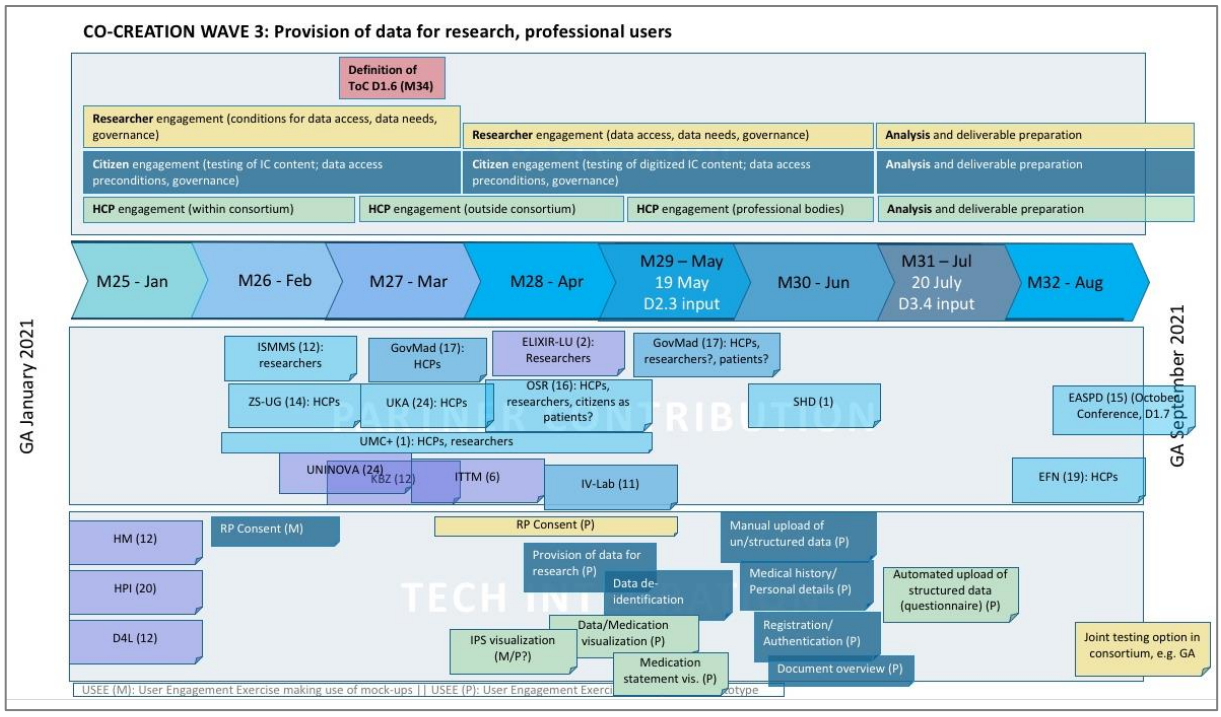

Figure 2 - Stabilized timeline for the third wave of co-creation.

The empirical work in wave 3 followed a two-pronged approach: first, our main focus was on the provision of data for research, bringing into conversation citizen user requirements and those of researchers, whom we conceptualized as potential professional users of the provided health data. Second, we traced how citizens actually

[1] Please note that the image of the wave timeline has been included as an illustration of the work structure and process. The details of when which engagements could be done and how are explicated out throughout the chapter.

interact with the platform prototype in the CUCs that started in the first and second quarter of year 3. We paid special attention to what frictions and challenges surfaced here also including feedback from supporting HCPs. We focused on the entire process of becoming a platform user, which does not end once the registration process has been completed, as well as with regard to the sharing process. More engagements with HCPs will continue in wave 4 (see 3.3.2), as in wave 3 particularly hospitals were still impacted by the COVID-19 situation. In what follows we will in more detail describe our empirical approach (within the continued COVID restrictions).

3.3.1 User engagements focusing on data provision (citizens and researchers)

In the first two waves of co-creation we had developed a broad array of user requirements and according performance criteria for a variety of situations. In the third wave of co-creation we more closely focused on the provision of data for research. At the beginning of the wave, the research platform consent was available in a stable draft version in English and German, and its content could be tested with citizens.

Participants: 9 participants in individual remote settings

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

Interaction: individual interaction

Duration: app. 90-120 mins each

Aim: Assess and evaluate the draft version of the consent for the Smart4Health research platform with a particular focus on the core data set to be provided, possible data journeys (Bates et al. 2016) and questions of governance

Support: Presentation

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 and Scapple.

Between February 11 and 24 we conducted **9 qualitative remote interviews with citizens** who assessed and evaluated the draft version of the research platform consent with us. Interview partners were diverse with regard to gender, age and level of education. With the exception of one, all of our remote interview partners had previous knowledge of the Smart4Health platform: some of them theoretically, as they had been participants in the co-creation workshops of wave 1, some of them practically, as they had been participants in the one-on-one testing sessions of the user portal in wave 2. Methodologically, this pre-disposition to the platform was crucial, in particular at a time when the research data platform as well as the research platform consent and the data access governance measures are still under development. It allowed us to trace:

- the pathway from citizens having become a user of the citizen health data platform, to becoming a provider to the research platform,
- the valuation mechanisms in deciding if data provision was something they would like to engage in and under what circumstances, and
- the break-off points and potential moments of friction.

The 9 remote interviews had a duration of about 1.5 to 2 hours each. We started out with a brief presentation of the project and the platform structure to re-familiarize our participants with the platform prototype and the scope of the project. We then moved into an in-depth discussion of the separate segments of the research consent. At the point in time of the first draft, the research consent contained:

1. an information sheet, followed by 14 questions that gave detailed explanations of the data provision process, the Smart4Health research platform and the MyScience app
2. a legal section on rights and
3. the declaration of consent.

First, we displayed the information sheet to the participants and asked them to read it slowly and carefully, always letting us know when to scroll. Already this first segment generated rich conversations, offering first insights into the dimensions that are relevant for their evaluation of the decision to make health data available for research and under which circumstances. Then we led them through the list of questions and asked them to select the ones they would be particularly interested in, which gave us additional insights into their evaluation processes. Four questions we were to discuss in any case, as they were crucial for an informed discussion of the provision process (*What kind of data do we ask you to provide? What happens when you provide your health data? Who can access your data for medical research? Under which circumstances does your health data leave the Smart4Health research platform?*) They had time to read through each question and its response, which resulted not only in an evaluation of the clarity and appropriateness of the information they received but also provided insights into citizens' valuation and assessment processes with regard to making available health and health related data for research. We ended the interview with a discussion of the declaration of consent as the moment where choices are specified, and the decision is brought to the point.

The initial analysis of these 9 interviews, which fed into the further development of the research consent made clear, that citizens required infrastructural transparency and clear governance processes and structures, as they were aware of the potential value health data could have for research (see section 5.4 for general insights regarding data provision for research).

Participants: 6 participants in individual remote settings

Type: researchers as potential professional users of the Smart4Health research platform

Interaction: individual interaction

Duration: app. 45-60 mins each

Aim: understand the needs of potential professional users of the research data platform, under what conditions a research platform like the one developed in Smart4Health would be interesting, and what problem it is a solution for

Support: Presentation

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 addition to the citizen interviews, between April and July 2021 we conducted **six qualitative remote interviews with researchers** based in Luxemburg, Italy, Portugal and the US. We conceptualized researchers as data users as mirror group to the citizens as data providers; citizen needs have to be carefully mapped with those of researchers and their relevant data practices. For that matter, we wanted to better understand the needs of those who are expected to work with and scientifically make use of the research data platform.

In the first part of the interview, we explored their current data-related work practices (e.g., the research questions they work on, the collaborations they are engaged in, what the research contributes to, and how the process of data access works for them at the moment). In the second part we presented the functioning principle of the Smart4Health research platform and explored where they see its potential for their research. In this context, the theme of the core data set, i.e. the basic set of data that needs to be available for the research platform to be perceived as valuable, was of particular relevance to us. The initial analysis of the researcher interviews led into the development of a first set of researcher requirements as professional user requirements (PURs).

The qualitative (remote) interviews with researchers will continue at the beginning of wave 4 of co-creation, as the **interviews with nurse researchers** that were planned in order to understand how the research data platform could support nursing research had to be shifted to Q4 of 2021 and five interview partners have been recruited by EFN for October 2021.

3.3.2 Tracing platform interactions: frictions in becoming and remaining a user (citizens and HCPs)

The second dimension of our empirical approach was to understand how citizens actually interact with the platform prototype in the CUCs and the potential effects this has on the specification of URs. Given that we conceptualize the Smart4Health platform that enables the citizen-centred EU-EHR exchange for personalised health as a sociotechnical infrastructure (Bowker & Star 1999; Slota & Bowker 2017) it is crucial to understand the infrastructural breaking points from the perspective of (potential) users. Following a mixed methods approach (qualitative interviews, observations and a quantitative questionnaire) we paid special attention to what frictions and challenges surfaced for CUC participants – with regard to the entire process of becoming a platform user, which does not end once the registration process has been completed, as well as with regard to the sharing process.

Participants: 5 participants in remote qualitative interview settings

Type: HCPs as support personnel for citizen users of the Smart4Health platform

Interaction: individual and group interaction

Duration: app. 30-60 mins each

Aim: to acquire a preliminary overview of the experiences that the CUC participants/users had so far

Support: Presentation

Documentation and analysis: audio recording and protocol, identify key themes for developing an online questionnaire and partner input template (FISC) (see Table 1 below)

As the CUC waves started in March 2021, we first conducted **three CUC-internal engagements with health care professionals (HCPs)**: CUC contact persons/CUC-partners in the two CUCs that were active (CUC4 and CUC 5) and in which citizens were already enrolled as participants. These engagements were held remotely, as travel was not possible in the first and second quarter of 2021 due to the COVID-19 pandemic. The aim of the engagements was for us to get a first overview of their experiences with the difficulties participants had had. We wanted to come to an understanding of the questions that routinely come up, what parts of the process seem difficult or non-transparent, and what the breaking points had been in the process that they had overseen and what they had to do, i.e. what they had to bridge, in order for the participants to become users of the platform.

While some engagements with HCPs could be done in this wave, more extensive engagements with HCPs and the return to face-to-face interviews had to be slightly postponed. During wave 3 HCPs in particular in hospitals were still under COVID-strain. Furthermore, due to the COVID-related delay of the CUCs, doctors' participation, e.g., in CUC3 started later than anticipated; premature interviews would not have been feasible, given that the involved doctors needed to familiarize themselves with the platform first and incorporate it into their interaction with patients. Therefore, qualitative interviews or other forms of engagement with doctors, nurses and other HCPs were shifted to the beginning of the next wave of co-creation, with the focus on cross-border care but will also cover some other aspects (September 2021 – April 2022, analysis to be presented in D1.7, M40).

At the point of writing this deliverable, three qualitative face-to-face interviews with hospital doctors in CUC 8 have been conducted in September 2021. The aim was to better understand what is needed at the clinical level in a multi-language cross-border setting with regard to data needs, e.g., clinical problems and conditions, allergies or the medication summary, as well as current practices of data exchange; these interviews are currently under analysis[2]. In addition to this, five nurses have been recruited by EFN for remote interviews in October 2021. One co-creation workshop is planned with representatives of service providers for persons with disabilities in the context of the 2nd Health Days co-located with EASPD's 25-year anniversary conference, also in October 2021. For Q4 of 2021, several USEEs and qualitative interviews are planned in CUC3, CUC4 and CUC7, including professional users.

[2] The analysis of the user engagements from wave 4 of co-creation will be presented in D1.7 ("Final Report on User Requirements and Performance Criteria", M40). The sharing of a key set of information and the translation thereof is discussed within the Use Design Case Mob.E.Health (T1.4.3); the description of this functionality will be reported in D1.8 ("Description of the Use Design Cases from the Citizen/User Perspective", M42).

Based on the insights we gained from CUC-internal engagements with HCPs outlined above, we developed an online questionnaire; ITTM developed and provided a data protection compliant technical solution that enables social science researchers to distribute anonymous links and at the same time keep control of the data (needs co-defined with UNIIVIE). The questionnaire was deployed in July 2021 in a mixed method approach in **five engagements** with citizens enrolled in CUC8 in Madeira, whereby we observed their platform interaction and led questionnaire-based interviews with a focus on registration, authentication, and arriving in the platform. The citizen engagement happened at the site to which citizens come to do their back training (see Figure 3). This setting was ideal to observe how they cognitively connect the platform use to the backpain training they get and the data they generate there.

Figure 3 - Madeira Digital Health and Wellbeing set-up in CUC8.

Participants: 5 participants in methods mix setting (questionnaire-based interviews, observation)

Type: citizens related to CUC 8

Interaction: individual interaction

Duration: 20 mins each

Aim: Understand how participants in CUC8 experience the registration and use of the Smart4Health platform

Support: Short questionnaire developed specifically for the purpose of eliciting interactions on their choices.

Documentation and analysis: participants (after IC) filled in a specifically developed questionnaire on a tablet together with us and explained along the way why they tick certain boxes, with what experiences of the platform this was connected and how they think they might potentially use the platform later. The questions and the detailed choices they had to make in order to express their evaluation of the platform experience was used as input to the broader co-creation approach.

Furthermore, and inspired by our CUC partners' rich narrations of frictions, we developed and included an additional method in our methodological toolbox: the **Friction Input and Story Collector (FISC)**. The FISC is a template with which we systematically collect user experiences that the CUC partner observe in their regular exchanges with CUC participants. The FISC collects instances when current implementations (of specific features, of the entire infrastructure) do not work as expected or do not work well enough within a situation – what we call ***frictions***

between users and technology. We here do not mean concrete problems or issues with one specific feature or a functionality as such – frictions cannot be broken down to a bug that simply needs a technical fix. Frictions are sociotechnical issues, as users can attribute them to both the current technical implementations, and their own user experience of the platform. Thus, frictions reflect sometimes messy and confusing situations for users and they need to be understood as such. Our method makes use of the power of narratives by users by sensitizing those on the ground to breaking points that surface in narratives (or snippets thereof).

Indications for such frictions can be moments when the explicit support of CUC partners is required (e.g., to overcome a problem, to stay in the project as a participant, etc.), and/or when users express adverse feelings. The frictions can cover a wide range and users can attribute them to both: the technology (e.g., frustration, relief after something worked) and to themselves (e.g., fear of doing something wrong, not understanding, feeling of not being the right user). Some users might tend to take the responsibility for something not working, while others (also) ascribe it to the technology/prototype. Frictions can relate to multiple features and do not need to be limited to a specific feature alone (but they can).

Frictions can well be overcome in the setting of the project, for instance with the CUC-partners' help. More importantly, they can be indicators for people discontinuing the use of the platform if it were out there "in the wild", i.e. without support. In order for the infrastructure to be sustainable and robust, the moments of frictions and what happens in them need to be understood.

Table 1 - Friction Input and Story Collector (FISC).

Friction Input and Story Collector (FISC) for CUC partners' user experiences	
Situation (Choose the one that frames your specific input and delete the others)	1. Registration, consent and verification 2. Log-in and 2-factor-authentication 3. Arriving in the platform and finding one's way around 4. Collecting health- and health-related data 5. Viewing, ordering, filtering health- and health-related data 6. Sharing data with a trusted person (HCP, partner, ...)
Title of the friction in that situation (i.e., what's the problem?)	*< E.g., log-in takes too long; where is the data?, … >*
Short description of the friction in that situation, with which feelings being expressed	*< If you find them helpful, use the following elements for describing the issue/challenge: Participants told us / complained that the … process is too … / that the functionality does not support them in … / that the … was missing …; They were frustrated by … whenever they … because … >*

Short description of expectations or best-case scenario	*< If the implementation did not work as expected: please explain what the expectation would have been; if the implementation did not work well enough: please explain what would have been the best case >*
Support given in that situation, and if necessary	*< Together we did… / we supported them by…; they found a workaround by … >*
Responsibility assigned to whom (technology, user themselves)	*< E.g., the platform; one's own system/phone/device,…; one's own capabilities; …>*
Has the friction been reported elsewhere?	*< E.g., as a bug report or helpdesk inquiry >*
Story about the situation and the friction	*Stories give us hooks for analysis. Sometimes a story contains many elements of different frictions; sometimes it just illustrates one friction particularly well.* *< Please take below as much space as possible in developing your description, and provide it in text form. >*

3.3.3 Smart4Health as a site for developing and refining co-creation methodologies: On the reusability of our approach

As mentioned above, in the course of the project we have drawn substantially from our methodological toolbox outlined in D1.2, which was well-equipped with established methods that social science research has to offer. In our empirical work, we selected specific methods for given empirical settings and also partly adapted them for our use (e.g., the card-based approach described in Felt et al. 2014 and Felt et al. 2018 was transformed into USEEs and, later, into rUSEEs). We did so, in order to facilitate co-creation in a complex and multi-dimensional project such as Smart4Health in the first place, and to stay capable of acting in a crisis situation such as the pandemic, which had substantial effects on face-to-face social science research across the board.

In addition to our methodological selection, deployment and adaptation, we developed two further tools to support our co-creation work: the **Performance Accountability Table** (PAccT), introduced in D1.5 and described in section 4.1 as well as the **Friction Input and Story Collector** (FISC), introduced and described in section 3.3.3. The PAccT serves as important collaborative device to ensure transparency and accountability with regard to the incorporation of user input, tracing user requirements across their articulation, implementation, validation and documentation. The FISC is a sensitizing tool for those on the ground, directly working with citizen users, for moments when current implementations did not work as expected or do not work well enough within a situation and where human support was needed to make the platform prototype work for the user. Both tools continue to be crucial in our collaborative work on the Smart4Health platform infrastructure; together they allow us to keep in the foreground that Smart4Health is a ***socio*-technical infrastructure** and that it is developed in **practices of infrastructuring** (Grisot & Vassilakopoulou, 2017), which involve decisions, compromises and agreements that have to be made explicit and traceable.

As task 1.3 is running until M40 and it is possible that the methodological developments will be ongoing, we will include a chapter reflecting on the re-usability of our methodology for similar projects in the deliverable concluding 1.7 (“Final Report on User Requirements and Performance Criteria”, M40).

3.4 Engagements with policy actors

The consortium recognizes the need to raise awareness and engage with policy actors as a mean to align on benefits, risks, and constraints of developing a citizen-centred health data platform. We considered this already at proposal stage by inviting partners such as EFN and later also EASPD to participate in the consortium. These partners are fully engaged and active in advocacy and policy as the project is maturing and showing results.

Beyond the consortium partners, contacts were established with national and international policy actors, such as national and regional governments (prime ministers, ministers and other responsible from different EU member states), representatives from OECD, regional authorities, associations, and networks. The main topic on these conversations was the basic concept of the project, namely that EU citizens may exercise on their rights to access, manage, and use their health and health care data in a fully digital and self-determined manner. The basic idea is as impressively simple as it is incredibly complex to implement in the EU. In addition, project objectives such as promoting citizen participation in health research through data provision for research, and health care personalization through personalized digital health services were received highly favourably by engaged policy and advocacy stakeholders.

In a later stage, and despite the COVID-19 pandemic, these engagements have continued already with some more concrete elements available. One of the main interactions with policy makers was the high-level event organised on 5 February 2020, by the EFN, at the European Parliament, focussing on digitalisation and European Electronic Health Records (EHR) co-creation. Bringing together more than 150 people, this was a good opportunity to exchange views on the policies and steps forward to co-design EHR, knowing that having a European Electronic Health Records' exchange format is a growing priority of the EU Institutions, as pointed out in the Council Conclusions on Health in the Digital Society - making progress in data-driven innovation in the field of health (2017/C440/05) and the European Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800). MEPs, Commission representatives of DG Research and DG Connect, Industry/SMEs, and Civil Society agreed on the importance of fostering end-user co-design in digital health. The main highlights of this event were: (i) the confirmation of co-creation as corner stone for the development of end-users targeted innovation, (ii) the importance of hearing the right stakeholders at the right time, (iii) confirmation of the position of the EU in continuing to be a driver of innovation and (iv) the MEPs vision towards a more integrated European health space. The report of this key event is available at https://anyflip.com/eumpx/bxrh/ (last accessed on: 2021-10-15).

Smart4Health continues efforts to realize aspects of this agenda in practice, arranging meetings and opportunities to discuss possible links and opportunities. One of the main examples are the working relationships that have been established with state-owned entities driving digital transformation of health care and EU eHealth initiatives, including Portugal's Servicos Partilhados do Ministerio de Saude (SPMS), Germany's Gematik GmbH, and the Netherlands' MedMij on concepts and standards to interoperate and integrate with national health registries, respectively. As a result, these institutions accepted and adopted the relevancy of the citizen-centred Smart4Health platform as complementary and interoperable extension of their respective eHealth agendas. While these interactions are important initial steps to lay

foundations for integrating with national and EU cross-border health information exchange infrastructures at a prototype level, broad practical realization of these objectives is clearly out of scope of the present mandate and resources provided in Smart4Health contractual agreements. Furthermore, the Austrian Smart4Health consortium partner participated in a high-level meeting "*Innovationsforum*" called by the umbrella organisation of all social insurance bodies in Austria in which the role of health data/health data sharing was extensively discussed and insights from Smart4Health could also be discussed.

More recently, the project has reinforced the engagement with relevant regional policy makers from Madeira, specifically the President of the Regional Government and the Regional Ministry of Health. As a result of this work, the "Madeira Digital Health and Wellbeing" initiative was launched in May 2021, with the full support of the regional authorities. It's worth to mention that the initiative involves not only Smart4Health but also Smart Bear and ICU4COVID and aims at making a concrete contribution for health digitization and education for digital health in the region of Madeira and beyond. We will strive to expand our foundational engagement with policy makers at national and EU levels up to the end of the project, as we have begun to test and evaluate our prototypical solutions in citizen-centred uses cases.

4 Ensuring performance accountability

Central to the Smart4Health project is its citizen-centeredness regarding both the goal of developing an interoperable EU-EHR prototype, and the means of achieving it through its dedication to co-creation. The input retrieved and generated from engagements with (potential) users – whether citizens or professionals (in health care or research) – demands taking it up with great care in the development process throughout the project.

It is thus of utmost importance not only to take user input into account, but also to remain transparent about where and how those inputs have been incorporated, and thus enable accountability for how the development performs under **the project's propositions of citizen-centeredness and co-creation**. To ensure this transparency and accountability throughout the iterative development process, the **Performance Accountability Table (PAccT)** has been instantiated by WP1 lead UNIVE in Y2 of the project (introduced in D1.5) and since then been in use as collective work environment across work packages (WPs). In the following section we will address its work process (4.1), and the updates it received in structure (4.2) and content (4.3).

Additionally, partners of WP2 and WP3 have taken stock of the URs implemented so far, and how the continuous input and feedback from co-creation engagements with (potential) citizen and professional users has been taken into account in developing features (4.4). While the iterative process of co-creating the main features of the infrastructure, the Use Design Cases (UDCs), will be described in more depth in D1.8 (M42) as will the validation of implementations in D1.10 (M50), an overview of implementations and relations to user input is valuable already at this point in time to substantiate the project's propositions.

4.1 Recapitulation of the PAccT process and its four spaces

In the following we recapitulate the process of working in the PAccT, which is reflected by its structurization into four spaces. Each space is devoted to a work status of a UR/PC: requirement, integration, validation and documentation. Thus, the PAccT serves to:

- list the elicited user requirements and their performance criteria,
- trace the collective decisions taken regarding their technical implementation,
- trace the assessment and validation of URs/PC in the CUCs, and finally
- document which URs/PC have been closed or related issues have been identified.

These diverse activities thus tie together the work done in WP1 for user participation and co-creation, in WP2/WP3 for technical implementation, and in WP4 for the CUCs. The relation of the four spaces to another and the UR/PC work carried out in them forms the PAccT process.

The PAccT continues to exist as evolving entity being updated, refined or also re-structured (see 4.2), and in two guises: as a spreadsheet table and online as a Kanban board in Jira. Whereas both include the four spaces, the online version proved being more suited for the work across the spaces, and the spreadsheet version more for in-depth work on the elicited URs and their PC in the requirement space. Regardless of

version and space though, each relies on collective work as outlined in the following brief summaries of the spaces (for a full description see D1.5).

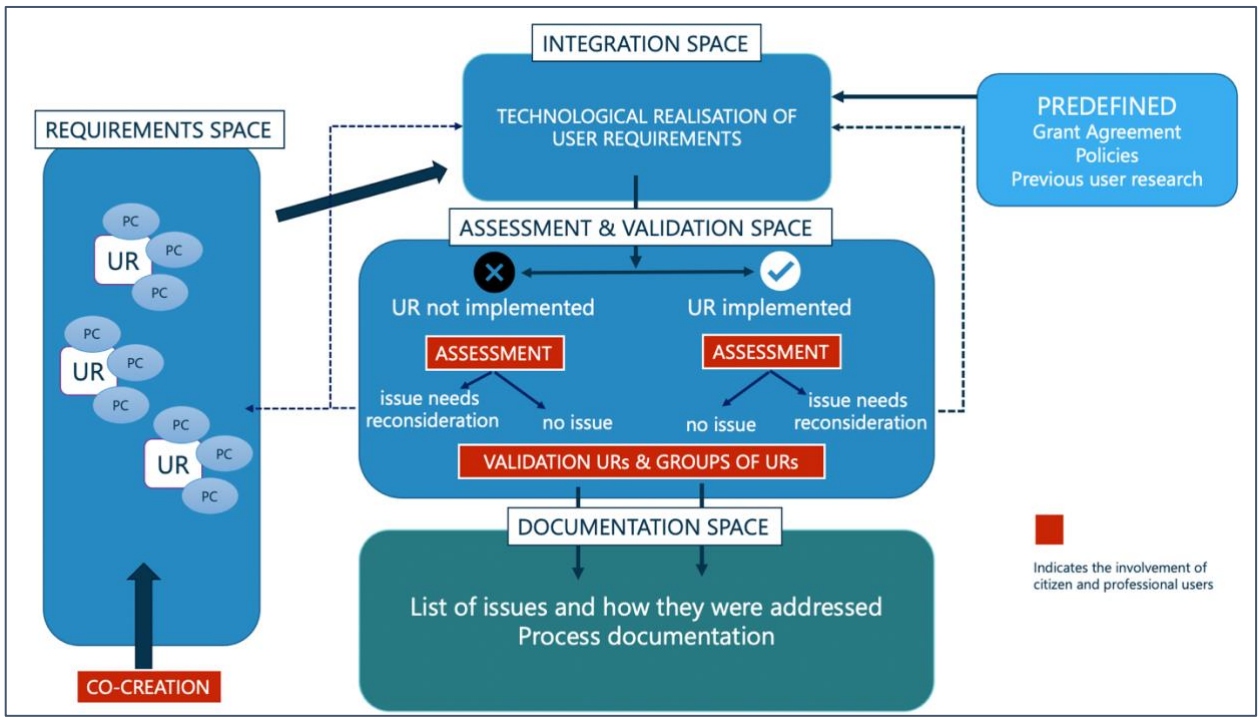

Figure 4 - The PAccT process ensuring transparency and accountability.

Requirements space

The requirements space collects the URs that have been elicited in co-creation engagements, along with their PC. A structure by situations shows to which platform interaction each UR/PC belongs, e.g., registering, sharing data, etc. To aid with the prioritization of URs/PC, partners with policy expertise (EFN, EASPD) indicate which PC – as concretization(s) of a UR – are related to policy discussions, and classify them in three categories/tiers of policy relations: legal documents, policy documents, and standards. In Jira, these can be filtered to get an immediate overview, alongside other filters (e.g., project year of a UR/PC). Finally, a section for open questions links to the implementation of URs/PC, which in Jira are included in the respective UR/PC.

Integration space

The URs and PC for which solutions are currently developed move into the integration space. Here technical partners also respond to open questions from the requirements space or pose new ones, and report on the implementation status of a UR/PC. Alternatively, solutions that are or have been worked on can (have) come from predefined frameworks, e.g., the grant agreement, previous D4L in-house user research, regulations, etc. When a (first) UR/PC implementation has been done, it moves into the assessment and validation space.

Assessment and validation space

While implemented URs/PC move into this space, also those do that have not or will not be implemented according to decisions made by the responsible technical partners. In any case, the specific UR/PC is collectively assessed regarding: if it addresses the problem defined by the UR/PC adequately, which open issues remain, or the reasons for not implementing it. From the assessment, four paths are possible outcomes. In case of a **non-implemented UR/PC** it can either:

- move back into the requirement space for being refined, or
- back into the integration space if the reasons against its implementation have been resolved.

In case of an **implemented UR/PC** it can either

- move back into the integration space for being adapted if it does not address the posed problem adequately, or
- move into the validation by qualitative and quantitative means.

After the validation a UR/PC can then either move back into the integration space for further iterations, or into the documentation space if validated successfully.

Documentation space

This space comprises both implemented and non-implemented URs/PC (after agreement in the assessment space). The collective decisions taken and justifications given for either path are traced in a separate document with two lists: one for closed/implemented URs/PC and another for issues around non-implemented URs/PC. In case a UR is implemented but does not address all of its PC, the closure list also documents justifications therefor, or why initial issues turned into non-issues. The issue list also gives space to disagreements and can also contain issues that emerged from other sources than the PAccT, e.g., discussions in workshops, email conversations, and more.

4.2 Re-structuration of the PAccT by UDCs

Up until the current third year of the project, the elicited URs/PC have been grouped solely by situations of engaging with and using the platform (e.g., 'consenting to platform use', 'data sharing', etc.), which currently amount to 18 situations in total (see Table 2). Thus, all URs that we had formulated were collected in the PAccT and classified according to specific situations. Initially, these have been developed *for* co-creation settings to cover anticipated platform engagements and stimulate discussions about them (S1-S16). Yet *from* settings with potential professional users, e.g., researchers, and qualitative analysis thereof, also new situations were developed (S20, S21).

Situations continue to be a structuring element in both the PAccT spreadsheet and board in Jira, by specifying for each UR/PC to which situation they belong. With this year, however, a higher-level order has been introduced by assigning situations to the six Use Design Cases (UDCs), which represent the main functionalities of the

infrastructure to be developed (MyHealthView, MyTrusted, MyScience, MyTime, MyWork and Mob.E.Health). While the UDCs are elaborated in their dedicated task T1.4, the URs/PC elicited in task T1.3 are oriented towards the UDCs.

Thus, after having completed the wave 3 of engagements as outlined above (see 3.3) with a growing number of URs as result, we turned to the UDCs as our central means of grouping. UNIVIE distributed the URs in the PAccT to separate spreadsheets for each UDC, while still retaining the fine-grained situational order in each. Some situations and their respective URs/PC then fit several UDCs, others were specific to only one UDC. The table below shows the outcome of this re-structuring process as an overview of which UDC comprises which situation(s).

Table 2 - Relation of UDCs and situations based on elicited URs.

UDC / Situation	MyHealth View	MyTrusted	MyScience	MyTime	MyWork	Mob. E.Health
S1 Registering for the 4HealthPlatform	X					
S2 Consenting to platform use	X					
S3 Collecting health data	X	X				
S4 Place of use[3]						
S5 Uploading health-related data				X	X	
S6 Workplace and health data					X	
S7 Sharing data (with the HCP)	X	X				
S8 Sharing data with a trusted person		X				
S9 Revoking access		X				
S10 Making data available for research			X			
S11 Being re-contacted after providing data for research			X			
S12 Defining emergency information						X
S13 Giving access to a doctor while being abroad						X

[3] This line is greyed out as the engagements so far did not yet provide sufficient input to elicit URs for this specific situation. It is expected that URs that pertain to this situation will be developed in wave 4 with its focus on cross-border mobility. The assignment of the situation to UDCs will then depend on the content of the elicited URs.

S14 Transparency with regard to access: now integrated into S3 and S7						
S15 De-registering	X					
S16 Deleting data	X					
S20 Applying for and accessing the research platform			X			
S21 Assessing data provenance and accuracy	X					

Whilst this re-structuring work has been done in the requirement space of the spreadsheet version of the PAccT, the assignment to one or more UDC(s) and a situation moves with a UR/PC throughout the four spaces of the PAccT. Although the grouped URs/PC have ultimately also been transferred into the PAccT in Jira, an intermediary yet in-depth step has been taken before in the requirement space by consolidating the URs in each UDC (see next section 4.3). Only after this analytic process by UNIVIE in several iterations for each UDC, the transfer of these UR/PC–situation–UDC relations into Jira was done. With the implementation of selectable filters for each UDC by HPI, amongst others, then helped to easily work with these relations.

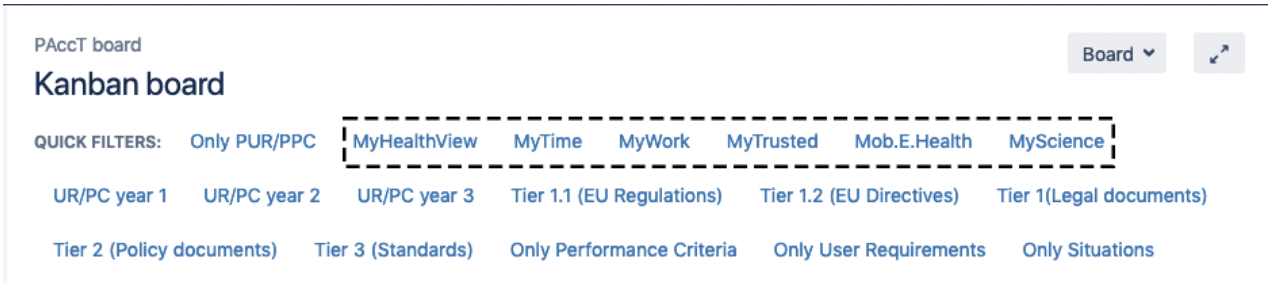

Figure 5 - PAccT UDC filter overview in Jira.

After setting a filter for UDCs (and any other option, e.g., project year), all URs/PC pertaining to it are shown, including a label that signifies the situation (e.g., S10), as well as in which space(s) of the PAccT they are currently placed in.

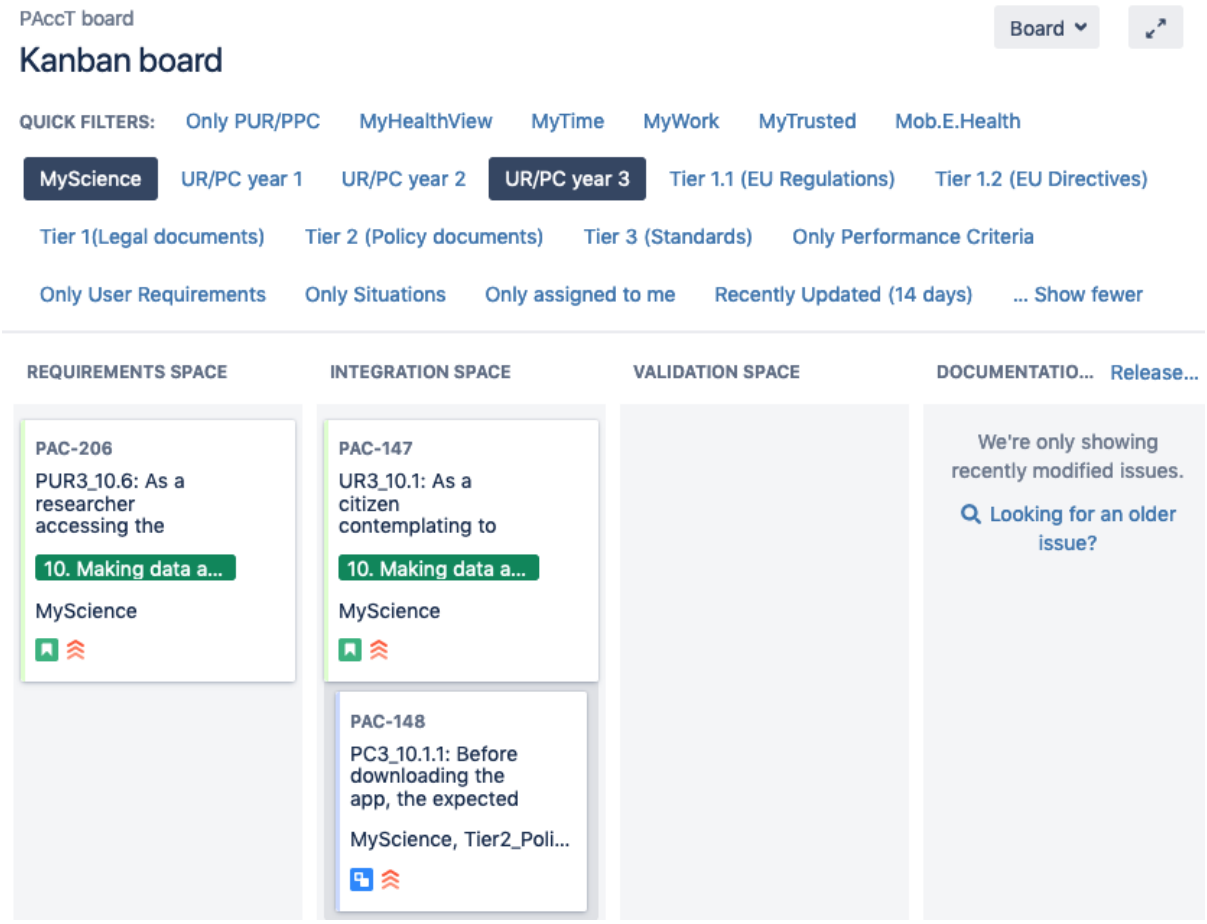

Figure 6 - PAccT filter selection example in Jira.

In this way, the collective work environment in Jira benefits from the UDCs as productive ordering principle that seamlessly extends the existing one by situations of URs/PC, regardless of their work status in the PAccT.

4.3 Consolidation of URs across waves

Through having successfully mitigated the challenges posed by the COVID-19 pandemic (see chapter 3), the elicitation of citizen and professional URs in WP1 was possible across all three project years and their respective empirical waves, which resulted in an increasing amount of URs. This, however, also required carefully revisiting and reviewing them in order to ascertain potentials for aligning new with previous URs, and in effect achieve a refined and consolidated specification of URs and PC across the waves.

Thus, whereas the previous section focuses on the PAccT structure, we move here to the ordering on the content level of URs/PC, i.e., within situations and UDCs. In the following we first give a brief overview of the empirical material analysed in the previous years, as background to elaborate then on this year's analytic process of drawing all collected URs/PC together. The achieved consolidation of URs across the empirical waves 1-3 is represented by the 3rd specification of URs and PC found as structured list in Annex I.

In the **first wave of co-creation** UNIVIE conducted and broadly analysed the material from the co-creation workshops (CCWs) with citizens independent of the CUCs, as these were not running yet, as well as the input received from EFN from their group discussions with nurse representatives. The qualitative analysis served to formulate citizen and professional URs and prepare their collective evaluation and prioritization. This was a prerequisite to formulate the according PC in Y2 for the first stabilized UR specification. Thereby the instrumental dimension of the work got pushed even further, as PC would define when a UR is fulfilled.

In the **second wave of co-creation** UNIVIE conducted remote User Engagement Exercises (rUSEEs) with citizens associated with the CUCs that were to start, one-on-one testing sessions with citizens independent of the CUCs, and one-on-one remote workshops with health care professionals associated with the project. The empirical material was again broadly analysed to formulate citizen and professional URs. Here it became apparent that newly elicited URs could have different relations to previous ones (see D1.5, chapter 5).

Some of the new URs were unrelated to any previous URs or implementations, while some were unrelated but spoke to an existing implementation. Others, again, were related to previous URs, which either have been implemented already and thus indicate a first assessment and validation, or have not yet been implemented. In either case, new URs related to previous ones indicate their importance, through user input saturating them.

In formulating the second set of URs we were thus able to observe that some of them strengthened or added specific dimensions to previously elicited URs. While first PC were formulated for some of the new URs, the formulation of PC for these Y2 URs required to consider yet further elicited URs from Y3, and thus bring them together first.

This year's **third wave of co-creation** encompassed again different kinds of engagements with citizens, now coming out of and being independent of the CUCs, a well as professionals in research and health care (see section 3.3.1 and 3.3.2 respectively for details). Based on the empirical material from these engagements, additional URs were formulated, in particular for the functionalities of providing data to research, sharing data, and overviewing, managing and navigating the collected data in the user portal. Following these foci and the new ordering of the PAccT by situations *and* UDCs, most of the newly elicited URs pertained to the UDCs MyScience, MyTrusted and MyHealthView respectively.

With all the URs having been grouped in the spreadsheet PAccT by UDCs already by this time, we moved to the software Scapple to freely map out all URs within a UDC, but without taking over the existing internal structure by situations. Thereby we could cluster the URs by their content and first overarching themes (e.g., transparency), which allowed us to not only see overlaps and potential for consolidation but also to develop more abstract thematic categories and articulate the main problem areas of users engaging with the platform infrastructure (see chapter 5). Although rooted in academic writing (Rico 1983), also here "clustering gives you a non-linear, visual, and flexible technique to understand and organize your material" (Charmaz 2006: 86).

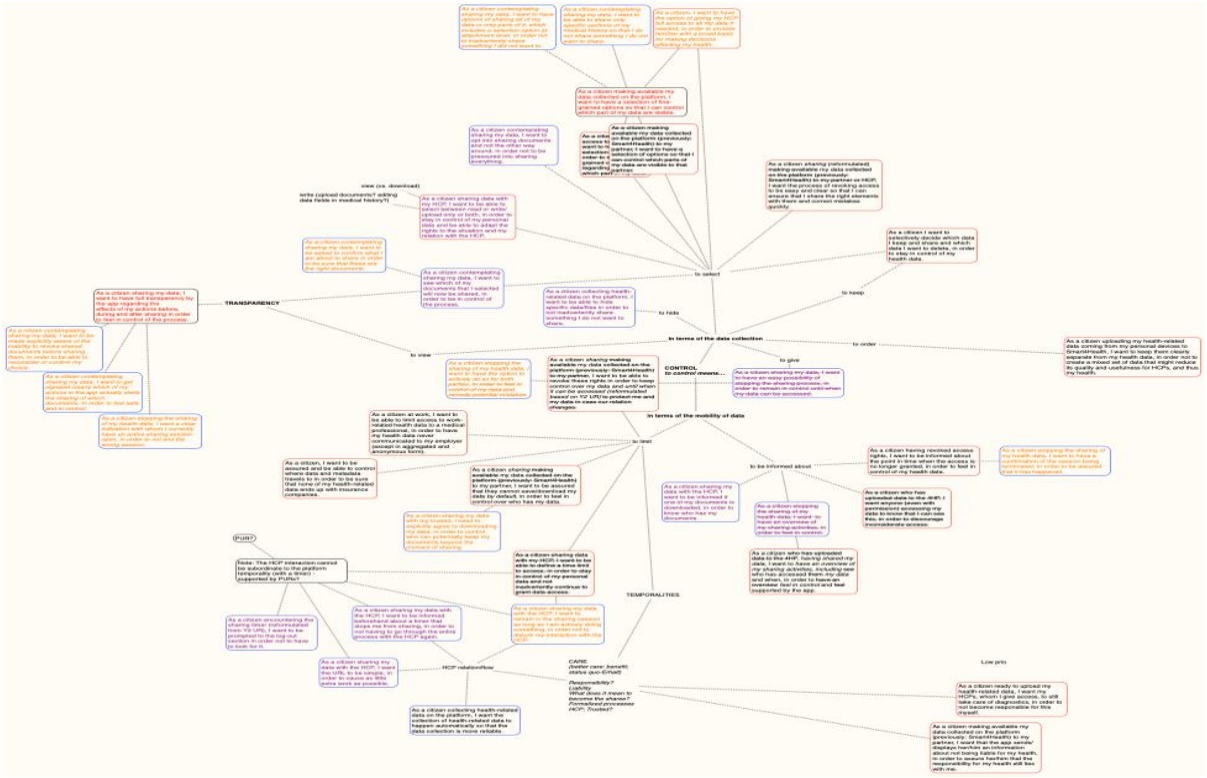

Figure 7 - UDC MyTrusted clustered UR map in Scapple.

The image above[4] shows an overview of the clustered map of URs for the UDC MyTrusted after several iterations and serves to illustrate the following outline of the mapping and clustering process. The clustering involved laying out all URs of a UDC and colour-coding their frame/box to indicate the project year, and the UR text to indicate:

- if it is a citizen or professional UR,
- if a new UR (Y2 or Y3) might better serve as a PC (e.g., when being rather instrumental) for another UR (regardless of year),
- or if it has been updated or integrated with another UR during this process already.

The categories seen in the image above as nodes, signify what the common theme of a UR cluster is about, e.g., control, choice, transparency. A summary of each in the context of a UDC as well as the relation of categories to another will be described in the next chapter 5. The placement of URs in a Scapple would matter in relation to other URs as well as to a category (or several ones) with their proximity in space indicating their relatedness to a category and their potential for being consolidated.

After the URs had been thematically analysed and clustered, consolidated, and reformulated, they were reintroduced into the spreadsheet PAccT. This step of newly listing the URs according to their categories and of bringing them into a specific order required a further moment of category specification and expansion, which enriched the

[4] Please note that the image of the UR map Scapple has been included as an illustration of the work process and not as a representation of the URs themselves. For a list of the URs readers should refer to the Annex.

narrative themes in chapter 5. Moreover, with all the consolidated URs from Y1-Y3 now in the PAccT, also the PC for each and every UR were formulated or updated, before transferring all the UR/PC updates into the online Jira version of the PAccT.

4.4 Implementation of User Requirements so far[5]

WP2 and WP3 are focused on implementing the prototype of the citizen-centred EHR exchange platform, as well as a user interface (the User Portal), services, and applications (such as a personalized health services app). All developments were flanked by multiple activities, and began from an initial, early version of a web application to manage unstructured health data, provided by D4L.

Following the first wave of the co-creation in Y1, where several co-creation workshops were conducted, including citizens, a first set of URs has been identified. In parallel and closely aligned to the elicitation of these requirements, described in detail in D1.3 (M12), the architecture and design of both the 4HealthNavigator (WP3) and the 4HealthPlatform (WP2) were specified. The deliverables showed that the URs have been addressed adequately with the proposed design of the components described in D2.1 (M12) and D3.1 (M12). All situations and URs of Y1 could be uniquely matched to the responsible components in D3.1. While D3.1 defines a blueprint for user interface and process functionalities of the 4HealthNavigator (4HN) to be ready for agile development, D2.1 reports on the planned architecture of the 4HealthPlatform and its technological components. The reported architecture leveraged on the designs from the technologies made available by D4L. The modifications and extensions necessary to realize the vision of Smart4Health, taking into consideration the URs and system requirements for CUCs are described. Of course, at that early stage, additional assumptions for the definition of the technical realization had to be made but were documented wherever necessary. The assumptions at this stage were many, but since then they are constantly vetted, detailed, validated, and extended in the context of the USEE workshops conducted in WP1 as described in D1.2 (M10). Thereby additional URs and details to the story maps have evolved. The agile development allows to iterate the implementations to meet the URs.

In month 18 of the project, D3.2 presents the user interface for the citizen-facing sign-up, login and account deletion in the 4HealthNavigator. This document builds on the prior work described above and on D1.4 (M12) on the citizen consent language. Underlining the regular refinements of the requirements, D3.2 considered a slightly updated version of the URs of Y1 which are all at least partially connected to the user account creation functionality, i.e., the URs of situations 1 (“Registering for the 4HP”), 2 (“Consenting to platform use”), and 15 (“Unsubscribing”). The deliverable documents that the URs significantly shaped the registration and consenting. With the work conducted, the partners have built a system to offer citizens a good user experience for the management of their accounts (in signing up, logging in, and deleting an

[5] In Annex 1 the current status of implemenation is reflected by the farthest right column in the PAccT table, which indicates the current space allocation of a UR in the PAccT (e.g., requirement, implementation, validation, or documentation space). Any allocation is part of the collective and continuous PAccT process (as described above) and thus subject to change.

account), such that regulatory, accessibility and technical requirements, as well as user requirements, are fulfilled. This was also achieved while fulfilling GDPR compliance and following the privacy-by-design principle, a key premise of the Smart4Health project. In this way, access to the sensitive citizen health and health-related information is given a strong protection.

Deliverable D3.2 exemplifies also that not all URs are realized right away, as UR2.1 and UR15.1 remained unaddressed. The former refers to the integration of a platform consent that uses shorter sentences or steps. The latter describes the possibility to set the citizen's account to an inactive mode, which the citizen can reactivate without data loss. Taking into consideration the valuable insights gathered during the rUSEEs, as future work we reassessed certain aspects of the functionality with the aim to come up with improvement plans for future iterations. In addition, it has been highlighted that the consortium needs to determine priorities among possible improvements to the platform. Therefore, partners in WP3 are working closely with those in WP 1 to determine such priorities, also balancing the cost and effort needed for each change.

At the end of Y2, D1.5 (M24) describes a substantially updated list of user requirements. At the same time, D2.2 (M24) reports on the design of the Citizen Health Data Platform (CHDP), as well as of its connection mechanisms via the Software Development Kit (SDK) and the data ingestion pipeline, and D3.3 (M24) reports on the management of access rights, and data sharing for the CHDP as well as the dynamic consent management used for the pipeline for data provision to research.

While the 1st specification of user requirements and performance criteria as reported in D1.3 (M12) has been used as a basis for the technical development towards D2.2 and D3.3, the work is well aligned with activities in WP1 towards D1.5. For example, D3.3 does present a more detailed set of specifications, while in parallel D1.5 already considers the technical developments presented in deliverables D2.2 and D3.3 and reports on the updated URs and PC, which draws on the entire set of empirical material collected in Y2 of the project.

For D2.2, URs, formulated as user stories, for registration and authentication (UR15.1 to 15.3), and information sharing (UR7.1 to 7.4, UR8.1 to UR8.3 and UR16.1) have been considered relevant to the CHDP. In D3.3, the latest formulations of URs and PC concerning the Dynamic Consent management are considered, indicating the status of realization reflecting the steps carried out in the context of the process of working with the PAccT. Most of these URs are addressing the consent formulation developed in the context of T1.5 Development of citizen/user consent language. These URs are technically realized within the Dynamic Consent management, as the consent formulations and user decisions can be easily modelled. In addition, D3.3 presents the updated list of URs and PCs related to data sharing: UR3.3, UR9.1 to UR9.3, UR14.1 and UR14.2.

Addressed URs within D2.3 (M30) on data provision to research (situation 10) and D3.4 (M32) on the User Portal realization (all situations under the UDC MyHealthView and related to the health data collection of a citizen user), are based on user engagements conducted by UNIVIE in the years 1, 2, and 3 of the project. Note that the user engagements in wave 3 had not been concluded then but are reported in this deliverable.

The intermediate result is a modular architecture of services put together to a production-ready system that fulfils the essential requirements of the prototype, and which exhibits extensibility properties with upcoming feedback and upon a wider adoption.

The development teams followed a product-centric, agile methodology tracking progress via an online ticket system. New versions of the developed system were released using continuous delivery processes, and the system was kept available with only few disruptions.

With the conclusion of T2.1 to T2.7 and T3.1 to T3.5, the teams of WP2/3 adjust to better accommodate upcoming work such as improvements and bug fixes. The functionality is under constant revision and expansion to, e.g., incorporate evolving URs. Subsequent improvements on implementations for closed tasks will be reported in the project periodic reports and in D2.5 4HealthPlatform Testing & Validation (M50) and D3.7 4HealthNavigator portal use case-oriented testing and validation (M50).

Within WP2 and WP3 there are other deliverables being worked on taking the latest stage of URs into account, i.e., D2.4 (M50) on 4HealthPlatform Data Centre Infrastructure, D3.5 (M50) with regards to internationalization, accessibility, and the exchange of electronic health records, and D3.6 (M50) on personalized health services.

For the technical development, input has been iteratively integrated from multiple streams and activities in other WPs:

- from waves of User Engagement Exercises (USEEs), including requirements captured in the Performance Accountability Table (PAccT) and iterated UDC narratives,
- from further feature discovery, such as the integration of structured health data visualization abilities, and
- from Citizen Use Cases (CUCs), as these progressively went live, and user feedback was and is received.

Also, it must be noted that the relevance of usability, feasibility, technical, and regulatory constraints is an important aspect to consider. It is our understanding that the Smart4Health project aims at building a prototype platform, however, given the sensitive nature of the health and health-related information it deals with, certain components need to be carefully implemented, e.g., to adhere to the GDPR regulation, to properly obtain access to health care provider systems, to identity management systems (eID/eIDAS), etc.

Finally, from a medical standpoint, it is important to clearly establish and communicate the goal of the platform (and associated apps) to avoid building a system that is rejected by regulatory entities or data protection organizations, e.g., for falling into the medical device category. To our knowledge, a system that supports the citizens in documenting their medical information does not run into this risk, and for this reason, we are building the CHDP along this direction.

5 Outlining the main problem areas of the platform infrastructure

5.1 Logic of the chapter

In this chapter we describe the main challenges of the platform infrastructure, which resulted from the qualitative analysis done for the consolidation of URs across waves (see section 4.3). In that process, categories such as transparency or control were identified that signify the common themes of one or more UR clusters. In the terminology of UR work, categories can be also understood as the overarching need that the related URs should be able to address.

Here we summarize these categories in the context of the UDCs that have been in focus in Y3 (MyHealthView, MyTrusted, MyScience) and how they relate to one another. Thereby, we not only provide an overview of UR categories but moreover articulations of main problem areas, and thus of challenges to be tackled, regarding major functionalities (the UDCs) of the platform infrastructure. These articulations are thus rooted in the co-creation work with actual and prospective citizen and professional users, and show how the same category comes to matter in the specific use context of a UDC, e.g., the need for transparency in providing data for research in MyScience, or in sharing data in MyTrusted.

The objective is to provide high-level insights from engagements with users regarding their needs and concerns when it comes to the platform infrastructure in-the-making. The following part summarises main lines of argumentation brought up. It also puts the input retrieved from citizens into conversation with that from professionals in health care and research. This allows to properly address citizens' perspectives, as citizens' needs also have to be aligned with those of health care professionals to assure that the platform can actually be used in practice and is beneficial.

The concrete user requirements are listed in Annex 1.

Before entering a broader description of our key observations – capturing the wider context of the user requirements –, we would like to draw attention to the fact that valuations, so the way people perceive the platform infrastructure and its functionalities, never happens in a straight forward manner but always in so-called **valuation constellations** (Waibel et al. 2021). Our analysis shows that citizens (but also health care professionals and researchers) never evaluate the platform infrastructure and its functionalities as a whole but rather make **situated assessments** of parts. This means that when listening to user needs formulated as requirements, we always have to be attentive to the triangle of valuator (who evaluates), valuee (what is exactly evaluated) and audience (to whom do they address the assessment).

People we engage with always can take on **specific roles** in a particular setting and at a specific point in time. For example, they might do something different when being at the doctor's office than when discussing with us outside a health care setting. And they might even change roles within one engagement exercise, e.g., at one time speaking as a father having to care for a sick relative, then as a citizen concerned with data protection, or speak in the name of others that could feel overwhelmed or excluded by the sheer amount of data work they are asked. Therefore, actors never have a uniform

view on the platform, which our analytic lens lets us attend to. We also have to carefully consider **what citizens actually evaluate** when they look at the platform, e.g., the complexity of the registration process, the sheer amount of data that is being collected, their feeling of losing control when providing data for research, etc. While embracing parts of this innovation, they might be quite concerned about others or even reject them. Finally, it is important to understand who citizens expect to listen to their reflections, so who is the audience addressed by certain utterances.

The following elaboration of the key points and the outline of the main problem areas that the platform infrastructure needs to address builds on the analysis of citizen engagements from the first three waves of co-creation. Before entering the three UDCs and related topics in detail we summarize the key points.

Key points

* **Empowerment** – the strong discourse that the Smart4Health will empower citizens to better care for their health in different situations also *raises high expectations* which then need to be met.

* **Transparency** – is a key request formulated across all engagement exercises and across all functionalities. Transparency is three-dimensional: informational, structural and processual and all three dimensions need to be fulfilled in order to create a solid trust relation. Transparency is then also the precondition for choice and control, two other key features central to the success and sustainability of the platform.

* **Control, Choice** – are two further points that are omnipresent in the engagements. Building on transparency, citizens, in particular when perceiving themselves as active and empowered, want to be and stay in control and want to have certain choices available (details in user requirements).

* **Temporalities** – This contains three main dimensions. First, choices and control of citizens should hold beyond the moment when they are made and remain stable. For example. present and future data flows should follow the same logic of control. Temporalities also matter in the HCP work and HCP-patient interactions; getting/giving access to health data (sharing) needs to be well fitting in the situation of consultation with the patient. Finally, also access to research data needs to be well temporalized.

* **Risk, responsibility, governance** – assurance of privacy and data protection need to be communicated clearly, but also assured in a transparent manner. Also the data access criteria and the members and workings of the data access committee need to be spelled out clearly.

5.2 MyHealthView: Overviewing, managing and navigating data

The MyHealthView functionality comprises the overview, management and navigation of personal health data and covers several situations: registration to the platform, consent and deregistration, and the collection of health data.

Empowerment and the expectation of control

In general, the development of the Smart4Health platform infrastructure strongly draws on a **narrative of citizen empowerment**. The functionalities of the platform assign citizens an active role in the collection of health and health-related data as well as in their management and in the decision-making of sharing them with trusted actors – they *should* be empowered citizens. Participants of our engagement exercises did embrace the role of an active citizen, ready to make choices and having the power to control and mobilize their health data. However, concerns were raised that not everybody is capable to perform that role. The citizens who embrace the empowerment narrative also voice the expectation of being and remaining in control of their data collection, i.e., of what health data they have at their disposal and where it may and may not flow, now and in the future.

If the order of the data that is currently in the platform is clear to citizens, they feel in control and can act confidently in situations where they need to/want to share data with a health care professional or another trusted person. Citizens want to be able to adapt the way the data is represented and ordered, so that they suit their needs and capabilities (see also below in MyTrusted). Furthermore, the data representation should be coherent across the different segments of the platform (i.e., in the way the health care professional can view the data, or in the way it is represented in the MyScience App that citizens can use when wanting to provide data for research).

Control was also voiced in a forward-looking manner – citizens wanted to be assured that they also have future control of the data collection. Given the efforts of collecting health data and of keeping them up to date and thus making them valuable, future access needs to be ensured, even if the password or the data key has been lost. Furthermore, citizens want to decide what data is stored and what data is deleted – and they want to be the only person being able to do so. While citizens could decide in the advance health directive to delegate uploading and deleting of data, this is still seen as keeping the demand of control and the active participant in deciding on this intact. Our thematic analysis of the user requirements from waves 1-3 showed that the expectation of control is closely related to one key-element: transparency, to which we will turn next.

Three-dimensional transparency ensuring a feeling of control

Citizens conceptualized transparency as a three-dimensional entity, and all three dimensions need to be considered for transparency to be fulfilled. First, they addressed **transparency in its informational dimension**. We saw this in particular in the context of the registration process, whereby informational transparency was key in their decision-making process to register. Informational transparency refers to questions on the procedures of data access, risks and benefits, duration of data storage and the potential of deregistration.

If informational transparency and, thus, understanding of the platform, its processes and protective measures is achieved, trust can be built and the decision for registration may be taken. The importance of informational transparency in the registration and consent process is not surprising, given the requirement of *informed* consent. Furthermore, it aligns well with an often-voiced position that claims that citizens only need to be informed for them to make a rational choice for platform use and, potentially, data provision; if they remain sceptical and hesitate, this is because they have not been informed enough.

However, as our analysis shows, the informational transparency is not sufficient. There is a second dimension to transparency, namely **relational transparency**. This kind of transparency goes beyond the processes within the platform and looks at the platform *infrastructure* and how it is part of a relational network. Citizens referred to relational transparency when they wanted to know who pays for the infrastructure, and whose interests might it cater to, or when they wanted the platform to be associated with national health care systems. This allowed them to assess whether or not they were facing risks to their privacy. The relationality also came up when they expressed their expectation that their Smart4Health account would be linked with national health data platforms as this relation was expected to support keeping data up to date.

Processuality is the third dimension of transparency, which refers to the platform prototype behaving in transparent ways. While the two previous dimensions were visible across all waves, the third dimension came to the fore most strongly in the remote user engagements and the one-on-one engagements with citizens in year two. There they had the opportunity to test parts of the platform prototype and the registration, upload, sharing and data provision functionalities, thus engaging hands-on with the prototype on a tablet, mobile phone, or their own computer.

Processual transparency points to the fact that citizens expect to see immediately and intuitively what actions they can and cannot take, that their actions deliver the expected outcomes and that their health data work is organised in an efficient manner, thus not being too time-consuming. Put differently, processual transparency requires the flow of actions to be clear, coherent, and time sensitive. And citizens expect clarity when it comes to the processes of registering, consenting, signing in, collecting and uploading data and in providing data for research. This also refers to practical issues such as names for classifications for citizens to order their data, clear visual indications as to what can be uploaded (e.g., maximum file size, data type), a good guiding system through the platform and a clear, easily understandable terminology for the processes.

Furthermore, processual transparency should also be ensured for HCPs, as citizens voiced concern that otherwise HCPs would not upload data to the platform. Citizens saw the HCPs as crucial collaborators in the data work of collecting previous and new health data, resulting in a complete and reliable data collection. For both, HCPs and researchers as potential professional users of the Smart4Health platform, it was crucial to be able to get information about the provenance of data, so that their reliability and potential value can be assessed (see also MyTrusted).

Only if transparency is ensured in all three above-mentioned dimensions citizens themselves feel able to enact control in the first place and thus embrace the empowered citizen role promised by the platform.

5.3 MyTrusted: Sharing data with trusted actors

"MyTrusted" refers to the functionality of sharing data with another trusted individual, whether in private or health care contexts. As such, it sets the citizen user in relation with either another citizen or a health care professional (HCP). In the following, the identified problem areas are thus between the sharer and the sharee.

Transparency of actions and data usefulness

In **sharing**, the processual dimension of transparency (as explained in the section above) matters most. From the engagements in wave 3 it was particularly apparent that citizens (as sharer) need transparency provided by the app before starting the sharing, about the effects their actions would have during and after it. Only then they would feel in control of this process and thus safe. This includes for example knowing exactly which action gives access to which selected data by being asked for confirmation, being aware that shared documents cannot be revoked after giving access to them, or having a clear indication with whom data is currently being shared. For example, the necessity to communicate a web-address in order to share was not realised before starting the sharing process, which caused irritation – spelling out a detailed web-address face-to-face was perceived as quite uncommon, also for digitally literate participants. When finally sharing data, and for it to be useful for the care relation, the HCPs as receiving end needed to know what the citizen user might have done with the data before sharing it.

HCPs for example need to know if and which parts of the medical history (being integrated in the user portal) have been self-reported and be able to distinguish between medical and self/patient-reported diagnoses/data to act on intelligible grounds[6]. This is also strongly related and supported by the need of citizens to separate their health-related data from health data in their collection, precisely for ensuring that the shared data is useful for HCPs and for the citizen's health in return. We will delve further into the control of data in the next section. The point here, however, is that particularly HCPs need to be able to quickly assess the quality and reliability of the shared data, and thus if it is useful to support the care work and if it does not disturb by adding time-consuming data work. This refers to both the content level of shared data, as well as the current work practices in place. While the latter is followed-up on in the third section, the former means that the data content needs to be recognizable for the HCP, for example by seeing unambiguous document titles with the option of having them translated by the app into the HCPs' language, or when a diagnosis was received and if it is still acute in the moment of sharing. In essence, HCPs thus need to be able to trust the data that is being shared with them in order to be supported in the care interaction and ultimately agree to using it.

[6] The challenge for citizens to self-report on risk factors in the medical history through an extensive list of conditions has been reported in detail in D1.5.

Control over data and citizen-HCP relation

In order for citizens to feel in control of their data in the context of sharing, the theme of being able to select what to share was very prominent. This ranges from fine-grained options, over larger groups of data to selecting all at once. Being in control also entails for citizens that no pre-selection of data to be shared is made for them, but that they need to opt-in to select whatever they want to share without restrictions in scope or content.

Having such control, however, is also recognized by citizens as a potential pitfall of sharing sensitive data inadvertently, for which they would then be responsible. Therefore, the need to exempt data from being shared/to hide data was voiced as a mechanism to mitigate such potential mistakes, which otherwise would only be possible by deleting those data and would run against the objective of using the app for collecting data. Regardless of that scenario though, the option of deleting data also supports the overall need for being in control over one's data collection.

The moment of actually selecting data for sharing is also crucial. Particularly in a consultation with an HCP, citizens would like to clearly know what the sharee/HCP needs, and HCPs would like to know what data the citizen could share. For one, also HCPs expect that citizens have the choice of selecting specific data, in order to only share a specific set of data and to avoid having to use time for sifting through diverse not so relevant data. For another, the categories provided by the app, and being able to freely choose from them, is important. These categories serve as basis for communicating about the data collection as well as for navigating in it. HCPs thus expect to see shared data in a well-structured manner. Furthermore, the consistency between HCP's view and that of the citizen is important, as well as being able to filter the shared data to quickly find the way to relevant data. Similar to citizens' choice in selecting what to share, HCPs also expressed the need of selecting what to download, to avoid having to download redundant data (e.g., an entire document with multiple attachments, when only one is relevant). Yet, also in this situation citizens are still in need to remain in control about their data, for example by agreeing that the sharee downloads data, being able to end the sharing session for both parties and determine when the granted access rights end.

Temporalities in the process and HCP work

With regards to the current work practices of HCPs in place, the need for a seamless integration of the sharing process into the time-pressed care work context is of paramount importance. This finds expression in rather avoidant terminology such as not having to help the citizen/sharer to fill out things in the app or to deal with time constraints imposed by it, e.g., a timer ending the sharing session and thus disrupting the care interaction, which should be supported by it. In essence, this underlines that the temporality inscribed in the app such as a timer running in the background, needs to be subordinate to that of the HCP work, and not the other way around.

On this end, the received input strengthens the need for *socio*-technical inter-operability in practice. Thus, the app needs to be able to integrate as much as possible into the existing care work, while requiring as little as possible adaptation from HCPs into the data work with it. Thereby the sharing of data can ensure that: it saves time

instead of demanding more, eases work instead of complicating it, and the data work does not stand in competition with the health care work but rather supports it.

However, the same goes for the citizen-facing end of activities with the app, as citizens expect to not get logged out by their app without prior notice, or without having had the chance to intervene or define oneself if and how long such a timer should run and be able to log them out. Otherwise, the app would be in control of this temporal dimension, not the citizen.

5.4 MyScience: Providing data for research

The MyScience notion refers to the functionality of providing data for research. Before citizens are able to do so, they have to install the MyScience App on their mobile devices and sign the informed consent for data provision.

Being in control through transparency

As in the previous sections, **control showed to be the central category** also with regard to data provision for research, with transparency as crucial for ensuring a feeling of control. When people consider providing their health and illness data for research, they are aware that the data are of potentially high value and they see this data as linked to their person/identity. The further data moves away from their reach (e.g., because they do not know/cannot assess the actors working with their data and the purpose of that work or the institutions they are associated with) and the less control they have over the purpose and actors of data access, the more forcefully they want to cut the link between the data and themselves (e.g., through full anonymization).

Transparency, thus, is crucial. If citizens agree to provide something they perceive as being of potential high value (i.e., their health data) they clearly expect, in return, to be respected as equal partners. They want to be taken seriously, want to get a realistic account of the processes and not an embellished version and underline that they intuitively recognize if the latter is the case. They interpret the behaviour of hiding important information either as cheating or as a form of paternalism, rejecting both.

In general, if the processes, possibilities and limitations of providing data for research are made (verbally and infrastructurally) transparent, trust seems to be substantially stronger. Also, in the case of data provision we see clear reference to the three-dimensional transparency mentioned above. Concretely it was argued as follows.

First, we saw the need for **informational transparency**, informing users about choices that can and cannot be made. This includes the selection mechanisms of data to provide for research or the potential pathways of data, to mention two points repeatedly raised.

Second, while citizens are aware that data literacy is key, **processual transparency** would be supported by consistent representations of health data across the platforms. If a citizen as user of the citizen health data platform has become familiar with how the data is represented there and knows how to navigate this part of the infrastructure, the data representation in the data provision process should not differ substantially in order to make selection a rather straightforward process. This means that the citizen health data platform and the research data platform need to be consistent in communication and representation.

Finally, **informational** and **relational transparency** was called for with regard to risks and protection as well as to governance and responsibility. **Citizens expect** clear communication concerning the protection of their data and they expect assurance that their data cannot be connected to them by actors unknown to them. They also want to know whom they can turn to, in case something goes wrong – this was seen as key. Accountabilities need to be defined, assumed by the relevant actors and communicated transparently. Furthermore, citizens were clear on wanting to get an understanding of who will be able to access data, under what circumstances and for what purposes as

well as how and by whom the decisions are made for researchers to access data in the first place. The Data Access Committee was perceived as a powerful body of control. Citizens thus wanted to know about who the members are and who they are affiliated with. Without transparency in this regard, trust cannot be built.

In a similar way, **researchers voiced** the need of knowing in detail the rules and criteria for access - including the duration of data use -, in order to perceive the data access process as fair and transparent and receive an explanation on the criteria not met, in case their application for data access was rejected. Also, temporalities were highly relevant; researchers wanted to have information on the timeframes of processing their applications, reassurance, that the decision-making process was fast and a confirmation that their application had been received and was processed, so to position themselves on the timeline.

On the relation between transparency and choice

As mentioned in the section on MyHealthView, participants largely did embrace the role of an active citizen, who is ready and willing to control their health data and make choices. In the context of MyScience, however, citizens tended towards having transparency regardless of how choice was possible. If choice was given, transparency was also seen as relevant. However, if there was no choice offered, they underlined the importance of transparency with regard to the reasons of why this is the case.

Both, choice and transparency have instrumental expressions, which are captured in a number of user requirements (see Annex I). Choice can be made instrumental through offering concrete selection possibilities, e.g., for what and by whom data may or may not be used or if citizens want or do not want to be re-contacted. The expectation of transparency was expressed by notions such as to be shown, to be informed, to be notified. In general, we witnessed the need for information on what actually health data is, what data provision and research with data actually means and what citizens can proactively decide, i.e., within what predefined limitations choices can be made.

Choice was also essential with regard to the research purpose, the future location of the data, the responsible actors and institutions as well as the kind of data to be provided. Choice had a clear temporal dimension. Citizens expected assurance that their choice would be respected not only in the here and now, but also in the further course of the data journey (Bates et al. 2016), i.e., choice needs to be respected throughout the process of using data for research. Dynamic consent, here, could support the placement of a transparent process which allows to revisit choice.

While choice was explicitly sought after, it was also seen as challenging and not everybody was perceived as being able to make well-supported choices. Citizens pointed to informational, knowledge-, literacy- and labour-related differences between people and groups of people. However, if choice is not given and thus control cannot be exerted, they expect a clear explanation why this is the case, an explanation that takes them seriously. This, again, ties these statements to the transparency dimension. Choice thus needs to be possible and information has to be accessible in order to add depth, if this is wanted (e.g., the evaluation of the data access committee or of the data access criteria). If a person then makes use of choice or not, e.g., because they are not capable or willing of doing so, is secondary.

The importance of a consistent user experience and role

If citizens accept the role of an informed, active, rational and self-determined actor when it comes to the health data platform, then they expect a similar role for them with regard to the research platform. If the relations to the two platforms are experienced very differently, this causes irritations and potentially diminishes their readiness to become a provider of health-related data. Actually, citizens expect being able to decide which data to provide, assessing if the protective measures are appropriate and taking over the responsibility if something goes wrong. At the same time, we met ambivalent feelings. They partly fear they lack experience to make the choice of data provision for research, caused by insecurities and feelings of being overchallenged.

However, transforming people into better informed, data-literate citizens will not be enough to get them on board for data provision; we had to learn that their **assessment of the infrastructure is complex**, **situated**, **shifting**. There is not one position they have towards the platform, but they sometimes shift registers in their thinking, assessment and evaluation, depending on what element they focus on. For instance, the narrative of public interest and benefit was often not seen as credible, as industry actors, particularly from the pharma industry, were routinely assumed to be on board. If there is neither choice nor transparency with regard to their ex- or inclusion, citizens immediately reject the narrative of public interest and collective benefit. This shows that **trust/scepticism is not absolute**, but an expression of the situated perception of the platform infrastructure (including the enrolled actors and mechanisms of value generation) and citizens' setting themselves in relation to public and/or private/corporate institutions.

6 Summary and final considerations

The objective of this deliverable has been to specify a third set of user requirements that describe the functionalities of the platform, to identify the related performance criteria, and to elaborate on the key points and outline the main challenges that the platform infrastructure needs to address.

In **Chapter 3** we discussed our methodological approach, in particular in and after the COVID-19 lockdowns. We first revisited the general approach to co-creation and offered some reflections on our methodological toolbox. Then, we delineated our third-wave engagements with citizens, health care professionals and researchers. Furthermore, we introduced the *Friction Input and Story Collector* (FISC) as an important methodological addition to our toolbox. Finally, we closed the chapter with an account of the project's engagements with policy actors so far.

In **Chapter 4**, then, we gave an update on Smart4Health's approach to ensure performance accountability (as introduced in D1.5). The chapter started with a recapitulation of the work with the project-internal Performance Accountability Table (PAccT), moved into a description of the restructuration of the PAccT and the user requirements therein. As reported, the restructuration happened according to the six broader functionalities of the platform – the Use Design Cases (UCDs) MyHealthView, MyTrusted, MyScience, MyTime, MyWork and Mob.E.Health – and involved also a refinement and consolidated specification of the URs and PC. The chapter ended with an overview of the technical implementation of the URs so far.

In **Chapter 5** we presented the main problem areas of the platform infrastructure, which resulted from the qualitative analysis done for the consolidation of URs across waves. The aim of the chapter was to provide high-level insights from engagements with users regarding their needs and concerns when it comes to the platform infrastructure in-the-making. The analysis followed the UDCs MyHealthView (the functionality of overviewing, managing and navigating data), MyTrusted (the functionality of sharing data with trusted actors) and MyScience (the functionality of providing data for research) and summarized the key challenges that need to be considered for the platform prototype to be functional, meaningful, and sustainable from a user perspective. We showed that certain aspects, such as transparency, control and choice, but also other features were prominent across all UDCs. Furthermore, it was clearly visible that the discourse on citizen empowerment did create quite high expectations on the side of users and thus calls for taking these promises very seriously when realising the platform prototype.

The URs and PC themselves were this time not included in the core text of the deliverable, which more strongly focused on the high-level insights from the analysis and the key points. Instead, the updated, consolidated and restructured list of URs and PC spanning wave 1-3 of co-creation were incorporated in the Annex.

The focus in the next wave of co-creation will be on cross-border care and in the further course of WP1 we will therefore continue to work with citizen users in the diverse settings of the CUCs. Qualitative interviews and other forms of engagement with medical personnel, nurses and other HCPs as well as nurse researchers were shifted to the beginning of the next wave of co-creation (September 2021 – April 2022, analysis to be presented in D1.7, M40) and will particularly look into to professionals'

needs at the clinical level in multi-language cross-border settings, e.g., with regard to medication plans and translation of drug names.

The URs and PC developed in wave 4 will be introduced into the list of URs/PC, structured according to UDCs. Furthermore, the analysis of the material collected in user engagement exercises will further substantiate the high-level insights and key points to consider presented in chapter 5. Further developments of URs/PC, high-level insights and key points will be presented in form of further reports on user requirements and performance criteria in D1.7 (M40).

Aspects of language translation, especially diagnoses and pharmaceuticals, will be specified during the upcoming reporting period, when (test) users will have structured data ingested/uploaded to their accounts.

Furthermore, we will continue to adapt our methodological toolbox and develop additional methodological approaches for facilitating co-creation processes. A chapter reflecting on the re-usability of our methodology for similar projects will be presented in the deliverable concluding 1.7 (“Final Report on User Requirements and Performance Criteria”, M40).

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List of Acronyms/Abbreviations

Acronym/ Abbreviation	Description
4HN	4HealthNavigator
4HP	4Health Platform
App	Application
app.	approximately
CCW	Co-Creation Workshop
CHDP	Citizen Health Data Platform
COVID-19	Corona Virus Disease 2019
CUC	Citizen Use Case
D	Deliverable
D4L	Data4Life gGmbH
DG	Directorate-General of the European Commission
EASPD	European Association of Service Providers for Persons with Disabilities
EC	European Commission
EFN	Fédération Européenne des Associations Infirmières AISBL
EHR	Electronic Health Record
eID	Electronic Identification
eIDAS	Electronic Identification, Authentication and Trust Services
ELIXIR-LU	European infrastructure for life science information – Luxembourg node
EU	European Union
FISC	Friction Input and Story Collector
GA	General Assembly
GDPR	General Data Protection Regulation
gGmbH	Gemeinnützige Gesellschaft mit beschränkter Haftung
GovMad	Government of Madeira
Horizon 2020	EU Research and Innovation funding programme 2014-2020
HCP	Health Care Professional
HM	Healthmetrix GmbH
HPI	Hasso-Plattner-Institute for Digital Engineering gGmbH

Acronym/ Abbreviation	Description
IC	Informed Consent
ICT	Information and Communication Technology
ICU	Intensive Care Unit
ICU4COVID	Cyber-Physical Intensive Care Medical System for Covid-19
IPS	International Patient Summary
ISMMS	Icahn School of Medicine at Mount Sinai
ITTM	Information Technology for Translational Medicine
LAUG	Longitudinal Accompanying User Groups
M	Month
(M)	Mockup
MEP	Member of the European Parliament
OECD	Organisation for Economic Co-operation and Development
OSR	Ospedale San Raffaele SRL
(P)	Prototype
PAccT	Performance Accountability Table
PC	Performance Criteria
PIN	Personal Identification Number
PUR	Professional User Requirement
Q	Quarter
QDA	Qualitative Data Analysis
RP	Research Platform
rUSEE	Remote User Engagement Exercise
SDK	Software Development Kit
Smart4Health	Citizen-centred EU-EHR exchange for personalised health
SME	Small and Medium-sized Enterprise
SPMS	Servicos Partilhados do Ministerio de Saude
T	Task
TelCo	Telephone Conference
ToC	Table of Contents
UDC	Use Design Case
UKA	Universitaetsklinikum Aachen

Acronym/ Abbreviation	Description
UMC+	University Medical Center Maastricht
UNINOVA	Instituto de Desenvolvimento de Novas Tecnologias
UNIVIE	Universitaet Wien
UR	User Requirement
US	United States of America
USEE	User Engagement Exercise
WP	Work Package
Y	Year
ZS-UG	ZS Unternehmen Gesundheit GmbH & CoKG

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Annex

List of user requirements and performance criteria (Y1-3)

This annex provides the list of User Requirements (URs) and Performance Criteria (PC) that have been elicited and developed in the first three waves of co-creation. While the URs and their PC are still grouped according to situations (as in D1.3 and D1.5), they are now structured according to the Use Design Cases (UDCs), as they describe and define the main functionalities of the platform infrastructure. The process of arriving at this new structure has been described in section 4.2.

Furthermore, a column has been added to the right side of the table that provides information of where the respective UR is currently located in the Performance Accountability Table (PAccT). Please note that the position of the UR in the PAccT is a snapshot, due to the PAccT's dynamic character.

(P)UR	User Requirement from Wave 1
(P)UR	User Requirement from Wave 2
(P)UR	User Requirement from Wave 3
(P)UR	User Requirement is no longer applicable
PC	Performance Criterion from Wave 1
PC	Performance Criterion from Wave 2
PC	Performance Criterion from Wave 3
PC	Performance Criterion no longer applicable
PC	Performance Criterion developed from a User Requirement
Requirement	At the point of writing, this UR is located in the Requirement Space of the Performance Accountability Table
Integration	At the point of writing, this UR is located in the Integration Space of the Performance Accountability Table
Validation and Assessment	At the point of writing, this UR is located in the Validation and Assessment Space of the Performance Accountability Table

1. User requirements and performance criteria from UDC MyHealthView (Y1-3)

UR #	User requirement	PC #	Performance criteria	PAccT Space
1. Registering for the 4HealthPlatform				
UR2_1.1	As a citizen registering for the platform, I want text only to 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).	PC2_1.1.1	The language selection remains consistent across all text sorts on the platform.	Validation and Assessment
UR3_1.1	As a citizen contemplating registering to Smart4Health, I want to know beforehand who will have access to my uploaded data, for how long it will be shared and if I have the right to withdraw, in order to value its trustworthiness.	PC1_1.1.1	The question of who has access to the uploaded data is explicitly addressed before a user has started the registration process.	Requirement
		PC1_1.1.2	The access possibilities are explained in a clear manner and are easy to understand.	
		PC1_1.1.3	Users need to have the possibility to ask questions before starting to register, in case doubts arise.	
UR3_1.2	As a citizen registering for Smart4Health, I need to have a good understanding of the risks and benefits in order to know what I will be using and make an informed decision.	PC1_2.2.1	The risks of enrolling in and using the platform have been thoroughly explained.	Requirement
		PC1_2.2.2	Strategies for risk mitigation have been thoroughly explained.	
		PC1_2.2.3	The benefits have been thoroughly explained.	
		PC2_1.2.1	*Text detailing risks and benefits can be expanded to be read more closely.*	
UR1_1.2	As a citizen contemplating registering to Smart4Health, I want to know how I can de-register before registering and what that means for my uploaded data, in order to avoid having to register and check if and how de-registering is possible.	PC1_1.2.1	The procedures for deregistration are explained before registration has been completed.	Validation and Assessment
		PC1_1.2.2	The consequences of deregistering for the uploaded data is explained.	
UR3_1.3	As a citizen registering for the platform, I want to have direct support by being able to contact someone and receiving a timely reply, in order to be taken seriously and have my questions answered.	PC1_2.3.1	Citizens can get in contact with the project consortium via an e-mail address that is monitored.	Requirement
		PC1_2.3.2	Citzens can get in contact with the project consortium via a phone number that is monitored.	
		PC1_2.3.3	Contact options are provided in multiple languages.	
UR1_1.3	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_1.3.1	Citizens can easily understand the scope of the project.	Validation and Assessment
		PC1_1.3.2	Citizens can easily find a list of who is involved in the development of Smart4Health (linked, max. 1 click from IC/startpage)	
		PC1_1.3.3	Citizens can easily determine who is funding the development of the platform (linked, max. 1 click from IC/startpage)	
		PC2_1.3.1	*Citizens can see what institutions the platform is associated with.*	
UR2_1.2	As a citizen contemplating registering for the platform, I want the platform to be associated with and promoted by the national healthcare system in order for me to feel safe and be assured that my privacy is protected (as they have that data already anyway).	PC2_1.2.1	The platform's relation with national healthcare systems is highlighted.	Validation and Assessment
UR2_1.3	As a citizen registering for the platform, I want to make a cookie selection once and for all and not be asked again, in order to feel my choice being taken seriously.	PC2_1.3.1	The cookie selection does not have to be redone in the same session.	Validation and Assessment
UR2_1.4	As a citizen registering for the platform, I want to get only those functionalities presented that I will be able to actually use after registering at this point in time.	PC2_1.4.1	The start page (carousel) and dashboard show only implemented and usable functionalities.	Validation and Assessment
UR2_1.5	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.	PC2_1.5.1	There is a visual indication on which items on the website are actionable and how to navigate them.	Validation and Assessment
		PC2_1.5.2	Users can easily identify actionable items.	
UR2_1.6	As a citizen validating my 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.	*PC2_1.6.1*	*Users are taken to the exact step in the process where they are supposed to take an action.*	Requirement
UR2_1.7	As a citizen authenticating my device, I want to be able to directly put in my country code so that I don't have to scroll through a long list.	PC2_1.7.1	There is the option of directly entering the country code.	Validation and Assessment

UR2_1.8	As a citizen registering for the platform, I want to clearly understand the reason for each step to assure me and build trust.	PC2_1.8.1 PC2_1.8.2	The user is led through the registration process in a coherent way. Each step of the registration process is explained in simple and accessible terms.	Validation and Assessment
UR2_1.9	As a person whose data may be on the Smart4Health platform I would want to know that only the Registered Data Controller and I can make the link between my data and my personal identity.	PC2_1.9.1 PC2_1.9.2	Citizens can easily find out who the registered data controller is. It is well explained who can make the link between the data and a users identity.	Validation and Assessment
2. Consenting to platform use				
UR1_2.1	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.	PC1_2.1.1 PC1_2.1.2 PC1_2.1.3 *PC2_2.1.1*	The sentences and sections in the IC are kept as short as possible. The language in the IC has been cleaned of jargon. The IC has been translated to Simple English/Leichter Lesen. *Legal terms and abbreviations are explained in an accessible way.*	Validation and Assessment
UR2_2.1	As a citizen going through the informed consent procedure, I want to be 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.	PC2_2.1.1	The consent text is displayed in an accessible way on mobile devices.	Validation and Assessment
UR2_2.2	As a citizen going through the informed consent procedure, I want to be guided by having a visual structure, in order to not miss any critical information and feel well informed without investing much time.	PC2_2.2.1	Users are visually guided through the informed consent procedure.	Validation and Assessment
3. Collecting health data				
UR2_3.1	As a citizen uploading health data to the platform, I want to be able to link national platforms and Smart4Health, in order not to be entirely responsible for keeping my health data up to date.	PC2_3.1.1 PC2_3.1.2	The citizen can link her/his S4H account with that on a national health data platform. Data can directly and automatically be ingested from national platforms.	Validation and Assessment
UR2_3.2	As a citizen uploading health data to the platform, I want to 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.	PC2_3.2.1	Citizen can view the uploaded attachments also in detail.	Validation and Assessment
UR2_3.3	As a citizen uploading health data to the platform, I want to have some clearly visible indication on the data type, maximum file size etc. in order to know what I can upload.	PC2_3.3.1	When uploading, the citizen is shown what data types and sizes can be uploaded.	Requirement
UR1_3.1	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.	PC1_3.1.1 PC1_3.1.2	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. There is textual and/or visual support information available at key moments of the process.	Validation and Assessment
UR1_3.3	As a citizen wanting to collect my data on the 4HP, I want the HCP to easily access my account in order to ensure that he/she will make use of it now and in the future so that I have an accurate and complete dataset.	PC1_3.3.1 PC1_3.3.2	The platform procedures fit with the workflow of the HCP, and ideally make it faster. With permission of the user, the HCP can upload data into the users's account without asking every time.	Validation and Assessment
UR2_3.4	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).	PC2_3.4.1	When uploading, the citizen is shown easy to understand classifications into which documents can fall.	Validation and Assessment
UR2_3.5	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.	PC2_3.5.1 PC2_3.5.2	The terminology in the documents section communicates clearly what can be done with which item. The terminology in the documents section communicates clearly how the items relate to one another.	Requirement
UR2_3.6	As a person with disabilities, I want to access and navigate the interface easily, in order to be included in using the platform despite any sensory (e.g. visual) impairments.	PC2_3.6.1	The interface is accessible for persons with sensory (e.g. visual) impairments.	Validation and Assessment

UR1_3.5	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.	PC1_3.5.1	Data coming from the HCP can be selectively accepted.	Validation and Assessment
UR2_3.7	As a citizen viewing my documents, I want to 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.	PC2_3.7.1 PC2_3.7.2 PC2_3.7.3	There are different modes of ordering the documents available. The mode of ordering the documents can be defined by the user. The order of the documents can be changed.	Requirement
UR2_3.8	As a citizen already having a S4H/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.	PC2_3.8.1 PC2_3.8.2	The document view is consistent across the S4H account and the Research App. The way documents are organized is consistent across the S4H account and the Research App.	Requirement
UR2_3.9	As a person whose data may be on the Smart4Health platform I would want to know that I can review it and check it is accurate.	PC2_3.9.1	The data's accuracy can be checked by the user.	Validation and Assessment
UR2_3.10	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.	PC2_3.10.1 PC2_3.10.2	There is an easliy understandable visual indication on how the documents are ordered. The visual indication is suitable for small and large data collections.	Requirement
UR2_3.11	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.	*PC2_3.11*	*There is a reliable separate identification procedure in place for regaining access to the account if password and registration key are lost.*	Validation and Assessment
UR1_5.3	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.	PC1_5.3.1	Option of having different areas for health data and health-related data is provided and can be selected.	Requirement
UR2_3.12	As a citizen collecting health-related data on the platform, I want the collection of health-related data to happen automatically so that the data collection is more reliable.	PC2_3.12.1	The connection to other apps allows for automatically uploading health-related data.	Requirement
UR2_3.13	As a citizen collecting health-related data on the platform, I want to be able to hide specific data/files in order to not inadvertently share something I do not want to share.	PC2_3.13.1	Citizens can select data/files to be hidden and non-shareable.	Requirement
UR2_6.1	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.	PC2_6.1.1	The citizen user at work can deselect any notifications about their posture or progress.	Requirement
UR3_3.1	As a citizen, I want my HCP to upload my previous and new health data in order to have an accurate and complete dataset and have as little work with it as possible.	PC1_3.2.1	HCPs have the possibility to upload previously collected data to the platform.	Requirement
15. De-registering				
UR1_15.1	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.	PC1_15.1.1 PC1_15.1.2 PC1_15.1.3	Deactivation of the account has been implemented. The collected data is kept when account is deactivated. Reactivation of the account has been implemented.	Requirement
UR1_15.2	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.	PC1_15.2.1 PC1_15.2.2 PC1_15.2.3	Deletion of the account has been implemented. Deletion of all collected data (in the CHDP) has been implemented. 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.	Validation and Assessment
UR1_15.3	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) and all my data have been deleted so that I rest assured that all traces of myself have been removed through the deletion request.	PC1_15.3.1 PC1_15.3.2	Before deleting the account, the citizen is informed about receiving a final confirmation (e.g. email, sms) when the deletion has been successfully done. After deleting the account, the citizen receives a final confirmation, that the deletion has been successfully done.	Validation and Assessment

16. Deleting data				
UR1_16.1	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.	PC1_16.1.1 PC1_16.1.2	Implemenation of options for selecting which data shall be deleted. The user has to confirm her/his desicion for deleting data.	Validation and Assessment
UR1_16.2	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.	PC1_16.2.1 PC1_16.2.2	Data deletion rights have been assigned only to account owner. Alignment with advance healthcare directive has been enabled.	Validation and Assessment
21. Assessing data provenance and accuracy				
PUR3_21.1	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.	PPC3_21.1.1	Self-reports by citizens are limited to issues they have knowledge of.	Requirement
PUR2_21.1	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.	PPC2_21.1.1	There is information available on the provenance of the data and who has assembled it.	Requirement
PUR1_21.1	As a nurse, I want to be able to enter/upload data easily, in order to not cause delays and lose trust in the system.	PPC1_21.1.1	HCPs can easily enter data.	Requirement

2. User requirements and performance criteria from UDC MyTrusted (Y1-3)

UR #	User requirement	PC #	Performance criteria	PAccT Space
3. Collecting Health Data				
UR1_5.3	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.	PC1_5.3.1	Option of having different areas for health data and health-related data is provided and can be selected.	Requirement
UR2_3.12	As a citizen collecting health-related data on the platform, I want the collection of health-related data to happen automatically so that the data collection is more reliable.	PC2_3.12.1	The connection to other apps allows for automatically uploading health-related data.	Requirement
UR2_3.13	As a citizen collecting health-related data on the platform, I want to be able to hide specific data/files in order to not inadvertently share something I do not want to share.	PC2_3.13.1	Citizens can select data/files to be hidden and non-shareable.	Requirement
UR1_14.2	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.	PC1_14.2.1	Those accessing data receive information that their access is logged.	Requirement
7. Sharing data (with the HCP)				
UR3_7.1	As a citizen sharing my data, I want to have full transparency by the app regarding the effects of my actions before, during and after sharing in order to feel in control of the process.	*PC3_7.1.1* *PC3_7.1.2* *PC3_7.1.3*	*There is transparency on the fact that documents cannot be revoked after they have been shared.* *There is transparency on which action starts the sharing of which document.* *Active sharing sessions and the participating actors are listed.*	Requirement
UR2_7.1	As a citizen contemplating sharing my data, I want to see which of my documents that I selected will now be shared, in order to be in control of the process.	*PC2_7.1.1*	*After having selected the documents, citizens confirm their choice.*	Requirement
UR1_7.4	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.	PC1_7.4.1 PC1_7.4.2 PC1_7.4.3	There are different options available for access by HCPs. Citizens themselves can define the access rights an HCP has. Citizens can check and adapt the access rights after having granted them.	Validation and Assessment
UR3_7.2	As a citizen making available my data collected on the platform, I want to have a selection of fine-grained options so that I can control which part of my data are visible.	*PC3_7.2.1* *PC3_7.2.2* *PC3_7.2.3* *PC1_7.1.1*	*There is the option to select all data or only parts of it for sharing.* *There is the option to select specific attachments for sharing.* *There is the option to select only parts of the medical history for sharing.* *Users have the option to grant HCPs access to all data at once.*	Integration
UR1_9.2	As a citizen sharing my data, 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.	PC1_9.2.1	An easy and clear option to de-select/revoke access is implemented.	Validation and Assessment
UR2_7.2	As a citizen contemplating sharing my data, I want to opt into sharing documents and not the other way around, in order not to be pressured into sharing everything.	PC2_7.2.1	Data sharing works via opting into sharing documents.	Validation and Assessment
UR1_16.1	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.	PC1_16.1.1 PC1_16.1.2	Implemenation of options for selecting which data shall be deleted. The user has to confirm her/his desicion for deleting data.	Validation and Assessment
UR1_6.1	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).	PC1_6.1.1	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.	Requirement

UR1_5.2	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.	PC1_5.2.1	Only the citizen user can enter the PIN from the sharing page into the app, and thus decide with whom to share.	Validation and Assessment
UR1_9.1	As a citizen sharing, I want to be able to revoke these rights in order to keep control over my data and until when it can be accessed.	PC1_9.1.1 PC1_9.1.2 PC1_ 9.1.3 *PC2_9.1.1*	Citizens can see and immediately understand to whom they have granted access. Access granted can be revoked at any time before it expires. Citizens can see and immediately understand for how long the granted access is valid. *Citizens can actively stop the sharing of health data for both parties*	Requirement
UR1_7.3	As a citizen sharing data with my HCP, I want to be able to define a time limit to access, in order to stay in control of my personal data and not inadvertently continue to grant data access.	PC1_7.3.1	Users are provided with different options to define a time limit of access.	Validation and Assessment
UR2_7.3	As a citizen sharing my data with the HCP, I want to remain in the sharing session as long as I am actively doing something, in order not to disturb my interaction with the HCP.	*PC2_7.3.1*	*Any platform activity by the citizen keeps the sharing process open.*	Validation and Assessment
UR2_7.4	As a citizen sharing my data with the HCP, I want 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.	PC2_7.4.1	Citizens are made aware about a timer that would interrupt their actions.	Requirement
UR2_7.5	As a citizen encountering the sharing timer, I want to be prompted to the log-out section in order not to have to look for it.	PC2_7.5.1	If there is a mandatory action, citizens are prompted to the requested next step.	Requirement
UR2_7.6	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.	PC2_7.6.1	The URL for sharing is simple and easy to communicate.	Validation and Assessment
UR2_7.7	As a citizen sharing my data with the HCP, I want to be informed if one of my documents is downloaded, in order to know who has my documents.	PC2_7.7.1	The sharing history contains information if one of the document has been downloaded.	Requirement
UR1_14.1	As a citizen having shared my data, I want to have an overview of my sharing activities, including who has accessed my data and when, in order to feel in control and supported by the app.	PC1_14.1.1 PC1_14.1.2	Access of others to data (via sharing) is logged. Access log is displayed for the citizen in a dedicated place.	Requirement
UR1_5.4	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.	PC1_5.4.1	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.	Validation and Assessment
PUR2_7.1	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.		n/a	Requirement
PUR2_7.2	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.	PPC_2_7.2.1	The patient/doctor interaction is not interrupted by a timer.	Requirement
PUR2_7.3	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.		n/a	Validation and Assessment
PUR1_1.1	As a nurse, I want to be able to enter/upload data easily, in order to not cause delays and lose trust in the system.		n/a	Requirement
PUR1_2.1	As a nurse, I want to be sure that the data I get to see from patients/citizens is relevant for my tasks and does not interfere with the work of others.	PPC1_2.1.1	As a nurse, I want to access Electronic Health Records in a standardised language.	Requirement
PUR1_1.2	As a nurse, I want to see if a patient-/citizen-action has been taken, such as when a medication has been received already, in order to get feedback by the system.	PPC1_1.2.1	The app traces if a citizen/patient action has been taken and is able to provide feedback to the HCP.	Requirement
PUR2_7.4	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.	PPC2_7.4.1	The sharee can select specific attachments within a document for download.	Requirement

PUR2_7.5	As an HCP receiving the medical history, I want to know if and which data are citizen-reported in order to treat them accordingly.	PPC2_7.5.1	There is indication if data has been citizen-reported.	Requirement
PUR2_7.6	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.	PPC2_7.6.1	Health data cannot be edited by the citizen.	Requirement
PUR2_7.7	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.	PPC2_7.7.1	There is the option to exclude patient-reported diagnosis from viewing the medical history.	Requirement
PUR2_7.8	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.	PPC2_7.8.1 PPC2_7.8.2	The medical history contains information on when the diagnosis was first received. The medical history contains information if a diagnosis is still acute.	Requirement
PUR2_7.9	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.	PPC2_7.9.1	Data and metadata can be accessed by the HCP.	Requirement
PUR2_7.10	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.	*PPC2_7.10.1*	*Document titles are translated into the language the platform is viewed in.*	Requirement
PUR2_7.11	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.	PPC2_7.11.1	The structure of data categories allows the citizen to easily search and select data during a conversation.	Requirement
PUR2_7.12	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.	PPC2_7.12.1	Clicking on full screen maximises an image by default without having to zoom in.	Requirement
PUR2_7.13	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.	PPC2_7.13.1 PPC2_7.13.2	There is a preview on documents available. The preview on documents contains metadata.	Requirement
PUR2_7.14	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.	PPC2_7.14.1	Filtering options for viewing patient data have been implemented.	Requirement
PUR2_7.15	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	PPC2_7.15.1	The information in the medical history is displayed in an accessible and well-structured way.	Requirement
PUR2_7.16	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.	PPC2_7.16.1	The sharee has the data displayed and ordered in the same way as the patient.	Requirement
PUR1_7.16	As a nurse, I want to be able to seamlessly upload existing health care data from the current health information system or EHR into the 4HP, in order to ensure a safe data migration and citizen support.	PPC1_7.16.1	Interoperability with existing health information systems is ensured widely.	Requirement
PUR2_7.17	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.	PPC2_7.17.1	The sharing URL is a simplified web address.	Validation and Assessment
PUR2_7.18	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.	PPC2_7.18.1	HCPs can filter for timeframes	Requirement

8. Sharing data with a trusted person				
UR1_8.1	As a citizen sharing with my partner, I want to be assured that they cannot save/download my data by default, in order to feel in control over who has my data.	PC1_8.1.1	A read-only sharing access is implemented, i.e. data download to another device is not officially supported.	Requirement
		PC2_8.1.1	*The trustee cannot download a file before the citizen has not agreed to this.*	
UR1_8.3	As a citizen making available my data collected on the platform 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.	PC1_8.3.1	The PIN-sharing site/link informs the receiving end about no added implications than in the current relation of sharer and sharee.	Requirement
9. Revoking access				
UR1_9.3	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.	PC1_9.3.1	Citizens receive feedback/confirmation after having revoked data access.	Requirement
		PC2_9.3.1	*The citizen has displayed a confirmation that the session has been terminated.*	

3. User requirements and performance criteria from UDC MyScience (Y1-3)

UR #	User requirement	PC #	Performance criteria	PAccT Space
10. Making data available for research				
UR1_10.1	As a citizen considering providing my data for research, I want to know for which kind of research (purpose, domain) my data is used, in order to exclude that data is used for purposes I do not condone.	PC1_10.1.1	Options to provide data for specific research purposes are provided.	Validation and Assessment
		PC1_10.1.2	Options to provide data for specific research purposes are clearly communicated/displayed.	
		PC1_10.1.3	Different options for data provision must be easy to select.	
		PC1_10.1.4	Data can be excluded from specific research purposes.	
UR2_10.2	As a citizen contemplating to provide my data for research, I want to know to which geographic locations my data will go, in order to assess the trustworthiness of potential recipients and local legal regulations.	PC1_10.2.1	Option to include data transfers to different locations is provided.	Validation and Assessment
		PC2_10.2.1	Data locations outside Europe can be excluded.	
UR1_10.3	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.	PC1_10.3.1	Option to include industrial research as a data recipient is provided.	Validation and Assessment
		PC1_10.3.2	Option to include academic research as a data recipient is provided.	
UR2_10.1	As a citizen providing my data for research, I want to be able to select which parts of my data I want to provide and which not, in order to feel in control and continue with the data provision.	PC2_10.1.1	Users can select data for provision.	Integration
UR2_10.3	As a citizen contemplating to provide my data for research, I want to know up front about the choices I have, in order to be able to decide quickly if I want to download the app.	PC2_10.3.1	Before the app download, the choices of data provision are explained.	Integration
UR2_10.4	As a citizen consenting to using the RP, I want to be able to adapt my initial choices also after having consented to using the app, in order to make an experience-based decision.	PC2_10.4.1	The choices made in the consent can be adapted afterwards.	Integration
UR3_10.1	As a citizen contemplating to provide my data for research, I want to know exactly what health data means and what data I am expected to provide, in order to be able to make this decision.	PC3_10.1.1	Before downloading the app, the expected data provision is explained in content and scope.	Integration
UR3_10.2	As a citizen contemplating to provide my data for research, I want to understand what it means to conduct health research within the platform and how my data is used therein, in order to be able to make this decision.	PC3_10.2.1	Before downloading the app, the use of provided data in the research platform is explained.	Integration
UR3_10.3	As a citizen contemplating to provide data for research, I want to have clearly communicated what I can and cannot do as a data provider, in order to have a realistic idea of my scope of action in the process.	PC3_10.3.1	Before downloading the app, the scope of possible actions in the app is outlined.	Integration
UR1_10.6	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.	PC1_10.6.1	Direct benefits of a specific data provision are outlined	Integration
		PC1_10.6.2	Indirect benefits of a specific data provision are outlined.	
		PC2_10.6.1	*The app can inform about outcomes of research that the citizen's data contributed to.*	
		PC2_10.6.2	*The app can show how often citizen's data was used for research.*	
UR3_10.4	As a citizen considering providing my data for research, I want to be able to know about the research conducted (with my data) and potential results, in order to feel like I am receiving something in return.	PC3_10.4.1	Before downloading the app, the types of research and potential results are outlined.	Integration
UR3_10.5	As a citizen contemplating to provide data for research, I want to have clearly communicated that data are valuable, in order to feel respected and taken seriously as data provider.	PC3_10.5.1	Before downloading the app, the value of data for research is explained.	Integration

UR2_10.5	As a citizen contemplating to provide my data for research, I want to know about the specific/concrete value my contribution could have instead of a generic narrative of helping (unspecified) others, in order to continue.	PC2_10.5.1	The value of the data provision for research and beyond is explained in the IC.	Integration
UR3_10.6	As a citizen considering providing my data for research, I want to know about the value of different kinds of data (e.g. fitness data) for research in order to make an informed decision about which data to provide.	PC3_10.6.1	The value of different data types is explained as help to make a selection.	Requirement
UR1_10.5	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.	PC1_10.5.1	Commitment of understanding of the non-alienability of health data is displayed in an introductory statement.	Validation and Assessment
UR1_10.4	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 while still contributing to research.	PC1_10.4.1	Option to provide data after citizen's death is provided.	Requirement
UR2_10.6	As a citizen contemplating to provide my data for research, I want to know 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.	PC2_10.6.1	Consequences of revoking consent are explained.	Integration
UR2_10.7	As a citizen reading the RP IC, I want 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.	PC2_10.7.1 PC2_10.7.2	The timeframe of the consent's validity is explained. The process for reconsenting is explained.	Integration
UR3_10.7	As a citizen considering providing my data for research, I want there to be clear accountabilities, mechanisms of control, and processes for the case that something goes wrong in order to feel like the providers are taking the protection of my data seriously.	PC3_10.7.1	The accountabilty of the data controller regarding a scope from data protection to data breach is explained.	Integration
UR3_10.8	As a citizen considering providing my data for research, I want there to be specific mechanisms of control that ensure that researchers on the S4H research platform stick to the rules in order to feel reassured that my data is not used for other purposes.	PC3_10.8.1	The accountabilty of the data controller regarding researcher access is explained.	Integration
UR2_10.8	As a citizen reading the RP IC, I want 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.	PC2_10.8.1 PC2_10.8.2	Compact sections contain all important points. No new points are introduced in the long version of the RC.	Integration
UR2_10.9	As a citizen consenting to using the RP, I want to have visual cues that indicate clearly how far in the process I am, in order to feel guided and continue without frustration.	PC2_10.9.1	Users see a visual representation of their progress in the consent process.	Requirement
UR2_10.10	As a citizen already having a S4H/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.	PC2_10.10.1	The look and feel of the data overview in the app follows the same logic as in the CHDP.	Requirement
UR2_10.11	As a citizen contemplating to provide my data for research, I want to know which of my data previously uploaded into the CHDP are eligible/useful for being provided for research, in order to continue.	PC2_10.11.1	The app shows which data in the CHDP are eligible for being provided to research.	Integration
UR2_10.12	As a citizen signing the consent, I want to have clearly indicated which selections are optional and which are mandatory, in order to to build trust and continue.	PC2_10.12.1 PC2_10.12.2	Mandatory and optional selections follow the same logic. Mandatory and optional selections can be distinguished.	Requirement
UR3_10.9	As a citizen considering providing my data for research, I want there to be a personal contact that I can consult if I have questions concerning the app and the project in order to build trust.	PC3_10.9.1	A personal contact option is provided for questions.	Integration
UR3_10.10	As a citizen considering providing my data for research, I want to be sufficiently informed about the processes of pseudonymization and anonymization in order to be able to assess the risks of re-identification.	PC3_10.10.1	The processes of anonymization and psedunyization, and their differences, are explained in the IC.	Integration
UR3_10.11	As a citizen considering providing my data for research, I want to know whether and how the GDPR applies to my data handled in the S4H research platform and MyScience app in order to draw on prior knowledge when assessing its modes of data protection.	PC3_10.11.1	How the GDPR relates to the research platform and the app is explained.	Integration

UR3_10.12	As a citizen considering providing my data for research, I want to be able to know who exactly is part of the Data Access Committee, what their affiliations are in order to assess whether I find this body of control trustworthy.	PC3_10.12.1	The DAC composition is outlined with institutional affiliations.	Integration
UR3_10.13	As a citizen considering providing my data for research, I want to know the criteria under which the Data Access Committee grants access as well as its control mechanisms in order to decide if they appropriately represent and protect me enough to continue.	PC3_10.13.1	The criteria on which the DAC acts are outlined sufficiently and in accessible language.	Integration
UR3_10.14	As a citizen reading the consent for data provision for research, I want to have an accessible and clear explanation of ELIXIR and its governance practices, in order to make an informed decision if I choose that option or not.	PC3_10.14.1	The role and governance of ELIXIR is explained.	Integration
11. Being re-contacted after providing data for research				
UR1_11.1	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.	PC1_11.1.1	When health-relevant research results are communicated, also a consultation by a qualified person is facilitated.	Integration
20. Applying for and accessing the research platform				
PUR3_10.1	As a researcher applying for data access, I want to receive a timely response that my proposal is being assessed, in order to be assured that my request is being considered.	PPC3_10.1.1	A confirmation of the access request being assessed is returned soon.	Integration
PUR3_10.2	As a researcher applying for access to the research platform, I want to get a fast decision, in order to proceed with my work.	PPC3_10.2.1	Decisions about access requests are made in 1-2 months.	Integration
PUR3_10.3	As a researcher applying for data access, I want to know in detail the rules and criteria for access, in order to feel assured that the assessment will be fair and transparent.	PPC3_10.3.1	The assessment criteria are accessible for applicants.	Integration
PUR3_10.4	As a researcher having the data access rejected, I want to be informed about the criteria that my proposal did not meet, in order to understand the decision and potentially resubmit my application.	PPC3_10.4.1	Rejected access requests are explained regarding the assessment criteria.	Integration
PUR3_10.5	As a researcher applying for access to the research platform, I want to know for how long I will have data access after my analysis, in order to ensure the reproducibility of published results.	PPC3_10.5.1	The duration of data access is explained at latest when applying for access.	Integration
PUR3_10.6	As a researcher accessing the research platform, I want to see at a glance which contexts the available data comes from (health data, health-related data, whether from work setting), in order to judge the possible scope of my analytic work.	PPC3_10.6.1	The dashboard shows the contexts of the available data.	Requirement

4. User requirements and performance criteria from UDC MyTime (Y1-3)

UR #	User requirement	PC #	Performance criteria	PAccT Space
5. Uploading health-related data (via Citizen Hub)				
UR1_5.1	As a citizen uploading my health-related data from personal devices to the 4HP, I want to be able to exclude specific fields, e.g. on eating or drinking habits, or location, in order to control what could be possibly seen when giving access.	PC5.1.1 PC5.1.2 PC5.1.3	Option of selecting specific fields of structured data for upload is provided. Selection of specific fields for upload is remembered. Selection of fields can be changed any time.	Validation and Assessment
UR1_5.2	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.	Validation and Assessment
UR1_5.3	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.	Requirement
UR2_3.12	As a citizen collecting health-related data on the platform, I want the collection of health-related data to happen automatically so that the data collection is more reliable.	PC2_3.12.1	The connection to other apps allows for automatically uploading health-related data.	Requirement
UR2_3.13	As a citizen collecting health-related data on the platform, I want to be able to hide specific data/files in order to not inadvertently share something I do not want to share.	PC2_3.13.1	Citizens can select data/files to be hidden and non-shareable.	Requirement

5. User requirements and performance criteria from UDC MyWork (Y1-3)

UR #	User requirement	PC #	Performance criteria	PAccT Space
5. Uploading health-related data (via Citizen Hub)				
UR1_5.2	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.	PC1_5.2.1	Only the citizen user can enter the PIN from the sharing page into the app, and thus decide with whom to share.	Validation and Assessment
UR2_3.12	As a citizen collecting health-related data on the platform, I want the collection of health-related data to happen automatically so that the data collection is more reliable.	PC2_3.12.1	The connection to other apps allows for automatically uploading health-related data.	Requirement
UR2_3.13	As a citizen collecting health-related data on the platform, I want to be able to hide specific data/files in order to not inadvertently share something I do not want to share.	PC2_3.13.1	Citizens can select data/files to be hidden and non-shareable.	Requirement
6. Workplace and health data				
UR1_6.1	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).	PC1_6.1.1	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.	Requirement
UR2_6.1	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.	PC2_6.1.1	The citizen user at work can deselect any notifications about their posture or progress.	Requirement

6. User requirements and performance criteria from UDC Mob.E.Health (Y1-3)

UR #	User requirement	PC #	Performance criteria	PAccT Space
12. Defining emergency information				
UR1_12.1	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 PC12.1.2 PC12.1.3	Different data fields are provided for input of emergency information. A selection of data fields by the citizen is possible. Only some data fields are mandatory, others are optional.	Validation and Assessment
UR1_12.2	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.	Validation and Assessment
UR1_12.3	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.	Requirement
UR1_8.4	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.	PC8.4.1	Alignment with healthcare directive has been enabled.	Requirement