Citizen-centred EU-EHR exchange for personalised health

Building today a healthier tomorrow

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

D1.1: Social Sciences and Humanities Framework Report.

Framing the research, development and design processes when building a prototype of a citizen-centred interoperable health-data exchange platform

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Short Abstract

Deliverable 1.1 provides the Social Sciences and Humanities Framework for the research, development and design processes *Smart4Health* will engage in when building a prototype of a citizen-centred interoperable health data exchange platform – the 4HealthPlatform. It aims at outlining the common understanding of the co-creation process the project envisages and lays out the aspects that need to be considered all along the project.

Grant Agreement:
826117

Further Information on the project

www.smart4health.eu

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Executive Summary

This is a slightly edited version of the Deliverable D1.1 of the Smart4Health project.

The objective of Deliverable 1.1 is to provide a general Social Sciences and Humanities (SSH) framework for *Smart4Health* project. This project aims to build the prototype for an interoperable health-data platform – the 4HealthPlatform – and a corresponding user portal – the 4HealthNavigator – in order to empower citizens to proactively engage in managing their health. Embracing a citizen-centred approach, the project will engage in a co-creation process predominantly involving citizen-users. This SSH framework will outline both the main approach and the kinds of questions that need to be asked during the research, development and design processes. Our report testifies to the consortium's awareness that the challenges of building such a health-data platform are never solely technical but are also always social.

After outlining the key features of the platform (chapter 2), the **five core chapters** of the report that follow will each highlight specific aspects of the Social Sciences and Humanities Framework for *Smart4Health*.

As the ways in which we understand the world around us, and ourselves, our bodies and our health, are the outcomes of relations created through technological means – in the case of this project through a health-data platform – chapter 3 outlines the general approach to the development and design of the 4HealthPlatform. To achieve a user-centred design and to integrate citizens' expectations, concerns and values, the project will: (1) use the four dimensions of responsible research and innovation (RRI) – anticipation, reflexivity, inclusion and responsiveness – as guiding principles; and (2) engage in a process of co-creation, closely engaging with citizen-users in a five-stage, cyclical process.

Shifting the perspective, chapter 4 focuses on the concept of “infrastructuring health”, i.e. the creation of a new data infrastructure with the aim of empowering citizens to care for their health in new ways. In three steps, this chapter stresses the importance of attentiveness to the visions, promises and values that are inscribed into the data-infrastructure; it invites to carefully reflect on the justifications given (and by whom) for needing such an infrastructure; and, finally, it points to the importance of closely observing the new ways of standardizing health through data.

Chapter 5 asks who the user of the health-data platform will be. This results in directing attention to non-users, and thereby to key issues that need to be examined during the process of developing, testing, and validating the prototype. These issues comprise questions about the in- and exclusion of different users, social justice, rationales of users, as well as how the diversity of users (and contexts of use) can remain in focus during the phase of building a prototype and beyond. Yet, we also draw attention to the fact that there might be a mismatch between imagined users and real-life users,

and that the platform might be used in ways that were not initially intended. All of this creates new challenges to be considered.

Chapter 6 moves the relations between data, health and citizenship to the core. It asks questions about what qualifies as good health data and about how data mediates a vision of health and our bodies (and suggests certain actions). Finally, it asks about how having access to the personal health data potentially changes what being a responsible citizen means.

Finally, chapter 7 explores the challenges raised by the need to adequately govern health-data infrastructures in order to assure societal trust. Given that the 4HealthPlatform is expected to work across national boundaries, we are confronted with a situation of multi-level governance. Many different actors shape and steer the ways in which health-data is produced, collected and made available. With this complex situation in mind, we suggest considering an experimentalist way of governance. This means organising forms of collective learning through systematically questioning assumption and practices, and admitting that we have little experience thus far in dealing with such a complex and sensitive infrastructure. Because the platform design and future use puts the citizen at the centre, we also need to consider what delegating responsibility to citizens means. How best we could include those citizens with a lower degree of ICT and data literacy, in order to empower them (and not overburden or even exclude them) is a key part of this consideration.

The deliverable concludes with a summary and final considerations. In essence, it reminds the reader why it is important to engage with the health-data platform development from the five different angles. Each of these angles provides specific sensitivities and invites to ask a set of questions that need to be considered along the design and construction process. Overall this SSH framework underlines the need to conceptualize the Smart4Health project not only as one that provides a digitally supported data-driven way for citizens to engage with their health, but also as a way of (re)infrastructuring health in the European context. Taking a responsible research and innovation approach, the project therefore engages in a process of co-creation – supported by citizen use cases –, being attentive to giving voice to a diverse range of citizen-users and carefully considering which societal values get embedded into and are realized through such a health-data platform. This is the strength of the Smart4Health project.

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1 Introduction[1]

The Horizon2020 project *Smart4Health*, funded by the European Commission (Grant number: 826117), aims at developing, testing and validating a secure, cloud-based, interoperable data platform prototype for electronic health records (EHR). Furthermore, this prototype shall entail integrated abilities for the aggregation of diverse sets of data beyond the EHR, as well as for sharing of them with trusted people and for data donation to the scientific community (see Figure 1).

The *Smart4Health* project aims to put the citizen and his/her health-related environment at the core of this new digital health infrastructure. This central objective of the project is spelled out along three lines[2].

- First, the aim of the project is to provide citizens throughout Europe with secure access to “an interoperable infrastructure to manage [their] own health information including wellbeing and fitness” – so data can consist of the electronic health record, but it will also “comprise self-quantified, citizen-generated data (IoT, wearables) and actionable Omics information, such as genomics”.
- Second, *Smart4Health* will develop a data infrastructure that provides “full possibility to provide/donate data for research and innovation, advancing knowledge, better prevention and personalised (precision) medicine”.
- Third, *Smart4Health* will allow European citizens “to self-determine the scope of data managed, with whom to share and to enter communication and interaction with other citizens”.

The idea of *Smart4Health* is to “enable the bridging between the diverse EU EHR [electronic health record] data and citizen-generated health data” and to “connect citizens to science and personalised health services.” The research and development work performed in the project is closely connected to the key priorities regarding digital health expressed in the mid-term review of the Digital Single Market in May 2017[3] and is in line with the General data protection regulation (EU) 2016/679 (GDPR) that is

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[1] Acknowledgement: We thank our project partners from EFN, I-VLAB, OSR, UKA, UNINOVA, ZS-UG, SHD and in particular Attila Wohlbrandt (HPI) and Andreas Kremer (ITTM) for their valuable feedback on the draft of this report. Our special thanks go to our colleagues researching in the domain of health and digitalisation — Klaus Høyer, Barbara Prainsack, Tamar Sharon and Sally Wyatt — for having taken the time to engage with us on the topics of this SSH framework and to support us in sharpening our argument.

[2] Quotes are taken from the project proposal text.

[3] In the mid-term review (COM 2017) the chapter on “Digital transformation of health and care” states as follows: “Digital technologies can help improve people’s health and address systemic challenges for healthcare systems. They can offer cost-effective tools to support the transition from a hospital-based health care model to a patient-centred and integrated one, improve access to care, and contribute to the sustainability and resilience of healthcare systems”. It further highlights that “high performance computing can unlock the potential of big data for health through advanced data infrastructure and data analytics. […] Health data generated in the EU and processed with patients’ explicit consent or other legal grounds permitted by the GDPR and subject to appropriate safeguards, can advance research in an unprecedented way”.

fully in force as of 25 May 2018. The latter grants, for the first time, European citizens not only the right to access their own data, but also to data portability, i.e. “to move, copy or transmit personal data easily form one IT environment to another (whether to their own systems, the systems of trusted third parties or those of new data controllers)”[4].

As the three objectives show, this project puts European citizens center stage – conceptually and methodologically. Producing an adequate solution for a portable, interoperable citizen health-data platform prototype will therefore **proceed in a process of co-creation/co-design involving citizens as well as diverse health-care professionals**. Through this approach, potential future users are put in the position of

- playing a central role in identifying needs, but also problems
- expressing values and concerns,
- proposing requirements to be met, and
- being involved in the testing when gradually building the prototype system.

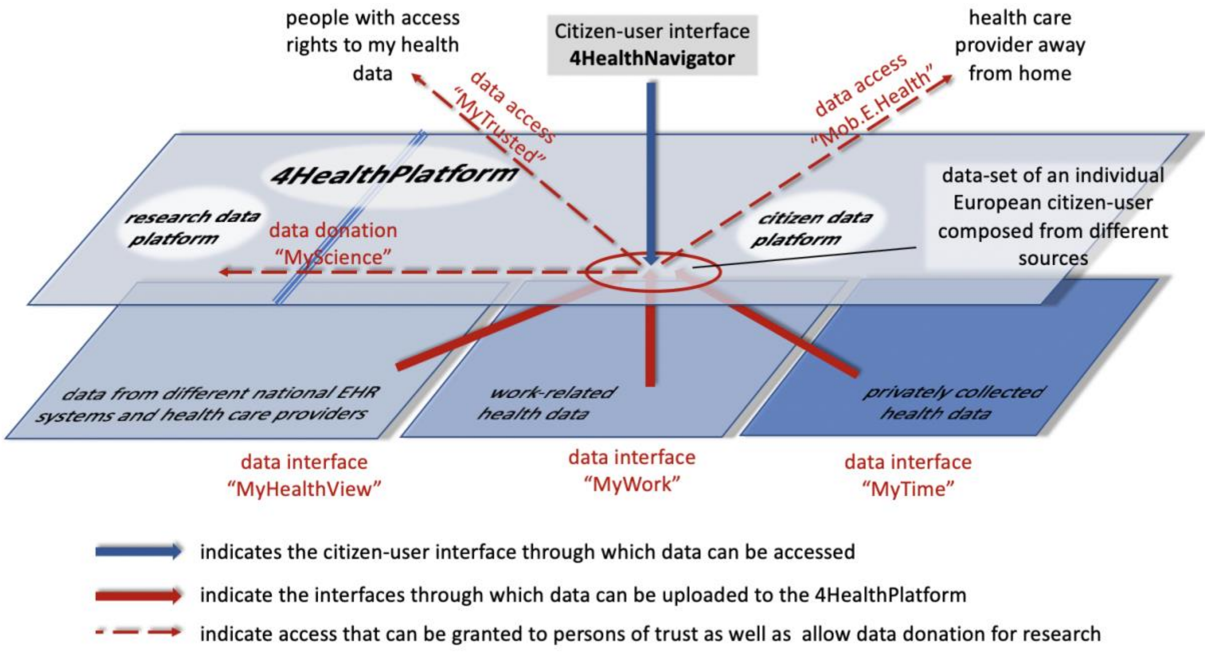

Figure 1 – Health data sources, access interfaces and data donation interface

As outlined in Figure 1, the data to be uploaded to the platform can come from three different sources:

- national electronic health records, as well as records from diverse health care providers

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[4] For a discussion of GDPR based user-centric interoperability of digital services from a legal perspective see (De Heert et al., 2018).

- health-related data that is collected in the context of work environments (e.g. data from wearables or physiotherapeutic treatments used to improve work related health)
- self-reported health-related data (produced through personal tracking devices, health apps, …).

A European citizen-user will then be able to create a data set composed from these different sources. Furthermore, the 4HealthPlatform will provide an interface to donate data for research purposes.

To assure the **uploading** of these three kinds of data in a user-friendly and secure manner, the necessary interfaces for data ingestion to the citizen's data space are designed and developed. Three so-called "Use Design Cases (UDCs)" – "MyHealthView", "MyTime" and "MyWork" – will be devoted to developing and designing the specific views and functions for the citizens. Three further Use Design Cases will then each focus on specific functionalities for allowing citizens to **give access** to their personal health data ("MyTrusted", "Mob.E.Health") or to donate their data to research ("MyScience").

The **4HealthNavigator**, which is the user portal, will connect citizens seamlessly with the 4HealthPlatform and provide access to different services.

In order to achieve this citizen-centeredness, the development process will concretely engage with users in eight so-called "**Citizen Use Cases (CUCs)**". They will involve citizen-users, professional users and other stakeholders (e.g. hospitals, national providers of EHRs) in different countries and empirical settings. They will cover a broad range of health care professionals interacting with citizens: general practitioners (GP), physiotherapists, hospital workforce, nurses, mobile caregivers. The Citizen Use Cases revolve around the core concern of backpain problems, as they are very widespread among the population (specific professional groups being highly affected) and have a detrimental socioeconomic impact (e.g. sick leave, work loss, early retirement).

Taken together, the UDCs describe the functionalities and the required elements of the *Smart4Health* prototype and the CUCs serve as case studies for the concrete and citizen-centered development, testing and evaluation of the overall platform and in particular the UDCs over the course of the project. The platform shall enable the European EHR exchange of health care data, of citizen-generated data about daily life and work (that may be relevant from a health and wellbeing perspective), and the donation of health data for research and innovation[5]. For that matter, the UDCs will help the user to delineate the data as coming from different sources and allow citizens to store, access, share, and, potentially, donate their health care and/or health-related data to research. Each of the six UDCs links citizens, data and potentially other health-related agents in specific ways and enables citizens to act on (and relate to) their data in new ways.

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[5] For the *Ethics of Data Donation* see e.g. Krutzinna and Floridi (2018).

For example, “MyHealthView” is meant to capture and support the management of health care data. It will show the overall health status (based on the health data collected in the health care system) and, thus, focus on actual daily management, navigation, and overview. “MyTime” is the area for citizen-generated health data, such as data generated via wearables or fitness trackers. “MyWork” has its focus on occupational health, safety and prevention at work and it allows the collection of citizen-generated health data (e.g. via specific wearables or by machines of physiotherapists testing and training their back muscles) in this context.

“MyTrusted” will offer the possibility of selectively sharing information with trusted *others* (e.g. medical professionals or other citizen-users). “Mob.E.Health“ shall be developed for situations of unanticipated care needs while travelling. It would, for example, allow a situated and temporally limited access to personal health data by emergency medical professionals. Finally, the “MyScience” use design case will approach questions of how to donate data for research, or how researchers might launch a call for citizens to participate in specific studies.

As can be seen from this short description of the scope of the project, the aim of *Smart4Health* is to construct the prototype of a large-scale health(care) data infrastructure that delivers benefits for citizens and health care professionals. The future vision of *Smart4Health* is that everybody living and working in the European Union should be able to access and share their own health and health care data easily and securely within the EU. The project therefore aims at supporting a digital transformation of the health (care) system. The core question for such an innovation is how it could be realized in a way that sufficiently considers societal needs and concerns, and the values of citizen-users. This requires taking into account existing power relationships, social and cultural disparities as well as existing inequalities (see Erikainen et al., 2019) and considering how the new digital health infrastructure might generate new ones or reify existing ones (see chapters 5 and 6 for more detailed reflections).

Indeed, there is a fine but consequential line

- between being in control of and being overburdened by data becoming essential to the care for one’s health,
- between being put in the position of accessing and managing personal health data and being made responsible for (accurate and/or complete) personal data representations, as well as
- between using health data to support informed decisions and uncritically equating an assemblage of health data with the health status of a person.

The aim of this report is to outline a broader Social Sciences and Humanities Framework guiding the *Smart4Health* project. The project plans to develop, test and validate a Europe-wide citizen-centred health-data exchange platform – the **4HealthPlatform** – and a corresponding user portal – the **4HealthNavigator**. The notion of “citizen-centred” points to the fact that future citizen-users should be at the core of the research, development and design processes leading to the prototype of the platform. The project underlines that the creation of this platform is guided by the idea of giving more agency to citizens and of turning them into central actors in the health(care) system. Yet, it is important to remain aware that building such a data infrastructure is always consequential and might bring along collateral effects which need consideration all along the development and design process.

In this light, the report **elaborates on the guiding logic of the project when it comes to building the health-data platform prototype.** The aim of this document, thus, is to spell out what such a **sociotechnical project** needs to consider in the different stages of its development in order **to become a sustainable infrastructure that is capable of supporting citizens' health and well-being as well as health-related research while at the same time caring for key societal values such as inclusion, justice and diversity**.

2 Responsible Research and Innovation as an underlying approach

Without any doubt, building such a citizen-centred, electronic health record exchange platform is an important innovation, both on a technological as well as on a societal level. It will do much more than simply collecting, describing and (re)presenting people's health data. Technologies always mediate the relation between humans and the world, between them and the social and material environments they live in – a relation that is gaining specific importance as mobility of citizens increases. In the context of health-related data, mobility points to a number of challenges. It addresses movements of people across national borders and, along with this, movement out of and into different health care systems. Yet, data also moves out of and into different traditions of recording and representing health-related data; this poses, for example, the challenge of reading and interpreting this data in a coherent manner (we will engage with these questions in chapter 6).

This relation of technological innovation to societal developments has been addressed by numerous analysts over the years. In the 1980s, analysts, such as Winner (1986), started to point to the fact that **technological innovations are shaped by values and, in turn, impact the ways in which we can live in the world,** often in invisible ways. Technologies can, indeed, ''authorize, allow, afford, encourage, permit, suggest, influence, block, render possible, forbid, and so on'' human action (Latour 2005, p. 72). This is of particular importance when it comes to questions of human health and how this will relate to the way data is collected and shared. **Designers**, then, can be seen as **materializing morality** by building technologies in specific ways and not others. Thus, as Verbeek (2006) would put it, they are doing "ethics by other means". As **technologies mediate between humans and the world,** they shape our perceptions and expectations, as well as our actions and practices and, thus, they mediate morality (Swierstra, 2015; Swierstra and Waelbers, 2012). This demands attending to "**history and political culture in ethical reasoning about technological futures**" (Jasanoff, 2016, p. 27), i.e. developing a sensitivity to the pre-existing value orders which get incorporated into our technological infrastructures and to the patterns of exclusion and injustice that need to be considered when building technologies and governing them.

In short: **How we understand the world around us, but also ourselves, our bodies and our health, is the outcome of relations created through technological means – in the case of this project, through building a health-data platform**. Envisioning, researching, developing and designing such a technology is never simply based on an already fixed and predefined set of ethical/moral/value related principles to be followed. These actions always also partake in shaping and realizing ethical/moral/value related principles in new ways.

The health-data platform developed in *Smart4Health*, the 4HealthPlatform, will mediate between citizens/patients and their understandings of their bodies and health status. It will thus contribute to the shaping of what counts as legitimate action regarding health and interconnected ways of living – even though this often happens implicitly. It will also invite citizen-users to consider access to data, to use them in taking action and to share their data. In that sense, it both stresses the role of the individual as an agent of his/her health, but will also invite donation for the collective good[6]. In fact, through the implementation of the General Data Protection Regulation (GDPR), we are witnessing a transfer of agency from the collective/political level to the individual level to decide about the use of his/her health data. At the same time, the process of digitisation is accompanied with considerable uncertainties and non-knowledge about its future impact. Therefore, it is essential to ask which values, ethical principles, and moral frames enter the processes of envisioning, researching, developing and designing such a citizen-centred electronic health record exchange platform and what kinds of new vulnerabilities or reification of existing ones might emerge (Jasanoff 2003)[7].

2.1 Responsible Research and Innovation: key dimensions

It is essential to carefully think through the different steps of this problem-oriented research and innovation process. To this end, we can draw on conceptual discussions, as well as on some of the more practical experiences with the “Responsible research and innovation (RRI)” approach, as defined in the framework of Horizon 2020 by the European Commission. The basic conceptual idea behind this frame was to support “transparent, interactive process[es] by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process” (von Schomberg 2011, p. 9). Involving citizens and stakeholders into the processes of innovation, is described as essential

- to “obtain relevant knowledge“ on the potential outcomes of innovations and
- for effectively assessing ”both outcomes and options in terms of societal needs and moral values“.

These insights should then become “functional requirements for design and development of new research, products, and services”[8].

In a way, RRI is the response to a growing awareness that innovations often come with unintended consequences and thus do not necessarily live up to the promises that were made when conceptualising and publicly arguing for their need. Simultaneously, by including citizens and stakeholders into the processes of innovation, there is hope for different kinds and more inclusive innovations. RRI can thus be seen as the attempt to ensure that **both the process and outcome of research and innovation are acceptable and socially desirable**.

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[6] For a discussion on the value of solidarity in donating data and contributing to the health care system see e.g. Prainsack and Buyx (2011)

[7] For an in-depth discussion of ethics, values and technological design see van den Hoven, Vermaas and van de Poel, 2014).

[8] Options for Strengthening Responsible Research and Innovation, European Commission, Directorate General for Research and Innovation Science in Society, EUR25766EN, 2013, https://ec.europa.eu

This means that **not solely market mechanisms should be the leading force in deciding “the normative dimension of what counts as an ‘improvement’”** (von Schomberg 2013, p. 54)**.** Instead, processes of engagement and deliberation – processes that integrate citizens and civil society actors – should allow a much more inclusive assessment of the value of innovations (Felt 2018). This points to a shift in attention from the (market) value *of* innovation, or a simple assessment of potential harm, to the **values** that are **embedded *in* and realized *through* innovations** (Felt, 2017). Attending to the values in technologies also acknowledges that different cultural contexts (in our case different traditions in understanding health and in organizing health care) potentially relate differently to technologies (such as a health-data system) and show preferences for specific technical solutions. Therefore, the exact direction of innovations, and the ways in which they imagine and attempt to shape societies, have to be carefully considered (Felt et al., 2007).

To implement RRI as a living concept, Stilgoe and co-authors (2013, p.1570) have identified four key-dimensions which need specific attention and fostering throughout the processes of research and innovation: “anticipation, reflexivity, inclusion and responsiveness”[9]. Thinking along these four RRI dimensions will allow us to better engage with the different aspects of the *Smart4Health* project (see Figure 2).

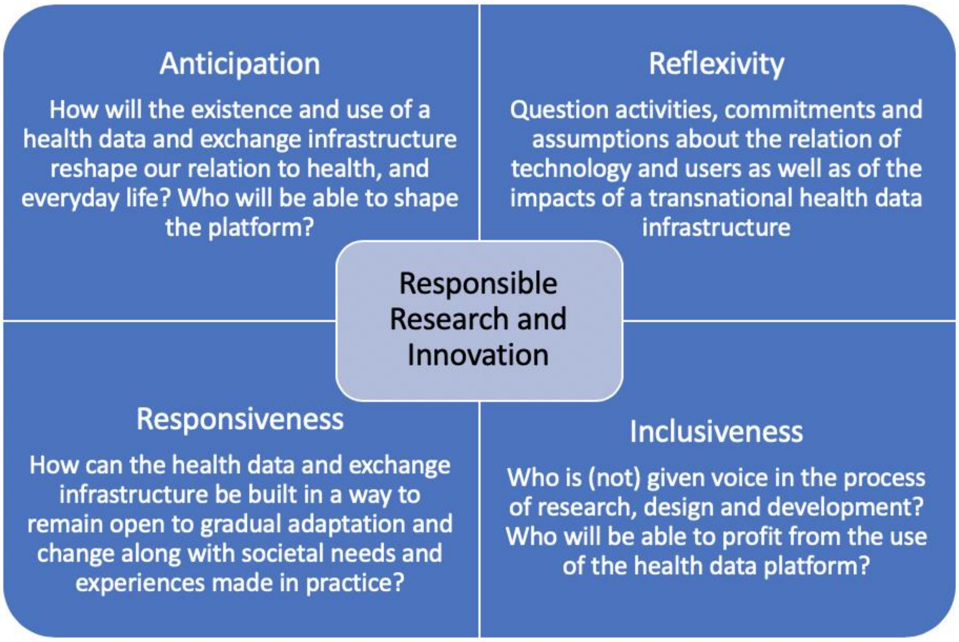

Figure 2 — Key dimensions of Responsible Research and Innovation (RRI) applied to the process of the Smart4Health platform development

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[9] For an overview of the questions to be asked under RRI see also (Owen and Pansera, 2019).

Anticipation refers to systematically thinking about the many different potential outcomes of innovation, (i.e. of the health-data platform), while concurrently admitting our limited capacities for foresight. Anticipatory thinking has a long-standing tradition in developing innovation. However, an RRI approach calls for a much broader take. First, it poses the question of who will be involved in defining what such a health-data infrastructure should achieve and for whom. Second, it requires us to broaden the basis for how health-related futures get imagined, going from a narrow expert/ scientist/developer driven idea to a more inclusive idea when deciding which health-related future should be realised through innovation. This will not only allow a better understanding of potential impacts of a digital transformation of health, but will above all allow for a more robust and legitimate decision making.

Reflexivity invites us to critically question "one's own activities, commitments and assumptions, being aware of the limits of knowledge and being mindful that a particular framing of an issue may not be universally held" (ibid., p. 1571). This means, in the case of *Smart4Health*, thinking about whose problems the new health-data infrastructure offers a solution to, and what kinds of potentially different commitments actors can have (from developers to different health care professionals). It also calls for considering what imaginations of potential users and use contexts every single actor brings to the design and implementation process. And it pushes us to reflect on absences, i.e. those elements that are getting less attention or are tacitly embedded in the research and innovation process, but that shape the process nevertheless.

Inclusion draws our attention to questions of power and who is given, or not given, voice in the evolution of any research and innovation process. It calls for different forms of user and stakeholder engagement in defining problems, identifying assumptions in framing, and suggesting, as well as assessing, solutions. As will be discussed in more details below, this means looking at both the imagined and the actually engaged users for whom the socio-technical solution is developed. It also reminds us that we need to look for those who, for whatever reason, might be excluded from any moments of participatory design and development. When it comes to health-related questions, it is of particular importance to give attention and space to social categories of difference, with specific regard for health status, age, professional occupation, gender or digital literacy.

Finally, **responsiveness** highlights the need to conduct research and innovation in ways that allow rethinking and adjusting "courses of action while recognising the insufficiency of knowledge and control" (ibid., p. 1572). For the design of the 4HealthPlatform, this means that both the process of building the prototype in the framework of this project, as well as the way the infrastructure will take shape, need to remain open to gradual adaptation and change. Societal needs and values expressed in practice and experiences made, can then be integrated into the development and design process.

Together, these dimensions should successfully "provide a framework for raising, discussing and responding" (ibid., p. 1570) to the key questions relevant to any sociotechnical trajectory that contemporary societies aim to embark upon – in our case, a sociotechnical trajectory which will reconfigure health care on numerous levels.

2.2 *Smart4Health*'s research and innovation process: a cyclical approach to co-creation

Following the premises of RRI, the research and innovation process in *Smart4Health* – as laid out in the project proposal – needs to be understood and performed in a cyclical manner. In principle, it contains five interconnected steps, which will be run through in several stages (see Figure 3). They contain a number of loops to get to a final prototype that is as inclusive as possible and still reflects the complexity of the interoperable endeavour in an adequate manner.

To this end, the project has chosen to **engage in a process of co-creation**, in order to define the requirements of the future health-data infrastructure and shape important elements/parts of it. If the health data infrastructure is supposed to **empower** citizen-users who care for their health, then we need to understand e.g. **how users conceptualize such possibilities, what issues and concerns they voice, and which rights and obligations/responsibilities for such "health-data related citizens" are being embedded into the infrastructure**. As will be outlined in chapter 6, this process needs to also consider questions of governance and ethical oversight. Once patient/citizen data will be stored on the platform, they might come to make a difference in patients' and citizens' lives and therefore needs close consideration.

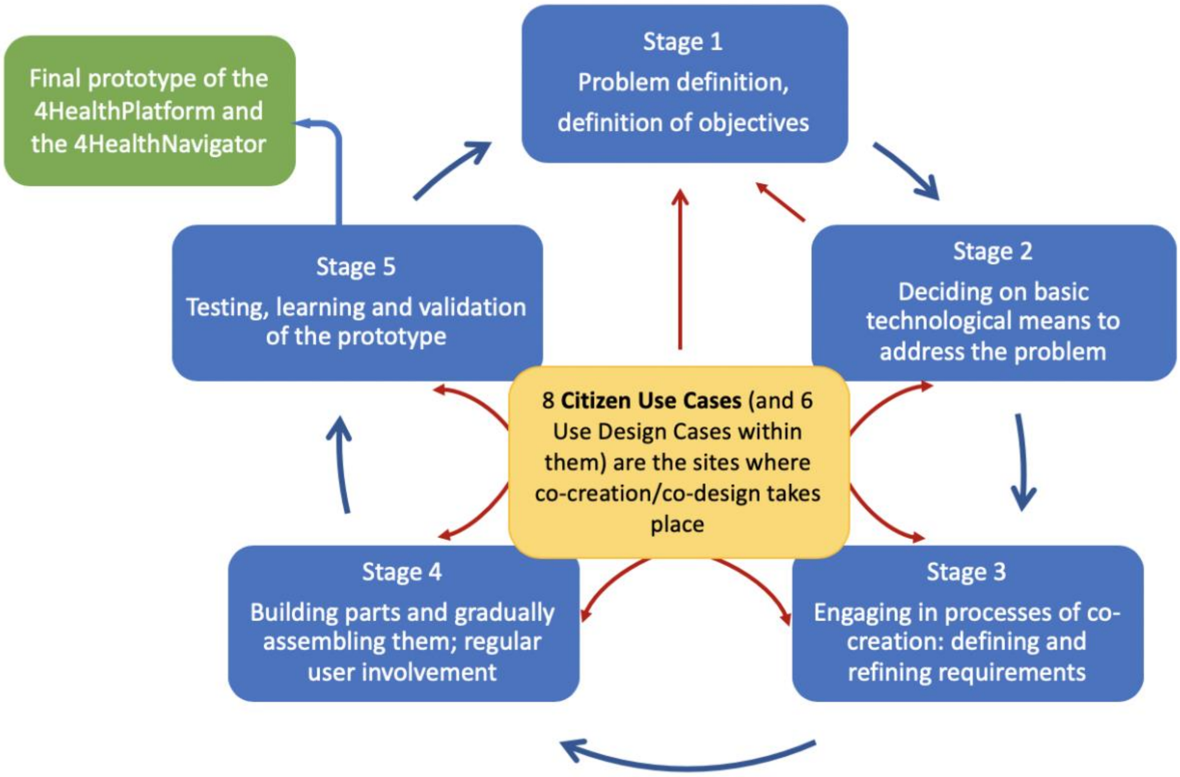

Figure 3 — Five-stage cyclical model for developing the prototype

Stage 1

The process starts with the **definition of a particular problem,** which goes hand in hand with **laying out objectives to be reached**. In the case of the *Smart4Health* project, the objective was defined as “the need of citizens to have access to and manage their health data” (project proposal). As problem definitions are key to the ways in which technological solutions get constructed, it is essential not to **take such statement as a given or as straightforward**. Who gets to define the problem at stake in the first place has implications for possible ways of acting, whose values count, and what interventions are made. A project that aims at innovating through building a citizen-centred health-data platform needs, therefore, to carefully question implicit assumptions about the values and needs of different users (citizen-users and professionals who will engage with these data in different contexts). It also needs to scrutinize the broader visions and the scenarios in and out of which the problems and needs are formulated. For example, policy debates very often refer to the need to rethink our health care systems in terms of resilience and sustainability, with the hope that digital health infrastructures will support cost-efficiency through lowering the number of days in hospital, avoiding non-adapted treatments when patients are not in their usual health care environment or supporting preventive measures. On the research side, the hopes are that applying data analytics to big data will improve diagnosis and treatments; this is reflected in the interface for data donation by citizen-users integrated in the Smart4Health prototype.

Stage 2

The process continues with a **selection of means,** which, in the case of *Smart4Health,* addresses both technological means and social science means. While the wider technological frame has already been described in the project application, this also entails starting the co-creation process through **telling a first story about potential citizen-users and what they might do, or not do, in order to create and manage their health data environment**. This leads to defining first requirements as a starting point (as they are drawn from first exchanges with the different actors involved in the CUCs, this part is linked to step 3) and developing the different elements of the new digital health infrastructure by focusing on a specific set of six Use Design Cases (as spelled out in the introduction). This takes place in **close interaction between social scientists and developers in the project,** exploring technological possibilities that can then be **iteratively adapted, gradually shaped and refined during the back and forth loops between step 2, 3, and 4.** However, we also have to be aware that **the choice of the starting point,** a first story and the involved persona, **matters** (Pruitt and Adlin, 2006) as they open-up specific solutions and might potentially close down others. We will come back to this point in chapter 5, the chapter on users and non-users.

Stage 3

A set of **potential citizen-users are identified and included in a process of co-creation**, which is facilitated through the engagement in concrete “Citizen Use Cases”.

A participatory approach[10] will enable a collectivization of the definition and the elaboration of problems and solutions. It will also open up spaces for mutual learning. This can then lead, for example, to the reshaping/rethinking of both concrete problems as defined in step 1, and the selection of means in step 2. Thus, technology developers learn about users' ways of thinking; this process will make space for diversity in users' voices, concerns, positions and use contexts. Users, in turn, also learn to explore and understand the potential and limits of such data infrastructures. The centre-piece of the development and design process in the project, therefore, will **create, facilitate and run a co-creation environment** (this will be elaborated in deliverable D 1.2), which connects the different steps in the development process. We will also engage with **professional users** along the process (e.g. medical doctors, physiotherapists or nurses who might be given access by citizen-users to their data during treatment or care), as they will help us to improve the usability experience for citizen-users.

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

Stage 4

The process of "**building" parts and gradually assembling them** is strongly based on stages 1-3. However, it also includes experiences from other data-intensive health-related use contexts in which technological elements have been developed. We will regularly **test specific solutions and functionalities** with users from the 8 Citizen Use Cases, thus going back to step 3 and refining the process. Several waves of engagement between users and (parts of) the platform will be held to ensure continuous co-creation and feedback into the other steps.

Stage 5

Once the building and **assembling process of the prototype** has started, phases of **testing, learning from them, improvement and gradual validation** sets in. This means going back to the CUCs and testing and validating specific design choices (of UDCs) and the overall prototype. At this point, we can go back to any of the previous steps and iterate them according to the experiences made. This, again, might go so far as to adapt or re-specify the definition of the problem, expressing limits and

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[10] For participatory design see for example Kensing and Blomberg (1998), Bratteteig and Wagner (2016), van der Velden and Mörtberg (2014) and Andersen et al. (2015).

potentialities in a more precise manner. However, we might also decide on additional or new means or see the need to involve other actors.

Going through these different steps comes with specific attention to the integration of different concerns, needs, expectations and positions, as well as regular feedback loops. It means to make the research, development and design processes more transparent and interactive. Through this process, societal actors, such as patients and citizens, health care professionals and platform developers, can become **mutually responsive** to another. The aim is to create a health-data platform, the 4HealthPlatform, and a related portal, including a user interface and services/ applications layer, the 4HealthNavigator, with a view to the (ethical) acceptability, accessibility, sustainability and societal desirability. This allows a productive embedding of the platform in diverse societal environments. Such an approach can assure advances in the health sector based on new forms of data flows, while caring for and respecting data protection and privacy frameworks.

KEY POINTS: What needs to be considered in the process leading towards the platform prototype?

- How we understand the world around us, our bodies and our health, is the outcome of relations created through technological means (in the case of this project, through building a health-data platform). **Technologies mediate the relations** between humans and the world; they are shaped by values and, in turn, impact the ways in which we can live and be in the world.
- This means that **values** are **embedded in** and **realized through** innovations. Furthermore, innovations often come with **unintended consequences** that differ from what has been promised in their initial conceptualization or in arguing for their relevance. It is crucial to **reflect on the values, ethical principles and moral frames** that enter into the **conceptualization** of the electronic health record exchange, and to remain open for reflection and adaptation over the course of the **development processes** of the platform.
- The framework of Responsible Research and Innovation (RRI) can help us here, as it seeks to ensure that the **process and outcome of research and innovation** are socially **acceptable** and **desirable**.
- There are four basic principles embedded in the process of RRI: **anticipatory thinking**, questioning the **values** and **choices** made, being as **inclusive as possible** in building a co-creation environment, and choosing solutions which can be **responsive** to **emerging needs and concerns**.
- In order to allow these basic principles to guide the development, Smart4Health follows a **five-step cyclical model**, which works with constant feedback loops with the 8 Citizen Use Cases at its core. Proceeding in this way should ensure the building of a citizen-centred model of a health-data platform.

3 Infrastructuring health

What does it mean to understand the interoperable EU-wide citizen-centred health data exchange system as key health-related **infrastructure**? In this report, we conceptualise an infrastructure as “not so much as a single thing”, but rather “as a bundle of heterogeneous things (standards, technological objects, administrative procedures) […] which involves both organizational work as well as technology” (Slota and Bowker, 2017, p. 531). Looking at *Smart4Health* from this angle means focusing on the **socio-technical arrangements** in which „technical, political, legal, and/or social innovations link previously separate, heterogeneous systems to form [a] more powerful and far reaching network“ (Edwards et al., 2009, p. 369) – and all of this is in-the-making. Concretely, in this project, the effort will consist of making national and institutional systems of electronic health records interoperable and feed them into the 4HealthPlatform. All this while simultaneously inviting citizens to generate and collect other forms of data, enlarging their data sets, and providing an interface to donate data for research (a research data platform will be part of the prototype built in the *Smart4Health* project) (see Figure 1).

While it is helpful to understand infrastructures as such a socio-technical arrangement, in this phase of the prototype making, we suggest not only focusing on the product, but also looking at the building of the platform as **a large-scale endeavour in infrastructuring health.** By using the notion of infrastructuring, and not infrastructure, we want to **draw the focus of our attention to the process, and not the product.** This means **being attentive to practices of imagining, researching, designing, making, and adapting, as well as testing, using and appropriating the health-data infrastructure prototype** that should come into being in this project. To that end, we are looking into and reflecting on the making and implementation of a specific structure through a process, by which practices and technological elements (hardware and software), form a social and technological, or a **socio-technical, network** (Grisot and Vassilakopoulou, 2017) related to health data[11]. Yet, infrastructuring health also means bringing into being specific kinds of citizens/patients, individually and collectively, who envisage, rethink and perform digitally supported and framed relations to their bodies and health, potentially in radically new ways.[12]

Engaging in infrastructuring health in the *Smart4Health* project entails bringing the health and information practices of a broad set of actors – ranging from patients to different health care professionals – into one socio-technical network. This socio-technical network includes many different contexts of use (e.g. personal, in a hospital, at the doctor’s, in research). At the same time, it offers new channels through otherwise distant actors can connect the coordinate themselves. Furthermore, it stretches over a number of otherwise nationally or locally organized health

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[11] For studies covering diverse aspects of infrastructing see Karasti and Blomberg (2017), Karasti, Pipek and Bowker (2018), Star and Bowker (2002), Ulriksen, Pedersen and Ellingsen (2017).

[12] See Felt and Fochler (2010) for the notion of “machineries for making publics.” They point to the fact that material arrangements of participation – in the case of this project this would be both the co-creation that will be organised as well as the health data infrastructure *Smart4Health* that is prototyped – always bring specific kinds of publics/patients/citizens into being. See also Korn et al. (2019) for a reflection on the relations of infrastructures and publics.

infrastructures, i.e. institutional data infrastructures or national electronic health records.

In doing this, infrastructuring is never a fully plannable exercise. We will not know beforehand which of these connections the infrastructure will stabilize in the future and become routinized, and which will not. Neither will we be able to foresee the practical use patterns that might emerge out of these new data practices. Aiming at such an interoperable Europe-wide citizen-centred health-data platform needs constant follow up, close observation, testing and reflection during the process of construction. This should be ensured through the cyclical process sketched in Figure 3 and through applying the four principles of Responsible Research and Innovation (Figure 2). Yet, even though it is beyond the scope of the project, it will be essential to continue such a follow-up process during implementation and use. This will mean **questioning,** within and beyond the project, **what "empowering the users**"– which is the central claim underlying promise – **means in practice for users**[13] **and what is made possible, for whom and under which circumstances** (e.g. Harris, Wathen and Wyatt 2010; see also chapter 6).

As has been pointed out by analysts studying infrastructures, these infrastructures never "grow de novo", and therefore always have to "wrestle with the 'inertia of the installed base' and inherit strengths and limitations from that base" (Star and Ruhleder, 1996, p. 113). They are **built on already existing information infrastructures and relations in the context of health care, on their strength and vulnerabilities** (e.g. how information was collected and stored in different places in the health care system and beyond before they became part of a wider infrastructure; see e.g. reflections in Hoeyer (2016) and Wadmann and Hoeyer (2018) on the Danish system). Yet, they also build on **socio-cultural routines and regulatory practices, the distribution of roles and responsibilities, as well as the trust relations** of actors involved in the system. Therefore, we have to scrutinize existing infrastructures and the relation they must develop with the 4HealthPlatform to be constructed. Yet, this also calls for closely considering **health and policy related cultures that are already in place in different nation states**, as well as their related governance structures (e.g. Felt, Fochler and Winkler, 2010[14]). They potentially become important forces in supporting or constraining developments – sometimes tacitly, sometimes explicitly – of such a health-data platform.

For the phase of designing and constructing the *Smart4Health* infrastructure, it seems promising to use an approach (Pollock and Williams, 2010; Monteiro et al., 2012; Hyysalo, 2010) which emphasizes the value and importance of **multi-sited and longitudinal studies.** This can be realized in two ways within the *Smart4Health* project. On the one hand, through the different Citizen Use Cases, we will be able to engage with citizen and professional users, but also different health-political contexts

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[13] In many of the reports and papers available on existing digital health infrastructures the notion of empowerment is straightforwardly introduced, without questioning what it potentially means for different people in different health-related environments.

[14] In this analysis we see how different technopolitical/biopolitical cultures, i.e. different culturally grown ways of dealing with biomedical issues such as organ transplantation or post-natal genetic testing, frame technological options differently.

(both on the level of different national health care systems, and institutional contexts). On the other hand, we will be following the development over a period of about 4 years, revisiting specific contexts of design, construction and use several times.

We have a few case studies which look into specific national health infrastructures and their development from a more qualitative point of view (e.g. Grisot and Vassilakopoulou (2017) for Norway; Hoeyer (2016) and Wadmann and Hoeyer (2018) for Denmark[15]). Moreover, there is little to no extensive comparative qualitative work that looks across different national electronic health care systems (e.g. Nøhr et al., 2017 for a selective comparative perspective; for an overview of digitization of health in Europe see SHS 2019[16]) and how they have been embraced and have become part of a wider health-care culture. In the case of *Smart4Health,* the new health-data platform has to be compatible with the pre-existing systems that are located in different national contexts, health care segments and insurance systems. Therefore, this cross-national integration of health-related data will be **challenging on at least two levels:** One is the **technical interoperability** of systems which will be exchanging data. The other is the **socio-cultural interoperability, which** will need to be addressed.

Within this project, we will engage with different sites in which the 8 Citizen Use Cases will be located, as well as remaining attentive to different (citizen and professional) users that are involved.

3.1 Visions, promises and values ‘scripted’ into the data-infrastructure

It is important to understand such a health-data infrastructure as more than its technical functioning. Infrastructures, as Larkin reminds us, “emerge out of and store within them forms of desire and fantasy” (Larkin 2013), they address different concerns and speak to certain values and not others. Therefore, it is essential to engage with and better understand what concrete **visions and promises** – e.g. of better health care, of “empowering citizens” through access to data – are built into an infrastructure. Whose visions are these? Whose values are being represented within them?

Hence, in our focus, we have to be attentive to the **power relations** that come into play. We have to care about the question of who can gain a voice in shaping an infrastructure and from what positions of power they arise. This helps us to understand

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[15] For Austria and Germany, there is an early questionnaire-based study of perception of Germans and Austrians towards EHRs which sheds some light on record keeping and relation to centralized collection of data (Hoerbst et al., 2010). Bonomi (2016) presents a comparative perspective on the electronic health records in a selected number of countries, pointing to similarities and differences. She includes Italy, Great Britain (England, Scotland andNorthern Ireland), Norway, Finland, Denmark and Sweden (the latter she summarizes under the “NorthernEurope” label.

[16] For a report by the Bertelsmann Stiftung comparing different national strategies see: https://www.bertelsmann-stiftung.de/en/our-projects/the-digital-patient/projektthemen/smarthealthsystems/; while the report captures the different actions in Europe in great detail, it does not engage with users beyond counting use etc. There is a stringent lack in more qualitative studies looking into how these infrastructures change users’ ways of understanding their health status. Quite a body of literature exists on the economic impact of digital health care infrastructures.

and reflect on who frames the ways in which this emerging new everyday health-data world is taking shape. Our main aim is to broadly interrogate the different normative voices: from policy and policy-related discourse over different professional-users to the multiplicity of citizen-users.

As the patient-data platforms are important players in the future vision of health care and, as this project aims to follow a citizen-/patient-centred design approach, we have to **question the promises that are being made** and the **meanings that get attached** to these developments. After all, they have the potential to radically reconfigure the health care environment of (some) individuals, fueling specific desires and creating specific needs. This requires asking questions about how these promises will be delivered and how practical social benefits “for all” will become tangible, e.g., through reconfiguring the health services in order to deliver them in a more equitable manner. In particular, this will mean being attentive to **how individual relations to health and health care,** and more **collective dimensions,** will relate to each other (see the discussion of individual vs collective approaches to discussing health data infrastructures, e.g. Sharon, 2018).

It is helpful here to think the research, development and design process of such an infrastructure using Akrich’s concept of a “script” being part of any technological innovation. Making the analogy between technologies and the production of a film, Akrich (1992, p. 208) suggests that “like a film script, technical objects define a framework of action together with the actors and the space in which they are supposed to act.” The concept of a script tries to capture how technological objects (in our case, a data-platform) enables, evokes or constrains specific actions and interactions. It also shapes human relations (e.g. in health care situations), as well as how it participates in creating new relationships between people, their health data and their relation to their bodies and lives. It evokes certain kinds of behaviors as (in)adequate and privileges certain actions over others.

For the 4HealthPlatform being developed in *Smart4Health*, for example, we can observe some **starting assumptions**, such as that *‘citizens want to start monitoring their health’* (e.g. through self-tracking) and that ‘*they want to become self-managing and proactive through engagement with their individual health data’*. The project takes for granted the increasing individual control over data (i.e. focus on informed consent or on privacy protection), while paying less attention to more collective approaches. This is in line with wider developments in the area of data-driven health measures. For example, a strong focus on informed consent as critical for a health data infrastructure is important, but it also puts the individual center stage and shifts responsibilities to the individual, while not asking broader questions. In a different example, expressing concerns mainly in terms of privacy protection shifts the discourse to compliance and contractual law. These are examples of choices that get and already have gotten scripted into the technological solutions and open up specific possibilities while not considering others.

In Akrich’s vision, the design processes are therefore key: they are the moments when scripts come into being, but also when responsibility gets distributed in specific ways.

As we have argued in the previous chapter, in the design phase needs, interests, capacities, behavior and ways of thinking about the health of future users are identified and materialized in the technological solution.

This approach invites a new way **of morally assessing technologies** with **specific attention to the design process and to the role they** (potentially come to) **play in their use contexts**. Responsibility, therefore, comes in two forms: responsibility of users (e.g. to collect and engage with health data), and also responsibility of the designers, as they are key in the process of inscribing specific value orders into technologies. Designers are quite powerful players in shaping “the mediating roles of technologies”, i.e. how technologies will enable users to perceive, appropriate and act in the health-related world. “But these roles also depend on the ways in which the technologies are used and on the ways in which the technologies in question allow unforeseen mediations to emerge” (Verbeek 2006, p. 371). Therefore, not only the design and development process matters, but the contexts of use, how users interpret and appropriate a technology also matters.

This explains the importance **of taking co-creation/co-design seriously**, i.e. to give voice to diverse sets of users with their visions and concerns, but also preferences for certain problem-solution packages and not others. This calls for carefully orchestrating how users, and those doing research, development and design, will remain in conversation when it comes to formulating requirements and assessing their practical realization. In short: technologies always contain a script, through which they attribute and delegate specific actions, they ascribe competencies, they assume shared values and they distribute responsibilities to users and technologies.

Building a health-data platform will create new **“geographies of responsibility”**, i.e. create a new distribution of responsibilities or transform or reinforce existing ones (Akrich 1992, p. 207-208). Indeed, as Petersen and co-authors (2019, p. 4) have highlighted, the technologies supporting the digitalization of health are “arguably integral to ‘responsibilising’ citizens, making them accountable (and potentially blameworthy) for health decisions, in line with a broad shift in the politics of citizenship under neoliberalism”. With that in mind, it is essential to be as inclusive as possible during development and design of the platform and to reflect the consequences of design choices.

Yet this is not an easy or straightforward process. Different groups of actors, or even groups that seem to be homogeneous, might favor different scripts and obvious contradictions might arise. Users might resist the given design or might create their own understandings of a technology. Finally, any technology can lead to unexpected positions and outcomes – in both positive and negative ways. It will be essential to identify these tensions, engage with them openly and be transparent about priorities when making choices. This means that the process will need to be adaptive and cyclical (as described above), making space and giving time to carefully balance the different perspectives and worlds of relevance. And, as Tromp and coauthors (2011) have pointed out, technologies often also aim at some form of behavioral change, or they ask users to embrace a specific role – in our case the citizen that cares for his/her health data. They do this in part, without explicitly acknowledging it. They also point to the potential conflict between collective and individual concerns, which needs careful balancing in making design choices.

The process of designing a health-data infrastructure, as captured in Figure 4, means that the 4HealthPlatform emerges out of a complex web of relations.

1. There is a relation of mutual shaping between the health-related environment and the health-data infrastructure being constructed. The pre-existing health-related environment (i.e. pre-existing institutions and infrastructures, individual and collective concerns as well as health policies) shape the technological solution, while the new health-data infrastructure will, in turn, also reshape the environment in terms of a digital transformation.

2. Developers and designers, the context of use, as well as the users themselves, are shaping and being shaped by the existing health-related environment.

3. Developers inscribe specific visions and values into the technology. They do so by anticipating specific users and contexts of use.

4. Users and non-users will come to matter, and not only in the version imagined by developers and designers in the early phase. They will be engaged in processes of co-creation through the 8 CUCs and will shape the infrastructure also through specific contexts of use, concrete ways of using it, through appropriating the technology, perceiving the meaning of their data and expressing specific expectations.

5. As an outcome of these processes, the health-data infrastructure will mediate the relation between different users and their **digitally transformed health-related environment**. This will impact how users perceive (their) health through data, which actions they are expected to take, what visions of health they can develop, and many more. Development and design are thus to be considered as a moral activity (Verbeek 2006) (see Figure 5).

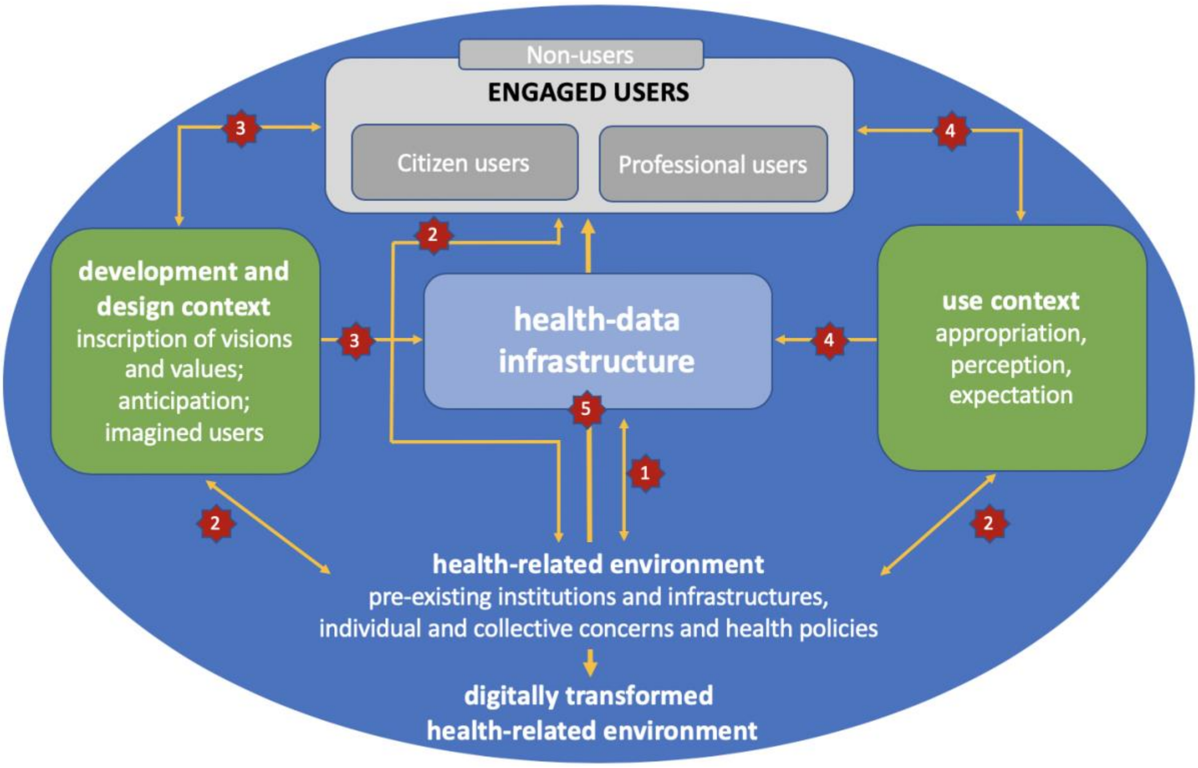

Figure 4 — Development and design as a "moral activity"

3.2 Reflect the justifications given for constructing the platform

Having reflected on the process of developing and designing such a health-data platform, this makes us aware that we have to go back to some of the very early arguments and look into the justifications that were given and the promises made when arguing in favour of such a platform. Justifications and promises are not regarded as solely discursive devices for building a convincing narrative, but they are understood as shaping actions and "having implications for conceptions of citizenship and established categories and distinctions" (Petersen, Tanner and Munsie, 2019). They thus represent an important element in shaping the final prototype. Tamar Sharon (2018) developed, inspired by Boltanski and Thévenot's (2006) work on "Justification", an in-depth analysis of stakeholders' argumentative strategies used in the context data of driven health initiatives. For the specific case of the *Smart4Health* project, we encountered at least three of the **moral repertoires of justification** she identified in her work. The central one is what she calls the "**vitalist repertoire**", which points to the fact that "good health, life and vitality are upheld as the highest values, (human) life and its proliferation is understood as having intrinsic value, the pursuit of the good life is framed in terms of the quest for health" (Sharon, 2018, p. 7). This is clearly framed in terms of individuals wanting and having to strive for healthier lives through engagement with their data. It links "health and vitality to virtue" and thus redefines what it means to be a responsible citizen.

Yet, as the research data platform is also part of the prototype being constructed in *Smart4Health*, other repertoires of justification can also be identified: the civic repertoire and the project repertoire. The **civic repertoire** “emphasizes the collective or general will over and above that of the individual” and conceptualises “the common good … as collective well-being”. (ibid., p. 5) This is to be achieved through the research made possible by individual data donation. The **project repertoire** of justification, in turn, conceptualises the common good “as innovation, specifically innovation that expands networks”. This repertoire of justification draws, in particular, on the idea that a data platform supported and actively used by citizens will allow bringing about “an exciting new future by approaching the research and health care system in an entirely innovative way”. The question that remains open is how such innovation strategies will come together with the values and imaginaries of citizens donating their data. This means that we see different and partly competing moral repertories that are present and need to be discussed in the process of construction.

With all this in mind, it will be essential to explore the different repertoires of justification throughout the time of the project and in very different contexts – and to reflect on the justifications given whenever key decisions are taken. This will allow for the identification of potential areas of tension, and we will see how these justifications will manage to face the ’reality tests’. It will make us reflect how the collective and individualistic view embedded in this prototype can come together in the long-term.

3.3 Standardization as key element in infrastructuring health

Infrastructuring always goes hand in hand with processes of standardization. Over the past century, we witnessed a variety of attempts to make health data comparable across time and space. Yet, in order to achieve this aim, “terminologies and communication routes need to be standardized, and technical standards have to be implemented so that the information systems of all these different parties can communicate smoothly” (Timmermans and Berg, 2003, p. 7). Guidelines on how to produce and store health data have been put in place in different health care institutions and research environments; education in the field of health care has, to a large degree, been standardized, as have diseases (International classification of diseases).

This will even become more important when aiming for the creation of **electronic health records, which are not only accessible across different (national) contexts, but also health records that share common basic quality standards.** This is essential, as electronic health records being used across different sites must not only assure that data/information and derived knowledge from them are preserved and made available, but that they can also be interpreted and used in a responsible manner independent of the original language and of the term-sets that were used in their creation. Indeed, while how to create a specific set of data might be standardized in a specific location or national context, it is far less clear how the creation of patient data through health care professionals is standardized across sites. It is not always the same sets of information about a patient’s health that is gathered, and, in part, the insurance structures and their reimbursement policies matter for what gets into a health record and what not.

It is identified as essential to orient towards common standards, or a harmonization of standards, on different levels. It is also essential to make different actors conform to them in order to turn data into useful information across sites. This requires, and is necessarily preceded by, acts of giving form and thus demands “investment in form”, which in turn might rely on different “formats of information” (Thévenot, 1984). Any such process of standardization always stands in tension between “disciplining uniformity”, i.e. achieving the ideal of sameness (objectivity) across very different sites, and the very difficult to “impossible accomplishment in the face of actual practice” (Thévenot, 2009).

Building and running an interoperable Europe-wide citizen-centred health data exchange platform, therefore, will demand specific attention to standardisation, yet also demand reflecting carefully on how standards are defined. This will be a major challenge, as different countries have already engaged in creating quite broad digital health care environments (incl. standard health care records and also other personal health data), such as the Netherlands, Denmark, Sweden, Belgium, Estonia, Norway, Poland, …..[17] This is important on three levels, and calls for asking three questions:

- How are the different elements of the health-data platform be standardized in practice?
- What is the role of daily practices, and pre-existing systems?
- Who will (not) be involved in the process of defining such standards?

KEY POINTS: What does it mean to look at infrastructuring health?

- We understand the development of the Smart4Health prototype as a large-scale endeavor in **infrastructuring health**. Infrastructuring health entails bringing health and information practices of a broad set of actors into **one socio-technical network**, one that reaches into many different contexts, enabling new connections.
- Infrastructures always build on **already existing (information) infrastructures** and relations, on their strengths and vulnerabilities. Infrastructures incorporate specific concerns, values and visions and their development testifies to power relations in who gets to articulate the initial justification and who gets to participate further.
- Processes of **standardization** are an important element of the development and stabilization of infrastructures. Therefore, we will pay particular attention to how standards are defined, how patient data is standardized across sites, and how different actors are made to conform to common standards in order to make the data that has been collected useful across sites.
- In our work, we will look more at the process (“**infrastructuring**”) than at the product (“**infrastructure**”). We will be attentive to practices of **imagining,**

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[17] For a comparison of digitization strategies in 17 countries, see https://blog.der-digitale-patient.de/en/smarthealthsystems-launched-digitization-strategy/.

researching, designing, making, and adapting as well as testing, using and appropriating the health-data infrastructure prototype that is supposed to come into being in this project. We will continuously reflect on the concrete visions, values and promises that are built into the infrastructure, and whose those are.

- This explains the importance **of taking co-creation/co-design seriously**, i.e. to open collaborative spaces in which diverse groups of potential users can articulate their visions and concerns, as well as their preferences for certain problem-solution packages and not others.

4 Users and non-users

The question of who should get a voice in the development and design process has been a question right from the start. While the notion “citizen-centeredness” already hints at the role that should be attributed to individual users, it is essential to more closely reflect on who “the user” is, or is imagined to be. In this way, we will also care for potential non-users; non-users who might be “created” through the conceptualization and design of the 4HealthPlatform.

4.1 Who are the (non) users?

While this is a question that is highly relevant to all technology development, in the domain of health, it takes complexity to a new level. When looking at health-related technologies, we find users as diverse as patients and their families, self-help groups, medical and health-related professionals, health care administrators, and care-givers – just to mention the most obvious ones. We could add health insurers, even though they act in a more indirect manner, or even other players in the socio-economic field, who might take health-related information as an important input when making choices. And to complexify the picture even more: any single user might have different needs when it comes to a variety of situations in which access to a data infrastructure (and its information) becomes important. So “**who is the user**?” becomes a highly non-trivial question, in particular when this means **prioritizing one user need** over another, or when balancing privacy issues with big questions of health care, and many more (Oudshoorn and Pinch, 2003; Hyysalo, Jensen and Oudshoorn, 2016).

We also have to be aware that by identifying specific individuals and groups, we also define the actual room for maneuver they have with regard to this technology. And by homogenizing these groups, we flatten the differences within each group and limit the diversity of their perceptions. In short, there are **no clear-cut categories, such as “patients” or “citizens”. The same holds for potential future users of health data which have been granted access, such as nurses, administrators, or doctors.** Each of these groups shows quite important internal differences with regard to needs, values and envisioned data-related health care. Also, categories such as gender, age, socio-economic status, and ethnic differences among users may all be relevant within each of the groups just mentioned. Due to the intersectionality of different social categories, and the effects they have, it is clear that not all users will have the same power in shaping the future technology in the end. While inequalities in getting one’s voice heard are unavoidable to a certain degree, it seems essential to reflect on the different options available, to acknowledge the difficulty in making clear-cut preferences, and to make choices transparent.

In particular, it will be key throughout the design process to reflect on the dynamics underlying the processes of “configuring the user as everybody” (Oudshoorn, Rommes and Stienstra, 2004). This means reflecting on the relation between the technology being designed and the identities of users imagined – studies have frequently pointed to the fact that age and gender are often not sufficiently considered in the design of information and communication technologies even though both are the large majority of potential users (e.g. Oudshoorn, Neven and Stienstra, 2016). This, in turn, also means reflecting where designers situate their own experiences and identities, which will flow into the design. Specifically, this will demand reflecting on the degree of **data literacy** that is presumed from future users, how technologically literate they have to be and what understandings of health and related individual responsibility they are ready to take. Oudshoorn and her co-authors (2004) also warn against the persuasive use of what Akrich (1995) calls “I-methodology”, which means all too strongly departing from one’s own experiences, attitudes and expectations and through this process, making pre-selections that can hardly ever be compensated for, even through processes of adaptation and participation.

We are also strongly invited to carefully address the group of non-users, in all their different forms, because they matter in designing and implementing a health-data platform. Wyatt and co-authors (2002) have argued in the case of internet (non)use, that it is important to distinguish at least four groups of non-users that have quite a different relation to the internet: the resisters, the rejecters, the socially or technologically excluded (who have no access) or the expelled (who were using it at one point, but can no longer do so, e.g. afford to do so). For the digital data platform developed in the framework of the *Smart4Health* project, it will be essential to empirically elaborate on the different user categories that might be potentially excluded and to reflect on what role they (can) play with regard to shaping the final product (this will be more extensively discussed in D1.2, i.e. the report on the methodological design of the co-creation environment).

Finally, even though the focus of the project is on citizen-users, health care professionals (such as doctors or nurses) and the contexts of use in which data sharing might be essential, are key elements to consider all throughout the process. These groups are on the other side of the data interface and it is important to better understand what kind of data (and in what format) is paramount for them when performing their professional tasks. In the case of these user groups, there is also a need to care for the differences within and to identify specific user practices that will play an important role in shaping the platform.

4.2 Inclusions and exclusions of users in health-data infrastructures

As infrastructures „form a juncture of social organization, moral order, and layers of technical integration” (Bowker and Star, 1999, p. 33), it is essential to revisit the question of how specific values are realized through infrastructures and how this might bring about in- or exclusion from health data infrastructures. The reason for this is that infrastructures, as mentioned above (see chapter 3), are also habit-forming: they tend to define what actions can/should be taken. To ask the value question is all the more important as infrastructures are – once successfully introduced – often taken for granted and become unquestioned and unquestionable. They stabilize values and permit certain types of relationships, while inhibiting others, thereby shaping the ways in which we – health care professionals, patients, citizens and analysts – think about the world.

Here the value of diversity in design has to come under our consideration. “Diversity” has become a central notion in contemporary health care provision and points to the growing attention given to addressing human differences in contemporary societies (Vertovec, 2012). Many analysts have pointed to the fact that there is already clear evidence that health is unequally distributed across and within nations, while overall population health is often used “as a proxy for social well-being” (Hall and Lamont, 2009). Therefore, diversity perspectives need to be integrated into the construction of the 4HealthPlatform.

This means being attentive to

- socio-cultural differences,
- different forms of understandings of health as well as of how health care is practiced in national/regional contexts,
- differences in socio-economic status and how health care systems address this,
- gender differences,
- different life phases (e.g. age, youth), and
- the degree in which people are “digital/data literate”.

As Erikainen and coauthors (2019, p. 8) have argued convincingly, digital developments always bring empowering and problematic potentials which are “both constrained and facilitated by concurrent socio-political movements. They are also constrained by modes of social and economic“ order that pre-date the digital era. And they remind us that “the ‘digital era’ itself has not materialised in the same way across contexts, but is unevenly inter- and intra-nationally distributed along the lines of broader global geo-political and socioeconomic as well as public health disparities” (ibid., p. 8).

Indeed, when speaking about “citizens” or “the public” in more general terms, very often attention is not sufficiently paid to the diversity of individuals, groups and communities that are addressed through these generic terms. Oudshoorn and coauthors (2016) clearly point to the fact how diversity gets lost when not considering sufficiently gender and age in the design of information and communication technologies. Using such broad terms does not capture the diversity of their social situation, their interests and values, their needs, and their health-related attitudes. When it comes to conceptualising the future use, designing, and building of a tool like the citizen-/patient-centred 4HealthPlatform, it is **essential to not only grasp, map and embrace the needs, interests and priorities of groups that are pro-actively seeking to engage with these new technological opportunities**.

Rather, it is also essential to deeply consider those who all too frequently fall outside the scope of innovations in the area of information and communication technologies: late technological adopters, vulnerable groups, minorities and socio-economically less favoured segments of populations. Such groups will have specific needs, which are potentially quite different from those who are already engaged in using data-intensive technologies. This carries the danger of altogether ignoring some groups in the scenario-building of the *Smart4Health* platform.

This poses problems on at least three levels:

First, we have to look at the health-data platform from the principle of **social justice,** which means asking questions of **access, equity and participation**. For this purpose, it will be essential to include users in the design process in ways which allow us to adequately respond to different needs and situations in life. This will also entail regularly scrutinizing potential "silent" exclusion and considering that methods of participation and co-creation are potentially more accessible to some users than to others. This will be assured through the thorough design of our participatory co-creation environments, but also by carefully scrutinizing the individuals (not) present in the development and design process (Pruitt and Adlin, 2006; Adlin and Pruitt, 2010).

We will also need careful reflection on what participation means in terms of "data-related participation": how can users engage with the **material infrastructure** of a platform (see Marres, 2012 on material participation), but also with **the ways in which data is presented and represented** there? We know from studies conducted well before the digital turn that health literacy more generally – i.e. the degree to which individuals can get access to, process, and understand the basic health information needed to make appropriate health-related decisions[18] – presents an enormous challenge to the delivery of adequate health care and quality outcomes. With the growing use of data to describe the health status of a person, the ability to read, understand and communicate through data – often called **data literacy** – is actually becoming an increasingly critical skill. This, in turn, creates the danger that people who are already struggling with health literacy will be left behind in an even more dramatic manner.

Yet, as a recent study has argued, the concept of data literacy has to be expanded "to include not just competencies in reading and working with datasets but also the ability to account for, intervene around and participate in the wider socio-technical infrastructures through which data is created, stored and analysed" – the authors call this ''**data infrastructure literacy**'' (Gray, Gerlitz and Bounegru, 2018). If these different forms of literacies – health, data and data infrastructure literacy – are not considered and sufficiently addressed, the already existing digital divide will likely increase and further widen existing health disparities.

Secondly, it is essential to consider both the question of uploading data, and how citizen-users are ready to share this data (either with trusted individuals or health care professionals or for research purposes). As the aspect of **granting access and data donation** are important features of this platform, it will **be essential to closely investigate during the co-creation process the reasons why users might or might not do so**. This will potentially need to be reflected in fine-grained choices between different options of what access and donation might mean. We find the first

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[18] For a discussion of the term „critical health literacy" see Chinn (2011).

hint of such choices in the recent Eurobarometer survey 460 on “Attitudes towards the impact of digitisation and automation on daily life” (EB, 2017). In the part on “digital health and care”, we learn that, on average, about 80% of European citizens (with Germany as one of the countries represented in our Citizen Use Cases scoring over 90%) have never used any electronic health service. Not unexpectedly, age and education matter[19], rising age lowers the chance of engagement, while higher education raises it. About 50% of the respondents, however, expressed their wish “to have online access to [their] medical or health records (health data, prescriptions and medical records about [them] allowing [them] to consult them at any time wherever [they] are”, with a significant difference between age groups and level of formal education. Here, we find that “respondents are much more willing to share their health and wellbeing data with doctors and health care professionals (65%) than with public authorities or public sector companies (21%) or with private sector companies (14%) – even if anonymised and for research purposes”. Overall, we can observe quite important national differences in responses here, with citizens from Sweden, Finland, the Netherlands and Denmark scoring among those most ready to share data under certain circumstances, while citizens from Italy and Germany score well below the EU-28 average (EB, 2017). As *Smart4Health* will have Citizen Use Cases in Germany, the Netherland, Portugal and Italy, it will be critical to see how this data matches the more qualitative experiences we will undertake in the co-creation environment.

Finally, we have to carefully consider the multiple dimensions of **diversity when it comes to health data**. When imagining and constructing the platform, diversity needs to be considered on at least four levels:

(1) In each step, we have to reflect how the different citizen-users might contribute or not contribute through “feeding” data from different sources into the platform and using them in health care situations. This means considering whose data would potentially **not** make it onto the platform.

(2) For citizens using the platform, we need to test and reflect on potential challenges in making sense of the data-related information available on the platform. This means reflecting on the way data is represented and made readable, and how this reflects the diverse capacities of reading, ordering and understanding data.

(3) Furthermore, the diversity of situations in health care provision, which would be improved through adequate access to data, should be considered. This means engaging with health (care) professionals in order to better grasp how the information a citizen-user could provide through the platform would support better health outcomes or health care.

(4) Finally, looking at the data platform through the lens of diversity means reflecting on the consequences if the quality and density of the data is very

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[19] It is interesting to retain, that while in the EUROBAROMETER 460 report all other aspects related to the impact of digitisation did discuss gender dimension this was totally absent in the part on “Digital Health and Care.” This is all the more astonishing as we know from other studies that health behaviour has an important gender dimension.

different for different groups and how segments of the population might not have their data on such a platform. This, in turn, might create quite substantial future inequalities once a health care system functions on the assumption of availability of such data.

These questions, and how they are considered, ultimately impact the ways in which the platform is useful and for whom, for both health care and for health-related research.

4.3 Real-life uses

While it is essential to engage with users as early on as possible in the design process, it is also important to consider two further moments: (1) when users actually encounter the innovation and (2) when they start to use it.

First, individuals come to adopt a technological innovation (such as the health-data platform produced in this project) either through their own desire or through nudging, through peer pressure or through the creation of situations in which engagement with the innovation appears as particularly inviting, if not more or less mandatory. Yet, they might neither perceive the usefulness nor the necessity of engaging with a health-data platform, or even be strictly opposed to it for a diverse set of reasons. The situations when encountering the technology will matter because how an innovation is perceived and will bring about rather different assumptions about it and responses to it.

Second, as Akrich (1992) already has pointed out (and a number of ethnographic studies have subsequently shown) people often appropriate technologies in ways unexpected to them and to others around them (Lie and Sørensen, 1996). Users can reinterpret, adapt or reinvent specific kinds of initially prescribed uses (Eglash et al., 2004). Adaptations require, however, that the user-technology relations show enough flexibility to allow this to happen in the first place. An example of adaptation and reinvention could be efforts by groups of citizens to collectivize data (data that was initially thought to be an individual good) and thus open up the possibility to act in ways which they see as better adapted to their cause.

Such studies have also pointed to the fact that a **frequent mismatch between the projections/imaginations of users and real-life usage exists, in particular when projects are already strongly predefined by policy goals.** Having a very narrow definition of what the goal of a technological innovation should be carries the danger of imagining and expecting people to be overly strategic, to follow only one kind of rationality and to always seek to optimise some rather specific benefit through technology use. Yet, in real life, **people react to a diverse set of impulses other than the promise of efficiency**. These may be everyday habits, community norms, moral convictions or family traditions. This diversity of influences, in the end, contributes to the mismatch between implicit or explicit expectations of everyday behaviour among users.

From the studies that have been carried out so far, we have learned that there are many variables which might actually shape user engagement with a health-data platform. As *Smart4Health* uses an opt-in approach, i.e. citizen-users need to proactively inscribe into the platform and (request to) transfer their data, this carries the danger of low participation and potentially only of rather selected user groups and will require to carefully consider the dimensions that could make the platform attractive to users.

KEY POINTS: What does it mean to be a user?

- Who the user is, is a complex, non-trivial question – especially when user-needs are being weighed and prioritized. Operating with large categories that are not clear-cut (e.g. “the citizen”; “the patient”) makes **diversity disappear** and can **flatten** consequential **differences** with regard to the articulation of needs, values and envisioned health- and data-related futures.
- Here it is crucial to consider those who all too frequently fall outside the scope of innovations in the area of information and communication technologies and, thus, evade a **reproduction** and **infrastructuring of exclusions**.
- It is also important to reflect on who the **non-users** are and how they can be addressed. It will be essential to empirically elaborate on the different user categories that might be potentially excluded and reflect on what role they (can) play with regard to shaping the final prototype.
- Reflection is necessary on three levels, in order to produce a meaningful and useful platform: (1) We have to look at the health-data platform from the principle of **social justice**, which means asking questions of **access**, **equity** and **participation**. (2) We need a fine-grained understanding of potential users’ **rationales** of granting access and donating data (or refraining to do so). (3) We need a deep understanding of the dimension of **diversity** with regard to Smart4Health as data infrastructure.
- It is important to engage with users not only in the process of design and development, but also in the course of their **further engagement** with the platform (i.e. when the actually encounter it and when they start using it).

5 Data, health and being a data/digital citizen

So far, we have mainly explored the process of developing and designing the health-data platform. In this chapter, we want to address the specificity of digital data, its relation to the notion of “health” and, finally, what this means in terms of citizenship through data, i.e. in terms of rights and obligations.

5.1 Digital health data

When speaking about health data a couple of decades ago, we would have imagined a paper file in a doctor’s office or in the hospital system. These dossiers would be physically moved around and supplemented when needed. These dossiers had a clear physical location with clear access rules to ensure the safety and privacy of the patient. These rules existed even though this meant, in cases of emergency, that it often proved difficult to get access to the right file in time. With the introduction of computerized systems and, in particular, with the introduction of a central storage, which enabled access and download (virtual duplication) from different physical locations, the questions of where a patient data file was and who could get access to it became much more complex. Therefore, health-related data was no longer this clear-cut physical entity, which was located in space and time, but it became multiple (Prainsack, 2019) in its ability to be in many places at the same time, used by both citizens and health care professionals.

The 4HealthPlatform to be developed in the framework of the *Smart4Health* project addresses the need of data availability for good care. Thus, it aims to make European citizens’ personal health data easily accessible from “everywhere,” both for themselves and for those they have granted access to their data (either through “MyTrusted” or “Mob.E.Health”). This calls for carefully investigating data protection, as regulated by the European data protection regulation, in practice. As the 4HealthPlatform is putting the citizen-user into the centre and giving him/her the possibility to share and to give access to their health-related data, it will be essential to raise awareness among platform users concerning issues of privacy and data protection. Putting such a digital platform at disposition creates new vulnerabilities for citizens and new forms of risks that need to be considered when it comes to health-related data.

However, creating such a health-data platform also demands addressing not only the question of standardization of data across different health care contexts and making systems interoperable on a technological level, but also addressing the question of the quality of the available data and what can and should be done with it. This is of particular importance, as the platform will bring together (1) data from existing electronic health records, and from other health care providers, (2) health-related data collected in work environments and (3) data produced by citizens themselves (see Figure 1).

This calls for addressing questions on several levels.

First, it is important **to reflect on what counts as health-related data**. While it might seem straightforward what health data is in the context of national electronic health records (and even these might be rather different in different nation states), it becomes more complex when we look at health-related data collected in other contexts. Such contexts could be in work environments or data produced by in private contexts (e.g. data from sensors or all kinds of self-tracking devices, observational data, etc.), which seem relevant to health and well-being. This is actually a key issue to be addressed, as **patient-generated health data** (PGHD) start to play an increasing role when it comes to health-related monitoring. This data can include reporting of symptoms, specific lifestyle choices, biometric data or other observational data collected by patients. However, and this is crucial to the *Smart4Health* project, we suggest speaking of **citizen/patient-generated health data** (CPGHD), as the collection of data also happens without being necessarily in the role of a patient, but is more concerned about keeping up a health status. This opens the key question: what count as health-related data in both work-related[20] and private environments? This is an essential question at a time when more and more, as well as very different kinds of data get collected in order to allow for developing predictions in the health-development of people (e.g. consider Google's efforts to use artificial intelligence to diagnose health issues).

Second, it is essential to reflect on **the existence of standards for these different kinds of data**. While some of these standards might be easily transferable and readable across sites (e.g. name and basic data of a patient, or some internationally already highly standardized tests), other key data is potentially much less structured and standardized. These could be doctors' personal notes about a patient, observation protocols concerning the health status by a patient, tracking of medication intake or data from personal tracking devices. At the same time, more and more providers of some form of health-related mobile apps (e.g. apps measuring blood pressure, sugar levels, ….) move onto the market. They collect all kinds of information, which people might want to upload and share on the platform. This poses the key-question of quality of data, which is essential for both potential use in research contexts, but also for citizens, e.g. when they share and compare self-collected data with other citizens.

Third, with regard to **data that can be donated to research** on this platform, analysts point to challenges of **quality assurance** in analysing such data and drawing conclusions. Despite many efforts at standardizing them, EHRs "are observational databases–the data reflects not only the health of the patients, but also patients' interactions with the health care system. For example, the date associated with a code for diabetes is when the physician actually made the diagnosis, not when the patient first developed the disease. Furthermore, the billing code used for that office visit might be influenced more by reimbursement policies than the original reason for the visit"

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[20] Moore, Upchurch, and Whittaker (2018) show convincingly the complexities when tracking devices which among other should improve employees' health are introduced to work environments. It points to the relations of dependence between employers and employees asking what consenting means in such a context of dependency. See also Moore and Robinson (2016).

(ibid., p.1). Then concerns are raised about “a serious and increasing risk that naïve use of Big Data analytical techniques without a full understanding of the complexities and limitations of EHR data is resulting in biased or incorrect medical findings“ (Agniel, Kohane and Weber, 2018, p. 1). Furthermore, patient collected data cannot be straightforwardly used without some form of quality control that would have to be considered in the process of data donation. While this is more of concern for those using data collected at platform level, it also means that citizens/patients need to learn how to read available data, understand the limits of available data and refrain from all too hasty conclusions from such data about their health status.

Finally, this also means that citizen-users will have to develop a **degree of data/digital-literacy** that goes well beyond what people usually possess in order to make patient-data valuable for their personal use. The question will then be, how this data is understood by those collecting and uploading them, but also how it can become useful data once donated to the research platform.

5.2 Mediated vision of health

When building a platform collecting patient data, it is essential to carefully reflect and test how citizen-users create a relation between the available data and their health status (see the reflections on the mediating role of technology in chapter 3). The health-data platform mediates the relation between citizen-users and their bodies and health, as well as their relation with health care professionals. It thus shapes how citizens situate and understand themselves with regard to health-related issues (see Figure 5), how we live in the world and how we relate to health issues while doing so. The assemblage of data available on the platform will organise new ways of how we can “see” our human bodies. Studying and better understanding this changing relationship of human–data assemblages and to bodies and selves (Lupton 2018) will be an important element in this project.

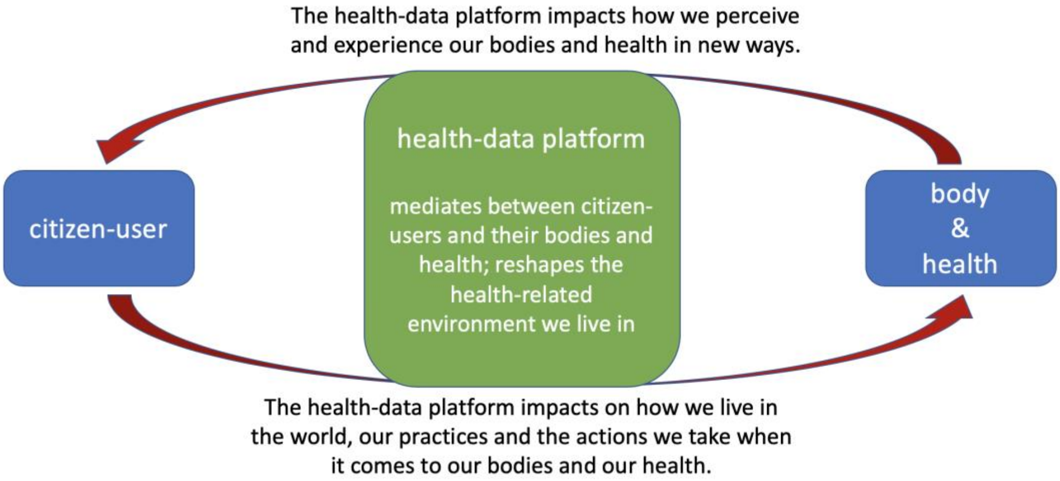

Figure 5 — Body and health mediated through the health-data platform

This does not stand without consequences. As citizen-users start to look through the health-data at their bodies and their health, it will **change their perceptions and experiences of their bodies and their health**. Yet the data will also become an essential part of how people make sense of their bodies and health. As a consequence, they have to learn to read the data in order to develop knowledge about their health status; they have to interact and engage with the data when choosing and selectively combining data sets. With the health-data infrastructure becoming an important mediator between citizen-users and their bodies/health, it thus becomes essential to reflect how user-generated health data starts to **transform people's ideas about health**, both within and beyond health care contexts (e.g. Ostherr et al., 2017). Indeed, "while user-generated health data appears to be part of a larger cultural trend in mobile device integration, health care is a unique domain with a specific set of histories, demands, and stakes" (ibid., p. 4) as it is governed through long-standing power relations between citizens/patients and health care professionals. It is still organised around highly specialized health care expertise. Therefore, it is not astonishing the see the emergence of e-patient movements seeking to realize a process of health data production which **generates value for them** and not for those manufacturers of tracking-devices or other institutional actors.

Sometimes the data infrastructure becomes an invisible presence on the basis of which treatment and prevention is offered. This, in turn, impacts how we perceive and experience our body and our health. Data starts to participate in sense-making about how we feel and how we are in the world, but such data also has the potential to guide our individual actions and choices. Together, this data-mediated vision of health and body brings along new kinds of practices of engaging with one's body and health. It also brings along different kinds of actions that are perceived as necessary when wanting to be a **responsible data citizen**.

It will therefore be essential to reflect how citizens/patients will make sense of and deal with the data that is collected and is meant to represent their health status. Thus, we will have to consider whether (and how) they perceive the collected data as their data doubles (e.g. Ruckenstein, 2014; Ruckenstein and Schüll, 2017) or how they engage with the idea of creating (through the ever more detailed collection of all kinds of health-related data) a kind of "digital twin" (e.g. for an ethical debate of this approach see Bruynseels, Santoni de Sio and van den Hoven (2018)). *Smart4Health* goes even beyond the collection of "classical" health data, as analysed and debated in existing literature: in the health-data platform constructed in this project, the 4HealthPlatform, users will be confronted with a set of data collected both by the health care system and by themselves.[21] This is in line with a more general call for engaging with citizens' understanding of big data, which in the end, they are expected to contribute to in one way or another (Michael and Lupton, 2016)

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[21] See Sharon and Zandbergen (2016) for the relation of self-tracking practices and data values; for biosensing technologies in everyday life see Nafus (2016) and Neff and Nafus (2016).

In short: data never delivers mere descriptions but also potentially **changes ways of experiencing ourselves**; data shapes the perception of our bodies, of how health and lives are related and of the developmental trajectories connecting pasts and futures.

5.3 Being a data/digital citizen

From the literature review it also became evident that there is a need for more qualitative investigations of how investments in diverse kinds of e-Health systems and data platforms providing citizens access to personal health data are actually contributing to their empowerment – as citizens. This implies that throughout the *Smart4Health* project, **it will be essential to question what the buzzword "empowerment" (omnipresent in policy discourse) means for different citizens in their everyday health-related environments.**

This entails questioning how citizens can relate data to information and knowledge and, in turn, how this leads to action. But it also means to look into how digital media can be regulated in ways to assure citizens' rights, to offer transparency to how data are handled and protected and how representations of data are produced (Petersen, Tanner and Munsie, 2019). As infrastructures never start from scratch (see chapter 4), it will be essential to reflect on **pre-existing power relations that do not disappear** through the introduction of digital health. Previous research on the internet use of citizens/patients has, for example, shown that the possibility of seeking health-related information on the web is seen more as moral work that is needed to recreate a fit between the citizen/patient and the health regime and it gets only very partially framed as an empowering moment, i.e. as a moment in which option of actual choice rise, concerns can be addressed and personal values can be realised (Felt, 2015).

This points to the need to empirically engage with the notions of health/data/ infrastructure literacy in the context of the co-creation environments described in chapter 3 of this report. We will have to identify specific forms of **difficulties** users encounter when collecting, storing and seeking to make sense of data on the platform. This means **reflecting on the representations of data** on the platform, explanatory texts which allow to understand/read them as well as some summary elements related to specific data segments. This is all the more important, as Lupton (2017, p.8) has argued convincingly, as we also need to consider the "affective atmospheres of digital health" and investigate "how people **feel** when they use [digital health] technologies but also how the technologies participate in feeling (or how they act as sensors working on the human body and generate affects in human bodies)".

Furthermore, we need to carefully reflect how access to data might improve individual and population health outcomes and how it can potentially create a more just distribution of health status within populations. This also calls for investigating how the different citizen- and professional users will be ready and able to use these data platforms as resources when engaged in health care practices. Use scenarios should therefore also be developed through interaction with future users – both citizen-users and health professionals. This is important, as studies have indicated the importance of health professionals embracing the use of digital health devices as this impacts how patients embrace digital solutions (e.g. Watt, Swainston and Wilson, 2019).

Finally, we also need to assess how the current approach to the design of personal e-health systems and data platforms “potentially leads to accentuate the gap between privileged and disadvantaged end users and health care recipients, rather than improving equity of access to health care services” (Showell and Turner, 2013).

KEY POINTS: Health-data citizenship and empowerment

- Developing a health-data platform requires us to pose the question of the **quality** of available data and what can and should be done with it. This is of particular importance as the platform will bring together (1) data from existing electronic health records, but also from other health care providers, (2) health-related data collected in work environments and (3) data produced by citizens.
- One has **to reflect on what counts as health-related data,** on the existence of **standards** for these different kinds of data and what this means for their **transferability** and **readability**. Furthermore, there is the challenge of **quality assurance** in analysing data donated to research and drawing conclusions from it. Finally, citizen-users will have to develop a degree of **data/digital literacy** which goes well beyond what people usually have.
- The platform will enable a **newly mediated vision** of citizen-users’ bodies and health that has the capacity to **change** their **perceptions** and **experience** as well as the **relationship** between citizens and health care professionals. It will be important to investigate how citizens/patients make sense of the data that is collected and meant to represent their health status.
- The buzzword “**empowerment**” is omnipresent in policy discourse and it needs to be well understood what it means for different citizens in their everyday health-related environments, especially since **pre-existing power relations and inequalities** will not disappear. It needs to be ensured that the platform does not inscribe new forms of **disempowerment** within a discourse of empowerment.

6 Governance of health-data infrastructures and informed choice

In this last chapter, we draw attention to the question of how new health-data infrastructures will be governed and what kinds of interactions are foreseen when allowing users informed choices. Digital governance in this context points to the "practice of establishing and implementing policies, procedures, and standards for the proper development, use and management of the infosphere", to use the definition given by Luciano Floridi (2018). While he underlines that we are far away from understanding how to govern the digital, he stresses the importance of seeing digital governance, the ethics of the digital and the regulation of the digital as "different normative approaches, complementary, but not to be confused with each other" (ibid., p. 2). Thus, digital governance will comprise guidelines from the regulatory context, but potentially go well beyond this. At the same time, digital ethics will be engaged in identifying and discussing moral problems related to digital developments with the aim of finding better solutions. In a similar move, governance might then go well beyond simply asking what is morally acceptable, but what is, morally, a better solution for citizen-users.

In this context, we must be aware of differentiations in top-down strategies and processual translations. On the one hand, there seems to be a coherent political agenda at the European level. It is expressed in different kinds of strategy documents, in guidelines and efforts of standardisation to frame and direct the process of digitising health and care. Citizens are described as the **main winners of such an effort,** either **directly** through accessing their electronic health records and having options of sharing them, or **indirectly** through the advancement of research through data donation. This is then formulated in terms of empowerment of citizens, as well as of improvements in citizen-centred care.

On the other hand, we have to consider the translation processes from policy to realities, where many **uncertainties** become visible. While on the European level, we see the effort of committing to more long-term strategies when it comes to information and communication technologies (ICT), its realization is subject to rather different and shifting local/national politics, different logics of prioritization and corresponding financial commitments. As a consequence, we are facing a **multi-level governance situation, where different actors shape and steer the ways in which health data are produced, collected and made available.**

When wanting to develop governance structures of a complex health data infrastructure, there is no clearly available model to draw on. We could look at the decades of struggles concerning the governance of biobanks (e.g. Tutton, Kaye and Hoeyer, 2004) and learn from them. However, while biobanks share the issue of data donation with the health-data infrastructure being prototyped in the *Smart4Health* project, the delegation of responsibility for collecting data from different sources, updating and sharing them with citizens creates new kinds of challenges. One path would be to organize governance processes in an **experimentalist way** (Sabel and

Zeitlin, 2000). This means to systematically question own assumptions and practices, to treat solutions as incomplete and to be changed, and to engage in an ongoing, mutual readjustment of ends and means triggered through comparing with other approaches to achieve a common goal. In short: we will need to organize collective learning of how to best govern such a complex new health-data infrastructure.

Multi-level governance gives expression to the idea that, for a European health-data platform to come into being, many interacting structures are at work in the emergent regional health economy. It makes us aware of the intimate entanglements between the local, national and European levels that have to coordinate not only on a technological level, but also on a socio-cultural level in order to make such an infrastructure work. This means that we need to already consider in the design process the **multiple actors engaged with different identities and interests which need to be coordinated in order to achieve a robust and sustainable infrastructure**. For example, citizens are expected to engage in the governance of their personal data. However, they might also decide to collectively engage in new kinds of health-data related practices, like sharing data among each other, (i.e. building data collectives). Health care institutions that collect data will potentially be asked to relate via citizens to a large-scale data infrastructure, which demands reflection on how this impacts data governance on institutional levels (e.g. through making data structures compatible).

Therefore, it is essential to better understand how citizens (as well as diverse users in different national and institutional contexts) relate and can relate to issues of data protection, privacy and key governance structures of data platforms. Good governance should allow users to enjoy the collective benefits while protecting their individual rights. From previous research in the health domain and from studies of national efforts to build electronic health records, we know about the challenges different national traditions in health insurance and care meet in this regard. We also know about the diverse forms of fears of data misuse that are often nationally rooted. This has a huge potential impact on how data gets collected, as well as how willing data producers are to share data, e.g. for research purposes. Furthermore, we know from research that the issue of who will run and receive access to data will impact citizen-users understanding of empowerment through health data (e.g. see Ebeling, 2019 on the situation in the US context). This requires the project to carefully **investigate how people perceive the actor networks undergirding the data platform and to shed light on trust relations and their basis**.

In chapter 4, we have described the 4HealthPlatform as a major health-related infrastructure. This also entails specific consideration when it comes to its governance structure. Large infrastructures are often out of sync with classical policy processes because their life span goes well beyond usual political life cycles; when they go across national borders, their influence commonly exceeds classical administrative authority’s jurisdiction. Therefore, governance and data protection will have to be imagined on a different scale, because problems in the functioning of the infrastructure might have substantial consequences for users and providers.

However, analysts discussing the role of citizens in managing their digital health data and related privacy issues have also pointed to the fact that data governance is often delegated to individuals. This potentially represents a major challenge for them, in particular, for citizen-users with a low degree of digital literacy. As Obar (2015) points to: “The average digital citizen wants privacy, and safety, but cannot complete all that is required for its protection.” In this context, the author speaks of “the fallacy of data privacy self-management” and suggests, in parallel to the role of citizens in a democracy, to “introduce a system of representative governance.” Obar points to a potential role of so-called “privacy-focused infomediaries”, who could support citizens in data management and in the protection from privacy issues. This could free people from some of the pressures exerted by and the concerns related to the ideal of the engaged and responsible digital citizen-patient who cares for his/her health (Felt 2015).

Furthermore, it means investigating the perception of the new General Data Protection Regulation (GDPR) in practice, e.g. how do citizens as patients or as caring for their health perceive the legal frames that are meant to ensure their protection? In a similar vein, users will have to adapt their practices accordingly. So far, patient treatment and data collection and usage have been subject to national and institution-specific rules and governance structures. Ethics boards, for example, would take care of how patient data can be used and what protective measures have to be implemented. In the case of a European wider health-data platform, the challenge will be to put in place a governance structure that oversees the overall functioning of the platform and accompanies future adaptations in order to fit with user demands and needs. At the same time, an ethics board that is on a cross-national level will need to make decisions when it comes to the demand of using data that is available on the research platform.

Informed Consent processes will be key in this domain and will need close consideration. They will need to respect not only the legal aspects related to data handling (which are generally captured by informed consent processes), but also the values and expectations of (future) users. This means offering an **informed choice** in a much wider sense than is foreseen in the legal provisions. We will not get deeper into this topic of different forms and processes of informed consent in this report. There will be a specific deliverable D 1.3 addressing informed consent processes and related informed consent language. In this context, we will also reflect on how citizen-users will be offered information in order to be able to make informed choices with regard to giving access to data.

Finally, governance can only be successfully put in place when addressing issues of data/digital/digital infrastructure literacy. Understanding and integrating users’ perceptions and capacity to read data will be an important point to consider in any design process.

KEY POINTS: How will new health data infrastructures be governed?

- In terms of governance, we find differences between national and European contexts, with the consequence of **multi-level governance** and different actors shaping and steering the ways in which health data is produced, collected and made available.
- Digital governance will build on guidelines from the regulatory context but also go beyond them. In order to understand how to best govern such a complex new health-data infrastructure, we will have to follow an experimental approach and engage in processes of collective learning.
- It already needs to be considered in the design and development process that there are **multiple actors engaged with different identities and interests.** They need to be coordinated in order to achieve a robust and sustainable infrastructure.
- The health data infrastructure developed in Smart4Health will face new kinds of **challenges** given the issue of data donation and the **delegation of responsibility** of collecting data from different sources, updating and sharing them **to citizens**.
- Good governance should allow users to enjoy the collective benefits while protecting their individual rights. The delegation of data governance to individuals will be a major challenge for citizens, especially when they have a low degree of **data literacy** to begin with. Governance can only be successfully put in place when issues of data/digital/digital infrastructure literacy are appropriately addressed.

7 Summary and final considerations

The Social Sciences and Humanities framework that has been established for *Smart4Health* aims at elaborating a social scientific guiding logic for the project. It considers multiple perspectives which will be crucially important for the different stages of developing such a health-data platform and for transforming it into a sustainable infrastructure capable of supporting citizens' health and well-being as well as health-related research while at the same time caring for key societal values such as inclusion, justice and diversity. Each of the chapters took one perspective into focus and outlined their dimensions, closing with a list of questions and key points to reflect upon during the process leading towards the platform prototype.

The report started by presenting an overview of the project and the sociotechnical engagement that was envisioned in its development and outlined the Responsible Research and Innovation (RRI) Framework as the underlying approach. It raised attention to the fact that innovations always support and realize specific values. The importance to reflect on these values and potentially adapt the direction the development is going pointed to the crucial integration of cyclical development processes with multiple iterations and feedback loops. This will ensure a better sociotechnical adaptability already in the course of the development. In that sense, the report in detail outlined a five-step cyclical model that stays true to the project's citizen-centred approach.

A health-data platform prototyped in *Smart4Health* would have the potential to substantially change how health and illness are mediated, understood and organized. For that matter, we suggest to conceptualize the development of the prototype as infrastructuring health and thereby focus not only on the technical, but also on sociocultural re-orderings. Over the course of the project, the consortium will be engaged in different practices of infrastructuring, such as imagining, researching, designing, making, and adapting as well as testing, using and appropriating the health-data infrastructure prototype. In this development process, visions and values are built in and potentially realized. Incorporating citizens into these processes is crucial as the collaborative spaces of co-creation and user engagement support the articulation and integration of alternative visions and diverging values to be realized.

The platform will enable new and different ways of how citizen-users see and relate to their bodies and health. This could lead to changes in their own perceptions and experiences and potentially transform the relationships between citizens and health care professionals. If we think these changes in terms of empowerment, it is important to ask questions of health, data as well as data-infrastructure literacy and their effects which in turn can define in- and exclusions. Therefore, it is essential to care for not reiterating existing power relations and inequalities, as this might subvert the aim of empowering citizens.

Finally, the report drew attention to the governance of new health data infrastructures such as the one developed in *Smart4Health*, arguing for experimental approaches and processes of collective learning in response to the complexity that these novel infrastructures bring into being.

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List of Acronyms/Abbreviations

Acronym/ Abbreviation	Description
CPGHD	Citizen/patient-generated health data
CUC	Citizen Use Case
EHR	Electronic Health Record
EU	European Union
GDPR	General Data Protection Regulation
GP	General Practitioner
ICT	Information and Communication Technologies
IoT	Internet of Things
PGHD	Patient-generated Health Data
RRI	Responsible Research and Innovation
SMEs	Small and Medium-sized Enterprises
UDC	Use Design Case

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