REal-time data monitoring for **S**hared, **A**daptive, **M**ulti-domain and **P**ersonalised prediction and decision making for **L**ong-term Pulmonary care **E**cosystems

D2.1: User needs and expectations for privacy-abiding RWD collection

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Abstract

This deliverable describes the design, application and results of the user research studies which form the basis for the identification of user needs and the specification of user requirements for the RE-SAMPLE virtual companionship programme. The focus in this deliverable is on the needs and expectations of patients and healthcare professionals with respect to: 1) the parameters that the primary end-users consider as necessary, desirable and feasible to collect, 2) the aspects related to the data collection procedure, and 3) the preferences with regard to data sharing and privacy.

Successful design and implementation of the RE-SAMPLE programme necessitates a good understanding of the current tasks and activities of the end-users, how they can be optimally supported by the technology and what aspects contribute to the development of trust. Sensitivity to preferences about the data collection procedure, privacy and data sharing is essential for the user acceptance of RE-SAMPLE. To design these services in such a way that they optimally support users and rightfully earn their trust, it is crucial to analyse their context of use, needs, expectations and values.

Following a human-centred design approach, an empirical study was designed that allows to investigate the context of use and elicit user needs and expectations. After a detailed description of the pilot sites and the study design, the results from each pilot site are presented with a special focus on parameters, data collection and sharing and privacy preferences. Based on the analysis, a list of parameters is presented, as well as the user requirements for the data collection procedure (including functional, service, organisational, content, usability and user experience requirements). This first set of user requirements will be extended in D2.4 *Functional specifications for the companionship programme* and updated based on the results of future end-user studies and other requirements (organisational, technical, legal).

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Symbols, definitions, abbreviations, and acronyms

6MWD	6-minute-walk distance test
6MWT	6-minute-walk test
ADL	Activities of Daily Living
ADO	Age, Dyspnoea, airflow Obstruction
BDI	Beck Depression Inventory
BMI	Body Mass Index
BODE	Body Mass Index, Obstruction, Dyspnoea, Exercise
CAT	COPD assessment Test
CATI	Computer Assisted Telephone Interviews
CBR	Centraal Bureau Rijvaardigheidsbewijzen – Dutch Central Office of Driving Licences
CPET	Cardiopulmonary Exercise Testing
Citizen science	a participatory research model in which non-professionals are actively involved in scientific research
CCC	Complex Chronic Condition
CCQ	Clinical COPD Questionnaire score
COPD	Chronic Obstructive Pulmonary Disease
COPD-SIB	COPD specific item bank to measure QoL in patients with COPD
CPAP	Continuous positive airway pressure mask
CSES	COPD Self-Efficacy Scale
D	Deliverable
DPO	Data Protection Officer
EE	Estonia
EQ-5D-5L	Standardised measure of health-related quality of life by EuroQol Group
FEV1	Forced Expiratory Volume
GOLD	Global Initiative for Obstructive Lung Disease
HADS	Hospital Anxiety and Depression Scale
HbA1c	Haemoglobin A1c test, measures amount of glucose attached to haemoglobin
HCP	Health Care Professional
IT	Italy
KCCQ	Kansas City Cardiomyopathy Questionnaire
M	Month
MLHFQ	Minnesota Living With Heart Failure Questionnaire
mMRC	modified Medical Research Council dyspnoea scale
MRC	Medical Research Council dyspnoea scale
MREC	Medical Ethical Research Committee
MUST	Malnutrition Universal Screening Tool
NL	The Netherlands
NRS 2002	Nutritional Risk Screening
NT-proBNP	N-terminal pro b-type natriuretic peptide
NYHA	New York Heart Association
OSA	Obstructive Sleep Apnoea
P	Patient
PIH	Partners in Health scale to
QoL	Quality of Life
RAND-36	36-item health-related quality of life survey instrument by RAND
RWD	Real World Data
SAQ	Seattle Angina Questionnaire
SF-36	Short Form (36) Health Survey

SGRQ	St. George’s Respiratory questionnaire, disease specific QoL assessment tool
SMAS-30	30-item Self-Management Ability Scale
STAI	State-Trait Anxiety Inventory
TASMAN	TAilored measurement for Self-Management Abilities in the Netherlands
UX	User Experience
VAS	Visual Analog Scale, validated measure for acute and chronic pain
WMO	Wet medisch-wetenschappelijk onderzoek met mensen (WMO) - Dutch Medical Research Involving Human Subjects Act
WP	Work Package

1. Introduction

The goal of RE-SAMPLE is to improve the care that is currently provided for people living with Chronic Obstructive Pulmonary Disease (COPD) and complex chronic conditions (CCC). The current disease management can be quite scattered and rather reactive, leaving room for improvement, for example, in terms of self-management and evidence-based proactive care.

RE-SAMPLE aims to support patients and healthcare professionals to manage COPD (accompanied by CCC) in a more optimal and personalised way, that takes into account patient preferences and ensures that the patient's values guide clinical decisions. This will be accomplished through the utilisation of real-world data (RWD) in an ecosystem of innovative eHealth services supporting the key actors along the patient journey (see Table 1).

Table 1: Overview RE-SAMPLE services

Virtual companion for the patient The goal of the virtual companion for the patient is to improve patient engagement, reduce patient burden and maintain work and social activities. The virtual companion for patients consists of three parts:	
RWD monitoring application	This monitoring application consists of sensing devices, subjective assessment of COPD and CCCs diagnosed at baseline through experience sampling and triage symptom diaries. For the patient, the application provides the opportunity to proactively manage their disease, as it predicts the disease progression. In that way, initiation of appropriate treatment can be started proactively, resulting in less severe complications, faster recovery and reduced healthcare utilisation.
Lifestyle coaching	As disease progression is influenced largely by lifestyle factors, the virtual companionship will offer several coaching strategies to improve a healthy lifestyle of the patient. The service will provide personalised coaching, virtual education and self-care modules, by e.g. online exercises and learning modules on appropriate and timely medication intake.
Communication	Communication in terms of support and as a guide for information. The virtual companion acts as a digital case manager for the patient and can support and guide in searching information, answering specific questions or connecting to a 'real-life' case manager.
Active support programme for the healthcare professional (HCP): The support programme offers timely and active support to the HCP in the following modules:	
Overview of data and alerts	Overview of the patient's data, such as health characteristics, health literacy, motivation, preferences and values in an understandable manner.
Risk profile	Based on the RWD ecosystem and the individual patient characteristics, the risk profile will show the probability of developing an exacerbation, which could result in an exacerbation alert.
Monitoring profile	Based on the RWD ecosystem and the individual patient characteristics, the monitoring profile shows the optimal set of parameters that should be monitored to reliably detect short- and long-term changes in CCC progression for that individual patient.
Communication	The active support programme enables communication with the virtual companion of the individual patients, and adaptation of the care plan.
Monitoring and communication console in a non-hospital setting:	

The service offers the patient the possibility to visit a local shared-care service centre for additional monitoring with potentially more expensive / state-of-the-art clinical devices.	
Additional monitoring	For example, (bio)markers that are potentially related to changes in COPD disease state or CCC progression. These additional RWD will lead to an updated risk profile.
Support and communication	The shared-care service centre will be staffed with trained case managers or technical physicians for support, education and performing tests on patients referred to this centre. The patient can visit the shared service centre at a moment that is convenient for them, at a time slot that can be reserved beforehand.

Successful design and implementation of the RE-SAMPLE programme necessitates a good understanding of the current tasks and activities of the end-users, how they can be optimally supported by the technology and what aspects contribute to the development of trust. Sensitivity to preferences about the data collection procedure, privacy and data sharing is essential for the user acceptance of RE-SAMPLE. To design these services in such a way that they optimally support users and rightfully earn their trust, it is crucial to analyse their context of use, needs, expectations and values.

The human-centred design framework as specified in (International Organization for Standardization, 2019) outlines six principles that should be followed to make interactive systems usable and useful for their end-users:

1. Design is based upon an explicit understanding of users, tasks, and environments
2. Users are involved throughout design and development
3. Design is driven and refined by user-centred evaluation
4. The process is iterative
5. The design addresses the whole user experience
6. The design team includes multidisciplinary skills and perspectives

While the framework outlines these principles and a set of human-centred design activities, it does not determine specific methods. To understand and specify the context of use, a variety of methods can be applied that help to understand user needs and learn from their experience (e.g., diaries, interviews, focus groups, workshops, co-design sessions). The knowledge gained through extensive user studies and literature is then used to identify user needs and specify the user requirements for the system development. Results from the user studies will be documented in a variety of ways (e.g., user profiles, personas, scenarios, prototypes, requirements) to support the design team producing design solutions that meet the requirements. Due to the multitude of services and features covered in the RE-SAMPLE companionship programme, the different studies conducted for the elicitation of user needs and specification of requirements are presented in two deliverables:

- D2.1 User needs and expectations for privacy abiding RWD collection [M8]
- D2.4 Functional specifications for the companionship programme [M9]

This deliverable will focus specifically on the RWD collection (parameters, privacy, collection procedure). The results related to the context of use (documented in user profiles, personas, patient journeys, scenarios) and further user requirements for the virtual companionship programme (related to self-management, decision making and coaching) will be reported in D2.4 *Functional specifications for the companionship programme*.

2. Objective

The objective of this deliverable is to present the results of the user research studies with a special focus on

1. the parameters that the primary end-users consider as necessary, desirable and feasible to collect,
2. aspects related to the data collection procedure, and
3. preferences with regard to data sharing and privacy.

In chapter 0, a short overview of the pilot sites is provided and the user research methods are described in detail. Chapter 4 presents a detailed account of the results from each pilot site that form the basis for the identification of desired parameters and the user needs and expectations about data collection and privacy.

In chapter 5 a list of parameters is presented, as well as the user requirements for the RWD collection procedure (functional, service, organisational, content, usability and user experience requirements). This deliverable ends with a short conclusion and an outlook on the next steps.

3. Methods

The basis for the specification of user requirements is the in-depth investigation of the context of use, including the users and their characteristics, their goals and tasks, and their technical and organisational environment. For this, a set of user studies has been designed that enable us to learn from the vast experience of our primary users and also identify opportunities for the RE-SAMPLE virtual companionship programme to support their tasks. The studies were conducted in all three pilot sites (see section 3.1), following the protocols and using materials prepared by Roessingh Research and Development (RRD), who carried out the studies at the Dutch hospital. The study setup and materials were presented to the partners in several online meetings and then adapted and translated by the Italian and Estonian partners to fit their setting and circumstances.

This chapter describes the pilot sites, where the user research studies were conducted, the study population and the methods used. The studies were designed to capture a broad picture of the context of use, beyond the immediate aims of this deliverable (i.e., not just parameters and preferences of data sharing and privacy).

3.1 Pilot sites

3.1.1 Medisch Spectrum Twente (the Netherlands, NL)

Medisch Spectrum Twente (MST) is characterized as a hospital with a large and wide range of care with a vast catchment area and a top clinical profile. MST is the largest teaching hospital in the Eastern part of the Netherlands. A total of 2500 patients with COPD per year are managed at the outpatient department of pulmonary medicine at MST and 1250 at the inpatient department. The COPD care is based on an integrated care approach in which for instance GPs, primary care physical therapy practices, local pharmacists and the Roessingh rehabilitation centre are involved. This forms a strong local ecosystem for chronic care with well-established connections with UT, Santeon and STZ hospital group, healthcare insurance and the EIP Twente 3-star reference site.

3.1.2 Gemelli Hospital (Italy, IT)

Gemelli is an academic medical centre and one of the most important and internationally acclaimed care providers in Italy. In 2018, Gemelli has obtained the status of IRCCS (Istituto di Ricovero e Cura a Carattere Scientifico) from the Italian Ministry of Health, a status granted to Excellency hospitals committed to healthcare and research. At the clinic 6500 mainly patients with COPD are currently being treated; 1500 patients are treated in outpatient visits every year. Gemelli is part of an ecosystem with Catholic University School of Medicine, the European Respiratory society, and a network of connected hospitals across Italy. A widespread activity on the territory guarantees the quickest response to the needs of the patients.

3.1.3 Tartu University Hospital (Estonia, EE)

Tartu University Hospital (TUK) is the largest provider of medical care in Estonia and the single university teaching hospital in Estonia. The lung clinic of Tartu University Hospital with 16 pulmonologists and 4 thoracic surgeons working in three departments and conducting over 15000 outpatient visits per year is the only lung organ clinic in Estonia. Of about 1200 hospitalisations to the lung clinic per year 100 are due to COPD exacerbations. About 1/3 of these patients die and 1/5 are readmitted during the subsequent year. There are about 300 new COPD cases per year. About 250 patients are on home oxygen and 100 on home ventilatory treatment. Of them 60% are patients with COPD. TUK is part of the Estonian ecosystem, including the Estonian Respiratory Society and the Estonian Connected Health Cluster as well as rehabilitation and primary care networks.

3.2 Study population

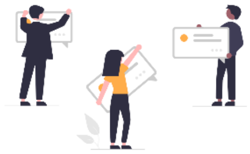
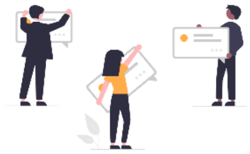
For the user research studies we focused on the two primary end-users, patients and healthcare professionals, and aimed to recruit at least N=20 patients and N=5 professionals from various medical backgrounds (pulmonology, psychiatry or psychology, physical therapy, nurse practice, cardiology, internal medicine, general practice). Inclusion criteria for HCPs were that they gave informed consent and that they have experience in treatment of patients with COPD, even if their main focus was on one of the CCCs.

Inclusion criteria for patients included that they have a clinical diagnosis of COPD and preferably at least one co-morbidity (diabetes, chronic heart failure, ischaemic heart disease, anxiety/depression), are >40 years, able to understand, read and write the language spoken in the country of the pilot site, and that they gave informed consent prior to participation.

3.3 Design of each study

In the following, the original setup and plan for the studies is outlined. Depending on the practical implications on the pilot sites, these were adapted to be applicable and to support rich data collection. For example, as it was difficult to recruit HCPs for a workshop, the protocol was adapted to a semi-structured interview. As many countries were severely affected by the COVID-19 pandemic, the studies were originally designed to be conducted in an online environment (e.g., via Microsoft Teams and utilising an online whiteboard platform like MIRO[1]), but could also be easily carried out face-to-face. Materials such as the protocol, PowerPoint slides, prototypes, templates and MIRO board were provided by RRD in advance to support the pilot sites.

Table 2: Overview of methods carried out in the user research studies including addressed topics

	**Workshop / Interviews with healthcare professionals:** - Current and desired parameters for the monitoring of COPD and CCCs - Learning about patient journeys from the HCPs' point of view - Self-management and coaching - Communication with patient - Shared-decision making process - Values
	**Diary study with patients:** - Evaluation of the day (symptoms, achievements) - Activities - Self-management
	**Interviews with patients:** - Health story - Experience with exacerbations and comorbidity - Controlling COPD - Use of eHealth - Privacy and data sharing - Self-management - Communicating and relationship with HCPs - Decisionmaking
	**Workshops and Co-Design with patients:** - Controlling and tracking their health - Privacy and data sharing - Values - Feedback on initial results - Co-designing user interface for data visualisation and consent for data sharing

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[1] https://miro.com/

For each study, participants were provided an information letter which outlined the study, the process, risks and benefits, their rights to withdraw, the data processing that ensures anonymity, contact details of persons involved and the informed consent form. In addition to the signed consent, researchers again asked the participants before starting the recording for their permission. After each study, the recordings were transcribed and saved by the researcher. All data was processed and kept in coded form, for example the participant's name, initials and other data that could directly identify them were omitted from the results. Only with the key to the code can data be traced back to the participant. The key to this code is stored securely at the research facility of the pilot. The data will be kept for the legally required period, and then destroyed. Only the researchers directly involved have access to this key.

3.3.1 *Workshop / Interviews Healthcare professionals*

Aim: As many of the HCPs will work with the RE-SAMPLE tools during the pilot, the first aim was to introduce RE-SAMPLE to them. The main goal of the workshops was to learn about their experience treating COPD patients, finding out which parameters they consider to be desirable and feasible to collect for disease management, finding out their preferences in communication with patients and shared-decision making, what they think is necessary to support the patient (e.g., in their self-management), and what they consider important in care (i.e., their values). Furthermore, we wanted to learn what a typical patient journey looks like from the professionals' point of view.

Procedure: The study itself was split into two workshops, as it was impossible to schedule a 3-hour time slot.

Workshop 1: Monitoring of COPD & CCCs, patient journeys

1. **Introduction**
   The moderator explains the goal of the meeting, asks for permission for audio-recording, and repeats the process that ensures participants' anonymity (as also outlined in the information letter). Participants and moderator(s) introduce themselves to the group, before the moderator then explains the RE-SAMPLE project and the motivation for this workshop.
2. **Monitoring COPD and CCC**
   Questions discussed in the group are (optional: Facilitated with MIRO board):
   - Importance of monitoring
   - Current parameters that are monitored
   - Parameters that are currently NOT monitored
   - Patients collecting data
3. **Feedback on parameters included in RE-SAMPLE**
   A list of parameters that have been developed as part of WP5 activities supporting the cohort study is presented to encourage discussion (Table 3).

Table 3: Parameters included in RE-SAMPLE, presented in the workshop with HCPs

General	COPD	CCC
Birth of age	GOLD-status and category	Presence of all comorbidities
Gender	COPD symptoms, number and duration of exacerbations	Number and duration comorbid exacerbations
Smoking status	Potential triggers for COPD exacerbations	Potential trigger for exacerbations
BMI	Actual triggers for COPD exacerbations	Actual trigger exacerbation
Pack-years	Lung function (spirometry)	Heart rate
Social role (in family and society)	Dyspnoea (mMRC)	Weight
Educational level	COPD QoL (CCQ, CAT, SGRQ, COPD-SIB)	Inflammatory markers (blood samples)

General QoL (SF-36, RAND-36))	COPD self-efficacy (CSES)	Symptoms relevant comorbidities
Health status (EQ-5D-5L, VAS)	6MWT	Heart failure: classification, severity of heart failure (NYHA classification and ejection fraction)
GP contact details	BODE & ADO score	Ischemic heart disease: history of myocardial infarction (health records)
Cognitive impairment (MMSE)	Inflammatory markers (blood samples)	Anxiety/depression: severity (HADS)
Medication overview (pharmacy record)	-	Diabetes: severity (HbA1c, other glucose measurements)
Physical activity (daily steps, distance, minutes of activity)	-	-
Wakeful-sleep rhythm	-	-

4. **Patient journey**
   The moderator explains the aim of patient journeys and gives an example of a patient journey for chronic pain patients. HCPs work together on a patient journey (starting just before the diagnosis of COPD) and identify where in the journey their specialisation comes in to provide care for a patient with COPD and CCC.
5. **Closing**

Workshop 2: Self-management and coaching, communication with patients, HCP's values

1. **Introduction**
   The moderator explains the goal of the meeting, asks for permission for audio-recording, and guarantees participants' anonymity. Participants and moderator(s) introduce themselves to the group, before the moderator then explains the RE-SAMPLE project and the motivation for this workshop.
2. **Self-management and coaching**
   Goal: find out what their understanding of self-management is, how it is currently supported
   - Importance of patients being engaged in self-management.
   - Support available for patients in relation to self-management support
   - Desirable support for patients to improve self-management
3. **Communication with your patient**
   Goal: find out how HCPs currently communicate with their patients and if/how they already include patients in the decision making process
   - Current ways of communication with patients
   - Current decision making process and involvement of patients
   - Their understanding and opinion about shared decision making
4. **Your values**
   Goal: find out what their personal values are; what they consider important in their work.
5. **Closing**

The detailed protocol of the workshop and the adaptation into the semi-structured interview guide can be found in Appendices A and B.

3.3.2 Patient pre-diary workshop

Aim: The main goal of the workshop was to kick-off the diary study. This included the introduction of RE-SAMPLE to the patients that participate in the experience diary study, explaining the procedure of the diary study and ensuring that they know how to fill in the online survey. The secondary goal of the workshop was to learn about their experience living with COPD, get initial ideas about privacy and sharing preferences.

Procedure:

1. **Introduction**
   The moderator explains the goal of the meeting, asks for permission for audio-recording, and repeats the process that ensures participants' anonymity (as also outlined in the information letter). Participants and moderator(s) introduce themselves to the group, before the moderator then explains the RE-SAMPLE project and the motivation for this workshop.
2. **Controlling and tracking your health**
   Goal: find out what data the patients already collect or want to collect, and what data they would be willing to collect.
   - Current data collection for disease management
   - Current data sharing with HCPs
   - Importance of measurements
3. **Privacy and sharing of data**
   Goal: find out what patients think about data sharing and privacy.
   Explaining technologies giving examples of health trackers and data that can be used (examples: Strava, Google, Facebook).
   - Opinions and preferences regarding data privacy.

   Presenting a scenario of a patient:
   - Discussion of data access and data types that professionals have access to
   - Level of control on data sharing and making decisions about that.
4. **Your values**
   Goal: find out what their personals values are in relation to the care they receive.
5. **Questions or remarks**
   Leaving room to discuss open questions or comments
6. **Introduction to the diary study**
   Explain how the diary study works, explain why this is important, what happens if they forgot to fill it in for one day, give contacts of a person who can help if something goes wrong during the next weeks.
7. **Practicing filling in the survey**
   When using a digital diary, practice the tool together with the patients by filling in the demographics questionnaire (see Appendix C). Guide patients if they have trouble filling the diary in.
8. **Closing**

The detailed protocol of the pre-diary workshop can be found in Appendix D.

3.3.3 Patient experience diary study

Aim: Getting insight about personal characteristics, health factors, psychological, behavioural, socioeconomic factors, learning from patients' experience, about their preferences, what kind of self-management and coping strategies they already apply. While these are also topics for the interviews (see section 3.3.4), mundane activities or small things that happen on a daily basis are easily forgotten and difficult to remember during an interview situation. A diary study was developed to complement the interviews to collect data about the behaviours, activities and experiences of patients over a longer period of time.

Procedure:

1. **Daily email**
   The day after the pre-diary workshop, the diary study begins. When an online survey is used (such as Qualtrics), patients daily receive an email with a link to the diary questions of the day.
2. **Evaluation of today**
   - Grading the day (from 1-worst day ever to 10-best day ever)

    - Explaining the grade (free text form)
    - More or less symptoms than yesterday?
    - Did they do all that was planned for today? If not: was it because of their health? Why was that?
3. **Self-management**
    - Activities to reduce symptoms? If yes, which ones? Why?
    - Received help today? From whom and for what?
    - More help needed? For what?
    - Any activities to make them feel better (mentally, physically?) If yes, what?
4. **Additional comments**
5. **Closing**

3.3.4 Patient experience interview study

Aim: Getting to know patient story and their patient journey, their experience living with and managing the diseases. Interviews can take place independently of when the diary study is running, can be conducted with a different group of patients or with the same patients. More in-depth knowledge of parameters that patients find necessary and acceptable, as well as their privacy and sharing preferences and values.

Procedure:

1. **Introduction**
   Participants and researcher introduce themselves, before the researcher then explains the RE-SAMPLE project and the motivation for this workshop. The researcher asks for permission for audio-recording and repeats the process that ensures participants' anonymity (as also outlined in the information letter).
2. **Demographics**
   Using the same demographics questionnaire as in diary study (see Appendix C).
3. **Health story**
   Goal: input for the patient journey.
4. **Experience with exacerbations and comorbidity**
   Goal: input for the desired parameters from the patient point of view.
5. **Controlling COPD**
   Goal: input for the desired parameters from the patient point of view.
6. **Use of eHealth**
   Goal: find out if patients are willing to use eHealth technologies.
7. **Data privacy and sharing preferences**
   Goal: find out preferences in terms of privacy and data sharing.
8. **Self-management**
   Goal: find out in what way patients are engaged in self-management activities.
9. **Relationship and communication with HCPs**
   Goal: input for patient journey, learning about the doctor-patient relationship.
10. **Decision making**
    Goal: input for patient journey, learning whether they are involved in shared decision making already and what their preferences are.
11. **Closing**

The detailed interview guide for the patient interviews can be found in Appendix F.

3.3.5 Patient post-diary workshop

Aim: Appropriate closing of the diary study, communicating initial results from interviews and diaries and getting feedback from patients on patient journey, user needs and values. Finally, the aim was to co-design with participants possible user interfaces for data visualisation and data sharing.

Procedure:

1. **Introduction**

Welcoming the participants and thanking them for filling in the diaries, before the researcher then explains the motivation for this workshop and the procedure. The researcher asks for permission for audio-recording and repeats the process that ensures participants' anonymity (as also outlined in the information letter).

2. **Feedback on initial results:**
   Goal: presenting to participants the early results from the interviews, pre-diary workshop and diary entries to receive feedback on
   a. Patient journey
   b. Values
   c. User needs
3. **Co-design**
   Goal: Identifying patient's preferences on data visualisation, privacy and data sharing options.
   a. Data collection & visualisation
   b. Data sharing
4. (optional) **Discussion on low-fidelity prototypes**
   In case participants struggle with co-designing user interfaces for data sharing, low-fidelity prototypes (see section 3.3.6) can be used to facilitate the discussion.
5. **Closing**

The detailed protocol for the post-diary workshop can be found in Appendix G.

3.3.6 Low-fidelity prototyping

Aim: Supporting conversations of rather abstract concepts like privacy and data sharing preferences. As participants might have difficulties imagining what privacy and the level of control means in relation to their RWD, we created some low-fidelity prototypes that communicate the basic concepts:

- Giving general consent to sharing specific type of data
- Giving general consent to sharing with specific recipient
- For each recipient: Giving consent to sharing specific type of data
- For each data type: Giving consent to sharing with specific recipient

Procedure: The prototypes were created as extra supporting material for the interviews and diary workshops.

The low-fidelity prototypes can be found in Appendix H.

3.4 Ethical approval procedures

The ethical approval procedures differed between the three countries. The hospitals in Italy and Estonia submitted one general ethical application for the cohort study (WP5) that included the user research activities conducted as part of WP2. The ethical application was approved in Estonia on 4th June 2021, and in Italy on the 4th August 2021. After that, the recruitment of patients could start in the respective setting.

In the Netherlands, medical ethical approval by an accredited Medical Ethical Research Committee (MREC) was sought for the cohort study (WP5) as that study is subject to the Dutch Medical Research Involving Human Subjects Act (WMO). Because people participate voluntarily in the user research studies conducted in WP2 and the studies do not infringe upon the physical or psychological integrity of participants, these kinds of studies are usually not subject to a medical ethical approval procedure (Peute, et al., 2020). However, an ethical approval was sought from the internal ethical board at the hospital to confirm that this was indeed a non-WMO study. The application was approved on 8th June 2021, confirming that the study is not subject to the WMO and therefore no medical ethical application was needed.

4. Results

This chapter describes the results of the user studies focusing only on the parameters, data collection procedure, data sharing and privacy, as well as feedback received from participants on early results and low-fidelity prototypes. The overview of participants in the studies in each country is provided in Table 4. At the time of writing, the diary study and post-diary workshop in Estonia were not concluded yet and therefore could not be included in the results.

Table 4: Overview participants in the studies conducted per country

	The Netherlands	Italy	Estonia
Workshop HCPs	N=12 (21.06.2021) N=12 (23.08.2021)	N=9 (24.06.2021)	N=5 (30.06.2021)
Interviews HCPs	N=7 (26.07. – 02.09.21)	n/a	n/a
Patient pre-diary workshop	N=3 (24.06.2021) N=2 (19.08.2021)	N=6 (14.09.2021)	Adaptation (one-on-one interviews, starting October 2021)
Patient diary study	N=4 (25.06. – 15.07.21) N=2 (20.08. – 09.09.21)	N=9 (15.09. – 05.10.21)	N=TBD (October 2021) In progress at the time of writing
Patient interview study	N=7 (28.06. – 16.07.21)	N=12 (11.09. – 05.10.21)	N=10 (09.07. – 21.07.21)
Patient post-diary workshop	N=3 (18.08.2021) N=2 (06.10.2021)	N=8 (06.10.2021)	TBD Not yet scheduled at the time of writing

All pilots sites worked with the same guides and material prepared by RRD (see section 3.3), however each pilot site used their discretion to adapt the method to fit the current situation and practical implications on the pilot site. The design of the study allowed for in-depths discussions of various topics, however, some aspects might not have been discussed in detail in all pilot sites (e.g., due to the lack of time or adaptations that were necessary). Furthermore, the low-fidelity prototypes were created to support discussions on privacy and data sharing and was provided to all pilot sites, but left to the discretion of the local researchers whether to include them. These extra materials were used in the Dutch pilot during interviews and post-diary workshops, and therefore also reported below in section 4.1.4.

4.1 The Netherlands

4.1.1 Workshop and interviews healthcare professionals

Two workshops of about one hour each were conducted with healthcare professionals on 21st June and 23rd August 2021 at the lung department of the hospital. Each workshop was attended by N=12 from the lung department (pulmonary nurses, pulmonologists, pulmonologists in training, students, researcher), some of which attended both. As it was difficult to schedule workshops with many HCPs present at the same time, and even more so from outside MST, we recruited N=7 HCPs from different backgrounds for individual interviews (psychiatrist, cardiologist, internist, physiotherapist, nurse specialist in diabetes, nurse specialist in heart failure, pulmonologist). These interviews were conducted online using Microsoft Teams. The HCP's working experience spanned from 1 to 46 years (mean 10.31 years).

Parameters:

General parameters that were mentioned were weight, blood pressure, heart rate, oxygen saturation, exercise capacity, lung function, dyspnoea at rest, dyspnoea frequency and dyspnoea severity, number of exacerbations, physical activity as measured by the daily step count, for muscle strength handheld dynamometry, and for a patient's physical capability the 6-minute-walk distance (6MWD) test or the CPET (Cardiopulmonary Exercise Testing, maximum capacity test to assess the performance of the heart and lungs at rest and during exercise). Questionnaires that were mentioned are the CCQ (Clinical COPD Questionnaire), MRC (Medical Research Council dyspnoea scale), QoL (Quality of Life), ADL (Activities of Daily Living questionnaire).

Monitoring the physical activity has been mentioned by several professionals, both in terms of understanding the patient's current level of activity, but also to identify worsening or improvements, which in turn could also motivate patients. *"How, what can I do? And also as a reminder "I have to be active or try to be a little bit more active". And maybe with a step counter you can also very nicely see if you make some progression, if you look maybe one month back. Then you maybe do see that things improve a little bit."* [HCP_Int2] Giving patients feedback in terms of trends or progress was also mentioned in another interview *"That's the biggest problem for the patient, they always train, and it's a progressive disease. And the thing they have influence on is how much they move. That's kind of the only thing, in combination with the medication taking and everything."* [HCP_Int6] The 6MWD, for example, helps in physiotherapy to tailor the training to a specific patient and also identify worsening and the likelihood of an exacerbation coming. *"We measure the 6 minute walking test, that's a quite easy test because we do it in our own practices. And there we can see a lot of differences. And also differences – and that's what we did the last years – if you ... some patients don't even have more problems by dyspnoea, but they can't walk anymore any longer. So that is a trigger that they are going to be in an exacerbation or something."* [HCP_Int6] Furthermore, the muscle strength is measured using a handheld dynamometer. A step counter or pedometer was mentioned as well to see the amount of activity, however, these might not automatically monitor other activities, such as cycling or swimming. Understanding what a person is capable of doing, is however very important. *"I think if you are talking about wearables or anything which could help the physiotherapist, it would be something to make it easier to see what does the patient do during the day. Because we now have, if we train we have those 6 minutes walking test, but if patients walk about, say 350 meters, if they train really hard, they maybe walk 360 or 370 meters. That is not a big difference. But I can imagine, if we can show the patient, if they have a wearable, which detects cycling and walking, maybe even the way of breathing better, and you follow that during a month and you do that in the next year again, you can ... it's a better way to stimulate on a positive way the patient I think. Because that's what it's all about. It's not about the training I give. It's about what they do in daily life."* [HCP_Int2]. Next to general physical activity, the importance of specific muscle training was also stressed *"You can do your cardiovascular training, but that is not enough. You should also have muscle training."* [HCP_Int7]. In the workshop, HCPs mentioned that they ask questions that are related to the activities of daily living (ADL), but are not applying the standardized ADL questionnaire.

Lifestyle parameters that were also mentioned included substance use, including alcohol and smoking, for example to support behaviour change. For patients who actively want to participate in a smoking cessation programme, how often and how much they smoke should be assessed at least once a week. It was highlighted by two professionals (HCP_Int_1, HCP_Int_7), that it is important to consider the way of asking these questions to avoid being too confronting and prevent socially desirable responding.

For patients who also have a chronic heart condition, measuring the NT-proBNP (N-terminal pro b-type natriuretic peptide) is useful to distinguish whether certain symptoms are caused by COPD or by the heart failure [HCP_Int2, HCP_Int3]. *"But it is difficult, because with the lungs with the COPD it's also… it's a hormone which elevates when the pressures in the heart go up. But since heart and lungs work together of course, with COPD patients you also have some increase of this hormone, of NT-proBNP. But for certain patients you know what the baseline level is, which can be a little bit elevated in a combined heart failure and COPD patient. And when it really increases in the NT-proBNP, my best guess would be that the heart failure is in an exacerbation. And not the COPD."* [HCP_Int2] For patients with combined COPD and heart condition, a baseline measure of NT-proBNP is useful to be able to compare a potential elevated value during exacerbation. A pulmonary screening, at least for OSAs (obstructive sleep apnoea) was also discussed, especially for patients with preserved ejection fraction [HCP_Int2]. To identify the cause of tiredness (e.g., anaemia), iron level and haemoglobin concentration are measured, which however seems to be on a case base, not something that is measured in all patients.

Patients with a chronic heart condition have to be careful with their fluid intake, as they often have fluids restrictions. Frequently measuring the body weight can be helpful in this patient group to identify a weight increase in the short term which is an indicator for a congestion and might trigger the prescription of diuretics [HCP_Int2].

Some patient groups also have to pay attention to their diet, for example salt intake (heart condition) and sugar intake (diabetes). Monitoring the diet to account for the specific restrictions can be useful.

Most patients with diabetes monitor their blood glucose level several times a day or with a continuous blood glucose monitor. The actual intake of prednisolone was also mentioned to be important, especially for patients with diabetes, as it has an effect on the blood glucose which might necessitate taking a different type of insulin to balance this [HCP_Int5]. Knowing whether prednisolone was actually taken after it was prescribed or recommended per the action plan is also helpful to identify overuse and underuse [HCP_Int7]. In the workshop, HCPs also mentioned that they ask the patients about their inhalator usage (inhalation technique, frequency) and therapy adherence.

Patients with hypertension often measure their blood pressure with their own devices at home, which is also encouraged, as the regular measurements at home can be more reliable.

Two specialists mentioned classifications that they also use when treating patients with COPD, a classification from cardiology and a category that represents the impact of COPD on their daily life and wellbeing. *"You record the NYHA class, that is the functional class. The New York Heart Association functional class. NYHA Class 1 is a very fit patient who only gets complaints with a lot of exercise. And the other extreme is class 4, that patient already has complaints in rest. That is a typical functional class which you use for heart failure, but you could as well use it for COPD patients, because what they tell you they can do will be caused by both diseases."* [HCP_Int2] *"We always put the patients in A, B, C or D. The A and B are the patients with less problems and less exacerbations, and the C and D are the people with more problems. In our first years, we only put them in the category for GOLD 1, 2, 3, 4. And that is only on the lung disease. And nowadays we don't just look at how bad or good they do spirometry, the lung function. We don't just look at what can they do, but also what they do."* [HCP_Int6]. The professional emphasised further that some patients might look good on paper in terms of their status and capabilities, but in practice are not doing so well. That is why for them the GOLD status alone is not sufficient.

Several healthcare professionals from various backgrounds expressed the need for parameters that indicate the wellbeing of the patient. This is currently lacking, even if in some areas a yearly QoL questionnaire is administered. A subjective scale of a patient's wellbeing would help professionals to also see the bigger picture, not just the objective clinical measures, but also how the patient feels in general. While HCPs do ask how a person is doing, it would help to do it more systematically. As one HCP stated, there can also be a mismatch between the clinical parameters and how the patient actual feels. Identifying a mismatch can support decision making *"So if he is telling me he is not doing fine, we intensify the treatment. But if I see for example that the patient indeed rates himself also as doing really well, say for example gives himself 10, and three month ago he was at a level over 6, then I see we have improved something. And maybe then I would also think by myself 'Ok the patient maybe is doing now so well, maybe we discuss doing nothing at this stage in time.'"* [HCP_Int2] Furthermore a mismatch between clinical and subjective parameters can also encourage a more in-depth conversation on what is going on. *"When the wellbeing being evaluated is quite poor, while I see only very stable numbers, then maybe it would encouraged me to ask further "why are you not being so well". Maybe that could help."* [HCP_Int2] Seeing how the wellbeing levels are changing over time can also be used as valuable feedback for the professionals: *"In the end you are a doctor to improve the wellbeing of the patient. Preferably in the short term and some treatments are targeted more on the long term. If you see something back of indeed that the patient has increased wellbeing, that's nice information to have."* [HCP_Int2]

For patients to rate their wellbeing could also support them to externalise their tacit knowledge of day-to-day variations and make it more explicit. As one HCP emphasises the importance to investigate the exacerbation story and the patterns preceding an exacerbation. Patients often feel it, they "just know" and according to that HCP, for the patient it is often the same pattern that precedes an exacerbation and those complaints: *"And they will, most of them will tell you the pattern. They will know, it's always the same. And they wait until they have the complaints, which are in the schedule, but then it's already a week later."*

[HCP_Int7] Although they often know or feel an exacerbation coming, they also seem to delay taking action and trying to find alternative explanations: "*They declare it by 'yeah today it was cold, the weather was not that good'. They always start already ... Or 'My wife was not nice to me' or something like that. Or 'I had troubles' They start already to translate it into something that it's not a problem."* [HCP_Int7] *"If I see patients, most of the lung patients they go too less. So they always wait too long. So if they come to my practice and we train, and I see 'wow it is not that good' and if it's Wednesday I always say: 'If it's still the same on Friday please call your doctor'"* [HCP_Int6]

The subjective experience of specific aspects was also mentioned. For example, one could ask the patient to grade the dyspnoea. *"How much dyspnoea the patient is experiencing, patient could grade that. 0 no dyspnoea, 1 a little dyspnoea, 4 very much dyspnoea. That would be of interest."*[HCP_Int2] This was also brought up in the workshop and furthermore that the limitations of daily life could be assessed once a month.

Next to the patient's subjective experience, it was also mentioned to take into account the observations of others, for example caregivers or partners. *"Sometimes I continued in asking some personal things before I went on. And I saw the communication between the partner and the patient. And sometimes I asked the partner "I hear that he says that. But tell me. Is that true? Do you believe that?" And then I saw the face of the partner."* [HCP_Int7]

Somewhat related to the patient's wellbeing is also what wellbeing means for them, in other words what are their goals, what do they want to be able to do and want to keep doing as long as possible. This was brought up in the workshop and HCPs expressed the need to understand these aspects better. Another aspect was the level of self-management, to get a better picture of a patient's situation: *"... and how does the patient do their self-management, I think that's one of the most important things. Do they know what their disease is like? What they can do themselves to make it the best?"* [HCP_Int6]. Possible questionnaires related to self-management were presented in the workshop, for instance the self-management ability scale (SMAS-30), the Tailored measurement for Self-Management Abilities in the Netherlands (TASMAN) or the Partners in Health scale (PIH) to measure self-management behaviour and knowledge in patients with chronic diseases. While the HCPs in the workshop did not consider these parameters as unimportant, they did not see what they would be able to do with the outcomes in their current care.

Data Collection:
As stated above, it was highlighted by two professionals (HCP_Int1, HCP_Int7), that it is important to consider the way of asking questions related to their lifestyle to avoid being too confronting. For example, the type and frequency of questioning should be adaptable to where the person is in the behaviour change process. *"Maybe that must be adaptable, like if people are really like pre-contemplation – if you use that model – you need to do a baseline assessment and then maybe like every three months like 'sorry I am going to bother you again with the questions you already asked, but I need to know if something has changed' and people that were pre-contemplation I can imagine that, if you ask them once a month 'Ok, you said you might want to change something in your smoking behaviour, how is that now?'"* [HCP_Int1]. Attention should also be paid how these questions are phrased to prevent communicating judgement that might encourage socially acceptable responses. *"It's like when I ask the patients 'Do you drink' they say 'some, a bit'. But if I ask 'How much can you have?' that's the question. And then 'Oh I can have 10 beers'. And the same with the smoking. 'Ok, I know you told me you quit smoking, but you sometimes smokes' – 'yes, yes' – 'Ok... I am not judging. Tell me, how much can you have?' – '5 ... ah 10 ... 10 a day. Less than before.' That's the way. So, you always should have double loop questions."* [HCP_Int7]

It was also mentioned that parameters should not only be measured for clinical purposes, but also for education purposes, in other words, to support patients understanding what these parameters mean and thereby support self-management. *"What I would prefer is that I can see and the patient can see, yeah, something of a general wellbeing, dyspnoea or exercise intolerance. That the patient gives himself or herself some kind of grade. That the patient also monitors for example blood pressure and weight. But most importantly, that would really help me, that the patient takes the conclusion out of it. [...] In eHealth, that is what you do, if you measure a lot and take in all the information, you also take away the input from the* *patient, you make decisions FOR the patient, you are not… not the patient making decisions themself.”* [HCP_Int2]

The difference between snapshot and continuous measurements was discussed in relation to blood glucose. Having a continuous glucose monitor gives much better insights and also reduces the burden for the patient to take a measurement. This can be likely also transferred to other parameters, where an automated data collection should be prioritized over manual data entries. HCPs in the workshop also emphasised the importance to distinguish between variables you measure once, for the characteristics (to get insight into the population) and the variables that are repeatedly measured.

Some patients also have to cope with other aspects besides living with COPD and CCC. *“I am also under the impression, that my patients are so busy with their day-to-day struggles and their trying to cope with their addiction that there is not a lot of room in their lives in paying attention to the COPD problems.”* [HCP_Int1] In addition, according to the HCPs, some patients also do not want to be reminded of their health conditions every day *“There are really patients who say ‘I really don’t want to deal every day with this disease.’”* [HCP_WS] Special attention should be paid that data collection does not add to their disease burden and that it also takes into account people with low levels of literacy. *“I am kind of wondering how those overwhelmed patients, or patients who have lower digital or reading skills would also be able to benefit from a programme like this. Because I think THOSE are the patients… […] But I think it’s the vast majority who struggle. If you look at the lung department, if I just look around in the waiting room, I see a lot of people from underprivileged situations. And I am wondering, ok, how can we help those patients, who are the majority and who have the highest disease burden and who benefit the least from the current programmes, how can we help THEM with such an extra programme?”* [HCP_Int1].

To ensure that the system is set up properly and that the patients do not run into every problem and no data is lost, one HCP with personal experience in such research recommends a service hotline. *“We had even with those low literacy people we had complete data. […] we installed it ourselves at the patient’s. And they had a hotline, that is VERY important. They should have ALWAYS a hotline, which works. […] You should have a 24/7 service for those patients. And it should not be a technical person only. Because if it is a technical person, he doesn’t understand the real question of low literacy patients. So, there should be someone who is REALLY involved in the study and REALLY knows the patients. And even takes a car to solve the problem at home. We had problems that they couldn’t get on the machine, it didn’t work, oh, they just wanted to stop it, it’s not good. And we went there and they had forgotten to plug it in the electric. Or the dog had eaten the cable. Very funny sometimes, but it happens. So if you don’t have proper technical support, but that is NOT a technician on the line, it does not work. […] And, you know… It doesn’t take you much time, because you can solve 99% of the cases. And if you don’t do that, you fail.” [HCP_Int7]*

In the second workshop, HCPs discussed that some of their patients with COPD(they estimated 5%) already collect some data (weight, oxygen saturation, body temperature) and document those in a booklet. In current practice however, there is little time to go with the patients through those notes. *“Well, let’s put it this way, the people who come with booklets and write everything down, they’re often so detailed that you’re not even going to discuss the book, then your consultation is over in no time. So it’s more that you ask in general, “how did it go?”, “have you needed any medication?”, “how much?’”* [HCP_WS] They also caution that some patients spend a lot of time on some measure, which however for them is not that useful. *“Patients spend a lot of time on that, hey, that medical saturation and only then think about how they feel. They hang a lot on that themselves. From ‘yes, I had 37.5 today and I normally always have 37.1 as my temperature’, I can’t do anything with that.”* [HCP_WS]. They expressed concerns if they would encourage patients too much to focus on these details if they discuss the booklet with them. Unlike diabetes patients who have to act on measurements on a daily basis, this is different for COPD patients, especially for these kind of measurements. They emphasised that for COPD patients there should be a balance between keeping track and not focusing too much on it. Furthermore, they also have a lot of patients who do not want to measure all sorts of things as they do not want to deal with their disease every day.

When it comes to using the data that is collected, for HCPs it was more important to see when alarm symptoms are deviating. They have no need to see the raw data but want to see “red flags” of deviating parameters, such as increase in daily complaints, sudden weight loss, sudden worsening in saturation, reduction in exercise tolerance. While they would like to be notified on these deviations, they also expressed that they do not want to have an alarm in real time. These red flags are important for the consultation, however, how they are displayed is very important *"Yes, but then it has to be very clear, in one picture, over a longer period of time. Not that you have to start scrolling and I don't know what, because otherwise it already just takes too much time. So it must be clear at a single glance."* [HCP_WS] As they are training patients to perform self-management, the HCPs considered that an alarm signal should be given first to the patient and only then to the provider. One HCP distinguished between two types of data: 1) data the patients need in those moments where they are getting worse, so they know whether they have to call the doctor or take action (for self-management), and 2) data the HCPs need in a consultation to see the disease progression.

4.1.2 Patient experience diary study and pre-post diary workshops

The diary study was conducted with six patients (N=6), split in two groups starting the three-week diary study at different times (ending in July or September 2021). Most of the patients joined both the pre-diary (N=5, online) and the post-diary workshop (N=5, face-to-face). Four of the participants were male, two were female and their age ranged from 63 to 74 (mean 67.8 years). All of the participants were diagnosed with COPD over ten years. All participants indicated to also have a chronic heart condition, one person also was diagnosed with diabetes. Their highest level of education was high school (N=2), trade school (N=1), university (N=2) or others (N=1). Most of the participants were retired (N=5), one was unable to work. Considering their living situation, N=2 participants lived alone, the others lived with 1 (N=1), with 2 (N=1), with 3 (N=1) or with more than 4 (N=1) family members together.

Asking about how much their condition affects their daily living activities, all participants had some problems with performing their usual activities (mean 3.16 on a scale from 1 having no problems to 5 being unable to perform their usual activities). No participant chose 1, two persons chose 4 as the highest value in this group. Participants assessed their level of digital skills with an average of 2.67 on a scale from 1 (really low) to 5 (really high). The lowest rating 1 was chosen by one person, all others rated their skills with 3.

Parameters:

The participants mentioned eight parameters: blood pressure, blood values, body temperature, heartbeat, lung capacity, oxygen saturation, sleep apnoea, and weight. Some participants have their own measurement devices at home to keep track of these parameters. For example, a pulse oximeter to measure their oxygen saturation. *"I walked twice for 15 minutes. When I got home, I measured the saturation; it was 75. This is what COPD does to me."* [MST010]. The parameters blood values and lung capacity are being measured by the GP or pulmonologist.

Most participants try to be active in different ways. These different activities need to be taken into account when developing an eHealth application which collects activity data. The activities these participants do are: walking, biking, exercising, golfing, work around the house (cleaning, gardening, tidying). *"I visited a museum today: normally I go by car, today by bike."* [MST007]

Data Collection:

The participants were asked whether they write down their measurements. Three said they do not write them down. Every morning one participant [MST007] writes down the amount of time they wore the CPAP mask at night in a paper diary (Continuous positive airway pressure; mask for sleep apnoea). Besides those parameters, two participants [MST007 / MST060] indicated they write down when they took extra medication to report it to the pulmonologist during their consult. However, another participant [MST010] indicated that they write down when they took extra medication, but they did not report this to the pulmonologist, only to a Cesar therapist. The reason for reporting this to the therapist is because this therapist shows personal interest in the participant, not in order to change the treatment. Regarding data to collect, one participant [MST007] indicated that they want to measure and keep track of for example blood values, but do not want to write down things like their mood: *"On the one hand, it is good to keep track of things, such as blood values, I think that is important. But to keep a diary with: 'today is a 6, tomorrow it is..', I don't think that such things will help me."* [MST007].

Regarding the number of times wanting to measure parameters, two participants [MST008 / MST011] want to measure their blood pressure every 14 days, one participant [MST007] wants to measure their blood values once in six months, another participant [MST060] wants to measure the blood values whenever he/she thinks something is off, and finally one participant [MST004] wants to measure their lung capacity during different weather conditions, to know whether weather influences their complaints.

Only one participant [MST008] indicated during the workshop that he/she uses a mobile application to keep track of his/her steps and cycling distance: *"Through my iPhone: counting number of steps and cycling distance. […] I do look forward to it, to see my step and cycling data."* [MST008].

When talking about the use of an app for collecting data, all participants indicated that they are okay to write down data or complete questionnaires once or twice a week, for 15 to 30 minutes each time. *"Half an hour is enough for me. Really no more than that. […] I don't want to deal with that every day, then you start thinking about it and the more you think about it, the more it bothers you."* [MST011]. One participant [MST007] indicated that incorporating reminders in the system would be very nice. If you forget to complete the questionnaire, the system sends you a reminder the next day to complete it.

Data Sharing and Privacy:
Participants had mixed feelings about sharing their data. Some participants were positive about sharing their data with healthcare professionals, others were more reluctant. Two participants [MST004 / MST011] are also willing to share their data with healthcare professionals outside the Netherlands, for example when being on vacation and something happens. *"With my motorcycle I go abroad, when I'm in my truck, I go abroad. So I think they should see my data with just one click."* [MST004]. The participants that were more reluctant want to decide themselves with whom they wish to share (or not) their data. One [MST060] said, they would share the data with treating specialists and with emergency medical services, but would not share their data with healthcare insurance, physical therapist, dietician, general practitioner, or relatives. The other participant [MST007] said they would share their data with healthcare professionals treating them in the hospital, general practitioner, researchers and with relatives, but would not share their data with healthcare insurance, CBR (Centraal Bureau Rijvaardigheidsbewijzen, the Dutch central office of driving licenses), physical therapist, or dietician. One other participant [MST008] only said that they would not want to share data with the company doctor.

Three participants [MST004 / MST007 / MST008] felt that sharing the number of steps they take was not necessary: *"I think that number of steps is overstated. One day you walk 100 steps, but you feel good."* [MST008]. Regarding heartbeat, one [MST004] was positive and one [MST007] was negative. According to the participant that does not want to share their heartbeat, heartbeat is not important to know for COPD patients without heart conditions. Furthermore, one participant [MST004] mentioned blood pressure, and one [MST008] mentioned sleep quality to share with others. One participant [MST060] indicated that they would feel like they are being controlled by the healthcare professionals if they had access to their health data: *"For me it's too much, I would feel very controlled. Whereas I think: 'I'm a grown-up, I can handle it myself'."* [MST060]. The same participant wants to give permission to access their data each time another healthcare professional needs to open their medical dossier, for example when their treating healthcare professional is sick.

When asking about privacy, three participants [MST004 / MST008 / MST011] are aware of it and handle it carefully, but one participant [MST007] has a less strong opinion: *"There's little privacy for me. In terms of health, I don't need a job, so it's not that people think: 'oh they have COPD, we won't hire them'."* [MST007].

Some participants [MST004 / MST008 / MST010] experience a big influence from weather conditions on their symptoms, others [MST007 / MST011 / MST060] do not experience this. *"I was feeling a little down today. I have a lot of trouble with the humidity, and I experience shortness of breath and am coughing a lot."* [MST010]. *"The weather doesn't bother me. What does bother me, is when I walk in Amsterdam or Utrecht. […] Because of the air quality in those cities."* [MST007].

User Needs Feedback:
During the post-diary workshop, participants received six user needs that were based on an initial analysis of the interviews and diaries, and they were asked to rank them from most important to least important. The needs they received were related to data collection (willingness to collect data but not spending too much time), data sharing (willingness to share data, but wanting to determine with whom), provision of health information, parameters to measure (e.g., sleep quality, steps, saturation), being active (which could mean biking, walking, grocery shopping, …), and support with making decisions (such as when to call the doctor, when to start with prednisolone etc. to prevent waiting too long). Participants ranked these user needs very differently. This shows us that every patient has their own needs. Being active and sharing data was in the top 3 for all diary-participants [MST004 / MST008 / MST010 / MST060], except for [MST007]. *"Being active, that's the most important thing for me. I could also get here with a mobility scooter, but I got here cycling. [...] Walking is bad for me, but cycling is very important to me."* [MST008]. *"Data sharing, because everyone knows I'm dealing with COPD, and giving more information to the professionals would help."* [MST004]. The ranking of the three least important user needs was more diverse. Two participants [MST007 / MST060] did not use all six user needs that were provided. [MST007] did not use the card "support with making decisions", while MST060 did not use "support with making decisions", "health information", and "parameters to measure". While [MST060] did not personally feel the need for "data collection", "data sharing", and "being active", they ranked them all on the same level. [MST060] added that if being asked to, they would help collecting data and contribute and similarly, they would share data but then wants to determine with whom.

4.1.3 Patient experience interview study

In total, seven patients (N=7) with COPD were interviewed between 28th June and 16th July 2021. The interviews took place online or in face-to-face meetings, given the patient's preferences. Two of the participants were male, five were female and their age ranged from 63 to 80 (mean 67.4 years). Most of the participants were diagnosed with COPD over ten years ago (N=4), two stated they had been diagnosed 3-5 years ago, one person did not remember. All participants indicated to also have a chronic heart condition. Their highest level of education was high school (N=2), or trade school (N=4) or others (N=1). Most of the participants were retired (N=4), two were unable to work and one was employed full time. In addition to being retired, two also indicated that they are unable to work. Two participants are doing voluntary work. Considering their living situation, N=3 participants lived alone, the others lived with 1 (N=3), or with 3 (N=1) family members.

Asking about how much their condition affects their daily living activities, all participants had some problems with performing their usual activities (mean 3.28 on a scale from 1 having no problems to 5 being unable to perform their usual activities). No participants chose 1, two persons chose 5. Participants assessed their level of digital skills with an average of 2.71 on a scale from 1 (really low) to 5 (really high). The highest rating was a four (N=2), while N=2 chose 1, the lowest possible option.

Parameters:
The participants mentioned three parameters; oxygen saturation, heart rate and blood pressure. Some participants mentioned to have a pulse oximeter to measure their oxygen saturation. "*I have a saturation meter. I use it daily when I don't feel well. Just to keep an eye on it. But it could also be that I don't use it for weeks, if all goes well.*" [MST005]. This pulse oximeter also gives them information about their heart rate. But one participant uses a wearable (Fitbit) to get insight in her heart rate. The parameter blood pressure was in all cases a parameter that was collect by the GP. "*Blood pressure does my GP… once every six months.*" [MST010].

Data Collection:
There was only one participant [MST010] who collects data on a regular basis and shared this data with a healthcare professional. This participant collects oxygen saturation, heart rate and sleep. This data was carefully written down in a paper diary. One participant [MST001] also collected oxygen saturation when he/she was feeling off and shared this data with his/her district nurse. Two participants mentioned collecting data by means of a wearable (Fitbit) [MST008 / MST009]. One participant is enthusiastic about this way of collecting data (number of steps, heart rate and sleep): "*I don't know if it's completely correct but it's nice that you can keep up with it a bit.*" [MST008]. The other person [MST009] was more sceptical:

"*In the beginning that I had this Fitbit, I also had it on all the time. But I found that so irritating, then you think, I'm on a 100 HR and then I think "What did I do?". You're just going to worry more.*". Both participants did not share their data with a healthcare professional. Also another participant [MST001] collected step data by using a mobile application. However, this participant was not very happy about this way of tracking, because then she would need to always carry her mobile phone with her to have her daily steps counted correctly. *"…but then you must have the phone with you. But when I walk once, I don't drag that thing with me. I don't walk any further. I'm alone at home."* [MST001] But she was very open and enthusiastic about the option to use a wearable to count steps: "*This thing you mentioned [bracelet to collect step data] seems very nice to me. Then I can also use it for my heart complaints*". Another participant [MST002] also shared this enthusiasm: *"I would love a watch that measures sleep quality"*. One participant [MST008] mentioned the collection of weight data on a weekly basis.

When discussing the possibility to collect data by means of questionnaire participants were reluctant. "*Completing online questionnaires? Not every day, terrible… once a week is enough for me*." [MST001]. A reason given by another participant for this reluctancy was the energy it would take to collect the data and complete the (online) questionnaire. This participant [MST009] prefers to use this energy to do more fun things: "*No need. That is it. Then I have to do that too. I do not feel like it. I'd rather do something else*".

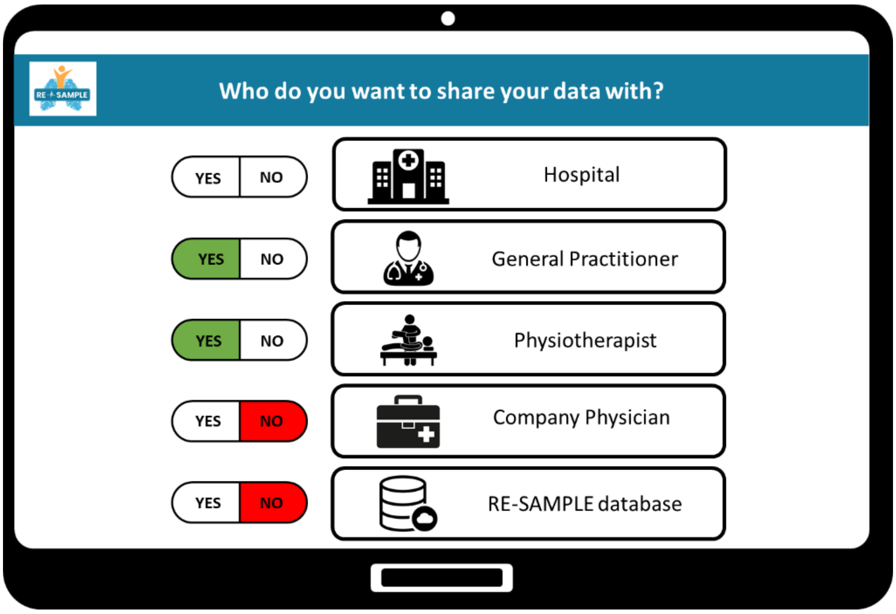
Data Sharing and Privacy:

Data sharing with healthcare professionals was not an issue for the participants, especially when it comes to healthcare data they were willing to share: "*No. This is about healthcare, I don't care, because it's important when something happens that everyone can be informed*". [MST009] The participants were positive about data sharing also because they assumed their healthcare professionals already have access to their data: "*With who I share my data? I have no problem with that. They can know everything about me. The GP already knows everything about me.*" [MST001]. Only one participant [MST013] was very reluctant and suspicious about sharing data in a more general context: *"Especially now, the more that people know about you, the worse that is… for the person in question".*

4.1.4 Low-fidelity prototyping

To facilitate the discussion around data sharing, privacy, giving consent and data visualisation, we developed some low-fidelity prototypes. These were used in the post-diary workshop and in four of the interviews to facilitate the conversation and to better understand patients' needs in relation to these topics.

The mock-ups shown during the post-diary workshop were clear to the participants. However, one [MST060] was in doubt whether all terms were clear for all patients. This participant did not know how to improve it but thought that not all patients with COPD will understand everything and suggested the language had to be simpler than what was shown in the prototypes during the workshop. When asked about the level of control over sharing data, three participants [MST004 / MST008 / MST010] indicated they do not think it is necessary to have very detailed level of control. They preferred just to consent to data sharing per organisation (e.g., hospital, general practitioner, etc.) and not to specify per organisation what kind of data would be shared. In other words, these participants preferred to simply select yes / no per organisation (Figure 1) over the very detailed specification of data types per organisation (Figure 2).



Who do you want to share your data with?

YES NO Hospital

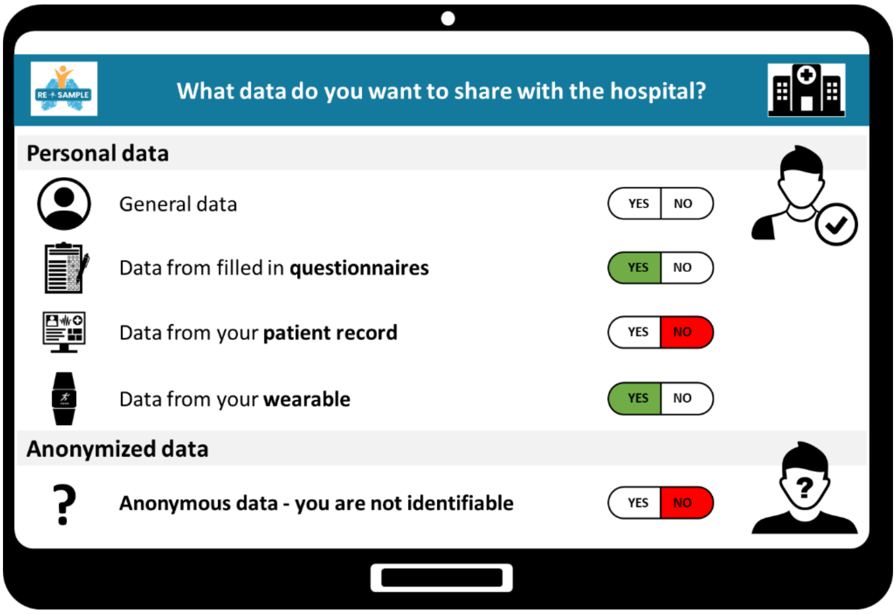
[✓ YES] NO General Practitioner

[✓ YES] NO Physiotherapist

YES [✓ NO] Company Physician

YES [✓ NO] RE-SAMPLE database

Figure 1: Mock-up data sharing on organisational level without specifying the type of data (yes/no option)



What data do you want to share with the hospital?

Personal data

General data YES NO

Data from filled in **questionnaires** [✓ YES] NO

Data from your **patient record** YES [✓ NO]

Data from your **wearable** [✓ YES] NO

Anonymized data

Anonymous data - you are not identifiable YES [✓ NO]

Figure 2: Mock-up data sharing, specifying the type of data per receiving organisation (here: hospital)

However, two other participants [MST007 / MST060] preferred it the other way around, they wanted to choose which data they want to share with which organisation (mock-up in Figure 2), because as one said: *"Then you have most of it in your own hands."* [MST007]. One participant [MST060] had a whole different vision of how to show this data sharing visualisation. The ideal option for them was if all their healthcare professionals are aware they use a mobile application, and the HCPs let them know that they want to have for example insight in the activity data, and then specifically ask the patient to share this: *"You receive a text message from the physical therapist: 'I want to see your activity data, do you give consent?'."* [MST060].

In general, participants in the interviews that saw these prototypes were all willing to share their data gathered by the future RE-SAMPLE mobile application: "*I don't have any. No secrets for anyone*" [MST010]. But they want to decide with whom they share their data: *"I have no problem with that. I don't really care. But I would like to determine it myself.*" [MST008] / "*But the data is not shared with my health insurance? And also not with google? It's protected? Then I would share my data. But I want to decide.*" [MST019]. The participants had no strong preference for one prototype. Only one participant preferred the option to drag the data icons (see Figure 3): "*To drag. I find this easier. Because it's on the* *phone*" [MST019]. The others were more in favour of the yes / no options (see Figure 1 and Figure 2): "*As it stands here. It also has to be on screen. Those old people want to read. Click here and click there*" [MST017]. But overall, they had no strong opinion about the three presented options: "*This is the easiest. But it does not matter much. Whether you enter yes or no or check a box*" [MST018]. The different levels of aggregation were appreciated by the participants. It gave them a sense of control: "*You have to give the people the opportunity*" [MST018]. There was no clear preference to control the data per type of data or per type of (care) facility. Some preferred per data: "*Then I would choose this, per data. I think that's easier*" [MST019]. And some preferred per facility: "*This is easy for everyone, with the yes and no. ... and that you can indicate per institution*" [MST008].

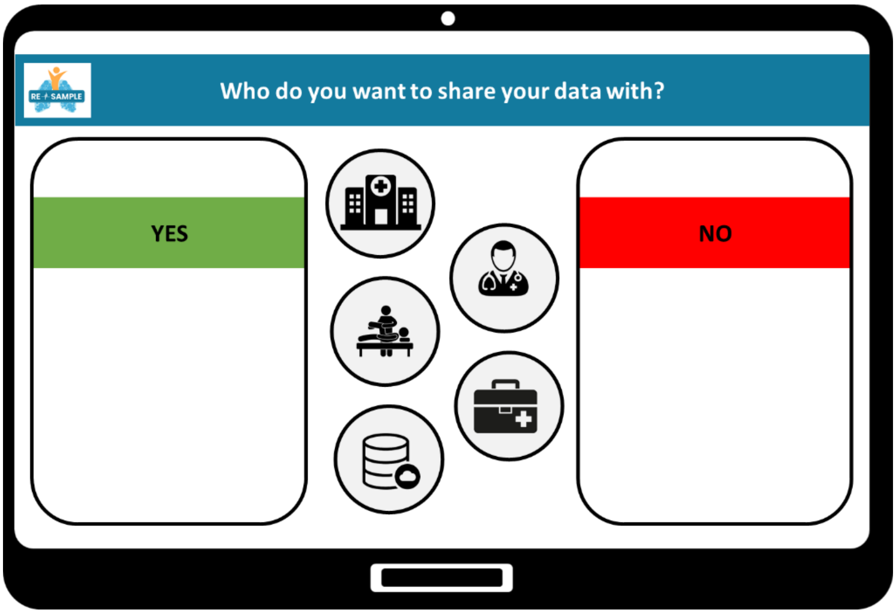


Figure 3: Mock-up data sharing on organisational level without specifying the type of data (drag icons option)

4.2 Italy

4.2.1 Workshop Healthcare professionals

In Italy, one workshop of about 1.5 hours was conducted on 24th June 2021 with nine healthcare professionals (N=9) from a variety of medical backgrounds (psychologist, pneumologists, nutritionist, internist, psychotherapist, including fellow pneumologists). Their working experience span from 6 to 14 years (mean 11 years), excluding fellow pneumologists with 1 year of experience.

Parameters:

General parameters that were mentioned were age, weight, height, weight loss over time, allergies and intolerances, spirometry (FEV1), for muscle strength handheld dynamometry, and for a patient's physical capability the 6-minute-walk distance (6MWD) test or the chair stand test. Symptoms to investigate are cough, sputum production and dyspnoea. It is also important to investigate the variation of these symptoms: change in sputum productions such as colour or volume and so on, even if these are subjective rather than objective aspects. Questionnaires that were mentioned are the modified Medical Research Council (mMRC) dyspnoea scale, COPD Assessment Test (CAT), for nutritional screening the NRS-2002 (Nutritional risk screening) or the MUST (Malnutrition Universal Screening Tool), for anxiety and depression the STAI (State-Trait Anxiety Inventory) test or the BDI test (Beck Depression Inventory).

The pneumonologists in the workshop discussed the importance of taking into account the observations of others, for example caregivers or partners. *"I also prefer my patient to be accompanied by a family member to assess both the subjective experience of the patient and the external observation. For example, a patient can tell that the dyspnoea is stable but a family member can tell me that the patient is moving less than before; for this reason, in my opinion, it is important to listen to two points of view and for the same one the questionnaires are more sensible."* [Pneumonologist2] The GP was also considered as a valuable source, for example, on the number of exacerbations and also adherence to therapy. Some doctors try to keep track of the number of exacerbations per patient by documenting it in the patient record with a date and the abbreviation eCOPD to be able to see a trend over the years.

For patients with heart failure, NT-proBNP was mentioned as a critical value, while patients with diabetes and COPD have to be monitored regarding blood sugar.

From the nutritionist point of view, weight and weight loss over time are very important as well as food intake. They also conduct bioimpedenziometry, a tool for the assessment of body composition, body fat and lean mass. To optimize the therapy to the weight and characteristics of the patient, nutritionists also ask many questions related to their food, e.g., when and how often they eat which meal, if they skip meals, whether they have difficulty chewing, digestive or bowel function difficulties, diarrhoea, bloating, meteorism, the type of food sources, how often they eat a specific food, like vegetable, fruit or source of fibres. The BMI was considered to be a rather outdated nutritional index, especially in the field of COPD: *"as this being a pathology that affects the adult population and over the years the body composition changes, decreasing muscle mass and increasing fat mass, this obviously can cover the reduction in weight and therefore mask a sarcopenia. The patient can be normal weight and sarcopenic or even overweight and sarcopenic. The so-called sarcopenic obesity which is an aspect that we very often find in patients with COPD."* [Nutritionist] Instead of the BMI, the nutritionist recommended to use the hand grip test or chair stand test instead.

The importance of evaluating the state of the muscle functions have been stressed both by pneumonologists and by nutritionists. Using a chair stand test helps to combine both specialties: *"It is performed with a simple chair and it brings together pulmonologists and nutritionists. We work a lot on the muscular aspect and these tests therefore evaluate both the muscular system and the respiratory system"* [Pneumonologist1]. – *"In clinical nutrition we use the hand grip test to evaluate the state of muscle function for upper limbs. While the chair stand test evaluates the strength of lower limbs, the hand grip test evaluates the upper limbs. It simply consists of pressing the hand on a dynamometer and the instrument records the muscular strength of the forearm."* [Nutritionist] These tests are especially important to recognize early stage of sarcopenia and to avoid muscle deconditioning. Muscle training can have a large impact on a patient's life, as stressed in the workshop: *"If a patient has lung damage but compensates with muscle exercise and he is very fit, he will have a much lower degree of dyspnoea and breathlessness, compared to a patient with equivalent damage but with less muscle. We cannot regrow the lung, but we can retrain the muscle, we can change the lifestyle of the patient, the food intake, the exercise with the improvement of the muscle, dyspnoea, and quality of life."* [Pneumonologist1]

The social context and quality of life was considered important by the psychologist *"what is interesting is the quality of life of the carers. An immediate understanding of what are the lifestyle habits, the possible social withdrawal for example, so a possible closure in terms of housing condition or not is extremely useful to be able to then undertake effective treatment. […] You could start with open questions, already age gives us important information then you could try to understand whether the patient is retired or not. If a patient is placed in a certain work environment, he tends to have a lower level of depression than those who experience a more closed condition. In these cases, we often also find a real agoraphobia, patients who live in the house feel safe and this obviously has negative effects on a myriad of variables even at the motor level trivially."* [Psychologist] Levels of anxiety and depression are measured using the STAI test or the BDI test.
From a cardiology point of view, the examination of OSAs and a quantification of the value of the ejection fraction was mentioned. *"It may be useful to have at least a quantification of the value of the ejection fraction also to frame as was already shown in the table if these patients are more in a picture of heart failure with reduced ejection fraction or as more often happens in patients with multiple comorbidity symptoms with preserved ejection fraction"* [Cardiologist]

Data Collection and Visualisation

The frequency of data collection and tests administered was discussed in relation to psychotherapy, where it was considered advisable to *"do this once a month to evaluate the effects of the psychotherapy approach but also to evaluate the various other systems of care undertaken for a particular patient"* [Psychotherapist].

The pneumonologists discussed their inability to see trends for a patient. They would like to have a trend chart or a graphical trend for a larger period of time, for example, for the CAT score, the data from the spirometry and also a trend for the exacerbation. *"In our experience, during the outpatient visit, we are unable to see the trend of the patient during the different visits. We only got text files of the previous visit, so we update the daily visit report, we write down a sort of trend, mostly for the spirometry data and the symptomatology, but it's an uncomfortable method, mostly ineffective. It would be ideal to have a digital platform in which to upload data, spirometry reports, scores and so on, to have a wider and easier view on the patient situation."* [Pneumonologist3]

4.2.2 Patient experience diary study and pre-post diary workshops

The diary study was conducted with nine patients (N=9) from 15th September until 5th October 2021, which was followed up by a post-diary workshop on the 6th October 2021 (online, attended by 8 diary-participants out of 9). In the Italian pilot, Microsoft Forms was used to create both the demographics questionnaire and the daily diary surveys. As only scales from 0 to 10 are available in this tool, the scales in the Italian pilot differ from the Dutch pilot. Furthermore, the responses of one participant were missing in the demographics questionnaire.

All diary study participants except one were male with an age ranging from 59 to 80 (mean 69.5 years). Participants were diagnosed more than 10 years ago (N=3), 6-10 years ago (N=1) or 3-5 years ago (N=3) and only one participant within the last 1-2 years. The highest level of education was university (N=5), high school (N=2) or other (N=1). Three participants had no additional chronic conditions, some had cardiovascular conditions (e.g., atrial fibrillation, hypertension) or rheumatoid arthritis. Except one freelancer and one person being unable to work, all others were retired and all participants lived together with one family member.

Asking about how much their condition affects their daily living activities, three participants did not experience many problems, the other N=5 however experienced more serious problems (mean 5.25 on a scale from 0 having no problems to 9 being unable to perform their usual activities). Three participants chose 7, one 8 and one 9 in this group. Participants assessed their level of digital skills with an average of 7.5 on a scale from 0 (really low) to 9 (really high).

Parameters:

The patients addressed many different parameters organized in different categories as follows:

- **Vitals:** blood pressure, body temperature, oxygen saturation and heart rate,
- **Spirometry exams** related to lung function,
- **Biomarkers** referring mainly to blood exams such as glycemia or glucose levels,
- **Symptoms:** fatigue, cough, dyspnoea, insomnia, more/less sputum, sleep apnoea,
- **Radiology exams** especially during diagnosis: CAT, X-Ray Thorax,
- **Risk factors:** number of cigarettes per day, depression,
- **Environmental factors:** warm and humid/cold weather, staying close to the sea,
- **Exercise:** steps per day,
- **Medicines/devices:** CPAP mask, TRIMBOW.

Regarding the management of the COPD, most of them regularly measure their blood pressure and oxygen saturation at home. "*I regularly measure my temperature, blood pressure, oxygen saturation and heart rate. It helps me feel secure but I can also report the measurements to my doctor if necessary."* [GEM0004] Spirometry parameters are measured at the hospital during the planned follow up visits with the pneumologist. Other blood exams can often be prescribed and controlled by the general practitioner. Radiology exams are mainly performed at the COPD diagnosis stage or for other comorbidities when present. *"I had a gastroscopy because I suffer from gastroesophageal reflux disease aside COPD. I didn't mention it to my pneumonologist during the follow up control, however he figured out that there was a connection to COPD as well."* [GEM0006].

In addition, a couple of patients [GEM0006, GEM0007] use a smartwatch to monitor their vitals and physical activity, or used one for a specific period.

As far as risk and environmental factors are concerned, patients either mentioned them in their diaries or during the pre- and post-diary workshops. "*When I go to the sea for some days, I feel much better.*" [GEM0006] "*When the weather gets colder, even a simple cold can significantly intensify my symptoms.*" [GEM0010]. Symptoms are reported regularly especially in the diaries but also during the discussion related to the patient journey. "*When I have symptoms such as fatigue and cough, I initially contact my general practitioner.*" [Pre-diary workshop] "*I don't know why I have so much phlegm/sputum even though I can breathe well and without coughing.*" [GEM0011], "*Insomnia is very hard for me. I want my calmness back.*" [GEM0002].

Concerning patient habits, most patients try to be active in various ways depending on the severity of their symptoms. Physical activities mentioned are walking alone or with company or with the dog, climbing the stairs ("*I try to walk more and climb the stairs but breathing calmly.*" [GEM0003]), swimming ("*I enjoy going swimming to the pool even though I have a little difficulty breathing.*" [GEM0011]), physiotherapy (*"I had physiotherapy sessions that helped me feel more energized strengthening my muscles."* [Pre-diary workshop]), respiration exercises (*"I practice yoga respiration exercises."* [GEM0002]), postural gymnastics ("*I started postural gymnastics but I don't manage to breathe very well.*" [GEM0001]*)*, doing chores at home or outside the home and going to the market. ("*Going to the market and walking helps me relax.*" [GEM0003]). Some of them also try to adapt their habits to improve their health conditions, even though it is not always easy "*I try not to smoke a lot even if I don't manage to do so. Smoking is a disease, you cannot simply quit. Something has to substitute the relaxation feeling you get with it.*" [GEM0007].

Data Collection:
The patients were asked whether they write down their measurements. Most of them said they do not write them down systematically but mostly when they experience more symptoms or perceive a deterioration of their symptoms. Some of them report their blood pressure and oxygen saturation on a daily basis in their diaries.

One patient [GEM0006] used a smartwatch in the past to report and monitor their vitals and steps but they later realized that it was not so useful for them on a daily basis. They experience a stable COPD phase at the moment, with little variation on their symptoms. Patient [GEM0011] mentioned that some irregular measurement in their smartwatch during cycling was the reason to undergo more exams and get their COPD diagnosed. Patient [GEM0004] instead mentioned they regularly use a smartwatch and a monitoring application since it makes them feel more secure. Additionally, this participant has the possibility to share these measurements with their doctor if necessary. At the same time, they agree that it would be better that these data are processed into more elaborate advices or alerts for the patient. "*Continuous monitoring can stress me more. I don't want to know all my measurements every day.*" In addition, some patients said that using smart devices to report this kind of data would be really useful only if there is a clinician who monitors and interprets them.

Regarding data collection time, most of the patients are willing to insert their data at most twice and preferably once per week. Some of them found diary questions somewhat repetitive on a daily basis. The preference related to the frequency of the data collection seems to vary with the severity of the disease and the presence of comorbidities. Patients with comorbidities and more symptoms that are persistent prefer to be monitored more often. Overall, patients appeared to trust medical experts' point of view concerning the selection of the parameters and their measurement frequency.

Most patients find an application sending them reminders related to medicine intake, alerts on vitals and exercise monitoring very useful. "*Monitoring my physical activity could motivate me to exercise more.*" [GEM0004]. They also confirmed that a *companion-like* application could be a nice way to keep all the necessary information related to their disease management together, but also a way of communicating with their caregivers in a more direct way.

Data Sharing and Privacy:
Most patients are open to share their data with medical experts and researchers. *"I don't mind as long as COPD related research can profit from my data and I can eventually get better treatment."* [GEM0006]. In addition, they all stressed that it is crucial that doctors have easy and quick access to patient data so that they can take more informed and timely decisions. Another aspect that emerged during the pre-diary workshop is the need for multidisciplinary disease management regarding patients with comorbidities. "*It is very crucial that more healthcare specialists share my data. I have many serious comorbidities and often my pneumologist doesn't have the complete image of my clinical condition (exams, medications) and vice versa. I usually don't think of addressing to my pneumologist problems other than the ones usually requested (another nuisance, medical issue)."* [GEM0004]

Some patients discussed data privacy aspects in more detail. "*It is important for me to know the objectives of the study and how my data will contribute to them. The objectives of the study have to be clearly explained and communicated."* [GEM00010]. Patient GEM0004 added: "*There should be in place a system of tracking/logging during data exchanges/processing in order to register any possible leakage of information, evaluate possible threats and guarantee high security throughout the whole project and all its phases."*

Finally, all patients agree that they cannot decide by themselves which data to share and which not to, because they don't feel competent to do so. "*For me as a patient, it is hard to know which data and by which professional should be accessed during the project."* [GEM0006]. Patient GEM0010 added: "*Data sharing it is not a problem. Our data are shared and available in many popular data platforms we use every day. Let's focus on more important issues."*

4.2.3 Patient experience interview study

In total, twelve patients with COPD (N=12) were interviewed in face-to-face meetings between the 11th of September and the 5th of October 2021. Most of the participants were male (N=10), two participants were female. The age of the participants ranged from 63 to 90 (mean 77.7 years). 6 participants were diagnosed with COPD over ten years ago, 3 participants were diagnosed 6-10 years ago, and 3 participants were diagnosed 3-5 years ago. All but one participant had one (N=3) or more (N=8) chronic conditions (e.g., chronic heart condition, hypertension, depression, diabetes, OSAs or others). The highest education of the participants ranged from university (N=5), high school (N=2), primary school (N=3), and other (N=2). Most of the participants were retired (N=10), only two participants were working full time. Concerning their living situation, most of the participants lived together with one family member (N=10), two participants lived alone.

Results regarding how much the condition of participants affects their daily living activities revealed a mean of 2.7 (on a scale from 1 having no problems to 5 being unable to perform their usual activities). Only one participant chose 5 and 4 participants chose 1. The average level of digital skills of the participants showed a mean of 3.1 on a scale form 1 (really low) to 5 (really high). The highest rating was 5 (N=2), three participants chose 1, the lowest possible option.

Parameters:
Participants in the Italian interview study mentioned several parameters that they are already measuring on a (more or less) regular basis: blood pressure, oxygen saturation, number of steps taken, heart rate, and blood glucose. Some measure these parameters when they have symptoms or when they go to the doctor or to the pharmacy. One participant deliberately reduced the frequency of some measurements: *"I monitor just the number of steps I take every day. I don't want to know very often my heart rate and how I sleep, because this kind of information makes me feel anxious"* [GEM0013]

Data Collection:
Interestingly, although patients stated that they measure some parameters, most of them state that they do not use technology or apps to do so (N=8). Two participants are using their smartwatches to measure, for example, sleep quality, blood pressure, heart rate. One person stated that they used an application before to measure their blood pressure, but it didn't work well. Some participants who never used technology stated they were not interested in it (N=1), did not believe or were unsure that it would help them (N=2),

others were open to try it if they were not complicated to use or if someone suggested it (N=3) and believe that it can help to manage their disease (N=3).

Data Sharing and Privacy:

With one exception, all participants stated that they have no problem with sharing their data with the healthcare professionals. Most of them stated that they do not mind about privacy and added that their data can be viewed by all healthcare professionals. One person stated that he/she cares about privacy, but it is ok if data are available to the health professionals they trust [GEM0013]. Looking at the participants' statements, their willingness to share data was strongly connected to sharing data with the healthcare professional. So it cannot be concluded that privacy is in general not important for them, as the participants connected data sharing always to the recipient (their healthcare providers). Only one person stated that they do not want to share their data, adding that their privacy is important to them.

4.3 Estonia

4.3.1 Workshop Healthcare professionals

The workshop with healthcare professionals in Estonia took place on 1st July 2021 and was attended by five participants from a variety of medical backgrounds (cardiologist, physiotherapist, respiratory nurse, pulmonologists, N=5). Their working experience span from 10 to 27 years (mean 20 years).

Parameters:

Healthcare professionals highlighted parameters of health should differ for every patient depending on their diagnosis and how severe it is. They thought "universal" parameters they currently use include letting people evaluate how often they feel out of breath, what medication they use and how frequent, how often they cough, whether they are able to excrete the sputum, how active they are (daily steps). In an ideal world, data about oxygen saturation would be a good indicator. For patients with CCCs, indicators such as weight, blood pressure, blood sugar levels, heart arrythmia would also be important to monitor. HCPs note that it would also be useful to check patients' level of anxiety and mental health. *"There is a need to understand whether the patient experiences anxiety due to emotional stress or if his health has actually deteriorated. They start hyperventilating, which can be controlled by calming down."* [HCP_WS] Furthermore, patients with chronic diseases isolate themselves, which, in turn, can make them less active and motivated: *"People with chronic diseases are often alone, don't socialize and thus lose their motivation to take medication properly, do health checks. It's like they feel they have nothing to live for."* [HCP_WS]

Data Collection:

HCPs mentioned that data collection should be flexible and allow the patient enough freedom. With regards to potential issues concerning data collection, HCPs have experienced false alarms due to a wrong baseline in previous studies. The baseline should take account patients' everyday activities (allow enough variability). Also, apparatuses and their use affect the results – (at the moment) smartwatches do not measure important health indicators accurately; a pulse oximeter can produce inaccurate results when patient's hands are cold, they wear nail polish etc. Educating patients and using quality devices would minimise the danger of false reports. Furthermore, HCPs expressed the number of indicators monitored should be kept minimal both for the sake of the patient and doctor (information overflow is unmotivating and may be counterproductive). *"People already live with their chronic diseases. The only thing they want is to forget it sometimes. Constant monitoring probably is not motivating."* [HCP_WS] HCPs do not want to see raw data; rather they expect visuals of trends. *"I do not want just data. I want visualisation of the patterns. Analysis, which already allows me to see any changes."* [HCP_WS]

4.3.2 Patient experience diary study and pre-/post-diary workshops

At the time of writing, the diary study just started and was still running until 29th October 20210, hence the results could not be included in this deliverable. Due to the current COVID-19 restrictions in Estonia, the diary study kicked off with one-on-one meetings. These restrictions made it impossible to hold in-person workshops with a group of people, and with the target population in Estonia, online workshops are unfortunately not feasible. The results of the diary study will be included in deliverable D2.4 *Functional specifications for the companionship programme*.

4.3.3 *Patient experience interview study*

The interviews with 10 patients (N=10) took place between 9th and 21st July 2021. Half of the participants were male, half were female and their age ranged from 58 to 80 (mean 69.1 years). Most of the participants were diagnosed with COPD over ten years ago (N=7), two stated they had been diagnosed 3-5 years ago, one person did not remember. Except of three persons, all others also have additional chronic conditions, such as cardiac condition (N=6), diabetes (N=3), or hypertension (N=2), with four patients having two chronic conditions in addition to the COPD. Their highest level of education was primary school (N=2), high school (N=6) or trade school (N=2). Most of the participants were retired (N=8), one was unable to work and one was employed part time. Considering their living situation, only two participants lived alone, the others lived with 1 (N=1), 2 (N=4), 4 (N=2) or more than four (N=1) family members together.

Asking about how much their condition affects their daily living activities, most participants had some problems with performing their usual activities (mean 2.925 on a scale from 1 having no problems to 5 being unable to perform their usual activities). Two participants indicated having no problem, no participant chose 5, but two chose 4 and one chose 4.5 on that scale. Participants assessed their level of digital skills with an average of 2.35 on a scale from 1 (really low) to 5 (really high). The highest rating was a four, which was chosen by two participants, while four chose 1, the lowest possible option.

Parameters:

Whilst HCPs mentioned primarily health indicators, patients also mentioned other parameters that they perceived were affecting and explaining their symptoms. They mentioned their health depends heavily on the temperature [researchers' note: at the time of conducting interviews, there was a heat wave and everybody was affected], air pollution (smoke, dust on the streets, exhaust gases), stress, seasonal changes (e.g. pollen), level of activity, atmospheric pressure, allergens. Some patients mentioned that they don't see the point why they would track their daily steps: *"I do not measure daily steps. Why should I, what do I do with this information? I know I am active, I go for walks."* [TUK_005] *"I know I am active. I have my own garden and all. I do not need to measure daily steps for knowing that."* [TUK_004]

Patients also reported that they cannot always distinguish different diseases and their symptoms from one another – for example, when a patient feels tired and dizzy, it could be due to problems with lungs, blood pressure, blood sugar etc. *"I haven't thought about how CCC would affect COPD or vice versa. They all feel the same, the only symptom is tiredness, but I don't know, if it is lungs or blood pressure. Only when I feel dryness in my mouth, then I understand that is may be due to blood sugar levels."* [TUK_008]

Data Collection:

In most cases, patients did not measure and record their health-related data. Some people with diabetes reported measuring and taking notes of their blood sugar levels for their doctor appointments. However, patients that did own necessary apparatus and measured their blood sugar levels or blood pressure reported they do this only to check their health indicators when they feel something is wrong. *"I measure blood pressure sometimes. More often when I had problems with heart, but now only when I need to. Like when I feel tired. But I do not take notes or monitor it. I only take note for myself. There is no use of measuring anything, only to calm myself down."* [TUK_004]

Participants were not excited about the idea of measuring and reporting their relevant health indicators regularly. Motivation to record their data was related to a need to monitor their health once their condition worsens or when doctors ask them to record the data.

Patients did not want to spend a lot of time recording the data – the data entry process should be quick, questions kept minimal. *"It doesn't bother, if it takes a couple of minutes. But I definitely wouldn't want to measure anything daily just for the sake of measuring."* [TUK_004] It was also mentioned there should be longer intervals between recording and not recording their health indicators – patients do not want to measure daily but were more positive towards the idea of recording their measurements 2-3 times a week or when they feel the need to. They expressed the idea that monitoring should be purposeful (related to their condition and necessary for maintaining health). Thus, patients need to gain something (e.g. health reports, alarms from the doctors) from their input to stay motivated and monitor their health.

Almost all interviewed COPD patients were elderly and did not consider themselves knowledgeable enough to use smartphones or computers for recording the data. Most of them also did not own any of the aforementioned devices. All patients had experience with electronic diaries, which they found easy to use despite lacking experience with it. *"I was afraid at first that I would ruin something, but I turned out it wasn't that hard. It took a couple of minutes, that was okay."* [TUK_010] *"I have electronic diary. I was shown how to use it. It doesn't take a lot of time, maybe a couple of minutes and it doesn't really bother me."* [TUK_008] Electronic diaries, paper diaries or CATI (computer assisted telephone interviews) methods were recommended for data collection. Patients mentioned data collection should be flexible, allow the patient enough freedom and if possible automatically: *"I would be better if the data would be collected automatically."* [TUK_010] *"If it doesn't take much time, it doesn't bother. But maybe doing it daily is too much. Maybe every two or three days? It is a little bit uncomfortable when I have to go somewhere. For example, when I visit my children, I have to take the diary with me and when I'd had to measure something then also some sort of apparatus. I don't think it would be a problem for me short-term, but doing it for long period of time... I think the interval of filling in the diary should be longer."* [TUK_007]

Data Sharing and Privacy:

The question of data sharing and privacy may not reflect patients' real interests. Most of the patients interviewed were elderly people who had little experience with technology, technological security, and privacy concerns in the digital era. The scenario of potential data collection and sharing was hypothetical for them and their responses reflected superficial understanding of the question. *"I don't know anything about privacy and I don't care. I probably do not even know what to be afraid of. As long as this data goes to health care specialists and they use it purposely, then I don't care."* [TUK_007]

Most of the patients expressed a lack of interest in their health-related and personal information. They were strongly convinced their health data could not be "used for something malicious"; that they were unimportant and no one would be interested in their information; their personal information (e.g. phone number, address) is public anyways. *"I have no fear! Who cares about my blood pressure? Who even knows me? I'm a nobody. I wouldn't care if there was my phone number or name of anything."* [TUK_008] Participants described that they get calls from random sellers, which made them think everybody has access to their number. *"Who would need this data? Except the doctors? I don't mind sharing phone number or address or other personal information either. Everyone already has this information anyways. Even if I don't have my number public, somehow still some product sellers have it."* [TUK_005] A fear of judging also reflected from their responses – patients were quick to add that they "have nothing to hide", which also could be one reason they expressed openness to sharing their information. However, whilst willing to share their information, it was quite clear that the patients still expected this information to be used by health care professionals only.

A couple of participants were more precise in their criteria of data sharing and thought their more detailed health data and personal information should only be accessible to their general practitioner and other specialist they are directly involved with. Patients considered the idea of being able to choose who can see their data and which aspects of it would be accessible. *"I think there should be an option to choose, who can access this data. Like when pulmonary doctor collects some data for my COPD, then only they can see it. I wouldn't want everyone to know I have it. It is a difficult disease to live with in itself. Maybe some general measurements like blood pressure could be accessible to all doctors, but things related to my COPD should stay between me and my pulmonary disease doctor."* [TUK_007] This, however, would also mean awareness-raising should be in question when implementing data monitoring and sharing systems in healthcare in the future – people need to understand, what the advantages and disadvantages of their decisions are.

Patients' willingness to share their information correlated with the potential benefits they would have in turn. *"Sharing it with everyone... it's a so-so-situation. It would be nice that I wouldn't have to summarise my problems every time I go to see a new specialist. And it would give some sort of security that someone monitors my health and lets me know if anything is wrong."* [TUK_010] For example, interviewees liked the idea that health personnel have all their relevant information and they would not have to give a detailed overview whenever they visit a new specialist. *"If this monitored data would be in patient portal, it would be good. Then I wouldn't have to explain everything over and over again."* [TUK_005] Also, patients expected they receive some feedback and security. They thought sharing information with HCP would mean their health is monitored at all times and HCPs contact them whenever there are worrying changes. *"When there would be some sort of automatic data collection, I would like that someone would let me know when there are changes or something."* [TUK_005] Some participants described this kind of control would make them feel safer and more relaxed. This is understandable, as patients with chronic diseases rarely have a chance to not be "in charge" of their well-being. Another patient interpreted this monitoring as shifting responsibility and reducing their burden: *"It would be pretty good if someone else would control my health. It would take some of the worry for it from my shoulders."* [TUK_004] Whether this is done by HPCs or the technology, it should be noted, that it is important to communicate clearly the responsibilities to set the right expectations.

4.4 Summary

Healthcare professionals from diverse medical backgrounds and patients in all countries listed many additional parameters that could be useful to collect and analyse for understanding the current situation of a patient, their disease progression and lifestyle improvements. Parameters that were only mentioned by patients and not by HCPs include sleep parameters (apnoea, quality, insomnia, CPAP usage), fatigue and dizziness, and parameters related to weather and air quality. While patients seem to be very open about data collection and sharing with their HCPs, they do not want to be burdened with manual entries on a regular basis. Furthermore, data collection should be tailored to the specific patient, reflecting their disease severity and the accompanying CCCs, kept minimal and if possible automatic, and should be purposeful and used for educating patients about their disease and self-management. Patients and HCPs saw an opportunity that RE-SAMPLE helps professionals to get a good overview over all relevant information, improving the current rather fragmented care situation. Finally, it was emphasised that the system takes end-users with low literacy (general, health and digital literacy) into account – not only in terms of usability aspects and how the content is phrased, but also in terms of setting up a service desk and a hotline to support users.

5. User requirements for developing RWD collection procedure and interface

This chapter describes the parameters and requirements that were specified based on the results summarised in chapter 4. It should be stressed that the methods used where qualitative and interactive in nature, allowing conversations to go in different directions. That means that while a specific parameter, user need or requirement might not have been explicitly mentioned by a group, they might still be agree with this being relevant but it just didn't come up in the interactive conversation. For example, only patients in the Netherlands explicitly mentioned blood values and lab results, which are likely to be relevant also for HCPs and patients in other countries, but was maybe considered trivial to explicitly mention.

5.1 Parameters

The parameters identified from the user studies with HCPs and patients in all three pilot sites are outlined in Table 5 below.

Table 5: Parameters identified by patients and HCPs in the pilot sites

Parameter	Sources
Allergies and intolerances	HCPs (IT), P-EE
Height	HCPs (IT)
Weight and weight loss	HCPs (NL, IT, EE), P-NL,
Number of exacerbations	HCPs (NL, IT)
Exacerbation patterns / exacerbation story	HCPs (NL)
Blood pressure	HCPs (NL, EE), P-NL, P-IT
Blood glucose level	HCPs (NL, IT, EE), P-IT, P-EE
Blood values / lab results	P-NL
NT-proBNP	HCPs (NL, IT)
Body temperature	HCPs (NL), P-NL, P-IT
Heart rate / heart arrythmia	HCPs (NL), P-NL, P-IT
Oxygen saturation	HCPs (NL, EE), P-NL, P-IT
Lung function / lung capacity / spirometry (FEV1)	HCPs (NL, IT, EE), P-NL, P-IT
Sleep apnoea	P-NL, P-IT
Sleep quality, insomnia	P-NL, P-IT
Dyspnoea (at rest, frequency, severity)	HCPs (NL, IT, EE), P-IT
(modified) Medical Research Council dyspnoea scale (MRC/mMRC)	HCPs (NL, IT)
Daily complaints	HCPs (NL)
Cough	HCPs (IT, EE), P-IT
Fatigue, Dizziness	P-IT, P-EE
Sputum production, change in sputum production	HCPs (IT, EE), P-IT
Mental health (anxiety, depression)	HCPs (IT, EE), P-IT
State-Trait Anxiety Inventory (STAI)	HCPs (IT)
Beck Depression Inventory (BDI)	HCPs (IT)
Exercise capacity	HCPs (NL)
Physical activity (steps, cycling, swimming, muscle training, golfing, housework, climbing stairs, respiration exercise, other)	HCPs (NL, IT, EE), P-NL, P-IT
Handheld dynamometry / hand grip test	HCPs (NL, IT)
6-minute-walk distance test (6MWD)	HCPs (NL, IT)
Cardiopulmonary Exercise Test (CPET)	HCPs (NL)

Chair stand test	HCPs (IT)
Classifications (NYHA, GOLD, COPD impact categories)	HCPs (NL)
Clinical COPD Questionnaire (CCQ)	HCPs (NL)
CPD assessment test (CAT)	HCPs (IT), P-IT
Pulmonary screening for OSA	HCPs (NL, IT)
Level of ejection fraction	HCPs (IT)
Medication intake (prednisolone, inhaler use)	HCPs (NL, EE), P-IT
Adherence to therapy	HCPs (IT)
CPAP mask usage	P-NL, P-IT
Lifestyle habits (e.g., social withdrawal)	HCPs (IT)
Alcohol consumption	HCPs (NL)
Smoking behaviour (quantity and frequency)	HCPs (NL), P-IT
Fluid intake	HCPs (NL)
Nutrition (salt, sugar)	HCPs (NL)
Nutritional risk screening (NRS-2002)	HCPs (IT)
Malnutrition Universal Screening Tool (MUST)	HCPs (IT)
Activities of Daily Living (ADL)	HCPs (NL)
Quality of Life (QoL)	HCPs (NL)
Wellbeing self-assessment	HCPs (NL)
Self-management ability scale (SMAS-30)	HCPs (NL)
Tailored measurement for Self-Management Abilities in the Netherlands (TASMAN)	HCPs (NL)
Partners in Health scale (PIH)	HCPs (NL)
Level of (digital/health) literacy	HCPs (NL)
Weather conditions (e.g. humidity, temperature)	P-NL, P-IT, P-EE
Air quality	P-NL, P-EE

5.2 Requirements for RWD collection

The requirements are documented using the eHealth notation table by Van Velsen, Wentzel, & Van Gemert-Pijnen (2013) specifying five different types of requirements, which will be also indicated in the requirement identifier.

- **(F) Functional and modality requirements:** technical features and the type of technology and operating systems the technology should work on. In this category we have also included privacy related requirements following users' statements.
- **(S) Service requirements:** specifying how the services surrounding the technology (e.g., marketing or user support) need to be organised.
- **(O) Organisational requirements:** specifying how the technology should be integrated in the organisational structure and working routines.
- **(C) Content requirements:** specifying the content that needs to be communicated via the technology, and (if applicable) language level, persuasive approach, special accessibility demands.
- **(U) Usability and user experience requirements:** specifying the user interface and interaction design of the technology and how UX factors such as trust or joy of use should be integrated in the technology.

In the requirements notation table, next to the unique identifier, a description of the requirement is provided accompanied with a rationale that justifies the need and the source(s) on which this requirement is based on. Where possible, a fit criterion is included to be able to test whether a solution fits the requirement. The requirements are prioritised using the MoSCoW method:

- **Must have:** most critical to the success of the technology
- **Should have:** important but not as critical as the must have requirements
- **Could have:** desirable, but not vital or critical to success.
- **Won't have:** least critical, not appropriate at this point in time.

In addition to outlining the requirements in deliverables, a spreadsheet will be shared with all partners that constitutes a living document that is searchable, can be filtered (e.g., for specific types or priorities or pilots) and easily and transparently updated. This is especially important as also other tasks and WPs will elicit additional technical, organisational and legal requirements (e.g., in WP3 and WP4).

5.2.1 Functional and modality requirements

Functional and modality requirements specify technical features and the type of technology and operating systems the technology should work on.

Requirement #F1	**Requirement type:** Functional
Description: The system enables the patient to specify with which entity their data is shared and can review the selection they have made.	
Rationale: Control over their own data increases the trust in RE-SAMPLE, user acceptance and willingness to collect data. This is also required by GDPR (request for consent must be presented in an accessible and understandable form, subjects must have the right to withdraw consent).	
Source: Patients (NL, EE), Art. 7 GDPR	**Priority:** Must have
Conflicts: Certain functionalities might be inhibited if the user does not consent to data sharing with certain entities.	
Fit Criterion: 1. **Usability testing:** The application allows participants to choose with whom their data are shared and can see an overview of this selection. 2. **Technical testing:** Data is exclusively shared with entities selected by the user.	
History: Created on October 12, 2021	

Requirement #F2	**Requirement type:** Functional
Description: The system offers the patient the option to specify in detail what type of data is shared with which entity and they can review the selection they have made. If patients do not want to make a detailed selection, they have to confirm that they consent to the default data types being shared.	
Rationale: Control over their own data increases the trust in RE-SAMPLE, user acceptance and willingness to collect data. Privacy sensitivity varies, for some this level of control is important for others it can be overwhelming. Thus, this level of control should be an option and not a forced choice for all. Users have to confirm in any case the default data types being shared, even if they do not want that level of control.	
Source: Patients (NL, EE)	**Priority:** Must have
Conflicts: Usability and easy selection of data sharing settings, as choosing not only the recipient of the shared data but also data type per recipient can be overwhelming.	
Fit Criterion: 1. **Usability testing:** The application allows participants to choose with whom specific data types are shared and can see an overview of this selection. 2. **Technical testing:** Specific type of data is exclusively shared with entities selected by the user.	
History: Created on October 12, 2021	
Requirement #F3	Requirement type: Functional

Description: The system provides the patient an overview of physical data that shows their progress over time.	
Rationale: COPD is a progressive disease where patients have only little control and improvements are only small even when training regularly. Showing progress in terms of being active and where they already improved can be stimulating and motivating. Furthermore, patients indicated that they do not want to know all measures every day.	
Source: HCPs (NL), Patients (NL, IT)	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: 1. **Usability and user experience testing:** The application allows participants to show their progress over time when it comes to their physical activity. Participants feel positive and motivated after reviewing this progression overview from the past time.	
History: Created on October 12, 2021	

Requirement #F4	**Requirement type:** Functional
Description: If consent is given by the patient to share activity data, the system provides HCPs an overview of the activity data over a longer period of time.	
Rationale: It is very difficult for HCPs to understand what a patient is doing during the day and what he/she is able to do, which is however helpful to tailor recommendations and see progression or decline.	
Source: HCPs (NL)	**Priority:** Could have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing and user experience testing:** HCP can view how active a patient is over a longer period of time to detect decline, see improvements. This is considered valuable for the consultation.	
History: Created on October 12, 2021	

Requirement #F5	**Requirement type:** Functional
Description: The system provides for HCPs an overview of specific parameters that indicate unusual deviations at a single glance (red flags).	
Rationale: HCPs indicated that they have no use in seeing raw data, but want to see when alarm symptoms are deviating, as these are for them “red flags”. Parameters that act as early alarm signals are: increase in daily complaints, sudden weight loss, sudden worsening in saturation, reduction in exercise tolerance.	
Source: HCPs (NL)	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing:** Participants can see immediately when certain parameters are out of range which indicate a “red flag” that they can then discuss with patients in their consultation.	
History: Created on October 12, 2021	

Requirement #F6	**Requirement type:** Functional
Description: When sufficient data has been collected, the system provides a visual representation of the data over a longer period of time (trends).	
Rationale: Healthcare professionals and patients can gain valuable insights when seeing the trends and progress of collected data over a longer period of time.	
Source: HCP (IT, EE, NL)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion:	

1. **Usability testing:** Participants find the option to see data trends and progress they have made over time.
History: Created on October 12, 2021

Requirement #F7	**Requirement type:** Functional
Description: The system supports the patient to interpret the data collected and for taking appropriate action.	
Rationale: Parameters should not only be measured for clinical purpose, but also for educational purposes, in other words, to support patients understanding what this means and hereby support self-management. For patients seeing a data overview alone is not interesting, or even makes them worried if they do not know what it means. Also observing continuous data can stress them even more. Without educational support, user acceptance of and motivation for data collection might decrease and experienced drawback outweigh benefits. Educating patients can also minimise the danger of false reports.	
Source: HCPs (NL, IT), Patients (NL, IT, EE)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing and user experience testing:** Participants understand what a data overview means for them, can take this into account in their self-management and are able to decide what actions to take (if any).	
History: Created on October 12, 2021	

Requirement #F8	**Requirement type:** Functional
Description: The system notifies patients when specific parameters are deviating (red flags).	
Rationale: Parameters that act as early alarm signals are: increase in daily complaints, sudden weight loss, sudden worsening in saturation, reduction in exercise tolerance.	
Source: HCPs (NL), Patients (EE)	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing:** Participants receive a notification about a red flag, understand what this means for them and are able to decide what actions to take (if any).	
History: Created on October 12, 2021	

Requirement #F9	**Requirement type:** Functional
Description: The system reminds the patient when a data request was not yet followed up upon. These reminder notifications are customizable (enable, disable, snooze).	
Rationale: While patients are willing to fill in questionnaires, they also might forget to do so. A gentle reminder to complete the questionnaire was appreciated.	
Source: Patients (NL, IT)	**Priority:** Should have
Conflicts: Reminders and notifications can add to the burden of patients (see Req #U1)	
Fit Criterion: n/a	
History: Created on October 12, 2021	

Requirement #F10	**Requirement type:** Modality
Description: Where possible, automatic data collection and data integration is preferred to manual data entry. Manual data collection is to be kept to a minimum.	
Rationale: Patients living with COPD and CCCs already experience a high disease burden, which has a high impact on their quality of life. They do not want to be constantly reminded or occupied with their	

disease. Willingness to fill in questionnaire is limited (frequency at most once or twice a week) as it takes a lot of energy from them, and they have no energy to spare.	
Source: Patients (NL, IT, EE), HCPs (NL, EE)	**Priority:** Must have
Conflicts: Data-dependent features will not work properly if certain data points or amounts of data are not available.	
Fit Criterion: 1. **User acceptance testing:** Participant using the companion over a period of time (e.g., 1 month) consider the frequency and workload of manual data entry appropriate.	
History: Created on October 12, 2021	

Requirement #F11	**Requirement type:** Functional
Description: The system logs data exchange and processing to identify threats to data security and possible data leaks.	
Rationale: Ensuring high security	
Source: Patients (IT), Art.32, 35 GDPR	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on October 12, 2021	

Requirement #F12	**Requirement type:** Functional
Description: The system allows tailored data collection requests for specific patients and to only collect data that is necessary to improve the care of that patient.	
Rationale: Parameters of health should differ for every patient depending on their diagnoses, and the severity of each of them. This also supports Req #U1 (the system should not add to the high disease burden of patients) and data minimisation principle.	
Source: HCPs (IT, EE), Patients (NL, IT, EE), #U1, Art. 5 GDPR	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on October 12, 2021	

5.2.2 Service requirements

Service requirements specify how the services surrounding the technology (e.g., marketing or user support) need to be organised.

Requirement #S1	**Requirement type:** Service
Description: Each pilot site has to ensure the availability of a service desk with a hotline that provides timely user support for the RE-SAMPLE companionship programme.	
Rationale: The success of data collection highly depends on the correct set-up of the companionship programme and a smooth onboarding of the users. Many patients do not own a mobile device and/or do not use wearables at this point and need support setting this up.	
Source: HCPs (NL), Patients (IT, EE), EE pilot context (First time tablet users)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: 1. **Internal review:** Before pilot start, ensure the set-up of the hotline / service desk and ensure that contact details are communicated for the participants in each country. 2. **Service desk evaluation:** Close evaluation whether problems are reported and solved in a timely manner.	

History: Created on October 12, 2021

Requirement #S2	**Requirement type:** Service
Description: End-user onboarding has to be accompanied by clear expectation management about who will act how when parameters deviate in an alarming manner.	
Rationale: The current care system does not allow for an additional alarm to be acted upon (cf. alarm fatigue) and HCPs taking responsibility for acting on RWD parameters deviating is also in contrast to self-management paradigm. Hence, the system indicates trends and "red flags" to HCPs to inform them and which can be used in the consultation. It is the patient's responsibility to take action after they are notified about red flags.	
Source: HCPs (NL), Req #O1	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on October 12, 2021	

5.2.3 *Organisational requirements*

Organisational requirements specify how the technology should be integrated in the organisational structure and working routines.

Requirement #O1	**Requirement type:** Organisational
Description: Trends and red flags in the clinical setting are used for communication and information purposes during the consultation and not to be seen as an alarm notification to be acted upon in real time by the clinician.	
Rationale: The current care system does not allow for an additional alarm to be acted upon (cf. alarm fatigue) and HCPs taking responsibility for acting on RWD parameters deviating is also in contrast to self-management paradigm. Hence, the system indicates trends and "red flags" to HCPs to inform them and which can be used in the consultation.	
Source: HCP (NL), Literature **(Alrajeh, et al., 2019)**	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on October 12, 2021	

Requirement #O2	**Requirement type:** Organisational
Description: The system supports multidisciplinary disease management between different specialties that manage the variety of CCCs and share their data and information with the system.	
Rationale: Healthcare professionals and patients identified the problem with scattered disease management and that different professionals do not see the full picture, as each department manages only specific diseases or areas.	
Source: HCP (NL), Patients (NL, IT)	**Priority:** Could have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on October 12, 2021	

5.2.4 *Content requirements*

Content requirements specify the content that needs to be communicated via the technology, and (if applicable) language level, persuasive approach, special accessibility demands.

Requirement #C1	**Requirement type:** Content
Description: The content of the system has to be suitable for people with low general, health, and/or digital literacy.	
Rationale: High percentage of the target group is of low (health) literacy and/or does not have extensive experience with technology.	
Source: HCP (NL), Patients (IT, EE, NL), Literature **(Dirven, Moser, Tange, Muris, & van Schayck, 2014; Roberts, Ghiassi, & Partridge, 2008)**	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: **1. Acceptance testing:** Early acceptance testing with people with low literacy / low digital literacy to demonstrate that the main functionality is understandable for them. **2. Usability testing:** Participants with low (health) literacy and/or low digital literacy are able to understand and use the main features of the programme without serious or critical usability issues.	
History: Created on October 12, 2021	

Requirement #C2	**Requirement type:** Content
Description: Data collection requests for sensitive areas are formulated with special care and frequency is tailored to the user's phase in the behaviour change process	
Rationale: Repeatedly asking users about certain lifestyle behaviours (e.g., alcohol, smoking, etc) can be very confronting, especially if the person is not yet motivated to make changes. They also often feel ashamed and guilty about their lifestyle. Depending on the behaviour change process phase (awareness, motivation, action, behaviour), the request frequency and conversation style should be adapted.	
Source: HCP (NL), Literature **(Dirven, Moser, Tange, Muris, & van Schayck, 2014)**	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: **1. Acceptance testing:** Participants in different phases of the behaviour change test prototypes with regard to the appropriateness of language and frequency.	
History: Created on October 12, 2021	

5.2.5 Usability and user experience requirements

Usability and UX requirements specify the user interface and interaction design of the technology and how UX factors such as trust or joy of use should be integrated in the technology.

Requirement #U1	**Requirement type:** User experience
Description: The system allows patients to opt-out of the collection of data, or reduce frequency of data collection and still benefit from other modules of the virtual companionship programme.	
Rationale: Patients living with COPD and CCCs already experience a high disease burden, which has a high impact on their quality of life. They do not want to be constantly reminded or occupied with their disease and high frequency of data collection and information overload can increase anxiety.	
Source: HCP (NL, EE), P (NL, IT, EE)	**Priority:** Must have
Conflicts: Data-dependent features will not work properly if data are not available.	
Fit Criterion: n/a	
History: Created on October 12, 2021	

6. Conclusions and future work

This deliverable outlined the parameters that healthcare professionals and patients considered necessary, desirable and/or feasible to collect. Special attention was paid to the aspect of the data collection procedure and preferences with regard to data sharing and privacy. This led to a first set of functional, service, organisational, content and usability/UX requirements, which will be updated and further extended in D2.4 *Functional specifications for the companionship programme* and revised based on the results of future end-user studies and other requirements (organisational, technical, legal).

The in-depth information collected in these first end-user studies will be used further to specify the context of use, the characteristics of end-users, their goals and preferences (beyond data sharing and privacy), from which further requirements will be derived. In addition, new technical, organisational and legal requirements will be elicited within WP3 and WP4. A spreadsheet will be shared with all partners that constitutes a living document that is easily searchable, can be filtered (e.g., for specific types or priorities or pilots) and easily and transparently updated.

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Appendices

Appendix A. Protocol workshop healthcare professionals

Demographics collected before the start of the workshop:

Gender ☐ male ☐ female ☐ other

Occupation and specialisation: ____

Work experience in healthcare (in years): _______________

Workshop 1 – Monitoring COPD & CCCs, patient journeys

Phase	**Time**	**Topic**	**Explanation**	**Materials**
Meeting invite	Several days before	E-mail invite	Send meeting invite via e-mail: Include the MS Teams link	
Introduction	09:00-09:05	Entry	Wait until all HCP are in MS Teams	
	09:05-09:15	Welcome and introduction	Facilitators: Introduce ourselves Let HCP introduce themselves Ask and/or write down information of: - Name - Gender - Occupation (and if any: specialisation) - Work experience in healthcare (years)	
	09:15-09:30	RE-SAMPLE & user requirement	Explain RE-SAMPLE project Explain aim of this workshop, procedure of today	PPT
Start recording		Start recording	Inform HCP that from now on the conversation will be recorded, Get informed consent again on audio Start recording	Audio recording
Discussion 1	9:30 – 10:00	Monitoring COPD and CCC	M1*: Open & share Miro board named 'Monitoring' and fill in the sticky notes with all parameters the HCP mention. M2**: Guide discussion Questions: a) How important is monitoring for your daily work with COPD patients? i) why b) Which parameters do you currently monitor (what, when, how visualized, alerts?) c) Is there anything that is NOT monitored now that you think would be valuable? (weather?) d) Do you think patients already collect data (e.g. with wearables)	Miro board, PPT

			i) What, and do you think they like to do? e) If you had much more time during your consult, what would you ask the patient that you think could be relevant as well? Thereafter, go back to PPT and show the parameters of WP2 cohort study: f) What do you think of these g) Do you have suggestions for adding or changing parameters?	
Patient Journey	10:00 – 10:30	Show patient journey	Create one general patient journey together. M1: Open & share Miro board named 'General patient journey' and fill in the journey. M2: Guide discussion as follows: **How to fill in patient journey:** "Pieces of a puzzle" Q1: On which part of the patient journey do you see yourselves? (puzzle piece) a) Where did the patient come from when they see you? b) Where do they go afterwards? Connections to other specialties? c) Are there pieces missing in this puzzle (other specialties not present in this session)? d) How would the journey differs for different CCC? e) Are there any phases in this patient journey missing? After the patient journey has been filled in, ask: "When you see this, are there any other parameters that we didn't discuss before but would be useful?" If yes, M1 fills this in within Miro board 'Monitoring'	Blanc digital patient journey
Closure	10:30	Closure	Anything we didn't ask… that they would like to add Inform about next meeting Any questions? Close workshop	
Stop recording		Stop recording		

*** = moderator 1**
**** = moderator 2**

Workshop 2 – Self-management and coaching, communication with patients, HCPs’ values

Phase	**Time**	**Topic**	**Explanation**	**Materials**
Meeting invite	Several days before	E-mail invite	Send meeting invite via e-mail: Include the MS Teams link	
Introduction	09:00-09:05	Entry	Wait until all HCP are in MS Teams	
	09:05-09:10	RE-SAMPLE	Recap of what is RE-SAMPLE	PPT
Start recording		Start recording	Inform HCP that from now on the conversation will be recorded, get informed consent again on audio Start recording	Audio recording
Discussion 2	09:10-10:00	Self-management & coaching, Communication with patient	M1: Open & share MIRO board ‘general patient journey’ from workshop 1. Now fill in purple sticky notes in ‘General patient journey’ about self-management and drag to the right position within patient journey where this is applicable. If not related to specific phase or step, keep in left corner. M2: Guide discussion on self-management and communication: Q2: **Self-Management and Coaching** h) How important is self-management for your patients? Which parts do they self-manage? i) Do you offer any other support (what, when, how) e.g. self-management, coaching, life-style? j) If time and costs were no issue, what do you think the patient needs to better manage their disease? Q3: **Communication with your patient** k) How do you communicate most often with your patients (what, when, how)? l) When you make decisions, how do you currently involve the patientt? i) What, when, how (ask for examples!) ii) Other specialties involved? iii) How important is that for you m) When you hear ‘shared-decision-making' what comes to mind, what do you think? For each point they provide: ask where to add in this journey?	

Discussion 3	10:00-10:25	Values of HCP	M1: Keep on sharing MIRO board, now fill in pink sticky notes ('Communication..') in 'General patient journey' and drag to the right position within patient journey where this is applicable. If not related to specific phase or step, keep in left corner. M2: Guide discussion on values of HCP: Q1: Your personal values in relation to your job and your patients a) What gives you energy in your job? b) Is there anything that is frustrating? Depending on the input they give, ask: "So if I understand you correctly, you mean that this .. (autonomy?) is really important for you in your work with COPD patients?" Q2: Is there anything that you would love to have that helps you in your work with COPD patients? (technological or otherwise) a) What problem would that solve?	
Closure	10:25 – 10:30	- Closure	Anything we didn't ask… that they would like to add Inform about next meeting Any questions? Close workshop	
Stop recording		Stop recording		

*** = moderator 1**
**** = moderator 2**

Appendix B. Interview guide healthcare professionals

As pragmatic alternative to workshops with several HCPs, a semi-structured interview guide was developed that covers the topics from the workshops.

Phase	Time	Topic	Explanation	Materials
Meeting invite/ reminder	1 day before	E-mail invite or e-mail reminder	- Send meeting invite via Teams if needed - Provide information for the room if needed	
Introduction	00:00 – 00:10	Welcome and introduction	Ask also after 1. Occupation and specialization 2. What is your background – number of years of experience in health care	
	00:10 – 00:15	RE-SAMPLE	- Explain RE-SAMPLE project and aim of this study -	
Start interview	00:15 – 1:00	Start interview	**Before starting, inform person that you will start recording**	

Introduction

1. My name is [xx] and…
2. Can you tell me a bit about yourself?
    a. What is your background. Occupation and specialization
    b. How long do you already work in health care [number of years]
    c. Experience with COPD patients – how often? [a lot / seldom / …]

Introduction RE-SAMPLE

[introducing the RE-SAMPLE project, aim and main features]
Do you have any questions? Otherwise, we're going to start the interview now.

Participant code:
date:
time:
Interviewer:

Interview guide – HCPs

The researcher then tells the participant the following again:

- PSEUDONYM: In the information letter we explained that we store and analyze your data in a pseudonymised way, this means that data that may lead to you is encrypted. So your name, or other personal data that may lead to you will not appear in the file, only your code will be named. Only authorized persons involved in this investigation will have access to your data and to the key to this code.
- VOLUNTARY: your participation is voluntary, you can choose at any time not to answer or stop without giving a reason.

START AUDIO RECORDING

-

Monitoring COPD and CCC **purpose: parameters for monitoring**

-

1. Can you tell me a bit about the way you work with COPD patients?
    a. How did your patients come to you? Referred by whom?
    b. How often do you meet the same patient? Do you feel you have sufficient time with your patient?
    c. What is the main focus area when working with COPD patients?
    d. Do you work closely with other specialties when you treat a COPD patients? Who?
2. How important is monitoring COPD/CCC for your daily work with your patients?
    a. Why
3. What parameters are currently being measured/monitored?
    a. COPD / CCC?
    b. When, how often, how
    c. How is this visualized/visible?
    d. Do you receive alerts?
4. Do you think patients already collect data themselves or keep certain data of themselves? For example, for disease management or prevention of deterioration?
    a. If so, what?
    b. Do you think patients are open to measuring more things, would they want to? Why do/don't you?
5. Is there something that is not yet being measured? What further information would you like from the patient that is not available now, but could help you in your work? parameters/variables, but also other information. are not currently measured/monitored, but could be useful (e.g. for disease management, or predicting COPD/CCC deterioration, or related to general health?)
    a. What is desirable
    b. What is achievable and what is not. (and why not)
6. If there was much more time in a consultation, what would you discuss with the patient? And why?

-

Self-management and coaching

7. How important is self-management for your patients? What would patients do about self-management, in your opinion?
    a. How often
    b. when
    c. Does the deterioration of illness or exacerbation still affect how much self-management/ what kind of self-management does the patient do?
8. Do you offer support in self-management or types of self-management?
    a. What, when, how (often),
    b. To whom? (maybe special groups depending on level of COPD/CCC?)
9. If time and money were not important, what else do you think the patient needs to better manage/control their illness?

Examples of preventive self-management :

- *Healthy lifestyle (nutrition/exercises)*
    - *Dietary adjustments*
    - *Quit smoking*
    - *Activities that reduce or prevent symptoms:*
        - *Physical: e.g. sports, household, walking with the dog, other activities*
        - *Mental: relaxation exercises, certain things that contribute to stress release, e.g. mindfulness, breathing exercises*
- *Making personal decisions in daily life (e.g. to reduce/reduce exacerbations or to manage illness)*
    - *Regulate the time of medication intake? (diabetes?)*
    - *Home adjustments*
    - *Ask for help from community or family members?*
- *Improved recognition of symptoms:*
    - *Improving knowledge about the diseases*
- *Improving self-management/ involvement in the disease:*
    - *Setting an alarm to remember to take medication*
    - *Use of other tools?*
    - *Stick to correct and timely medication intake*

Communication with your patient

Goal: to find out how HCP currently communicates with their patients and whether/how they now involve the patient in decisions they make.

10. How do you usually communicate with your patients?
    a. What, when, how, (ask for examples)
11. When you make decisions, how do you currently involve the patient?
    a. What, when, how? (ask for examples)
    b. Are there other specializations involved?
12. When you hear the concept of shared decision making, what do you think about? What does this mean for you? How do you see that?
    a. How important do you think this is for the patient?
    b. How important is this for you?

Your values in relation to your work with your patients

We would like to find out what the values of caregivers are in relation to their work with patients. Because values can also be supported or hindered with technology. Therefore, I would like to ask you, what is most important to you in your work with COPD patients.

13. What gives you energy in your work with COPD patients?

14. Are there things that frustrate you in your work with patients with COPD or other chronic diseases

15. What values should definitely be taken into account when setting up and developing the RE-SAMPLE care technology?

16. How can RE-SAMPLE healthcare technology help you in your work and support you?

Examples Values:
Independence, convenience, self-direction, trust, proximity, privacy, equality, individuality, efficiency

Privacy, professional autonomy, autonomy of the patient in his own course of illness, work of added value, honesty to the patient, improving QoL, making the patient feel involved, effective cooperation/communication with colleagues/other specialties

General needs

We are coming now to the end of our interview. Just one more general question

17. Is there anything you would like to have, use, adapt that would help you in your work with COPD patients? This may be technological, practical, organisation, etc, anything.
    a. Why, what problem would this solve?
18. Is there anything else that you would like to share that I didn't ask you about?

Appendix C. Demographics questionnaire for patients

1. What is your gender?
    - ☐ male
    - ☐ female
    - ☐ other

2. What is your year of birth? ________________ (YYYY)

3. Besides COPD, what other chronic conditions do you have? _________________

4. For how long are you diagnosed with COPD?
    - ☐ <1 year
    - ☐ 1-2 years
    - ☐ 3-5 years
    - ☐ 6-10 years
    - ☐ more than 10 years
    - ☐ I don’t know

5. What is the highest degree or level of education you have completed?
    - ☐ Primary school
    - ☐ High school
    - ☐ Trade school
    - ☐ University
    - ☐ Other: _________________________________

6. What is your current employment status?
    - ☐ Employed full time
    - ☐ Employed part time
    - ☐ Seeking opportunities
    - ☐ Retired
    - ☐ Unable to work
    - ☐ Voluntary work
    - ☐ Other: _________________________________

7. How many other family members do you live together with?
    - ☐ 0
    - ☐ 1
    - ☐ 2
    - ☐ 3
    - ☐ 4
    - ☐ >4

Health related quality of life & Health literacy

8. How much does your health affect your usual activities (e.g. work, study, housework, family or leisure activities)?
   Scale from 1= I have no problems with performing my usual activities to 5 = I am unable to perform my usual activities

9. How often do you experience problems understanding texts (such as leaflets) about your health or an illness?

Never	Seldom	Sometimes	Often	Always

10. How confident do you feel when you fill out medical forms?

Not confident at all	Somewhat confident	Fairly confident	Confident	Very confident

11. How often does someone help you to read brochures, forms or letters from the hospital, pharmacy or your GP?

Never	Seldom	Sometimes	Often	Always

Digital literacy

12. I think that my level of digital skills is as follows:

1= really low 5 = really high

Appendix D. Protocol pre-diary study workshop with patients

Phase	Time	Topic	Explanation	Materials
Meeting invite	7 days before	E-mail invite	Send e-mail invite for MS Teams meeting Include the MS Teams link	
Introduction	09:00 – 09:05	Entry	Wait until all participants are in MS Teams	
	09:05 – 09:10	Introduction	Researcher and participants introduce themselves	
	09:10 – 09:30	RE-SAMPLE & User requirement	Introduction to RE-SAMPLE project Explain aim of this workshop, procedure of today	PPT
Start recording		Start recording	Inform participants that from now on the conversation will be recorded Get informed consent again on audio Start recording	Audio recording
Data collection	09:30 – 09:50	Discussion 1 Controlling and tracking your health	M1: fill in sticky notes in template of 'Data collection, privacy & sharing' on MIRO M2:guide discussion on: - Do you currently measure anything to control your disease? (e.g. via smartphone/smartwatch)? Do you keep track of anything? Maybe you make notes of something related to your health? ○ What, when, how? - Does your practitioner or physician currently has insights in your measurements? If yes, in what? - Do you think it is important to measure your health? ○ Why (not)? - Does your practitioner/ nurse/ doctor currently keeps track of measures of your health? - What else would you like to measure that you think would help you to control your disease better. Imagine this could be anything.. also anything that you might be unable to measure right now. - Is there something that influences your health? Maybe in a positive or a negative	PPT, MIRO

			way (e.g. external or internal factors influencing health)? - What would you like to share or discuss with your HCP during the consult when you would have an hour instead of the 10 minutes now? ○ What problem would that solve?	
Data privacy and sharing	09:50 – 10:10	Discussion 2 Privacy and sharing your data Privacy	M2: First give short explanation about technology for measuring health. Then guide discussion on: Q1: What do you think about safeguarding your privacy? Is this important for you? - Why (not), when, what data etc. Thereafter M2 reads scenario: *Joan is 58 years old and suffers from diabetes type 2. Also she suffers from heart failure for 4 years. The doctor suggested using an app to monitor her health. By using the app, Joan has a clear view on her symptoms and can see her risk of deteriorating.* *Her doctor also has insight into her data and keeps a close eye on Joan's health. The doctor can also view her data and receives alerts if things worsen for Anne. In this way the doctor can adjust the medication early or initiate the right therapy. In this way, the doctor tries to prevent any deterioration for Joan.* *To use the app, Joan must first create an account and enter some information about herself, such as date of birth, home address, etc. Also her health is tracked by a smartwatch by measuring the amount of steps taken, her sleep quality, her heartbeat, blood pressure and her glucose levels. At some points in time, Joan needs to do short tests at home or at the hospital, that she cannot do at home.* *All the information is needed for the app to predict when Joan is doing fine and when she needs help to prevent her from worsening.* Imagine this can also be introduced for patients with COPD. We will discuss the following statements. Per statement, we would like to hear from you if you think this is good or bad and why. Feel free to refer this to your situation, how would you feel if this was you? What do you think about this situation? What would you like to change, where would you be comfortable with? The following statements are shown on a slide:	PPT, MIRO

		Data Sharing	Statement 1: Who can look into her data? Only doctors and nurses who are involved in care for Joan. Statement 2: Which data can they look into? All data that she inserts on a daily basis (dates and amount of medications taken, daily steps taken, sleep quality, heart rate, blood pressure). Ask the participants: if this was you, would you agree/disagree. Discuss this per statement. The following statements are shown on a slide: Statement 3: Joan cannot choose per item which data to share - There is only one option: to share all data, or not share all data Statement 4: Joan can decide herself who to share her data with, e.g. the GP, physiotherapist, or occupational physician. She can decide per company to share or not to share her data. Statement 5: Joan finds it annoying to make all these decisions about her privacy and data sharing all on her own Ask the participants: if this was you, would you agree/disagree. Why?	
Values of Patients	10:10 – 10:30	Discussion 3 Your values	M2: give participants 5 minutes to think about what is important for them in their life (what gives you energy/what frustrates you? Can be on different levels; received care, personal life, etc.) Guide discussion in the group, let everyone have their own moment to explain. - What gives you energy? What drives you (e.g. live independent lifestyle: being able to perform my hobby, to care for children, to go to work, do other activities?) o How can we better support you with that? - When controlling your disease yourself or by caregivers, what do you find frustrating? (processes, e.g. not able to get in contact with doctor soon, or takes so long to being referred to. But also feelings, e.g. feeling not heard, feeling insecure. o How can we better support you with that? What do you need/expect (from others)?	PPT, MIRO

Diary study	10:30 – 11:00	Explanation Diary study	Explain when, where and how to fill in the patient diary. Let participants fill in the demographics questionnaire as example to try out live whether it works and have the opportunity to answer questions and help them in case there are problems.	PPT, qualtrics
Conclude	11:00		Any questions? Close workshop	
Stop recording		Stop recording		

*** = moderator 1**
**** = moderator 2**

Appendix E. Protocol patient diary study

The day after the pre-diary workshop, the diary starts. Send the diary for 21 consecutive days to the participants. After the diary study, you should have for each participant the demographic information and 21 diary entries. It is no problem if participants to fill in a day, that can happen. They can still answer the diary from the day before, or maybe skip it and start working on the diary for that day.

Evaluation of today

1. What grade would you give today? *Scale 1 to 10: 1 is worst day ever, 10 is best day ever.*

   1 2 3 4 5 6 7 8 9 10

2. Could you explain your grade? (How did you feel today? What went well and what didn't go well?)

3. Did you experience more symptoms today than yesterday?
   - ○ much less
   - ○ somewhat less
   - ○ about the same
   - ○ somewhat more
   - ○ much more

4. Did you do everything you planned to do for today?
   - ○ Yes
   - ○ No

   a. If 4 is answered no: Was this because of health?
      - ○ Yes
      - ○ No

   b. If 4 is answered no: Why were you unable to do everything you had planned to do for today?

Theme: Ability to solve yourself (or self-solving ability)

5. Did you do anything specifically today to reduce your symptoms?
   - ○ Yes
   - ○ No

a. If 5 is answered yes: what did you do and why:

6. Did someone help you today?
   - ○ Yes
   - ○ No

a. If 6 is answered yes: Who helped you and where did you receive help in today?

7. Would you have liked to receive more help today?
   - ○ Yes
   - ○ No

a. If 7 is answered yes: Where would you have liked to receive more help in?

8. Did you do anything specific today to make you feel better mentally and/or physically? This could be anything that works for you.
   - ○ Yes
   - ○ No

a. If 8 is answered yes: What did you do today to make you feel better mentally and/or physically?

9. Is there anything else you would like to share with us today?

Theme: Closure

Thank you for completing today's diary. Your answers have been registered. You can now exit the screen. See you tomorrow!

Appendix F. Protocol patient interview study and interview guide

Phase	Time	Topic	Explanation	Materials
Meeting invite/ reminder	1 day before	E-mail invite or e-mail reminder	Send meeting invite via Teams if needed Provide information for the room if needed	
Introduction	09:00 – 09:05	Entry		
	09:05 – 09:10	Welcome and introduction	Researcher and participant introduce themselves	
	09:10 – 09:30	RE-SAMPLE	Explain RE-SAMPLE project and aim of this study	
Start interview	09:30 – 10:30	Start interview	First discuss the questionnaire about the demographics, thereafter start recording	Audio recorder & Interview guide
Start audio recorder			Before starting, inform patient that you will start recording	Audio device, batteries, etc

Participant code:
Date:
Time:
Interviewer:

Interview guide – Patient experience interview study

- Fill in demographic questionnaire together: researcher has printed demographic questionnaire, asks the questions and fills in the questionnaire for the participant.

Please mention to the participant:

a. PSEUDONIMIZED: In the information letter we explained that your data will be stored with and analysed in a pseudonymised way, this means that the data is identified by a code, and not by your name, or any other personal data. In this way, your information or your data cannot be traced back to you. only authorized persons, involved in this research have access to your data and the key of this code.
b. VOLUNTARY: your participation is voluntary, you can choose to not provide an answer or to stop any time without giving a reason.

After this, start the recording and the interview. Mention to the participant that from now on the audio is being recorded.

START AUDIO RECORDING

Health story

goal: input for general patient journey

First I would like to talk to you about how your COPD began and what doctors you visited, so basically your story.

1. Could you tell me how COPD started? Did you have certain symptoms before you were diagnosed? Why did you decide to go to the GP and how did you feel?
2. How did the process of diagnosing go? Which specialists did you visit?
   a. Ask per step: How did you experience this? What was good, what could have been done better?
3. What happened after the diagnosis? Were you asked to come to regular check-ups?
   a. Which specialists did you visit?
4. How is your situation now? Do you have regular check-ups?
5. Could you describe how a good day is for you?
6. Could you describe how a bad day is for you?

Exacerbations & comorbidity

goal: input for parameters

7. When you have an exacerbation/ a worsening, do you feel it coming?
   a. How does it start for you?
   b. What do you then usually experience? Any triggers/symptoms?
8. [INFLUENCE WEATHER/POLLEN?]:Can you predict an exacerbation? Are there any environmental circumstances in which you know for yourself you have a higher chance to exacerbate? Do you avoid certain circumstances or situations to prevent an exacerbation?
9. Can you tell me how such a worsening usually goes for you? What care do you then generally receive or what do you do for yourself?
   a. Do you think the care you receive fits to what you need?
      i. Why (not)?
10. You mentioned you were also suffering from [COMORBIDITY], can you feel the difference between a worsening of [COMORBIDITY] and a worsening of COPD?
    a. How?
    b. If not: what makes it so difficult?
11. Do you think suffering from [COMORBIDITY] influences how much you suffer from COPD and vice versa?

Controlling COPD/CCC

goal: find out monitoring parameters

12. Do you feel you have a grip on your COPD and/or [COMORBIDITY]? E.g. do you feel you have control over it?
    a. Why (not)?
13. In order to control your health, COPD or [COMORBIDITY], do you measure anything OR keep track of anything OR maybe write down certain things?
    a. Why, when, how often, what information does it give you?
14. Does your GP / lung physician currently measure any data of you on a regular basis?
    a. If yes, what, how often, and do you have insights in the data as well?
15. Is there anything you can think of that will help you in managing the diseases better in the future? Anything you would like to know/have insights in/measure/keep track of? Anything you think can be useful for you in controlling your diseases?

Use of eHealth **goal: find out if they are willing to use eHealth technologies**

16. Do you currently use any devices to measure your health? E.g. smartwatch to measure your steps, sleep pattern or your heartrate?
    a. If yes, which, how often etc.
17. Do you currently use any apps on your phone to measure your health? E.g. use apps on your smartphone?
18. Do you think using these technologies would make it easier for you or your HCP in managing your disease?
    a. Why (not)
19. Would you be willing to use technology (e.g. a smartwatch/smartphone) to measure how you are doing and have better insights in your disease?
    a. Why (not)

Data privacy and sharing **goal: find out preferences**

When you think about using a technology to measure your health, this could for example be done by using a smartphone or a smartwatch. This technology could measure much data of you daily, e.g. daily steps, sleep quality, blood pressure, heartrate, time medication intake, and so on. The data that you can collect could help you to get a better insight in your disease.

20. When you think about using such a technology, we would like to hear your opinion on data privacy, is this important for you?
21. In the technology there is the option to determine yourself who has insights in your health records/data (e.g. physiotherapist/GP/occupational physician/etc.). Is it important for you that you can decide who is seeing your data?
22. In the technology there is the option to determine yourself which data you want to share, and which data you don’t want to share. For example, you might want to share your personal data (name, house address, e-mail address, etc.) but you don't want to share your data of your smartwatch (sleep or steps data from Garmin/fitbit) or your data of your health records. Is it important for you that you can decide who is seeing what type of data?

Self-management **goal: find out if patients do self-**

23. When you have a bad day, do you perform any activities to reduce your symptoms?
    a. What, how often, why?
24. Are there any activities that you perform to prevent an exacerbation? Or in general to make your feel better?
    a. Physical exercises
    b. Mental exercises
    c. Lifestyle adaptations
25. Have you ever been recommended to do something specific? What activities do you know that could improve your health?
26. Do you feel your GP/lung physicians give you the right tools and help you to do any self-management activities? Maybe he/she provides you movies with physical exercises, or folders about how to take the medication right and on time.
    a. Would you like to have more help in prevention or self-management? If yes: in what way?
27. How important is it for you to take care of your health yourself? Would you like to learn more about how to do it? Or what you can do?

Relationship and communication with HCPs **goal: find out relationship**

So far we spoke about your health and what you are doing – which is so important for us to learn as you are the expert. But there are other people that you come in contact with and rely on and we would like to learn how that works.

28. How often do you visit your GP?
    a. Is this only related to your COPD or also for your [COMORBIDITY]?
29. How often do you visit a lung physician?
30. Are there any other specialist that you see regularly?
31. Do you feel there is enough time during a consult with your GP/ lung physician / [OTHER SPEC]?
32. Do you feel that your GP/ lung physician / [OTHER SPEC] has good knowledge on how your health currently is?
    a. Why (not)?
33. Do you feel that your lung physician/ GP knows you as a person? And knows what is important for you in your life?
    a. And takes your personal characteristics into account when making a decision for you?

Decision-making **goal: find out preferences**

34. How are decisions, e.g. for treatment and/or medication-use, currently made?
    a. What do you think of this way of decision-making? Do you think you are being involved enough?
    b. What kind of decision are you thinking of now?
35. Who would you say is actually making the decisions in your care?
    a. How do you feel about this?
    b. Do you feel you have the opportunity to make decisions together with your HCP?
36. Are you also making any decisions yourself when it comes to your health?
    a. If yes: which ones? Do your doctors know about these decisions?
    b. Would you like to play a bigger role in making decisions? If yes: when, why, when not?

-

(IF DIFFICULT TO ANSWER, ASK:)

- c. *When it has been determined that during an exacerbation you are being hospitalized, is this decision made by your GP? How does this decision come about, do you have any influence on this decision?*
- d. *When the lung physician makes the decision to, e.g. change medication intake,*
    - i. *Did they ask you about your opinion/what you want? Or are you solely informed?*
    - ii. *Do you have any influence on the decision/ are you involved in deciding how to proceed?*

37. Before decisions are made, do you feel that the decisions are weighted for if they fit into your personal life? Do you feel your HCP thinks along what is important for you and take that into account when making the decisions?

Appendix G. Protocol post-study workshop with patients

Phase	Time	Topic	Explanation	Materials
Meeting invite	7 days before	E-mail invite	Send e-mail invite for MS Teams meeting Include the MS Teams link	
Introduction	9:00 – 9:05	Entry	Wait until all participants are in MS Teams	
	9:05 – 9:10	Introduction	Welcoming participants to the workshop and thanking them for filling in the diaries for 21 days. Explain aim of this workshop, procedure of today	
Start recording		Start recording	Inform participants that from now on the conversation will be recorded Get informed consent again on audio Start recording	Audio recording
Feedback	9:10 – 9:25	Patient journey	Showing the initial version of the patient journey (based on pre-diary workshop, interviews and diary entries). Asking participants to give feedback and reflect whether they recognise their own journey.	PPT, printed patient journey
	9:25 – 9:40	Values	Based on previous studies, 6 values were identified, aspects that were identified as important for patients. • **Altruism** *It is important for me that I can help others. (e.g., neighbours, children, grandchildren)* • **Showing Strengths:** *I don't want to appear sick, but be strong for and in front of others. (I should take care of my children, they shouldn't take care of me)* • **Respect:** *I want to be taken seriously, feel understood and not judged. (The disease is invisible, but I don't want to explain it to everyone.)* • **Independence:** *I want to be able to do things myself. I find it difficult to ask for help. I don't want to be a bother. (showers, walking the dog, grocery shopping, only call the doctor if really necessary)* • **Trust and Doctor-Patient Relationship:** *It is important for me that my doctor / nurse really knows me as*	PPT, printed values and empty boxes

			a person. (I don't regularly call, but when I call, they know it's serious. I don't want to explain everything at every visit.) • **Setting Priorities:** *Preserving energy for things that are important for me. (accepting help in the household / with daily tasks to have more energy to do other things)* Ask patients to discuss whether they recognise these values themselves and to prioritise them. Provide blank value boxes so that participants can also add new ones.	
	9:40 – 9:55	User Needs	Based on previous studies, 6 user values were identified, aspects that were identified as important for patients. • **Data Collection:** *I can collect information, but I don't want to spend a lot of time filling in questionnaires. (I am me, I am not the disease)* • **Data Sharing:** *I am willing to share my data with healthcare professionals, but I want to determine myself who I share my data with.* • **Health Information:** *I want to be informed about my COPD or CCC, its consequences, how to cope, what to expect, how to accept changes, …* • **What to measure:** ○ Sleep quality ○ Steps ○ Saturation • **Being active is for me:** ○ Biking ○ Take a walk (with the dog) ○ Working in garden ○ Grocery shopping ○ Doing laundry, cleaning dish washer ○ … • **Decision support:** *I want to be supported to decide when the right moment is to call the doctor, start with prednisolone, to stop being active etc., as often I am waiting too long or go over my limit.*	PPT, printed user needs and empty boxes

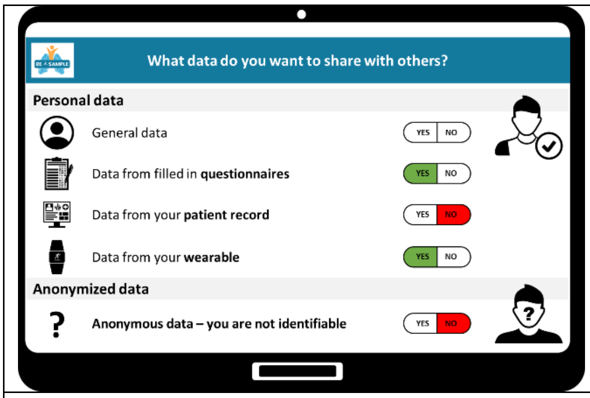
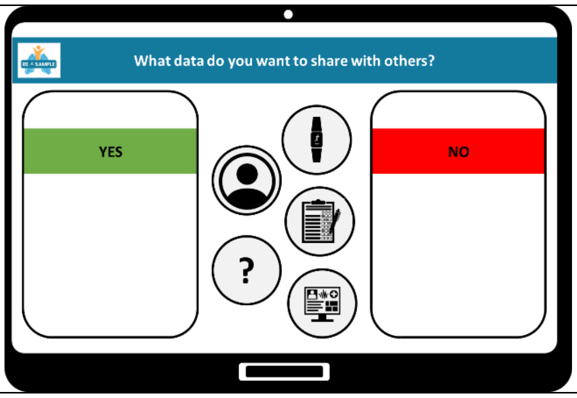
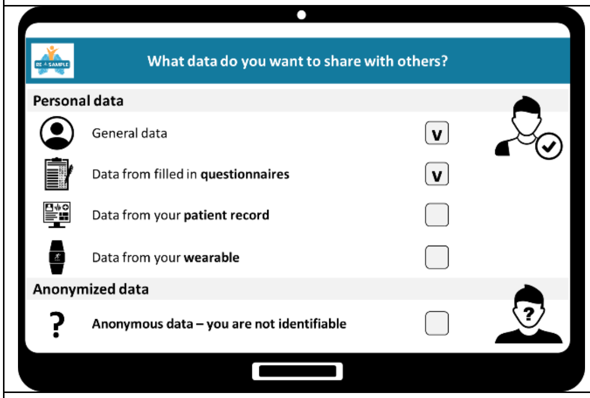
			Ask patients to discuss whether they recognise these user needs themselves and to prioritise them. Provide blank user needs boxes, so that participants can also add new ones	
Co-Design	9:55 – 10:15	Data collection & visualisation	Present scenario for visualising “steps taken” • *Your doctor recommended you to be physically active and monitor how many steps you take to see whether your health is stable or if it becomes more difficult to move.* • *You are wearing a tracker that automatically counts your steps. How would the perfect screen look for you showing your activity over time* Present scenario for visualising “saturation” • *You are measuring your oxygen saturation with your own device.* • *How would the perfect screen look for you to insert the result in the RE-SAMPLE application?* • *Inserting the measures helps also to see how the saturation develops over time. How would the perfect screen look for you showing your saturation?* Ask participants to draw their ideas on the tablet frame paper sheets. Discuss their ideas afterwards in the group	PPT, printed tablet frames
	10:15 – 10:35	Data sharing	Present scenario for data sharing • *Your personal health data can come from the patient record, questionnaires, trackers that measure automatically, or other devices (e.g. oximeter)* • *How would the perfect screen look for you where you can decide who you want to share data with and what you are sharing already.* Ask participants to draw their ideas on the tablet frame paper sheets. Discuss their ideas afterwards in the group	PPT, printed tablet frames
		Low-fidelity prototypes (optional)	In case participants struggle creating their own ideas for data sharing, make use of the prototypes to facilitate the discussion.	PPT, printed prototypes

Conclude	10:35 – 10:40		Any questions? Close workshop	
Stop recording		Stop recording		

Appendix H. Low-fidelity prototypes

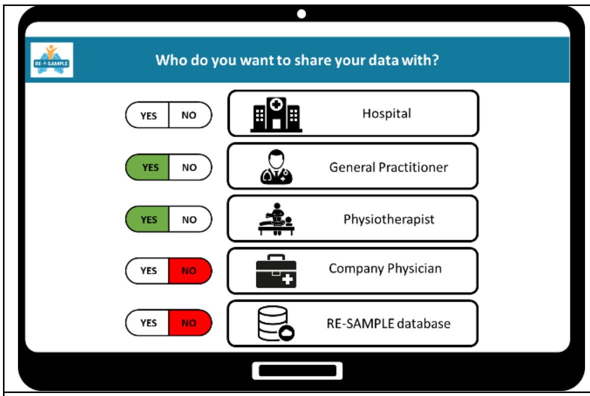
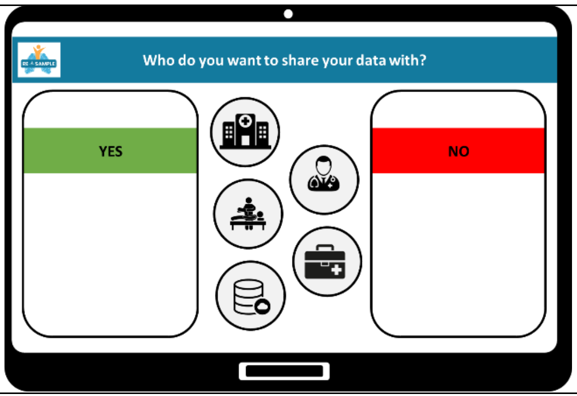
Giving general consent to sharing specific type of data

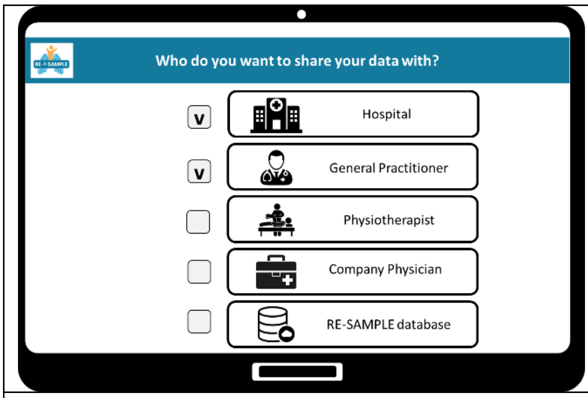
The following three interfaces allow users to consent to sharing specific data types, without specifying with whom data is being shared.

 What data do you want to share with others? Personal data General data YES NO Data from filled in **questionnaires** [✓ YES] NO Data from your **patient record** YES [✓ NO] Data from your **wearable** [✓ YES] NO Anonymized data **Anonymous data – you are not identifiable** YES [✓ NO]	 What data do you want to share with others? YES NO
Consent by tapping yes/no	Consent by drag&drop of icons to the yes/no fields
 What data do you want to share with others? Personal data General data ☑ Data from filled in **questionnaires** ☑ Data from your **patient record** ☐ Data from your **wearable** ☐ Anonymized data **Anonymous data – you are not identifiable** ☐	
Consent by activating fields	

Giving general consent to sharing with specific recipient

The following three interfaces allow user to consent to sharing data with specific recipients, without specifying the type of data.

 Who do you want to share your data with? YES NO Hospital [✓ YES] NO General Practitioner [✓ YES] NO Physiotherapist YES [✓ NO] Company Physician YES [✓ NO] RE-SAMPLE database	 Who do you want to share your data with? YES NO
Consent by tapping yes/no	Consent by drag&drop of icons to the yes/no fields



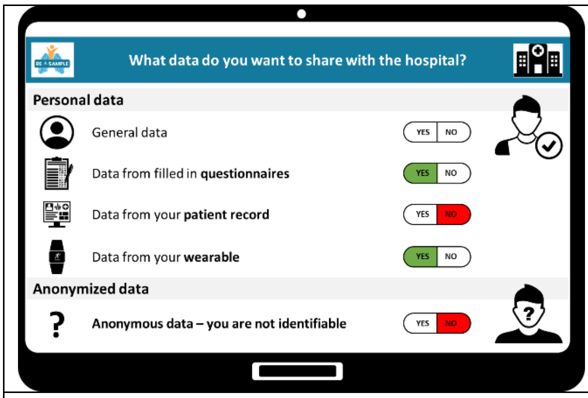
Who do you want to share your data with?

☑ Hospital
☑ General Practitioner
☐ Physiotherapist
☐ Company Physician
☐ RE-SAMPLE database

Consent by activating fields

For each recipient: Giving consent to sharing specific type of data

The following examples show how users can decide for each recipient, what type of data they want to share with these.

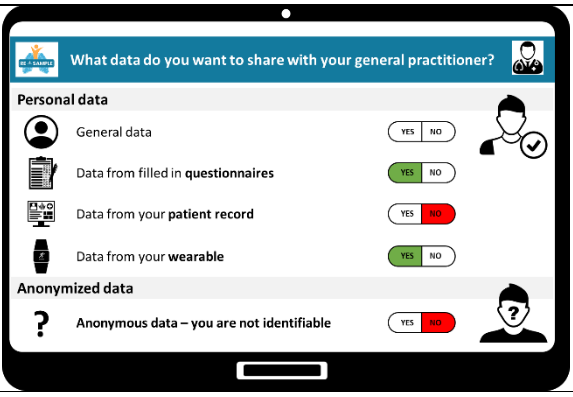


What data do you want to share with the hospital?

Personal data
General data YES NO
Data from filled in **questionnaires** [✓ YES] NO
Data from your **patient record** YES [✓ NO]
Data from your **wearable** [✓ YES] NO

Anonymized data
Anonymous data – you are not identifiable YES [✓ NO]

Consent to sharing data with hospital

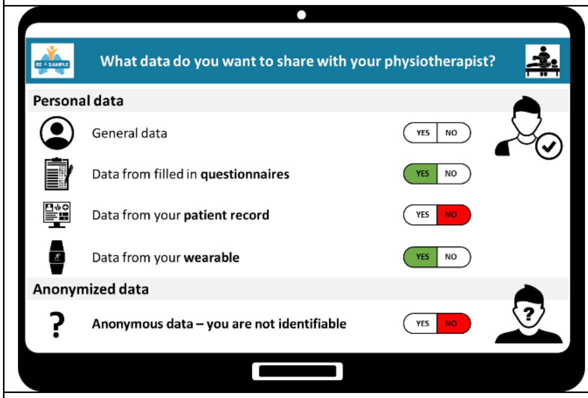


What data do you want to share with your general practitioner?

Personal data
General data YES NO
Data from filled in **questionnaires** [✓ YES] NO
Data from your **patient record** YES [✓ NO]
Data from your **wearable** [✓ YES] NO

Anonymized data
Anonymous data – you are not identifiable YES [✓ NO]

Consent to sharing data with the GP

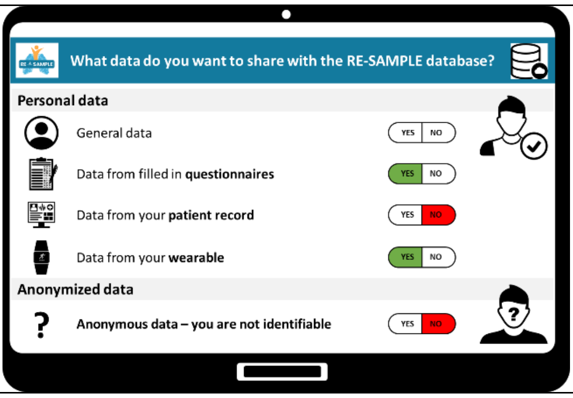


What data do you want to share with your physiotherapist?

Personal data
General data YES NO
Data from filled in **questionnaires** [✓ YES] NO
Data from your **patient record** YES [✓ NO]
Data from your **wearable** [✓ YES] NO

Anonymized data
Anonymous data – you are not identifiable YES [✓ NO]

Consent to sharing data with physiotherapist



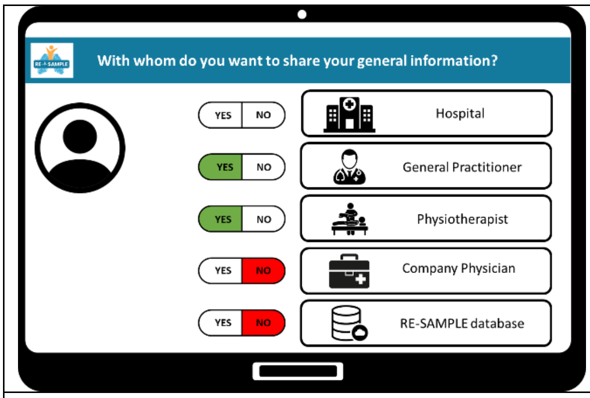
What data do you want to share with the RE-SAMPLE database?

Personal data
General data YES NO
Data from filled in **questionnaires** [✓ YES] NO
Data from your **patient record** YES [✓ NO]
Data from your **wearable** [✓ YES] NO

Anonymized data
Anonymous data – you are not identifiable YES [✓ NO]

Consent to sharing data with RE-SAMPLE

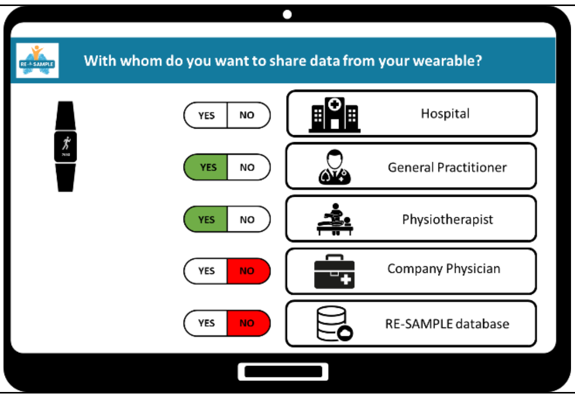
For each data type: Giving consent to sharing with specific recipient
The following examples show how users can decide for each data type with whom they want to share these.



With whom do you want to share your general information?

YES NO Hospital
[✓ YES] NO General Practitioner
[✓ YES] NO Physiotherapist
YES [✓ NO] Company Physician
YES [✓ NO] RE-SAMPLE database

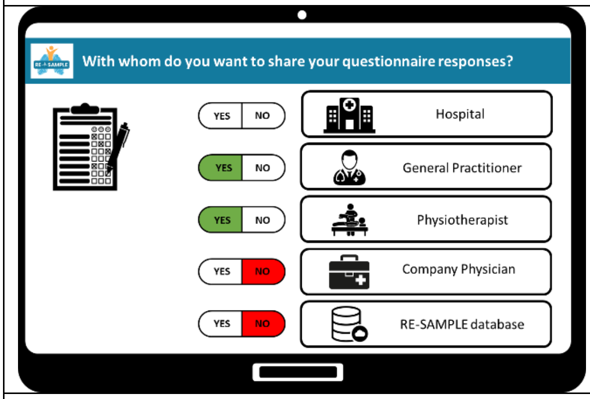
Consent to sharing general personal information



With whom do you want to share data from your wearable?

YES NO Hospital
[✓ YES] NO General Practitioner
[✓ YES] NO Physiotherapist
YES [✓ NO] Company Physician
YES [✓ NO] RE-SAMPLE database

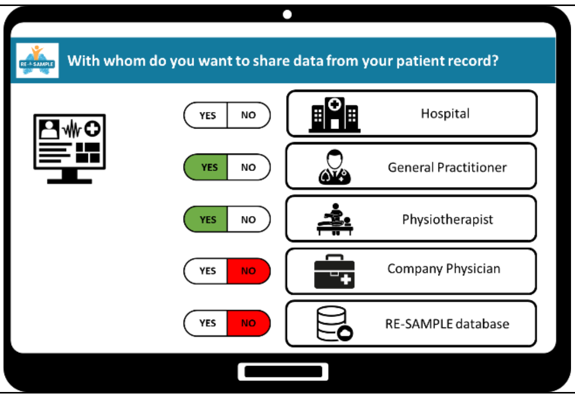
Consent to sharing data from wearable



With whom do you want to share your questionnaire responses?

YES NO Hospital
[✓ YES] NO General Practitioner
[✓ YES] NO Physiotherapist
YES [✓ NO] Company Physician
YES [✓ NO] RE-SAMPLE database

Consent to sharing questionnaire responses



With whom do you want to share data from your patient record?

YES NO Hospital
[✓ YES] NO General Practitioner
[✓ YES] NO Physiotherapist
YES [✓ NO] Company Physician
YES [✓ NO] RE-SAMPLE database

Consent to share data from patient record