

REal-time data monitoring for Shared, Adaptive, Multi-domain and Personalised prediction and decision making for Long-term Pulmonary care Ecosystems

D5.9: End-user involvement for design and evaluation $-3^{\rm rd}$ year

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Abstract

The goal of RE-SAMPLE is to develop an ecosystem of innovative eHealth services that support patients and healthcare professionals (HCPs) to manage Chronic Obstructive Pulmonary Disease (COPD) and accompanying complex chronic conditions (CCCs) in a more optimal and personalised way. Continuous engagement with end-users and other stakeholders is key to ensuring that the design of the virtual companion and the integrated care protocols respond well to their needs, values, and expectations, as well as to their daily practices in life and work.

This deliverable gives an overview of the end-user involvement activities carried out from M24 until M39. It describes the current status of the end-user panel, the continuous and bi-directional feedback exchanged between end-users and the RE-SAMPLE consortium, and the results of four iterations of end-user studies: three with patients and one with HCPs. Furthermore, two extra iterations are conducted and described.



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Symbols, definitions, abbreviations, and acronyms

ASQ	After-Scenario Questionnaire	
Citizen science	A participatory research model in which non-professionals are actively	
	involved in scientific research	
CCC	Complex Chronic Condition	
CeHReS	Centre for eHealth and Wellbeing Research	
COPD	Chronic Obstructive Pulmonary Disease	
D	Deliverable	
DPO	Data Protection Officer	
FAQ	Frequently asked questions	
GOLD	Global Initiative for Chronic Obstructive Lung Disease	
GP	General Practitioner	
HCP	Healthcare professional	
HUBBI	eHealth UsaBility Benchmarking Instrument	
ISO	International Organization for Standardization	
M	Month	
MREC	Medical research ethics committee	
SDM	Shared decision making	
SMART	Specific, Measurable, Achievable, Relevant, Time-Bound	
WMO	Dutch law: Medical Research Involving Human Subjects Act	
WP	Work Package	



1. Introduction

The goal of RE-SAMPLE is to develop an ecosystem of innovative eHealth services that support patients and healthcare professionals (HCPs) to manage Chronic Obstructive Pulmonary Disease (COPD) and accompanying complex chronic conditions (CCCs) in a more optimal and personalised way. Considering that the design problem, the development of the application and the implementation of the application are very complex with many heterogeneous stakeholders, early and continuous involvement of key stakeholders in the design process is crucial. Stakeholder involvement is one of the principles in human-centred design for interactive systems (International Organization for Standardization (ISO), 2019), which is also the foundation of the CeHReS¹ roadmap, a widely used holistic approach to improve the uptake and impact of eHealth technologies in practice (van Gemert-Pijnen, et al., 2011). Furthermore, the benefits of involving citizens/patients have been increasingly acknowledged in the field of health and medical research, for example, through Citizen Science, patient and public involvement, action research or similar participatory approaches (Borda, Gray, & Laura, 2019; Wiggins & Wilbanks, 2019). Through continuous engagement with end-users and other stakeholders, we can learn from their expertise and experience regarding living with and/or managing the conditions. This knowledge can help us to identify how the RE-SAMPLE programme can be best incorporated into the daily lives of patients and in the processes of the healthcare setting. This in turn can then be tested and evaluated with the end-users to ensure that their needs and expectations are correctly translated and taken into account in the design of the virtual companion and the integrated care protocol.

The first iteration of end-user studies was described in D5.7 End-user involvement for design and evaluation, which focused on the early detection of barriers and usability issues of the Healthentia app used in the monitoring cohort. D5.8 End-user involvement for design and evaluation -2^{nd} year describes four iterations of end-user studies focusing on usability and user experience, data visualisation on the clinicians' dashboard, risk prediction and shared decision making, and patients' view on data utilisation, risk prediction and virtual coaching. The current deliverable gives an overview of the end-user involvement activities carried out from M24 until M39. It describes the results of four iterations of end-user studies:

- Second iteration (section 5.1): Usability benchmarking and user experience assessment. This iteration focuses on assessing the user experience and usability of the Healthentia app in real life
- Sixth iteration (section 5.2): Focus groups with patients about shared decision making.
- Seventh iteration (section 5.3): Final usability test of the app with patients.
- Eighth iteration (section 6.1): Final usability test of the clinical dashboard with healthcare professionals.

Furthermore, two extra iterations are conducted with patients as described in sections 7.1 and 7.2. These iterations were conducted as student assignments.

¹ CeHReS is an acronym for Centre for eHealth and Wellbeing Research



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2. Objective

The objective of this deliverable is to report on the activities of continuous involvement of end-users, the end-user panel and the results of end-user studies performed to support the iterative design and evaluation of the RE-SAMPLE virtual companionship programme.

Section 3 outlines the adaptations made in the process of using the end-user panel and the status of the end-user panel. Section 4 shows the continuous and bi-directional feedback exchanged between end-users and the RE-SAMPLE consortium. Furthermore, section 5 presents three end-user iteration studies with patients, and section 6 focuses on one end-user iteration study with HCPs. Next to this, section 7 describes two extra end-user iteration studies with patients conducted by master students. Finally, in section 8 we conclude this deliverable.



3. RE-SAMPLE End-User Panel

As described in D5.8 End-user involvement for design and evaluation -2^{nd} year, the set-up and groups of the RE-SAMPLE end-user panel were changed. In the first months of the third year, we made some small adaptations, which are described in this deliverable. These adaptations were developed by RRD and the UT.

3.1 Adaptations

We changed the process a little bit from the moment a person signs up for the end-user panel. We chose, for each country, the contact person of the end-user panel. For the Netherlands, this is someone from MST. For Italy, this is someone from GEM. For Estonia, this is someone from TUK. For other countries signing up in English, someone from RRD is managing the process. These contact persons are responsible for contacting the members of the end-user panel from their country. Furthermore, we slightly changed the introductory survey and incorporated a survey for the other roles. The introductory surveys for the different end-users are added in *Appendix A: Introductory surveys end-user panel*.

3.2 Process following sign-up

After a person signs up for the end-user panel, an automatic e-mail is sent to re-sample@utwente.nl and the contact person of that country/language. This subscriber is then added to the list of panel members by someone from the UT. This overview is confidential as only people responsible for the end-user panel can access it. Furthermore, the person receives afterwards an automatic welcome e-mail (sent by the UT) including the baseline/demographic questionnaire that (s)he is being asked to complete. If this person does not complete the questionnaire in one week, a reminder is sent through e-mail. Templates in each language are written which can be used. Someone from RRD then informs the contact person to send an e-mail to the panel member. All completed questionnaires are added in one Excel file uploaded in the Teams by someone from RRD.

3.3 Process recruitment for a study

In order to better manage the end-user studies, we defined a standard process in the consortium for the organisation of such studies and the recruitment of end-users to be involved. To support this process, we created an Excel file listing all the members from the end-user panel.

- 1. A month before something is asked of the end-users, the researchers will inform the contact person of that country via email. (To avoid that too many studies are being conducted simultaneously and end-users will be spammed with e-mails).
- 2. The contact person fills in the study description, start and end date, and number of participants in the end-user panel Excel file (tab "studies").
- 3. The contact person fills in the end-user panel Excel file (tab "general"), the contact date of each end-user for each study.
- 4. The contact person e-mails the end-users and adds the template of the e-mail sent to the document "Templates emails sent".

During this process, the contact persons will try to contact the right people for the study based on their interests measured through the baseline/demographic questionnaire, see end-user panel Excel file (tab "general").

3.4 Promotion

To promote the RE-SAMPLE project and the end-user panel, a flyer was created by RRD and HOPE that included a short summary of the project and the end-user panel and a QR code to the sign-up page for the end-user panel. This flyer is available in Dutch, Italian, Estonian and English. In the summer of 2023, the Dutch version was distributed in MST on paper in the waiting rooms of the lung department and digitally on TV screens in those waiting rooms as well. The Italian version was distributed in GEM on paper in the first week of October. The Estonian version was distributed in TUK on paper in the summer of 2023.



3.5 Current status end-user panel

As of the 30th of April 2024, N=32 people have signed up to be part of the end-user panel in total. In addition, 40 patients and 22 HCPs who participated in the Dutch studies gave their consent to be contacted again in the future by RRD.

The RE-SAMPLE end-user panel was utilised to recruit participants for the sixth end-user iteration. Ten participants from the end-user panel participated in the focus groups about shared decision making. Furthermore, the RRD contact list was utilised to recruit participants for the studies from master students at RRD (the two extra iterations described in section 7). All patients received an e-mail, and for one study 7 signed up and participated and the other 7 signed up and 6 participated (due to personal circumstances the last patient could not participate anymore).



4. Continuous end-user feedback

4.1 Participants in the cohort study

Some participants of the cohort study shared unprompted feedback with the RE-SAMPLE consortium about the Healthentia app. This feedback is listed in Table 1, and most errors were fixed directly.

Table 1: Feedback from participants in the cohort study.

Time	Cohort	Description	Comment
July 2023	All pilot sites	Participants are logged out automatically after one year, but the cohort is not finished.	Fixed.
August 2023	TUK (EE)	Participants receive too many notifications about completing questionnaires (sometimes even 8 per day). Due to this, participants do not know anymore which questionnaire they need to complete.	Those notifications are turned off.
August 2023	TUK (EE)	English titles of questionnaires in the notifications.	Fixed.
September 2023	MST (NL)	Participants called, noticed changes in the app: a new widget with heart rate. Participants are positive about this change. But saw a slight real-time difference on the Garmin watch and the Healthentia app.	Explained that this is due to the time needed to synchronise data. When looking at data from e.g. yesterday, there is no difference in Garmin and in Healthentia app.

4.2 Participants in the end-user studies

Feedback is not a one-way pathway. When building a relationship with end-users, it is also important to keep them in the loop and to share early results and/or summaries of the studies they participated in. Sometimes this also led to unprompted feedback by phone or email by some participants.

Sharing results from the end-user sessions is important. By doing this, the project also gives something back and not only asks for information *from* participants.

4.2.1 End-user walkthrough – May 2023

After finalising the end-user walkthrough, a summary of the results was sent to various stakeholders as videos. These stakeholders included the participants of the end-user walkthrough, the end-user panel from RRD (consisting of persons with COPD and healthcare professionals), Dutch physical therapist practices, the cohort and the COPD network inventory list. Furthermore, we also shared it on social media with the public. The story shared in the video, is attached to Appendix B: Summaries shared with stakeholders. The videos now available Dutch (https://www.youtube.com/watch?v=c6JqtZdVU5M) and **English** (https://www.youtube.com/watch?v=446NxNCFRSo). Within the English video, you can choose to have Italian or Estonian subtitles.

4.2.2 Interviews about health data monitoring, risk prediction and virtual coaching – May 2023 Interviews with persons with COPD were conducted in the Autumn of 2022, described in D5.8 Enduser involvement for design and evaluation – 2^{nd} year. These interviews were focusing on health data monitoring, risk prediction and virtual coaching. The results from these interviews were summarised in a feedback video. This was sent to the participants of the interviews, the end-user panel from RRD (consisting of persons with COPD and healthcare professionals), Dutch physical therapist practices, the cohort and the COPD network inventory list. We received e-mails from various people. First of all, two Dutch pulmonologists (from hospitals other than MST) were enthusiastic about the project and wanted



to have an online meeting to learn more about the RE-SAMPLE project. Furthermore, we received an e-mail from the Italian Respiriamo Insieme Community that they are interested in the project, but would like to have Italian subtitles in the videos to be able to share them with their community. So we added Italian and Estonian subtitles to the English videos.

The feedback videos are available online in Dutch (https://www.youtube.com/watch?v=J05X78uUY58) and English (https://www.youtube.com/watch?v=2rYrLyQ4A9E&t=93s). The text is available in this deliverable in Appendix B: Summaries shared with stakeholders.

4.2.3 Increasing effective engagement in eHealth for COPD self-management through Value Sensitive Design – Nov 2023

Evaluation workshops with persons with COPD were conducted at the beginning of 2023, as described in section 7.2 of this deliverable. The results from the evaluation workshop of the different concepts developed were summarised in a feedback video. This was sent to the participants of the workshops, the end-user panel from RRD (consisting of persons with COPD and healthcare professionals), Dutch physical therapist practices, the cohort and the COPD network inventory list.

The feedback videos are available online in Dutch (https://www.youtube.com/watch?v=2-bZNq5AmLM) and in English (https://www.youtube.com/watch?v=2rYrLyQ4A9E&t=93s). The English video has also subtitles in Italian available. The text is available in this deliverable in Appendix B: Summaries shared with stakeholders.



5. Iterative development of the Virtual Companion for patients

5.1 Usability benchmarking and user experience assessment (Ongoing)

The second iteration of end-user studies focuses on assessing the user experience and usability of the Healthentia app in real life. For this, patients included in the cohort study were asked to report their experience of daily use and assess the usability of the current system used for data collection (i.e., the Healthentia app). This section describes the first results of this iteration.

5.1.1 Methods

5.1.1.1 Study design

As described in D5.7 *End-user involvement for design and evaluation*, the eHealth UsaBility Benchmarking Instrument (HUBBI) questionnaire that was used during the first iteration will also be used during the next iterations of the end-user studies. This benchmarking allows us to assess and compare the usability of the Healthentia app over time. This questionnaire is completed one week after a patient starts using the Healthentia app.

Next to the benchmark, the second iteration end-user studies includes also two additional studies with cohort participants who have used the Healthentia application for a longer period. This gives us insights into the user experience, the extent of usability and the nature of usability issues that might not be detected during a one-time and guided use during a short period in the lab setting. Two additional questionnaires were developed, in which special attention was paid to the issues identified in the first iteration of end-user studies. These questionnaires were prompted 4 weeks after starting using the Healthentia app, and 1-2 weeks after experiencing an exacerbation.

5.1.1.2 Participants

To evaluate the usability and user experience of the Healthentia app in real life, patients from the cohort study were asked to complete several questionnaires. The aim is to gather a total of 120 completed HUBBI questionnaires, 40 from each pilot site (the Netherlands, Italy and Estonia), a total of 120 completed user experience questionnaires after 4 weeks of use, also 40 from each pilot site, and a total of 60 completed user experience questionnaires after 1-2 weeks after an exacerbation, 20 from each pilot site.

5.1.1.3 Study procedure

Patients are continuously being recruited for the cohort study. One week after patients start using the Healthentia app, they receive the HUBBI questionnaire via the app. This questionnaire consists of 18 statements measuring Healthentia's usability. Four weeks after patients start using the Healthentia app, they receive a link to the user experience questionnaire via the app. This questionnaire is being asked outside of the Healthentia app, within Qualtrics. The questionnaire consists of a total of 33 questions. Furthermore, 1-2 weeks after patients experience an exacerbation, they receive a link to another user experience questionnaire via the app. This questionnaire is also being asked outside of the Healthentia app, within Qualtrics. The questionnaire consists of a total of 24 questions. The study procedure and all questionnaires are shown in *Appendix C: Study procedure and instruments second iteration end-user study*.

5.1.1.4 Data analysis

Participants' responses to the HUBBI questionnaire were exported from Healthentia as a commaseparated file with an entry for each question that was answered. Each entry listed information that included details such as the participant ID, study site, questionnaire ID, questionnaire name, question ID, and response. These data were then processed and plotted using R (version 4.2.2) which involved the following steps:

1. The table with responses was inverted to get a row with responses per participant.



- 2. The dataset was then relabelled to become more human-interpretable. That is, 'ds.ShortId' was relabelled to 'SubjectID' and the response fields for the specific questions were re-labelled from their database numbering to question IDs that indicated the subscale they corresponded to (e.g., '7563' would become 'BSP3').
- 3. Scores for the basic system performance subscale questions 3 and 4 were reversed. These were 'I experienced system errors' and 'I get stuck when using the system', respectively.
- 4. Then, as pre-processing for creating the plots, the mean scores for each subscale per participant were computed.
- 5. To generate the radar plots, the mean value per subscale was computed for the included set of participants using the 'radarchart' function.
- 6. To generate the boxplots the preprocessed responses for the questions in each subscale were plotted using the 'boxplot' function.

This process was followed with the data for all participants and each of the sites specifically.

The two user experience questionnaires were analysed using Excel. Descriptive statistics (mean, standard deviation, percentages, minimum, maximum) were used to describe the results.

5.1.2 Results

5.1.2.1 HUBBI

We report on the HUBBI data collected until April 10th, 2024 (date of exporting the responses from Healthentia). A total of 190 responses was collected for all three pilot sites, of which 58 were from MST (the Netherlands), 74 from GEM (Italy) and 58 from TUK (Estonia).

In the previous deliverable for Task 5.5 (D5.8 End-user involvement for design and evaluation), the Healthentia app scored an overall score of 3.8 on a scale of 1 (bad usability) to 5 (good usability). For the purpose of comparison with the new results, scores for the specific subscales of those previously reported results are shown in Figure 1. As previously stated, when observing this HUBBI outcome radar chart, all scores in the green field indicate that that part is good, yellow means okay but can be improved and orange or red means that aspect of the usability is bad. For the previously reported outcomes, the dimensions of task-technology fit was considered good. There were no scores in orange or red, which is also good. However, there were quite a few in yellow (basic system performance, interface design, navigation & structure, information & terminology, guidance & support and satisfaction).



Figure 1: HUBBI scores of the Healthentia app as reported in D5.8.



A depiction of the HUBBI scores for all participants in the cohort can be found in Figure 2. The Healthentia app scored an overall score of 3.5 on a scale from 1 (bad usability) to 5 (good usability). This is a slight decrease compared to the previous analysis in D5.8 *End-user involvement for design and evaluation*. As can be seen, most domains stayed relatively the same as in Figure 1, with Guidance and Support and Information and Technology slightly increased and Task-Technology Fit slightly decreased. There are no domains in the orange or red part, so again that is good. But all the domains are in the yellow part, so some improvements could be useful to improve the usability of the app.

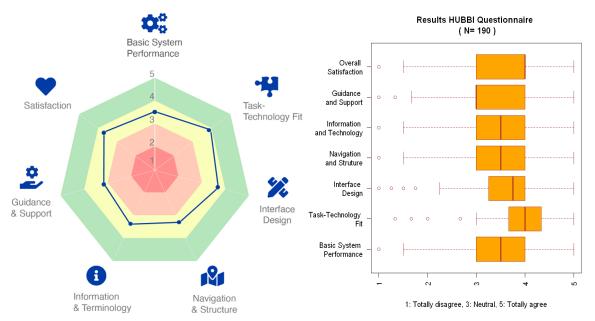


Figure 2: A spider plot and boxplot showing the responses to the HUBBI questionnaire for all participants in the cohort.

Figure 3, Figure 4 and Figure 5 show the responses split out for the three study sites, MST, GEM, and TUK, respectively. The Healthentia app scored an overall score of 3.6 in MST and GEM and an overall score of 3.4 in TUK. In none of the three sites, there are domains in the orange or red part of the spider plot. However, also these plots show that most domains are in the yellow part. So the usability could be improved on all the domains of the HUBBI. The differences between the three sites are small. No major differences are found.



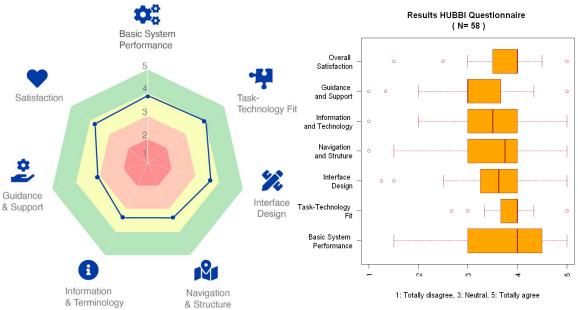


Figure 3: A spider plot and boxplot showing the responses to the HUBBI questionnaire for participants from the MST site.

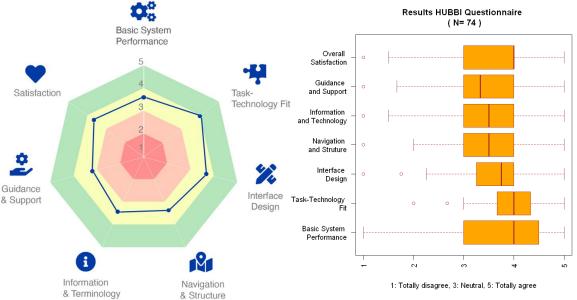


Figure 4: A spider plot and boxplot showing the responses to the HUBBI questionnaire for participants from the GEM site.



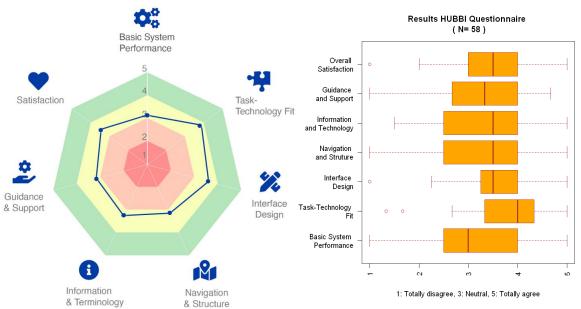


Figure 5: A spider plot and boxplot showing the responses to the HUBBI questionnaire for participants from the TUK site.

5.1.2.2 User experience questionnaires

We collected data for the user experience questionnaires 4 weeks after the use of the app and 1-2 weeks after an exacerbation until the 30th of April, 2024. We will first show the results of the first questionnaire, 4 weeks after use. This questionnaire was completed by 59 participants, of which 16 participants were from the MST site, 25 from the GEM site and 18 from the TUK site. Table 2 shows the demographics of the total group who completed the user experience questionnaire after 4 weeks of using the app.

Table 2: Demographics participants user experience questionnaire 4 weeks after use of app.

Demographic	Sub-category	% or M (SD) Min-Max
Gender	Male	78.0
	Female	16.9
	Other	5.1
Age		71.5 (9.2) 53.0 – 99.0
Highest level of education	Primary school	8.5
	High school	27.1
	Trade school	25.4
	University	27.1
	Other	11.9
Employment status	Full time	18.6
	Part time	8.5
	Retired	62.7
	Unable to work	1.7
	Retired but doing voluntary work	3.4
	Full time and doing voluntary work	1.7
	Voluntary work	1.7
	Other	1.7



Demographic	Sub-category	% or M (SD) Min-Max
Number of family members living together		1.3 (0.9) 0.0 – 4.0
Digital skills		2.9 (0.9) 1.0 – 5.0

In general, the participants scored their general and overall experience with the Healthentia app an average of 3.6 (SD=1.0), on a scale from 1 (very poor) to 5 (very good). This shows that their general and overall experience is acceptable. Most participants use the app for completing their daily symptoms questionnaires. Furthermore, they use the app to look at their daily step activity, heart rate, sleep and saturation. A quarter of the participants experienced problems with the app during their first weeks of use: they did not understand every part of the app, they had difficulties using technology in general, they could not complete a specific questionnaire, or they experienced some days the app was not working at all.

Within the Healthentia mobile application, there are multiply ways to find technical help, the tutorial, the frequently asked questions (FAQ) and the conversational agent. A total of 6 participants used the tutorial. Half of them thought the tutorial was informative while 4 of them understood the app better after going through the tutorial and could better navigate through the app. A total of 4 participants used the FAQ. Three participants found the FAQ informative, 2 participants understood the app better after reading the FAQ and 3 participants could better navigate through the app after reading the FAQ. Furthermore, a total of 3 participants used the conversational agent. Two of them found the conversational agent informative and understood the app better, one of them could better navigate through the app after using the conversational agent.

A final part of this user experience questionnaire is about completing questionnaires to monitor symptoms and disease progression. The participants were asked whether they experienced problems completing these questionnaires, whether they understood how to complete the questionnaires and whether it was clear to them what the start and end of a questionnaire was. Regarding experiencing problems, there was an average score of 3.4 (SD=1.3), on a scale from 1 (strongly agreeing with experiencing problems) to 5 (strongly disagreeing with experiencing problems). Regarding understanding how to complete the questionnaires, there was an average score of 4.1 (SD=0.9) on a scale from 1 (strongly disagreeing with understanding) to 5 (strongly agreeing with understanding). Regarding clear start and end, there was an average score of 4.2 (SD=0.8) on a scale from 1 (strongly disagreeing with clear start and end). Finally, we also asked them about the time they needed to complete the questionnaires. The majority indicated that the time needed is okay. However, some thought it takes too long to complete all the questionnaires needed, or that it is even useless to complete these questionnaires.

The second user experience questionnaire, 1-2 weeks after an exacerbation, was completed by 9 participants, (7 from MST site, 2 from GEM site). Table 3 shows the demographics of the total group who completed the user experience questionnaire 1-2 weeks after an exacerbation.

Table 3: Demographics participants user experience questionnaire 1-2 weeks after an exacerbation.

Demographic	Sub-category	% or M (SD) Min-Max
Gender	Male	77.8
	Female	22.2
Age		69.4 (8.5) 54.0 – 79.0
Highest level of education	Primary school	22.2
	High school	33.3
	Trade school	33.3
	Other	11.1



Demographic	Sub-category	% or M (SD) Min-Max
Employment status	Full time	11.1
	Part time	22.2
	Retired	55.6
	Full time and doing voluntary work	11.1
Number of family members living together		1.1 (0.8) 0.0 – 2.0
Digital skills		2.7 (0.9) 1.0 – 4.0

Of the 9 participants, 3 were invited to do a blood test. Only one found the process clear and useful that the Healthentia app determined that the blood draw was needed, one wanted to have more guidance to know what was expected from them, and one found it useless that the Healthentia app determined that the blood draw was needed. The other 6 participants were asked why no laboratory tests were done. They said that they did not receive any message that it was needed.

Because of worsening of symptoms participants were asked to complete additional questionnaires in the Healthenthia app. Eight participants completed these questionnaires. The participants were asked whether they experienced problems completing these questionnaires, whether they understood how to complete the questionnaires and whether it was clear to them what the start and end of a questionnaire was. Regarding experiencing problems, there was an average score of 3.7 (SD=0.5), on a scale from 1 (strongly agreeing with experiencing problems) to 5 (strongly disagreeing with experiencing problems). Regarding understanding how to complete the questionnaires, there was an average score of 3.9 (SD=0.4) on a scale from 1 (strongly disagreeing with understanding) to 5 (strongly agreeing with understanding). Regarding clear start and end, there was an average score of 3.9 (SD=0.7) on a scale from 1 (strongly disagreeing with clear start and end) to 5 (strongly agreeing with clear start and end). Their general experience with completing these questionnaires was good, and the time that was needed to complete these questionnaires was also good.

5.2 Focus groups about shared decision making (April 2023 - August 2023)

The sixth iteration of end-user studies consisted of focus groups with patients with COPD about shared decision making (SDM). The goal of this study was to investigate patients' preferences for technology-supported SDM and user-interaction during SDM consultations. The study ran from April 2023 to August 2023, and focus groups were held in the Netherlands. The plans for this study were reviewed and approved by the Ethical Committee for Humanities & Social Sciences of the University of Twente under application number 220066.

5.2.1 Methods

During the first part of the focus groups, patients were introduced to a scenario of technology-supported layered SDM. This process consisted of three layers with structured steps to decide together on (1) a health domain(s) to tackle such as physical activity, sleep, medication adherence or coping with COPD (2) a treatment option by amongst other things, informing patients about available options considering their preferences, values, self-efficacy, and expectations, and (3) a personalised treatment plan using Specific, Measurable, Achievable, Relevant, and Time-Bound (SMART) goals.

In the second part of the focus group, patients could choose their preferred delivery mode during SDM consultations with healthcare providers. They could choose between text or images, bar plots or graph plots, and table charts or pie charts. Examples of the visualisations which patients could choose from can be seen in Figure 6 below.

All focus groups were thematically analysed in Atlas.ti.





Figure 6: Examples of the visualisations which patients could choose from. On the left image, patients could choose between bar plots and line graphs when discussing their physical activity levels, whereas patients could choose between text or images when discussing which health domain to tackle.

5.2.2 Results

5.2.2.1 Participants

At the beginning of the workshops, patients provided their informed consent and had the opportunity to fill in a questionnaire with demographic data and their experience with SDM tools. In total three focus groups were held with in total 10 patients with COPD. The results of the questionnaire can be seen in Table 4. Patients had an average age of 73.1 (5.9) years. Most patients (N=9) had no experience with SDM tools and/but mentioned that they perceive tools for SDM as either useful or sometimes useful.

Table 4: Participants' demographics and experience with SDM (N=10).

Demographic	Sub-category	% or M (SD) Min-Max
Gender	Male	50
	Female	50
	Other	0
Age (N=9)		73.1 (5.9) 66.0 – 84.0
Highest level of education	Secondary vocational education	50
	Higher Professional Education	40
	Academic university education	0
	Other	0
	Missing data	10
Employment	Retired	90
	Other	10
COPD GOLD stage	I	0
	П	40
	III	20
	IV	20
	Unknown	20
Comorbidities	None	50
	Anxiety/depression	10
	Diabetes	20
	Chronic heart failure (CHF)	10
	Ischemic heart disease (IHD)	0
	Diabetes and CHF	10



Demographic	Sub-category	% or M (SD) Min-Max
Experience with SDM-tools	Yes	0
	Maybe	0
	No	90
	Missing data	10
Attitude towards SDM-tools	Never useful	0
	Sometimes useful	30
	Useful	20
	Very useful	0
	Other	10
	Missing data	40

5.2.2.2 Part I: Technology-supported shared decision making

In this section of the focus group, patients talked about what they liked when it came to each step of the SDM process. The pictures below illustrate the scenarios which were discussed.

Concerning the first layer (Figure 7), patients were divided on whether they felt the need to discuss health domains with their healthcare provider. Some patients expressed a reluctance to discuss it, while others acknowledged the importance of discussing it if it was causing concern. Regarding insights into behaviour, most patients did not prefer to discuss insights into their behaviour with a chatbot. Patients adamantly refused to engage with a conversation robot, preferring human interaction. One patient preferred researching on the internet and speaking with someone knowledgeable over the phone. Meanwhile, other patients mentioned a preference for completing a questionnaire rather than talking to a chatbot.

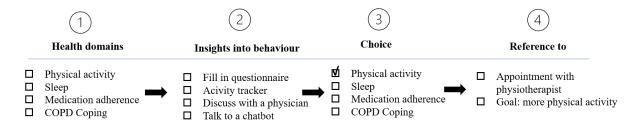


Figure 7: First layer of the SDM-process with the aim to decide on a health domain to tackle.

Concerning the second layer (Figure 8), patients emphasised the importance of having a conversation with their general practitioner to discuss treatment options. They also expressed concerns about trying multiple medications without much success over a prolonged period. Regarding inform talk, patients also highlighted the importance of understanding how and why certain treatments are recommended, expressing a desire for detailed explanations. Patients emphasised the value of information, mentioning that they often read the package leaflet to understand the potential side effects of medication, underscoring the importance of being adequately prepared.

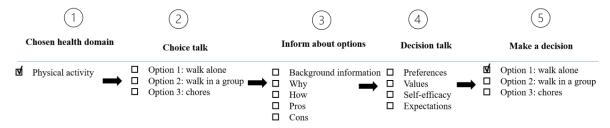


Figure 8: Second layer of the SDM-process with the aim to decide on a treatment option.



Concerning the last layer of the SDM-process (Figure 9) patients discussed their preference for personalising goals and developing treatment plans. While most patients viewed guided support positively, considering it a reliable option, they also recognised the demanding schedules of healthcare professionals like physiotherapists. Consequently, they expressed reservations about expecting intensive support from these providers due to their existing workload, and thus limited time. In addition, patients also expressed skepticism about a systematic approach via a physiotherapist, indicating their preference for seeking help only when specific issues arise. Lastly, patients mentioned that motivational tools could be handy to achieve their goals.

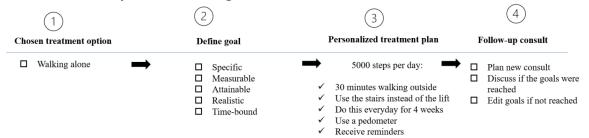


Figure 9: Third layer of the SDM-process with the aim to decide together on a personalised treatment goal.

5.2.2.3 Part II: User interaction during SDM consultations

Patients expressed varying preferences for the presentation of information during SDM consultations with their healthcare professional as can be seen in Table 5. There was an equal split between those favoring text-based and image-based formats when deciding together on a health domain to discuss. When it came to visualising data regarding the number of steps taken, a clear preference emerged for bar plots, while no patients opted for graph plots. Similarly, for representing sleep data, most patients leaned towards bar plots, although a few expressed a preference for pie charts or had no specific preference. Interestingly, when the visualisation included sleep goals, the majority preferred bar plots with goals integrated. Regarding medication data, patients favored the use of smileys over check marks, with some having no specific preference. Finally, in presenting treatment plans, a notable preference emerged for text-based formats, with no patients opting for text combined with images.

Table 5: Patient preferences for user-interaction during SDM consultations (N=10).

Visualisation	Options	%
Health domain visualisation	Text based (N=5) Image based (N=5)	50 50
Data visualisation- Number of steps	Bar plot (N=10) Graph plot (N=0)	100
Data visualisation- Number of steps	Table chart (N=8) Pie chart (N=2)	80 20
Data visualisation- Sleep	Bar plot (N=6) Pie chart (N=2) No preference (N=2)	60 20 20
Data visualisation- Sleep	Bar plot (N=1) Bar plot with sleep goal (N=8) No preference (N=1)	10 80 10
Data visualisation- Medication	Smileys (N=6) Check marks (N=0) No preference (N=1) Missing data (N=3)	60 0 10 30



Visualisation	Options	%
Data visualisation- Treatment	Text based (N=9)	90
plan	Text + image based (N=0)	0
	Missing data $(N=1)$	10

Finally, the focus groups mainly showed that information provision, SDM roles, contact support, mode of information delivery, time, preparation, and goal setting are important constructs to improve SDM. For user-interaction, personalising the delivery mode is an important contributing factor for improving SDM. The findings of this study provided insight into relevant elements for SDM, especially with the addition of a new actor - technology - in the SDM process. Moreover, patients gave their preferences concerning the SDM layered process including user-interactions which showed variability in preferences that can enable the development of meaningful data-driven patient profiles for SMD and user interaction.

5.3 Final usability test of the app for persons with COPD (March 2024 – April 2024)

The seventh iteration of end-user studies focuses on assessing the usability of the final Healthentia app before starting with the evaluation study. For this, in all three pilot sites (the Netherlands, Italy, Estonia) persons with COPD were asked to participate in this one-time usability test. This section describes the methods and results of this iteration.

Before continuing with the methods and results of the final usability tests of the app, we want to share our initial idea for this iteration. Our initial idea was to evaluate the usability and user experience of the final Healthentia app in a one-week home study, with a mixed methods approach (interviews and questionnaires). Participants would then use the app for 8 days, starting on the first day with a physical meeting at the hospital, with phone calls on the following working days to assess the usability and user experience. On the last day, participants would be asked to complete questionnaires about their acceptance towards the app and the usability of the chatbot within the app. This protocol was ready to be implemented (see Appendix D: Initial protocol final usability test Healthentia app for the full protocol). However, during a WP5 biweekly online meeting, the consortium decided to change this protocol to a one-time usability test within the hospitals. The reason for this was because of concerns arising with the pilot sites. To be able to implement this protocol, participants would be asked to not listen to the advices given within the app, because it was the first time the action plans and coaching dialogues would be tested. However, according to the pilot sites, it was not feasible to implement this protocol, because they were not sure if their patients would listen to their advice to not take any actions based on the coaching dialogues and action planning advices within the app. So because of these concerns, we chose to transform the final usability test to a one-time test within the hospitals.

5.3.1 Methods

5.3.1.1 Study design

To answer our objective, we conducted a usability test within all three pilot sites: the Netherlands, Italy and Estonia. Participants were asked for a single usability evaluation session in a lab setting. The participants had to complete two tasks. These tasks reflected the most important additions to the functionalities of the Healthentia app. The execution of these tasks was accompanied by a think-aloud protocol, and the moderator wrote down the usability issues that occurred during the task performance. Afterwards, the participants needed to complete one questionnaire, the Bot Usability Scale (Borsci, et al., 2022). Each session concluded with a short semi-structured interview. All participants provided informed consent prior to participation. An overview of the protocol of this study can be found in *Appendix E: Final protocol for final usability test of Healthentia app*.

5.3.1.2 Participants

For this usability test of the Healthentia app, we focused on people with COPD already included in the observational cohort. We aimed to include 5 participants per pilot site.



5.3.1.3 Study parameters

The study parameters were: number of usability issues, satisfaction with virtual coach, and user experience.

Number of usability issues: the elicitation of usability issues is considered one of the most important elements in usability testing. It provides a list of identified usability issues that need to be addressed before the implementation of the system. These usability issues often are joined with a severity score, to prioritise the issues that are most important to solve. Usability issues are collected via a think-aloud protocol, in which participants verbalise their thoughts, and moderator notes during the usability test. Each usability issue is given a severity score using the index of Duh et al. (Duh, Tan, & Chen, 2006) that distinguishes three severity levels:

- A **minor** usability problem occurs infrequently among the participants and/or the problem only increases task completion time slightly;
- A **serious** usability problem occurs frequently among the participants and/or the problem severely increases task completion time;
- A **critical** usability problem occurs when all participants have the same problem and/or the problem prevents participants from completing tasks.

Satisfaction with the virtual coach: the participants' satisfaction with the virtual coach was measured through a questionnaire, the Bot Usability Scale (Borsci, et al., 2022). This questionnaire comprises eleven items in which users will have to score each statement on a 5-point Likert scale ranging from strongly disagree to strongly agree.

User experience: user experience was measured with a short semi-structured interview with each participant. We focused on the virtual coach and the action planning.

5.3.1.4 Study procedure

Before participation, each participant filled in an informed consent form. Then, the usability test commenced. First, participants received the demographics questionnaire. Then, they received information about the think-aloud protocol. Next, a concurrent think-aloud protocol was administered in which they were given two tasks to complete within the Healthentia app while verbalising their thoughts. These tasks were:

- 1. I have a couple of dialogues ready for you. You will start with dialogue #1. Go through the dialogue and try to think aloud what you think when reading the dialogue.
- 2. Now I have one scenario for you to go through. Go through the scenario and try to think aloud what you think when reading and conducting the scenario. You will be asked to complete the daily diary in the app. After you complete the daily diary, you will receive advice to take action. If you receive this, please open this action and read it.

After they completed both tasks, they completed one questionnaire about their satisfaction with the virtual coach: Bot Usability Scale (Borsci, et al., 2022). We concluded the session with a semi-structured interview. The whole study procedure can be found in *Appendix E: Final protocol for final usability test of Healthentia app*.

5.3.1.5 Data analysis

Descriptive statistics (frequency, mean, percentages) are computed for the demographics. For the usability issues, audio transcripts are used to identify usability issues using the following process:

- 1. One researcher from the pilot site identifies all errors in the think-aloud transcripts and observational notes.
- 2. One researcher from RRD creates an overview of usability issues by grouping similar errors into one usability issue (e.g., recurring errors from clicking on non-clickable elements are grouped as 'the user has difficulty distinguishing clickable from non-clickable elements in the interface').



3. The same researcher from RRD assigns each usability issue with a severity score (minor, serious, or critical), following a procedure from (Duh, Tan, & Chen, 2006).

Qualitative analysis was used to analyse the semi-structured interview transcripts.

5.3.1.6 Ethics

The medical-ethical committee of East Netherlands has reviewed this study (reference number 2021-13175) and concluded that it does not fall under the Medical Research Involving Human Subjects Act (WMO). This means that no medical-ethical approval is needed to conduct this study.

5.3.2 Results

5.3.2.1 Demographics

A total of five people with COPD participated in this iteration (all from the GEM site), of which 60% were female and 40% male. The average age of the group was 74.8 years old (SD=8.8). Regarding their highest level of education, one person (20%) finished primary school, and the others trade school (80%). Only one of the participants is working full-time, the others (80%) are retired.

All participants were diagnosed with COPD for more than 6 years and the majority (60%) already more than 10 years ago. Furthermore, all participants did have one or more other chronic conditions (60% had anxiety and depression, 60% had hypertension, 60% had diabetes, 40% had hyperchloremia, and 20% had chronic renal failure).

The health related quality of life of the participants had an average score of 3.4 (SD=1.1), on a scale from 1 (low quality of life) to 5 (high quality of life). Besides that, the health literacy of the participants had an average score of 2.7 (SD=0.6), on a scale from 1 (low health literacy) to 5 (high health literacy).

Regarding digital skills, participants scored their skills an average of 3.4 (SD=1.5), on a scale from 1 (low digital skills) to 5 (high digital skills). All participants use a smartphone, while only one participant also uses a tablet.

5.3.2.2 Chatbot usability scale

The chatbot usability scale gives an overall score of the usability of a chatbot, but also scores about 5 different aspects: perceived accessibility to chatbot functions, perceived quality of chatbot functions, perceived quality of conversation and information provided, perceived privacy and security, and time response. The scale of the scores is between 1 (poor usability) and 5 (best usability).

Overall, the app scored an average of 3.6 (SD=0.3). Regarding the different aspects, the scores were:

- Perceived accessibility to chatbot functions \rightarrow 3.6 (SD=0.9)
- Perceived quality of chatbot functions \rightarrow 3.9 (SD=0.1)
- Perceived quality of conversation and information provided \rightarrow 3.6 (SD=0.3)
- Perceived privacy and security \rightarrow 2.8 (SD=0.4)
- Perceived time response \rightarrow 3.4 (SD=0.5)

This shows us that the Healthentia app scored best on the perceived quality of the chatbot functions, and lowest on the perceived privacy and security. However, all scores were mediocre. This means that the usability of the virtual coach within Healthentia can be improved.

5.3.2.3 Usability issues

During the performed tests, no usability issues occurred with the Healthentia app.



5.3.2.4 User experience interview

During the interviews, the participants only made small comments about their use of the Healthentia app. These comments were as follows:

- Positive feedback on using the app; the person is currently already carrying out physical activity on their own, so they find the virtual coach's messages useful.
- They find the use of the virtual coach useful, especially for monitoring their symptoms related to anxiety and depression.
- Caregiver found it useful for the person with COPD: it also suggests support for those who assist patients, because it is emotionally tiring to look after a relative with COPD.
- Useful tool: It's useful to have a virtual coach who encourages you!
- A little difficult to understand how it works, but overall useful!



6. Iterative development of the Active Support Programme for healthcare professionals

6.1 Final usability test of the clinical dashboard (March 2024 – April 2024)

The eighth iteration of end-user studies focuses on assessing the usability of the clinical dashboard before starting with the evaluation study. For this, in all three pilot sites (the Netherlands, Italy, and Estonia) healthcare professionals were asked to participate in this one-time usability test. This section describes the results of this iteration.

6.1.1 Methods

6.1.1.1 Study design

To answer our objective, we conducted a usability test within all three pilot sites: the Netherlands, Italy and Estonia. Participants were asked for a single usability evaluation session in a lab setting. The participants had to complete seven tasks. These tasks reflected the most important functionalities of the clinical dashboard. The execution of these tasks was accompanied by a think-aloud protocol, the measurement of task metrics (task completion, time on task, task satisfaction), and the moderator wrote down the usability issues that occurred during the task performance. Afterwards, the participants needed to complete one questionnaire, the HUBBI (Broekhuis & Van Velsen, 2022). Each session concluded with a short semi-structured interview. All participants provided informed consent prior to participation. An overview of the protocol of this study can be found in *Appendix F: Final protocol for final usability test of clinical dashboard*.

6.1.1.2 Participants

For this usability test of the clinical dashboard, we focused on including healthcare professionals working with the RE-SAMPLE technology during the clinical evaluation in WP7. We aimed to include 5 healthcare professionals per pilot site.

6.1.1.3 Study parameters

The study parameters were: number of usability issues, task metrics, usability benchmarking score and user experience.

Number of usability issues: the elicitation of usability issues is considered one of the most important elements in usability testing. It provides a list of identified usability issues that need to be addressed before the implementation of the system. These usability issues often are joined with a severity score, to prioritise the issues that are most important to solve. Usability issues are collected via a think-aloud protocol, in which participants verbalise their thoughts, and moderator notes during the usability test. Each usability issue is given a severity score using the index of Duh et al. (Duh, Tan, & Chen, 2006) that distinguishes three severity levels:

- A **minor** usability problem occurs infrequently among the participants and/or the problem only increases task completion time slightly;
- A **serious** usability problem occurs frequently among the participants and/or the problem severely increases task completion time;
- A **critical** usability problem occurs when all participants have the same problem and/or the problem prevents participants from completing tasks.

Task metrics: usability task metrics are one of the most objective measures to get an indication of the system's usability. It measures how well a participant performs on a task. In this study, we measure the following task metrics: task completion, time on task, and task satisfaction. *Task completion* is measured by whether the participant completes the task or not. *Time on task* is measured in seconds and *task satisfaction* with the After-Scenario Questionnaire (ASQ), a three-item questionnaire (Lewis, 1991).



Usability benchmarking scores: usability benchmarking is necessary to get a general indication of the system's usability. In this study, this will be measured by the HUBBI (Broekhuis & Van Velsen, 2022). We slightly adapted the HUBBI to enable its use for the clinical dashboard. This HUBBI comprises sixteen items in which users have to score each statement on a 5-point Likert scale ranging from strongly disagree to strongly agree.

User experience: user experience was measured with a short semi-structured interview with each participant.

6.1.1.4 Study procedure

Before participation, each participant filled in an informed consent form. Then, the usability test commenced. First, participants received the demographics questionnaire. Then, they received information about the think-aloud protocol. Next, a concurrent think-aloud protocol was administered in which they were given seven tasks to complete within the clinical dashboard while verbalising their thoughts. These tasks were:

- 1. It is time for a weekly check of the status of your patients! Start with patient test001. Are there any alerts for this patient in the past week? If yes, what alert is there? Tell your answer to the researcher.
- 2. Now go to patient test002. Check the medical actions that are suggested in the past week by the action plan of the patients. Which medical actions are suggested? Tell your answer to the researcher.
- 3. For patient test003 a new goal needs to be set for physical activity. Please start a shared decision making process and follow the steps to decide together on a daily step goal. Change the daily step goal to a number you think is suitable.
- 4. Patient test001 will come in for a 6-month follow-up visit today. Check the questionnaire answers of this patient with a focus on changes of symptoms. Did the symptoms of this patient change in the last four week? If yes, what changes are there? Tell your answer to the researcher.
- 5. Check for patient test002 whether there are any risk predictions regarding severe exacerbation. If so, what percentage of probability of severe exacerbation is given there? Tell your answer to the researcher.
- 6. Have a look at the explanation for today's prediction (any exacerbations) of patient test002. What are the main risk factors? Should the goal setting or the treatment be adjusted based on this information?
- 7. Have a look at the simulations regarding BMI of patient test002. Would a higher or lower value lower the patient's risk for an exacerbation? Should the goal setting be adjusted based on this information?

After each task, the participants were given the ASQ to measure task satisfaction. After carrying out all tasks, they filled out the HUBBI. Last, a short semi-structured interview was conducted to discuss participants' experience with the clinical dashboard. The general procedure can be found in *Appendix F: Final protocol for final usability test of clinical dashboard*.

6.1.1.5 Data analysis

Descriptive statistics (frequency, mean, percentages) are computed for the demographics and the task metrics. For the usability issues, audio transcripts are used to identify usability issues using the following process:

- 1. One researcher from the pilot site identifies all errors in the think-aloud transcripts and observational notes.
- 2. One researcher from RRD creates an overview of usability issues by grouping similar errors into one usability issue (e.g., recurring errors from clicking on non-clickable elements are grouped as 'the user has difficulty distinguishing clickable from non-clickable elements in the interface').



3. The same researcher from RRD assigns each usability issue with a severity score (minor, serious, or critical), following a procedure from the following reference (Duh, Tan, & Chen, 2006).

Qualitative analysis was used to analyse the semi-structured interview transcripts.

6.1.1.6 Ethics

The Medical Research Ethics Committee (MREC) of East Netherlands has reviewed this study (reference number 2021-13175) and concluded that it does not fall under the Medical Research Involving Human Subjects Act (WMO). This means that no medical-ethical approval is needed to conduct this study.

6.1.2 Results

Before starting with the usability test of the clinical dashboard, researchers from MST site conducted the usability test of the clinical dashboard as well. Based on their testing, the protocol was slightly adapted as well as the clinical dashboard.

6.1.2.1 Demographics

A total of 6 participants took part in this study, 3 from the GEM site and 3 from the TUK site. Of those, 2 (33.3%) were male and 4 (66.7%) were female participants. The average age was 41.7 (SD=14.4) years. Half of the participants were working as pulmonologists and the other half were in residency or specialising in pulmonology. On average, the participants had 14.7 (SD=13.6) years of work experience in healthcare. 50% see COPD patients daily, 33.3% see COPD patients weekly, and 16.7% see COPD patients monthly. Furthermore, 50% had experience with eHealth (electronic health records). Finally, most thought eHealth is useful (50%) or very useful (33.3%), and one participant (16.7%) thought it could be useful at times. No one thought that eHealth is not useful at all.

6.1.2.2 Usability issues

A total of 30 usability issues were identified. After deduplication (participants who had similar issues), there remained 17 unique usability issues left: 12 minor issues, 3 serious issues and 2 critical issues.

Minor issues are issues that happen infrequently across participants or do not have a large effect on task completion time, for example, because participants find a workaround or find out quickly the correct procedure. It does not prevent the user from completing his or her task. The identified minor issues were:

- Patient list did not open on the first trial.
- Red dot behind the "Alerts" drags attention, however no acute alerts could be seen.
- It is difficult to find the right items in general.
- The shared decision making tool was not found.
- Subject overview page could be more logically structured.
- It is not clear why risk estimations should be part of hospital data.
- In SDM open questions and shortlist for answers do not match.
- SDM process is more a general description of the procedure than practical aid, it does not lead to the concrete shared decision.
- It was not possible to delete the first number in the upper limit box when setting a step goal. It was possible to enter 70 000 but not 8000.
- Priority in immediately identifying the patient with a high alert in the dashboard.
- It was difficult to view the alerts.
- It was difficult to select questionnaires.

Serious issues are issues that occur often or have a serious impact on task completion time. The user is however able to complete the task within the allocated time. The identified serious issues were:

- Different date formats are used, which is confusing.



- The SDM-process is a bit long and complex, there is a risk of missing the steps. It is difficult to enter the goal linked to physical activity and send the SDM evaluation questionnaire.
- It is unclear where to find whether a patient has an exacerbation.

Critical issues are issues that happen to all participants or prevent the user from completing the task. The identified critical issues were:

- The risk prediction figures are incomprehensible.
 - o E.g.: This level of predictivity is a statistical index, how useful is it to the patient?
 - o E.g.: It is not possible to understand what parameters have been used to the risk prediction estimate
 - o E.g.: Time progression on graphs is not always from left to right.
- In the current format it is complicated to track the dynamics/meaning of the questionnaire answers.
 - E.g.: It is unclear what a specific score means. Without explanations, it does not say anything.

6.1.2.3 Usability benchmark HUBBI

The HUBBI provided an overall score of 3.1 on a 1-5 scale. However, it also provides a score per subdimension: basic system performance (i.e., no crashes, errors), task-technology fit (suitable for the user, context, health goals), interface design (i.e., visibility, readability, lay-out), navigation & structure (i.e. understanding of system elements and awareness of location within system), information & terminology (i.e. understandability of medical and non-medical terminology), guidance & support (i.e. error support, sufficient feedback) and satisfaction (i.e. satisfaction with system and support towards health goals). Figure 10 shows the scores per subdimension. All scores in the green field indicate that that part is good, yellow means okay but can be improved and light red or red means that aspect of the usability is bad. None of the dimensions are considered good. The dimensions are all in the yellow part, light red part or in between those parts. This shows that the usability of the clinical dashboard can be improved on all of these dimensions, especially interface design and guidance & support scores badly and needs to be adapted.

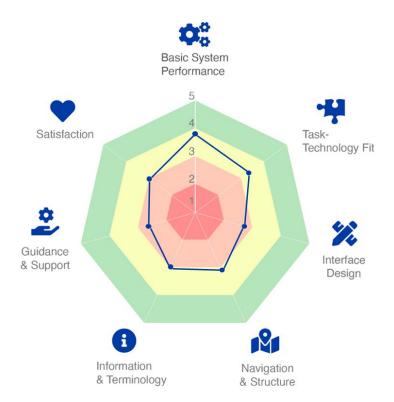


Figure 10: HUBBI dimensions of clinical dashboard according to healthcare professionals.



6.1.2.4 Task performance

All participants had to complete seven tasks. The easiest task was task 1, which all participants were able to complete. The average completion time was below 1.5 minutes. The task satisfaction was 4.7, which is lower than expected since all participants were able to complete the task quite fast. The most difficult tasks were tasks 2, 3 and 6. Only three participants were able to complete these tasks. Table 6 provides a complete overview of the task performance scores per task.

Table 6: Task performance scores.

Task	n	Task completion rate (%)	Av. task completion time (sec.)	Task satisfaction (N=6)
Task 1: Alerts	6 out of 6	100%	82.0	4.7
Task 2: Medical actions	3 out of 6	50%	60.0	3.6
Task 3: Steps	3 out of 6	50%	239.3	3.1
Task 4: Change of symptoms	3 out of 6	50%	100.0	3.2
Task 5: Risk predictions	5 out of 6	83.3%	107.2	4.2
Task 6: Risk factors	3 out of 6	50%	60.0	3.4
Task 7: BMI	5 out of 6	83.3%	59.6	3.9

6.1.2.5 User experience interview

After conducting all 7 tasks, participants were shortly interviewed about their opinion regarding the clinical dashboard. The HCPs thought the clinical dashboard could be helpful one day, depending on how real-time data can be used during the care process. It also needs some interface polishing to have a clearer overview. When asking whether the clinical dashboard was easy to use in general, the HCPs had different views. For some it was easy to use, for the others it was not. For the last one, it was difficult to find the right place, there is too much information. But they did mention that with time and practice it will become easier to use.

The appearance of the clinical dashboard in general was okay. It could be improved. For example, the whole text was sometimes not visible, or too small. Another important improvement point mentioned was the risk predictions part. The following aspects were mentioned about this part of the clinical dashboard:

- The symptoms of COPD and heart failure seem to move in parallel. How to distinguish between exacerbation of heart failure and exacerbation of COPD in this situation?
- In exacerbation modelling, it is difficult to understand the red/blue scale. This is not intuitively obvious. Online help that explains the graph would be needed.
- In AI prediction graph the red/blue should be switched. Red should always mean negative and blue positive.
- The data are illogically structured, like risk prediction under the tab hospital data.
- The level of predictivity is a statistical index, how useful is it to the patient?

Regarding the shared decision making tool, HCPs mentioned that the process is a bit long and complex, which creates the risk of missing a particular step.

In general, the clinical dashboard can support the HCPs in their work with (some) people with COPD, if all of the relevant data are directly visible in one main page. For example, directly identifying which patients have an alert when opening the dashboard. The HCPs were willing to use the clinical dashboard.



7. Extra investigations into the patient perspective by students

Within the RE-SAMPLE project, we have supervised students who explored the patient perspective even further. We communicated these insights within the RE-SAMPLE consortium. First of all, one master student investigated how the design of a self-management tool for COPD patients could be optimised to create an intuitive and accessible user interface that promotes engagement, usability and positive user experience, while considering the specific needs and preferences of people with COPD. Secondly, another master student investigated how an engaging eHealth technology powered by artificial intelligence that supports self-management needs to be designed with value sensitive design.

7.1 Breathless Battles: The Optimisation of an eHealth Application for Support in Self-Management for COPD Patients with Complex Chronic Conditions through Human-centred Design (March 2022- November 2023)

Abstract

COPD is a progressive lung disease that makes it difficult to breathe. There is no cure for COPD, but it is possible to manage the symptoms and slow the progression of the disease. Self-management of the disease and symptoms is an essential part of treatment. COPD patients often have difficulty understanding and managing their disease.

The objective of this thesis was to optimise a self-management tool for COPD patients called Healthentia by improving its intuitiveness and accessibility and by doing so promoting the aspects of engagement, usability and a positive user experience. This was done by Human Centered Design principles. First, the context of use was defined in a usability report. Second, this usability report was used for the ideation phase. New concepts and ideas for Healthentia were created and evaluated here, which led to the final proposed prototype. At last, this prototype was evaluated through a usability test with COPD patients.

Four main findings emerged. Firstly, the multifaceted nature of user satisfaction and engagement was highlighted. Notably, the completion time did not seem to influence user satisfaction and engagement, but rather the COPD patients' confidence and ease of navigation in the Healthentia prototype. Secondly, a clear distinction was found between the needs of inexperienced and experienced COPD patients. Experienced patients acknowledge the potential value of the Healthentia prototype for inexperienced COPD patients. However, this still needs to be validated with inexperienced COPD patients and unfortunately, the optimised prototype's precise utility for experienced COPD patients remains unclear. Thirdly, using a well-established design system as a building block for the optimisation of a health tool does not guarantee optimal usability for every target group. Especially for elderly target groups, which have their unique needs for digital tools. Lastly, it was shown how Human Centered Design could be optimised for COPD patients and how this can be used in future studies with this target group.

To conclude, this thesis used a holistic approach to optimise the self-management tool Healthentia for COPD patients. The insights gained from this research contribute valuable knowledge for design and usability considerations of digital health tools tailored to the specific needs of COPD patients.

The full version of this thesis can be found through the following link: http://essay.utwente.nl/97680/.

7.2 Increasing effective engagement in eHealth for COPD self-management through Value Sensitive Design (Sept 2022 – May 2023)

Abtract

People living with COPD and other complex chronic conditions would benefit from increased self-management of their disease, as this can slow down the progression of the disease and may prevent hospitalisations. A new European project called RE-SAMPLE aims to realise this goal through provision of virtual coaching driven by Artificial Intelligence in an app. The research described in this thesis investigates how to reach effective engagement of the patient in using this eHealth tool to improve their self-management, to ultimately improve their quality of life.



Value Sensitive Design is applied to identify and define the values that are most important to the target group. Furthermore, Capability Sensitive Design is used to complement Value Sensitive Design with an ethical theory. Connecting the capabilities that follow from Capability Sensitive Design to the values in the value hierarchy ensures consistency and completeness of the hierarchy. Next, the key values are used to define extreme user personas, to make the system as inclusive as possible. After the concept development, the conclusions of the analysis and the concepts are evaluated by six patients during a workshop. From this evaluation workshop it is concluded that the expansion concept scored best on the key values for effective engagement. In the recommendations, a concept proposal and guidelines are provided for further development of the eHealth tool.

The evaluation is limited as the participants are not the extreme users of the system. Therefore, future research should include developing a prototype for the proposed concept and conducting more elaborate user testing. Also, for validation and optimisation of the system, it should be tested by people who are struggling with technology and self-management of their disease. From this research it can be concluded that an iterative and participatory design process, alongside a thorough analysis of the patient values and capabilities, contributes to the engagement of users in the eHealth technology.

The full version of this thesis can be found through the following link: http://essay.utwente.nl/94876/.



8. Conclusions

This deliverable presented the end-user involvement activities carried out from M24 until M39. It described the changes we made in RE-SAMPLE's end-user panel, the continuous end-user feedback, the results of three iterations of end-user studies with patients, the results of one iterations of end-user studies with HCPs, and the results of two extra investigations into the patient perspective by master students.



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Appendices

Appendix A: Introductory surveys end-user panel

Person with COPD

RE-SAMPLE - Registration end-user panel (patient)

Start of Block: Introduction and Informed Consent

This questionnaire is part of the European project <u>RE-SAMPLE</u>. The purpose of RE-SAMPLE is to develop eHealth applications that support patients and healthcare professionals. This technology will help patients to manage COPD and complex chronic conditions. You receive this questionnaire, because you signed up for our <u>end-user panel</u>. As explained, with this questionnaire we want to know a bit more about you, because sometimes we are looking for a specific group of people for our studies. When we have prepared a study fitting your answers, we will contact you about this via e-mail.

Participation

Completing this survey will take you approximately 15 minutes. Participation in the questionnaire is entirely voluntary. You can quit with the questionnaire whenever you want. You do not need to fill in a reason for this. You can stop by closing the tab or window of this survey. Only responses from completed questionnaires will be used in this study.

Privacy protection and processing of your data

The data in this questionnaire will be collected without your name and contain no personal data that can be traced back to you. The answers you give will only be used as part of the RE-SAMPLE project and processed by researchers at Roessingh Research and Development.

The privacy regulations that are applied to all research conducted at Roessingh Research and Development can be found here http://www.rrd.nl/en/privacy-declaration/. If you have any questions about this survey, please contact your contact person mentioned in the e-mail.

Statement of Consent

○ I agree to participate in this study. I hereby declare that I have read the information on the study. I understand that my data will be anonymised and may be used for scientific publications. I voluntarily participate in this study and know that I can stop my participation at any time. (1)
End of Block: Introduction and Informed Consent
Start of Block: Demographics
The first questions are related to general demographics.
Q1 Which e-mail address did you use for signing up for the RE-SAMPLE end-user panel?



Q2 Which country do you live?
O The Netherlands (1)
O Italy (2)
O Estonia (3)
Other, please specify: (4)
Q3 What is your gender?
O Male (1)
O Female (2)
O Prefer to self-describe: (3)
Q4 What is your year of birth? ▼ 1900 (1) 2003 (104)
Q5 What is the highest degree or level of education you have completed?
O Primary School (1)
O High School (2)
O Trade School (3)
O University (4)
Other, please specify: (5)

Q6	What is you	r employment status?	
		Full time employment (1)	
		Part time employment (2)	
		Seeking opportunities (3)	
		Retired (4)	
		Unable to work (5)	
		Voluntary work (6)	
		Other, please specify: (7)	
Q7	Q7 How many family members do you live together with?		
	0 (1)		
	O 1 (2)		
	O 2 (3)		
	O 3 (4)		
	O 4 (5)		
	O more th	nan 4 (6)	
En	d of Block:	Demographics	

Start of Block: COPD Background

Q8 \$	Q8 Since when do you have COPD?		
	C Less than 1 year (1)		
	1-2 years (2)		
	3-5 years (3)		
	O 6-10 years (4)		
	11-20 years (5)		
	omore than 20 years (7)		
	O I don't k	know. (8)	
Q 9 1	Q9 Besides COPD, what other conditions do you have?		
		Diabetes (1)	
		Chronic heart failure (2)	
		Heart disease (3)	
		Anxiety (4)	
		Depression (5)	
		Other, please specify: (6)	
		None (7)	
Q 10	Q10 What do you know about COPD?		
	I believe I know everything on this topic (1)		
	O I know	as much as I need to know (2)	
	○ I know too little (3)		
	O I do not	know and I do not want to know (4)	



Q11 How much does your health affect your daily activities (e.g. work, study, housework, family or hobbies)?
1: I have no problems with performing my daily activities (1)
2: I have small problems but can perform all my daily activities (2)
3: I have some problems and performing all my daily activities takes a lot of effort (3)
4: I have many problems and therefore I cannot perform al my daily activities (4)
5: I am unable to perform my usual activities (5)
End of Block: COPD Background
Start of Block: COPD experience and self-management
Q12 When your complaints worsen or when you experience a lung attack, do you feel this coming?
○ Yes (1)
O No (2)
Display This Question:
If $Q12 = 1$
Q13 How do you feel that coming? How do you know?
Display This Question:
If Q12 = 1
Q14 What do you do when you feel it coming?



thara anything	g you struggle with a	ot that paint?		
mere anymmig	g you struggte with a	u mai pomi:		
re there any ev	ents in which you k	now for yourself	your complaints	will worsen?

		any activities that you perform to prevent a worsen eneral to make your feel better? (You can enter multi	
_		Physical exercise, like: (1)	
-		Mental exercise, like: (2)	
-		Lifestyle adaptions, like: (3)	
-		Social activities, like: (4)	
-		Other, please specify: (5)	
1	make me fe	No, I do not perform any activities to prevent a wor eel better. (6)	sening of my complaints or to
Q19	What activ	vities do you know that could improve your health?	
		th COPD often means trying out what works for you a nen living with COPD that you would have wished to	
Q21	If you cou	ald wish for anything that would help you controlling	your COPD, what would that be?



Q22 Who or what gave you the most useful information for coping with the disease?				
Conversation with the doctor (1)				
O Conver	O Conversation with the nurse (3)			
O Conver	O Conversation with another COPD patient (4)			
O Books, leaflets (5)				
Cartelevision, Internet (6)				
Other,	Other, please specify: (7)			
End of Block:	COPD experience and self-management			
Start of Block	: RE-SAMPLE			
Q23 Which ste choose several)	eps within the RE-SAMPLE project seems interesting to you to think about? (you can			
	Data collection (e.g. complaints, questionnaires) (1)			
	User-friendliness of a programme on a mobile phone (2)			
	Measurements with patients (e.g. lung function, blood sampling) (3)			
	Communication with patients (e.g. recruitment, sharing results) (4)			
	Development of tailored care (personalised support with the disease) (5)			
	Implementation of tailored care (6)			
	Privacy: protection of patient data (7)			
	Other, please specify (8)			
End of Block:	RE-SAMPLE			



Start of Block: Technology use

Q24 Whic	h of the following communication devices do you use? (you can choose several)
	Smartphone (1)
	Tablet (2)
	Laptop (3)
	None of these devices (4)
	Other, please specify: (5)
-	ou use any devices to measure your health? (e.g. smartwatch to measure your steps, sleep tygen or your heartrate?)
	Smartwatch (1)
	Oximeter (2)
	Activity Tracker (e.g. Pedometer) (3)
	Smartphone App (4)
	None (5)
	Other, please specify: (6)
	ou use any apps or programs on your phone to measure your health at the moment? (E.g. an acourages you to exercise)
ON	o (1)
O Ye	es, namely: (you can enter multiple apps) (2)
End of Blo	ock: Technology use
Start of Bl	ock: Digital literacy



Q27 I think that my level of digital skills (like the use of smartphone, tablet, laptop) is as follows:
1: really low (1)
O 2: low (2)
○ 3: average (3)
○ 4: high (4)
5: really high (5)
End of Block: Digital literacy
Start of Block: Health literacy
Q28 How often do you experience problems understanding texts (such as leaflets) about your health or an illness?
O Never (1)
O Few (2)
O Sometimes (3)
Often (4)
O Always (5)
Q29 How much confidence do you have when you fill out medical forms?
O No confidence at all (1)
A little confidence (2)
Reasonable confidence (3)
O Much confidence (4)
O Very much confidence (5)



Q30 How often does someone help you to read information leaflets, forms or letters pharmacy or your General Practitioner (GP)?	from the hospital,
O Never (1)	
O Seldom (2)	
O Sometimes (3)	
Often (4)	
O Always (5)	
End of Block: Health literacy	
Start of Block: Reason participation	
This is the last question of this questionnaire.	
Q31 Why did you sign up for our RE-SAMPLE end-user panel?	
	-
	-
	_
	-
End of Block: Reason participation	



RE-SAMPLE - Registration end-user panel (healthcare professional)

Start of Block: Introduction and informed consent

This questionnaire is part of the European project <u>RE-SAMPLE</u>. The purpose of RE-SAMPLE is to develop eHealth applications that support patients and healthcare professionals. This technology will help patients to manage COPD and complex chronic conditions. You receive this questionnaire, because you signed up for our <u>end-user panel</u>. As explained, with this questionnaire we want to know a bit more about you, because sometimes we are looking for a specific group of people for our studies. When we have prepared a study fitting your answers, we will contact you about this via e-mail.

Participation

Completing this survey will take you approximately 5 minutes. Participation in the questionnaire is entirely voluntary. You can quit with the questionnaire whenever you want. You do not need to fill in a reason for this. You can stop by closing the tab or window of this survey. Only responses from completed questionnaires will be used in this study.

Privacy protection and processing of your data

The data in this questionnaire will be collected without your name and contain no personal data that can be traced back to you. The answers you give will only be used as part of the RE-SAMPLE project and processed by researchers at Roessingh Research and Development.

The privacy regulations that are applied to all research conducted at Roessingh Research and Development can be found here http://www.rrd.nl/en/privacy-declaration/. If you have any questions about this survey, please contact your contact person mentioned in the e-mail.

Statement of Consent

I agree to participate in this study. I hereby declare that I have read the information on the study. I understand that my data will be anonymised and may be used for scientific publications. I voluntarily participate in this study and know that I can stop my participation at any time. (1)
End of Block: Introduction and informed consent
Start of Block: Demographics
The first questions are related to general demographics.
Q1 Which e-mail address did you use for signing up for the RE-SAMPLE end-user panel?



Q2 Which country do you live?					
O The Netherlands (1)					
O Italy (2)					
O Estonia (3)					
Other, please specify: (5)					
Q3 What is your gender?					
O Male (1)					
O Female (2)					
O Prefer to self-describe: (3)					
Q4 What is your year of birth? ▼ 1900 (1) 1998 (99)					
Q5 What is the highest degree or level of education you have completed?					
O Primary School (1)					
O High School (2)					
○ Trade School (3)					
O University (4)					
Other, please specify: (5)					

Q6	What is yo	our employment status?	
		Full time employment (1)	
		Part time employment (2)	
		Voluntary work (3)	
		Other, please specify: (4)	
Q7	What is yo	our profession?	
	O Physic	cian, please specify specialism: (1)	
	O Nurse	e, please specify department + role: (2)	
	O Param	nedic, please specify which: (3)	
En	d of Block	: Demographics	
Sta	rt of Blocl	k: Reason participation	
Thi	s is the last	t question of this questionnaire.	
Q8	Why did y	ou sign up for our RE-SAMPLE end-user panel?	
En	d of Block	: Reason participation	



RE-SAMPLE - Registration end-user panel (other)

Start of Block: Introduction and informed consent

This questionnaire is part of the European project <u>RE-SAMPLE</u>. The purpose of RE-SAMPLE is to develop eHealth applications that support patients and healthcare professionals. This technology will help patients to manage COPD and complex chronic conditions. You receive this questionnaire, because you signed up for our <u>end-user panel</u>. As explained, with this questionnaire we want to know a bit more about you, because sometimes we are looking for a specific group of people for our studies. When we have prepared a study fitting your answers, we will contact you about this via e-mail.

Participation

Completing this survey will take you approximately 5 minutes. Participation in the questionnaire is entirely voluntary. You can quit with the questionnaire whenever you want. You do not need to fill in a reason for this. You can stop by closing the tab or window of this survey. Only responses from completed questionnaires will be used in this study.

Privacy protection and processing of your data

The data in this questionnaire will be collected without your name and contain no personal data that can be traced back to you. The answers you give will only be used as part of the RE-SAMPLE project and processed by researchers at Roessingh Research and Development.

The privacy regulations that are applied to all research conducted at Roessingh Research and Development can be found here http://www.rrd.nl/en/privacy-declaration/. If you have any questions about this survey, please contact your contact person mentioned in the e-mail.

Statement of Consent

O I agree to participate in this study. I hereby declare that I have read the information on the study. I understand that my data will be anonymised and may be used for scientific publications. I voluntarily participate in this study and know that I can stop my participation at any time. (1)
End of Block: Introduction and informed consent
Start of Block: Demographics
The first questions are related to general demographics.
Q1 Which e-mail address did you use for signing up for the RE-SAMPLE end-user panel?



Q2 Which country do you live?					
O The Netherlands (1)					
O Italy (2)					
O Estonia (3)					
Other, please specify: (5)					
Q3 What is your gender?					
O Male (1)					
O Female (2)					
O Prefer to self-describe: (3)					
Q4 What is your year of birth? ▼ 1900 (1) 1998 (99)					
Q5 What is the highest degree or level of education you have completed?					
O Primary School (1)					
O High School (2)					
O Trade School (3)					
O University (4)					
Other, please specify: (5)					

Q6	What is you	ur employment status?	
		Full time employment (1)	
		Part time employment (2)	
		Voluntary work (6)	
		Other, please specify: (7)	
pati	ent nor a h	ar sign up process for our RE-SAMPLE end-user panel, you indicated you nealthcare professional. Please specify in the textbox beneath your roner of COPD patient, hospital department manager)	
End	l of Block:	Demographics	
Sta	rt of Block	: Participation reason	
This	s is the last	question of this questionnaire.	
Q8	Why did yo	ou sign up for our RE-SAMPLE end-user panel?	
End	l of Block:	Participation reason	



Appendix B: Summaries shared with stakeholders

Summary end-user walkthrough

RE-SAMPLE is a European project that focuses on people who are living with COPD. The goal of RE-SAMPLE is to develop a technology that will support patients and caregivers. This technology will help patients manage their COPD and other chronic conditions.

At the beginning of 2022, a study was conducted to investigate the acceptance of the eHealth technology within RE-SAMPLE early in the development process. In the study, we conducted so called 'end-user walkthroughs' by which participants are guided through the future use of the technology and presented with personas, scenarios and a simple prototype.

1. End-user walkthrough

By conducting this study, we have collected a lot of useful information about the attitudes and acceptance of the prototypes and received useful feedback whether the prototypes were understandable. This is important to know early on because then we can improve the design to make them better and more useful for future users. In the following we will briefly summarise the main outcomes of the study.

The end-user walkthroughs were carried out in person with 20 people with COPD in Italy and the Netherlands, and through an online survey with healthcare professionals.

During the in-person sessions with patients, we introduced a persona of a patient with COPD, which is a fictional description that we created based on what we learned from previous meetings with patients. We also presented scenarios, which are stories about how that person will use the RE-SAMPLE technology and showed them how certain parts of the technology would look like. For this, we used a prototype. After patients looked at this, we asked them a couple of questions. We first asked them to answer this question from the perspective of the persona. But as they are also living with COPD and may differ from that persona, we also asked what they thought about this from their perspective. This led to many interesting results.

In addition, 48 healthcare professionals filled in the online survey. They mainly gave feedback on what the technology needs to look like to support healthcare providers, and in particular, what data must be included in the technology, so they are able to monitor and guide their patients.

2. People with COPD

We learned a lot from the patients who participated in this study. The participants' impressions of the prototypes varied a lot. Some of the screens were perceived as somewhat unclear, because the language used was difficult to understand or contained English terms for example. This is something that should be changed to make it understandable for everyone.

3. Positive features

One feature that was included in the scenario was coaching. Participants got to see a conversation between the persona and a virtual coach. This coach asked a few questions regarding the current struggles of the persona. Based on the responses given, the virtual coach recommended education or coaching modules (for example on energy management) that would fit the need of the persona.

Participants appreciated the feature of coaching because they are currently missing certain specific information about possible activities. For example, what they could do to manage their energy levels. This could help them manage their health better. However, how the virtual coach acts, must be aligned with the needs of the patient, otherwise they will not use it. For example, the coach should not ask too much from a person who does not like to get asked questions all the time.



Another feature of the technology was the 'symptom diary', where patients can document their symptoms and get an overview with 'trends and progress'. That way, patients can see a visualisation of their health data and how they are doing overtime. Participants in our study perceived this as positive and thought this would encourage them to pay attention to their daily activities.

Finally, the prototype also included 'peer to peer' support which supports the connection between patients. Participants were very positive about the possibility of contacting other people with COPD. While not everyone would want to use that for themselves, participants all agreed that many people with COPD could benefit from contact with others who understand their situation.

4. Recommendations

Many useful recommendations were provided, which help us to make the RE-SAMPLE technology more useful and valuable. For example, it was mentioned that there must be a feature so that people can be forwarded for their behaviours that contribute positively to their health. This can help to make people aware of the positive behaviours and encourage them to continue to do so. In addition, it was also mentioned that there should be more information in the technology. For example, about the possible activities and exercises that one can perform to stay active.

Another important result was that the technology should motivate but not force certain things. People with COPD should be able to make their own choices about what and how to use the technology and should be free to do so without a technology constantly trying to impose certain actions. In addition, some people with COPD indicated that the daily use of the technology would constantly remind them of their COPD condition. This is something they did not want.

5. Healthcare professionals

The results of the survey with healthcare professionals showed that most participants found the prototypes very clear, useful and insightful. It was indicated that it is nice to have an overview of different data of the patient. Although a number of different data types were shown in the prototype, some healthcare professionals indicated that they still missed some data, e.g. nutrition saturation, lung measurements and physical activity. In addition, it was also recommended that the most important data of the patients should be merged in one screen. Healthcare professionals indicated that there are currently too many tabs open, so that a lot of time is lost when looking through everything.

Although several possible areas for improvement were mentioned, participants were positive about the future RE-SAMPLE technology and the possible benefits it brings. The results of this study showed again how valuable it is to involve future users in the development process of a technology. We again learned a lot from participants, which will help us to develop RE-SAMPLE in such a way that really supports healthcare professionals and people living with COPD in their daily care.

6. What's next?

What's next?

The development of the RE-SAMPLE solution is ongoing, and we will continue to involve end-users so that we get feedback at different points in time. Only then we can make sure that we understood well what people need and that our technology is well developed.

Would you like to be involved and think along with the RE-SAMPLE project? Please feel free to contact us!

Thank you for your time and attention, The RE-SAMPLE team of Roessingh Research and Development



Summary interviews about health data monitoring, risk prediction and virtual coaching

RE-SAMPLE is a European project that focuses on people with COPD. The goal of RE-SAMPLE is to develop a technology that supports patients and caregivers. This technology will help patients manage their COPD and other chronic conditions.

In the end, we want that RE-SAMPLE is useful and will be used in practice. But how should the RE-SAMPLE technology communicate with people with COPD? To answer this, we asked people with COPD to take part in an interview. In this interview, we focused on utilisation of health data, on risk predictions and on the use of a virtual coach.

1. Study method

Roessingh Research and Development (RRD) developed an interview guide which we used in three countries: in the Netherlands, Italy and Estonia. This was very important, because there could be differences between cultures. In total, 21 people with COPD participated in the interviews.

2. Data utilisation

We started the interviews with asking the people with COPD whether they agree or disagree with four statements. We found different opinions between the different countries on one statement. In all countries, most people agreed with the statements on the left, that gathering your own health data is important to monitor complaints, and that it is important to have access to their health data gathered by their healthcare professionals. Furthermore, in all countries most thought it is not difficult to receive the requested health data from their healthcare professional.

However, when we look at the statement on the top right of your screen, we found differences. In the Netherlands, most people disagreed: they don't necessary trust the health data received from their healthcare professionals more than the health data gathered by themselves. They have the same trust in the data gathered by their healthcare professionals and the data gathered by themselves.

When we go to Italy, we see that most agreed with this statement. They do trust the health data from their healthcare professional more than their own.

And in Estonia, half of the people agreed and the other half disagreed with this statement. The reason why people agreed with the statement was because the healthcare professionals are the experts. And the ones who disagreed have the same trust in the data gathered by healthcare professionals and gathered by themselves.

3. Monitoring health

In the second part of the interview we showed the participants several mock-ups of how the future RE-SAMPLE technology could look like. We asked them to go through those mock-ups and give us feedback about this. In all countries, the first impression of most people was positive. They thought it looks intuitive for collecting health data, it was easy to read, and they also thought that using this technology could improve the visits to the healthcare professional as you can easily share your health data with them. However, they also gave us valuable feedback and ideas which we can use for the development of the actual RE-SAMPLE technology. For example, to add some explanations to figures displaying their health state. Or to also show averages of their physical activity of the past month.

4. Health predictions

After these mock-ups, we continued with the topic of predictions about their health. We asked them how they feel regarding receiving predictions about their health. Opinions were divided. Some people were positive about this as they can learn a lot from this, or can prepare themselves for changing



something. But participants also thought that it is not possible to predict your health. So, they were a bit skeptic as well.

The topics participants wanted to receive predictions about differed across the countries. In all countries, participants wanted to receive predictions about dyspnea and health in general. Furthermore, in the Netherlands they wanted to receive predictions about their age, about weather, about their well-being and about their COPD symptoms in 10 years.

Other topics mentioned during the interviews in Italy were predictions about exacerbations, physical activity and fatigue.

For Estonia, these were also predictions about exacerbations, and furthermore a bad mood and diseases you are prone to.

5. Virtual coaching

The last part of the interviews focused on virtual coaching. Participants received mock-ups of a conversation between the virtual coach and the technology user. They could read this conversation and were then asked for their first impression. They mostly had positive responses and thought the coach could be useful for several goals. For example, for adapting their lifestyle, for improving their mood, for raising awareness about their physical activity.

In the Netherlands, participants did mention that virtual coaching would be specifically beneficial for people newly diagnosed with COPD. The reason for this was that those people have a lot to learn about for example what's good for them and what's not.

6. Thank you!

Although several possible areas for improvement were mentioned, participants were positive about the future RE-SAMPLE technology and the possible benefits it brings. The results of this study showed again how valuable it is to involve future users in the development process of a technology. We again learned a lot from participants, they are the experts when it comes to living with and managing COPD. Their input helps us to develop RE-SAMPLE in such a way that it really supports people living with COPD in their daily care.

7. What's next?

What's next?

The development of the RE-SAMPLE solution is ongoing, and we will continue to involve end-users so that we get feedback at different points in time. Only then we can make sure that we understood well what people need and that our technology is well developed.

Would you like to be involved and think along with the RE-SAMPLE project? Please feel free to contact us!

Thank you for your time and attention,

The RE-SAMPLE team of Roessingh Research and Development



Summary increasing effective engagement in eHealth for COPD self-management through Value Sensitive Design

RE-SAMPLE is a European project that focuses on people with COPD. The goal of RE-SAMPLE is to develop a technology that supports patients and caregivers. This technology will help patients manage their COPD and other chronic conditions.

It is very important that this technology is accessible to all users. But how do we ensure that everyone can use the RE-SAMPLE technology? To find an answer to this, several concepts were developed and presented to people with COPD during an evaluation workshop.

1. Evaluation workshop

During this workshop, the goals when using the technology were first discussed. Followed by the facilitators and barriers of using the app. Then, the most important components of the app were discussed and finally, the three different concepts were assessed.

2. COPD goals

Based on previous interviews, the needs and goals of people with COPD when using technology were analysed. This led to a list of 10 goals, for example, minimalizing disease progression, being stable, being in control over the symptoms and the disease, and accepting the disease and living a positive life.

During the evaluation workshop, the goals were rated by people with COPD on their importance to determine which goals were most important. 'Independence' was rated as most important but other goals also seemed to be important. These goals in using the technology will be used for further development.

3. Facilitators and barriers

Furthermore, we looked at different types of users and what would make using the technology easier or more difficult for them. In doing so, we looked for facilitators and barriers related to trustworthiness, ease of use; supporting independence and emotional well-being.

This has led to an extensive list of facilitators and barriers in the use of the app that can be taken into account in the design process. For trustworthiness, for example, it is important that the nurse looks at the progress in the app together with the patient and that the app does not provide conflicting information.

4. App components

In the third part of the workshop, the different components of the application were ranked. First based on the added value of the components for someone who lives with COPD for several years. Second, for someone who just got diagnosed with COPD.

The most important components were: sharing health information with the doctor, an exacerbation alert, a request to call, and learning to manage and prevent symptoms.

5. Concept evaluation

In the last part of the workshop, the different concepts were evaluated. A couple new ideas were shared about how the technology could look like. Every idea was rated on expectations related to trustworthiness, the usability, increasing the independence, and improving emotional well-being. Finally, participants were asked whether they would use the technology if it would look like this.



The first idea that was shared with the participants was the latest concept developed within the RE-SAMPLE project. On this screen, a weekly overview is presented at the top, with the coach below to ask how the user feels today. Furthermore, there is an overview of open tasks visible, such as reporting today's symptoms; habits, and the weekly report. At the very bottom are options to go to an information library with information about COPD, a network where the user can see how others in their environment are working on achieving their goals, and behind the last option, the profile settings can be adjusted.

The second idea was a newly developed concept, which however was to a large extend the same as the previous one. However, this app has a different home screen. It shows an overview of progress in achieving goals on the screen. This can also be a goal other than the step goal. Furthermore, important values are visible at a glance when opening the app. Other information can be found by clicking on an option at the bottom of the screen. These features can be enabled as soon as the user is ready for it. The features available depend on the person's purpose in using the app, such as how much information they want to see and their expertise in using apps. People with more experience in dealing with COPD can choose to switch on all options immediately.

The last new concept takes into account that not everyone is ready to use a symptom tracking app. That is why the technology in this concept is presented in a digital photo frame instead of a smartphone. This photo frame can be placed somewhere in the house of the user. During the day there are several photos presented of, for example, family, friends or a chosen theme such as nature. At the end of the day, a virtual coach comes into the picture and asks how things are going. By clicking on one of the emojis, the user is directed into a short questionnaire about the symptoms of that day. The next day, certain advice appears into the photo frame in the morning, for example, for starting or maintaining a healthy habit. At the end of the day, after the questionnaire, you will be asked whether the advice has been followed and if not, why not.

From the evaluation of these concepts, it was concluded that the proposal for the app, with a dashboard with the progress of the step goal and quick insight into the heart rate and oxygen content, received the best scores . The participants would prefer to use this technology to support them in learning how to manage their disease. Although the participants were also enthusiastic about the photo frame, this would not support them optimally. The participants were ready to read more information about COPD and would like to be able to use all the functionalities. For people with COPD who have less or no experience with the use of smartphones, the photo frame could still be a nice interim solution.

6. Future research

In future research, it is important that people with COPD remain involved to ensure that the technology is well aligned with their needs. The results of the workshop will be taken into account as guidelines in the further development. As a result of this and other studies, a prototype will be developed and tested by people with COPD to identify new areas for improvement. Only in this way we can ensure that we understand what people need and that our technology is well developed.

7. What's next?

Would you like to be involved and think along with the RE-SAMPLE project? Please feel free to contact us!

Thank you for your time and attention,

The RE-SAMPLE team of Roessingh Research and Development



Appendix C: Study procedure and instruments second iteration end-user study

Study procedure

Phase	Name	Description		
1	eHealth Usability Benchmarking	Administration of HUBBI questionnaire as <i>usability baseline measure</i> 1 week after initial usage. Questionnaire is implemented in Healthentia and will be triggered automatically 7 days after the first log-in into the Healthentia app.		
2	User experience assessment "4 weeks usage"	Administration of questionnaire "UX assessment: 4 weeks after usage". The questionnaire is implemented in Qualtrics and preferred language can be chosen. All questions are the same for each country. The questionnaire will be administered by providing the URL in a notification in the Healthentia app. This notification will be triggered automatically after a patient has used the Healthentia for 4 weeks.		
	Qualtrics URL			
3	User experience assessment "exacerbation"	Administration of questionnaire "UX assessment: 1-2 weeks after exacerbation". The questionnaire is implemented in Qualtrics and preferred language can be chosen. Depending on the country selected at the beginning of the survey, questions not applicable for TUK (Estonia) will not be prompted. The questionnaire will be administered by providing the URL in a notification in the Healthentia app. This notification will be triggered manually through the pilot administration in the Healthentia dashboard. A manual is provided by iSprint on how to this is done.		
	Qualtrics URL			

Usability benchmarking (1 week after initial usage)

eHealth Usability Benchmarking Instrument (HUBBI)

HUBBI was adapted to include the name of the system (i.e., "Healthentia") to be assessed. Rated on a 5-point Likert Scale

- 1. I experienced system errors while using the Healthentia app.
- 2. I get stuck when using the Healthentia app.
- 3. The Healthentia app is convenient to use at home.
- 4. The Healthentia app is suitable for me.
- 5. The Healthentia app is helpful to monitor people with one or more chronic health conditions.
- 6. I can see everything clearly in the Healthentia app.
- 7. The signals, warnings and cues in the Healthentia app are easy to interpret.
- 8. The layout of each page of the Healthentia app is appealing.
- 9. The messages in the Healthentia app are well-structured.
- 10. I know where in the Healthentia app I can find the information I need.
- 11. I understand the relationships among the different parts of the Healthentia app.
- 12. The Healthentia app information is easy to understand.
- 13. The Healthentia app offers clear explanations for difficult medical topics.
- 14. The error messages in the Healthentia app tell me how to fix problems clearly.
- 15. The Healthentia app sufficiently explains how to perform system procedures e.g. create account, log on, change settings, connect with other devices.
- 16. The Healthentia app provides sufficient feedback to support me in managing my health.
- 17. Overall, I am satisfied with the Healthentia app.
- 18. I like how the Healthentia app contributes to my health.



User experience assessment: 4 weeks after use (exported from Qualtrics)

RE-SAMPLE: Usability- 4 weeks after use

Start of Block: Introduction and informed consent RE-SAMPLE

This questionnaire is part of the European project RE-SAMPLE. The purpose of RE-SAMPLE is to develop eHealth applications that support patients and healthcare professionals. This technology will help patients to manage COPD and complex chronic conditions.

Who are we?

Roessingh Research and Development (RRD) is a research organisation in the area of rehabilitation technology and digital health care assistance located in Enschede (The Netherlands) and one of the project partners in RE-SAMPLE.

Participation

Completing this survey will take you approximately 10 minutes. Participation in the questionnaire is entirely voluntary. You can quit with the questionnaire whenever you want. You do not need to fill in a reason for this. You can stop by closing the tab or window of this survey. Only responses from completed questionnaires will be used in this study.

Privacy protection and processing of your data

The data in this questionnaire will be collected without your name and contain no personal data that can be traced back to you. The answers you give will only be used as part of the RE-SAMPLE project and processed by researchers at RRD. The privacy regulations that are applied to all research conducted at Roessingh Research & Development can be found here: http://www.rrd.nl/en/privacy-declaration/

o Yes, I agree to participate in this study.

End of Block: Introduction and informed consent RE-SAMPLE				
Start of Block: Demographics RE-SAMPLE				
Q1 What is your gender? o Male o Female o Prefer to self-describe:				
Q2 What is your year of birth? ▼ 1900 2003				
Q3 What is the highest degree or level of education you have completed? o Primary School o High School o Trade School o University				



Q4 W	hat is your employment status?
1.	Full time employment
2.	Part time employment
3.	Seeking opportunities
	Retired
5.	
	Voluntary work
7.	Other:
Q5 Ho	w many family members do you live together with?
0	0
О	1
О	2
О	3
О	4
O	more than 4
End of	f Block: Demographics RE-SAMPLE
Start o	of Block: Digital literacy RE-SAMPLE
Q6 I th	ink that my level of digital skills (like the use of smartphone, tablet, laptop) is as follows:
О	1: really low
О	2: low
О	34
0	4: high 5: really high
End of	f Block: Digital literacy RE-SAMPLE
Start o	of Block: Usability
O7 In 1	the RE-SAMPLE study, you are using the Healthentia mobile application for some time now to
monito	or your symptoms and disease progression. What is your general and overall experience with the
Health	entia mobile application?
О	Very good
О	Good
О	Acceptable
О	Poor
0	Very poor
Q8 Co	uld you explain your answer?
09 Co	uld you tell us how you use the app? What features to do use?
Q) C0	and you tell as now you use the app: what reatures to do use:



Q10 Did you have problems during the first weeks of using the Healthentia mobile application? o No
o Yes
Q11 Could you explain your answers?
Within the Healthentia mobile application there are multiply ways to find technical help, the tutorial, the FAQ and the conversational agent. Did you use the following technical help feature?
Q12 The tutorial
o Yes o No
To what extend do you agree to the following statements:
Display This Question: $If Q12 = Yes$
Q13 The tutorial of the Healthentia mobile application was very informative
o Strongly Agree o Agree
o Agree o Undecided
o Disagree
o Strongly agree
Display This Question:
If $Q12 = Yes$ Q14 The tutorial of the Healthentia mobile application help me to understand the application better
o Strongly Agree
o Agree
o Undecided o Disagree
o Strongly disagree
Display This Question: If Q12 = Yes
Q15 The tutorial of the Healthentia mobile application help me to navigate through the application
better
o Strongly Agree o Agree
o Agree o Undecided
o Disagree
o Strongly disagree
Display This Question: If Q12 = Yes



Q16 Could you explain your answers?



Did you use this technical help feature?
Q17 The FAQ
o Yes
o No
To what extent do you agree with the following statements:
Display This Question:
If $Q17 = Yes$
Q18 The FAQ of the Healthentia mobile application was very informative o Strongly agree
o Agree
o Undecided
o Disagree
o Strongly disagree
Display This Question:
If $Q17 = Yes$ Q19 The FAQ of the Healthentia mobile application help me to understand the application better
o Strongly Agree
o Agree
o Undecided
o Disagree
o Strongly disagree
Display This Question:
If $Q17 = Yes$
Q20 The FAQ of the Healthentia mobile application help me to navigate through the application better o Strongly agree
o Strongly agree o Agree
o Undecided
o Disagree
o Strongly disagree
Display This Question:
If Q17 = Yes
Q21 Could you explain your answers?
Did you use this technical help feature?
Q22 The conversational agent
o Yes
o No



Display This Question:

If Q22 = Yes

Q23 To what extent do you agree with the following statements:

Display This Question:

If Q22 = Yes

Q24 The conversational agent of the Healthentia mobile application was very informative

- o Strongly agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:

If Q22 = Yes

Q25 The conversational agent of the Healthentia mobile application help me to understand the application better

- o Strongly Agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:

If Q22 = Yes

Q26 The conversational agent of the Healthentia mobile application help me to navigate through the application better

- o Strongly Agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:

If Q22 = Yes

Q27 Could you explain your answers?

One of the features of the Healthentia mobile application is to complete questionnaires to monitor your symptoms and disease progression.

Q28 To what extent do you agree with the following statements:

	Strongly agree	Agree	Undecided	Disagree	Strongly disagree
In general, I have some	0	0	0	0	0
problems to fill					



in the questionnaire					
In general, I understand how to fill in the questionnaires.	0	0	0	O	0
The start and end of a questionnaire are clear to me.	0	0	0	O	0

Q29 Could you explain your answers?	
Q30 What do you think of the time that it take to complete the questionnaires in the Healthentia mobile application?	
Q31 Is there anything else you would like to tell us about your experience using the Healthentia mobile application?	
End of Block: Usability	

Start of Block: Continuous feedback RE-SAMPLE

Q32 May we approach you for one of the options below?

- o Yes, I would like to receive a summary of the results of this questionnaire.
- o Yes, I am happy to be approached for follow-up research. (We may send you information about new research in the future. At that time you can decide whether or not you want to participate in that study.)
- o No

Display This Question:

If Q32 = Yes, I would like to receive a summary of the results of this questionnaire.

Or Q32 = Yes, I am happy to be approached for follow-up research. (We may send you information about new research in the future. At that time you can decide whether or not you want to participate in that study.)
Q33 Enter your e-mail address here. Your e-mail address will only be used for the options you have indicated above. The answers to the questionnaire will not be linked to your email address.

End of Block: Continuous feedback RE-SAMPLE



User experience assessment: 1-2 weeks after exacerbation (exported from Qualtrics)

RE-SAMPLE: Usability- 1-2 weeks after exacerbation identification

Start of Block: Introduction and informed consent RE-SAMPLE

This questionnaire is part of the European project RE-SAMPLE (https://www.re-sample.eu). The purpose of RE-SAMPLE is to develop eHealth applications that support patients and healthcare professionals. This technology will help patients to manage COPD and complex chronic conditions.

Who are we?

Roessingh Research and Development (RRD) (http://www.rrd.nl/en/) is a research organisation in the area of rehabilitation technology and digital health care assistance located in Enschede (The Netherlands) and one of the project partners in RE-SAMPLE.

Participation

Completing this survey will take you approximately 15 minutes. Participation in the questionnaire is entirely voluntary. You can quit with the questionnaire whenever you want. You do not need to fill in a reason for this. You can stop by closing the tab or window of this survey. Only responses from completed questionnaires will be used in this study.

Privacy protection and processing of your data

The data in this questionnaire will be collected without your name and contain no personal data that can be traced back to you. The answers you give will only be used as part of the RE-SAMPLE project and processed by researchers at RRD. The privacy regulations that are applied to all research conducted at Roessingh Research & Development can be found here: http://www.rrd.nl/en/privacy-declaration/

o I agree to participate in this study.

Full time employment
 Part time employment
 Seeking opportunities

4. Retired

End of Block: Introduction and informed consent RE-SAMPLE
Start of Block: Demographics
Q1 What is your gender? o Male o Female o Prefer to self-describe:
Q2 What is your year of birth? ▼ 1900 2003
Q3 What is the highest degree or level of education you have completed?
o Primary School
o High School
o Trade School
o University
o Other
Q4 What is your employment status?



5.	Unable	to	work

- 6. Voluntary work
- 7. Other: _____

Q5 How many family members do you live together with?

- o 0
- o 1
- o 2
- o 3
- o 4
- o more than 4

End of Block: Demographics

Start of Block: Digital literacy RE-SAMPLE

Q6 I think that my level of digital skills (like the use of smartphone, tablet, laptop) is as follows:

- o 1: really low
- o 2: low
- o 34
- o 4: high
- o 5: really high

End of Block: Digital literacy RE-SAMPLE

Start of Block: Usability

Q7 From which country are you?

- o Estonia
- o Italy
- o The Netherlands

Skip To: Q14 If Q7 = Estonia

Q8 Due to worsening in symptoms you were recently invited to do a blood test. Was the blood draw done?

- o Yes
- o No

 $Display\ This\ Question:$

If
$$Q8 = Yes$$

Q9 I found the process clear.

- o Strongly agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:

If
$$Q8 = Yes$$

Q10 I needed more guidance to know what was expected from me.



O	Strongl	y	agree

- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:

If
$$Q8 = Yes$$

Q11 It was useful that the Healthentia application determined that the blood draw was needed.

- o Strongly agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:

If
$$Q8 = Yes$$

Q12 How did you experience this?

Display This Question:

If
$$Q8 = No$$

Q13 Why were the laboratory tests not done?

Q14 Because of worsening of symptoms you were asked to fill in additional questionnaires in the Healthentia mobile application. Did you complete those?

- o Yes
- o No

Display This Question:

If
$$Q14 = Yes$$

Q15 To what extent do you agree with the following statements:

Display This Question:

If
$$Q14 = Yes$$

Q16 In general, I have problems to fill in the questionnaires.

- o Strongly agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:

If
$$Q14 = Yes$$

Q17 In general, I understand how to fill in the questionnaires.

- o Strongly agree
- o Agree



- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:

If Q14 = Yes

Q18 The start and end of a questionnaire are clear to me.

- o Strongly agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:

If Q14 = Yes

Q19 How did you experience this?

Display This Question:

If Q14 = No

Q20 Why did you not complete the questionnaires?

Q21 What do you think of the time that it take to complete the questionnaires in the Healthentia mobile application?

Q22 Is there anything else you would like to tell us about your experience using the Healthentia mobile application?

End of Block: Usability

Start of Block: Continuous feedback RE-SAMPLE

Q23 May we approach you for one of the options below?

- o Yes, I would like to receive a summary of the results of this questionnaire.
- Yes, I am happy to be approached for follow-up research. (We may send you information about new research in the future. At that time you can decide whether or not you want to participate in that study.)
- o No

Display This Question:

If Q23 = Yes, I would like to receive a summary of the results of this questionnaire.

 $Or\ Q23 = Yes$, I am happy to be approached for follow-up research. (We may send you information about new research in the future. At that time you can decide whether or not you want to participate in that study.)



Q24 Enter your e-mail address here. Your e-mail address will only be used for the options you have indicated above. The answers to the questionnaire will not be linked to your email address.

End of Block: Continuous feedback RE-SAMPLE



Appendix D: Initial protocol final usability test Healthentia app



REal-time data monitoring for Shared, Adaptive, Multi-domain and Personalised prediction and decision making for Long-term Pulmonary care Ecosystems

Usability / user experience test – Jan 2024



This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 965315. This result reflects only the author's view and the European Commission is not responsible for any use that may be made of the information it contains.



Project name : RE-SAMPLE

Country :
Organisation :
Date :
Unique identifier :



Preparation of researcher before first physical meeting with participant

Preparation	Done?
Goals are needed within the dashboard of that participant	
(for example steps goal)	
Participant needs to receive action planning training	
All modules need to be activated for the participant to be able to use the app	
as during MVP light study (like coaching domains, action planning)	
Create a personal Process of study based on start day (see example in this	
document).	
The example process can be found in the following PowerPoint file: RE-	
SAMPLE_iteration 7_usability test patients_process	



First physical meeting with participant [First day of study]

Phase	Topic	Description	Min.	Materials
1	Start of study	Can only start after onboarding of coaching and action planning.	2	Coffee/tea, biscuits
		Thank participant for participating, coffee/tea + biscuit. Introduce yourself, ask participant to introduce themself.		
		Today will be the first day of your one-week usability and user experience test. As start, I will give you some background information on why we are conducting this study.		
2	Explanation of study	In this research we want to study the usability and user experience of the Healthentia app. The results of this study will be used for finalising the development of the app in RE-SAMPLE.	7	
		As already explained during the cohort study, the RE-SAMPLE project aims to develop a healthcare technology that supports patients and caregivers in a personal way in managing COPD and other chronic conditions, such as chronic and/or ischemic heart failure, diabetes mellitus, anxiety disorders and/or depression.		
		With the results of this research, we hope to make the healthcare technology developed in RE-SAMPLE as usable as possible. This study is the last part, before the complete app will be used in a large, long-term evaluation.		
		Within this study, you will be able to test the first complete version of the app for one week. This version includes, among others, a digital coach who can give you coaching dialogues or who advices you whether or not to take action based on your daily symptoms.		
		As this is a first test, we want to ask you to not take any actions based on the coaching dialogues or advices of action. We want to see whether everything is clear and whether all functionalities work properly. So, I want to ask you to mainly focus on that part. For example: Do you understand everything the app is advising you to do? Or is some information lacking? Or are technical errors occurring when using this version of the app? How would you feel if you would use it?		
		Do you have any questions about this?		
		During the week of testing, I will call you every morning (except for the weekend) to ask some short questions about your experience with the app. This call will last for around 10 minutes.	7	Questionnaire 2 and questionnaire 3
		During our last call (on the[include date here]), we will have a longer call (around 15-20 minutes). We will end the study, and after asking you some short questions, we will complete two questionnaires together. I will already give you a print of these questionnaires, so we can both look at the questions while completing it. During our last call, I will ask you to have these questionnaires in front of you. And you can then give me your answers by phone.		You can explain the process by showing Process of study



		Do you have any questions about this process?		
		Do you want to set some time slots for our daily call?		
		- If so: plan all calls together with the participant		
3	Informed		3	Informed
	Consent			Consent Form
4	Demo- graphics		3	Questionnaire 1
5	App change	Help participant to change to the test version of the app (including coach and action plans)	3	
6	Wrap-up and thanks		3	



Daily call protocol [Starts from second day of study]

Phase	Topic	Description					
1	Good	{Short start of the call}					
	morning	- Good morning [name].					
		- How are you doing?					
		- Etc.					
2	Explanation	As explained previously, you are participating in a one-week study to test the					
	of research	extended app of RE-SAMPLE; but not to act on advices that you receive.					
		Every morning, I will call you to ask some short questions about your experience with the app.					
Start the	e recording and is	nform participant about this.					
3	Questions	0. [Only during the first call] First of all, how is your general impression now					
	Questions	you've used it one day?					
		1. Are there any technical problems you have been dealing with during the use					
		of the app?					
		 2. Did you receive any coaching dialogues yesterday/during the weekend? a. If yes → What was the dialogue about? 					
		 b. If yes → What is your opinion about the interaction with the coach? 					
		c. If yes → What do you think about the timing of the dialogue?					
		d. If yes → What is your opinion about the tone of voice of the dialogue?					
		3. Did the digital coach tell you anything you would need to do/change?					
		a. If yes → What was its advice?					
		b. If yes → To what extent was it clear what the action plan/advice entailed?					
		c. If yes \rightarrow If you read such an action plan/advice, what did you think					
		about this? Would you be able to execute that advice or do you need					
		more information? Would you listen to such an advice? Please explain your answer.					
		d. If yes \rightarrow Do you want to have more information in general within the					
		action plan? If so, what kind of information is missing for you?					
4	Wrap-up and	{Ending the call}					
	thanks	- Those were the questions I wanted to ask you. Do you have any more					
		comments you want to share with me? Or questions you would like to ask					
		me? Explain to participant \rightarrow they don't have to get on the coaching advises and					
		 Explain to participant → they don't have to act on the coaching advices and action planning. It's just a test. 					
		- I want to thank you for your time and help with this research!					
		- I will speak to you tomorrow. Enjoy your day!					
		- Bye.					



Daily call protocol [Last day of study]

Phase	Topic	Description
1	Good	{Short start of the call}
•	morning	- Good morning [name].
	morning	- How are you doing?
		- Etc.
2	Explanation	As explained previously, you are participating in a one-week study to test the
_	of research	extended app of RE-SAMPLE; but not to act on advices that you receive.
		Every morning, I will call you to ask some short questions about your experience
		with the app. Today is the last day of the study.
Start the	e recording and i	nform participant about this.
3	Questions	1. Are there any technical problems you have been dealing with during the use
		of the app?
		 2. Did you receive any coaching dialogues yesterday/during the weekend? a. If yes → What was the dialogue about? b. If yes → What is your opinion about the interaction with the coach? c. If yes → What do you think about the timing of the dialogue?
		d. If yes → What is your opinion about the tone of voice of the dialogue?
		3. Based on the different coaching dialogues you received in the last week, what is your opinion about the content of the dialogues?
		a. To what extent did these dialogues match your own needs?
		i. Please explain your answer.
		ii. Could you give an example of a dialogue topic that did
		not match your needs? Or a topic that did match your needs?
		iii. What kind of topics would match your needs?
		4. Based on the different coaching dialogues you received in the last week,
		what is your opinion about the frequency of the dialogues?
		5. Did the digital coach tell you anything you would need to do/change?
		a. If yes → What was its advice?
		b. If yes → To what extent was it clear what the action plan/advice entailed?
		c. If yes → If you read such an action plan/advice, what did you think about this? Would you be able to execute that advice or do you need more information? Would you listen to such an advice? Please explain
		your answer.
		d. If yes → Do you want to have more information in general within the action plan? If so, what kind of information is missing for you?
		6. Those were the questions I wanted to ask you. Do you have any more
		comments you want to share with me? Or questions you would like to ask me
4	Acceptance	Complete the acceptance questionnaire (questionnaire 2) and the chatbot usability
	questionnaire + chatbot usability scale	scale (questionnaire 3), together with participant. Participant has a printed version. Go through all the questions together.
5	Wrap-up and	{Ending the call}
	thanks	- Based on the results of this study, we will probably make some changes within the app before we will start with our long-term evaluation of the app. So, your input was very valuable for us.
		I want to thank you for your time and help with this research!Bye.
		- byc.



Process of study

(Example below: study starts on Monday, ends on Monday)

Day 1 (Monday)
Physical meeting

Day 2 (Tuesday)
Phone call

Day 3 (Wednesday) Phone call

Day 4 (Thursday)
Phone call

Day 5 (Friday Phone call Day 6 (Saturday) None Day 7 (Sunday) None Day 8 (Monday) Phone ca<u>ll</u>

Use of app



DOCUMENTS FOR PARTICIPANT



RE-SAMPLE – Usability test Healthentia app

Dear sir/madam,

You have indicated that you would like to participate in a user test, that is part of the research project RE-SAMPLE. In this study, we would like to get more insight into the usability of the Healthentia app. By usability, we mean whether people can use the app easily and whether there are any problems or system errors they encounter.

Participation in this study is voluntary. You decide whether you want to participate. Before you make your decision, it is important to know more about the study. Please read this information letter carefully and feel free to ask one of the researchers for explanations if you have any questions. In order to participate, we need to have your written informed consent. If you want to participate, please fill in the informed consent form.

General information

This study is conducted by [name of organisation]. We are looking for about 5 participants for this study. The information in this letter describes the purpose of this study, the methods we will use, the time you will spend on this study and how we will handle your personal data. If you have any questions after reading this letter, please feel free to contact us.

Goal of this study

The aims of this user test are:

- 1. To gain an overview into possible usability issues with the Healthentia app
- 2. To gain insight into how people rate the usability of the Healthentia app
- 3. To gain insight into people's opinions, wishes and needs regarding the Healthentia app
- 4. Investigating whether the Healthentia app is suitable to use

Background of this study

This research is part of the European project RE-SAMPLE. Within this project, a healthcare technology is being developed for COPD patients with other chronic conditions and their caregivers. The aim of this technology is to support patients and caregivers in controlling COPD and the other chronic lung diseases. This research is funded by the European Horizon 2020 research programme.

In this study, we will map the usability of the Healthentia app . This app will be used as the basis for RE-SAMPLE's healthcare technology, and is already being used within the cohort study. We now have a new version ready, which we want to evaluate soon in a long-term study. However, before we can do this, we need to study the usability of this newest version within a user test. With the results of this user test, we will improve the app and be able to conduct the long-term evaluation.

In the newest version of the app, we included, among others, a digital coach who gives coaching dialogues and an action plan which advices users whether or not to take action based on the daily symptoms. As this is a first test with this version of the app, we want to ask you to not take any actions based on the coaching dialogues or action planning. We want to see whether everything is clear and whether all functionalities work properly.

How is this study being conducted?

This research will involve your participation in 1) a physical meeting at the hospital, 2) a one-week user test (8 days), and 3) a short daily phone call with the researcher. During the first physical meeting, the researcher will explain the user test and helps you downloading the newest version of the Healthentia app. Furthermore, you will be asked to complete a short questionnaire about your demographics. Then you will be asked to use the app for one week at home. Every day, except during the weekend, the researcher will call you to ask you some short questions about the use of the app. This phone call will be recorded by the researcher. At the end of the one-week user test, you will be asked to complete a questionnaire about your experience.

What are the risks and benefits when participating to this study?

There are no reasonably foreseeable risks, discomforts, or disadvantages connected to your participation. You do not have to answer any questions if you feel these make you uncomfortable.

There will no direct benefit to you, but your participation is likely to help us to understand how technology developed within RE-SAMPLE can best support patients. You will not be paid for your participation in this study. You will not be reimbursed for expenses.



If you do not wish to participate or want to withdraw your consent

Your participation in this research is entirely voluntary. It is your choice whether to participate or not and you can withdraw from the study at any point without providing any reason for doing so.

What happens to your data?

The recordings of this study will be transcribed and saved by the researcher. Questionnaires will be collected and data will be saved by the researcher. All your data will be processed and kept in coded form, for example your name, initials and other data that could directly identify you are therefore omitted from the results. We will keep the research data for 10 years. Your data will be stored by the investigator of [name of your organisation] and can only be viewed by those directly involved in the study, such as the investigator and coordinating investigator(s) and by supervisory bodies such as the Health Care Inspectorate. The results will only be processed at the group level and published in scientific literature in which you as a person cannot be identified or traced. Anonymised data will be kept for scientific purposes at [name of your organisation]. You can withdraw your consent for the use of your personal data at any time.

For general information on your rights regarding the processing of your personal data, please visit the website [Link to the privacy statement of your organisation].

For questions or complaints about the processing of your personal data, you can contact the researchers below or the Data Protection Officer of [name of your organisation]. For this study the data protection officer is [name, email address, phone number of your DPO].

How do you provide your consent to the study?

You can take your time and think about participating this study. If you want to take part, please complete the consent form attached to this information letter. You and the researchers will both receive a signed copy of this consent form.

Do you have any questions?

If you have any questions about the study, please contact the researcher:

- Name
- Organisation
- Email address
- Phone number



RE-SAMPLE – Usability test Healthentia app

- I have read the information letter. I have had the opportunity to ask questions. My questions were answered well enough. I had enough time to decide whether to participate.
- I know that my participation is voluntary, that I can refuse to answer questions and I can withdraw at any time without providing any reason for doing so.
- I give the researchers permission to collect and use my data. The researchers will only do this to answer the research question of this study.
- I give the researchers permission to audio record our phone calls to go discuss my experience of the app.
- I understand that my words may be quoted in publications and other research outputs in a way that does

not reveal my identity.
- I
□ do
□ do not
Give permission to contact me after this study if I want to participate in a follow-up study.
- I want to participate in this study
My name is (participant):
Signature: Date ://
I certify that i have fully informed this participant about the research in question.
If new information becomes available during the study that could influence the participant's consent, I will let the participant know in time.
Name researcher (or representative):
Signature:/



Questionnaire 1: Demographics
1. What is your gender?
Male
Female
Other
2. Wat is your year of birth (YYYY)?
3. Besides COPD, what other chronic conditions do you have?
4 T. 4 . 4 . 4 . 4 . 4 . 4 . 6 . 5 . 5 . 6 . 6 . 6 . 6 . 6 . 6 . 6
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, namely:
Ctrict, namery.
6. What is your current employment status?
Employed full time
Employed part time
Seeking opportunities
beeking opportunities



Retired Unable to wor Voluntary wor Other, namely	rk					
7. How many famil					•	,
0	1	2	3		4	>4
8. How much doe activities)? I have no problems performing my usual activities	,	ect your usual	activities (e.g.	. work,	study, housew	I am unable to perform my usual activities
1	2		3		4	5
9. How often do yo	ou experience prob		ling texts (sucl	h as leaf	lets) about you Often	r health or an illness? Always
10. How confident	do you feel when	you fill out med	lical forms?			
Not confident a	t Somewh	at Fairl	y confident	C	onfident	Very confident
all	confider	nt				
GP? Never	Seldom	So	ometimes	r letters	from the hosp Often	ital, pharmacy or your Always
12. I think that my	level of digital ski	lls is as follows				Doelly high
Really low	2		3		4	Really high 5
1	2				-	3
13. Which of the fo	_	you use?				



Smartwatch (Fitbit/Garmin/Apple watch)
Tablet
None
Other, namely:



Questionnaire 2: Acceptance questionnaire (T7.3)	Strong	disagte ^e Disagte ^e	-Ventral	Agree	Strongly agis
1. If the RE-SAMPLE VCP would be available for me, I would definitely use it	1	2	3	4	5
2. I would recommend the RE-SAMPLE VCP to others	1	2	3	4	5
3. Using the RE-SAMPLE VCP helps me to manage my COPD	1	2	3	4	5
4. Using the RE-SAMPLE VCP helps me to monitor my COPD	1	2	3	4	5
5. It was easy to learn how to use the RE-SAMPLE VCP	1	2	3	4	5
6. The RE-SAMPLE VCP is easy to use	1	2	3	4	5
7. It find it easy to get the RE-SAMPLE VCP to do what I want it to do	1	2	3	4	5
8. The amount of information provided by the RE-SAMPLE VCP fits perfectly with the amount of information I need	1	2	3	4	5
9. The advices provided by the RE-SAMPLE VCP are too generic	1	2	3	4	5
10. The activities advised by the RE-SAMPLE VCP fits very well to the kind of daily activities I like to do	1	2	3	4	5
11. The RE-SAMPLE VCP fits very well to the current stage of my disease	1	2	3	4	5

	*	Shuffy likelie				
	Strongly	Disaggee	Pentral	Agree	Shough affee	
12. Using the RE-SAMPLE VCP improves the communication between me and my healthcare professionals	1	2	3	4	5	
13. Using the RE-SAMPLE VCP improves my relationship with my healthcare professionals	1	2	3	4	5	
14. I find it easy to search for specific information in digital environments	1	2	3	4	5	
15. I can easily distinguish between correct and incorrect digital information	1	2	3	4	5	
16. I find it easy to store and organise digital content so that I can easily find it again	1	2	3	4	5	

Questionnaire 3: Chatbot usability scale		iisagje ^e			agre
	Stions	Disagles Disagles	Petitral	Agree	Strongly agree
1. The chatbot function was easily detectable	1	2	3	4	5
2. It was easy to find the chatbot	1	2	3	4	5
3. Communicating with the chatbot was clear					
4. The chatbot was able to keep track of context	1	2	3	4	5
	1	2	3	4	5
5. The chatbot's responses were easy to understand	1	2	3	4	5
6. I find that the chatbot understands what I want and helps me achieve my goal	1	2	3	4	5
7. The chatbot gives me the appropriate amount of information	1	2	3	4	5
8. The chatbot only gives me the information I need					
9. I feel like the chatbot's responses were accurate	1	2	3	4	5
	1	2	3	4	5
10. I believe the chatbot informs me of any possible privacy issues	1	2	3	4	5
11. My waiting time for a response from the chatbot was short					
	1	2	3	4	5

Appendix E: Final protocol for final usability test of Healthentia app



REal-time data monitoring for Shared, Adaptive, Multi-domain and Personalised prediction and decision making for Long-term Pulmonary care Ecosystems

Usability / user experience test – March 2024



This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 965315. This result reflects only the author's view and the European Commission is not responsible for any use that may be made of the information it contains.



Project name : RE-SAMPLE

Country :
Organisation :
Date :
Unique identifier :



Checklist preparation before usability test

Task	Done?
Inform iSprint when a patient will come in for a usability test: let her know which	
account/email address will be used for testing the app.	
The app needs to be downloaded, installed, logged in (with the email address you	
mentioned to Danae) on a smartphone or tablet from the hospital. Participants do	
not use their own app on their own smartphone for this test.	
Translate the documents needed in this file to your own language.	



Protocol usability / user experience test

Phase	Topic	Description	Min.	Materials
1	Start of study	Thank participant for participating, coffee/tea + biscuit. Introduce yourself, ask participant to introduce themself.	2	Coffee/tea, biscuits
		You are going to do several tests in a moment, I will first give you some background why we are conducting this study.		
2	Explanation of study	In this research we want to study the usability and user experience of the Healthentia app. The results of this study will be used for finalising the development of the app in RE-SAMPLE.	5	
		As already explained during the cohort study, the RE-SAMPLE project aims to develop a healthcare technology that supports patients and caregivers in a personal way in managing COPD and other chronic conditions, such as chronic and/or ischemic heart failure, diabetes mellitus, anxiety disorders and/or depression.		
		With the results of this research, we hope to make the healthcare technology developed in RE-SAMPLE as usable as possible. This study is the last part, before the complete app will be used in a large, long-term evaluation.		
		Within this study, you will be able to test new functionalities of the app. These functionalities include a digital coach who can give you coaching dialogues and who advices you whether or not to take action based on your daily symptoms. We want to see whether everything is clear. So, I want to ask you to mainly focus on that part. For example: Do you understand everything the coach is advising you to do? Or is some information lacking? How would you feel if you would receive such advices?		
		Do you have any questions about this?		
3	Informed Consent		3	Informed Consent Form
4	Demo- graphics		3	Questionnaire 1
5	Think aloud	You're about to get started with Thinking Aloud. This means that while you perform a number of tasks you are sharing your thoughts at the same time. We ask you to tell us what you think while you are busy with the tasks. What do you notice, what do you doubt and what choices do you make? When you are silent for more than 5 seconds, I will ask you if you can speak your thoughts out loud.	2	
		Start audio recorder + screen capture Task 1: I have a couple of dialogues ready for you. You will start with dialogue #1. Go through the dialogue and try to think aloud what you think when reading the dialogue.		Usability issues form
		Task 2: Now I have one scenario for you to go through. Go through the scenario and try to think aloud what you think when reading and conducting the scenario. You will be asked to complete the daily diary in the app. after you completed the daily diary, you will receive advice to take		Scenario #4 Usability issues form



		action. If you receive this, please open this action and read it.		
6	Questionaire	Participant completes Chatbot usability scale	5	Questionnaire 2
7	Short interview		10	Interview Questions
8	Wrap-up and thanks		3	



Interview Questions

- 1. What is your opinion on the interaction with the virtual coach?
 - a. Please explain your answer.
- 2. What is your opinion on the tone of voice of the dialogue?
 - a. Please explain your answer.
- 3. What is your opinion on the content of the dialogues?
 - a. How would you feel if you receive such dialogues within the RE-SAMPLE app?
 - i. Please explain your answer.
 - b. To what extent did these dialogues match your own needs?
 - i. Please explain your answer.
 - ii. Could you give an example of a dialogue topic that did not match your needs? Or a topic that did match your needs?
 - iii. What kind of topics would match your needs?
- 4. What is your opinion on the frequency such dialogues need to be triggered within the app?
 - a. Please explain your answer.
 - b. E.g. would you want to receive such dialogues every day? Once a week, twice a week? Etc. What would be the best frequency for you personally?
- 5. Did the digital coach tell you anything you would need to do/change?
 - a. If yes \rightarrow What was its advice?
 - b. If yes \rightarrow To what extent was it clear what the action plan/advice entailed?
 - c. If yes → If you read such an action plan/advice, what did you think about this? Would you be able to execute that advice or do you need more information? Would you listen to such an advice? Please explain your answer.
 - d. If yes → Do you want to have more information in general within the action plan? If so, what kind of information is missing for you?
 - e. If yes → What do you think about the timing of the advices after you completed the daily diary questionnaire?
- 6. Those were the questions I wanted to ask you. Do you have any more comments you want to share with me? Or questions you would like to ask me?



Usability issues form

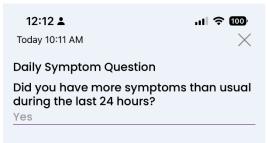
Usability issues occurred during task 1 – g	oing through dialogues
Usability issues occurred during task 2 – a	ection plan

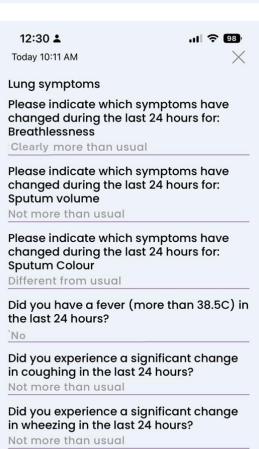


Scenario #1 – Needs to be filled in in the app by iSprint before start of study

There is a slight change in symptoms. You're experiencing more shortness of breath, and the colour of your mucus is different than normal. Complete the daily diary within the test version of the app with the following answers:

- 1. More symptoms than usual
- 2. Clearly more shortness of breath than usual
- 3. Not more mucus than usual
- 4. Different colour of mucus than usual
- 5. No fever, no change in coughing and no wheezing



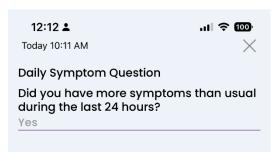


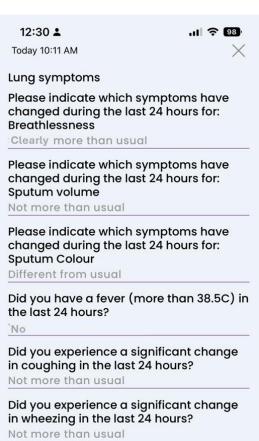


Scenario #2 – Needs to be filled in in the app by iSprint before start of study

There is a slight change in symptoms. You're experiencing more shortness of breath, and the colour of your mucus is different than normal. Complete the daily diary within the test version of the app with the following answers:

- 1. More symptoms than usual
- 2. Clearly more shortness of breath than usual
- 3. Not more mucus than usual
- 4. Different colour of mucus than usual
- 5. No fever, no change in coughing and no wheezing







DOCUMENTS FOR PARTICIPANT



RE-SAMPLE - Usability test Healthentia app

Dear sir/madam,

You have indicated that you would like to participate in a usability test, that is part of the research project RE-SAMPLE. In this study, we would like to get more insight into the usability of the Healthentia app. By usability, we mean whether people can use the app easily and whether there are any problems or system errors they encounter. Participation in this study is voluntary. You decide whether you want to participate. Before you make your decision,

Participation in this study is voluntary. You decide whether you want to participate. Before you make your decision, it is important to know more about the study. Please read this information letter carefully and feel free to ask one of the researchers for explanations if you have any questions. In order to participate, we need to have your written informed consent. If you want to participate, please fill in the informed consent form.

General information

This study is conducted by [name of organisation]. We are looking for about 5 participants for this study. The information in this letter describes the purpose of this study, the methods we will use, the time you will spend on this study and how we will handle your personal data. If you have any questions after reading this letter, please feel free to contact us.

Goal of this study

The aim of this user test is to gather insight into people's opinions, wishes and needs regarding the new functionalities of the Healthentia app

Background of this study

This research is part of the European project RE-SAMPLE. Within this project, a healthcare technology is being developed for COPD patients with other chronic conditions and their caregivers. The aim of this technology is to support patients and caregivers in controlling COPD and the other chronic lung diseases. This research is funded by the European Horizon 2020 research programme.

In this study, we will map the usability of the Healthentia app . This app will be used as the basis for RE-SAMPLE's healthcare technology, and is already being used within the cohort study. We now have a new version ready, which we want to evaluate soon in a long-term study. However, before we can do this, we need to study the usability of this newest version within a user test. With the results of this user test, we will improve the app and be able to conduct the long-term evaluation.

In the newest version of the app, we included, among others, a digital coach who gives coaching dialogues and an action plan which advices users whether or not to take action based on the daily symptoms. During this usability test we will focus on these new functionalities.

How is this study being conducted?

This research will involve your participation in a one-time usability test. During this study, you will be asked to complete a short questionnaire about your demographics. Then you will be asked to go through some coaching dialogues and scenarios. During these steps, you will be asked to think aloud what you think. Finally, as a last step, you will be asked to complete a questionnaire and you will be asked some short interview questions about the dialogues and scenarios to gather your opinion about these functionalities. This test will be audio-recorded by the researchers.

What are the risks and benefits when participating to this study?

There are no reasonably foreseeable risks, discomforts, or disadvantages connected to your participation. You do not have to answer any questions if you feel these make you uncomfortable.

There will no direct benefit to you, but your participation is likely to help us to understand how technology developed within RE-SAMPLE can best support patients. You will not be paid for your participation in this study. You will not be reimbursed for expenses.

If you do not wish to participate or want to withdraw your consent

Your participation in this research is entirely voluntary. It is your choice whether to participate or not and you can withdraw from the study at any point without providing any reason for doing so.

What happens to your data?

The recordings of this study will be transcribed and saved by the researcher. Questionnaires will be collected and data will be saved by the researcher. All your data will be processed and kept in coded form, for example your name, initials and other data that could directly identify you are therefore omitted from the results. We will keep the research data for 10 years. Your data will be stored by the investigator of [name of your organisation] and can only be viewed by those directly involved in the study, such as the investigator and coordinating investigator(s) and by supervisory



bodies such as the Health Care Inspectorate. The results will only be processed at the group level and published in scientific literature in which you as a person cannot be identified or traced. Anonymised data will be kept for scientific purposes at [name of your organisation]. You can withdraw your consent for the use of your personal data at any time. For general information on your rights regarding the processing of your personal data, please visit the website [Link to the privacy statement of your organisation].

For questions or complaints about the processing of your personal data, you can contact the researchers below or the Data Protection Officer of [name of your organisation]. For this study the data protection officer is [name, email address, phone number of your DPO].

How do you provide your consent to the study?

You can take your time and think about participating this study. If you want to take part, please complete the consent form attached to this information letter. You and the researchers will both receive a signed copy of this consent form.

Do you have any questions?

If you have any questions about the study, please contact the researcher:

- Name
- Organisation
- Email address
- Phone number



RE-SAMPLE – Usability test Healthentia app

- I have read the information letter. I have had the opportunity to ask questions. My questions were answered well enough. I had enough time to decide whether to participate.
- I know that my participation is voluntary, that I can refuse to answer questions and I can withdraw at any time without providing any reason for doing so.
- I give the researchers permission to collect and use my data. The researchers will only do this to answer the research question of this study.
- I give the researchers permission to audio record the user test.
- I understand that my words may be quoted in publications and other research outputs in a way that does not

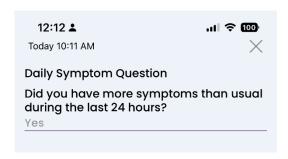
reveal my identity.	
- I	
□ do	
□ do not	
Give permission to contact me after this study if I wa	nt to participate in a follow-up study.
- I want to participate in this study	
My name is (participant):	
Signature:	Date ://
I certify that I have fully informed this participant about the re	search in question.
If new information becomes available during the study that c participant know in time.	could influence the participant's consent, I will let the
Name researcher (or representative):	
Signature:	Date://

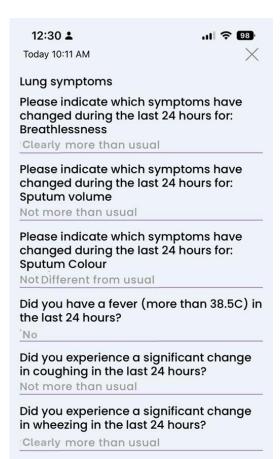


Scenario #3 – Needs to be filled in by participant during session

There is a slight change in symptoms. You're experiencing more shortness of breath, and the colour of your mucus is different than normal. Complete the daily diary within the test version of the app with the following answers:

- 1. More symptoms than usual
- 2. Clearly more shortness of breath than usual
- 3. Not more mucus than usual
- 4. No change in colour of mucus
- 5. No fever, no change in coughing, but clear change in wheezing







Questionnaire 1: Demographics						
1. What is your gender?						
Male						
Female						
Other						
2. Wat is your year of birth (YYYY)?						
2 Decides CODD sub-		4 1.	9			
3. Besides COPD, who	at other chronic conditi	ons ao you n	iave?			
4. For how long are yo	ou diagnosed with COP	PD?				
<1 year						
1-2 years						
3-5 years						
6-10 years						
More than 10 year	urs					
I don't know						
5. What is the highest	degree or level of educ	ation you ha	ve comple	ted?		
Primary school						
High school						
Trade school						
University						
Other, namely:						
6. What is your curren	t employment status?					
Employed full tir	ne					
Employed part tin	me					
Seeking opportur	nities					
Retired						
Unable to work						
Voluntary work						
Other, namely:						
	nembers do you live to					
0	1	2	3		4	>4
	ur health affect your us	ual activities	(e.g. work	, study,	, housework, fa	mily or leisure activities)?
I have no						I am unable to
problems performing my						perform my usual activities
usual activities						
1	2	3			4	5



	Seldom	Sometimes	Often	Always
How confident do	von fool when von fill	out madical forms?		
Not confident at	you feel when you fill Somewhat	Fairly confident	Confident	Very confident
all	· · · · · · · · · · · · · · · · · · ·		0022200220	, org community
Never	meone help you to read Seldom	d brochures, forms or let Sometimes	ters from the hospita	al, pharmacy or your Always
Nevel	Seldom	Sometimes	Often	Aiways
		0.11		
2. I think that my leve	el of digital skills is as	follows:		Really high
Really low				
Really low 1	2	3	4	5
	2	3	4	·
· ·	2	3	4	·
Ĭ			4	•
1 3. Which of the follow	2 wing devices do you us		4	•
3. Which of the follow			4	•
3. Which of the followard Computer/laptop Smartphone	wing devices do you us	se?	4	·
3. Which of the followard Computer/laptop Smartphone		se?	4	•
3. Which of the followard Computer/laptop Smartphone	wing devices do you us	se?	4	•
3. Which of the follow Computer/laptop Smartphone Smartwatch (Fitbi	wing devices do you us	se?	4	



Questionnaire 2: Chatbot usability scale		Surguely disagles Fedural Pries			
	Strongly	disartee Disaglee	\ estral	Agiee	Strongly agree
1. The chatbot function was easily detectable	1	2	3	4	5
2. It was easy to find the chatbot	1	2	3	4	5
3. Communicating with the chatbot was clear	1	2	3		5
4. The chatbot was able to keep track of context			_		
	1	2	3	4	5
5. The chatbot's responses were easy to understand	1	2	3	4	5
6. I find that the chatbot understands what I want and helps me achieve my goal	1	2	3	4	5
7. The chatbot gives me the appropriate amount of information	1	2	3	4	5
8. The chatbot only gives me the information I need				1	
	1	2	3	4	5
9. I feel like the chatbot's responses were accurate	1	2	3	4	5
10. I believe the chatbot informs me of any possible privacy issues	1	2	3	4	5
11. My waiting time for a response from the chatbot was short		2	3	4	5



Appendix F: Final protocol for final usability test of clinical dashboard



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

Usability test – March 2024



This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 965315. This result reflects only the author's view and the European Commission is not responsible for any use that may be made of the information it contains.



Project name : RE-SAMPLE

Country :
Organisation :
Date :
Unique identifier :



Protocol usability test

Phase	Topic	Description	Min.	Materials
1	Welcome	Welcome participant, offer coffee/tea/cookie	2	Coffee/tea,
		Introducing yourself.		cookies
		You are going to do several tests in a moment, I will		
		first give you some background why we are		
	77 1	conducting this study.	2	
2	Explanation	In this research we want to map the usability of the	3	
	of research	Healthentia dashboard. The results of this study will		
		be used for the development of a healthcare technology in the European Horizon2020 project RE-		
		SAMPLE.		
		The RE-SAMPLE project aims to develop a healthcare		
		technology that supports patients and caregivers in a		
		personal way in managing COPD and other chronic		
		conditions, such as chronic and/or ischemic heart		
		failure, diabetes mellitus, anxiety disorders and/or		
		depression.		
		Wild do to Call to the control of		
		With the results of this research, we hope to make the		
		healthcare technology developed in RE-SAMPLE as usable as possible.		
3	Informed	usable as possible.	3	Informed
	Consent		3	Consent Form
4	Demo-		3	Questionnaire 1
	graphics			
5	Think Aloud	You're about to get started with Thinking Aloud. This	2	
		means that while you perform a number of tasks with		
		the Healthentia dashboard, you are sharing your		
		thoughts at the same time. We ask you to tell us what		
		you think while you are busy with the tasks. What do		
		you notice, what do you doubt and what choices do		
		you make? We will practice this first. When you are silent for more than 5 seconds, I will ask you if you		
		can speak your thoughts out loud.		
	-	Exercise:	5	
		Take a few minutes to look around in the Healthentia	3	
		dashboard		
		Link to dashboard: https://demo.healthentia.com		
		Start audio recorder (+ screen capture)	1	Audio recorder
	-		1	
		For every task, you have 5 minutes to complete it. If	1	
		the 5 minutes are over and it is not done, you do not need to finish the task.		
	-	Task 1: It is time for a weekly check of the status of	5	Printed task
		your patients! Start with patient test001. Are there any	3	description 1 +
		alerts for this patient in the period 20/2/2024-		Stopwatch
		5/3/2024? If yes, what alert is there? Tell your answer		
		to the researcher.		
		Task 1: after-scenario questionnaire	2	Task 1: ASQ
		Task 2: Now go to patient test002. Check the medical	5	Printed task
		actions that are suggested by the action plan of the		description 2 +
		patients between the following dates: 01-03-2024 –		Timer
		08-03-2024. Which medical actions are suggested?		
	-	Tell your answer to the researcher.	2	Tools 2. ASO
	-	Task 2: after-scenario questionnaire	2 5	Task 2: ASQ
		Task 3: For patient test003 a new goal needs to be set for physical activity. Please start a shared decision	J	Printed task description 3 +
		making process and follow the steps to decide together		Stopwatch
		making process and ronow the steps to decide together		Stopwatch



		on a daily step goal. Change the daily step goal to a number you think is suitable.		
		Task 3: after-scenario questionnaire	2	Task 3: ASQ
		Task 4: Patient test001 will come in for a 6-month	5	Printed task
		follow-up visit today. Check the questionnaire		description 4 +
		answers of this patient with a focus on changes of		Stopwatch
		symptoms. Did the symptoms of this patient change in		•
		the period 20/2/2024-5/3/2024? If yes, what changes		
		are there? Tell your answer to the researcher.		
		Task 4: after-scenario questionnaire	2	Task 4: ASQ
		Task 5: Check for patient test002 whether there are	5	Printed task
		any risk predictions regarding severe exacerbation. If		description 5 +
		so, what percentage of probability of severe		Stopwatch
		exacerbation is given there? Tell your answer to the		
		researcher.		
		Task 5: after-scenario questionnaire	2	Task 5: ASQ
		Task 6: Have a look at the explanation for today's	5	Printed task
		prediction (any exacerbations) of patient test002. What		description 6 +
		are the main risk factors? Should the goal setting or the		Stopwatch
		treatment be adjusted based on this information?	_	
		Task 6: after-scenario questionnaire	2	Task 6: ASQ
		Task 7: Have a look at the simulations regarding BMI	5	Printed task
		of patient test002. Would a higher or lower value		description 7
		lower the patient's risk for an exacerbation? Should the		+Stopwatch
		goal setting be adjusted based on this information?	2	T. 17 100
		Task 7: after-scenario questionnaire	2	Task 7: ASQ
6	HUBBI		8	Questionnaire 2
	Questionnaire			
7	Short		5	Interview
	interview			Questions
8	Wrap-up and		3	
	thanks			



Task metrics + notes (for moderator)

Task 1

Description: It is time for a weekly check of the status of your patients! Start with patient test001. Are there any alerts for this patient in the period 20/2/2024-5/3/2024? If yes, what alert is there? Tell your answer to the researcher.

After end of task 1: Participants completes the after-scenario questionnaire

	Notes from moderator about task 1	
Time to complete (mm:ss)		
Answer of participant (right answer = Patient transitioned into exacerbation)		Task completed (it's completed if participant gave the right answer)? Yes / No
Issues that occurred during task performance		
(also indicate if these issues occurred multiple times during the same task)		
(you can take a picture of the screen to show the problem)		



Description: Now go to patient test002. Check the medical actions that are suggested by the action plan of the patients between the following dates: 01-03-2024-08-03-2024. Which medical actions are suggested? Tell your answer to the researcher.

After end of task 2: Participants completes the after-scenario questionnaire

Notes from moderator about task 2						
Time to complete (mm:ss)						
Answer of participant (right answer = The patient received on 2024/03/02 an action to tackle anxiety and depression symptoms (do a relaxation	Task completed (it's completed if participant gave the right answer)? Yes / No					
exercise) and on 2024/03/05 an action to tackle COPD symptoms (take prednisolone).) Issues that occurred during task						
performance (also indicate if these issues occurred multiple times during the same task)						
(you can take a picture of the screen to show the problem)						



Description: For patient test003 a new goal needs to be set for physical activity. Please start a shared decision making process and follow the steps to decide together on a daily step goal. Change the daily step goal to a number you think is suitable.

After end of task3: Participants completes the after-scenario questionnaire

Notes from moderator about task 3				
Time to complete (mm:ss)				
Task completed (Yes=changed the daily step goal by first using the	Yes / No			
shared decision tool)				
Issues that occurred during task performance				
(also indicate if these issues occurred multiple times during the same task)				
(you can take a picture of the screen to show the problem)				



Description: Patient test001 will come in for a 6-month follow-up visit today. Check the questionnaire answers of this patient with a focus on changes of symptoms. Did the symptoms of this patient change in the period 20/2/2024-5/3/2024? If yes, what changes are there? Tell your answer to the researcher.

After end of task 4: Participants completes the after-scenario questionnaire

Notes from moderator about task 4						
Time to complete (mm:ss)						
Answer of participant (right answer = Depression and anxiety symptoms score changed from 10 to 200 to 400 to 110 and to 200.		Task completed (it's completed if participant gave the right answer)? Yes / No				
COPD symptoms changed from 330 to 10 to 104 to 104 to 330 to 1120 to 330 to 330.						
CHF symptoms changed from 211 to 201 to 301 to 623 to 301 to 301.)						
Issues that occurred during task performance						
(also indicate if these issues occurred multiple times during the same task)						
(you can take a picture of the screen to show the problem)						



Description: Check for patient test002 whether there are any risk predictions regarding severe exacerbation. If so, what percentage of probability of severe exacerbation is given there? Tell your answer to the researcher.

After end of task 5: Participants completes the after-scenario questionnaire

	Notes from moderator about task 5	
Time to complete (mm:ss)		
Answer of participant	Task completed (it's complete	
(right answer = 12.952%)	participant gave the right answer)?	
	Yes /	No
Issues that occurred during task		
performance		
(also indicate if these issues		
occurred multiple times during the		
same task)		
() ()		
(you can take a picture of the		
screen to show the problem)		



Description: Have a look at the explanation for today's prediction (any exacerbations) of patient test002. What are the main risk factors? Should the goal setting or the treatment be adjusted based on this information?

After end of task 6: Participants completes the after-scenario questionnaire

Notes from moderator about task 6					
Time to complete (mm:ss)					
Answer of participant (right answer = Main risk factors (3 factors): Number of exacerbation in last year, presence of chronic heart failure, BMI score.	Task completed (it's completed if participant gave the right answer)? Yes / No				
Adjustments needed: Only the BMI can change. Other factors cannot be changed.) Issues that occurred during task					
performance					
(also indicate if these issues occurred multiple times during the same task)					
(you can take a picture of the screen to show the problem)					



Description: Have a look at the simulations regarding BMI of patient test002. Would a higher or lower value lower the patient's risk for an exacerbation? Should the goal setting be adjusted based on this information?

After end of task 7: Participants completes the after-scenario questionnaire

Notes from mo	derator about task 7
Time to complete (mm:ss)	
Answer of participant (right answer =	Task completed (it's completed if participant gave the right answer)?
Higher BMI: there is a slight increase from 17.86 to 17.88 (5% BMI increase), and a slight increase in exacerbation from 17.86 to 17.94 (10% BMI increase).	Yes / No
Lower BMI: BMI 5% decrease is same exacerbation risk. BMI 10% decrease is slightly bit higher exacerbation risk (from 1786 to 17.89).	
Adjustments needed: no)	
Issues that occurred during task performance	
(also indicate if these issues occurred multiple times during the same task)	
(you can take a picture of the screen to show the problem)	



Interview questions

- 1. You have now performed a number of tasks using the Healthentia dashboard. What is your general impression of the dashboard?
 - a. What do you like or dislike about it?
 - b. In your opinion, what went well or badly?
- 2. Did you find it easy to use the dashboard?
 - a. Why yes/no?
- 3. What do you think of the appearance of the Healthentia dashboard?
 - a. Do you like the colours?
 - b. Is everything easy to read?
- 4. Do you think the Healthentia dashboard could support you in your work with COPD patients?
 - a. Why yes/no?
- 5. Would you like to use the Healthentia dashboard?
 - a. Why yes/no?



DOCUMENTS FOR PARTICIPANT



RE-SAMPLE - Usability test Healthentia dashboard

- I have had the opportunity to ask questions. My questions were answered well enough. I had enough time to decide whether to participate.
- I know that my participation is voluntary, that I can refuse to answer questions and I can withdraw at any time without providing any reason for doing so.
- I give the researchers permission to collect and use my data. The researchers will only do this to answer the research question of this study.
- I understand that my words may be quoted in publications and other research outputs in a way that does not reveal my identity.

- I	
□ do	
□ do not	
Give permission to contact me after this study if I w	ant to participate in a follow-up study.
- I want to participate in this study	
My name is (participant):	
Signature:	Date ://
I certify that i have fully informed this participant about the r	
If new information becomes available during the study that participant know in time.	could influence the participant's consent, I will let the
Name researcher (or representative):	
Signature:	Date: / /



Questionnaire 1: Demographics
1. What is your gender? Male Female Other
2. Wat is your year of birth (YYYY)? 3. What is your profession (and specialisation)?
4. How many years of work experience in healthcare do you have?
5. What is your frequency of seeing COPD patients? Daily Weekly Monthly Yearly Other, namely:
6. Do you have any experience with eHealth? No Maybe, namely: Yes, namely:
7. What is your attitude towards using eHealth technologies? eHealth is not useful at all eHealth can be useful at times eHealth is useful eHealth is very useful Other, namely:



Task descriptions for participants [print version]

Task 1

It is time for a weekly check of the status of your patients! Start with patient test001. Are there any alerts for this patient in the period 20/2/2024-5/3/2024? If yes, what alert is there? Tell your answer to the researcher.

~------

Task 2

Now go to patient test002. Check the medical actions that are suggested by the action plan of the patients between the following dates: 01-03-2024-08-03-2024. Which medical actions are suggested? Tell your answer to the researcher.

***-----**

Task 3

For patient test003 a new goal needs to be set for physical activity. Please start a shared decision making process and follow the steps to decide together on a daily step goal. Change the daily step goal to a number you think is suitable.

%€-----

Task 4

Patient test001 will come in for a 6-month follow-up visit today. Check the questionnaire answers of this patient with a focus on changes of symptoms. Did the symptoms of this patient change in the period 20/2/2024-5/3/2024? If yes, what changes are there? Tell your answer to the researcher.



Check for patient test002 whether there are any risk predictions regarding severe exacerbation. If so, what percentage of probability of severe exacerbation is given there? Tell your answer to the researcher.

***-----**

Task 6

Have a look at the explanation for today's prediction (any exacerbations) of patient test002. What are the main risk factors? Should the goal setting or the treatment be adjusted based on this information?

*****-----

Task 7

Have a look at the simulations regarding BMI of patient test002. Would a higher or lower value lower the patient's risk for an exacerbation? Should the goal setting be adjusted based on this information?



 $Task\ 1: After\ Scenario\ Questionnaire\ (ASQ)$

	Totally disagr						Totally agree
1. I found performing this task easy	1	2	3	4	5	6	7
	, I	Z	3	4	3	O	<i>I</i>
2. Performing this task did not take me much time	1	2	3	4	5	6	7
3. The dashboard gave me enough help to complete the task							
55p. 555.	1	2	3	4	5	6	7



Task 2: After Scenario Questionnaire (ASQ)

	Totally disagr						Totally agree
1. I found performing this task easy							
	1	2	3	4	5	6	/
2. Performing this task did not take me much time	1	2	3	4	5	6	7
3. The dashboard gave me enough help to complete the task							
	1	2	3	4	5	6	7



Task 3: After Scenario Questionnaire (ASQ)

	Totally disagr						Totally agree
1. I found performing this task easy							
	1	2	3	4	5	6	/
2. Performing this task did not take me much time	1	2	3	4	5	6	7
3. The dashboard gave me enough help to complete the task							
	1	2	3	4	5	6	7



Task 4: After Scenario Questionnaire (ASQ)

	Totally disagr						Totally agree
1. I found performing this task easy							
	1	2	3	4	5	6	/
2. Performing this task did not take me much time	1	2	3	4	5	6	7
3. The dashboard gave me enough help to complete the task							
	1	2	3	4	5	6	7



Task 5: After Scenario Questionnaire (ASQ)

	Totally disagr						Totally agree
1. I found performing this task easy				4		0	7
	1	2	3	4	5	6	7
2. Performing this task did not take me much time	1	2	3	4	5	6	7
3. The dashboard gave me enough help to complete the task							
	1	2	3	4	5	6	7



Task 6: After Scenario Questionnaire (ASQ)

	Totally disagr						Totally agree
1. I found performing this task easy							
	1	2	3	4	5	6	/
2. Performing this task did not take me much time	1	2	3	4	5	6	7
3. The dashboard gave me enough help to complete the task							
	1	2	3	4	5	6	7



Task 7: After Scenario Questionnaire (ASQ)

	Totally disagr						Totally agree
1. I found performing this task easy							
	1	2	3	4	5	6	/
2. Performing this task did not take me much time	1	2	3	4	5	6	7
3. The dashboard gave me enough help to complete the task							
	1	2	3	4	5	6	7



Questionnaire 2: HUBBI (adapted for healthcare professionals) 1. I experienced system errors while using the Healthentia dashboard 2. I get stuck when using the Healthentia dashboard 3. The Healthentia dashboard is convenient to use at the 5 hospital 4. The Healthentia dashboard is suitable for me 5. The Healthentia dashboard is helpful to monitor people with one or more chronic health conditions 6. I can see everything clearly in the Healthentia dashboard 7. The signals, warnings and cues in the Healthentia dashboard are easy to interpret 8. The layout of each page of the Healthentia dashboard is appealing 9. The messages in the Healthentia dashboard are wellstructured 10. I know where in the Healthentia dashboard I can find the information I need 11. I understand the relationships among the different parts of the Healthentia dashboard



				જ્વાં જાણું	ల్ '
	Totally di	Jisatie ^e	P either di ^e	Agice Iv	Tatally agree
12. The Healthentia dashboard information is easy to understand	1	2	3	4	5
13. The error messages in the Healthentia dashboard tell me how to fix problems clearly	1	2	3	4	5
14. The Healthentia dashboard sufficiently explains how to				· ·	
perform system procedures e.g. create account, log on, change settings, connect with other devices	1	2	3	4	5
15. The Healthentia dashboard provides sufficient feedback to					
support me in monitoring my patients	1	2	3	4	5
16. Overall, I am satisfied with the Healthentia dashboard	1	2	3	4	5

