



# An Integrated Solution for Sustainable Care for Multimorbid Elderly Patients with Dementia



## WP2: User Requirement Definition and Design of CAREPATH System Architecture

### D2.1: User Requirements Analysis

**Contractual Date of Delivery to the EC:** 30 November 2021 (M5)

**Actual Date of Delivery to the EC:** 14 January 2022

**Participant(s):** <sup>2</sup>Fraunhofer, <sup>1</sup>EXYS, <sup>3</sup>SKB, <sup>4</sup>WARWICK, <sup>5</sup>UHCW, <sup>6</sup>SESCAM, <sup>8</sup>CITST, <sup>9</sup>SRDC, <sup>10</sup>OCT

**Author(s):** <sup>2</sup>Henrike Gappa, <sup>2</sup>Yehya Mohamad, <sup>2</sup>Carlos Velasco, <sup>1</sup>Angelo Consoli, <sup>1</sup>Jaouhar Ayadi, <sup>1</sup>Luca Gilardi, <sup>3</sup>Wolfgang Schmidt-Barzynski, <sup>3</sup>Antje Steinhoff, <sup>4</sup>Theodoros N. Arvanitis, <sup>5</sup>Timothy Robbins, <sup>6</sup>Pedro Abizanda Soler, <sup>8</sup>Oana Cramariuc, <sup>8</sup>Cristiana Ciobanu, <sup>9</sup>Gokçe Banu Laleci Erturkmen, <sup>10</sup>Lionello Ferrazzini

**Type:** (P-prototype, R-report, O-other, ORDP-Open Research Data Pilot, DEM-Demonstrator, ET-Ethics): R

**Dissemination level:** PU

**Version:** 1v9

**Total number of pages:** 75



*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945169.*

## Executive Summary

This deliverable describes how a human-centred development process in accordance to ISO 9241-2010:2019 "Ergonomics of human-system interaction" [3] has been implemented in CAREPATH. This process includes thorough investigation of the target end users' needs. Acknowledged methods of human-centred design were used for this purpose such as interviews with target end user groups that are multimorbid older patients with Mild Cognitive Impairment (MCI) or mild dementia, informal caregivers and health professionals from various disciplines. Beyond this, ideation workshops were conducted to support development of innovative clinical decision support features including risk assessment of patients that will result in warnings about e.g., early detected deterioration of conditions of patients' comorbidities on base of health data collected by a Health/Home Monitoring Platform and self-recordings from patients documented on the CAREPATH platform.

For user requirements specification it was a major challenge to aggregate the information inherent in the aforementioned sources to a traceable set of more prescriptive user requirements. The Volere template for requirements specification proved to be useful for this step, since the results need to be documented in a way that can be communicated effectively to developers of the CAREPATH project. To ensure that specified system requirements can be followed up on, a requirements specification workflow was implemented in CAREPATH with support of the bug tracking platform Atlassian Jira. A description of this workflow as well as the features of the Volere requirements specification template are included in this deliverable.

In accordance to T2.1 'User Requirements Analysis' an initial set of requirements was created in CAREPATH as presented in appendix D. However, user requirements specification will continue and lead to the development of the first viable CAREPATH prototype. User evaluation of this prototype will result in the refinement of this initial set of user requirements which will be discussed in the next version of this deliverable namely D2.6 'Requirements Re-engineering'.

## Table of contents

<b>1</b>	<b>INTRODUCTION</b>	<b>6</b>
1.1	PROJECT INFORMATION	6
1.2	DOCUMENT SCOPE	6
1.3	DOCUMENT STRUCTURE	6
<b>2</b>	<b>HUMAN-CENTRED DESIGN APPROACH IN CAREPATH</b>	<b>7</b>
<b>3</b>	<b>USER REQUIREMENTS SPECIFICATION</b>	<b>8</b>
3.1	INTERVIEWS WITH PATIENTS, INFORMAL CAREGIVERS AND HEALTH PROFESSIONALS	8
3.1.1	<i>Interviews with patients</i>	9
3.1.1.1	Test sample patients	9
3.1.1.2	Interview guideline	9
3.1.1.3	Results	10
3.1.2	<i>Interviews with informal caregivers</i>	12
3.1.2.1	Test sample	12
3.1.2.2	Interview guideline	13
3.1.2.3	Results	13
3.1.3	<i>Interviews with health professionals</i>	14
3.1.3.1	Test sample	14
3.1.3.2	Interview guideline	15
3.1.3.3	Results	16
3.2	IDEATION WORKSHOPS	17
3.2.1	<i>Key scenarios for CAREPATH Clinical Decision Support Modules (CDSM)</i>	18
3.2.2	<i>Early warnings from Advanced Early Warning Smart Decision Tools (AEWSDT)</i>	19
3.3	USER REQUIREMENTS DESCRIPTION IN THE VOLERE FORMAT	20
3.3.1	<i>User requirements workflow</i>	21
3.3.2	<i>Status of user requirements specification</i>	22
<b>4</b>	<b>CONCLUSION</b>	<b>25</b>
<b>5</b>	<b>APPENDIX A – INTERVIEW GUIDELINE PATIENTS</b>	<b>26</b>
<b>6</b>	<b>APPENDIX B – INTERVIEW GUIDELINE INFORMAL CAREGIVERS</b>	<b>40</b>
<b>7</b>	<b>APPENDIX C – INTERVIEW GUIDELINE HEALTH PROFESSIONALS</b>	<b>49</b>
<b>8</b>	<b>APPENDIX D – INITIAL SET OF USER REQUIREMENTS</b>	<b>58</b>
<b>9</b>	<b>REFERENCES</b>	<b>74</b>
<b>10</b>	<b>DOCUMENT HISTORY</b>	<b>75</b>

## List of figures

<i>Figure 1: Screenshot of inclusion criteria for interviews with patients</i> .....	9
<i>Figure 2: Screenshot of inclusion criteria for interviews with informal caregivers</i> .....	13
<i>Figure 3: Screenshot of inclusion criteria for interviews with health professionals</i> .....	15
<i>Figure 4: Results second ideation workshop</i> .....	19
<i>Figure 5: Results of third ideation workshop</i> .....	20
<i>Figure 6: Screenshot of a JIRA Volere template</i> .....	21
<i>Figure 7: CAREPATH user requirements workflow</i> .....	22
<i>Figure 8: Created CAREPATH user requirements (issues)</i> .....	22
<i>Figure 9: Distribution of user requirements among WP3 and WP4</i> .....	23
<i>Figure 10: Distribution of user requirement types</i> .....	23
<i>Figure 11: Priorities of user requirements</i> .....	24

## Abbreviations

AEWSDT	Advanced Early Warning Smart Decision Tools
CAREPATH	An integrated Solution for Sustainable Care for Multimorbid Elderly Patients with Dementia
CDSM	Clinical Decision Support Modules
DoA	Description of Action
EHR	Electronic Health Record
H/HMP	Health/Home Monitoring Platform
I.C.	Intrinsic capacity
MCI	Mild Cognitive Impairment
PEP	Patient Empowerment Platform
PROM	Patient Reported Outcome Measures
WP	Work Package

# 1 Introduction

## 1.1 Project information

CAREPATH is a Horizon 2020's funded project (Grant agreement ID: 945169), proposing an ICT based solution for the optimization of clinical practice in the treatment and management of multimorbid older patients with Mild Cognitive Impairment (MCI) or mild dementia. In order to achieve this, CAREPATH will elaborate on a methodology for computer interpretable clinical guidelines and computationally derived best clinical practice for best suitable treatment of this patient group. Thereby, a multidisciplinary care approach is considered, with a focus on the very individual needs of these patients to be translated into personalized care plans for increasing their independence and Quality of Life (QoL).

The CAREPATH project started on July the 1<sup>st</sup>, 2021 and will end on June the 30<sup>th</sup>, 2025.

## 1.2 Document scope

In this deliverable the methods and procedures applied in CAREPATH to implement a human-centred design approach will be described. Eliciting user requirements is considered crucial in this approach to ensure that developments will meet the needs of target users of a product, system or service. Therefore, it was the goal of 'T2.1 User requirements analysis' (M01-M46) to create an initial set of user requirements that can serve as viable base of prototype development in CAREPATH. Interviews with target user groups of the CAREPATH system were used as method to collect user requirements and ideation workshops were conducted with health professional and developers of the project consortium to gain a better understanding of useful clinical decision support features in the context of CAREPATH (for more information see Section 3.2).

During prototype development it is to expect that new user requirements will emerge and existing ones may need refinement when evaluated by expert walkthroughs of the consortium involving where possible target end users and a dedicated usability study. Therefore, user requirements collection is an ongoing process, so this document shall be considered a living document that will be updated as part of 'D2.4 Final Holistic CAREPATH Architecture, System Specification and Collection of User Requirements' and 'D2.6 Requirements Re-engineering'.

## 1.3 Document structure

The deliverable is organized as follows:

- Chapter 1 - provides most importantly information about the scope deliverable
- Chapter 2 – describes the human-centred design approach applied in CAREPATH
- Chapter 3 – describes the user requirements specification process implemented in CAREPATH and the methodologies used to elicit proper user requirements with target end users such as interviews and ideation workshops
- Chapter 4 – concludes on findings from the user requirements specification process
- Appendix A – includes the interview guideline for patients
- Appendix B – presents the interview guideline for informal caregivers
- Appendix C – shows the interview guideline for health professionals
- Appendix D – presents a list of user requirements defined so far.

## 2 Human-centred design approach in CAREPATH

For all CAREPATH developments a strict human-centred design approach is followed in accordance to ISO 9241-210 'Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems' [3]. The goal of this ISO norm is to provide requirements and recommendations in order to implement properly human-centred design principles and activities that will apply throughout the life cycle of an IT-based product, system or service. Such activities include:

- Thorough understanding of the target user(s), their tasks and use environments (context of use)
- Involvement of target users in the design and development process
- User evaluations to drive refinement and adjustment of design solutions
- Implementation of an iterative development process
- Consideration of user experience principles in the design process
- Involvement of a multidisciplinary team in the development process

All such activities will take place in CAREPATH or have already been initiated. For instance, the recommendation to involve a multidisciplinary team in the design is ensured by project partners contributing expert knowledge from different domains such as varying health subjects (geriatrics, GP, sociology), software/hardware engineering, AI (Artificial Intelligence) and usability engineering. The project foresees iterative development processes by evaluation of prototypes through group-based expert walkthroughs [1] and a Technical Validation and Usability study for refinement of the CAREPATH platform according to users' needs before the clinical study will start. Target user groups of the CAREPATH platform have been identified in the beginning of the project which are:

- Health professionals from potentially all medical fields (CAREPATH multidisciplinary care approach)
  - however, to focus development, it was decided to narrow down the target groups to groups of health professionals that will participate in the clinical studies at pilot sites (e.g., medical doctors (geriatrics, GPs) nurses at clinics and mobile nursing services, occupational therapist)
- Multimorbid older patients with diagnosed Mild Cognitive Impairment (MCI) or mild dementia
- Informal caregivers

In order to involve target user groups from the beginning of the project interviews were conducted at pilot sites with altogether:

- 16 multimorbid older patients with MCI or mild dementia
- 16 informal caregivers
- 16 health professionals from various disciplines (see above)

Interviews were seen to be the most suitable format due to the continuing pandemic situation not recommending group formats and limited availability of interviewees making it difficult to find a common date to conduct focus groups or the like. The interviews served as main source to collect user requirements in regard to the CAREPATH platform from the perspective of the various target user groups. In course of these interviews, interviewees were asked whether they are willing to participate in the design process. Fortunately, from all CAREPATH target user groups some interviewees indicated their willingness to participate in the design process where the consortium will seek to take advantage of. More detailed information on the design and results of the interviews is available at section 3.1.

In CAREPATH it is aimed to offer clinical decision support to optimize the treatment of multimorbid older patients with MCI or mild dementia. Since the treatment of this patient group is rather complex, beyond this, it is of high importance to consider the patients' individual health situation and medical guidelines do not offer guidance for this purpose so far, it was necessary to investigate what information would be helpful for health professionals and how could it be derived with CAREPATH tools in a safe manner. To receive a clear understanding of these issues four 1-hour ideation workshops were conducted with health professionals and developers of the CAREPATH consortium. One workshop dealt with CAREPATH Clinical Decision Support Modules and sketching ideas on useful key scenarios of the modules in everyday clinical practice when treating the patient target group. As one result of this workshop it was decided to have more ideation workshops on the CAREPATH Advanced Early Warning Smart Decision Tools to receive a better understanding of how 'early warnings' could look like in predicting patients' intrinsic capacity and dementia profile. For further details on how the ideation workshops were conducted and their outcomes (see Section 3.2).

## 3 User requirements specification

The ISO 9241-210 standard does not prescribe specific methods on how to achieve human-centred design principles, they are to be chosen according to the current state of the art and what is appropriate under the respective project goals. Based on practical experiences from other R&D projects it was decided that collecting an initial set of user requirements from the target user groups was most suitable to achieve a viable base for starting prototype development in CAREPATH. As already mentioned during prototype development more user requirements will evolve and existing ones refined through evaluation of prototypes by consortium members with their various backgrounds and where possible involvement of target end users as well as a standard usability study before the CAREPATH platform will be used in the clinical study.

User requirements are descriptions of how a system is expected to perform from the user's perspective and to provide specifications of system properties and attributes. In CAREPATH the Volere format was chosen for specification of user requirements as recommended by Robertson & Robertson [5]. This format provides a means to ensure consideration of all important aspects of requirements specification which has proven to be of high value in driving appropriate technical realization of user requirements [2]. Furthermore, user requirements are processed according to a predetermined workflow from creation to validation once implemented assuring that they always remain applicable. The Volere template describes a user requirement by, e.g., a short summary, a rationale and a testable fit criterion which supports to close the well-known user-developer gap by acknowledging the different form of needs expression on users' and developers' side. For more details on the Volere format and the workflow of user requirements implemented in CAREPATH, please refer to 3.3.

In order to ensure a valid source for user requirements collection it is mandatory to involve real end users of the envisioned development. Therefore, interviews with patients and informal caregivers were conducted to investigate (self-)management of their health and care situation, as well as problems and needs following thereof. Interviews with health professional from various disciplines took also place focussing on problems with the treatment of multimorbid older patients with MCI or mild dementia and how clinical decision support tools can support best personalized treatment decisions. As mentioned, ideation workshops with health professionals of the consortium and developers were held to investigate useful clinical decision support features.

In the following chapters the methodology to collect user requirements from real end users and its results will be described as well as how user requirements specification was performed in CAREPATH.

### 3.1 Interviews with patients, informal caregivers and health professionals

Conducting interviews with target end user groups was considered most appropriate to involve real end users in the elicitation of user requirements first of all due to the pandemic situation not favouring group formats such as focus groups and limited availability of volunteers making it difficult to find a commonly agreed date for a workshop where in addition to that, volunteers would have needed to come to the hospitals outside of their routine appointments. Interviews are an acknowledged method for gathering valid in-depth information suitable particularly in early design stages where issues to be considered for technical development are still broad [5][6]. They also offer a valuable means to gather information about opinions and attitudes of target end user towards IT-based environments such as CAREPATH and necessary pre-conditions for user acceptance in particular when they are semi-structured. Therefore, semi-structured interviews were conducted at pilot sites with altogether:

- 16 multimorbid older patients with MCI or mild dementia
- 16 informal caregivers
- 16 health professionals from various disciplines.

In order to ensure that results of the interviews are comparable among pilot sites and address future CAREPATH target groups appropriately, inclusion criteria were agreed on. Since the project did not have a data protection agreement in place yet when conducting the interviews, no personal data were taken of interviewees. They were conducted under 'Patient and Public Involvement (PPI)' or similar regulations at each country involved. For language reasons partners at pilot sites conducted the interviews according to interview guidelines which were collaboratively achieved as part of WP2, T2.1 work. The interview guidelines offered also possible response options. This approach supported interviewers in addressing key themes the consortium aimed to investigate and allowed to gain well comparable data at the end. All response options were always enhanced by an 'other' field and clinical partners were instructed that the response options are only to understand as a thematic preselection, they may also use to keep documentation of the interviews in reasonable limits. However, the consortium is much interested in information provided beyond these. Experience from FIT in other e-health projects has proven that this approach is yielding valid results for user



requirements collection [4]. The interviews including all CAREPATH target user groups took place from October 2021 until December 2021 and were conducted by pilot partners at their premises.

### 3.1.1 Interviews with patients

Interviews with patients were conducted with 4 patients at each pilot site. In the following a description of the inclusion criteria, the interview guideline and a summary of results.

#### 3.1.1.1 Test sample patients

As mentioned, pilot sites included interviewees according to the inclusion criteria. The following table of inclusion criteria was provided to pilot sites to ensure that the interviewees meet the inclusion criteria. It was also used to ensure that the group of patients involved in the interviews represents crucial characteristics of the CAREPATH patient target group, e.g., in regard to gender and different living situations (alone or with caregiver) which are expected to have impact on the user requirements.

Age ≥ 65 years	Yes <input type="checkbox"/>
Adequate visual and auditory acuity	Yes <input type="checkbox"/>
6 years of formal education after the age of 5 years	Yes <input type="checkbox"/>
MCI or Dementia (2 patients of each) <ul style="list-style-type: none"> <li>• NIAAA core clinical criteria for probable AD dementia</li> <li>• Mild Cognitive Impairment due to Alzheimer’s Disease</li> </ul>	Yes <input type="checkbox"/> Yes <input type="checkbox"/>
MMSE score ≥ 22 points and CDR-GS 0.5 or 1.0.	Yes <input type="checkbox"/>
Multimorbidity (at least one) <ul style="list-style-type: none"> <li>• Diabetes mellitus, hypertension, heart failure, chronic obstructive pulmonary disease, asthma, stroke, chronic kidney disease, frailty, sarcopenia, coronary artery disease</li> </ul>	Yes <input type="checkbox"/>
Sex (include 2 patients of each sex)	Male <input type="checkbox"/> Female <input type="checkbox"/>
Living at home	Yes <input type="checkbox"/>
Informal caregiver availability <ul style="list-style-type: none"> <li>• Patient living with caregiver (2 patients)</li> <li>• Patient not living with caregiver (2 patients)</li> </ul>	Yes <input type="checkbox"/> Yes <input type="checkbox"/>
Informal caregiver <ul style="list-style-type: none"> <li>• Older person like spouse (2 patients)</li> <li>• Young person like son or daughter (2 patients)</li> </ul>	Yes <input type="checkbox"/> Yes <input type="checkbox"/>
Independence in BADL	Yes <input type="checkbox"/>
Patient and informal caregiver use at least one electronic device	Yes <input type="checkbox"/>

**Figure 1: Screenshot of inclusion criteria for interviews with patients**

#### 3.1.1.2 Interview guideline

The goal of patient interviews was to gain a better understanding of how the organization of everyday life is affected by their health conditions and what specific tasks they need to fulfil in order to manage their condition such as proper medication intake, managing everyday life, dealing with different health professionals etc. The consortium is aware that people with cognitive impairments are a vulnerable user group and that the special situation when interviewing this user group needs to be considered. Therefore, questions were worded as simple and concrete as possible and in most cases the informal caregivers were present at the interviews to help responding, if necessary, and make the interviewee be comfortable with the situation as much as possible.

The full interview guideline is available in appendix A, chapter 5. In the following a short summary of what topics were investigated:

- Technical expertise of patients and possible accessibility issues when using electronic devices such as a smartphone, tablet, smartwatch etc.
- Self-management of the health conditions at home, tasks to-do such as proper medication intake, measuring health parameters etc., communication with medical doctors, possible problems with self-management and support preferences
- Impact of the cognitive impairment on achieving activities of everyday life such as household and leisure time activities, issues they experience and what they would like help with
- Exercising and an appropriate diet are understood as crucial in the treatment of multimorbid older patients with MCI or mild dementia, therefore, the current practice and preferences of patients were investigated in regard to these issues
- One goal of CAREPATH is to empower patients in self-managing their health conditions. So, feeling in control of the health situation and possible open needs and preferences in regard to, e.g., being informed about the current personal health status were investigated in the last part of the interview.

### 3.1.1.3 Results

First of all, it shall be mentioned that patients could deal well with the interview situation. 8 patients even offered to help with the design of PEP. In case of questions that require hypothesizing, i.e. whether it could be helpful when talking to their doctors, if their blood pressure measurements were recorded, was for some patients too difficult as it was to expect, so they answered with 'don't know'. Except for three interviews, informal caregivers were present at the interviews as well and in few cases helped to answer questions or were asked about their opinion on an issue. However, all interviews were mainly answered by patients, so results can be understood as reflecting their preferences and needs. In the following, interview results will be summarized as most relevant for elicitation of user requirements and the technical realization of the CAREPATH platform. The presentation will be organized according to topics covered in the interview guideline.

#### Technical expertise:

- All in all 13 patients used smartphones, 3 patients also a laptop and 1 additionally a tablet
- Except for 2 interviewees who were not able not use their smartphones at all at the moment due to a decline of their cognitive abilities, usage of the electronic device varied from 2 to 12 years. 5 patients could not remember for how long they have been using their smartphones.
- 7 patients said they use their devices for calls, 7 for messaging and chats (e.g. WhatsApp), 4 for searching the Internet
- Patients thought that using an app/application is easy, if they are used to it, e.g., use it since many years or, e.g., a relative has taught them how to use it
- 10 patients were able to use their devices independently, if nothing unusual happens. Relatives and informal caregivers help in case of problems.

#### Main difficulties and accessibility problems when using an electronic device:

- To keep up with changes/updates/phone system and different apps. Seems like big task and too confusing
- Problems remembering necessary steps, especially after updates
- Mouse control
- Selection by fingertip
- Swipe gesture causes problems, pressing a button should be enough
- Pinch gesture is a problem
- Responsiveness of touch screen
- Buttons too small
- Too much information at once
- Problems with information processing
- Too many functions
- Sound quality not sufficient for limited hearing
- No understanding of the information on the display
- Fear of touch, fear of scammers, accidentally revealing information, fear of destroying the device

- Patients feel observed with voice input controls, fear of fraudsters.

#### Self-management of the health condition at home:

- Tasks patients said they were asked to do by their medical doctors: medication intake (n=10), measure blood pressure (n=7), drink more/less fluid (n=5), do exercises (n=4), go for walks (n=4), measure blood sugar (n=4), measure weight (n=3), watch your diet (n=2)
- 12 patients said they know what their daily tasks are to take care of their conditions, 4 patients said they know from their informal caregiver
- When presented the example daily care plan, that could be shown to patients on a tablet to support them in achieving their daily care task properly, 6 patients responded that this could be of help to them, 10 stated that they do not think so. Reasons provided were that they do not have many tasks to do, that it is everyday routine for them and 4 patients would feel supervised. However, 8 informal caregivers were interested in receiving such a plan for them as well their care dependent to be aware of the to-dos and their status.
- 6 patients stated that they need help with taking their medication, 10 patients are able to manage this on their own with established methods such as pill box, daily plan etc.
- 14 patients said that they do not document medication intake, when asked whether this could be helpful in their opinion when talking to medical doctors 5 patients said 'yes' and 5 did not know.
- 9 patients measure health parameters such as blood pressure whereas 5 do not. However, majority does not document them (n=12), but 7 think it would be helpful to have such a documentation when talking to medical doctors, 2 think that they do not need this, because they take long always most recent results. When asked when they take their measurements 11 patients stated when they do not feel well.

#### Impact of the cognitive impairment on achieving activities of everyday life:

- 8 patients stated that they need help with everyday activities, mainly shopping, preparing meals and household activities, 8 patients said that they do not need help
- 9 patients admitted that they forget things they wanted to do, e.g., call a friend, a family member, or listen to concerts on the radio, 5 patients thereof would like to be reminded of these, 2 patients are reminded by their spouse
- In regard to writing notes for themselves: 8 patients stated they want to remind themselves of doctor's appointments, the medication list and to document symptoms such how they feel, headaches, constipation issues etc., shopping list, 5X symptoms, e.g., pain, breath shortness, also for communication with doctors.

#### Gaming:

- Since PEP also aims to provide some fun activities for cognitive stimulation and acceptance of the platform, patients were asked about their leisure time activities and games they would like to play. Activity most selected was watching TV (n=15), followed by playing games (n=7), looking at family videos (n=5), calling family members (n=5) and calling friends (n=4). When asked about favourite games, the one named with vast majority was Sudoku (n=9), Patients play games alone or with others, however, their preference is to play with others though (n=8).

#### Exercises and nutrition:

- Doing exercises and keeping an appropriate nutrition is understood in CAREPATH as a substantial part of treatment, therefore these topics were investigated in the interviews:
- 8 patients said that they are exercising, 8 patients are not doing this (going for walks is seen by some patients as exercising)
- 2 patients are exercising with help of a physiotherapist, one with the informal caregiver, no patient is going to a sports club or the like.
- Patients are not using any apps or videos for exercising, 1 patient has an exercise chair and vibrating plate
- If exercising with the help of technology. 6 patients prefer exercising by myself, 2 patients be rather in groups, 3 patients were not sure.

#### Diet:

- 8 patients think that they have an equilibrated diet, 8 patients do not think so. Reasons provided are that they eat what they want, cannot cook, like sweet food or live with an eating disorder
- 10 patients think that following a healthy diet cannot be achieved in their case, because meals are coming from external sources, patients do not want to change habits, they cannot cook, their wife cooks whose food they like.

#### Control over health status:

- 8 patients stated that they have good overview on their health status, 3 patients did not know
- In the opinion of 7 patients utilizing technology could help to receive better overview on the personal health condition by, e.g., checking results of blood pressure measurements (n=7), weight (n=4), sleep (n=3), pain (n=3), medication intake (n=2)
- 11 informal caregivers stated that they would be much interested in being presented recordings from patients' health measurements
- 12 patients would like to have the opportunity to get in contact with doctors' outside of regular appointments in case they do not feel well or have questions about medication intake.

Findings of the interviews served as base for user requirements collections which can be viewed in appendix D, chapter 8 and will be further used as source of information for CAERPATH technical developments. As it was to expect only about 50% of the patients can imagine that a technical solution such as CAREPATH can support them in coping with their health conditions better by providing, e.g., a daily care plan. This is probably due to the fact that the benefit is not easy to imagine for this patient group and the technical solution competes with meanwhile established personal coping strategies. The clinical studies will show whether patients will see advantages in CAREPATH by offering a much optimized treatment approach. The benchmark to adopt such a solution will be most likely whether they experience an improvement in their quality of life.

The technical expertise seems to vary a great deal in this patient group (2 years -12 years) and obstacles reported in using electronic devices and applications are very much in line with what is addressed in design recommendations for people with dementia, so according user requirements were defined (see user requirements CARE-11 and CARE-12). What became also clear from the interviews is that much care needs to be taken that patients will not feel overwhelmed with too many tasks and new situations they may easily experience as obstructive. Besides this they aim to lead a self-determined life as much as possible and seek support only where deemed necessary.

A bit surprising result of the interviews was that the necessity to do exercises (mentioned by only 4 patients) and adhere to a healthy diet (mentioned by 2 only patients) seems hardly to be addressed in the treatment of this patient group, at least not to the knowledge of the patients. Another interesting result was that knowing about health measurements as indicator for a good health condition is given much priority over medication intake, hinting at that the relation is not seen.

### 3.1.2 Interviews with informal caregivers

Informal caregivers play a major role in the care of multimorbid older patients with MCI or mild dementia and are seen as important partners in fostering acceptance and adoption of CAREPATH services by patients. Beyond this, they often feel overburdened with their care tasks and so their needs and preferences are also in focus of the project. Therefore, interviews were conducted with 4 informal caregivers at each pilot site to collect their preferences and needs. In the following a description of the inclusion criteria, the interview guideline and a summary of results.

#### 3.1.2.1 Test sample

As for patient interviews, pilot sites were provided criteria for including an appropriate group of informal caregivers to cover properly gender aspects and different care situations, e.g., the informal caregiver is living in the same household as the care dependent or at a different location. The age group of the informal caregiver was also considered to have an impact on the user requirements, therefore, this aspect was as well included in the inclusion criteria. The inclusion criteria were as follows:

Sex (include 2 informal caregivers of each sex)	Male <input type="checkbox"/> Female <input type="checkbox"/>
Informal caregiver • Living with the patient (2 informal caregivers) • Not living with the patient (2 informal caregivers)	Yes <input type="checkbox"/> Yes <input type="checkbox"/>
Informal caregiver • Older person like spouse (2 informal caregivers) • Young person like son or daughter (2 informal caregivers)	Yes <input type="checkbox"/> Yes <input type="checkbox"/>
Informal caregiver uses at least one electronic device	Yes <input type="checkbox"/>

**Figure 2: Screenshot of inclusion criteria for interviews with informal caregivers**

### 3.1.2.2 Interview guideline

The interview guideline for informal caregivers addressed mainly issues informal caregivers may experience in the care for a care dependent, e.g., meet the requirements to ensure a safe life of the care dependent at home and how H/HMP and PEP features could be used to support informal caregivers in these tasks. The interview guideline for informal caregivers can be viewed at appendix B, chapter 6. The investigated topics can be summarized as follows:

- Technical expertise and possible accessibility issues
- Management of the care situation, e.g., is support needed with keeping track of the care dependents to-dos to manage his/her health condition such as medication intake and appointments with health professionals or difficulties with organizing leisure activities, feeling sure about the care dependents health situation
- Affordable time to support the care dependent in dealing with devices from H/HMP and PEP
- Design of H/HMP sensors and devices, so they will be accepted by the care dependent.

### 3.1.2.3 Results

In the following a summary of results from interviews with informal caregivers according to investigated topics.

Technical expertise and obstacles in using devices and/or applications:

- All informal caregivers seem to be experienced with technology, all of them are using a smartphone and are using it since many years (at least 5 years). They are using laptops for browsing the Internet and/or work, 5 of them are owning a tablet. Devices are used for standard applications such as email, online banking, chatting with family, video chats etc. 1 informal caregiver is using a smartwatch and a GPS tracker to follow up on their care dependent. Problems encountered are most of all with gestures such as the pinch gesture and insufficient responsiveness to touch – at least in the eyes of the informal caregivers. Too small screen of mobile devices was another obstacle, because scrolling is very cumbersome and disorienting leading to loss of information.

Management of the care situation at home:

- A clear majority of informal caregivers stated that they need help with managing the care situation (n=10 vs. n=5 who said that for now they can handle the situation), mainly with:
  - Keeping track of appointments they have to make with medical doctors and/or therapists (n=4)
  - Taking to and picking up relatives from appointments with therapists, friends, social activities etc. (n=4)
  - Worries that they cannot leave the house, because they do not know what is happening when they are away (n=4). They are mainly afraid that the care dependent might fall, starts wandering in the house or leaves the house (n=4), accidents may happen with using the kitchen, water spilling etc. (n=3)



- Make sure the relative keeps a healthy diet (n=3)
  - Make sure that the relative is taking medication as prescribed (n=2)
  - Keep track of noticing when a medication is running out (n=2)
  - Make sure the relative does physical exercises (n=2).
- When asked about whether informal caregivers feel sometimes unsure about their relative's health situation, 7 informal caregivers answered with 'No', 1 felt unsure and 8 informal caregivers stated that they feel unsure with mainly:
    - Risk of fall (n=7)
    - Deterioration of cognitive status they do not notice (n=5)
    - Deterioration of physical status they do not notice (n=3)
    - Behavioural problems and conflicts (n=3).
  - Affordable time to support the care dependent in dealing with devices from H/HMP and PEP varied much from 5-10 mins to offering continuous support. This seems to dependent much on the situation of the informal caregiver, e.g., informal caregivers living together with the care dependent offered, e.g. continuous support whereas informal caregivers still working or living somewhere else 5-10mins.

Design of H/HMP sensors and devices:

Design requirements that were stated by informal caregivers together with their care dependent:

- Be comfortable to wear (n=11)
- Easy to handle, e.g. closing of the smartwatch is easy to open (n=10)
- Need to be able to find the device in case it is misplaced, e.g., the smartwatch (n=9)
- Be seamless (n=5)
- Might be taken off and nobody notices it (n=5).

It was mentioned that usage of the sensors and devices must be safe and that patients do not feel spied on.

In summary, it became obvious from the interviews that informal caregivers clearly need support with their care tasks and that a lot of the tasks mentioned by them can be supported with technology environments such as CAREPATH, e.g., keeping track of appointments they have to make with medical doctors and/or therapists, counteracting worries that they cannot leave the house, because they do not know what is happening when they are away, e.g., the care dependent may fall or leave the house which could be observed by H/HMP and a message sent to the informal caregiver informing him/her about a potentially harmful situation. In regard to design of the sensors and devices used in CAREPATH it must be ensured most importantly that they are comfortable to wear and easy to handle. It is also crucial that they can be searched for in case of misplacement. The issue of feeling safe and not spied on also needs to be taken into account for acceptance of the platform. Since informal caregivers seem to have rather extensive experience with technology and offered to invest some time to support their care dependent in using the CAREPATH platform, it appears likely that they are willing to help their relative in becoming familiar with the applications for patients.

### 3.1.3 Interviews with health professionals

Health professionals of various disciplines are a main target group of the CAREPATH platform. Therefore, 4 interviews with health professionals from different health care domains were conducted at each pilot site. In the following chapters the inclusion criteria and the types of health professionals selected for interviews, the interview guideline and a summary of interview results are presented.

#### 3.1.3.1 Test sample

The CAREPATH platform aims to support a multidisciplinary care approach in the treatment of multimorbid older patients with MCI and mild dementia. Therefore, the consortium seeks to involve health professionals from various disciplines in the clinical studies at pilot sites. To ensure that the needs of health professionals who have already agreed to participate in the clinical study are covered, interviews were carried out with a representative of each group. These are:

SESCACM - 1 hospital medical doctor, 1 GP, 1 occupational therapist, 1 hospital nurse  
 CITST – 1 hospital medical doctor, 2 GPs, 1 hospital nurse  
 UHCW – 2 hospital medical doctors from various disciplines, e.g., geriatrics, 2 hospital nurses  
 SKB – 1 hospital medical doctor, 2 GPs, 1 nurse working for a mobile nursing service.

Inclusion criteria were:

Type of health professional	Please select:
GP	<input type="checkbox"/>
Hospital medical doctor	<input type="checkbox"/>
Nurse	<input type="checkbox"/>
Allied professional	<input type="checkbox"/>
<p>Note: please ensure that the gender aspect is taken into account (ratio women/men spread almost evenly among interviewees at each trial site) and that the professional experience of the interviewee is at least 3 yrs.</p>	

**Figure 3: Screenshot of inclusion criteria for interviews with health professionals**

### 3.1.3.2 Interview guideline

The interview guideline for health professionals aimed to investigate the main problems in the treatment and care of multimorbid older patients with MCI or mild dementia from point of view of the various health professionals and how could their work be best supported with features foreseen for the CAREPATH platform. The full interview guideline is available in appendix C, chapter 7 In the following a short summary of covered topics:

- Main problems in the treatment and care of multimorbid older patients with MCI or mild dementia, e.g., lack of appropriate medical guideline for patients' complex health condition, success of treatment depends very much on the individual health condition, communication among the care team, patients as reporters about their health condition in particular in retrospect.
- Useful health measurement results and feedback from environmental sensors that could be offered by H/HMP
- Useful analysis of H/HMP measurements to support treatment and care for multimorbid older patients with MCI or mild dementia
- Assessment of risks the CAREPATH patient target group is particularly vulnerable to and that are relevant for health professionals' work
- Relevant parameter to determine a 'dementia profile' as foreseen in CAREPATH to support clinical decision support
- Appropriate reminding of patients about self-management tasks, e.g., medication reminders
- Provision of educational materials and if yes, what kind, e.g., links to websites, diet and/or exercise plans
- Non-pharmacological interventions CAREPATH can monitor and/or implement to help improve the quality of life of the CAREPATH patient target group such as games, routines in everyday life, exercising, life story work
- Polypharmacy and medication appropriateness issues, e.g., drug-drug interactions, non-pharmaceutical interactions such as drug-food or drug interactions with not prescribed pharmaceutical products
- Appropriate presentation of detected polypharmacy or medication appropriateness issues.

### 3.1.3.3 Results

In the following a summary of results from interviews with health professionals as relevant for user requirement elicitation. The interviews also showed valuable results for development of CDSM tools, e.g. health professionals gave examples of which health parameters should be analyzed in combination, which will not be reported on here, but be used as further resource for implementation.

Main problems in the treatment of multimorbid older patients with MCI or mild dementia were seen in:

- A required treatment for one condition can have a negative impact on another condition (n=12)
- Patients themselves cannot provide so much information about their current health status and its history, so the multidisciplinary team lacks relevant information (n=11)
- The multidisciplinary care team is not always coordinated well (n=9)
- Communication among the multidisciplinary care team is missing (n=8)
- There are neither clear recommendations nor guidelines for this patient group (n=8)
- Requirements from medical guidelines for specific conditions or diseases can conflict with others (n=8)
- Physicians do not like, cannot, or are not trained to prescribe or deprescribe against the recommendations and prescriptions of previous physicians (n=6).

Useful measurement results from H/HMP:

- Well-being after drug intake (n=12) and ask for symptoms (n=10)
- Well-being overall on a day (n=11) and ask for symptoms (n=10)
- The average mood of the patient (n=11)
- Health professionals were also much interested in being presented results of health measurements, blood sugar and heart rate measurements were named most often (n=10) followed by body temperature (n=9), medication intake (n=8) and blood oxygen saturation (n=8)
- In regard to reminders for patients 14 health professionals stated that they could be helpful for patients, 5 said that they should only be used for medication intake to not overly bother the patient
- All health professionals (n=16) would like to be pointed out to significant changes in the collected health/home monitoring parameters and PROMs by being analysed mainly in relation to each other and medication intake
- Risk assessment and early warnings derived from constant analysis of data collected on H/HMP in combination with information from patient's EHR
- Health professionals were all interested in receiving results from risk assessment and early warnings on conditions potentially harmful for patients. In the following a list of risk where health professionals were most interested in:
  - Loss in management of activities of daily living (n=13)
  - Decline in mobility (n=13)
  - Risk of fall (n=12)
  - Behavioural problems (n=12)
  - Risk of pre-existing chronic condition worsening (n=12)
  - Risk of new frailty (n=11)
  - Risk of progression of frailty (n=11)
  - Risk of developing new comorbidity (n=11)
  - Problems with urinary or faecal continence (n=11)
  - Risk of medication errors (n=11)
  - Risk of poor adherence to medication intake (n=11).

Educational materials:

- 15 health professionals would like to provide educational material such as links to useful websites, safe information about a condition or a diet plan.

Communication:



- All health professionals considered it useful, if there were a possibility for direct communication between them and the entire care team (medical doctors, psychologists, physiotherapist, social worker etc.).

Non-pharmacological interventions that could help improve the quality of life of multimorbid older adults with MCI/mild dementia multimorbid was seen by health professionals mainly in:

- Exercising (n=13)
- Routines in everyday life (n=12)
- Suggesting a diet (n=9)
- Play cognitively stimulating games such as memory games (n=9).

All health professionals considered polypharmacy and medication appropriateness issues such as drug-drug interaction, adverse drug interaction and possible side effects of drugs as important to be informed about. Besides these health professionals named most often to address:

- Non-pharmaceutical interactions such as drug-food, drug-non pharmaceutical products (n=11)
  - Non-pharmaceutical interactions such as drug-food, drug-non pharmaceutical products (n=11)
  - Non-pharmaceutical interactions such as drug-food, drug-non pharmaceutical products (n=10)
  - Interaction with of over-the-counter medications (n=9)
  - If an alternative prescription can be recommended (n=6)
- An important question from user requirements perspective is how detected issues should be presented to health professionals. The preferred solution was:
    - Mark all drugs in question in red. When selecting either one of these drugs detailed information is provided on the detected issues (n=10).

From the interview results it can be understood that health professionals are aware of several problem areas in the treatment of the CAREPATH target patient group which includes lacking or contradicting medical guidelines and lacking communication among the multidisciplinary care team. An interesting result was that the most often stated problem in the treatment of multimorbid older patients with MCI or mild dementia was that treating such patients is difficult, because a required treatment for one condition can have a negative impact on another condition. This finding stresses the importance of well reconciled medical guidelines for this patient group and the importance of being informed as thorough as possible about a patient's health status to come to the best suitable decision.

Detailed information about a patient's health status can be provided by H/HMP which was considered useful by health professionals in particular when supported by CDSM tools which allow to interpret the large data volume provided by H/HMP. The need with help on grasping the impact of collected health measurements and PROMs became also apparent in that all health professionals would like to receive results of a variety of risk assessments, analysis of potential polypharmacy issues also in combination with non-pharmaceutical products.

## 3.2 Ideation workshops

As described in the DoA developments in CAREPATH are based on the already existing e-health platforms C3-Cloud, IONIS and imergo®-ICP which have been developed by CAREPATH consortium members in course of previously EU-funded e-health projects. However, neither one of these platforms includes a fully developed clinical decision support functionality incorporating among others risk assessment utilizing AI-algorithms, analysis of data from a H/HMP platform and patient's EHR in particularly not for complex health conditions such as multimorbid older patients living with MCI or mild dementia.

Beyond this, CAREPATH aims to utilize the concept of intrinsic capacity and a dementia profile for risk assessment to provide early warnings for health professionals in case CAREPATH has discovered a deterioration in a patient's cognitive abilities or conditions due to his/her multimorbidities (to elaborate further on these topics is part of WP3 work and will be covered in according deliverables, in this deliverable only aspects relevant for user requirements collection will be addressed).

Intrinsic capacity (IC) is a fairly new concept and is defined as '...a composite of all the physical and mental attributes on which an individual can draw, not only in older age, but across their lives. Healthy ageing of an individual ('the process of developing and maintaining the functional ability that enables wellbeing in older age') depends upon their IC and their socio-economic and physical environments and the interaction

between them...'<sup>1</sup>. This concept shares many elements with the concept of 'frailty', however, it tries to shift away from the so far prevailing disease-oriented view to a more holistic view on how the health situation of a patient evolves, i.e. its trajectories. This concept is not established in common clinical practice yet, so from user requirements perspective there was no valid base to build on requirements specifications. Therefore, an ideation workshop on CDSM modules was initiated to develop as a first step key scenarios on how CDSM based on the concept of intrinsic capacity could be used in nowadays clinical practice.

Ideation is part of Design Thinking, a process established by David Kelly, Terry Winograd, and Larry Leifer (Stanford University) with the goal to support the development of new innovative solutions.<sup>2</sup> This matched well with the situation in CAREPATH where a new concept was to be investigated that at the end will need to be applicable in the real world in course of a clinical study aiming to prove evidence of CAREPATH system applications. Therefore, conducting ideation workshops was considered the most suitable method to investigate utilization of the concept of intrinsic capacity for development of CDSM tools and elicitation of according user requirements.

All ideation workshops took place online and participants were presented the underlying concept of ideation which is similar to brainstorming, but goes beyond it in that it is thinking without boundaries. Ideation is a 'process of generating a broad set of ideas on a given topic, with no attempt to judge or evaluate them'<sup>3</sup>. In case of CAREPATH this means collecting ideas on useful early warnings for the treatment of the CAREPATH patient target group without considering whether these can be implemented on base of patient data collected by H/HMP and PEP. This will come in the next step. So, the goal of ideation is to:

- Generate a quantity of ideas (quality comes next)
- Wild ideas are welcome (think outside the box, question the obvious)
- Stay on topic
- Build on already mentioned ideas
- Be judgement-free.

### 3.2.1 Key scenarios for CAREPATH Clinical Decision Support Modules (CDSM)

The ideation workshop on building key scenarios was held on 4<sup>th</sup> of October 2021, from 03:00 pm - 04:30 pm (CET). A poll was created for this workshop and clinical and technical partners were invited. A presentation was given to workshop participants about CAREPATH CDSM and its goals. To start sketching ideas on suitable key scenarios for CDSM a typical clinical scenario for a routine check-up of a multimorbid older patient with mild dementia was provided.

Results of this workshop from clinical partners view were:

- Limitations of using clinical decision support need to consider requirements from local guidelines
- A first step to investigate key scenarios on how CDSM can come into treatment systematically could be to clarify the current care pathways at pilot sites
- Information of interest provided by CDSM:
  - Drug-drug interactions
  - Analysis of coupled data, e.g., increase in weight coupled with increased glucose values
  - Offer treatment suggestions based on data correlation
  - Offer treatment suggestions based on data analysis
- Visualize changes in patients' health data as collected by H/HMP and PEP
- Provide an Excel sheet for clinical partners on health/environmental data that can be offered to clinicians.

As a conclusion of the workshop, it was agreed that intrinsic capacity is not an established concept in clinical practice and will be difficult to measure to serve as main base for CDSM. Before thinking further about key scenarios, clinical partners asked for more workshops on ideating about which and how patient health data

---

<sup>1</sup> <https://www.who.int/ageing/health-systems/clinical-consortium/CCHA2017-backgroundpaper-1.pdf>

<sup>2</sup> <https://dschool.stanford.edu/resources/getting-started-with-design-thinking>

<sup>3</sup> <https://www.nngroup.com/articles/ux-ideation/>

as collected by H/HMP and PEP can be used to serve as base for CDSM including the concept of intrinsic capacity. Since this mainly affects development work of the Advanced Early Warning Smart Decision Tools (AEWSDT) in WP3, it was decided to continue with joint WP2/WP3 ideation workshops on AEWSDT and early warnings as expected to be provided by these tools.

### 3.2.2 Early warnings from Advanced Early Warning Smart Decision Tools (AEWSDT)

When collecting live incoming patient data from H/HMP and PEP, the main goal of AEWSDT is to gain higher knowledge about the patient's current health status and derive therefrom preventive actions, in case a deterioration has been detected (for a detailed description of AEWSDT see DoA chapter 1.3.1 Description of the CAREPATH platform and WP3 T3.3 and T3.4). Risk stratification and early warnings on long term outcomes are part of CDSM as one outcome of AEWSDT. Three ideation workshops on 'WP2/WP3 Early Warnings' were conducted to gain a better understanding on how patient data collected by H/HMP and PEP can be used for clinical decision support and how the concept of intrinsic capacity fits into this. Each workshop could only last for one hour due to limited availability of in particular clinical partners due to the ongoing pandemic situation.

In the first workshop a presentation was given by the technical partner EXYS on H/HMP, the patient data collected by this platform and for what these could be possibly used for. The clinical partner SESCAM gave a presentation on the concept of intrinsic capacity, how it may fit into clinical practice and compares to other concepts such as Quality of Life which is the main parameter to prove evidence of the CAREPATH system in the clinical studies.

Main result of this workshop was that intrinsic capacity is a very broad concept which will be difficult to measure, so it can serve as valid base of clinical decision support. Beyond this, evaluating trajectories of patients' health developments is a more long-term endeavour. Therefore, it was decided that patients' intrinsic capacity will be evaluated in the beginning and at the end of their enrolment in the clinical study for comparison of the status. For clinical decision support by AEWSDT risks and early warnings as relevant for clinical practice shall be evaluated. What type of risks and requirements of clinical partners in regard to how these shall be presented was the topic of two following ideation workshops.

In the second and third ideation workshop a question was presented at the beginning to trigger ideation. In the second workshop this was:

- What kind of early warnings could be useful to improve the treatment and care of multimorbid older patients with MCI/mild dementia?

In this workshop several useful early warnings were discussed about risks relevant for the treatment and care of the CAREPATH target patient group, e.g., the risk of fall and to whom these should be communicated (see Figure 4). To proceed on collecting relevant risks efficiently, it was decided to initiate an Excel-file where risks with rules for how early warnings shall be generated, alert classes etc. be entered by clinical partners and suggestions made by also technical partners on how to achieve those. This Excel was circulated among consortium members to contribute and served as base for the third ideation workshop.

#### What kind of early warnings could be useful?

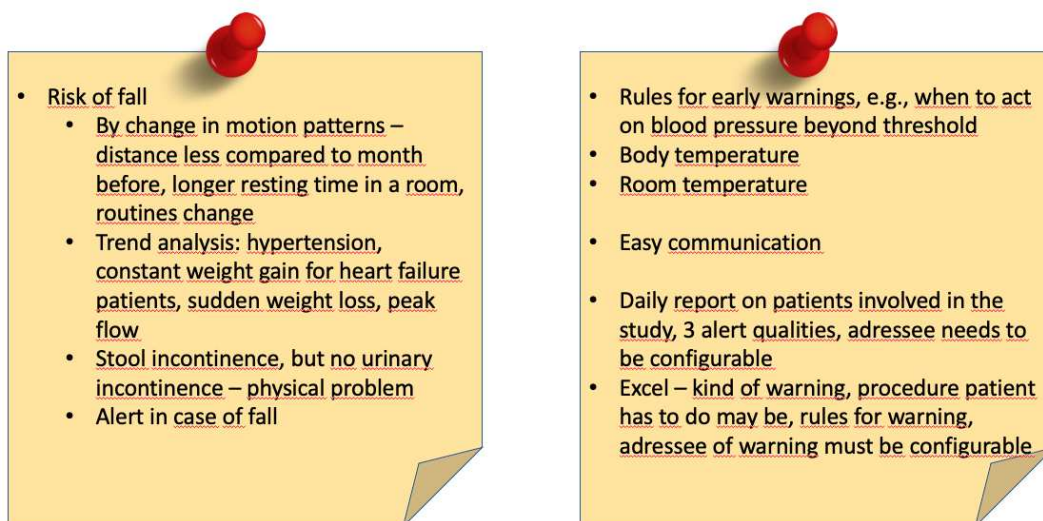
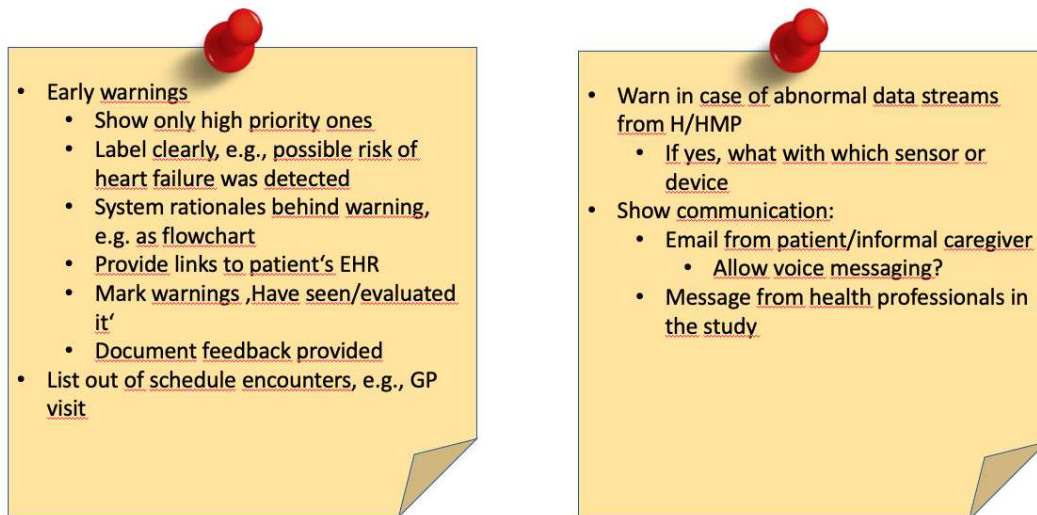


Figure 4: Results second ideation workshop

In the third ideation workshop results of the first round of risk collection were discussed and comments provided by clinical and technical partners clarified. Beyond this, it was discussed how early warnings shall be presented to health professionals. It was decided that a daily report should be generated for health professionals indicating in case a potential risk has been detected by AEWSDT. The type of risk, on what base it was detected with a link to the patient's health data on the CAREPATH platform shall be part of this report to evaluate the health situation. Necessary communication among health professionals and health professionals and patients or informal caregivers was also discussed (see Figure 5).

## Daily report on patient's status



**Figure 5: Results of third ideation workshop**

As a result of the ideation workshops an Excel-file with 27 possible risks to investigate in CAREPATH were identified, e.g., risk of heart failure or risk of arrhythmia and will now serve as base for development of AEWSDT and followed up on by WP3 work.

### 3.3 User requirements description in the Volere format

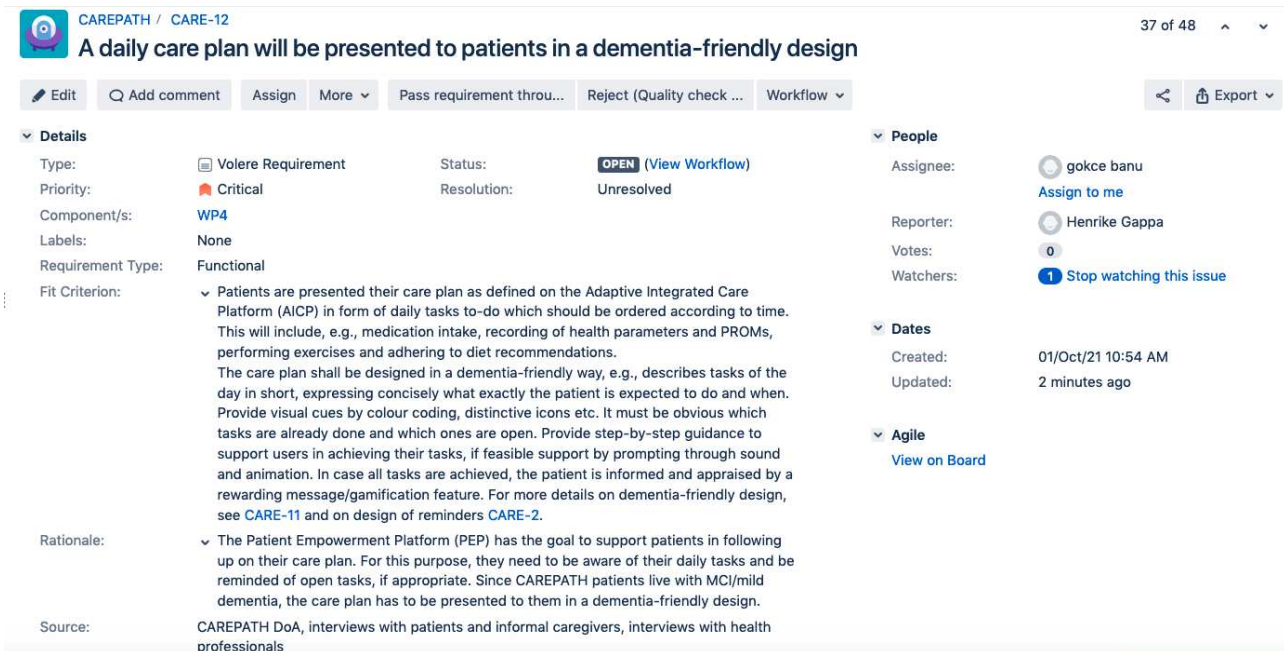
In CAREPATH user requirements are described in the Volere format and created as well as processed on the web-based bug tracking platform Jira (<http://www.atlassian.com/software/jira>) which can be considered a well-established tool for agile software engineering. Jira offers a Volere template for user requirements specification which was used in CAREPATH (see Figure 6). Most important fields will be described shortly in the following:

- The *'summary'* of a requirement contains a one-sentence description of the requirement. The description is the intent of the requirement and should be clear and brief (see first line in the screenshot below: A daily care plan)
- The *priority* of a user requirement defines the relevance of this requirement in relation to other requirements. It allows classification of the specified user requirement in 5 categories: 'Blocker', 'Critical', 'Major', 'Minor', 'Nice to have'. In CAREPATH user requirements with label 'Critical' have to be implemented for a viable first *prototype*.
- The *'component'* field describes in CAREPATH to which work package the user requirement belongs to, so it is easier to structure the user requirements and determine the appropriate assignee which is the work package leader. The assignee is the responsible whose task is to ensure that the user requirement is implemented which will be in most cases a joint effort among several work packages and task leaders.
- Selection of a *'requirement type'* classifies a user requirement as either functional or non-functional. Functional requirements describe what a system shall do, i.e. how a functionality shall behave to



fulfil users' needs. Non-functional requirements refer mainly to properties and characteristics of a system, e.g., security requirements, the look and feel.

- The description of a user requirement's '*fit criterion*' is very important for technical realization, because it includes the quantified goals that the implementation has to meet. It sets the standards to which developers are able to construct their developments.
- The '*rationale*' of a user requirement expresses why the user requirement is important and how it contributes to the system's purpose. It supports understanding of the fit criterion.
- The *source* of a user requirement provides information about where this requirement was derived from to ensure validity.



CAREPATH / CARE-12 37 of 48

### A daily care plan will be presented to patients in a dementia-friendly design

Edit Add comment Assign More Pass requirement throu... Reject (Quality check ... Workflow Export

**Details**

Type: Volere Requirement Status: **OPEN** (View Workflow)

Priority: Critical Resolution: Unresolved

Component/s: WP4

Labels: None

Requirement Type: Functional

Fit Criterion:

- Patients are presented their care plan as defined on the Adaptive Integrated Care Platform (AICP) in form of daily tasks to-do which should be ordered according to time. This will include, e.g., medication intake, recording of health parameters and PROMs, performing exercises and adhering to diet recommendations.
- The care plan shall be designed in a dementia-friendly way, e.g., describes tasks of the day in short, expressing concisely what exactly the patient is expected to do and when. Provide visual cues by colour coding, distinctive icons etc. It must be obvious which tasks are already done and which ones are open. Provide step-by-step guidance to support users in achieving their tasks, if feasible support by prompting through sound and animation. In case all tasks are achieved, the patient is informed and appraised by a rewarding message/gamification feature. For more details on dementia-friendly design, see CARE-11 and on design of reminders CARE-2.

Rationale:

- The Patient Empowerment Platform (PEP) has the goal to support patients in following up on their care plan. For this purpose, they need to be aware of their daily tasks and be reminded of open tasks, if appropriate. Since CAREPATH patients live with MCI/mild dementia, the care plan has to be presented to them in a dementia-friendly design.

Source: CAREPATH DoA, interviews with patients and informal caregivers, interviews with health professionals

**People**

Assignee: gokce banu  
Assign to me

Reporter: Henrike Gappa

Votes: 0

Watchers: 1 Stop watching this issue

**Dates**

Created: 01/Oct/21 10:54 AM

Updated: 2 minutes ago

**Agile**

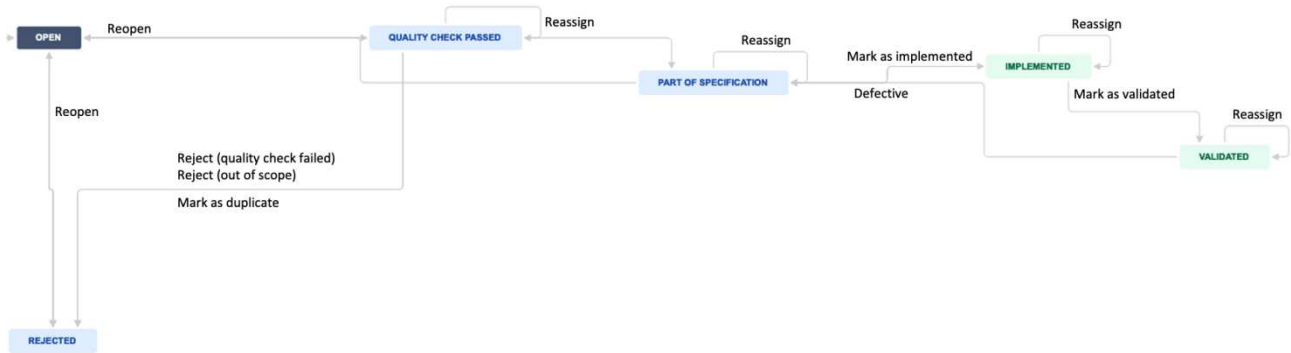
View on Board

Figure 6: Screenshot of a JIRA Volere template

### 3.3.1 User requirements workflow

For proper processing of user requirements in CAREPATH a workflow was implemented on Jira that allows to track the status of a user requirement from its initial creation to the final validation when successfully implemented. The implemented workflow can be viewed in Figure 7. In CAREPATH all user requirements were created by a usability professional as part of T2.1. Once a user requirement has been defined its status is on 'Open' and it will be assigned for a quality check to a consortium member. In CAREPATH this is the technical partner, the user requirement was assigned to. This partner may comment on whether the user requirement is from his/her view unclear, out of scope of the project or may be a duplicate of another user requirement and therefore, after consultation with the creator of the user requirement, rejects a user requirement. If the assignee accepts the user requirement, it has passed the quality check and the technical partner responsible for its implementation will add it to the system specification and thus moves it to status 'Part of specification'.

During the implementation process a user requirement might be reassigned to different technical partners who are then in charge of achieving the next step in the development process. In case the implementation is finalized, the user requirement receives status 'Implemented' and the creator validates whether the implementation has achieved the fit criterion or not. Depending on the result the creator will process the user requirement to status 'Validated' or moves it back to status 'Part of specification' with a comment on what is missing in the implementation.



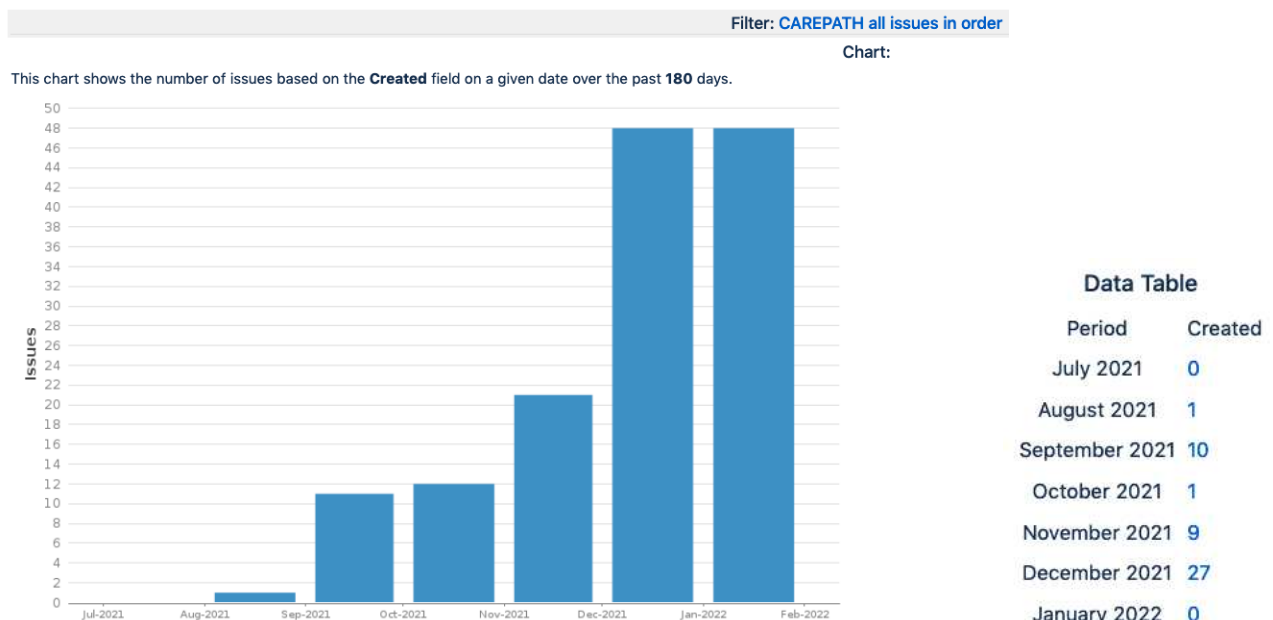
**Figure 7: CAREPATH user requirements workflow**

### 3.3.2 Status of user requirements specification

In the first 6 months of the project, an initial set of user requirements has been created to support development of a first viable prototype of the CAREPATH platform. In total 48 user requirements have been defined so far. At the moment all user requirements are on status 'Open', because they are under investigation by technical partners and will gradually be moved to status 'Part of specification'. A detailed list of all available user requirements can be viewed in appendix D, chapter 8.

Jira allows to create reports to facilitate monitoring of the user requirements specification process. In the following a selection of Jira reports will be presented to depict the status of user requirements specification in CAREPATH:

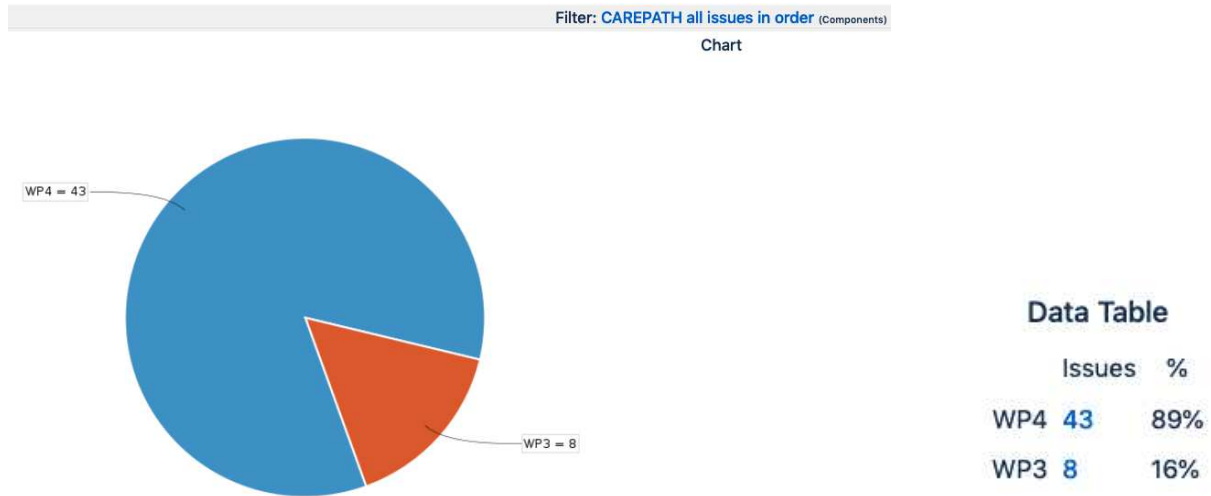
- This chart shows how definition of user requirements has evolved until now. As it can be seen user requirements have been created once results from, e.g., ideation workshops and interviews were available to support technical development as soon as possible.



**Figure 8: Created CAREPATH user requirements (issues)**

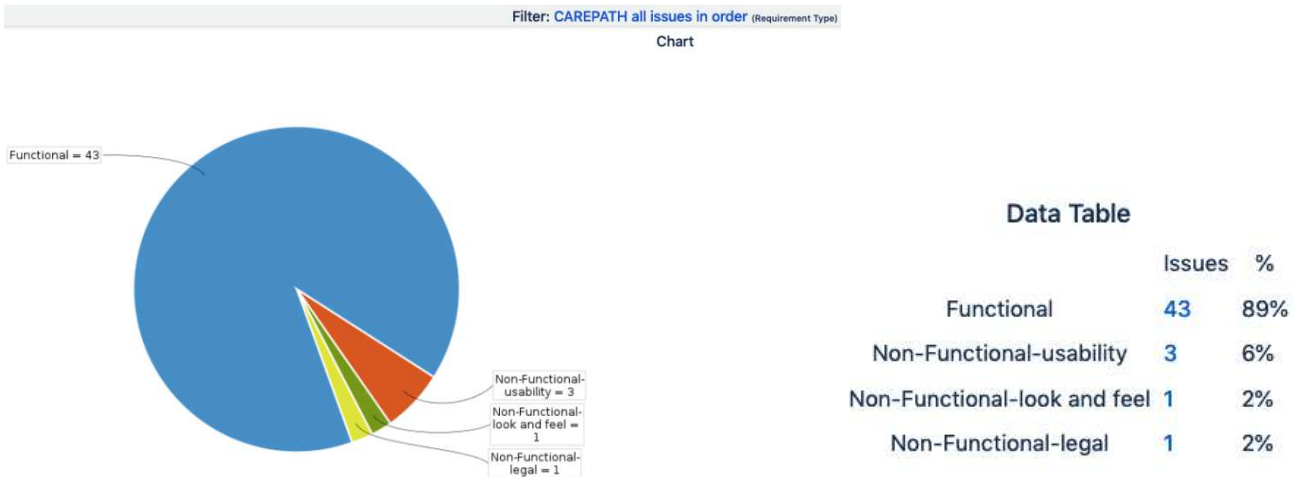
- The following chart shows how many user requirements have been defined for work package (WP) 3, WP4 or both. WP3 and 4 are the developing work packages in CAREPATH, therefore only these have been selected, however other work packages, e.g., WP6 with medical guideline work will have to contribute as well. The vast majority of user requirements has been assigned to WP4, because it

mainly provides the user interfaces for end users. However, as mentioned WP3 and other work packages will be involved in the development as well.



**Figure 9: Distribution of user requirements among WP3 and WP4**

As it is depicted in the following chart, the number of functional user requirements exceeds the number of non-functional user requirements by far which is usually the case, because the main goal of user requirements specification is to describe what a system shall do, i.e. how it shall behave to implement users' needs and preferences.



**Figure 10: Distribution of user requirement types**

As mentioned, in this phase of the project it was the goal to define user requirements that are useful to implement a first viable prototype of the CAREPATH platform, therefore, almost all user requirements are on priority 'Critical' which means need to be implemented for the clinical study.

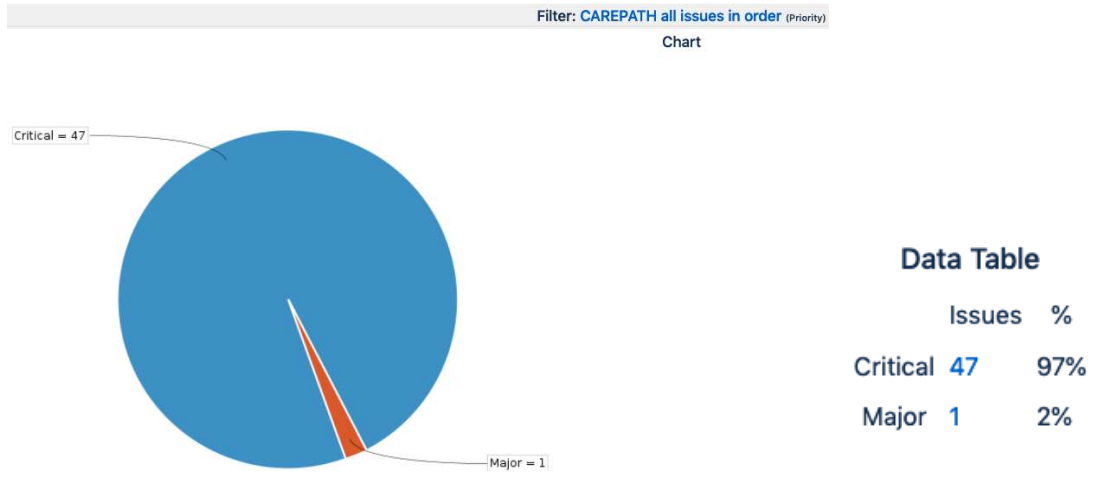


Figure 11: Priorities of user requirements



## 4 Conclusion

The CAREPATH project has implemented a human-centred development process in accordance to ISO 9241-210:2019. The specific challenges in developing an ICT based solution for the optimization of clinical practice in the treatment and management of multimorbid patients with MCI or mild dementia are addressed in this process. Involving target end users from the beginning of the project to ensure usefulness and usability of CAREPATH developments was achieved by conducting interviews with representatives of target end user groups and conducting ideation workshops with health professionals and developers of the project on features of CDSM tools relevant for clinical everyday practice. An initial set of user requirements was defined primarily on base of findings from these sources.

In the next step technical partners will evaluate user requirements and make them part of system specification, if agreed on. Prototype development will start according to user requirements and prototypes will be evaluated by the consortium, where possible, with patients, informal caregivers and health professionals who have indicated in the interviews their willingness to help with the design of the CAREPATH platform. The consortium will seek to implement such a co-design approach which is considered very useful to ensure a user-friendly design of applications. This is a particular challenge when designing for users with a cognitive impairment such as MCI or mild dementia. By evaluating prototypes, it will become apparent, if user requirements need refinement and which ones are missing. This work will be to achieve in the following development phase.

## 5 Appendix A – interview guideline patients



### An Integrated Solution for Sustainable Care for Multimorbid Elderly Patients with Dementia



User Requirement Definition and Design of CAREPATH System  
Architecture

## Interview Guideline for Patients



*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945169.*

## Inclusion criteria

Age ≥ 65 years	Yes <input type="checkbox"/>
Adequate visual and auditory acuity	Yes <input type="checkbox"/>
6 years of formal education after the age of 5 years	Yes <input type="checkbox"/>
MCI or Dementia (2 patients of each) <ul style="list-style-type: none"> <li>• NIAAA core clinical criteria for probable AD dementia</li> <li>• Mild Cognitive Impairment due to Alzheimer’s Disease</li> </ul>	Yes <input type="checkbox"/> Yes <input type="checkbox"/>
MMSE score ≥ 22 points and CDR-GS 0.5 or 1.0.	Yes <input type="checkbox"/>
Multimorbidity (at least one) <ul style="list-style-type: none"> <li>• Diabetes mellitus, hypertension, heart failure, chronic obstructive pulmonary disease, asthma, stroke, chronic kidney disease, frailty, sarcopenia, coronary artery disease</li> </ul>	Yes <input type="checkbox"/>
Sex (include 2 patients of each sex)	Male <input type="checkbox"/> Female <input type="checkbox"/>
Living at home	Yes <input type="checkbox"/>
Informal caregiver availability <ul style="list-style-type: none"> <li>• Patient living with caregiver (2 patients)</li> <li>• Patient not living with caregiver (2 patients)</li> </ul>	Yes <input type="checkbox"/> Yes <input type="checkbox"/>
Informal caregiver <ul style="list-style-type: none"> <li>• Older person like spouse (2 patients)</li> <li>• Young person like son or daughter (2 patients)</li> </ul>	Yes <input type="checkbox"/> Yes <input type="checkbox"/>
Independence in BADL	Yes <input type="checkbox"/>
Patient and informal caregiver use at least one electronic device	Yes <input type="checkbox"/>

### Short introduction to the project and the purpose of the interview:

We are conducting a research project called CAREPATH that has the goal to improve the treatment of older people living with dementia and other (one or more) conditions, known as “multimorbidity”, for instance diabetes or hypertension. For this purpose, we are developing technology for medical doctors, therapists and patients. We would like to find out how you follow up on your health and well-being needs and whether there are any problems you may have with this. We would also like to find out about what could help you to ease managing your everyday life as independently as possible. We are very much interested in hearing about problems you have to deal with. And, if you have ideas on how these could be improved by technology, please let us know. Thank you very much for your help!

Note to interviewer: in the following interview guideline text marked grey is for instruction of interviewers and documentation support. It shall give you an idea on what information we are looking for, but of course we are interested in any other information.

## 1. Technical expertise and accessibility issues

1.1 Are you using any electronic devices such as a smartphone, tablet, computer, a smart-watch or a fitness tracker?

( ) No - go to section 2

If yes, please record in short in the following table:

- What device(s) the patient is using and for how long (rough estimation in 3-month steps, e.g., 3 mos, 6 mos, 9 mos, 1 yr, etc.). If known, record the brand name of the device.
- What a device is used for. In case it is an app/application, record the brand name, if known.
- What makes it easy to use and why.
- What makes it difficult to use and why.
- Whether the device can be used alone or not and what the patient does in case s/he needs help, but the help is not available at the moment, e.g., waits for the informal caregiver to come, tries him-/herself.

In case a device is used for different purposes, record these in separate rows, please.

We are looking for information on what patients are used to, what facilitates usage, what poses obstacles. In the text boxes below the table some known problems are listed when using a device or apps/applications. You may use these as ‘openers’ to ask about possible problems. However, we are also much interested in problems not listed.

Please read instructions above the table on how to use the listed problems for quick documentation. An example is provided below as ‘Alternative short documentation’.

Device and estimation for how long used	What used for?	Easy to use Why?	Difficult to use Why?	Can be used alone? If not, what
-----------------------------------------	----------------	------------------	-----------------------	---------------------------------

Brand name?	Brand name of, e.g., app?		happens in case no help is available?
<b>Example:</b> Tablet, ca. 1 yr. (Samsung)	Video chats with family (Zoom)	Once in the video chat, it is easy. Works by itself. Button to leave a chat is easy to find.	Steps to join a video chat can be difficult sometimes, patient gets lost.  Enlarging the Zoom window with the pinch gesture to see the family better is difficult.  Alternative short documentation: d) when enlarging the Zoom window to see the family members better.

List of possible obstacles when using devices or apps/applications. To support you in fast recording of problems, you may use the according letter for your convenience in the documentation. Please record though the context, in which the problem occurs.

Possible problems with devices

Possible problems with apps/application

- a) Control of the mouse
- b) Make selections by finger tap on a smartphone/tablet
- c) Wipe gesture on a smartphone/tablet
- d) Pinch gesture on a smartphone/tablet
- e) Device has too small buttons to push
- f) Device is too complicated to operate
- g) I do not understand the information on the display
- h) Information on the display is too small
- i) It is running out of battery too fast
- j) Disturbing me
- k) Not comfortable

- a) Font type too small
- b) Buttons too small
- c) Too much information at once (cluttered screen)
- d) Problem to remember where clicking on a button or menu will take me to (navigation mechanism)
- e) Problems to remember steps needed to do what I wanted to do
- f) I get lost sometimes
- g) If I get lost, I do not find back
- h) Language too complicated

1.2 Do you need a username and/or a password for any of your apps/devices?

No

Yes: How do you use his? Can you use it alone or what do you need help with?

(We are looking for information about an approach to provide credentials that works for patients and what poses obstacles.)

1.3 In case you have misplaced your XXX (electronic device the patient is using, e.g., a smartphone), what could help you to find it?

- If I can make the device make noise
- If I can make the device start blinking
- If my informal caregiver could localize the device and tell me where to find it
- Other:

## 2. Care organisation at home

2.1 When you meet with your medical doctors or therapists. What do they ask you to do?

It might be that patients are not able to remember well about tasks to-do. In that case ask the informal caregiver to help. We are interested in receiving an overview on what tasks typically belong to the care plan of our target patient group.

Go through the following list with patients and note in 'Other'-option, if patients are asked to do something that is not on the list.

- Take your medication
- Measure your weight
- Take your blood pressure measurements
- Take your blood sugar values
- Make sure you sleep enough
- Do physical exercises
  - If yes:
    - Exercises shown to you by a physiotherapist
    - On your own, e.g., go to the gym, use online exercise programs
- Go for walks
- Drink more/less water/fluid
- Watch your diet (lose/gain weight)
- Drink less alcohol
- Smoke less
- Make appointments to see other medical doctors or therapists
- Play games, e.g., memory games
- Join a group with people with similar health problems that offers activities such as play/crafts/sports afternoons or short excursions
- Other: . . . . .
- Help was needed by the informal caregiver to answer these questions

2.2 Do you know what are your **daily** tasks to follow-up on your health and well-being?

- Yes
  - How do you know about your daily to-dos?
    - Informal caregiver tells me
    - Calendar (in print)
    - Other:
- No
  - What could help you to have a better overview?

2.3 Your daily tasks that are necessary to take care of your health and well-being could be presented to you on a tablet, for instance (show example of daily care plan (PowerPoint) (see below)). Do you think this could be helpful for you?

Yes

Do you have suggestions for improvement of this example?

.....

No

It would be of big help for us, if you could tell us, if there is a reason for that?

.....

2.3.a Involve the informal caregiver in this question and ask:  
Would it be of help for you, if you had access to such a plan, so you would know about the to-dos and their status?

Yes

Do you have any suggestions for improvement?

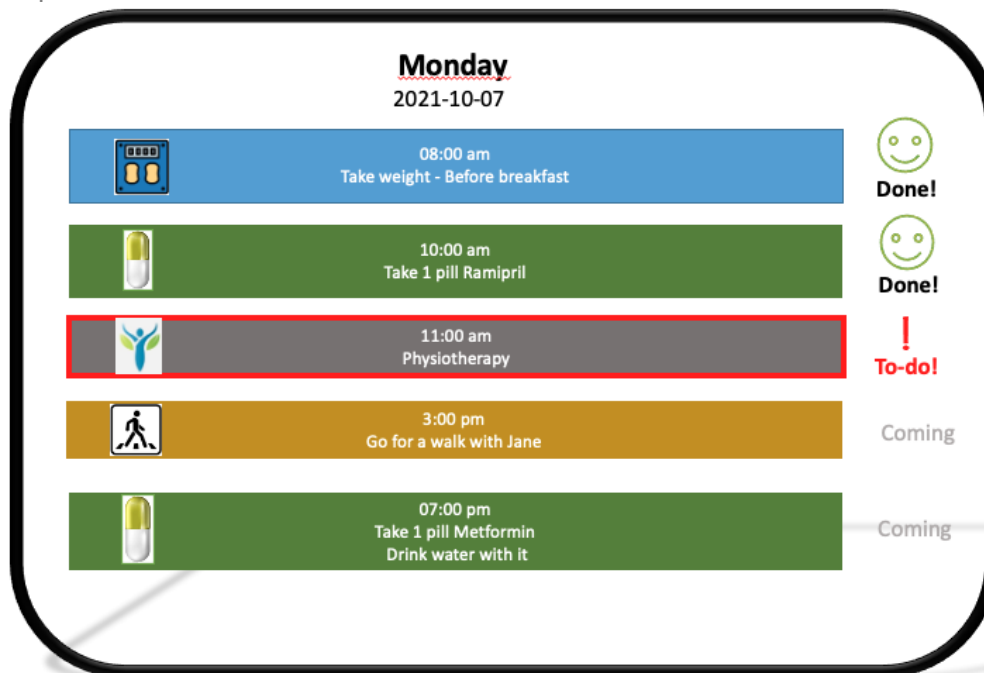
.....

No

It would be of big help for us, if you could tell us, if there is a reason for that?

.....

The following image of a possible daily care plan is supposed to be shown to patients on a separate sheet.



2.4 Do you need help with taking your medications?

No - go to 2.4.2

Yes

What help is needed?

Remember intake

Remember which medication needs to be taken

Remember schedule of medication, e.g., only every other day

Cut or smash pills, drop-out from blister

- Remember where it is
- Others: . . . . .

**2.4.1 How do you manage medication intake?**

- My spouse/son/daughter/friend (informal caregiver) tells me when to take which medication
- A professional caregiver is giving me the medication
- I use a pill box
- I have a calendar for medication intake (in print format)
- I have a daily list
- I am reminded about medication intake by, e.g. my smartphone (note the device/app):
- Others: . . . . .

**2.4.2 Are you documenting your medication intake?**

- No – go below
- Yes: How are you documenting it?
  - On paper, e.g., a calendar
  - The informal caregiver does it
  - The professional caregiver does it
  - Keep empty blisters
  - Electronically (how):
  - Other: . . . . .

If No:

Do you think it would be helpful to have such documentation, so you can remember better what was previously?

- Yes
- No
- I don't know

Involve the informal caregiver in this question and ask:

What is your opinion on this?

. . . . .  
. . . . .

This question shall go first to the patient:

Do you think it would be helpful to have such documentation when talking to your medical doctors?

- Yes
- No
- I don't know



**2.5 Are you measuring health parameters at home like blood pressure, blood sugar, weight etc.?**

In case health parameters have been talked about in course of 2.1 already and it is clear that the patient is really recording them, then select 'Yes' and go to 2.5.3.

- No - go to 2.5.1
- Yes: **Which ones?** - then go to 2.5.3

Go through the following list with patients and note in 'Other'-option, what other measurements they are taking.

- Weight
- Blood pressure
- Temperature
- Oxygen saturation
- Heart rate
- Blood sugar
- Step counts
- Duration of walks
- Others . . . . .

If No:

**2.5.1 Do you think it would be helpful to take such measurements, so you can remember better what was previously?**

- Yes
- No
- I don't know

Involve the informal caregiver in this question and ask:

**What is your opinion on this?**

.....  
.....

This question shall go first to the patient:

**2.5.2 Do you think it would be helpful to have recordings of these readings when talking to your medical doctors? - then go to 3.1**

If linked to this question from 2.5.3, go on with 2.5.4 and then 3.1

- Yes
- No
- I don't know

Involve the informal caregiver in this question and ask:

**What is your opinion on this?**

.....  
.....

**2.5.3 How are you documenting your measurements:**

- Not at all – go to 2.5.2
- On paper
- The informal caregiver does it
- The professional caregiver does it
- Electronically (how):
- Other:

**2.5.4 How do you know when to take a measurement?**

- Reminded by informal caregiver
- I do not feel well (pain, palpitations etc.)
- Other: . . . . .

### 3. Coping with cognitive impairment and management of everyday life

3.1 Do you need help with everyday activities such as go shopping, prepare meals, do household tasks, drink enough, manage finances, use the telephone, use public transport?

- No
- Yes

Which ones and what problems? (we are looking in particular for problems that could be supported by technology)

3.2 Do you forget sometimes things you wanted to do, e.g., call a family member on his/her birthday, call a friend to go-out with, remember appointments with medical doctors/therapists, watch your favourite TV-show, go to the library to get new books?

- No
- Yes

Would you like to be reminded about them?

- Yes
- No

Is there a reason for that?

3.3 Would you like to write notes to yourself, e.g., about things to take along when visiting a medical doctor/therapist, things you do not want to forget to tell your informal caregiver or a friend?

- No
- Yes

What would you like to take notes on? Please list:

.....  
.....  
.....

3.4 What do you do in your leisure time?

Go through the following list with patients and note in 'Other'-option, if patients are doing something in their leisure time that is not on the list.

- Watch TV
- Listen to music
- Read books, magazines, newspapers
- Call friends
- Call family members
- Look at family videos
- Look at photo album
- Go for walks
- Meet friends
- Go to social clubs, religious groups etc.
- Go to a day-care centre
- Play a music instrument or sing
- Volunteering
- Manual work: gardening, drawing, pottery, etc.
- Play games - please go to the table below to specify further which games etc.
- Other: .....

In case the patient said s/he is not playing games:

Are there reasons for that? Which ones:

Please list in the following table which games the patient plays, whether s/he plays those alone, with somebody else or both and what is his/her preference.

Game	Alone	With others	Both	Preference
<b>Example: Sudoku</b>			X	Primarily with others

**4. Exercise and diet control**

4.1 Do you do regular physical exercise?

- Yes
- No

Is there a reason for this? - then go to 4.6

- I don't know (try to find out with the help of the informal caregiver)

4.2 Where do you practice physical exercise?

- At home
- Outdoors
- Gym
- Sports clubs, older adult clubs, day-care or similar
- Other: .....

4.3 Do you need help with your physical exercises?

- No
- Yes

Who helps you with your physical exercise?

- No one is available, unfortunately
- Informal caregiver
- Professional caregiver, please note from which profession (e.g. PT, OT):
- Other:
- I don't know (try to find out with the help of the informal caregiver)

4.4 Do you use any electronic device or app/applications to do physical exercises, e.g., a special online program?

- No
- Yes

Please note the device and the app/application and a possible comment about it

Device	App/application	Comment

- I don't know (try to find out with the help of the informal caregiver)

4.5 When thinking about using a physical exercise program that is offered to you on a tablet, computer or the like, what type of physical exercise program would you prefer?

Go with the patient through the following list and record in 'Other'-option, in case they have a preference not listed

- Program where you exercise by yourself
- Program where you exercise in a group
- I don't know
- Other: .....

4.6 Do you think your diet is equilibrated, meaning you eat enough fruit, vegetables, legumes, fish, meat, eggs, and dairy products?

- Yes
- No, what is the problem:
- I don't know

Would you like to know?

- Yes
- No

4.7 Technology can help you to follow a diet that can improve your wellbeing. It could help you with making a daily plan about food you should not forget to eat (e.g. 3 fruits, a diary product), give you advice for proper cooking and shopping. Would it be of interest to you to receive help with a diet suitable for you?

- No

Is there a reason for that?

.....  
.....

Do you think something else could be of help for you?

- Yes

Go with the patient through the following list and record in 'Other'-option, in case s/he is interested in something else

- Making a daily plan for you about food you should not forget to eat, e.g. 3 fruits, a diary product
- Advice for cooking, e.g., recipes
- Advice for shopping the right food, e.g. what you should be on your shopping list
- Remind you to eat and drink
- Others: .....

4.8 Do you think you drink enough fluids?

- Yes

No, what is the problem:

- I don't know

Would you like to know?

- Yes

- No

## 5. Improvement of personal care management

5.1 Do you think you have a good overview on your health status?

- Yes

- No

- I don't know

If 'No' or 'I don't know':

What could help you to improve this?

5.2 Technology can help you to receive a good overview on your health status, e.g. how is my blood pressure today, am I OK? Would you consider it helpful if you could check results from, for instance, blood pressure measurements, how many steps you walked today, and how long did you sleep?

- No

Is there a reason for that?

- Yes

What would you like to know about?

- Blood pressure measurements
- Weight curve
- How active was I, e.g. how many steps did I walk today
- Did I sleep enough
- How did I feel?
- Did I have pain?
- Medication recordings

Other: . . . . .

I don't know

5.2.a Involve the informal caregiver in this question and ask:

Would you like to be shown the results of these recordings, e.g., in form of line graphs with blood pressure recordings, steps walked per day, duration of walks etc.?

No

Is there a reason for that?

Yes

Would be something of particular interest to you?

5.3 In case you would like to ask your medical doctor(s) questions about your treatment or your condition(s), do you record those before seeing your medical doctor(s)?

No

Yes (how are you documenting this?):

My informal caregiver does this

On paper

Electronically (how):

Other: . . . . .

5.4 Would it be helpful for you, if you could get in contact with your medical doctor(s) outside of regular appointments, e.g. via text/voice messaging?

No

Yes: How and in what situations?

**Thank you very much for your help!**

Question to **interviewer**:

All-in-all, who has responded mainly to the questions?

patient

informal caregiver

Relation to the patient:

spouse

son/daughter

grandchild

friend

Other: . . . . .

Is the patient

Living alone

Living with his/her informal caregiver

Other: . . . . .

In case you think it is appropriate and will not pose too much burden on the patient, ask whether the patient and/or informal caregiver is willing to support us in the development of the Patient Empowerment Platform by for instance looking at a mock-up once in a while or trying out a prototype of a game.

Please cross here, in case the patient and/or informal caregiver is willing to support us:

Willing to help us with the design of the Patient Empowerment Platform

## 6 Appendix B – interview guideline informal caregivers



### An Integrated Solution for Sustainable Care for Multimorbid Elderly Patients with Dementia



User Requirement Definition and Design of CAREPATH System  
Architecture

## Interview Guideline for Health Professionals



*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945169.*



Type of health professional	Please select:
GP	<input type="checkbox"/>
Hospital medical doctor	<input type="checkbox"/>
Nurse	<input type="checkbox"/>
Allied professional	<input type="checkbox"/>
<p>Note: please ensure that the gender aspect is taken into account (ratio women/men spread almost evenly among interviewees at each trial site) and that the professional experience of the interviewee is at least 3 yrs.</p>	

Each clinical trial site is asked to do 4 interviews with health professionals and should include all types of health professionals that will participate in the clinical study at their site.

### **Short introduction to the project and the purpose of the interview:**

The aim of CAREPATH: An Integrated Solution for Sustainable Care for Multimorbid Elderly Patients with Dementia, an EU-funded project under the H2020 programme, is to offer an ICT-based solution for optimising the clinical practice in the treatment and management of multimorbid older adults with Mild Cognitive Impairment (MCI) or mild dementia. In order to achieve this, CAREPATH will elaborate on a methodology for computer interpretable clinical guidelines and computationally derived best clinical practice for best suitable treatment of this patient group. Thereby, a multidisciplinary care approach is considered, with a focus on the very individual needs of patients in this group to be translated into personalized care plans.

To provide computationally derived best clinical practice suggestions, CAREPATH will include a clinical decision support system that will conduct, among others, risk assessment that is based on data from patients' electronic health records and other health-related data, as collected by a Health/Home Monitoring system, installed at the patients' homes. These health data will be processed by artificial intelligence (AI) algorithms to predict the development of patients' conditions. In terms of dementia-associated multimorbidity, the scope of CAREPATH will include frailty, sarcopenia, nutritional risk, diabetes, heart failure, chronic obstructive pulmonary disease (COPD), chronic kidney disease (CKD), stroke, cardiovascular disease and hypertension.

The project is in its beginning stage and we are very much interested in your opinion on what needs to be improved in the treatment and management of multimorbid older adults with MCI or mild dementia and how such a clinical decision support system should be designed to best support you in your daily treatment and care tasks.

-----

-----

**Note to interviewer:** in the following interview guideline text marked grey is for instruction of interviewers and documentation support. It shall give you an idea on what information we are looking for, but of course we are much interested in any other information.

**Important!** - inform the interviewee about which patient group the term 'patient' shall refer to in this interview: the target patient group of CAREPATH are multimorbid older adults living with MCI/mild dementia. Therefore, in the following interview the term 'patient' refers to this specific group of patients.

### Interview guideline

1. What do you think are the main obstacle(s) in the treatment of patients who are multimorbid older adults with MCI/mild dementia?

Go through the following list with health professionals and note in the 'Other'-option, if they mention an obstacle that is not on the list.

There are neither clear recommendations nor guidelines for this patient group  
 Requirements from medical guidelines for specific conditions or diseases can conflict with others. For example, thight control of diabetes may produce hypoglycemias, falls or cognitive decline, thight control of blood pressure could worsen orthostatic hypotension, or introduction of beta-blockers for coronary artery disease may produce depression.  
From your professional experience do you know of any conflicts originating in contradictory medical guidelines? What are the most relevant issues:

.....  
.....

Treating such patients is difficult, because a required treatment for one condition can have a negative impact on another condition

From your professional experience do you know of treatments that often have adverse effects? What are the most relevant issues:

.....  
.....

Reaction to a treatment depends much on the personal health condition, frailty status or intrinsic capacity of a patient

In case needed here definition of 'intrinsic capacity': Intrinsic capacity (IC) is a composite of all the physical and mental attributes on which an individual can draw, not only in older age, but across their lives WHO, 2017).

TIC (Technology and Information Resources) are lacking, e.g. resources such as websites, applications or apps that help in the process of decision-making with these patients

The multidisciplinary care team is not always coordinated well

Communication among the multidisciplinary care team (primary care physicians, geriatricians, other specialists, social worker, therapists, nurses etc.) is missing, delayed or difficult

The patients themselves cannot provide so much information about their current health status and its history, so the multidisciplinary team lacks relevant information

Patients do not know about the treatments they are receiving from multiple specialists

Ask the following 2 questions only medical doctors:

Training on medication appropriateness is lacking

Physicians do not like, cannot, or are not trained to prescribe or deprescribe against the recommendations and prescriptions of previous physicians

Other:

.....  
.....

2. The CAREPATH system includes a Health/Home Monitoring platform which allows health professionals to ask patients to fill in on a tablet patient-reported outcome measures

(PROMs) or simple questions such as ‘How do you feel today?’. Is there any information you would be interested in?

Go through the following list with health professionals and note in the ‘Other’-option, if they mention something of interest for them that is not on the list.

Well-being of the patient after drug intake, e.g., by a Likert scale visualized by smileys (happy face, neutral face, sad face)

If the result is out of expected range: shall the system ask for symptoms?  Yes

No

Well-being of the patient overall on a day, e.g., by a Likert scale visualized by smileys (happy face, neutral face, sad face)

If the result is out of expected range: shall the system ask for reasons?  Yes

No

The average mood of the patient

New necessities for visiting a health professional (request may come from patient or informal caregiver). For example, do you need to advance your physician visit?

Hand-made questionnaire(s) on (please note the topic):

.....

Validated questionnaires (please note which one(s)):

.....

Other:

.....

.....

3. The Health/Home Monitoring platform in CAREPATH is able to collect health parameters such as blood pressure, sleep and steps walked. Beyond this, it can analyze movement to detect wandering behavior and localize the patient outdoors. The platform also gathers data from the patient’s physical environment, e.g., room temperature. The result of the Health/Home Monitoring platform can be presented to you, e.g., on a dashboard visualizing results of the recordings in line graphs, bar charts, tables or the like for quick overview.

Which kind of health measurements or parameters from the patient’s physical environment are of particular interest for your treatment/care purposes?

Go through the following list with health professionals and note in the ‘Other’-option health measurements or parameters from patient’s physical environment that are not on the list.

Blood pressure

Blood sugar

Heart rate

Weight

Steps walked

Distance walked

Walking pace

Body temperature

Blood oxygen saturation

Sleep time

Stress

Medication intake

Duration of use of electronic devices?

Duration of use of household appliances?

Not of interest for my professional field

Other:

.....

.....

4. Do you think patients should receive reminders about medication intake, taking their weight etc. on an electronic device such as a tablet or smartwatch?

No. Is there a reason for that? Please

note:.....

Yes. Reminders about what would be most relevant:

.....

Anything else to consider about providing appropriate reminders:

.....  
.....

5. Data collected on the CAREPATH Health/Home Monitoring platform can be analyzed according to your needs. What information would be of help to you to support you in your treatment/care decisions?

Go through the following list with health professionals and note in the 'Other'-option, information they are interested in, but are not on the list.

Point out to you significant changes in the collected health/home monitoring parameters, e.g., high blood pressure, change in sleep, decreasing activity, decreasing use of household appliances

Which parameters would be relevant for you?

.....

Analyze health parameters in relation to each other to detect symptoms that need your attention

Which health parameters should be related (please specify):

.....

Analyze patient-reported outcome measures (PROMs) and health parameters in relation to detect symptoms that need your attention

Which PROMs and health parameters should be related (please specify):

.....

Analyze medication intake recordings in relation to health measurements

Medication recordings should be related with which health parameters (please specify):

.....

Analyze health data from patient's Electronic Health Record (EHR) in relation to health measurements collected by the CAREPATH Health/Home Monitoring platform

Which health data from patient's EHR should be related to which health parameters (please specify):

.....

Other:

.....

6. From constant analysis of data collected on the Health/Home Monitoring platform in combination with information from patient's EHR, the CAREPATH system conducts a risk assessment which will result in early warnings on conditions potentially harmful for a patient. For your treatment or care purposes what are most important risks to follow-up on?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a risk that is not on the list.

- Heart conditions
- Cognitive decline
- Behavioural problems (such as apathy, agitation, wandering, insomnia, delusions, hallucinations, eating symptoms, inappropriate sexual behaviour) – Which ones:

.....

- Activity at night
- Stress
- Loneliness
- Decline in hobbies
- Loss of skills in managing activities of daily living independently
- Decline of mobility
- Risk of new frailty
- Risk of frailty progression
- Loss of intrinsic capacity
- Risk of falls
- Risk of developing new comorbidity
- Risk of pre-existing chronic condition worsening
- Problems with urinary or faecal continence
- Risk of medication errors
- Risk of poor adherence to medication intake
- Decrease of medication effectiveness
- Burden on informal caregiver is increasing
- Poor social network
- Other:

.....

7. Risk assessment in CAREPATH will be based among others on a so-called 'dementia profile'. In your opinion, what patient health data should be considered to determine the cognitive status of a patient?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a type of health data that is not on the list.

- Diagnoses. Which ones are most relevant:

.....

- Assessments of cognitive status. Which ones are most relevant:

.....

- Psychological and behavioural assessments. Which ones are most relevant:

.....

- Blood pressure
- Status of steps walked
- Status of walking distance
- Status of walking pace

Assessments such as status on how independent a patient can manage his/her everyday life.

Other:

.....  
.....

8. Would you like to provide educational materials for the patient, e.g., background information or tips on how to deal with a condition the patient is suffering from, an exercise or diet plan?

No

Yes

What kind of material(s)?:

Online brochures or booklets

Links to websites with safe information about a condition

Links to websites of self-help groups

Links to video clips, e.g., about healthy cooking channels, exercises

Diet plan

Recipes

Exercise plan

Other:

.....

9. Do you think it would be useful, if there were a possibility for direct communication between you or the care team and the patient/informal caregiver?

Yes. In case the communication feature shall involve not only you, but other groups of health professionals, e.g., social workers, physiotherapists, medical doctors etc., please note here whom to include:

.....  
.....

No

10. What non-pharmacological interventions could CAREPATH monitor and implement to help improve the quality of life of multimorbid older adults with MCI/mild dementia multimorbid?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a type of non-pharmacological intervention that is not on the list.

Diet

Exercise

Routines in everyday life

Provide a quiet ambient

Social contacts

Games Which ones:.....

Reminiscence therapy

Music therapy

Art therapy

Life story work

Other: .....

The following questions 11, 12, 13 are only for medical doctors. For other health professionals please proceed to question 14.

11. Polypharmacy and medication appropriateness issues play an important role in the treatment of multimorbid patients with MCI/mild dementia. In CAREPATH a component will be developed that evaluates a patient's medication plan in regard to polypharmacy and medication appropriateness issues. What issues are important for you to know about?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a polypharmacy/medication appropriateness issue that is not on the list.

- Drug-drug interactions
- Adverse drug reaction
- Possible side effects of drugs
- Non-pharmaceutical interactions such as drug-food, drug-non pharmaceutical products.

Which ones are relevant for your professional field:

.....  
 Negative influence on geriatric syndroms like frailty, cognitive decline, functional decline, depression, urinary continence, falls. Which ones are relevant for your professional field:

- .....
- Not recommendable for older patients (medication appropriateness)
  - Dose adjustment to multimorbidity and age
  - Possibility of medicines conciliation
  - Interaction with of over-the-counter medications. Which ones are most relevant:

.....  
 Interaction with herbs or other non-pharmacological products. Which ones are most relevant:

- .....
- Number of prescribed drugs exceeds recommended amount
  - If an alternative prescription can be recommended
  - Other:

12. In case a polypharmacy or medication appropriateness issue is detected by the CAERPATH system, how shall the system present the detected issue(s) to you besides providing a warning, e.g., after a medication prescription?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a presentation form that is not on the list.

- In a report listing all prescriptions in question and providing detailed information on the detected issues, e.g., possible drug-drug interaction between which drugs due to which substance(s), possible adverse effects of which drug etc.. This report could be presented, e.g., immediately after a medication prescription.
- Mark all drugs in question in red. When selecting either one of these drugs detailed information is provided on the detected issues, e.g., possible drug-drug interaction between which drugs due to which substance(s), negative effects on other conditions, intrinsic capacity or geriatric syndroms
- Should information on polypharmacy or medication appropriateness issues include also a link to a medication data bases for further reading



- Should information on polypharmacy or medication appropriateness issues include also link(s) to medical guidelines where the drug is recommended for treatment for further reading
- Other:

13. Do you think it would improve treatment, if medical doctors (with help of IT personnel) could add new rules to the polypharmacy and medication appropriateness component that are specific to their treatments purposes?
- No
  - Yes – can you give an example?:

The following question is only for health professionals other than medical doctors:

14. Which health information about a patient is of particular importance to you when treating or caring for multimorbid older adults with MCI/mild dementia?

- Prescription (why do you see the patient)
- Diagnoses
- Medication plan
- Lab tests
- Health measurements such as blood pressure, sleep
- Family member history
- Allergies and intolerances
- How independent a patient can manage his/her everyday life. What aspects of everyday life are most relevant for you:

.....  
 Results from assessments. Which ones:

.....  
 Other:  
.....  
.....

**Thank you very much for your help!**

Question to **interviewer**:

In case you think it is appropriate ask whether the health professional is willing to support us in the development of the CAREPATH platform for health professionals by for instance looking at a mock-up once in a while or trying out a prototype.

Please cross here, in case the health professional is willing to support us:

- Willing to help us with the design of the CAREPATH platform for health professionals

## 7 Appendix C – interview guideline health professionals



### An Integrated Solution for Sustainable Care for Multimorbid Elderly Patients with Dementia



User Requirement Definition and Design of CAREPATH System  
Architecture

## Interview Guideline for Health Professionals



*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945169.*

Type of health professional	Please select:
GP	<input type="checkbox"/>
Hospital medical doctor	<input type="checkbox"/>
Nurse	<input type="checkbox"/>
Allied professional	<input type="checkbox"/>
Note: please ensure that the gender aspect is taken into account (ratio women/men spread almost evenly among interviewees at each trial site) and that the professional experience of the interviewee is at least 3 yrs.	

Each clinical trial site is asked to do 4 interviews with health professionals and should include all types of health professionals that will participate in the clinical study at their site.

### **Short introduction to the project and the purpose of the interview:**

The aim of CAREPATH: An Integrated Solution for Sustainable Care for Multimorbid Elderly Patients with Dementia, an EU-funded project under the H2020 programme, is to offer an ICT-based solution for optimising the clinical practice in the treatment and management of multimorbid older adults with Mild Cognitive Impairment (MCI) or mild dementia. In order to achieve this, CAREPATH will elaborate on a methodology for computer interpretable clinical guidelines and computationally derived best clinical practice for best suitable treatment of this patient group. Thereby, a multidisciplinary care approach is considered, with a focus on the very individual needs of patients in this group to be translated into personalized care plans.

To provide computationally derived best clinical practice suggestions, CAREPATH will include a clinical decision support system that will conduct, among others, risk assessment that is based on data from patients' electronic health records and other health-related data, as collected by a Health/Home Monitoring system, installed at the patients' homes. These health data will be processed by artificial intelligence (AI) algorithms to predict the development of patients' conditions. In terms of dementia-associated multimorbidity, the scope of CAREPATH will include frailty, sarcopenia, nutritional risk, diabetes, heart failure, chronic obstructive pulmonary disease (COPD), chronic kidney disease (CKD), stroke, cardiovascular disease and hypertension.

The project is in its beginning stage and we are very much interested in your opinion on what needs to be improved in the treatment and management of multimorbid older adults with MCI or mild dementia and how such a clinical decision support system should be designed to best support you in your daily treatment and care tasks.

-----

-----

**Note to interviewer:** in the following interview guideline text marked grey is for instruction of interviewers and documentation support. It shall give you an idea on what information we are looking for, but of course we are much interested in any other information.

**Important!** - inform the interviewee about which patient group the term 'patient' shall refer to in this interview: the target patient group of CAREPATH are multimorbid older adults living with MCI/mild dementia. Therefore, in the following interview the term 'patient' refers to this specific group of patients.

### Interview guideline

1. What do you think are the main obstacle(s) in the treatment of patients who are multimorbid older adults with MCI/mild dementia?

Go through the following list with health professionals and note in the 'Other'-option, if they mention an obstacle that is not on the list.

There are neither clear recommendations nor guidelines for this patient group  
 Requirements from medical guidelines for specific conditions or diseases can conflict with others. For example, thight control of diabetes may produce hypoglycemias, falls or cognitive decline, thight control of blood pressure could worsen orthostatic hypotension, or introduction of beta-blockers for coronary artery disease may produce depression.  
From your professional experience do you know of any conflicts originating in contradictory medical guidelines? What are the most relevant issues:

.....  
.....

Treating such patients is difficult, because a required treatment for one condition can have a negative impact on another condition

From your professional experience do you know of treatments that often have adverse effects? What are the most relevant issues:

.....  
.....

Reaction to a treatment depends much on the personal health condition, frailty status or intrinsic capacity of a patient

In case needed here definition of 'intrinsic capacity': Intrinsic capacity (IC) is a composite of all the physical and mental attributes on which an individual can draw, not only in older age, but across their lives WHO, 2017).

TIC (Technology and Information Resources) are lacking, e.g. resources such as websites, applications or apps that help in the process of decision-making with these patients

The multidisciplinary care team is not always coordinated well

Communication among the multidisciplinary care team (primary care physicians, geriatricians, other specialists, social worker, therapists, nurses etc.) is missing, delayed or difficult

The patients themselves cannot provide so much information about their current health status and its history, so the multidisciplinary team lacks relevant information

Patients do not know about the treatments they are receiving from multiple specialists

Ask the following 2 questions only medical doctors:

Training on medication appropriateness is lacking

Physicians do not like, cannot, or are not trained to prescribe or deprescribe against the recommendations and prescriptions of previous physicians

Other:

.....  
.....

2. The CAREPATH system includes a Health/Home Monitoring platform which allows health professionals to ask patients to fill in on a tablet patient-reported outcome measures

(PROMs) or simple questions such as ‘How do you feel today?’. Is there any information you would be interested in?

Go through the following list with health professionals and note in the ‘Other’-option, if they mention something of interest for them that is not on the list.

Well-being of the patient after drug intake, e.g., by a Likert scale visualized by smileys (happy face, neutral face, sad face)

If the result is out of expected range: shall the system ask for symptoms?  Yes

No

Well-being of the patient overall on a day, e.g., by a Likert scale visualized by smileys (happy face, neutral face, sad face)

If the result is out of expected range: shall the system ask for reasons?  Yes

No

The average mood of the patient

New necessities for visiting a health professional (request may come from patient or informal caregiver). For example, do you need to advance your physician visit?

Hand-made questionnaire(s) on (please note the topic):

.....

Validated questionnaires (please note which one(s)):

.....

Other:

.....

.....

3. The Health/Home Monitoring platform in CAREPATH is able to collect health parameters such as blood pressure, sleep and steps walked. Beyond this, it can analyze movement to detect wandering behavior and localize the patient outdoors. The platform also gathers data from the patient’s physical environment, e.g., room temperature. The result of the Health/Home Monitoring platform can be presented to you, e.g., on a dashboard visualizing results of the recordings in line graphs, bar charts, tables or the like for quick overview.

Which kind of health measurements or parameters from the patient’s physical environment are of particular interest for your treatment/care purposes?

Go through the following list with health professionals and note in the ‘Other’-option health measurements or parameters from patient’s physical environment that are not on the list.

Blood pressure

Blood sugar

Heart rate

Weight

Steps walked

Distance walked

Walking pace

Body temperature

Blood oxygen saturation

Sleep time

Stress

Medication intake

Duration of use of electronic devices?

Duration of use of household appliances?

Not of interest for my professional field

Other:

.....

.....

4. Do you think patients should receive reminders about medication intake, taking their weight etc. on an electronic device such as a tablet or smartwatch?

No. Is there a reason for that? Please

note:.....

Yes. Reminders about what would be most relevant:

.....

Anything else to consider about providing appropriate reminders:

.....  
.....

5. Data collected on the CAREPATH Health/Home Monitoring platform can be analyzed according to your needs. What information would be of help to you to support you in your treatment/care decisions?

Go through the following list with health professionals and note in the 'Other'-option, information they are interested in, but are not on the list.

Point out to you significant changes in the collected health/home monitoring parameters, e.g., high blood pressure, change in sleep, decreasing activity, decreasing use of household appliances

Which parameters would be relevant for you?

.....

Analyze health parameters in relation to each other to detect symptoms that need your attention

Which health parameters should be related (please specify):

.....

Analyze patient-reported outcome measures (PROMs) and health parameters in relation to detect symptoms that need your attention

Which PROMs and health parameters should be related (please specify):

.....

Analyze medication intake recordings in relation to health measurements

Medication recordings should be related with which health parameters (please specify):

.....

Analyze health data from patient's Electronic Health Record (EHR) in relation to health measurements collected by the CAREPATH Health/Home Monitoring platform

Which health data from patient's EHR should be related to which health parameters (please specify):

.....

Other:

.....

6. From constant analysis of data collected on the Health/Home Monitoring platform in combination with information from patient's EHR, the CAREPATH system conducts a risk assessment which will result in early warnings on conditions potentially harmful for a patient. For your treatment or care purposes what are most important risks to follow-up on?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a risk that is not on the list.

- Heart conditions
- Cognitive decline
- Behavioural problems (such as apathy, agitation, wandering, insomnia, delusions, hallucinations, eating symptoms, inappropriate sexual behaviour) – Which ones:

.....

- Activity at night
- Stress
- Loneliness
- Decline in hobbies
- Loss of skills in managing activities of daily living independently
- Decline of mobility
- Risk of new frailty
- Risk of frailty progression
- Loss of intrinsic capacity
- Risk of falls
- Risk of developing new comorbidity
- Risk of pre-existing chronic condition worsening
- Problems with urinary or faecal continence
- Risk of medication errors
- Risk of poor adherence to medication intake
- Decrease of medication effectiveness
- Burden on informal caregiver is increasing
- Poor social network
- Other:

.....

7. Risk assessment in CAREPATH will be based among others on a so-called 'dementia profile'. In your opinion, what patient health data should be considered to determine the cognitive status of a patient?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a type of health data that is not on the list.

- Diagnoses. Which ones are most relevant:

.....

- Assessments of cognitive status. Which ones are most relevant:

.....

- Psychological and behavioural assessments. Which ones are most relevant:

.....

- Blood pressure
- Status of steps walked
- Status of walking distance
- Status of walking pace



Assessments such as status on how independent a patient can manage his/her everyday life.

Other:

.....  
.....

8. Would you like to provide educational materials for the patient, e.g., background information or tips on how to deal with a condition the patient is suffering from, an exercise or diet plan?

No

Yes

What kind of material(s)?:

Online brochures or booklets

Links to websites with safe information about a condition

Links to websites of self-help groups

Links to video clips, e.g., about healthy cooking channels, exercises

Diet plan

Recipes

Exercise plan

Other:

.....

9. Do you think it would be useful, if there were a possibility for direct communication between you or the care team and the patient/informal caregiver?

Yes. In case the communication feature shall involve not only you, but other groups of health professionals, e.g., social workers, physiotherapists, medical doctors etc., please note here whom to include:

.....  
.....

No

10. What non-pharmacological interventions could CAREPATH monitor and implement to help improve the quality of life of multimorbid older adults with MCI/mild dementia multimorbid?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a type of non-pharmacological intervention that is not on the list.

Diet

Exercise

Routines in everyday life

Provide a quiet ambient

Social contacts

Games Which ones:.....

Reminiscence therapy

Music therapy

Art therapy

Life story work

Other: .....

The following questions 11, 12, 13 are only for medical doctors. For other health professionals please proceed to question 14.

11. Polypharmacy and medication appropriateness issues play an important role in the treatment of multimorbid patients with MCI/mild dementia. In CAREPATH a component will be developed that evaluates a patient's medication plan in regard to polypharmacy and medication appropriateness issues. What issues are important for you to know about?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a polypharmacy/medication appropriateness issue that is not on the list.

- Drug-drug interactions
- Adverse drug reaction
- Possible side effects of drugs
- Non-pharmaceutical interactions such as drug-food, drug-non pharmaceutical products.

Which ones are relevant for your professional field:

.....  
 Negative influence on geriatric syndroms like frailty, cognitive decline, functional decline, depression, urinary continence, falls. Which ones are relevant for your professional field:

- .....
- Not recommendable for older patients (medication appropriateness)
  - Dose adjustment to multimorbidity and age
  - Possibility of medicines conciliation
  - Interaction with of over-the-counter medications. Which ones are most relevant:

.....  
 Interaction with herbs or other non-pharmacological products. Which ones are most relevant:

- .....
- Number of prescribed drugs exceeds recommended amount
  - If an alternative prescription can be recommended
  - Other:

12. In case a polypharmacy or medication appropriateness issue is detected by the CAERPATH system, how shall the system present the detected issue(s) to you besides providing a warning, e.g., after a medication prescription?

Go through the following list with health professionals and note in the 'Other'-option, if they mention a presentation form that is not on the list.

- In a report listing all prescriptions in question and providing detailed information on the detected issues, e.g., possible drug-drug interaction between which drugs due to which substance(s), possible adverse effects of which drug etc.. This report could be presented, e.g., immediately after a medication prescription.
- Mark all drugs in question in red. When selecting either one of these drugs detailed information is provided on the detected issues, e.g., possible drug-drug interaction between which drugs due to which substance(s), negative effects on other conditions, intrinsic capacity or geriatric syndroms
- Should information on polypharmacy or medication appropriateness issues include also a link to a medication data bases for further reading

- Should information on polypharmacy or medication appropriateness issues include also link(s) to medical guidelines where the drug is recommended for treatment for further reading
- Other:

13. Do you think it would improve treatment, if medical doctors (with help of IT personnel) could add new rules to the polypharmacy and medication appropriateness component that are specific to their treatments purposes?
- No
  - Yes – can you give an example?:

The following question is only for health professionals other than medical doctors:

14. Which health information about a patient is of particular importance to you when treating or caring for multimorbid older adults with MCI/mild dementia?

- Prescription (why do you see the patient)
- Diagnoses
- Medication plan
- Lab tests
- Health measurements such as blood pressure, sleep
- Family member history
- Allergies and intolerances
- How independent a patient can manage his/her everyday life. What aspects of everyday life are most relevant for you:

.....  
 Results from assessments. Which ones:

.....  
 Other:  
.....  
.....

**Thank you very much for your help!**

Question to **interviewer**:

In case you think it is appropriate ask whether the health professional is willing to support us in the development of the CAREPATH platform for health professionals by for instance looking at a mock-up once in a while or trying out a prototype.

Please cross here, in case the health professional is willing to support us:

- Willing to help us with the design of the CAREPATH platform for health professionals

## 8 Appendix D – Initial set of user requirements

Issue key	Summary	Priority	Assignee	Component/s	Fit Criterion	Rationale	Requirement Type	Source
CARE-1	Health professionals need to have access to a patient's health data.	Critical	theo.arvanitis	WP4	Health professionals are granted access to a patient's health data according to their role (if required on name-base (TBD clinicians)) and are allowed to add/change information in a patient's health record as authorized. Data requirements and authorization rules are described in detail in the document 'Data requirements and authorization rules'. The latest version of the document is available at EXYS cloud WP2 > Data requirements.	Several groups of health professionals are involved in the care and treatment of multimorbid patients with MCI/mild dementia. All of these have to have access to a patient's health data as needed to fulfill their tasks. However, patients' rights as set forth in GDPR need to be considered.	Functional	CAREPATH Bi-weekly 2021-08-24
CARE-2	Patients need to be reminded of to-dos as defined in their care plan.	Critical	gokce.banu	WP4	<p>Reminders shall be:</p> <ul style="list-style-type: none"> <li>• Selectable: Patients will be presented reminders as defined in their care plan, e.g. for medication intake, fill in PROMs, take weight measurements and daily activities as agreed with the patient. For informal caregivers it needs to be configurable that they do not receive reminders even if they have access to their care-dependent's care plan in case they do not wish so. This could be defined on the Adaptive Integrated Care Platform or by informal caregivers themselves.</li> <li>• Noticeable: It needs to be ensured that patients are able to notice the reminders, e.g. be presented as push notification on their smartwatch with multimodal stimuli (e.g., tactile, auditory, visual). Personal preferences may need to be considered for this purpose, so reminder output shall be configurable.</li> <li>• Present according to an escalation scheme: An escalation scheme shall be implemented in case a reminder is ignored by the patient (TBD by clinicians). Escalation schemes may vary depending on the task to-do to not annoy patients by reminders (TBD clinicians).</li> <li>• Disappear In case a reminder has not been confirmed within 4 hrs, it shall disappear and from then on the task stays highlighted as before (status 'due'). It can still be confirmed by clicking on the task. This avoids cluttering of reminders and allows to confirm tasks later on, e.g., in case there was no time to do so.</li> <li>• Clear wording: The reminder needs to present clearly what the patient is expected to do. E.g. in regard to medication safety issues have to be considered, i.e. it is to ensure that patients take the right medication in the prescribed dosage. This issue may require personalized reminder messages to be defined on the Adaptive Integrated Care Platform.</li> </ul> <p>Implementation of reminders shall consider GDPR and security issues.</p>	Due to cognitive decline patients with MCI/mild dementia have difficulties with self-managing their disease(s), e.g. take in medication as prescribed. Being affected by multimorbidities will most likely worsen the situation, since more tasks need to be fulfilled by patients. When designing reminders, it is to consider that patients and/or their informal caregivers do not feel bothered by reminders, so reminders and their appearance need to be configurable, e.g., on the Adaptive Integrated Care Plat+12form.	Functional	CAREPATH DoA

CARE-3	Patients need to be able to confirm tasks to do.	Critical	gokce.banu	WP4	Patients may confirm tasks either by clicking on a reminder or the task to-do on the task list (patient's daily care plan). The patient is then asked to confirm by either 'Yes' or 'No' whether the task was done or not. In case of 'Yes' the system informs the patient that the confirmation was received and presents a rewarding message/gamification feature. In case of 'No' the patient can optionally indicate why not, e.g., select from a list with predefined rationales such as 'was sick', 'no time' etc. (options TBD with clinicians).	In case a reminder is presented to the patient or a task is indicated as 'due' on patient's daily care plan, the patient needs to be able to confirm whether the task was done or not. If not, the patient should have the option to indicate why not, e.g., the medication was not taken, because feeling sick. This is important feedback for clinicians.	Functional	CAREPATH DoA, experience from previous research projects PICASO and POLYCARE
CARE-4	In CAREPATH personal data are processed according to GDPR as well as national/regional policies and legislations on data protection and security	Critical	angelo consoli	WP4	In CAREPATH a data protection agreement shall be signed by all partners that regulates how GDPR-compliant treatment of personal data will be achieved in the project. Compliance to national, if applicable, regional etc. laws shall be achieved by data protection officers approving the agreement on behalf of the clinical trial sites.	When processing personal data in CAREPATH as defined in the EU-General Data Protection Regulation (GDPR) it needs to be ensured that the core principles of this regulation are adhered to, e.g., lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity, confidentiality and accountability.	Non-Functional - > legal	Legal requirement
CARE-5	User actions can be traced on the CAREPATH platform.	Critical	gokce.banu	WP4	Users' actions on all components of the CAREPATH platform shall be logged, e.g., in form of an activity log. In case of enquiries by ,e.g., patients, it shall be possible to disclose the requested information in a readable/understandable format.	For data protection purposes users actions shall be traceable on the CAREPATH platform, so it can be followed up on, e.g. which health professional has authored which data or accessed which patient's health data. Same applies for patient-generated data on the Health/Home Monitoring Platform.	Functional	Legal requirement
CARE-6	For data integrity and security reasons, it is necessary to ensure that patient data cannot be interpreted while being transferred.	Critical	gokce.banu	WP4	Patient data will be encrypted before being sent, e.g. from the home of the patient, and only decrypted when received, e.g., at the clinical trial site.	It is to ensure that patient data will be transferred secure and without any risk of falsification or transcription errors, for instance when transferred from the Health/Home Monitoring Platform at patients' homes to the clinical trial sites.	Functional	Security requirement
CARE-7	The Health/Home Monitoring Platform shall employ minimally intrusive, dementia-friendly and safe devices and technologies	Critical	angelo consoli	WP4	Devices used for the Health/Home Monitoring platform need to be minimally intrusive, integrating seamless as much as possible into patients' environment. They also need to be comfortable to wear, i.e. not experienced as disturbing or restrictive by patients in any way otherwise they are likely to be taken off. In regard to an appealing look, gender aspects are relevant to consider, e.g. smaller wrists of women potentially influencing accuracy of measurements, colour and design preferences.  Beyond this, it is crucial that the special requirements of multimorbid patients with MCI/dementia are considered. Among those are declines in visual acuity, hearing and/or fine motor skills. Therefore, displays need to have good contrast, information shall be presented in a well-perceivable and clear and scarce style, only buttons and other operation means should be available that are needed and convenient and easy to operate. In addition, devices and technologies must be robust and follow an error-resistant design approach, i.e. users shall be supported to avoid errors, in case errors happen this should not lead to system failures etc..	To avoid stigmatisation and foster acceptance of devices and technology used for health/home monitoring it is important that devices are not experienced as privacy-intrusive, are comfortable to wear and have an appealing look. Furthermore, they need to be designed dementia-friendly for safe usage.		Interviews with informal caregivers WP2/WP3 ideation workshop on Early Warnings Recommendations by Alzheimer Society, literature review, e.g., Cote et al. (2021). Evaluation of Wearable Technology in Dementia: A Systematic Review and Meta-Analysis, Front.Med) Tom Grey et al. (2015). Universal Design Guidelines. Dementia Friendly Dwellings for People with Dementia, their Families and Carers. Centre for Excellence in Universal Design Experience from previous research projects PICASO, POLYCARE and WebDA

					<p>Cognitive declines also need to be considered which affects learnability, attention focusing and may cause disorientation. Thus, users need step-by step guidance, have a means to exit wherever they are and start all over again. Maintenance tasks such as necessity to load a smartwatch or tablet shall be kept as minimal as possible by ensuring a long lasting battery life and on-time reminder when action is required.</p> <p>All aforementioned issues may cause safety issues with need to be investigated thoroughly when determining devices and technologies used by the Health/Home Monitoring Platform, before installation at patients' homes and thereafter.</p>			
CARE-8	Patients are provided readily available and dementia-friendly designed materials with instructions on how to use sensors, devices, and the applications provided to them.	Critical	angelo consoli	WP4	Patients are provided readily available materials on how to use properly sensors and devices of the Health/ Home Monitoring Platform and applications provided to them, e.g., on their tablet. Materials could be video clips on patients' tablets demonstrating how devices are used or instructions in print form, e.g. an instruction manual. When designing these materials the special requirements of people with MCI/dementia need to be considered (see CARE...).	For the trials patients need to have information readily available, e.g., in form of an instruction manual', video clips or the like, on how to use properly sensors and device of the Health/ Home Monitoring Platform and applications provided to them, e.g., on their tablet.	Functional	Recommendations Alzheimer Society, WCAG 2.1
CARE-9	The Health/Home Monitoring Platform monitors proper data collection at patients' homes.	Critical	angelo consoli	WP4	The Health/Home Monitoring Platform employs procedures monitoring that data are coming in from patients' homes as expected, i.e. all sensors, devices and applications appear active and in use. Data monitoring does not give hints, that there is a malfunction, e.g., because a device like the smartwatch is not worn properly. In case of doubt a responsible at the clinical trial sites is immediately informed to undertake action, e.g., contact the patient or informal caregiver.	The Health/Home Monitoring Platform needs to monitor data coming in from sensors and devices at patients' homes to avoid corrupted or even loss of data due to misplaced sensors, operating problems by patients /informal caregivers etc.	Functional	Experience from field trials in other research projects such as PICASO and POLYCARE.
CARE-10	Patients or informal caregivers should be able to create a 'leave of absence' message during the clinical study.	Critical	gokce.banu	WP4	Patients or informal caregivers participating in the clinical studies are able to create a 'leave of absence' message indicating the period of time they will not be able to use the Health/Home Monitoring Platform or any other CAREPATH applications. In case they are able to still use selected sensors, applications or devices, e.g., take a long the smartwatch or the tablet to fill in medication intakes or PROMs, they should be able to indicate this.	In case patients participating in the clinical study will not be able to use the Health/Home Monitoring Platform or other CAREPATH applications, because they are, e.g., on vacation, they should be able to send a 'leave of absence' message to the responsible person at the clinical trial site indicating the period of time they will be away, so the trial site is informed about why no data are coming in from this patient and for how long this will be.	Functional	Experience from other research projects, e.g., PICASO and POLYCARE
CARE-11	Applications used by patients with MCI/mild dementia shall be designed dementia-friendly.	Critical	gokce.banu		<p>When designing services and applications for people with MCI/dementia special requirements need to be considered (please refer to resources mentioned below for further details).</p> <p>UI-design, e.g.,: ensure high contrast (see WCAG 2.1), large buttons and icons, minimalistic design (present only what is really necessary), avoid cluttered screen, avoid scrolling, use colours with care, because colour stimuli can override each other and inhibit proper attention focusing, implement a consistent</p>	Due to cognitive decline and other co-morbidities people with MCI/dementia have special design requirements that need to be taken into account when designing services or applications for this user group.	Non-Functional - > usability	Literature review (see fit criterion)



					<p>design approach</p> <p>Content, e.g.: information/instructions shall be clear and short, use simple words, provide step-by-step instructions (avoid being chatty though), structure content (headings, section breaks), on mobile devices content can be viewed in landscape and portrait mode, follow up on what users are familiar with from their past, e.g. use pictures from the 50 fifties or earlier, adapt to individual abilities, e.g., offer games with different levels to account for heterogeneousness of this user group</p> <p>Operation/navigation, e.g.: provide always an exit key (e.g. home key) to return to the beginning and start all over again, offer a help button, consistent navigation structure, behave as expected (avoid changes in navigation or layout), account for limited learnability, provide visual and sound selection cues</p> <p>Further resources: WCAG 2.1: <a href="https://www.w3.org/TR/WCAG21/">https://www.w3.org/TR/WCAG21/</a></p> <p>Kerkhof et al. (2017). Selecting apps for people with mild dementia: Identifying user requirements for apps enabling meaningful activities and self-management</p> <p>Williams, R. Dementia Digital Design Guidelines (includes a mapping of requirements of people with dementia and WCAG 2.0). Available at: <a href="https://www.alzheimers.org.uk/blog/how-design-website-someone-affected-dementia">https://www.alzheimers.org.uk/blog/how-design-website-someone-affected-dementia</a></p>			
CARE-12	A daily care plan will be presented to patients in a dementia-friendly design	Critical	gokce.banu	WP4	<p>Patients are presented their care plan as defined on the Adaptive Integrated Care Platform in form of daily tasks to-do which should be ordered according to time. This will include, e.g., medication intake, recording of health parameters and PROMs, performing exercises and adhering to diet recommendations.</p> <p>The care plan shall be designed in a dementia-friendly way, e.g., describe tasks of the day in short and concise including what exactly is the patient expected to do and when. Provide visual cues through colouring, icons etc. for different tasks to do. It must be obvious which tasks are already done and which ones are open. Provide step-by-step guidance to support users in achieving their tasks, if feasible support by prompting through sound and animation. In case all tasks are achieved, the patient is informed and appraised by a rewarding message/gamification feature. For more details on dementia-friendly design, see CARE-11 and on design of reminders CARE-2.</p>	In CAREPATH patients are expected to follow-up on their care plan. For this purpose they need to be aware of their daily tasks besides being reminded of open tasks. Since CAREPATH patients live with MCI/mild dementia, the care plan has to be presented to them in a dementia-friendly design.	Functional	CAREPATH DoA and sources of CARE-11



CARE-13	Informal caregivers should have access to all PEP services	Critical	gokce.banu	WP4	Informal caregivers in the clinical study shall have access to all PEP services as available to their care-dependent provided that care-dependents have agreed to this. In a production environment this may need to be configurable, e.g., informal caregiver does not want access to the care plan of the person s/he cares for or patient does not want to grant access to his/her care plan for informal caregiver.	In order to support informal caregivers in managing their care tasks, access to all services provided on PEP (Patient Empowerment Platform) shall also be accessible to informal caregivers. This includes patients' daily care plans and the status of tasks (e.g., confirmed or not confirmed) as well as access to games, diet and exercise plans, educational materials, health tips etc. that have been uploaded there by health professionals. For the clinical study it will be aimed for that informal caregivers are willing to access PEP services in principle for evaluation purposes - usage is voluntary though – provided that patients have agreed to this.	Functional	Interviews with informal caregivers
CARE-14	Results of health measurements and PROMs from H/HMP are presented to patients and informal caregivers	Critical	gokce.banu	WP4	Results of health measurements and PROMs collected by H/HMP are presented to patients and/or informal caregivers as selected by medical doctors. Individual thresholds or beyond threshold values shall be visualized only if defined by medical doctors. It shall be possible to select different configurations for patients and informal caregivers, e.g., the informal caregiver is presented more results of health measurements than the patient or vice versa. Same applies to visualization of individual thresholds or beyond threshold values.  Patients and/or their informal caregivers are able select a time period from which they want to be presented all available recordings as configured for them.	Results of health measurements generated by the Health/Home Monitoring platform (H/HMP) such as blood pressure measurements and PROMs reported by patients, e.g., pain ratings, shall be presented to patients and informal caregivers, to enable them to judge better about the patient's current health situation. It should also be possible to look at such recordings in retrospective, so patients and informal caregivers can achieve an objective understanding of how the patient's health condition is developing.  In order to avoid that patients feel overwhelmed by the information presented, it shall be configurable by medical doctors which data from H/HMP and PROMs shall be presented to patients and/or informal caregivers. Same applies to whether individual thresholds or beyond threshold values shall be visualized to patients and/or informal caregivers, allowing them to identify whether a measurement is within or without an expected range, because such information may cause anxiety.	Functional	Interviews with patients and informal caregivers Experience from previous e-health projects, e.g., PICASO and POLYCARE
CARE-15	Patients shall be supported in proper medication intake and documentation thereof	Critical	gokce.banu	WP4	Foreseen medication intake shall be presented on a patient's care plan as scheduled on the Adaptive Integrated Care Platform. It shall describe clearly when (time) what medication (e.g. brand name/picture) and how much (dosage) shall be taken by the patient and support the patient in achieving this task (see CARE-12). This may include pointing the patient to a device (e.g., pill box) s/he using for management of medication intake.  Medication intake shall be recordable by either clicking on a reminder or the according task on a patient's daily care plan. In case the patient has taken the medication as prescribed follow procedure as described in CARE-3. In case not, offer the possibility to enter why a medication was not taken, which could be supported by a drop-down list with preconfigured	Medication intake is an important feature of a patient's daily care plan and for patients with MCI/mild dementia proper intake often poses a problem, because patients forget when to take what. To compensate for these circumstances, patients are often advised to use pill boxes or the like which does not support timely intake necessarily. Beyond this, documentation of medication intake usually does not take place, although it provides a very valuable source of information for treatment decisions, e.g., knowing about reasons why a medication was not taken as well as when and how much medication was taken prescribed only for use as-needed. In CAREPATH intake of non-pharmacological medication shall also	Functional	DoA Experience from other e-health projects, e.g., PICASO and POLYCARE

					<p>response options (was vomiting, stomach ache, felt sick (TBD by clinical partners)). It should also be possible to document in case the patient has changed the dosage or the input time. A very similar approach shall be followed for medication the patient is advised to take only as needed. In this case dosage and input time needs to be recordable.</p> <p>Once documentation of medication intake is completed and saved by the system, the patient is informed about this and a rewarding message/gamification feature is presented to the patient.</p>	<p>be part of the patient's care plan to judge better on medication appropriateness, side-effects etc.</p>		
CARE-16	Patients shall be supported in conducting and recording exercises	Critical	gokce.banu	WP4	<p>The patient's care plan includes the task on when to do exercises as defined on the Adaptive Integrated Care Platform. As part of the task a list of specified exercises, links to an exercise plan, poster or video on PEP, where exercises are explained are presented in accordance to how this is defined on the Adaptive Integrated Care Platform.</p> <p>Patients are able to document when exercises are done or if this has not been possible, record optionally why not, which could be supported by a drop-down list (could not do all, pain, too tired, too much, no time (TBD by clinical partners)).</p> <p>Once documentation of exercises is completed and saved by the system, the patient is informed about this and a rewarding message/gamification feature is presented to the patient.</p>	<p>Exercising is an important part of patients' well-being and therefore will part of their care plans. It can be done in many different ways. Exercises to-do can be explained and trained by physiotherapists, a patient may have a professional exercise plan, uses video clips for instruction or a poster depicting the exercises.</p>	Functional	<p>WP2 bi-weekly Discussion of interview guidelines for patients and informal caregivers</p>
CARE-17	Patients shall be supported in filling out and recording PROMs	Critical	gokce.banu	WP4	<p>Filling out PROMs shall be as easy as possible for patients which requires dementia-friendly wording and design of response options. PROMs can be filled out by either clicking on a reminder or the according task on a patient's daily care plan as defined in the Adaptive Integrated Care Platform. It shall be possible to complete PROMs in several turns, so the current state shall always be stored and the patient is guided to where responses are still missing. If applicable, PROM-specific guidelines have to be applied on when a PROM is considered complete or not despite of missings. Once a PROM is completed and saved by the system the patient is informed about this and a rewarding message/gamification feature is presented to the patient.</p> <p>In case the PROM could not be completed by the patient, it shall be possible to record optionally why not, which could be supported by a drop-down list (too much, too often, no time (TBD by clinical partners)).</p>	<p>Patient-reported Outcome Measures (PROMs) can serve as valuable source of information in regard to how active a disease is at a given time, how patients feel after medication intake etc. PROMs are part of the clinical study protocol in CAREPATH and therefore patients in the trials will be asked to fill those. Besides ensuring that wording of the PROMs is understandable for patients with MCI/mild dementia, it will also be a challenge on how to deal with missings. It is to expect that patients might not answer all questions for various reasons (do not know, loose concentration, feel overburdened etc.), so might be necessary to define PROM-specific guidelines from when on a PROM is considered as 'done' despite of missings or remains 'due'.</p>	Functional	<p>WP2 bi-weekly Discussion of interview guidelines for patients and informal caregivers DoA Experience from other e-health projects, e.g. PICASO, POLYCARE, WebDA</p>

CARE-18	Patients shall be supported in adhering to diet recommendations	Critical	gokce.banu	WP4	Diet recommendations as selected by health professionals are available for patients and informal caregivers on PEP. A task will be presented to patients as scheduled by health professionals prompting them to keep to their diet. Patients/informal caregivers may link directly from this task to their selected diet plan on PEP. Patients are able to confirm this task by 'Yes' or 'No'. In case of 'No' patients are able to provide a reason why they could not adhere to their diet, e.g., they developed symptoms as diarrhea, do not like it, food is provided now by 'meals on wheels' services (see CARE-3).	Adhering to a diet that considers the individual health situation of patients is an important part of the treatment of multimorbid older patients with MCI/mild dementia. Therefore, patients shall be provided diet recommendations on PEP as defined on their care plan.	Functional	WP2 bi-weekly meetings Discussion of interview guidelines for patients and informal caregivers WP2/WP3 ideation workshop on Early Warnings
CARE-19	Informal caregivers are sent alerts in case a potentially harmful situation is detected by H/HMP	Critical	gokce.banu	WP4	An alert is sent to an informal caregiver's preferred device for such instances, in case a potentially harmful situation has been detected by H/HMP and the informal caregiver has agreed to such alerts.	Informal caregivers shall be informed in case a potentially harmful situation is detected by the Health/Home Monitoring platform, e.g., wandering behaviour in case the informal caregiver is out of the house or a fall has been detected.	Functional	WP2/WP3 ideation workshop Interviews with informal caregivers
CARE-20	Sensors and devices used in the clinical trials shall be removeable without leaving a trace in patients' homes	Critical	angelo consoli	WP4	It is ensured that sensors and devices used in the clinical trials can be removed after the study without leaving any trace in patients' homes.	For ethics reasons and acceptance of participating in the clinical study, it needs to be ensured that once the clinical study is over, all sensors and devices that were used in the study can be removed without leaving any trace in patients' homes.	Functional	Ethics considerations
CARE-21	Health professionals shall be pointed specifically to alerting risks of their patients (early warnings) and corrupted/lost data from H/HMP	Critical	gokce.banu	WP3	<p>Health professionals shall be presented a daily report on patients' status who belong to the intervention group at their trial site and use the CAREPATH platform. The status report will include:</p> <ul style="list-style-type: none"> <li>Early warnings as detected by the Advanced Early Warning Smart Decision tools</li> <li>Only the ones with 'alert 1' - priority (remaining ones will be presented immediately on opening a patient's health record, 'alert 1' warnings will be listed here as well with status (see bullet points below))</li> <li>They shall include a link to the patient's health record, so it can be directly accessed by health professionals</li> <li>Depict the rationale for why an early warning was triggered to health professionals on request, e.g., in form of a flow chart</li> <li>Offer a functionality to mark the early warning as 'Have seen' or 'Evaluated' and add system-generated by whom (e.g. health professional's first/last name from his/her user profile (TBD by clinical partners which information is necessary)</li> <li>Allow to document feedback about the early warning</li> </ul> <p>Information about detected 'abnormal' data streams, in case data collected by H/HMP are not coming from a patient's home as expected. It will be listed:</p> <ul style="list-style-type: none"> <li>When from which device/sensor abnormal data streams were detected</li> <li>Link to patient's health record on CAREPATH to check more precisely which data were recorded/not recorded, appear corrupted etc.</li> <li>Patient's first/last name and contact details such as email address, phone number. In case the informal</li> </ul>	<p>Receiving early warnings, in case a potential risk was detected by the rich data base on patient's health status, e.g., from Health/Home Monitoring Platform (H/HMP) in combination with information from patient's EHR, can serve as important input to the treatment and care of multimorbid older patients with MCI/mild dementia. It may even help to prevent harmful situations for patients. Therefore, early warnings as detected by the Advanced Early Warning Smart Decision Tools need to be brought to the immediate attention of health professionals caring for a patient.</p> <p>In the CAREPATH clinical study this shall be achieved by presenting a daily report to health professionals at clinical trial sites that includes early warnings of high priority. Since proper patient data collection by the H/HMP is crucial for detecting early warnings, this report shall also inform health professionals in case any abnormalities in the data stream coming from patients' homes is detected.</p> <p>Note: how to deal with potential emergency situations, e.g., the CAREPATH system has detected that the patient has fallen, will be defined in the ethics protocol of the clinical study which might differ among trial sites.</p>	Functional	WP2/WP3 ideation workshops on Early Warnings

					<p>caregiver is the contact person for such cases, then his/her contact details are listed as well.</p> <ul style="list-style-type: none"> <li>• Access to communication with patient/informal caregiver, e.g., patient/informal caregiver may have informed by phone, PEP or email that the patient is away for some days and therefore will not collect any or only some data</li> </ul> <p>It is configurable by health professionals when and how often the daily report should be generated. It shall also be possible to generate a report on demand.</p> <p>Which type of risks and how they shall be assessed in CAREPATH will be documented in a dedicated Excel file on 'Early Warnings'. This is a living document which will be improved and refined in course of the development phase of the project.</p>			
CARE-22	Patients shall be able to document drink consumption	Critical	gokce.banu		<p>The task to drink with an instruction what is the goal/day shall appear on patient's daily care plan as defined by medical doctors. Same with reminders where medical doctors shall decide together with patients/informal caregivers whether reminders shall be presented or not. The patient/informal caregiver is able to confirm whether this task was done or not. If yes, the patient/informal caregiver is able to document the drink consumption, e.g., 1 l/day.</p> <p>In case a smart cup is used that documents drinking consumption via Bluetooth automatically (suggestion EXYS), a daily goal of drink consumption shall be presented on patient's daily care plan. The status of achievement of the daily goal should be visualized to the patient, e.g., a progressing bar, and if achieved a rewarding message/gamification feature be presented to the patient. Besides this, drinking consumption shall be presented on PEP as it is the case with other health measurements such as steps walked.</p>	Drinking not enough or too much is often a problem for older people depending on their morbidities, however, is very important for the well-being of this patient group and may even cause serious health problems.	Functional	WP2/WP3 ideation workshop on Early Warnings, interviews patient/informal caregivers and interviews health professionals
CARE-23	CAREPATH shall allow for easy communication between health professionals and patients/informal caregivers	Critical	gokce.banu	WP4	<p>Patients and informal caregivers are offered several ways to communicate with health professionals responsible to run the clinical study at pilot sites. For this purpose contact details of responsible health professionals shall be available by a well-visible 'Contact' menu on PEP where most important name(s) and phone number(s) are presented in a dementia-friendly design. Same for communication by email, where this could be achieved, e.g., by a contact form with clear labels and instructions on how to fill in the form.</p>	Patients and/or informal caregivers may have questions about functioning of the sensors/devices in their homes, do not feel sure about the handling etc., so there needs to be an easy way for patients/informal caregivers to contact health professionals running the clinical study. 'Easy' means here that patients and/or informal caregivers are able to communicate according to their personal preferences and abilities.	Functional	WP2/WP3 ideation workshops on Early Warnings, WP2 bi-weekly
CARE-24	Communication with patients and informal caregivers needs to be accessible by all health professionals involved in running the clinical study at pilot sites	Critical	gokce.banu	WP4	<p>All communication with patients and/or informal caregivers relevant for health professionals involved in running the clinical study at pilot sites, e.g., problems with devices, reaction to early warnings, is available on the Adaptive Integrated Care Platform. The communication is directly accessible, e.g., by patient name. It may have to offer some filtering options, e.g., definition of time period of communication (TBD by pilot sites). Since patients and/or informal caregivers may also get in contact with responsible health</p>	Since several health professionals will be involved in running the clinical study at pilot sites and may have to take decisions, e.g. in case early warnings have been detected, it is important that all of them have immediate access to communication that has taken place with patients and informal caregivers. This includes notes that health professionals should take from phone calls, so the information is available to	Functional	WP2/WP3 ideation workshops on Early Warnings



					professionals by phone, a feature that allows to document such conversations needs to be available.	colleagues.		
CARE-25	Must be possible to search for misplaced sensors and devices	Critical	angelo consoli	WP4	Patients and informal caregivers are provided means by which they can search for misplaced sensors and devices, e.g., the tablet has a SIM-card that can be called. In case this is not possible replacement or other measures need to be foreseen to avoid loss of data.	Older people living with MCI/mild dementia have a tendency to misplace objects causing a lot of distress on part of the older person as well as their informal caregiver. Sometimes it appears even impossible to find the object.	Functional	Interviews informal caregivers
CARE-26	Medical doctors need to be provided all medical guidelines relevant for patients' morbidities enrolled in the CAREPATH clinical study	Critical	gokce.banu	WP4	Medical doctors are provided all nationally relevant medical guidelines for patients with MCI/mild dementia and co-morbidities addressed in CAREPATH, e.g., diabetes, heart failure. Where possible, medical doctors can be pointed to where the treatment in the medical guideline is described they are defining at the moment, e.g., a certain medication. Same with the medical guidelines developed in CAREPATH, where the rationales for treatment recommendations need to be clearly understandable by medical doctors for safety reasons as well as to ease feedback in regard to appropriateness.	Medical doctors will treat in the CAREPATH clinical study multimorbid older patients with MCI/mild dementia and thus need to have access to the according nationally relevant medical guidelines to search for treatment information. In CAREPATH a Supra and later on the CAREPATH Best Practice Guideline will be developed that aims at taking better into account the complex personal needs of multimorbid older patients with MCI/mild dementia. These new guidelines also need to be provided to medical doctors for treatment decisions.	Functional	WP2/WP3 ideation workshops on Early Warnings
CARE-27	Health professionals need to be able to overrule system-generated suggestions, adjustments, decisions and the like	Critical	gokce.banu	WP4	It is always possible for health professionals to overrule or adjust system-generated suggestions, adjustments or any other decisions as authorized. For safety reasons, it shall be clearly indicated for medical doctors, e.g., by highlighting, text labels or the like, if suggestions or any other adjustments, decisions etc. are system-generated.	In CAREPATH Clinical Decision Support Modules will be developed that will among others present system-generated suggestions and will make adjustments to patient's care plan activities on base of, e.g., patient health data collected by the Health/Home Monitoring Platform. However, rationales for such system-generated actions may not consider properly, e.g., individual thresholds for certain vital parameters and therefore health professionals as authorized shall be able to overrule any system-generated suggestion as well as any other system-generated adjustment or decision.	Functional	WP2 bi-weekly on care plan definition, WP2/WP3 ideation workshops on Early Warnings
CARE-28	Health professionals need to be able to understand and review the rationale for system-generated suggestions, adjustments and decisions	Critical	gokce.banu	WP4	Rationales behind system-generated suggestions, adjustments or decisions are presented to health professionals on request, e.g., by flowcharts.	The Clinical Decision Support Modules in CAREPATH conduct risk assessments, analyze patients' health data in combination, e.g., weight and blood pressure, consider medical guidelines and will provide based on this among others system-generated treatment suggestions and adjust care plan activities. Health professionals need to be able to understand the rationales that have led to this suggestion or adjustment, also to provide feedback in case it is inappropriate.	Functional	WP2 bi-weekly on care plan definition, WP2/WP3 ideation workshops on Early Warnings

CARE-29	Health professionals need to be able to create a care plan	Critical	gokce.banu	WP4	<p>Health professionals shall be able to create jointly a patient's care plan. Authorization rules (read/write rights) are defined in the Excel-file 'Data requirements and authorization rules'. From this care plan, the daily care plan of patients will be automatically generated to present care plan activities in form of daily tasks ordered by time when due on a patient's tablet. For this purpose, care plan definitions need to include the following information:</p> <ul style="list-style-type: none"> <li>- Timing of a task (necessary parameters TBD with clinical partners): <ul style="list-style-type: none"> <li>- From when to when shall a task be active (e.g. from 2021-12-07 until 2022-02-04, it could also end 'never')</li> <li>- How often repeated (e.g. every day; on specific days: Monday, Wednesday, Friday; every 2 weeks)</li> <li>- How often repeated per day and if yes, when (e.g. 3 times at 08:00 am, 01:00 pm, 06:00 pm; 2 times 'in the morning' and 'in the evening')</li> <li>- Only to-do 'As needed', e.g., on-demand medication</li> </ul> </li> </ul> <p>Note: medication intake might be defined already according to national standards in a similar format in patient's EHR</p> <ul style="list-style-type: none"> <li>- Reminder definition: shall reminders be generated, if yes <ul style="list-style-type: none"> <li>- For whom (only for patients, only for informal caregivers or for both)</li> <li>- Timing of reminders: when shall reminders be triggered, e.g. 15 mins after the task was scheduled, but the task has not been confirmed yet or even 15 mins. before the task, e.g. for timely medication intake</li> <li>- Should a personalized reminder message be defined (could improve adherence and wordings of reminders should be clear to avoid misunderstandings or even harmful situations, e.g. reminder before medication intake is due should be 'Please take in ...', reminder after medication intake rather ask 'Have you taken ...'). This issue could be supported by providing templates for different use cases.</li> <li>- Shall reminders follow an escalation protocol as agreed by clinical partners</li> </ul> </li> <li>- Information on whether informal caregiver should have access to patient's care plan as agreed</li> </ul> <p>All care plan activities foreseen in CAREPATH should be definable on the Adaptive Integrated Care Platform. For generation of a patient's daily care plan task types to be defined are until now (consortium may decide to add task types during user requirements collection phase) :</p> <ul style="list-style-type: none"> <li>- Medication intake</li> <li>- Taking vital sign parameters that cannot be collected automatically by H/HMP, e.g., blood pressure, weight, blood sugar</li> <li>- Fill out PROMs</li> <li>- Exercise regularly</li> <li>- Consider diet recommendations</li> <li>- Document appetite</li> </ul>	<p>Health professionals from different health disciplines will jointly create and work on a patient's care plan according to their professional expertise. Health professionals may not have the same rights, e.g., physiotherapists will not be authorized to prescribe medication, only medical doctors who may thereby even overrule medication prescriptions by another medical doctor.</p> <p>Care plans are foreseen to be presented to patients on their tablet in form of a daily care plan that will describe all tasks a patient should achieve on a specific day or be reminded of regularly. Health professionals will define all such tasks and their timing on the Adaptive Integrated Care Platform, so patients' daily care plan can be automatically generated from there. This care plan may include reminders on tasks which the patient should not forget about, e.g., medication intake.</p>	Functional	WP2/WP3 ideation workshops on Early Warnings, interviews with health professionals, interviews with patients and informal caregivers
---------	------------------------------------------------------------	----------	------------	-----	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------	--------------------------------------------------------------------------------------------------------------------------------------

					<ul style="list-style-type: none"> <li>- Drink consumption</li> <li>- Play games</li> <li>- Appointments with health professionals</li> </ul>			
CARE-30	Health professionals need to know who has authored information on the Adaptive Integrated Care Platform	Critical	gokce.banu	WP4	For all information on the Adaptive Integrated Care Platform that has been stored and is presented to health professionals, a clear authorship is identifiable by, e.g., first/last name and role of the author (TBD by clinicians what information is necessary).	In a multidisciplinary treatment approach, health professional from different medical disciplines will collect health data and work jointly on a patient's care plan. It might be necessary to, e.g., communicate about a certain treatment decision or incident, so it must be clearly identifiable who as authored which information on the Adaptive Integrated Care Platform.	Functional	
CARE-31	All results from patient's health data collected on H/HMP and PEP are presented to health professionals	Critical	gokce.banu	WP4	<p>All health data recorded by H/HMP and on PEP by patients are visualized to health professionals as authorized. Individual thresholds as defined on patient's care plan are indicated in the visualization.</p> <p>Confirmation of tasks either on the daily care plan or by reminders, e.g., medication intake shall also be visualized indicating by colouring or highlighting whether done or not. In case of medication intake this could be indicated by, e.g., colour green meaning 'taken' and red 'not taken'. Additional information provided by the patient, e.g., why a task could not be achieved is indicated at the according recording.</p>	In CAREPATH patients' health data are collected by the Health/Home Monitoring Platform (H/HMP), PROMs and other responses to the daily care plan are provided by patients on Patient Empowerment Platform (PEP). All these collected data shall be visualized to health professionals, so they can receive very quickly an overview of a patient's health status. To support this, individual thresholds as defined on a patient's care plan, e.g., steps walked should be at least 5000, blood pressure measurements should not exceed 150/90 will be indicated in the visualization, e.g., by a red line.	Functional	WP2 bi-weekly, interviews health professionals
CARE-32	Health professionals need to be supported in analysis and interpretation of results from patient's health data collected on H/HMP and PEP	Critical	theo.arvanitis	WP3	<p>It shall be possible to sort and filter a patient's health data according to type and time period, so visualizations can be directly compared as selected by health professionals, e.g. medication intake, blood pressure and blood sugar in the same time period.</p> <p>Besides such manual comparison, analysis of health data collected by H/HMP, on PEP by patients and may be from patient's EHR should be conducted by CAREPATH Decision Support Modules according to rules defined with help of clinical partners and outcome of interviews with health professionals.</p> <p>CAREPATH Decision Support Modules shall also point out to health professionals, if there is a significant change in patient's health data collected by H/HMP and on PEP. What is considered a 'significant' change may have to be defined individually in patient's care plan and/or rules defined with help of clinical partners.</p> <p>An explanation of how CAREPATH Decision Support Modules came to the conclusions as presented to health professionals shall be available on demand, e.g., by a flow chart.</p>	There will be a lot of health data collected by H/HMP and recorded by patients on PEP, therefore, health professionals need to be supported in analyzing and interpreting such data. For this purpose it needs to be possible to sort and filter health data according to type and time period, so it is possible to, e.g., compare medication intake with blood pressure measurements in a certain time period to check whether there is anything hinting at medication intake causing high blood pressure. Such manual evaluations can provide important information for improved treatment decisions, however, they are very time-consuming, important information might be overlooked and will therefore be supported by CAREPATH Decision Support Modules according to rules as defined with help of health professionals.	Functional	WP2/WP3 ideation workshops on Early Warnings, interviews with health professionals



CARE-33	Health professionals need to define which information from data collected on H/HMP and PEP shall be visualized to patients and/or informal caregivers	Critical	gokce.banu	WP4	Health professionals are able to select on the Adaptive Integrated Care Platform which patient data collected by the Health/Home Monitoring Platform and on PEP by patients should be presented/visualized to patients and/or informal caregivers. It should be possible to differentiate between both user groups since their information requirements and abilities are varying.	Feeling in control of the personal health status is very motivating for patients in adhering to a care plan and accepting the technical environment that provides such information. Patients may also feel safer which can have a positive impact on the patient's well-being, so the possibility to present such information on PEP should be used and evaluated in CAREPATH for the intended patient target group as a means of patient empowerment. Care needs to be taken though that the information is easy to understand and not overwhelming. In case a patient develops easily anxiety, e.g., if a result exceeds a personal threshold, then this needs to be taken into account as well. Thus, results visualized to patients on PEP need to be personalized according to patient's preferences and abilities. Same for informal caregivers who are often much interested in being able to receive information about the health status of the relative they care for.	Functional	Interviews with patients and informal caregivers
CARE-34	It needs to be possible for patients/informal caregivers to record symptoms and events	Critical	gokce.banu	WP4	Patients/informal caregivers are able to record per day, whether patients suffered from any remarkable symptoms, e.g., they felt dizzy or an important event happened, e.g., they fell. On the Adaptive Integrated Care Platform (AICP) such recordings shall be shown to medical docotors and be considerable by Clinical Decision Support Modules (CDSM) and Advanced Early Warning Smart Decision Tools for analysis.	Knowing about remarkable symptoms and events can serve as very valuable source of information for health professionals involved in the treatment and care of patients, e.g., in regard to appropriateness of medication prescriptions and potential worsening of a patient's health status. It will also support communication between patients and health professionals particularly in case the patient is living with MCI/mild dementia and therefore has problems with remembering if and when such instances happened.	Functional	Interviews with health professionals
CARE-35	Patients shall be able to record medication with same timing all at once	Critical	gokce.banu	WP4	Medication with identical intake time shall be presented together on patient's daily care plan. In such case it shall be possible to confirm medication intake altogether rather than one-by-one, e.g., by asking 'Have you taken all of your medications? Yes/No'. In case of 'No' the patient is able to select which one was not taken and provide information on what s/he has done differently, e.g., not taken at all or 1 pill instead of 2 pills, with the option to provide a rationale for that, e.g., stomach ache (see CARE-3).	Patients have to take in very often several medications at the same time. For usability reasons, it shall be possible then to document intake of all medications at once, instead of having to confirm each medication intake separately.	Functional	Experience from previous e-health projects, e.g., PICASO

CARE-36	Health professionals are able to recommend a suitable diet for patients	Critical	gokce.banu	WP4	<p>The assessment questionnaire MUST is available on the Alternative Integrated Care Platform (AICP) and on PEP, so it can be filled out by health professionals at the pilot sites and patients/informal caregivers themselves. In case it is filled out by patients/informal caregivers, results need to be made available for health professionals at the pilot sites.</p> <p>Depending on the results of the assessment and consideration of patient's comorbidities an individual diet profile is determined by AICP with suitable diet recommendations. This result is presented to health professionals to make it part of a patient's care plan. Health professionals shall define then, how often a task should appear on a patient's daily care plan prompting him/her to keep to their recommended diet. The MUST questionnaire, rules for consideration of patient's comorbidities and suitable diet recommendations following thereof are provided by medical doctors at the pilot sites.</p>	Offering patients diet recommendations that consider the patient's individual health situation is an important part in the treatment of multimorbid older patients with MCI/mild dementia. Therefore, an assessment procedure (MUST) in combination with consideration of a patient's comorbidities will be used in CAREPATH to determine a patient's individual diet profile and to suggest an according diet. The suggestions will include concrete recommendations on what kind of food the patient should eat and, if applicable, which ones to avoid.	Functional	WP2 bi-weekly
CARE-37	Patients and informal caregivers can preview a patient's daily care plan and other documented events	Critical	gokce.banu	WP4	<p>Patients and informal caregivers are able to preview tasks defined by themselves, informal caregivers and health professionals. A possible format could be a calendar. However, this preview shall include only selected types of tasks, e.g., not every medication intake but rather a medication intake that is foreseen only bi-weekly, appointments with health professionals or other upcoming events.</p>	<p>In order to receive overview and plan better adherence to defined (care) tasks, patients and informal caregivers should be able to preview upcoming tasks, particularly if they do not happen on a daily base.</p>	Functional	
CARE-38	Health professionals need to be able to create follow-up appointments for patients	Critical	gokce.banu	WP4	<p>On the Adaptive Integrated Care Platform (AICP) health professionals are able to define follow-up appointments as part of a patient's care plan. In the follow-up appointment it shall be defined with which type of health professional a patient should make an appointment(s) with, e.g., cardiologist or physiotherapist and optionally the name of the health professional. A time frame shall be defined until when the follow-up appointment shall be arranged. If agreed with the patient, a reminder can be defined which will fire a defined amount of time, e.g., 2 days before the time frame expires.</p> <p>Optionally, a message can be added explaining what kind of treatment the patient should ask for. In case the addressed health professional has also access to AICP a handover comment (what is the health professional expected to do, e.g., perform an MRI of right shoulder) can be included.</p> <p>If the follow-up appointment has been processed by the patient and/or informal caregiver, this will be indicated on the patient's care plan on AICP by 'Done' or the like with the date when processed.</p>	<p>Health professionals need to refer patients to other health professionals to follow-up on a certain condition, e.g., high blood pressure (cardiologist) or decline in mobility (physiotherapist). They should have an overview on whether follow-up appointment(s) have been taken care of or not.</p>	Functional	DoA, multidisciplinary care approach

CARE-39	Patients/informal caregivers need to be able to document appointments with health professionals and other events	Critical	gokce.banu	WP4	Patients/informal caregivers are offered a functionality that allows them to document appointments with health professionals, e.g., physiotherapist, GP and upcoming events, e.g., meeting with a friend or achieving activities of daily living. The functionality shall allow to document day and time of occurrence and will be presented as a task on patients' daily care plan. Optionally, patients are able to define if they would like to be reminded of a task the day before, e.g., an appointment with a health professional. The design of this functionality needs to be dementia-friendly, so in principle patients are able to use it independently (see CARE-11). This functionality shall be designed in close collaboration with pilot site partners and patients/informal caregivers who have indicated that they are willing to help with the design.	Multimorbid older patients with MCI/mild dementia will most likely see health professionals from different disciplines such as geriatricians, GPs, physiotherapists etc. and therefore have many appointments to keep track of which can become overwhelming. Therefore, being reminded of appointments was mentioned as helpful by patients and informal caregivers in the interviews. Same with other events such as meeting with a friend, calling son/daughter and coping with activities of daily living such as shopping, thinking about meals and preparation thereof. According to results of interviews, it is rather individual what patients would like to remind themselves about.	Functional	DoA, multidisciplinary care approach, interviews with patients and interviews with informal caregivers
CARE-40	Patients shall be able to confirm follow-up appointments	Critical	gokce.banu	WP4	Patients and/or informal caregivers are able to confirm follow-up appointments by selecting this task on their daily care plan. When confirmed, they are able to edit the date and time of the appointment and proceed as described in CARE-39.	In case patients are asked to arrange a follow-up appointment they need to be able to confirm it and enter the date and time when the appointment is scheduled.	Functional	Interviews with patients, interviews with informal caregivers
CARE-41	Health professionals need to be able to define additional instructions for patients on how to achieve a task properly	Critical	gokce.banu	WP4	Health professionals have the option to define additional instructions when defining tasks (care plan activities) for their patients. These instructions will be presented together with the task they belong to, e.g., a certain medication intake or a self-measurement (see examples in the rationale). Health professionals need to define the conditions under which an additional instruction shall be presented. They shall be supported in this task where possible with predefined options to choose from (e.g. present instruction always, once a week, only if systolic value exceeds value-X etc.).	When achieving a task, it can be crucial for patient's health to provide further instructions such as 'drink 1 glas of water' with this medication intake, take medication 'only on empty stomach'. In addition to that, in case health measurements taken by patients are out of expected range, this can be due to incorrect accomplishment of the task, e.g., higher blood pressure can be caused by physical activity before taking the measurement, so the patient should be instructed to 'sit 3-5 mins before taking blood pressure' to avoid anxiety on patient's side about a too high measurement result and ensure validity of data for further decisions.	Functional	WP2 bi-weekly
CARE-42	Patients are presented additional instructions as defined by health professionals	Critical	gokce.banu	WP4	Patients will be presented additional instructions as defined by health professionals on the Adaptive Integrated Care Platform (AICP) (see CARE-41).	In order to support patients in proper carrying out of the tasks on their daily care plans, additional instructions might be necessary, e.g., a certain medication should be taken only with a meal.	Functional	
CARE-43	Definitions of care plan activities shall be reusable	Major	gokce.banu	WP4	Health professionals are offered templates with prefilled prescriptions, e.g., standard medication prescriptions or treatments according to their clinical practice which they can easily take over in a patient's care plan and adjust where applicable to the patient's needs.	Many prescriptions and patient treatments are repetitive, e.g., medication prescriptions for certain diseases are almost the same for all patients affected by this disease. To ease the definition of a care plan, such definitions of care plan activities shall be reusable, e.g., provided in form of templates and adjustable to a patient's needs.	Non-Functional - > usability	
CARE-44	All applications for patients and informal caregivers are available in the pilot	Critical	gokce.banu	WP4	All applications for patients and informal caregivers are available in the national language of the pilot sites.	In CAREPATH pilots will be run in UK, Spain, Rumania and Germany. It is to ensure that all UIs presented to patients and informal caregivers are available in the	Non-Functional - > usability	

	sites' national language					national language of the pilot sites.		
CARE-45	Health professionals need to be informed in case of issues with medication prescriptions	Critical	theo.arvanitis	WP3	<p>In case a medication is prescribed on the Adaptive Integrated Care Platform, it will be evaluated for issues with polypharmacy and medication appropriateness on base of:</p> <ul style="list-style-type: none"> <li>- medication details provided in a suitable medication database</li> <li>- rules defined in consultation with clinical partners about issues with: <ul style="list-style-type: none"> <li>- intake by older people</li> <li>- certain geriatric syndromes</li> <li>- other relevant diseases (e.g. diabetes)</li> <li>- effects of phytopharmaceuticals and other supplements taken by the patient</li> </ul> </li> </ul> <p>Beyond this, if adverse effects are to anticipate with diets, e.g., a vitamin-K rich diet may interfere with intake of anticoagulants, a warning will be provided to health professionals to clarify such issues with the patient/informal caregiver.</p> <p>In case an issue is detected, all drugs in question shall be marked in, e.g., red. Detailed information is provided on the detected issues, e.g., drug-drug interaction between which drugs due to which substances, negative effects on other conditions, intrinsic capacity or geriatric syndromes. Where possible, a link(s) shall be provided to guidelines where the drug is recommended for treatment for further reading.</p>	The treatment of multimorbid older patients involves most often medical doctors from different medical disciplines who treat their patients according to stipulated guidelines. However, medication recommended to be prescribed for one condition may not be appropriate for another condition, e.g., may have adverse effects. This applies also to medicinal products that are sold in drug stores or over the counter, e.g., pain killers, vitamin supplements and phytopharmaceuticals (herbs) that are taken by patients without prescriptions. To avoid such conflicts, patients' medication plans shall be evaluated in CAREPATH for polypharmacy and medication appropriateness issues.	Functional	DoA, CAREPATH Essential information for clinical studies, interviews with health professionals, WP2/WP3 bi-weekly
CARE-46	Patients/informal caregivers shall be able to document intake of non-prescribed medication, phytopharmaceuticals and other supplements	Critical	gokce.banu	WP4	<p>Patients/informal caregivers can document medication, phytopharmaceuticals or other supplements they are taking, but have not been prescribed by medical doctors. They can document substance(s), company name, national drug-ID, when and how much they take in of a medication or supplement. The national drug-ID is available on every drug packaging - in Germany it is the 'PZN' number. Since it might not be known to all informal caregivers where to find the national drug-ID, an explanation should be available in written format as well as a picture of the nationally applicable drug-ID to support patients/informal caregivers in providing this information. However, this feature should be optionally, because they may not find it or it might not be available on all supplements they are taking.</p>	In order to improve their health condition patients tend to take phytopharmaceuticals (herbs) and other supplements as well as non-prescribed medication such as pain killers sold over the counter. However, such drugs or supplements may have adverse effects on medication prescribed by medical doctors, so they need to know about what patients are taking to deprescribe, if necessary, or make the patient/informal caregiver aware of such effects.	Functional	DoA, CAREPATH Essential information for clinical studies, interviews with health professionals, WP2/WP3 bi-weekly
CARE-47	Health professionals can review information provided by patients/informal caregivers on non-prescribed medications, phytopharmaceuticals and other supplements	Critical	gokce.banu	WP4	<p>Health professionals are able to review the information provided by patients/informal caregivers on non-prescribed medications, phytopharmaceuticals and other supplements taken by patients, correct it, if necessary, and check it off as part of a patient's medication plan to be shown on his/her daily care plan for documentation.</p>	Health professionals need to check the information provided by patients/informal caregivers about intake of non-prescribed drugs, phytopharmaceuticals (herbs) and other supplements to ensure that it is correct and can be adequately analyzed by CAREPATH Clinical Decision Support Modules.	Functional	DoA, CAREPATH Essential information for clinical studies, interviews with health professionals, WP2/WP3 bi-weekly

	taken by patients							
CARE-48	Patients are able to play a cognitively stimulating	Critical	Lionello.ferrazzini	WP4	A cognitively stimulating game is offered on PEP to play by patients optionally together with someone else. The game considers dementia-friendly design recommendations (see CARE-11). According to interviews with patients most of them play Sudoku alone or together with others in their leisure time. However, it shall be decided by clinical and developing partners together whether this would be a suitable game to be implemented in CAREPATH.	People living with dementia have often difficulties finding leisure time activities they enjoy and where the cognitive impairment does not pose an obstacle in carrying out the activity. Technology can compensate for some issues arising from cognitive impairments, such as forgetfulness and problems with attention focusing by considering dementia-friendly design recommendations. Besides this, joyful experiences with technology will foster acceptance of the technology environment employed for CAREPATH.	Functional	DoA, interviews with patients

## 9 References

- [1] Følstad, A. (2007). Group-based expert walkthrough, COST294-MAUSE, The 3rd International Workshop R3UEMS: Review, Report and Refine Usability Evaluation Methods, Athens, 5 March 2007, Pages: 58-60
- [2] Fricker, S.; Thümmler, C.; Gavras, A. (2015). Requirements Engineering for Digital Health. Springer, Heidelberg
- [3] ISO (2019) 9241-210:2019 Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems
- [4] Richter, J.G.; Chehab, G.; Schwartz, C.; Ricken, E.; Tomczak, M.; Acar, H.; Gappa, H.; Velasco, C.A.; Rosengren, P.; Povilionis, A.; Schneider, M.; Thestrup, J. (2021). The PICASO cloud platform for improved holistic care in rheumatoid arthritis treatment- experiences of patients and clinicians. *Arthritis Research & Therapy* 23 (2021), Art. 151, 13 pps. <http://dx.doi.org/10.1186/s13075-021-02526-7>
- [5] Robertson, S.; Robertson, J.R. (2012): Mastering the requirement process. Getting Requirements right. 3. Edition, Addison Wesley, London, ACM Press Books.
- [6] Rubin, J.; Chisnell, D. (2008): Handbook of Usability Testing: How to Plan, Design, and Conduct Effective Tests. John Wiley and Sons, Inc., Indianapolis, IN.



## 10 Document History

Date	Changes	Version	Authors
2021-09-07	Initial draft	1v0	Henrike Gappa
2021-09-28	Initial draft human-centred design approach, methodology user requirements elicitation	1v1	Henrike Gappa
2021-10-15	Initial draft methodology ideation workshops	1v2	Henrike Gappa
2021-12-02	Initial draft methodology interviews	1v3	Henrike Gappa, Yehya Mohamad, Pedro Abizanda Soler, Timothy Robbins, Wolfgang Schmidt-Barzynski, Antje Steinhoff, Cristiana Ciobanu, Oana Cramariuc, Gokce Banu Laleci Erturkmen, Theo Arvanitis, Jaouhar Ayadi, Angelo Consoli, Lionello Ferrazzini
2021-12-15	Finalization methodology user requirements elicitation	1v4	Henrike Gappa, Yehya Mohamad
2021-12-23	Finalization human-centred design approach, results from ideation workshops	1v5	Henrike Gappa, Yehya Mohamad, Carlos Velasco, Pedro Abizanda Soler, Timothy Robbins, Wolfgang Schmidt-Barzynski, Antje Steinhoff, Cristiana Ciobanu, Oana Cramariuc, Gokce Banu Laleci Erturkmen, Theo Arvanitis, Jaouhar Ayadi, Angelo Consoli, Lionello Ferrazzini
2022-01-03	Results from interviews	1v6	Henrike Gappa, Yehya Mohamad
2022-01-07	Results user requirements analysis	1v7	Henrike Gappa, Yehya Mohamad, Carlos Velasco
2022-01-10	Pre-final version to be submitted to the internal reviewers	1v8	Henrike Gappa, Yehya Mohamad, Carlos Velasco
2022-01-14	Final version to be submitted	1v9	Henrike Gappa, Yehya Mohamad, Carlos Velasco

- End of document -