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

CAREPATH

WP2: User Requirement Definition and Design of CAREPATH System Architecture

D2.4: Final holistic CAREPATH Architecture, System Specification and Collection of User Requirements

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Executive Summary

This deliverable comprises and updates deliverable D2.6. User requirements re-engineering that continued throughout the period after D2.6. Stakeholder walkthroughs of the CAREPATH prototypes were conducted by the consortium, especially the clinical partner. The periods of laboratory testing and TVU led to re-engineering of many components of CAREPATH. Additionally, brainstorming and discussion sessions in the bi-weekly joint meetings of WP02/WP04 with the entire consortium led to the new requirements and revisions of some other requirements.

User requirements specification has continued throughout the entire project duration and led to the final requirement list and the development of the final CAREPATH prototype. This final version of the deliverable D2.4 'Final holistic CAREPATH Architecture, System Specification and Collection of User Requirements' is being presented at the end of the project.

The new requirements were analysed on their influence on T2.1, T2.2 and T2.3. Special effort was spent to specify the impact on the functional specification of the new or updated requirements. All requirements were taken up by WP04 and elaborated further in this WP and finally implemented.

Deliverable D2.4 contains the translation of user requirements as well as technical requirements and the details of their implementation done in WP04.

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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
TVU	Technical Validation and Usability
CI	Clinical Investigation

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 the 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 1st, 2021 and will end on June the 30th, 2025.

1.2 Document scope

This deliverable is an update of D2.6 as it was planned in 'T2.1, T2.2 and T2.3 User requirements analysis' (M01-M46) to summarize all user requirements that have served as a viable base of prototype development in CAREPATH. Interviews with target user groups of the CAREPATH system were used as a method to collect user requirements and ideation workshops were conducted with health professionals and developers of the project consortium to gain a better understanding of useful clinical decision support features in the context of CAREPATH. The last results were reported in deliverable D2.6.
The newly elicited requirements were analysed upon their influence on the CAREPATH architecture developed in T2.2 and the system specification done in T2.3., subsequently accepted requirements were then implemented in WP4.
During laboratory tests and TVU new user requirements emerged, and existing ones needed refinement when evaluated by expert walkthroughs of the consortium. Therefore, user requirements collection was an ongoing process, so this document was considered a living document in its form as Jira requirement collection.
WP4 finally translated user requirements into technical requirements, implemented all re-engineered requirements and provided them to the end users of CAREPATH.

1.3 Document structure

The deliverable is organized as follows:

- Chapter 1 – provides, most importantly, information about the scope of deliverables.
- Chapter 2 – 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 3 – concludes with findings from the user requirements specification process.
- Appendix A – presents a list of user requirements defined so far.
- Appendix B – provides an example of a bi-weekly minutes.

2 Final user requirements specification and System Architecture

2.1 Methodology

As reported in D2.1, the CAREPATH project has implemented a human-centred development process in accordance with 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. An initial set of user requirements was defined primarily on base of findings from these sources, reported in D2.1 and D2.6. Many of the new requirements were elicited in WP2 walkthroughs and bi-weekly meetings others were identified in the process of WP5. These requirements identified in WP5 were handed over to WP2 to conduct the re-engineering process on them.

In WP2, we have continuously used mainly three instruments for the collaboration of the whole CAREPATH consortium in the elicitation or user requirements

1. Mailing list to distribute information among WP2 participants and to coordinate tasks and actions.
2. Microsoft Teams bi-weekly meetings, the results of these online meetings were protocolled in a Word file (See an example in Appendix B) and sent to the consortium via the mailing list, and the video recordings were uploaded to the project cloud space. In these meetings following an agreed agenda many actions were conducted:
    a. Discuss pending user requirements.
    b. Present mock-ups of CAREPATH prototypes.
    c. Brainstorm solutions for issues arising during the design and implementation in WP3 and WP4.
3. Cloud storage to share documents, where all protocols, video recordings and auxiliary files are stored and shared among the CAREPATH consortium.

Clinical partners were requested in all steps of the process to ask representatives of the target user groups about their opinions on suggested requirements. The requirements were finally documented in Jira only after they were agreed among the CAREPATH consortium especially the clinical partner, so the new requirements were entered in three periods. The first period was from January until March 2022 and the second period was from November 2022 until January 2023, the third period spans the time until writing this deliverable April 2025, where laboratory testing and TVU took place. Between these periods the requirements' engineering process was ongoing, so every requirement got an assignee that is responsible for its further maintenance and implementation.
All accepted requirements were handed over to T2.2 to evaluate their impact on the architecture and then to T2.3 to create a specification. The next step was to implement these requirements in the CAREPATH prototype mainly in WP4 and/or WP3.

2.2 Final System Architecture

The first version of the CAREPATH architecture was designed early in the project's lifetime, a detailed report was provided in deliverable D2.3. The architecture was split into six logical layers (See Figure 1): bottom up, the persistence layer, the knowledge layer, the service layer, the application layer, the security and privacy layer, and the presentation layer. Additionally, the architecture includes connectors to external systems, which are a crucial component of the design.

- The Persistence layer includes the database hard- and software based on SQL and non-SQL repositories.
- The Knowledge layer includes the subcomponents for organising the required data and knowledge. These subcomponents are domain knowledge, reports, history, guidelines/policies and Interoperability components to integrate external knowledge into CAREPATH.
- The Service layer includes all the core CAREPATH components: the Home Health Monitoring Platform (H/HMP), Advanced Early Warning Smart Decision Tools (AEWSDT), the Polypharmacy and Drug-Drug Interaction and the Physical Activity service.
- The Application layer includes all core CAREPATH applications: the Adaptive Integrated Care Plan Platform (AICP), the Patient Empowerment Platform (PEP), the Informal Caregiver Aid Platform (ICAP) and the Home/Health Monitoring Platform (H/HMP).
- The Security and Privacy layer is responsible for user authentication, management of users' rights according to their role(s) and data encryption for data exchange through external APIs. The authentication methods that can be used are included in it also.
- The presentation layer includes all the user interfaces needed for interaction with the services of CAREPATH. Its main component is the User Interface (UI) manager, which is responsible for the proper visualisation of the results in different devices (e.g. desktop PCs, laptops, mobile devices) and platforms in a unified manner. The user interfaces are designed as wireframes, and they are presented in the deliverable D2.5 "Specifications of all Components and Customisation Requirements".

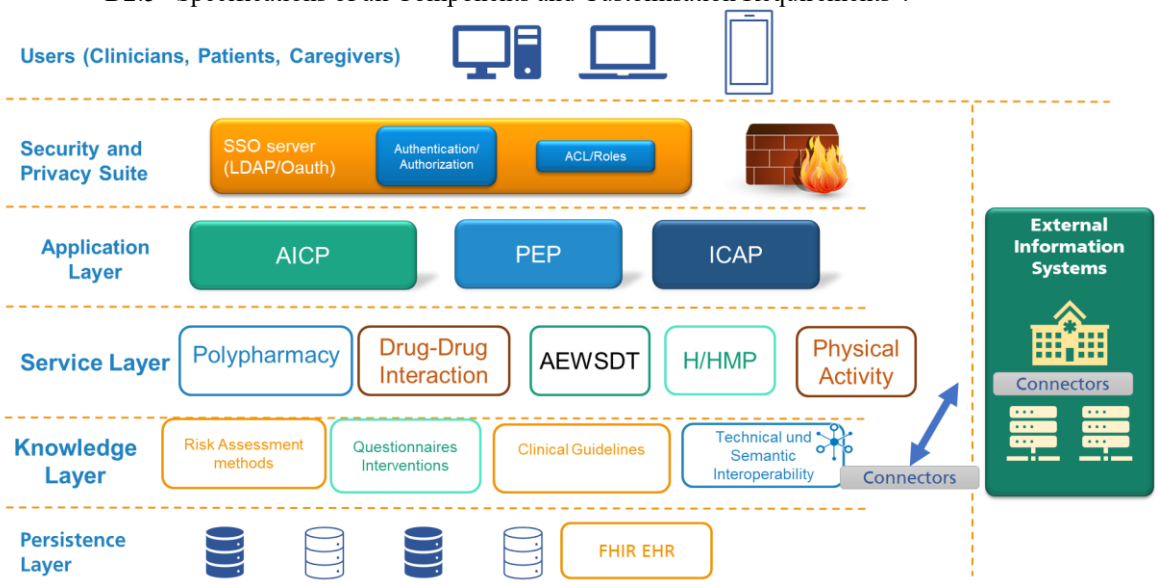

Figure 1: Final Architecture of CAREPATH

The CAREPATH architecture evolved throughout the project's lifetime, so e.g. the Physical Activity service was introduced in the Service layer that provides physicians with customized exercises that they can prescribe to patients in the AICP. A new application was designed in the Application Layer, the Informal Caregiver Aid Platform (ICAP), which provides informal caregivers with a separate application from the Patient Empowerment Platform (PEP).

2.3 User and Technical Requirements

The following table (See Table 1) presents a compilation of all user requirements that were gathered during the CAREPATH project.

Table 1 - User Requirements

User requirement ID	Summary	Updates of user requirements or newly defined ones

User requirement ID	Summary	Updates of user requirements or newly defined ones
CARE-1	Health professionals need to have access to a patient's health data.	
CARE-2	Patients need to be reminded of to-dos as defined in their care plan.	Reminders are configurable by health professionals and patient/informal caregivers, reminders can be dismissed, agreed escalation scheme.
CARE-3	Patients need to be able to confirm tasks to do.	- in case confirmation of a task is long overdue, a reminder is generated automatically. - system checks off automatically tasks that are achieved on the PEP platform where possible.
CARE-4	In CAREPATH personal data are processed according to GDPR as well as national/regional policies and legislations on data protection and security.	
CARE-5	User actions can be traced on the CAREPATH platform.	
CARE-6	For data integrity and security reasons, it is necessary to ensure that patient data cannot be interpreted while being transferred.	
CARE-7	The Health/Home Monitoring Platform shall employ minimally intrusive, dementia-friendly and safe devices and technologies.	
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.	
CARE-9	The Health/Home Monitoring Platform monitors proper data collection at patients' homes.	
CARE -10	Patients or informal caregivers should be able to create a ‚leave of absence' message during the clinical study.	
CARE-11	Applications used by patients with MCI/mild dementia shall be designed dementia friendly.	Content and functionalities on PEP to be presented to patients can be configured according to patients' needs and capabilities.
CARE-12	A daily care plan will be presented to patients in a dementia-friendly design.	Content and functionalities, e.g., reminders, on patients' daily care plans are presented as configured by health professionals and/or patients/informal caregivers.
CARE-13	Informal caregivers should have access to all PEP services.	PEP should be configurable according to informal caregivers' preferences and be accessible by various end devices, in particular mobile end devices
CARE-14	Results of health measurements and PROMs from H/HMP are presented to patients and informal caregivers.	Provide help on what results mean in regard to the patient's (health) status by visualization, e.g., arrow signs (arrow up – has improved, horizontal arrow - is stable, arrow down - has worsened.
CARE-15	Patients shall be supported in proper medication intake and documentation thereof.	
CARE-16	Patients shall be supported in conducting and recording exercises.	

User requirement ID	Summary	Updates of user requirements or newly defined ones
CARE-17	Patients shall be supported in filling out and recording PROMs.	
CARE-18	Patients shall be supported in adhering to diet recommendations.	
CARE-19	Informal caregivers are sent alerts in case a potentially harmful situation is detected by H/HMP.	
CARE-20	Sensors and devices used in the clinical trials shall be removeable without leaving a trace in patients' homes.	
CARE-21	Health professionals shall be pointed specifically to alerting risks of their patients (early warnings) and corrupted/lost data from H/HMP.	Classification schema for early warnings.
CARE-22	Patients shall be able to document their drink consumption.	
CARE-23	CAREPATH shall allow for easy communication between health professionals and patients/informal caregivers.	
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.	
CARE-25	Must be possible to search for misplaced sensors and devices.	
CARE-26	Medical doctors need to be provided all medical guidelines relevant for patients' morbidities enrolled in the CAREPATH clinical study.	Information needed for monitoring and treatment of multimorbid older patients, e.g., interaction of specific treatments
CARE-27	Health professionals need to be able to overrule system-generated suggestions, adjustments, decisions and the like.	
CARE-28	Health professionals need to be able to understand and review the rationale for system-generated suggestions, adjustments, and decisions.	
CARE-29	Health professionals need to be able to create a care plan.	Patients' health data from patients' EHRs at pilot sites needs to be taken over as much as possible to minimize double documentation efforts to the extent possible
CARE-30	Health professionals need to know who has authored information on the Adaptive Integrated Care Platform.	
CARE-31	All results from patient's health data collected on H/HMP and PEP are presented to health professionals.	Health professionals need to be able to adapt the thresholds of certain measured parameters to the individual health conditions of a certain patient.
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.	

User requirement ID	Summary	Updates of user requirements or newly defined ones
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.	
CARE-34	It needs to be possible for patients/informal caregivers to record symptoms and events.	- author of the recording must be clearly indicated on AICP. - voice recognition shall be considered with low priority, because not within the scope of the project.
CARE-35	Patients shall be able to record medication with same timing all at once.	
CARE-36	Health professionals are able to recommend a suitable diet for patients.	
CARE-37	Patients and informal caregivers can preview a patient's daily care plan and other documented events.	
CARE-38	Health professionals need to be able to create follow-up appointments for patients.	Aspect that appointment procedures/system differ among EU-countries, contact details of the health professional the appointment is with needs to be added.
CARE-39	Patients/informal caregivers need to be able to document appointments with health professionals and other events.	Aspect that appointment procedures/system differ among EU-countries, contact details need to be added.
CARE-40	Patients shall be able to confirm follow-up appointments.	
CARE-41	Health professionals need to be able to define additional instructions for patients on how to achieve a task properly.	Aspect that appointment procedures/system differ among EU-countries.
CARE-42	Patients are presented additional instructions as defined by health professionals.	
CARE-43	Definitions of care plan activities shall be reusable.	
CARE-44	All applications for patients and informal caregivers are available in the pilot sites' national language.	
CARE-45	Health professionals need to be informed in case of issues with medication prescriptions.	
CARE-46	Patients/informal caregivers shall be able to document intake of non-prescribed medication, phytopharmaceuticals and other supplements in text format. Health professionals should be able to convert them in structured data.	
CARE-47	Health professionals can review information provided by patients/informal caregivers on non-prescribed medications, phytopharmaceuticals and other supplements taken by patients.	

User requirement ID	Summary	Updates of user requirements or newly defined ones
CARE-48	Patients are able to play a cognitively stimulating games.	Consortium shall explore whether introducing gamification features such as challenges among patients and online gaming with, e.g., the informal caregiver poses a feasible and motivating option.
CARE-49	Migrating EHR Data into Patient Data Store as FHIR Resources.	
CARE-50	Storing patient data collected by Home/Health Monitoring Platform into Patient Data Store as FHIR Resources.	
CARE-51	Provide Smart watch API to push reminder notification to watch.	
CARE-52	H/HMP will detect a potentially harmful situation and write the corresponding notification to Patient Data Store as a FHIR Resource.	
CARE-53	Advanced Early Warning Decision Tools to detect and record alert notifications to Patient Data Store.	
CARE-54	H/HMP will store the drinking consumption activity detected by smart cup to Patient Data Store as FHIR resources.	
CARE-55	CAREPATH services need to be provided in the native language of health professionals.	
CARE-56	Information on the CAREPATH platform shall be presented for health professionals according to their personal profile.	
CARE-57	Patient/informal caregiver needs to be able to document unplanned appointments/visits with health professionals.	
CARE-58	Patients and their informal caregivers are made aware of changes in the care plan.	
CARE-59	Health professionals need to be aware of changes to the care plan and new examination results since last visit to the platform.	
CARE-60	Patients/informal caregivers shall be able to change or cancel appointments – new user requirement.	
CARE-61	Health professionals need to be supported with the risk assessment of their patients.	
CARE-62	Health professionals are supported in the adjustment of patients' personal goals.	
CARE-63	The look and feel of apps on PEP is the same.	The following are new user requirement of the last project period
CARE-64	Patients are enabled to easily navigate among apps on PEP.	
CARE-65	Patients and informal caregivers need to be provided a help functionality on PEP.	
CARE-66	Easy access to the CAREPATH tablet/PEP for patients and informal caregivers.	
CARE-67	Patients need to be able to take health measurements as defined on their daily care plan.	
CARE-68	Health professionals need to know about	

User requirement ID	Summary	Updates of user requirements or newly defined ones
	patients' gaming activities and results.	
CARE-69	Health professionals need to be able to document patients' drink consumption goals.	
CARE-70	Informal caregivers can create content for the gaming feature 'Slide show' in an easy way.	
CARE-71	Health professionals are able to recommend an appropriate exercise via Vivifrail program to patients.	
CARE-72	Medical doctors are able to evaluate medication plans of patients of the control group in regard to potential polypharmacy issues.	
CARE-73	Medical doctors will be reminded in case a patient's decree is missing.	
CARE-74	Patients need to be notified when health professionals make an update to their configuration.	
CARE-75	Patients/informal caregivers need to be able to see general dietary recommendations such as: • Oral health • Dental treatment • High-fibre meals	
CARE-76	Patients and informal caregivers need to be able to see the patient's number of steps goal if there is no exercise plan for that day.	
CARE-77	Admins need to be able to see and export the single ease questionnaire results of all patients.	
CARE-78	Patients need to report the usability of specific functionalities of the application using single ease questionnaires. These questionnaires should be prompted based on specific rules to avoid overwhelming patients, while ensuring good coverage of usability, e.g., • Displaying the SEQ on first use of a button, then a week later, and again a month later • Displaying a maximum of 3 questionnaires per day	
CARE-79	Healthcare professionals need to be able to see and update a patient's allergies.	
CARE-80	Patients, informal caregivers, and healthcare professionals need to be able to view project-related information, e.g., project name, sponsor, and legal representative.	
CARE-81	Patients shall be supported in playing memory games	
CARE-82	On the AICP dashboard, the diagrams from the H/HM data should allow for more	New user requirement from running TVU

User requirement ID	Summary	Updates of user requirements or newly defined ones
	granularity e.g. to see the sensor data aggregation for one day of blood pressure, steps counter, opening windows and doors etc.	

3 Final Implementation details (WP4)

Following the submission of Deliverables 4.4 (M15) and 4.5 (M27), eight new user requirements have emerged. In parallel, the technical requirements of the PEP and AICP have also been updated accordingly. These updates include new technical requests aligned with the latest user requirements, as well as additional ones inferred from previous user requirements. Thirteen new technical requests have been defined for PEP: 2 for Calendar (Appointment), 1 for Exercise, 1 for Diet, 2 for Symptom, 4 for Reminder, 1 for Contact, and 2 for Others. Additionally, seven new technical requests have been defined for AICP: 2 for the daily report, 1 for care plan management, and 4 for others.

During this period, the care plan update pages were also revised based on the feedback from healthcare professionals. This revision includes new panel requests, the addition of new items, and the removal of some unnecessary elements. Below is the list of updates to the care plan management pages:

- Physical Examination Page
  - Other Relevant Findings Panel is added.
- Lab Results Page
  - Glucose is added to the Lab Results panel.
- Geriatric Assessment Page
  - Dyslipidaemia, hypothyroidism, malignancy, peptic disease and sleep apnoea options are added to the High Prevalent Disabling Diseases panel.
  - Abuse, balance impairment, delirium, faecal incontinence, frailty, functional decline, immobility, sarcopenia, social isolation and urinary incontinence options are added to the High Prevalent Geriatric Syndromes panel.
  - Other Relevant Diseases panel is added.
  - An allergies panel is added with options: Beta-lactam allergy, metamizole allergy, NSAIDS allergy and other antibiotics allergy.
  - Questionnaires are grouped.
- MCI & Mild Dementia Management Page
  - Frontotemporal dementia, Lewy body disease, other dementia and vascular dementia options are added to the Existing Diagnosis from EHRs panel.
- Sarcopenia & Frailty Page
  - Gait speed is added to the Grip Tests and Gait Speed panel.
  - The possibility of severe sarcopenia and frailty stage options are added to the Diagnosis panel.
- Hypertension Treatment Page
  - The number of falls is removed from the Measurements & Hypertension Grade panel.
  - The sleep apnoea option is added to the Comorbidity panel.
  - Chest pain, headache, impaired vision and lower limb oedema options are added to the symptoms panel.
  - ‘Has the patient experienced a new fall since the last visit?’ option is added to the Assessments panel.
- Diabetes Diagnosis Page
  - Glucose is added to the Lab Tests panel.
  - Depression, dizziness, falls, hypoglycaemia, polyphagia, polyuria, thirst and urinary incontinence options are added to the Symptoms panel.
- Diabetes Treatment Page
  - Glucose is added to the Lab Tests panel.
  - Diabetic nephropathy and diabetic polyneuropathy options are added to the Additional Diabetes Complications panel.

- COPD Treatment Page
  - Interstitial lung disease and sleep apnoea options are added to the Comorbidity panel.
- CAD Management Page
  - Cerebrovascular disease, dyslipidaemia, peripheral artery disease and stroke options are added to the Comorbidity panel.
- HF Management Page
  - Ankle swelling, chest pain, lower limb oedema, nocturia and polyuria options are added to the Symptoms panel.
- Stroke Management Page
  - Cardiovascular disease, congestive heart failure, diabetes, dyslipidaemia, hypertension and peripheral artery disease options are added to the Comorbidity panel.
  - Atherothrombotic stroke, cardioembolic stroke, cerebral small vessel disease, haemorrhagic stroke, ischemic stroke, stroke and transient ischaemic attack options are added to the diagnosis panel.
- CKD Management Page
  - Dyslipidaemia and vitamin D deficiency options are added to the Comorbidity panel.
- Nutrition and Hydration Page
  - Physical Examination Parameters panel is added with weight, height and BMI values.
  - Dysphagia is added and malnutrition is removed from the Comorbidity panel.
  - Allergies Panel is added with options: Eggs, milk, mould, peach, peanut, pollen, pineapple, seafood, strawberry
  - Edentulism and teeth problems options are added to the Assessments panel.

3.1 PEP

3.1.1 Daily Care Plan

Table 2 - Technical requirements of daily care plan

Daily care plan			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-DCP-01	Patients should be presented daily activities (tasks) for medication intake, fill in PROMs, take weight measurements, perform exercise, adhere to diet, document drink consumption as defined in their care plan as well as perform custom tasks.	CARE - 2 CARE-12	Included
TR-PEP-DCP-02	If additional instructions have been provided by HP, they should be presented together with the task they belong to, e.g., ‘drink 1 glass of water’ with this medication intake, take medication ‘only on empty stomach’, ‘sit 3-5 mins before taking blood pressure’.	CARE-41 CARE-42	Included
TR-PEP-DCP-03	Tasks should be ordered according to time.	CARE-12	Included
TR-PEP-DCP-04	Tasks should be displayed with visual clues such as colour coding, distinctive icons etc.	CARE-12	Included
TR-PEP-DCP-05	It must be obvious which tasks are already done and which ones are open.	CARE-12	Included
TR-PEP-DCP-06	Step-by-step guidance should be provided to support users in achieving their tasks, if feasible support by prompting through sound and animation.	CARE-12	Included
TR-PEP-DCP-07	Patients shall be able to mark tasks as done any time they want.	CARE-2 CARE-3 CARE-15 CARE-16	Included

		CARE-18 CARE-22	
TR-PEP-DCP-08	In case a task is marked as done, patient should be presented a rewarding message feature.	CARE-3 CARE-15 CARE-16 CARE-17 CARE-22	Included
TR-PEP-DCP-09	A task should be flagged as "late" if it is not marked as done on time.	CARE-2	Included
TR-PEP-DCP-10	In case a task is not marked as done on time, patient shall be able to optionally indicate why not, e.g., select from a list with predefined rationales such as 'was sick', 'no time', 'was vomiting', 'stomach-ache', 'too tired', 'too much', 'developed symptoms', 'do not like it' etc.	CARE-3 CARE-15 CARE-16 CARE-17 CARE-18 CARE-35	Included
TR-PEP-DCP-11	In case all tasks are achieved, the patient is informed and appraised by a rewarding message/gamification feature.	CARE-12 CARE-15 CARE-16 CARE-17	Included
TR-PEP-DCP-12	Patients/informal caregivers should be linked directly from diet task to their selected diet plan .	CARE-18	Included
TR-PEP-DCP-13	Patients/informal caregivers should be able to indicate if the follow-up appointment has been processed.	CARE-38 CARE-40	Included
TR-PEP-DCP-14	Patients and informal caregivers should be alerted on changes made by HPs in the care plan, e.g., highlighted by an alert signal such as a red bell, so they become aware of the change.	CARE-58	Included
TR-PEP-DCP-15	The change in the care plan should be clearly presented, e.g., a change in medication dosage or a change in diet plan, so they understand clearly what the change is about and who has prescribed it, so they know whom to ask in case of question.	CARE-58	Included
TR-PEP-DCP-16	Safety controls should be implemented for some tasks such as medication, e.g., after pressing the YES button the patient should be asked if the medication was taken as prescribed.	Key scenario CITST (Reminders for task to-do)	Included
TR-PEP-DCP-17	If the task is not acknowledged or dismissed for a certain period of time, then the platform should inform the caregiver.	Key scenario CITST (Reminders for task to-do)	Included
TR-PEP-DCP-18	Informal caregivers should be able to write notes on tasks, e.g., pick up time for the appointment, transport plan for the appointment, who will accompany the patient.	Key scenario UHCW (Patient: View open appointments)	Included

3.1.2 Weekly Care Plan

Table 3 - Technical requirements of weekly care plan

Weekly care plan			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-WCP-01	Patients and informal caregivers should be able to preview upcoming tasks defined by patients, informal caregivers and health professionals, particularly if they do not happen on a daily base.	CARE-37	Included

TR-PEP-WCP-02	Patients and informal caregivers should be able to preview 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.	CARE-37	Excluded: Depending on how many tasks there will be at the end, it might become too much information.

3.1.3 Calendar (Appointments)

Table 4 - Technical requirements of calendar (appointments)

Calendar (Appointments)			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-CAL-01	A calendar view should be provided by PEP.	Key scenario CITST (Patient: Confirming to-dos) & UHCW (Patient: View open appointments)	Included
TR-PEP-CAL-02	The calendar should coordinate with both Apple and Android calendar functionalities.	Key scenario UHCW (Patient: View open appointments)	Excluded: The system already sends notifications beforehand. Integrating tasks with Android calendar might be confusing.
TR-PEP-CAL-03	The view of the calendar should be modifiable such that it shows the current day or a week or a full month.	Key scenario CITST (Patient: Confirming to-dos) & UHCW (Patient: View open appointments)	Included
TR-PEPM-CAL-04	Upon selection of a day on calendar, the task list should be presented to the user including task description and time.	Key scenario CITST (Patient: Confirming to-dos)	Included
TR-PEP-CAL-05	The calendar should show which appointments are upcoming, what condition they are for, who they are with, when they are and where they are.	Key scenario UHCW (Patient: View open appointments)	Included
TR-PEP-CAL-06	The calendar should show the number to call if there is a need to change or cancel the appointment.	Key scenario UHCW (Patient: View open appointments)	Excluded
TR-PEP-CAL-08	Patient should be able to see any notes sent from the informal to the patient and the informal caregiver should be able to see that they have been read.	Key scenario UHCW (Patient: View open appointments)	Included
TR-PEP-CAL-09	In case patient/informal caregiver must arrange the appointment by themselves, they should be able to see and schedule their unscheduled appointments created by HPs.	CARE-40	Included
TR-PEP-CAL-10	In case patient/informal caregiver must arrange the appointment by themselves, they should be notified in the home page of the application when there is an	CARE-40	Included

	unscheduled appointment created by HPs.		

3.1.4 Medications

Table 5 - Technical requirements of medications

Medications			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-MED-01	Patients should be presented clearly when (time) what medication (e.g., brand name/picture) and how much (dosage) shall be taken.	CARE-15 CARE-35	Included
TR-PEP-MED-02	Patients should be pointed to a device (e.g., pill box) in case s/he is using for management of medication intake.	CARE-15	Included
TR-PEP-MED-03	Patients should be able to document in case s/he has changed the dosage or the input time.	CARE-15	Included
TR-PEP-MED-04	Patients should be able to record the dosage and input time for medications that they are advised to take only as needed.	CARE-15	Partially included: In case patient took the medication different than prescription, she/he can indicate this as a comment.
TR-PEP-MED-05	Patients should be able to confirm medication intake altogether rather than one-by-one, e.g., by asking 'Have you taken all of your medications? Yes/No'.	CARE-35	Included
TR-PEP-MED-06	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.	CARE-35	Included
TR-PEP-MED-07	Patients and informal caregivers should be able to document non-prescribed medication such as pain killers sold over the counter, phytopharmaceuticals (herbs) or other supplements they are taking, but have not been prescribed by medical doctors. They should be able document substance(s), company name, national drug-ID, when and how much they take in of a medication or supplement.	CARE-46 Issue Tracker-115	Partially Included: This is something too complex for our target patient group. A free text area is filled by HPs and displayed on PEP.
TR-PEP-MED-08	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 national drug-ID information (because it might not be known to all informal caregivers where to find the national drug-ID).	CARE-46	Excluded: This is something too complex for our target patient group.
TR-PEP-MED-09	Patients and informal caregivers should be able to take notes even if a medication task is checked as completed, e.g., I or Carmen felt dizzy after taking this medication, so she decided not to take it anymore at the following days.	Key scenario SKB (Patient: View health measurements and self-recordings)	Included

3.1.5 Exercises

Table 6 - Technical requirements of exercises

Exercises			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-EXE-01	Exercises should be presented with poster or video in accordance to how it is defined on AICP.	CARE-16	Included
TR-PEP-EXE-02	For the days patient is not asked to do exercise, he/she should see his/her number of steps goal in exercise screen.	CARE-65	Included

3.1.6 PROMs

Table 7 - Technical requirements of PROMs

PROMs			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-PRM-01	Results of PROMs reported by patients should be presented to patients and informal caregivers.	CARE-14	Excluded: It has been decided not to display PROMs to patients.
TR-PEP-PRM-02	Patients and informal caregivers shall be able to select a time period from which they want to be presented all available PROM results as configured for them.	CARE-14	
TR-PEP-PRM-03	Wording of the PROMs should be dementia-friendly and understandable for patients.	CARE-17	
TR-PEP-PRM-04	It should be possible to complete PROMs in several turns, so the current state should always be stored, and the patient is guided to where responses are still missing.	CARE-17	
TR-PEP-PRM-05	When possible, PROM-specific guidelines should be applied to deal with missing parts, because patients might not answer all questions for various reasons (do not know, loose concentration, feel overburdened etc.), and consider PROM as completed despite of missing parts.	CARE-17	

3.1.7 Diet & Drink Consumption

Table 8 - Technical requirements of diet and drink consumption

Diet & Drink consumption			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-DIE-01	Patients/Informal caregivers should be able to document the drink consumption per day.	CARE-22	Included but can be excluded in the future. Some of the clinicians think that it is not necessary.
TR-PEP-DIE-02	A daily goal of drink consumption should be presented on patient's daily care plan.	CARE-22	Included
TR-PEP-DIE-03	Drink consumption should appear in the task list, e.g., drink a glass of water, and patient should be able to indicate whether it is done	Key scenario CITST (Patient: Confirming to-dos)	Excluded: Follow-up of drink consumption is not that much needed.
TR-PEP-	Patients and informal caregivers should be able to fill	CARE-36	Included

DIE-04	out the assessment questionnaire MUST.		
TR-PEP-DIE-05	Patients/Informal caregivers should be able to see general dietary recommendations.	CARE-64	Included

3.1.8 Custom Tasks

Table 9 - Technical requirements of custom tasks

Custom tasks			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-CT-01	Patients and informal caregivers shall be able to create custom tasks with date and time information, e.g., meeting with a friend or achieving activities of daily living.	CARE-2 CARE-39	Included
TR-PEP-CT-02	Patients and informal caregivers shall be able to document appointments that have not been set by HP as custom task.	CARE-39 CARE-57	Included
TR-PEP-CT-03	Patients should be able to be reminded of a task the day before, e.g., an appointment with a health professional.	CARE-39	Included: Better to remind an hour ago instead of a day before.
TR-PEP-CT-04	PEP should provide a predefined list of categories for custom tasks, e.g., meeting with a friend, calling son/daughter and coping with activities of daily living such as shopping, thinking about meals and preparation thereof.	CARE-39	Included

3.1.9 Symptoms & Events

Table 10 - Technical requirements of symptoms and events

Symptoms & events			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-SYM-01	Patients and informal caregivers should be able to record per day, whether patients suffered from any remarkable symptoms, e.g., they felt dizzy, started to notice less appetite, or an important event happened, e.g., I fell on the stairs today, I slipped in the bathroom. The source of this information (patient or informal caregiver) should also be recorded.	CARE-34 Feedback SKB	Included
TR-PEP-SYM-02	Patients and informal caregivers should be able to record symptoms and events by selecting from a list, e.g., detection of fall, motion etc.	Key scenario SESCAM (Document symptoms)	Included
TR-PEP-SYM-03	Patients and informal caregivers should be able to record symptoms and events in free text areas as well, e.g., “Carmen tripped over the carpet/slipped on the wet floor in the bathroom. I found her lying on the floor and had to help her to get up. She would not have managed by her own. She has several bruises at her right arm and at the forehead. She had to take a longer rest afterwards.” Or “Carmen is moving unstable after she fell in the bathroom. Carmen gets slower and	Key scenario SESCAM (Document symptoms) & SKB (Patient: View health measurements and self-recordings)	Included

	unstable in motion. She needs to hold on to the furniture while walking".		
TR-PEP-SYM-04	Patients should be able to record an audio message if they want.	Key scenario SESCAM (Document symptoms)	Excluded: Too detailed for our target patient group.
TR-PEP-SYM-05	Patients and informal caregivers should be reminded to document symptoms and be able to record them on the home page of the application without needing to open the symptoms page.	CARE-34	Included
TR-PEP-SYM-06	Patients and informal caregivers should be able to see past symptoms on a monthly calendar for a comprehensive overview.	CARE-34 Issue Tracker 373	Included

3.1.10 Reminders & Push Notifications

Table 11 - Technical requirements of reminders and push notifications

Reminders & Push notifications			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-REM-01	Patients should receive push notifications on daily activities.	CARE-2	Included
TR-PEP-REM-02	Informal caregivers shall be able to configure that they do not receive reminders & push notifications in case they don't wish so.	CARE-2	Included
TR-PEP-REM-03	Push notifications shall be presented on patients' smartwatch with multimodal stimuli (e.g., tactile, auditory, visual) as well.	CARE-2	Included
TR-PEP-REM-04	Patients shall be able to configure push notification output preference (via tablet, smartwatch, or both etc.).	CARE-2	Included
TR-PEP-REM-05	A reminder shall disappear from reminder list when the corresponding task is mark as done by the patient.	CARE-2	Included
TR-PEP-REM-06	A reminder shall disappear from reminder list after the task is overdue, even if it is not marked as done by the patient.	CARE-2	Included
TR-PEP-REM-07	Reminders should present clearly what the patient is expected to do, i.e., ensure that patients take the right medication in the prescribed dosage.	CARE-2	Included
TR-PEP-REM-08	Patients shall be able to mark tasks as done by clicking on a reminder. When clicked, a pop-up shall appear and ask patient to confirm by either "Yes" or "No" whether the task was done or not. e.g., Reminder - please do not forget to take your medication Ramipril with the option to confirm medication intake or dismiss the reminder. In case the patient confirms, s/he is asked as in the usual confirmation procedure in a pop-up, e.g., 'Have you taken your medication as prescribed? Yes/No etc. which the patient can follow-up on.	CARE-3	Included
TR-PEP-REM-09	In case "Yes" is clicked on confirmation pop-up, patient should be presented a rewarding message feature.	CARE-3	Included
TR-PEP-REM-10	In case "No" is clicked on confirmation pop-up, patient shall be able to optionally indicate why not, e.g., select from a list with predefined rationales such as 'was sick', 'no time' etc.	CARE-3	Included
TR-PEP-REM-11	Alerts should be sent to informal caregivers (according to their preferred device) in case a potentially harmful situation has been detected by H/HMP.	CARE-19	Included
TR-PEP-REM-12	Unless patient presses one of the YES or NO buttons on the screen, the reminders should keep coming every 15 minutes or so.	Key scenario CITST (Patient: Confirming to-dos)	Excluded: This can be annoying for patient. A single reminder for a task would be sufficient.
TR-PEP-REM-13	A reminder should be sent to patients at the end of the day to fill in something about how their day went or how they felt: How did you feel today? Is there	Key scenario SESCAM (Document	To be discussed: If the decision is to keep it, it will be

	anything important you want to tell us?	symptoms)	implemented after the initial prototype.
TR-PEP-REM-14	A reminder should be sent to patients when a change is made on his/her care plan, e.g., an appointment for a blood test, an appointment with a dietician, change in meal plan.	Key scenario SESCAM (Follow-up on a diet plan)	Included
TR-PEP-REM-15	A reminder should be logged as "viewed" when patient reads it.	Key scenario SESCAM (Follow-up on a diet plan)	Included
TR-PEP-REM-16	The alerting level should gradually increase if the reminder is not acknowledged by patient.	Key scenario CITST (Reminders for task to-do)	Excluded: This can be annoying for patient. A single reminder for a task would be sufficient.
TR-PEP-REM-17	Informal caregivers should be able to configure whether to retrieve alerts in case a potentially harmful situation has been detected by H/HMP.	CARE-19	Included
TR-PEP-REM-18	Informal caregivers should be able to select device(s) that s/he prefer to receive alerts.	CARE-19	Included
TR-PEP-REM-19	A reminder should be sent to patients when a change is made to his/her user configuration, e.g., updating the measurement types visible to the patient.	CARE-63 Issue Tracker 325	Included
TR-PEP-REM-20	A reminder should be sent to patients if they have not provided feedback on their exercise plan for a week.	CARE-16	Included
TR-PEP-REM-21	A reminder should be sent to patients if they have not provided feedback on their diet for a week.	CARE-18	Included
TR-PEP-REM-22	A reminder should be sent to patients if they have not played memory games for a week.	CARE-70	Included

3.1.11 H/HMP data

Table 12 - Technical requirements of H/HMP data

H/HMP data			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-HMP-01	Results of home/health measurements should be presented to patients and informal caregivers if selected by healthcare professionals.	CARE-14	Included
TR-PEP-HMP-02	Individual thresholds and beyond threshold values (if defined by healthcare professionals) shall be displayed to patients and informal caregivers.	CARE-14	Included
TR-PEP-HMP-03	Patients and informal caregivers shall be able to select a time period from which they want to be presented all available recordings as configured for them.	CARE-14	Included
TR-PEP-HMP-04	Charts can also be provided.		Included

3.1.12 Leave of Absence

Table 13 - Technical requirements of leave of absence

Leave of absence			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-LOA-01	Patients or informal caregivers shall be able to indicate "leave of absence" by a message (i.e., on vacation) indicating the period of time they will not be able to use the CAREPATH applications.	CARE-10	Included
TR-PEP-LOA-02	In case patients 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.	CARE-10	Included

3.1.13 Contact

Table 14 - Technical requirements of contact

Contact			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-CON-01	PEP should provide a contact menu for enabling patients and informal caregivers to communicate with HPs.	CARE-23	Included
TR-PEP-CON-02	Contact details of responsible HPs such as name(s), phone number(s) should be presented in a dementia-friendly design.	CARE-23	Included
TR-PEP-CON-03	Patients and informal caregivers should be able to send messages directly to their care team on the Contact page.	CARE-23	Included

3.1.14 Patient Dashboard

Table 15 - Technical requirements of patient dashboard

Patient dashboard			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-PD-01	The status of the patient shall be presented in a patient dashboard to the informal caregiver.	CARE-2	Included

3.1.15 Memory Games

Table 16 - Technical requirements of memory games

Memory games			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-MG-01	Patients have the possibility to play cognitively stimulating games.	CARE-48 CARE-11	Included
TR-PEP-MG-02	The games can be played by patients optionally together with someone else.	CARE-48 CARE-11	Excluded: multiplayer game option is under study

3.1.16 Other

Table 17 - Technical requirements of other components

Other			
ID	Requirement Description	Corresponding User Req.	Status
TR-PEP-OTH-01	There should be an About page that displays project-related information, e.g., project name, sponsor, legal representative.	CARE-69	Included
TR-PEP-OTH-02	Patients should be prompted with single ease questionnaires that collect information about the usability of the application's functionalities. The prompting should follow specific rules, e.g., • Displaying the SEQ on first use of a button, then a week later, and again a month later • Displaying a maximum of 3 questionnaires per day	CARE-67	Included

3.2 AICP

3.2.1 Care Team Management

Table 18 - Technical requirements of care team management

Care team management		
ID	Requirement Description	Corresponding User Req.
TR-AICP-CTM-01	The system shall enable several groups of health professionals to be involved in the care and treatment of multimorbid patients with MCI/mild dementia. This will be referred as “Care team”.	CARE-1
TR-AICP-CTM-02	All care team members should be granted access to a patient’s health data according to their role.	CARE-1
TR-AICP-CTM-03	All care team members should be allowed to add/change information in a patient’s health record as authorized.	CARE-1
TR-AICP-CTM-04	Nurses should be able to record blood pressure and weight information in anamnesis.	Key scenario SKB (Doctors appointment)
TR-AICP-CTM-05	Nurses should be able to check if the results of all lab tests requested from patient are stored in CAREPATH platform.	Key scenario SKB (Doctors appointment)
TR-AICP-CTM-06	In case a member is removed from the care team, he/she should be notified in AICP.	Feedback of SKB in D4.6

3.2.2 Home Page

Table 19 - Technical requirements of home page

Home page		
ID	Requirement Description	Corresponding User Req.
TR-AICP-HOM-01	HPs should see a list of early warnings of all the patients he/she is responsible for. This would enable a doctor to have a quick overview over all alerts form all patients without having to go through all the care plans of the patients the doctor is responsible.	Feedback SKB in D4.6
TR-AICP-HOM-02	The system shall provide an overview of all patients who have a recent early warning so that HP can take care the early warning alerts easily (Connected to TR-AICP-PL-02).	Feedback SKB
TR-AICP-HOM-03	A warning message should be shown to HPs on top of the screen when AICP is opened if out-of-range values have been detected by H/HMP with a link to the platform where she can look at these findings.	Key scenario Fraunhofer
TR-AICP-HOM-04	HPs should be able to see upcoming appointments (in a calendar view if possible).	Biweekly WP4 meetings
TR-AICP-HOM-05	HPs should be reminded advance directives every three months.	3rd GA in Bielefeld

3.2.3 Patient List

Table 20 - Technical requirements of patient list

Patient list		
ID	Requirement Description	Corresponding User Req.
TR-AICP-PL-01	The system should present the patients in alphabetical order according to the last name.	Key scenario Fraunhofer
TR-AICP-PL-02	The system shall provide an overview of all patients who have a recent early warning so that HP can take care the early warning alerts easily (Connected to TR-AICP-HOM-02).	Feedback SKB
TR-AICP-PL-03	HPs should be able to select by date which (of all) patients are coming on which day. This function can be provided in a calendar view.	Feedback SKB in D4.6
TR-AICP-PL-04	The system shall provide a filter functionality, such that: • Prioritize the patients who have an early warning message that the HP has not reacted to yet. Highlight these patients with an icon or something similar. • Show me the patients having an appointment today. • Show me all the patients. These filters can be selected on top through radio buttons.	Biweekly WP4 meetings

3.2.4 Patient summary dashboard

Table 21 - Technical requirements of patient summary dashboard

Patient summary dashboard		
ID	Requirement Description	Corresponding User Req.
TR-AICP-PSD-01	HPs should be able to see if a patient or informal caregiver has sent a "leave of absence" message indicating the period he/she will be away.	CARE-10
TR-AICP-PSD-02	HPs should be able to customize information presentation on the Patient summary dashboard according to their personal preferences, e.g., types of patient health data they want to be presented first from H/HMP measurement results and default values for the period they want to see data about as collected by H/HMP and PEP. Another example is for dieticians it might be most relevant to see a patient's weight curve, for geriatricians this might be blood pressure measurement results.	CARE-56
TR-AICP-PSD-03	HPs need to be aware of changes to the care plan and new examination results since last visit to the platform (Connected to TR-AICP-CP-21).	CARE-59
TR-AICP-PSD-04	Patient summary box should include the most important things which are age, weight, dementia profile, and functional impairment profile (Height is not important).	2nd GA in Milano
TR-AICP-PSD-05	Patient summary box should include the items listed in TR-AICP-PSD-07 as the default view. It should be customizable so that other items can also be added.	2nd GA in Milano
TR-AICP-PSD-06	Patient dashboard will be completely customizable. Therefore, there should be a separate customization screen for HPs to define their patient dashboard view.	Biweekly WP4 meetings
TR-AICP-PSD-07	A patient summary box can be fixed at top, containing single values like age, weight, height, systolic BP, diastolic BP, glucose etc., and also some fixed parameters such as "leave of absence" status, existence of unread/not acted early warning messages, disease status of patient (has diabetes, has COPD etc. among the list of chronic diseases that CAREPATH covers), link to patient notes.	Biweekly WP4 meetings

TR-AICP-PSD-08	The rest of the screen will be customizable as well. In here, following information can be presented:
	• Medical history of patient from EHR
	  ○ Conditions
	  ○ Medications
	  ○ Lab results
	  ○ Vital signs
	• Patient provided data
	  ○ Symptoms & events
	  ○ Health measurements
		Biweekly WP4 meetings

3.2.5 Notifications Sent to Healthcare Professionals

Table 22 - Technical requirements of notifications sent to healthcare professionals

Notifications sent to healthcare professionals		
ID	Requirement Description	Corresponding User Req.
TR-AICP-NOT-01	In case reminder configuration of patient/informal caregiver on daily tasks is changed, a message will be sent to the clinical team indicating that there was a change and what has been changed, so they can decide whether they need to react on it.	CARE-2
TR-AICP-NOT-02	In case a configuration was changed on PEP, a message shall be sent to the clinical team to decide whether they need to react on it.	CARE-11 CARE-13
TR-AICP-NOT-03	HPs shall be informed when an Early warning message is triggered.	CARE-21

3.2.6 Patient-provided Data (Health measurement, Symptoms & events, Patient comments & feedback)

Table 23 - Technical requirements of patient provided data

Patient provided data		
ID	Requirement Description	Corresponding User Req.
TR-AICP-PPD-01	HPs should be able to display data recorded by patient in PEP.	CARE-31
TR-AICP-PPD-02	The measurements which are above the threshold value defined by the HP should be highlighted, e.g., by a red line.	CARE-31
TR-AICP-PPD-03	HPs should be able to sort and filter a patient's 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.	CARE-32
TR-AICP-PPD-04	The findings of CAREPATH Decision Support Modules, e.g., a significant change in patient's health data collected by H/HMP and on PEP, should be displayed to HPs.	CARE-32
TR-AICP-PPD-05	HPs should be able to display the symptoms (e.g., they felt dizzy) and events (e.g., they fell) recorded by patient or informal caregivers per day.	CARE-34
TR-AICP-PPD-06	HPs should be able to see whether the patient or the informal caregiver is the author of the symptom/event recording.	CARE-34
TR-AICP-PPD-07	Charts should be provided when possible.	Feedback SKB in D4.6
TR-AICP-PPD-08	The data and comments provided by the patient should be displayed according to the selected time, e.g., since the last doctor´s appointment.	Feedback SKB in D4.6
TR-AICP-PPD-09	HPs should be able to select a period to display the results.	Biweekly WP4 meetings
TR-AICP-PPD-10	HPs should be able to define threshold values for patient provided data.	CARE-14
TR-AICP-PPD-11	If a threshold is set, it will be shown with the observation value. If observation is displayed in a chart, threshold value will be a separate line.	Biweekly WP4 meetings

TR-AICP-PPD-12	Medication intake of patient should be displayed near patient's measurements so that HPs can analyse them in the same page.	Feedback of SKB after analysing the system

3.2.7 H/HMP Data

Table 24 - Technical requirements of H/HMP data

H/HMP data dashboard		
ID	Requirement Description	Corresponding User Req.
TR-AICP-HMP-01	HPs should be able to display data retrieved from H/HMP in a dashboard.	CARE-31
TR-AICP-HMP-02	HPs should be able to define threshold values for measurements in H/HMP.	CARE-14
TR-AICP-HMP-03	HPs should be able to configure which H/HMP data will be shown to patients and informal caregivers (Connected to TR-AICP-CON-02).	CARE-14 CARE-33
TR-AICP-HMP-04	HPs should be able to configure 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 (Connected to TR-AICP-CON-04).	CARE-14
TR-AICP-HMP-05	Charts can also be provided. Threshold values should be indicated with a line on charts as well.	Key scenario Fraunhofer
TR-AICP-HMP-06	A visualization of how results are to interpret should be provided, e.g., different arrow signs indicating the status of the patient in regard to a specific result (arrow up – has improved, horizontal arrow - is stable, arrow down - has worsened).	CARE-14

3.2.8 Early Warnings

Table 25 - Technical requirements of early warnings

Early warnings		
ID	Requirement Description	Corresponding User Req.
TR-AICP-EW-01	Early warnings should include a link to the patient's health record.	CARE-21
TR-AICP-EW-02	HPs should be provided why an early warning was triggered, e.g., in form of a flow chart.	CARE-21
TR-AICP-EW-03	HPs should be able to mark the early warning as "Have seen" or "Evaluated" (so that HPs can indicate that they took an action for it, e.g., changed the care plan) and system should be able store the details of HP (e.g., name and surname) who marked the early warning.	CARE-21
TR-AICP-EW-04	HPs should be able to take notes about the early warning.	CARE-21 Feedback SKB
TR-AICP-EW-05	Early warnings should also include the abnormalities in the data stream coming from patients' home.	CARE-21
TR-AICP-EW-06	HPs should be able to classify early warnings as life threatening, severe, not severe, false alarm.	Feedback SKB CARE-21
TR-AICP-EW-07	HPs should be able to adjust threshold parameters (early warnings and H/HMP data are correlated, (See TR-AICP-HMP-02).	Feedback SKB
TR-AICP-EW-08	HPs should be able to give feedback to the alert on AICP:	Feedback SKB in

	a. It has been taken care of: action of doctor is documented b. The task is delegated to another person in health care team and this feedback is collected also on AICP c. The alert was false/low risk/medium risk/high risk, i.e., adverse event d. outcome: e.g., patient needed to be admitted to hospital because of heart attack	D4.6
TR-AICP-EW-09	No need to implement a mechanism to take action on early warnings. Taking notes on them is enough.	2nd GA in Milano
TR-AICP-EW-10	HPs should be able to display summary of early warnings since the last visit (e.g., 2 early warnings about BP, 3 related with a device etc.).	2nd GA in Milano
TR-AICP-EW-11	Early warnings that have been read should be hidden in the main list, but HPs should be able to make them visible via a filter.	2nd GA in Milano
TR-AICP-EW-12	HPs should be able to filter the early warnings by (i) its type, e.g., displaying only early warnings related to increase of room temperature, (ii) by its status, e.g., showing early warnings that have not been evaluated or read yet, and (iii) by its priority.	Feedback of SKB after analysing the system
TR-AICP-EW-13	HPs should be able to edit the priority of early warnings.	Biweekly WP4 meetings
TR-AICP-EW-14	The system should store information on who read the early warning and HPs should be able to display it.	Feedback of SKB after analysing the system
TR-AICP-EW-15	When the link to patient's health record that caused the triggering of early warning message is clicked, the system should display the measurements 3 days before and after the date of the health record.	Feedback of SKB after analysing the system

3.2.9 Daily report

Table 26 - Technical requirements of daily report

Daily report		
ID	Requirement Description	Corresponding User Req.
TR-AICP-DR-01	HPs should be presented a daily report on patients' status.	CARE-21
TR-AICP-DR-02	Daily report should include the early warnings with "Alert 1" priority and early warnings related to abnormalities.	CARE-21
TR-AICP-DR-03	HPs should be able to configure when and how often the daily reports should be generated.	CARE-21
TR-AICP-DR-04	It should be possible to generate a daily report on demand.	CARE-21
TR-AICP-DR-05	Patient's daily task adherence as well as symptoms reported should be presented to HPs.	Feedback of SKB after analysing the system
TR-AICP-DR-06	HPs should be provided filters to show only a specific type of task, e.g., medication intake, health measurements, custom tasks etc.	Feedback of SKB after analysing the system
TR-AICP-DR-07	HPs should be informed if patient has not provided any feedback on daily tasks in the last three days.	Feedback of SKB after analysing the system
TR-AICP-DR-08	Daily report should include the symptoms reported by the patient.	Feedback of SKB after analysing the

		system
TR-AICP-DR-09	HPs should be provided filters to show only a specific task, e.g., take your medications before the breakfast, measure your blood pressure at 4:00 PM.	Feedback retrieved in wp4 meetings
TR-AICP-DR-10	HPs should have a comprehensive view that shows the days patient took all of their medications and the days they missed at least one.	Feedback retrieved in wp4 meetings

3.2.10 Care Plan Management

Table 27 - Technical requirements of care plan management

Care plan		
ID	Requirement Description	Corresponding User Req.
TR-AICP-CP-01	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.	CARE-22
TR-AICP-CP-02	HPs should be able to overrule or adjust system-generated suggestions, adjustments or any other decisions.	CARE-27
TR-AICP-CP-03	System-generated suggestions or any other adjustments should be clearly indicated for HPs, e.g., by highlighting text labels etc.	CARE-27
TR-AICP-CP-04	Rationales behind system-generated suggestions, adjustments or decisions should be presented to HPs.	CARE-28
TR-AICP-CP-05	HPs should be able to provide feedback in case a suggestion is inappropriate.	CARE-28
TR-AICP-CP-06	HPs from different health disciplines should be able to create a care plan jointly.	CARE-29
TR-AICP-CP-07	HPs should be allowed to create a care plan items that they are authorized. For instance, physiotherapists will not be authorized to prescribe medication, only medical doctors who may thereby even overrule medication prescriptions by another medical doctor.	CARE-29
TR-AICP-CP-08	HPs should be able to see who authored which part/information of a care plan.	Feedback of Fraunhofer after analysing the system
TR-AICP-CP-09	HPs should be able to directly access a certain part of the care plan, e.g., BP, Lifestyle management.	Feedback of Fraunhofer after analysing the system
TR-AICP-CP-10	Care plan can contain following task types: - Medication intake (Section 2.1.12) - Taking vital sign parameters that cannot be collected automatically by H/HMP, e.g., blood pressure, weight, blood sugar - Fill out PROMs (Section 2.1.14) - Exercise regularly (Section 2.1.13) - Consider diet recommendations (Section 2.1.15) - Document appetite - Drink consumption - Play games - Appointments with health professionals (Section 2.1.16)	CARE-29
TR-AICP-CP-11	HPs should be able to define timing of a task: - From when to when shall a task be active (e.g., from 2021-	CARE-29

	12-07 until 2022-02-04, it could also end 'never') - How often repeated (e.g., every day; on specific days: Monday, Wednesday, Friday; every 2 weeks) - 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')	
TR-AICP-CP-12	HPs should be able define "as needed" tasks, e.g., on-demand medication.	CARE-29
TR-AICP-CP-13	HPs should be able to define reminders for tasks.	CARE-29
TR-AICP-CP-14	HPs should be able to define personalized reminder messages for patients.	CARE-29
TR-AICP-CP-15	HPs should be able to configure whether informal caregiver should have access to patient's care plan	CARE-29
TR-AICP-CP-16	HPs should be able to define threshold values for specific measurements/parameters of patients.	CARE-31
TR-AICP-CP-17	HPs should be able to define follow-up appointments as part of a patient's care plan. (See Appointments section).	CARE-38
TR-AICP-CP-18	HPs should have the option to define additional instructions when defining tasks (care plan activities) for their patients, e.g., 'drink 1 glass of water' with this medication intake, take medication 'only on empty stomach', 'sit 3-5 mins before taking blood pressure'.	CARE-41
TR-AICP-CP-19	HPs need to be aware of changes to the care plan and new examination results since last visit to the platform. (Connected to TR-AICP-PSD-06)	CARE-59
TR-AICP-CP-20	HPs should be enabled to write a message about care plan change which will then be displayed to patients in PEP	3rd GA in Bielefeld
TR-AICP-CP-21	HPs should be able to display and update patient's allergies.	CARE-68

3.2.11 Medication Management

Table 28 - Technical requirements of medication management

Medication management		
ID	Requirement Description	Corresponding User Req.
TR-AICP-MED-01	HPs should be able to schedule medication intake for patients.	CARE-15
TR-AICP-MED-02	HPs should be able to configure the approach of presenting medication intake, i.e., either a simplified or more elaborate version. The simplified version will be for patients who are using a pill box. The elaborate version of medication intake is intended for patients who can manage their medication intake independently, so are familiar with, e.g., the name of a drug.	CARE-15
TR-AICP-MED-03	HPs should be able to advise patient to take a medication only as needed.	CARE-15
TR-AICP-MED-05	Intake of non-pharmacological medication shall also be part of the patient's care plan to judge better on medication appropriateness, side-effects etc.	CARE-15
TR-AICP-MED-06	HPs shall be 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.	CARE-43

TR-AICP-MED-07	When a medication is prescribed, it should be evaluated for issues with polypharmacy and medication appropriateness.	CARE-45
TR-AICP-MED-08	HPs should be warned if adverse effects are to anticipate with diets.	CARE-45
TR-AICP-MED-09	In case an issue is detected, all drugs in question should be marked in, e.g., red. Detailed information should be 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.	CARE-45

3.2.12 Exercise Management

Table 29 - Technical requirements of exercise management

Exercises		
ID	Requirement Description	Corresponding User Req.
TR-AICP-EXE-01	HPs should be able to create exercise plan for patients.	CARE-16
TR-AICP-EXE-02	Exercise plan should be precise, i.e., HPs should define which exercise will be performed which day instead of saying 3 times a week.	CARE-16
TR-AICP-EXE-03	Exercise plan should be fetched automatically from VIVIFRAIL service.	Consortium decision during the meetings
TR-AICP-EXE-04	HPs should be able to define exercises that should not be given to patient.	3rd GA in Bielefeld
TR-AICP-EXE-05	Exercises should be performed by patients one day apart.	3rd GA in Bielefeld
TR-AICP-EXE-06	For the days patient is not asked to do exercise, he/she should be asked to walk 10000 steps.	3rd GA in Bielefeld

3.2.13 Diet Planning

Table 30 - Technical requirements of diet planning

Diet planning		
ID	Requirement Description	Corresponding User Req.
TR-AICP-DIE-01	HPs should be able to fill out the assessment questionnaire MUST for patients.	CARE-36
TR-AICP-DIE-02	In case MUST questionnaire is filled by patients or informal caregivers; results should be displayed to HPs.	CARE-36
TR-AICP-DIE-03	Depending on the results of the questionnaire assessment and consideration of patient's comorbidities, AICP should determine individual diet profile and recommend a suitable diet plan.	CARE-36
TR-AICP-DIE-04	HPs should be able to define how often a task should appear on a patient's daily care plan prompting him/her to keep to their recommended diet.	CARE-36

3.2.14 Appointments & Referrals

Table 31 - Technical requirements of appointments & referrals

Appointments & Referrals		
ID	Requirement Description	Corresponding User Req.
TR-AICP-APP-01	HPs should be able to define follow-up appointments as part of a patient's care plan.	CARE-38
TR-AICP-APP-02	HPs should be able to define with which type of health professional a patient should make a follow-up appointment(s), e.g., cardiologist or physiotherapist, for which condition an appointment is for, and optionally the name of the health professional.	CARE-38 Key scenario Fraunhofer
TR-AICP-APP-03	In case patient/informal caregiver must arrange the appointment by themselves, HPs should be able to define a time frame until when the follow-up appointment shall be arranged.	CARE-38
TR-AICP-APP-04	In case patient/informal caregiver must arrange the appointment by themselves, HPs should be able to set a reminder which will fire a defined amount of time, e.g., 1 days before the time frame expires.	CARE-38
TR-AICP-APP-05	HPs should be able to add a message explaining what kind of treatment the patient should ask for in the external appointment (referral).	CARE-38 Key scenario Fraunhofer
TR-AICP-APP-06	HPs should be able to provide a handover comment to other HP in the internal appointment (referral) where HP has access to AICP (e.g., (what is the health professional expected to do, e.g., perform an MRI of right shoulder).	CARE-38
TR-AICP-APP-07	HPs should be able to display all the appointments of patient in a calendar, what condition they are for, who they are with, when they are and where they are; so that s/he can arrange new appointments without clashing with others and by taking into account the travelling time.	Key scenario CITST (Patient: Confirming to-dos)
TR-AICP-APP-08	Changes or cancellations of appointments by patients/informal caregivers shall be presented to health professionals.	CARE-60

3.2.15 Care Plan Adherence Screen

Table 32 - Technical requirements of care plan adherence

Care plan adherence		
ID	Requirement Description	Corresponding User Req.
TR-AICP-CPA-01	HPs should be able to display confirmation of tasks by patient on daily care plan.	CARE-31
TR-AICP-CPA-02	HPs should be able to see the information provided by the patient in case a task has not been completed.	CARE-31
TR-AICP-CPA-03	HPs should be able to display the statistics daily, weekly, monthly, since the creation time of the care plan, or in a specific period time.	3rd GA in Bielefeld
TR-AICP-CPA-04	The system should remember the selected time period when opening care plan adherence screen next time as well as when opening other pages like daily report or home data.	Feedback of SKB after analysing the system
TR-AICP-CPA-05	HPs should be able to display the adherence of previous care plan as well.	Feedback of SKB after analysing the system

3.2.16 Goals

Table 33 - Technical requirements of goals

Goals		
ID	Requirement Description	Corresponding User Req.
TR-AICP-GOL-01	Health professionals shall see current personal goals at each consultation for review.	CARE-62
TR-AICP-GOL-02	HPs shall be able to review a patient's "compliance" against each goal and either make no change, change the goal or delete the goal.	CARE-62
TR-AICP-GOL-03	The system should show other potentially relevant goals for a patients' underlying medical condition, which can be added.	CARE-62
TR-AICP-GOL-04	HPs can prioritise goals that are most important to focus on.	CARE-62

3.2.17 Reminder & Push notification management

Table 34 - Technical requirements of reminder & push notification management

Reminders & Push notification management		
ID	Requirement Description	Corresponding User Req.
TR-AICP-REM-01	HPs shall be able to configure the daily activities (tasks) that patient and/or informal caregiver receives reminders (push notifications).	CARE-2 CARE-22
TR-AICP-REM-02	HPs shall be able to define personalized reminder messages for the patients, i.e., patients take the right medication in the prescribed dosage.	CARE-2
TR-AICP-REM-03	HPs should be able to define reminders for tasks by indicating: - For whom (only for patients, only for informal caregivers or for both) - Timing of reminders such that 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	CARE-29

	task, e.g., for timely medication intake	
TR-AICP-REM-04	HPs should be able to define personalized reminder messages for task reminders.	CARE-29
TR-AICP-REM-05	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 …')	CARE-29
TR-AICP-REM-06	Templates should be provided for different use cases.	CARE-29
TR-AICP-REM-07	Reminders should follow an escalation protocol.	CARE-29

3.2.18 Notes

Table 35 - Technical requirements of notes

Notes		
ID	Requirement Description	Corresponding User Req.
TR-AICP-CON-01	HPs should be able to display all communications with patients and informal caregivers.	CARE-24
TR-AICP-CON-02	The communications should be directly accessible by patient name.	CARE-24
TR-AICP-CON-03	Filtering options should be provided (TBD by pilot sites).	CARE-24
TR-AICP-CON-04	HPs should be able to document phone conversations made by patients and informal caregivers.	CARE-24

3.2.19 Configuration Management for Patients

Table 36 - Technical requirements of configuration management for patients

Configuration management for patients		
ID	Requirement Description	Corresponding User Req.
TR-AICP-CON-01	Functionalities and content of PEP shall be configurable to the needs and capabilities of patients; hence, HPs should be able to see the same configuration (settings) page present in PEP and edit it.	CARE-11
TR-AICP-CON-02	HPs shall be able to configure which type of H/HMP measurements will be presented to patients/informal caregivers (Connected to TR-AICP-HMP-03).	CARE-14 CARE-33
TR-AICP-CON-03	It should be possible to define 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.	CARE-14
TR-AICP-CON-04	HPs should be able to configure 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 (Connected to TR-AICP-HMP-04).	CARE-14
TR-AICP-CON-05	HPs shall be able to configure the timing of reminders that are sent before a daily task. (Patients can also configure this on PEP).	CARE-29

3.2.20 Risk Assessment

Table 37 - Technical requirements of risk assessment

Risk assessment		
ID	Requirement Description	Corresponding User Req.
TR-AICP-RIS-01	HPs should be presented a list of applicable individual risks on first consultation of a patient. On this list they can select as to whether which risks are valid and grade the severity of the risks. Health professionals can review risks on subsequent consultations as to whether there are new risks to add or whether the level of the risk has changed. Recommendations are provided based on those risks and these can be accepted or rejected.	CARE-61

3.2.21 Others

Table 38 – Other technical requirements

Others		
ID	Requirement Description	Corresponding User Req.
TR-AICP-OTH-01	HPs should be provided all nationally relevant medical guidelines for patients with MCI/mild dementia and co-morbidities addressed in CAREPATH, e.g., diabetes, heart failure, as well as the CAREPATH best practice guideline to be developed in the project.	CARE-26
TR-AICP-OTH-02	For all information on the AICP that has been stored and is presented to HPs, a clear authorship should be identifiable by, e.g., first/last name and role of the author.	CARE-30
TR-AICP-OTH-03	HPs should be able to configure a personal profile where they can define, e.g., types of patient health data they want to be presented first from H/HMP measurement results and default values for the period they want to see data about as collected by H/HMP and PEP.	CARE-56
TR-AICP-OTH-04	Information on the CAREPATH platform shall be presented for HPs according to their personal profile, e.g., for dieticians it might be most relevant to see a patient's weight curve, for geriatricians this might be blood pressure measurement results.	CARE-56
TR-AICP-OTH-05	All the content shall be available in the national language of the pilot sites.	CARE-44 CARE-55
TR-AICP-OTH-06	When the health measurements that are part of daily care plan are retrieved and saved to FHIR repository, then its corresponding Observation to mark the task as complete should be generated automatically.	CARE-3
TR-AICP-OTH-07	List of tasks (daily activities) shall be generated from care plan.	CARE-2 CARE-29
TR-AICP-OTH-08	Intrinsic capacity of patients shall be presented to clinicians in every 2 months.	Biweekly WP4 meetings
TR-AICP-OTH-09	Educational materials and lab tests shall be covered in AICP.	Biweekly WP4 meetings
TR-AICP-OTH-10	Automatic input of lab results shall be possible.	Feedback SKB in D4.6
TR-AICP-OTH-11	There should be automatic alerts for values out of range.	Feedback SKB in D4.6
TR-AICP-OTH-12	There should be a specific page for displaying polypharmacy recommendations of control group.	3rd GA in Bielefeld
TR-AICP-OTH-13	HPs should be able to generate a QR code for patients to use when	3rd GA in Bielefeld

	logging in to PEP.	
TR-AICP-OTH-14	There should be a specific page for displaying single ease questionnaire results of all patients.	CARE-66
TR-AICP-OTH-15	It should be possible to export the single ease questionnaire results of the patients.	CARE-66
TR-AICP-OTH-16	There should be an "About" page that displays project-related information, e.g., project name, sponsor, legal representative.	CARE-69 Issue Tracker 144
TR-AICP-OTH-17	It should be possible to export polypharmacy recommendations of control group patients.	Feedback retrieved in WP4-WP2 meetings

4 Lessons learned

The user requirements engineering process for the CAREPATH project has provided several critical insights that will enhance future integrated healthcare projects involving diverse user groups such as clinicians, patients, informal caregivers, and administrators. Below are the key lessons learned:

1. **Stakeholder Engagement is Crucial**: Engaging all user groups early and continuously throughout the requirements engineering process ensured that diverse perspectives were considered. Regular workshops and feedback sessions facilitated a better understanding of each group's needs and concerns.
2. **Understanding User Needs**: Conducting thorough interviews and surveys with clinicians, patients, caregivers, and administrators revealed unique requirements that were not initially anticipated. This highlighted the importance of empathy and active listening in capturing the real-life experiences and challenges faced by each user group.
3. **Iterative Approach**: Implementing an iterative approach to requirements gathering allowed for adjustments based on user feedback. Prototyping and testing concepts with real users helped refine functionalities, ensuring that the final solution is user-friendly and meets the practical needs of the stakeholders.
4. **Focus on Personalization**: The necessity for personalized care plans emerged as a key requirement. Understanding that multimorbid older patients with MCI or mild dementia have varying needs emphasized the importance of flexibility in the proposed ICT solution.
5. **Interdisciplinary Collaboration**: Involving professionals from various disciplines (e.g., healthcare, IT, economics) enriched the requirements engineering process. This collaboration fostered innovative ideas and solutions that addressed the multifaceted nature of patient care.
6. **Communication and Clarity**: Ensuring clear communication among all stakeholders was vital. Developing a shared vocabulary and clear documentation helped mitigate misunderstandings and aligned expectations across diverse user groups.
7. **Regulatory and Ethical Considerations**: Navigating the regulatory landscape and addressing ethical concerns regarding patient data privacy and security were essential. Engaging legal and ethical experts early in the process helped guide the project in compliance with relevant regulations.
8. **Evaluation of Impact**: Establishing metrics for evaluating the impact of the proposed solutions on patient outcomes and quality of life is critical. Planning for post-implementation assessment should be part of the initial requirements to ensure continuous improvement.

These lessons learned will guide future projects in optimizing integrated healthcare solutions, ensuring they are responsive to the needs of all stakeholders involved in patient care.

5 Conclusions

This deliverable is an update of D2.1, D2.2, D2.3, D2.5 and D2.6 as a continuation of the user requirement engineering process of the CAREPATH project. The process involved steps described in T2.1, T2.2 and T2.3. Identified user requirements were submitted to the implementation work packages WP3 and WP4.

PEP and AICP development continued after the deliverable submissions and they have been updated based on discussions from WP4 & WP2 meetings, feature requests on the Issue Tracker, and feedback from healthcare professionals. This included the implementation of new features, as well as updating the current screens. The user and technical requirements for both PEP and AICP have been updated accordingly.

6 Document History

Date	Changes	Version	Authors
2024-12-14	Initial draft	1v0	Yehya Mohamad
2025-01-22	Initial draft update D2.4	1v2	Yehya Mohamad
2025-02-28	WP4 related updates	1v3	A. Emre Akpınar
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2025-04-28	Final version for submission	1v5	Yehya Mohamad
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- End of document -