C3-Cloud

"A Federated Collaborative Care Cure Cloud Architecture for Addressing the Needs of Multi-morbidity and Managing Poly-pharmacy"

PRIORITY Objective H2020-PHC-25-2015 - Advanced ICT systems and services for integrated care

D9.2 Quantitative and qualitative evaluation criteria for C3-Cloud Pilot Application

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Abbreviations and Acronyms	
ADE	Adverse Drug Event
ASSIST	Cost-benefit evaluation tool
BC	Basque Country (pilot site)
C3DP	Coordinated Care and Cure Delivery Platform
DoA	Description of Action
eCCIS	eCare Client Impact Survey
eCUIS	eCare User Impact Survey
HCIL	Human-Computer Interaction Lab
MDT	Multi-Disciplinary Team
MRC	Medical Research Council
PAR	Pilot Application Requirement
PCPDP	Personalized Care Plan Development Platform
PEP	Patient Empowerment Platform
Predictive modelling	Budget-Impact-Analysis tool based on discrete event simulation
QUIS7	Seventh edition
RJH	Region Jämtland Härjedalen (pilot site)
SO	Specific C3-Cloud Objective
SPSS	Statistics software package for statistical data analysis
SQuaRE	Software product Quality Requirements and Evaluation
SWFT	South Warwickshire Foundation Trust (pilot site)
UTAUT	Unified Theory of Acceptance and Use of Technology
PDCA	Plan-Do-Check-Act

Table 1: List of abbreviations and acronyms

EXECUTIVE SUMMARY

This deliverable “D9.2 – Quantitative and Qualitative evaluation criteria” is the scientific protocol for the C3-Cloud project and specifies the evaluation criteria for the C3-Cloud pilot application (a piloting trial of the software in three European Countries).

The protocol presents descriptions of planning and the relevant steps for carrying out the evaluation as described in the Description of Action for Work Package 9, tasks T9.1, T9.2, T9.3 and T9.5. It embeds the evaluation in its scientific background, and explains its objectives, study participant sampling methodology, data collection, data management and statistics. Chapter 1 gives an introduction and the study rationale, including the research question. Chapter 2 gives details on the study design, the setting, its duration and the timeline for the data collection and evaluation. Chapter 3 elaborates on the different evaluation layers 1 to 4, the measures of data collection and the involvement of patients, multi-disciplinary team members and C3-Cloud partners. Chapters 4 and 5 specify the sampling and randomization of the piloting trial participants. Details on the statistical methods and data analysis are given in chapter 6. Chapter 8 includes all the questionnaires as Annex.

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1. Introduction and study rational

1.1. Purpose of the task as described in Description of Action

This deliverable presents the planned qualitative and quantitative evaluation criteria presented for the evaluation of the C3-Cloud project. This deliverable was written within the scope of T9.1, while the procedures described will be performed in T9.2 (Component Testing and Usability Studies), T9.3 (Pilot Application Evaluation) and T9.5 (Modelling Large-Scale Impact).

The information has been developed in English and will support the pilot sites with their national ethics applications for the technology trial. Appropriate translations into Spanish and Swedish will be completed by the pilot sites, where necessary.

This deliverable will feed into a central ethics application document that is currently being developed in Task 1.4 and overseen by the C3-Cloud Ethics Committee for the local ethics applications at the three pilot sites).

1.2. Aims of the C3-Cloud System / Rationale

The over-arching societal challenge addressed by C3-Cloud is: "How can we effectively care for and support elderly patients with multi-morbidity needs?" and several challenges have been identified for the provision of integrated care to elderly patients with multi-morbid chronic conditions, described below.

Challenge 1: Traditionally, the adoption of clinical practice guidelines has been promoted to managing chronic conditions. However, clinical practice guidelines are currently single disease centred, and often fall short to organise care for patients with multi-morbidity.
Challenge 2: Poly-pharmacy induced by multi-morbidity itself is an important factor that leads to a significant cost in the health system affecting patients, as well as institutions/healthcare organisations.
Challenge 3: Managing multi-morbidity, through the current treatment methods, results in speciality silos and fragmented care, involving multiple health and social care providers who are not effectively communicating and sharing information.
Challenge 4: Patients and their informal caregivers including family members often do not have a voice in the management of their own care.
Challenge 5: Existing organisational models and care pathways are inadequate for integrated care delivery to the multi-morbid elderly.
Challenge 6: Currently, there exists evidence base, biased towards patients with single diseases, which limits the potential to develop the next-generation of multi-disease care pathways.

In essence, there is an increasing need to organise the care around the patient and not the disease, taking into account his or her multiple physical and psycho-social conditions. An integrated, patient-centred care and cure delivery architecture need to be developed considering the realities of multi-morbidity and poly-pharmacy. This needs to take into account the medical, technological, organisational and socio-economical challenges of creating a collaboration environment for all of the stakeholders involved in the holistic continuum of care.

Consequently and in an approach to tackle the above challenges, C3-Cloud developed the following objectives (see also Figure 1):

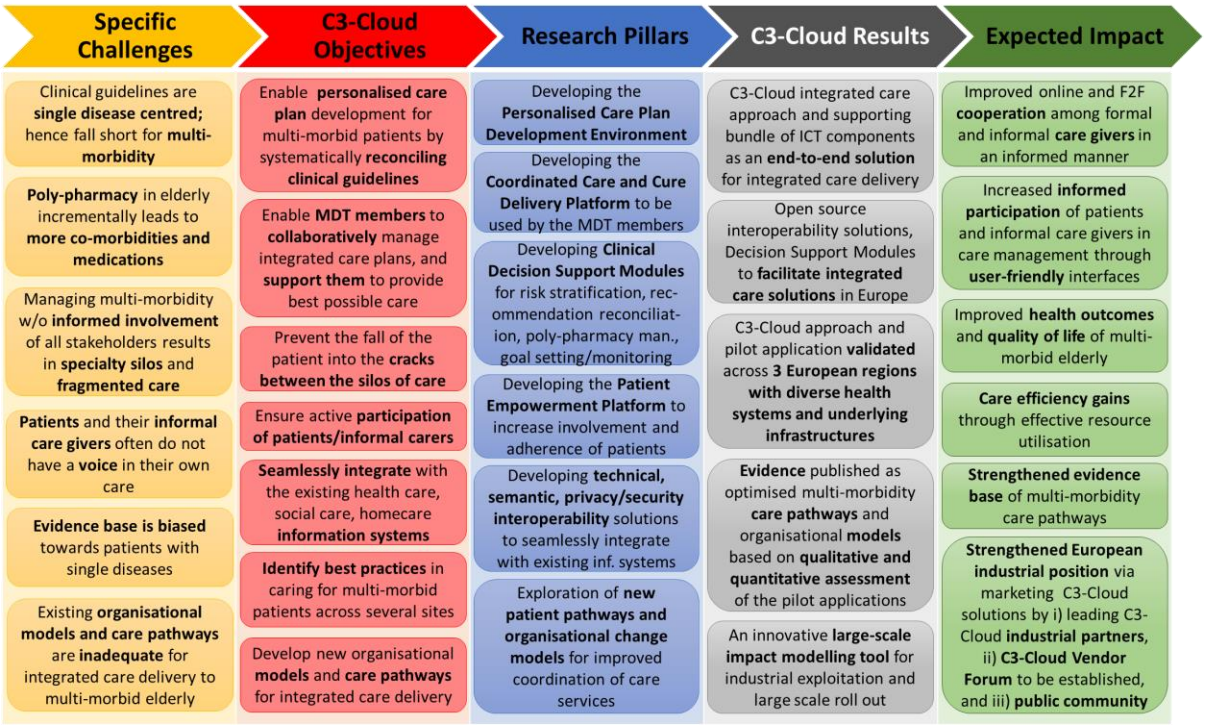

Figure 1: From Specific Challenges to the Expected Impacts of the C3-Cloud Project

Objective 1: Enable the development of personalised care plans for multi-morbid conditions through systematic and semi-automatic reconciliation of digitally represented clinical guidelines for individual chronic conditions, by a group of collaborating health and social caregivers, and with the informed participation of the patients and their informal caregivers.

Objective 2: The C3-Cloud project aims to provide an innovative online platform through which multi-disciplinary team (MDT) members can collaboratively manage (execute, monitor and update when necessary) the integrated personalised care plans for patients with multi-morbid conditions.

Objective 3: The C3-Cloud project will provide several Clinical Decision Support Modules to support personalised care plan development and collaborative management of care plan execution.

Objective 4: the C3-Cloud project will ensure the active participation of patients and their informal caregivers to the management of their multi-morbid chronic conditions through a Patient Empowerment Platform to alleviate the non-adherence problem.

Objective 5: the C3-Cloud project will provide an Interoperability Middleware addressing technical, semantic and privacy/security interoperability challenges to seamlessly integrate with the existing health care, social care and home/community care information systems for enabling patient-centric interoperable care coordination in an informed manner with the involvement of all stakeholders.

Objective 6: the C3-Cloud project will demonstrate the applicability of its integrated care approach and supporting set of innovative ICT components in varying clinical, technological and organisational settings by piloting in three European regions with quite different health and social care systems and ICT landscapes.

Objective 7: the C3-Cloud project will use the C3-Cloud system, populated with data from its pilot sites, to examine the interactions between clinical guidelines for different conditions, in order to help identify best practices in caring for patients with multiple conditions, by aligning the elements of the respective clinical guidelines.

Objective 8: the C3-Cloud project will develop, experiment and refine new adaptive models of integrated and person-centred care and organisational change management guidelines, in order to achieve the design and implementation of integrated care supported with ICT in diverse settings.

Based on the C3-Cloud objectives, a number of expected impacts of the C3-Cloud application are anticipated, some of which will be quantitatively and qualitatively evaluated, including:

- Improved online and face-to-face cooperation within and among formal and informal caregivers and the patients;
- Increased informed participation of patients and informal caregivers in the care management;
- Care efficiency gains through effective resource utilization.
- Improved health outcomes and quality of life of multimorbid elderly patients;

It is crucial to evaluate the C3-Cloud application with regard to expected and unexpected impacts that it will have. The evaluation approach proposed in this deliverable thereby aims to maximise the utility of the C3-Cloud solution. The C3-Cloud utility is multi-dimensional because an integrated care solution is complex in terms of the social, technical and financial dimensions that it has an impact on. For instance, to be able to treat patients with multiple chronic conditions (the target group of the C3-Cloud solutions), organisational structures will need to be changed; professionals need to work in new physical and virtual teams; patients can become more empowered and drivers of their own healthcare and shifts in resource use may be introduced.

Due to the multi-dimensional utility of C3-Cloud impacts, the evaluation and impact assessment is split into four layers. This will help to maximize the utility of C3-Cloud evaluation and guide more smoothly through the holistic structure of the evaluation. Each evaluation layer 1-4 targets specific stakeholders (i.e. experts, MDT members, patients or informal caregivers) and different areas of the evaluation (e.g., user-centred design; usability and usefulness; utility; ease of use; safety; patient empowerment; user experience; process quality; impact modelling or resource utilization).

Indicators were developed for each evaluation layer 1-4 in order to monitor and evaluate the expected impacts of the C3-Cloud solution. For each evaluation layer, several tools or measurements will be used, e.g. questionnaires, user observation, interviews or testing protocols. In addition, C3-Cloud can have unexpected impacts. To investigate also unexpected impacts, the evaluation approach will provide room for qualitative feedback and input from involved stakeholders (patients, informal caregivers, MDT members and experts).

1.3. Research question

The overall hypothesis of the C3-Cloud software application is that: “The use of the C3-Cloud application by the multi-disciplinary team and patients together with their informal caregivers improves the management of multi-morbid patients with poly-pharmacy.”

Based on this hypothesis, the study objective was defined as follows: “The objective is, to evaluate the user-centred design, the usefulness, usability, feasibility and user experience of the C3-Cloud pilot application among patients, their informal caregivers and MDT members”. For this, a number of C3-Cloud application outcome propositions will be monitored and the C3-Cloud impact will be modelled for large-scale deployment of the C3-Cloud application.

The leading research question for the evaluation of the 15-month piloting trial of the C3-Cloud application is therefore:

“Is the use of a personalised ICT tool that facilitates coordinated care planning, treatment optimisation and patient self-management acceptable to patients with multiple long-term conditions and their team of health professionals?”

This research question will be answered by means of four evaluation layers (see chapter 2.1) that will be applied in the context of the 15 month C3-Cloud piloting trial. This approach helps to answer sub-questions as defined below for each evaluation layer. :

Evaluation layer 1: End–users from the three pilot sites have been actively involved in the identification of the pilot application requirements (PAR) (see deliverable D8.1) and in the proposal of the organisational model changes, which enable the delivery of patient-centred care supporting C3-Cloud care model (see **Figure 2** – 'User centred Design' from M1 – M12). The respective tasks T8.1 and T4.2 were already completed in M4 and M12 and support the ongoing evaluation. The respective deliverables D8.1 "Use Cases and Requirement Specifications of the Pilot Application" and D4.2 "New Organisational Models for Improved Delivery of Integrated Care" describe those activities and findings.

In addition to that, evaluation layer 1 involved 15 patients and 30 MDTs in the pilot sites in order to test the user-centred design of the C3-Cloud components. Furthermore, ICT experts from the C3-Cloud technical partners will use protocols to carry out component testing and application testing to ensure that functional and non-functional requirements are met. The testing criteria for the component testing have been described in detail in deliverable D9.1 "Functional and non-functional testing criteria".

Sub-questions to be answered in layer 1 evaluation include:

- What are the requirements and needs that C3-Cloud users have for using the software? (This is an iterative approach in which C3-Cloud users are presented the new developments and can express their opinion.
- Are the requirements met by all components?
- Are all application components well integrated?

Evaluation layer 2 studies the usability and usefulness of the C3-Cloud components. Layer 2 will evaluate the usability and ease of use of C3-Cloud software components for the end users by involving four health ICT experts from the University of Warwick, 10-20 patients and 16-20 MDT members (**Table 2**) in each pilot site. An adapted version of the QUIS7 questionnaire will be used, complemented by qualitative elements such as interviews and user observations, to understand the how and why of user behaviour and the usefulness of the C3-Cloud application. Layer 2 will provide feedback to T7.4 to inform the technical partners on the usability of the C3-Cloud software components to reconfigure and update the C3-Cloud components. The procedure for layer 2 is described in chapter 3.2 ("Layer 2 procedures").

Sub-questions to be answered in layer 2 evaluation include:

- Is the C3-Cloud application perceived as acceptable to experts, patients and MDT members?
- What is the usefulness of the C3-Cloud application?
- Where is improvement needed?

Evaluation layer 3 evaluates the user experience, satisfaction and acceptability of the C3-Cloud application and patient training material by means of a 15-month trial (M30-M44) in the three pilot sites. Layer 3 involves about 150 patients and 52 MDT members to gain deep qualitative insights.

Sub-questions to be answered in layer 3 evaluations include:

- What is the user's satisfaction with the C3-Cloud application?
- How is healthcare perceived by its recipients in the context of C3-Cloud?
- Are there unexpected impacts of the C3-Cloud application?

Evaluation layer 4 is the impact assessment and the modelling of the C3-Cloud large-scale impact. This layer defines an approach that allows predicting and evaluating the impact of the C3-Cloud application, especially the use of resources. This approach builds on resources developed in the CareWell project: the cost-benefit assessment framework "ASSIST" developed by empirica, on the one hand, and the "Predictive Modelling" developed by Osakidetza, on the other hand. Layer 4 prepares the modelling of the large-scale impact of C3-Cloud implementation after the 15-month exploratory trial, which will be carried out in T9.5. Layer 4 involves about 720 intervention patients, 720 control patients and 62 MDT members to gain high-volume data on both, qualitative parameters and quantitative measures, for the impact modelling.

Sub-questions to be answered in layer 4 evaluation include:

- What is the impact of C3-Cloud on healthcare resource utilization?
- How frequently have end-users used the C3-Cloud application?
- What is the acceptability of the C3-Cloud application among end-users?
- What is the perceived utility of the C3-Cloud solution to end-users?

Note: The Description of Action (DoA) specifies that 600 patients and 600 controls will be observed for the C3-Cloud piloting trial and its evaluation ("observation goal"). This implies that an unknown number of patients and controls may withdraw from their participation during the piloting trial. Therefore, a dropout margin must be added to the observation goal. A 20% dropout margin is assumed and will therefore be added to the observation goal, adding to 720 patients and 720 controls to be recruited for the piloting trial participation (the "recruitment goal"). In addition, it is anticipated that 14% of all patients that will be approached for participation, will deny participation from the outset. Thus, the number of patients that will be approached for participation (the "approaching goal") must be 14% larger than the recruitment goal, adding up to 821 patients and 821 controls in the three pilot sites. This document will further refer to the recruitment goal (720 patients and 720 controls) when specifying the evaluation layer 4.

Table 2 shows the number of involved participants per pilot site and evaluation layer. The number of trial participants in each pilot site for evaluation layer 4 reads as follows: "minimum number of trial participants as defined in the DoA + 20% dropout rate + 14% denial rate" and sums the total number of trial participants that will be approached for participation.

2. Study design and duration

2.1. Study design

For complex interventions, the UK's Medical Research Council (MRC) recommends employing modelling and exploratory trials first before aiming at Randomised Controlled Trials (RCTs) and long-term implementation. This enables the continuous development and iterative improvement of the new technology in the continuum of increasing evidence. This research adopts the MRC recommendation and in that it divides the development and evaluation of the new technology (the C3-Cloud software) in the four evaluation layers, ensuring continuous, open feedback loops to the development team in evaluation layers 1 and 2 for the software improvement. This subsequently lead to the C3-Cloud application trial (evaluation layer 3) and is followed by the large-scale impact modeling (evaluation layer 4).

Each evaluation layer targets specific research objectives and involves different subsets of the study population or experts at different times before, during or after the C3-Cloud application trial. The specific procedures for each evaluation layer are outlined in chapter 3.

The efforts of this evaluation therefore not only evaluate feasibility but also further improve the C3-Cloud application and its implementation.

	Layer 1 – User Centred Design		Layer 2 – Usability / Usefulness			Layer 3 – Exploratory trial for application evaluation		Layer 4 – Monitoring for Modelling large-scale impact		
Pilot Region	**Patients**	**MDT members**	**Health ICT Experts**	**Patients**	**MDT members**	**Patients**	**MDT members**	**Patients**	**Controls**	**MDT members**
South Warwickshire	5	8	4	10	16	50	16	100+20+17	100+20+17	16
Basque Country	5	8	-	20	16	50	16	250+50+42	250+50+42	16
Jämtland Härjedalen	5	14	-	10	20	50	20	250+50+42	250+50+42	30
Total	**15**	**30**		**40**	**52**	**150**	**52**	**821**	**821**	**62**

Table 2: Number of study participants per evaluation layer

In summary (see Table 2):

Evaluation layer 1 will employ C3-Cloud software component and application tests along defined protocols by making use of 4 health ICT experts from the University of Warwick, 15 patients and 30 MDT members in the pilot sites.

Evaluation layer 2 included a heuristic evaluation and a questionnaire, in preparation for layer 3 evaluation. Layer 2 involves 4 health ICT experts from the University of Warwick, 40 patients and 52 MDT members in the 3 pilot sites.

Evaluation layer 3 will employ an exploratory technology trial that uses baseline and closure patient observations. Approximately 150 intervention patients and 52 MDT members will be involved in layer 3 evaluations by answering questionnaires and being involved in interviews.

Evaluation layer 4 will employ a predictive modelling tool that will be developed in the scope of T9.5 to model the C3-Cloud impact when scaled up, using intervention and control patient data. Approximately 720 intervention and 720 control patients and 62 Members of the multidisciplinary teams (MDT members) will be involved in layer 4 evaluation by answering questionnaires and giving access to their anonymized C3-Cloud data.

2.2. Study Setting

Study settings include all settings that are in any way relevant for the provision of health care, i.e. healthcare centres, GP's offices, hospitals, patients' homes.

Participants will be enrolled and the evaluation will be conducted at the following three pilot sites regions:

- South Warwickshire, UK
- Basque Country, Spain
- Region Jämtland Härjedalen, Sweden

2.3. Study duration

The total study duration is from M1 - M45, which includes the evaluation layers 1 to 4. Evaluation layers 1 and 2, however, have started already in M1 with tasks T8.1 and T4.2 on the user centred design, design of use cases and organizational models, informed by feedback of patients and MDT members. Layers 1 and 2 will be finalized approximately by M26. The results of layers 1 and 2 will be presented in deliverable D9.5.

The technology exploratory trial (layer 3 and 4 evaluation) however has a duration of 15 months, starting from M30 until M45. The results of this research are anticipated to become available by the end of M48.

Table 3 presents a project month reference table. If this document refers to, for example, M30, this means October 2018.

Month	Year	Project Month	Month	Year	Project Month
May	2016	1	May	2018	25
June	2016	2	June	2018	26
July	2016	3	July	2018	27
August	2016	4	August	2018	28
September	2016	5	September	2018	29
October	2016	6	October	2018	30
November	2016	7	November	2018	31
December	2016	8	December	2018	32
January	2017	9	January	2019	33
February	2017	10	February	2019	34
March	2017	11	March	2019	35
April	2017	12	April	2019	36
May	2017	13	May	2019	37
June	2017	14	June	2019	38
July	2017	15	July	2019	39
August	2017	16	August	2019	40
September	2017	17	September	2019	41
October	2017	18	October	2019	42
November	2017	19	November	2019	43
December	2017	20	December	2019	44
January	2018	21	January	2020	45
February	2018	22	February	2020	46
March	2018	23	March	2020	47
April	2018	24	April	2020	48

Table 3: Project Months reference table

2.4. Timeline for evaluation

The following figure presents the list of evaluation means and questionnaires including an indication when they will be used for the different evaluation layers with the patients, informal caregivers and MDT members. The full questionnaires can be seen in the Annex.

The list of each evaluation means is indicated on the y-axis, the x-axis indicates the project months for the sequence of each evaluation. Layer 1 is highlighted in blue bars, layer 2 in turquoise bars, layer 3 in olive bars and layer 4 highlighted in purple bars.

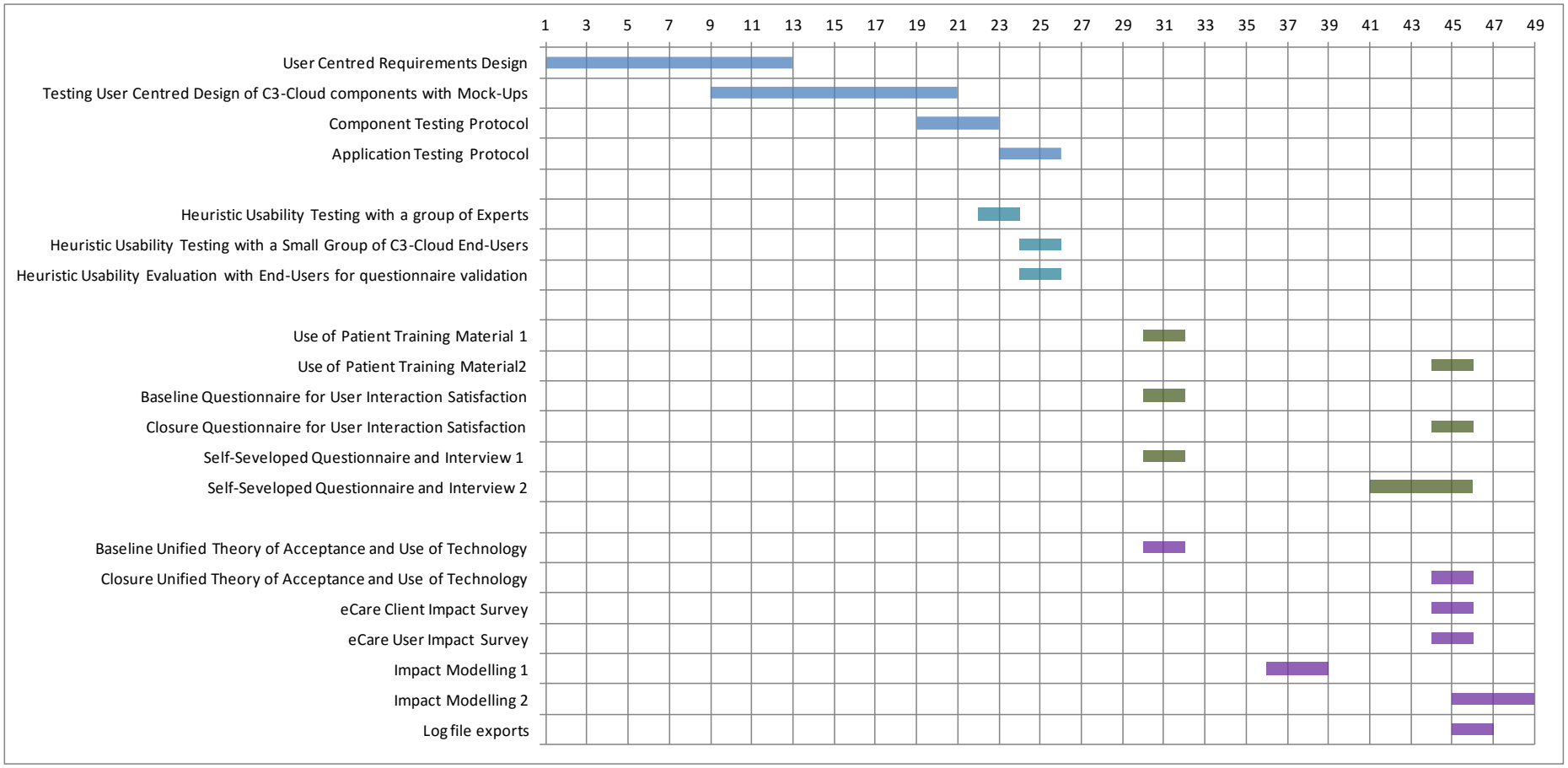

Figure 2: Timeline of evaluation phases (without preparation phases)

3. Study Phases

The study is divided in a pre-trial phase, a trial phase and a post-trial phase. Evaluation layers 1 and 2 will be carried out before the trial (M1 – M26). Evaluation layer 3 will be carried out during the 15-month trial (M30 – M45) and evaluation layer 4 will be carried out during and after the trial (M30 – M48). The following sections describe the research protocol for all 4 evaluation layers, including the research methods.

3.1. Layer 1 evaluation: user-centred design

Evaluation layer 1 aims to evaluate the user-centred design of the C3-Cloud application. With about 15 patients and 30 MDT members involved, it uses user-centred design testing with software mock-ups, a component testing protocol and an application testing protocol as evaluation means. This will test the design of the C3-Cloud components (e.g. functionality, content provided, language used, level of detail, user-friendliness) and their application chain (evaluating if all components are well integrated).

Sub-questions to be answered in layer 1 evaluation include:

- What are the requirements and needs that C3-Cloud users have for using the software?
- Are the requirements met by all components?
- Are all application components well integrated?

3.1.1. User Centred Design Testing with Mock-Ups

As a part of the C3-Cloud application design, it will be explored in detail how the solutions provided by C3-Cloud components can be deployed at each pilot site, and what kind of extensions are needed as there is no 'single integrated care model' that can be applied universally. Thus, patients and MDT members are presented C3-Cloud component (PEP and C3DP) mock-ups and their feedback and comments are used for software adaption.

More details are provided in the following tables: Table 4 provides a summary of the research methods; Table 5 describes the procedure for data collection; and Table 6 summarises the timeline for activities at the 3 pilot sites.

Summary of research methods			
Type of evaluation	**Involved partner**	**Interviewees**	**Data collection**
Discussion group	Kronikgune, pilot sites	About 4 patients for the PEP mockups and 13 MDT members for C3DP mockups at each pilot site	M7-M22 (Basque Country has done this initially in M7-M8; the other two sites will follow until M22)
Purpose and Research Objectives			
Purpose	Pilot sites ask their health professionals and patients and for feedback about the C3DP and PEP mock-ups respectively in order to evaluate whether they fulfil their requirements.		
Research Objectives	To know if the project approach can help patients to: improve their understanding of treatment options; to become more involved and to participate in the follow-up of their illness together with the MDT.		
	Review of the requirements through presentation of software mock-ups and the possibility to comment them.		

	To obtain from the end-users (patients and MDT members) a first feedback on the design of the C3-Cloud components (PEP and C3DP, respectively) that are being developed in the project.
	Collect feedback
	Send qualitative feedback to the C3-Cloud component developers to use it for the revision of the software components.

Table 4: Summary and research methods for the presentation of C3-Cloud mock-ups to MDT members and patients

Evaluation Description
The procedures described below were already done in the Basque Country in M7 and serve as an example for the other two pilot sites who will do this exercise in a similar manner until M22 with 4 patients and 5 MDT members who are conveniently selected. This allows for iterative improvements of the C3-Cloud components development, taking into account feedback from the early exercise, which is repeated at a later stage of the development, providing additional feedback. **Review of C3DP mock-ups in Basque Country** 1. The mock-ups proposed by SRDC were reviewed and commented by pilot sites, in order to evaluate if they fulfil their requirements. On top of that, concrete questions were required from the pilot sites (i.e. several data elements needed to be agreed on possible "value sets" by the pilot sites) 2. The MDT members were questioned about the presented mock-ups. a. In a first meeting, Kronikgune and 2 MDT members (one GP and one pharmacist) gathered for 1.5 hours. The objective of the meeting was to review the mock-ups provided by SRDC in September 2016. As a result, general and more specific comments on the mock-ups were sent to SRDC to inform them for possible improvements on the mock-ups. b. In a second meeting, 11 MDT members (GPs, specialists, nurses, pharmacists and managers) met. The MDT members confirmed the comments of the previous meeting 3. The MDT feedback was collected and send to SRDC. SRDC collected all the feedback and revisited the mock-ups to address the comments received from the MDT members. **Review of PEP mock-ups in Basque Country** Kronikgune gathered 4 patients (suffering diabetes or renal failure or both conditions) for 2 hour meeting and gave a brief presentation on the C3-Cloud project. This was followed by a presentation of the Patient Empowerment Platform (PEP) by showing the different screenshots, provided previously by MEDIXINE, which correspond to different functionalities of the PEP. The presentation was followed by a moderated discussion group to gather the patients' opinion. The discussion group was moderated by a set of 7 questions: 1. To what degree do you think the use of the C3-Cloud services can contribute to improving your understanding of health information that you receive from health professionals, as well as information received in a written form such as test results, medical reports, etc.? 2. To what degree do you think the use of the C3-Cloud services will help you better understand your health/disease, its possible developments, and treatment options available? 3. Do you think the use of the C3-Cloud services will contribute to making you become more involved in monitoring your health status and treatment progress, and if so to what degree? 4. To what extent do you think the use of the C3-Cloud services will help you better adhere to treatment plans and lifestyle adjustments? 5. Do you think the use of the C3-Cloud services will help you become more actively involved during a consultation with healthcare professionals, and if so to what extent?

6. How will the use of the C3-Cloud service impact on your relationship with healthcare professionals? 7. Other issues emerged in respect of empowerment In addition, the design of the PEP was discussed along the following topics: 1. Functionality 2. Content 3. The language used 4. The level of detail (“granularity”) 5. How it is presented to the user (“user-friendliness”)

Table 5: Description of the data collection for the presentation of C3-Cloud mock-ups to MDT members and patients

Timeline of Activities		
Deadline	**Partner**	**Activity**
M7 – M8	KG, OSAKI	Presenting the mock-ups to patients and MDT members; moderating a focus group to gather feedback; presenting the feedback to the technical partners in the form of a summary.
M15	KG, OSAKI	Review of PEP and C3DP mock-ups
M20	SWFT; RJH	Review of state-of-the-art PEP and C3DP mock-ups
M22	SWFT; RJH	Presenting the mock-ups to patients and MDT members; moderating a focus group to gather feedback; presenting the feedback to the technical partners in the form of a summary.
M40	KG	Results will be presented in D9.5

Table 6: Timeline of activities for the presentation of C3-Cloud mock-ups to MDT members and patients

3.1.2. C3-Cloud Component Testing

The C3-Cloud application consists of a variety of components: the Personalized Care Plan Development Platform; the Coordinated Care and Cure Delivery Platform; the Patient Empowerment Platform, Clinical Decision Support Modules; Interoperability Middleware (including technical and semantic interoperability as well as privacy and security middleware). The component testing protocol, as described in D9.1, gives instructions to test all C3-Cloud software components if they meet the functional and non-functional pilot application requirements (PAR) as detailed in D9.1.

Table 7 summarises the research methods for component testing; Table 8 describes the procedure for testing and its reporting; and Table 9 lists the activities and timeline for the component testing.

Summary of research methods		
Type of evaluation	**Involved partner**	**Data collection**
Testing protocol, Delphi method	INSERM, technical partners	M19 – M23
Purpose and Research Objectives		

Purpose	To test if all C3-Cloud components can perform the functional and non-functional requirements.
Research Objectives	To introduce the C3-Cloud component testing with associated evaluation models.
	Ensuring that functional and non-functional component requirements are met as they were specified in the traceability matrix presented in deliverable D9.1.

Table 7: Summary of Component Testing

Evaluation Description
"C3-Cloud Component Testing" tests whether the C3-Cloud software can perform the (functional and non-functional) requirements. It is an independent testing of each component. The software development teams of each component perform its component tests. The functional/non-functional test cases for the C3-Cloud software components will be defined based on requirements Specifications of the C3-Cloud Architecture, and by complying with the IEEE 829 Standard for Software and System Test Documentation. The "EuroRec labelling tool" will be used for the documentation of the component testing: The major asset is they already got the process, software suite and the feature to produce the documentation we need and have designed National ethics application in the pilot sites is not needed for the component testing as it does not involve patients.

Table 8: Description of the process and reporting for component testing

Timeline of Activities		
Deadline	**Partner**	**Activity**
M19 – M23	INSERM, technical partners	The component testing will be carried out along the protocol specified in deliverable D9.1 as soon as each C3-Cloud component becomes available.
M26	INSERM	Results of the application testing will be reported in D9.3

Table 9: Timeline of activities for Component Testing

3.1.3. C3-Cloud Application Testing Protocol

Application Testing is related to the scenarios and pilot application requirements described in D8.1 "Use Cases and Requirements Specifications of the Pilot Application". Starting from the scenario described in D8.1, the Pilot Application Requirements (PAR) of the three pilot sites were mapped with use cases and described in deliverable D3.2 "Requirements Specification of the C3-Cloud Architecture". D3.2 was subsequently updated in D3.3 "Conceptual Design of the C3-Cloud Architecture".

The proposed Application Testing approach evaluates the integration of C3-Cloud components and carries out functional testing of the C3-Cloud application in whole, which includes:

- Testing the functioning of all C3-Cloud components together and evaluating "how well the components are integrated".
- Testing how users interact with the C3-Cloud application (linked to usability studies) and evaluating the interaction with respect to the Pilot Application Requirements (defined in D8.1 and D9.1).

The C3-Cloud application consists of a variety of components for which 60 different PARs have been identified and mapped to different required high-level components: Patient Empowerment Platform (PEP); Personalized Care Plan Development Platform (PCPDP); Coordinated Care and Cure Delivery Platform (C3DP); Technical Interoperability Suite; Semantic Interoperability Suite; Clinical Decision Support Modules; Security and Privacy Suite and in some cases to already existing local care systems.

The principal standard steps of the C3-Cloud evaluation strategy are: prepare, establish, specify, design, execute and report. This needs to take into account the medical, technological, organisational and socio-economic challenges of creating a collaboration environment for all of the stakeholders involved in the holistic continuum of care.

The application testing protocol was developed by INSERM and is presented in chapter 3.1.3.1.

Summary of research methods		
Type of evaluation	**Involved partner**	**Data collection**
Testing protocol	INSERM, technical partners, pilot sites, patients	M23 – M25
Purpose and Research Objectives		
Purpose	To proof our hypothesis that: "The use of the C3-Cloud application by the MDT and patients improve the management of multi-morbid patients with poly-pharmacy."	
Research Objectives	To introduce the Application Testing criteria used for the evaluation of C3-Cloud application.	
	To organize these criteria into a comprehensive evaluation framework.	

Table 10: Summary of Application Testing

Evaluation Description
Application Tests are related to the scenario described in D8.1 and use cases described in deliverable D3.2 Requirements Specification of the C3-Cloud Architecture and updated in D3.3 Conceptual Design of the C3-Cloud Architecture. Layer 1 user-centred design is part of tasks 3.2, 3.3, 4.2, 8.1 and 8.2. The principal standard steps of the C3 Cloud evaluation strategy are as follow: prepare, establish, specify, design, execute and report. The C3-Cloud 'layer 1 evaluation - User centred design' will follow the standard process defined on the evaluation reference model and guide ISO/IEC standard also known as Software engineering - Software product Quality Requirements and Evaluation (SQuaRE). Application testing includes the evaluation of the integration of C3-Cloud components and functional testing of the application as a whole and evaluates if all C3-Cloud components work well together. Application testing is linked to usability studies and it considers how people interact with the software. INSERM proposes the Delphi method for the « Validation and Prioritization of the Application Testing criteria Questionnaire ». The Delphi approach permits « *to obtain the most reliable opinion*

consensus of a group of experts by subjecting them to a series of questionnaires in-depth interspersed with controlled opinion feedback » (Dalkey & Helmer, 1963) based on the following three steps: **Brainstorming:** In a first round, a list of Questions Proposal formulated in concordance with the Pilot Application Scenario Requirements identified in D8.1 (Figure 4) will be sent to the evaluation participants. This is to formulate an initial list of relevant questions for which we will evaluate the degree of agreement of participants on Likert scales (Figure 5). Likert scale enables respondents to indicate their level of agreement with a statement. Users will be asked to note their agreement on each question proposal, from "strongly disagree" to "strongly agree" with a possibility to add comments. The experts give their answer on a 5 point Likert scale with a neutral point and they can validate, modify, delete or add questions with the justifications and arguments. **Refining and prioritization**: In the second round, the median and histogram of the first answers on the agreement of each question proposal is given. Participants will be asked to: • Confirm or modify their first notes of agreement for each question and comment on their positioning especially in cases where they modify their vote. • Give for each question, a second note of the relevance of the question proposals from "5, very important" to "1, not important". **Analysis:** We will communicate the validated questions with their degree of relevance. Then both MDT members and patients will be asked to make further comments on these proposals based on the results achieved. Examples for the DELPHI method survey include: https://mesydel.com; http://www.kernwert.com; http://www.evalandgo.fr; https://www.keysurvey.fr. Evaluation reporting will be done by INSERM in deliverable D9.3 (M26) under reference to the list of use cases and requirements of the traceability matrix (D9.1; Appendix 5.2) and by using the EuroRec Quality Assessment Suite (D9.1, Section 5.1). National ethics application in the pilot sites is not needed for the application testing as it does not involve patients' sensitive data.

Table 11: Description of the data collection for Application Testing

Timeline of activities		
Deadline	**Partner**	**Activity**
M18	INSERM	Description of the functional application testing criteria
M25	INSERM and technical partners	The (functional) application testing and the (non-functional) usability studies are supposed to start after the end of component testing and integration of all components.
M20	INSERM, pilot sites	Sampling of evaluation participants: The group of participants (15 patients and 30 MDTs total) should be issued from the three pilot sites BC, SWFT and RJH, via the collaboration of local patients and MDT members and with the use of patient scenarios. Participants will be selected by the pilot sites using convenience sampling, however they should have a good understanding of the tested application and the context of its deployment in the respective pilot site.
M21	INSERM	Building the questionnaires based on the consensus of the sampled patients and MDT members under consideration of non-responses and dropout participants.

M21	INSERM, pilot sites, patients, MDT members	The subject of evaluation (Application Testing) will be clearly explained to the participants (by mail or telephone).
M21	INSERM, pilot sites, patients, MDT members	A first questionnaire for brainstorming will be circulated to the evaluation participants.
M23	INSERM, pilot sites, patients, MDT members	Approximately, 2 months after the first questionnaire, a second questionnaire for refining the evaluation will be circulated to the evaluation participants
M24	INSERM, pilot sites, patients, MDT members	A final version of the questionnaire should be circulated not later than 3 weeks after getting the validation of the second round.
M26	INSERM	Results of the application testing will be reported in D9.3

Table 12: Timeline of activities for Application Testing

As an example, Figure 3 shows a simplified application testing workflow based on a C3-Cloud key scenario linked to a use case and defined by an application testing criteria.

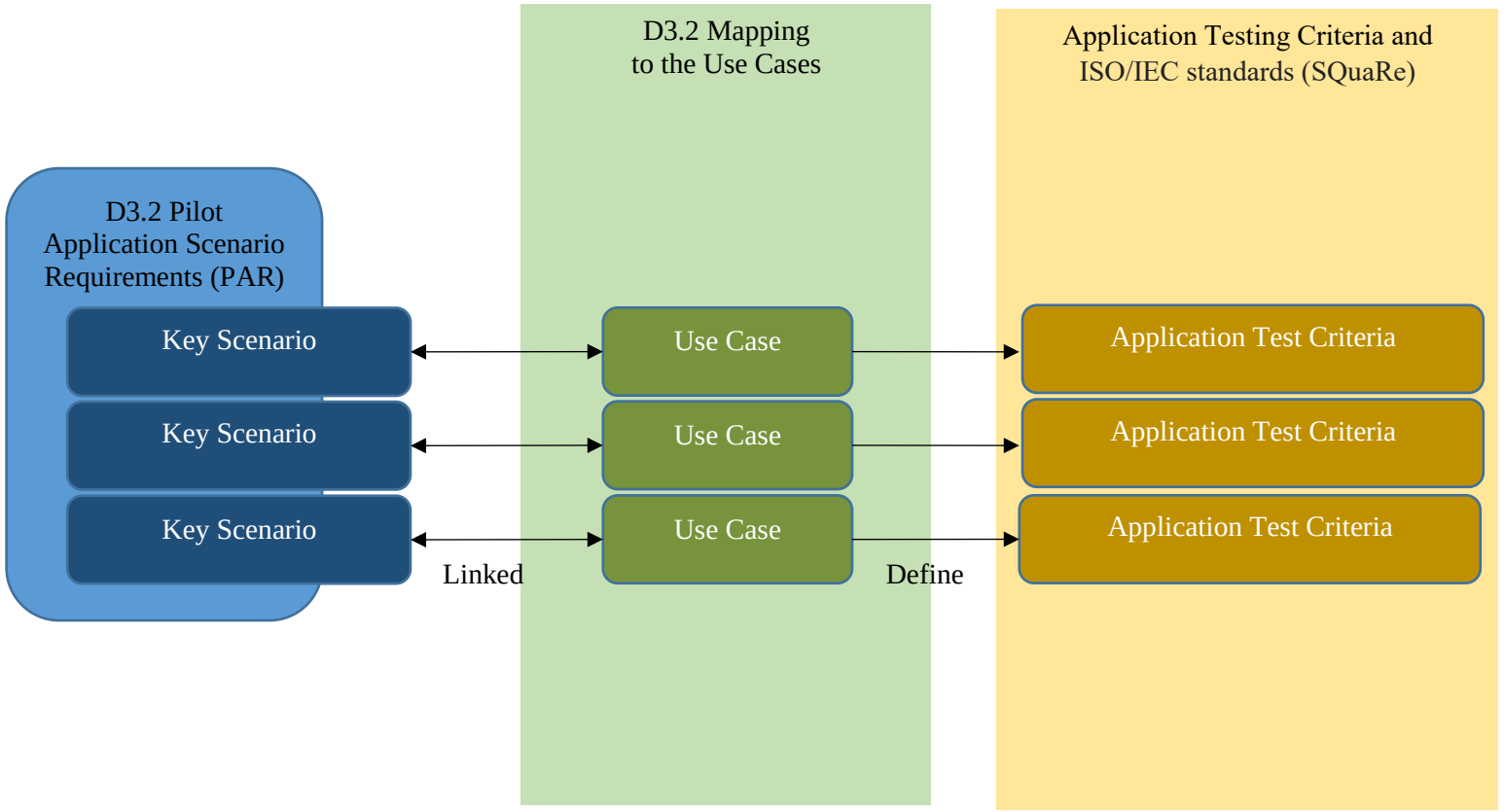

Figure 3: Simplified application test cases definition workflow

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases	Dimension	Application Testing Criteria	1st round Questions Proposal -DELPHI-
PAR-23	As a Patient/Informal Care Giver, I want to be able to remotely **get in touch with** social care services	Basque Scenario-Encounter B	Patient Empowerment Platform	PEP-3.1: **Communicate via Safe messaging** PEP-3.2: **Communicate via Video appointment**	Organizational	– Acceptability – Effective Communication between Patient/Informal Care Giver and social care services – Time saving for clinical workload	Does the system enable: – The patient to send messages to social care services – The social care services to send messages to patient? – The patient and social care service to reply to received messages thus continue an on-going conversation?

Figure 4: Use case mapping of the Pilot Application Requirements identified in D8.1 and D3.2 with 'Dimension', 'Application Testing criteria' and 'Question Proposal'

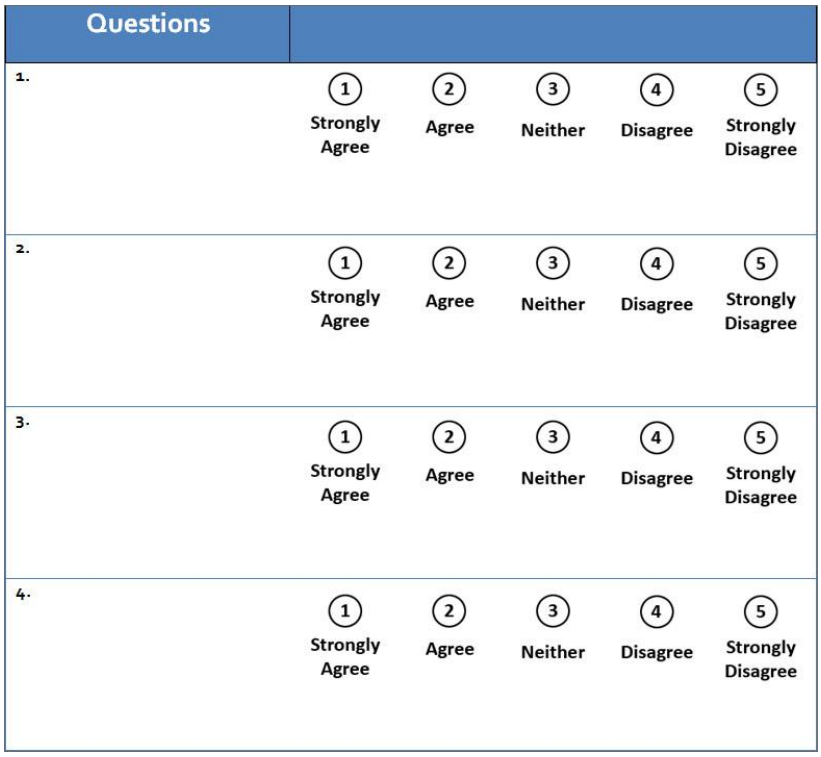

Figure 5: Likert Scale Template Sample

3.1.3.1. Generic Application testing criteria

By referring to the 60 different Pilot Application User Requirements (PAR), we will classify the PAR into a larger set (called "dimension") that are frequently used in application assessment frameworks. These dimensions are classified into the following six groups: *Economic outcomes, clinical outcomes, educational outcomes, technical outcomes, users' perspective* (users are patients, informal caregivers and MDT members) and *organizational outcomes*. The groups are associated with predefined application testing criteria as shown in Table 13.

Dimension	Criteria
Economic outcomes	Costs of health care resources utilization: number of technical visits, days in the hospital, consultation with MDT, emergency visits, hospitalization and readmission rate
	Cost of technical maintenance
Clinical outcomes	Patient-reported outcomes: quality of life, health status rate, activity day living
	Disease-oriented outcomes: mortality rate, morbidity rate and functional capacity
	Patient adherence to care plan: diet adherence, medication adherence and physical activity adherence
	Physician adherence to guidelines
Educational outcomes	Knowledge of diseases (Heart Failure, Renal Failure, Psychiatric Disorder)
	Self-care knowledge and behaviour

	Primary care physician education
	Caregiver involvement
Technical outcomes	Ergonomics: Intuitive functions and design, quick switch on/off, set up and configuration of system
	Characteristics: platform connection with other devices, authentication, secure storage, maintainability and availability of service
Users' perspective	Patient perception: feeling of patient, cognitive feedback, acceptability of technology and service, reliability of information and communication technology, willingness to pay, patient's motivation, social network, self-efficacy and confidence, adaptation to telephone/portable device monitoring, easy to use, access to care providers, satisfaction with new technology and compliance with new technology
	Care provider perception: satisfaction, utility, acceptability of technology, easy to use, compliance with new technology, coordination with other actors
Organizational	Administrative: assurance policy, hospital policy
	Clinical: acceptability of MDT members, Intra-communication between MDT members, Inter-communication between patient and MDT, Time saving for the clinical workload.

Table 13: Dimension and Application Testing Criteria Summary

The generic application testing criteria presented in Table 13 may be further adapted to the specific care context in which C3-Cloud is developed (considering the patients inclusion criteria such as heart failure, renal failure, diabetes or depression).

3.2. Layer 2 evaluation: Usability and usefulness

Evaluation layer 2 studies the usability, usefulness and ease of use of the C3-Cloud components for the end-users in three pilot sites by means of an adapted QUIS7 questionnaire. The QUIS7 will be described in detail in section 3.3.2. This is complemented by interviews and user observations, to understand the how and why of user behaviour. Layer 2 will provide feedback to T7.4 to inform the technical partners on the usability of the C3-Cloud software components to reconfigure and update the C3-Cloud components.

Evaluation layer 2 studies the usability and usefulness of the C3-Cloud components. Layer 2 will evaluate the usability and ease of use of C3-Cloud software components for the end users by involving four health ICT experts from the University of Warwick and between 10 - 20 patients and 16 - 20 MDT members in the pilot sites, as specified in Table 2. An adapted version of the QUIS7 questionnaire will be used, complemented by qualitative elements such as interviews and user observations, to understand the how and why of user behaviour and the usefulness of the C3-Cloud application. Layer 2 will provide feedback to T7.4 to inform the technical partners on the usability of the C3-Cloud software components to reconfigure and update the C3-Cloud components. The procedure for layer 2 is described in chapter 3.2 ("Layer 2 procedures").

3.2.1. Heuristic Usability Evaluation with 4 Experts

The protocol for the heuristic usability testing with four health ICT experts from the University of Warwick is currently being developed by WARWICK and will be finalized before M21 for the start of the heuristic evaluations. It will be carried out in the scope of T9.2, based based on a storyboard guiding through the usage of the Patient Empowerment Platform (PEP) (developed by Medixine) and the Care and Cure Delivery Platform (C3DP) (C3DP evaluation storyboard/walkthrough will be written by Warwick University).

Summary and research methods			
Type of evaluation	**Involved partner**	**Interviewees**	**Data collection**
Heuristic evaluation	Warwick, Empirica	4 health ICT experts from Warwick	M22- M24
Purpose and Research Objectives			
Purpose	Provision of quick and inexpensive usability feedback to our software developers for early corrective measures		
Research Objectives	Small-sale identification and categorization of usability issues		

Table 14: Summary and research methods of Heuristic Usability Evaluation with Four Experts

Evaluation Description
Heuristic evaluation is a discount usability engineering method which was first described in presentations at the CHI'90 conference in 1990 and then more comprehensively discussed by Jakob Nielsen in 1994 in his book, "Usability inspection methods". Since then it has become one of the most widely used methods in the industry (Nielsen, Technology Transfer of Heuristic Evaluation and Usability Inspection, 1995). According to Nielsen, it is "a usability engineering method for finding the usability problems in a user interface design so that they can be attended to as part of an iterative design process" (Nielsen, 1995). Involving multiple evaluators (Nielson recommends three to five), the users are asked to discover the answer to given questions by using the system several times (at least twice). This will be done by mock-ups and dummy patient data that follows a storyboard developed by Medixine and SRDC. The storyboard will be refined to touch as diverse a set of scenarios as possible and to ensure that the storyboard tackles all the research objectives (see chapters 1.2 and 1.3). The expert users will be observed individually during the Nielson walkthrough when they perform certain tasks according to the storyboard and will be encouraged to think aloud. Their feedback will be categorized and compared with a list of recognized usability principles (the "heuristics") (Nielsen, How to Conduct a Heuristic Evaluation, 1995). The results will be fed back to the software development partners. National ethics application in the pilot sites is not needed for heuristic evaluation as it the evaluation is done with dummy patient and MDT data and not with real data.

Table 15: Description of the data collection of Heuristic Usability Evaluation with 4 Experts

Timeline of activities		
Deadline	**Partner**	**Activity**

M20	Warwick	Naming the 4 experts for the heuristic evaluation
M21	Warwick	Refining the Storyboard that was initially developed by Medixine
M21	Warwick	Planning the Nielsen walkthrough with C3-Cloud component mock-ups (alternatively, if applicable, working C3-Cloud component versions and dummy data will be used instead of mock-ups)
M21	Warwick; Medixine; SRDC	Setting up realistic dummy-data for patients and MDT members to be used for the mock-ups
M22	Warwick, empirica	Performing the Nielsen Walkthrough with the 4 health ICT experts
M40	Warwick, empirica	Presentation of interim results in D9.5

Table 16: Timeline of activities of Heuristic Usability Evaluation with 4 Experts

3.2.2. Heuristic Usability Evaluation with a small group of C3-Cloud End-Users

The protocol for the heuristic usability testing with a small group of C3-Cloud end-users is currently being developed by WARWICK and will be finalized before M22 for the start of the heuristic evaluations. The evaluation will involve 40 patients and 52 MDT members who will answer a questionnaire on user interaction satisfaction (QUIS7) just after a Nielsen walkthrough with C3-Cloud software component mock-ups (or a test version of the PEP and C3DP if already available). The full set of items of the QUIS7 questionnaire can be seen in the Annex. The presented QUIS7 in Annex 8.2 is a preliminary, adapted version of the QUIS7, which will be tested for further use during the trial (see chapter 3.3.2) during the heuristic usability testing, presented in this section.

Summary and research methods			
Type of evaluation	**Involved partner**	**Interviewees**	**Data collection**
Nielson heuristic evaluation and a questionnaire	Warwick, empirica, Pilot sites	Patients: 10 (SWFT), 20 (BC) and 10 (RJH) MDTs: 16 (SWFT), 16 (BC) and 20 (RJH)	M24 – M26
Purpose and Research Objectives			
Purpose	Provision of quick and inexpensive usability feedback to our software developers for early corrective measures		
Research Objectives	Medium-scale identification and categorization of usability issues of the C3-Cloud components		
	Testing of the adapted QUIS7 questionnaire items for use with increased number of C3-Cloud users in layer 3 (chapter 3.3.2)		

Table 17: Summary and research methods of Heuristic Usability Evaluation with a small group of C3-Cloud End-Users

Evaluation Description
For the heuristic evaluation, the users will be observed in small groups (maximum 5 at a time) during this process and will be encouraged to think aloud while notes are taken. However, no questions with respect to reaching achieving the task will be answered. This is followed by a feedback session for which the users are mixed again, to allow for more comprehensive feedback and stipulate discussion and exchange among participants. The participant feedback will be categorized and compared with a list of recognized usability principles (Nielsen's "heuristics"). The results will be fed back to the software development partners. Just after the Nielsen walkthrough observations, the participants will be asked to fill in an adapted version of the QUIS7 questionnaire. Rather than gathering information on the User Interaction Satisfaction, this exercise serves to test the adapted questionnaire for use in evaluation layer 3 (see chapter 3.3.2) National ethics application in the pilot sites is not needed for heuristic evaluation as it the evaluation is done with dummy patient and MDT data and not with real data. Patients to be recruited

Table 18: Description of the data collection for Heuristic Usability Evaluation with a small group of C3-Cloud End-Users

Timeline of activities		
Deadline	**Partner**	**Activity**
M21	Empirica	Develop a trial activity checklist for pilot sites
M21	Warwick	Planning the Nielsen walkthrough with C3-Cloud component mock-ups or working versions and dummy data
M21	Warwick, Medixine	Setting up realistic dummy-data for patients and MDT members to be used for the mock-ups.
M22	Pilot sites	Pilot sites identify suitable participants: 40 patients and 52 MDT members in the three pilot sites. The patients must be of the same age group as the piloting trial patients but not necessarily have the same conditions (convenience sampling will be applied).
M22	Warwick	Plan the scenarios (walkthroughs) and the recruitment of patients and MDT members
M23	Osakidetza, RJH	Translate mock-up data to local language (where necessary) and
M23	Osakidetza, RJH	Identification of fluent Spanish and Swedish speakers for the walkthrough with patients and MDT members
M24-26	Pilot sites, patients, MDTs	The detailed mock-ups of the user interfaces to be presented to the actual users of C3-Cloud pilots
M24-26	Pilot sites, patients, MDT members, empirica	The adapted QUIS7 questionnaire will be handed out to the heuristic usability evaluation participants and their answers will be collected
M26	Pilot sites	The results from the questionnaires will be presented to the technical partners
M27	Empirica	Testing of the adapted QUIS7 questionnaire for further use in layer 3 evaluation
M40	Warwick, empirica	Presentation of interim results in D9.5

Table 19: Timeline of activities for Heuristic Usability Evaluation with a small group of C3-Cloud End-Users

3.3. Layer 3 evaluation: 15-month exploratory trial

With the involvement of 150 patients and 52 MDT members during the 15-month piloting trial, the layer 3 evaluates the user experience, satisfaction and acceptability of the C3-Cloud application and patient training material.

3.3.1. Use of Patient Training Material

WP9 will undertake a limited evaluation of whether the training materials were used and how frequently. Data will be gathered on user experience and whether users feel more knowledgeable about their conditions and if they feel more self-empowered to take care of their conditions. It will also consider whether the materials are a contributing factor to improving care/care coordination, and how recommendations for future enhancements or new materials will be documented during the trial.

The full set of items for patient training material evaluation can be seen in Annex 8.1.

The patient training material that is developed or provided in C3-Cloud is described in D5.1 and includes 5 outputs that will be evaluated at different times and via different methods:

Output/ Type of Material	When are the Materials Issued to the Trial Participants?	When to Evaluate	Evaluation Method
Output 2 – Video	It should be mandatory for trial participants to watch the video at the start of the trial (after enrolment). It can also be watched at any other time during the trial at the patient's discretion	M30 - M31	Short, structured, paper-based questionnaire handed out to trial participants by research nurses (or a suitable alternative) at each site (see Annex 8.1)
Output 4 – Information leaflet about the training materials	Leaflet will be given out during enrolment and will also be available electronically in PEP		
Output 5 – Wallet card	To be given out during enrolment		
Output 1 - Core Materials (existing leaflets, web pages, etc.)	At various points throughout the trial, e.g. information about the disease at diagnosis, dietary info when the goal is to lose weight, etc.	M44 - M45	Short, structured, paper-based questionnaire handed out to trial participants by research nurses (or a suitable alternative) at each site (see Annex 8.1)
Output 3 – Peer support groups/info sources	Offered to trial participants at the discretion of the MDT member at appropriate stages in their care plan		

Table 20: Outputs of patient training material and its evaluation

Summary and research methods			
Type of evaluation	**Involved partner**	**Interviewees**	**Data collection**
Questionnaire	Pilot sites; empirica	150 patients	M30-M31
Questionnaire	Pilot sites; empirica	150 patients	M44-M45
Purpose and Research Objectives			
Purpose	Evaluation of the acceptability of training material that is provided or referenced by C3-Cloud applications, but which was not developed by C3-Cloud (outcomes 1 and 3) Evaluation of the acceptability of training material that developed and provided by C3-Cloud (outcomes 2, 4 and 5)		
Research Objectives	To assess whether the patients and their informal caregivers found the training materials useful and informative.		
	To assess whether the material was easy to understand		
	To assess whether it helped them to increase their understanding of their disease and its management.		
	To assess whether it encouraged them to adopt a higher degree of self-management.		

Table 21: Summary and research methods of patient training material evaluation

Evaluation Description	
M30-31 data collection	Some patient training material will be evaluated at the trial baseline: Training material "Output 2 (i.e. the video), "output 4" (i.e. the patient information leaflet about training materials) and "output 5" (i.e. the wallet card). A short, structured, paper-based questionnaire will be sent via mail or e-mail to trial participants by research nurses (or a suitable alternative) at each site. The questionnaire will not be issued via the PEP, as this may introduce bias in the case that patients are unable, or not as confident in, using the PEP itself. **Empirica; Pilot sites and Patients** will be involved in filling and collecting in the questionnaires
M44-M45 data collection	Some patient training material will be evaluated at the end of the trial: Training material "Output 1" (i.e. the Core materials such as existing leaflets, web pages, etc.) and Output 3 (i.e. Peer support groups). Short, structured, paper-based questionnaire (see Annex 8.1) will be handed out to 150 patients by research nurses (or a suitable alternative) at each pilot site. Suggestions or any recommendations for future enhancements to the training materials, or for the inclusion of new materials, will be addressed with trial participants as an open question in the questionnaires. **Empirica; Pilot sites; and Patients** will be involved in filling in and collecting the questionnaires. In addition to the above, the following evaluation activities will be undertaken:

	Medixine will produce a PEP log-file output in the context of layer 4 evaluation to assess the frequency of usage of digitally assess patient training materials during the trial (for the outcomes where this is applicable).

Table 22: Description of the data collection for the patient training material evaluation

The following timeline of activities for the patient training material evaluation is preliminary and subject to ongoing discussion with the three pilot sites. An early version however is presented here and will be updated in D9.5.

Timeline of activities		
Deadline	**Partner**	**Activity**
M26	Empirica	Final revision of the patient training material questionnaire
M27	BC, RJH	Translation of the questionnaire and interview questions
M30 – M31	Pilot sites, patients, empirica	After patients had their first training, the questionnaire for output 2, 4 and 5 will be filled and collected
M40	Empirica	Results of the output 2, 4 and 5 evaluation will be reported in D9.5
M40 – M45	Pilot sites, patients, empirica	At the end of the piloting trial, patients receive a questionnaire with open questions to evaluate outputs 1 and 3.
M48	Empirica	Results of the output 1 and 3 evaluation will be reported in D9.6

Table 23: Timeline of activities for the patient training material evaluation

3.3.2. Questionnaire for User Interaction Satisfaction

The Questionnaire for User Interaction Satisfaction (QUIS) is a tool developed by a multi-disciplinary team of researchers in the Human-Computer Interaction Lab (HCIL) at the University of Maryland at College Park in 1988 to assess the user's subjective satisfaction with human-computer interfaces. It measures attitude towards the following interface factors: screen factors, terminology and system feedback, learning factors, system capabilities, technical manuals, online tutorials, multimedia, voice recognition, virtual environments, internet access and software installation. In addition to English, the QUIS 7.0 is available in Spanish. Thus, it must only be translated to Swedish by our partners at Region Jamtland Harjedalen (RJH). It will run on any platform that supports a full implementation of JavaScript. The QUIS, in general, have been used in a medical research titled “Measurement of CPOE End-User Satisfaction Among ICU Physicians and Nurses” (Hoonakker, Carayon, & Walker, 2010) and recently a mobile application evaluation tilted “Usability evaluation of mobile applications using ISO 9241 and ISO 25062 standards”(Moumane, Idri, & Abran, 2016). By applying the questionnaire, one aims to improve the usability efficiency of a computer-based platform. Within the scope of C3-Cloud layer 2 evaluation, we will use QUIS 7.0 for both MDT members and patients. The results will be used, in an iterative fashion, for shaping the design and redesign of the C3-Cloud platform, discovering the potential areas for the improvement in human-computer interaction, and the comparative subjective user evaluation of the platform.

The full set of the adapted QUIS7 items can be seen in Annex 8.2.

Summary and research methods			
Type of evaluation	**Involved partner**	**Interviewees**	**Data collection**
Baseline questionnaire QUIS7	Warwick, empirica, pilot sites	150 Patients, 52 MDT members	M30 - M31
Closure questionnaire QUIS7	Warwick, empirica, pilot sites	150 Patients, 52 MDT members	M44 – M45
Purpose and Research Objectives			
Purpose	To explore a baseline and closure user satisfaction with the C3-Cloud software components		
Research Objectives	Evaluating the following categories of user interaction satisfaction: • Overall User Reactions • Screen • Terminology and System Information • Learning • System Capabilities • Technical Manuals and On-line help • Online Tutorials • Multimedia • Software Installation		

Table 24: Summary of QUIS7

Evaluation Description
A second QUIS7 round will be conducted directly after the initial user-training at the beginning of the trial. Patients and MDT members fill in the QUIS7 to evaluate their first impression as a baseline measurement which will be compared to the end-term measurement. Ethics application for the QUIS must, therefore, go through national ethics committees applications. Subsequently, Warwick together with empirica will evaluate remaining issues and develop recommendations for the technical partners what issues users have that can potentially be resolved. A third QUIS7 round will be conducted at the end of the trial. Patients and MDT members fill in the QUIS7 to evaluate their first impression as an end-term measurement which will be compared to the baseline measurement. It must be decided if this third QUIS7 round would be through the same patients as round 2 or not.

Table 25: Description of the data collection for QUIS7

Timeline of activities		
Deadline	**Partner**	**Activity**
M28	Empirica, pilot sites	Plan the collection of the questionnaires together with the pilot sites
M28	Pilot sites	Create lists of volunteers for the questionnaires (convenience sampling) for each pilot site

		SWFT: 50 patients and 16 MDT members; **BC**: 50 patients and 16 MDT members; **RJH**: 50 patients and 20 MDT members
M30 – M31	Pilots sites	Conduct the baseline questionnaires with the patients just after patients and MDT members have gone through the initial C3-Cloud component training sessions.
M32	Pilot sites	Report findings to empirica
M44 – M45	Pilots sites	Conduct the closure questionnaires with the patients
M45	Pilot sites	Report findings to empirica
M48	Empirica	The results will be reported in D9.6

Table 26: Timeline of activities for QUIS7

3.3.3. Self-developed Questionnaire and Interview

In addition to the other established questionnaires used for the evaluation, empirica, together with clinicians from the pilot sites and WP9 partners, develops a set of qualitative questions. Those will be specifically designed to evaluate the impact of C3-Cloud implementation on patients, their informal caregivers, MDT members and the wider service system.

The most recent set of questionnaire items and interview items can be seen in Annex 8.4. This list is however subject to ongoing changes and only a preliminary version. The list will be refined before the national ethics applications in M20.

Summary of research methods			
Type of evaluation	**Involved partner**	**Interviewees**	**Data collection**
Interview and Questionnaire	Empirica, pilot sites	150 Patients, 52 MDT members	M30 – M31 M41 – M45
Purpose and Research Objectives			
Purpose	To evaluate the impact of C3-Cloud implementation on patients, their informal caregivers, MDT members and the wider service system. Identifying and categorizing usability issues.		
Research Objectives	The objective is to investigate if the hypothesized C3-Cloud impact propositions are similarly experienced by the research population.		
	Evaluating Ease of use and usability; patient's perspective on clinical optimization, clinical and process quality changes, to a certain extent the clinical effectiveness (e.g. reduction of conflicts between clinical guidelines) and healthcare resource utilization.		

Table 27: Summary of research methods for self-developed questionnaires

Evaluation Description
The evaluation uses open and closed questionnaires, interviews and log files, targeting patients and MDT members.

It will evaluate the impact the different software components and focuses on the following evaluation topics: usefulness; ease of use/usability; safety; user experience; process quality and changes; healthcare resource utilization; clinical effectiveness; frequency of use of C3-Cloud components; patients' perspective on clinical optimization. A subset of the total sample of intervention patients and MDT members will be sampled (150 patients and 52 MDT members).

Table 28: Description of the data collection for self-developed questionnaires

Timeline of activities		
Deadline	**Partner**	**Activity**
M22	Pilot sites	Translation of the questionnaires and interview topic guides
M29	Pilot sites, empirica	Informing the patients and MDT members about the questionnaire and interviews and planning the interviews
M30 - M31	Pilot sites, empirica	Conducting the baseline interviews
M41 – M45	Pilot sites, empirica	Conducting the closure interviews

Table 29: Timeline of activities for self-developed questionnaires

3.4. Layer 4 evaluation: monitoring for impact modelling

Layer 4 prepares the modelling of the large-scale impact of C3-Cloud implementation after the 15-month exploratory trial, which will be carried out in T9.5. Layer 4 involves about 720 intervention patients, 720 control patients and 62 MDT members to gain high-volume data on qualitative parameters and quantitative measures.

3.4.1. Unified Theory of Acceptance and Use of Technology

The University of Warwick will develop a protocol and a C3-Cloud-adapted version of the UTAUT (Unified Theory of Acceptance and Use of Technology) questionnaire (Venkatesh, Morris, & Davis, User acceptance of information technology: Toward a unified view, 2003) to provide a reduced set of generic questions. The UTAUT will be conducted at the beginning of the pilot trial, just after the C3-Cloud application users (patients and MDT members) had training sessions to use the C3-Cloud components. The questionnaire will be repeated just before the end of the trial. The results from the initial UTAUT will be compared to the closure UTAUT questionnaire to evaluate differences in acceptance and use of C3-Cloud technology over the project duration.

The full set of UTAUT items can be seen in Annex 8.3.

Summary of research methods			
Type of evaluation	**Involved partner**	**Interviewees**	**Data collection**
Baseline Questionnaire (UTAUT)	Warwick, empirica, pilot sites	150 Intervention patients, 52 MDT members	M30 – M31

Closure Questionnaire (UTAUT)	Warwick, empirica, pilot sites	150 Intervention patients, 52 MDT members	M44 – M45
Purpose / motivation and Research Objectives			
Purpose / motivation	UTAUT aims at explaining user intention towards the application of a new technology and the resulting user behaviour. In C3-cloud, UTAUT will be used to assess the likelihood of success of adoption and use of the Personalised Care Plan Development Platform, the Coordinated Care and Cure Delivery Platform and Patient Empowerment Platform (PEP). End users will include both healthcare professionals and patients/informal carers, and therefore 2 different questionnaires will be used of the two groups (see templates at Annex 6.2).		
Research Objectives	To determine factors of performance expectancy, effort expectancy, social influence, cultural and language influence, adoption timeline and associated facilitating conditions on the intended adoption behaviour of the users of the C3-Cloud technology.		

Table 30: Summary of research methods for UTAUT

Description
The unified theory of acceptance and use of technology (UTAUT) was developed through review and consolidation of constructs from earlier research, including the Technology Acceptance Model (TAM3). TAM has been introduced to the world of e-commerce by Vankatesh and Bala (2008). According to them: "TAM was developed to predict individual adoption and use of new ITs. It posits that individuals' behavioral intention to use an IT is determined by two beliefs: perceived usefulness, defined as the extent to which a person believes that using an IT will enhance his or her job performance and perceived ease of use, defined as the degree to which a person believes that using an IT will be free of effort. It further theorizes that the effect of external variables (e.g. design characteristics) on behavioural intention will be mediated by perceived usefulness and perceived ease of use". In short "the TAM focuses on the determinants that influence Perceived Usefulness and Perceived Ease of Use of an innovation" (Jeffrey, 2015). For layer 4 evaluation, we will use a revised version of TAM: UTAUT, proposed by Venkatesh et al. (2003). UTAUT has already been used by Eckhard et al. to study 152 firms in Germany, who found out the impacts of the workplace's social influence on the adoption of technology (Eckhardt, Laumer, & Weitzel, 2009). Furthermore, UTAUT was used by Verhoeven et al. to study the technology impact on the behavioural change of some 714 freshmen after 6 months at a large university (Verhoeven, Heerwegh, & De Wit, 2010). UTAUT will be adapted to fit the purpose of the C3-Cloud evaluation. The Ethics application will be done through the Biomedical and Scientific Research Ethics Committee (BSREC) at the University of Warwick. Ethics applications must not be done through the national ethics boards as the UTAUT is not an intervention but an observation.

Table 31: Description of the UTAUT

Timeline of activities		
Deadline	**Partner**	**Activity**
M26	Warwick	Developing the protocol and the adapted UTAUT questionnaire items.

M27	Pilot sites	Translating the UTAUT questionnaire items to Spanish and Swedish language.
M30 - 31	Warwick, empirica, pilot sites, intervention patients, MDT members	Conducting the initial session of UTAUT questionnaires just after the 150 intervention patients and 52 MDT members had the training sessions to use the C3-Cloud components.
M44 - M45	Warwick, empirica, pilot sites, intervention patients, MDT members	Conducting the closure session of UTAUT questionnaires just before the end of the pilot trial.
M46	Warwick, empirica	Performing a regression analysis on the baseline and closure UTAUT results.
M48	Warwick, empirica	Reporting of the UTAUT results in D9.6

Table 32: Timeline of activities for UTAUT

3.4.2. eCare Client Impact Survey

The eCare Client Impact Survey (eCCIS), developed by empirica, will be used to evaluate the utility that the C3-Cloud application brings to the intervention patients. The full set of eCCIS items can be seen in Annex 8.4. The evaluation layer 3 sub-sample of 150 intervention patients will be used to conduct this questionnaire.

Summary of research methods			
Type of evaluation	**Involved partner**	**Interviewees**	**Data collection**
Questionnaire (eCCIS)	empirica, pilot sites	150 Intervention patients	M44-M45
Purpose and Research Objectives			
Purpose	The eCare Client Impact Survey evaluates the utility that the C3-Cloud application brings to the intervention patients (the 'clients').		
Research Objectives	Generate data on the service utility for intervention patients that will feed into the merged ASSIST and predictive modelling tool.		

Table 33: Summary of research methods for eCCIS

Evaluation Description
The instrument was originally developed by Work Research Centre (WRC) in collaboration with empirica in the CommonWell project (www.commonwell.eu) and further refined in the INDEPENDENT project (www.independent-project.eu). For exemplary results of its usage, see the final outcome reports of both projects. It primarily measures how care recipients (clients, patients) and informal carers (relatives, neighbours or friends) perceive the utility of an e-Care service. To this can be added scales addressing time use, willingness-to-pay and perception of care integration. For both care recipients and informal carers, the summary assessment module covers overall satisfaction with the service, whether the service is worth the effort involved in using it and whether the respondent would want to continue using the service or to use it again. The eCCIS is a model questionnaire that needs to be adapted (in 5 steps) to the purposes of a specific evaluation and the

local or national setting. The instrument will usually be applied retrospectively, i.e. when the respondent leaves the evaluation or the service. However, some parts of the instrument, e.g. the modules on time use and other specific impacts, can also be applied at earlier measurement points in order to measure changes over time.

Table 34: Description of the eCCIS

The timeline of activities for the eCCIS is subject to ongoing discussion with the three pilot sites. **Table 35** below is preliminary and will be updated in D9.5.

Timeline of activities		
Deadline	**Partner**	**Activity**
M44 – M45	Empirica, pilot sites, patients, MDT members	This questionnaire will be conducted at the end of the trial to feed into the impact evaluation and the scale-up modelling (ASSIST/predictive modelling)

Table 35: Timeline of activities for eCCIS

3.4.3. eCare User Impact Survey

The eCare User Impact Survey (eCUIS), developed by empirica, will be used to evaluate the utility that the C3-Cloud application brings to the MDT members. The full set of eCUIS items can be seen in Annex 8.6. The evaluation layer 3 sub-sample of 52 MDT members will be used to conduct this questionnaire.

Summary of research methods			
Type of evaluation	**Involved partner**	**Interviewees**	**Data collection**
Questionnaire (eCUIS)	empirica, pilot sites	52 MDT members	M44-M45
Purpose and Research Objectives			
Purpose	The eCare User Impact Survey evaluates the utility that the C3-Cloud application brings to the MDT members (the ‘users’).		
Research Objectives	Generate data on the service utility for MDT members that will feed into the merged ASSIST and predictive modelling tool.		

Table 36: Summary of research methods for the eCUIS

Evaluation Description
The instrument was originally developed by Work Research Centre (WRC) in collaboration with empirica in the CommonWell project (www.commonwell.eu) and further refined in the INDEPENDENT project (www.independent-project.eu). For exemplary results of its usage, see the final outcome reports of both projects. The eCUIS – eCare User Impact Survey primarily measures how care recipients (clients, patients) informal carers (relatives, neighbours or friends) and service provider staff perceive the utility of an e-Care service. To this are added scales addressing time use, willingness-to-pay and perception of care integration. For both care recipients and informal carers,

the summary assessment module covers overall satisfaction with the service, whether the service is worth the effort involved in using it and whether the respondent would want to continue using the service or to use it again. The eCUIS is also a model questionnaire that needs to be adapted (in 5 steps) to the purposes of a specific evaluation depending on the questions and other considerations. The instrument will usually be applied retrospectively, i.e. when the respondent leaves the evaluation or the service. Parts of the instrument and especially the modules on time use and specific impacts can also be applied at earlier measurement points in order to measure changes over time.

Table 37: Description of the eCUIS

The timeline of activities for the eCUIS is subject to ongoing discussion with the three pilot sites. **Table 38** below is preliminary and will be updated in D9.5.

Timeline of activities		
Deadline	**Partner**	**Activity**
M45	Empirica, pilot sites, patients, MDT members	This questionnaire will be conducted at the end of the trial to feed into the impact evaluation and the scale-up modelling (ASSIST/predictive modelling)

Table 38: Timeline of activities for eCUIS

3.4.4. Log file exports

The logfile exports aggregate anonymized data from MDT members and patients on their use of the C3-Cloud software components and focuses on the following evaluation topics: healthcare resource utilization; clinical effectiveness; frequency of use of C3-Cloud components. The data exports will inform empirica and Osakidetza for T9.5 in modelling the large-scale impact of C3-Cloud solutions.

In addition, logfiles exports from the electronic health records of the intervention and also the control patients will be done, to evaluate differences in healthcare resource utilization during the 15-month piloting trial. This includes for example: medication reduction; re-admissions; number of adverse drug events; number of virtual sessions; or resource redistribution.

Summary of research methods		
Type of evaluation	**Involved partner**	**Data collection**
Anonymized logfile exports from C3-Cloud repositories and electronic health records	Technical partners (SRDC, Medixine, Cambio, Warwick, INSERM), empirica	M30-M45
Purpose and Research Objectives		
Purpose	Logfile exports will be done to provide data for the impact and large-scale modelling for the C3-Cloud application.	
Research Objective	Evaluating, based on a modelling approach, what the large-scale impact of C3-Cloud solutions is.	

Table 39: Summary of research methods for log file exports

Evaluation Description
For the impact evaluation and large-scale modeling, the layer 4 evaluation gathers logfile data on indicators such as usage of C3-Cloud components (for the patients and MDT members) as well as resource utilization (for patients and controls) as detailed in the Annex. This data will be aggregated for a statistical data analysis evaluation (see chapter 6).

Table 40: Description of the data collection for log file exports

Timeline of activities		
Deadline	**Partner**	**Activity**
M30-M45	Patients and MDT members	They use the C3-Cloud software components and generate a pool of data on the frequency and types of use
M44	Technical partners	Production of anonymized logfile/data exports from the C3-Cloud software components and electronic health records (for the controls) based on indicators developed by empirica and Osakidetza in the scope of T9.5.
M45	Technical partners	Provision of logfile/data exports for empirica and Osakidetza for usage in the ASSIST/Predictive Modelling Merger (T9.5)

Table 41: Timeline of activities for log file exports

3.4.5. Impact Modelling

In addition to the other established questionnaires used for the layer 4 evaluation, empirica, together with Osakidetza and WP9 partners will develop a set of qualitative and quantitative questions. These will be specifically designed to evaluate the impact of C3-Cloud implementation on patients, MDT members and the wider service system. The current, preliminary set of items and propositions that will be evaluated with the impact modelling tool are listed in Annex 8.6. This list will, however, is subject to ongoing revision until the national ethics applications in M20 and items may be added later during the development phase of the impact modelling tool.

Summary of research methods		
Type of evaluation	**Involved partner**	**Data collection**
Using Expert interviews for estimations, data exports from the C3-Cloud system	Empirica, Osakidetza, pilot sites, technical partners	M30 – M45
Purpose and Research Objectives		
Purpose	In line with the specific C3-Cloud objectives (SO) SO6 and SO8 detailed in the DoA, C3-Cloud will develop an innovative large-scale impact modeling tool for industrial exploitation and large-scale rollout, by merging the Predictive Modelling of Resource Use tool developed by Osakidetza in the CareWell project and the cost-benefit analysis tool for	

	innovative ICT services 'ASSIST' developed by empirica. This merger-tool will combine both approaches to make use of their complementary strengths and will be used for large-scale impact modelling of the C3-Cloud application by evaluating the estimated/predicted impact of C3-Cloud application.
Research Objectives	Evaluation of C3-Cloud service utilization (e.g. number of care plans developed, intensity of use, number of virtual sessions or time use for C3-Cloud tasks)
	Evaluation of healthcare resource utilization with C3-Cloud services
	Help decision makers to decide on further using the C3-Cloud application to foster exploitation and innovation.
	Identification of disadvantaged stakeholders that are affected by benefit shifts during change management.

Table 42: Summary of research methods for the ASSIST and Predictive Modelling Merger

Evaluation Description
Assist cost-benefit analysis tool ASSIST is an assessment and evaluation tool for telemedicine that was developed in the context of a project funded by the European Space Agency, which ran from 2010 to 2012. It was originally developed for use in the context of telemedicine and telehealth services, specifically to assess the economic viability of telemedicine pilot projects. During the validation phase, ASSIST was successfully applied by five telemedicine projects. A core aim of ASSIST is to facilitate the transposition of a pilot project into routine service operation and to support service providers in achieving a sustainable economic model where service benefits are higher than service costs. It also facilitates the transposition of a pilot project into routine service operation and supports service providers in achieving a sustainable economic model. In short, It consists of a methodological approach, a service assessment model and a software toolkit to help project leaders, entrepreneurs and start-ups to objectively and rigorously evaluate their solution from an evidence-based multi-stakeholder (individuals and organisations that are actively involved or passively affected by a telemedicine service) perspective. The tool's assessment process is also in three steps: 1- Service assessment model setup (the service change is analyzed to identify the key components like applicable governance and the reimbursement model, stakeholders and the financial impacts (costs and benefits on the stakeholders), 2- Data collection and monetization and 3- Calculation of performance measure (the main outcome measure is based on the ratio of total costs to total benefits, i.e. including financial costs and benefits, resource costs and benefits and intangible costs and benefits). **Predictive modelling** The Deming's cycle, also known as the Plan-Do-Check-Act (PDCA) cycle, is an iterative four-step management method used for the control and continuous improvement of processes and products. Modelling serves to calculate the Budget Impact Analysis (BIA) by reproducing the natural history of multi-morbid patients in both the standard scenario and the new scenario related to the new intervention which results in implementation, effectiveness (how does new intervention affect the number of contacts to health professionals) and costs. A BIA projects the burden of the target population within the conventional or baseline scenario and analyses how this burden would change if the intervention achieved the organizationally defined goal. At first, the BIA provides the long-term perspective and then it helps explore the potential impact of the intervention.

Developing an impact modelling tool by merging ASSIST and predictive modelling, will inform decision making in the management of integrated care and on the expected impact of scaling up the use of C3-Cloud. C3-cloud means a Collaborative Care Cure Cloud Architecture for Addressing the Needs of Multi-morbidity and Managing Poly-pharmacy that will require being transferred to other countries. In this line, the objective of layer 4 evaluation in T9.1 and T9.5 is to develop a new tool for informing integrated care management taking profit of two approaches (ASSIST and predictive modelling) that have been previously applied in other European projects like CareWell and SmartCare. By merging them, we try to improve reliability and validity of the tool as this new tool would incorporate the comprehensive perspective applied by ASSIST and the flexible engine developed in modelling to represent mathematically the natural history of the disease. The conceptual model would include not only the health system but also the complete set of stakeholders. Model parameterization is a challenge as data required for all stakeholders cannot probably be obtained from evidence-based sources. 720 patients and 62 MDT members will be followed over the trial duration and compared with a control group.

Table 43: Description of the data collection for ASSIST and Predictive Modelling Merger

Timeline of activities		
Deadline	**Partner**	**Activity**
M30	empirica, Osakidetza	Setting up a model for the large-scale impact assessment
M31	empirica, Osakidetza and pilot sites	Developing indicators or propositions on the impact of C3-Cloud application together with the pilot sites
M33	empirica, Osakidetza and pilot sites	Gathering data for modelling large-scale impact with expert interviews in the pilot sites.
M34	empirica, Osakidetza	Predictive testing phase of large-scale impact modelling, using estimations
M40	empirica	Delivering interim evaluation results of the C3-Cloud pilot application (based on T4.1, T4.2, T9.3 and T9.5 input)

Table 44: Timeline of activities for ASSIST and Predictive Modelling Merger

4. Sampling for evaluation layers 1 and 2

The sampling of research participants for layers 1 and 2 will be done based on convenience sampling. Available experts and volunteering patients or MDT members will be employed for layer 1 evaluation and approached by the pilot sites. Layer 2 evaluation will make use of available experts and patients and MDT members from the same age group as the actual C3-Cloud patients during the trial, but not necessarily with the same or similar characteristics (with respect to inclusion and exclusion criteria): the pilot sites have freedom with respect to the selection of participants.

Table 2 shows the number of involved participants in evaluation layers 1 and 2.

5. Sampling for evaluation layers 3 and 4

The 15-month pilot technology trial needs a more careful sampling of study participants (intervention and control patients, MDT members) based on specific inclusion and exclusion criteria. The main information is summarized below, while Deliverable D10.2 can be taken for reference and more detailed information on the recruitment procedures for the trial participants. The preparation for the recruitment of the majority of participants for the 15-month piloting trial (1,440 patients and 62 MDT members) starts in M20 and recruitment should be finalized by M26, to allow for sufficient time for MDT member training and patient training.

As this research is a pilot technology trial, a power calculation for the expected primary outcome was not done to determine the necessary sample size. Rather the number of involved participants serves to validate the feasibility and acceptability of the findings and to inform future research about an expected difference in primary outcomes for more accurate randomized controlled trials with appropriate statistical power.

Table 2 shows the number of involved participants for evaluation layers 3 and 4. Figure 6 illustrates the pool of patients for evaluation layers 3 and 4, from which the trial participants will be sampled at random.

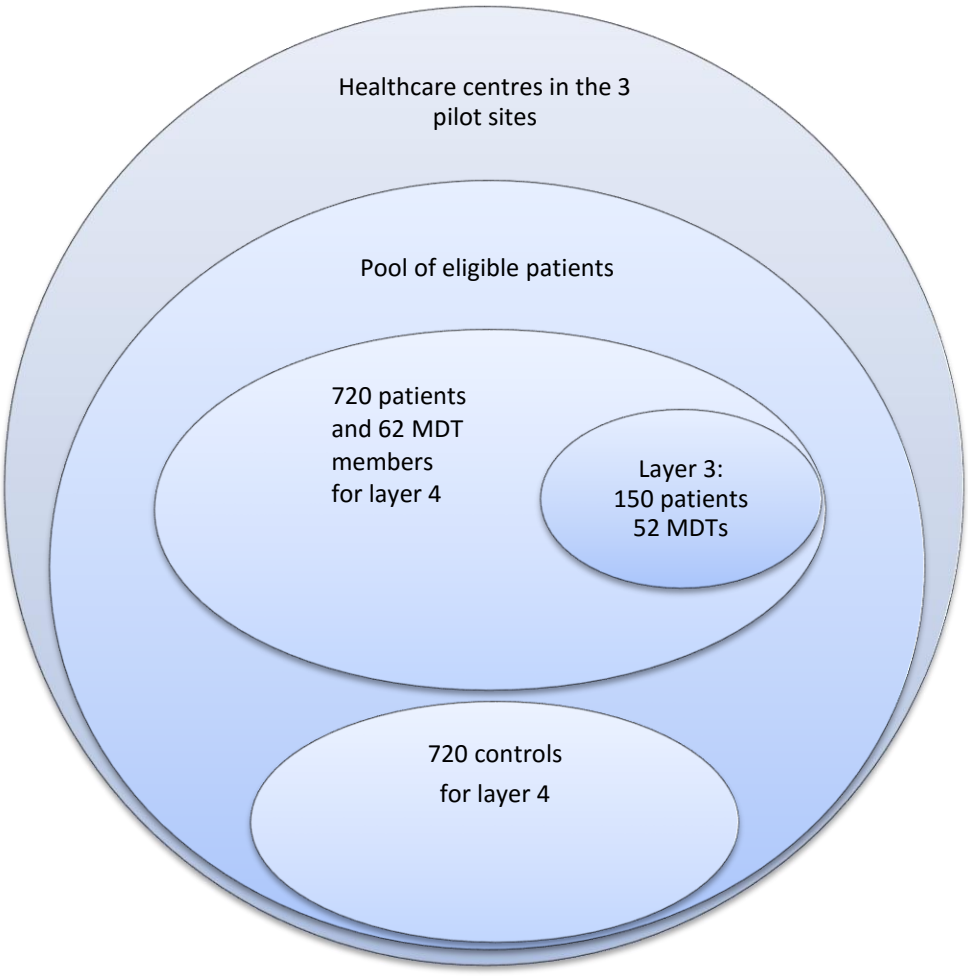

Figure 6: Sampling of study participants from health care centres for layers 3 and 4

5.1. Inclusion criteria

As developed and stated in deliverable D10.2, patients are eligible for recruitment if:

They are aged 65 or older
They are multimorbid patients that suffer from two or more of the following four conditions in various disease combinations (two conditions set as the minimum threshold): • Type II Diabetes • Renal Failure with eGFR/GFR 30 – 59 (measured or estimated glomerular filtration rate) • Heart Failure in compliance with NYHA I-II (New York Heart Association classification of heart failure) • Mild or moderate depression
They still live and generally plan on living in their home (or in the community) for the 15-month trial duration.
They or their informal caregiver pass the ICT Handling Self-Check (see Deliverable D10.4, Annex 8.3) (i.e. they have access to and some familiarity with the use of ICT).
They, or their informal caregiver, have stable access to the internet and at least one of the following devices readily available to use the C3-Cloud components: Computer; Notebook; Smartphone; Tablet. This includes the use of Internet Browsers to open the C3-Cloud patient dashboards online.
They are able to provide informed consent.

Table 45: Patient inclusion criteria

5.2. Exclusion criteria

The exclusion criteria include almost completely the reverse of the inclusion criteria. In reference to deliverable D10.2 patients are not eligible for recruitment if:

They are aged 64 or below
They suffer from any of the following conditions: • Severe Renal Failure with eGFR/GFR <30 • Severe Heart Failure in compliance with NYHA III-IV • Severe depression
They have other debilitating conditions that impair their decision making capability or their life expectancy (e.g. end-of-life patients or cancer patients)
They or their informal caregivers do not pass the ICT Handling Self-Check (i.e. they do not have access to suitable IT devices and do not have some familiarity with the use of ICT).
They have disabilities or other health conditions that would prevent their active involvement in the study project or which prevent them from carrying out essential functions of the trial.
They live in a care institution, for instance in a residential home or nursing home.
Their health care expenses are covered by a private insurance: in the C3-Cloud pilot sites, private insurances have no data exchange with EHRs.
They do not speak the regional language: English for SWFT; Spanish for the Basque country; Swedish for RJH
They are unable to provide informed consent for study participation.

Table 46: Patient exclusion criteria

Patients with further chronic diseases and other co-morbidities or symptoms, for example, frailty, sleeping problems, malnourishment or anxiety, will not be excluded from recruitment. Informal caregivers who pass the ICT Handling Self-Check can substitute for the patient if the patient does not pass the ICT Handling Self-Check – the patient-informal caregiver pair can then still be recruited.

5.3. Blinding of trial participants

Since the C3-Cloud software components must be actively used during the 15-month pilot application trial by patients, their informal caregivers and the MDs, the trial has to be performed unblinded. Patients (including their informal caregivers) will, therefore, know if they are an intervention or control patient and MDT members will know if they currently treat an intervention or a control patient. However, the sampling of patients to either the intervention or the control group will be randomized to avoid selection bias.

The unblinded design is appropriate to reach primary study objectives. Tight monitoring of the patients will protect against attrition bias and adequate countermeasures will be taken during the study if necessary.

5.4. Randomization

Once the pilot sites have provided a list of eligible patients who meet the inclusion and exclusion criteria (see D10.2), they must be randomized to avoid selection bias. The randomization will be done along the following aspects:

- Creating a subset of eligible patients who meet the inclusion criteria from the totality of eligible patient in the healthcare centre.
- Allocation of the patients to either the intervention or control group
- Allocation of a smaller sample of patients from the intervention group to a sub-sample for evaluation layer 3

These aspects are further elaborated below.

5.4.1. Randomization round 1

In the first round of randomization, the three pilot sites lists of all patients that meet the inclusion criteria (except the ICT Handling Self-Check) will be used to create three local lists with a random sample of patients that will be approached for study participation and who will be informed about the research project. This first randomization round generates lists with a number of patients that is 14% larger than the actual recruitment target (including a 20% dropout rate) of patients per pilot site, to adjust for patients that are approached but deny their participation and for patients that do not pass the ICT Handling Self-Check (see Table 47). All approached patients receive a patient information sheet and the ICT Handling Self-Check (for the ICT Handling Self-Check, please seek reference to deliverable D10.4, Annex 8.4).

	Randomized Sample-Size for patients in randomization round 1		
South Warwickshire	200 + 20% (40) + 14% (34)	=	**274**
Basque Country	500 + 20% (100) + 14% (84)	=	**684**
Jämtland Härjedalen	500 + 20% (100) + 14% (84)	=	**684**
Total			**1,642**

Table 47: Sample-size for the randomization round 1

5.4.2. Randomization round 2

In the second round of randomization, patients will be randomized to either the intervention branch or the control branch of the study just after they have signed the informed consent form. This will be done at the level of individual patients (Figure 7) and not the level of care centres or members of the MDT members. This allows minimizing confounding factors when analysing the results (e.g. health professional's knowledge and skills, available resources, organizational differences between health centres). Figure 7 illustrates the randomization level of study participants to either the intervention or the control branch: A health care centre employs several members of the MDT members who each treat several candidate patients. Randomization is done at the level of individual patients and per pilot site as to ensure that the anticipated number of intervention patients and controls is being recruited to each branch at each site.

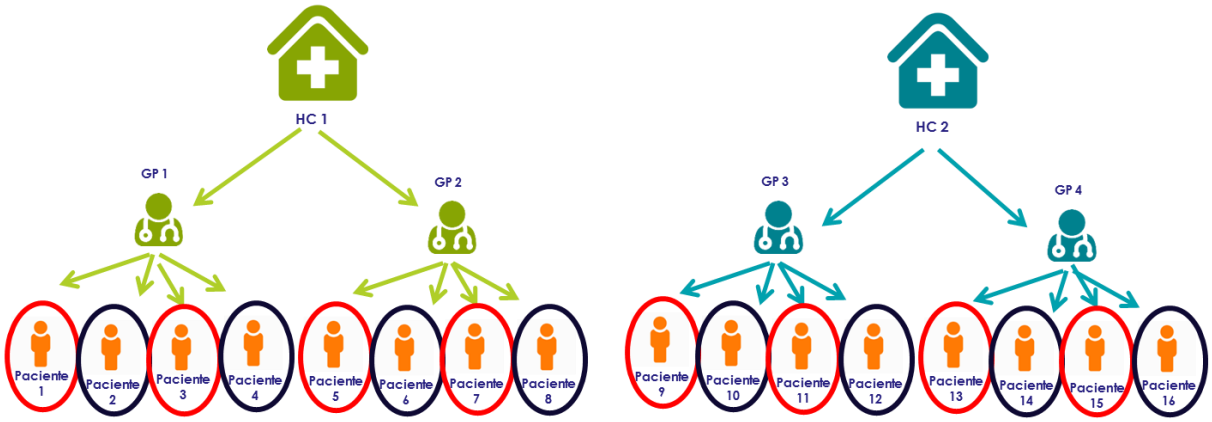

Figure 7: Randomization of study participants at patient level

In the illustrated exemplary scenario, patients circled in red (1, 3, 5, 7, 9, 11, 13 and 15) would be allocated to the intervention branch and patients circled in blue (2, 4, 6, 8, 10, 12, 14 and 16) would be allocated to the control branch.

An online-based tool will be used to systematically randomize each consented patient in the pilot sites to either the intervention or the control branch:

- When an MDT member has obtained informed consent for study participation from the patient, an online tool will be used to obtain a C3-Cloud patient identification number, which also codes the allocation to either the intervention or the control group.
- The assignment of either intervention or control patient will be communicated to the patient once the healthcare professional has gotten the information from the online tool.
- The result and the C3-Cloud patient identification number will be noted on the informed consent sheet and the C3-Cloud electronic patient record.
- The randomization will be done systematically until the defined number of patients and controls in each pilot site is reached.

5.4.3. Randomization round 3

In the third round of randomization, the list of intervention patients will be used to select a random sample of patients that will participate in evaluation layer 3 and answer the respective questionnaires.

6. Statistical methods and data analysis

6.1. Analysis and reporting of quantitative data

Descriptive statistics will be used for the analysis and reporting of this technology exploratory trial. The trial will be reported according to the CONSORT guidelines.

Continuous data will be summarised by the means; categorical data by percentages. A two-tailed student t-test will be used for comparison between groups. Linear regression will be used to adjust for baseline covariates (age and sex as a minimum). Residuals will be checked for normality. Fisher's exact test or the Chi-squared test will be used for categorical variables with nominal scales and the Mann-Whitney U test for categorical variables with ordinal scales. No subgroup analyses are planned. Missing values will not be imputed but reported in tables. All tests will be assessed at the 5% statistical significance level. The SPSS statistical computer package will be used to analyse the data.

6.2. Analysis of qualitative data

Qualitative analysis will follow the guidance by Yin on „Case Study Research: Design and Methods (Yin, 2009). Reporting will follow established scientific practice such as the STROBE statement (J.P., et al., 2007).

A summary of the qualitative questionnaires (for example the Patient Training Material Evaluation; Self-developed questionnaire) and focus or discussion groups (for example the Delphi method) must be provided by the partner who carries out the data collection for the respective evaluation. Qualitative data will be analyzed compared and reported per pilot site (briefly) and as a summary for all the pilot sites.

Pilot sites will be provided with a guide, including the timeline for all necessary activities and instructions on how to perform an interview, a focus group, how to collect the questionnaires and how to use LimeSurvey. This is, however, out of the scope of this deliverable.

The data analysis will check for a number of possible confounders, including:

Possible Confounders	Variable format
Year of Birth	Date
Gender	Binary
Level of education	Categorical
Marital Status	Categorical
People older than 18 living in household	Categorical
Mobile phone use	Binary
PC/laptop use	Binary

Table 48: List of possible cofounders

6.3. Data management

A LimeSurvey online tool will be established on empirica (WP9 leader) servers for the following questionnaires: Patient Training Material Evaluation; QUIS7; UTAUT; eCCIS; eCUIS. Pilot site patients will use an online link or a printed questionnaire version to answer each respective questionnaire. Patients who cannot use the online version of the questionnaire, will receive assistance from a study assistant in the pilot sites, who transfers the patients' hardcopy inpout in the online LimeSurvey. The questionnaire data is stored safely on empirica

Each pilot site will be responsible for collecting their own data, and cleaning data in accordance with this evaluation protocol. An internal timetable to plan all activities (beyond what is described in this deliverable already) will be developed by empirica, the pilot sites and the technical partners, to inform the partners of the procedures and to ensure timely data aggregation.

De-identified logfile extracts from the C3-Cloud platform (patients) and electronic health records (controls) from each pilot site will be uploaded to a central C3-Cloud online data sharing platform, hosted by Warwick.

The pilot sites are responsible for ongoing upload of collected data to the central online data sharing platform during the evaluation period. The deadline for data upload to the central web-database will be 1st week of each month when a certain evaluation was due (compare with the timetable in Figure 2, starting at enrolment.

6.4. Data cleansing

The following data cleansing will be performed when the data has been collected in the central web-based database before performing the analyses and to avoid that errors impact the study results:

Missing Values	• If one subject has <50% missing values, the remaining values are allowed in analyses. • Analyses that requires some of the missing data will be run without the values, and reporting will present the total number of subjects in all analyses.
Outlier	• If a value is considered to be a realistic outlier, the value will remain unchanged. • Sensitivity analysis will be carried out to assess the impact of the outliers. • If a value is considered to be an unrealistic outlier, the value will be re-coded as missing.
Range Check	• A value is considered illegal if it falls outside the min-max range of possible values, and will be re-coded as missing.
Categorical variables	• All observations must relate to the predefined categories, otherwise the value will be registered as missing.

Table 49: Data Cleansing

7. Future work

This research protocol does not yet include a description of the evaluation of the use of medical devices. At the moment of submission of this deliverable, there is an ongoing discussion among the consortium in how and where medical devices will be used. A description of the evaluation of medical devices will be added to the central ethics applications document that is used by the pilot sites for their national ethics applications in M20.

Also, the use of patient questionnaire for their individual health assessment, using a set of disease specific and general questionnaire, is currently an ongoing discussion among the consortium. If and how the use of these questionnaires for patients and MDT members will be evaluated, is subject to further discussion and will also be addressed in the central ethics applications documents.

8. Annex

8.1. Patient training material evaluation

The questionnaires below will be used for the patient training material evaluation.

Questions to evaluate "Output 1 - Core Materials (existing leaflets, web pages, etc.)" and "Output 3 – Peer support groups"

1. What did you like most about the offered training material?
Your answer:
2. Please describe in your own words the main problems you have faced (if any) with the use of the training material?
Your answer:
3. Please describe in a few words if and how the training material affected your capability to manage your health?
Your answer:
4. Is the way and sequence in which training material or care plans are offered to you helpful and appropriate / adequate?

Your answer:
5. What additional material or information do you think would be helpful to you?
Your answer:
6. Do you think the provided material helps you to learn from other patients with multi-morbidity?
Your answer:
7. What are your thoughts about supporting and getting support from other patients by engaging with them in support groups?

Your answer:

8. Please rate the following statement:

"The way in that my Patient Empowerment Platform directed me to training material was intuitive and natural".

I strongly agree	**I agree**	**I neither agree, nor disagree**	**I disagree**	**I strongly disagree**

9. What are your suggestions / recommendation for future enhancements to the training material?

Your answer:

Questionnaire on "Output 2 – Video", "Output 4 –Information Leaflet about the training materials" and "Output 5 – Wallet card"

The following questionnaire will be presented only once for all outputs 2, 4 and 5.

Statement	I strongly agree	I agree	Neither agree nor disagree	I disagree	I strongly disagree	Not applicable
Overall, I am satisfied with how easy to understand the training materials were.						
I feel comfortable using the training materials.						
I believe the training materials are useful to improve my capability and confidence to manage my health condition.						
I trust the information in the training materials that were presented to me.						
The way in that my Patient Empowerment Platform directed me to training material was intuitive and natural.						
The training materials encourage me to take positive steps in the improvement and management of my health condition.						

The following questionnaire will be presented to the patients for all outputs 2, 4 and 5 separately.

Please rate the following:

How easy or difficult was it to understand the information in the materials provided?

Very easy	Easy	Average	Difficult	Very difficult	Not applicable

How do you rate the material overall in its capability to support you using the PEP?

Very good	Good	Average	Bad	Very bad	Not applicable

How often did you watch/use/access the material?

More than once a week	Once a week	Every other week	Once a month	Every other month	On specific occasions	Only once during the project	Not applicable

Question	Yes Definitely	Yes to some extent	no
Is the way and sequence in which training materials are offered helpful and adequate?			
Are the training materials useful in supporting you in PEP usage?			

Do you now know what you can do to help yourself, managing your health condition better?			
Did the training materials help you with your understanding of the disease?			
Were you encouraged to adopt a higher degree of self-management?			
Do you think the provision of training materials make it easier to use the PEP?			

8.2. QUIS7

The presented QUIS7 questionnaire is a preliminary, adapted version of the QUIS. This adapted QUIS7 questionnaire will be tested during the heuristic usability testing with a small group of C3-Cloud users (chapter 3.2.2).

Identification number:

_____

System code: _____ PEP

_____ PCPDP and C3DP

Age: _____

Gender: _____**male**

_____**female**

PART 1: Overall User Reactions

Please circle the numbers, which most appropriately reflect your impressions about using this computer system.

Not Applicable = NA.

3.1	Overall reactions to the system:	Terrible wonderful 1 2 3 4 5 6 7 8 9	NA
3.2		frustrating satisfying 1 2 3 4 5 6 7 8 9	NA
3.3		dull stimulating 1 2 3 4 5 6 7 8 9	NA
3.4		difficult easy 1 2 3 4 5 6 7 8 9	NA
3.5		Inadequate power adequate power 1 2 3 4 5 6 7 8 9	NA
3.6		rigid flexible 1 2 3 4 5 6 7 8 9	NA

PART 2: Screen

4.1	Characters on the computer screen	hard to read ... easy to read 1 2 3 4 5 6 7 8 9	NA
4.1.1	Image of characters	fuzzy ... sharp 1 2 3 4 5 6 7 8 9	NA
4.1.2	Character shapes (fonts)	barely legible ... very legible 1 2 3 4 5 6 7 8 9	NA
4.2	Highlighting on the screen	unhelpful ... helpful 1 2 3 4 5 6 7 8 9	NA
4.2.2	Use of blinking	unhelpful ... helpful 1 2 3 4 5 6 7 8 9	NA
4.2.3	Use of bolding	unhelpful ... helpful 1 2 3 4 5 6 7 8 9	NA
4.3	Screen layouts were helpful	never ... always 1 2 3 4 5 6 7 8 9	NA
4.3.1	Amount of information that can be displayed on the screen	inadequate ... adequate 1 2 3 4 5 6 7 8 9	NA
4.3.2	Arrangement of information on screen	illogical ... logical 1 2 3 4 5 6 7 8 9	NA
4.4	Sequence of screens	Confusing ... clear 1 2 3 4 5 6 7 8 9	NA
4.4.1	Next screen in a sequence	unpredictable ... predictable 1 2 3 4 5 6 7 8 9	NA
4.4.2	Going back to the previous screen	impossible ... easy	NA

4.4.3	Progression of work-related tasks	1 2 3 4 5 6 7 8 9 Confusing clearly marked 1 2 3 4 5 6 7 8 9	NA

Please write your comments about the screens here:

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PART 3: Terminology and System Information

5.1	Use of terminology throughout system	inconsistent consistent 1 2 3 4 5 6 7 8 9	NA
5.1.2	Work related terminology	inconsistent consistent 1 2 3 4 5 6 7 8 9	NA
5.1.3	Computer terminology	inconsistent consistent 1 2 3 4 5 6 7 8 9	NA
5.2	Terminology relates well to the activities you are doing?	never always 1 2 3 4 5 6 7 8 9	NA
5.2.1	Computer terminology is used	too frequently appropriately 1 2 3 4 5 6 7 8 9	NA
5.2.2	Terminology on the screen	ambiguous precise 1 2 3 4 5 6 7 8 9	NA
5.3	Messages which appear on screen	inconsistent consistent 1 2 3 4 5 6 7 8 9	NA
5.3.1	Position of instructions on the screen	inconsistent consistent 1 2 3 4 5 6 7 8 9	NA
5.4	Messages which appear on screen	confusing clear 1 2 3 4 5 6 7 8 9	NA
5.4.1	Instructions for commands or functions	confusing clear 1 2 3 4 5 6 7 8 9	NA
5.4.2	Instructions for correcting errors	confusing clear	NA

		1 2 3 4 5 6 7 8 9	
5.5	Computer keeps you informed about what it is doing	never always 1 2 3 4 5 6 7 8 9	NA
5.5.1	Animated cursors keep you informed	never always 1 2 3 4 5 6 7 8 9	NA
5.5. 2	Performing an operation leads to a predictable result	never always 1 2 3 4 5 6 7 8 9	NA
5.5.3	Controlling amount of feedback	impossible easy 1 2 3 4 5 6 7 8 9	NA
5.5.4	Length of delay between operation	unacceptable acceptable 1 2 3 4 5 6 7 8 9	NA
5.6	Error messages	unhelpful helpful 1 2 3 4 5 6 7 8 9	NA
5.6.1	Error messages clarify the problem	never always 1 2 3 4 5 6 7 8 9	NA
5.6.2	Phrasing of error messages	unpleasant pleasant 1 2 3 4 5 6 7 8 9	NA

Please write your comments about terminology and system information here:

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PART 4: Learning

6.1	Learning to operate the system	difficult easy 1 2 3 4 5 6 7 8 9	NA
6.1.1	Getting started	difficult easy 1 2 3 4 5 6 7 8 9	NA
6.1.2	Learning advanced features	difficult easy 1 2 3 4 5 6 7 8 9	NA
6.1.3	Time to learn to use the system	slow fast 1 2 3 4 5 6 7 8 9	NA
6.2	Exploration of features by trial and error	discouraging encouraging 1 2 3 4 5 6 7 8 9	NA
6.2.1	Exploration of features	risky safe 1 2 3 4 5 6 7 8 9	NA
6.2.2	Discovering new features	difficult easy 1 2 3 4 5 6 7 8 9	NA
6.3	Remembering names and use of commands	difficult easy 1 2 3 4 5 6 7 8 9	NA
6.3.1	Remembering specific rules about entering commands	difficult easy 1 2 3 4 5 6 7 8 9	NA
6.4	Tasks can be performed in a straight-forward manner	never always 1 2 3 4 5 6 7 8 9	NA

6.4.1	Number of steps per task	too many … just … right 1 2 3 4 5 6 7 8 9	NA
6.4.2	Steps to complete a task follow a logical sequence	never … always 1 2 3 4 5 6 7 8 9	NA
6.4.3	Feedback on the completion of sequence of steps	unclear … clear 1 2 3 4 5 6 7 8 9	NA

Please write your comments about learning here:

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PART 5: System Capabilities

7.1	System speed	too slow fast enough 1 2 3 4 5 6 7 8 9	NA
7.1.1	Response time for most operations	too slow fast enough 1 2 3 4 5 6 7 8 9	NA
7.1.2	Rate information is displayed	too slow fast enough 1 2 3 4 5 6 7 8 9	NA
7.2	The system is reliable	never always 1 2 3 4 5 6 7 8 9	NA
7.2.1	Operations are	undependable dependable 1 2 3 4 5 6 7 8 9	NA
7.2.2	System failures occur	frequently seldom 1 2 3 4 5 6 7 8 9	NA
7.2.3	System warns you about potential problems	never always 1 2 3 4 5 6 7 8 9	NA
7.3	System tends to be	noisy quiet 1 2 3 4 5 6 7 8 9	NA
7.3.1	Mechanical devices such as fans, disks, and printers	noisy quiet 1 2 3 4 5 6 7 8 9	NA
7.3.2	Computer generated sounds are	annoying pleasant 1 2 3 4 5 6 7 8 9	NA
7.4	Correcting your mistakes	difficult easy 1 2 3 4 5 6 7 8 9	NA
7.4.1	Correcting typos		

7.4.2	Ability to undo operations	complex simple 1 2 3 4 5 6 7 8 9 inadequate adequate 1 2 3 4 5 6 7 8 9	NA NA
7.5 7.5.1 7.5.2	Ease of operation depends on your level of experience You can accomplish tasks knowing only a few commands You can use features/shortcuts	never always 1 2 3 4 5 6 7 8 9 with difficulty easily 1 2 3 4 5 6 7 8 9 with difficulty easily 1 2 3 4 5 6 7 8 9	NA NA NA
Please write your comments about system capabilities here: _____ _ _____ _ _____ _			

PART 6: Technical Manuals and On-line help

8.1	Technical manuals are	confusing clear 1 2 3 4 5 6 7 8 9	NA
8.1.1	The terminology used in the manual	confusing clear 1 2 3 4 5 6 7 8 9	NA
8.2	Information from the manual is easily understood	never always 1 2 3 4 5 6 7 8 9	NA
8.2.1	Finding a solution to a problem using the manual	impossible easy 1 2 3 4 5 6 7 8 9	NA
8.3	Amount of help given	inadequate adequate 1 2 3 4 5 6 7 8 9	NA
8.3.1	Placement of help messages on the screen	confusing clear 1 2 3 4 5 6 7 8 9	NA
8.3.2	Accessing help messages	difficult easy 1 2 3 4 5 6 7 8 9	NA
8.3.3	Content of online help messages	difficult easy 1 2 3 4 5 6 7 8 9	NA
8.3.4	Amount of help given	inadequate adequate 1 2 3 4 5 6 7 8 9	NA
8.3.5	Help defines specific aspects of the system	inadequately adequately 1 2 3 4 5 6 7 8 9	NA
8.3.6	Finding specific information using the online help	difficult easy 1 2 3 4 5 6 7 8 9	NA
8.3.7	On-line help		

		useless helpful 1 2 3 4 5 6 7 8 9	

Please write your comments about technical manuals and on-line help here:

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PART 7: Online Tutorials

9.1	Tutorial was	useless helpful 1 2 3 4 5 6 7 8 9	NA
9.1.1	Accessing on-line tutorial	difficult easy 1 2 3 4 5 6 7 8 9	NA
9.2	Manoeuvring through the tutorial was	difficult easy 1 2 3 4 5 6 7 8 9	NA
9.2.1	Tutorial is meaningfully structured	never always 1 2 3 4 5 6 7 8 9	NA
9.2.2	The speed of presentation was	unacceptable acceptable 1 2 3 4 5 6 7 8 9	NA
9.3	Tutorial content was	useless helpful 1 2 3 4 5 6 7 8 9	NA
9.3.1	Information for specific aspects of the system was complete and informative	never always 1 2 3 4 5 6 7 8 9	NA
9.3.2	Information was concise and to the point	never always 1 2 3 4 5 6 7 8 9	NA
9.4	Tasks can be completed	with difficulty easily 1 2 3 4 5 6 7 8 9	NA
9.4.1	Instructions given for completing Tasks	confusing clear 1 2 3 4 5 6 7 8 9	NA
9.4.2	The time given to perform tasks	inadequate adequate 1 2 3 4 5 6 7 8 9	NA

9.5	Learning to operate the system using the tutorial was	difficult easy 1 2 3 4 5 6 7 8 9	NA
9.5.1	Completing system tasks after using only the tutorial	difficult easy 1 2 3 4 5 6 7 8 9	NA

Please write your comments about on-line tutorials here:

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PART 8: Multimedia

10.1	Quality of still pictures/photographs	bad good 1 2 3 4 5 6 7 8 9	NA
10.1.1	Pictures/Photos	fuzzy clear 1 2 3 4 5 6 7 8 9	NA
10.1.2	Picture/Photo brightness	dim bright 1 2 3 4 5 6 7 8 9	NA
10.2	Quality of movies	bad good 1 2 3 4 5 6 7 8 9	NA
10.2.1	Focus of movie images	fuzzy clear 1 2 3 4 5 6 7 8 9	NA
10.2.2	Brightness of movie images	dim bright 1 2 3 4 5 6 7 8 9	NA
10.2.3	Movie window size is adequate	never always 1 2 3 4 5 6 7 8 9	NA
10.3	Sound output	inaudible audible 1 2 3 4 5 6 7 8 9	NA
10.3.1	Sound output	choppy smooth 1 2 3 4 5 6 7 8 9	NA
10.3.2	Sound output	garbled clear 1 2 3 4 5 6 7 8 9	NA
10.4	Colours used are	Unnatural natural 1 2 3 4 5 6 7 8 9	NA
10.4.1	Amount of colours available		

		Inadequate adequate 1 2 3 4 5 6 7 8 9	NA
Please write your comments about multimedia here: _____ _ _____ _ _____ _ _____ _			

PART 9: Teleconferencing

11.1	Setting up for conference	difficult easy 1 2 3 4 5 6 7 8 9	NA
11.1.1	Time for establishing the connections to others	too long just right 1 2 3 4 5 6 7 8 9	NA
11.1.2	Number of connections possible	too few enough 1 2 3 4 5 6 7 8 9	NA
11.2	Arrangement of windows showing connecting groups	confusing clear 1 2 3 4 5 6 7 8 9	NA
11.2.1	Window with view of your own group is of appropriate size	never always 1 2 3 4 5 6 7 8 9	NA
11.2.2	Window(s) with view of connecting group(s) is of appropriate size	never always 1 2 3 4 5 6 7 8 9	NA
11.3	Determining the focus of attention during conference was	confusing clear 1 2 3 4 5 6 7 8 9	NA
11.3.1	Telling who is speaking	difficult easy 1 2 3 4 5 6 7 8 9	NA
11.4	Video image flow	choppy smooth 1 2 3 4 5 67 8 9	NA
11.4.1	Focus of video image	fuzzy clear 1 2 3 4 5 6 7 8 9	NA
11.5	Audio output	inaudible audible 1 2 3 4 5 6 7 8 9	NA
11.5.1	Audio is in sync with video images	never always	NA

		1 2 3 4 5 6 7 8 9	
11.6	Exchanging data	difficult easy 1 2 3 4 5 6 7 8 9	NA
11.6.1	Transmitting files	difficult easy 1 2 3 4 5 6 7 8 9	NA
11.6.2	Retrieving files	difficult easy 1 2 3 4 5 6 7 8 9	NA
11.6.3	Using online chat	difficult easy 1 2 3 4 5 6 7 8 9	NA
11.6.4	Using shared workspace	difficult easy 1 2 3 4 5 6 7 8 9	NA

Please write your comments about teleconferencing here:

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PART 10: Software Installation

12.1	Speed of installation	slow fast 1 2 3 4 5 6 7 8 9	NA
12.2	Customization	difficult easy 1 2 3 4 5 6 7 8 9	NA
12.2.1	Installing only the software you want	confusing clear 1 2 3 4 5 6 7 8 9	NA
12.2.2	Removing old software versions	with difficulty automatic 1 2 3 4 5 6 7 8 9	NA
12.3	Informs you of its progress	never always 1 2 3 4 5 6 7 8 9	NA
12.4	Gives a meaningful explanation when failures occur	never always 1 2 3 4 5 6 7 8 9	NA

Please write your comments about software installation here:

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8.3. UTAUT

Unified Theory of Acceptance and Use of Technology Questionnaire

Template for Patients and Informal Carers

Please answer <u>all</u> questions by ticking <u>the most appropriate box</u> for each of the following statements:

1. Personal Information
1.1 What is your patient Identification Number for C3-Cloud? .....
1.2 How old are you? ☐20-25 ☐26-31 ☐32-37 ☐38-43 ☐44-49 ☐50-55 ☐56-61 ☐62+
1.3 What is your gender? ☐ Male ☐ Female
1.4 Do you have any previous experience with self-management systems? ☐Yes ☐ No **If so, how many years?** ……..……..
1.5 Are you a career of a person with a chronic condition? ☐Yes ☐ No *If yes, answer the questions on behalf of the person you are caring for.*
1.6 Are you willing to use the *C3-Cloud Tools and System*? ☐Yes ☐No ☐ To some extent ☐ Not sure

2. Performance Expectancy	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
2.1 I would find the *[C3-Cloud System]* useful in the management of my condition							
2.2 Using the *[C3-Cloud System]* would enable me to complete self-management tasks at a quicker pace							
2.3 Using the *[C3-Cloud System]* would increase my efficiency in managing my condition							
2.4 Using the *[C3-Cloud System]* would increase the quality of self-management of my condition							
2.5 Overall, the *[C3-Cloud System]* would fit well with the way I live and get on with everyday tasks							

3. Effort Expectancy	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
3.1 My interaction with the *[C3-Cloud System]* will be clear and understandable							
3.2 Learning to operate the *[C3-Cloud System]* has been easy for me							

3.3 I think that I will find it easy to become skilful at using the *[C3-Cloud System]*							
3.4 The will facilitate my daily tasks for my condition's self-management							
3.5 I believe that interacting with the *[C3-Cloud System]* will **not** mentally exhaust me							
4. Social Influence	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
4.1 The people who influence my behaviour in my caring team think that I should use the *[C3-Cloud System]*							
4.2 The fellow patients who will receive the benefits of the *[C3-Cloud System]* inspire me to use it							
4.3 Within my caring team, the management has communicated their plans to introduce the *[C3-Cloud System]* to support self-management							
4.4 Before the system is put to use, the caring team will offer sufficient preparation							
4.5 Overall, my caring team has been supportive of this technology							
5. Facilitating Conditions	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
5.1 The manual is comprehensive enough							
5.2 The use of *[C3-Cloud System]* is smooth (no technical errors)							
5.3 The steps followed by the system are logical to use, apply, and recall							
5.4 There is technical support available if I need it							
5.5 When I get stuck, a sufficient resource will be available to help me out							
6. Cultural Trends and Language Factors	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
6.1 I believe that my country uses the technological advancements in positive ways							
6.2 In general, my local community is open-minded about using technology							
6.3 In my local community, the use of technology in healthcare is appreciated							

6.4 I feel comfortable about using the [*English*] language while dealing with technology							
6.5 I find the *[C3-Cloud System]* very relevant to my community's needs							
7. Technology Anxiety	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
7.1 I like to keep up with new technology							
7.2 I am open to change my self-management habits if necessary							
7.3 I am likely to become technology-oriented due to the nature of my condition and needs							
7.4 If I were given enough time and sufficient resources to absorb change, I am likely to accept it							
7.5 Overall, I am not that anxious about using technology							
8. Adaption Timeline	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
8.1 I had adequate time to get trained on using the system							
8.2 I received sufficient information and/or training during this time							
8.3 I had enough time to get used the system environment							
8.4 If the system became available, I think I would be able to improve the quality of my condition's self-management immediately							
8.5 Overall, I think I will be allowed enough time to get into the habit of using this system if it becomes available							
9. Behavioral Intention	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
9.1 I intend to learn how to use the system to the best of my abilities							
9.2 I intend to use the system as often as needed							
9.3 I intend to promote the system to the community							
9.4 I intend to suggest ideas to further enhance the system if I had any							
9.5 Overall, I intend to put this system to full use							

9. Your opinion matters. Please leave either a general or a specific comment below if you would like to. If you are concerned about certain sections, just mention their number as a reference point.
Thank you!

Unified Theory of Acceptance and Use of Technology Questionnaire

Template for Healthcare Professionals

Please answer <u>all</u> questions by ticking <u>the most appropriate box</u> for each of the following statements:

1. Personal Information

1.1 What is your patient Identification Number for C3-Cloud? .....

1.2 How old are you? ☐20-25 ☐26-31 ☐32-37 ☐38-43 ☐44-49 ☐50-55 ☐56-61 ☐62+

1.3 What is your gender? ☐ Male ☐ Female

1.4 What is your job title?

……..……..…

1.5 What is your clinical (or professional) specialty?

……..……..……..……

1.6 Do you have any previous experience with Integrated Care? ☐Yes ☐ No

If so, how many years? ……..……..

1.7 Are you willing to use the *C3-Cloud Tools and System*? ☐Yes ☐No ☐ To some extent ☐ Not sure

2. Performance Expectancy	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
2.1 I would find the *[C3-Cloud System]* useful in my job							
2.2 Using the *[C3-Cloud System]* would enable me to complete tasks at a quicker pace							
2.3 Using the *[C3-Cloud System]* would increase my productivity							
2.4 Using the *[C3-Cloud System]* would increase the quality of my work							
2.5 Overall, the *[C3-Cloud System]* would fit well with the way I work and the service I provide							

3. Effort Expectancy	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
3.1 My interaction with the *[C3-Cloud System]* will be clear and understandable							
3.2 Learning to operate the *[C3-Cloud System]* has been easy for me							
3.3 I think that I will find it easy to become skilful at using the *[C3-Cloud System]*							

3.4 The will facilitate my daily job							
3.5 I believe that interacting with the *[C3-Cloud System]* will **not** mentally exhaust me							
4. Social Influence	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
4.1 The people who influence my behaviour at work think that I should use the *[C3-Cloud System]*							
4.2 The patients who will receive the benefits of the *[C3-Cloud System]* inspire me to use it							
4.3 Within my organization, the management has communicated their plans to introduce the *[C3-Cloud System]* to the staff							
4.4 Before the system is put to use, the management will offer sufficient preparation							
4.5 Overall, my organization has been supportive of this technology							
5. Facilitating Conditions	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
5.1 The manual is comprehensive enough							
5.2 The use of *[C3-Cloud System]* is smooth (no technical errors)							
5.3 The steps followed by the system are logical to use, apply, and recall							
5.4 There is technical support available if I need it							
5.5 When I get stuck, a sufficient resource will be available to help me out							
6. Cultural Trends and Language Factors	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
6.1 I believe that my country uses the technological advancements in positive ways							
6.2 In general, my local community is open-minded about using technology							
6.3 In my local community, the use of technology in healthcare is appreciated							
6.4 I feel comfortable about using the English language while dealing with technology							
6.5 I find the *[C3-Cloud System]* very relevant to my community's needs							

7. Technology Anxiety	Strongly Disagree	Very Much Disagree	Disagree	Not Sure	Agree	Very Much Agree	Strongly Agree
7.1 I like to keep up with new technology							
7.2 I am open to change my work habits if necessary							
7.3 I am likely to become technology-oriented due to the nature of my field							
7.4 If I were given enough time and sufficient resources to absorb change, I am likely to accept it							
7.5 Overall, I am not that anxious about using technology							
8. Adaption Timeline	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
8.1 I had adequate time to get trained on using the system							
8.2 I received sufficient information and/or training during this time							
8.3 I had enough time to get used the system environment							
8.4 If the system became available, I think I would be able to improve the quality of my work immediately							
8.5 Overall, I think I will be allowed enough time to get into the habit of using this system if it becomes available							
9. Behavioral Intention	**Strongly Disagree**	**Very Much Disagree**	**Disagree**	**Not Sure**	**Agree**	**Very Much Agree**	**Strongly Agree**
9.1 I intend to learn how to use the system to the best of my abilities							
9.2 I intend to use the system as often as needed							
9.3 I intend to promote the system to my colleagues							
9.4 I intend to suggest ideas to further enhance the system if I had any							
9.5 Overall, I intend to put this system to full use							
9. Your opinion matters. Please leave either a general or a specific comment below if you would like to. If you are concerned about certain sections, just mention their number as a reference point.							

Thank you!

8.4. Self-developed evaluation items and interview items for layer 3

8.4.1. Items for MDT members on the C3DP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: ease of use/usability Method: interviews Unit: open questions Deadline: Before component usage (M22)	How do you currently access and compile all needed patient health data to make informed treatment decisions?	MDT members can use the Coordinated Care & Cure Delivery Platform C3DP to compile all patient data on the multiple chronic conditions in one place. Conventionally, this was a very tedious process.	This questionnaire item will serve as baseline measurement and will be compared to the midterm measurement	MDT members have a better overview of all health data for their multimorbid patients in one place (the EHR). All patient data can be compiled in one electronic patient record.
Evaluation Topic: ease of use/usability Method: Interviews Unit: Open questions, Likert Scale Deadline: After component usage (M42)	How does the C3DP platform empower you, as part of the MDT, in the access and compilation of the needed patient health data? How does it affect your work processes, if patients have other medical conditions that are not within the C3Cloud scope (i.e. besides Diabetes Type II, renal failure, heart failure or depression)? Do you have to get back to alternative data sources? Do you, therefore, value the	MDT members can use the Coordinated Care & Cure Delivery Platform C3DP to compile all patient data on the multiple chronic conditions in one place. Conventionally, this was a very tedious process.	This questionnaire item will serve as midterm measurement and will be compared to the baseline measurement	MDT members have a better overview of all health data for their multimorbid patients in one place (the EHR). All patient data can be compiled in one electronic patient record.

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
	C3Cloud components less valuable?			
Evaluation Topic: Safety Method: Likert Scale Unit: Likert Scale Deadline:	C3DP usage reduces clashes between treatment alternatives for multimorbid patients, and thus increases the safety of their care. I strongly agree - ... - neutral - ... - I strongly disagree	Automated warnings to the MDT in the C3DP	No comparator plausible?!	A detection of treatment conflicts/clashes is calculated in the software algorithms. In case of conflicts, an automated warning is pushed to the clinician.
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for Type of Measurement: Unit: number of messages (different issues) sent by the patient to the MDT via the PEP Deadline:		MDT members use the C3DP		MDT members have a more complex communication with the Patients while reconciling the treatment across multiple diseases.
Evaluation Topic: Safety Type of Measurement: Unit: Deadline:		MDT members receive alarms through the C3DP if patients have health deterioration		Accelerated MDT notification in case of patients health deterioration leads to increased patient safety: MDT members can react quicker.
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the	How has C3Cloud helped you to react on patients' health deterioration?	Receives notifications in case that the PEP logs patient activities.		a quicker decision on treatment options; quicker reaction to health

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
components help the clinicians to find solutions for issues in care provision? etc.) Method: Interviews Unit: Deadline:				deterioration; increased patient safety
Evaluation Topic: Healthcare resource utilization Method: Likert Scale Unit: Minutes per patient per month Deadline:	Have you saved time by using C3DP to collect patient questionnaires (such as the PIRU) when comparing it to conventional alternative software solutions? If yes, how many minutes per patient per month	patient questionnaires (e.g. PIRU) will be automatically pushed to the C3DP		MDT members must not collect questionnaires (time saving).
Evaluation Topic: Safety Method: Unit: Deadline:		Using the C3DP improves the clinicians grasping of care processes		increased patient safety; improved quality of care plans; * clinicians have better knowledge on care processes and a more holistic view of the patient
Evaluation Topic: Use of C3-Cloud components and its usefulness Method: Interviews Unit: Deadline: **Other Comments:** Clinicians may not want to know if they are responsible for certain	Assigning responsibilities for issues or tasks in the C3DP to the clinicians may increase their resistance to use C3DP		Increased resistance to use C3DP or PCPDP. Decreased usage of the C3Cloud components.	

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
issues? Making them aware by means of C3DP may lead to resistance				
Evaluation Topic: Clinical & process quality and changes Method: Unit: Deadline:		C3DP advises a different frequency to follow up after hospital discharge than the routine follow up protocol		The patient follow up strategies (and frequency of contacts) may change by C3Cloud usage: more involvement of MDT members by more information in the C3Cloud components (e.g. alerts on health deterioration) could lead to different follow up strategies. ==> C3Cloud may also change/improve the way of coordination of MDT members.

8.4.2. Items for MDT members on the PCPDP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: clinical & process quality and changes Method: Likert Scale	Under specific consideration of my patient's multimorbidity, I experience treatment goal setting for them as complicated when using the PCPDP	MDT members can use the Personalized Care Plan Development Platform PCPDP	This questionnaire item will serve as midterm measurement and will be compared	MDT members can use the PCPDP to define and reconcile treatment goals for multimorbid patients

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Unit: Closed questionnaire, Likert Scale (yes very much - .. -- … - no not at all) Deadline: After component usage (M42)	Did the PCPDP allow for sufficient flexibility in goal setting? Was the suggested treatment advice useful for you and your patient? Is the template for treatment goal definition in the PCPDP appropriate? Does the definition of treatment goals in the PCPDP aid the clinical treatment outcomes?		to the baseline measurement	
Evaluation Topic: clinical & process quality and changes Method: Likert Scale Unit: Deadline:	The PCPDP facilitated my access to evidence-based knowledge for decision making! I strongly agree - ... - neutral - ... - I strongly disagree	Automated advise to the MDT	No comparator plausible?!	Before the C3-Cloud solution, the health professional had to go through the guidelines himself (often clinicians would refer to evidence-based knowledge (papers, guidelines, …). With the C3-Cloud solutions, the advice comes automated at the right time. This implies that clinical decisions will be rather made on a systematic review of guidelines.
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the		MDT members use PCPDP for care plan management instead		increased utility of the PCPDP when compared to previously existing tools

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
components help the clinicians to find solutions for issues in care provision? etc.) Method: log files Unit: number of patient contacts in the PCPDP Deadline: Other Comments: Measure automatic records of PCPDP usage (e.g. the number of patient contacts) to see if clinicians use other tools besides PCPDP in parallel. This would give an indication of PCPDP utility.		of previously existing tools		Conflicts in clinical processes can occur when PCPDP is used in parallel to previous existing tools for care plan management.
Evaluation Topic: usefulness Method: Open questionnaire Unit: number of alternative EHRs or care plan tools that are in use Deadline:	Do you use other tools besides PCPDP in parallel? Why do you use or do you not use the PCPDP? Is C3Cloud component lacking any functionality, so that you are using other tools?		MDT members use PCPDP for care plan management instead of previously existing tools	increased utility of the PCPDP when compared to previously existing tools Conflicts in clinical processes can occur when PCPDP is used in parallel to previous existing tools for care plan management.
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc.) Method: Unit: When to obtain the data (Deadline):		PCPDP informs MDT members on conflicts/issues of different treatment options.		PCPDP will increase the clinician's knowledge base on potential conflicts/issues in treatment options

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Other Comments: We mentioned this in the DoA - so we should think about how to monitor that.				
Evaluation Topic: use of C3-Cloud components and its usefulness Method: Interviews The Unit of analysis: Deadline:	Has PCPDP supported or helped you in detecting conflicts between different clinical guidelines for multimorbid patients?	Conflicts in treatment options are made explicit in the PCPDP		Increased Utility: the PCPDP helped physicians to detect and avoid conflicts in treatment options for multimorbid patients.

8.4.3. Items for MDT members CDSM

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Clinical & process quality and changes Method: Interviews Unit: Open questions on the habits of clinicians Deadline: Interviews before component usage (M22)	How do you handle contradictory / non-reconciled clinical guidelines in the treatment planning for multimorbid patients?	MDT members can use the Clinical Decision Support Modules CDSM	The same clinicians that use C3Cloud components will be interviewed on their usage of clinical guidelines before component implementation. Another interview will be conducted with the same clinicians after	Using the C3Cloud components, the MDT members receive improved advice and suggestions from the CDSM (based on "reconciled" clinical guidelines), that are specifically valid for single diseases.

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
			C3Cloud component implementation and the usage of CDSM. Is there an improvement or more meaningful knowledge in how MDT members can handle the differences in clinical guidelines for the different diseases?	
Evaluation Topic: Clinical & process quality and changes Method: Closed questionnaires Unit: Likert Scale Deadline: Interviews after component usage (M42)	Did CDSM serve to provide improved advice and suggestions for treatment plans (based on reconciled medical guidelines)? Likert Scale (Yes / No / slightly, …..) Why or how did CDSM serve to provide improved advice and suggestions for treatment plans?	MDT members can use the Clinical Decision Support Modules CDSM	The same clinicians that use C3Cloud components will be interviewed on their usage of clinical guidelines before component implementation. Another interview will be conducted with the same clinicians after C3Cloud component implementation	Using the C3Cloud components, the MDT members receive improved advice and suggestions from the CDSM (based on "reconciled" clinical guidelines), that are specifically valid for single diseases.

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
			and the usage of CDSM. Is there an improvement or more meaningful knowledge in how MDT members can handle the differences in clinical guidelines for the different diseases? Comparison of interview data (opinions of clinicians on CDSM usage) to their answers from the baseline question, how they handle contradictory clinical guidelines in treatment planning	
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc.)	Has C3Cloud component usage been more convenient for you than conventional alternative software solutions	The use of PCPDP and C3DP will facilitate the discussion about		Explicit choices for treatment activities and medication regimen

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
use of C3-Cloud components and its usefulness Method: Interview Unit: Deadline:		clinical decisions among clinicians		
Evaluation Topic: use of C3-Cloud components and its usefulness Method: Interview Unit: Deadline: Other comments: Evaluate if clinicians find the usage of the platform cumbersome (slow, difficult in usage); see if the usual session time per patient is increased with the C3Cloud platform usage.	Has C3Cloud component usage been more convenient for you than conventional alternative software solutions	The ease of C3-Cloud component usage is an improvement when compared to previously used alternative platforms		Reduced time use on C3-Cloud component usage in comparison to alternative / previously used platforms
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc.) Method: Likert Scale Unit: Yes -- don't know---not at all, ... Deadline: Other Comments: Lateral thinking: Clinicians rather think lateral and not so much rational. Usual diagnosis is not a	When using C3-Cloud components: Do you believe you make treatment decisions more rational than before (when before it was rather lateral)?	C3Cloud components direct clinicians into rather rational than lateral thinking, when searching for disease patterns or treatment options!		C3Cloud component usage improves rational thinking among clinicians

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
rational process but rather looking for patterns * The c3 process is very rational and does not work well with a the usual clinical way of working! * Non-hard data involved, focused on the moment and on the first impression * Looking at current problem * The question could be asked if it is possible to follow another order.				
Evaluation Topic: Clinical & process quality and changes Method: Closed questionnaires Unit: Likert Scale Deadline: After component usage (M42)	How difficult do you perceive it to access clinical guidelines and to receive treatment guidance from them, for multimorbid patients? (very difficult - neutral - not difficult at all, ….) Do you believe you safe time through CDSM usage, when comparing it to your own approaches to access clinical guidelines and treatment advice (without CDSM)? If yes, how much time do you think you safe per patient visit?	By using CDSMs, the MDT members can access clinical guidelines easier and receive treatment advise easier	This questionnaire item will serve as midterm measurement and will be compared to the baseline measurement	Improved ease of use of clinical guidelines

8.4.4. Items for patients on the PEP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Patient's perspective on clinical optimization Method: The Unit of analysis: Deadline: Other Comments: * Will interaction improve quantitatively and/or qualitatively? * Issues, comments to the care plan etc can be noted down to feed into the follow-up care plan creation		Patients use the PEP for communicating with their MDT		Patients have a more complex communication with the MDT, while the reconciliation of their treatment across multiple diseases takes place. Follow-up care plans can be changed on the basis of knowledge from this communication
Evaluation Topic: Patient's perspective on clinical optimization Method: Unit: number of comments on the care plan (made by patients in the PEP) When to obtain the data (Deadline):		Patients can review the care plan in the PEP, including the treatment goals and all activities and the drug regimen		Increase patient involvement; increased adherence to treatment

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Patient's perspective on clinical optimization Method: Unit: Deadline:		increased involvement of patients in treatment goal setting		Patients are actively involved in the goal setting by making comments in the PEP on the treatment goals and treatment plan.
Evaluation Topic: Patient's perspective on clinical optimization Method: Interview Unit: When to obtain the data (Deadline): **Other Comments:** Does the availability of information in C3DP/PEP really change the treatment goals? Do clinicians think that? Do patients have this information?	Has PEP usage in fact resulted in different treatment goals than those that you had agreed with your GP before being enrolled to the C3CLoud project?	Availability of clinical information in the C3DP and PCPDP and the reconciliation of care plans and clinical guidelines will, in fact, change the treatment goals for multimorbid patients		treatment goals are changed on the basis of reconciled clinical guidelines or on the availability of clinical parameters from the PEP
Evaluation Topic: Patients' User experience Method: Interview Unit:	Do you find such information useful, or is it rather "too much noise" for you What should the frequency of notifications to you as a patient be?	Access to the care plan in the PEP helps patients to see what steps/treatment has to be		Improved adherence to treatments

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
When to obtain the data (Deadline): **Other Comments**: Some patients may be grateful to be pushed towards treatments, others may feel compromised be frequent system alerts/reminders!		followed at which point in time?		
Evaluation Topic: Patient's perspective on clinical optimization Method: Unit: Deadline:		PEP usage increases patients' knowledge of the disease process and increases their involvement in care processes.		Improved adherence to treatments; improved patient empowerment, improved health literacy
Evaluation Topic: Patient's perspective on clinical optimization Type of Measurement: The Unit of analysis: Deadline: **Other Comments:** Confidence in patients may be boosted by a more focused guidance! The less the patient has to do, the better it is (Pontus).		Patients can see a focused guidance (treatment processes to follow) on the basis of the care plan in the PEP		More focused guidance may push the confidence in patients to adhere to care plans

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Patients' User experience Method: Unit: Deadline: **Other Comments:** Patients have high expectations towards C3-Cloud (e.g. expect immediate feedback when data is sent towards the PEP) and may be disappointed if no immediate response is triggered!		Patients enter data in the PEP / C3DP and expect immediate feedback		Delayed feedback or no immediate response on data entries may disappoint patients
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc.) Method: Closed questionnaire Unit: Deadline:	http://www.who.int/chp/knowledge/publications/adherencerep.pdf; multidimensional character of adherence; here we may focus on condition-related factors and characteristics of the therapies	PEP informs about medication goals	Baseline and closure questionnaire	The patient shows a better taking behaviour
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to	What are barriers towards taking your medication as prescribed? In how far did C3-Cloud support you in addressing these barriers?	PEP informs about medication goals	Baseline and closure questionnaire	The patient report barriers and beliefs associated with adherence

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
find solutions for issues in care provision? etc.) Method: Interview Unit: Deadline:				
Evaluation Topic Patient's perspective on clinical optimization Method: Diabetes knowledge questionnaire; HF knowledge Unit: Deadline:		The PEP provides knowledge about disease	Baseline and closure questionnaire	increased patient's knowledge of disease

8.4.5. Items for patients on the C3DP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Patients' User experience Method: PIRU questionnaire The Unit of analysis: Deadline:		patient questionnaires (e.g. PIRU) will be automatically pushed to the C3DP		Patients fill in the PIRU online and submit and transfer it to the C3DP automatically (increase of patient convenience)

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc.) Method: Closed questionnaires Unit: Deadline: whenever the patient is coming without appointment or uses an appointment for reporting a problem	Did the patient show signs of decompensations? Yes / No how severe is the decompensation light; moderate; severe	The C3DP addresses gaps in treatment and timely reaction to deterioration	comparing to control group	Reduction in decompensation

8.4.6. Items for patients on the PCPDP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc. Method: Interview The Unit of analysis: Deadline: **Other Comments:** Does PEP data indeed modify the care process?	Has PCPDP usage in fact resulted in a different care plan than you would have determined if you did not use C3Cloud components?	Availability of clinical information in the C3DP and PCPDP and the reconciliation of care plans and clinical guidelines will, in fact, change the care plans for multimorbid patients		care plans are changed on the basis of reconciled clinical guidelines or on the availability of clinical parameters from the PEP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Does the information that is generated by the measurements and the PEP have an influence on the care process, or would clinicians suggest the exact same care processes also without the PEP? • Increased information sharing by PEP usage could have an impact on the treatment goals and care plans. Can we use the evaluation questionnaires to investigate among clinicians, if they feel that this is the case?				

8.4.7. Items for patients on the CDSM

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc.) Method: Closed questionnaires The Unit of analysis: Deadline: Whenever the patient is coming without appointment or uses an appointment for reporting a problem	Did you treat the patient for drug-drug, drug-disease interaction other than in a medication review?	The C3DP addresses gaps in treatment and timely reaction to health deteroriation	comparing to control group	Reduction in interactions (drug-drug, drug-disease)

8.5. eCCIS

The following annex presents the eCCIS model questionnaire for clients (patients) and informal caregivers (informal caregivers) that needs to be adapted to the purposes of a specific evaluation, depending on the research questions to be answered and other considerations such as overall instrument length / respondent burden or resources available for evaluation. The adaptation consists of the following steps:

Num	Adaption steps
1	Decide which module to apply. Delete unused modules.
2	Decide which questions within each module are applicable. Delete questions that are not applicable, add additional questions when needed.
3	Adapt reference to the intervention being measured in each question so that a respondent understands what he/she is being asked about. Possible alternative references are given in square brackets, followed by “xxx AltRef” in each question. Other references can be used. References not used should be deleted.
4	Delete information needed for the setting up of the questionnaire. Paragraphs that can be deleted each begin with “[xxx this paragraph to be deleted]”.
5	Delete numeric codes assigned to answer categories [provided in square brackets].

The adaption will be done before using the questionnaire in the pilot sites.

eCCIS for clients (patients)

Module 1: Time use

The explanation for the respondent: First, we would like to ask you a few questions about the time you spend using the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>].

[xxx this paragraph to be deleted] This module is for measuring the time spent by the respondent for using the service. Depending on the service scenario under investigation, the questions need to be adapted to cover different activities for which time is being spent. Common examples include the time spent doing telehealth readings, time for regular visits by or to a social or health care provider (including travel time, if applicable) or using an online service (such as a patient information website or similar).

1.	In relation to your usage of the telehealth equipment [xxx AltRef: telemonitoring equipment / <given name of device set> / <given name of service>], can you tell me how often you usually do your telehealth readings?				
	Less than once per week ☐ [1]	About 2 to 4 times a week ☐ [2]	About every day ☐ [3]	More than 1 time per day ☐ [4]	Don't know ☐ [9]
2.	How much time do you usually spend doing your telehealth [xxx AltRef: telemonitoring / <given name of device set> / <given name of service>] readings?				
	Less than 10 minutes per session ☐ [1]	Between 10 minutes and half an hour per session ☐ [2]	More than half an hour per session ☐ [3]	Don't know ☐ [9]	
3.	In relation to your usage of the telecare equipment [xxx AltRef: social alarm / <given name of device set> / <given name of service>], can you tell me how often you usually use it?				
	Less than once per week ☐ [1]	About 2 to 4 times a week ☐ [2]	About every day ☐ [3]	More than 1 time per day ☐ [4]	Don't know ☐ [9]
4.	How much time do you usually spend using your telecare [xxx AltRef: social alarm / <given name of device set> / <given name of service>]?				

	Less than 10 minutes per session ☐ [1]	Between 10 minutes and half an hour per session ☐ [2]	More than half an hour per session ☐ [3]	Don't know ☐ [9]
5.	In relation to your visits to the GP, can you tell me how often you usually go to see him or her?			
	Less than once per month ☐ [1]	1 to 4 times a month ☐ [2]	More than once per week ☐ [3]	Don't know ☐ [9]
6.	How much time does one visit usually take you, including the time it takes you to get there?			
	Less than an hour ☐ [1]	Between one and two hours ☐ [2]	More than three hours ☐ [3]	Don't know ☐ [9]
7.	In relation to your visits to the specialist [xxx AltRef: <type of specialist> (e.g. cardiologist) / <name of individual specialist>], can you tell me how often you usually go to see him or her?			
	Less than once per month ☐ [1]	1 to 4 times a month ☐ [2]	More than once per week ☐ [3]	Don't know ☐ [9]
8.	How much time does one visit usually take you, including the time it takes you to get there?			

	Less than an hour ☐ [1]	Between one and two hours ☐ [2]	More than three hours ☐ [3]	Don't know ☐ [9]
9.	In relation to visits by the home nursing service [xxx AltRef: community nurses / <given name of service> / <name of individual nurse>], can you tell me how often they usually come to see you?			
	Less than once per month ☐ [1]	1 to 4 times a month ☐ [2]	More than once per week ☐ [3]	Don't know ☐ [9]
10.	How much time does one visit usually take?			
	Less than an hour ☐ [1]	Between one and two hours ☐ [2]	More than three hours ☐ [3]	Don't know ☐ [9]
11.	In relation to visits by the social care service [xxx AltRef: home care service / <given name of service> / <name of individual nurse>], can you tell me how often they usually come to see you?			
	Less than once per month ☐ [1]	1 to 4 times a month ☐ [2]	More than once per week ☐ [3]	Don't know ☐ [9]
12.	How much time does one visit usually take?			
	Less than an hour ☐ [1]	Between one and two hours ☐ [2]	More than three hours ☐ [3]	Don't know ☐ [9]
13.	In relation to your usage of the web portal [xxx AltRef: <given name of web portal> / <given name of service>], can you tell me how often you usually access it?			
	Less than once per week ☐ [1]	About 2 to 4 times a week ☐ [2]	About every day ☐ [3]	More than 1 time per day ☐ [4]	Don't know ☐ [9]
14.	How much time do you usually spend using the web portal [xxx AltRef: <given name of web portal> / <given name of service>]?			

	Less than 10 minutes per session ☐ [1]	Between 10 minutes and half an hour per session ☐ [2]	Between half an hour and 1 hour per session ☐ [3]	More than 1 hour per session ☐ [4]	Don't know ☐ [9]

Module 2: Specific service-related impacts

The explanation for the respondent: Now, we would like to ask you a few questions about how you feel the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] has affected you.

[xxx next three paragraphs to be deleted] This module addresses any specific impacts that can be expected to be generated by the service under evaluation and to be perceivable by the respondent. Potential areas of impact to be addressed include the motivation to perform physical activities, the ability to perform physical activities, level of anxiety, sense of safety and security, feeling of independence / self-determination, emotional well-being, social connectedness or isolation, ability to manage own chronic disease, or ability to manage activities of daily living.

Where applicable, the term "the new service" should be adapted to the actual name of the service or system, especially if this can be expected to be more familiar to the respondent (e.g. the COPD programme, the telecare service). This may also be necessary if the respondent is actually not aware of anything new being put in place, e.g. because for her/him it is the first contact with the service.

With a view to respondent burden, overlaps with other instruments measuring similar or identical constructs should be avoided. For the same reason, it may also make sense to limit the number of questions used to between three and five.

1.	To what extent, if any, has the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] affected **your motivation** to perform daily physical activities?
	It has increased my motivation a lot ☐ [1] *It has increased my motivation a little* ☐ [2] *It has not affected my motivation* ☐ [3] *It has decreased my motivation a little* ☐ [4] *It has decreased my motivation a lot* ☐ [5] <u>If you want to, you can provide further details on your answer below :</u> _____ _____ _____

2.	To what extent, if any, has the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] affected **your ability** to perform daily physical activities?
	It has increased my ability a lot ☐ [1] *It has increased my ability a little* ☐ [2] *It has not affected my ability* ☐ [3] *It has decreased my ability a little* ☐ [4] *It has decreased my ability a lot* ☐ [5] If you want to, you can provide further details on your answer below : _____ _____ _____ _____ _____ _____
3	To what extent, if any, has the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] affected your **emotional wellbeing**?
	It has increased my emotional wellbeing a lot ☐ [1] *It has increased my emotional wellbeing a little* ☐ [2] *It has not affected my emotional wellbeing* ☐ [3] *It has decreased my emotional wellbeing a little* ☐ [4] *It has decreased my emotional wellbeing a lot* ☐ [5] If you want to, you can provide further details on your answer below : _____ _____ _____ _____ _____ _____
4.	To what extent, if any, has the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] affected **your ability to get along with your health condition in day-to-day life**?

	It has increased my ability a lot ☐ [1] *It has increased my ability a little* ☐ [2] *It has not affected my ability* ☐ [3] *It has decreased my ability a little* ☐ [4] *It has decreased my ability a lot* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____ _____
5.	To what extent, if any, has the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] affected your **anxiety about your health condition**?
	It has decreased my anxiety about my health a lot ☐ [1] *It has decreased my anxiety about my health a little* ☐ [2] *It has had no impact on my anxiety about my health* ☐ [3] *It has increased my anxiety about my health a little* ☐ [4] *It has increased my anxiety about my health a lot* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____ _____
6.	To what extent, if any, has the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] affected **how lonely you feel**?
	It has decreased how lonely I fell a lot ☐ [1] *It has decreased how lonely I fell a little* ☐ [2] *It has not affected how lonely I fell* ☐ [3] *It has increased how lonely I fell a little* ☐ [4] *It has increased how lonely I fell a lot* ☐ [5]
	If you want to, you can provide further details on your answer below : _____

	_____ _____
7.	To what extent, if any, has the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] affected **your relationship with your family carer**?
	It has improved our relationship a lot ☐ [1] *It has improved our relationship a little* ☐ [2] *It has not affected our relationship* ☐ [3] *It has made our relationship a little worse* ☐ [4] *It has made our relationship a lot worse* ☐ [5]
	<u>If you want to, you can provide further details on your answer below :</u> _____ _____ _____
8.	To what extent, if any, has the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] affected **your relationship with the professional carers looking after you**?
	It has improved our relationship a lot ☐ [1] *It has improved our relationship a little* ☐ [2] *It has not affected our relationship* ☐ [3] *It has made our relationship a little worse* ☐ [4] *It has made our relationship a lot worse* ☐ [5]
	<u>If you want to, you can provide further details on your answer below :</u> _____ _____ _____

Module 3: Summary assessment

The explanation for the respondent: Now, we would like to ask you a few questions about how satisfied you are in general with the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>].

[xxx this paragraph to be deleted] Module 3 covers the overall satisfaction of the respondent with the service received. Its main aim is to determine in how far specific benefits or dis-benefits were perceived as being crucial

for the overall experience. Furthermore, it addresses the issue of service sustainability from the respondent's point of view.

1.	Overall, taking everything into account, **how satisfied** are you with the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>]?
	Very satisfied ☐ [1] *Fairly satisfied* ☐ [2] *Neither satisfied nor dissatisfied* ☐ [3] *Fairly dissatisfied* ☐ [4] *Very dissatisfied* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____ _____
2.	Again, taking everything into account, is the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] **worth the effort** involved in using it?
	Yes Very much so ☐ [1] *Yes mostly* ☐ [2] *Neither worth it nor not worth it* ☐ [3] *No mostly not* ☐ [4] *No certainly not* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____ _____
3.	Would you want to **continue using** the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] in the future? [xxx AltQst] Would you want to **use** the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] **again**, in case you should need it?
	Definitely yes ☐ [1] *Probably yes* ☐ [2] *I am not yet decided* ☐ [3] *Probably not* ☐ [4] *Certainly not* ☐ [5]
	If you want to, you can provide further details on your answer below :

	_____ _____ _____

Module 4: willingness-to-pay

[xxx next 4 paragraphs to be deleted] Module 4 measures the respondent's willingness to pay for the new service. The module should be primarily used in cases where the introduction of a service fee is being considered, in order to determine what amounts might be acceptable to what parts of the target population.

The module comes in two versions, one for self-completion and a second for application by an interviewer.

Note that the introductory text is an integral part of the module and should be applied. It needs to be adapted to the specific evaluation. Since willingness to pay is usually strongly dependent on income, the respective questions should be applied as long as there is no case-level data on income from the same respondents.

Currency amounts, both for the possible fee and for household income categories, need to be adapted to the circumstances of the area where the service is being evaluated.

WTP for self-completion

Introduction (please adapt)

We would like to find out how valuable the service that you have received in the past months is to you, especially with respect to your <health/wellbeing/other>. We have therefore designed a short questionnaire for you to complete.

We are asking you to imagine a situation where you have to pay a monthly fee for the service. The amount of the fee you would be willing to pay (if you had to) gives us an indication of how you value <health/wellbeing/other> gains from the service compared with other things you might want to spend your money on. There are no right or wrong answers.

Please read each question carefully and follow the instructions. This questionnaire is confidential and no identifying information will be used.

1.	Thinking just about your health and wellbeing, would the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] be worth at least something to you?
	Yes ☐ [1] No ☐ [2] → Please tell us why below (Question 3).
2.	Now suppose that you were told that the monthly fee for the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] would be one of the amounts given below. Would you say 'Yes, I'd pay that' or 'No, I'd rather live without the service's help'? Or would you be unsure?

	10€ per month		20€ per month		30€ per month
Yes	☐ [1]	Yes	☐ [1]	Yes	☐ [1]
No	☐ [2]	No	☐ [2]	No	☐ [2]
Unsure	☐ [3]	Unsure	☐ [3]	Unsure	☐ [3]

3. If the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] is not worth anything to you, please let us know why you feel this way:

_____

_____

_____

4. To be able to better understand your answer, could you please tell us what the monthly net income of your household is? (Net income is the income of all household members, regardless of source, less taxation and compulsory insurance).

Less than 1200 €	Between 1200 and 2000 €	Between 2000 and 4000 €	More than 4000 €	I don't know → go to question 5	I would rather not tell → go to question 5
☐ [1]	☐ [2]	☐ [3]	☐ [4]	☐ [8]	☐ [9]

5. If you do not know the exact amount or do not want to reply to this question, could you tell us which of the following statements best describes your current financial situation?

Things are very difficult	I have trouble making ends meet	I have to be careful but I get by	Comfortable	Very comfortable	Don't know or would rather not tell
☐ [1]	☐ [2]	☐ [3]	☐ [4]	☐ [5]	☐ [9]

6. Is there anything else you would like to add about how valuable the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] is to you?

	_____ _____ _____ _____ _____ _____

WTP for interview application

Note to interviewer

In applying this questionnaire, please follow the instructions given throughout the document. These are always marked with the abbreviation INT followed by a colon and the instruction. Start by reading the introduction text to the respondent, then go to question 1, reading out the question and the answer options. Depending on the answers given, continue with the next question as indicated. If there is no question indicated, please continue with the one immediately following.

INT: Read aloud to the respondent. (please adapt)

We would like to find out how valuable the service that you have received in the past months is to you, especially with respect to your <health/wellbeing/other>. We have therefore designed a short questionnaire for you to complete.

We are asking you to imagine a situation where you have to pay a monthly fee for the service. The amount of the fee you would be willing to pay (if you had to) gives us an indication of how you value <health/wellbeing/other> gains from the service compared with other things you might want to spend your money on. There are no right or wrong answers.

This questionnaire is confidential and no identifying information will be used.

1.	Thinking just about your health and wellbeing, would the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] be worth at least something to you?
	Yes ☐ [1] → *INT:* go to question 3 No ☐ [2] → *INT:* go to question 2
2.	Please explain why the service is not worth anything to you?
	_____ _____ _____ _____ → *INT:* Got to question 7

3.	Suppose that you were told that the fee for new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] would be 20€ per month. Would you say 'Yes, I'll pay that' or 'No, I'd rather live without the service's help'? Or would you be unsure?
	Yes ☐ [1] → *INT:* go to question 5 Unsure ☐ [2] → *INT:* go to question 5 No ☐ [3] → *INT:* go to question 4
4.	Is there any amount less than 20€ that you would be prepared to pay per month?
	Yes ☐ [1] No ☐ [2] If yes, what is the most you would be prepared to pay? _____ _____ → *INT:* Got to question 7
5.	Suppose that you were told instead that the fee for the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] would be 30€ per month. Would you say 'Yes, I'll pay that' or 'No, I'd rather live without the service's help'? Or would you be unsure?
	Yes ☐ [1] → *INT:* go to question 6 Unsure ☐ [2] → *INT:* go to question 6 No ☐ [3] → *INT:* go to question 6
6.	What is the HIGHEST fee you would be prepared to pay per month for the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>]?
	_____ _____ → *INT:* Got to question 7
7.	To be able to better understand your answer given in the last question, could you please tell us what the monthly net income of your household is? (Net income is the income of all household members, regardless of source, less taxation and compulsory insurance).

	Less than 1200 € ☐ [1]	Between 1200 and 2000 € ☐ [2]	Between 2000 and 4000 € ☐ [3]	More than 4000 € ☐ [4]	I don't know → *INT:* go to question 8 ☐ [8]	I would rather not tell → *INT:* go to question 8 ☐ [9]
8.	If you do not know the exact amount or do not want to reply to this question, could you tell us which of the following statements best describes your current financial situation?					
	Things are very difficult ☐ [1]	I have trouble making ends meet ☐ [2]	I have to be careful but I get by ☐ [3]	Comfortable ☐ [4]	Very comfortable ☐ [5]	Don't know or would rather not tell ☐ [9]

Module 5: Perception of integration

The explanation for the respondent: Finally, we would like to ask you in how far you think the new service [xxx AltRef: the service / the care you received in relation to your condition / <given name of service>] is well co-ordinated.

1.	When it comes to information about your health and well-being, do you feel that you have to **repeat this information** a lot when talking to different people treating and caring for you?	
	No, I usually have to give such information only once	☐ [1]
	I sometimes have to repeat information	☐ [2]
	I have to repeat information quite frequently	☐ [3]
	Yes, I have to keep repeating such information almost constantly	☐ [4]
	Don't know / not sure	☐ [9]
	If you want to, you can provide further details below: _____ _____ _____	
2.	Taking everything into account, do you feel that the different people treating and caring for you **work well together** to give you the best possible care and support?	

	Yes, all of them work well together ☐ [1] *Most of them work well together* ☐ [2] *Some of them work well together* ☐ [3] *No, they do not work well together* ☐ [4] *Don't know / not sure* ☐ [9]
	If you want to, you can provide further details below: _____ _____ _____

eCCIS for informal caregivers (informal caregivers)

Module 1: Time use

The explanation for the respondent: First, we would like to ask you a few questions about the time you spend using the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>].

[xxx this paragraph to be deleted] This module is for measuring the time spent by the respondent in using the service. Depending on the service scenario under investigation, the questions need to be adapted to cover different activities for which time is being spent. Common examples include the time spent helping a cared-for person doing telehealth readings, time for accompanying the cared for person on visits to health and care providers, time for own visits by or to a carer support service or time for using an online service (such as an information website).

1.	In relation to the telehealth equipment [xxx AltRef: telemonitoring equipment / <given name of device set> / <given name of service>] used by the person you are caring for, can you tell me how often you usually help the person doing the telehealth readings?				
	Less than once per week ☐ [1]	About 1 to 4 times a week ☐ [2]	About every day ☐ [3]	More than 1 time per day ☐ [4]	Don't know ☐ [9]
2.	How much time do you usually spend helping with the telehealth [xxx AltRef: telemonitoring / <given name of device set> / <given name of service>] readings?				
	Less than 10 minutes per session ☐ [1]	Between 10 minutes and half an hour per session ☐ [2]	More than half an hour per session ☐ [3]	Don't know ☐ [9]	
3.	In relation to the telecare equipment [xxx AltRef: social alarm / <given name of device set> / <given name of service>] used by the person you are caring for, can you tell me how often you usually help the person using it?				
	Less than once per week ☐ [1]	About 1 to 4 times a week ☐ [2]	About every day ☐ [3]	More than 1 time per day ☐ [4]	Don't know ☐ [9]
4.	How much time do you usually spend helping with the telecare [xxx AltRef: social alarm / <given name of device set> / <given name of service>]?				
	Less than 10 minutes per session	Between 10 minutes and half an hour per session	More than half an hour per session	Don't know	

	☐ [1]	☐ [2]	☐ [3]	☐ [9]	
5.	In relation to visits to the GP by the person you are caring for, can you tell me how often you usually go with the person to see him or her?				
	Less than once per month	1 to 4 times a month	More than once per week	Don't know	
	☐ [1]	☐ [2]	☐ [3]	☐ [9]	
6.	How much time does going on one visit usually take you, including the time it takes you to get there?				
	Less than an hour	Between one and two hours	More than three hours	Don't know	
	☐ [1]	☐ [2]	☐ [3]	☐ [9]	
7.	In relation to visits to the specialist [xxx AltRef: <type of specialist> (e.g. cardiologist) / <name of individual specialist>] by the person you are caring for, can you tell me how often you usually go with the person to see him or her?				
	Less than once per month	1 to 4 times a month	More than once per week	Don't know	
	☐ [1]	☐ [2]	☐ [3]	☐ [9]	
8.	How much time does going on one visit usually take you, including the time it takes you to get there?				
	Less than an hour	Between one and two hours	More than three hours	Don't know	
	☐ [1]	☐ [2]	☐ [3]	☐ [9]	
9.	In relation to your own participation in care planning meetings [xxx AltRef: care planning meetings held by <provider> / <given name of meetings>], can you tell me how often you usually go there?				
	Less than once every half year	Every 4 to 6 months	Every 1 to 3 months	More than once per month	Don't know
	☐ [1]	☐ [2]	☐ [3]	☐ [4]	☐ [9]

10.	How much time does going on one meeting usually take you, including the time it takes you to get there?				
	Less than an hour ☐ [1]	Between one and two hours ☐ [2]	More than three hours ☐ [3]	Don't know ☐ [9]	
11.	In relation to your own visits to the carer support organization [xxx AltRef: <given name of organization>], can you tell me how often you usually go there?				
	Less than once per month ☐ [1]	1 to 4 times a month ☐ [2]	More than once per week ☐ [3]	Don't know ☐ [9]	
12.	How much time does going on one visit usually take you, including the time it takes you to get there?				
	Less than an hour ☐ [1]	Between one and two hours ☐ [2]	More than three hours ☐ [3]	Don't know ☐ [9]	
13.	In relation to your usage of the web portal [xxx AltRef: <given name of web portal> / <given name of service>], can you tell me how often you usually access it?				
	Less than once per week ☐ [1]	About 1 to 4 times a week ☐ [2]	About every day ☐ [3]	More than 1 time per day ☐ [4]	Don't know ☐ [9]
14.	How much time do you usually spend using the web portal [xxx AltRef: <given name of web portal> / <given name of service>]?				
	Less than 10 minutes per session ☐ [1]	Between 10 minutes and half an hour per session ☐ [2]	Between half an hour and 1 hour per session ☐ [3]	More than 1 hour per session ☐ [4]	Don't know ☐ [9]

Module 2: Specific service-related impacts

The explanation for the respondent: Now, we would like to ask you a few questions about how you feel the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] has affected you.

[xxx next three paragraphs to be deleted] This module addresses any specific impacts that can be expected to be generated by the service under evaluation and to be perceivable by the respondent. Potential areas of impact to be addressed include the motivation to perform physical activities, the ability to perform physical activities, level of anxiety, sense of safety and security, feeling of independence / self-determination, emotional well-being, social connectedness or isolation, ability to manage own chronic disease, or ability to manage activities of daily living.

Where applicable, the term "the new service" should be adapted to the actual name of the service or system, especially if this can be expected to be more familiar to the respondent (e.g. the COPD programme, the telecare service). This may also be necessary if the respondent is actually not aware of anything new being put in place, e.g. because for her/him it is the first contact with the service.

With a view to respondent burden, overlaps with other instruments measuring similar or identical constructs should be avoided. For the same reason, it may also make sense to limit the number of questions used to between three and five.

1.	To what extent, if any, has the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] affected your **ability to manage the care activities** you are doing for the person you are caring for?
	It has increased my ability a lot ☐ [1] *It has increased my ability a little* ☐ [2] *It has not changed my ability* ☐ [3] *It has decreased my ability a little* ☐ [4] *It has decreased my ability a lot* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____ _____
2.	To what extent, if any, has the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] affected **your relationship with the person you care for**?
	It has improved our relationship a lot ☐ [1] *It has improved our relationship a little* ☐ [2] *It has not affected our relationship* ☐ [3] *It has made our relationship a little worse* ☐ [4] *It has made our relationship a lot worse* ☐ [5]
	If you want to, you can provide further details on your answer below : _____

	_____ _____
3.	To what extent, if any, do you feel that the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] **supports you** in your role as a carer?
	It makes me feel a lot more supported ☐ [1] *It makes me feel a little more supported* ☐ [2] *It has not changed how supported I feel* ☐ [3] *It makes me feel a little less supported* ☐ [4] *It makes me feel a lot less supported* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____ _____ _____
4.	To what extent, if any, has using the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] affected **your level of anxiety** about the health and well-being of the person you care for?
	It has reduced my anxiety a lot ☐ [1] *It has reduced my anxiety a little* ☐ [2] *It has not affected my anxiety* ☐ [3] *It has increased my anxiety a little* ☐ [4] *It has increased my anxiety a lot* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____
5.	To what extent, if any, has the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] affected your **emotional wellbeing**?

	It has increased my emotional wellbeing a lot ☐ [1] *It has increased my emotional wellbeing a little* ☐ [2] *It has not affected my emotional wellbeing* ☐ [3] *It has decreased my emotional wellbeing a little* ☐ [4] *It has decreased my emotional wellbeing a lot* ☐ [5] If you want to, you can provide further details on your answer below : _____ _____ _____ _____ _____ _____

Module 3: Summary assessment

The explanation for the respondent: Now, we would like to ask you a few questions about how satisfied you are in general with the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>].

[xxx this paragraph to be deleted] Module 3 covers the overall satisfaction of the respondent with the service received. Its main aim is to determine in how far specific benefits or dis-benefits were perceived as being crucial for the overall experience. Furthermore, it addresses the issue of service sustainability from the respondent's point of view.

1.	Overall, taking everything into account, **how satisfied** are you with the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>]?				
	Very satisfied	*Fairly satisfied*	*Neither satisfied nor dissatisfied*	*Fairly dissatisfied*	*Very dissatisfied*
	☐ [1] ☐ [5]	☐ [2]	☐ [3]	☐ [4]	
	If you want to, you can provide further details on your answer below : _____ _____ _____				

2.	Again, taking everything into account, is the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] **worth the effort** involved in using it?
	Yes Very much so ☐ [1] *Yes mostly* ☐ [2] ☐ [3] *Neither worth it nor not worth it* ☐ [4] ☐ [5] *No mostly not* *No certainly not*
	If you want to, you can provide further details on your answer below : _____ _____ _____
3.	Would you want to **continue using** the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] in the future? [xxx AltQst] Would you want to **use** the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] **again**, in case it should be necessary?
	Yes, very much so ☐ [1] *Yes I think so* ☐ [2] ☐ [3] *I am not yet decided* ☐ [4] ☐ [5] *No I do not think so* *No certainly not*
	If you want to, you can provide further details on your answer below : _____ _____ _____

Module 4: Willingness-to-pay

[xxx next 4 paragraphs to be deleted] Module 4 measures the respondent's willingness to pay for the new service. The module should be primarily used in cases where the introduction of a service fee is being considered, in order to determine what amounts might be acceptable to what parts of the target population.

The module comes in two versions, one for self-completion and a second for application by an interviewer.

Note that the introductory text is an integral part of the module and must be applied. It needs to be adapted to the specific evaluation. Since willingness to pay is usually strongly dependent on income, the respective questions should be applied as long as there is no case-level data on income from the same respondents.

Currency amounts, both for the possible fee and for household income categories, need to be adapted to the circumstances of the area where the service is being evaluated.

WTP for self-completion

Introduction (please adapt)

We would like to find out how valuable the service that you have received in the past months is to you, especially with respect to your <role as a carer / the support your receive as a carer>. We have therefore designed a short questionnaire for you to complete.

We are asking you to imagine a situation where you have to pay a monthly fee for the service. The amount of the fee you would be willing to pay (if you had to) gives us an indication of how you value the benefits of the service compared with other things you might want to spend your money on. There are no right or wrong answers.

Please read each question carefully and follow the instructions. This questionnaire is confidential and no identifying information will be used.

1.	Thinking just about your role as a carer, would the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] be worth at least something to you?
	Yes ☐ [1] No ☐ [2] → Please tell us why below (Question 3).
2.	Now suppose that you were told that the monthly fee for the service would be one of the amounts given below. Would you say 'Yes, I'd pay that' or 'No, I'd rather live without the service's help'? Or would you be unsure?

	10€ per month		20€ per month		30€ per month
Yes	☐ [1]	Yes	☐ [1]	Yes	☐ [1]
No	☐ [2]	No	☐ [2]	No	☐ [2]
Unsure	☐ [3]	Unsure	☐ [3]	Unsure	☐ [3]

3.	If the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] is not worth anything to you, please let us know why you feel this way:
	_____ _____ _____

4.	To be able to better understand your answer, could you please tell us what the monthly net income of your household is? (Net income is the income of all household members, regardless of source, less taxation and compulsory insurance).

Less than 1200 €	Between 1200 and 2000 €	Between 2000 and 4000 €	More than 4000 €	I don't know → go to question 5	I would rather not tell → go to question 5
☐ [1]	☐ [2]	☐ [3]	☐ [4]	☐ [8]	☐ [9]

5.	If you do not know the exact amount or do not want to reply to this question, could you tell us which of the following statements best describes your current financial situation?

Things are very difficult	I have trouble making ends meet	I have to be careful but I get by	Comfortable	Very comfortable	Don't know or would rather not tell
☐ [1]	☐ [2]	☐ [3]	☐ [4]	☐ [5]	☐ [9]

6.	Is there anything else you would like to add about how valuable the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] is to you?
	_____ _____ _____ _____ _____ _____

WTP for interview application

Note to interviewer

In applying this questionnaire, please follow the instructions given throughout the document. These are always marked with the abbreviation INT followed by a colon and the instruction. Start by reading the introduction text to the respondent, then go to question 1, reading out the question and the answer options. Depending on the answers given, continue with the next question as indicated. If there is no question indicated, please continue with the one immediately following.

INT: Read aloud to the respondent. (please adapt)

We would like to find out how valuable the service that you have received in the past months is to you, especially with respect to your <role as a carer / the support you receive as a carer>. We have therefore designed a short questionnaire for you to complete.

We are asking you to imagine a situation where you have to pay a monthly fee for the service. The amount of the fee you would be willing to pay (if you had to) gives us an indication of how you value the benefits of the service compared with other things you might want to spend your money on. There are no right or wrong answers.

This questionnaire is confidential and no identifying information will be used.

1.	Thinking just about your role as a carer, would the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] be worth at least something to you?
	Yes ☐ [1] → *INT:* go to question 3 No ☐ [2] → *INT:* go to question 2
2.	Please explain why the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] is not worth anything to you?
	_____ _____ _____ → *INT:* Got to question 7
3.	Suppose that you were told that the fee for the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] would be 20€ per month. Would you say 'Yes, I'd pay that' or 'No, I'd rather live without the service's help'? Or would you be unsure?
	Yes ☐ [1] → *INT:* go to question 5 Unsure ☐ [2] → *INT:* go to question 5 No ☐ [3] → *INT:* go to question 4
4.	Is there any amount less than 20€ that you would be prepared to pay per month?

	Yes ☐ [1] No ☐ [2] If yes, what is the most you would be prepared to pay? _____ _____ → *INT:* Got to question 7
5.	Suppose that you were told instead that the fee for the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>] would be 30€ per month. Would you say 'Yes, I'll pay that' or 'No, I'd rather live without the service's help'? Or would you be unsure?
	Yes ☐ [1] → *INT:* go to question 6 Unsure ☐ [2] → *INT:* go to question 6 No ☐ [3] → *INT:* go to question 6
6.	What is the HIGHEST fee you would be prepared to pay per month for the new service [xxx AltRef: the service / the support you received in relation to your caring role / <given name of service>]?
	_____ _____ → *INT:* Got to question 7
7.	To be able to better understand your answer given in the last question, could you please tell us what the monthly net income of your household is? (Net income is the income of all household members, regardless of source, less taxation and compulsory insurance).

Less than 1200 €	Between 1200 and 2000 €	Between 2000 and 4000 €	More than 4000 €	I don't know → *INT:* go to question 8	I would rather not tell → *INT:* go to question 8
☐ [1]	☐ [2]	☐ [3]	☐ [4]	☐ [8]	☐ [9]

8.	If you do not know the exact amount or do not want to reply to this question, could you tell us which of the following statements best describes your current financial situation?

	Things are very difficult	I have trouble making ends meet	I have to be careful but I get by	Comfortable	Very comfortable	Don't know or would rather not tell
	☐ [1]	☐ [2]	☐ [3]	☐ [4]	☐ [5]	☐ [9]

Module 5: Perception of integration

1.	When it comes to information about the health and well-being of the person you are caring for, do you feel that you have to **repeat this information** a lot when talking to different people treating and caring for that person?
	No, I usually have to give such information only once ☐ [1] *I sometimes have to repeat information* ☐ [2] *I have to repeat information quite frequently* ☐ [3] *Yes, I have to keep repeating such information almost constantly* ☐ [4] *Don't know / not sure* ☐ [9]
	If you want to, you can provide further details on your answer below : _____ _____ _____
2.	Taking everything into account, do you feel that the different people treating and caring for the person you are caring for **work well together** to give that person the best possible care and support?
	Yes, all of them work well together ☐ [1] *Most of them work well together* ☐ [2] *Some of them work well together* ☐ [3] *No, they do not work well together* ☐ [4] *Don't know / not sure* ☐ [9]
	If you want to, you can provide further details on your answer below : _____ _____ _____

8.6. eCUIS

The following annex presents the eCUIS model questionnaire for users (service provider staff) that needs to be adapted to the purposes of a specific evaluation, depending on the research questions to be answered and other considerations such as overall instrument length / respondent burden or resources available for evaluation. The adaptation consists of the following steps:

Num	Adaptation steps
1	Decide which module to apply. Delete unused modules.
2	Decide which questions within each module are applicable. Delete questions that are not applicable, add additional questions when needed.
3	Adapt reference to the intervention being measured in each question so that a respondent understands what he/she is being asked about. Possible alternative references are given in square brackets, followed by "xxx AltRef" in each question. Other references can be used. References not used should be deleted.
4	Delete information needed for the setting up of the questionnaire. Paragraphs that can be deleted each begin with "[xxx this paragraph to be deleted]".
5	Delete numeric codes assigned to answer categories [provided in square brackets].

Module 1: Time use

The explanation for the respondent: First, we would like to ask you a few questions about the time you spend using the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>].

[xxx this paragraph to be deleted] This module is for measuring the time spent by the respondent in using the service. Depending on the service scenario under investigation, the questions need to be adapted to cover different activities for which time is being spent. Common examples include the time spent helping a cared-for person doing telehealth readings, time for accompanying the cared for person on visits to health and care providers, time for own visits by or to a carer support service or time for using an online service (such as an information website).

1.	In relation to the telehealth equipment [xxx AltRef: telemonitoring equipment / <given name of device set> / <given name of service>] used by your clients/patients, can you tell me how often you usually help the person doing the telehealth readings?					
	Less than once per week	About 1 to 4 times a week	About every day	More than 1 time per day	Never	Don't know
	☐ [1]	☐ [2]	☐ [3]	☐ [4]	☐ [5]	☐ [9]

2.	How much time do you usually spend helping with the telehealth [xxx AltRef: telemonitoring / <given name of device set> / <given name of service>] readings?
	Less than 10 minutes per session ☐ [1] | Between 10 minutes and half an hour per session ☐ [2] | More than half an hour per session ☐ [3] | Don't know ☐ [9]
3.	In relation to the telecare equipment [xxx AltRef: social alarm / <given name of device set> / <given name of service>] used by your clients/patients, can you tell me how often you usually help the person using it?
	Less than once per week ☐ [1] | About 1 to 4 times a week ☐ [2] | About every day ☐ [3] | More than 1 time per day ☐ [4] | Never ☐ [5] | Don't know ☐ [9]
4.	How much time do you usually spend helping with the telecare [xxx AltRef: social alarm / <given name of device set> / <given name of service>]?
	Less than 10 minutes per session ☐ [1] | Between 10 minutes and half an hour per session ☐ [2] | More than half an hour per session ☐ [3] | Don't know ☐ [9]
5.	In relation to consultations in your practice by your clients/patients, can you tell me how often they usually come to visit you?
	Less than once per month ☐ [1] | Once a month ☐ [2] | 2 to 4 times a month ☐ [3] | More than once per week ☐ [4] | Don't know ☐ [9]
6.	How much time does one consultation usually take you, including the time for preparation and follow-up?
	Less than 15 minutes ☐ [1] | Between 15 and 30 minutes ☐ [2] | Between 30 and 45 minutes ☐ [3] | More than 45 minutes ☐ [4] | Don't know ☐ [9]

7.	In relation to home visits to your clients/patients, can you tell me how often you usually do them?				
	Less than once per month ☐ [1]	Once a month ☐ [2]	2 to 4 times a month ☐ [3]	More than once per week ☐ [4]	Don't know ☐ [9]
8.	How much time does one visit usually take you, including the time to get there?				
	Less than 15 minutes ☐ [1]	Between 15 and 30 minutes ☐ [2]	Between 30 and 60 minutes ☐ [3]	More than 60 minutes ☐ [4]	Don't know ☐ [9]
9.	In relation to care planning meetings [xxx AltRef: care planning meetings held by <provider> / <given name of meetings>], can you tell me how often you attend them in relation to one client/patient?				
	Less than once every half year ☐ [1]	Every 4 to 6 months ☐ [2]	Every 1 to 3 months ☐ [3]	More than once per month ☐ [4]	Don't know ☐ [9]
10.	How much time does going on one meeting usually take you, including the time it takes you to get there?				
	Less than 30 minutes ☐ [1]	Between 30 and 60 minutes ☐ [2]	Between 1 and 2 hours ☐ [3]	More than 2 hours ☐ [4]	Don't know ☐ [9]
11.	In relation to your usage of the electronic care record [xxx AltRef: <given name of ECR> / <given name of service>], can you tell me how often you usually access it in relation to one client/patient?				
	Less than once per week ☐ [1]	About 1 to 4 times a week ☐ [2]	About every day ☐ [3]	More than 1 time per day ☐ [4]	Don't know ☐ [9]
12.	How much time do you usually spend using the electronic care record [xxx AltRef: <given name of ECR> / <given name of service>] in relation to one client/patient?				

	Less than 10 minutes per session ☐ [1]	Between 10 and 20 per session ☐ [2]	Between 20 and 30 minutes per session ☐ [3]	Between 30 and 60 minutes per session ☐ [4]	More than 1 hour per session ☐ [5]	Don't know ☐ [9]

Module 2: Specific service-related impacts

The explanation for the respondent: Now, we would like to ask you a few questions about how you feel the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>] has affected your work.

[xxx next three paragraphs to be deleted] This module addresses any specific impacts that can be expected to be generated by the service under evaluation and to be perceivable by the respondent. Potential areas of impact to be addressed include xxx.

Where applicable, the term "the new service" should be adapted to the actual name of the service or system, especially if this can be expected to be more familiar to the respondent (e.g. the COPD programme, the telecare service).

1.	To what extent, if any, has the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>] affected your **ability to manage your overall workload**?
	It has increased my ability a lot ☐ [1] *It has increased my ability a little* ☐ [2] *It has not changed my ability* ☐ [3] *It has decreased my ability a little* ☐ [4] *It has decreased my ability a lot* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____ _____
2.	To what extent, if any, has the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>] affected your **ability to provide care to individual clients/patients**?

	It has increased my ability a lot ☐ [1] *It has increased my ability a little* ☐ [2] *It has not changed my ability* ☐ [3] *It has decreased my ability a little* ☐ [4] *It has decreased my ability a lot* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____ _____
3.	To what extent, if any, has the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>] affected your **efficiency**?
	It has increased my efficiency a lot ☐ [1] *It has increased my efficiency a little* ☐ [2] *It has not changed my efficiency* ☐ [3] *It has decreased my efficiency a little* ☐ [4] *It has decreased my efficiency a lot* ☐ [5]
	If you want to, you can provide further details on your answer below : _____ _____ _____ _____
4.	To what extent, if any, has the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>] affected your **relationship with your clients/patients**?
	It has improved our relationship a lot ☐ [1] *It has improved our relationship a little* ☐ [2] *It has not affected our relationship* ☐ [3] *It has made our relationship a little worse* ☐ [4] *It has made our relationship a lot worse* ☐ [5]

	If you want to, you can provide further details on your answer below : _____ _____
5.	To what extent, if any, has the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>] affected your **level of work-related stress**? *It has reduced my work-related stress a lot* ☐ [1] *It has reduced my work-related stress a little* ☐ [2] *It has not affected my work-related stress* ☐ [3] *It has increased my work-related stress a little* ☐ [4] *It has increased my work-related stress a lot* ☐ [5] If you want to, you can provide further details on your answer below : _____ _____ _____ _____ _____ _____
6.	To what extent, if any, has the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>] affected your **satisfaction with your work**? *It has increased my satisfaction with my work a lot* ☐ [1] *It has increased my satisfaction with my work a little* ☐ [2] *It has not changed my satisfaction with my work* ☐ [3] *It has decreased my satisfaction with my work a little* ☐ [4] *It has decreased my satisfaction with my work a lot* ☐ [5] If you want to, you can provide further details on your answer below : _____ _____ _____ _____ _____ _____

Module 3: Summary assessment

The explanation for the respondent: Now, we would like to ask you a few questions about how satisfied you are in general with the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>].

[xxx this paragraph to be deleted] Module 3 covers the overall satisfaction of the respondent with the service. Its main aim is to determine in how far specific benefits or dis-benefits were perceived as being crucial for the overall experience. Furthermore, it addresses the issue of service sustainability from the respondent's point of view.

1.	Overall, taking everything into account, **how satisfied** are you with the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>]?
	Very satisfied ☐ [1] *Fairly satisfied* ☐ [2] ☐ [3] *Neither satisfied nor dissatisfied* ☐ [4] *Fairly dissatisfied* ☐ [5] *Very dissatisfied*
	<u>If you want to, you can provide further details on your answer below :</u> _____ _____ _____
2.	Again, taking everything into account, is the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>] **worth the effort** you spend using it?
	Yes Very much so ☐ [1] *Yes mostly* ☐ [2] ☐ [3] *Neither worth it nor not worth it* ☐ [4] *No mostly not* ☐ [5] *No certainly not*
	<u>If you want to, you can provide further details on your answer below :</u> _____ _____ _____

3.	If the decision was solely up to you, would you want to **continue working with** the new service [xxx AltRef: the service / the changes to the way you provide care to your clients/patients / <given name of service>] in the future?

8.7. Evaluation Items for Impact Modelling in layer 4

The following annex presents a preliminary version of the evaluation items for the impact and scale-up modeling. The specific items will be further developed together with the analysis tool in T9.3 and T9.5 by empirica and Osakidetza.

8.7.1. Items for MDT members on the C3DP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Usefulness Method: Unit: Log files Deadline: M42 Who can obtain the data: SRDC	Have treatment options that were suggested by C3DP been ignored, accepted or refused?	MDT members use the C3DP to plan treatment activities	Comparison between recommended activities versus activities that are ultimately carried out.	Clashes between different treatment options will become more visible to clinicians. In consequence, they may change their attitude towards treatment options when receiving C3DP advice. Between the treatment options, clinicians can make more rational choices.
Evaluation Topic: Use of C3-Cloud components and its usefulness Method: Log files Unit: When to obtain the data (Deadline):		C3Cloud components improve the collaboration among clinicians and other professionals in the MDT members		The number of MDT members (!! Not only the number of doctors!!) involved in the treatment activities should increase with the implementation of C3Cloud components
Evaluation Topic: Healthcare resource utilization Method:		Number of (reduced) hospital admissions		

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Unit: Deadline:				
Evaluation Topic: Healthcare resource utilization Type of Measurement: Unit: Deadline:		Number of (reduced) hospital re-admissions		
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc.) Method: Unit: Deadline:		Number of (reduced) adverse drug events ADE		

8.7.2. Items for MDT members on the C3DP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Clinical & process quality and changes Method: The Unit of analysis:	Have treatment goals been defined for C3CLoud patients? Have the treatment goals been followed (i.e. appropriate actions been taken and activities	MDT members can use the Personalized Care Plan Development Platform PCPDP	Comparison of planned V.s conducted care plans/activities /	MDT members can use the PCPDP to define and reconcile treatment goals for multimorbid patients

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Deadline: Who can obtain the data: local systems in the pilot sites; feedback from the patients (e.g. from the PEP: how well do patients perceive the follow up with their treatment goals?)	performed according to treatment goals)?		treatments (from the log files)	
Evaluation Topic: Healthcare resource utilization Method: Unit: When to obtain the data (Deadline):		Reconciliation of activities for multiple diseases in the PCPDP		Being able to reconcile activities across multiple diseases allows to define who is an adequate MDT member to treat the patient (who is least expensive and most effective to reach the treatment goals): This leads to a gain in efficiency
Evaluation Topic: Safety Method: Log files Unit: Deadline:	How many conflicts were detected AND avoided per case?	Conflicts in treatment options are made explicit in the PCPDP		Increased patient safety: The PCPDP helped physicians to detect and avoid conflicts in treatment options for multimorbid patients.

8.7.3. Items for MDT members on the CDSM

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Clinical & process quality and changes Type of Measurement: Unit: Log files Deadline: Log file analysis after component implementation and usage Who can obtain the data: Logfile reports can be obtained in the C3DP in each pilot site locally. This leaves us with 3 log files! CDSM logfiles could be extracted for patient groups (not for individual patients) Who are the responsible persons? @Mustafa	Has CDSM been accessed? Has the process in CDSM been completed or interrupted in between? How often did MDT members seek advice? (is automatic and not proactively) How often did they receive it? How often did they adhere to the given advice? Has the suggested guideline been followed or ignored or refused?	MDT members can use the Clinical Decision Support Modules CDSM	There is no comparator software that can be used! "Comparison" will be done based on "did the component serve to reach what it is aimed for?"	Using the C3Cloud components, the MDT members receive advice and suggestions from the CDSM (based on "reconciled" clinical guidelines), that are specifically valid for single diseases.
Evaluation Topic: Healthcare resource utilization Method: Interviews Unit: Minutes Deadline: Interviews before component implementation (M22) Who can obtain the data: The Interviews with clinicians / MDT members	How do you currently access clinical guidelines for multimorbid patients and how do you receive treatment advice? How much time do you think you spend on those activities per patient consultation?	By using CDSMs, the MDT members can access treatment advise easier and more timely	This questionnaire item will serve as baseline measurement and will be compared to the midterm measurement	Saved time for not having to look up all clinical guidelines

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Healthcare resource utilization Method: Interviews Unit: Minutes Deadline: Interviews after component implementation (M42) Who can obtain the data: The Interviews with clinicians / MDT members	Do you believe you safe time through CDSM usage, when comparing it to your own approaches to access clinical guidelines and treatment advice (without CDSM)? If yes, how much time do you think you safe per patient consultation?	By using CDSMs, the MDT members can access treatment advise easier and more timely	This questionnaire item will serve as midterm measurement and will be compared to the baseline measurement	Saved time for not having to look up all clinical guidelines
Evaluation Topic: Safety Type of Measurement: Unit: Deadline:		traceable and explicit clinical decisions		Before the C3-Cloud solution, clinical decisions were not explicit and not traceable. With C3Cloud this will change!
Evaluation Topic: Healthcare resource utilization Method: Log files (timestamps in C3DP?) Likert Scale Unit: Minutes per patient visit Deadline: Other Comments: Do conventionally designated time slots per patient still reflect the actual time usage per patient? Or do time slots not fit anymore?	Have you saved time by using C3-Cloud components when comparing it to conventional alternative software solutions? If yes, how many minutes per patient visit?	The efficiency of care provision during patient visits has increased		Reduced time spent on sessions with patients
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the		Changes in poly-pharmacy		

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
components help the clinicians to find solutions for issues in care provision? etc.) Method: Unit: Deadline:				
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc.) Type of Measurement: The Unit of analysis: Deadline:		Impact on clinical parameters		

8.7.4. Items for MDT members on the PEP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Clinical effectiveness (e.g. medication reduction, reduction of conflicts between clinical guidelines, do the components help the clinicians to find solutions for issues in care provision? etc.) Method: Log files The Unit of analysis: Deadline: Other Comments: Have clinicians more knowledge about the care processes that the patients are undergoing? Do they see the advantage or not? Do they really use this information? Do they really want to have this information? If not this could also lead to resistance to use the components!	Has PEP usage led to increased adherence of treatment activities? Compare the treatment goals and prescribed activities for the patient with the activities which were performed by the patient at home (and which are transmitted to the C3DP).	Patients use the PEP and their data entries are pushed to the C3DP.	Comparison of planned vs performed activities	Increased adherence to care plan/treatment: the PEP increases the knowledge of MDT members and clinicians and allows them to monitor treatment adherence of their patients

8.7.5. Items for patients on the PEP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Patients' User experience Method: Unit: Likert Scale	I find it easy to adhere to treatment activities suggested by members of care team!	Patients use the Patient Empowerment Platform PEP for self-	Comparison with values in final Likert Scale questionnaire	Reading the care plan on the PEP increases the adherence to prescriptions and treatment plans

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Deadline: M22	I strongly agree - ... - neutral - ... - I strongly disagree I feel involved in the planning activities to treat my multimorbidities. I strongly agree - ... - neutral - ... - I strongly disagree I have a high personal motivation to actively follow my treatment plan and carry out treatment activities on my own. I strongly agree - ... - neutral - ... - I strongly disagree	empowerment and treatment advise		
Evaluation Topic: Patients' User experience Method: Likert Scale The Unit of analysis: Deadline: M42	I find it easy to adhere to treatment activities suggested by members of care team! I strongly agree - ... - neutral - ... - I strongly disagree I feel involved in the planning activities to treat my multimorbidities. I strongly agree - ... - neutral - ... - I strongly disagree	Patients use the Patient Empowerment Platform PEP for self-empowerment and treatment advise	Comparison with values in baseline Likert Scale questionnaire	Reading the care plan on the PEP increases the adherence to prescriptions and treatment plans

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
	I have a high personal motivation to actively follow my treatment plan and carry out treatment activities on my own. I strongly agree - ... - neutral - ... - I strongly disagree			
Evaluation Topic: Use of C3-Cloud components and its usefulness Method: Unit: Deadline: M42 Who can obtain the data: SRDC Other comments: Will adherence or commitment to the care plan change indeed? EXAMPLE: The clinicians plan to measure blood pressure every day. If the patient only feeds data to the PEP once a week, a comparison of the expected 7 values per week to the received 1 value per week is an indication that the PEP has NOT increased the patient's motivation to follow the treatment plan.	Is there a difference between the expected number of clinical values /measurements and the actual number of reported clinical values/measurements	Patients use the Patient Empowerment Platform PEP for self-empowerment	Comparison of expected values (based on planned treatment activities to be carried out by the patient) with the actual received values that are fed back from the patients in the PEP	Reading the care plan on the PEP increases the adherence to prescriptions and treatment plans
Evaluation Topic: Safety Type of Measurement: Unit: Glucose levels, blood pressure monitoring;	What is the number of alarms that were issued per patient case? What was the type of alarm that was issued? (e.g. on blood pressure, glucose levels etc)	remote monitoring readings are automatically pushed to the PEP		Data is accessible to the MDT and the patients on the C3DP and PEP immediately. Increases patient safety as alarms

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Deadline:	What share of the alarms has been reacted upon (and how?)?			can be issued without further ado

8.7.6. Items for patients on the C3DP

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Health outcomes (too much for the scope of C3Cloud? How to measure this? (is a stagnation of health deterioration already a positive health outcome? The time to determine health outcomes may be much longer than the study duration)) Method: Closed questionnaires Unit: e.g. BMI; Blood pressure, etc. Deadline: Who can obtain the data: EHR controls		An improvement of clinical parameters by usage of PCPDP and C3DP and PEP		The utility of C3CLoud components is assumed to be high if clinical patient parameters improve.

8.7.7. Items for MDT members on the CDSM

Evaluation topic / Method / Unit of analysis and Deadline	Question	Impact	Comparator	What is the outcome?
Evaluation Topic: Health outcomes The Unit of analysis: When to obtain the data	increase/ reduction / variation ?	The C3DP improves management of clinical goal setting with an impact on HbA1c; PEP	comparing to control group	Better overview of clinicians does lead to increased awareness of clinical goals.PEP improves patient understanding of clinical

(Deadline): Obtain all values available during the course of the trial Who can obtain the data: How to obtain from control group? Comment: (too much for the scope of C3Cloud? How to measure this? (is a stagnation of health deterioration already a positive health outcome? The time to determine health outcomes may be much longer than the study duration)) Method: Clinical parameter from HER		improves compliance to goal		goals and performance towards it It can be expected to improve Cholesterol, but can also lead to relaxing Cholesterol goals to avoid negative effects. We aim to control Cholesterol for exploration. A lower variation suggests better adherence
Evaluation Topic: Health outcomes Method: Clinical parameter from HER Unit: Deadline: Obtain all values available during the course of the trial Who can obtain the data: How to obtain from control group Comment: (too much for the scope of C3Cloud? How to measure this? (is a stagnation of health deterioration already a positive health outcome? The time to determine health outcomes may be much longer than the study duration)	increase/ reduction / variation mmHg	Better overview of clinicians does lead to increased awareness of clinical goals.PEP improves patient understanding of clinical goals and performance towards it. It can be expected to improve Cholesterol, but can also lead to relaxing Cholesterol goals to avoid negative effects. We aim to control Cholesterol for exploration. A lower variation suggests better adherence	comparing to control group	The C3DP improves management of clinical goal setting with an impact on blood pressure; PEP improves compliance to goals

Evaluation Topic: Health outcomes (too much for the scope of C3Cloud? How to measure this? (is a stagnation of health deterioration already a positive health outcome? The time to determine health outcomes may be much longer than the study duration)) Method: Clinical parameter from EHR Unit: Deadline: Obtain all values available during the course of the trial Who can obtain the data: How to obtain from control group?	increase/ reduction / variation mmol/l	The C3DP improves management of clinical goal setting with an impact on Cholesterol; PEP improves compliance to goals	comparing to control group	Better overview of clinicians does lead to increased awareness of clinical goals. PEP improves patient understanding of clinical goals and performance towards it. It can be expected to improve Cholesterol, but can also lead to relaxing Cholesterol goals to avoid negative effects. We aim to control Cholesterol for exploration. A lower variation suggests better adherence
Evaluation Topic: Health outcomes (too much for the scope of C3Cloud? How to measure this? (is a stagnation of health deterioration already a positive health outcome? The time to determine health outcomes may be much longer than the study duration)) Method: Clinical parameter from HER Unit: Deadline: Obtain all values available during the course of the trial Who can obtain the data: How to obtain from control group?	increase/ reduction / variation BMI kg/m²	The C3DP improves management of clinical goal setting with an impact on weight; PEP improves compliance to goals	comparing to control group	Better overview of clinicians does lead to increased awareness of clinical goals. PEP improves patient understanding of clinical goals and performance towards it. It can be expected to improve Cholesterol, but can also lead to relaxing Cholesterol goals to avoid negative effects. We aim to control Cholesterol for exploration. A lower variation suggests better adherence

9. List of references

Dalkey, N., & Helmer, O. (1963, April). An Experimental Application of the DELPHI Method to the Use of Experts. *Management Science; Vol. 9; Issue 3*, pp. 458-467.

Eckhardt, A., Laumer, S., & Weitzel, T. (2009). Who influences whom? Analyzing workplace referents' social influence on IT adoption and non-adoption. *Journal of Information Technology*.

Hoonakker, P. L., Carayon, P., & Walker, J. M. (2010, January 01). Measurement of CPOE End-User Satisfaction Among ICU Physicians and Nurses. *Applied Clinical Informatics*, pp. 268-285.

J.P., V., von Elm, E., Altman, D. G., Gøtzsche, P. C., Mulrow, C. D., Pocock, S. J., . . . Egger, M. (2007, November 18). Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Explanation and Elaboration.). *Epidemiology*, pp. 805-35.

Jeffrey, D. A. (2015). Testing the Technology Acceptance Model 3 (TAM 3) with the Inclusion of Change Fatigue and Overload, in the Context of Faculty from Seventh-day Adventist Universities: A Revised Model. Michigan, USA: Andrews University Dissertations.

Moumane, K., Idri, A., & Abran, A. (2016, April 29). Usability evaluation of mobile applications using ISO 9241 and ISO 25062 standards. *Springerplus.*, p. 548.

Nielsen, J. (1995, January 1). *How to Conduct a Heuristic Evaluation*. Retrieved from www.nngroup.com: https://www.nngroup.com/articles/how-to-conduct-a-heuristic-evaluation/

Nielsen, J. (1995). Technology Transfer of Heuristic Evaluation and Usability Inspection. *IFIP INTERACT'95 International Conference on Human-Computer Interaction.* Lillehammer, Norway.

Venkatesh, V., & Bala, H. (2008). Technology Accaeptance Model 3 and a Research Agenda on Interventions. *Decision Sciences*, p. 275.

Venkatesh, V., Morris, M. G., & Davis, G. B. (2003). User acceptance of information technology: Toward a unified view. *MIS Quarterly*, pp. 425-478.

Verhoeven, J. C., Heerwegh, D., & De Wit, K. (2010). Information and communication technologies in the life of university freshmen: An analysis of change. *Computers & Education*.

Yin, R. K. (2009). *Case Study Research: Design and Methods.* Sage.

10. List of Tables

11. List of Figures