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

D8.3 Deployment of C3-Cloud Pilot Application

Work Package:	WP8 C3-Cloud Pilot Application Development & Deployment
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Document History:

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EXECUTIVE SUMMARY

WP8 is responsible for the Pilot Application Development and Deployment. Following the requirements and use cases definitions (Task 8.1) and application design (Task 8.2), Task 8.3 is responsible for deployment and operation of C3-Cloud Pilot Application. The deployment phase of Task 8.3 started from March 2018 (Month 23) until October 2018 (Month 30). The operation phase of Task 8.3 will span for the remaining period of the project. Close collaboration between the technical partners and pilot site IT teams ensured the proper installation and configuration of pilot IT infrastructure and the integration and deployment of 17 C3-Cloud software artefacts, produced by the 7 high-level components in South Warwickshire, Basque Country and Region Jämtland Härjedalen. This follows a refinement of the deployment design in deliverable D8.2 "Design of the Implementation of the Pilot Application Scenarios". Ensuing industry best practice, pilot applications are fully tested in a staging environment with anonymised multi-morbidity patient samples before being replicated to the production system. The deliverable D8.3 is a description of the demonstrator of Deployment of C3-Cloud Pilot Application. This document describes the final delivery of C3-Cloud components, detailed pilot application architecture and the phased deployment process. Due to information governance restrictions, a demonstration of live systems cannot be presented in a public deliverable. Links to a demo version of C3-Cloud system are provided in the document, with screenshots being captured to illustrate key system workflow. A follow-up of the evaluation feedback reported in deliverable D9.3 "Test and Evaluation Report of C3-Cloud Components" is also included in this deliverable, relating to improvements made in the software components.

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1. DOCUMENT OVERVIEW

1.1 Purpose

This document reports on the work package 8 demonstrator deliverable Deployment of C3-Cloud Pilot Application. The report is organized as follows:

Section 2 follows up the evaluation feedback, reported in D9.3 and describes how they are handled.

Section 3 summarizes the implemented features of all C3-Cloud components that are ready to be deployed in pilot sites.

Section 4 details the architecture of pilot applications and their physical deployment.

Section 5 describes the process that has been undertaken to implement the deployment.

Section 6 provides instructions on how to access a demo version of C3-Cloud system and describes the key system workflow with screenshots.

1.2 Scope

The scope of work task 8.3 is deployment and operation of C3-Cloud Pilot Application. The task started in March 2018 (Month 23) and will span for the remaining period of the project. During the deployment phase in this task, all three pilot sites, South Warwickshire, Basque Country and Region Jämtland Härjedalen, ensured the readiness of required physical infrastructure, based on the application deployment design by deliverable D8.2. The technical partners, SRDC, MEDIXINE, WARWICK, INSERM and CAMBIO, have implemented all C3-Cloud high-level components and are in the process of deploying copies of those components on each site. Components are installed, configured and assembled based on site specific requirements. Before real patient data is imported into the pilot system, anonymous multi-morbidity sample data is deployed in a staging environment in each site, in order for local teams of pilot sites to learn and test the entire application. By Month 30 of the project (October 2018), deployment in staging environments have been completed and now the work is ongoing for deployment in production environment. This delay does not impede planning and execution of evaluation studies, as there is a soft transition process in the first 3 months of the pilot operation without any data collection for validation. The production system will have data backup and access control enabled for operation.

1.3 Context

Based on the requirements specification and architecture design of work package 3, work packages 5, 6 and 7 implemented and integrated the C3-Cloud software components, which were further tested in task 9.2. Following the deployment design of task 8.2, the task 8.3 installed and configured the software components in each pilot site. The staging environment will be used by task 9.4 to support user training workshops. During the remaining period of task 8.3, pilot systems will be operated in line with the evaluation studies in work package 9. During operation, technical partners will provide technical support under the governance of data protection agreements and apply some minor updates and bug-fixes that could not be caught during component testing.

1.4 Abbreviations and Acronyms

Abbreviation / Acronym	Definition
C3DP	Coordinated Care and Cure Delivery Platform
CAMBIO	Cambio Healthcare Systems AB
CDS	Clinical Decision Support
CDSM	Clinical Decision Support Modules

Abbreviation / Acronym	Definition
CHF	Chronic Heart Failure
CKD	Chronic Kidney Disease
DM	Diabetes Mellitus Type 2
DoA	Description of Action
ETL	Extract-Transform-Load
FHIR	Fast Healthcare Interoperability Resources
GDL	Guideline Definition Language
IdP	Identity Provider
INSERM	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE
MDT	Multidisciplinary Care Team
MEDIXINE	MEDIXINE OY
NAT	Network Address Translation
OSAKI	Servicio Vasco de Salud Osakidetza
PEP	Patient Empowerment Platform
RJH	REGION JAMTLAND HARJEDALEN
SIS	Semantic Interoperability Suite
SPS	Security and Privacy Suite
SRDC	SRDC YAZILIM ARASTIRMA VE GELISTIRME VE DANISMANLIK TICARET ANONIM SIRKETI
SWFT	SOUTH WARWICKSHIRE NHS FOUNDATION TRUST
TIS	Technical Interoperability Suite
WARWICK	THE UNIVERSITY OF WARWICK

2. D9.3 FEEDBACK FOLLOW-UP

The two front-end facing components, C3DP and PEP, have benefited from feedback for improvements during the usability and application testing in Task 9.2, and reported in deliverable D9.3 Test and Evaluation Report for C3-Cloud Components in Month 26 (June 2018). Unstructured feedback, expressed through the think-aloud method by the test participants, has been particularly useful. The following sections present how the project has responded to the feedback received (D9.3, Section 4.4) and incorporated them in relevant tasks, such as development, deployment and training.

2.1 C3DP-related Feedback

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
G1	Testers were generally very positive about the C3-Cloud concept and experienced it as very promising, helpful and easy to use.	Positive response - no action	
G2	Testers liked how it was very clinically focused.	Positive response - no action	
G3	The fact that C3DP suggests goals and activities was experienced very positive and helpful.	Positive response - no action	
G4	Testers would not want to use two or more IT systems in parallel. They prefer to see the functionality incorporated into their existing systems.	Training	This action has been follow-up in Task 9.4. The Project Guide Book for Healthcare Professionals (current version 0.10) includes detailed explanation in the FAQs section to answer questions such as: - Does C3-Cloud totally replace the local system? - Do you have to use the local system along with the C3-Cloud system for the care of an intervention patient during C3-Cloud study? - Does the C3-Cloud system allow overwriting data from local health information systems? - Can you add, modify, and/or remove information in C3DP? - How to reconcile contradictory goals/activities/education materials from different MDTs? The outputs of Task 9.4 will be delivered in April 2019 in deliverable D9.4.
G5	Super user support was needed to complete the testing as there were too many uncertainties.	Training	Super users (healthcare professionals who are able to train staff in using the system) are already included as key roles in the training of the three local plans. Task 9.4. will keep monitoring their role.

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
G6	Testers felt that systems need to be more user-friendly and intuitive before it would be accepted by clinicians during the technology trial or even as part of routine practice. Currently, the sequence of steps in the user interface is not always clear and there are uncertainties as to what the next step is. However, “simple tasks or activities” were experienced as intuitive.	Improvement	Completed - simpler interfaces have been implemented.
G7	The C3DP crashed once and the tester could not find a safe way of closing the system. It is encouraged to implement a safe way of closing the system if it crashes or freezes.	Improvement Training	General error handling has been improved to prevent crashing of the app. In Task 9.4, information about how to reopen the application if an error occurs, will be included in the User Manual for C3DP. If it happens that the logout button is not working, then the only option is to close the browser tab or the browser completely and open the URL in a new browser tab again. This will not cause any harm to the app; in the worst case scenarion, a few recent data updates before the crash might be lost.
G8	One user experienced that only half the screen was displayed and the other half was cut off.	Training	In Task 9.4, in the User Manual, the sections covering troubleshooting and technical support will include information on how users can report errors and issues.
G9	When one user logged off the C3DP, a message similar to „Trying to retrieve information" was displayed, but the user could not find a safe close button and thus had to quit the connection.	Training	Similar to Feedback #G7, information about how to reopen the application if an error occurs will be included in the User Manual for C3DP. This will be followed up by Task 9.4.
G10	The application testing and usability testing questionnaires were too long and did not allow the issues that testers encountered to be clearly identified. Testers felt that it would have been more efficient to integrate the questions into the walkthrough document so that they could answer the questions as they were testing the relevant sections on the C3-Cloud platforms. Furthermore, it was an issue for some test users that the platforms were not in their native language, despite having language facilitators readily available.	Evaluation questionnaires Language	Not all material was yet fully available during the initial testing (e.g., training material). During the technology trial, users will only answer the questionnaires at two instances to assess overall acceptability and usability. Thus, an integration of questions in the workflow is not feasible. It should also be avoided to ask users multiple times to respond to evaluation questions. The platforms and the evaluation questionnaires will be available in English, Swedish & Spanish for the trial, allowing users to select their native language.

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
G11	Regarding the information available on the platform: All users should be informed before using the platforms what information they can expect to find and where it can be found on the platform.	Training	Action being followed up in Task 9.4 (Similar to Feedback #G4).
S1	Testers found the method of initially adding and managing care team members very complicated. This needs to be presented in a more user friendly way. Taking into account the complexity of the primary care staff databases it is suggested to select first the role and then select the name of the care team member.	Improvement	Improvement completed - search by roles and name implemented.
S2	It is also unclear what the functionality of 'Assign Existing Care Team' is.	Improvement	Completed - functionality removed.
S3	During the testing there were different visual presentations of the care team. Testers preferred the view below and wondered if this view can be utilized to set up and manage the care team instead of the option presented during the testing.	Improvement	Decided to keep as is, since in the current scope, it is not possible to re-use that management screen in the care plan initialization screen.
S4	The 'Leave Care Team' button below is confusing – it should be clarified that this button deletes a member of the team. Some of the testers thought that its functionality is to just exit from the current screen.	Improvement	Completed - label has been renamed.
S5	Updating care team members or authorizing a new care team member was not possible during the test session.	Improvement Training	Functionality has been updated and this is also in the training materials.
S6	Users find in unclear why the roles of MDT members must be entered manually when setting up the new care team. The role should already be defined in the account settings when the MDT member receives access to the C3DP.	Improvement	Updated
S7	What happens with scheduled appointments if the respective care team member leaves the organization? E.g., transfer of the appointment to a different / new team member or cancellation of the appointment?	Training	Action to be followed up in Task 9.4 (Similar to Feedback #G4 and #G11). Appointments created via C3DP are not integrated with the scheduling systems of the pilot sites. Also, when a member leaves a care team, the whole care team is informed so that necessary updates in the care plan can be done.
S8	The link of a meal photo could not be left-clicked on after it had been added from the PEP. Testers had to right click on the link and open it in a new explorer tab.	Bug	Fixed
S9	The questionnaire on "medication side effects" did not save in PEP and was therefore not showing in the C3DP.	Bug	Fixed

Feed back #	Detailed feedback	Feedback handling category	Actions by related component team or task
S10	There were different, confusing criteria for medications. E.g., drugs that could cause hypoglycaemia and metformin were listed on different sets.	Improvement Training	Medication suggestions are related to clinical guidelines. Specific inconsistencies of medications related to clinical concepts can be noted in the study for potential improvements of guideline reconciliation and decision support.
S11	Testers struggled to understand the use of the high-level goals on the care plan page (see below). It is not obvious that they have to select the appropriate tab before creating goals and activities. They need to be prompted to select a tab before they create a goal or an activity.	Improvement Training	Improvement completed. "Other" category can be used if existing high level goal are not suitable. This feature is also documented in the user manual and incorporated in the training.
S12	On the care plan view “Glucose Management”: When there is a lot of content shown under the heading “patient data” using the mouse wheel to scroll down to the next heading is not easily possible. It will first scroll through all entries under the heading “Patient Data”, then scrolling will be ineffective for a short time and only after that it is possible to fully scroll down the screen. This finding was not easily reproducible but happens more often when the testers wanted to quickly scroll down to other headings (skipping the “Patient Data” heading”).	Improvement	Improvements have been done, especially for the first creation of a care plan. The user manual will include clear instructions.
S13	The “Save” button on the “Chronic Disease Profile” was not easy to find. Data entries were lost sometimes as users thought it would save automatically (in the perceived absence of a “Save”-button”)	Improvement	Completed - A warning will be presented when a change is done but not saved.
S14	It was not possible to select ‘Pilates’ material in the guidance.	Training	Information has been included in the User Manual for C3DP in Task 9.4.
S15	‘Further Suggestions’ and ‘Education Materials’ in the care plan sometimes do not contain any content. This is indicated by greyed-out, centric text. The text should be left-bound – as is all the other text and should be slightly more readable, i.e. more black tone to be used.	Improvement	Updates completed.
S16	‘Further Suggestions’ box: Users thought they are supposed to add something here rather than just receiving additional suggestions for their reference.	Training	In Task 9.4, the User Manual has included this information and will be highlighted during the training sessions.

Feed back #	Detailed feedback	Feedback handling category	Actions by related component team or task
S17	Users were unclear if 'Further Suggestions' would also suggest goals or activities. If that were the case, then the users suggested including them in the specific sections of goals and activities to be shown to the professionals as suggested goals/activities from the CDS. The suggestions can be very helpful for more complex patients and could be easily overseen if they are in other section. Users said that a clinician could miss crucial information if he/she does not know that it is available.	Improvement	Updates completed and information in the user manual.
S18	Where dates should be entered, the default value should be the current day's date.	Improvement	Completed
S19	If repeated monthly appointments are set up, the system does not recognise weekend days when scheduling. Therefore, it is possible to accidentally schedule appointments for non-working days.	Improvement	In the system, single appointments need to be added. The clinical decision support does not include repeated appointments. To resolve the issue of accidental scheduling of appointments on non-working days, a warning will be implemented when appointments are scheduled on weekends.
S20	Treatment follow-up activities needs to display who the follow up is planned to be with.	Existing feature - no action	
S21	Testers were unclear how they would see notifications for new activities, photos, questionnaire completion or other things, which may have been submitted by the patients.	Improvement Training	Update completed. This is also detailed in the User Manual for C3DP (current version v0.7 in Section 3.9 Patient provided data).
S22	'System Notifications' tab under 'messages' should be next to 'All', 'Patients' and 'Care Team Members' and not on the right side (see below). In addition, these items should look like tabs that can be clicked on. Otherwise on cannot know that clicking the text filters the messages. Likewise, 'Filter Messages' should also be on the left. Testers found the options in this section a bit confusing.	Improvement Training	Updates have been done after considering most of the suggestions.
S23	The alarm bell at the top right of the screen is not the best way of notifying users of new messages. It could be beneficial to distinguish between message notifications and system notifications. For message notifications it would be better to have number in brackets next to 'messages' (see below).	Improvement Training	Updates completed and information is also included in the user manual.
S24	The system notifications should provide a functionality to filter for notifications that relate to only the current active (selected) patient.	Improvement	Completed - filtering has been implemented.

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
S25	Testers wondered if a reminder is sent to the healthcare professional and / or the patient if a scheduled appointment has been missed?	Training	Similar to Feedback #S7.
S26	Issues were experienced with appointment duplication with some patients – all have same date. It should be clarified if this is just an issue in the test session or not.	Improvement	Warnings to be implemented; e.g., if there are appointments within a 5-day period.
S27	Is it possible to see if patients have opened/read assigned training materials	Out of scope Improvement	Out of scope
S28	Testers missed a 'help' icon or general 'search' function.	Improvement Training	The user manual will be accessible via the C3DP.
S29	Testers missed a link to the 'training manual' in the system as a resource in case they needed support.	Improvement Training	The user manual will be accessible via the C3DP.
S30	It was not possible to use the search function to find a patient who is already under the care of a professional who is currently logged in and reviewing the same patient. An error message should indicate this.	Improvement	The feedback is unclear. Several professionals can view the same patient and collaborative planning can be done. Changes to the care plan will be notified to all collaborators.
S31	The list of 'My Patients' should be available as both: the card format and also a list format. Testers said that the card-view can get very lengthy as the number of patients increases.	Improvement	Completed
S32	To see a photo uploaded from the PEP one needs to refresh the C3DP. The new item is not pushed to the C3DP automatically!	Improvement	Completed - real time updates in the user interface
S33	Some users wondered how a new patient would be added to the platform.	Training	The process from participant recruitment to addition to the system and usage is being finalised and will be discussed at the Bonn Plenary meeting in early November 2018.
S34	When you open charts (e.g., the BMI progress chart), there is no 'x' to close the chart. Some users did not realise they had to click on the system background to close the chart.	Improvement	Completed
S35	When a chart is open, the '3-bars button' for further options offers different file format options. It was unclear why the different options were offered. Instead, maybe offer a functionality to 'download' the chart?	Existing feature - no action	
S36	"Medical Summary Page" and "Chronic Disease Profile" screens seem to contain duplicated content and look very much alike. The difference between both is unclear and users were not sure if both are needed in the final C3DP version.	Improvement Training	Updates completed

Feed back #	Detailed feedback	Feedback handling category	Actions by related component team or task
S37	'Save' and 'Cancel' boxes are very small when goals or activities are opened. They could be more obvious and at the bottom of the window (see below).	Improvement	Updates completed
S38	It is unclear if the search function for training materials only searches for the first word in the search box. It needs to be able to search on any word that is typed in the search box.	Improvement Training	Updates completed. The user manual will be updated to reflect this.
S39	When click on the 'Chronic Disease Profile' tab, the page heading is 'Medical Summary Profile template for Type 2 Diabetes'. This is confusing.	Improvement	Updates completed
S40	When clicking 'Care Plan' and 'Previous Care Plans' the sub-menu 'Care Plan" closes. This is confusing as it is not the case when clicking 'Care Plan' and 'Care Team'	Bug	Fixed
S41	When clicking 'Care Plan' and 'Previous Care Plans': First thing shown is 'Active Care Plans' and only below are 'Closed Care Plans', which is confusing. The sub-categories in the 'Active' and 'Closed' care plans (e.g. Title / Start Date / Last Update / Next Review) are not aligned vertically (see below).	Improvement	Updates completed
S42	It is not clear how a care plan can be 'closed'.	Improvement Training	Updates completed. This information is already included in current User Manual for C3DP (v0.7, section 3.5.10 Care Plan Preferences), as part of Task 9.4.
S43	The button "Next Review Date" has no apparent function but the mouse icon changes on mouse-over. It should also be explicit that this refers to the next review date of the care plan. The word 'Next' may be deleted in the button'. The button could also be on the left side instead of the right side (see below).	Improvement	Updates completed and information has been added to the user manual.
S44	Where previous readings are available, e.g. 'vital signs' the last reading should be visible with an option to click the previous ones. It should not just be a number in a box (see below)	Improvement	Updates completed
S45	'Add New Goal' and 'Add New Activity'-buttons on the care plan could be on the left side instead of the right side.	Improvement	It was decided to keep the layout as is, but in a more visible way.
S46	Screens should be as minimalistic as possible. Testers wondered if it is necessary to repeat menus at the left sidebar and at the top? E.g. "Home / My Patients / Activities / Messages".	Existing feature - no action	
S47	Testers were confused when the left sidebar menu suddenly changed when switching to "Messages". They did not know how to get back to the previous sidebar menu.	Improvement	Completed

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
S48	The high-level goals in the Care Plan view should be fixed on the top screen and not disappear when scrolling down – should always be visible wherever you are in the screen (see below)	Improvement	Completed
S49	The 'Medical Summary' screen contains a lot of data in each of the sections. A simplification should be considered.	Improvement	Updates completed - screens have been simplified.
S50	Testers missed a key for the symbols of goals, activities and education. The symbols used were not always clear (see below).	Improvement	Updates completed
S51	On the 'Chronic Disease Profile' screen: It is not clear why the user has to check (or can check) again the medication since it is expected that the C3DP has already extracted that information from the local systems onto the medical summary screen. If the aim is for the Clinical Decision Support to launch recommendations on drug-drug or drug-disease interactions, this should be done automatically without the need to manually tick this off again. In the case of Osakidetza an authorized healthcare professional adds a new drug into Osabide Global, then refreshes the C3DP 'Medical Summary' screen and finally needs to check out this new drug on the Chronic Illness Profile screen. That are too many steps and raises concerns about false entries.	Training	This action has been followed up in Task 9.4. The information has been included in the User Manual for C3DP (current version v0.7, Section 3.5.1. High-Level Goals and Patient Data sections). Clarifications will also be included in the online video tutorial and training sessions.
S52	The 'Active Patients' on the 'Home'-screen should be highlighted when hovering or on mouse-over. This would make it clearer where to click when the user wants to select a specific patient (see below).	Improvement	Updates completed
S53	It is suggested to highlight the current active care plan tab in the left menu-bar more. Currently it is difficult to differ between the light and the slightly darker blue highlighting.	Improvement	Updates completed
S54	When adding an activity or medication request: Users suggest adding a glossary or explanatory pop-up on mouse over for the different 'Status'-options. Otherwise it is difficult to select the appropriate option.	Improvement Training	Simplification completed and explanations added to the system. Task 9.4 has also completed the inclusion of the information in the User Manual for C3DP (v0.7, section 3.5.2. Adding / updating

Feed back #	Detailed feedback	Feedback handling category	Actions by related component team or task
			a goal; section 3.5.3. Adding / updating an activity; and section 3.5.4. Adding / updating an educational material).
S55	There is an information overload in some pages, e.g. the clinical summary page. As BC suggests this could be simplified and with an option to expand the information within certain areas if required.	Improvement	Updates completed
S56	Text is sometimes grey or shaded. This suggests a non-active link while it was not the case in C3DP.	Improvement	Completed - consistency checked
S57	The "All" tab in the care plan and the specified high level goals do not always give the same information. It was not clear if this is a data inconsistency.	Improvement	Updates completed (related to Feedback #S11)
S58	Current status of Clinical Decision Support: Users changed the Blood Pressure data of a patient, yet the C3DP did not adjust the suggested drug treatment. Users were thus unclear if this is a bug of just because they used an early version of the final product.	Improvement	Input from the Clinical Reference Group (CRG) was sought on this topic. It has been agreed that only the clinical decision support modules should propose the targets based on the clinical guidelines.
S59	When adding a new goal, the goal detail box ('create another goal') should automatically open for completion. Currently, adding a new goal opens a list and there is no prompt to add further information. Instead the user has to click on 'Create another Goal' to add further information.	Improvement	Updates have been implemented - The flow has been updated and the user will now be prompted to fill in the details of a newly added goal or activity.
S60	List of goals/activities: It would help if the care plan goals and activities could be grouped by category. This would allow a professional to expand currently relevant goals or activities.	Improvement	Updates implemented - colour coding match high level goals and icons added for different categories.
S61	The 'Medications'-list under the high-level goal 'BP management' does not update when a drug is prescribed. If, for example calcium channel blockers are prescribed the 'Medications' on the HL-goal 'BP Management' should automatically change the item 'Calcium Channel Blockers' to 'Yes'. Otherwise this will lead to an extra process (see below).	Improvement Training	As this is related to the clinician actions, a note has been added in the user manual for prescription in local systems.
S62	'Adding a goal with a target value': When setting a metabolic control goal by selecting the goal that the system offers (e.g. HbA1C), the MDT member cannot see the target value unless he/she edits the goal again or set a new target value.	Improvement	Updates completed

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
S63	Communication between the tab 'All' and the other 'High level goals' is confusing: When a new goal related to BP is created a in the tab 'All' (for instance the goal 'Keep blood pressure under control') it is not shown in the high level goal 'BP management' tab. The user expects that both tabs communicate each other.	Improvement	Updates completed - after the right high level goals have been selected, goals and activities can be moved across categories. Instructions have been added to the user manual.
S64	When a calcium channel blocker is prescribed, this was not shown in the medical summary.	Improvement	Related to Feedback #S61
S65	If a drug is prescribed in activities, it is not shown in the medication list. The chronic disease profile also does not update with the drug that has been prescribed.	Improvement	Related to Feedback #S61
S66	Users should not be able to select drugs which were outside of the selected drug group. If for example the group "calcium channel blocker" is selected, any drug can be selected also outside of the group of calcium channel blockers.	Improvement	This is planned for implementation using the Anatomical Therapeutic Chemical classification system (ATC) hierarchy.
S67	Medication prescriptions can easily be left as 'draft' (see below). Users should be made aware that it is necessary to change it to 'complete' or an alternative process should be defined	Improvement Training	Updates completed. Task 9.4 has followed up this action and explanations were included in the User Manual for C3DP (current version v0.7, section 3.5.3.2.2. Medication).
S68	Editing an existing activity and saving the changes triggered an error message: "Activity couldn't be updated". However, the activity was updated on the care plan.	Bug	Issue resolved
S69	When creating new activities, the mandatory questions, particularly who it's assigned to etc., should be in the detail form. It is confusing to have to click on sub-links.	Improvement	Updates completed - simplifications implemented.
S70	It should be impossible to assign activities to 'Anyone'. Any activity needs to be assigned to a named individual. Otherwise there is a higher risk of it being overlooked.	Training	Task 9.4 has followed-up this action and the user manual includes explanations for the process (current version v0.7, section3.5.3. Adding / updating an activity).
S71	When adding a new activity, the 'Add Activity'-menu is shown. In that menu, the button to 'Create Another Activity' is greyed out. This gives the impression that is cannot be selected.	Improvement	Updates completed
S72	When adding a new activity "medication request" and a product was searched and selected already, users must click "change" and start searching from scratch instead of deleting some letters in the search box using the keyboard. This is not intuitive.	Improvement	Updates completed

Feed back #	Detailed feedback	Feedback handling category	Actions by related component team or task
S73	Users could benefit from being prompted automatically to complete activities after a new goal is created.	Improvement	This was discussed with the Clinical Reference Group. Activity suggestions will be presented in the application.
S74	When adding a new activity the selection of a category should be mandatory.	Improvement	Updates completed
S75	When adding a new activity: Consider changing the term 'Performer' to 'Performed By' or another suitable term.	Improvement	Updates completed
S76	When adding a 'Medication Request' activity, users should not need to click on links (e.g. '+Add Dosage Instruction' or '+Add Note') to show additional data entry options (see below).	Improvement	Updates completed
S77	When adding a new activity ('Device Request'): Searching for any 'BYOD' does not give any results. 'Select Device' has only one option. Where are additional options for devices defined?	Improvement Scope clarification	Feature has been implemented and available in pilot sites using those sensor devices.
S78	When listing the activities: The function of the buttons 'Assigned To: Anyone / Me / Care Team / Patient' was confusing for some users. Instead of thinking of it as a filter, some users thought that clicking one of the buttons will assign 'performer status' of the previously created activity to the respective person group that was clicked (see below).	Improvement	Updates completed
S79	When selecting where an activity is to be performed, "Patient's home" shows twice.	Bug	Fixed
S80	When creating new activities in the activities tab, it was difficult to capture that users need to set the agent of the activity. Initially, users thought that, by selecting "Me" or "Patient", they were already creating a new activity for that specific agent.	Improvement	Updates completed - activity performers are added automatically based on the type of activity.
S81	Lipid options were wrong: options that were shown in the walkthrough document screenshot did not match what testers could see on the screen when testing the C3DP.	Improvement	This was potentially due to the clinical decision support modules implemented at the time of testing. In the final system, the clinical decision support suggestions are based on the clinical guidelines.
S82	The HBA1c reference range is incorrect.	Test data not realistic Training	The incorrect range might have been due to unrealistic test data used. The data in the study will reflect the content from local electronic health record systems.
S83	Haemoglobin is spelled incorrectly.	Bug	Same as in Feedback #S82

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
S84	Units for recording alcohol are incorrect.	Improvement	Updates completed
S85	The terminology needs to be addressed in general.	Improvement	Improvements have been made.
S86	On the medical summary page, the following words are suggested to be revised: 'Onset' in the Condition section should be 'Date of Diagnosis' 'Onset' in the Medication section should be 'Commenced' 'Onset' in the Risks/Scores section should be Date'	Improvement	Updates completed
S87	When creating a new care plan 'Addressed Conditions' (see below) may need rephrasing. It is also unclear how it is decided what conditions the list here suggests. The list can be possibly very long of many conditions apply or are possible.	Improvement	Updates completed
S88	The 'Code' when adding an activity needs to be logical; e.g., for food photos this is a link rather than a code.	Improvement	Updates completed
S89	'Classification of Drugs/Medications': the current C3DP version shows different classification criteria. We propose to try unifying the classification criteria according to a single criteria, i.e. glycaemia related drug/medication.	Improvement	Related to Feedback #S10
S90	Users suggest to consider renaming 'Further Suggestions' as it may be misleading as it does not reflect the aim and meaning that they experienced it to be during the test session.	Improvement	Updates completed

2.2 PEP-related Feedback

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
G1	Test user patients felt that the system has great potential but they did not feel that they would want to use it in its current format. Thus, patients aged 65+ over may struggle using it and recommend that system usage needs to be much simpler.	Improvement Training	The user interface, especially the home page has been simplified. Description of the interface is also in the user manual.
G2	The text in the training material and the PEP manual is not simple enough and the terminology is too technical. Patients were not motivated to follow the training material.	Training Training material	In the scope of Task 9.4, new training materials are being developed with this aim to address these concerns. The materials will be able to be tested (in terms of readability and easy to use) by a small cross section of staff and/or patients in each site.
G3	The font-size of the training material was too small for some users.	Training Training material	In Task 9.4, this has already been taken into account for Project Guide Books. The font size has already been updated to Arial size 14. Task 9.4 will monitor the font size of all documents to ensure this requirement.
G4	Navigation through the system needs to be simplified and patients need to be guided through the system. Navigation test or instruction text is needed throughout the system. Users did not always understand what was expected from them.	Improvement Training	The user interface has been simplified. In Task 9.4, we aim to develop simpler and clearer user manuals. In addition, the on line video tutorials will complement the user manuals and include platform walkthroughs, aiming for an easy navigation through the systems.
G5	Some testers found the PEP quite intuitive. However, the concern was raised that it is important to clearly indicate towards patients what they need to do next or what action is expected from them. That was not always the case.	Incomplete specification Training	In Task 9.4, training materials are being developed. The care plans and activities displayed to the patients originate from the C3DP component, where the multi-disciplinary team developed the care plan. A focus of the training will be on how activities intended for the patient are presented.
G6	The PEP must be translated in the national languages before deployment.	Local configuration	As part of Task 8.3 for terminology management and local deployment. Plans and meetings have been organised for local teams to check that the terminology used is suitable in their local language.
G7	When test users could not answer a test question, they were unclear if that was based on their lack of skill or due to a non-existing functionality of the demo-version of the PEP.	Unclear feedback - no action	Questionnaires can be set locally through local configuration.

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
G8	A feedback button on goals and activities was missing on the PEP while it was actually explained in the training manual.	New feature	This feature has been Implemented and also explained in the user manual. Similar to Feedback #S28.
G9	The user manual is quite lengthy. The length could be reduced by rephrasing the objectives in bullet points and reorganizing the content of section 3 with a more "executive" aim, tackling only the activities a user can perform.	Training Training material	This action is being followed-up in Task 9.4, where the user manuals are being further developed.
S1	On the login-page: The title 'Patient Empowerment Platform' should be shown clearly at the top of the screen below with some simple instructions:	Improvement	The page has been renamed at the UK pilot site.
S2	The header should show 'Patient Empowerment Platform' next to C3CLOUD in the black bar below:	Improvement	
S3	The page 'Home' needs to be better structured. It has an information overload and looks too similar to the page 'Care Plan'.	Improvement Specification incomplete	Updates completed, related to Feedback #S4 and #S5.
S4	The front screen (see below) should present only the title of the system (PEP), some instructions about what the patient can or should do next and the button to 'View complete care plan'. Detailed information should only be presented on next page:	Improvement Specification incomplete	Updates completed
S5	Simplify and structure the information presented: e.g. 'Goals', 'Activities' (Medications) or 'Guidance'.	Improvement Specification incomplete	Updates completed
S6	The 'Careplan'-page could show only the headings (the bolt-printed headings in the figure below) of any goals, activities or guidance. The heading could be highlighted if any care plan changes occurred and have not been seen since the last logout. The presentation of specific content regarding 'Goals', 'Activities' and 'Guidance' could be done at a next level after clicking on the respective heading. Patients want the screens to be as minimal as possible.	Improvement Specification incomplete	Updates completed - the page has been restructured.
S7	The font size needs to be larger; especially if the project is targeting patients aged 65+. Alternatively, on option to increase font size should be readily available.	Improvement Training Visual guideline	Related to Feedback #G3
S8	The name of the person currently logged on to the PEP that is displayed on the top right corner: It could be made explicit that this is the name of the person who is logged in, e.g. 'You are logged in as XYZ'.	Misunderstanding - no action	
S9	Patients disliked the need to scroll down the screens. One patient said she would not want to use the system if she had to scroll down. In addition, she suggested displaying goals, activities and guidance material on separate screens.	Improvement Visual guideline	Updates completed - titles and timings are currently shown to improve the display.

Feed back #	Detailed feedback	Feedback handling category	Actions by related component team or task
S10	It was not intuitive for the users that clicking an arrow would open or close headings or boxes to show or hide additional information. This needs to be more obvious.	Improvement	Explanations have been added to the user manual about the display and how to expand and close sections.
S11	It should be possible to click on goals, activities, guidance, appointments or messages on the top bar below – similar as it is possible to click the 'Home', 'Careplan', 'Tracking' and 'Questionnaires' categories:	Improvement Training	To keep the interface simple, there needs to be a balance in the number of items on the menu. In Task 9.4, explanations to clarify this item will be added in the user manual.
S12	It is suggested using colours to identify actions for patients and to support patients in identifying where and action is required and where the data presented is just for information.	Improvement	This feedback needs to be further clarified and will be discussed with the Clinical Reference Group.
S13	Questionnaires did not save in the system, e.g. 'Medication side effects'	Configuration error Training	Error has been fixed. Task 9.4 will follow-up on this action and include a section in the user manual on how to deal with errors (on how to provide general non-clinical feedback and how to contact)
S14	Buttons for 'Next' and 'Previous' screens should be available when completing questionnaires.	Local configuration Training	This action has been followed-up in Task 9.4 as part of the PEP local admin training sessions; the first one with all the three sites was held on the 19/10/2018. There are further site specific sessions planned.
S15	When a questionnaire is submitted, the 'Home'-screen is shown. Users expected to come back to the 'Careplan'-screen or even to the next questionnaire that they should fill in.	Improvement	Not in current scope.
S16	'Activities and goals on the care plan should be grouped by type rather than using colour coding, e.g. group all 'General' activities together and group all 'Observations' together, etc.	Improvement Incomplete specification	Currently, the display of activities and goals reflect the information as received from the C3DP, where the care plans are created.
S17	Users suggest grouping care plan activities along other criteria more adapted to the patients. For instance: 'Diet and Lifestyle' could include 'Photo upload', 'Walking', etc. The category 'Treatment' could include 'Medication', 'Questionnaires' related to medication side effect and 'Blood Pressure Observations'.	Improvement Incomplete specification	Similar to Feedback #S17. The groupings reflect options in the C3DP unless otherwise specified.
S18	Users were unclear if a patient should be able to see their past care plans.	Not in specification - no action Training	In Task 9.4, it will be stated clearly that a patient will only have one care plan that is continuously updated.
S19	Users wondered if patients can request material from their care team.	No action - feature not in specification Training	This will be followed up in Task 9.4 during training.
S20	The questionnaire 'Medication Side Effects' had some questions in the wrong order.	Bug Training	Configuration error fixed.

Feed back #	Detailed feedback	Feedback handling category	Actions by related component team or task
S21	The questionnaire 'Medication Side Effects' did not save after completing it on the PEP. It was thus also not shown in the C3DP.	Bug Training	In Task 9.4, the user manual will include a section about how to deal with errors.
S22	Additional information provided for each goal was not always helpful (see below). It should be further elaborated what content is shown to the patient here.	Improvement Incomplete specification	Care plan goals and activities originate from the C3DP, where the care plan is developed. Configurations can be done to change the display, however, more information is needed on requirements. This will be clarified further with the Clinical Reference Group.
S23	'Activities' do not clearly explain to the patient what they are expected to do.	Improvement Incomplete specification	Similar to Feedback #S22, the descriptions of activities originate from the C3DP and information aimed at patients need to be provided by the healthcare team.
S24	Users could not click on 'Appointments' on the 'Home'-screen (see below). Concerns were raised about showing appointments in the PEP at the SWFT pilot site: the PEP will not be used for scheduling at SWFT. Showing appointments and referrals on the PEP needs caution, as they will be handled outside of the PEP system.	Improvement Unclear specification	This is being followed up in Task 8.3 as a local configuration to switch off this feature as specified by the pilot site needs.
S25	Users assume they would be able to schedule an appointment through the PEP.	Not in specification - out of scope Training	In Task 9.4, information about the features available will be included in the user manual and Project Guide Book.
S26	The message envelope-icon on the right should be placed with the other tabs on the left. 'Settings' should stay separate (see below).	Local configuration Training	This action has been followed-up in Task 9.4 as part of the PEP local admin training sessions; the first one with all the three sites was held on the 19/10/2018. There are further site specific sessions planned.
S27	Users were unclear how patients will be notified of a 'New care plan'. Does a notification message go to an email account or through the messaging functionality in the PEP?	Incomplete specification	Email notifications are available for participants with emails when added to C3-Cloud.
S28	Users did not find an option to give feedback to the care team about the care plan or the goals and activities presented in it.	New feature Training	Related to Feedback #G8. This feature has been implemented and documented in the user manual.
S29	Any dates should be in British format.	Local configuration Training	This action has been followed-up in Task 9.4 as part of the PEP local admin training sessions; the first one with all the three sites was held on the 19/10/2018. There are further site specific sessions planned.
S30	The current labelling of activities can be confusing (e.g., 'Questionnaire' or "Observe"). One of the users thought it was a clickable button to update the progress an activity. Users suggest changing the design in order to make clearer the differences of activity categories.	Improvement Incomplete specification	Improvement completed.

Feedback #	Detailed feedback	Feedback handling category	Actions by related component team or task
S31	When submitting a questionnaire through the PEP, the final page should state 'This is a summary of your previous data input. You can edit it if needed. When ready, please "submit" it'.	Local configuration Training	This action has been followed-up in Task 9.4 as part of the PEP local admin training sessions; the first one with all the three sites was held on the 19/10/2018. There are further site specific sessions planned.
S32	Open Tracker' on the 'Careplan'-screen (see below) is not an adequate term for the button to open the charts. Instead it could say something like: 'Show Previous Observations' or 'See Previous Photos. Also, 'Add New' should say something like: 'Add New Photo'.	Improvement	Updates completed. Instructions have been added to the local admin guide.
S33	The heading 'Guidance' should be changed so it is clearer that it contains educational information that the patient should review. An introductory sentence could for instance say: 'Your healthcare professional has suggested that you review the following material'.	Local configuration Training	This action has been followed-up in Task 9.4 as part of the PEP local admin training sessions; the first one with all the three sites was held on the 19/10/2018. There are further site specific sessions planned.
S34	All main pages or sections on the PEP should have some text stating what the section is about and what the patient can or should do there.	Improvement	Improved and restructured layout completed.
S35	The activity descriptions need rewording. Users wished they were more encouraging / inviting rather than ordering them to do something.	Related to C3DP - no action	Descriptions need to be updated in the C3DP by the healthcare professionals.

3. C3-CLOUD COMPONENT FEATURES

During the implementation work in work packages 5, 6 and 7, followed by the testing process in task 9.2, the 7 C3-Cloud high-level components have produced 17 installable artefacts, which implemented the technical requirements in D3.2 following the architecture design of D3.3.

Table 1 summaries the produced installable artefacts by each C3-Cloud high-level component. As designed in D8.2, the two PEP components will be installed natively and the other 15 components will be delivered as Docker images. The following sub-sections provide further information on the delivered implementation of each high-level component, including its technology stack and the installable artefacts that are ready to be deployed.

Table 1 C3-Cloud Component Installable

Component	Number	Installable
PEP	2	• IIS Web App • SQL Server database
C3DP	3	• C3DP Web App • C3DP Event API • Complementary CDS Services
FHIR Repository	2	• FHIR Repository Server • MongoDB database
SPS	3	• SPS Server & Manager • MongoDB Database • Redis Data Store
SIS	3	• Structure Mapping Service • Redis data store • Terminology Mapping Service
TIS	2	• TIS Service • MongoDB database
CDSM	2	• GDL2 CDS Service • Drug Interaction Service

3.1 C3DP

The Collaborative Care and Cure Delivery Platform (C3DP) is the Web application for collaborative and personalized care plan management by the members of a multidisciplinary team of care (MDT). In the C3-Cloud architecture, C3DP sits at the top of the hierarchy and is indeed directly integrated with all the other C3-Cloud software components and indirectly with the local EHR/EMR systems of the pilot sites. All the patient data required for care planning is fetched from the C3-Cloud FHIR Repository, which is continuously fed with existing EHR data of the pilot sites via TIS and SIS. Patient provided data via PEP is also stored within the C3-Cloud FHIR Repository. C3DP visualizes this data and helps the health professionals to easily manage the integrated care coordination process for multi-morbid elderly patients, with the support of Clinical Decision Support (CDS) services automating the recommendations from the evidence-based clinical guidelines. This process is formalized as a FHIR

CarePlan resource, which consists of building blocks like “Goal” and different types of “Activity” resources.

The main functionalities enabled by C3DP can be summarised as follows:

- Review of patient medical summary
- Cross-check of all patient data that are needed as input by the Clinical Decision Support (CDS) services
- Management of the care plan building blocks; goals, activities and education materials
    - Manual entry from scratch
    - Recommendations from the CDS services
    - Transfer from the older care plan
- “Execution” of a care plan
    - Updating the progress of goals and activities
    - Re-execution of CDS services during planned and unplanned encounters
    - Automatic linking of patient provided data to the care plan activities
    - Commenting on the care plan items
    - Semi-automatic update of the care plan template and associated CDS service bindings as the major diseases of the patient accumulates
    - Exporting a care plan as a PDF document
    - Closing a care plan
- Management of the care team
    - Inviting new care team members
    - Removing existing care team members
- Communication among care team members and with the patient / informal care giver
    - Asynchronous messaging
    - Organization of tele/video conferences
- Dashboard view
- Patient provided data view
    - Questionnaires responded by the patient
    - Vital sign measurements provided by the patient
    - Photographs sent electronically by the patient
    - Messages sent by the patient
- Activity calendar
- Real-time system notifications
- Administration functionalities for the pilot site coordinators:
    - Batch message sending to care team members or patients
    - Management of all care team members and patients
    - Management of education materials
    - Management of value sets (i.e. terminology systems)

- Management of organizations and locations
- Export of anonymised data for evaluation studies

A demo version of C3DP has been made available to all C3-Cloud participants at https://app.srdc.com.tr/c3dp/ since September 2017. This installation has been continuously kept up-to-date with the recent developments in the application.

Further details regarding C3DP can be found in C3-Cloud deliverables D7.4 - C3-Cloud Coordinated Care and Cure Delivery Platform and D7.3 - Personalised Care Plan Development Platform.

C3DP is decomposed into the following deployable artefacts, all of which are packed as a Docker image:

- **C3DP Web App**: C3DP Web Application is the main end-user interfacing component that enables users to manage the care plans of their patients. It is a rich client-side Web application implemented with Angular framework. It depends on some external packages like ng-fhir as a FHIR client and Socket.IO as a client to subscribe to events from the C3DP Event API. Semantic UI is preferred as the CSS design framework. Responsive design principle is followed to support not only large screens of computers, but also screen sizes of tablets. A clean object-oriented model of the care plan and corresponding resources like conditions, observations, goals, activities, etc., is being maintained in Typescript. Angular framework and the external packages are kept up-to-date to prevent any conflict. The Docker image is based on nginx:alpine image.
- **C3DP Event API**: It provides real-time notifications to inform users or the system itself. It is implemented with Node.js using Express web application framework as REST API and Socket.IO for real-time notifications. Clients (C3DP Web App or PEP) subscribe to the events by sending a subscribe event to the Socket.IO server in the Event API. When a new event occurs like creating or updating a care plan, the client sends the details of this event to the C3DP Event API and the request is handled by Express routes. Then, C3DP Event API makes the necessary operations and notifies the subscribed clients back via Socket.IO and stores the notifications in the C3-Cloud FHIR Repository. C3DP Event API has also an endpoint to handle events related to PEP. The Docker image is based on node:alpine image.
- **Complementary CDS Services**: During the design phase of the CDS services, it has been observed that some CDS suggestions are static and do not directly depend on the clinical status of the patient, unlike most other CDS services. At first, it was decided to embed such suggestions into the C3DP Web App directly, but later this duality between CDS services has become harder to manage. Therefore, these static CDS services have also been implemented as REST services compliant with the CDS Hooks specification, similar to the other GDL2 based services. The full list of these services is provided below:
  - DM Self-monitoring of Blood Glucose
  - DM Management of Gastroparesis
  - DM Management of Neuropathic Pain
  - DM Management of Autonomic Neuropathy
  - DM Management of Erectile Dysfunction
  - DM Management of Eye Disease
  - CKD Self-management
  - CKD Lifestyle and Dietary Advice
  - Screening assessment of suspected depression

  They are all implemented with Node.js using Express web application framework. The implementation also includes the full set of Type 2 Diabetes CDS services, which are implemented by SRDC and used for a long time before the full set became available from the GDL2 based implementation. The Docker image of this artefact is based on node:alpine image.

3.2 FHIR Repository

C3-Cloud FHIR Repository acts as the centralized data repository for existing clinical data of the patients and newly created care planning related data. It stores the data, which arrive from EHR systems via TIS and newly created or updated care plan data from other C3-Cloud components like C3DP and PEP, as HL7 FHIR resources. SRDC provides its FHIR Repository product named onFHIR for free for this purpose, but any other FHIR STU3 server can be used as well. A public deployment of SRDC onFHIR Repository to be used for testing and development purposes in C3-Cloud is available since April 2017, first at http://app.srdc.com.tr/fhir/stu3 and then at http://app.srdc.com.tr/c3cloud/fhir, and lastly at https://app.srdc.com.tr/c3cloud/fhir-secure. onFHIR was tested successfully at the 15th FHIR Connectathon in Madrid on 6-7 May 2017. FHIR specification conformance of onFHIR has been validated by the Crucible and Touchstone FHIR testing tools and onFHIR performs at the top among tens of FHIR servers. onFHIR also outperforms the publicly available FHIR servers both in read and write operations.

Thanks to C3-Cloud FHIR Repository's automatic auditing functionality, audit trail records are kept for each access and manipulation of data as FHIR AuditEvent resources as well. These audit resources are available from the same API for authorized users with administrator roles as any other FHIR resource. For example, the Audit Viewer interface of the SPS reads the audit records from this API.

Further details regarding C3-Cloud FHIR Repository can be found in C3-Cloud deliverables D7.4 - C3-Cloud Coordinated Care and Cure Delivery Platform and D7.3 - Personalised Care Plan Development Platform.

C3-Cloud FHIR Repository is decomposed into the following deployable artefacts, all of which are packed as a Docker image:

- **FHIR Repository Server**: The backend implementation of the FHIR STU3 REST API and Search API specifications to full extent. C3-Cloud FHIR Repository, which is based on the onFHIR Secure Health Data Repository product of SRDC is fully compliant with the FHIR STU3 specification. C3-Cloud FHIR Repository is also extensible and configurable for adding custom operations over standard FHIR API. An example for such custom functionalities is the CDS Hooks client, which is implemented specifically for the CDS service interaction needs of the C3-Cloud project. C3DP uses this endpoint to collate all the required patient data needed for calling a CDS service and then doing the actual call to the CDS service, collating the results from the CDS service and finally providing them to the caller. Both onFHIR and C3-Cloud specific operations are implemented natively in Scala. The Docker image is based on java8 image by SRDC.
- **MongoDB Database**: FHIR Repository Server uses MongoDB as the NoSQL database. The most recent version 4.0 is used for deployment. The official Docker image is used without any modification.

3.3 SPS

The Security and Privacy Suite (SPS) is responsible for authentication and authorisation of Care Team Members, while they are managing personalised care plans of patients and accessing sensitive personal data; and ensuring that all data exchange within and across C3-Cloud software components is encrypted and properly auditable.

In the C3-Cloud architecture, the patient's electronic health records received from the local EHR systems via the TIS, patient reported observations from the PEP, and the care plan of the patient managed through C3DP are all managed in the C3-Cloud FHIR Repository. Hence, each of these client apps, i.e. TIS, PEP and C3DP needs to be authenticated and authorized to access (read, write, and update) patient data to C3-Cloud FHIR Repository, via the functionalities provided by the SPS. All such operations need to be logged for ensuring accountability via SPS.

SPS enables authentication of the care team members into the C3-Cloud applications in two ways: i) via their already existing accounts (e.g., username-password) provided by the local authorities by

integrating with the existing Identity Provider (IdP) systems of the pilot sites; and ii) by creating C3-Cloud specific user accounts for those users whose IdP's cannot be integrated with the SPS, e.g. the social care workers.

The SPS has three sub-components:

- **C3-Cloud SPS Server** provides services for user registration, privacy policy management and endpoints defined in **OpenID Connect 1.0** standard to perform authentication and authorization (Authorization Endpoint, Token Endpoint, etc.). By implementing OpenID Connect API, it serves C3-Cloud Identity Provider (IdP), which is the default IdP when the IdP of some users (e.g., social care workers) of the pilot sites cannot be integrated within the scope of the project. The SPS Server also manages the C3-Cloud Access Control Policy Store.
- **C3-Cloud SPS Manager** is a web application for representing the functionalities of C3-Cloud SPS Server with the following user interfaces; single sign on UIs, policy management UI, client registration UI, user registration UI and audit viewer UI.
- **Audit Record Repository** is a FHIR repository that maintains audit trail records implemented as FHIR AuditEvent resource. In C3-Cloud architecture, the C3-Cloud FHIR Repository is used as the Audit Record Repository. An extra instance of the same repository is not created for practical reasons.

Further details regarding SPS can be found in C3-Cloud deliverable D6.3 - Open Source Privacy and Security Toolkits for the C3-Cloud Architecture.

SPS is decomposed into the following deployable artefacts, all of which are packed as a Docker image:

- **SPS Server & Manager**: The SPS is based on onAuth security and privacy framework of SRDC, which has been implemented within the scope of not just C3-Cloud but also further international and local projects of SRDC. It is a generic framework to cover the needs of healthcare and other vertical domains. It implements the widely preferred modern authorization specifications, such as OpenID Connect 1.0 and OAuth 2.0. Each user is authenticated with the OAuth 2 flow and authorized for the allowed scopes with a JWT token. This token is exchanged between components to ensure that a user / system is authorized. This deployable artefact includes both backend and frontend implementation. Backend is implemented natively in Scala and the frontend is implemented in Angular framework. The Docker image is based on java8 image by SRDC, in which an nginx server is also installed for serving the frontend.
- **MongoDB Database**: SPS uses MongoDB as the NoSQL database. The configuration of the pilot site environment including the privacy policy, registered clients, roles, users, etc. are all kept in the MongoDB database. The most recent version 4.0 is used for deployment. The official Docker image is used without any modification.
- **Redis Data Store**: SPS uses Redis as a cache for keeping the active the tokens of all clients that have recently acquired a valid token, for preventing calls to the underlying MongoDB database whenever possible. The official Docker image is used without any modification.

3.4 PEP

The objective of the Patient Empowerment Platform (PEP) is to provide patients with access to their published care plan and associated relevant information, thereby increasing patient and informal care giver participation in decision making. It aims to provide a computerized means to improve the interaction between patients and health professionals, as well as to collect relevant data to enable monitoring of care plan related activity status and progress. It directly interacts with the C3-Cloud Coordinated Care and Cure Delivery Platform (C3DP) to be informed about new and updated care plans and to send back patient reported observations. It also directly communicates with the supported set of sensor devices to record patient measurements.

PEP is shown to the users as a responsive web application giving them access to their own interactive care plan. The system is tightly integrated with the C3DP and both receive the integrated care plans

constructed by professionals in C3DP and allows the patient to report their progress and compliance back to C3DP. The integration also involves sending patient data from PEP for the professionals to see in C3DP.

The main functionalities of PEP are

- Make published care plans available to patient access users
- Allow patients to actively collect data related to the care plan activities
- Allow health professionals and patients to communicate with each other using secure messaging
- Provide patients with access to relevant self-management material
- Provide all PEP users with secure access to information and functionality

PEP is decomposed into the following deployable artefacts:

- **PEP IIS Web App** – Contains the business logic and user interfaces for the application. PEP IIS app is based on Medixine Suite, an adaptable platform and web application for developing interactive web applications for both professionals and patients. The application is developed in a backend-frontend model that separates the view logic from the operative logic making sure that user interface development does not cause problems with logical operations which decreases the risk caused by UI modifications. The application exposes its operational logic through secure REST API endpoints that are also used by C3DP. The application's content is configured separately from application logic and different pilot sites have different configurations, including different questionnaires, language packages and login providers.
- **PEP SQL Server** – The data storage component for Medixine Suite which has been adapted to fit the needs in the project. It is based on SQL Server (v2012-2017) and a custom schema that allows configuring dynamically new data types that can be strongly validated.

PEP contains an endpoint that allows pre-configured external devices to send their data into the solution if they are capable of transmitting measurements using HTTPS. Medixine also provides an Android based hub software that is capable of transmitting measurements received via Bluetooth to PEP. PEP is made to be configurable so that new data models for new devices can be configured on the run. Already implemented integrations include, for example, Blood Pressure, Blood Glucose, SpO2, Pulse, Activity Details, Sleep details, Weight and Spirometry. All device data is transmitted to PEP anonymously (not including patient identifiers) and using TLS encryption. The data is only linked to an actual patient record inside PEP and then passed on to C3DP for integration.

3.5 SIS

The Semantic Interoperability Suite (SIS) handles both structural mappings among different information models and resolves semantic mismatches due to the use of different terminology systems and different compositional aggregations, used to represent the same clinical concept. Due to local implications of terminologies used, the SIS is developed in close relation with the pilot sites.

Two different types of mappings are performed in the semantic interoperability suite: structural mappings and semantic mappings. Structural mappings are involved in the translation between local pilot sites data in local format and FHIR resources data format used in C3-Cloud. Semantic mappings perform the transcoding between coding systems used in local sites and within C3-Cloud components.

The functional requirement specifications for SIS can be summarised as follows:

- SIS maps input data from pilot sites, provided in their local format, to corresponding FHIR resources.
- SIS provides coding values and related coding system used from locally coded pilot site data.

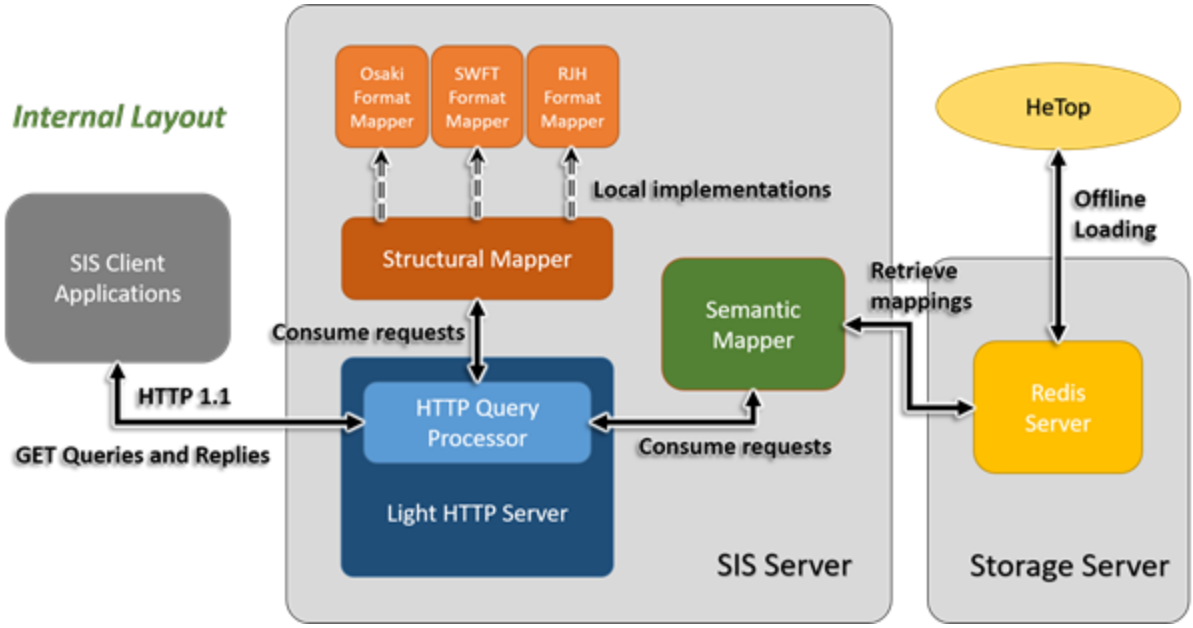

Figure 1 Semantic Interoperability Suite Architecture

The architecture of the SIS is provided in Figure 1. SIS is articulated around two main sub-components: SIS Structural Mapper and SIS Semantic Mapper.

SIS Structural Mapper

The structural mapper of SIS is the internal SIS sub-component in charge of the generation of FHIR resources, which have to be filled with data provided in pilot site local format by TIS. To achieve its purpose, the structural mapper consists of pilot site dedicated local format mappers. These mappers provide precise mappings to create correspondence to every relevant data exported by the pilot site to its correct interpretation and place in FHIR resource. FHIR resources mapped from pilot site data are defined in the C3-Cloud data dictionary, which is defined in D6.1 - C3-Cloud Technical Interoperability Implementation Guidelines and Open Source Toolkits.

SIS Semantic Mapper

The semantic mapper of SIS is in charge of transforming, using the vocabulary used to describe data exported by pilot site into standard codes that will be used in the high-level components of C3-Cloud. A clinical concept mapping sheet is being maintained as the source of truth, which includes all the clinical concepts that are needed by the CDS services, in reference terminologies like SNOMED-CT and WHO ATC, and all the local codes that are used by the pilot sites for these concepts.
The main features of the SIS semantic mapper are the following:

- C3-Cloud SIS is implemented as a fully deployable exchange suite, running on independent Docker containers.
- It is based on HTTP communication standards, with embedded JSON content.
- It supports FHIR inputs and outputs, and previously mapped local format pilot site inputs.
- SIS is developed using Java 8 Maven.
- Regarding the terminology server, Python 3 is used to develop an application that reads the mappings from use case files and creates an HTTP service (Flask) that is able to achieve the tasks listed in the specifications.
- The C3-Cloud Semantic Interoperability Suite can be easily deployed by running its related Docker image as containers.

The Structural Mapper generates JSON encoded FHIR resources. The semantic mapping is based on a pre-filled registry containing, for each concept, the corresponding code(s) for each site's terminology, and the code used as reference by C3-Cloud. The registry is continuously updated, via a

dedicated service method during the time of the project. Multiple codes can be specified for a single concept if the used terminology has several codes corresponding to the concept (narrower-than relation). Multiple terminologies are used as reference, in order to match each concept exactly.
The semantic mapping service is called in two different scenarios:

- Inside the 6.2 interoperability suite, in order to perform the transcoding of local codes to standard codes.
- By C3DP, in order to match patient data coded in pilot sites' terminologies to the clinical concepts that are needed by the CDS services.

The details of the Semantic Interoperability Suite are explained in the deliverable D6.2 – C3-Cloud Semantic Interoperability Platform.

3.6 TIS

The Technical Interoperability Suite (TIS) is the integration engine that enables data transfer between Local EHRs and C3-Cloud. Following an Extract-Transform-Load (ETL) approach, TIS extracts patient data from local EHRs, transforms the data into FHIR resources using the SIS Structure Mapping Service, and loads the FHIR data into the C3-Cloud FHIR repository. TIS is an extensible platform that provides both a suite of ETL toolkits to support development of integration pipelines for a particular context of use and a task execution engine that allows to schedule and manage the execution of ETL pipelines. A web-based control panel is available that allows users to register patients, schedule pre-configured integration tasks and monitor the task execution. In addition to allowing a user to import data through the control panel, TIS also exposes a REST service that allows a data integration pipeline to be triggered by another software component (e.g., C3DP) in a synchronous manner.

TIS has been integrated with SIS Structure Mapping Service, SPS OpenID Connect, C3-Cloud FHIR Repository, and C3DP Event API. A set of pipelines have been developed for all the integration scenarios for C3-Cloud pilot EHR system API. Table 2 summarises the patient data API that each pilot site exposes. All the pipelines follow a similar pattern: retrieve patient data by patient identifiers, invoke SIS Structure Mapping service to transform the data into FHIR resources, combine all resources into a FHIR transaction bundle, include an AuditEvent with timestamp in the transaction bundle, and commits the transaction bundle into the FHIR Repository. If it is the first data import i.e. the patient has not been created in the repository, TIS will add a FHIR Patient resource to the bundle, which includes C3-Cloud study identifier and evaluation groups, and notifies C3DP by sending a PatientCreated event through C3DP Event API. If error occurs in any step of the pipeline execution, TIS logs the error in the database and presents it to the control panel.

Table 2 Pilot Patient Data API

Pilot Site	Patient Data API	API Description
OSAKI	HCRWS	A SOAP service to return CDA data for a patient
	DBP_WS	A SOAP service to return observation data for a patient in XML
RJH	Diagnoser	A REST service to return all diagnoses for a patient in JSON
	Journalanteckningar	A REST service to return all journal notes for a patient in JSON
	Laboratoriesvar kemi	A REST service to return all laboratory response chemistry for a patient in JSON
	Läkemedelslista	A REST service to return all medicines for a patient in JSON
	Patient	A REST service to return demographic data for a patient in JSON

Pilot Site	Patient Data API	API Description
	Vårdkontakter	A REST service to return all care contacts for a patient in JSON
SWFT	EMIS export file	A CSV file containing all patient primary care data exported by EMIS report system every day
	Lorenzo/EMIS Community export file	A CSV file combining all secondary care (from Lorenzo) and community care (from EMIS Community) encounters exported every day

TIS was initially developed in Java 8 and used Spring Boot 1.5 as the web application framework and MySQL 5.7 as the backend database, in which the task execution engine implementation relied heavily on the Java 8 streams library. New versions of TIS were later migrated to Kotlin, a concise multiplatform language that runs on Java virtual machine and is fully interoperable with Java. The new implementation is now based on the asynchronous and non-blocking model provided by Spring Boot 2.0, MongoDB 4.0 and Kotlin 1.2 coroutines. The control panel is a javascript based web app developed using React 16 and a React UI library Ant Design 2.

TIS produced two installable artefacts for deployment: TIS Service and MongoDB database. TIS Service is a web application that bundles all web services for scheduling and executing integration tasks and the control panel user interface. The MongoDB database stores all the data required to support TIS Service e.g. pre-configured integration tasks. Both installable artefacts are packaged and delivered as Docker images.

3.7 CDSM

The Clinical Decision Support Modules (CDSM) support MDT in care planning and monitoring for a patient with multi-morbidity by making recommendations on care plan goals and activities and alerting disease-drug or drug-drug interactions. The care plan goal and activity recommendations follow the rules from NICE guidelines that were presented as flowcharts in deliverable D7.1. As described in deliverable D7.2, all the guideline based CDS rules are implemented in Guideline Definition Language (GDL) version 2 using the Cambio GDL2 Editor. Table 3 lists all implemented GDL2 guidelines that cover various aspects in care management for patients with the 4 diseases (type 2 diabetes, mild to moderate CKD, mild to moderate CHF and mild to moderate depression). The guidelines started with rules for single diseases based on the flowcharts in D7.1 and then incorporated all 52 guideline reconciliation rules that were defined in ANNEX 1-9 of D7.2 to detect and propose resolutions for guideline clashes and detect duplicate, unnecessary or contraindicating medications.

Table 3 GDL2 Guidelines

Lifestyle Advice
DM Blood Pressure Management
DM Lipid Management
DM HbA1c Targets
DM Blood Glucose Management
DM Diabetic Foot Problem
DM Diet Management
QRISK2
CKD Referral Service
CKD GFR Monitoring Frequency Service
CKD BP Treatment Service

CKD CVD Prevention and Treatment Service
CHF Stability Review
CHF Vaccination Recommendation
CHF Diuretics Recommendation
CHF Pharmacological Treatment
Depression Psychological Treatment
Depression Antidepressant Treatment
Drug Interaction based on reconciliation rules

Because of local variations in the routine clinical practice across the three pilot sites, the guidelines are customised to meet site specific requirements. One example is each site has a varied selection of lab tests for follow-up monitoring. Another example is for glomerular filtration rate (GFR) estimation, where RJH uses the revised Lund-Malmö equation instead of the Modification of Diet in Renal Disease (MDRD) Study equation. So, a separate version of the GDL2 guidelines are maintained for each site that can deal with local variation as well as site specific coding systems. The guidelines are also translated to Spanish and Swedish for use in OSAKI and RJH pilots respectively.

All the GDL2 guidelines are deployed into Cambio GDL2 Engine and packaged as a single CDS service. Cambio GDL2 Engine is a web service application based on Spring Boot. The service is integrated with C3DP through FHIR based CDS-Hooks API. GDL2 CDS Service is delivered as a Docker image for deployment.

The drug interaction service provides warning of potential adverse interactions between drugs, as well as a list of side-effects, for use by the rest of the C3-Cloud architecture. The service implements the interactions between drugs, as specified by the National Institute of Care Excellence's implementation of the British National Formulary (BNF). BNF is a pharmaceutical reference book, used by the UK NHS. The information provided by the service, is identification of potential adverse interaction between drugs, the effects of the interaction, the severity of the interaction, as well as the basis on which the interaction has been specified by the NICE-BNF. For example, Acarbose is a drug active ingredient Alpha-glucosidase inhibitor commonly used by patients with type 2 diabetes, which reduces the effects of carbohydrates on blood sugar. Acarbose is listed as having a pharmacokinetic interaction with the active ingredient Digoxin used in patients with Congestive Heart Failure to improve quality of life and prevent hospitalisation. The interaction is listed as moderate in criticality having as effect decreased concentration of Digoxin (Figure 2). In addition to interactions, the service provides a list of side-effects for each substance, along with their frequency (i.e., common, uncommon and rare).

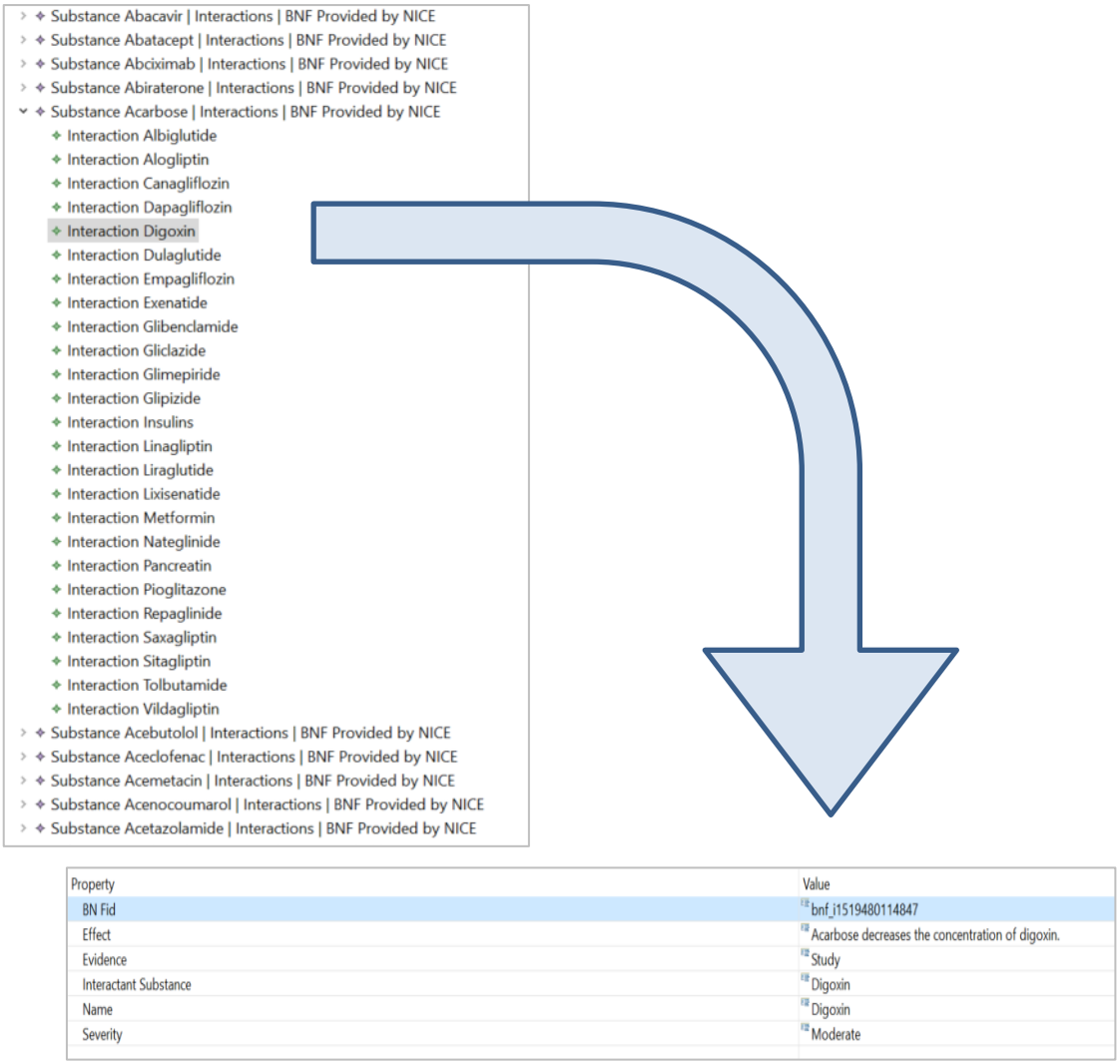

Figure 2 Extract from the list of substances and interactions in Eclipse (and Acarbose – Digoxin interaction)

The service is designed to receive a list of active ingredients of the drugs a patient may be taking. The list is checked in the database and returns a data object containing the interaction information as well as the list of side-effects. The information can be shown to the C3DP dashboard notifying the MDT members of potential risks. The C3DP logic can also use the side-effects list to advise MDT members as well as patients, further enabling the negotiation of the care plan between patients and MDT members.

The information collected by the NICE BNF is encoded as an object oriented database (OOD), using the Eclipse Modelling Framework (EMF). The OOD defines the relationships between the main concepts e.g., interactions and drugs, and contains instances for each active ingredient. The current database contains 108,600 objects of interactions and 26,403 objects of side-effects for 1,009 substances. The database presently uses the eclipse tool infrastructure to operate as a service, receiving requests and sending back the information. Plans for its portability as a tool independent server side service are in place. The plans entail using a secure server python application, and SQL database, to which the current OOD will be ported.

4. PILOT ARCHITECTURE

All C3-Cloud components are installed and operated on the premises of pilot site IT environments. The components integrate with a variety of local IT systems, such as the patient data API for data synchronization and the local authentication systems in order to provide single-sign-on for patients and health professionals. Every site provides both a staging environment and a production environment, where the staging environment resembles the architecture and configuration of the production system for quality assurance testing. The following sections describe the pilot application architecture and how it is hosted at each site.

4.1 OSAKI

Application Architecture

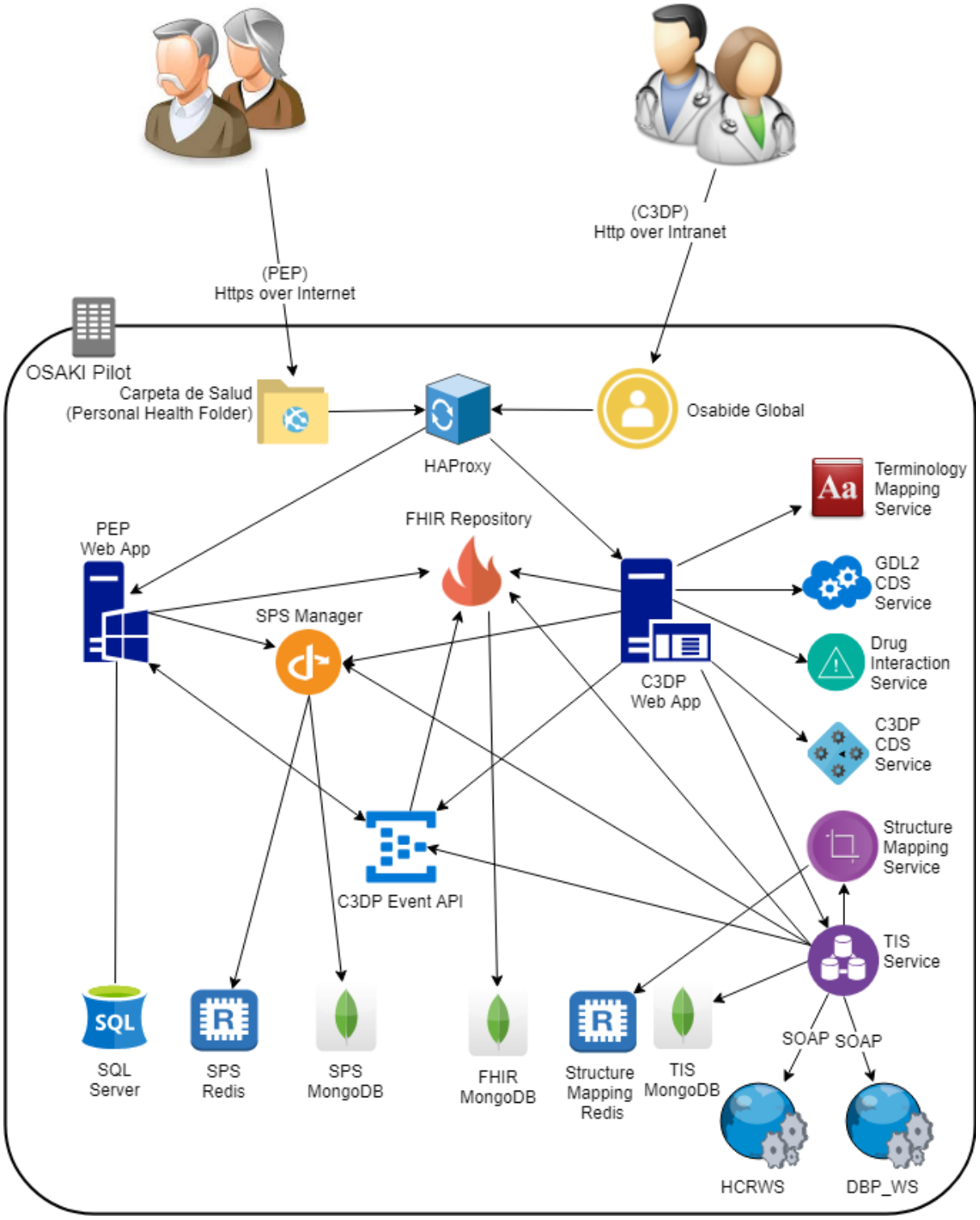

Figure 3 OSAKI pilot application architecture

Figure 3 illustrates how the 17 C3-Cloud installable artefacts are assembled and integrated within the OSAKI pilot. The arrow connectors in the figure indicate the communication channels between the components and the message flow direction. While PEP Web App is Internet facing and patients will

have secured access through HTTPS, MDT professionals can only visit C3DP Web App through the enterprise intranet. All network traffic to C3-Cloud pilot application is proxied by HAProxy, an open source load balancing proxy server. The HTTPS traffic from Internet terminates at the HAProxy server, so all communication within the intranet is through HTTP only. OSAKI exposes two SOAP web services for sharing patient data. HCRWS allows to retrieve patient demographics, conditions, medications, allergies, nursing care, etc., as CDA. DBP_WS provides observations data including vital signs and lab tests. The two services are exposed as intranet SOAP endpoints which TIS Service can invoke through intranet URLs.

A proprietary approach has been followed for MDT member authentication integration upon the request and restrictions of the Osakidetza pilot site, because Osakidetza systems do not implement standard protocols such as OpenID, OAuth or SAML, and it was not possible to directly provide access to their LDAP either for security reasons. Upon the proposal of Osakidetza, SRDC has agreed with them to achieve integration via a proprietary Java Web Token (JWT).

No Osakidetza staff will be able to access C3DP directly. They will always first login to their EHR system Osabide Global, which they do every day for their operational work. Osabide Global will then provide a link to C3DP, which will direct the user to the C3DP when clicked. Thanks to integration via JWT token sharing, single sign-on will be achieved and the users will not need to be authenticated again in C3DP. The flow in the figure below shows how an MDT member can access C3DP in the case of Osakidetza (and also a patient to PEP).

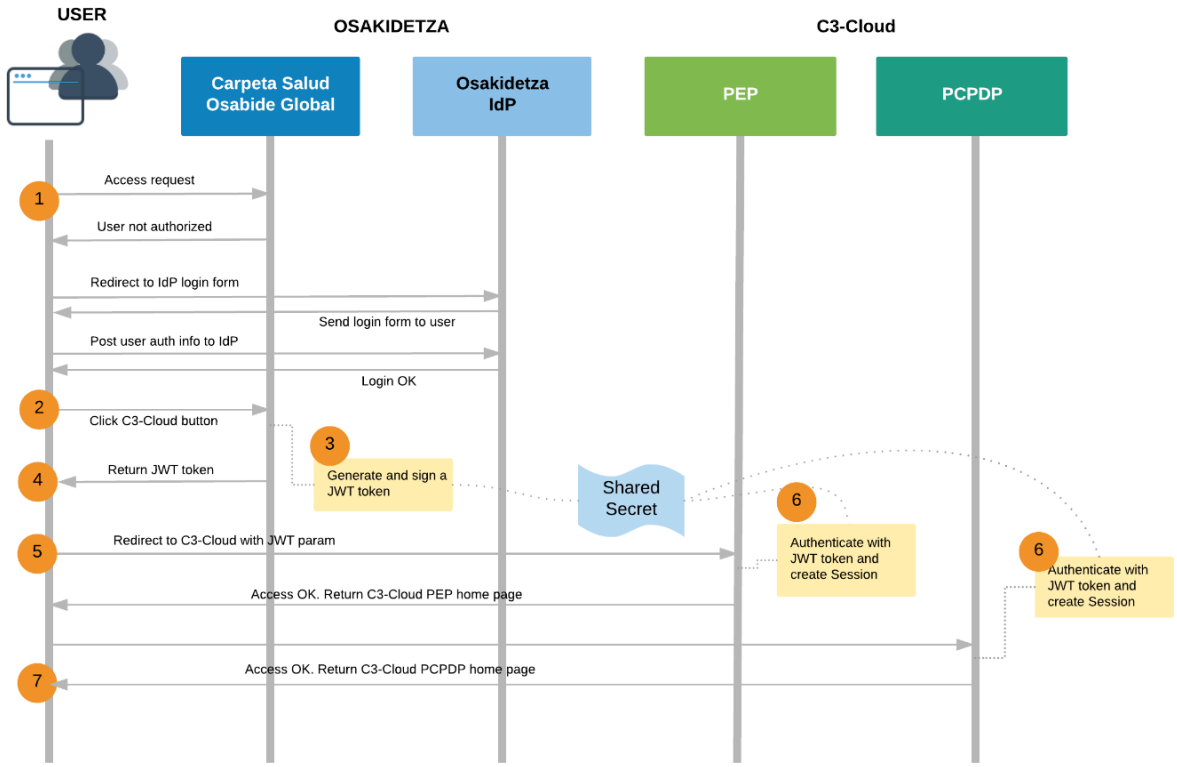

Figure 4 OSAKIDETZA User authentication flow

Taking as example an MDT member, the whole process to access C3DP involves:

1. An MDT member authenticates in Osabide global against Osakidetza's LDAP intranet service.
2. The MDT member accesses Osabide Global and clicks a button to access C3-Cloud C3DP for care plan management.

3. Osabide Global generates a JWT token with basic information about the MDT member and signs it with a secret. JWT token expires in a short period of time (few seconds).
4. The JWT token is sent back to user's browser.
5. User's browser redirects to C3DP sending JWT token as a parameter.
6. C3DP picks up the token and validates it with the same secret that Osabide Global used to sign it. If the token is validated correctly, a C3DP session is created via the integration with the SPS.
7. C3DP via SPS checks that a request can only access information associated with the MDT member passed in the JWT token.

This integration has already been completed. The format of the JWT token is as follows:

• **sub**: (standard). It can contain a string or a URI. It is fixed to "c3cloud-auth".

• **iss**: (standard). It can contain a string or a URI. It is fixed to "osakidetza-og".

• **aud**: (standard). It can contain a string or a URI. It is fixed to "c3dp".

• **exp**: (standard). It is a number that represents date and hour in "seconds since epoch" format as defined by POSIX 6. This is the token expiration date.

• **nbf**: (standard). It is a number that represents date and hour in "seconds since epoch" format as defined by POSIX 6. This is the token valid date.

• **iat**: (standard). It is a number that represents date and hour in "seconds since epoch" format as defined by POSIX 6. This is the creation date of the token.

• **jti**: (standard). It contains a string as JWT ID. It is used as a composite string in this integration: [current-date]@[username]@osakidetza.

• **id_prof**: (custom). It is a number that identifies the logged in user. It is used to provide the id professional (DNI) in this integration.

• **professional**: (custom). It is a string that identifies the professional. It is used to provide the id internal.

• **role**: (custom). It is a string that identifies the professional role. It can be one of these:

- Call Center Nurse: Enfermera Consejo Sanitario, C3_CS
- GP: Medico Atención Primaria, C3_MED_AP
- Primary Care Nurse: Enfermera de Atención Primaria, C3_ENF_AP
- Specialist: Medico Atención Especializada, C3_MED_AE
- Specialist Nurse: Enfermera de Atención especializada, C3_ENF_AE
- Advanced Nurse: Enfermera Gestora de Competencias Avanzadas, C3_ENF_ECGA

As in the case of other pilot sites, there are also social care workers involved in C3-Cloud piloting who are not Osakidetza staff. As it is not possible to integrate with social care workers' IdPs, it has been agreed to use the OpenID Connect 1.0 compliant C3-Cloud default IdP, which is a sub-component of the C3-Cloud SPS.

"Carpeta de Salud" is the Personal Health Folder (PHF) where Euskadi citizens can see and download their clinical reports and information, introduce health data and request appointments. Patients participating in C3-Cloud project will be included in a specific program within the corporate module for Integral Program Management (GIP module of Osabide Global). To be able to access "Carpeta de Salud", Euskadi patients have an identification card issued by Izenpe, an organization promoted by the Basque Government and the Provincial Councils that provides electronic signature services.

As long as the patients are active in the "C3-Cloud" program of Osabide Global, they will be able to access an exclusive menu item to link to the PEP. The services of the PEP will not be embedded in the

Health Folder interface itself, but they will be directly managed by accessing the PEP platform. The link to the PEP from "Carpeta de Salud" will not require double authentication, since the patient is authenticated when entering the PHF, and the PEP will only be provided with the patient's CIC code (ID for patients used by Osakidetza), and from that CIC can be invoked to different WS of Osakidetza to obtain both their clinical and demographic data. Patient authentication integration between "Carpeta de Salud" and PEP is based on sharing a signed JWT token. A JWT token is signed with a secret that is shared among all systems. This way, all systems can sign and verify tokens and trust one in each other.

This flow shows how a patient user could access C3-Cloud PEP through "Carpeta de Salud":

1. Patient authenticates in "Carpeta de Salud" using Izenpe services
2. Patient accesses "Carpeta de Salud" and clicks a button to access C3-Cloud PEP
3. "Carpeta de Salud" generates a JWT token with basic information about the citizen and signs it with a secret. JWT token expires in a short period of time (few seconds).
4. The JWT token is sent back to user's browser.
5. User's browser redirects to C3-Cloud PEP sending JWT token as a parameter.
6. PEP picks up the token and validates it with the same secret that "Carpeta de Salud" used to sign it. If token is validated correctly, PEP creates a session.
7. PEP checks that a request can only access information about the citizen passed in the JWT token. This is to avoid a malicious hacker to access information about other citizen with a valid JWT token.

Physical Architecture

OSAKI provides 4 server machines to host C3-Cloud components plus one proxy server (Table 4). Two Linux servers are used to host the 15 components that run in Docker containers. The 10 Docker based application services are hosted in the Docker application server (c3cloud01), while the 5 MongoDB and Redis databases are hosted in the Docker database server (c3cloud02). The two Windows servers host PEP IIS Web App (c3cloud03) and its SQL Server database (c3cloud04). The Windows server for PEP Web App has both a public IP address so patients can connect from Internet, and a private IP address to allow other components to communicate within the local network. Apart from that PEP Web server, all the other servers have only private intranet IP addresses and so can only be accessible from the OSAKI enterprise intranet. The same servers are used to run both the staging environment and the production environment. Table 5 and Table 6 list the domain names of all C3-Cloud installable artefacts and the hosts and ports to which they are assigned in the staging deployment and production deployment respectively. Network Address Translation (NAT) is set up to map the assigned domains names to the hosts and ports where each application is running. One SSL certificate is installed for the PEP Web server.

Table 4 OSAKI physical servers

Server Name	Description	CPU	RAM	DISK	OS	IP
c3cloud00	HAProxy, SSL/TLS Termination	Core2 duo	3G~4 G	250G	Red Hat 7.5	N/A
c3cloud01	Docker Containers Application Server	8 cores	32G	200G	Red Hat 7.5	10.70.40.55
c3cloud02	Docker Containers Database Server	4 cores	8G	100G	Red Hat 7.5	10.70.40.58
c3cloud03	Windows Application Server	2 cores	4G	200G	Windows Server 2012	212.142.248.173 192.168.208.53

c3cloud04	Windows Database Server	4 cores	8G	200G	Windows Server 2012 SQL Server 2012	10.70.40.64

Table 5 OSAKI staging deployment

Artefact	Domain Name	Server	Port
PEP IIS Web App	stagingc3cloud.osakidetza.eus	c3cloud03	443
PEP SQL Server	stagingpepdb.osasunet	c3cloud04	1433
C3DP Web App	stagingc3cloud.osasunet	c3cloud01	6001
C3DP Event API	stagingc3dpeapi.osasunet	c3cloud01	6002
C3DP CDS Services	stagingc3dpcds.osasunet	c3cloud01	6003
FHIR Repository Server	stagingfhir.osasunet	c3cloud01	6005
FHIR Repository MongoDB	stagingfhirdb.osasunet	c3cloud02	6006
SPS Manager	stagingsps.osasunet	c3cloud01	6004
SPS MongoDB	stagingspsdbmon.osasunet	c3cloud02	6007
SPS Redis	stagingspsdbred.osasunet	c3cloud02	6008
Structure Mapping Service	stagingsms.osasunet	c3cloud01	6101
Structure Mapping Service Redis	stagingsmsdbred.osasunet	c3cloud02	6102
Terminology Mapping Service	stagingtms.osasunet	c3cloud01	6103
TIS Service	stagingtis.osasunet	c3cloud01	6104
TIS MongoDB	stagingtisdb.osasunet	c3cloud02	6105
GDL2 CDS Services	stagingcds.osasunet	c3cloud01	6106
Drug Interaction Service	stagingdis.osasunet	c3cloud01	6107

Table 6 OSAKI production deployment

Artefact	Domain Name	Server	Port
PEP IIS Web App	c3cloud.osakidetza.eus	c3cloud03	443
PEP SQL Server	pepdb.osasunet	c3cloud04	1433
C3DP Web App	c3cloud.osasunet	c3cloud01	5001
C3DP Event API	c3dpeapi.osasunet	c3cloud01	5002
C3DP CDS Services	c3dpcds.osasunet	c3cloud01	5003
FHIR Repository Server	fhir.osasunet	c3cloud01	5005
FHIR Repository MongoDB	fhirdb.osasunet	c3cloud02	5006
SPS Manager	sps.osasunet	c3cloud01	5004
SPS MongoDB	spsdbmon.osasunet	c3cloud02	5007
SPS Redis	spsdbred.osasunet	c3cloud02	5008
Structure Mapping Service	sms.osasunet	c3cloud01	5101

Structure Mapping Service Redis	smsdbred.osasunet	c3cloud02	5102
Terminology Mapping Service	tms.osasunet	c3cloud01	5103
TIS Service	tis.osasunet	c3cloud01	5104
TIS MongoDB	tisdb.osasunet	c3cloud02	5105
GDL2 CDS Services	cds.osasunet	c3cloud01	5106
Drug Interaction Service	dis.osasunet	c3cloud01	5107

4.2 RJH

Application Architecture

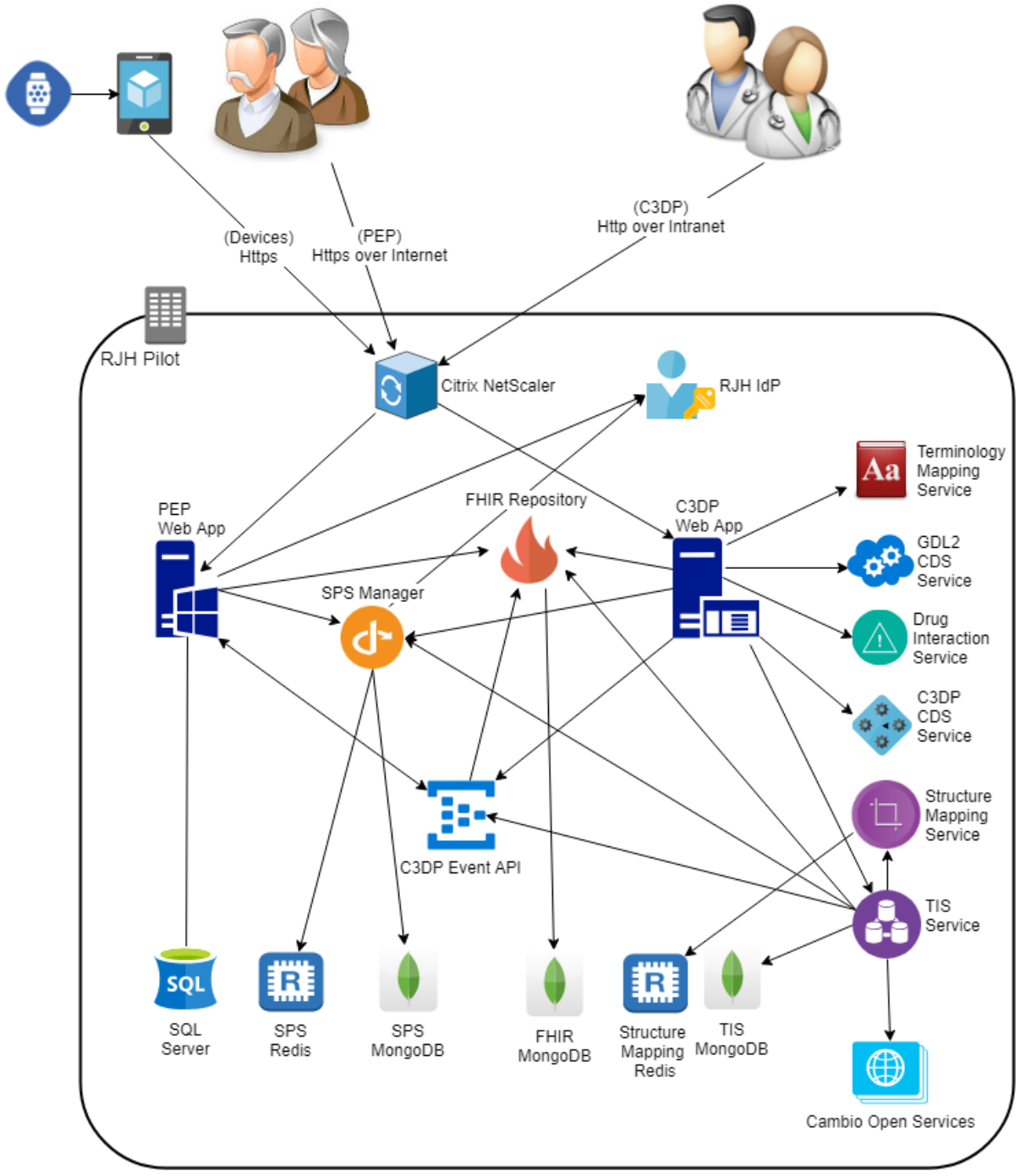

Figure 5 RJH pilot application architecture

Figure 5 illustrates how the 17 C3-Cloud installable artefacts are assembled and integrated within the RJH pilot. The application architecture of RJH pilot is similar to that of OSAKI pilot. The PEP Web App is Internet facing so patients can access through HTTPS. MDT professionals should only visit C3DP Web App through the enterprise intranet. RJH uses Citrix NetScaler to monitor server health and manage network and application traffic. NetScaler is a Citrix web and application delivery controller that maximizes the performance and availability of all applications and data. Similarly to the OSAKI pilot, all Internet traffic are protected by HTTPS and the local intranet communication uses plain HTTP only. RJH uses Cambio COSMIC and so deploys Cambio Open Services for patient data access. Cambio Open Services are RESTful API services hosted in Microsoft Azure Cloud, which facilitates

third-party integration. The Partner API provides 6 endpoints which cover demographics, diagnoses, journal notes, medicines, laboratory responses and care contacts of a patient in a time range. The Open Services API are protected by Cambio Authorization Service, an OpenID Connect/OAuth2 provider deployed along with the Open Services. The TIS Service integrates with the Authorization Service and Open Services API following the OAuth2 client credentials grant type.

For MDT professional authentication, SPS is integrated with the IdP of RJH. RJH is using Microsoft Active Directory Federation Services (MS ADFS) as their IdP. During summer-autumn 2017, RJH updated their IdP to the latest release, i.e. MS ADFS 2016, which supports natively the OpenID Connect 1.0 specification. This has been a great advantage as the SPS has already been implemented in compliance with the OpenID Connect 1.0 specification for user authentication and authorization. The OpenID Connect configuration of RJH ADFS setup including the token endpoints is available at https://idp.regionjh.se/adfs/.well-known/openid-configuration.

When a user opens the C3DP, it is redirected to the login page of the SPS, and there two options are provided to the RJH users: i) login with their existing RJH accounts, or ii) login via default C3-Cloud IdP. RJH health professionals select the first option and then they are redirected to the original RJH login page. When the login is successful, the SPS acquires the id token of the user and provides it to the C3DP along with an access token, just like the case in C3-Cloud IdP authentication. The second option will be used only by the social care workers of RJH, who do not have any user accounts maintained by RJH.

An example id token for a demo user is provided below:


```
{
  "aud": "b5532df7-5a21-4507-81d6-2bfa48eb5b69",
  "iss": "https://idp.regionjh.se/adfs",
  "iat": 1522848102,
  "exp": 1522851702,
  "auth_time": 1522848102,
  "nonce": "219945098322415982888586289718099112547",
  "sub": "azJ8hQU7cKZXTrDxSE5XOz/PTd2CNzlfFsA2kcrR4jQ=",
  "upn": "c3cloud@jll.jllad.se",
  "unique_name": "JLL\\c3cloud",
  "pwd_exp": "7176991",
  "sid": "S-1-5-21-1458514816-1055937895-1845911597-48586",
  "email": "c3cloud@dummy.org",
  "role": "Role",
  "family_name": "Surname",
  "given_name": "Givenname",
  "apptype": "Confidential",
  "appid": "b5532df7-5a21-4507-81d6-2bfa48eb5b69",
  "authmethod":
"urn:oasis:names:tc:SAML:2.0:ac:classes:PasswordProtectedTransport",
  "ver": "1.0",
  "scp": "allatclaims profile openid"
}
```


In Sweden, BankID is the leading electronic identification solution. It has been developed by several large banks and is used by members of the public, authorities and companies. Sweden´s national population e-health services, e.g. order prescriptions drugs, booking doctor appointments and reading medical records, all use BankID as identification method for patients. Today about 7.5 million people use BankID on a regular basis for both private and public services.

PEP is therefore integrated with RJH´s IdP that supports BankID authentication. Patients that doesn't have a BankID yet can easily get one from their respective bank and the issuing bank is guaranteeing the customer´s identification. BankID is available on smart card, computers, mobile phones and tablet devices, which gives the individual alternatives to find the most suitable method.

Connected monitoring devices are integrated to PEP solution. The devices are CE-marked medical devices providing singular observations about the patient's vital signs. The following devices are chosen:

- A&D UA-651 BLE Blood Pressure Monitor (Systolic and Diastolic BP, pulse)
- A&D UC-351PBT-Ci Body Scale (Body mass)

The connected devices are Bluetooth capable and allow remote reading of measurements. The connectivity to PEP solution will be facilitated by an Android-based hub software that can be installed on any compatible Android device. The following Android device is recommended:

- HMD Nokia 1

The measurements are delivered securely from the hub software to PEP using HTTPS protocol encrypted with TLS encryption. The transmissions are anonymous containing only the measurement, device metadata and unique and un-guessable identification code for the devices. PEP has a special endpoint for receiving observation transmissions using hub or device identifiers. It also has a function for creating mappings between devices or hubs and patient records, making it possible to connect the measurements to patients in the solution.

Measurements can be observed in PEP either as separate data points or over time in charts. PEP is tightly coupled with C3DP interfaces and data is moved between systems using event notifications. Every time a discreet measurement is uploaded to PEP, C3DP is notified and can fetch the measurements that have been made identifiable.

The following steps describe how devices are configured in RJH pilot:

1. The pilot team acquires the device kit components (measurement device, data transfer phone) and the device kits are assembled.
2. The device kits are registered in the PEP component of the local pilot production deployment.
3. The local admin assigns a selected kit in PEP to the patient and the device kit is handed out to the patient.
4. The patient uses the device kit at home for the period agreed with the local pilot team.
5. All measurement values are uploaded automatically from device to the C3-Cloud system.
6. The uploaded values are transferred to FHIR in the same way as manually entered values.
7. At the end of the period, the patient returns the device kit and the kit is removed from the patient in the C3-Cloud system.

Physical Architecture

RJH provides 7 servers to host C3-Cloud components (Table 7). Two Debian Linux servers are used as the staging servers to host the Docker container components (RJHvC3CloudTest and RJHvC3CloudDbTest). The other two Debian servers of higher specification are used as the production servers. RJH provides shared IIS Web Server and SQL Server to host the PEP web application and its SQL database. One instance of shared IIS Web Server is used for staging (RJHvIISExtTest). The other instance is used for production (RJHvIISExt). The shared SQL Server is used to host both the staging and production PEP databases. The IIS server has both a public IP address so patients can connect from Internet, and a private IP address to allow other components to communicate within the local intranet. Apart from that PEP IIS server, all the other servers have only private intranet IP addresses and so can only be accessible from the RJH enterprise intranet. Table 8 and Table 9 list the domain names of all C3-Cloud installable artefacts and the hosts and ports to which they are assigned in the staging environment and production environment respectively. Network Address Translation (NAT) is set up to map the assigned domains names to the hosts and ports where each application is running. One SSL certificate is installed for the PEP Web server.

Table 7 RJH physical servers

Server Name	Description	CPU	RAM	DISK	OS	IP

RJHvC3CloudTest	Docker Containers Application Staging Server	4 cores	16G	200G	Debian	10.122.128.70
RJHvC3CloudDbTest	Docker Containers Database Staging Server	2 cores	4G	100G	Debian	10.121.0.30
RJHvC3Cloud	Docker Containers Application Production Server	2 cores	4G	200G	Debian	10.122.128.90
RJHvC3CloudDb	Docker Containers Database Production Server	4 cores	8G	200G	Debian	10.121.0.40
RJHvIISExtTest	Shared IIS Server for Staging	4 cores	8G	50G	Windows Server 2016	194.14.51.83 192.168.3.132
RJHvIISExt	Shared IIS Server for production	4 cores	8G	100G	Windows Server 2016	194.14.51.76 192.168.3.133
RJHvSQLExt	Shared SQL Server for both Staging and Production	2 cores	6G	350G	Windows Server 2016 SQL Server 2016	192.168.6.43

Table 8 RJH staging deployment

Artefact	Domain Name	Server	Port
PEP IIS Web App	c3peptest.regionjh.se	RJHvIISExtTest	443
PEP SQL Server	RJHvSQLExt.jll.jllad.se	RJHvSQLExt	1433
C3DP Web App	c3dpwebtest.jll.jllad.se	RJHvC3CloudTest	6001
C3DP Event API	c3dpapitest.jll.jllad.se	RJHvC3CloudTest	6002
C3DP CDS Services	c3dpcdstest.jll.jllad.se	RJHvC3CloudTest	6003
FHIR Repository Server	c3fhirtest.jll.jllad.se	RJHvC3CloudTest	6005
FHIR Repository MongoDB	c3fhirdbtest.jll.jllad.se	RJHvC3CloudDbTest	6006
SPS Manager	c3spstest.jll.jllad.se	RJHvC3CloudTest	6004
SPS MongoDB	c3spsdbtest.jll.jllad.se	RJHvC3CloudDbTest	6007
SPS Redis	c3spsredistest.jll.jllad.se	RJHvC3CloudDbTest	6008
Structure Mapping Service	c3smstest.jll.jllad.se	RJHvC3CloudTest	6101
Structure Mapping Service Redis	c3smsredistest.jll.jllad.se	RJHvC3CloudDbTest	6102
Terminology Mapping Service	c3tmstest.jll.jllad.se	RJHvC3CloudTest	6103
TIS Service	c3tistest.jll.jllad.se	RJHvC3CloudTest	6104
TIS MongoDB	c3tisdbtest.jll.jllad.se	RJHvC3CloudDbTest	6105
GDL2 CDS Services	c3gdl2test.jll.jllad.se	RJHvC3CloudTest	6106
Drug Interaction Service	c3distest.jll.jllad.se	RJHvC3CloudTest	6107

Table 9 RJH production deployment

Artefact	Domain Name	Server	Port
PEP IIS Web App	c3pep.regionjh.se	RJHvIISExt	443
PEP SQL Server	RJHvSQLExt.jll.jllad.se	RJHvSQLExt	1433
C3DP Web App	c3dp.jll.jllad.se	RJHvC3Cloud	5001
C3DP Event API	c3dpapi.jll.jllad.se	RJHvC3Cloud	5002
C3DP CDS Services	c3dpcds.jll.jllad.se	RJHvC3Cloud	5003
FHIR Repository Server	c3fhir.jll.jllad.se	RJHvC3Cloud	5005
FHIR Repository MongoDB	c3fhirdb.jll.jllad.se	RJHvC3CloudDb	5006
SPS Manager	c3sps.jll.jllad.se	RJHvC3Cloud	5004
SPS MongoDB	c3spsdb.jll.jllad.se	RJHvC3CloudDb	5007
SPS Redis	c3spsredis.jll.jllad.se	RJHvC3CloudDb	5008
Structure Mapping Service	c3sms.jll.jllad.se	RJHvC3Cloud	5101
Structure Mapping Service Redis	c3smsredis.jll.jllad.se	RJHvC3CloudDb	5102
Terminology Mapping Service	c3tms.jll.jllad.se	RJHvC3Cloud	5103
TIS Service	c3tis.jll.jllad.se	RJHvC3Cloud	5104
TIS MongoDB	c3tisdb.jll.jllad.se	RJHvC3CloudDb	5105
GDL2 CDS Services	c3gdl2.jll.jllad.se	RJHvC3Cloud	5106
Drug Interaction Service	c3dis.jll.jllad.se	RJHvC3Cloud	5107

4.3 SWFT

Application Architecture

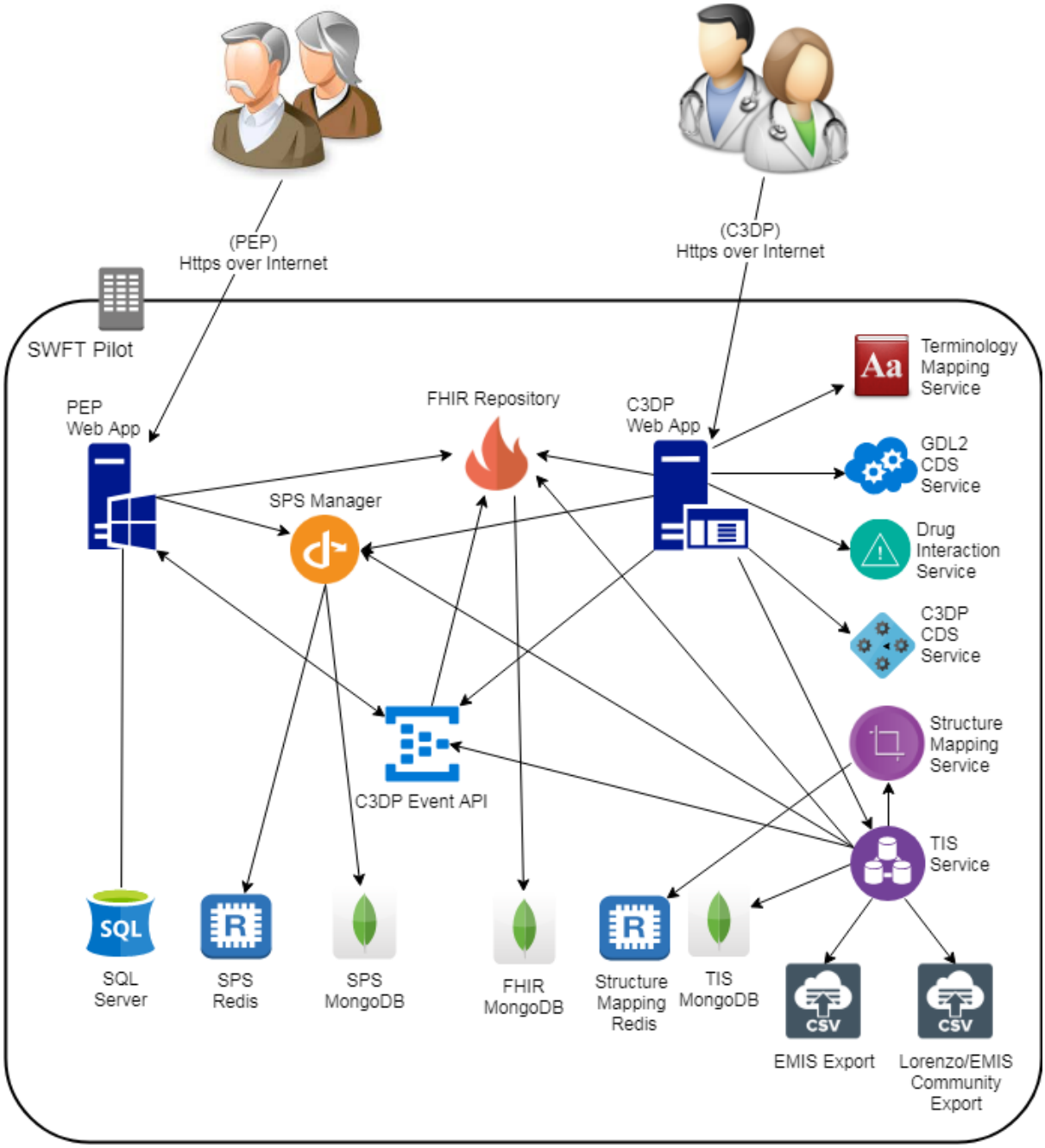

Figure 6 SWFT pilot application architecture

Figure 6 illustrates how the 17 C3-Cloud installable artefacts are assembled and integrated within the SWFT pilot. The application architecture of SWFT pilot is simpler compared to those of OSAKI and RJH as there are no local authentication integration. Both the PEP Web App and the C3DP Web App are Internet facing so patients and MDT professionals will access through HTTPS. While there is no proxy in the pilot, both PEP and C3DP will be presented via SWFT Sophos UTM perimeter appliances. SWFT does not provide a direct API integration. Instead, CSV files are exported from the EMIS primary care reporting system and Lorenzo/EMIS Community systems every day. The CSV export from the EMIS reporting system has about 100 columns and contains patient's demographics, encounters, diagnoses, medications, procedures, allergies, vital signs, lab tests, family history, social history, etc., in the primary care setting. The CSV export from Lorenzo/EMIS Community contains all care contacts

in the secondary care and community care settings consolidated into a single file. Both CSV files are copied to a shared folder in the SWFT server automatically on a daily basis, from where they are loaded by TIS at a scheduled time.

The information security experts of SWFT clearly indicated that they cannot attempt integration with their IdP for less than 100 users, which is the case in the C3-Cloud project. Therefore, SWFT agreed to use the OpenID Connect 1.0 compliant C3-Cloud default IdP that is provided within the SPS for all SWFT MDT members. C3-Cloud specific user accounts will be created for all SWFT MDT members via SPS to be used during the pilot studies. Similarly, PEP native authentication mechanism is used to authenticate patients. Patients will be handed usernames and passwords to log on during recruitment.

Physical Architecture

SWFT provides 2 server machines to host C3-Cloud (Table 10). Both servers are windows based following SWFT local IT policy. One server is dedicated to PEP to host both the IIS web server and the SQL database (SVFWHC3SQL). The other server hosts all the 15 Docker container applications (SVFWHC3APPSW10). Because Windows Server 2012 does not have native Docker engine support, Windows 10 is installed on the server instead with Docker support enabled. Both servers have only private IP addresses as SWTF does not allow public IP to be exposed. Instead SWFT maps public URLs to local server addresses for patients and MDT professionals to access the system. The same servers are used to run both the staging environment and the production environment. Table 11 and Table 12 list the domain names of all C3-Cloud installable artefacts and the hosts and ports to which they are assigned in the staging deployment and production deployment respectively. NAT is set up to map the assigned domains names to the hosts and ports where each application is running. One SSL certificate is installed for the PEP Web server and one SSL certificate is installed for the C3DP Web server.

Table 10 SWFT physical servers

Server Name	Description	CPU	RAM	DISK	OS	IP
SVFWHC3SQL	Windows Server for PEP	4 cores	32G	40G	Windows Server 2102 R2 SQL Server 2016 Standard	10.193.192.231
SVFWHC3APPSW10	Windows Server for Docker Containers	8 cores	48G	100G	Windows 10 1803 build	10.193.192.230

Table 11 SWFT staging deployment

Artefact	Domain Name	Server	Port
PEP IIS Web App	STAGEC3PEPWEB.SWFT.NHS.UK	SVFWHC3SQL	443
PEP SQL Server	STAGEC3PEPSQL.SWFT.NHS.UK	SVFWHC3SQL	1433
C3DP Web App	STAGEC3DPWEB.SWFT.NHS.UK	SVFWHC3APPSW10	6001
C3DP Event API	STAGEC3DPAPI.SWFT.NHS.UK	SVFWHC3APPSW10	6002
C3DP CDS Services	STAGEC3DPCDS.SWFT.NHS.UK	SVFWHC3APPSW10	6003
FHIR Repository Server	STAGEC3FHIR.SWFT.NHS.UK	SVFWHC3APPSW10	6005
FHIR Repository MongoDB	STAGEC3MDBFHIR.SWFT.NHS.UK	SVFWHC3APPSW10	6006
SPS Manager	STAGEC3SPS.SWF.NHS.UK	SVFWHC3APPSW10	6004
SPS MongoDB	STAGEC3MDBSPS.SWFT.NHS.UK	SVFWHC3APPSW10	6007

Artefact	Domain Name	Server	Port
SPS Redis	STAGEC3SPSRDS.SWFT.NHS.UK	SVFWHC3APPSW10	6008
Structure Mapping Service	STAGEC3SMS.SWFT.NHS.UK	SVFWHC3APPSW10	6101
Structure Mapping Service Redis	STAGEC3SMSRD.SWFT.NHS.UK	SVFWHC3APPSW10	6102
Terminology Mapping Service	STAGEC3TMS.SWFT.NHS.UK	SVFWHC3APPSW10	6103
TIS Service	STAGEC3TISWEB.SWFT.NHS.UK	SVFWHC3APPSW10	6104
TIS MongoDB	STAGEC3TISMDB.SWFT.NHS.UK	SVFWHC3APPSW10	6105
GDL2 CDS Services	STAGEC3GDLCDS.SWFT.NHS.UK	SVFWHC3APPSW10	6106
Drug Interaction Service	STAGEC3DIS.SWFT.NHS.UK	SVFWHC3APPSW10	6107

Table 12 SWFT production deployment

Artefact	Domain Name	Server	Port
PEP IIS Web App	C3PEPWEB.SWFT.NHS.UK	SVFWHC3SQL	443
PEP SQL Server	C3PEPSQL.SWFT.NHS.UK	SVFWHC3SQL	1433
C3DP Web App	C3DPWEB.SWFT.NHS.UK	SVFWHC3APPSW10	5001
C3DP Event API	C3DPAPI.SWFT.NHS.UK	SVFWHC3APPSW10	5002
C3DP CDS Services	C3DPCDS.SWFT.NHS.UK	SVFWHC3APPSW10	5003
FHIR Repository Server	C3FHIR.SWFT.NHS.UK	SVFWHC3APPSW10	5005
FHIR Repository MongoDB	C3MDBFHIR.SWFT.NHS.UK	SVFWHC3APPSW10	5006
SPS Manager	C3SPS.SWF.NHS.UK	SVFWHC3APPSW10	5004
SPS MongoDB	C3MDBSPS.SWFT.NHS.UK	SVFWHC3APPSW10	5007
SPS Redis	C3SPSRDS.SWFT.NHS.UK	SVFWHC3APPSW10	5008
Structure Mapping Service	C3SMS.SWFT.NHS.UK	SVFWHC3APPSW10	5101
Structure Mapping Service Redis	C3SMSRD.SWFT.NHS.UK	SVFWHC3APPSW10	5102
Terminology Mapping Service	C3TMS.SWFT.NHS.UK	SVFWHC3APPSW10	5103
TIS Service	C3TISWEB.SWFT.NHS.UK	SVFWHC3APPSW10	5104
TIS MongoDB	C3TISMDB.SWFT.NHS.UK	SVFWHC3APPSW10	5105
GDL2 CDS Services	C3GDLCDS.SWFT.NHS.UK	SVFWHC3APPSW10	5106
Drug Interaction Service	C3DIS.SWFT.NHS.UK	SVFWHC3APPSW10	5107

5. DEPLOYMENT PROCESS

As described in section 4, each pilot site has its specific IT hosting constraints and architecture requirements. C3-Cloud components have to be assemble and customised according to individual circumstances of each site. Technical partners collaborate with pilot site IT teams to make C3-Cloud

pilot systems available to use in the site staging and production environments. The whole deployment process divides into three phases: preparation, staging deployment and production deployment.

5.1 Preparation

In the preparation phase, pilot sites ensure the IT infrastructure required for the deployment is ready and provide technical partners remote access to the servers. In the meantime, technical partners test all components in the development environment and build the final software release to be installed. Activities in this phase include:

- Following the integration (Task 7.4) and component testing (Task 9.2), technical partners (SRDC, MEDIXINE, WARWICK, INSERM, CAMBIO) finalise software features based on testing and evaluation feedback and build the final release of C3-Cloud software ready to be deployed.
- Pilot sites (OSAKI, RJH, and SWFT) acquire and prepare the hardware servers, install operation systems and database software according to the physical architecture design in section 4.
- Technical partners and pilot sites agree on the domain names of all installable components. Pilot sites register the domain names in DNS service and acquire SSL certificates for Internet facing components, i.e. PEP Web App in OSAKI and RJH, PEP Web App and C3DP Web App in SWFT.
- Pilot sites set up required network services such as SMTP provider for sending emails, and open network ports necessary for component installation, such as port 22 for SSH connection and 8170 for IIS web deploy.
- OSAKI and RJH prepare their patient data API services and identity providers and make them available in the pilot infrastructure. SWFT prepares the automated file copying service and makes the CSV exports available in a shared folder on the server.
- OSAKI sets up a private Docker registry at docker-registry-c3cloud.osakidetza.eus for C3-Cloud so technical partners can push Docker images to the registry from developer machines and pull images to pilot servers during installation. SRDC has also set up its own private Docker registry as a backup at nexus.srdc.com.tr for C3DP related components only.
- Every technical partner signs one-to-one non-disclosure agreement (NDA) with pilot sites and applies for a VPN account in order to access the pilot servers remotely.
- Technical partners test VPN connections and make sure all installation dependency is satisfied in pilot servers.

5.2 Staging Deployment

During the staging deployment phase, technical partners install and configure all components in the staging environment at each site according to the architecture design in section 4. Test accounts are created in C3DP and PEP. Pilot sites prepare anonymised multi-morbidity patient samples and load the samples into the staging system. Trainings are provided to health professionals and pilot study management team so end users in each site become efficient with the system. A comprehensive testing is carried out by both pilot team and technical partner as a final attempt to reassure bugs are fixed before the system goes live. The installation and configuration process of each component is detailed below.

Installation and configuration of FHIR Repository

Thanks to the usage of private Docker registries, the installation of C3-Cloud FHIR Repository is quite an easy task. When a new version of FHIR Repository is to be deployed to a pilot site, after a successful build with testing in SRDC development computers, the Docker image c3cloud/repo is built from scratch and then pushed to the private Docker registry.

For installation, it is enough to pull the Docker image from the registry and run it. Necessary update, start and stop scripts are provided to the pilot sites for facilitating this task. C3-Cloud FHIR Repository is a server-side application and it has one primary configuration file, application.conf, that is provided externally to the Docker container so that configuration updates can be done without the need for a re-build of the whole Docker image. The same Docker image is used in all 3 pilot sites, with different configuration files.

The primary configuration file application.conf enables the following configurations:

- MongoDB connection parameters
- FHIR Repository Base URL, extension and port setting
- SPS related configurations (SPS endpoint, registered client id configuration, etc.)
- Auditing
- CDS service configurations (CDS endpoint, id, required clinical data definition, associated high-level goals, etc.)
- Valid time intervals of some expiring patient data such as medications, lab results

This configuration is done once by the product owner SRDC at the beginning, and after that it is not necessary to update unless there is an important change with the above-mentioned configurations, such as a CDS endpoint change. Detailed configuration and maintenance guidelines will be provided to the IT staff of the pilot sites.

FHIR Repository has further advanced configuration parameters in other setting files, e.g. for updating the list of supported FHIR resources, search parameters or even operations. However, it is not necessary to do such advanced configuration management during the C3-Cloud pilot study.

The official MongoDB Docker image is used as it is, so apart from the connection port, database name and authentication configuration, no other configuration is needed.

In the staging environment, all Docker containers, data volumes and networks are run with a "c3cloud_test" prefix.

Installation and configuration of C3DP

The installation of C3DP is managed again via private Docker registries, similarly to the FHIR Repository. The C3DP is composed of 3 deployable artefacts, each of which is a Docker image in its own:

1. **C3DP Web App**: There are a few important configuration parameters embedded in the source environment configuration file of C3DP, such as the FHIR Repository endpoint, SPS related configurations, Event API endpoint. These need to be configured before building the C3DP Angular application. Hence, each pilot site has its own copy of C3DP Web App Docker image. Apart from this, there is no other configuration file of C3DP Web App. Once installed, further configurations related to pilot site specific content are enabled via the C3DP graphical user interface for administration. As explained in Section 3.1, this includes management of core education materials, value set (i.e. terminology systems), organizations and locations by the pilot site coordinators.
2. **C3DP Event API**: The same Docker image named c3cloud/event-api is used in all 3 pilot sites. It does not require any configuration. The HTTP endpoint configuration is managed by the reverse proxy or web server at the pilot site level, e.g. either via nginx or HAProxy.
3. **Complementary CDS Services**: The same Docker image named c3cloud/srdc-cds is used in all 3 pilot sites. It does not require any configuration. The HTTP endpoint configuration is managed by the reverse proxy or web server at the pilot site level, e.g. either via nginx or HAProxy.

Detailed configuration and maintenance guidelines will be provided to the IT staff of the pilot sites.

In the staging environment, all Docker containers, data volumes and networks are run with a "c3cloud_test" prefix.

Installation and configuration of SPS

The installation of SPS is managed again via private Docker registries, similarly to the FHIR Repository. SPS Server & Manager has one primary configuration file, application.conf, that is provided externally to the Docker container so that configuration updates can be done without the need for a re-build of the whole Docker image. The same Docker image is used in all 3 pilot sites, with different configuration files.

The primary configuration file application.conf enables the following configurations:

- MongoDB connection parameters
- Redis connection parameters
- SPS base URL, extension and port setting
- FHIR Repository base URL
- SMTP configuration for sending account registration emails to users
- Timeout duration configuration for created access tokens

This configuration is done once by the product owner SRDC at the beginning, and after that it is not necessary to update unless there is an important change with the above-mentioned configurations.

In addition, SPS Server also has some advanced configurations that can be managed either via configuration files and some of which via the SPS Manager UI. These include the default privacy policy of the pilot site including the FHIR resources, user roles, permissions and assignment of permissions to specific actions defined on FHIR resources (e.g. "a doctor can update a CarePlan but a nurse assistant can only read it"). SPS enables role-based access control for both structural and functional roles, but only the first one is preferred by the C3-Cloud pilot sites. Configuration of software clients to access sensitive patient data in the C3-Cloud FHIR Repository can also be done via both setting files and the SPS Manager UI.

Finally, for those pilot sites that enabled integration with their existing Identity Provider (IdP) systems (i.e. Osakidetza and RJH), the configuration of such IdPs is enabled via the configuration files. It would not be much necessary to update these configurations during the lifetime of the pilots, but still, minor updates such as binding of local roles to C3-Cloud SPS roles might be needed.

Detailed configuration and maintenance guidelines for all these configurations will be provided to the IT staff of the pilot sites.

The official MongoDB and Redis Docker images are used as they are, so apart from the connection port, database name and authentication configuration, no other configuration is needed.

In the staging environment, all Docker containers, data volumes and networks are run with a "c3cloud_test" prefix.

Installation and configuration of PEP

PEP installation consists of two parts: Configuring the web app and configuring the database.

The configurations required for each pilot site include the following:

- web.config
    - security settings for the selected fqdn (mainly content-security-policy)
    - connection string for database connection
    - smtp settings
- \setup\custom.mxsetup
    - available cultures
    - default time zone
    - error alerting mail address
    - available authentication methods
    - site settings to set the proper urls
    - special application settings agreed on with a pilot site

1. Installing PEP SQL Server: A SQL Server installation should be performed by the hosting party following directions given by Medixine. After installation a database should be created with a _CI_AS collation for the desired culture. The database installations will be delivered as incremental SQL scripts that are simply run against the database to upgrade it to a newer version. The database schema and seed data are maintained in source control by Medixine.
2. Installing PEP IIS Web App: The web application will be delivered as a ready-for running application folder. Settings for different sites can be included in two different ways: 1) Settings that do not explicitly have to be installed on-site (for example because they contain sensitive unencrypted information that cannot be stored outside the hosting environment) should be included in Medixine's configuration control and will automatically be included in every build. Different configurations can be stored and used in build process for different sites. 2) Settings that cannot be stored in Medixine's configuration control can be set in web.config and custom.mxsetup files in each environment.

Installation can be automated so that releases are installed to environments automatically using Medixine's release management system (Visual Studio Team Services). This requires the pilot sites to open the release port for Medixine's build server. Manual installation is also easy, only requiring the proper application folder be dropped into a folder. The application is stateless and doesn't store any information in the application folder.

Installation and configuration of TIS

The deployable components of TIS are comprised of a Web service application and a MongoDB database. The Web service application is bundled with a web user interface. The installation of both components are managed via C3-Cloud Docker registry. For installation, it is enough to pull the Docker images from the registry and run them, while both components need post-installation configuration in order to run properly for a site. The TIS Service component is shipped with a configuration file application.properties. The file is shipped outside the Docker image so that it can be updated with site specific settings once the image is pulled to the server host. The following parameters in the configuration file will be updated:

- The TIS MongoDB connection URL
- The FHIR Repository server address inside the pilot
- The Structure Mapping service address inside the pilot

The official MongoDB image is used as it is. After the MongoDB image is pulled to the server host, the database is updated with an initial database import. The import contains the database schema i.e. MongoDB collections and initial data particularly the data integration tasks specific for the pilot. In order to ensure data persistence, a Docker volume is created in the host machine and bind mounted to the MongoDB Docker image. As the component owner, WARWICK manages all the Docker configuration so no extra support is required from local team. Detailed maintenance guidelines are provided to the IT staff of the pilot sites.

In the staging environment, all Docker containers and volumes are run with a "c3cloud_test" prefix.

Installation and configuration of SIS and CDS

The installation of SIS and CDS components are managed via C-Cloud Docker registry too. All component Docker images are preconfigured and pushed to the private Docker registry provided by OSAKI. For installation, it is enough to pull the Docker images from the registry and run them. Because the same images are used for all 3 sites and all the images are self-contained with all configuration built-in, no additional configuration is required in the host server.

5.3 Production Deployment

When the staging deployment is complete, technical webinars are organised by technical partners to walk through the system and provide instructions to pilot site local teams on how to operate and support.

Installation and administration guides are provided for all components as part of the support. After the pilot application is fully tested in the staging environment and pilot site local teams have enough knowledge of the application, the staging system is replicated to the production environment. After the production system is up and running, pilot sites disable the granted VPN access to pilot servers and take over the responsibility of system operation. In preparation for the evaluation study, pilot site teams create real user accounts and initialize the system with baseline data import. Pilot sites also enable system backup following local disaster recovery procedures. Because backup or recovery of individual components or databases is of too much overhead and is beyond local team capability, all pilot sites choose to back up entire virtual machines.

- In Osakidetza, the virtual machines are backed up daily (Monday to Friday) with 1 month retention on disk.
- In RJH, the backup is a daily routine with snapshots of all the servers. The snapshots are then saved to a backup SAN for archival. SQL Server is "informed" before the snapshot is taken so that no databases are in an inconsistent state.
- In SWFT, snapshots of the virtual machines are taken daily as part of SWFT normal disaster recovery procedures.

During evaluation studies, technical partners will provide technical support and apply minor update or bug-fixes to ensure pilot smooth operation. Pilot sites may re-enable VPN access to relevant technical partners when it is deemed necessary to troubleshoot a technical issue in the live system. As soon as the issue is resolved, the VPN access is revoked. This process is governed by data protection agreement (DPA) with each site.

6. DEMONSTRATOR

Because access to deployed systems are restricted under local information governance, public demonstration of the live systems are not included in this deliverable. A demo system is prepared instead in the development environment, where component owners make their components accessible at public endpoints. Links to a demo version of each component are provided as follows:

- **C3DP**: A demo version of C3DP has been made available to all C3-Cloud participants at https://app.srdc.com.tr/c3dp/ since September 2017. Please get in touch for a demo account.
- **PEP**: A demo version of PEP is available at https://c3clouddev.medixine.com/.
- **TIS**: A demo version of TIS is available at http://tis.wmg.warwick.ac.uk/.
- **SIS**: A demo version of SIS structure mapping service is available at: http://houblon.limics.upmc.fr/c3c/transform/. A demo version of SIS terminology mapping service is available at http://cispro.chu-rouen.fr/c3-cloud/.
- **CDS**: A demo version of CDS modules are available at https://cds-platform.com/services/c3cloud/.

The following screenshots demonstrate key system workflow using one of the anonymous diabetes patient samples provided by SWFT. The demonstration comprises three major parts of C3-Cloud: patient data synchronization, care plan management and patient empowerment.

6.1 Patient Data Synchronization

When patients are recruited, their data need to be synchronized from pilot site EHR systems to C3-Cloud, so that MDT members can use the data to create and monitor care plans. The data

synchronization process is driven by TIS and SIS Structure Mapping service. TIS provides a user interface to help manage the steps.

1. Patient local identifiers are used to retrieve their health data from the local EHR system, so as the first step the patient local identifier needs to be registered in TIS in order to initiate the process. As shown in Figure 7, a new patient is added with his/her patient id "A0001". TIS also allows to add other information in order to support the evaluations studies, including a C3-Cloud study identifier, whether patient falls in the layer 3 or layer 4 evaluation group, and whether the patient uses a medical device during the study.

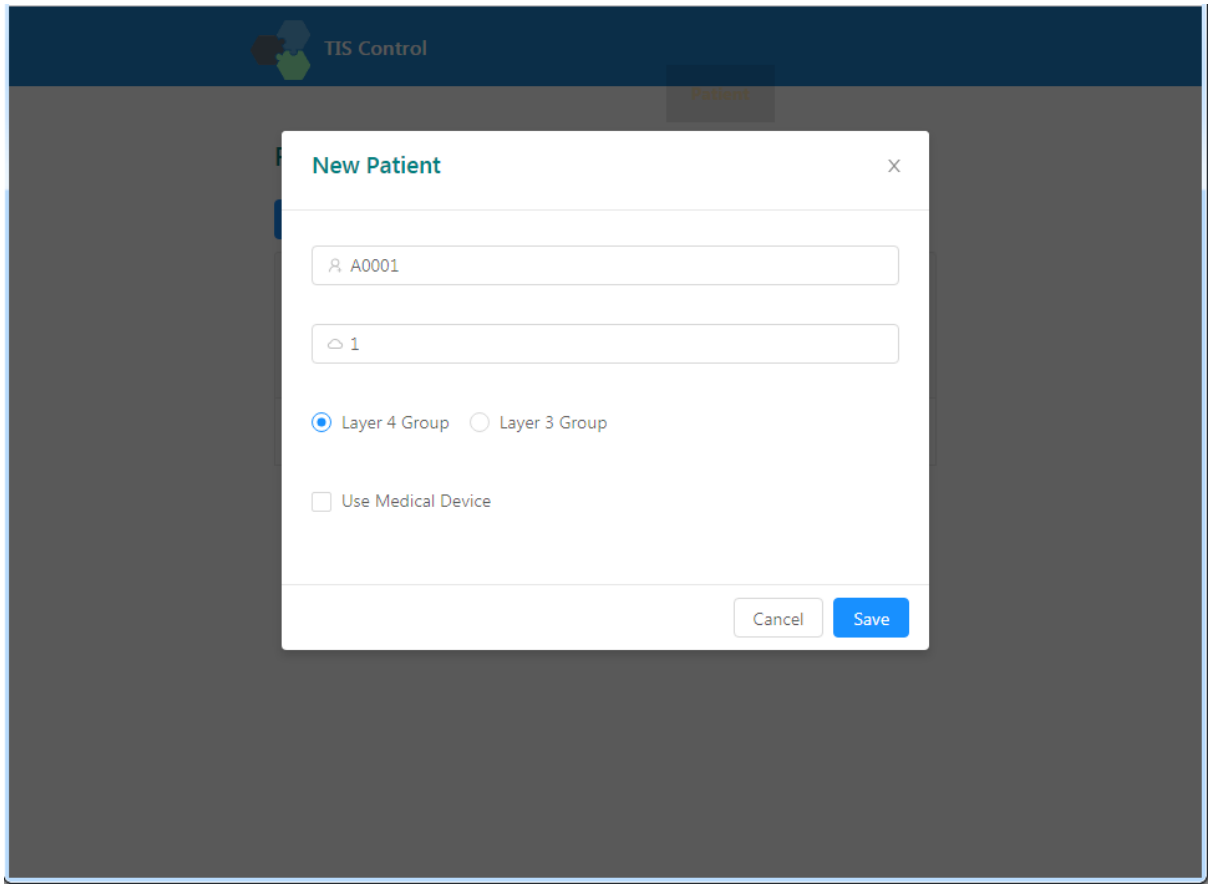

Figure 7 Register a new patient

2. Click the Save button, the patient is added to the list of all registered patients. There is only one patient in the list at the moment as show in Figure 8.

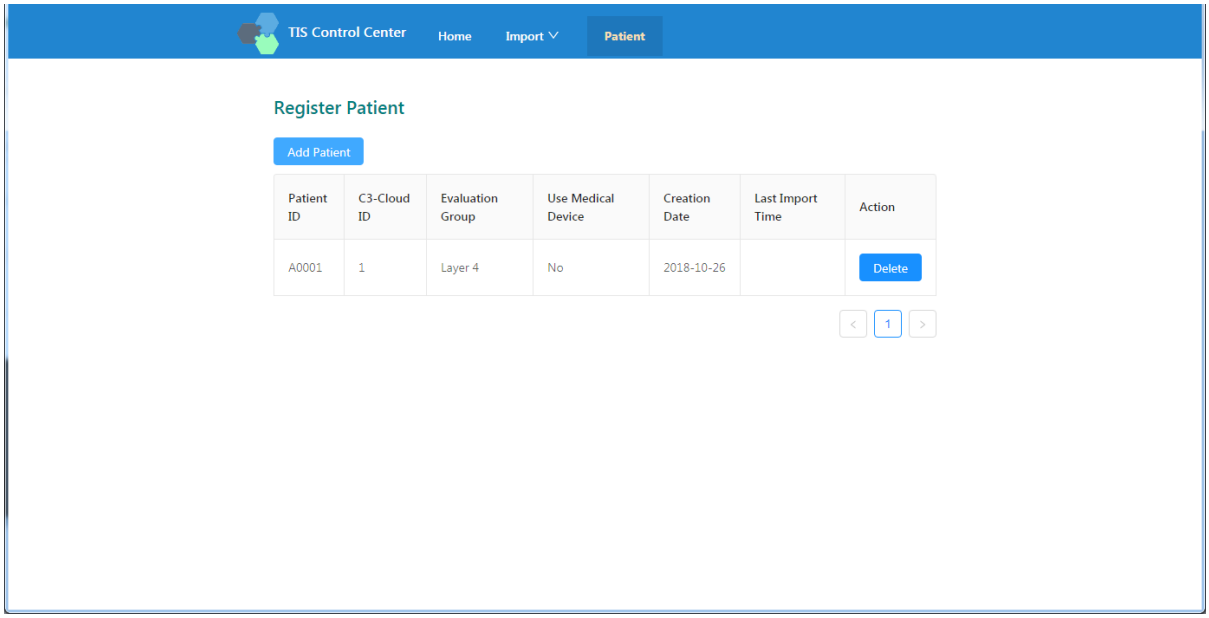

Figure 8 Patient list in the system

3. The next step is to schedule a data synchronization task. First go to Import -> Defined Task. Because we are using SWFT data samples which are provided as a CSV file, two data integration pipelines are available to import the CSV. The "EMIS-CSV-Import-All" imports all patients in the CSV file. The "EMIS-CSV-Import-By-Id" imports only a specific patient who is identified by the id in the CSV file. As show in Figure 9, user can either execute a pipeline right away, or schedule a task. "Execute" will run the task once immediately. "Schedule" allows to run the task in future and periodically.

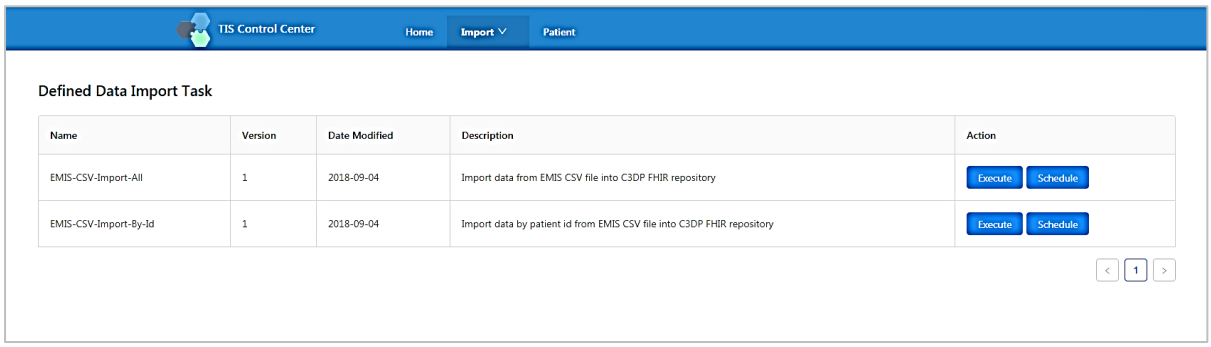

Figure 9 Select a predefined data integration task

4. Figure 10 shows the interface to schedule the "EMIS-CSV-Import-By-Id" task. The "emis_file_uri" points to the location of the CSV file. Patient id needs to match what is registered in step 1. The task can start from a specific time and repeat every hour, day, week or month. In C3-Cloud, the most common routine is to synchronize data every day. The task will run until either manually stopped through the UI or at a specific time.

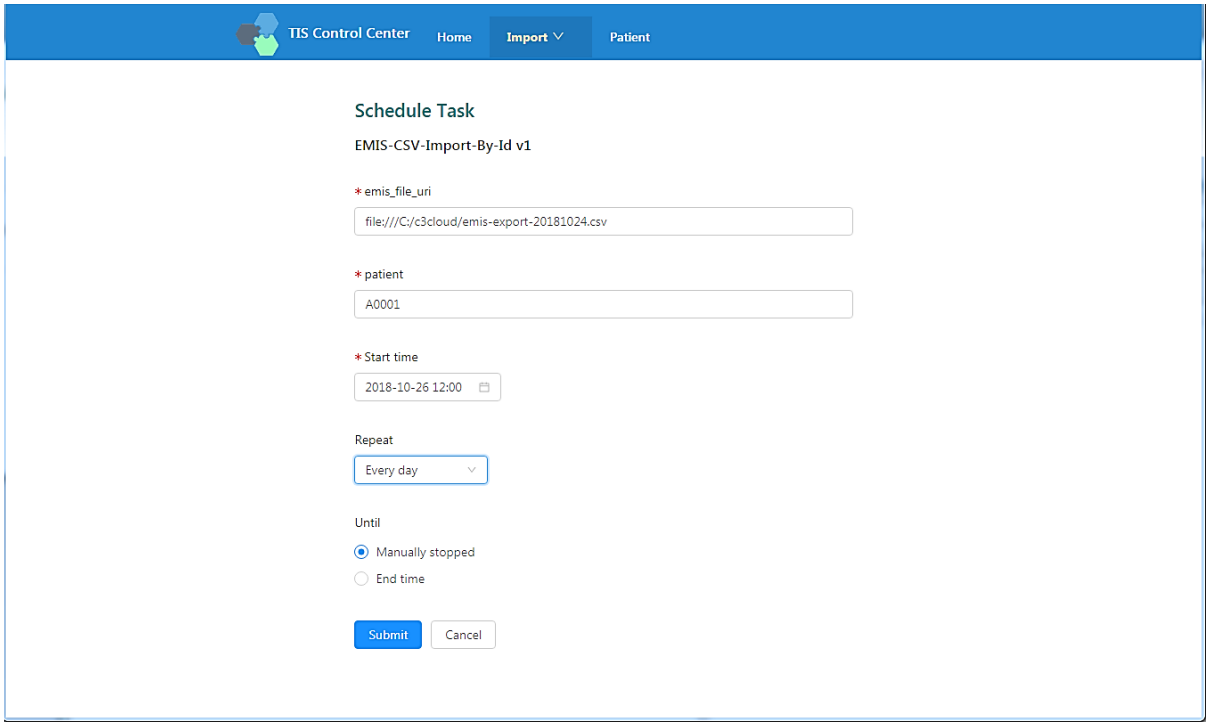

Figure 10 Schedule an import task

5. Click Submit, the scheduled task will show up in the scheduled task list (Import → Scheduled Task). The page shows total number of executions and the most recent execution time.

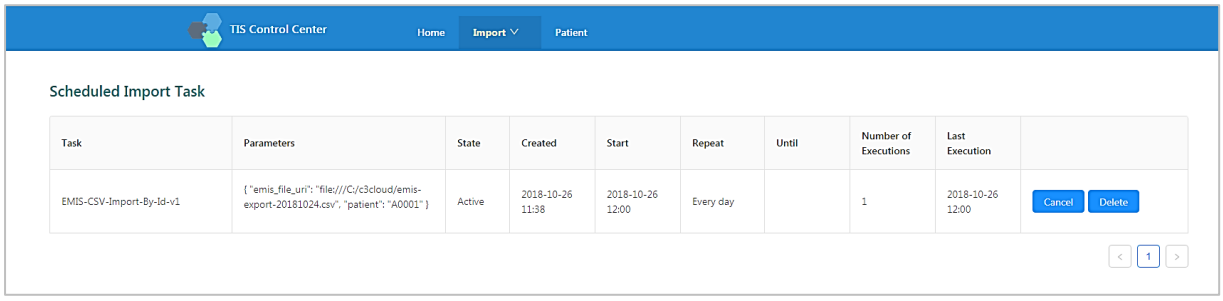

Figure 11 Task schedule list

6. The status details of individual executions can be checked at the Task Execution Log page (Import → Execution Log), which will help diagnose if error occurs.

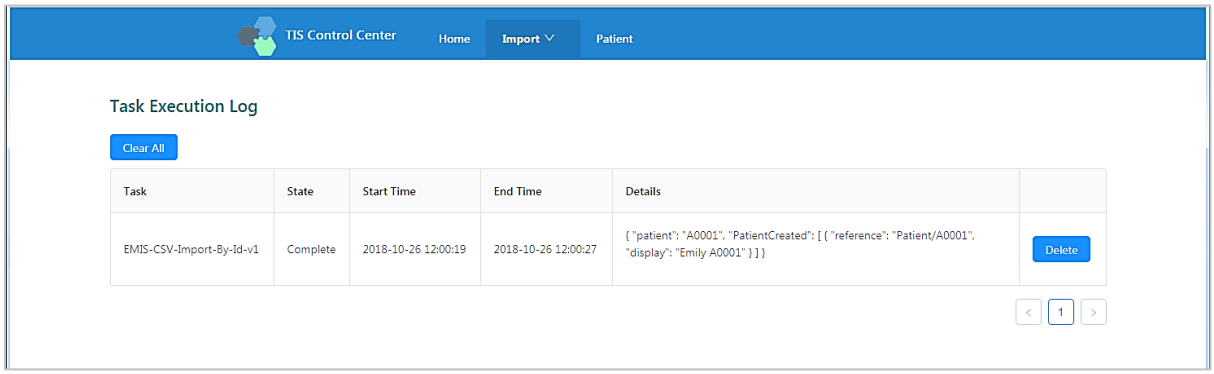

Figure 12 Execution log

Behind the scene, SIS Structure Mapping service is invoked by TIS to transform the CSV data into FHIR resources. The service is a RESTful API. Figure 13 and Figure 14 show the screenshots of using Postman to invoke the service by hand.

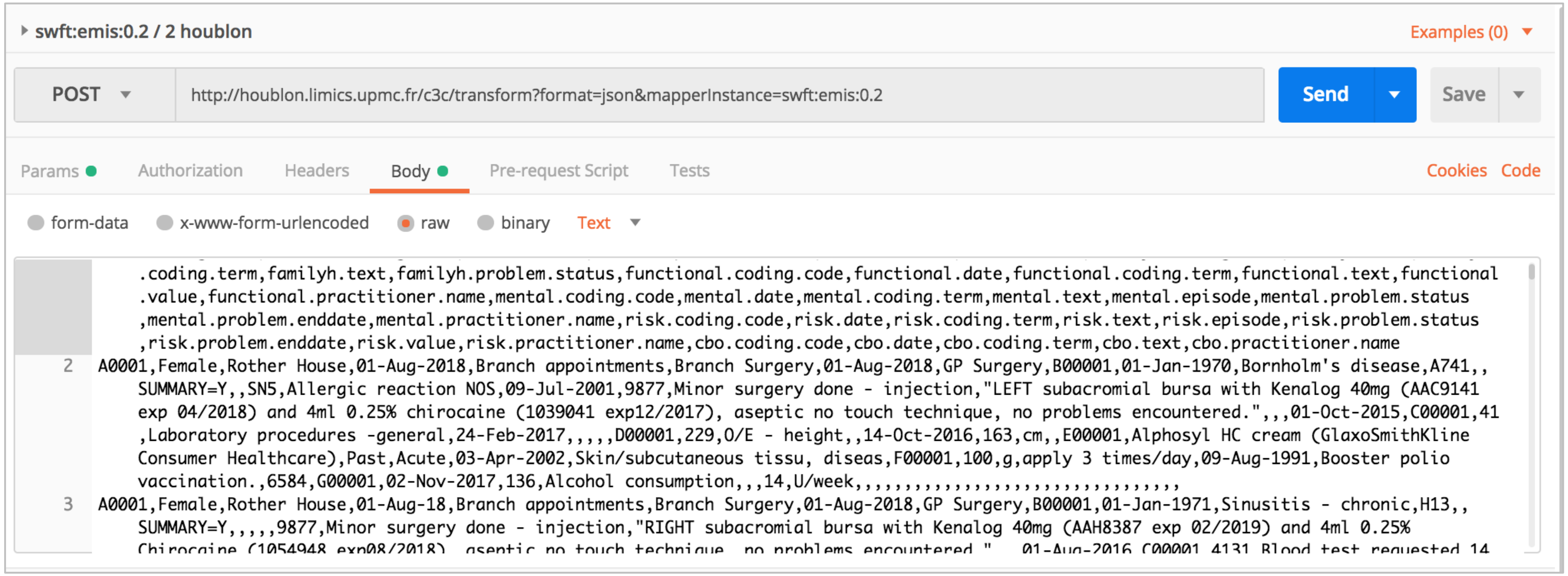

Figure 13 Structure mapping service request

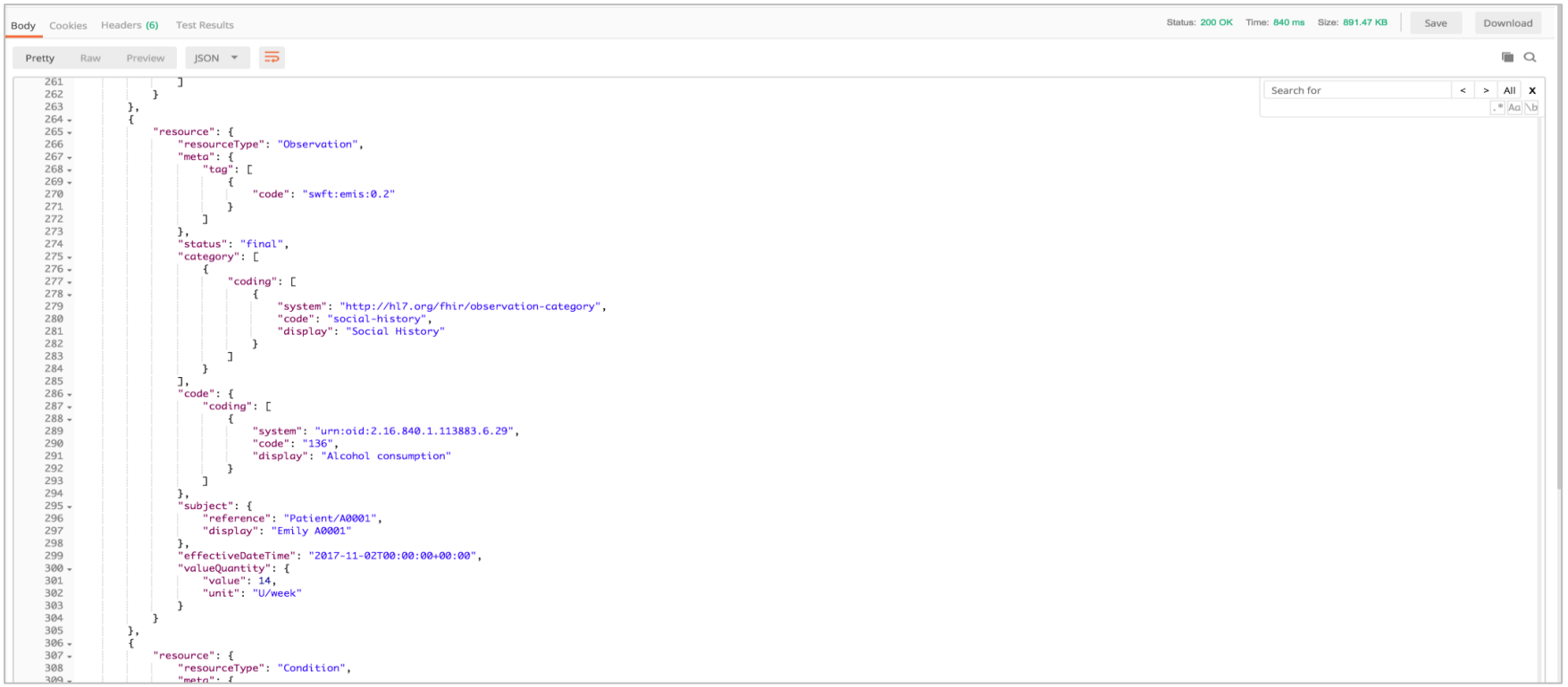

Figure 14 Structure mapping service response

6.2 C3DP Care Plan Management

A short demonstration of main care plan management functionalities of C3DP are presented in this section. It should be noted that this demonstration does not cover all details of C3DP usage. Detailed step-by-step usage instructions have been provided as a user manual within the scope of Task 9.4 - Exploratory Trial Preparation - User Training Workshops.

The first step is logging in to the C3DP system. When the user opens the C3DP web application, a welcome screen will appear (Figure 15), and users can navigate to the C3-Cloud authentication provider (Figure 16) by clicking the sign in button. The user can use either the local IdP of the pilot site or the local authentication provider (Figure 17) of the C3-Cloud for logging in to the system.

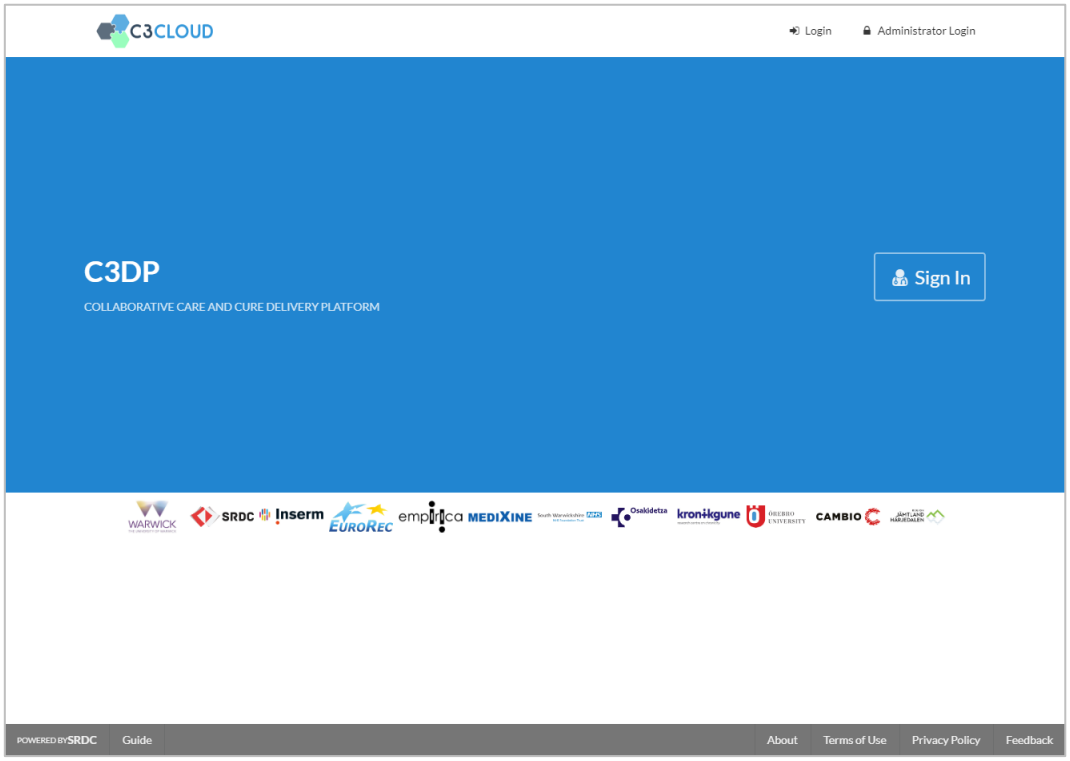

Figure 15 – C3DP Login Page

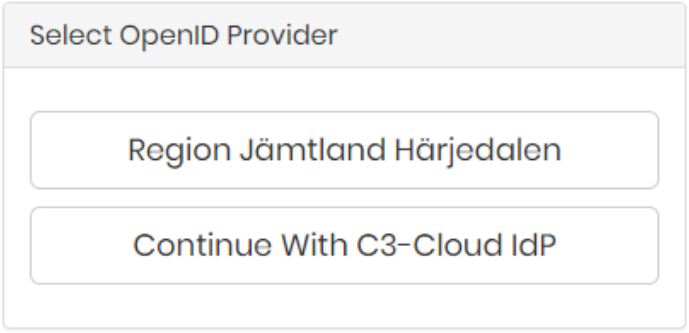

Figure 16 – C3-Cloud authentication provider

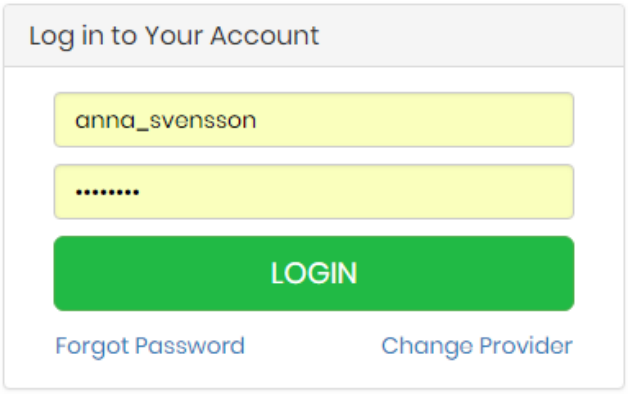

Figure 17 – C3-Cloud local authentication provider

Authenticated users will proceed to the home screen which shows the recent patients, messages, activities and notifications of the user (Figure 18).

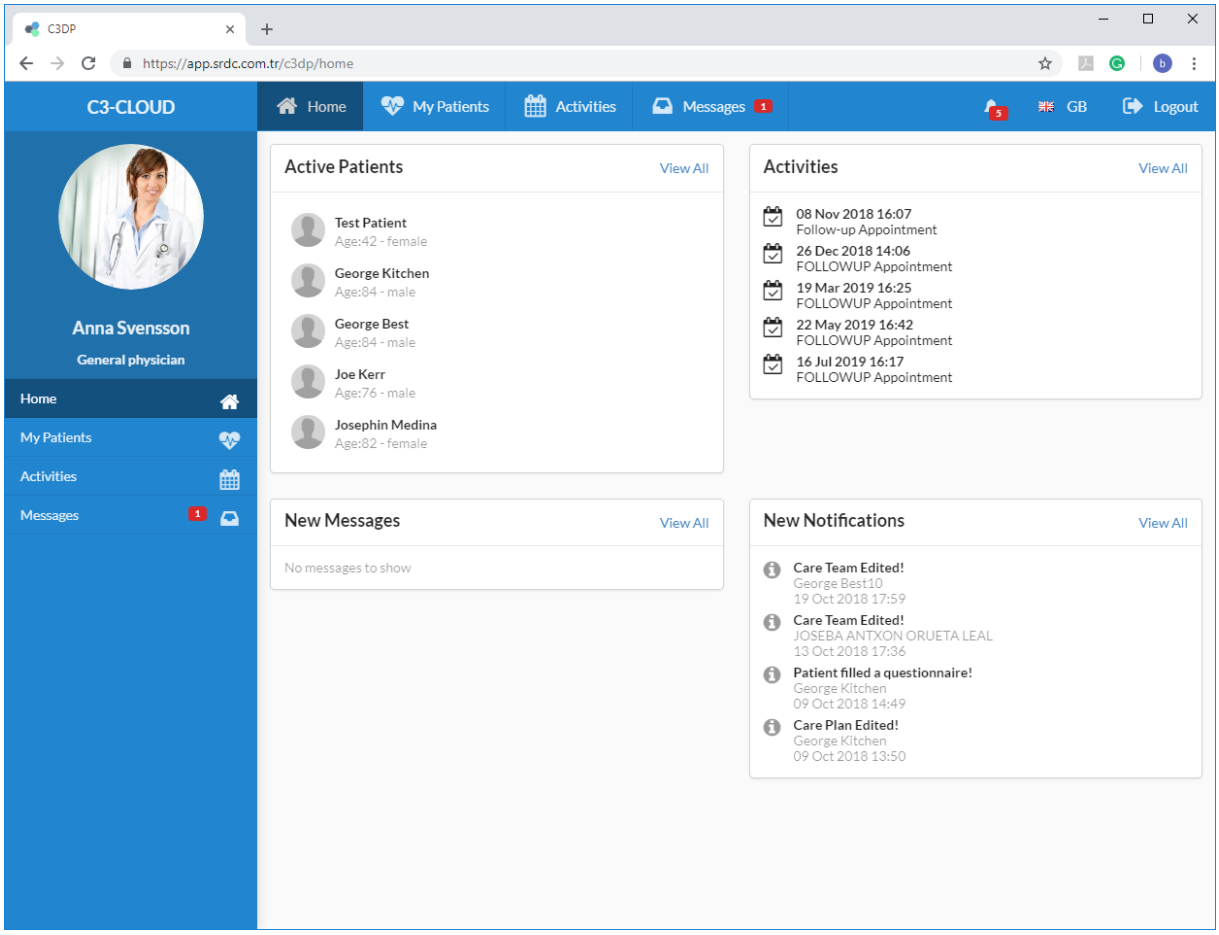

Figure 18 - Home Screen of C3-Cloud System

Users can see the list of their patients in “My Patients” screen (Figure 19). Using the “Add Patient” button, they can also search for other patients and create a new care plan for the patient or join the care team of this patient (Figure 20).

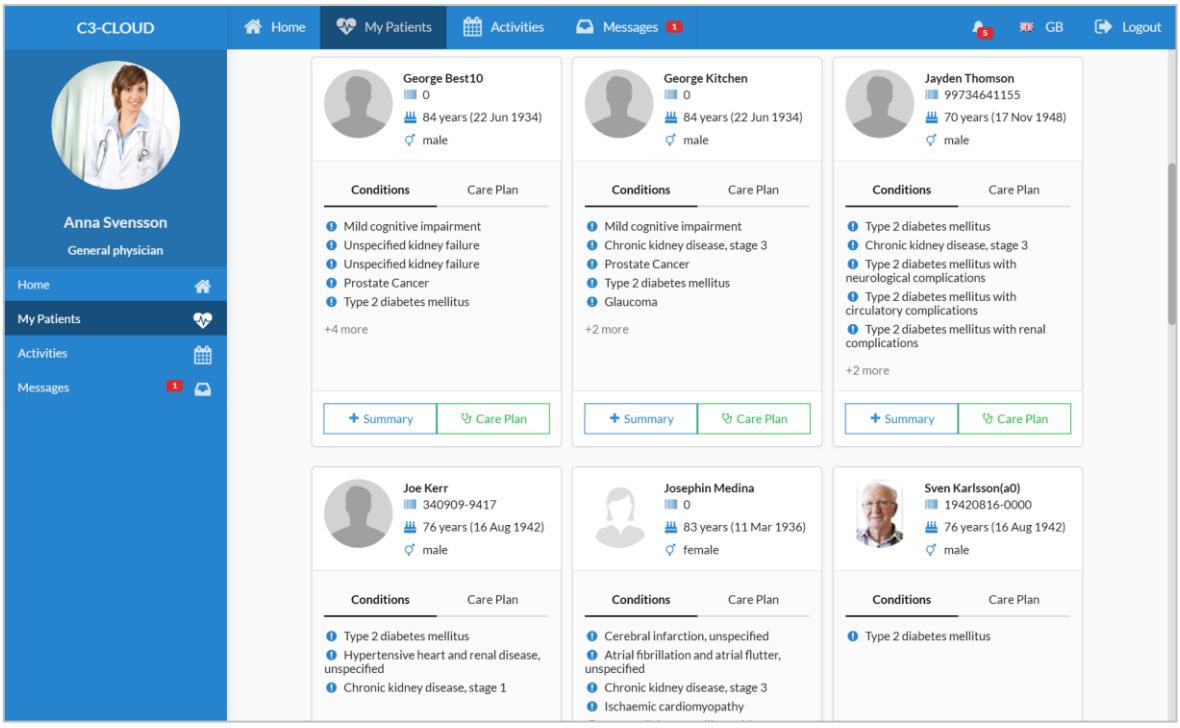

Figure 19 - All your patients with a care plan

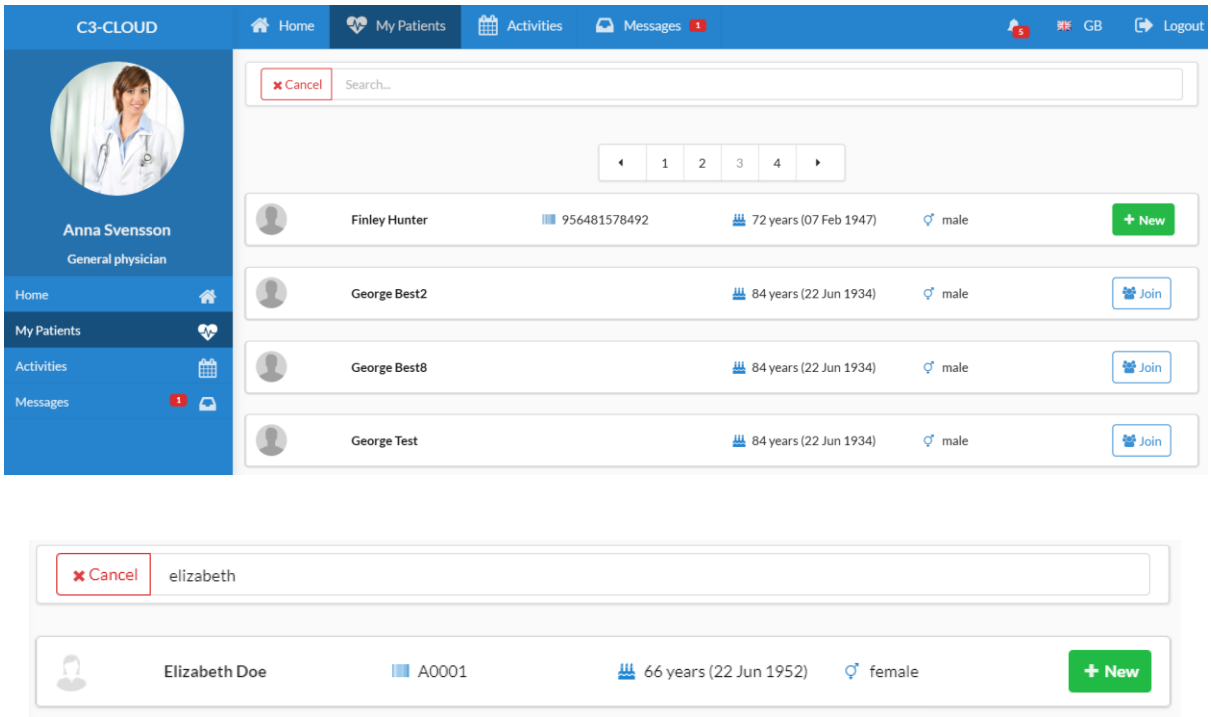

Figure 20 - Searching among all patients in the C3-Cloud system

The user is navigated to the “Medical Summary” page before creating a new care plan (Figure 21). Patient’s conditions, medications, observations, etc. are shown in this page.

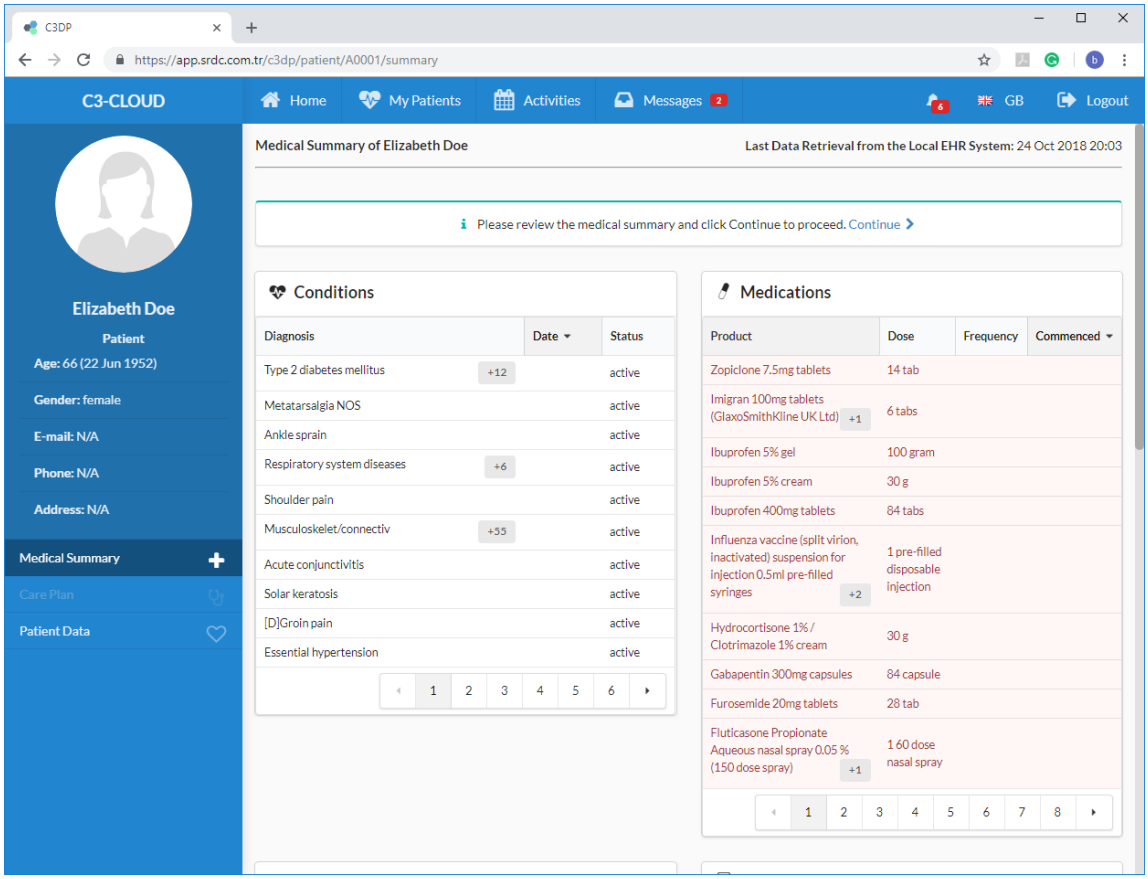

Figure 21 - Medical Summary

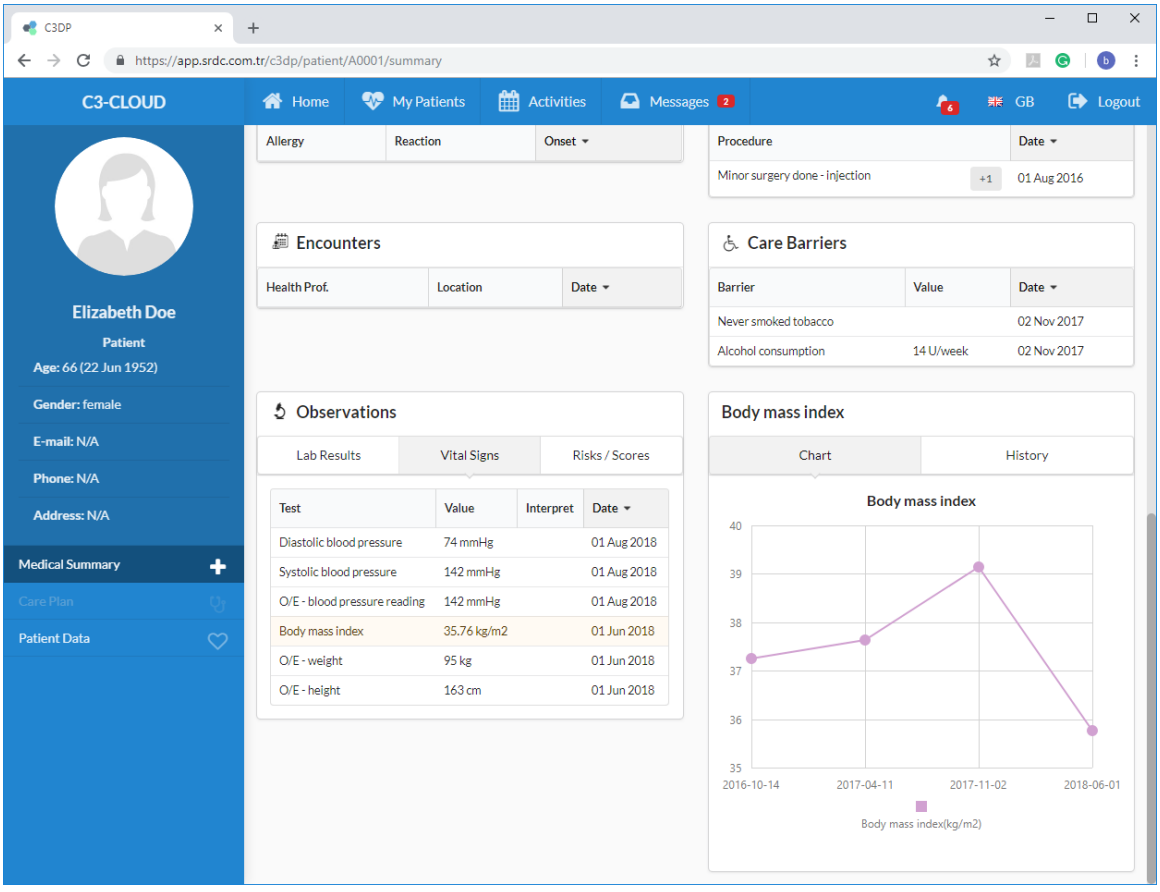

Figure 22 - View Observation as Chart

Then, the user proceeds to the care plan initialization page. The title of the care plan, the main diseases that the care plan is based on, the medication that are wanted to be added to the care plan and the care team members are set in this page (Figure 23, Figure 24).

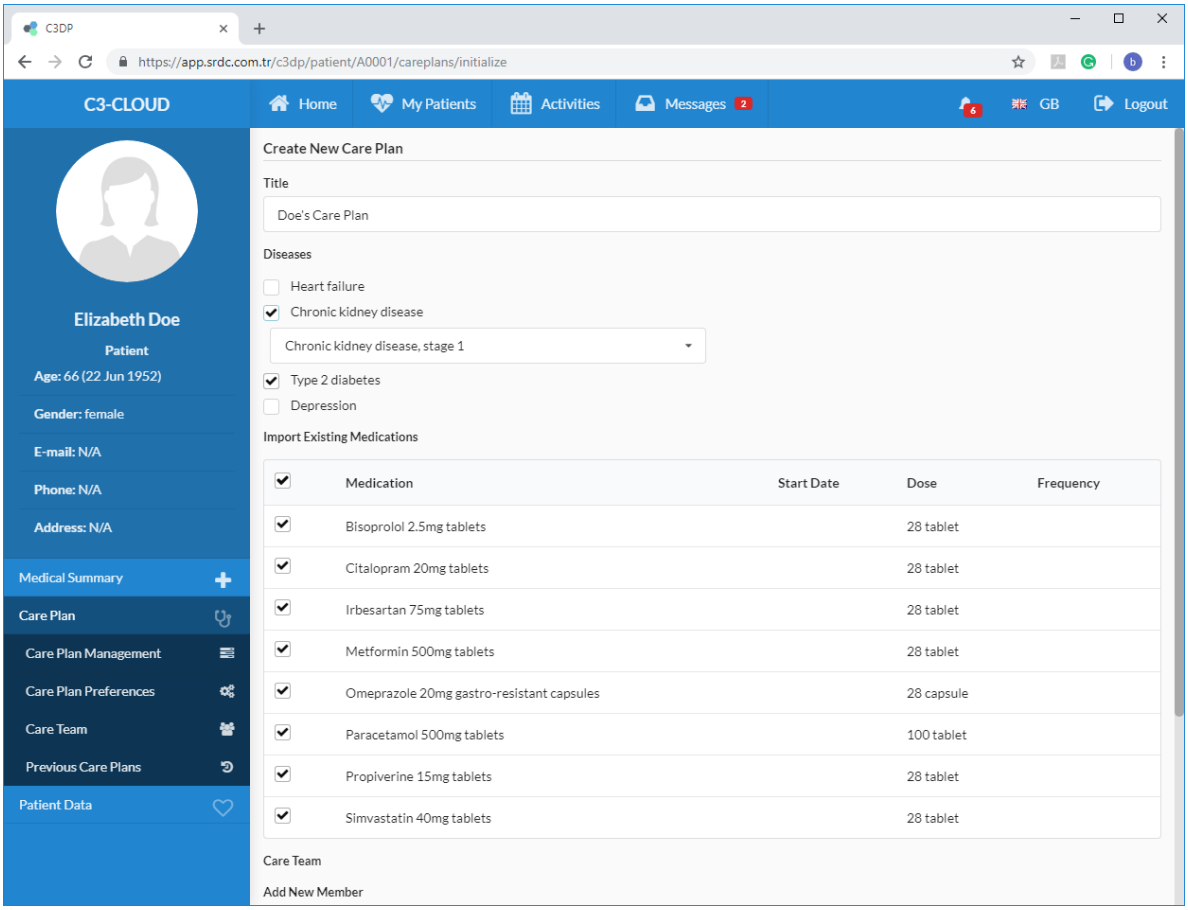

Figure 23 - Care Plan initialization form

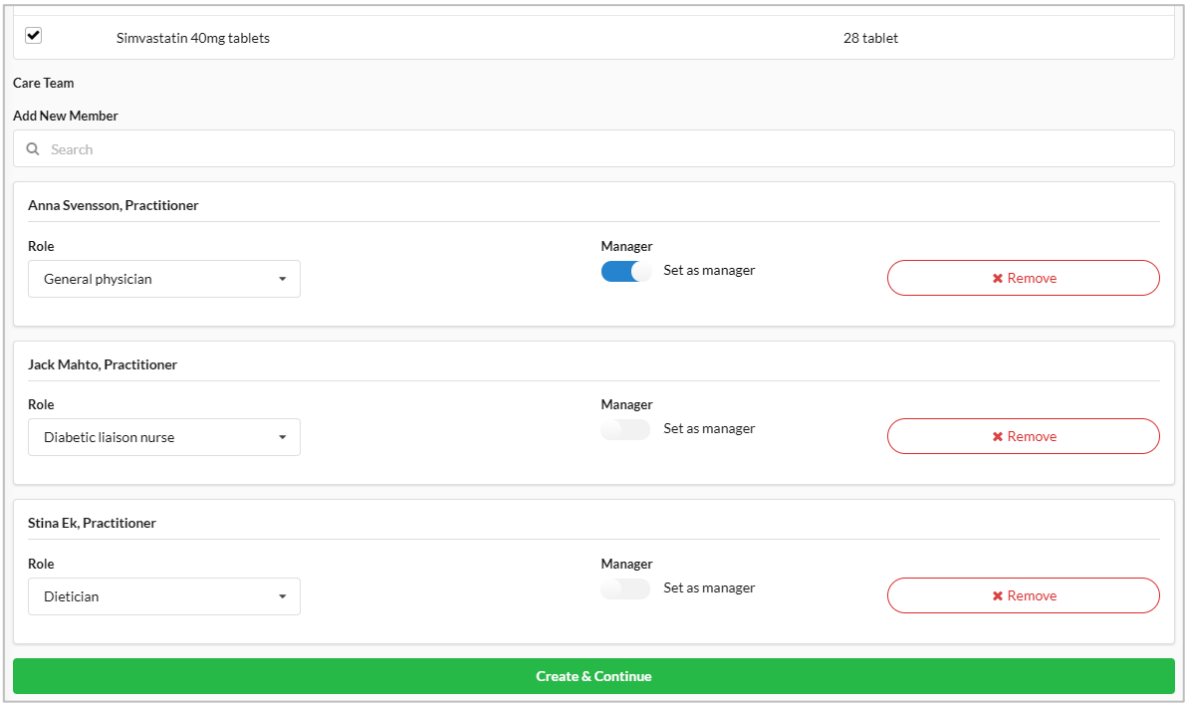

Figure 24 - Care Team creation within the Care Plan initialization form

After the initialization, the user can manage the care plan using the “Care Plan Management” screen (Figure 25).

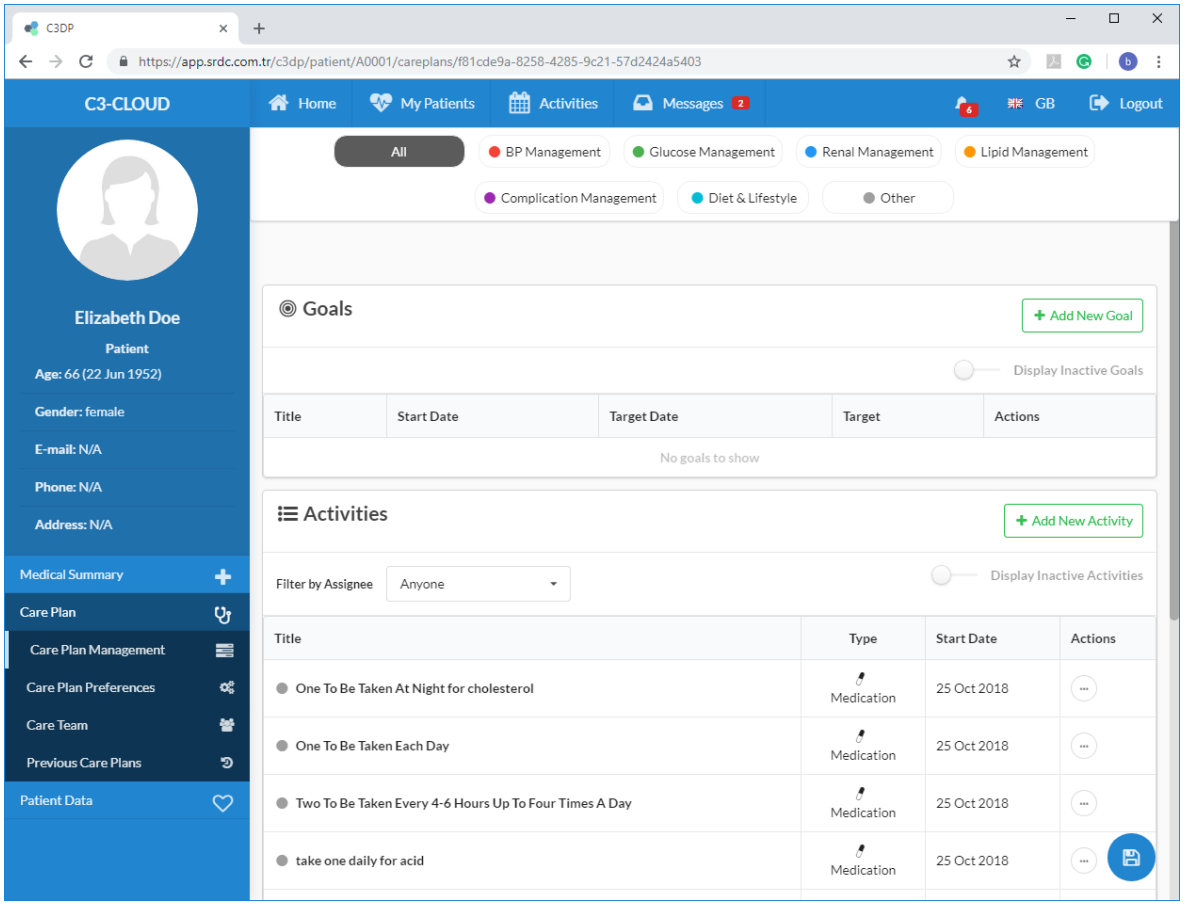

Figure 25 - Care Plan View

The care plan includes several high-level goals according to selected main diseases. Under each high-level goal, there is an editable “Patient Data” section which includes the patient data that are needed by the CDS services as input (Figure 26).

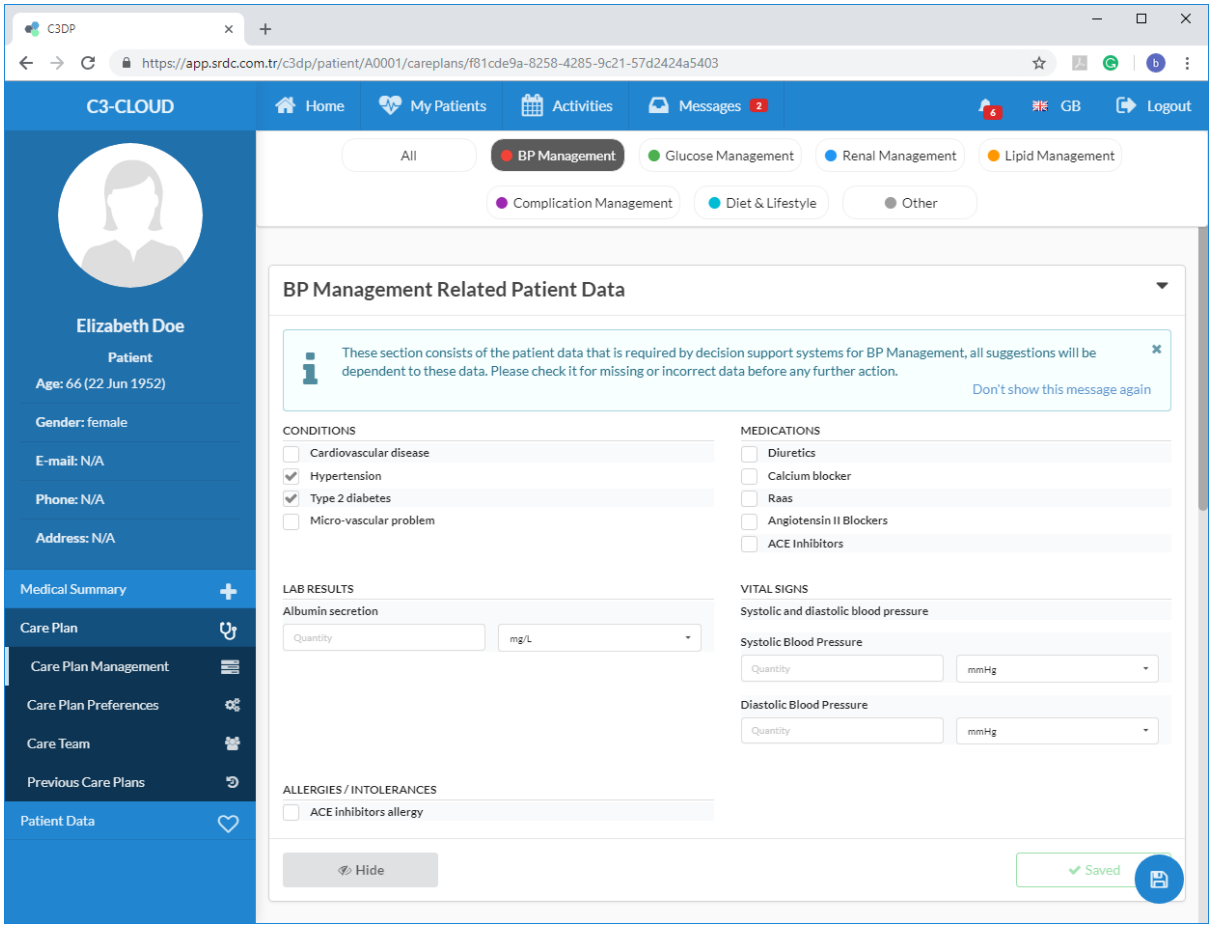

Figure 26 - BP Management-Patient Data

CDS services generate suggestions based on the patient data and they are shown when the user is adding a new goal or activity. For example, a personalized HbA1c goal is suggested by the HbA1c Target CDS service in Figure 27.

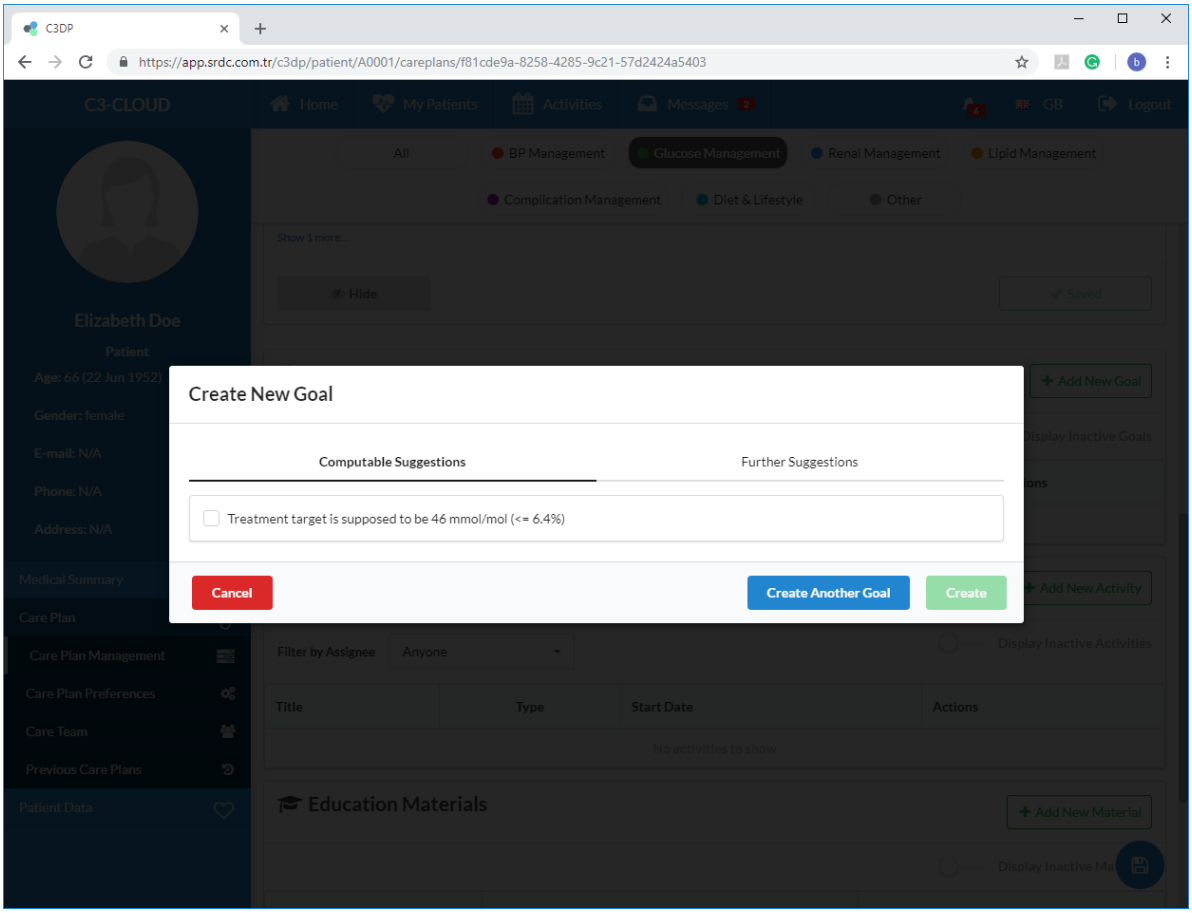

Figure 27 - CDS Suggestions for Goals

When creating a goal from CDS suggestions or manually, the user will see the goal form below (Figure 28).

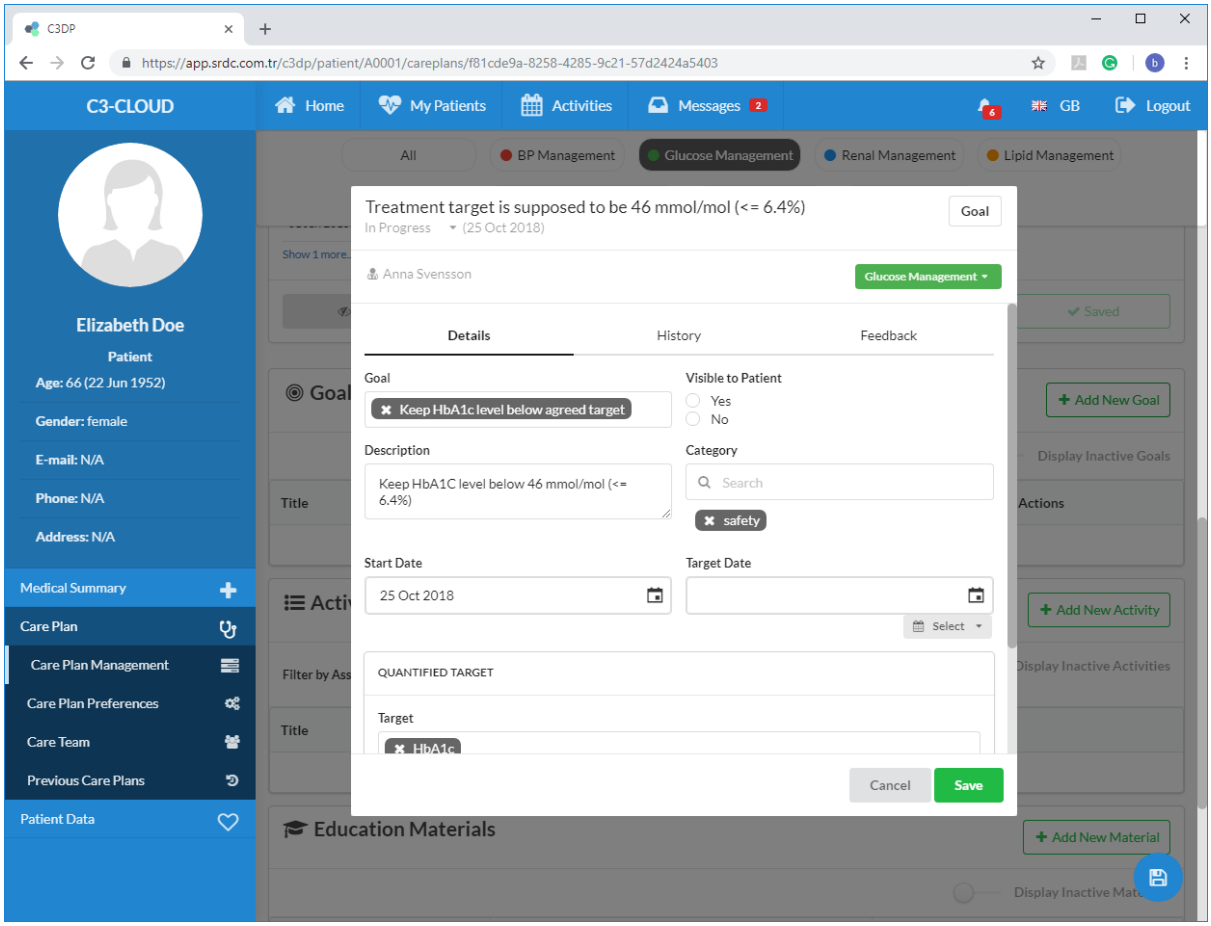

Figure 28 - Create Goal Suggested by CDS

The CDS services also suggest activities like medications, diets, laboratory tests, referrals or follow-up appointments. For example, “ACE Inhibitor Prescription” is suggested by the Blood Glucose Management CDS service in Figure 29.

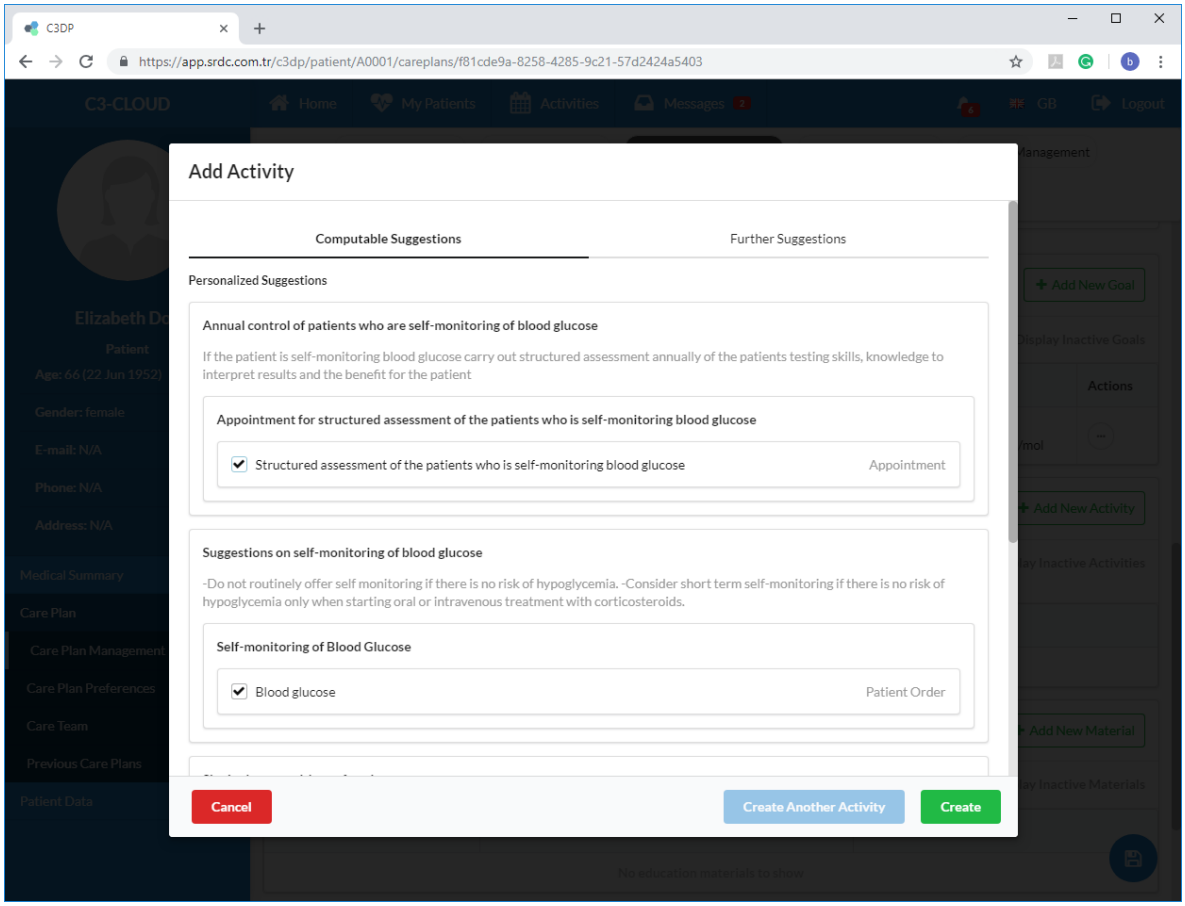

Figure 29 - Adding a new Activity: suggestions by CDS services

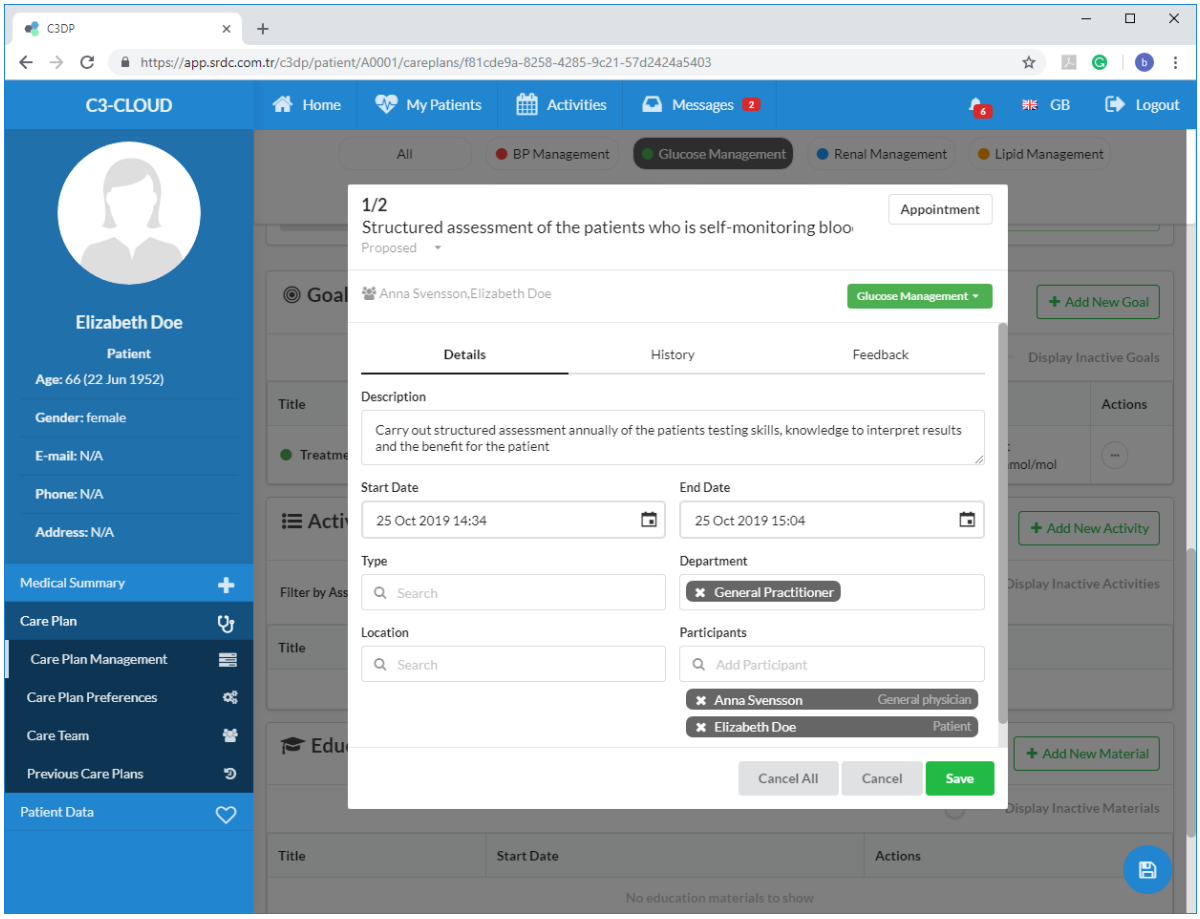

Figure 30 – Adding ACE Inhibitor Prescription to the Care Plan

The user can also add several types of activities manually. As an example, a patient questionnaire is added to the care plan by searching among the existing questionnaires in the system in Figure 31.

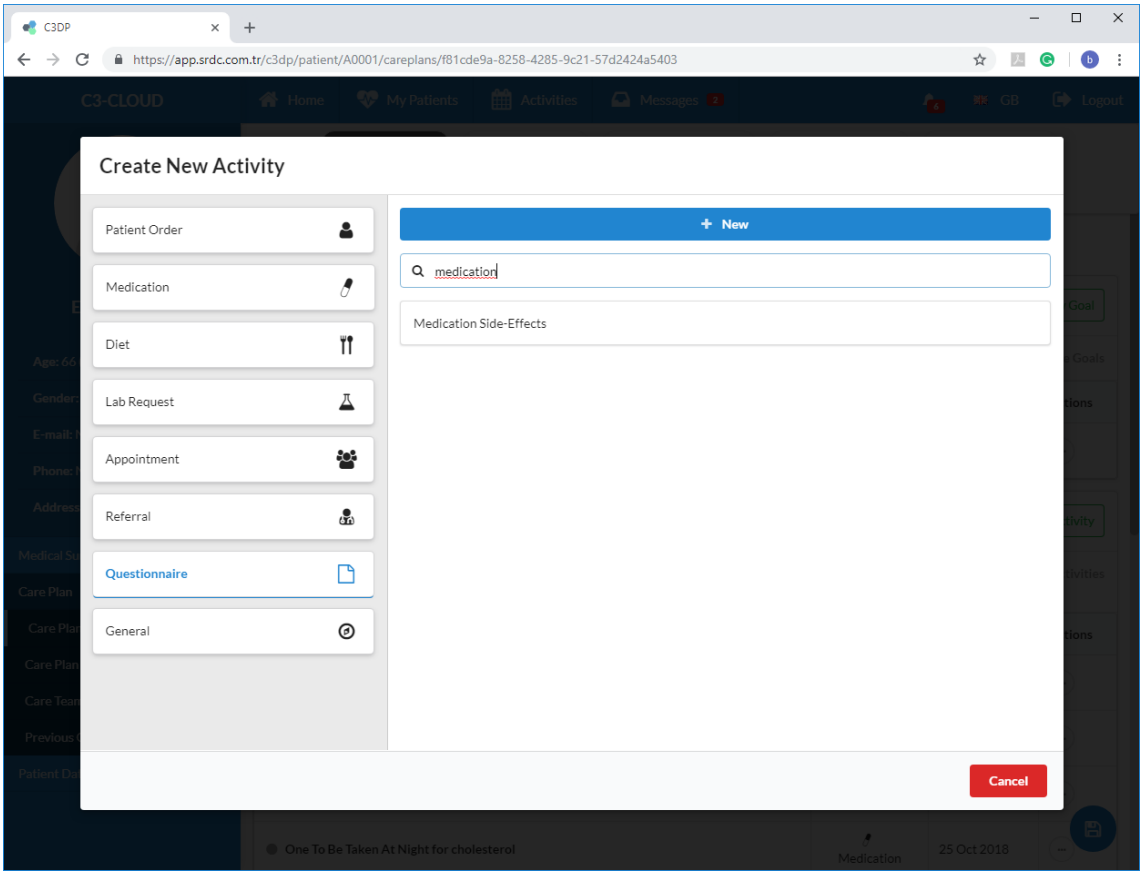

Figure 31 – Searching among the Existing Questionnaires

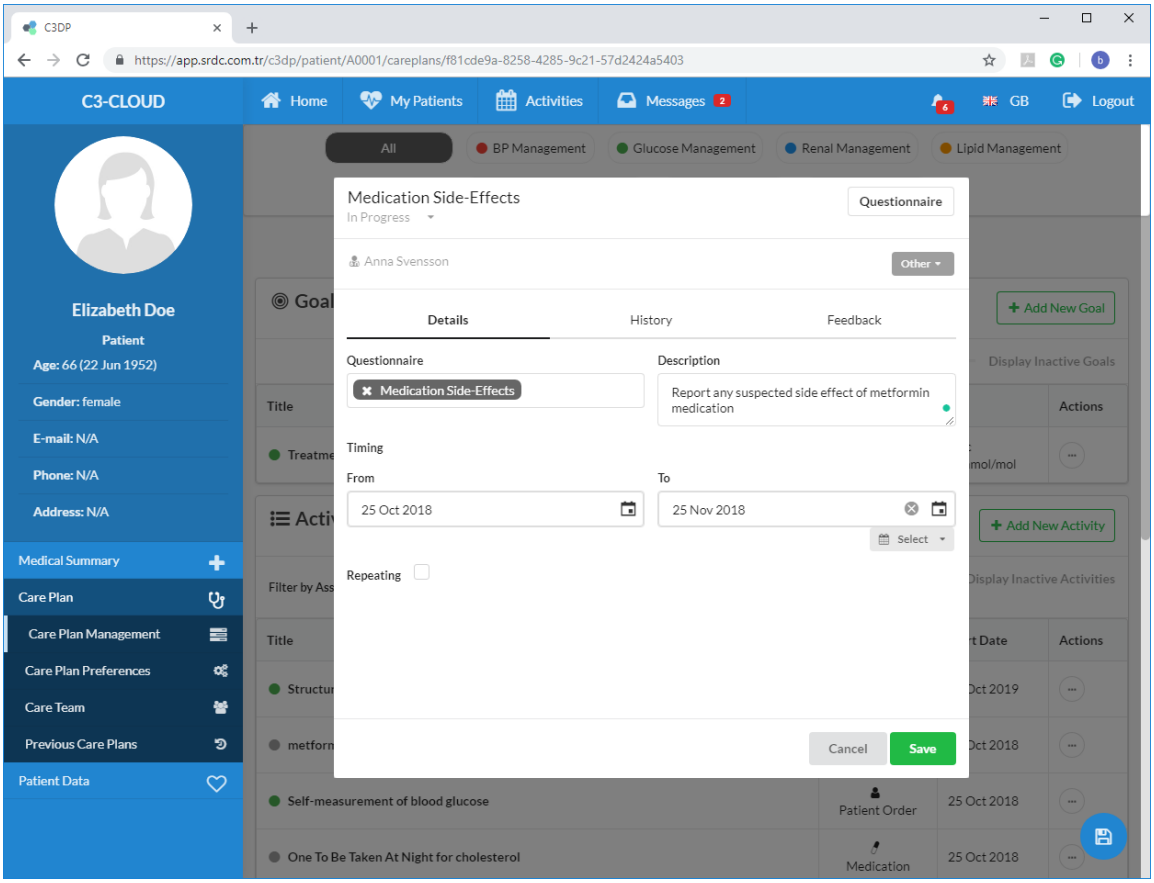

Figure 32 - Adding a Questionnaire to the Care Plan

Another care plan element is the “Education Materials”. The user can search the predefined materials, upload a new material or reference to a material via URL and then add it to the care plan (Figure 33).

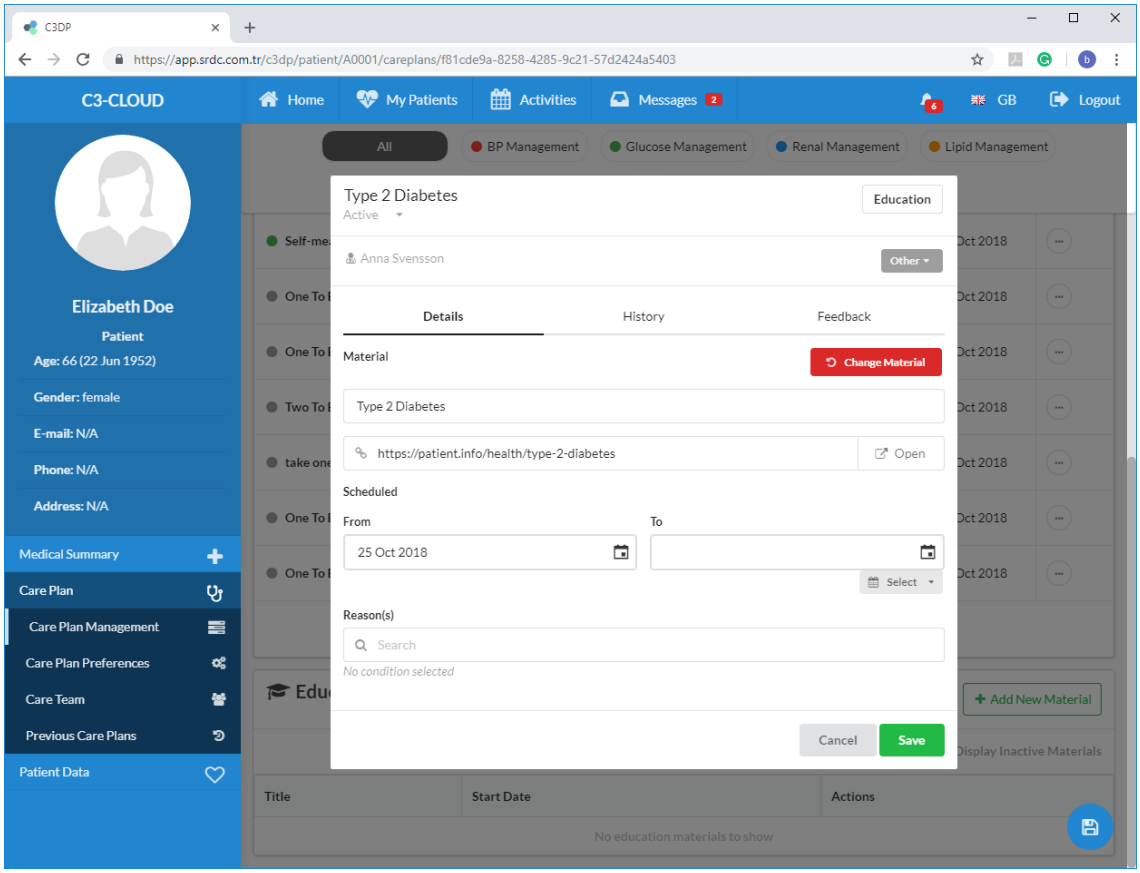

Figure 33 – Adding an Education Material to the Care Plan

When the initialization of the care plan is completed, the user informs the other members of the care team and also the patient and their informal care givers about this new care plan by pressing the ‘Active & Publish’ button at the bottom right (Figure 34).

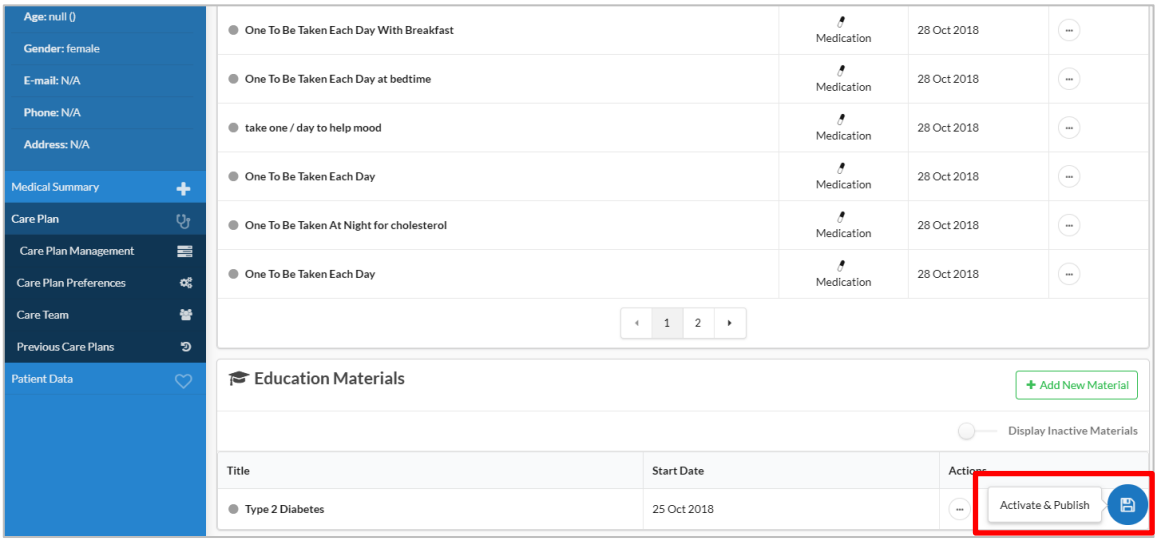

Figure 34 - Publishing the Care Plan to inform the Care Team and the Patient / Informal Care Giver

Users can also follow their incoming activities and appointments from the calendar on the “Activities” screen (Figure 35).

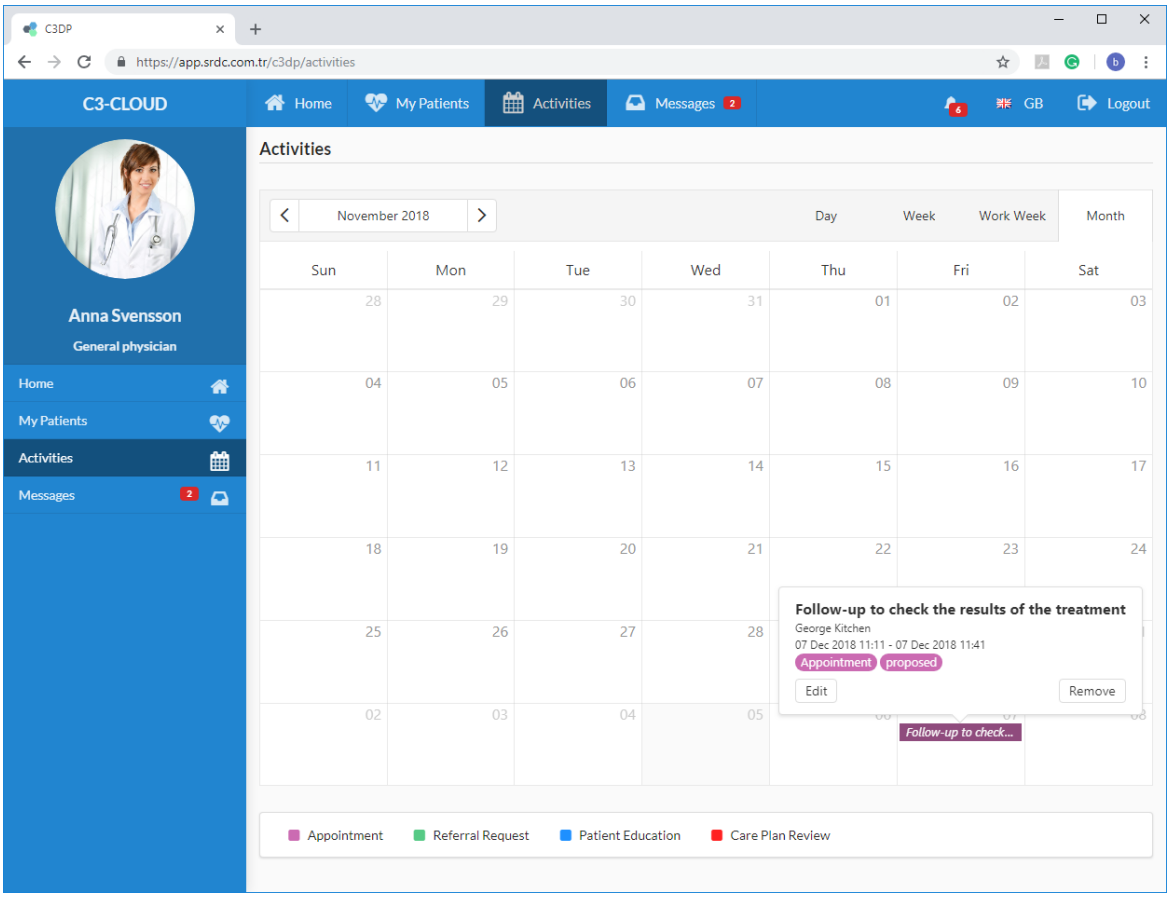

Figure 35 - Scheduled Activities

Users can communicate with other practitioners or with the patients via C3DP messaging interface. They can also see their notifications and invitations (e.g. care team participation invitation) from this interface (Figure 36).

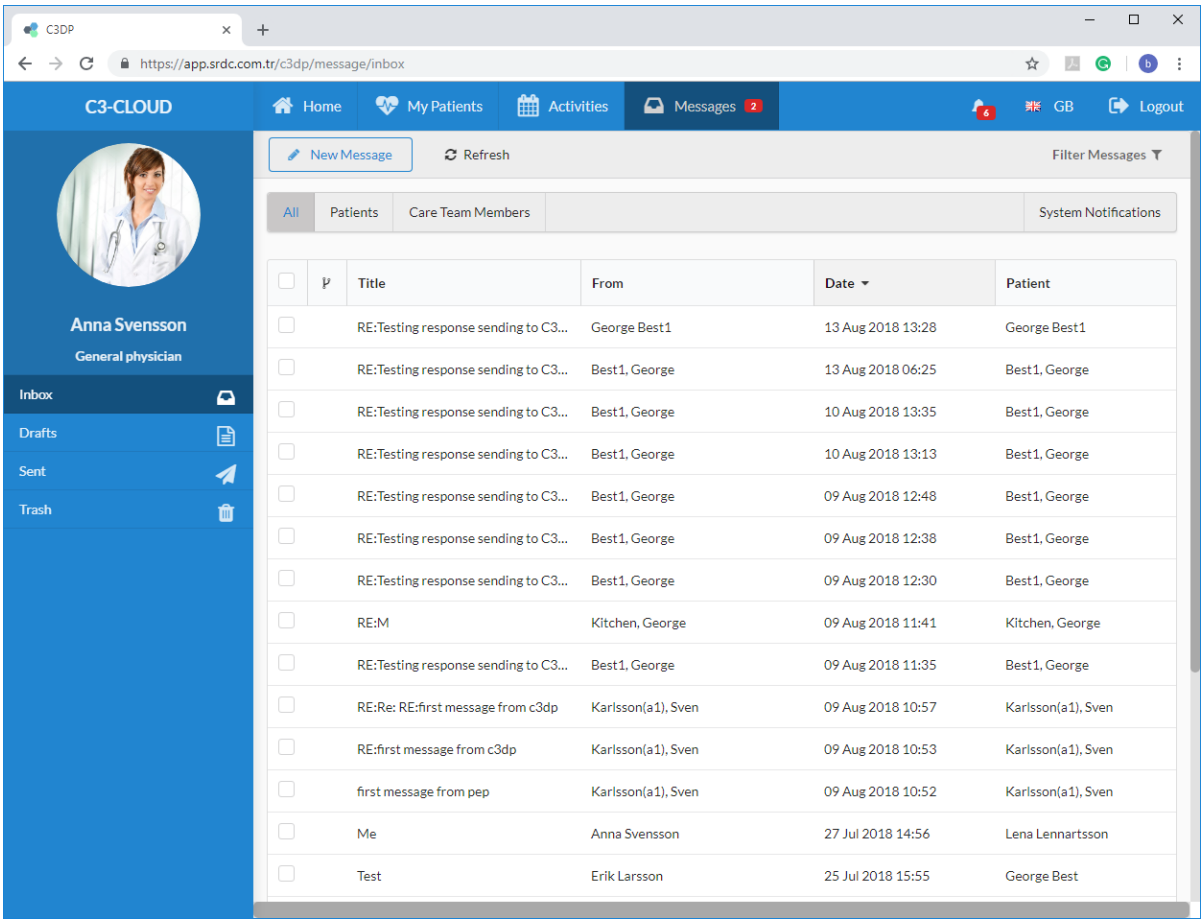

Figure 36 - Messages

6.3 PEP Patient Engagement

The main functionalities of PEP include

- Make the care plans created by the MDT available to the patient
- Provide patients with access to relevant self-management material
- Allow health professionals and the patient to communicate with each other using secure messaging
- Allow the patient to actively collect data related to the care plan activities
- Provide all PEP users with secure access to information and functionality

The patient has received an email notification that the C3-Cloud care plan has been updated and has logged in to the C3-Cloud system to view it (Figure 37).

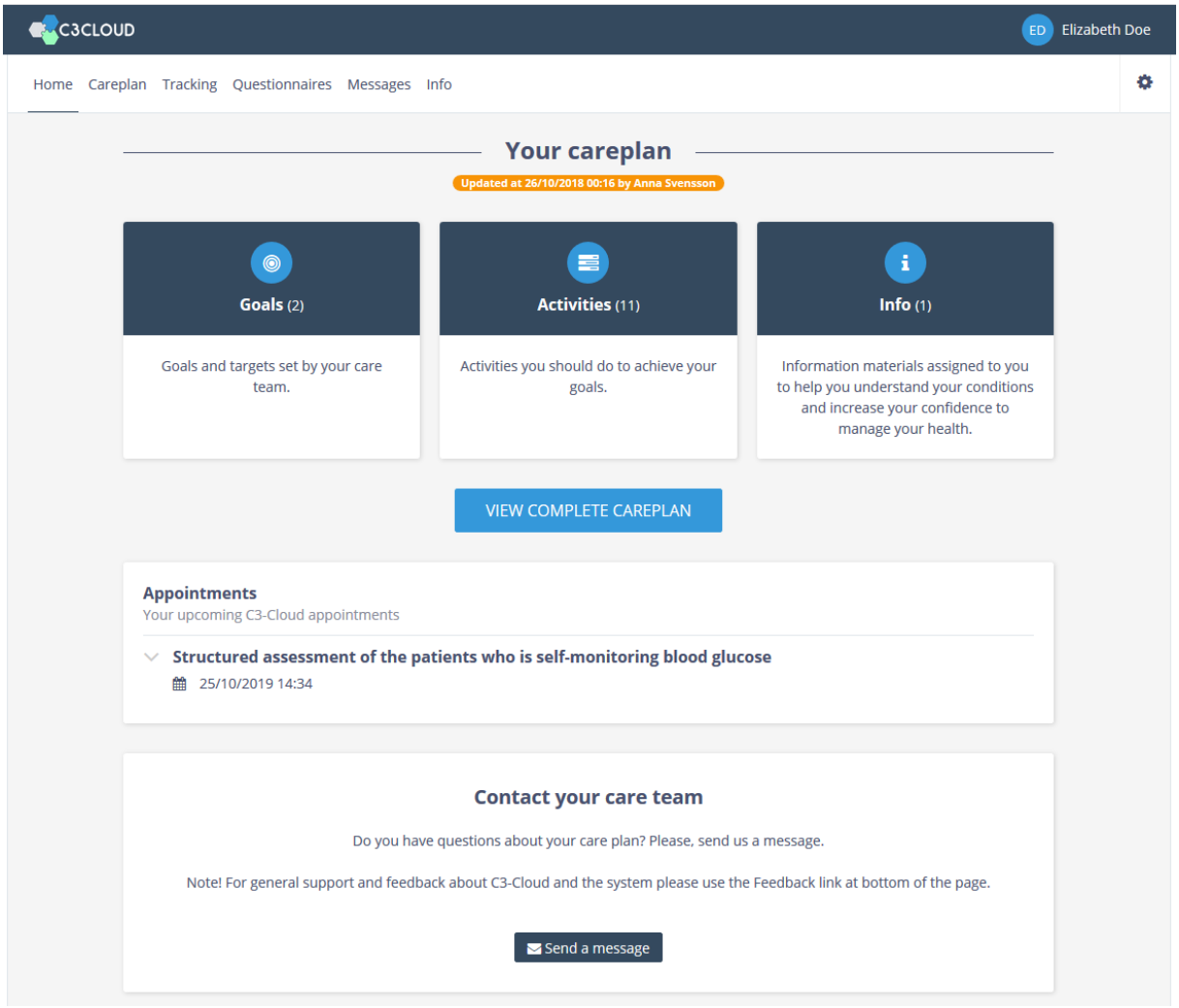

Figure 37 Home screen of PEP

The patient opens the full care plan to view all the goals, activities and info materials the MDT professional have added to the care plan in C3DP (Figure 38).

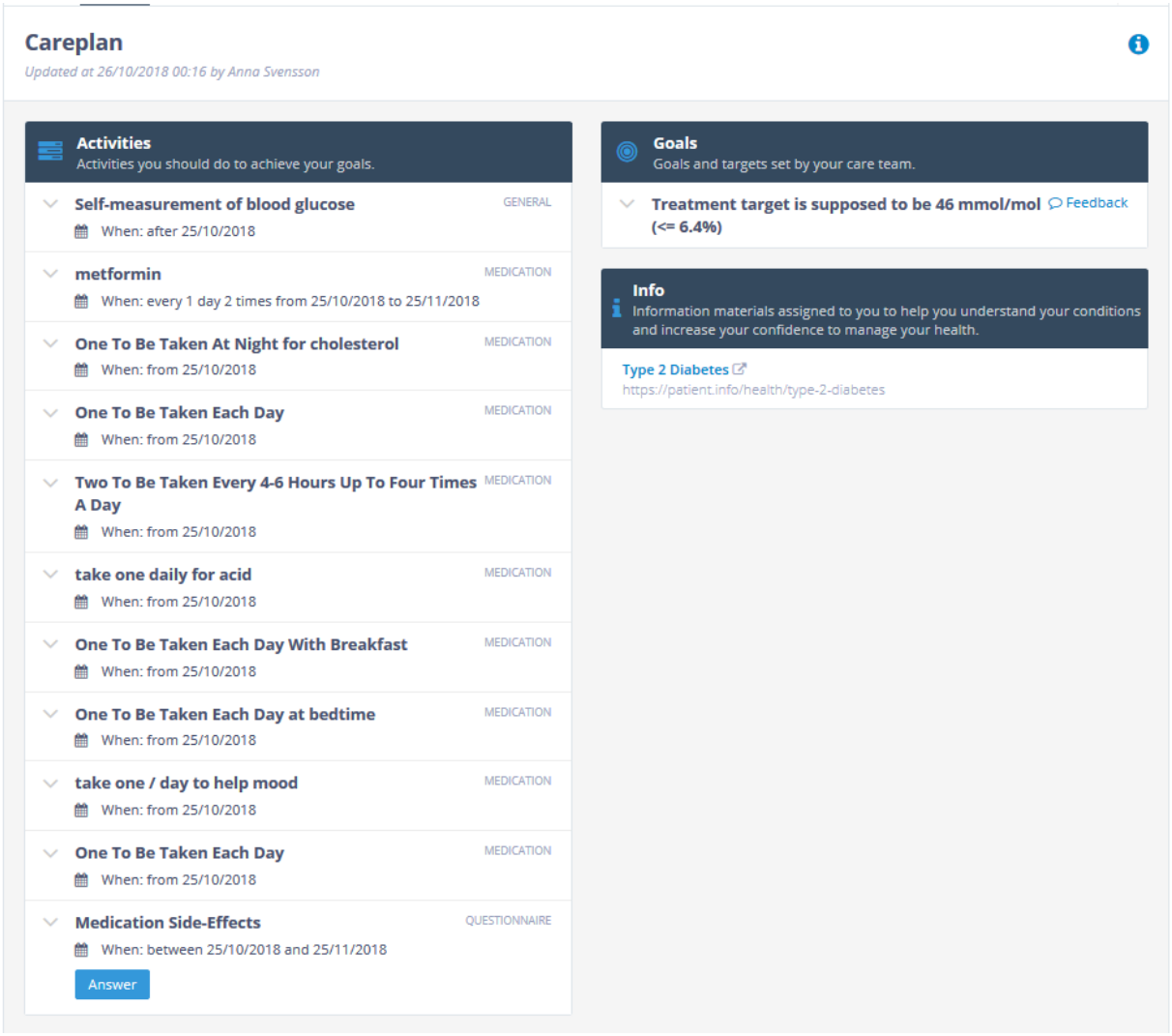

Figure 38 Care plan details

The patient opens the info materials the MDT has assigned to the care plan in C3DP (Figure 39).

Figure 39 Information materials

The patient can give structured feedback on any of the care plan goals (Figure 40).

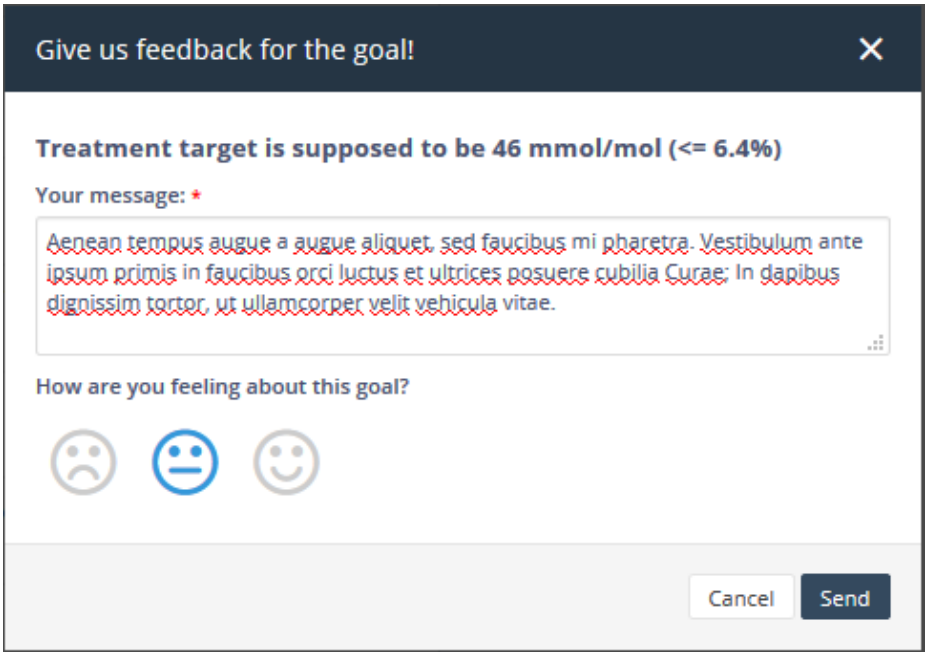

Figure 40 Patient feedback

The patient contacts the care team using the messaging functionality (Figure 41).

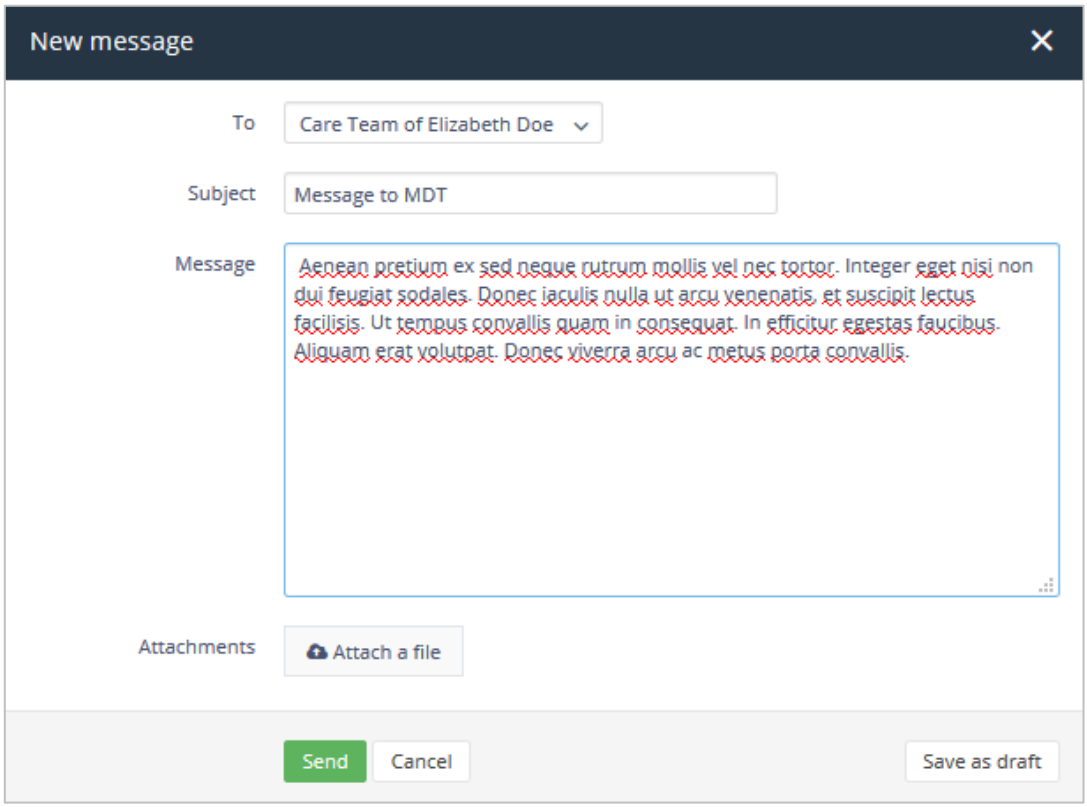

Figure 41 Message to MDT

The MDT has requested the patient to complete a questionnaire (Figure 42). The patient fills in the questionnaire (Figure 43 - Figure 44).

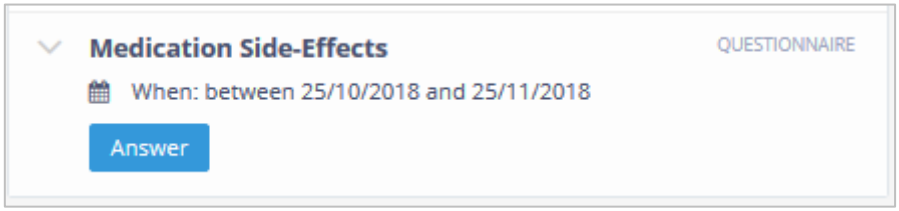

Figure 42 Questionnaire reminder

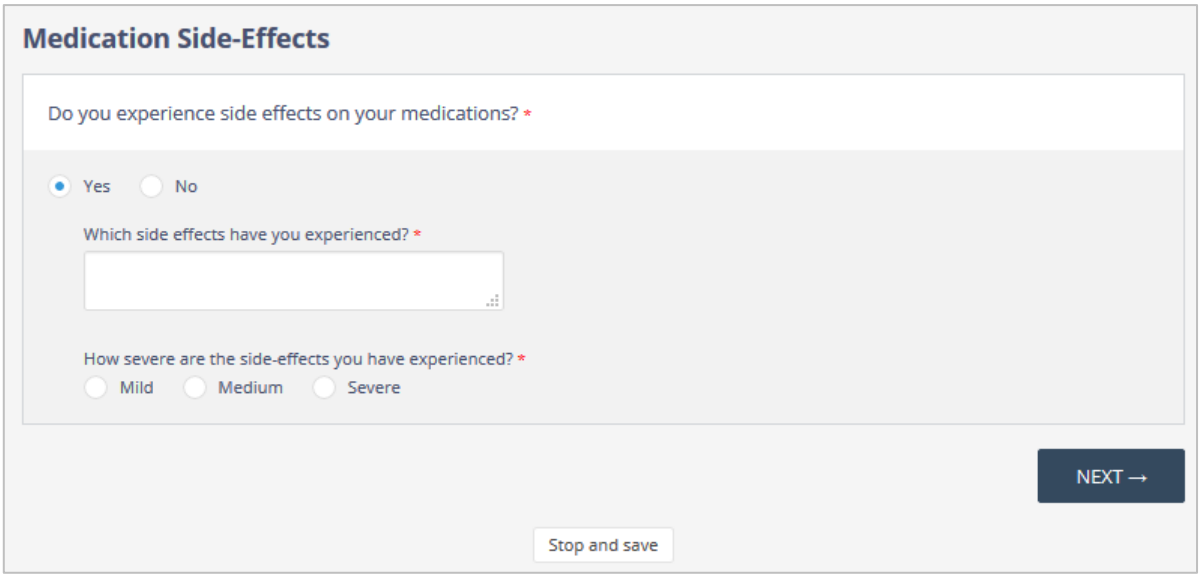

Figure 43 Fill in a questionnaire

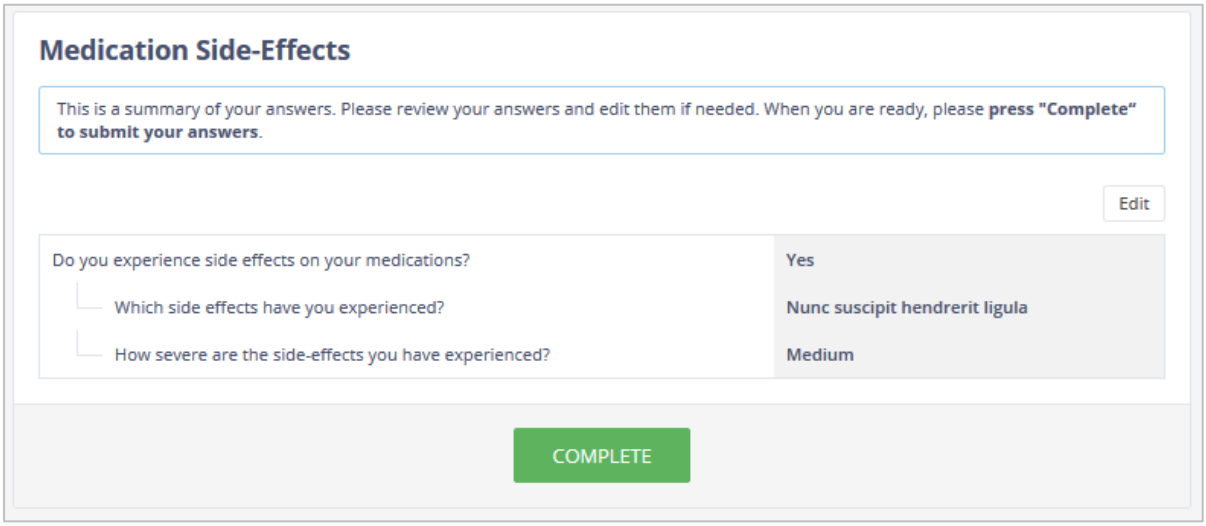

Figure 44 Complete and submit the questionnaire

The MDT has requested the patient to add observation data. The patient adds values according the timing set by the MDT (Figure 45).

Figure 45 Submit observation data