



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

D3.2 Requirements Specification of the C3-Cloud Architecture

Work Package: WP3 Design of C3-Cloud System Architecture
Due Date: 30 September 2016
Actual Submission Date: 30 September 2016
Project Dates: Project Start Date: 01 May 2016
 Project End Date: 30 April 2020
 Project Duration: 48 months
Deliverable Leader: SRDC

Project funded by the European Commission within the Horizon 2020 Programme (2014-2020)		
Dissemination Level		
PU	Public	X
CO	Confidential, only for members of the consortium (including the Commission Services)	
EU-RES	Classified Information: RESTREINT UE (Commission Decision 2005/444/EC)	
EU-CON	Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC)	
EU-SEC	Classified Information: SECRET UE (Commission Decision 2005/444/EC)	

Document History:

Version	Date	Changes	From	Review
V0.1	2016-05-09	Initial Document	SRDC	All Consortium
V0.2	2016-05-12	Use case template is updated to include additional headings that are proposed by the use case template recommended by CEN for capturing eHealth related use case descriptions	EUROREC, SRDC	All Consortium
V0.3	2016-05-27	Template has been slightly updated to be conformant to IEEE 29148:2011 Standard	SRDC	All Consortium
V0.4	2016-06-08	Initial SRDC Contribution for Sections 3.6, 3.8 and 3.9	SRDC	All Consortium
V0.5	2016-07-08	PEP Use cases are added	MEDIXINE, SRDC	All Consortium
V0.6	2016-07-08	Technical Interoperability Platform Use cases are added	WARWICK	All Consortium
V0.7	2016-07-29	PEP use cases are updated Semantic Interoperability Platform Use cases are added Decision Support Module Use cases are added SRDC reviewed all use cases and consolidated them, Flow diagrams in Section 3.10 are drawn	MEDIXINE, INSERM, WARWICK, SRDC	All Consortium
V0.8	2016-08-09	Section 4.7 completed Some of the use cases are categorized as super use cases in a separate section Gaps between user requirements and use cases are handled for PCPDP and C3DP components	SRDC	WP3 Participants
V0.9	2016-08-16	System requirements for Security and Privacy Suite (Section 4.5) and C3DP (Section 4.8) completed WARWICK, MEDIXINE and INSERM updated use cases and Section 4 contributions merged	WARWICK, SRDC, INSERM, MEDIXINE	All Consortium

Version	Date	Changes	From	Review
V1.0	2016-08-25	Section 2 is drafted Section 4 inputs from Warwick and Medixine are merged Flow diagrams are finalized Initial draft of Traceability Matrix is provided Initial draft of Information Exchange Matrix is provided	WARWICK, SRDC, MEDIXINE	WP3 Participants
V1.1	2016-09-05	Kronikgune's comments are addressed, Abbreviation list is added, Traceability matrix is updated, Executive Summary is provided	WARWICK, SRDC, MEDIXINE, OSAKIDETZA, KRONIKGUNE	WP3 Participants
V1.2	2016-09-08	INSERM Inputs, SRDC, MEDIXINE, WARWICK edits	WARWICK, SRDC, MEDIXINE,INSE RM	WP3 Participants
V1.3	2016-09-20	Review from WARWICK, Comments from KronikGune, RJH, SWFT are addressed	SRDC, WARWICK, OSAKIDETZA, KRONIKGUNE, RJH, SWFT	All Consortium
V1.4	2016-09-23	Input from INSERM, KRONIKGUNE, WARWICK Updates of PCPDP-2, PCPDP-6 Use cases and related requirements in Section 4 (by SRDC)	SRDC, INSERM, KRONIKGUNE, WARWICK	All Consortium
V1.5	2016-09-29	Discussions from face to face meeting have been reflected. Updates suggested by internal review by EUROREC and empirica have been realized	All Consortium	All Consortium
V1.6	2016-09-30	Final document	WARWICK	

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EXECUTIVE SUMMARY

The purpose of Deliverable 3.2 is to gather and analyse the scientific and technical requirements of the C3-Cloud architecture. The detailed technical requirements have been analysed for each of the high level C3-Cloud components and documented as a System Requirement Specification Document (SyRS) in accordance with the IEEE Std. 29148:2011 standard (Systems and Software engineering- Life cycle processes – Requirements engineering).

The system requirements of the C3-Cloud architecture are based on end-users' requirements analysed in Task 8.1 "Requirements and Use-cases of C3-Cloud Pilot Application" and the draft functional specifications of C3-Cloud components given in C3-Cloud Description of Action (DoA). By examining the pilot application scenarios reported in D8.1, 60 high level pilot application requirements (PARs) have been identified. Within the scope of Task 3.2, these scenarios and extracted high level requirements have been carefully examined, and the required functionalities have been first mapped to high level C3-Cloud components identified in DoA, then 72 different technical use cases have been identified to address these PARs. Elaborating these use cases in detail enabled us to extract and document formal requirement specification of the C3-Cloud components. A total of 348 requirements have been identified which are categorized as *Functional, Information, System Interface, User Interface, Usability, Performance, Reliability, Maintainability and Security* requirements.

The document is organised as follows:

Section 2 gives a high level overview of C3-Cloud system by defining the System Scope, System Overview which includes general overview of the major elements of the system, definition of major system capabilities, how they interact, and a high level component diagram. Section 2 also presents a common vocabulary in line with the definitions agreed in D8.1 and WP4.

In Section 3, a total of 72 use cases have been defined covering the scope of all of the high level C3-Cloud components to depict the expected functionality. Major process flows are depicted through UML activity diagrams.

In Section 4, the detailed formal requirement specification of the C3-Cloud components is presented listing the Functional, Information, System Interface, User Interface, Usability, Performance, Reliability, Maintainability and Security requirements.

The requirements documented in this document are linked to the user scenario descriptions defined in D8.1 through the Requirements Traceability Matrix presented in Appendix 1 of this document (a.k.a. Traceability to User Requirements). In addition to this, in Section 2.5, the mapping of the use cases defined in this document to the requirements expressed in D8.1 are presented. Finally, in Appendix II, an Information Exchange Matrix is presented as a summary of Information exchange requirements listed for each component in Section 4.

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1 DOCUMENT OVERVIEW

1.1 Purpose

The purpose of Deliverable 3.2 is to gather and analyse the scientific and technical requirements of the C3-Cloud architecture. The system requirements of the C3-Cloud architecture are based on end-users' requirements analysed in Task 8.1 "Requirements and Use-cases of C3-Cloud Pilot Application" and the draft functional specifications of C3-Cloud components given in C3-Cloud Description of Action. The Requirements Specification document will guide C3-Cloud project in further phases, specifically the design phase.

1.2 Methodology and Conformance Statement

The conception of this Requirements Specification Document follows the recommendations of the well-established standard IEEE Std. 29148:2011 (Systems and Software engineering- Life cycle processes – Requirements engineering) which already incorporates guidelines provided by IEEE STD 830-1998 and IEEE STD 1233-1998.

This document corresponds to the IEEE System Requirement Specification Document (SyRS). In line with the guidelines provided in IEEE Std. 29148:2011, in Section 2, a high level overview of C3-Cloud system is presented by defining the System Scope, System Overview which includes general overview of the major elements of the system, including human elements, and how they interact, and a high level component diagram, definition of major system capabilities, conditions and constraints and the user characteristics. Section 2 also presents a common vocabulary, in line with the definitions agreed in D8.1 and WP4.

In Section 3, although not directly mandated by IEEE guidelines, we present an overview of the expected functionalities of the C3-Cloud System through use cases. For each of the high level C3-Cloud components a number of use cases have been defined to depict the expected functionality. Major process flows are depicted through UML activity diagrams.

In Section 4, as suggested by IEEE Std. 29148:2011, the detailed formal requirement specification of the C3-Cloud components is presented. Namely the Functional, Information, System Interface, User Interface, Usability, Performance, Reliability, Maintainability and Security requirements are presented. Constraints, Policies and Regulations that may affect the implementation of the listed requirements, and also the assumptions and dependencies among requirements are also documented in this section.

In IEEE Std. 29148:2011 jargon, D8.1 corresponds to Stakeholders Requirements Specification Document (StRS). The requirements documented in this document are linked to the user scenario descriptions defined in D8.1 through the Requirements Traceability Matrix presented in Appendix I of this document (a.k.a. Traceability to User Requirements). In addition to this, in Section 2.5, the mapping of the use cases defined in this document to the requirements expressed in D8.1 are presented. The Requirements Specification Matrix also provides links to Architectural Design Document, i.e. D3.3 (a.k.a. Traceability to Design), links to the Test Case Descriptions to be defined in C3-Cloud Functional and Non-functional Testing Criteria for C3-Cloud Components, i.e. D9.1 (a.k.a Traceability to Test Cases), and the verification results to be documented in D9.3-Test and Evaluation Report for C3-Cloud Components (a.k.a Traceability to Verification Results). Finally, in Appendix II, an Information Exchange Matrix is presented as a summary of Information exchange requirements listed for each component in Section 4.

1.3 Reference documents

The following documents were used or referenced in the development of this document:

- C3-Cloud Description of Action (DoA)

- C3-Cloud Deliverable 8.1 - Use Cases and Requirement Specifications of the Pilot Application (Month 4)
- IEEE STD 29148-2011: “Systems and Software engineering- Life cycle processes – Requirements engineering”
- IEEE STD 830-1998: “IEEE Recommended Practice for Software Requirements Specifications”
- IEEE STD 1233-1998: “IEEE Guide for Developing System Requirements Specifications”

1.4 Abbreviations and Acronyms

Table 1 List of Abbreviations and Acronyms

Abbreviation/ Acronym	DEFINITION
ADL	Activities of Daily Living
API	Application Programming Interface
ARR	Audit Record Repository
ATNA	Audit Trail and Node Authentication
C3DP	Coordinated Care and Cure Delivery Platform
CAMBIO	Cambio Healthcare Systems AB
C-CDA	Consolidated Clinical Document Architecture
CDM	Clinical Decision Modules
CDS	Clinical Decision Support
CDSM	Clinical Decision Support Modules
CEN	European Committee for Standardization
CRUD	Create, Read, Update, Delete
CTM	Care Team Member
DoA	Description of Action
DSS	Decision support Service
EHR	Electronic Health Report
Eurorec	EUROPEAN INSTITUTE FOR HEALTH RECORDS
FHIR	Fast Healthcare Interoperability Resource
FORTA	Fit for the Aged
FR	Functional Requirement
GP	General Practitioner
HL7	Health Level 7
IADL	Instrumental activities of daily living
ICT	Information Communication Technology
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating Healthcare enterprise
INSERM	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE
IR	Information Requirement
ISO	International Organization for Standardization
KG	ASOCIACION CENTRO DE EXCELENCIA INTERNACIONAL EN INVESTIGACION SOBRE CRONICIDAD
LCS	Local Care Systems
LDAP	Lightweight Directory Access Protocol
MDT	Multidisciplinary Care Team
MEDIXINE	MEDIXINE OY
MTTR	Mean Time To Repair

Abbreviation/ Acronym	DEFINITION
NA	Not Applicable
NFR	Non-functional Requirement
OECD	Organisation for Economic Co-operation and Development
ORU	OREBRO UNIVERSITY
OSAKI	Servicio Vasco de Salud Osakidetza
PAR	Pilot Application Requirements
PCPDP	Personalized Care Plan Development Platform
PEP	Patient Empowerment Platform
PHF	Personal Health Folder
PHR	Personal Health Record
PIC	Patient/Informal Care Giver
RJH	REGION JAMTLAND HARJEDALEN
SIR	System Interface Requirement
SIS	Semantic Interoperability Suite
SPS	Security and Privacy Suite
SRDC	SRDC YAZILIM ARASTIRMA VE GELISTIRME VE DANISMANLIK TICARET ANONIM Sirketi
START	Screening Tool to Alert doctors to Right (i.e. appropriate, indicated) Treatments
STOPP	Screening Tool of Older Persons' Prescriptions
SWFT	SOUTH WARWICKSHIRE NHS FOUNDATION TRUST
TIS	Technical Interoperability Suite
TTP	Trusted Third Party
UIR	User Interface Requirement
XACML	eXtensible Access Control Markup Language
XSPA	Cross-Enterprise Security and Privacy Authorization
WARWICK	THE UNIVERSITY OF WARWICK
WHO	World Health Organisation

2 OVERVIEW OF REQUIREMENTS FROM THE PERSPECTIVE OF THE OVERALL C3-CLOUD SYSTEM

2.1 System Purpose

A growing share of the population in OECD countries is age 65 and over: 15% in 2010, and expected to reach 22% by 2030 (1). Life expectancy of elderly has also increased significantly in the last 50 years. People at age 65 in OECD countries will expect to live for 21 years on average for women and 17 years for men, which is an almost 40% increase since 1960 (2). However, older age is associated with an increased accumulation of multiple chronic conditions: multi-morbidity, including a growing number of functional and cognitive impairments (3).

More than half of all older people have at least three chronic conditions, and a significant proportion has five or more (4). A recent US study indicates that more than 95% of the Medicare patients with a chronic disease like congestive heart failure, depression, or diabetes have at least another chronic condition, and the majority (80%, 71%, and 56%, respectively) have four or more chronic conditions (5). Chronic diseases are the main reason for poor health and restricted activity, affecting over one third of Europe's population and accounting for 70% of healthcare expenditure in Europe (6).

Multi-morbidity creates diverse and sometimes contradictory needs, which challenge patients and the delivery of health services. The clinical management of patients with multi-morbidity is much more complex and time-consuming than those with single diseases. WHO Europe reports that while the number of older people living alone is increasing, the availability of informal care by family members is declining due to greater distances between the members and increased rates of divorce (7). There is consequently a growing demand for health care services to handle multiple chronic conditions, and for social-care services to enable such patients perform everyday activities, supported by informal carer or home / community care services.

Currently those with chronic conditions and long-term care needs experience shortcomings and gaps in care provision. This is particularly prominent at the interfaces within and between health and social care delivery organisations. Achieving good quality integrated care is an acknowledged difficulty in many health systems.

Unfortunately, current European medical models (e.g. as directed by clinical guidelines) focus primarily on short and medium term interventions on the basis of single conditions, failing to integrate care planning well across providers and often overlooking the interconnected basis of chronic diseases. One of the primary roles of General Practitioners (GPs) is to try and provide holistic care for the patients with multiple co-morbidities. GPs already spend a lot of time trying to integrate the requirements of several single disease guidelines and the requests of their single organ/system specialist doctors into the practical management of the patients who often have priorities in conflict with what the care team members might think is the best way forward or ideal care plan for them. Yet, the communication between the parties is often disjointed or non-existent and the patients view often does not appear to have been sought let alone considered.

As a response to these challenges, the C3-Cloud objective is to improve the quality of care experienced by patients with multi-morbidity needs by effectively coordinating, caring and supporting them within and across health and social care delivery organisations. It aims to facilitate this by establishing an underlying information and communication technology (ICT) infrastructure to enable a collaborative

and continuous coordination of patient-centred care activities by a multidisciplinary care team and informal caregivers.

2.2 System Scope

C3-Cloud will establish an ICT infrastructure enabling a collaborative care and cure cloud to facilitate continuous coordination of patient-centred care activities by a multidisciplinary care team and patients/informal care givers. It will provide a Personalised Care Plan Development Platform which will allow collaborative creation and execution of personalised care plans for multimorbid patients through systematic and semi-automatic reconciliation of clinical guidelines, with the help of Clinical Decision Support Modules for risk prediction and stratification, recommendation reconciliation, poly-pharmacy management and goal setting. Fusion of multimodal patient and provider data will be achieved via C3-Cloud Interoperability Middleware for seamless integration with existing information systems. An Integrated Terminology Server with advanced semantic functions will enable meaningful analysis of multimodal data and clinical rules. Active patient involvement and treatment adherence will be achieved through a Patient Empowerment Platform ensuring patient needs are respected in decision making and taking into account preferences and psychosocial aspects. Co-design and 4-layered multi-method multi-stakeholder evaluation will lead to a user friendly solution. To demonstrate feasibility, pilot studies will focus on diabetes, heart failure, renal failure, depression in different comorbidity combinations. Pilots will operate for 15 months in 3 European regions with diverse health and social care systems and ICT landscape, which will allow for strengthening the evidence base on health outcomes and efficiency gains. C3-Cloud adaptive patient pathways and organisational models validated by patient organisations and a clinical reference group, change management and training guidelines will be shared with the European community.

Based on our Description of Action, C3-Cloud aims to facilitate the realization of these objectives through the implementation of the following high level components:

- ***A Personalized Care Plan Development Platform*** that enables the development of personalised care plans for multi-morbid conditions through systematic and semiautomatic reconciliation of digitally represented clinical guidelines for individual chronic conditions, by a group of collaborating health and social care givers, and with the informed participation of the patients and their informal care givers
- ***A Coordinated Care & Cure Delivery Platform*** as an innovative online means for multidisciplinary care team members (MDT) to collaboratively manage (execute, monitor, update) the integrated personalised care plans for patients with multi-morbid conditions
- ***Clinical Decision Support Modules*** to support personalised care plan development and execution by clinical guideline reconciliation, risk stratification, poly-pharmacy management and goal setting and monitoring
- ***A Patient Empowerment Platform*** to ensure active participation of patients and their informal care givers to the management of their multi-morbid chronic conditions alleviating the non-adherence problem
- ***Interoperability Middleware*** addressing *technical, semantic and privacy/security interoperability* challenges to seamlessly integrate with the existing health care, social care and home/community care information systems for enabling patient-centric interoperable care coordination in an informed manner with the involvement of all stakeholders

The high level interaction of these components with each other and their distribution to work packages are depicted Figure 1 and Table 2 as envisioned in our DoA.

Table 2 Overview of components and functions described in the Requirements specification document

WORKPACKAGE	COMPONENTS AND FUNCTIONS BY TASK	PARTNERS RESPONSIBILITIES	HIGH LEVEL COMPONENTS IDENTIFIED
Workpackage 5 Patient Empowerment Platform	Task 5.1 Development of Self-Management Training Materials for Increasing Patient Adherence to Care Plans	SWFT KG, ORU, RJH	Patient Empowerment Platform
	Task 5.2 Data Collection and Feedback Mechanism	MEDIXINE WARWICK	
	Task 5.3 Development of the Responsive Multi-Channel Patient Empowerment Platform	MEDIXINE WARWICK, SRDC, OSAKI	
Workpackage 6 Interoperability Middleware	Task 6.1 Technical Interoperability Platform	WARWICK SRDC, OSAKI, CAMBIO	Technical Interoperability Suite
	Task 6.2 Semantic Interoperability Platform	INSERM WARWICK, SRDC, EuroRec	Semantic Interoperability Suite
	Task 6.3 Privacy Protection and Security within the C3-Cloud Architecture	SRDC WARWICK	Security and Privacy Suite
Workpackage 7 Coordinated Care and Cure Delivery Platform	Task 7.2 Clinical Decision Support Modules for Personalised Care Plan Development and Execution	WARWICK INSERM, OSAKI, CAMBIO	Clinical Decision Support Modules
	Task 7.3 Personalised Care Plan Development Platform	SRDC MEDIXINE, CAMBIO	Personalised Care Plan Development Platform
	Task 7.4 Development of Coordinated Care and Cure Delivery Platform through Integration of C3-Cloud Components	SRDC WARWICK, INSERM, EuroRec, MEDIXINE, OSAKI, CAMBIO	Coordinated Care and Cure Delivery Platform

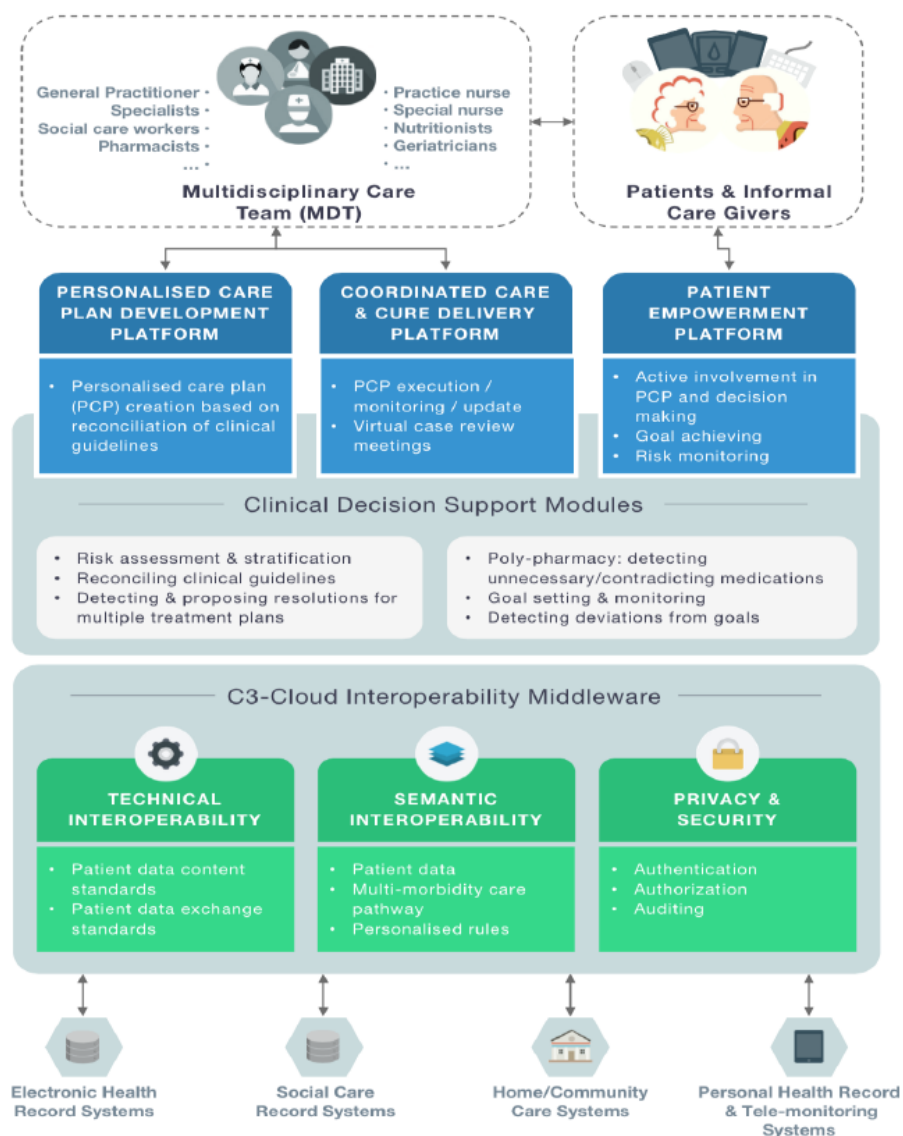


Figure 1 A draft C3-Cloud Architecture (from Description of Action)

In our Description of Action, high level components and their envisioned functionalities have already been defined. The objective of Task 3.2 is to analyse the detailed technical requirements for each of these high level components to guide the succeeding conceptual design phase, and document them in a Requirements Specification Document in accordance with the well-established standards IEEE Std. 830-1998 and IEEE Std. 1233-1998. Although the Description of Action provides a high level description of objectives for each of these components, the detailed specifications of each of them need to be collaboratively agreed upon by examining the end user requirements and the opportunities and constraints introduced by the current applications landscapes at end user sites.

In line with these objectives, in Task 8.1, in the first four months of the project, the requirements of pilot applications and also the as-is application landscape of the pilot sites have been examined to identify different pilot application scenarios to be realized within the scope of C3-Cloud Project. Then by examining these pilot application scenarios, high level pilot application requirements have been documented in Section 5 of D8.1 through collaboration with Task 3.2. Within the scope of Task 3.2, these scenarios and extracted high level requirements have been carefully examined, and the required functionalities have been first mapped to high level C3-Cloud components (which has been documented in D8.1), then the technical use cases have been identified to address these requirements. This mapping is presented in Section 2.5 where a new column “Mapping to the Use Cases” has been added to the table

that has already been presented in Section 5 of D8.1. Detailed description of these use cases can be found in Section 3.

2.3 System Overview

2.3.1 System Context

In this section a general overview of C3-Cloud high level components, and how they interact is presented.

The Coordinated Care and Cure Delivery Platform (C3DP), is one of the core components of the system integrating the functionalities of all of the other components to facilitate collaborative management of the care of the patients with multi-morbid conditions. It is the direct interface to care team members, for defining, updating, reconciling, sharing care plans, utilization of clinical decision support modules supporting these operations, organizing online care plan review meetings, receiving patient data from local care systems (via the Technical Interoperability Suite (TIS)) and Patient Empowerment Platform and providing an easy to navigate dashboard for care team members to see basic medical history of the patient along with the care plan lifecycle history.

Personalized Care Plan Development Platform (PCPDP) is a sub module of C3DP, which enables creation and update of a care plan specialized for a specific patient collaboratively by a care team.

The objective of Patient Empowerment Platform (PEP) is to provide access for patient to the published care plan and its information and thus increase patient and informal carer participation to decision making. It aims to provide computerized means to improve the interaction between patients and health professionals and provide computerized means to collect relevant data and information to enable monitoring of care plan related activity status and progress. It directly interacts with C3DP to be informed about new care plans and updated care plans, and to send patient reported observations. It also communicates with TIS to retrieve patient data from local care systems, and when needed from medical sensor devices (to address the interoperability challenges). It also directly communicates with the supported set of Medical Devices to record patient measurements.

Clinical Decision Support Modules (CDSM) provide decision support aids to provide clinical guideline based diagnosis and treatment suggestions, to carry out risk assessments and to provide guidance about polypharmacy management and being utilized by C3DP and PCPDP during the creation and update of care plans.

Technical Interoperability Suite (TIS) provides interoperability interfaces to enable seamless data exchange with the local care systems and tele-monitoring devices although the data exchange protocols and clinical data representation formats may be heterogeneous across C3-Cloud components and the IT systems utilized in local care sites. TIS provides a standard based data exchange protocol, while it utilizes Semantic Interoperability Suite (SIS) to address content level interoperability challenges. SIS provides interfaces to semantically mediate different clinical data representation formats utilized by C3-Cloud components and local care sites, incorporating data format and terminology mapping features.

Security and Privacy Suite is responsible for guaranteeing 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 audited properly. All of the C3-Cloud components utilizes its audit logging feature, and it also provides a single-sign on mechanism to enable the care team members to use C3-Cloud applications by using a single account, the one that is already being used in local care system (when integration with local care sites' identity provider sites is possible).

A closer look to the high level components and their interaction is depicted in the component diagram below.

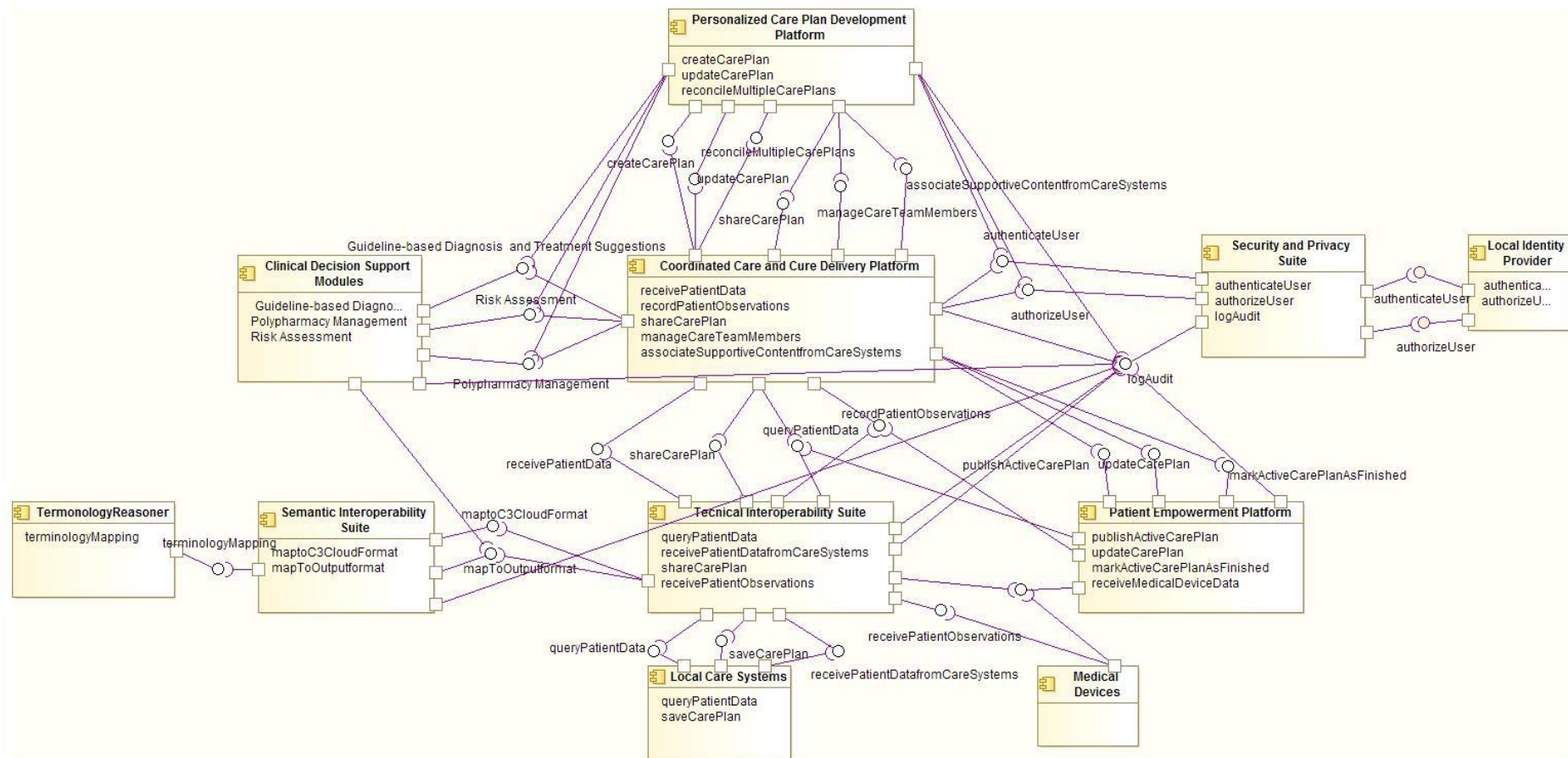


Figure 2 High Level C3-Cloud Component Diagram

2.3.2 System Functions

In this section a closer look to the functionalities of high level C3-Cloud components is given. Detailed description of these features are provided in Section 3 as use case definitions and in Section 4 as formal requirements.

Brief Overview of C3-Cloud Component Functionalities

An overview of the Coordinated Care and Cure Delivery Platform (C3DP) Functionalities

- Manage care team membership operations (inviting and adding new members, removing members, exploring care team members)
- Asynchronous messaging within care team members
- System notifications to care team members
- Managing the organization of virtual care plan review meetings
- Sharing care plans with care team members
- Recording patient observations from PEP
- Retrieving patient data from local sites as supportive content to care plans
- Monitoring care plan events (subscription for events, processing of events, and sending notifications to subscribed parties)
- Providing a dashboard to care team members to monitor the updates in the care plan, and also a general overview of patient medical summary (conditions, medications, vital signs, lab results, risks scores etc.)
- Provide educational materials to Health Professionals
- Support collaborative management of care plan during the whole lifecycle, including updating and sharing care plans in the care of referrals and transfer of care among care centers
- Closing a finalized care plan, and achieving it

An overview of the Personalized Care Plan Definition Platform (PCPDP) Functionalities

- Creating a new care plan (from scratch, by utilizing a core care plan, by reconciling multiple care plans for multiple conditions)
- Updating an existing care plan
- Supporting the use of decision support modules to identify repetitions, inconsistencies, contraindications, missing goals, interventions, calculate risk scores during care plan definition and update
- Tagging care plan items for follow-up or review
- Export care plan
- Import care plan
- Find care plan for a patient

An overview of the Patient Empowerment Platform (PEP) Functionalities

- Make published care plans available to patient access users
- Send reminders to patients to help them comply and stay on track with the interventions and activities included in the care plan
- Allow patients to actively collect data related to the care plan activities

- Allow health professionals and patients to communicate with each other using either messages or video
- Provide patients with access to relevant self-management material
- Provide patient with automated health coaching
- Provide all PEP users with secure access to information and functionality.

An overview of the Security and Privacy Suite (SPS) Functionalities

- Creating a user account for a new Care Team Member without an account linked with the C3-Cloud system
- Authenticating a Care Team Member or an Administrator and starting a secure session for him/her in C3-Cloud applications
- Guaranteeing that no unauthorised user is able to access or modify sensitive data
- Providing a dynamic mechanism for management of the access control policies, instead of static rules hard-coded in application source code
- Ensuring that all data exchange between C3-Cloud applications is audited appropriately

An overview of the Technical Interoperability Suite (TIS) Functionalities

TIS enables information exchange between local care system/PHR and C3-Cloud components, including:

- Patient data and clinical documents from local care system to PCPDP and C3DP via querying or subscription mechanisms
- Patient measurements from tele-monitoring device or PHR to C3DP or PEP
- Care plan from PCPDP or C3DP to local care system

An overview of the Semantic Interoperability Suite (SIS) Functionalities

Semantic Interoperability Suite (SIS) enables data conversion between local care information systems and C3-Cloud high level components, by terminology mappings and information model transcoding.

An overview of the Clinical Decision Support Modules (CDSM) Functionalities

CDSM will be delivered through a unified platform following HL7 decision support service standard, where different knowledge modules can be created to provide decision support on:

- diagnosis and treatment of specific diseases by following clinical guidelines,
- polypharmacy management,
- risk assessment and stratification

2.3.3 System Actors and Human User Characteristics

In the following table an overview of system actors and human user actors of C3-Cloud components are presented:

Type	Actor / role	Description
Human User	Administrator	The user having administrative privileges to define security and privacy configurations and can define new C3-Cloud data sources in Semantic Interoperability Suite
System	Care systems	IT systems used for Primary Care, Secondary Care, Social Care, Home/Community Care, Tele-monitoring/PHR

Type	Actor / role	Description
Human User	Care Team Member	A person involved in the care team of the patient which may include the Patient, Informal Care Giver, and Health Professionals
System	Clinical Decision Support (CDS) Modules	Auxiliary services that aids Health Professionals in the clinical decision making process
System	Coordinated Care and Cure Delivery Platform (C3DP)	C3-Cloud component, that coordinates the execution and monitoring of a care plan by a multidisciplinary care team
System	EHR System	Information systems deployed at local care sites for managing electronic health records or the patients
System	Health Coaching Engine	The system component that generates health coaching messages delivered via PEP System.
Human User	Health Professional	Physicians, nurses being involved in Care Team
Human User	Informal Caregiver	A person acting on behalf of the patient.
Human User	Knowledge Engineer	A user who has the domain knowledge and expertise to create and update knowledge modules for clinical decision support modules.
Human User	Knowledge Manager	A clinical expert who is able to validate clinical decision support rules and their safety for use.
Human User	Patient	The patient being treated as a part of C3-Cloud
Human User	Patient access user	User, who is either the patient self or a person acting on behalf of the patient (personal caregiver).
System	Personalised Care Plan Development Platform (PCPDP)	C3-Cloud component that enables the development of personalised care plan definitions
System	PEP System	C3-Cloud Patient Empowerment Platform
System	PEP System Client	The connected systems interact with PEP via the available service APIs. Examples are PCPDP and C3DP
Human User	PEP User	Anyone using PEP System
System	PHR/Tele-monitoring System	A personal health record system and/or remote monitoring platform that collects patient observations including the readings from wireless medical sensor devices
System	Secure Node	All C3-Cloud applications and external data sources communicating securely with each other
System	Security and Privacy Suite (SPS)	A set of C3-Cloud components that deals with authorization, authentication, secure data exchange and audit trails
System	Semantic Interoperability Suite (SIS)	A set of C3-Cloud components that enables semantic mediation of different content models and terminology systems used by different IT systems
System	SIS User	The systems which are clients of Semantic Interoperability Suite (such as CDS Modules, TIS)
System	Technical Interoperability Suite (TIS)	A set of C3-Cloud components that enables two disparate systems to seamlessly communicate with each other
Human User	User	Meta user of C3-Cloud components including Administrators and Care Team Members

2.4 Definitions

Care Plan: Dynamic, personalized plan including identified needed healthcare activity, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process.

Care Pathway: Method for the patient-care management of a well-defined group of patients during a well-defined period of time.

Clinical Decision Support Modules (CDSM): Reusable Clinical Decision Support Modules that are necessary for personalised care plan development and execution. Different types of CDSMs are targeted to be built in C3-cloud including:

- Patient risk stratification
- Suggest the set of risk factors, based on the current conditions of the patient
- Reconcile multiple treatment plans to create an integrated care plan, personalise care plans according to patient data
- Manage poly-pharmacy
 - like Beer's list, FORTA, Drug Burden Index, START and STOPP criteria
 - indicate contraindications across multiple treatment plans due to drug-drug, drug-disease and drug-body part interactions
 - measure the burden of exposure to multiple drugs, by exploiting the principles of pharmacokinetics (e.g., dose) and pharmacodynamics (e.g., dose response, maximal effect)
- Indicate contraindications across multiple treatment plans
- Identify disease stage
- Monitoring care plan results
- Detect deviations from the outcome goals
- Monitor treatment continuously to realize benefit-risk assessment of drugs to ensure the drugs are producing the intended effects, remain appropriate and to detect any medicine-related problems as soon as possible

Clinical Guideline: Set of systematically developed statements to assist the decisions made by healthcare actors about healthcare activities to be performed with regard to specified health issues.

Coordinated Care and Cure Delivery Platform (C3DP): A platform to support collaborative execution of care plans for chronic conditions over a prolonged period of time in the scope of predefined care pathways. Platform supports the management and update of care plans during the transition of care among care providers; management of care team (adding, removing care team members); collecting the most recent context of the patient from EHRs, and PHRs and sharing them along with the updated care plan; act as a workflow engine to guide the execution of care pathway guiding about the previous and subsequent steps in the care pathway; promotes the coordination, collaboration and communication among care team members to discuss and share goals of care, interventions and monitoring the outcomes (via care team messaging, negotiation and virtual care plan review meetings).

Core Care Plan: Reusable content and structure for a potential care plan for a specified set of circumstances (a.k.a Care Plan Template). These will be created based on the clinical decision support modules processing the clinical guidelines to suggest treatment goals and interventions.

Goal: A goal is a defined outcome or condition to be achieved in the process of patient care. Goals include patient-defined overarching goals (e.g., alleviation of health concerns, desired/intended positive outcomes from interventions, longevity, function, symptom management, comfort) and health concern-specific or intervention-specific goals to achieve desired outcomes.

Health Concern: A Health Concern is a health related matter that is of interest, importance or worry to someone, who may be the patient, patient's family or patient's health professional. Health Concerns are added to track non-optimal physical or psychological situations drawing the patient to the Healthcare system. These may be from the perspective of the Care Team Member or from the perspective of the patient. They represent issues that require intervention(s) to increase the likelihood of achieving the goals of care for the patient and they specify the condition oriented reasons for creating the plan. Health Concerns may be derived from a variety of sources within an EHR (such as Problem List, Family History, Social History, Social Worker Note [e.g. Self Care activities coded as ADLs and IADLs, Mental Status Observations, Functional Status Observations]) and can also be used to note other types of barriers and restrictions for care such as Caregiver Characteristics, Characteristics of Home Environment, Cultural and Religious Restrictions etc.

Intervention: Interventions are actions taken to maximize the prospects of the goals of care for the patient, including the removal of barriers to success. Interventions can be planned, ordered, historical. Interventions include actions that may be ongoing (e.g., maintenance medications that the patient is taking, or monitoring the patient's health status or the status of an intervention). Instructions are nested within interventions and may include self-care instructions. Instructions are information or directions to the patient and other care providers including how to care for the individual's condition, what to do at home, when to call for help, any additional appointments, testing, and changes to the medication list or medication instructions, clinical guidelines and a summary of best practice. A Handoff communication in a plan of treatment among the Care Team Members is also noted as an Intervention.

Outcomes: In the care planning workflow, the judgment about how well the person is progressing towards the goal is based on the observations made about the status of the patient with respect to interventions performed in the pursuit of achieving that goal. Outcome observations are noted as the outcome of care resulting from the interventions used to treat the patient. Patient's progress towards achieving the goal is also noted. Outcome observations can be linked with associated Goals and Interventions.

Personalized Care Plan Definition Platform (PCPDP): A Web based collaborative platform enabling the development of personalized care plans for multi-morbid conditions through systematic and semi-automatic reconciliation of multiple care plans (based on clinical guidelines) by also taking into account the most recent patient context retrieved from EHR of the patient by a Care Team composed of health and social care givers and patients and their informal care givers.

Super Use Case: Use cases that present high level features of the system that can be realized by integrating other use cases

2.5 Mapping of the Use cases with the pilot application requirements identified in D8.1.1

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
PAR-1	As a Patient/Informal Care Giver, I need to access Patient Empowerment Platform to learn about treatment options, about how drugs	Basque Scenario- Encounter A, B RJH Scenario –	Patient Empowerment Platform	PEP-5.1: Access self-management material

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
	work along with their benefits and side effects	Encounter A, B, D SWFT Scenario-Encounter A, B, C		
PAR-2	As a Patient/Informal Care Giver, I need to access Patient Empowerment Platform to learn about my condition (when possible through interactive educational material)	Basque Scenario-Encounter A, B RJH Scenario – Encounter A, B, C, G SWFT Scenario-Encounter A, B, C	Patient Empowerment Platform	PEP-5.1: Access self-management material
PAR-3	As a Health Professional in the MDT, I need to access the EHRs of the patient	Basque Scenario-Encounter A, C, D, E, F RJH Scenario – Encounter A, B, C, D, E, F, G, H, K, L SWFT Scenario-Encounter A, B, C	Local EHR system (named Osabide Global in Osakidetza, Basque Country Cambio Cosmic in RJH)	NA ("C3DP-14: Care Plan Dashboard" will provide a brief summary of recent patient status, though)
PAR-4	As a Health Professional in the MDT, I need to access the EHRs of the patient to record clinical assessment findings and the diagnosis.	Basque Scenario-Encounter A, C, D, E, F SWFT Scenario-Encounter C	Local EHR system (named Osabide Global in Osakidetza, Basque Country)	NA (As it is already handled by Local systems)
PAR-5	Personalised Care Plan Development Platform and Coordinated Care and Cure Delivery Platform needs to be	Basque Scenario-Encounter A, B, C, D, E, F	Local EHR system (named Osabide Global in Osakidetza, Basque Country)	TIS-1: Query Patient Data TIS-4: Map Information

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
	updated about the recent context of the patient (i.e. new clinical assessment findings, diagnosis, lab results, referrals, consult notes, discharge notes), in order to share them with all MDT and also in order to be able to run Clinical Decision Support Modules with the most recent patient context while assisting MDT members	RJH Scenario – Encounter A, B, C, D, E, F, G, H, K, L SWFT Scenario- Encounter A, B, C	Country, Cambio Cosmic in RJH) Personalised Care Plan Development Platform Coordinated Care and Cure Delivery Platform Technical Interoperability Suite Semantic Interoperability Suite	Models and Terminologies TIS-5: Receive Patient Data SIS-1: Map specific data to C3-Cloud format and codes SIS-4: Access to specific data format and codes C3DP-12: Associate Supportive Content from Care Systems C3DP-14: Care Plan Dashboard
PAR-6	As a Health Professional in the MDT, in each encounter I want to review patient's health record, check the progress and any risks of non-adherence (compliance) and complication, and define new or update existing goals and timing, intervention and self-care activities	Basque Scenario- Encounter A, B, C, D, E, F RJH Scenario- Encounter A, B, C, D, F, G, H, J, K, L SWFT Scenario- Encounter A, B, C	Local Care Systems Patient Empowerment Platform Coordinated Care and Cure Delivery Platform Personalised Care Plan Development Platform	C3DP-14: Care Plan Dashboard PCPDP-4: Update Existing Care Plan
PAR-7	As a Health Professional in MDT, I want the support of Personalised Care Plan Development Platform for reconciliation of clinical guidelines for multiple conditions (such as hypertension, diabetes, renal failure and heart failure)	Basque Scenario- Encounter A, B, E RJH Scenario – Encounter A, C, F, H SWFT Scenario- Encounter A, B, C	Personalised Care Plan Development Platform Clinical Decision Support Modules	PCPDP-5: Review Care Plan for Reconciliation PCPDP-6: Reconcile Care Plans for Multiple Conditions CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
PAR-8	As a Health Professional in MDT, I want the Clinical Decision Support Modules to continuously scan data from patient device measurements and patient herself (e.g. questionnaires) as well as new clinical guidelines to alert me when there is a need to update the care plan of the patient	Basque Scenario-Encounter D, F RJH Scenario-Encounter B	Clinical Decision Support Modules Coordinated Care and Cure Delivery Platform Patient Empowerment Platform Technical Interoperability Suite	TIS-3: Push Patient Observations PEP-2.1: Measure and collect patient observation data according the timings defined in care plan PEP-2.2: Complete patient questionnaires according the timings defined in care plan PEP-1.4: Flag care plan treatment interventions and the corresponding goals as achieved PEP-1.5: Flag care plan treatment interventions and the corresponding goals as not achieved PEP-2.3: Notify connected systems of new and changed patient-observed data C3DP-11: Record Patient Observations CDSM-5: Risk Assessment
PAR-9	As a Health Professional in MDT, I want the support of Clinical Decision Support Modules to advise me medication updates based on the current conditions/medications of the patient by also considering drug interactions	Basque Scenario-Encounter A, B, D, E, F RJH Scenario – Encounter A, C, D, F, H, K SWFT Scenario-Encounter A, B, C	Clinical Decision Support Modules	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
PAR-10	As a Health Professional in MDT, I want the support of Clinical Decision Support Modules to advise me goals, interventions such as treatment options including medications, diagnostic procedures, goal-oriented lifestyle and activity modifications based on the current conditions of the patient	Basque Scenario- Encounter A, B, D, E, F RJH Scenario – Encounter A, C, F, H SWFT Scenario- Encounter A,B, C	Clinical Decision Support Modules	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions
PAR-11	The tools supporting editing of care plans shall make clear the responsible editors of different sections of care plan	Basque Scenario- Encounter A, B, D, E RJH Scenario – Encounter F SWFT Scenario- Encounter C	Personalised Care Plan Development Platform	C3DP-14: Care plan Dashboard
PAR-12	As a Patient, I want to see the care plan listing the identified problems, potential risks, goals, management strategies and intended outcomes	Basque Scenario- Encounter A, B, C, D, E, F RJH Scenario – Encounter A, B, C, D, F, H, J, K SWFT Scenario- Encounter A, B, C	Personalised Care Plan Development Platform & Patient Empowerment Platform	PEP-1.1: Publish active care plan to patient PEP-1-6: Update care plan PEP-1.2: View active care plan
PAR-13	As an Informal Care Giver appointed on behalf of the patient, I want to see and accept/reject the care plans of my loved ones listing the identified problems, potential risks,	RJH Scenario – Encounter L SWFT Scenario-	Coordinated Care and Cure Delivery Platform & Patient Empowerment Platform	PEP-4.5: Authenticate patient access user to use PEP functionality PEP-4.7: Invite personal caregiver to access related

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
	goals, management strategies and intended outcomes	Encounter A, C		patient's workspace PEP-4.8: Access selected patient's workspace
PAR-14	As a Health Professional in MDT, I want to share the updated care plan along with my clinical notes/progress notes/discharge summary with all MDT members	Basque Scenario- Encounter A, B, C, D, E, F RJH Scenario – Encounter A, B, C, D, F, G, H, J, K, L SWFT Scenario- Encounter A, B, C	Coordinated Care and Cure Delivery Platform	C3DP-10: Share Care Plan with Care Team Members
PAR-15	It should be possible to export the approved care plan from the Personalised Care Plan Development Platform to the patient's medical record	Basque Scenario- Encounter A, B, C, D, E, F RJH Scenario – Encounter A, B, C, D, F, G, H, J, K, L	Local Care Systems Personalised Care Plan Development Platform Technical Interoperability Suite Semantic Interoperability Suite	PCPDP-9: Export Care Plan TIS-2: Share Care Plan SIS-2: Map C3-Cloud data to specific format and codes
PAR-16	As a Patient, I want to be notified if my existing care plan is updated, highlighting the changes	Basque Scenario- Encounter A, B, D, F RJH Scenario – Encounter C, D, F, G, H, J, K SWFT Scenario- Encounter A, B, C	Personalised Care Plan Development Platform & Patient Empowerment Platform Technical Interoperability Suite Semantic Interoperability Suite	PEP1-6: Update care plan PEP-1.2: View active care plan

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
PAR-17	As an Informal Care Giver appointed on behalf of the patient, I want to be notified if the existing care plans of my loved ones are updated, highlighting the changes	RJH Scenario – Encounter L SWFT Scenario-Encounter A, C	Personalised Care Plan Development Platform & Patient Empowerment Platform	PEP1-6: Update care plan PEP-4.8: Access selected patient's workspace
PAR-18	As a Patient I want to give access rights to my loved ones to view my care plan	Basque Scenario-Encounter E RJH Scenario – Encounter E SWFT Scenario-Encounter A, C	Patient Empowerment Platform	PEP-4.5: Authenticate patient access user to use PEP functionality
PAR-19	As an Informal Care Giver I want to see a copy of the care plan of my loved ones (if access is granted)	RJH Scenario – Encounter A SWFT Scenario-Encounter A, C	Personalised Care Plan Development Platform & Patient Empowerment Platform	PEP-4.5: Authenticate patient access user to use PEP functionality PEP-4.7: Invite personal caregiver to access related patient's workspace PEP-4.8: Access selected patient's workspace
PAR-20	As a Patient I want to be advised about how to follow the care plan	Basque Scenario-Encounter A, B, D, E, F SWFT Scenario-Encounter A, B, C	Patient Empowerment Platform	PEP-1.3: Send care plan related treatment intervention reminder PEP-5.1: Access self-management material
PAR-21	As a Patient I want to get SMS notifications about my interventions planned in my care plan (such as medications)	RJH Scenario – Encounter E	Patient Empowerment Platform	PEP-1.3: Send care plan related treatment intervention reminder

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
PAR-22	As a Patient, I need to access drug interaction information	Basque Scenario-Encounter A	Patient Empowerment Platform & related local sites (Osasun eskola and i-Botika web pages for Basque Country)	PEP-5.1: Access self-management material
PAR-23	As a Patient/Informal Care Giver, I want to be able to remotely get in touch with social care services	Basque Scenario-Encounter B	Patient Empowerment Platform	PEP-3.1: Communicate via Safe messaging PEP-3.2: Communicate via Video appointment
PAR-24	As a Patient I want to be able to schedule next appointment with my Primary Care Provider	Basque Scenario-Encounter A, C, F	Local Booking system of the primary care (Osarean for Basque Country)	NA
PAR-25	As a Social Worker/Specialist, I want a mechanism to become a part of MDT	Basque Scenario-Encounter B SWFT Scenario-Encounter B	Coordinated Care and Cure Delivery Platform	“C3DP-2: Invite a Care Team Member”
PAR-26	As a Social Worker/Specialist, I want to access the recent context (i.e. care plan) of the patient after my membership to MDT is approved by the Care (Plan) Manager	Basque Scenario-Encounter B RJH Scenario-Encounter E SWFT Scenario-Encounter B, C	Coordinated Care and Cure Delivery Platform	C3DP-14: Care Plan Dashboard
PAR-27	As a Health Professional in MDT, I want to specify the next Care Plan Review meeting	Basque Scenario-Encounter B, F	Personalised Care Plan Development Platform	PCPDP-3: Define New Care Plan PCPDP-4: Update Existing Care Plan
PAR-28	As a Health Professional in MDT, I want to define	Basque Scenario-Encounter B	Personalised Care Plan Development Platform	PCPDP-3: Define New Care Plan

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
	new specialized care plans for the patient	RJH Scenario-Encounter E SWFT Scenario-Encounter B, C		PCPDP-2: Add New Care Plan from a Core Care Plan
PAR-29	As a Social Worker / Health Professional in MDT, I want to initiate referrals to another Specialist by sharing the information about the patient's medical history including the recent diagnosis, reasons for referral and requested services	Basque Scenario-Encounter B, C, D, E RJH Scenario-Encounter E, F, G	Local Care Systems Coordinated Care and Cure Delivery Platform Technical Interoperability Suite	C3DP-12: Associate Supportive Content from Care Systems C3DP-16: Support Referral TIS-1: Query Patient Data TIS-5: Push Patient Data
PAR-30	As a Health Professional in MDT, I want to invite another Specialist to MDT after referrals so that they can see the information about the patient's medical history including the recent diagnosis, reasons for referral and requested services, and also active and previous care plans	Basque Scenario-Encounter D, E RJH Scenario-Encounter E, F, G	Local Care Systems Coordinated Care and Cure Delivery Platform	C3DP-2: Invite a Care Team Member C3DP-3: Add Care Team Member
PAR-31	As a Health Professional in MDT, I want to invite Homecare social care providers such as Municipality nurses and nurse assistants to MDT so that they can see the information about the patient's medical history including the recent diagnosis, reasons for referral and requested services, and also active and previous care plans	RJH Scenario-Encounter H, J, L SWFT Scenario-Encounter B	Local Care Systems Coordinated Care and Cure Delivery Platform	C3DP-2: Invite a Care Team Member C3DP-3: Add Care Team Member

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
PAR-32	Coordinated Care and Cure Delivery Platform needs to be updated about the recent context of the patient from the social care services in order to share them with all MDT and also in order to be able to run Clinical Decision Support Modules with the most recent patient context while assisting MDT members	Basque Scenario-Encounter B RJH Scenario – Encounter H, J, L SWFT Scenario-Encounter B, C	Local Social Care Systems Coordinated Care and Cure Delivery Platform Technical Interoperability Suite Semantic Interoperability Suite	TIS-1: Query Patient Data TIS-4: Map Information Models and Terminologies TIS-5: Push Patient Data SIS-1: Map specific data to C3-Cloud format and codes C3DP-12: Associate Supportive Content from Care Systems
PAR-33	As a member of MDT, I want to be able to communicate with the other members of MDT via asynchronous messaging and video calls	Basque Scenario-Encounter D, E RJH Scenario-Encounter H	Coordinated Care and Cure Delivery Platform	C3DP-6: Send Message to Care Team Member(s) C3DP-7: Manage Messages C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting C3DP-9: Organize Virtual Care Review Meeting
PAR-34	As a member of MDT, I want to access web based educational material related with the care of the patient	Basque Scenario-Encounter A RJH Scenario-Encounter H	Coordinated Care and Cure Delivery Platform	C3DP-15: Access Educational Material
PAR-35	As a MDT Member, I want to access the readings from remote monitoring systems such as wireless medical sensor devices	Basque Scenario-Encounter C, D, F RJH Scenario-Encounter B	Local Care Systems (Including Remote monitoring systems and EHR systems) and/or Patient Empowerment Platforms Coordinated Care and Cure Delivery Platform	TIS-3: Push Patient Observations PEP-2.1: Measure and collect patient observation data according the timings defined in care plan

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
			Technical Interoperability Suite	PEP-4.8: Access selected patient's workspace PEP-4.6: Authenticate health professional user to use PEP functionality PEP-2.3: Notify connected systems of new and changed patient-observed data C3DP-11: Record Patient Observations C3DP-14: Care Plan Dashboard
PAR-36	As a Patient/Informal Care Giver, I want to access the readings from remote monitoring systems such as wireless medical sensor devices from the Patient Empowerment Platform	Basque Scenario- Encounter C, D, F RJH Scenario – Encounter B	Local Care Systems (Including Remote monitoring systems and EHR systems) Patient Empowerment Platform Technical Interoperability Suite	TIS-3: Push Patient Observations PEP-2.1: Measure and collect patient observation data according the timings defined in care plan PEP-4.5: Authenticate patient access user to use PEP functionality PEP-4.8: Access selected patient's workspace
PAR-37	As a Health Professional in MDT, I want to be notified about the deviations of the remote monitoring systems readings from the set goals in the care plan and the abnormal results, which can trigger updates in the care plan. The thresholds to identify abnormal results will be set by Health Professionals.	Basque Scenario- Encounter D RJH Scenario – Encounter B	Remote monitoring systems and EHR systems) and/or Patient Empowerment Platform Coordinated Care and Cure Delivery Platform Clinical Decision Support Modules	C3DP-13: Monitor Change TIS-3: Push Patient Observations PEP-2.1: Measure and collect patient observation data according the timings defined in care plan PEP-2.3: Notify connected systems of new and

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
				changed patient-observed data C3DP-11: Record Patient Observations CDSM-5: Risk Assessment
PAR-38	As a Health Professional in MDT, I want to be notified about the selected pre-emergency situations detected through the abnormal results in remote monitoring results via SMS messages. The thresholds to identify abnormal results will be set by Health Professionals.	RJH Scenario – Encounter B	Remote monitoring systems and EHR systems) and/or Patient Empowerment Platform Coordinated Care and Cure Delivery Platform Clinical Decision Support Modules	C3DP-13: Monitor Change TIS-3: Push Patient Observations PEP-2.1: Measure and collect patient observation data according the timings defined in care plan PEP-2.3: Notify connected systems of new and changed patient-observed data C3DP-11: Record Patient Observations CDSM-5 Risk Assessment
PAR-39	As a Patient I want to be notified about the selected pre-emergency situations detected through the abnormal results in remote monitoring results via SMS messages	RJH Scenario – Encounter B	Remote monitoring systems and EHR systems) and/or Patient Empowerment Platform Coordinated Care and Cure Delivery Platform Clinical Decision Support Modules	PEP-2.1: Measure and collect patient observation data according the timings defined in care plan PEP-2.3: Notify connected systems of new and changed patient-observed data C3DP-11: Record Patient Observations C3DP-13: Monitor Change CDSM-5 Risk Assessment
PAR-40	As a Health Professional in MDT, I want to be notified about the identified trends for the	Basque Scenario- Encounter C	Remote monitoring systems and EHR systems) and/or Patient	C3DP-13: Monitor Change

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
	selected remote monitoring systems readings	RJH Scenario – Encounter C	Empowerment Platforms Coordinated Care and Cure Delivery Platform Clinical Decision Support Modules	TIS-3: Push Patient Observations PEP-2.1: Measure and collect patient observation data according the timings defined in care plan PEP-2.3: Notify connected systems of new and changed patient-observed data C3DP-11: Record Patient Observations CDSM-5: Risk Assessment
PAR-41	As a Health Professional in MDT, I want to update the care plan when triggered by notifications about the deviation of readings of remote monitoring systems and abnormal results	Basque Scenario- Encounter D RJH Scenario – Encounter B	Personalized Care Plan Development Platform Coordinated Care and Cure Delivery Platform	C3DP-13: Monitor Change TIS-3: Push Patient Observations PEP-2.1: Measure and collect patient observation data according the timings defined in care plan PEP-2.3: Notify connected systems of new and changed patient-observed data C3DP-11: Record Patient Observations PCPDP-4: Update Existing Care Plan
PAR-42	As an Informal Care Giver, I want the ability to get on online contact with MDT members of my loved ones	Basque Scenario- Encounter E	Patient Empowerment Platform	PEP-4.5: Authenticate patient access user to use PEP functionality PEP-3.2: Communicate via Video appointment

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
				PEP-3.1: Communicate via Safe messaging
PAR-43	As a Health Professional in MDT, I want to be able to review the recent patient context from C3DP and organise a virtual case review meeting	Basque Scenario-Encounter E	Coordinated Care and Cure Delivery Platform	C3DP-14: Care Plan Dashboard C3DP-9: Organize Virtual Care Review Meeting
PAR-44	As a Health Professional in MDT, I want to be advised by the Clinical Decision Support Modules employed by C3DP, about treatment options (such as starting/stopping drugs based on the most recent context of the patient including the changes in the recent remote monitoring results)	Basque Scenario-Encounter D, E RJH Scenario – Encounter B	Coordinated Care and Cure Delivery Platform Clinical Decision Support Systems	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions C3DP-13: Monitor Change
PAR-45	As a Patient, I want to access a copy of my discharge summary along with discharge care plan	Basque Scenario-Encounter E	Local EHR system (named Osabide Global in Osakidetza, Basque Country) Coordinated Care and Cure Delivery Platform Patient Empowerment Platform	C3DP-10: Share Care Plan with Care Team Members PEP-1.1: Publish active care plan to patient PEP-4.8: Access selected patient's workspace
PAR-46	As a Health Professional, I want the support of Clinical Decision Support Modules for identification of diagnosis based on recent lab results based on clinical guidelines	Basque Scenario-Encounter E RJH Scenario-Encounter A	Personalised Care Plan Development Platform Clinical Decision Support Modules	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions
PAR-47	As a Health Professional in MDT, I want the Patient to have the ability to fill in questionnaires via the Patient Empowerment Platform	Basque Scenario-Encounter D RJH Scenario-Encounter B	Patient Empowerment Platform	PEP-2.2: Complete patient questionnaires according the timings defined in care plan

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
PAR-48	As a Patient, I need to upload photos of my meals to the Patient Empowerment Platform	RJH Scenario-Encounter B	Patient Empowerment Platform	PEP-2.1: Measure and collect patient observation data according to the timings defined in care plan PEP-2.3: Notify connected systems of new and changed patient-observed data C3DP-11: Record Patient Observations
PAR-49	As a Health Professional in MDT, I want to access patient specified information such as questionnaires filled, deviations from the care plan and reasons presented by the patient, files uploaded via the Patient Empowerment Platform	Basque Scenario-Encounter D RJH Scenario-Encounter B	Patient Empowerment Platform Coordinated Care and Cure Delivery Platform	PEP-2.2: Complete patient questionnaires according the timings defined in care plan PEP-2.3: Notify connected systems of new and changed patient-observed data C3DP-11: Record Patient Observations C3DP-14: Care Plan Dashboard
PAR-50	As a Patient, I want to get in contact with the Health Professionals in MDT via messaging	RJH Scenario-Encounter B SWFT Scenario-Encounter A	Patient Empowerment Platform	PEP-3.1: Communicate via Safe messaging
PAR-51	As a Patient, I want to get in contact with the Health Professionals in MDT via video conferencing	RJH Scenario-Encounter B, G SWFT Scenario-Encounter A	Patient Empowerment Platform	PEP-3.2: Communicate via Video appointment
PAR-52	As a Patient, I want to have automatic coaching regarding life style, blood	Basque Scenario-Encounter A	Patient Empowerment Platform	PEP-5.2: Subscribe to health coaching programs

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
	pressure and blood glucose measurements.	RJH Scenario-Encounter B	Clinical Decision Support Modules	PEP-5.3: Generate and deliver health coaching program messages to patient
PAR-53	As a Patient I want to have personalised guidance/information from the Patient Empowerment Platform based on my most recent context (answers given on questionnaires and on data from the EHR (diagnoses, medication, lab) but also based on data from devices)	Basque Scenario-Encounter A, B, C RJH Scenario-Encounter B, H	Patient Empowerment Platform Clinical Decision Support Modules Remote Monitoring Systems Local Care Systems Technical Interoperability Suite Semantic Interoperability Suite	PEP-4.8: Access selected patient's workspace
PAR-54	As a Health Professional in MDT, I want to get timely notifications about the interventions in the care plan that need to be carried out by me	Basque Scenario-Encounter B RJH Scenario-Encounter I	Coordinated Care and Cure Delivery Platform	C3DP-7: Manage Messages
PAR-55	As a Health Professional in MDT, I want to get notifications when the patient makes many unsuccessful log-in attempts to use Patient Empowerment Platform	RJH Scenario-Encounter L	Patient Empowerment Platform Coordinated Care and Cure Delivery Platform	A mechanism to record unsuccessful login attempts at PEP will be worked on during design phase. C3DP-11: Record Patient Observations C3DP-7: Manage Messages
PAR-56	The system shall enable to ascertain who the lead clinician and care plan manager would be	SWFT Scenarios RJH Scenario-Encounter F	Coordinated Care and Cure Delivery Platform Personalized Care Plan Development Platform	PCPDP-1 Create Care Plan
PAR-57	The system shall ensure authentication of users, preferably with their existing business user accounts	Basque, RJH and SWFT scenarios – All encounters	Security and Privacy Suite	SPS-1: Create Care Team Member Account SPS-2: Authenticate User

Requirement ID	Pilot Application Scenario Requirements	Mapping to Pilot Scenarios	Mapping to High Level components	Mapping to the Use Cases
PAR-58	The system shall ensure that no unauthorised user is able to access sensitive data	Basque, RJH and SWFT scenarios – All encounters	Security and Privacy Suite	SPS-3: Authorize User
PAR-59	The system shall provide a mechanism for dynamic management of access control policies	Basque, RJH and SWFT scenarios – All encounters	Security and Privacy Suite	SPS-4: Manage Access Control Policies
PAR-60	The system shall audit all data access and exchange transactions for non-repudiation	Basque, RJH and SWFT scenarios – All encounters	Security and Privacy Suite	SPS-5: Log Audit

3 DESCRIPTION OF THE USE CASES

In this section for each of the functionalities promised to be realized in Description of Action (as presented in Table 2) the responsible partners have documented a number of use cases.

3.1 Use Cases for Patient Empowerment Platform

The following metadata is applicable for all the use cases defined in this section related with the patient empowerment platform, and hence will not be repeated in each use case definition:

Domain	Long term care of patients with chronic conditions
Scale	Intra-hospital, Intra-Care Center (including acute care centers and long term care centers such as nursing homes, and homes of the patients).
Business Case	Provide access for patient to the published care plan and its information and thus increase patient and informal carer participation to decision making. Provide computerized means to improve the interaction between patients and health professionals and provide computerized means to collect relevant data and information to enable monitoring of care plan related activity status and progress.
Context	Current practice in care planning and execution does not engage and involve patients extensively and computerized tools for active collaboration and communication between patient and health professionals are not utilized to their full potential.

3.1.1 Use cases related with Care Plan Management, Feedback, Data Collection Mechanisms and Multi-Channel Communication Platform

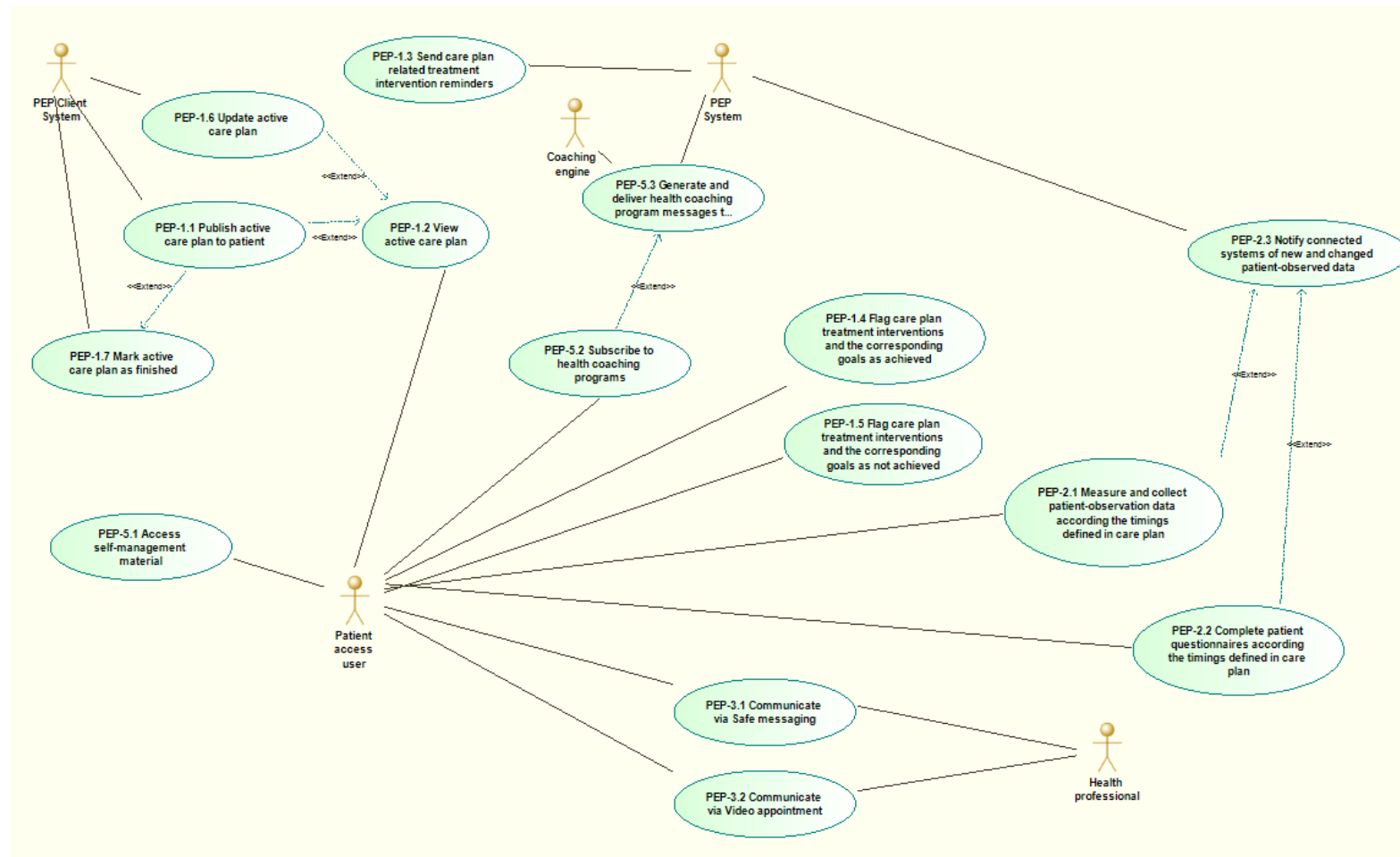


Figure 3 Use case Diagram for Care Plan Management, Feedback, Data Collection Mechanisms and Multi-Channel Communication Platform

Use case	Primary actor
Care Plan Management and Feedback	
PEP-1.1: Publish active care plan to patient	PEP System Client
PEP-1.2: View active care plan	Patient access user
PEP-1.3: Send care plan related treatment intervention reminders	PEP System
PEP-1.4: Flag care plan treatment interventions and the corresponding goals as achieved	Patient access user
PEP-1.5: Flag care plan treatment interventions and the corresponding goals as not achieved	Patient access user
PEP-1.6: Update active care plan	PEP System Client
PEP-1.7: Mark active care plan as finished	PEP System Client
Data Collection	
PEP-2.1: Measure and collect patient-observation data according the timings defined in care plan	Patient access user
PEP-2.2: Complete patient questionnaires according the timings defined in care plan	Patient access user
PEP-2.3: Notify connected systems of new and changed patient-observed data	PEP System
Communication between Professionals and Patients	
PEP-3.1: Communicate via Safe messaging	Health Professional
PEP-3.2: Communicate via Video appointment	Health Professional
Self-management	
PEP-5.1: Access self-management material	Patient access user
PEP-5.2: Subscribe to health coaching programs	Patient access user
PEP-5.3: Generate and deliver health coaching program messages to patient	Health coaching engine

3.1.1.1 PEP-1.1: Publish active care plan to patient

Title	PEP-1.1: Publish active care plan to patient
Description	PEP System Client publishes an active care plan to PEP and thus makes it available to the empowered patient and PEP System. If the patient already has an active care plan, the published care plan replaces the currently active care plan. This use case ends when the published care plan has been stored and the patient has been notified.
Purpose	Make a new care plan available to authorized PEP Users and to the PEP System functionality.
Information	Care plan.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	PEP System Client.

Trigger	PEP System Client has new care plan for a specific patient, ready to be published to the patient.
Frequency	Whenever a new care plan is defined or an existing care plan is updated

Preconditions

1. None.

Minimal Postconditions

1. None.

Success Postconditions

1. The active care plan is stored in PEP System and is available to authorized users.
2. PEP system has sent a notification to patient of the new care plan using the preferred notification channel.

Main Flow

1. PEP System Client publishes the active care plan to the PEP system via integration with C3DP.
2. PEP System stores the care plan.
3. PEP System sends a notification to the patient that a new care plan has been published and is available.

Alternative Flows

1. An active care plan exists already and the current active care plan is replaced by the published care plan. See PEP-1.6.

Open Issues

None.

3.1.1.2 PEP-1.2: View active care plan

Title	PEP-1.2: View active care plan
Description	Patient has received a notification of a new published or an updated care plan and either the patient or a personal caregiver logs in to PEP System to view the information provided in the care plan and to find out about the planned patient activities included in the care plan. This use case ends when the user has opened and read the published care plan.
Purpose	Enable patient to view the care plan and information contained in the care plan.
Information	Care plan.
Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-1.1 Publish active care plan to patient
Actor(s)/Participants	Patient access user.
Trigger	Patient has received a notification of a new or updated care plan.
Frequency	At least once per published care plan.

Preconditions

1. PEP System Client has published a new, active care plan to the patient or updated the active care plan.
2. A notification has been sent to the patient.

Minimal Postconditions

1. None.

Success Postconditions

1. PEP System has marked the care plan as read in PEP System.
2. Event subscription notification of care plan read has been generated and sent to subscribing systems.

Main Flow

1. Patient access user logs in and sees that there is a new, unread care plan.
2. Patient access user opens the care plan.
3. PEP System displays the relevant information in the care plan including goals, health concerns, interventions and planned patient activities. If the care plan includes changes, the changes are highlighted.
4. A notification event that the care plan has been accessed and read is generated and sent to subscribing systems.

Alternative Flows

1. None.

Open Issues

None.

3.1.1.3 PEP-1.3: Send care plan related treatment intervention reminder

Title	PEP-1.3: Send care plan related treatment intervention reminder
Description	In this use case, the PEP System monitors the active care plans for treatment interventions reminders, and sends reminder messages to patients according the timings defined in the care plans. This use case ends when the care plan is retired and marked as non-active (completed, aborted).
Purpose	Support patient in the execution of the interventions included in the active care plan.
Information	Care plan.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	PEP System
Trigger	Active care plan has been published and stored.
Frequency	According timings defined in care plan details.

Preconditions

1. Patient has received an active care plan, that includes interventions with set timings and reminders enabled.
2. Patient contact information for used communication channels (email, sms) has been set and is up-to-date.

Minimal Postconditions

1. None.

Success Postconditions

1. Patient has received the planned reminder messages on the chosen notification channel.

Main Flow

1. PEP System monitors the active care plans for treatment intervention reminders.
2. When a reminder is due, PEP System sends the configured reminder message to the patient.

Alternative Flows

1. None.

Open Issues

1. Will the care plan contain the information which notification channel to use for these reminders or is it determined otherwise?
2. Is the notification channel for this type of reminders determined by service provider or may the patient choose which channel to use? Please note differences between different channels. For instance, some incur higher usage costs than others and messages on some channels are picked up quicker than on others, so the service provider may want to force certain channel to be use and not allow patient to choose.

3.1.1.4 PEP-1.4: Flag care plan treatment interventions and the corresponding goals as achieved

Title	PEP-1.4: Flag care plan treatment interventions and the corresponding goals as achieved
Description	Patient has performed a planned treatment intervention, for which the systems cannot automatically detect that the intervention has been completed and the patient wants to inform the care team of the progress. The patient or a personal caregiver logs in and sets the planned intervention status as achieved.
Purpose	Enable patient to report and share with professionals care plan treatment intervention progress
Information	Care plan.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	Patient access user
Trigger	Patient chooses to update care plan treatment intervention status manually.
Frequency	Optionally once for each intervention and goal.

Preconditions

1. Patient has an active care plan with treatment interventions and corresponding goals.

Minimal Postconditions

1. None.

Success Postconditions

1. The selected treatment intervention status is updated to “achieved”.

Main Flow

1. Patient access user logs in and opens the care plan.
2. The system displays the relevant information in the care plan including goals, health concerns, interventions and planned patient activities.
3. The user chooses the right treatment intervention and updates the status to “achieved”.

Alternative Flows

1. None.

Open Issues

None.

3.1.1.5 PEP-1.5: Flag care plan treatment interventions and the corresponding goals as not achieved

Title	PEP-1.5: Flag care plan treatment interventions and the corresponding goals as not achieved
Description	The patient cannot perform a planned treatment intervention and wants to inform the care team of the progress. The patient or a personal caregiver logs in and sets the planned intervention status as not achieved.
Purpose	Enable patient to report and share with professionals care plan treatment intervention progress
Information	Care plan.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	Patient access user
Trigger	Patient chooses to update care plan treatment intervention status manually.
Frequency	Optionally once for each intervention and goal.

Preconditions

1. Patient has an active care plan with treatment interventions and corresponding goals.

Minimal Postconditions

1. None.

Success Postconditions

1. The selected treatment intervention status is updated to “not achieved”.

Main Flow

1. Patient access user logs in and opens the care plan.
2. The system displays the relevant information in the care plan including goals, health concerns, interventions and planned patient activities.
3. The user chooses the right treatment intervention and updates the status to “not achieved”.

Alternative Flows

1. None.

Open Issues

None.

3.1.1.6 PEP-1.6: Update care plan

Title	PEP-1.6: Update a patient's active care plan
Description	PEP System Client updates the active care plan and publishes the updated care plan to PEP System. This use case ends when the published care plan has been stored and the patient has been notified.
Purpose	Make a changed care plan available to authorized PEP Users and to the PEP System functionality.
Information	Care plan
Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-1.2: View active care plan
Actor(s)/Participants	PEP System Client.
Trigger	PEP System Client has an updated care plan for a specific patient, ready to be published to the patient.
Frequency	Whenever a new care plan is defined or an existing care plan is updated

Preconditions

1. None.

Minimal Postconditions

1. None.

Success Postconditions

1. The active care plan is stored in PEP System and is available to authorized users.
2. PEP system has sent a notification to patient of the new care plan using the preferred notification channel.

Main Flow

1. PEP System Client publishes the active care plan to the PEP system via integration.
2. PEP System stores the care plan.
3. PEP System sends a notification to the patient that a new care plan has been published and is available.

Alternative Flows

None.

Open Issues

None.

3.1.1.7 PEP-1.7: Mark active care plan as finished

Title	PEP-1.7: Mark active care plan as finished
Description	An active care plan is closed/retired if there is no longer the need of a care plan. This use case ends when the active care plan has been fully processed and archived.
Purpose	Marking the care plan as no longer in use.
Information	Care plan

Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-1.1: Publish active care plan to patient
Actor(s)/Participants	PEP System Client
Trigger	By PEP System Client via service APIs directly or indirectly via use case PEP 1.1 when another active care plan is published for the patient.
Frequency	Once per published care plan.

Preconditions

1. Patient has an active care plan in PEP System.

Minimal Postconditions

1. None.

Success Postconditions

1. The selected care plan has been archived and is no longer in use.

Main Flow

1. PEP System Client sends message via integration to the PEP system that the active care plan is closed.
2. PEP System processes the active care plan and closes all ongoing activities of the care plan.
3. PEP System sends a notification to the patient that the care plan has been closed.

Alternative Flows

If there are activities still ongoing a minimal care plan would be sufficient. See PEP-1.6 for update of care plan

Open Issues

None.

3.1.1.8 PEP-2.1: Measure and collect patient observation data according to the timings defined in care plan

Title	PEP-2.1: Measure and collect patient observation data according to the timings defined in care plan
Description	The patient is assigned the task to perform measurements and collect data during a set period using devices handed out to the patient. The specifics of the monitoring activity are defined in the active care plan. This use case ends when the remote monitoring period is finished.
Purpose	Enable the patient and the informal caregivers to collect relevant data to the C3-Cloud components using connected medical devices.
Information	Care plan. Patient observations.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-

Actor(s)/Participants	Primary: Patient access user. Other: Health professional. PEP System.
Trigger	A care plan with prescribed remote monitoring activity is published to patient.
Frequency	Frequency determined by the timings defined in the care plan.

Preconditions

1. Patient has an active care plan with prescribed remote monitoring.

Minimal Postconditions

1. None.

Success Postconditions

1. The prescribed care plan remote monitoring activity is marked as completed.

Main Flow

1. The responsible care team health professional and the patient agree to meet to start remote monitoring for the patient.
2. Health professional reviews the patient settings and adjusts them if needed.
3. Health professional user assigns the measurement devices to the patient in PEP System and hands out the devices to the patient. The professional provides needed guidance and training to the patient at the same time.
4. Patient performs measurements as planned using the provided devices during the set period.
5. The measurement data is uploaded automatically from the devices to PEP System.
6. PEP System sends a notification to the patient after each successfully uploaded measurement.
7. PEP System generates for each uploaded value an event subscription event, which is sent to PEP System Client subscribing to this event.
8. When the end of the prescribed monitoring period is reached, the patient stops performing measurements. The devices are returned to the care team and device assignments are removed.

Alternative Flows

1. The measurement activity is not started as planned and the activity is set as not achieved.
2. Ongoing measurement activity is stopped before the planned end of the activity period.
3. If required, “TIS-3: Push Patient Observations” use case is utilized as an interoperability means with medical devices.

Open Issues

None.

3.1.1.9 PEP-2.2: Complete patient questionnaires according the timings defined in care plan

Title	PEP-2.2: Complete patient questionnaires according the timings defined in care plan
Description	The patient is assigned the task to complete relevant questionnaire during a set period. The specifics of the questionnaire activity is defined in the active care plan. The patient is sent a reminder when it is time to fill in the questionnaire. The patient logs in and completes the questionnaire. This use case ends when activity defined in the care plan has been completed.
Purpose	Enable the patient and the informal caregivers to provide relevant information to the C3-Cloud components using online questionnaires.
Information	Care plan. Questionnaire response.
Parent	-
Included sub-use cases	-

Extended sub-use cases	-
Actor(s)/Participants	Patient access user
Trigger	Patient has been assigned a task to complete a questionnaire according set timing in the active care plan and time has come to complete the task.
Frequency	Frequency determined by the timings defined in the care plan.

Preconditions

1. Patient has an active care plan with prescribed questionnaire activity.
2. The questionnaire is available from PEP system.

Minimal Postconditions

1. None.

Success Postconditions

1. Care plan activity is marked as completed.
2. The completed questionnaires with answers are available for further processing and use.

Main Flow

1. User is sent a reminder of the questionnaire to be completed.
2. User logs in to PEP System and finds the task to complete the questionnaire.
3. User fills in and answers all questions.
4. The user may interrupt filling the questionnaire and return later to complete the questionnaire.
5. If questionnaire is configured to allow answer review, the user sees a summary of the questions and answers at the end of the questionnaire. The user may in this case modify and correct the answers if needed.
6. When the questionnaire is completed by the user, an event is generated and sent to C3-Cloud systems subscribing to this event.

Alternative Flows

1. Patient access user does not start to fill in the questionnaire as planned.
2. Patient access user completes the questionnaire only partially.

Open Issues

None

3.1.1.10 PEP-2.3: Notify connected systems of new and changed patient-observed data

Title	PEP-2.3: Notify connected systems of new and changed patient-observed data
Description	The PEP System can be configured to notify connected systems of the events that occur in PEP System. For each system the system administrator configures which event notifications that system wants to receive and the address of that systems endpoint listening to event notifications.
Purpose	Allow connected PEP Client Systems to react to and start processing when there is new patient-provided data in PEP System.
Information	Event subscription notification message.
Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-2.1: Measure and collect patient observation data according the timings defined in care plan PEP-2.2: Complete patient questionnaires according the timings defined in care plan

Actor(s)/Participants	PEP System, PEP Client System
Trigger	On every data event in PEP System.
Frequency	When there is a data event in PEP System.

Preconditions

1. Relevant event subscriptions have been configured in PEP System.

Minimal Postconditions

1. None.

Success Postconditions

1. Subscriber systems have received the event notification message.

Main Flow

1. PEP system triggers new or updated patient-observed data event.
2. PEP system looks up event configuration and if there are any systems subscribing to the triggered event, an event notification message is sent to all subscribing systems.

Alternative Flows

1. None

Open Issues

None.

3.1.1.11 PEP-3.1: Communicate via Safe messaging

Title	PEP-3.1: Communicate via Safe messaging
Description	Either health professional or patient access user sends a new message to the other party. The other party is notified and reads the received messages. If needed, the conversation can be continued as long as needed between the health professionals and patient access users. This use case ends when the started conversation thread is completed and closed.
Purpose	Enable improved interaction between patients and their carers using text.
Information	Safe messages exchanged between care team members and patient.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	Care Team Members/Health professional and Patient access user.
Trigger	Either health professional or patient access user sends a new message to the other party.
Frequency	As needed.

Preconditions

1. Safe Messaging has been activated for the care team and the patient.

Minimal Postconditions

1. None

Success Postconditions

1. Safe messaging conversation is completed and closed.

Main Flow

1. Either a health professional sends a new message to the patient or the patient to the care team.
2. The other party is notified of the new message and logs in to read the message and can act upon the message.
3. If needed the user can reply to the message and the patient and the professionals can continue the conversation as long as needed.
4. When the active conversation is completed, the conversation thread is closed.

Alternative Flows

1. None

Open Issues

None.

3.1.1.12 PEP-3.2: Communicate via Video appointment

Title	PEP-3.2: Communicate via Video appointment
Description	Professional wants to have a video appointment with the patient to discuss about the health of the patient and other relevant matters. The professional books a video appointment for the patient. When the video appointment is due, both parties log in and join the video appointment. The participants complete the video appointment and when finished, leave the appointment. This use case ends when the participants have left the appointment and it is closed.
Purpose	Enable improved interaction between patients and their carers using video, voice and text.
Information	-
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	Care Team Members/Health professional and Patient access user.
Trigger	Professional wants to have a video appointment with the patient.
Frequency	As needed.

Preconditions

1. None.

Minimal Postconditions

1. None

Success Postconditions

2. Video appointment has been completed.

Main Flow

1. Health professional books a new video appointment for the patient.
2. When the appointment is created, a video appointment task is automatically assigned to the patient.
3. When the appointment is due, the system sends a reminder to the patient.
4. When the patient logs in, he/she sees the upcoming appointment task and can join the video appointment session.

5. The patient is now in the video appointment lobby waiting for the video appointment to start.
6. When the professional joins the video appointment, the video appointment starts.
7. When the professional and the patient are ready, the video appointment is finished and the participants leave the session.

Alternative Flows

1. Video appointment is cancelled before it is due.
2. Patient does not show up to video appointment.
3. Professional cannot make the video appointment when it is due.

Open Issues

None.

3.1.1.13 PEP-5.1: Access self-management material

Title	PEP-5.1: Access self-management material
Description	Self-management material for patients has been published to public information sites. The patient access user (patient or informal caregiver) can easily discover relevant information and access this information material.
Purpose	Enabling patients to access self-management material
Information	Self-management material
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	Patient access user.
Trigger	Patient access user wants to access self-management material.
Frequency	As needed.

Preconditions

1. The self-management material has been published to a public information site and is accessible to patients and informal caregivers.

Minimal Postconditions

1. None

Success Postconditions

1. Patient access user has successfully accessed the chosen material.

Main Flow

1. Patient access user logs in to PEP System.
2. Patient opens the information bank section and is presented with links to relevant self-management information.
3. Patient chooses which self-management material to access.

Alternative Flows

1. None.

Open Issues

None.

3.1.1.14 PEP-5.2: Subscribe to health coaching programs

Title	PEP-5.2: Subscribe to health coaching programs
Description	PEP User browses available health coaching programs and subscribes to programs relevant to the selected patient.
Purpose	Manage health coaching subscriptions of a patient.
Information	Health coaching programs and subscriptions
Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-5.3: Generate and deliver health coaching program messages to patient
Actor(s)/Participants	Patient access user.
Trigger	Patient wants to have additional guidance using automated health coaching.
Frequency	As needed.

Preconditions

1. Patient has contact information set on the communication channels used to deliver health coaching messages.

Minimal Postconditions

1. None

Success Postconditions

1. Patient health coaching subscriptions are up-to-date and receives messages from the subscribed programs.

Main Flow

1. The user opens and views the available health coaching programs.
2. The user chooses which programs to subscribe to for the patient.
3. The user completes the subscription of each program.

Alternative Flows

1. None.

Open Issues

None.

3.1.1.15 PEP-5.3: Generate and deliver health coaching program messages to patient

Title	PEP-5.3: Generate and deliver health coaching program messages to patient
Description	The Health Coaching Engine generates coaching messages to subscribers according the timings defined in each program.
Purpose	Generate and deliver health coaching messages to subscribers.
Information	Health coaching programs, subscriptions and messages

Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	Health coaching engine, PEP System
Trigger	When program subscription message generation is triggered based on the program timings.
Frequency	According the timings in the subscribed health coaching programs.

Preconditions

1. Patient has contact information set on the communication channels used to deliver health coaching messages.

Minimal Postconditions

1. None

Success Postconditions

1. Health coaching messages of subscribed coaching programs have been delivered to patient.

Main Flow

1. The health coaching engine generates messages for each program subscription according the timings defined in the program.
2. The health coaching engine generates a new message to be delivered.
3. The health coaching engine sends the message to PEP System.
4. PEP System delivers the message to the patient on the communication channel defined in the program.

Alternative Flows

1. None.

Open Issues

None.

3.1.2 Use cases related to PEP Security and Privacy

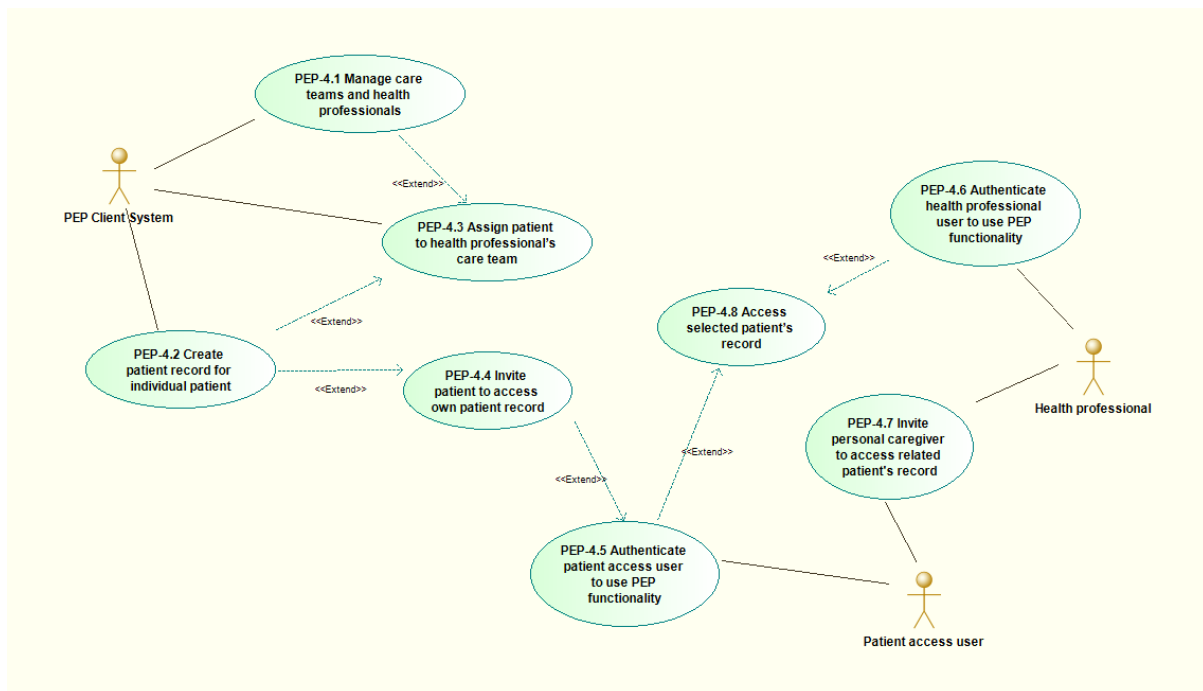


Figure 4 Use Case Diagram for PEP Security and Privacy

Use case	Primary actor
PEP-4.1: Manage care teams and health professionals	PEP System Client
PEP-4.2: Create patient record for individual patient	PEP System Client
PEP-4.3: Assign patient to health professional's care team	PEP System Client
PEP-4.4: Invite patient to access own patient record	PEP System Client
PEP-4.5: Authenticate patient access user to use PEP functionality	Patient access user
PEP-4.6: Authenticate health professional user to use PEP functionality	Health professional
PEP-4.7: Invite personal caregiver to access related patient's workspace	Health professional or patient
PEP-4.8: Access selected patient's workspace	PEP User

3.1.2.1 PEP-4.1: Manage care teams and health professionals

Title	PEP-4.1: Manage care teams and health professionals
Description	The care teams and the health professionals are synchronized from a central repository to PEP System. If no centralized repository exists, the teams and the professionals can be managed manually using the admin functionality of the PEP System.
Purpose	Create and manage teams and accounts for health professionals
Information	Care team Health professional

Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	PEP System Client
Trigger	When a care team and/or health professional is added to the C3-Cloud solution centralized repository.
Frequency	As needed.

Preconditions

1. None.

Minimal Postconditions

1. None

Success Postconditions

1. Care teams and health professional users are up-to-date and synchronized with the centralized repository.

Main Flow

1. PEP System Client creates the care teams and the health professional users using the available service APIs.

Alternative Flows

1. Care teams and health professional are created manually in PEP system.

Open Issues

None.

3.1.2.2 PEP-4.2: Create patient record for individual patient

Title	PEP-4.2: Create patient record for individual patient
Description	The patient records are synchronized from a central repository to the PEP System. If no centralized repository exists, the patient records can be managed manually using the admin functionality of the PEP System.
Purpose	Create record for patient enrolled into C3-Cloud solution and enable storage of the information needed and used by PEP component for this enrolled patient.
Information	Patient record.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	PEP System Client
Trigger	When a new patient is added to the C3-Cloud solution centralized repository.
Frequency	Once per patient.

Preconditions

1. None.

Minimal Postconditions

1. None

Success Postconditions

1. Patient records are up-to-date and synchronized with the centralized repository.

Main Flow

1. PEP System Client creates the patient records using the available service APIs.

Alternative Flows

1. Patient records are created manually in PEP system.

Open Issues

- We need to decide whether the patient records will be retrieved from the local care systems. If this is the case then we can use TIS functionalities, in particular the “TIS-1: Query Patient Data” use case. Another alternative can be retrieving the care records already synchronized with C3DP, for this C3DP can open up its care records repository to PEP as APIs.
- Security and privacy concerns related with storing patient records in an external patient empowerment platform will be discussed with pilot sites and required deployment scheme and security and privacy measures will be agreed on. In any case patient data will not be shared outside the care zone of the pilot site.

3.1.2.3 PEP-4.3: Assign patient to health professional’s care team

Title	PEP-4.3: Assign patient to health professional’s care team
Description	Health professional can access the patients with whom they have a relationship via the care teams. In this use case these mappings are managed via the service APIs from a centralized repository. If no centralized repository exists, the relationships can be managed manually using the admin functionality of the PEP System.
Purpose	Authorize care team members to access the individual patient's information.
Information	Care team assignments.
Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-4.1: Manage care teams and health professionals PEP-4.2: Create patient record for individual patient
Actor(s)/Participants	PEP System Client
Trigger	When a patient is assigned to a care team in the PCPDP
Frequency	Once per care team and patient.

Preconditions

1. Patient record must exist in PEP System.
2. Care team must exist in PEP System.

Minimal Postconditions

1. None

Success Postconditions

1. Patient is assigned to care team in PEP System and the health professionals in the care team can access the patient record in PEP.

Main Flow

1. PEP System Client assigns the patient to the selected care team using the service APIs.

Alternative Flows

1. Care team and patient relationship assignments are created manually in PEP system.

Open Issues

None.

3.1.2.4 PEP-4.4: Invite patient to access own patient workspace

Title	PEP-4.4: Invite patient to access own patient workspace
Description	When a new patient is enrolled into C3-Cloud solution, the patient is invited to access the Patient Empowerment Platform. The patient opens the invitation and registers. The invitation is created automatically via service APIs when a new patient is registered in a centralized repository. If no centralized repository exists, the patient can be invited using the admin functionality of the PEP System.
Purpose	Authorize patient to register and access own workspace which enables to view his/her own EHRs.
Information	Patient access invitation.
Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-4.2: Create patient record for individual patient
Actor(s)/Participants	PEP System Client
Trigger	When a new patient is registered in the C3-Cloud solution centralized repository.
Frequency	Once per patient.

Preconditions

1. None.

Minimal Postconditions

1. None

Success Postconditions

1. None

Main Flow

1. An invitation to access PEP System is sent to the patient.
2. The patient opens the invitation and registers to PEP System.

Alternative Flows

1. Patient access invitations are done manually in PEP system.

Open Issues

None.

3.1.2.5 PEP-4.5: Authenticate patient access user to use PEP functionality

Title	PEP-4.5: Authenticate patient access user to use PEP functionality
Description	When the patient access user wants to use the PEP functionality, the user logs in using the configured authentication mechanism. Upon first login, the user completes a registration form.
Purpose	Authenticating a User and starting a secure session for him/her in C3-Cloud applications.
Information	
Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-4.4: Invite patient to access own patient workspace
Actor(s)/Participants	Patient access user
Trigger	Patient access user wants to use the PEP functionality.
Frequency	Every time the patient access user uses the system.

Preconditions

1. None.

Minimal Postconditions

1. None

Success Postconditions

1. Patient access user is logged in and can access the PEP functionality.

Main Flow

1. Patient opens PEP System in browser.
2. PEP System authenticates the user using the configured mechanism.
3. If this the first login for the user, the user is redirected to a registration page.
4. After successful login the user can access the functionality and information available in PEP System.

Alternative Flows

1. None

Open Issues

None.

3.1.2.6 PEP-4.6: Authenticate health professional user to use PEP functionality

Title	PEP-4.6: Authenticate health professional user to use PEP functionality
Description	When a health professional user wants to use the PEP functionality, the user logs in using the configured authentication mechanism.
Purpose	Authenticating a User and starting a secure session for him/her in C3-Cloud applications.
Information	

Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-4.1: Manage care teams and health professionals
Actor(s)/Participants	Health professional
Trigger	Health professional user wants to use the PEP functionality.
Frequency	Every time the health professional uses the system.

Preconditions

1. None.

Minimal Postconditions

1. None

Success Postconditions

1. Health professional is logged in and can access the PEP functionality.

Main Flow

1. Health professional opens PEP System in browser.
2. PEP System authenticates the user using the configured mechanism.
3. After successful login the user can access the functionality and information available in PEP System.

Alternative Flows

1. None

Open Issues

None.

3.1.2.7 PEP-4.7: Invite personal caregiver to access related patient's workspace

Title	PEP-4.7: Invite personal caregiver to access related patient's workspace
Description	The health professionals and/or the patient can invite personal caregivers to help the patient and to act on behalf of the patient. An invitation is sent to the personal caregiver, who can use the invitation to register. After registration, the personal caregiver can log in and act on behalf of the patient.
Purpose	Authorize informal caregiver to register and access selected patient's workspace.
Information	Patient access user invitation.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	Health Professional. Patient.
Trigger	Health professional or the patient wants to give access to an informal caregiver.
Frequency	Once per invited informal caregiver

Preconditions

1. None.

Minimal Postconditions

1. None

Success Postconditions

1. Informal caregiver has registered and can log in to PEP System.

Main Flow

1. Health professional or the patient sends an invitation to the informal caregiver.
2. The informal caregiver opens the invitation and registers to PEP System.

Alternative Flows

1. None

Open Issues

None.

3.1.2.8 PEP-4.8: Access selected patient's workspace

Title	PEP-4.8: Access selected patient's workspace
Description	The user has logged in and has selected the patient from the set of patient's the user is authorized to access. The user opens the patient specific workspace to use the available functionality.
Purpose	Enable health professional to access a patient's workspace for which the health professional has been authorized.
Information	-
Parent	-
Included sub-use cases	-
Extended sub-use cases	PEP-4.5: Authenticate patient access user to use PEP functionality PEP-4.6: Authenticate health professional user to use PEP functionality
Actor(s)/Participants	PEP User (either Patient access user or Expert).
Trigger	Health professional or the patient wants to give access to a personal caregiver.
Frequency	Once per invited personal caregiver

Preconditions

1. User has logged in to PEP System.

Minimal Postconditions

1. None

Success Postconditions

1. User has access to the functionality and information that the user's roles is authorized to access.

Main Flow

1. The PEP User selects the patient and can access the PEP information and functionality of the selected patient.

Alternative Flows

1. None

Open Issues

None.

3.2 Use Cases for Technical Interoperability Suite

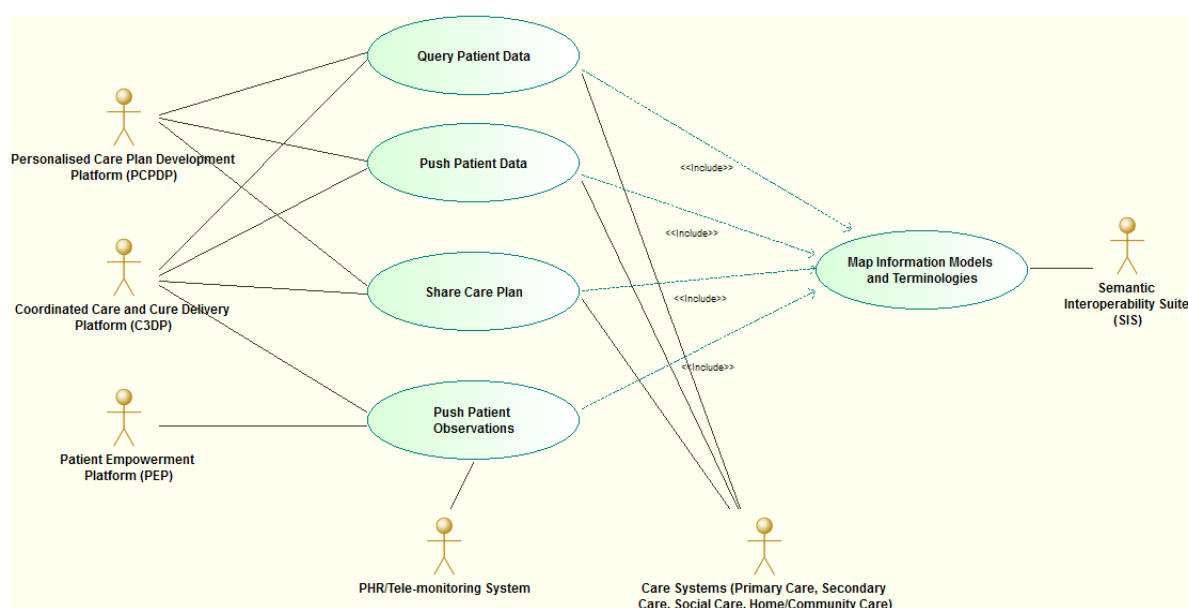


Figure 5 Use Case Diagram for Technical Interoperability Suite

Five use cases have been identified for the Technical Interoperability Platform, which are:

- TIS-1: Query Patient Data
- TIS-2: Share Care Plan
- TIS-3: Push Patient Observations
- TIS-4: Map Information Models and Terminologies
- TIS-5: Push Patient Data

The following metadata is applicable for all the use cases defined in this section related with enabling technical interoperability, and hence will not be repeated in each use case definition:

Domain	Intra-organisational/Inter-organisational Care Data Access
Scale	Regional
Business Case	Technical interoperability platform enables health data sharing between C3-Cloud high level components, including information systems of local care providers and tele-monitoring devices, in order to support integrated care plan development, care plan progress monitoring and evaluation, as well as patient engagement across multiple care settings.
Context	Interoperability Middleware

3.2.1 TIS-1: Query Patient Data

Title	TIS-1: Query Patient Data
Description	This use case queries and extracts patient data from participant care systems (including primary care, secondary care, social care, home/community care).

Purpose	So C3-Cloud system components PCPDP and C3DP can get updates on patient status and use the information to create care plan, update care plan, and monitoring care plan execution progress during the process of care plan creation and execution.
Information	Clinical documents captured as part of clinical workflows (e.g. visit summary, consultation note, operative note, discharge summary, etc.) Discrete data elements in care records
Parent	-
Included sub-use cases	TIS-4: Map Information Models and Terminologies
Extended sub-use cases	-
Scope	Technical Interoperability Platform
Actor(s)	Personalised Care Plan Development Platform (PCPDP) Coordinated Care and Cure Delivery Platform (C3DP) Care Systems (Primary Care, Secondary Care, Social Care, Home/Community Care)
Trigger	Triggered by PCPDP or C3DP to get update on patient status
Frequency	When PCPDP or C3DP need to update on patient status

Preconditions

1. A care system's information system is integrated with the technical interoperability platform.
2. Organisational policies are in place to allow patient data to be shared between the care system's information system and C3-Cloud.
3. Security mechanisms are established between the care system's information system and C3-Cloud high level components to authenticate and authorize the request, audit the access, and protect data transport.
4. Use of specific patient information models and terminologies are agreed on between PCPDP or C3DP and the technical interoperability platform.

Minimal Postconditions

1. PCPDP or C3DP are informed of the querying patient data request outcome, whether the request succeeds or fails.

Success Postconditions

1. Patient data of the specifically requested patient are retrieved from the care system.
2. The retrieved patient data are received and saved by PCPDP or C3DP.

Main Flow

1. C3-Cloud PCPDP or C3DP requests the technical interoperability platform to retrieve patient data for a specific patient from a care system's information system.
2. The technical interoperability platform sends a request to the care system's information system for the patient data.
3. The care system's information system retrieves the patient data and sends it to the technical interoperability platform.
4. The technical interoperability platform transforms the received patient data into a unified format and maps the terminology codes being used in the source system to codes which have been selected to use by PCPDP or C3DP via the use case "TIS-4: Map Information Models and Terminologies".
5. The technical interoperability platform sends the transformed patient data which are in the unified format and terminology to PCPDP or C3DP.
6. PCPDP or C3DP receives and saves the patient data.

Alternative Flows

3a. Request rejected

1. The care system's information system rejects the request because the patient data are not allowed to be shared
2. The technical interoperability platform notifies PCPDP or C3DP of the rejection.

3b. Data not available

1. The care system's information system cannot find the requested data for the patient.
2. The technical interoperability platform notifies PCPDP or C3DP of the failure.

3c. System failure

1. The care system's information system fails to serve the request because of internal technical issues.
2. The technical interoperability platform notifies PCPDP or C3DP of the failure.

Notes

This use case assumes a “pull” model for patient data sharing between C3-Cloud and care systems, where the process is initiated by C3-Cloud. TIS-5 adds a “push” model for data sharing.

3.2.2 TIS-2: Share Care Plan

Title	TIS-2: Share Care Plan
Description	This use case sends the integrated care plan created or updated by C3-Cloud to participant care systems (including primary care, secondary care, social care, home/community care) for execution.
Purpose	So the participant care systems can execute the integrated care plan created/updated by the MDT team via PCPDP or C3DP.
Information	Care Plans
Parent	-
Included sub-use cases	TIS-4: Map Information Models and Terminologies
Extended sub-use cases	-
Scope	Technical Interoperability Platform
Actor(s)	Personalised Care Plan Development Platform (PCPDP) Coordinated Care and Cure Delivery Platform (C3DP) Care Systems (Primary Care, Secondary Care, Social Care, Home/Community Care)
Trigger	Triggered by PCPDP or C3DP to send care plans to care systems
Frequency	When PCPDP or C3DP need to send care plans for execution by care systems

Preconditions

1. A care system is integrated with the technical interoperability platform.
2. Organisational policies are in place to allow care plan to be shared between C3-Cloud and the care system.
3. Security mechanisms are established between the care system and C3-Cloud to authenticate and authorize the request, audit the access, and protect data transport.
4. Use of specific patient information models and terminologies are agreed on between PCPDP or C3DP and the technical interoperability platform.

Minimal Postconditions

1. PCPDP or C3DP are informed of the sharing care plan request outcome, whether the request succeeds or fails.

Success Postconditions

1. The care plan for the specifically requested patient is accepted by the care system.

Main Flow

1. C3-Cloud PCPDP or C3DP requests the technical interoperability platform to send care plan for a specific patient to a care system.
2. The technical interoperability platform transforms the care plan which is in the unified format into the care system compatible format and maps the terminology codes in the care plan to codes used by the receiving care system via the use case “TIS-4: Map Information Models and Terminologies”.
3. The technical interoperability platform sends the transformed care plan to the care system.
4. The care system confirms its receipt of the care plan.
5. The technical interoperability platform notifies PCPDP or C3DP that the care plan has been successfully accepted by the care system.

Alternative Flows

- 4a. Care plan rejected
 1. The care system rejects the care plan request either because the request is not authorised or the content of care plan is not recognised.
 2. The technical interoperability platform notifies PCPDP or C3DP of the rejection.
- 4b. Patient not found
 1. The care system cannot find the requested patient.
 2. The technical interoperability platform notifies PCPDP or C3DP of the failure.
- 4c. System failure
 1. The care system fails to serve the request because of internal technical issues.
 2. The technical interoperability platform notifies PCPDP or C3DP of the failure.

Notes

This use case assumes care systems are able to execute C3-Cloud care plans. If the local care system cannot execute the plan in an automated manner, C3-Cloud care team members may need to manually implement the plan through the local EHR interface.

3.2.3 TIS-3: Push Patient Observations

Title	TIS-3: Push Patient Observations
Description	This use case pushes patient observations collected by a participant tele-monitoring system/PHR to C3-Cloud PEP or C3DP.
Purpose	So C3-Cloud PEP or C3DP can monitor and assess patient risks.
Information	Patient observations collected by tele-monitoring or PHR
Parent	-
Included sub-use cases	TIS-4: Map Information Models and Terminologies

Extended sub-use cases	-
Scope	Technical Interoperability Platform
Actor(s)	PHR/Tele-monitoring System Patient Empowerment Platform (PEP) Coordinated Care and Cure Delivery Platform (C3DP)
Trigger	Triggered by PHR/Tele-monitoring
Frequency	When PHR/Tele-monitoring receives update on patient observations

Preconditions

1. A PHR/Tele-monitoring System is integrated with the technical interoperability platform.
2. Organisational policies are in place to allow patient data to be shared between the PHR/Tele-monitoring system and C3-Cloud.
3. Security mechanisms are established between the PHR/Tele-monitoring system and C3-Cloud to authenticate and authorize the request, audit the access, and protect data transport.
4. Use of specific patient information models and terminologies are agreed on between PEP or C3DP and the technical interoperability platform.

Minimal Postconditions

1. The operation of pushing patient observations is audited, whether the operation succeeds or fails.

Success Postconditions

1. Patient observation data are received and saved by PEP or C3DP.

Main Flow

1. PHR/Tele-monitoring System sends the technical interoperability platform patient observation data for a specific patient.
2. The technical interoperability platform transforms the received patient data into a unified format and maps the terminology codes being used in the source system to codes which have been selected to use by PEP or C3DP via the use case “TIS-4: Map Information Models and Terminologies”.
3. The technical interoperability platform sends the transformed patient data which are in the unified format and terminology to PEP or C3DP.
4. PEP or C3DP receives and saves the patient data.
5. The technical interoperability platform notifies the PHR/Tele-monitoring System that the patient data has been successfully accepted by PEP or C3DP.

Alternative Flows

3a. System failure

1. PEP or C3DP fails to serve the request because of internal technical issues.
2. The technical interoperability platform notifies PHR/Tele-monitoring System of the failure.

Open Issues

None.

3.2.4 TIS-4: Map Information Models and Terminologies

Title	TIS-4: Map Information Models and Terminologies
Description	Care systems have diverse implementations of patient information models and coding schemes. This use case uses the semantic interoperability platform to map information

	models and terminologies for patient data and care plan between C3-Cloud and care systems.
Purpose	So C3-Cloud system components PCPDP, C3DP and PEP can operate on unified information model and terminologies.
Information	Clinical documents captured as part of clinical workflows (e.g. visit summary, consultation note, operative note, discharge summary, etc) Discrete data elements in care records Patient observations collected by PHR or tele-monitoring systems Healthcare terminologies Care Plan
Parent	-
Included sub-use cases	
Extended sub-use cases	-
Scope	Technical Interoperability Platform
Actor(s)	Semantic Interoperability Platform
Trigger	Triggered by the use case TIS-1 Query Patient Data, the use case TIS-2 Share Care Plan, the use case TIS-3 Push Patient Observations, or the use case TIS-5 Push Patient Data
Frequency	When the use cases TIS-1, TIS-2, and TIS-3, and TIS-5 are triggered

Preconditions

1. Use of specific information models and terminologies are agreed on between PCPDP, C3DP or PEP and the technical interoperability platform.
2. Information model mappings are available in the semantic interoperability platform.
3. Terminology mappings are available in the semantic interoperability platform.

Minimal Postconditions

1. The semantic interoperability platform notifies whether the mapping request succeeds or fails.

Success Postconditions

- a1. The patient data received from a care system or tele-monitoring system are transformed into the unified format processable by PCPDP, C3DP or PEP.
- a2. The terminology codes in source patient data are mapped to C3-Cloud selected terminology codes.
- b1. The care plan received from PCPDP or C3DP is transformed into the format processable by the target care system.
- b2. The terminology codes in the care plan are mapped to care system terminology codes.

Main Flow

1. The technical interoperability platform requests the semantic interoperability platform to map patient data including codes to the C3-Cloud format and codes, or the technical interoperability platform requests the semantic interoperability platform to map C3-Cloud care plan including codes to the specific format and codes required by a target care system.
2. The semantic interoperability platform converts the format and codes as requested.

Alternative Flows

- 2a. The semantic interoperability platform fails to convert either the format or the codes.

Open Issues

None.

3.2.5 TIS-5: Push Patient Data

Title	TIS-5: Push Patient Data
Description	This use case pushes patient data from participant care systems (including primary care, secondary care, social care, home/community care) to C3-Cloud.
Purpose	C3-Cloud system components PCPDP and C3DP can receive updates on patient status and use the information to create care plan, update care plan, and monitoring care plan execution progress during the process of care plan creation and execution.
Information	Clinical documents captured as part of clinical workflows (e.g. visit summary, consultation note, operative note, discharge summary, etc.) Discrete data elements in care records
Parent	-
Included sub-use cases	TIS-4: Map Information Models and Terminologies
Extended sub-use cases	-
Scope	Technical Interoperability Platform
Actor(s)	Personalised Care Plan Development Platform (PCPDP) Coordinated Care and Cure Delivery Platform (C3DP) Care Systems (Primary Care, Secondary Care, Social Care, Home/Community Care)
Trigger	Triggered by Care Systems to send update on patient status
Frequency	When a requested clinical document is generated or when patient care records are updated during clinical encounters.

Preconditions

1. A care system is integrated with the technical interoperability platform.
2. Organisational policies are in place to allow patient data to be shared between the care system and C3-Cloud.
3. Triggers have been set up in care systems to send patient data when a requested clinical event happens.
4. Security mechanisms are established between the care system and C3-Cloud to authenticate and authorize the request, audit the access, and protect data transport.
5. Use of specific patient information models and terminologies are agreed on between PCPDP or C3DP and the technical interoperability platform.

Minimal Postconditions

1. The operation of pushing patient data is audited, whether the operation succeeds or fails.

Success Postconditions

1. The patient data are received and saved by PCPDP or C3DP.

Main Flow

1. The trigger in a local care system is activated.
2. The local care system requests the technical interoperability platform to send patient data for a specific patient to PCPDP or C3DP.
3. The technical interoperability platform transforms the received patient data into a unified format and maps the terminology codes being used by the source system to codes which have been selected to use by PCPDP or C3DP via the use case “TIS-4: Map Information Models and Terminologies”.

4. The technical interoperability platform sends the transformed patient data which are in the unified format and terminology to PCPDP or C3DP.
5. PCPDP or C3DP receives and saves the patient data.
6. The technical interoperability platform notifies the local care system that the patient data has been successfully accepted by PCPDP or C3DP.

Alternative Flows

3a. System failure

1. PCPDP or C3DP fails to serve the request because of internal technical issues.
2. The technical interoperability platform notifies the local care system of the failure.

Notes

This use case assumes the local care system is able to set triggers on clinical workflow events so the operation of sending patient data can be activated when the requested clinical documents or patient data elements are available. If a care system cannot set triggers, C3-Cloud will have to fall back onto TIS-1 to query patient data.

3.3 Use Cases for Semantic Interoperability Suite

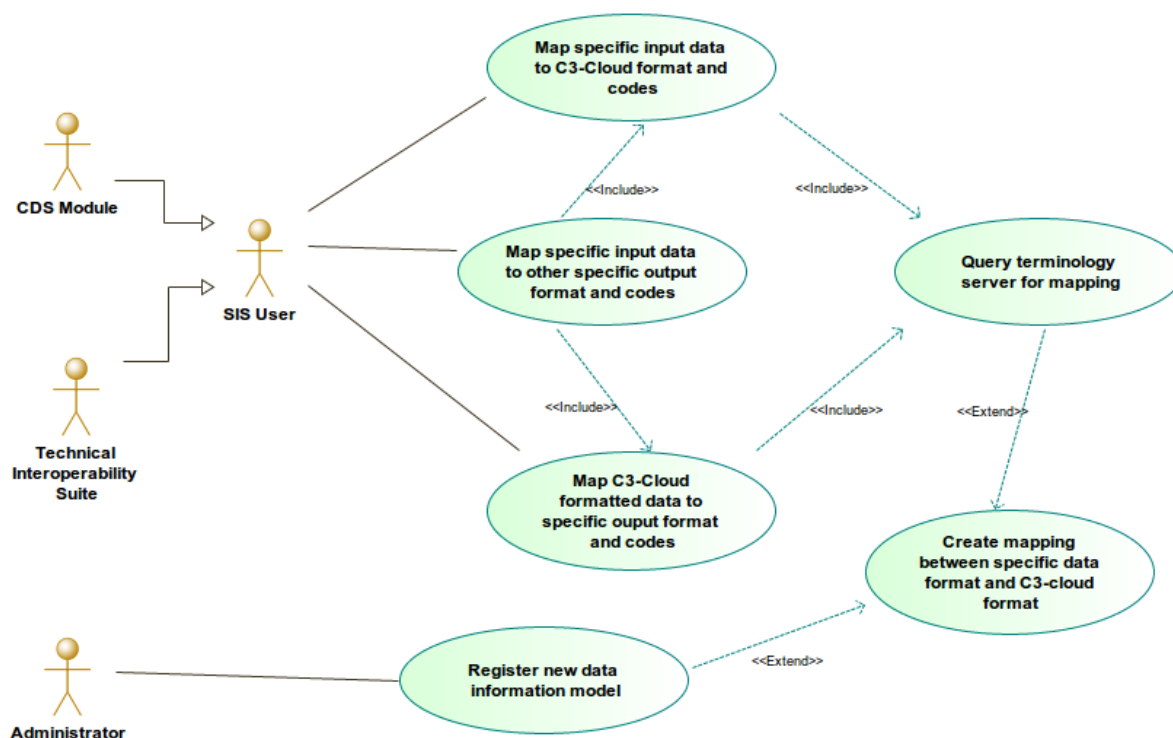


Figure 6 Use Case Diagram for Semantic Interoperability Suite

The following metadata is applicable for all the use cases defined in this section related with the semantic interoperability platform, and hence will not be repeated in each use case definition:

Domain	Intra-organisational/Inter-organisational Care Data Access
Scale	Cross-border/Regional
Business Case	Handle structural mappings among different information models and resolve semantic mismatches due to use of different terminology systems and different

	compositional aggregations to represent the same clinical concept
Context	Interoperability Middleware

3.3.1 SIS-1: Map specific input data to C3-Cloud format and codes

Title	SIS-1: Map specific input data to C3-Cloud format and codes
Description	The semantic interoperability suite maps data from a target system with specific format and codes to the C3-Cloud unified format and codes (HL7 FHIR). .
Purpose	Request the mapping of care data in a specific format to the C3-Cloud interoperability format.
Information	The input data for mapping.
Included sub-use cases	SIS-4: Query terminology server for mapping
Extended sub-use cases	-
Actor(s)/Participants	SIS User (CDS Modules / TIS)
Trigger	Triggered by the Technical Interoperability Suite or a CDS Module.
Frequency	When a semantic mapping is requested per Technical Interoperability Suite or a CDS Module from a specific format to C3-Cloud format.

Preconditions

1. Information model source is provided by the SIS user and the terminology source used is notified.
2. The data to map is provided by the SIS user.

Minimal Postconditions

None.

Success Postconditions

1. The specific data in input are transformed into HL7 FHIR resources (C3-Cloud internal format).
2. The specific terminology codes in input are mapped to C3-Cloud terminology codes.

Main Flow

1. SIS receive a mapping request from the Technical Interoperability Suite or a CDS Module.
2. The Terminology server is queried for mapping from input terminology.
3. Data are converted to C3-Cloud format.
4. Data are returned as a result.

Alternative Flows

- 3a. Source terminology is not known by the Terminology server.
 1. Mapping fails, querier is notified.
- 4a. Source information model is not registered.
 1. Mapping fails, querier is notified.

Open Issues

None.

3.3.2 SIS-2: Map C3-Cloud formatted data to specific output format and codes

Title	SIS-2: Map C3-Cloud formatted data to specific output format and codes
Description	The semantic interoperability suite maps C3-Cloud data from the core system to a target system with specific format and codes.
Purpose	Request the mapping of C3-Cloud formatted care data to a specific format.
Information	The data to convert.
Parent	-
Included sub-use cases	SIS-4: Query terminology server for mapping
Extended sub-use cases	-
Actor(s)/Participants	SIS User (CDS Modules / TIS)
Trigger	Triggered by the Technical Interoperability Suite or a CDS Module.
Frequency	When a semantic mapping is requested per Technical Interoperability Suite or a CDS Module from C3-Cloud format to a specific format.

Preconditions

1. Information model output is provided by the SIS user and the terminology to use in output is notified.
2. The data to map is provided by the SIS user.

Minimal Postconditions

None.

Success Postconditions

1. The C3-Cloud data in input are transformed into the specific data format.
2. The C3-Cloud terminology codes in input are mapped to the specific terminology codes.

Main Flow

1. SIS receive a mapping request form the Technical Interoperability Suite or a CDS Module.
2. The Terminology server is queried for mapping to output terminology.
3. Data are converted to output format.
4. Data are returned as a result.

Alternative Flows

- 3a. Output terminology is not known by the Terminology server.
 1. Mapping fails, querier is notified.
- 4a. Output information model is not registered.
 2. Mapping fails, querier is notified.

Open Issues

None.

3.3.3 SIS-3: Map specific input data to other specific output format and codes

Title	SIS-3: Map specific input data to other specific output format and codes
Description	The semantic interoperability suite maps data from a target system with specific format and codes to another target system with another specific format and codes.
Purpose	Request the mapping of care data in a specific format to other specific format.
Information	The data to convert.
Parent	-
Included sub-use cases	SIS-1: Map specific input data to C3-Cloud format and codes SIS-2: Map C3-Cloud formatted data to specific output format and codes
Extended sub-use cases	-
Actor(s)/Participants	SIS User (CDS Modules / TIS)
Trigger	Triggered by the Technical Interoperability Suite or a CDS Module.
Frequency	When a semantic mapping is requested per Technical Interoperability Suite or a CDS Module from a specific format to C3-Cloud format.

Preconditions

1. Information model source and destination are provided by the SIS user, as well as terminology used in input and terminology to use in output.

Minimal Postconditions

None.

Success Postconditions

1. The specific data in input are transformed into the specific data format in output.
2. The specific terminology codes in input are mapped to the specific terminology codes in output.

Main Flow

1. SIS receive a mapping request from the Technical Interoperability Suite or a CDS Module.
2. Input data are mapped to C3-Cloud format and codes (see SIS-1).
3. Resulting data are mapped to output format and codes (see SIS-2).
4. Data are returned as a result.

Alternative Flows

- 3a. Mapping to C3-Cloud format and codes has failed.
 1. Mapping fails, querier is notified.
- 4a. Mapping to output format and codes has failed.
 3. Mapping fails, querier is notified.

Open Issues

None.

3.3.4 SIS-4: Query terminology server for mapping

Title	SIS-4: Query terminology server for mapping
Description	The semantic interoperability suite access to its mapping information related to a specific data source terminology to map it to C3-Cloud terminology.
Purpose	Perform a mapping of a concept between the C3-Cloud format and a specific format
Information	The information data to map.
Parent	-
Included sub-use cases	-
Extended sub-use cases	SIS-5: Create mapping between specific data format and C3-cloud format
Actor(s)/Participants	Semantic Interoperability Suite
Trigger	Triggered by a mapping request.
Frequency	When a semantic mapping is requested per Technical Interoperability Suite or a CDS Module from a specific format to C3-Cloud format.

Preconditions

1. The terminology to use in is notified.

Minimal Postconditions

Success Postconditions

1. Mapping codes are returned.

Main Flow

1. A terminology codes mapping is requested, between C3-Cloud core terminology and a given terminology.
2. Codes are translated.

Alternative Flows

- 2a. No mapping is known for the given terminology.
 1. Mapping fails, querier is notified.

Open Issues

C3-Cloud terminology has to be defined.

3.3.5 SIS-5: Create mapping between specific data format and C3-cloud format

Title	SIS-5: Create mapping between specific data format and C3-Cloud format
Description	An administrator provides a mapping between a specific data source and the C3-Cloud data format.
Purpose	Provide and make available mapping for a new data source format.
Information	The semantic mapping related to the data format.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	Administrator
Trigger	Triggered by an administrator when a new data format is registered.
Frequency	When a new data format is registered.

Preconditions

1. The terminology to register in is notified.

Minimal Postconditions

None.

Success Postconditions

1. The terminology mapping is stored.
2. Administrator is notified.

Main Flow

1. Administrator register a new terminology to be used in C3-Cloud.
2. A terminology code mapping matrix is provided.
3. The matrix is stored as a mapping to this terminology.

Alternative Flows

- 2a. Related terminology is already registered, the new mapping provided override the previous one.

Open Issues

None.

3.3.6 SIS-6: Register new data information model

Title	SIS-6: Register new data information model
Description	An administrator provides new data information model to be used in mapping from and to C3-Cloud data format.
Purpose	Register a new care data format.
Information	The related data information model.
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Actor(s)/Participants	Administrator
Trigger	Triggered by an administrator when a new data format is registered.
Frequency	When a new data source format is registered.

Preconditions

1. The information model to register in is specified.

Minimal Postconditions

None.

Success Postconditions

1. The information model is stored.
2. Administrator is notified.

Main Flow

1. Administrator register a new information model to be used in C3-Cloud.
2. A parsing definition is provided.
3. The definition is stored for this information model.

Alternative Flows

- 2a. Related information model is already registered, the new definition provided override the previous one.

Open Issues

It's not clear for us by now if terminology used is linked to information model, or if this two components of the mapping (information model and terminology) are independent and multiples combinations are possible. For now, the second option is described, information model used and terminology used are two distinct information of a source data.

3.4 Use Cases for Security and Privacy Suite

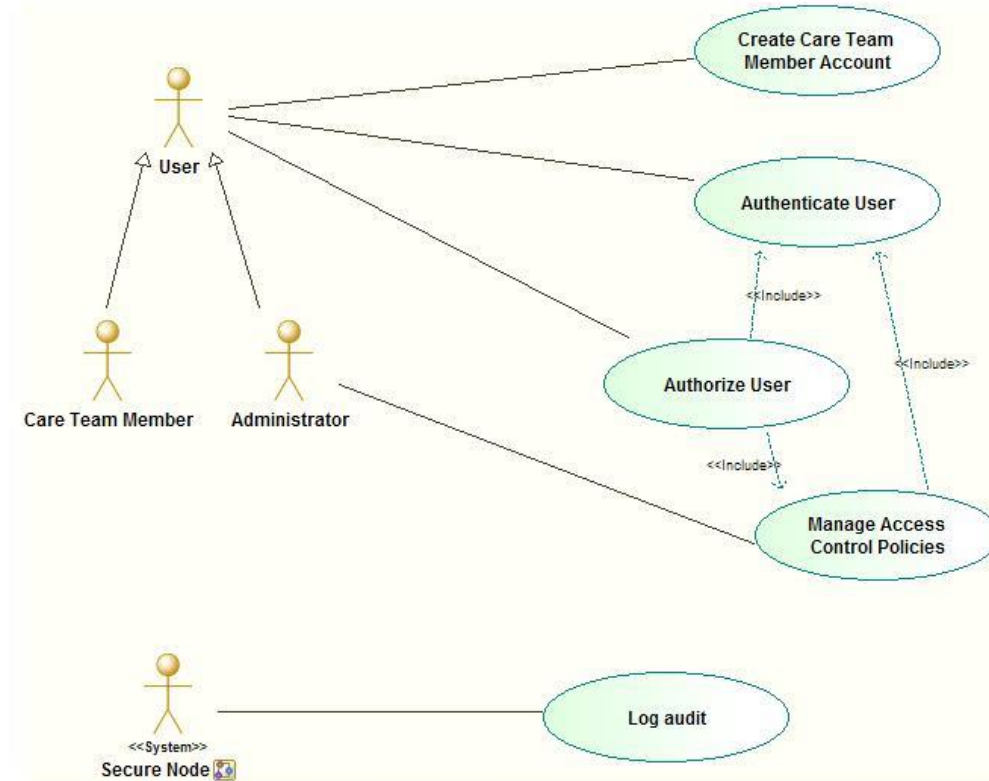


Figure 7 Use Case Diagram for Security and Privacy Suite

Five use cases have been identified for the Security and Privacy Suite of C3-Cloud. These are:

- SPS-1: Create Care Team Member Account
- SPS-2: Authenticate User
- SPS-3: Authorise User
- SPS-4: Manage Access Control Policies
- SPS-5: Log Audit

The following metadata is applicable for all the use cases defined in this section related with the security and privacy of sensitive personal data, and hence will not be repeated in each use case definition:

Domain	Security and privacy of sensitive personal data
Scale	Regional
Business Case	Guaranteeing 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 audited properly.
Context	Currently, user authentication and authorisation are usually managed within institutions, and they are limited to be applied in regional settings. Similarly, auditing of all transactions in a regional setting from a centralised location is not possible either.

3.4.1 SPS-1: Create Care Team Member Account

Title	SPS-1: Create Care Team Member Account
Description	A user account for a new Care Team Member, who is not member of an organisation identity provider system of which is already integrated with the C3-Cloud applications, is created to be used for login to Personalised Care Plan Development Platform (PCPDP) and Coordinated Care and Cure Delivery Platform (C3DP). Normally, Care Team Members such as GPs, specialists or nurses will continue using their business user accounts thanks to the integration to be achieved between their organisation's identity provider system (e.g. LDAP, Active Directory) and C3-Cloud Security and Privacy Suite. Those users will not need to create new user accounts. Therefore, this use case is for possible Care Team Members that do not have such business accounts, or their organisation's identity provider is somehow not integrated with C3-Cloud.
Purpose	Creating a user account for a new Care Team Member without an account linked with the C3-Cloud system.
Information	Care Team Member user account data
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Security and Privacy Suite Personalised Care Plan Development Platform Coordinated Care and Cure Delivery Platform
Actor(s)	Care Team Member Administrator
Trigger	A new Care Team Member, without a business user account or whose organisation's identity provider system (e.g. LDAP, Active Directory) is not integrated with C3-Cloud, joins a care team
Frequency	Whenever such a new Care Team Member joins a care team

Preconditions

1. Candidate Care Team Member does not already have a valid user account to be used in C3-Cloud applications.
2. Candidate Care Team Member does not have a business user account, or his/her organisation's identity provider system is somehow not integrated with C3-Cloud.
3. Candidate Care Team Member has a valid email address.

Minimal Postconditions

1. Candidate Care Team Member is informed about the outcome of the user account creation request, whether it is approved or not.

Success Postconditions

1. A new user account is created for the Care Team Member.
2. Care Team Member's registration data is stored in the internal Identity Provider System of the C3-Cloud Security and Privacy Suite.

Main Flow

1. Candidate Care Team Member navigates to the user registration page of the C3-Cloud Security and Privacy Suite from Personalised Care Plan Development Platform (PCPDP) or Coordinated Care and Cure Delivery Platform (C3DP).
2. Candidate Care Team Member provides the necessary credentials (name, surname, email address, password, phone number, role, etc.) for registration.
3. Candidate Care Team Member clicks the register button.
4. C3-Cloud Security and Privacy Suite informs the Administrator about user account registration request via an email.
5. Administrator reviews and approves the request via C3-Cloud Security and Privacy Suite.
6. C3-Cloud Security and Privacy Suite sends an email to the Care Team Member's registered email address for the approval of registration.
7. Care Team Member opens his/her email account and clicks on the link in the received email and approves the registration.

Alternative Flows

- 5.1. Administrator reviews the registration request, but does not approve due to invalid or missing data.
- 5.2. C3-Cloud Security and Privacy Suite sends an email to the Care Team Member's registered email address informing the rejection of registration request.

Open Issues

None.

3.4.2 SPS-2: Authenticate User

Title	SPS-2: Authenticate User
Description	A Care Team Member or an Administrator is signing in to the C3-Cloud system to use Personalised Care Plan Development Platform (PCPDP) or Coordinated Care and Cure Delivery Platform (C3DP). Through enabling a single sign-on mechanism, the users will be able to use C3-Cloud applications by using a single account, which is indeed the business account they use daily in their organisations (exceptional users are registered through the previous use case). <u>Note:</u> Patient user account management and authentications are handled through the Patient Empowerment Framework.
Purpose	Authenticating a Care Team Member or an Administrator and starting a secure session for him/her in C3-Cloud applications.
Information	User account data
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Security and Privacy Suite Personalised Care Plan Development Platform Coordinated Care and Cure Delivery Platform
Actor(s)	Care Team Member Administrator
Trigger	A notification to a Care Team Member about an update in the care plan of one of his/her patients, or manually with his/her own decision to check the care plan / status of a

	patient. Similarly, a notification to the Administrator about a system request / update, or manually.
Frequency	Every system access when previous session is expired

Preconditions

1. User has a valid C3-Cloud account.

Minimal Postconditions

1. User is informed about the outcome of the sign-in operation, whether it is successful or not.

Success Postconditions

1. User is authenticated and logged on the C3-Cloud system, and ready to use the corresponding C3-Cloud application.

Main Flow

1. User opens the C3-Cloud application of interest, i.e. Personalised Care Plan Development Platform (PCPDP) or Coordinated Care and Cure Delivery Platform (C3DP).
2. User clicks on his/her identity provider (i.e. associated organisation) among a list of identity providers displayed on the log on page provided by C3-Cloud Security and Privacy Suite.
3. User is forwarded to his/her identity provider's sign in page.
4. User enters his/her credentials and clicks sign in.
5. The identity provider authenticates the user and provides the authentication response to the C3-Cloud application of interest (i.e. relying party)
6. The authenticated User is navigated to the user interface of the corresponding C3-Cloud application.

Alternative Flows

- 5.1. The identity provider does not authenticate the user with the provided credentials.
- 5.2. The user is informed about the negative outcome.

Open Issues

None.

3.4.3 SPS-3: Authorise User

Title	SPS-3: Authorise User
Description	A Care Team Member or an Administrator is trying to perform a CRUD (Create, Read, Update, Delete) operation on a specific resource, such as updating the care plan of a patient, through the Personalised Care Plan Development Platform (PCPDP) or Coordinated Care and Cure Delivery Platform (C3DP). This use case ensures that the User is authorised to perform that specific operation on a specific resource.
Purpose	Guaranteeing that no unauthorised user is able to access or modify sensitive data.
Information	User account data, resource metadata, type of operation, access control policies
Parent	-
Included sub-use cases	SPS-2: Authenticate User SPS-4: Manage Access Control Policies

Extended sub-use cases	-
Scope	Security and Privacy Suite Personalised Care Plan Development Platform Coordinated Care and Cure Delivery Platform
Actor(s)	Care Team Member Administrator
Trigger	A notification to a Care Team Member about an update in the care plan of one of his/her patients, or manually with his/her own decision to check the care plan / status of a patient. Similarly, a notification to the Administrator about a system request / update, or manually.
Frequency	Every system access when previous session is expired

Preconditions

1. User is already authenticated.
2. Access control policies are already defined through the SPS-4: Manage Access Control Policies.

Minimal Postconditions

1. User is informed about the outcome of the operation attempt, whether it is successful or not.

Success Postconditions

1. User is authorised to perform the operation he/she wants through the C3-Cloud application of interest.

Main Flow

1. User tries to perform a CRUD operation on a specific resource via Personalised Care Plan Development Platform (PCPDP) or Coordinated Care and Cure Delivery Platform (C3DP).
2. C3-Cloud application of interest requests any additional attribute of the User, which is necessary to decide on the authorisation to perform the operation, from his/her Identity Provider.
3. Identity Provider provides the requested attributes to the C3-Cloud application acting as the relying party.
4. C3-Cloud application of interest provides the User attributes and information about the requested resource and operation to the Authorisation Manager of the Security and Privacy Suite.
5. Acting as the Policy Decision Point, the Authorisation Manager checks the User attributes and requested resource and operation against the access control policies in its database.
6. The Authorisation Manager approves the request of the User and sends the positive result to the C3-Cloud application of interest (i.e. relying party).
7. User seamlessly performs his/her operation.

Alternative Flows

- 6.1. The Authorisation Manager does not authorise the access request of the User due to missing or insufficient credentials.
- 6.2. The user is informed about the negative outcome.

Open Issues

None.

3.4.4 SPS-4: Manage Access Control Policies

Title	SPS-4: Manage Access Control Policies
Description	The Administrator manages access control policies through the Authorisation Manager of the C3-Cloud Security and Privacy Suite. These policies are applied within the Personalised Care Plan Development Platform (PCPDP) or Coordinated Care and Cure Delivery Platform (C3DP) while granting authorisations to users for specific operations. Permission definitions can be role-based (e.g. nurse, GP, specialist) and assigned to types of resources (e.g. care plan, referral note, calendar) and operations (e.g. create, read, update, delete).
Purpose	Providing a dynamic mechanism for management of the access control policies, instead of static rules hard-coded in application source code.
Information	Access control policy
Parent	-
Included sub-use cases	SPS-2: Authenticate User
Extended sub-use cases	-
Scope	Security and Privacy Suite
Actor(s)	Administrator
Trigger	With the will of the Administrator at any time or in case of a privacy breach detection
Frequency	At first setup, and then whenever there is a need to update access control policies

Preconditions

1. Administrator is authenticated.

Minimal Postconditions

1. Administrator is informed about the update operation of the access control policies, whether the operation is successful or not.

Success Postconditions

1. Access control policies are successfully updated and are ready to be used in further authorisation decisions.

Main Flow

1. Administrator lists access control policies through the user interface of the Authorisation Manager of the C3-Cloud Security and Privacy Suite.
2. Administrator decides to update an existing policy.
3. Access control rules in the selected policy document are displayed to the Administrator.
4. Administrator defines new rules and/or updates existing rules by specifying the necessary roles (e.g. nurse, GP, specialist), types of resources (e.g. care plan, referral note, calendar) and operations (e.g. create, read, update, delete).
5. Administrator saves the changes in the policy.
6. Authorisation Manager reflects those changes in its database.
7. Authorisation Manager informs the Administrator about the outcome of the save operation.

Alternative Flows

- 2.1. Administrator decides to create a policy document from scratch.
- 2.2. Continue from step 4 in the main flow.

Open Issues

None.

3.4.5 SPS-5: Log Audit

Title	SPS-5: Log Audit
Description	This use case is for auditing all kinds of interactions in/out any data provider system and data requester system in the overall C3-Cloud environment.
Purpose	Ensuring that all data exchange between C3-Cloud applications is audited appropriately.
Information	Audit trail record
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Security and Privacy Suite
Actor(s)	Secure Node (i.e. all C3-Cloud applications and external data sources communicating with each other)
Trigger	Whenever a clinical data exchange is done between a data provider system and data requestor system.
Frequency	Whenever a clinical data exchange is done between a data provider system and data requestor system.

Preconditions

1. An Audit Record Repository (ARR) is setup, which accepts standards based (e.g. IHE ATNA Profile) audit messages.
2. Secure Node has established a secure communication with the Audit Record Repository.

Minimal Postconditions

1. Audit Record Repository notifies the result of the operation to Secure Node.

Success Postconditions

1. Audit records are successfully saved to Audit Record Repository and available for viewing in ARR User Interface.

Main Flow

1. Following a clinical data exchange with another C3-Cloud application or external data source (e.g. EHR System), Secure Node extracts relevant data from the transaction and creates an audit message by using these data.
2. Secure Node sends the audit message to the Audit Record Repository.
3. Audit Record Repository saves the audit message.
4. Audit Record Repository informs Secure Node about the result of the save operation.

Alternative Flows

- 3.1. Audit Record Repository is not able to process the audit log it receives.
- 3.2. Audit Record Repository informs the Secure Node about the problem with an error report.

Open Issues

The deployment sites for Audit Record Repository will be decided by pilot sites. It is usually deployed at local care zones, e.g. inside firewalls of care sites. As it will contain information related with more than one care site, it can be hosted by the regional authority acting as the trusted third party. To be discussed during Task 8.2.

3.5 Use Cases for Clinical Decision Support Modules

As specified in C3-Cloud Description of Action, implementation of Clinical Decision Support Modules (CDSM) shall be based on HL7 Decision Support Services (DSS) specification for delivering standards compliant DSS artefacts. In the context of HL7 DSS, a decision support service can be conceptually understood as the guardian of one or more modules of medical knowledge, wherein each DSS knowledge module is capable of utilizing coded patient data to arrive at machine-interpretable conclusions regarding the patient under evaluation. The scope of a typical DSS knowledge module is the assessment of a single patient in a specified topic area. The topic area may be narrow (e.g., the need for a glycated haemoglobin test for a patient with diabetes) or broad (e.g., the existence of contraindications to any medications prescribed or about to be prescribed for a patient). HL7 DSS defines a service-oriented architecture where a client system can use the HL7 DSS API to interact with any HL7 DSS compliant clinical decision support (CDS) service. However, development and deployment of knowledge modules and CDS rules are outside the scope of HL7 DSS specification. Implementation of C3-Cloud CDSM therefore needs to extend those functions defined in HL7 DSS and provides necessary support for design and authoring of knowledge modules required by C3-Cloud use cases.

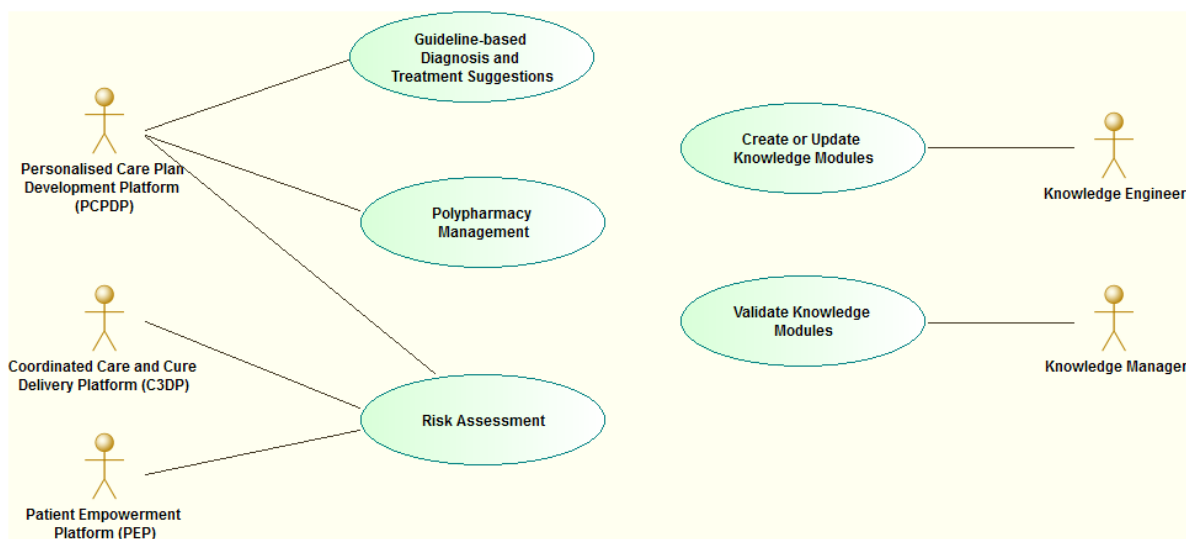


Figure 8 Use Case Diagram for Clinical Decision Support Modules

In compliance with HL7 DSS conceptual architecture, five use cases have been identified for the C3-Cloud Clinical Decision Support Modules, which are:

- CDSM-1: Create or Update Knowledge Modules
- CDSM-2: Validate Knowledge Modules
- CDSM-3: Guideline-based Diagnosis and Treatment Suggestions
- CDSM-4: Polypharmacy Management
- CDSM-5: Risk Assessment

The following metadata is applicable for all the use cases defined in this section related with clinical decision support modules, and hence will not be repeated in each use case definition:

Domain	Clinical Decision Support
Scale	Regional
Business Case	Clinical decision support modules (CDSM) provide guideline based alerts, reminders or suggestions to support clinical pathways, and also implement widely accepted polypharmacy criteria and risk assessment algorithms to support care plan reconciliation and patient risk stratification.
Context	Clinical Decision Support

3.5.1 CDSM-1: Create and Update Knowledge Modules

Title	CDSM-1: Create and Update Knowledge Modules
Description	This use case creates or updates the DSS knowledge modules.
Purpose	So C3-Cloud system components PCPDP, C3DP and PEP can use the knowledge modules for CDS evaluation.
Information	Clinical guidelines Polypharmacy criteria Risk assessment algorithms (Note: In the context of HL7 DSS, CDS rules are organized as knowledge modules. So depending on the specific use case, C3-Cloud could have one or many DSS knowledge modules to cover each guideline, criteria or algorithm, or could have a comprehensive knowledge module to cover all guidelines, criteria and algorithms (if theoretically possible))
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Clinical Decision Support
Actor(s)	Knowledge Engineer
Trigger	Triggered by Knowledge Engineer to create or update a knowledge module.
Frequency	When a new knowledge module needs to be deployed or an existing knowledge module needs to be updated.

Preconditions

1. Knowledge engineer has been authorised to create or update knowledge modules.

Minimal Postconditions

1. Knowledge engineer is informed whether the operation succeeds or fails.

Success Postconditions

1. Knowledge module is created or updated.

Main Flow

1. Knowledge engineer signs into the system.
2. Knowledge engineer
 - a. Creates new module
 - b. Opens an existing module and updates
3. Knowledge engineer saves the module
4. Knowledge engineer signs out.

Alternative Flows

- 3a. Knowledge engineer cannot save the module because system fails.

Open Issues

None.

3.5.2 CDSM-2: Validate Knowledge Modules

Title	CDSM-2: Validate Knowledge Modules
Description	This use case validates a new or updated CDS knowledge module.
Purpose	Ensure the knowledge module is safe to use.
Information	Clinical guidelines Polypharmacy criteria Risk assessment algorithms
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Clinical Decision Support
Actor(s)	Knowledge Manager
Trigger	Triggered by Knowledge Manager to review and validate a knowledge module.
Frequency	When a new knowledge module is created or an old knowledge module is updated.

Preconditions

1. A knowledge module is created or updated.
2. The knowledge module has not been approved to use.

Minimal Postconditions

1. The validation operation is recorded.

Success Postconditions

1. Knowledge module is validated and approved to use.

Main Flow

1. Knowledge Manager reviews and tests the knowledge module.
2. Knowledge Manager confirms the module is valid and safe to use.
3. Knowledge Manager approves the module to be used in production.

Alternative Flows

- 2a. Knowledge Manager suggests the module is invalid and unsafe to use.

Open Issues

None.

3.5.3 CDSM-3: Guideline-based Diagnosis and Treatment Suggestions

Title	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions
Description	This use case provides diagnosis and treatment suggestions based on clinical guidelines.
Purpose	Enable C3-Cloud PCPDP to use the suggestions to create personalised care plan.
Information	Clinical guidelines
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Clinical Decision Support
Actor(s)	Personalised Care Plan Development Platform (PCPDP)
Trigger	Triggered by PCPDP to get CDS suggestions on a patient.
Frequency	When PCPDP creates or updates patient care plan.

Preconditions

1. A knowledge module encoding the requested guideline is created.
2. Patient information requested by the knowledge module

Minimal Postconditions

1. PCPDP is informed whether the evaluation succeeds or fails.

Success Postconditions

1. PCPDP receives the CDS suggestions.

Main Flow

1. PCPDP requests the decision support system to evaluate a patient's condition and make diagnostic/treatment suggestions based on clinical guidelines.
2. PCPDP sends the decision support system the patient information and indicates which knowledge module to use.
3. Decision support system evaluates the patient information using the designated knowledge module.
4. Decision support system sends PCPDP the evaluation result.

Alternative Flows

- 3a. Knowledge module invalid
 1. Decision support system cannot evaluate the patient because the knowledge module is invalid to use.

2. Decision support system notifies PCPDP the error.

3b. No suggestions

1. Decision support system evaluates the patient information but is unable to make any suggestion based on patient's condition and knowledge rules.
2. Decision support system notifies PCPDP no suggestions were made.

Open Issues

None.

3.5.4 CDSM-4: Polypharmacy Management

Title	CDSM-4: Polypharmacy Management
Description	This use case detects polypharmacy issues in the care plan and suggest optimisations.
Purpose	So C3-Cloud PCPDP is alerted to polypharmacy issues and use the suggestions to update the care plan.
Information	Patient Data Polypharmacy Criteria Knowledge Modules Medication Reconciliation Suggestions
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Clinical Decision Support
Actor(s)	Personalised Care Plan Development Platform (PCPDP)
Trigger	Triggered by PCPDP to get Polypharmacy suggestions on a care plan.
Frequency	When PCPDP creates or updates patient care plan.

Preconditions

1. A knowledge module encoding the requested polypharmacy evaluation is created.
2. Patient information and treatment plan requested by the knowledge module is available.

Minimal Postconditions

1. PCPDP is informed whether the evaluation succeeds or fails.

Success Postconditions

1. PCPDP receives the polypharmacy suggestions.

Main Flow

1. PCPDP requests the decision support system to detect polypharmacy issues in a patient's treatment plan.
2. PCPDP sends the decision support system the patient information and his/her treatment plan, and indicates which knowledge module to use.
3. Decision support system evaluates the patient treatment plan using the designated knowledge module.
4. Decision support system sends PCPDP the evaluation result.

Alternative Flows

3a. Knowledge module invalid

1. Decision support system cannot evaluate the patient because the knowledge module is invalid to use.
2. Decision support system notifies PCPDP the error.

3b. No issues

1. Decision support system evaluates the patient information but detects no issues based on patient's information and knowledge rules.
2. Decision support system notifies PCPDP no issues were detected.

Open Issues

None.

3.5.5 CDSM-5: Risk Assessment

Title	CDSM-5: Risk Assessment
Description	This use case assesses patient's current condition and make risk predictions.
Purpose	So C3-Cloud C3DP or PEP can use the risk predictions to monitor patients.
Information	Patient Data Risk Assessment Knowledge Modules Risk Predictions
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Clinical Decision Support
Actor(s)	Coordinated Care and Cure Delivery Platform (C3DP) Patient Empowerment Platform (PEP)
Trigger	Triggered by C3DP or PEP to assess a patient.
Frequency	When C3DP or PEP receive update on patient's condition.

Preconditions

1. A knowledge module encoding the risk calculation is created.
2. Patient information requested by the knowledge module is available.

Minimal Postconditions

1. C3DP or PEP is informed whether the evaluation succeeds or fails.

Success Postconditions

1. C3DP or PEP receives the risk assessment result.

Main Flow

1. C3DP or PEP request the decision support system to calculate a patient's risk.
2. C3DP or PEP send the decision support system the patient information and indicate which knowledge module to use.

3. Decision support system evaluates the patient information using the designated knowledge module.
4. Decision support system sends C3DP or PEP the evaluation result.

Alternative Flows

3a. Knowledge module invalid

1. Decision support system cannot evaluate the patient because the knowledge module is invalid to use.
2. Decision support system notifies C3DP or PEP the error.

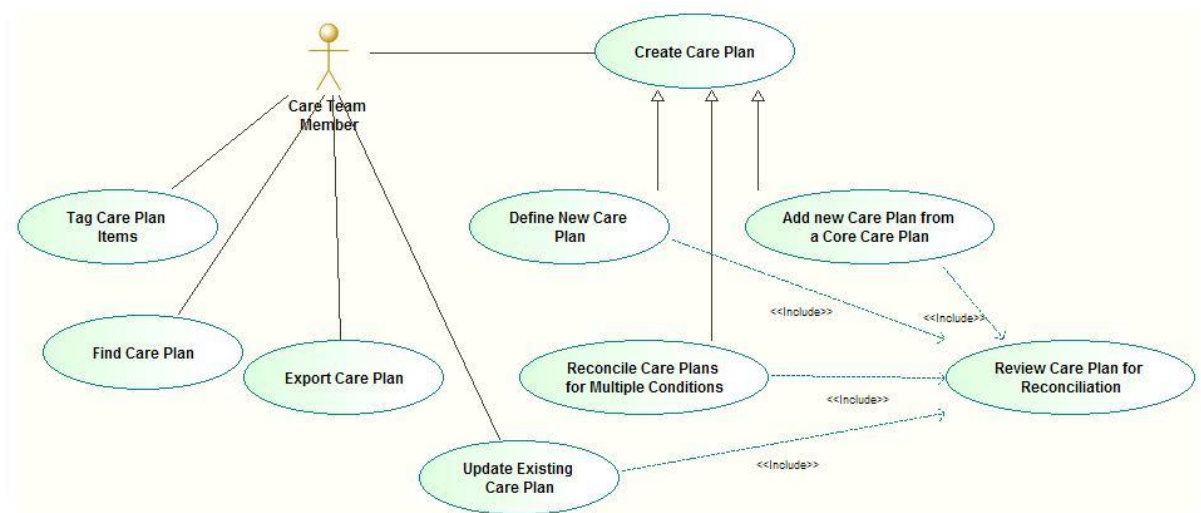
3b. Patient information missing

1. Decision support system cannot evaluate the patient because requested patient information is missing.
2. Decision support system notifies C3DP or PEP the error.

Open Issues

None.

3.6 Use Cases for Personalised Care Plan Development Platform



Ten use cases have been identified for the Personalized Care Plan Development Platform of C3-Cloud. These are:

- PCPDP-1: Create Care Plan
- PCPDP-2: Add new Care Plan from a Core Care Plan
- PCPDP-3: Define new Care Plan
- PCPDP-4: Update Existing Care Plan
- PCPDP-5: Review Care Plan for Reconciliation
- PCPDP-6: Reconcile Care Plans for Multiple Conditions
- PCPDP-7: Find Care Plan
- PCPDP-8: Tag Care Plan Items
- PCPDP-9: Export Care Plan
- PCPDP-10: Import Care Plan

The following metadata is applicable for all the use cases defined in this section related with the creation and update of a care plan by multidisciplinary care team members, and hence will not be repeated in each use case definition:

Domain	Long term care of patients with chronic conditions
Scale	Intra-hospital, Intra-Care Center (including acute care centers and long term care centers such as nursing homes)
Business Case	Definition and update of the care plan through a computerized tool that assists the medical practitioner through clinical decision support modules and which also facilitates collaborative authoring of care plans by multi-disciplinary care teams will enhance quality of the care given to the patients with chronic conditions, will decrease medical errors, and hence decrease the overall cost.
Context	Currently care plans are usually manually described, without the support of clinical decision support mechanisms that help the medical practitioners to efficiently specialize the care plans to the context of the patient.

3.6.1 PCPDP-1 Create Care Plan

Title	PCPDP-1: Create Care Plan
Description	Care Team Member defines a new care plan either by adapting an existing core care plan (PCPDP-2: Add New Care Plan from a Core Care Plan), or by defining a new care plan from scratch (PCPDP-3: Define New Care Plan) or by reconciling multiple care plans for addressing the needs of patients with multi-morbidity (PCPDP-6: Reconcile Care Plans for Multiple Conditions).
Purpose	Adding a new care plan for the patient
Information	Care Plan
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member
Trigger	A new care plan is needed for the patient to address a new condition
Frequency	Once after a new diagnosis is added

Note: for the details please see the following use cases:

- PCPDP-2: Add New Care Plan from a Core Care Plan
- PCPDP-3: Define New Care Plan
- PCPDP-6: Reconcile Care Plans for Multiple Conditions

3.6.2 PCPDP-2: Add New Care Plan from a Core Care Plan

Title	PCPDP-2: Add new Care Plan from a Core Care Plan
Description	Care Team Member selects the current condition of the patient, the system utilizes CDSM modules (via CDSM-3: Guideline-based Diagnosis and Treatment Suggestions) and loads a core care plan template to the Personalized Care Plan Definition Platform (PCPDP) based on the suggestions from CDSMs to customize it for the needs of the patient.
Purpose	Adding a new care plan for the patient based on the suggestions provided by guideline based decision support modules for a given condition
Information	Care Plan
Parent	PCPDP-1: Create Care Plan
Included sub-use cases	PCPDP-4: Update Existing Care Plan C3DP-12: Associate Supportive Content from Care Systems PCPDP-10: Import Care Plan C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting CDSM-5: Risk Assessment CDSM-3: Guideline-based Diagnosis and Treatment Suggestions
Extended sub-use cases	-
Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member Care systems
Trigger	A new care plan is needed for the patient to address a new condition
Frequency	Once after a new diagnosis is added

Preconditions

1. Care Team Member is authorized to create a care plan for the patient (Required Care Team Member accounts are created via “SPS-1: Create Care Team Member account”, necessary access rights are defined via “SPS-4: Manage Access Control Policies” use case, and the related Care Team Members are authenticated and authorized to use the system via “SPS-2: Authenticate User” and “SPS-3: Authorize User” use cases)
2. Clinical decision support Modules are available to suggest treatment suggestions based on clinical guidelines. These will be utilized to create the core care plan.
3. There has been an interoperability platform established to communicate with the Care Systems and to gather the machine processable clinical documents (such as Continuity of Care Document) (Though SIS (“SIS-6: Register ned data information model” and “SIS-5: Create mapping between specific data format and C3-Cloud format” use cases) and TIS Use cases)

Success Postconditions

1. Care Team Member has created a new care plan based on the guideline based goal and intervention suggestions via the PCPDP
2. Care plan is shared with Care Team Members including the Patient
3. Care Team Members are notified about the existence of new care plan

Minimal Postconditions

Main Flow

1. The patient's most recent status, that will be utilized while the care plan will be defined, are retrieved from the Care Systems and associated as supportive documents (such as continuity of care document) with the newly defined care plan via the "C3DP-12: Associate Supportive Content from Care Systems" use case (By definition this use case utilizes "TIS-1: Query Patient Data", "TIS-4: Map information Models and Terminologies" and "SIS-1: Map specific input data to C3-Cloud format and codes" use cases to retrieve and semantically mediate the data to a format that can be processed by C3DP).
2. Care Team Member selects the Condition that will be marked as the Health Concern from a list through type ahead search mechanism
- 2.1 While adding new Health Concerns, Care Team Member (Health Professional) can issue clinical decision support modules for identifying the risk score of the patient for the selected conditions via "CDSM-5: Risk Assessment" use case
3. PCPDP searches the repository of clinical guidelines, presents the list of matching ones with the selected Condition, and utilizes "CDSM-3: Guideline based Diagnosis and Treatment Suggestions" to create a core care plan based on the goal and intervention suggestions
4. PCPDP visualizes the care plan template listing the details of Goals, Interventions suggested by the CDSM services
5. Care Team Member creates a new care plan for the specific patient by updating/customizing the core care plan for the patient via the "PCPDP-4: Update Existing Care Plan" use case

Alternative Flows

Alternative Flow: Import Existing Care Plan

- 3.1 Care Team Member imports an existing care plan via the "PCPDP-10: Import Care Plan" use case

Alternative Flow: Invite to Virtual Care Review Meeting

- 1.1 Care Team Member may invite other selected Care Team Members to a Virtual Care Plan Review Meeting via "C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting" use case for collaboratively customizing the core care plan.

Open Issues

None

3.6.3 PCPDP-3: Define New Care Plan

Title	PCPDP-3: Define new Care Plan
Description	Care Team Member defines a new care plan for the patient through the Personalised Care Plan Definition Platform (PCPDP).
Purpose	Defining a new care plan for the patient

Information	Machine processable Care Plan definition
Parent	PCPDP-1: Create Care Plan
Included sub-use cases	C3DP-12: Associate Supportive Content from Care Systems C3DP-2: Invite a Care Team Member C3DP-3: Add Care Team Member PCPDP-5: Review Care Plan for Reconciliation C3DP-10: Share Care Plan with Care Team Members C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting CDSM-5: Risk Assessment CDSM-3: Guideline-based Diagnosis and Treatment suggestions
Extended sub-use cases	-
Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member Care Systems
Trigger	A new care plan is needed for the patient to address a new condition
Frequency	Once after a new diagnosis is added

Preconditions

1. Care Team Member is authorized to create a care plan for the patient (Required Care Team Member accounts are created via “SPS-1: Create Care Team Member account”, necessary access rights are defined via “SPS-4: Manage Access Control Policies” use case, and the related Care Team Members are authenticated and authorized to use the system via “SPS-2: Authenticate User” and “SPS-3: Authorize User” use cases)
2. There has been an interoperability platform established to communicate with the Care Systems and to gather the machine processable clinical documents (such as Continuity of Care Document) (Through SIS (“SIS-6: Register new data information model” and “SIS-5: Create mapping between specific data format and C3-Cloud format” use cases) and TIS Use cases)

Minimal Postconditions

1. The Care plan repository remains in a consistent state even if the operation of care plan definition is aborted or failed.

Success Postconditions

1. Care Team Member has defined a new care plan for the patient via the PCPDP, the new care plan is saved to the Care Plan repository.
2. Care plan is shared with Care Team Members including the Patient
3. Care Team Members are notified about the existence of new care plan

Main Flow

1. The patient’s most recent status, that will be utilized while the care plan will be defined, are retrieved from the Care Systems and associated supportive documents (such as continuity of care document) with the newly defined care plan via the “C3DP-12: Associate Supportive Content from Care Systems” use case. (By definition this use case utilizes “TIS-1: Query Patient Data”, “TIS-4: Map information Models and Terminologies” and “SIS-1: Map specific input data to C3-Cloud format and codes” use cases to retrieve and semantically mediate the data to a format that can be processed by C3DP).

2. Care Team Member defines the Care Team Members for the patient. When needed new members are invited to the Care Team via the “C3DP-2: Invite a Care Team Member” and added to the Care Team via the “C3DP-3: Add Care Team Member” use case once they accept the invitation. (Within the scope of this use case (C3DP-3), once the new Care Team Members are added to the care team, this information is notified to the PEP system as well via the “PEP-4.1: Manage care teams and Health professionals” and “PEP-4.3: Assign patient to health professional’s care team” use cases)
3. Care Team Member defines and adds new Health Concerns (either as active or previous conditions or as risk factors) to the care plan definition.
- 3.1 While adding new Health Concerns, Care Team Member (Health Professional) can issue clinical decision support modules for identifying the risk score of the patient for the selected conditions via “CDSM-5: Risk Assessment” use case
4. Care Team Member can utilize the clinical decision support modules that suggest goals and interventions given a health concern to be addressed based on clinical guidelines via the “CDSM-3: Guideline-based Diagnosis and Treatment suggestions” use case
5. Care Team Member defines and adds new Goals to the care plan definition and links them with the previously added Health Concerns.
6. Care Team Member defines and adds new Interventions and links them with the previously added Goals
7. Care Team Member defines the intervals for future Care Plan Review Meetings and notes them in the care plan definition
8. Care Plan is reviewed for internal inconsistencies through the “PCPDP-5: Review Care Plan for Reconciliation” use case
9. The new care plan along with the associated supportive documents is shared with the Care Team Members through “C3DP-10: Share Care Plan with Care Team Members Use Case” (which will in turn share the care plan with Patient Empowerment Platform via the “PEP-1.1-Publish active care plan to patient” use case)

Alternative Flows

Alternative Flow: Initiating Virtual Care Review Meeting to define a care plan

- 8.1 Care Team Member may invite other selected Care Team Members to a Virtual Care Plan Review Meeting via “C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting” use case

Alternative Flow: Exporting the Care Plan to share with local Care Systems

- 9.1. Care Team Member may export the care plan as a document and share it with local Care Systems via “PCPDP-9: Export Care Plan” and “TIS-2: Share Care Plan” use case. (“TIS-2: Share Care Plan” may need to mediate the C3-Cloud Care plan model to the preferred models by local Care Systems via the “TIS-4: Map information Models and Terminologies” and “SIS-2: Map C3-Cloud formatted data to specific output format and codes” use cases)

Open Issues

None.

3.6.4 PCPDP-4: Update Existing Care Plan

Title	PCPDP-4: Update Existing Care Plan
Description	Care Team Member updates an existing care plan for the patient through the Care Plan Definition Platform (PCPDP).
Parent	-

Included sub-use cases	PCPDP-5: Review Care Plan for Reconciliation C3DP-12: Associate Supportive Content from Care Systems C3DP-10: Share Care Plan with Care Team Members C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting C3DP-2: Invite a Care Team Member C3DP-3: Add Care Team Member C3DP-4: Remove Care Team Member CDSM-5: Risk Assessment CDSM-3: Guideline-based Diagnosis and Treatment suggestions
Purpose	Updating an existing care plan for the patient
Information	Care Plan
Extended sub-use cases	-
Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member
Trigger	An update in the patient's condition, goals, preferences, assessment of goals and interventions necessitates an update in the care plan.
Frequency	After each care plan review meeting and whenever triggered by a new unplanned encounter, a new patient recorded observation or a trigger from the Care Systems and/or C3DP notifying the existence of new clinical documents such as Diagnostic Reports, Referral Notes, Consult Note

Preconditions

1. Patient has an active care plan
2. A planned care plan review encounter or an unplanned encounter or a patient reported observation has resulted/revealed an update in the patient's condition, goals, preferences, assessment of goals and interventions that necessitates an update in the care plan.
3. Care Team Member is authorized to update a care plan for the patient (Required Care Team Member accounts are already created via "SPS-1: Create Care Team Member account", necessary access rights are defined via "SPS-4: Manage Access Control Policies" use case, and the related Care Team Members are authenticated and authorized to use the system via "SPS-2: Authenticate User" and "SPS-3: Authorize User" use cases)
4. There has been an interoperability platform established to communicate with the Care Systems and to gather the machine processable clinical documents (such as Continuity of Care Document) (Though SIS ("SIS-6: Register new data information model" and "SIS-5: Create mapping between specific data format and C3-Cloud format" use cases) and TIS Use cases)

Minimal Postconditions

Success Postconditions

1. Care Team Member has updated the existing care plan for the patient via the PCPDP
2. Care Team Members (including the patient) are notified about the changes to the plan

Main Flow

1. Care Team Member reviews the Care Team Members for the patient together with the patient, and if necessary adds new Care Team Members or removes existing ones if the care relationship is over (via the "C3DP-4: Remove Care Team Member" use case). When needed new members are invited to the Care Team via the "C3DP-2: Invite a Care Team Member" and added to the

Care Team via the “C3DP-3: Add Care Team Member” use case once they accept the invitation. Within the scope of this use case (C3DP-3), once the new Care Team Members are added to the care team, this information is notified to the PEP system as well via the “PEP-4.1: Manage care teams and Health professionals” and “PEP-4.3: Assign patient to health professional’s care team” use cases)

2. Care Team Member reviews the existing Health Concerns in the care plan definition and updates them if necessary. Other than the details of the specific condition/risk definitions, the Status, Effective Time, Author (Health Professional or Patient) of Health Concern, the priority assigned by the Patient or the Health Professional assigned to the Health Concern can be updated.
3. Care Team Member can add new Health concerns to the care plan definition
- 3.1 While adding new Health Concerns, Care Team Member (Health Professional) can issue clinical decision support modules for identifying the risk score of the patient for the selected conditions via “CDSM-5: Risk Assessment” use case
4. Care Team Member can utilize the clinical decision support modules that suggest goals and interventions given a health concern to be addressed based on clinical guidelines via the “CDSM-3: Guideline-based Diagnosis and Treatment suggestions” use case
5. Care Team Member reviews the existing Goals in the care plan definition and updates them if necessary.
6. Care Team Member can add new Goals to the care plan definition
7. Care Team Member can review the status of the existing ‘planned’ Interventions in the care plan definition, and based on the information received from the EHRs and the PHR of the patient, can mark the ones that have been achieved.
8. Care Team Member can define and add new planned Interventions and link them with the previously added Goals
9. Care Team Member reviews the previously set Goals, and achieved Interventions to address these goals and notes Outcome observations to indicate the progress of patient to achieve these Goals by linking them with the previously added Goals and Interventions
10. Care Team Member defines the next scheduled Care Plan Review Meetings and notes them in the care plan definition
11. Care plan is reviewed for internal inconsistencies through the “PCPDP-5: Review Care Plan for Reconciliation” use case
12. Care Team Member can optionally associate supportive documents (such as consultation note, progress note, diagnostic reports) with the newly updated care plan via the “C3DP-12: Associate Supportive Content from Care Systems” use case
13. The updated care plan along with the supportive content is shared with Care Team Members through “C3DP-10: Share Care Plan with Care Team Members” use case (which will in turn share the updated care plan with Patient Empowerment Platform via the “PEP-1.6- Update care plan” use case)

Alternative Flows

Alternative Flow: Virtual Care Plan Review Meeting

- 10.1 Care Team Member may invite other selected Care Team Members to a Virtual Care Plan Review Meeting via “C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting” use case

Alternative Flow: Care Team Negotiation initiated by the Care Team Member proposing updates

- 10.1 Care Team Member may initiate an asynchronous negotiation with Care Team Members to discuss a new proposal for updating a care plan item through the “C3DP-6: Send Message to Care Team Member(s)” use case

Alternative Flow: Care Team Negotiation initiated by the Care Team Member receiving a notification about the updated care plan

- 12.1 A Care Team Member receiving a notification that a care plan has been updated can review the updated care plan and initiate an asynchronous negotiation if s/he has a disagreement with one or more of the updated care plan items and has a “counter proposal” through the “C3DP-6: Send Message to Care Team Member(s)” use case

Open Issues

None.

3.6.5 PCPDP-5: Review Care Plan for Reconciliation

Title	PCPDP-5: Review Care Plan for Reconciliation
Description	System reviews the care plan definition with the support of auxiliary Clinical Decision Support Modules and identifies inconsistencies, duplicates, conflicts between care plan items and also with respect to Electronic Health Records of the Patient for the review of the Care Team Member (s), who reviews these results and updates the care plan accordingly through the Care Plan Definition Platform (PCPDP).
Purpose	Identifying and eliminating the inconsistencies, duplicates and conflicts in care plan definition
Information	Care Plan
Parent	-
Included sub-use cases	C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting
Extended sub-use cases	-
Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member Clinical Decision Support Modules
Trigger	This Use case is triggered by the system whenever a new care plan is created or an existing care plan is updated.
Frequency	Whenever a new care plan is created or an existing care plan is updated.

Preconditions

1. A new care plan is created or an existing care plan is updated
2. Machine Processable Electronic Health Records of the Patient (such as Continuity of Care Document, Transfer of Care Summary, Discharge Summary, Referral Summary, Consult Note) are available to Clinical Decision Support Modules (They have been imported to C3DP via “C3DP-12: Associate Supportive Content from Care Systems” use case)
3. Clinical Decision Support Modules are up and running

Minimal Postconditions

Success Postconditions

1. The inconsistencies, duplicates and conflicts in care plan definition and with respect to existing health records of the patient are identified and eliminated

Main Flow

1. PCPDP invokes the related Clinical Decision Support Modules to review the care plan definition and the existing EHR of the patient to identify missing relevant interventions in the care plan given the demographics and current conditions of the patient by utilizing “CDSM-3: Guideline-based Diagnosis and Treatment Suggestions” and “CDSM-4: Polypharmacy Management” use cases and marks them visually to present to the Care Team Member (s).
2. PCPDP invokes the related Clinical Decision Support Modules to review the care plan definition and the existing EHR of the patient to identify contraindicating interventions by utilizing “CDSM-3: Guideline-based Diagnosis and Treatment Suggestions” and “CDSM-4: Polypharmacy Management” use cases and marks them visually to present to the Care Team Member (s).
3. Care Team Member reviews the identified problems and resolves them by updating the care plan definition by using PCPDP-4: Update Care Plan

Alternative Flows

Alternative Flow: Virtual Care Plan Review Meeting

- 3.1 Care Team Member may invite other selected Care Team Members to a Virtual Care Plan Review Meeting via “C3DP-8 Invite Care Team Members to a Virtual Care Plan Review Meeting” use case to resolve the identified issues.

Open Issues

None.

3.6.6 PCPDP-6: Reconcile Care Plans for Multiple Conditions

Title	PCPDP-6: Reconcile Care Plans for Multiple Conditions
Description	Multiple care plans loaded to the systems are selected for addressing multiple conditions of the patient. System reviews the care plan definitions with the support of auxiliary Clinical Decision Support Modules and identifies inconsistencies, duplicates, conflicts between care plan items for the review of the Care Team Member(s), who reviews these results and updates the care plan accordingly through the Care Plan Definition Platform (PCPDP). It also includes reconciliation of the individual care plans prepared by the different professionals involved in the patient care (such as nursing –hospital and primary care- plans, nephrologist plan, psychiatrist plan)
Purpose	Identifying and eliminating the inconsistencies, duplicates and conflicts in multiple care plan definitions
Information	Care Plan
Parent	PCPDP-1: Create Care Plan
Included sub-use cases	CDSM-3: Guideline based Diagnosis and Treatment Suggestions C3DP-10: Share Care Plan with Care Team Members
Extended sub-use cases	-

Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member Clinical Decision Support Modules
Trigger	This use case is triggered manually whenever a new care plan is needed to be created for a patient with multimorbidity by reconciling multiple care plans designed to address different Health Concerns
Frequency	Whenever a new care plan is needed to be created for a patient with multimorbidity

Preconditions

1. Care Team Member is authorized to create a care plan for the patient (Required Care Team Member accounts are created via “SPS-1: Create Care Team Member account”, necessary access rights are defined via “SPS-4: Manage Access Control Policies” use case, and the related Care Team Members are authenticated and authorized to use the system via “SPS-2: Authenticate User” and “SPS-3: Authorize User” use cases)
2. There has been an interoperability platform established to communicate with the Care Systems and to gather the machine processable clinical documents (such as Continuity of Care Document) (Though SIS (“SIS-6: Register new data information model” and SIS-5: Create mapping between specific data format and C3-Cloud format” use cases) and TIS Use cases)
3. (Or) Multiple care plans already exist for the patient to address different Health concerns
4. Clinical Decision Support Modules are up and running

Minimal Postconditions**Success Postconditions**

1. The inconsistencies, duplicates and conflicts in the selected care plan definitions are identified and eliminated. Health Concerns, Goals and Interventions are reviewed, selected and prioritized.

Main Flow

1. Care Team Member loads suitable core care plans for the patient with multi-morbid conditions by utilizing CDSM services via CDSM-3: Guideline based Diagnosis and Treatment Suggestions use case (or selects the existing individual care plans already been defined for the patient for his individual conditions)
2. Care Team Member reviews the goals, and interventions proposed by individual care plans and selects and prioritize them.
3. PCPDP invokes the related Clinical Decision Support Modules to review the care plan definition and the existing EHR of the patient to identify missing relevant interventions in the integrated care plan given the demographics and current conditions of the patient by utilizing “CDSM-3: Guideline-based Diagnosis and Treatment Suggestions” and “CDSM-4: Polypharmacy Management” use cases and marks them visually to present to the Care Team Member (s).
4. PCPDP invokes the related Clinical Decision Support Modules to review the integrated care plan definition and the existing EHR of the patient to identify contraindicating interventions by utilizing “CDSM-3: Guideline-based Diagnosis and Treatment Suggestions” and “CDSM-4: Polypharmacy Management” use cases and marks them visually to present to the Care Team Member (s).
5. Care Team Member reviews the identified problems and resolves them by updating the care plan definition. Health Concerns, Goals and Interventions are reviewed, selected and prioritized.
6. The updated care plan is shared with Care Team Members through “C3DP-10: Share Care Plan with Care Team Members” use case (which will in turn share the care plan with Patient Empowerment Platform via the “PEP-1.1- Publish active care plan to patient” use case)

Alternative Flows

Alternative Flow: Virtual Care Plan Review Meeting

- 3.1 Care Team Member may invite other selected Care Team Members to a Virtual Care Plan Review Meeting via “C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting” use case to resolve the identified issues.

Alternative Flow: Exporting the Care Plan to share with local Care Systems

- 6.1 Care Team Member may export the care plan as a document and share it with local Care Systems via “PCPDP-9: Export Care Plan” and “TIS-2: Share Care Plan” use case. (“TIS-2: Share Care Plan” may need to mediate the C3-Cloud Care plan model to the preferred models by local Care Systems via the “TIS-4: Map information Models and Terminologies” and “SIS-2: Map C3-Cloud formatted data to specific output format and codes” use cases)

Open Issues

None.

3.6.7 PCPDP-7: Find Care Plan

Title	PCPDP-7: Find Care Plan
Description	The “Find Care Plan” capability supports the ability of Care Team Members to discover existing plans for a patient in order to make the plan accessible for reading, reviewing and changing. The resulting plans may be either active or archived.
Purpose	Locating an existing care plan for the patient
Information	Care Plan
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member
Trigger	Manual through the PCPDP
Frequency	Whenever a Care Team Member is invited to a new Care Team for a patient and wants to discover existing plans for the patient in order to make the plan accessible for reading, reviewing and changing.

Preconditions

1. Individual must either be a patient or another member of the Care Team in order to look up a plan.

Minimal Postconditions

Success Postconditions

1. Care Team Member can access the care plan for reading, reviewing and changing.

Main Flow

1. Care Team Member searches the PCPDP with Patient ID, and locates the list of care plans
2. Care Team Member chooses the active care plan for reading, reviewing and changing.

Alternative Flows

None.

Open Issues

None.

3.6.8 PCPDP-8: Tag Care Plan Items

Title	PCPDP-8: Tag Care Plan Items
Description	Care Team Member reviews the care plan definition and marks care plan items of interest for planning and discussion. As an example, these markings may indicate to follow up, to correct, to consolidate or reconcile various plan sections or items. Example Tags could be: Follow up item, Conflicting item, Duplicate item, No Longer Relevant Item, Item Review required
Purpose	Marking care plan items of interest for planning and discussion.
Information	Care Plan
Parent	-
Included sub-use cases	C3DP-10: Share Care Plan with Care Team Members C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting
Extended sub-use cases	-
Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member
Trigger	Manual through the PCPDP
Frequency	Whenever a Care Team Member is reviewing the care plan and wants to tag certain care plan items for further actions related to planning and discussion.

Preconditions

1. None.

Minimal Postconditions**Success Postconditions**

1. Selected items are tagged and if the Care Team Member chooses to do so, the annotated care plan is shared with other Care Team Members.

Main Flow

1. Care Team Member reviews a care plan definition and selects care plan items (i.e. Health Concerns, Goals, Interventions, Outcome Assessments) requiring review or follow-up
2. Care Team Member marks them by selecting from a predefined set of tags such as “Follow up item, Conflicting item, Duplicate item, No Longer Relevant Item, Item Review required”

Alternative Flows

Alternative Flow: Virtual Care Plan Review Meeting

- 2.1 Care Team Member may want to share these tags with Care Team Members, and the annotated care plan is shared with Care Team Members through “C3DP-10: Share Care Plan with Care Team Members” use case
- 2.2 Care Team Member may invite other selected Care Team Members to a Virtual Care Plan Review Meeting via “C3DP-8: Invite Care Team Members to a Virtual Care Plan Review Meeting” use case to discuss these tags

Open Issues

None.

3.6.9 PCPDP-9: Export Care Plan

Title	PCPDP-9: Export Care Plan
Description	PCPDP can create a care plan snapshot and export it as a machine processable Care Plan document such as a C-CDA Care Plan Document.
Purpose	Exporting a machine processable care plan document as a care plan snapshot
Information	Care Plan
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member
Trigger	Manual through the PCPDP
Frequency	Whenever a Care Team Member wants to share a care plan snapshot with an external system.

Preconditions

1. Care plan is in a consistent state.

Minimal Postconditions

Success Postconditions

1. A Machine Processable care plan Document is created

Main Flow

1. Care Team Member selects a care plan definition
2. Care Team Member exports a care plan snapshot as a machine processable care plan Document such as a C-CDA Care Plan Document

Alternative Flows

None.

Open Issues

- Which formats need to be supported?
 - C-CDA Care Plan Document
 - Is there a CEN document template, EN ISO 13940 seems to provide a meta model for Care Plans?
 - Any other proprietary or standard formats adopted by pilot sites?

3.6.10 PCPDP-10: Import Care Plan

Title	PCPDP-10: Import Care Plan
Description	PCPDP can import an existing care plan document represented in a machine processable format to be read, reviewed and changed by the Care Team Member.
Purpose	Importing a machine processable care plan document to PCPDP
Information	Care Plan
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Personalized Care Plan Definition Platform (PCPDP)
Actor(s)	Care Team Member
Trigger	Manual through the PCPDP
Frequency	Whenever a Care Team Member wants to import an existing care plan snapshot received from an external system to the PCPDP.

Preconditions

1. Care plan to be imported is in a machine processable care plan format that is accepted by the PCPDP.

Minimal Postconditions

Success Postconditions

1. External care plan document is imported and represented as a care plan definition in PCPDP

Main Flow

1. Care Team Member selects an external care plan document in a supported format
2. PCPDP parses the care plan document and creates a care plan definition in PCPDP

Alternative Flows

None.

Open Issues

- Which formats need to be supported?
 - C-CDA Care Plan Document
 - Is there a CEN document template, EN ISO 13940 seems to provide a meta model for Care Plans?
 - Any other proprietary or standard formats adopted by pilot sites?

3.7 Use Cases for Coordinated Care and Cure Delivery Platform

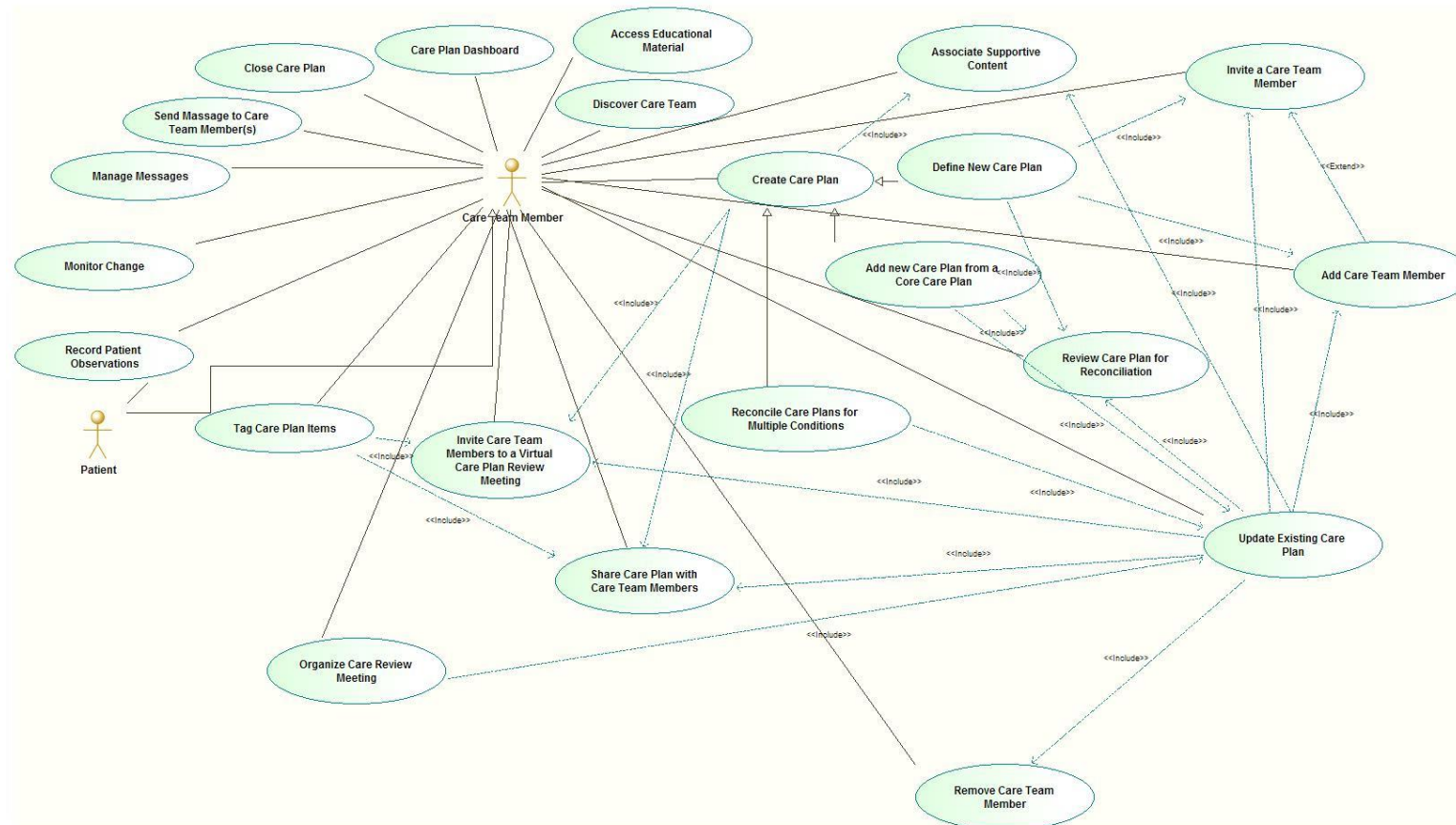


Figure 9 Use Case Diagram for C3DP

Fourteen use cases have been identified for the Coordinated Care and Cure Delivery Platform of C3-Cloud. These are:

- C3DP-1: Close Care Plan
- C3DP-2: Invite a Care Team Member
- C3DP-3: Add Care Team Member
- C3DP-4: Remove Care Team Member
- C3DP-5: Discover Care Team
- C3DP-6: Send Message to Care Team Member(s)
- C3DP-7: Manage Messages
- C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting
- C3DP-9: Organize Virtual Care Review Meeting
- C3DP-10: Share Care Plan with Care Team Members
- C3DP-11: Record Patient Observations
- C3DP-12: Associate Supportive Content
- C3DP-13: Monitor Change
- C3DP-14: Care Plan Dashboard
- C3DP-15: Access Educational Material

The following metadata is applicable for all the use cases defined in this section related with the creation and update of a care plan by multidisciplinary care team members, and hence will not be repeated in each use case definition:

Domain	Long term care of patients with chronic conditions
Scale	Intra-hospital, Intra-Care Center (including acute care centers and long term care centers such as nursing homes, and homes of the patients)
Business Case	Collaborative monitoring of the execution of care plans by multi-disciplinary care teams through a computerized tool supported with clinical decision support modules will enhance quality of the care given to the patients with multiple chronic conditions, will decrease medical errors, and hence decrease the overall cost.
Context	The current practice for collaborative management of a care plan by a multi-disciplinary care team is through physical case review meetings without support of computerized tools

3.7.1 C3DP-1: Close Care Plan

Title	C3DP-1: Close Care Plan
Description	Care Team Member marks the care plan as closed to indicate that the plan is no longer in use.

Purpose	Marking the care plan as no longer in use.
Information	Care Plan
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Manual through the C3DP
Frequency	Whenever a care plan needs to be archived as it is no longer in use (e.g. patient heals; care team member decides to create a new plan and closes an existing plan; a duplicate plan can be closed)

Preconditions

1. Patient has an active care plan.

Minimal Postconditions**Success Postconditions**

1. Care plan is marked as closed and archived.

Main Flow

1. Care Team Member selects an active care plan
2. Care Team Member marks the care plan as 'closed' to indicate it is no longer in use
3. Care Team Members receives a notification
4. Care plan is archived as an available item for future retrievals.
5. PEP is notified via the "PEP-1.7: Mark active care plan as finished" use case

Alternative Flows

None.

Open Issues

None.

3.7.2 C3DP-2: Invite a Care Team Member

Title	C3DP-2: Invite a Care Team Member
Description	An authorized Care Team Member invites an individual to participate as a collaborator in coordination of care activities of a patient
Purpose	Inviting a new Care Team Member
Information	Care Plan metadata
Parent	-

Included sub-use cases	-
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Manual through the C3DP
Frequency	Whenever a Care Team Member (Patient, Care Giver, Health Professional) requires to add another individual (another Health Professional or a Care Giver) to the care team

Preconditions

1. Patient has provided consent to invite the new Care Team Member.

Minimal Postconditions**Success Postconditions**

1. Care Team Membership invitation is received by the invitee
2. Recipient responds positive or negatively to the Care Team Membership invitation

Main Flow

1. Care Team Member selects an invitee from the repository of care givers. If person of interest is not in the list, his/her contact details are added to the system
2. A communication with the details of the request to join the specific patient's care team is prepared through the C3DP
3. Care Team Membership invitation is sent to the selected invitee.
4. The recipient responds through the link to indicate whether s/he wants to be a part of the care team

Alternative Flows

Alternative Flow: Recipient accepts the Care Team Member invitation

- 4.1 If the Recipient accepts to be a part of the care team, s/he has given the access details about the C3DP and PCPDP

Open Issues

None.

3.7.3 C3DP-3: Add Care Team Member

Title	C3DP-3: Add Care Team Member
Description	An authorized Care Team Member having administrative rights adds an individual as a Care Team Member
Purpose	Adding a new Care Team Member
Information	Care Team Member Metadata
Parent	-

Included sub-use cases	PEP-4.1: Manage care teams and Health professionals PEP-4.3: Assign patient to health professional's care team
Extended sub-use cases	C3DP-2 Invite a Care Team Member
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Manual through the C3DP
Frequency	Whenever an invitation is received, and the invitee accepts to be a Care Team Member

Preconditions

1. The new Care Team Member has already accepted the invitation to be a Care Team Member of the selected patient

Minimal Postconditions**Success Postconditions**

1. New and existing Care Team Members receive communication informing them of new membership
2. New individual joins the patient's Care Team and starts receiving change updates.

Main Flow

1. The inviting Care Team Member adds the new Care Team Member to the selected care plan definition
2. A communication with the details of the new Care Team Member is sent to patient's Care Team through the C3DP
3. The new Care Team Member joins the patient's Care Team and starts receiving change updates.
4. Once the new Care Team Members are added to the care team, this information is notified to the PEP system as well via the "PEP-4.1: Manage care teams and Health professionals" and "PEP-4.3: Assign patient to health professional's care team" use cases)

Alternative Flows

None.

Open Issues

None.

3.7.4 C3DP-4: Remove Care Team Member

Title	C3DP-4: Remove Care Team Member
Description	An authorized Care Team Member having administrative rights removes a Care Team Member from the Care Team permanently or inactivates his/her membership
Purpose	Removing a new Care Team Member
Information	Care Team Member metadata
Parent	-

Included sub-use cases	-
Extended sub-use cases	
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Manual through the C3DP
Frequency	Whenever the care relationship with a Care Team Member becomes inactive

Preconditions

1. Care Team Member becomes no longer involved with the care of the patient
2. Patient has consented for the removal/inactivation of the Care Team Member

Minimal Postconditions**Success Postconditions**

1. Inactivated and Removed Care Team Member receives communication informing him about inactivation/termination of his membership
2. Inactivated and Removed Care Team Member no longer receives change updates
3. Removed/Inactivated Care Team Member has no longer access rights to shared care plan

Main Flow

1. The authorized Care Team Member removes the new Care Team Member from the selected care plan definition
2. The removed/inactivated Care Team Member receives a notification about the operation
3. The removed/inactivated Care Team Member no longer receives change updates, nor accesses care plans of the patient.

Alternative Flows

None.

Open Issues

None.

3.7.5 C3DP-5: Discover Care Team

Title	C3DP-5: Discover Care Team
Description	A newly joined Care Team Member lists and reviews the other Care Team Members
Purpose	Learn about the members of the Care Team
Information	Care Team Member metadata
Parent	-
Included sub-use cases	-
Extended sub-use cases	

Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Manual through the C3DP
Frequency	Whenever the a newly joined Care Team Member wishes to learn about the other Care Team Members

Preconditions

1. A care team has already been established for the patient
2. The user is in the care team of the patient to be authorized to discover other care team members.

Minimal Postconditions**Success Postconditions**

1. A list of care team members and their details becomes accessible

Main Flow

1. The authorized Care Team Member searches the other members of the care team via the C3DP
2. The C3DP provides a list of care team members where their details (contact points, specialties) can be navigated.

Alternative Flows

None.

Open Issues

None.

3.7.6 C3DP-6: Send Message to Care Team Member(s)

Title	C3DP-6: Send Message to Care Team Member(s)
Description	An authorized Care Team Member can send messages to one or more Care Team Member(s) via the C3DP. This can involve initiating asynchronous messaging to negotiate about the updates in care plans.
Purpose	Electronic, asynchronous communication with Care Team Members
Information	Message
Parent	-
Included sub-use cases	-
Extended sub-use cases	
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Manual through the C3DP
Frequency	Whenever a Care Team Member wishes to asynchronously communicate with the other Care Team Members over C3DP

Preconditions

1. None.

Minimal Postconditions**Success Postconditions**

1. An acknowledgement of receipt by receiving systems
2. One or more care team members receive new message / communication

Main Flow

1. The authorized Care Team Member initiates a new messaging thread, by identifying a topic
2. Care Team Member selects the recipients of the message from the Care Team Members
3. Care Team Member composes the message content as a text message, and optionally attaching files. Messages can be optionally directly linked with Care Plan items (by tagging them when necessary as tagged as “proposal”, “reject”, “counter proposal” or “accept”).
4. Care Team Member sends the message to the selected recipients

Open Issues

None.

3.7.7 C3DP-7: Manage Messages

Title	C3DP-7: Manage Messages
Description	Care Team Members can view their messages, tag them, list them based on the tags via the C3DP
Purpose	Managing the messages received via C3DP
Information	Message
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Manual through the C3DP
Frequency	Whenever a Care Team Member wishes to go over his/her messages Whenever a notification is received indicating a new message

Preconditions

1. Care Team Member has a history of sent and received messages

Minimal Postconditions**Success Postconditions**

1. Care Team Member tags and lists his/her messages as s/he likes through the C3DP

Main Flow

1. Care Team Member can list the messages s/he received/sent/read/unread
2. Care Team Member can list the messages according to the tags s/he previously created
3. Care Team Member can list the messages s/he received from a specific Care Team/ Care Team Member
4. Care Team Member can list the messages s/he received from a specific Patient/Informal Care Giver
5. Care Team Member can list the messages s/he received related with a specific patient
6. Care Team Member can list the messages sent by the C3DP system as notifications (which are automatically tagged as “System Notifications”) such as “New Care Team Member Invitation”, “Update in the Shared Care Plan”, “New Shared Care Plan”, “Reminder for Care Plan Interventions to be carried out”
7. Care Team Member can create new tags, and can tag the messages selected by selecting from the list of tags

Alternative Flows

None.

Open Issues

None.

3.7.8 C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting

Title	C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting
Description	A Care Team Member sends an invitation to organize a joint virtual Care Plan Review Meeting by reserving a slot in another Care Team Member’s schedule
Purpose	To invite Care Team Members to joint Care Plan Review Meetings
Information	Meeting Invitation
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Manual through the C3DP
Frequency	Whenever a virtual Care Review Meeting needs to be organized.

Preconditions

1. Care Team Members need to jointly go over the care plan for discussing disagreements, reconciliation of multiple care plans or jointly design new Care Plan items

Minimal Postconditions

Success Postconditions

1. A slot in Care Team Member's schedule is reserved, and a notification is sent to inform about the invitation

Main Flow

1. An invitation for the Virtual Care Plan Review Meeting is prepared by editing the metadata and a notification is sent to the corresponding Care Team Members
2. Care Team Members decline/accept the invitation

Alternative Flows

None.

Open Issues

None.

3.7.9 C3DP-9: Organize Virtual Care Review Meeting

Title	C3DP-9: Organize Virtual Care Review Meeting
Description	<p>Care Team Members jointly review and update care plan via the C3DP and care plan is accepted by all participants</p> <p>It can be initiated as a result of a special invitation by a Care Team Member to:</p> <ul style="list-style-type: none"> * discuss the recent updates in the care plan; * collaboratively define new care plan items; * collaboratively customize a core care plan for the patient; * collaboratively handle the reconciliation to address the identified inconsistencies, duplicates, conflicts as a result of PCPDP-5: Review Care Plan for Reconciliation, PCPDP-6: Reconcile Care Plans for Multiple Conditions, or negotiation through C3DP-6: Send Message to Care Team Member(s); or as a part of the planned routine care plan review meetings to perform a joint evaluation of the ongoing care plan execution (the overall consistency, appropriateness, completeness and effectiveness of the whole plan or selected goals and interventions by considering the current status of the patient)
Purpose	To jointly review care plans
Information	Care Plan and Associated Clinical Documents
Parent	-
Included sub-use cases	PCPDP-4: Update Care Plan
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Manual through the C3DP after an invitation has been sent and accepted by Care Team Members, or automatically for routine Care Review Meetings set in the care plan definition

Frequency	Whenever a virtual Care Review Meeting needs to be organized
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Preconditions

1. Care Team Members have already accepted meeting invitation via the “C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting” use case

Minimal Postconditions**Success Postconditions**

1. Care plan has been reviewed, updated if necessary and agreed by all participants.

Main Flow

1. Care Team Members can jointly view the care plan via the C3DP
2. An audio connection is established between them
3. One of the Care Team Members is assigned as the Editor
4. Care Team Members discuss over the audio connection, while the Editor is updating the care plan when necessary (via the “PCPDP-4: Update Care Plan” use case), and all the other members can visualize the updates via the C3DP
5. Care Team Members agree on the updated/edited care plan definition

Alternative Flows

None.

Open Issues

None.

3.7.10 C3DP-10: Share Care Plan with Care Team Members

Title	C3DP-10: Share Care Plan with Care Team Members
Description	The newly defined or the updated care plan is shared with all Care Team Members including the Patient (via the Patient Empowerment Platform) along with the associated supportive content
Purpose	To synchronize the new/updated care plan definition among all the Care Team Members along with the associated supportive content
Information	Care Plan and Associated Clinical Documents
Parent	-
Included sub-use cases	PEP-1.1- Publish active care plan to patient PEP-1.6- Update Care Plan
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	PCPDP-2: Add New Care Plan from a core care plan, PCPDP-3: Define New Care Plan, PCPDP-4: Update Existing Care Plan, PCPDP-6: Reconcile Care Plans for Multiple Conditions

Frequency	Whenever a new care plan is defined or an existing care plan is updated
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Preconditions

1. A Care Team has already been established
2. A new care plan is defined or an existing care plan is updated
3. The supporting documents (if any) have already been saved to the platform via the “C3DP-12: Associate Supportive Content from Care Systems” use case

Minimal Postconditions**Success Postconditions**

1. The new/updated care plan has been shared with all Care Team Members along with the associated supporting content, and becomes accessible from their C3DP.
2. A notification is available for the recipient Care Team Members via their C3DP

Main Flow

1. The C3DP saves the newly defined or updated care plan to the shared server
2. The new/updated care plan becomes available from the C3DP systems of each Care Team Member along with the associated supporting content
3. An informative notification is sent to each Care Team Member via the messaging subsystem of C3DP as a system message
4. The care plan with is notified to the Patient Empowerment Platform either via the “PEP-1.1- Publish active care plan to patient” or via “PEP-1.6- Update Care Plan” use case depending on the fact that the care plan is a new one or an updated one.

Alternative Flows

None.

Open Issues

None.

3.7.11 C3DP-11: Record Patient Observations

Title	C3DP-11: Record Patient Observations
Description	This use case enables capturing patient made observations/assessments at any stage of the care process between Care Plan Review Meetings. These can be results of assessment scales and instruments (e.g. for activities of daily living), results of forms or questionnaires as instructed by the care plan, or notes from the patients about the realization of the interventions needed to be carried out by the patient or about the patient set goals etc. They are received from the Patient Empowerment Platform and recorded, to be reviewed by care team. A specific notification is sent to care team members who have subscribed to monitoring specific changes via the “C3DP-13: Monitor Change” use case, which can trigger the Care Team Member to update the care plan if necessary. These patient made observations are also reviewed as a part of regular routine Care Plan Review meetings.
Purpose	To capture observations/assessments made at any stage of the care process between Care Plan Review Meetings by the patient via the Patient Empowerment Platform, and record them to C3DP so that they can trigger care plan update if relevant, or can be assessed during regular Care Plan Review Meetings by the care team

Information	Patient Observation Data
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	PEP System Patient
Trigger	Patient records observations via the Patient Empowerment Platform, and these are sent to C3DP
Frequency	Whenever a new patient recorded observation is sent by the Patient Empowerment Platform

Preconditions

1. Patient is actively using the Patient Empowerment Platform
2. PEP system is configured to send notifications to C3DP about the new and updated patient observations (results of questionnaires, measurements from personal devices, flags about care plan items (goal/intervention achieved, not achieved))

Minimal Postconditions**Success Postconditions**

1. Patient recorded observations are received from PEP system (via PEP-2.3: Notify connected systems of new and changed patient-observed data) and successfully stored in C3DP platform to be reviewed by care team members
2. Special notification is sent to the care team members who have subscribed to monitoring specific changes via the “C3DP-13: Monitor Change” use case

Main Flow

1. The C3DP saves the patient recorded observations to be reviewed by care team members
2. Special notification is sent to the care team members who have subscribed to monitoring specific changes via the “C3DP-13: Monitor Change” use case

Alternative Flows*Alternative Flow: Patient Observations reviewed during regular Care Plan Review Meetings*

- 2.1 Care Team Members review the recorded observations while assessing the overall consistency, appropriateness, completeness and effectiveness of the whole plan or selected goals and interventions as a part of “C3DP-9: Organize Virtual Care Review Meeting”

Alternative Flow: Patient Observation triggers an update in the care plan

- 2.1 Care Team Member receiving notification checks the recorded observations and if necessary initiates the update of the care plan via the “PCPDP-4: Update Existing Care Plan” use case

Open Issues

None.

3.7.12 C3DP-12: Associate Supportive Content from Care Systems

Title	C3DP-12: Associate Supportive Content
Description	<p>Relevant records from the patient EHRs maintained in the respective Care Systems are recorded in the C3DP. Examples:</p> <ul style="list-style-type: none"> • Active allergies, medications, procedures, diagnostic tests from a summary of care record can be integrated to C3DP in the beginning of the care planning process • During the care of the patient, Care Team Members can create “Transfer Summary” or “Referral Note” or “Continuity of Care Document” which should be associated with the care plan, and shared among the care team members as a part of the care plan • A Care Team Member receiving the result of an important diagnostic test can change the care plan accordingly based on the new results, and needs to share this new diagnostic test result along with the updated care plan • A Care Team Member to whom the patient has just been referred to can finish his assessment, updates the care plan if needed, and shares the “Consultation Note” along with the updated care plan with the care team.
Purpose	To associate supportive historical or recent EHR records with the active care plan
Information	Clinical Documents such as Transfer Summary” or “Referral Note” or “Continuity of Care Document” and/or Patient data as observations, conditions, medications, etc.
Parent	-
Included sub-use cases	TIS-1: Query Patient Data TIS-4: Map Information Models and Terminologies TIS-5: Push Patient Data
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member Care Systems
Trigger	Manually triggered by the Care Team Member via C3DP. An internal trigger from the Care System to the Care Team Member can also trigger this.
Frequency	Whenever a new Care Team Member is invited; a new care plan is created, or a recent EHR record (such as diagnostic results) results in an update in the care plan

Preconditions

1. There has been an interoperability platform (a.k.a. Technical Interoperability Suite) established to communicate with the Care Systems and to retrieve the machine processable clinical documents (such as Transfer Summary, Discharge Summary, Continuity of Care Document, Referral Note, Consultation Note, Progress Note etc.)

Minimal Postconditions

Success Postconditions

1. The associated supportive content is saved in the system to be later shared along with the care plan via the “C3DP-10: Share Care Plan with Care Team Members” use case.

2. The associated supportive content is shared with Clinical Decision Support Modules when necessary as patient context information

Main Flow

1. The Care Team Member selects and exports the required Clinical documents from the Care Systems and imports these to the C3DP manually
2. C3DP uses “TIS-4: Map Information Models and Terminologies” use case to map the clinical document to be imported to the unified format processable by C3DP. (By definition this use case utilizes “SIS-1: Map specific input data to C3-Cloud format and codes” use case to semantically mediate the data to a format that can be processed by C3DP)
3. C3DP processes and saves the imported Clinical Documents and associates them with the active care plan with their metadata

Alternative Flows

Pull Model from the Care System

1. The Care Team Member initiates the “TIS-1: Query Patient Data” use case to retrieve the required patient data from the Care Systems in the unified format that it can process (By definition this use case utilizes “TIS-4: Map information Models and Terminologies” and “SIS-1: Map specific input data to C3-Cloud format and codes” use cases to semantically mediate the data to a format that can be processed by C3DP)
2. C3DP processes and saves the retrieved and mapped patient data/clinical documents and associates them with the active care plan with their metadata

Push Model by the Care System

1. The Care Team Member selects the required Clinical documents/patient data from the Care Systems and triggers the transfer of these to the C3DP via the Technical Interoperability Suite
3. “TIS-5: Push Patient Data” use case is triggered to receive the respective patient data and map them to the unified format processable by C3DP and pushes this data to C3DP. (By definition this use case utilizes “TIS-4: Map information Models and Terminologies” and “SIS-1: Map specific input data to C3-Cloud format and codes” use cases to semantically mediate the data to a format that can be processed by C3DP)
2. C3DP processes and saves the imported Clinical Documents/patient data and associates them with the active care plan with their metadata

Open Issues

Security and privacy concerns related with storing patient records in an external platform will be discussed with pilot sites and required deployment scheme and security and privacy measures will be agreed on. In any case patient data will not be shared outside the care zone of the pilot site.

3.7.13 C3DP-13: Monitor Change

Title	C3DP-13: Monitor Change
Description	A Care Team Member can indicate his/her desire to be alerted regarding specific changes to the care plan content especially regarding the outcomes of the interventions (such as patient reported observations via the Patient Empowerment Platform, new lab results)
Purpose	To be alerted when observations regarding the execution of care plan are notified
Information	Notification

Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member
Trigger	Care Team Member manually subscribes to receive notifications regarding specific changes to the care plan content especially regarding the outcomes of the interventions
Frequency	Once for each care plan

Preconditions

1. The Care Team Member is in the care team of the patient

Minimal Postconditions**Success Postconditions**

1. Care Team Member's subscription preference is noted in the system
2. Care Team Member is notified (alerted) whenever a specific change to the care plan content is observed especially regarding the outcomes of the interventions

Main Flow

1. The Care Team Member selects the patient and the types of events that s/he would like to subscribe via the C3DP
2. C3DP saves the subscription preferences
3. Whenever a subscribed event is notified, the Care Team Member is alerted via the messaging system.
 - 3.1 If it is a notification that needs to be delivered to the Patient, PEP is notified

Alternative Flows

None.

Note: The notification message to be sent to Care Team Member will not include any sensitive patient data. Care Team Member will be invited to C3DP to see detailed notification message.

Open Issues:

- Depending on the severity of the notification, it will be decided whether the notification will be directly delivered to the patient or via Health Professional's involvement.
- The notifications may need to be sent based on the roles of the MDT members. Based on the pilot design, a mechanism to deliver notifications based on site specific roles will need to be developed.

3.7.14 C3DP-14: Care Plan Dashboard

Title	C3DP-14: Care Plan Dashboard
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Description	This use case guides the Care Team Member to see/monitor the activities carried out during the care delivery process for a selected patient. It enables them to see the previous care plans defined, updated for the patient, patients encounters during the life time of the multi-disciplinary care delivery process, the clinical documents created in this process such as transfer of care summary, discharge summary, referral note etc. from a single dashboard.
Purpose	To support coordinated collaborative execution of collaborative care delivery process by visualizing the previous steps and results.
Information	Care Plan and Associated Clinical documents
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member (Physician in a Hospital, GP, Nurses in Nursing Facility, Patient/Care Giver)
Trigger	Manually by the care team members
Frequency	During the execution of coordinated care delivery process

Preconditions

1. A care plan, or multiple care plans have been defined for the patient
2. Patient's medical history and recent context information have already been imported to C3DP through TIS and SIS from local Care Systems and PEP
3. Care Team Member is authorized to see patient's care plan dashboard

Minimal Postconditions

1. Care Team Member accesses to the care plan dashboard through a web interface

Success Postconditions

1. Care Team Member accesses to the care plan dashboard through a web interface and can check the care plan execution history as well as patient's medical context

Main Flow

1. An authorized Care Team Member logs in to the C3DP and selects one of his/her patients
2. Care Team Member can check medical history of the patient to see recent encounters, lab results, conditions, vital sign measurements, risk assessment results
3. Care Team member can see the active and retired care plans
4. Care Team Member can see the history of actions within the lifetime of a care plan (when it has been updated, the clinical documents, information exchanged within the life time of the care plan). The responsible editors of different sections of care plan are made clear.
5. Care Team Member can see patient feedback received from the PEP

Alternative Flows

None.

Open Issues

None.

3.7.15 C3DP-15: Access Educational Material

Title	C3DP-15: Access Educational Material
Description	This use case enables the Care Team Member to access educational material regarding the care of the patient via the C3DP
Purpose	To provide access to educational material for Care Team Members.
Information	Educational Material
Parent	-
Included sub-use cases	-
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member (Physician in a Hospital, GP, Nurses in Nursing Facility, Patient/Care Giver)
Trigger	Manually by the care team members
Frequency	During the execution of coordinated care delivery process

Preconditions

1. Educational Material are prepared and made available to C3DP

Minimal Postconditions

1. Care Team Member accesses the educational material specific to their interests, and roles

Success Postconditions

1. Care Team Member accesses the educational material specific to their interests, and roles

Main Flow

1. An authorized Care Team Member logs in to the C3DP
2. Care Team Member can access educational material specialized to his/her needs over C3DP

Alternative Flows

None.

Open Issues

None.

3.7.16 C3-Cloud Super Use Cases supported by C3DP

In this section a number of super use cases are presented demonstrating how the use cases defined for all of the components can be utilized by C3DP to support execution and monitoring of care plans in collaboration with local care systems. These are:

- C3DP-16: Support Transfer of Care
- C3DP-17: Support Referral
- C3DP-18: Support Collaborative Management of Care Plan

3.7.16.1 C3DP-16: Support Transfer of Care

Title	C3DP-16: Support Transfer of Care
Description	This use case addresses the needs for complete transfer of care between care settings (for example from an acute care center such as hospital to a home care center such as nursing facility or to the home of the patient), and the exchange of care plan and supporting documents between the respective entities. As it is a super use case it will utilize the other use cases that should be issued to realize the scenario.
Purpose	To support transfer of care between care settings and joint execution of care plan
Information	Care Plan and Associated Clinical documents
Parent	-
Included sub-use cases	PCPDP-1: Create Care Plan PCPDP-4: Update Existing Care Plan C3DP-12: Associate Supportive Content from Care Systems C3DP-10: Share Care Plan with Care Team Members” C3DP-18: Support Collaborative Management of Care Plan
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member (Physician in a Hospital, GP, Nurses in Nursing Facility, Patient/Care Giver) Care Systems PEP System
Trigger	Manually by the care team in acute care centers
Frequency	Whenever a patient is needed to be discharged from an acute care center

Preconditions

1. Patient’s treatment in acute hospital stay is concluded
2. It is determined by the patient and care team in the acute care center that a care plan will be required at discharge to more fully address the complex, interrelated medical, behavioral, functional and environmental issues that will shape the patient’s post-discharge care in another facility or at home

Minimal Postconditions

Success Postconditions

1. The care plan and the associated supportive content is successfully shared between Care Team Members
2. Necessary collaboration environment has been set up for the joint execution of care plan

Main Flow

1. The Care Team Member in acute care facility (such as the attending physician in the hospital), prepares the Transition of Care information (for example as a Transfer Summary document) with the help of his Care Systems
2. The Care Team in acute care facility completes a final prioritization of the patient's health concerns, goals and proposed interventions in order to provide the receiving facility with a care plan at the time of transfer via the "PCPDP-1: Create Care Plan" use case which also includes the following important steps:
 - 2.1 The new Care Team Members in the receiving facility are invited to the Care Team and they are added to the Care Team via the "C3DP-2: Invite a Care Team Member" and "C3DP-3: Add Care Team Member" use cases.
 - 2.2 The Transition of Care information prepared as supportive content (transfer summary clinical document) is associated with care plan via the "C3DP-12: Associate Supportive Content from Care Systems" use case
 - 2.3 The finalized care plan is shared with the Care Team Members (including the GP of the Patient, Care Team Members at the Nursing Facility, the Patient and his/her Care givers via the Patient Empowerment Platform) via the "C3DP-10: Share Care Plan with Care Team Members" use case through the C3DP
3. Alternatively, if a care plan already exists, it is updated accordingly, via "PCPDP-4: Update Care Plan" use case and shared with the Care Team Members (including the GP of the Patient, Care Team Members at the Nursing Facility, the Patient and his/her Care givers via the Patient Empowerment Platform) via the "C3DP-10: Share Care Plan with Care Team Members" use case through the C3DP
4. Joint care of the patient continues routinely including this new Care Team Member in the team as well via the "C3DP-18: Support Collaborative Management of Care Plan" use case.

Alternative Flows

None.

Open Issues

None.

3.7.16.2 C3DP-17: Support Referral

Title	C3DP-17: Support Referral
Description	This use case addresses the needs for extending the care team of the patient via referrals and execution of joint care planning as a result of referrals
Purpose	Invitation of new care team members and support joint execution of care plan as a result of referrals.
Information	Care Plan and Associated Clinical documents
Parent	-
Included sub-use cases	C3DP-2: Invite a Care Team Member C3DP-3: Add Care Team Member PCPDP-4: Update Care Plan C3DP-12: Associate Supportive Content from Care Systems C3DP-10: Share Care Plan with Care Team Members

	C3DP-5: Discover Care Team PCPDP-7: Find Care Plan C3DP-18: Support Collaborative Management of Care Plan
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member (Physician in a Hospital, GP, Nurses in Nursing Facility, Patient/Care Giver) Care Systems PEP System
Trigger	Manually by the care team members
Frequency	Whenever the care of the patient needs to include another Health Professional in the scope of referrals

Preconditions

1. Patient's treatment is coordinated within the scope of an agreed care plan
2. Patient's current condition requires a referral to an additional health professional

Minimal Postconditions**Success Postconditions**

1. An additional health professional is added to the care team of the patient
2. Care plan is updated according as a result of referral and shared with care team

Main Flow

1. The authorized Care Team Member (such as the GP of the patient, Physician in the nursing facility or in the acute care center) identifies the need for a referral to another health professional
2. The authorized Care Team Member identifying the need for referral prepares the associated supportive content such as the "Referral Note" summarizing patient's current condition and the reasons for referral via his/her Care Systems
3. The health professional to whom the referral will be made is invited to the Care Team and s/he is added to the Care Team via the "C3DP-2: Invite a Care Team Member" and "C3DP-3: Add Care Team Member" use cases.
4. Care plan of the patient is updated to add this new Care Team Member (via" PCPDP-4: Update Care Plan" use case)
5. The Referral Note prepared as supportive content is associated with care plan via the "C3DP-14: Associate Supportive Content from Care Systems" use case
6. The care plan and the associated Referral note is shared with the new Care Team Member via the "C3DP-10: Share Care Plan with Care Team Members" use case through the C3DP
7. Receiving Care Team Member reviews these documents, after the respective encounter with the patient, prepares the "Consult Note" document via the EHR, and associates it with care plan via the "C3DP-12: Associate Supportive Content from Care Systems" use case
8. If necessary, receiving Care Team Member updates the care plan (via" PCPDP-4: Update Care Plan" use case) and updated care plan is shared with the Care Team Members (including the GP of the Patient, Care Team Members at the Nursing Facility, the Patient and his/her Care givers via the Patient Empowerment Platform) via the "C3DP-10: Share Care Plan with Care Team Members" use case through the C3DP
9. Joint care of the patient continues routinely including this new Care Team Member in the team as well via the "C3DP-18: Support Collaborative Management of Care Plan" use case.

Alternative Flows

- 9.1 The new Care Team Member can discover other Care Team Members (via “C3DP-5: Discover Care Team”)
- 9.2 The new Care Team Member can discover all the care plans of the patient (archived or active) via the “PCPDP-7: Find Care Plan” use case

Open Issues

None.

3.7.16.3 C3DP-18: Support Collaborative Management of Care Plan

Title	C3DP-18: Support Collaborative Management of Care Plan
Description	This use case is a super use case supporting the update of the care plan based on Patient Observations received from PEP (such as filled questionnaires, reported difficulties in achieving goals, realizing interventions, medical device observations) and planned and unplanned event in routine clinical workflow (such as encounters, transfer of care, referrals).
Purpose	Collaborative management (review, update) of care plan in response to patient observations and planned and unplanned events in clinical workflow
Information	Care Plan, Clinical Documents and Patient Observations
Parent	-
Included sub-use cases	PCPDP-4: Update Care Plan C3DP-10: Share Care Plan with Care Team Members C3DP-14: Care Plan Dashboard PCPDP-9: Tag Care Plan Items C3DP-5: Discover Care Team C3DP-6: Send Messages to Care Team Member(s) C3DP-7: Manage Messages C3DP-13: Monitor Change C3DP-9: Organize Virtual Care Review Meeting C3DP-17: Support Referral C3DP-16: Support Transfer of Care C3DP-12: Associate Supportive Content from Care Systems PEP-1.1: Publish active care plan to patient PEP-1.2: View active care plan PEP-1.3: Send care plan related treatment intervention reminder PEP-1.4: Flag care plan treatment intervention and the corresponding goals as achieved PEP-1.5: Flag care plan treatment intervention and the corresponding goals as not achieved PEP-1.7: Mark active care plan as finished PEP-2.3: Notify connected systems of new and changed patient-observed data PEP-2.2 Complete patient questionnaires according the timings defined in care plan PEP-2.1: Measure and collect patient observation data according the timings defined in care plan PEP-4.2: Create patient record for individual patient PEP-4.4: Invite patient to access own patient workspace PEP-4.5: Authenticate patient access user to use PEP functionality PEP-4.6: Authenticate health professional user to use PEP functionality PEP-4.7: Invite personal caregiver to access related patient’s workspace PEP-4.8: Access selected patient’s workspace PEP-2.3: Notify connected systems of new and changed patient-observed data PEP-3.1: Communicate via Safe messaging

	PEP-3.2: Communicate via Video appointment PEP-5.1: Access self-management material TIS-1: Query Patient Data TIS-3: Push Patient Observations C3DP-11: Record Patient Observations C3DP-1: Close Care Plan CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management CDSM-5: Risk Assessment
Extended sub-use cases	-
Scope	Coordinated Care and Cure Delivery Platform (C3DP)
Actor(s)	Care Team Member (Physician in a Hospital, GP, Nurses in Nursing Facility, Patient/Care Giver) Care Systems PEP System
Trigger	Manually by the care team members
Frequency	Continuously during the life time of a care plan

Preconditions

1. A new care plan is defined for the patient to be shared with Care Team Members
2. (Optionally) An existing care plan is updated to be shared with Care Team Members
3. Care Team Member is authorized to use the system (Required Care Team Member accounts are created via “SPS-1: Create Care Team Member account”, necessary access rights are defined via “SPS-4: Manage Access Control Policies” use case, and the related Care Team Members are authenticated and authorized to use the system via “SPS-2: Authenticate User” and “SPS-3: Authorize User” use cases)
4. There has been an interoperability platform established to communicate with the Care Systems and to gather the machine processable clinical documents (such as Continuity of Care Document) (Though SIS (“SIS-6: Register ned data information model” and “SIS-5: Create mapping between specific data format and C3-Cloud format” use cases) and TIS Use cases)

Minimal Postconditions

1. Care Plan is in a consistent state and the most recent version is always shared with all Care Team Members

Success Postconditions

1. Coordinated Care Delivery process continues execution via C3DP and PEP, by notifying Care Team Members including Health professionals and Patients and Informal Care Givers about the required actions and by updating the care plan when necessary
2. Care Plan is in a consistent state and the most recent version is always shared with all Care Team Members

Main Flow

1. The newly created or updated care plan is shared with all care team members via the “C3DP-10: Share Care Plan with Care Team Members” use case
2. The Care Team Members receiving notification about the new care plan can start using C3DP to:
 - 2.1 Examine Care Plan via “C3DP-14: Care Plan Dashboard” use case

- 2.2 Tag care plan items to be discussed, updated via the “PCPDP-9: Tag Care Plan Items” use case
- 2.3 Discover other care team members via the “C3DP-5: Discover Care Team” use case
- 2.4 Communicate with other care team members via the “C3DP-6: Send Messages to Care Team Member(s)” and “C3DP-7: Manage Messages” use cases
- 2.5 Subscribe to receive notifications regarding the specific changes to the care plan content especially regarding the outcomes of the interventions (such as patient reported observations via the Patient Empowerment Platform, new lab results) via the “C3DP-13: Monitor Change” use case
- 2.6 In case of a new Encounter (either planned or unplanned) with patient occurred, the Care Team Member updates the care plan by utilizing “PCPDP-4: Update Existing Plan” use case, and the execution of the care plan is continued from Step 1.
- 2.7 In case of routine care plan review meetings, care team members can organize virtual care team meetings via the “C3DP-9: Organize Virtual Care Review Meeting” use case, where the “PCPDP-4: Update Care Plan” use case is utilized via the online tool. Then the execution of the care plan is continued from Step 1.
- 2.8 In case of a need a referral, the “C3DP-17: Support Referral” use case Then the execution of the care plan is continued from Step 1.
- 2.9 In case of transfer of care, the “C3DP-16: Support Transfer of Care” use case Then the execution of the care plan is continued from Step 1.
- 2.10 In case of a new notification is received indicating that a new observation result (such as lab result) is available from the local Care systems via the “C3DP-12: Associate Supportive Content from Care Systems” use case (push or pull mode), the system invokes the CDSM services (poly pharmacy management, provide diagnostic and treatment suggestions, risk assessment) (via the “CDSM-3: Guideline-based Diagnosis and Treatment Suggestions”, “CDSM-4: Polypharmacy Management” and “CDSM-5: Risk Assessment” use cases) to see whether there are any inconsistencies in the care plan, missing or duplicate treatment interventions, contraindicating treatment interventions, new risks and these are notified to the care team members. Care Team member examines the new results and initiates the “PCPDP-4: Update Existing Plan” use case if necessary to update the care plan. Then the execution of the care plan is continued from Step 1.
- 3. In parallel, the newly defined Care Plan is published to PEP via the “PEP-1.1: Publish active care plan to patient”
- 3.1 Patient records are retrieved from local Care Systems (via “TIS-1: Query Patient Data” use case), and the Patient is invited to access own patient record via the “PEP-4.2: Create patient record for individual patient” and “PEP-4.4: Invite patient to access own patient workspace”. Then the patient can access his records via “PEP-4.8: Access selected patient’s workspace” use case
- 3.2 If necessary, Informal Care Givers can be invited to access patients’ records via “PEP-4.7: Invite personal caregiver to access related patient’s workspace” use case. Then after being authenticated they can access the records via the “PEP-4.5: Authenticate patient access user to use PEP functionality” and “PEP-4.8: Access selected patient’s workspace” use cases
- 3.3 Authorized Health Professionals can also access patient’s workspaces via the “PEP-4.6: Authenticate health professional user to use PEP functionality” and “PEP-4.8: Access selected patient’s workspace” use cases
- 3.4 The patient is invited to view his/her care plan via “PEP-1.2: View active care plan”
- 3.4.1 When necessary PEP system send notifications via the PEP to the patient about treatment interventions via the “PEP-1.3: Send care plan related treatment intervention reminder” use case
- 3.4.2 Patient can flag care plan goals and interventions as achieved or not achieved via the “PEP-1.4: Flag care plan treatment intervention and the corresponding goals as achieved” and “PEP-1.5: Flag care plan treatment intervention and the corresponding goals as not achieved” use cases
- 3.4.2.1 PEP system notifies the C3DP about the patient feedback via the “PEP-2.3: Notify connected systems of new and changed patient-observed data” use case

- 3.4.3 Patient completes the questionnaires related with care plan via the PEP through the “PEP-2.2 Complete patient questionnaires according the timings defined in care plan” use case
- 3.4.3.1 PEP system notifies the C3DP about the patient feedback via the “PEP-2.3: Notify connected systems of new and changed patient-observed data” use case
- 3.4.4 PEP collects the patient observations via medical devices at the set intervals specified by the care plan via the “PEP-2.1: Measure and collect patient observation data according the timings defined in care plan” use case. If required, “TIS-3: Push Patient Observations” use case is utilized as an interoperability means with medical devices.
- 3.4.4.1 PEP system notifies the C3DP about the patient feedback via the “PEP-2.3: Notify connected systems of new and changed patient-observed data” use case
- 3.4.5 Patient can communicate with Health Professionals in his/her care team via the “PEP-3.1: Communicate via Safe messaging” and “PEP-3.2: Communicate via Video appointment” use cases
- 3.4.6 Whenever requires the Patient can access training material via the “PEP-5.1: Access self-management material” use case
- 3.5 Whenever a notification about patient observations are received by C3DP via the “C3DP-11: Record Patient Observations”, first they are saved to care plan repository, then, based on the subscription configuration, if the subscription criteria holds, the subscribed Care Team Members are notified by the C3DP. The system invokes the CDSM services (poly pharmacy management, provide diagnostic and treatment suggestions, risk assessment) (via the “CDSM-3: Guideline-based Diagnosis and Treatment Suggestions”, “CDSM-4: Polypharmacy Management” and “CDSM-5: Risk Assessment” use cases) to see whether there are any inconsistencies in the care plan, missing or duplicate treatment interventions, contraindicating treatment interventions, new risks and these are notified to the care team members. Reviewing the notifications and the data, Care Team Members initiate “PCPDP-4: Update Existing Plan” use case if necessary to update the care plan. Then the execution of the care plan is continued from Step 1.
- 4. If the care of the patient is concluded, the care plan is closed via the “C3DP-1: Close Care Plan” use case, after which the care plan is marked as closed and archived, and the care team members are notified
- 4.1 PEP is notified about this via the “PEP-1.7: Mark active care plan as finished” use case

Alternative Flows

None.

Open Issues

None.

3.8 Flow Diagrams

The super use case presented in the previous section are integrating the other use cases to depict important flows of C3-Cloud system. In addition to these, a number of the other use cases in C3DP also highly utilize other use cases to realize the aimed functionality. These present important hints about how different high level components are interacting with each other within the scope of use cases.

In this section, these flows will be depicted as Activity diagrams. Unlike traditional activity diagrams, in these diagrams some of the “Activities” are modelled as other “use cases” to be able to depict the integration of use cases.

The activity diagrams of the following use cases are presented below:

- PCPDP-2: Add new Care Plan from a Core Care Plan
- PCPDP-3: Define new Care Plan
- PCPDP-4: Update Existing Care Plan

- C3DP-16: Support Transfer of Care
- C3DP-17: Support Referral
- C3DP-18: Support Collaborative Management of Care Plan

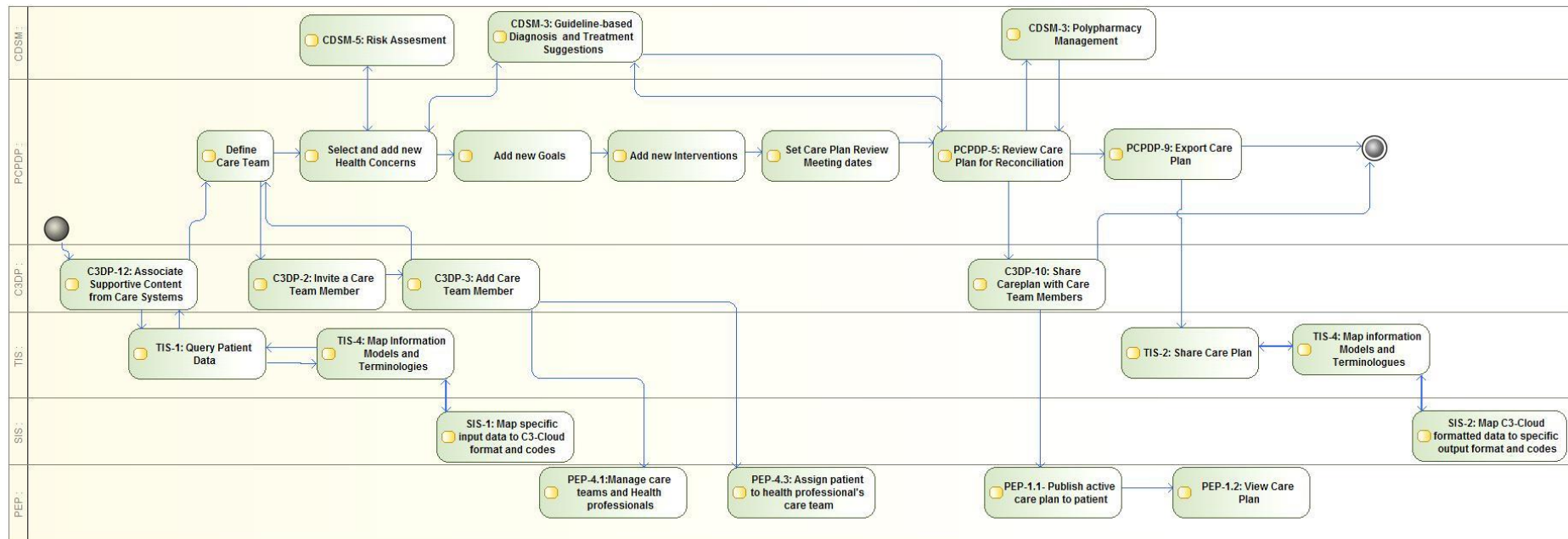


Figure 10 Activity Diagram of “PCPDP-3: Define New Care Plan” use case

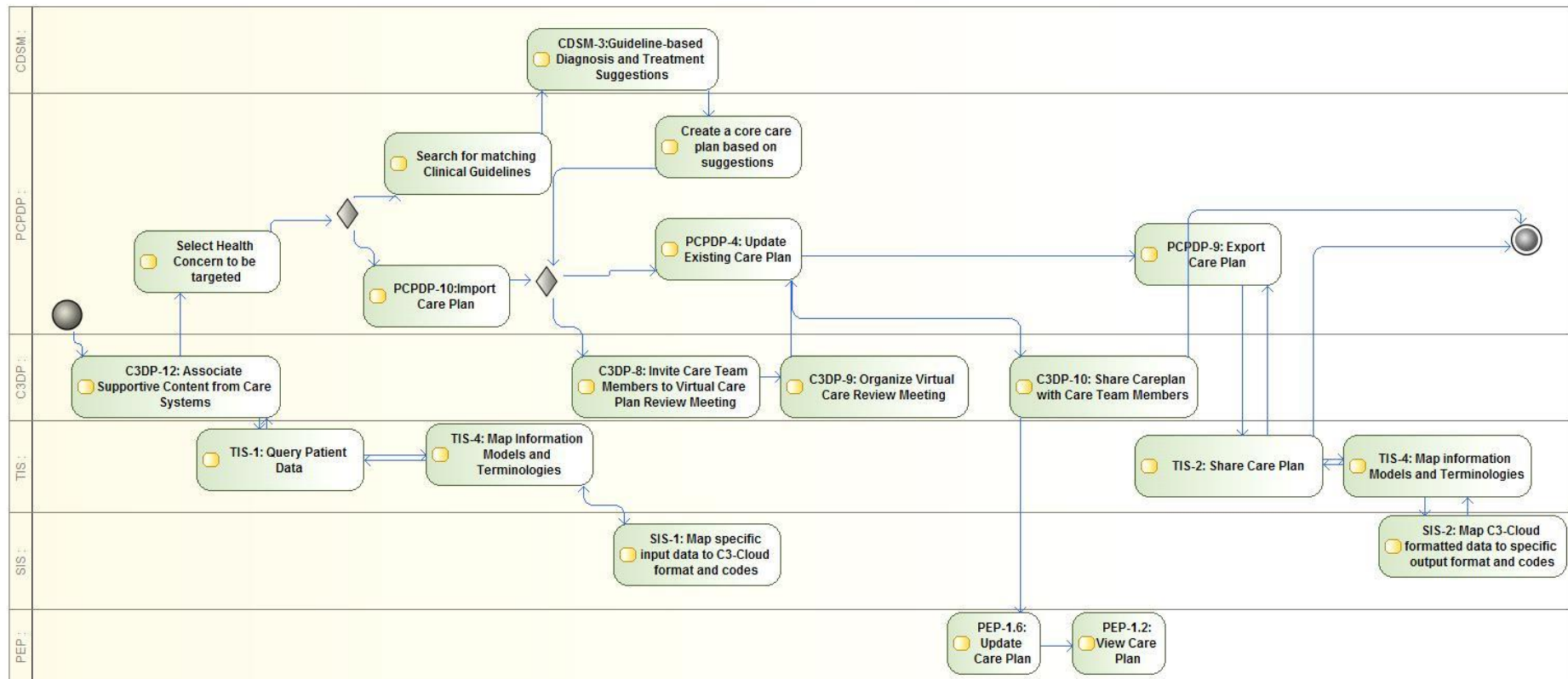


Figure 11 Activity Diagram of "PCPDP-2: Add New Care Plan from a Core Care Plan" use case

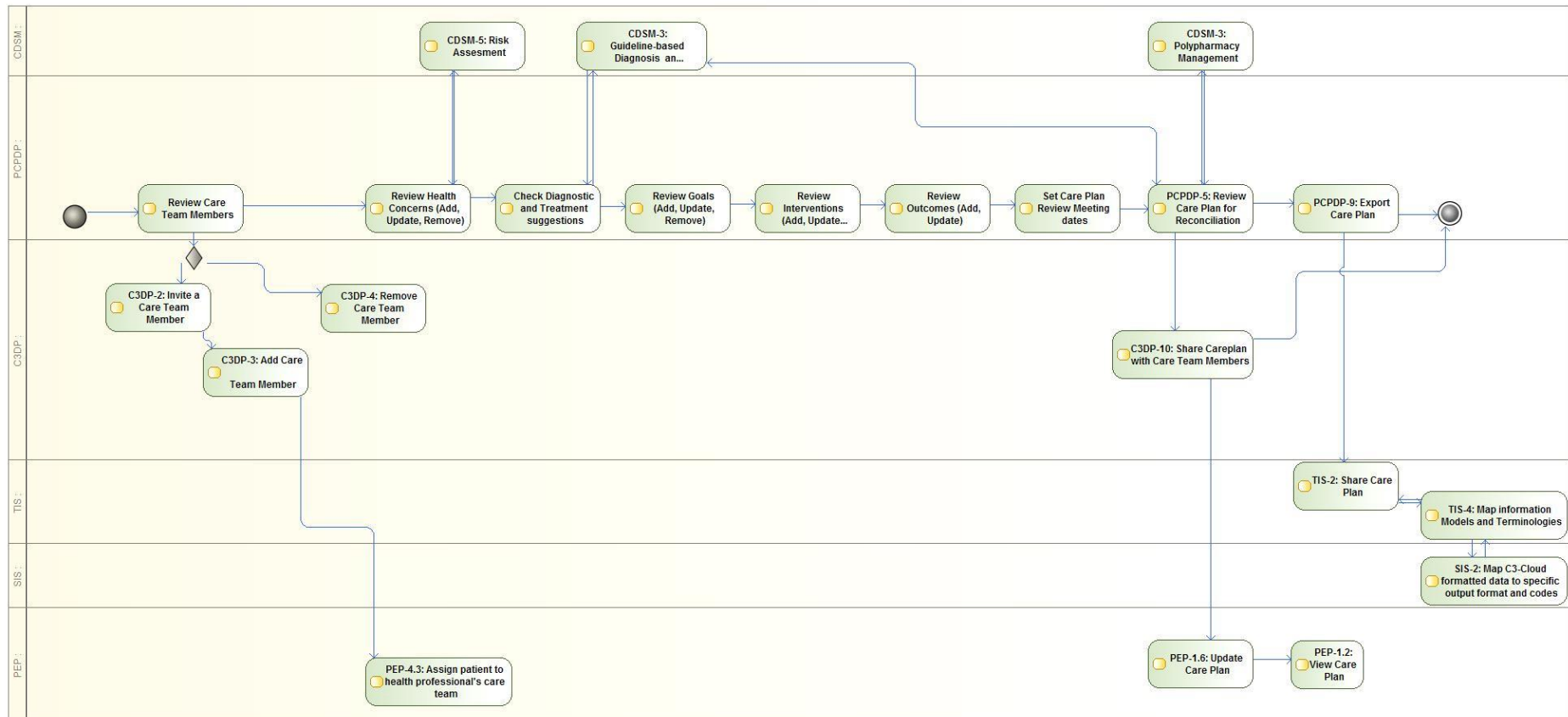


Figure 12 Activity Diagram of "PCPDP-4: Update Care Plan" use case

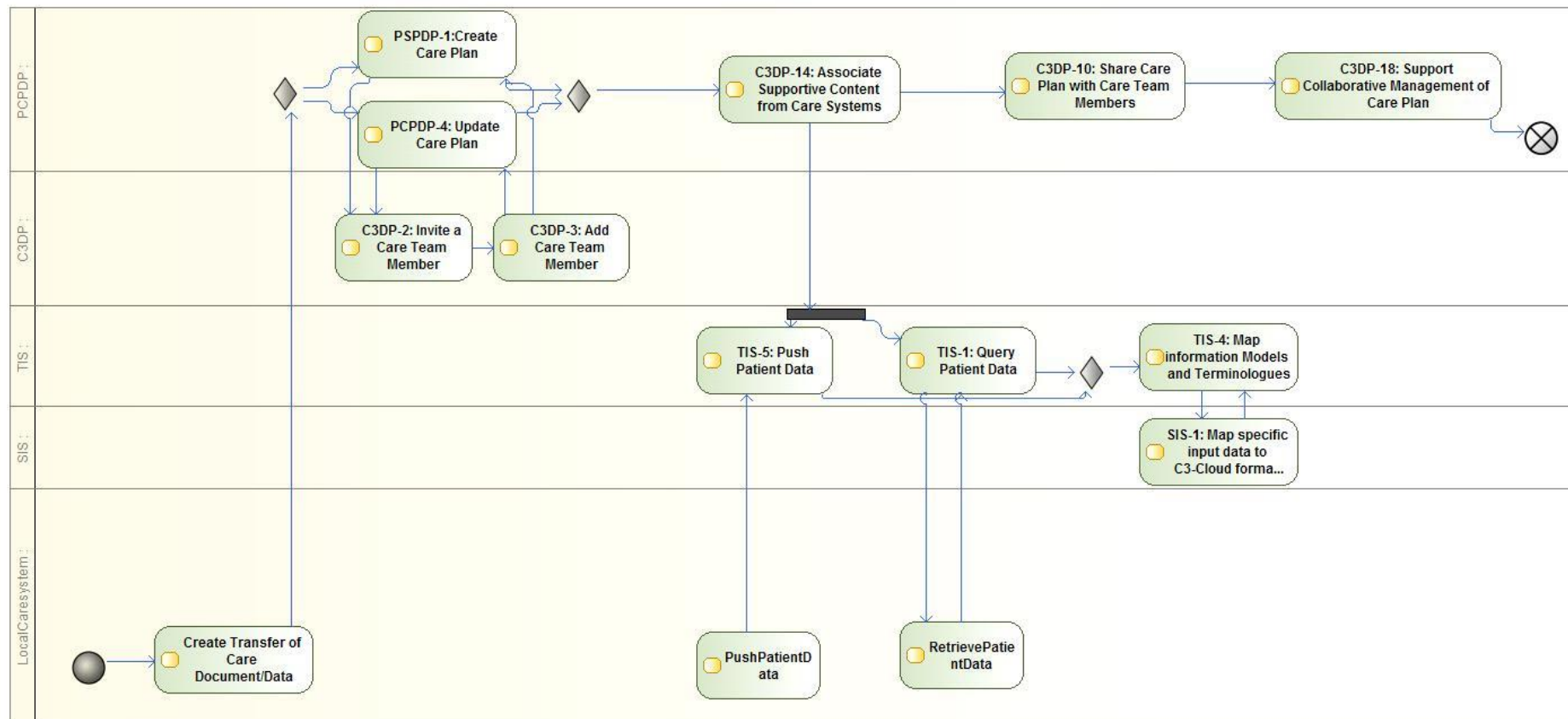


Figure 13 Activity Diagram of “PCPDP-16: Support Transfer of Care” use case

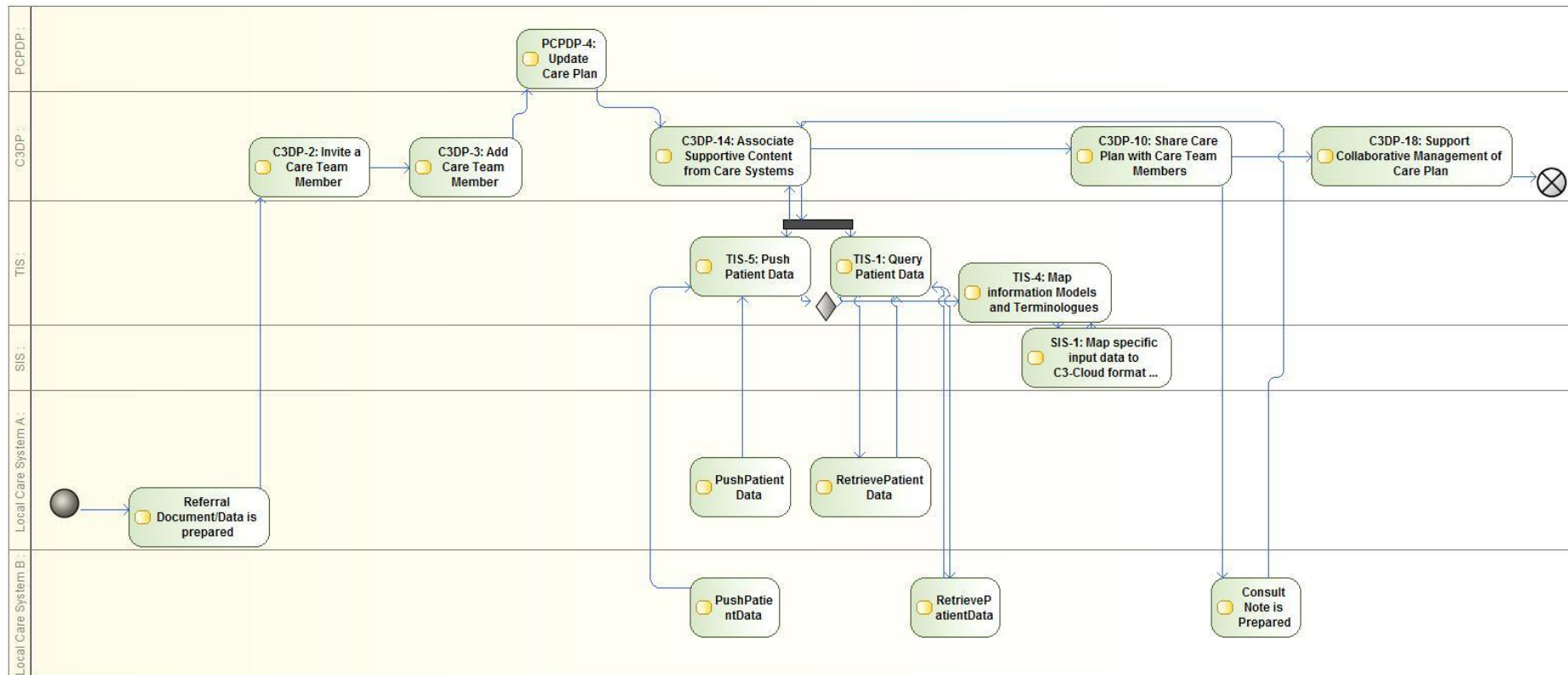


Figure 14 Activity Diagram of "PCPDP:17-Support Referral" use case

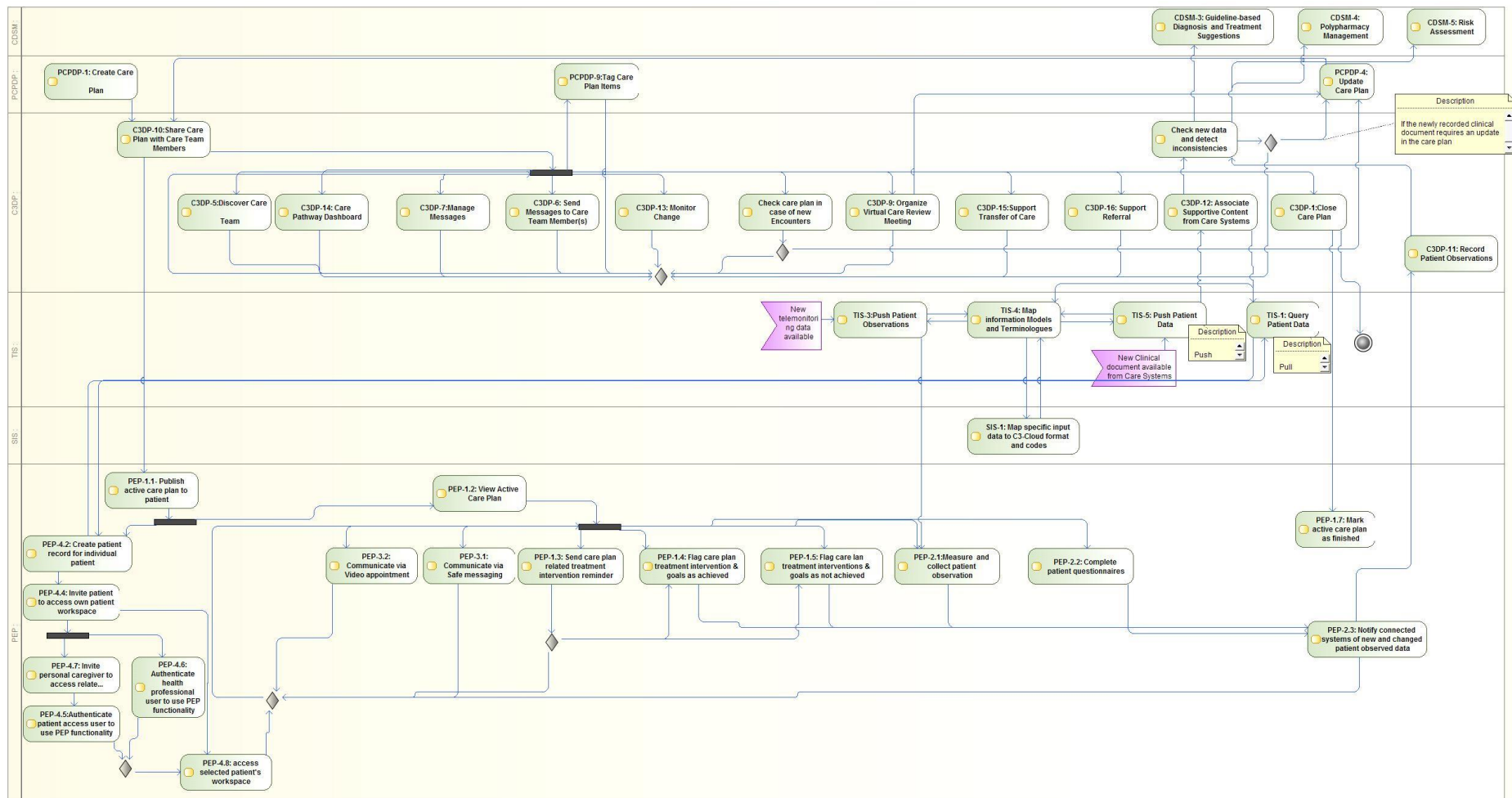


Figure 15 Activity Diagram of " C3DP-18: Support Collaborative Management of Care Plan " use case

4 C3-CLOUD SYSTEM REQUIREMENTS SPECIFICATION DESCRIPTION

4.1 System Requirements Specification for Patient Empowerment Platform

Description/System Context	Provide access for patient to the published care plan and its information and thus increase patient and informal carer participation to decision making. Provide computerized means to improve the interaction between patients and health professionals and provide computerized means to collect relevant data and information to enable monitoring of care plan related activity status and progress.
Related use case	<ul style="list-style-type: none"> • PEP-1.1: Publish active care plan to patient • PEP-1.2: View active care plan • PEP-1.3: Send care plan related treatment intervention reminders • PEP-1.4: Flag care plan treatment interventions and the corresponding goals as achieved • PEP-1.5: Flag care plan treatment interventions and the corresponding goals as not achieved • PEP-1.6: Update active care plan • PEP-1.7: Mark active care plan as finished • PEP-2.1: Measure and collect patient-observation data according the timings defined in care plan • PEP-2.2: Complete patient questionnaires according the timings defined in care plan • PEP-2.3: Notify connected systems of new and changed patient-observed data • PEP-3.1: Communicate via Safe messaging • PEP-3.2: Communicate via Video appointment • PEP-5.1: Access self-management material • PEP-5.2: Subscribe to health coaching programs • PEP-5.3: Generate and deliver health coaching program messages to patient • PEP-4.1: Manage care teams and health professionals • PEP-4.2: Create patient record for individual patient • PEP-4.3: Assign patient to health professional's care team • PEP-4.4: Invite patient to access own patient workspace • PEP-4.5: Authenticate patient access user to use PEP functionality • PEP-4.6: Authenticate health professional user to use PEP functionality • PEP-4.7: Invite personal caregiver to access related patient's workspace • PEP-4.8: Access selected patient's workspace
General function	<p>The features of PEP can be summarized as:</p> <ul style="list-style-type: none"> • Make published care plans available to patient access users. • Send reminders to patients to help them comply and stay on track with the interventions and activities included in the care plan. • Allow patients to actively collect data related to the care plan activities. • Allow health professionals and patients to communicate with each other using either messages or video.

	<ul style="list-style-type: none"> • Provide patients with access to relevant self-management material. • Provide patient with automated health coaching. • Provide all PEP users with secure access to information and functionality.
User characteristics	Patient access users (patient self or their informal caregivers acting on behalf of the patient) and health professionals acting on behalf of the patient.

4.1.1 Functional requirements

- PEP-FR-1. The system shall process and store a new care plan published by a PEP Client System in such way that it can perform its automated duties and display the care plan to PEP Users.
- PEP-FR-2. The system shall notify the patient when a new care plan is published to the patient.
- PEP-FR-3. The system shall display the published, active care plan to PEP Users (the patient, authorized informal caregivers and health professionals).
- PEP-FR-4. The system shall mark the care plan as read when the care plan has been accessed by the patient or an informal caregiver.
- PEP-FR-5. PEP Users and/or a PEP Client System shall be able to set the contact information of the patient needed to receive treatment intervention reminder messages.
- PEP-FR-6. The system shall send treatment intervention reminder messages to patients according the timings defined in the patient's active care plan.
- PEP-FR-7. The patient or another PEP user on behalf of the patient shall be able to mark a treatment intervention goal as achieved.
- PEP-FR-8. The patient or another PEP user on behalf of the patient shall be able to mark a treatment intervention goal as not achieved.
- PEP-FR-9. The system shall process and store an updated care plan published by a PEP Client System in such way that it can perform its automated duties and display the care plan to PEP Users.
- PEP-FR-10. The system shall notify the patient when an updated care plan is published to the patient.
- PEP-FR-11. The system shall set an active care plan as inactive when a PEP Client System notifies that the active care plan has been closed.
- PEP-FR-12. The system shall support measurement device assignment to the patient when the patient care plan includes prescribed remote monitoring.
- PEP-FR-13. The system shall support upload of patient measurement data from connected devices.
- PEP-FR-14. The system shall send a notification to the patient when a prescribed questionnaire activity becomes active.
- PEP-FR-15. The system shall send a notification to the patient if the prescribed questionnaire activity end time is reached before the activity has been completed.
- PEP-FR-16. The patient or another PEP User on behalf of the patient shall be able to start any time during the prescribed activity's active period to answer and complete the questionnaire.
- PEP-FR-17. The patient or another PEP User on behalf of the patient may interrupt and return later to complete the questionnaire.
- PEP-FR-18. The system shall enable the patient to send messages to health professionals.
- PEP-FR-19. The system shall enable the health professionals to send messages to patients.
- PEP-FR-20. The system shall enable the patient and health professionals to reply to received messages and thus continue an ongoing conversation.
- PEP-FR-21. The system shall enable the communication between a health professional and a patients using video.
- PEP-FR-22. Health professional and/or a PEP Client System shall be able to create a future video appointment between a health professional and a patient.
- PEP-FR-23. The patient and the health professional shall be able to join the video appointment when it is due.

- PEP-FR-24. The system shall support the configuration of links to self-management material published to patients.
- PEP-FR-25. Any PEP User shall be able to access the self-management material via the system.
- PEP-FR-26. The system shall support patients or PEP Users acting on behalf of the patient to subscribe to health coaching programs for the selected patient.
- PEP-FR-27. The health coaching engine shall monitor coaching program subscriptions and generate coaching messages to be delivered to a patient.
- PEP-FR-28. The system shall receive messages from the health coaching engine and deliver the messages to the patient.
- PEP-FR-29. The system shall display sent coaching messages to PEP users.
- PEP-FR-30. PEP Users shall be able to invite the patient to access the patient's own record.
- PEP-FR-31. PEP Users shall be able to invite an informal caregiver to access the selected patient's workspace.
- PEP-FR-32. The system shall send the patient access invitation to the invited person (patient or informal caregiver) by email.
- PEP-FR-33. The invited person (patient or informal caregiver) shall be able to register to the C3 Cloud solution using the information contained in the invitation and an additional invitation code. The additional invitation code shall be delivered separately from the invitation email.
- PEP-FR-34. Any patient access user shall be able to log in to PEP System using their login credentials.
- PEP-FR-35. Any health professional user shall be able to log in to PEP System using their login credentials.
- PEP-FR-36. A logged in PEP User shall be able to select and open the record of any of the patient's the user is authorized to access and act on behalf of.

4.1.2 Information requirements

- PEP-IR-1. The care plan shall contain information needed to automatically guide, control, and monitor the execution and progress of the care plan activities and interventions.
- PEP-IR-2. The care plan shall contain all information needed to display the care plan to PEP Users.
- PEP-IR-3. An updated care plan shall contain the change information needed to highlight changes in updated care plan versions.
- PEP-IR-4. The care plan shall contain the information needed to schedule and generate the treatment intervention reminder messages.
- PEP-IR-5. The care plan information shall support the inclusion of prescribed remote monitoring information (measurement types, timings and goal/limit values).
- PEP-IR-6. The care plan information shall support the inclusion of prescribed questionnaire activities.

4.1.3 System interface requirements

- PEP-SIR-1. All essential PEP Client System interfaces used by PEP shall support synchronous use.
- PEP-SIR-2. A PEP Client System shall publish the care plans in a machine processable format to PEP System.
- PEP-SIR-3. A PEP Client System shall publish updated versions of an active care plan in a machine processable format to PEP System.
- PEP-SIR-4. A PEP Client System shall notify PEP System when a care plan is closed.
- PEP-SIR-5. The system shall notify PEP Client Systems when the care plan has been accessed by the patient or by an informal caregiver.
- PEP-SIR-6. The system shall notify PEP Client Systems when a PEP User changes manually the status of a treatment intervention goal.
- PEP-SIR-7. The system shall notify PEP Client Systems when a new patient observation is stored.
- PEP-SIR-8. The system shall notify PEP Client Systems when a questionnaire has been completed.
- PEP-SIR-9. The Health coaching engine shall send coaching messages via PEP System.

PEP-SIR-10. A PEP Client System shall manage the care team and the health professional information in PEP System.

PEP-SIR-11. A PEP Client System shall create a unique record in PEP System for each enrolled patient.

PEP-SIR-12. A PEP Client System shall manage which patients have a relationship with which care teams.

4.1.4 User Interface requirements

PEP-UIR-1. The system shall provide user interfaces for PEP Users to view the active, published care plan of the selected patient.

PEP-UIR-2. The system shall provide user interfaces for PEP Users to manage the patient contact information.

PEP-UIR-3. The system shall provide user interfaces for patient access users to access and use care plan related functionalities.

PEP-UIR-4. The system shall provide user interfaces for PEP Users to access and manage collected data of a patient (observations and completed questionnaires).

PEP-UIR-5. The system shall provide user interfaces for patient access users to communicate with health professionals.

PEP-UIR-6. The system shall provide user interfaces for patient access users to access self-management material.

PEP-UIR-7. The system shall provide user interfaces for PEP Users to manage health coaching subscriptions and view received coaching messages.

PEP-UIR-8. The system shall provide user interfaces to manage patient and informal caregiver access to a patient's workspace.

4.1.5 Performance requirements

PEP-NFR-1. All system functions shall respond within reasonable time.

PEP-NFR-2. All essential PEP Client System interfaces shall respond within reasonable time.

4.1.6 Usability requirements

PEP-NFR-3. All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.

PEP-NFR-4. All system user interfaces should be designed in such manner that the user understands and knows what to do on each screen. All screens should include additional instructions and help text whenever needed.

PEP-NFR-5. All error messages should explain how to recover from the error and propose a fall-back mechanism

4.1.7 Reliability requirements

PEP-NFR-6. The system shall not fail if an unsupported format of care plan is returned or pushed by PEP Client Systems.

4.1.8 Maintainability requirements

None.

4.1.9 Security requirements

PEP-NFR-7. The system shall provide a role based user access control mechanism

PEP-NFR-8. The system shall provide a log-in screen for users

PEP-NFR-9. The system shall check the authorization of users to perform the operations supported by the system.

PEP-NFR-10. All operations shall be audited.

4.1.10 Constraints, Policies and Regulations

None from RJH.

Basque Country: PERSONAL HEALTH FOLDER (PHF) of Basque Country is the current access of patients to access their Health Record. PEP will take into account it.

Open Issues

Pilot countries will provide more feedback about PAR-53: “As a Patient I want to have personalised guidance/information from the Patient Empowerment Platform based on my most recent context (answers given on questionnaires and on data from the EHR (diagnoses, medication, lab) but also based on data from devices)”, clarifying the need with some concrete examples, and whether anything different than guidance about already personalized care plan interventions is required. This will be discussed during design phase.

4.2 System Requirements Specification for Technical Interoperability Suite

Description/System Context	Technical Interoperability Suite (TIS) enables information sharing between local care information systems and C3-Cloud high level components.
Related use case	TIS-1: Query Patient Data TIS-2: Share Care Plan TIS-3: Push Patient Observations TIS-4: Map Information Models and Terminologies TIS-5: Push Patient Data
General function	TIS enables information exchange between local care system/PHR and C3-Cloud components, including: <ul style="list-style-type: none"> • Patient data and clinical documents from local care system to PCPDP and C3DP via querying or subscription mechanisms. • Patient measurements from tele-monitoring device or PHR to C3DP or PEP • Care plan from PCPDP or C3DP to local care system
User characteristics	NA

4.2.1 Functional requirements

TIS-FR-1. The system shall send queries to local care system for patient records

TIS-FR-2. The system shall send queries to local care system for clinical documents

TIS-FR-3. The system shall receive queries for patient records from PCPDP or C3DP

TIS-FR-4. The system shall receive queries for clinical documents from PCPDP or C3DP

TIS-FR-5. The system shall subscribe to clinical events generated by local care system

TIS-FR-6. The system shall receive patient records from local care system

TIS-FR-7. The system shall receive clinical documents from local care system

TIS-FR-8. The system shall send patient records to PCPDP or C3DP

- TIS-FR-9. The system shall send clinical documents to PCPDP or C3DP
- TIS-FR-10. The system shall receive care plan from PCPDP or C3DP
- TIS-FR-11. The system shall send care plan to local care system
- TIS-FR-12. The system shall receive patient measurements from tele-monitoring device or PHR
- TIS-FR-13. The system shall send patient measurements to C3DP
- TIS-FR-14. The system shall send patient measurements to PEP
- TIS-FR-15. The system shall send patient records in source format to SIS
- TIS-FR-16. The system shall send clinical documents in source format to SIS
- TIS-FR-17. The system shall send patient measurements in source format to SIS
- TIS-FR-18. The system shall receive patient records in converted format from SIS
- TIS-FR-19. The system shall receive clinical documents in converted format from SIS
- TIS-FR-20. The system shall receive patient measurements in converted format from SIS

4.2.2 Information requirements

- TIS-IR-1. Patient records or clinical documents received from local care system shall comply with the clinical data requirements listed in Appendix III: Clinical Data Requirements
- TIS-IR-2. Patient measurements received from tele-monitoring systems or PHR shall comply with the clinical data requirements listed in Appendix III: Clinical Data Requirements
- TIS-IR-3. The converted patient records or clinical documents received from SIS shall conform to C3-Cloud FHIR profile
- TIS-IR-4. The care plan received from PCPDP or C3DP shall conform to C3-Cloud FHIR profile

4.2.3 System Interface requirements

- TIS-SIR-1. The system shall provide FHIR-based API for PCPDP or C3DP to query and extract patient records and clinical documents
- TIS-SIR-2. Local care system shall provide API to query and extract patient records and clinical documents
- TIS-SIR-3. Local care system shall provide API to subscribe clinical events
- TIS-SIR-4. Local care system shall send patient records or clinical documents when subscribed clinical events are triggered
- TIS-SIR-5. PCPDP or C3DP shall provide FHIR-based API to receive patient records or clinical documents
- TIS-SIR-6. Tele-monitoring device or PHR shall send patient measurements at regular intervals or when pre-defined events are triggered
- TIS-SIR-7. C3DP shall provide FHIR-based API to receive patient measurements
- TIS-SIR-8. PEP shall provide FHIR-based API to receive patient measurements
- TIS-SIR-9. SIS shall provide API to convert patient records or clinical documents into C3-Cloud FHIR format

4.2.4 User Interface requirements

None

4.2.5 Performance requirements

- TIS-NFR-1. The call to local care system API should return results in reasonable time (such as less than 10 sec)
- TIS-NFR-2. The call to PCPDP or C3DP API should return in reasonable time (such as less than 10 sec)
- TIS-NFR-3. The call to PEP API should return in reasonable time (such as less than 10 sec)
- TIS-NFR-4. The call to SIS API should return in reasonable time (such as less than 10 sec)

4.2.6 Usability requirements

None

4.2.7 Reliability requirements

- TIS-NFR-5. The system shall not fail if local care system fails to respond. The failure should be logged and appropriate error messages should be produced.
- TIS-NFR-6. The system shall not fail if PCPDP or C3DP fail to respond. The failure should be logged and appropriate error messages should be produced.
- TIS-NFR-7. The system shall not fail if PEP fails to respond. The failure should be logged and appropriate error messages should be produced.
- TIS-NFR-8. The system shall not fail if SIS fails to respond. The failure should be logged and appropriate error messages should be produced.

4.2.8 Maintainability requirements

- TIS-NFR-9. The Technical Interoperability Suite's Mean Time To Repair (MTTR) shall not exceed 24 hours

4.2.9 Security requirements

- TIS-NFR-10. The system shall establish a secure communication channel when transporting patient records or clinical documents from local care system to PCPDP or C3DP
- TIS-NFR-11. The system shall establish a secure communication channel when transporting patient care plan from PCPDP or C3DP to local care system
- TIS-NFR-12. The system shall establish a secure communication channel when transporting patient measurements from tele-monitoring device or PHR to PEP or C3DP
- TIS-NFR-13. The system shall establish a secure communication channel when transporting patient records or clinical documents to and from SIS
- TIS-NFR-14. All communications with local care system, tele-monitoring device or PHR, PCPDP, C3DP, PEP and SIS shall be audited

4.2.10 Constraints, Policies and Regulations

None from RJH.

SWFT:

- An information / data sharing agreement would need to be in place between SWFT and any third party who hosted a system that expected to receive data from a SWFT system.
- The completion of "Privacy Impact Assessment" questionnaire is required if personal confidential information is used or affected by a project, whether it is implementing a new system or a change in business process. The completed questionnaire will provide 'pointers' for the Trust in relation to the need for example, for an Information Sharing Agreement, a Data Processing Agreement, specific Consent forms, a specific Privacy Notice etc.

Basque Country the same as SWFT

Assumptions and dependencies

- It is assumed that data sharing agreements have been approved and signed between local care system or PHR and C3-Cloud

- It is assumed that security mechanisms have been agreed and enforced to protect confidential information transport

Open Issues

- Data sharing agreements
- Transport protocols to exchange EHRs and Care Plans with pilot sites needs to be agreed upon

4.3 System Requirements Specification for Semantic Interoperability Suite

Description/System Context	Semantic Interoperability Suite (TIS) enables data conversion between local care information systems and C3-Cloud high level components, by terminology mappings and information model transcoding.
Related use case	SIS-1: Map specific input data to C3-Cloud format and codes SIS-2: Map C3-Cloud formatted data to specific output format and codes SIS-3: Map specific input data to other specific output format and codes SIS-4: Query terminology server for mapping SIS-5: Create mapping between specific data format and C3-cloud format SIS-6: Register new data information model
General function	SIS enables data conversion between local care system/PHR and C3-Cloud components, including: <ul style="list-style-type: none"> • Information model transcoding • terminology mappings
User characteristics	NA

4.3.1 Functional requirements

- SIS-FR-1. The system shall receive patient records in source format from TIS
SIS-FR-2. The system shall receive clinical documents in source format from TIS
SIS-FR-3. The system shall receive patient measurements in source format from TIS
SIS-FR-4. The system shall send patient records in converted format from TIS
SIS-FR-5. The system shall send clinical documents in converted format from TIS
SIS-FR-6. The system shall send patient measurements in converted format from TIS
SIS-FR-7. The system shall receive information model specifications from Administrator
SIS-FR-8. The system shall receive terminology definitions from Administrator

4.3.2 Information requirements

None

4.3.3 System Interface requirements

- SIS-SIR-1. The system shall provide API to perform mapping query.

4.3.4 User Interface requirements

- SIS-UIR-1. The system shall provide user interfaces for Administrator for register new information model of data source.

SIS-UIR-2. The system shall provide user interfaces for Administrator for register new terminology mapping.

4.3.5 Performance requirements

SIS-NFR-1. The call to SIS API should return in reasonable time

4.3.6 Usability requirements

None

4.3.7 Reliability requirements

SIS-NFR-2. The system shall not fail if a mapping is impossible to achieve. The failure should be logged and appropriate error messages should be produced.

4.3.8 Maintainability requirements

SIS-NFR-3. The Semantic Interoperability Suite's Mean Time To Repair (MTTR) shall not exceed 24 hours

4.3.9 Security requirements

SIS-NFR-4. The system shall establish a secure communication channel when receiving requested and transmitting output.

SIS-NFR-5. All communications of SIS shall be audited

4.3.10 Constraints, Policies and Regulations

SWFT:

- Any data transmitted to a third party system must use transport layer security of at least 128bit SSL secured through commercial provider issued certificates
- Personally identifiable data from a clinical record can only be used as part of care delivery and with consent from the patient.
- Patient data cannot be held outside the EU
- All our internal systems are firewalled from the internet and N3.

None from RJH.

None from Basque Country.

Assumptions and dependencies

- It is assumed that manipulated data are covered by adequate data sharing agreements
- It is assumed that security mechanisms have been agreed and enforced to protect confidential information transport
- It is assumed it will be possible to integrate with at least one identity provider system in each pilot site

Open Issues

- Data sharing agreements
- Data formats for EHRs and Care Plans that can be exported and consumed by pilot sites needs to be agreed upon

- In the regular practice, each pilot site will have its own Audit Record Repository (ARR) in its own care zone. An alternative or an additional location is a Trusted Third Party (TTP) that Warwick can provide.
- Exact identity provider systems of the pilot sites and their capabilities need to be identified and analysed in detail.
- Exact standards and protocols to be used in user authentication, single sign-on, authorisation and auditing need to be decided.

4.4 System Requirements Specification for Security and Privacy Suite

Description/System Context	Security and Privacy Suite is responsible for guaranteeing 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 audited properly.
Related use case	<ul style="list-style-type: none"> • SPS-1: Create Care Team Member Account • SPS-2: Authenticate User • SPS-3: Authorise User • SPS-4: Manage Access Control Policies • SPS-5: Log Audit
General function	<p>The features of Security and Privacy Suite (SPS) can be summarized as:</p> <ul style="list-style-type: none"> • Creating a user account for a new Care Team Member without an account linked with the C3-Cloud system • Authenticating a Care Team Member or an Administrator and starting a secure session for him/her in C3-Cloud applications • Guaranteeing that no unauthorised user is able to access or modify sensitive data • Providing a dynamic mechanism for management of the access control policies, instead of static rules hard-coded in application source code • Ensuring that all data exchange between C3-Cloud applications is audited appropriately
User characteristics	Care Team Members that are authorised to manage personalised care plans of patients; institutional/regional administrators that are authorised to monitor the activities and transactions taking place among systems and users of systems; and all C3-Cloud software components that are required to audit their transactions.

4.4.1 Functional requirements

SPS-FR-1. Whenever available, the system should integrate with the existing organisational identity provider systems (e.g. LDAP, Active Directory) and allow associated Care Team Members to continue using their regular business user accounts in C3-Cloud software components such as PCPDP and C3DP.

SPS-FR-2. For any Care Team Member without a business user account or whose organisation's identity provider system cannot be integrated with C3-Cloud SPS somehow, the system shall support user account creation in the internal Identity Provider System.

SPS-FR-3. The system shall support new user account creation with approval of both parties for enhanced security; i.e. the Care Team Member and the Administrator of the regional/institutional setting.

SPS-FR-4. The system shall enable rejection of new user account creation request by the Administrator.

- SPS-FR-5. The system shall enable single sign-on mechanism; i.e. the users shall be able to use C3-Cloud applications by using a single account.
- SPS-FR-6. The system shall display a list of integrated identity providers on the log on page and allow the user to select his/her associated identity provider.
- SPS-FR-7. The system shall automatically forward the user to the selected identity provider's sign in page, and upon providing of the necessary credentials and authentication by the selected identity provider, the authentication response shall be forwarded to the C3-Cloud application of interest (i.e. PCPDP and C3DP) and the authenticated user be navigated to the user interface of the C3-Cloud application.
- SPS-FR-8. In case of authentication failure, the user shall be informed about the outcome appropriately.
- SPS-FR-9. The system shall provide the Administrator with the ability to manage access control policies through the Authorisation Manager subcomponent of the SPS.
- SPS-FR-10. The Authorisation Manager subcomponent shall support permission definitions based on roles (e.g. nurse, GP, specialist) that can be assigned to types of resources (e.g. care plan, referral note, calendar) and operations (e.g. create, read, update, delete).
- SPS-FR-11. The Authorisation Manager subcomponent shall enable definition of new policies/rules or update of existing policies/rules at any time.
- SPS-FR-12. The Authorisation Manager subcomponent shall store machine processable permission definitions in a repository.
- SPS-FR-13. When a Care Team Member tries to perform a CRUD operation on a specific resource via PCPDP or C3DP, these applications shall provide the user attributes and information about the requested resource and operation to the Authorisation Manager.
- SPS-FR-14. PCPDP or C3DP should be able to request additional attributes of the user from the associated identity provider when necessary.
- SPS-FR-15. The Authorisation Manager acting as the Policy Decision Point shall check the user attributes and requested resource and operation against the access control policies in its repository, and shall either approve or deny the operation.
- SPS-FR-16. The system shall have an Audit Record Repository (ARR) that accepts and stores standards based audit trail records.
- SPS-FR-17. Whenever a clinical data exchange is done between a data provider system and data requestor system, each system acting as the Secure Node shall create corresponding audit trail records and send them to the ARR.
- SPS-FR-18. Audit Record Repository shall inform the Secure Node about the result of the save operation.

4.4.2 Information requirements

- SPS-IR-1. User identity data including the secrets (password, authentication/authorization tokens) shall be stored in encrypted secure storage.
- SPS-IR-2. The authentication request, response and user attributes shall all be represented in widely recognised industrial standards such as OpenID Connect.
- SPS-IR-3. The access control policies shall be represented in widely recognised machine processable formats such as OASIS XACML and XSPA.
- SPS-IR-4. Audit trail records shall be based on widely accepted standards and profiles such as IHE ATNA and shall at least include information on timestamp, user requesting access/update to record(s), subsystem that the user is using to access/update to record(s), operation, details of query if it is a query, the identifiers(s) of the accessed/updated records.

4.4.3 System Interface requirements

- SPS-SIR-1. All identity providers shall provide a software interface to accept authentication requests by C3-Cloud applications, and pass back the authentication tokens and user identity attributes to client C3-Cloud systems in a secure way after authenticating the user.

SPS-SIR-2. The Authorisation Manager subcomponent of the SPS shall provide a software interface to receive resource access requests (user identity attributes, the resource to be accessed and the operation to be performed) for ensuring authorised access.

SPS-SIR-3. The Audit Record Repository (ARR) subcomponent of the SPS shall provide a standards-based software interface for all C3-Cloud components acting as Secure Nodes to submit their audit trail records.

4.4.4 User Interface requirements

SPS-UIR-1. The system shall provide a sign-in interface for Care Team Members and Administrators to authenticate users into C3-Cloud applications (PCPDP, C3DP and SPS components).

SPS-UIR-2. The system shall provide a user interface for account creation for Care Team Members without a business user account or whose organisation's identity provider system cannot be integrated with C3-Cloud SPS for a reason.

SPS-UIR-3. The system shall provide user interface on top of the Authorisation Manager for Administrators to define/update access control policies.

SPS-UIR-4. The system shall have an Audit Record Repository (ARR) User Interface for Administrators to monitor, query and filter all the audit trail records in the ARR.

4.4.5 Performance requirements

SPS-NFR-1. After authentication, the identity providers should pass the authentication tokens and user identity attributes to client C3-Cloud systems in a reasonable time (less than 3 seconds).

SPS-NFR-2. The policy decision making of the Authorisation Manager should be completed in a reasonable time (less than 2 seconds).

SPS-NFR-3. The call to audit trail record submission interface of the Audit Record Repository should return in less than 2 seconds.

4.4.6 Usability requirements

SPS-NFR-4. All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.

SPS-NFR-5. All screens should have a help button.

SPS-NFR-6. Error messages should explain how to recover from the error and propose a fall-back mechanism.

4.4.7 Reliability requirements

SPS-NFR-7. The system shall not fail if authentication tokens or user identity attributes are invalid or in an unsupported format; appropriate error messages should be returned and the user shall not be authenticated.

SPS-NFR-8. The system shall not fail when the Authorisation Manager cannot be reached (e.g. is down); the users shall be informed and invited to try again later.

SPS-NFR-9. The system shall not fail if an unsupported audit trail record is tried to be submitted; appropriate error messages should be returned.

4.4.8 Maintainability requirements

SPS-NFR-10. The Security and Privacy Suite's Mean Time To Repair (MTTR) shall not exceed 24 hours.

4.4.9 Security requirements

- SPS-NFR-11. All software interfaces shall be secured by node-to-node authentication (SSL/TLS)
- SPS-NFR-12. All operations (create, read, delete, update, execute) shall be audited.

4.4.10 Constraints, Policies and Regulations

SWFT:

- Any data transmitted to a third party system must use transport layer security of at least 128bit SSL secured through commercial provider issued certificates
- Personally identifiable data from a clinical record can only be used as part of care delivery and with consent from the patient.
- Patient data cannot be held outside the EU
- All our internal systems are firewalled from the internet and N3

None from RJH.

None from Basque Country.

Assumptions and dependencies

- It is assumed it will be possible to integrate with at least one identity provider system in each pilot site.

Open Issues

- In the regular practice, each pilot site will have its own Audit Record Repository (ARR) in its own care zone. An alternative or an additional location is a Trusted Third Party (TTP) that Warwick can provide.
- Exact identity provider systems of the pilot sites and their capabilities need to be identified and analysed in detail.
- Exact standards and protocols to be used in user authentication, single sign-on, authorisation and auditing need to be decided.

4.5 System Requirements Specification for Clinical Decision Support Modules

Description/System Context	Clinical decision support modules (CDSM) are used to perform risk assessment and stratification of elderly people for inclusion in integrated care programmes; to reconcile clinical guidelines for individual diseases to develop personalised care plans; to detect and propose resolutions for guideline clashes; to detect duplicate, unnecessary or contraindicating medications; and to track deviations from the outcome goals set in the care plan.
Related use case	CDSM-1: Create or Update Knowledge Modules CDSM-2: Validate Knowledge Modules CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management CDSM-5: Risk Assessment
General function	CDSM will be delivered through a unified platform following HL7 decision support service standard, where different knowledge modules can be created to provide decision support on diagnosis and treatment of specific diseases by following clinical guidelines, on polypharmacy management and on risk assessment and stratification.
User characteristics	Knowledge engineers who create or update knowledge modules for a specific clinical scenario; care team members who validate a knowledge module is safe

	to use in the relevant clinical context; care team members who use a knowledge module to evaluate patients in a clinical scenario.
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4.5.1 Functional requirements

- CDSM-FR-1. The system shall allow to create a new knowledge module
- CDSM-FR-2. The system shall allow to update an old knowledge module
- CDSM-FR-3. The system shall allow to validate a knowledge module
- CDSM-FR-4. The system shall list all knowledge modules
- CDSM-FR-5. The system shall display metadata of a knowledge module
- CDSM-FR-6. The system shall evaluate patient data using a knowledge module
- CDSM-FR-7. The system shall have knowledge modules to provide clinical guideline based diagnosis and treatment suggestions
- CDSM-FR-8. The system shall have knowledge modules to provide polypharmacy management suggestions
- CDSM-FR-9. The system shall have knowledge modules to provide risk assessment

4.5.2 Information requirements

- CDSM-IR-1. The patient data for CDS evaluation shall conform to C3-Cloud FHIR profile
- CDSM-IR-2. The system shall support the clinical guidelines that will be agreed upon in Task 7.1.
- CDSM-IR-3. The system shall support the following polypharmacy criteria:
 1. Beer's list
 2. FORTA
 3. Drug Burden Index
 4. START
 5. STOPP
- CDSM-IR-4. The system shall support the risk assessment algorithms listed as a part of clinical guidelines that will be agreed upon in Task 7.1.

4.5.3 System Interface requirements

- CDSM-SIR-1. The system shall provide web service API conforming to HL7 DSS standard

4.5.4 User Interface requirements

- CDSM-UI-1. The system shall provide user interface for knowledge engineers to create or update knowledge modules
- CDSM-UI-2. The system shall provide user interface for care team members to validate knowledge modules

4.5.5 Performance requirements

- CDSM-NFR-1. The operations to create or update knowledge modules should return in reasonable time (such as less than 10 sec)
- CDSM-NFR-2. The operation to list and display knowledge module metadata should return in reasonable time (such as less than 5 sec)
- CDSM-NFR-3. The operation to evaluate patient using a knowledge module should return results in reasonable time (such as less than 20 sec)

4.5.6 Usability requirements

- CDSM-NFR-4. All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.
- CDSM-NFR-5. Error messages should explain how to recover from the error and propose a fall-back mechanism.

4.5.7 Reliability requirements

- CDSM-NFR-6. The system shall not fail if wrong knowledge modules are referenced. The failure should be logged and appropriate error messages should be produced.
- CDSM-NFR-7. The system shall not fail if input patient data are invalid. The failure should be logged and appropriate error messages should be produced.

4.5.8 Maintainability requirements

- CDSM-NFR-8. The Clinical Decision Support System's Mean Time To Repair (MTTR) shall not exceed 24 hours

4.5.9 Security requirements

- CDSM-NFR-9. The system shall provide a login screen to knowledge engineers and care team members
- CDSM-NFR-10. The system shall check authorizations of knowledge engineers to create or update knowledge modules
- CDSM-NFR-11. The system shall check authorizations of care team members to validate knowledge modules
- CDSM-NFR-12. All operations to create, update or validate knowledge modules and evaluate patients shall be audited

4.5.10 Constraints, Policies and Regulations

None.

Assumptions and dependencies

- It is assumed that clinical guidelines, polypharmacy criteria and risk assessment algorithms have been identified and approved to be implemented in C3-Cloud

Open Issues

- Clinical guidelines, polypharmacy criteria and risk assessment algorithms

4.6 System Requirements Specification for Personalised Care Plan Development Platform

Description/System Context	Personalized Care Plan Development Platform is a sub module of Coordinated Care and Cure Delivery Platform (C3DP), which enables creation and update of a care plan specialized for a specific patient collaboratively by a care team.
Related use case	<ul style="list-style-type: none"> • PCPDP-1: Create Care Plan • PCPDP-2: Add new Care Plan from a Core Care Plan • PCPDP-3: Define new Care Plan • PCPDP-4: Update Existing Care Plan • PCPDP-5: Review Care Plan for Reconciliation • PCPDP-6: Reconcile Care Plans for Multiple Conditions • PCPDP-7: Find Care Plan • PCPDP-8: Tag Care Plan Items • PCPDP-9: Export Care Plan • PCPDP-10: Import Care Plan
General function	<p>The features of PCPDP can be summarized as:</p> <ul style="list-style-type: none"> • Creating a new care plan (from scratch, by utilizing a core care plan, by reconciling multiple care plans for multiple conditions) • Updating an existing care plan • Supporting the use of decision support modules to identify repetitions, inconsistencies, contraindications, missing goals, interventions, calculate risk scores during care plan definition and update • Tagging Care Plan Items • Export Care Plan • Import Care Plan • Find Care Plan for a Patient
User characteristics	Health Professionals, Social Care Providers who have the expertise and authorization for managing care plan definitions in cooperation with the patients

4.6.1 Functional requirements

- PCPDP-FR-1. The system shall maintain a repository of machine processable care plans
- PCPDP-FR-2. The system shall utilize Clinical Decision Support Modules that suggests treatment goals and interventions based on clinical guidelines to create core care plans targeting selected health concerns
- PCPDP-FR-3. The system shall communicate with Technical Interoperability Suite (TIS) to access clinical data of a selected Patient
- PCPDP-FR-4. The system shall support the capability to define a care plan from scratch
- PCPDP-FR-5. The system shall support the capability to define care plans by adopting core care plans (based on the suggestions provided by clinical decision support modules)
- PCPDP-FR-6. The system shall support selecting the targeted health concerns from patient's medical history as the target of care plan
- PCPDP-FR-7. The system shall support utilization of Clinical Decision Support Modules (CDSM) features to calculate risk factors for the patient that can be added as health concerns
- PCPDP-FR-8. The system shall support editing the details of health concerns such as editing the priority for patient or for the health professional.
- PCPDP-FR-9. The system shall support visualization of the details of care plan templates
- PCPDP-FR-10. The system shall support the capability to personalize core care plans as care plans for a specific patient by updating the core care plan definition accordingly
- PCPDP-FR-11. The system shall enable definition of a new care team
- PCPDP-FR-12. The system shall enable invitation of new care team members
- PCPDP-FR-13. The system shall enable removal of care team members from the care team
- PCPDP-FR-14. The system shall inform PEP about Care Team Member updates

- PCPDP-FR-15. The system shall support the capability to utilize the clinical decision support modules that suggest goals and interventions given a health concern to be addressed based on clinical guidelines
- PCPDP-FR-16. The system shall enable the definition of new goals for the care plan
- PCPDP-FR-17. The system shall enable linking care plan goals with health concerns set as the target of the care plan
- PCPDP-FR-18. The system shall enable reviewing the details of existing goals in the care plan definition and updating them if necessary.
- PCPDP-FR-19. The system shall enable the definition of new interventions in the care plan
- PCPDP-FR-20. The system shall enable linking interventions with goals set as the target of the care plan
- PCPDP-FR-21. The system shall enable reviewing the status of the existing 'planned' interventions in the care plan definition, and based on the information received from the EHRs and the PHR of the patient, provide support to mark the ones that have been achieved.
- PCPDP-FR-22. The system shall enable noting outcome observations to indicate the progress of patient to achieve these goals by linking them with the previously added goals and interventions
- PCPDP-FR-23. The system shall enable setting planned care plan review meeting dates
- PCPDP-FR-24. The system shall support utilization of CDSM services to review the care plan definition and the existing EHR of the patient to identify missing relevant interventions in the care plan given the demographics and current conditions of the patient
- PCPDP-FR-25. The system shall support utilization of CDSM services to review the care plan definition and the existing EHR of the patient to identify contraindicating interventions
- PCPDP-FR-26. The system shall mark the missing relevant interventions and contraindicating interventions visually to present to the Care Team Member (s).
- PCPDP-FR-27. The system shall enable utilization of C3DP and TIS functionalities to associate supportive documents (such as consultation note, progress note, diagnostic reports) with the newly updated care plan
- PCPDP-FR-28. The system shall enable utilization of C3DP functionalities to share the defined care plan with Care Team Members including the patients via PEP
- PCPDP-FR-29. The system shall enable utilization of C3DP functionalities to invite care team members to virtual care plan review meetings to collaboratively define, personalize, update and reconcile care plan definitions
- PCPDP-FR-30. The system shall enable utilization of C3DP functionalities to initiate an asynchronous negotiation with care team members to discuss a new proposal for updating a care plan item
- PCPDP-FR-31. The system shall support the capability to share the exported care plan with local care systems via TIS functionalities
- PCPDP-FR-32. The system can open up multiple care plans in case of multimorbid conditions and enable the care team members to review the goals, and interventions proposed by individual care plans and to select and prioritize them.
- PCPDP-FR-33. The system shall support utilization of the related CDSM services to review the care plan definition and the existing EHR of the patient to identify missing relevant interventions in the integrated care plan given the demographics and current conditions of the patient
- PCPDP-FR-34. The system shall support utilization of the related CDSM services to review the integrated care plan definition and the existing EHR of the patient to identify contraindicating interventions
- PCPDP-FR-35. The system shall mark the identified inconsistencies visually to present to the care team member (s) while reconciling multiple care plans
- PCPDP-FR-36. The system shall support review of the identified problems and to resolve them by updating the care plan definition. It shall support reviewing, selecting and prioritizing health concerns, goals and interventions
- PCPDP-FR-37. The system shall enable discovery of existing plans for a patient by the authorized care team members in order to make the plan accessible for reading, reviewing and changing

- PCPDP-FR-38. The system shall enable tagging care plan items (i.e. health concerns, goals, interventions, outcome assessments) requiring review or follow-up.
- PCPDP-FR-39. The system support export operation to create a care plan snapshot and share it as a machine processable Care Plan document
- PCPDP-FR-40. The system shall support importing an existing care plan document represented in a machine processable format to the system
- PCPDP-FR-41. The system shall enable to ascertain who the lead clinician and care plan manager would be

4.6.2 Information requirements

- PCPDP-IR-1. Care plan to be imported shall be in a machine processable format, such as C-CDA Care Plan Document template, HL7 FHIR Care Plan Resource
- PCPDP-IR-2. The system shall export the care plan snapshot in the machine processable formats supported by C3-Cloud pilot sites
- PCPDP-IR-3. The input and output to Clinical Decision Support Modules shall be through FHIR resources
- PCPDP-IR-4. The patient data retrieved from TIS services shall be in the format of FHIR resources

4.6.3 System Interface requirements

- PCPDP-SIR-1 The CDSM services shall be accessible through a standardized API such as HL7 DSS SFM
- PCPDP-SIR-2 Separate CDSM services shall be accessible for (a) calculating risk factors for the patient (b) identifying missing relevant interventions in the care plan given the demographics and current conditions of the patient (c) identifying contraindicating interventions in the care plan definition considering the poly-pharmacy indices, drug-to-drug & drug-to-condition contraindications.
- PCPDP-SIR-3 TIS services for retrieving patient data shall be accessible through a standardized API such as FHIR services
- PCPDP-SIR-4 C3DP shall provide an interface to PCPDP for inviting care team members to virtual care plan review meetings
- PCPDP-SIR-5 C3DP shall provide an interface to PCPDP for sharing the defined care plan with Care Team Members
- PCPDP-SIR-6 C3DP shall provide an interface to PCPDP for retrieving patient data from local care systems
- PCPDP-SIR-7 C3DP shall provide an interface to PCPDP for initiating an asynchronous negotiation with Care Team Members
- PCPDP-SIR-8 PEP shall provide an interface to PCPDP for sharing the care plan with the patient and her informal care givers

4.6.4 User Interface requirements

- PCPDP-UIR-1. The system shall provide user interfaces for authorized Care Team Members for creating, deleting and updating care plan Items i.e. health concerns, goals, interventions, outcome assessments
- PCPDP-UIR-2. The system shall provide menu items for importing care plans
- PCPDP-UIR-3. The system shall provide menu items for exporting care plans
- PCPDP-UIR-4. The system shall provide menu items for finding care plans for a given patient
- PCPDP-UIR-5. The system shall provide menu items for locating matching clinical guidelines for a given health concern

4.6.5 Performance requirements

- PCPDP-NFR-1. The call to CDSM services should return a result in reasonable time (such as less than 10 sec)
- PCPDP-NFR-2. The call to TIS services for retrieving patient data should return a result in reasonable time (such as less than 15 sec)

4.6.6 Usability requirements

- PCPDP-NFR-3. All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.
- PCPDP-NFR-4. All screens should have a help button.
- PCPDP-NFR-5. Error messages should explain how to recover from the error and propose a fall-back mechanism.

4.6.7 Reliability requirements

- PCPDP-NFR-6. The system shall not fail if an unsupported care plan format is tried to be imported, appropriate error messages should be displayed
- PCPDP-NFR-7. The system shall not fail if an unsupported format of patient data is returned by TIS, it should be saved as a non-machine processable supporting clinical data
- PCPDP-NFR-8. The system shall return to a stable state when care plan definition, and update operations are failed to be completed due to inappropriate user input

4.6.8 Maintainability requirements

- PCPDP-NFR-9. The Personalized Care Plan Definition platform's Mean Time To Repair (MTTR) shall not exceed 24 hours

4.6.9 Security requirements

- PCPDP-NFR-10. The system shall provide a role based user access control mechanism
- PCPDP-NFR-11. The system shall provide a log-in screen for care team members
- PCPDP-NFR-12. The system shall check the authorization of care team members to access/create/update a care plan for a specific patient
- PCPDP-NFR-13. All operations (such as create, delete, update of care plan items) shall be audited

4.6.10 Constraints, Policies and Regulations

None from RJH.

Basque Country:

- The technological environment needed to enable the integration of the PCPDP with the ecosystem of information systems of OSAKIDETZA requires:
 - Java 8
 - EJBs 3.2 with JPA 2.1 to access the data
 - To the layer over JSF 2.2 (implementation Web Primefaces 5.1)
 - REST services implementing the standard: Java API for RESTful Web Services (JAX-RS 2.0) – (JSR 339)
 - Service layer Web SOA to provide access to native customers. This Web layer is based on the standards Java EE 7: JSR 109, JSR 224, JSR 181, JSR 67, JSR 93
 - Java Authentication and Authorization Service (JAAS) to the authentication in the application.

- This feature and the use of the easements provided by these standards will bring the following benefits in all phases of the software life cycle
 - Simplifies the possible evolution of software over time.
 - It provides a modular architecture based on services and components.
 - Simplifies the source code.
 - Efficient exploitation of the data model.
 - Improve significantly the user experience when browsing the new Web interfaces.
- The construction of platform components will enable to adapt the different integration interfaces listed in WP6.
- The provision of information to this new Medical Record module should be part of the project scope.
- Once the project is completed, the information that is not hosted in the Medical Record of patients should be included while the information stored on the PCPDP should be destroyed.

Assumptions and dependencies

- It is assumed that as a result of Task 7.1, we will identify the clinical guidelines for the selected diseases for C3-Cloud pilot sites, and they will be utilized by the Clinical Decision Support Modules to suggest treatment goals and interventions to support presenting core care plans to the users.
- It is assumed that it will be possible to retrieve machine processable patient data from local care sites

Open Issues

- Exact input/output format of CDSM services need to be agreed upon
- The care plan export formats required by the pilot sites need to be agreed upon
- Exact input/output format of TIS services to retrieve patient data need to be agreed upon
- The means of Patient / Informal Care Giver involvement in the care plan creation process through PEP need to be agreed upon (e.g. continuous involvement during editing or final approval/rejection only)

4.7 System Requirements Specification for Coordinated Care and Cure Delivery Platform

Description/System Context	Coordinated Care and Cure Delivery Platform (C3DP) is a platform to support collaborative execution of care plans for chronic conditions over a prolonged period of time in the scope of predefined care pathways. It is the backbone of C3-Cloud, integrating all of the components.
Related use case	C3DP-1: Close Care Plan C3DP-2: Invite a Care Team Member C3DP-3: Add Care Team Member C3DP-4: Remove Care Team Member C3DP-5: Discover Care Team C3DP-6: Send Message to Care Team Member(s) C3DP-7: Manage Messages C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting C3DP-9: Organize Virtual Care Review Meeting

	C3DP-10: Share Care Plan with Care Team Members C3DP-11: Record Patient Observations C3DP-12: Associate Supportive Content C3DP-13: Monitor Change C3DP-14: Care Plan Dashboard C3DP-15: Access Educational Material C3DP-16: Support Transfer of Care C3DP-17: Support Referral C3DP-18: Support Collaborative Management of Care Plan
General function	<p>The features of C3DP can be summarized as:</p> <ul style="list-style-type: none"> • Manage care team membership operations (inviting and adding new members, removing members, exploring care team members) • Asynchronous messaging within care team members • System notifications to care team members • Managing the organization of virtual care plan review meetings • Sharing care plans with care team members • Recording patient observations from PEP • Retrieving patient data from local sites as supportive content to care plans • Monitoring care plan events (subscription for events, processing of events, and sending notifications to subscribed parties) • Providing a dashboard to care team members to monitor the updates in the care plan, and also a general overview of patient medical summary (conditions, medications, vital signs, lab results, risks scores etc.) • Provide educational materials to Health Professionals • Support collaborative management of care plan during the whole lifecycle, including updating and sharing care plans in the care of referrals and transfer of care among care centers • Closing a finalized care plan, and achieving it
User characteristics	Health Professionals, Social Care Providers who have the expertise and authorization for managing care plan definitions in cooperation with the patients

4.7.1 Functional requirements

- C3DP-FR-1. The system shall support closing a care plan that is no longer in use and archive it
- C3DP-FR-2. The system shall send a notification to care team members whenever a care plan is marked as closed
- C3DP-FR-3. The system shall notify PEP whenever a care plan is marked as closed
- C3DP-FR-4. The system shall enable an authorized care team member to invite another individual to a care team.
- C3DP-FR-5. The system shall prepare a communication with the details of the request to join the specific patient's care team, and send it through the channel specified.
- C3DP-FR-6. The system shall provide an interface to the invitee to indicate whether s/he wants to be a part of the care team.
- C3DP-FR-7. When the invitee accepts to be a part of the care team, the system shall provide the access details about the C3DP and PCPDP
- C3DP-FR-8. The system shall notify the care team members about the new care team member added
- C3DP-FR-9. The system shall notify PEP whenever a new care team member is added
- C3DP-FR-10. The system shall enable an authorized care team member to inactivate the membership of another care team member

- C3DP-FR-11. The system shall notify the inactivated member about the inactivation/termination of his membership
- C3DP-FR-12. The system shall notify PEP whenever a care team member's membership is inactivated/terminated
- C3DP-FR-13. The system shall enable the authorized care team members to explore the details of (such as contact points, specialties) of the other care team members
- C3DP-FR-14. The system shall enable an authorized care team member to send asynchronous messages to one or more care team member(s)
- C3DP-FR-15. The system shall support the capability to link the messages with care plan items, when necessary by tagging them as "proposal", "reject", "counter proposal" or "accept".
- C3DP-FR-16. The system shall support care team members to view their messages, tag them, list them based on the tags
- C3DP-FR-17. The system shall support care team members to list the messages s/he received from a specific Care Team/ Care Team Member
- C3DP-FR-18. The system shall support care team members to list the messages s/he received from a specific Patient/Informal Care Giver
- C3DP-FR-19. The system shall support care team members to list the messages s/he received related with a specific patient
- C3DP-FR-20. The system shall support care team members to list the messages sent by the C3DP system as notifications (which are automatically tagged as "System Notifications") such as "New Care Team Member Invitation", "Update in the Shared Care Plan", "New Shared Care Plan", "Reminder for Care Plan Interventions to be carried out"
- C3DP-FR-21. The system shall support care team members to send an invitation to organize a joint virtual Care Plan Review Meeting
- C3DP-FR-22. The system shall provide an interface to invited care team members to accept/reject virtual care plan review meeting invitations
- C3DP-FR-23. The system shall support organizing virtual care plan review meetings where an audio connection is established and where care team members follow the updates performed by an editor via web based PCPDP tool
- C3DP-FR-24. The system shall notify care team members whenever a new care plan is defined or an existing care plan is updated by making the care plan available via C3DP along with all the supporting clinical documents (if any)
- C3DP-FR-25. The system shall notify PEP that a new care plan is defined or an existing care plan is updated
- C3DP-FR-26. The system shall provide an interface to capture the patient made observations/assessments from PEP. These include readings from personal medical devices, results of assessment scales and instruments (e.g. for activities of daily living), results of forms or questionnaires as instructed by the care plan, or notes from the patients about the realization of the interventions needed to be carried out by the patient or about the patient set goals.
- C3DP-FR-27. Whenever a new patient recorded data is received from the PEP, the system shall check care team members' subscriptions to receive notifications about these events and if necessary shall send system notifications via messaging platform
- C3DP-FR-28. The system shall support manually importing clinical documents of the patients in to the system and associating them with the active care plan
- C3DP-FR-29. Upon manual import of clinical documents, the system shall utilize TIS features to mediate the unsupported clinical document formats in to the formats supported by C3DP
- C3DP-FR-30. The system shall support the capability to manually initiate the retrieval of patient data from local care systems by utilizing TIS services in pull mode
- C3DP-FR-31. The system shall provide an interface to accept the patient data from local care systems via TIS services in push mode
- C3DP-FR-32. Whenever new patient data is retrieved from local care systems or from PEP, the system shall invoke the CDSM services (poly pharmacy management, provide diagnostic and treatment suggestions, risk assessment) to see whether there are any inconsistencies in the care plan, missing or duplicate treatment interventions, contraindicating treatment interventions, new risks and these are notified to the care team members.

- C3DP-FR-33.** As a result of the notifications received upon the retrieval of new patient data and execution of CDSM services, the system shall provide the capability to update the care plan via the PCPDP
- C3DP-FR-34.** The system shall provide mechanisms to subscribe to events in the lifetime of care plan execution (predefined set of events corresponding to changes in the care plan, associated patient data from local care systems and PEP, and patient feedback)
- C3DP-FR-35.** Whenever a subscribed event is detected by the system, the system shall send notifications about these events via messaging platform
- C3DP-FR-36.** Whenever a subscribed event is detected by the system, if the patient needs to be notified, the system shall send notifications about these events to PEP to be delivered to the patient
- C3DP-FR-37.** The system shall provide a dashboard through which the authorized care team members can see/monitor the activities carried out during the care delivery process for a selected patient; see the previous care plans defined/updated for the patient, patient encounters during the life time of the multi-disciplinary care delivery process, the clinical documents/patient data created in this process such as transfer of care summary, discharge summary, referral note; see a brief overview of the patient's medical summary including recent encounters, lab results, conditions, vital sign measurements, risk assessment results, patient reported data and feedback from PEP.
- C3DP-FR-38.** The system shall clearly mark the responsible editors of different sections of care plan
- C3DP-FR-39.** The system shall provide access to educational materials for care team members based on their roles and needs via web based interfaces

4.7.2 Information requirements

- C3DP-IR-1.** The patient data retrieved from TIS services shall be in the format of FHIR resources
- C3DP-IR-2.** The patient reported observations to be retrieved from PEP shall be in the format of FHIR resources
- C3DP-IR-3.** The input and output to Clinical Decision Support Modules shall be through FHIR resources

4.7.3 System Interface requirements

- C3DP-SIR-1.** The CDSM services shall be accessible through a standardized API such as HL7 DSS SFM
- C3DP-SIR-2.** Separate CDSM services shall be accessible for (a) calculating risk factors for the patient (b) identifying missing relevant interventions in the care plan given the demographics and current conditions of the patient (c) identifying contraindicating interventions in the care plan definition considering the poly-pharmacy indices, drug-to-drug & drug-to-condition contraindications.
- C3DP-SIR-3.** TIS services for retrieving patient data shall be accessible through a standardized API such as FHIR services
- C3DP-SIR-4.** C3DP shall provide an interface to TIS to receive patient data in push mode from local care systems as FHIR resources
- C3DP-SIR-5.** C3DP shall provide interfaces to PEP to receive patient recorded data as FHIR resources
- C3DP-SIR-6.** PEP shall provide an interface to receive notifications about new/updated/closed care plans
- C3DP-SIR-7.** PEP shall provide an interface to receive notifications about new/updated/terminated care team members

4.7.4 User Interface requirements

- C3DP-UIR-1. The system shall provide user interfaces for authorized Care Team Members for managing messages from care team members
- C3DP-UIR-2. The system shall provide user interfaces for authorized Care Team Members for managing system notifications
- C3DP-UIR-3. The system shall provide user interfaces for organizing virtual care plan review meetings
- C3DP-UIR-4. The system shall provide user interfaces for defining subscription rules to receive care plan event notifications
- C3DP-UIR-5. The system shall provide a dashboard for visualizing the events in care plan lifecycle
- C3DP-UIR-6. The system shall provide a dashboard for visualizing the patient's medical summary
- C3DP-UIR-7. The system shall provide user interfaces for accessing educational material

4.7.5 Performance requirements

- C3DP-NFR-1. The call to CDSM services should return a result in reasonable time (such as less than 10 sec)
- C3DP-NFR-2. The call to TIS services for retrieving patient data should return a result in reasonable time (such as less than 15 sec)
- C3DP-NFR-3. The audio connection to be supported for organizing virtual care plan review meetings shall provide acceptable voice quality
- C3DP-NFR-4. The patient dashboard shall be available for review within seconds

4.7.6 Usability requirements

- C3DP-NFR-5. All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.
- C3DP-NFR-6. All screens should have a help button.
- C3DP-NFR-7. Error messages should explain how to recover from the error and propose a fall-back mechanism.

4.7.7 Reliability requirements

- C3DP-NFR-8. The system shall not fail if an unsupported format of patient data is returned or pushed by TIS, it should be saved as a non-machine processable supporting clinical data
- C3DP-NFR-9. The system shall not fail if an unsupported format of patient recorded observation is pushed by PEP, it should be saved as a non-machine processable supporting data
- C3DP-NFR-10. The system shall return to a stable state when the virtual care plan review meeting is interrupted due to system failure (power, internet connection failure)

4.7.8 Maintainability requirements

- C3DP-NFR-11. The C3DP Mean Time To Repair (MTTR) shall not exceed 24 hours

4.7.9 Security requirements

- C3DP-NFR-12. The system shall provide a role based user access control mechanism
- C3DP-NFR-13. The system shall provide a log-in screen for care team members
- C3DP-NFR-14. The system shall check the authorization of care team members to perform the operations supported by C3DP
- C3DP-NFR-15. All operations shall be audited

4.7.10 Constraints, Policies and Regulations

SWFT: Rules around co-ownership and what this means in practice (such as rules around recording decisions etc.) are needed.

None from RJH.

Basque Country:

- The technological environment needed to enable the integration of the C3DP with the ecosystem of information systems of OSAKIDETZA requires:
 - Java 8
 - EJBs 3.2 with JPA 2.1 to access the data
 - To the layer over JSF 2.2 (implementation Web Primefaces 5.1)
 - REST services implementing the standard: Java API for RESTful Web Services (JAX-RS 2.0) – (JSR 339)
 - Service layer Web SOA to provide access to native customers. This Web layer is based on the standards Java EE 7: JSR 109, JSR 224, JSR 181, JSR 67, JSR 93
 - Java Authentication and Authorization Service (JAAS) to the authentication in the application.
- The construction of platform components will enable to adapt the different integration interfaces listed in WP6.
- The provision of information to this new Medical Record module should be part of the project scope.
- Once the project is completed, the information that is not hosted in the Medical Record of patients should be included while the information stored on the C3DP should be destroyed.

Assumptions and dependencies

- It is assumed that it will be possible to retrieve machine processable patient data from local care sites
- Currently it is assumed that the local care sites may optionally push clinical data to C3DP, if this is not possible we will utilize the manual upload option or manual retrieval from care sites option.
- We assume that Health Professionals and Social Workers will use C3DP messaging platform, while Patients use PEP messaging platform. We need to figure it out how messaging between Health Professionals/Social Workers and Patients will be handled via C3DP and PEP. We may need to create messages in one platform and send it to the other platform to create a seamless messaging experience for patients and Health Professionals/Social Workers.

Open Issues

- The existing HL7 FHIR resources may not be adequate to exchange patient reported observations between PEP and C3DP, necessary extensions may need to be done as new FHIR profiles
- Exact input/output format of TIS services to retrieve patient data need to be agreed upon

5 REFERENCES

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6 APPENDICES

6.1 Appendix I: Requirement Traceability Matrix

The requirement traceability matrix consists of the following columns:

- **Requirement ID:** This column should contain the unique identifier of the requirement. It could be a system generated number if using a utility, or manually assigned in a requirements document by the requirements author/analyst.
- **Description:** This column should be populated with a brief description of the requirement.
- **Associated Use Case:** This column should be populated with a description of the use case linked to the requirement.
- **Associated User Requirement:** This column should be populated with a link to the User Requirements defined in D8.1 to indicate that this requirement addresses the needs of the selected user scenarios
- **Status:** This column should be populated with the current status of the requirement. (Proposed, Validated, Obsolete, Designed, Implemented, Tested)
- **Type:** This column should be populated with the type of requirement: (Functional, Information, System Interface, User Interface, Performance, Reliability, Maintainability, Security, Usability)
- **Priority:** This column should be populated with the importance of the requirement as designated by/or agreed upon by the users. (H – High, M – Medium, L – Low).
- **Assigned To:** Identifies the C3-Cloud Partner responsible for fulfilling this requirement.
- **System Component(s):** This column should be populated with a description of the high level system component(s) linked to the requirement (PEP, TIS, SIS, SPS, CDSM, PCPDP, C3DP).
- **Architectural/Design Document:** This column should be populated with a reference of the related subsection of the architectural/design document (D3.3) linked to the requirement. (a.k.a. "Trace To Design")
- **Software Module(s):** This column should be populated with a description of the software module(s) linked to the requirement. (To be defined in D3.3 as a result of Conceptual Design)
- **Test Case Number:** This column should be populated with the test case number linked to the requirement. To be defined in D9.1. (a.k.a. "Trace to Test Case")
- **Implemented In:** This column should be populated with the module that the requirement has been implemented in.
- **Verification:** This column should be populated with a link to the verification document linked to the requirement. A subsection of D9.3

Template for Traceability Matrix:

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architectural/ Design Document</i>	<i>Software Module(s)</i>	<i>Test Case Number</i>	<i>Implemented In</i>	<i>Verification</i>

In this deliverable first 7 columns will be completed, it will be a living matrix that will be completed during the lifetime of the project in Deliverables D3.3, D9.1 and D9.3.

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
PEP-FR-1	The system shall process and store a new care plan published by a PEP Client System in such way that it can perform its automated duties and display the care plan to PEP Users.	PEP-1.1 Publish active care plan to patient	PAR-15, PAR-16, PAR-6	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-2	The system shall notify the patient when a new care plan is published to the patient.	PEP-1.1 Publish active care plan to patient	PAR-15, PAR-16, PAR-6	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-3	The system shall display the published, active care plan to PEP Users (the patient, authorized informal caregivers and health professionals).	PEP-1.2 View active care plan	PAR-18, PAR-19, PAR-53	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-4	The system shall mark the care plan as read when the care plan has been accessed by the patient or an informal caregiver.	PEP-1.2 View active care plan	PAR-18, PAR-19	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-5	PEP Users and/or a PEP Client System shall be able to set the contact information of the patient needed to receive treatment intervention reminder messages.	PEP-1.3 Send care plan related treatment intervention reminders	PAR-20	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-6	The system shall send treatment intervention reminder messages to patients according the timings defined in the patient's active care plan.	PEP-1.3 Send care plan related treatment intervention reminders	PAR-20, PAR-53	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-7	The patient or another PEP user on behalf of the patient shall be able to mark a treatment intervention goal as achieved.	PEP-1.4 Flag care plan treatment interventions and the corresponding goals as achieved	None	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-8	The patient or another PEP user on behalf of the patient shall be able to mark a treatment intervention goal as not achieved.	PEP-1.5 Flag care plan treatment interventions and the corresponding goals as not achieved	None	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-9	The system shall process and store an updated care plan published by a PEP Client System in such way that it can perform its automated duties and display the care plan to PEP Users.	PEP-1.6 Update active care plan	PAR-15, PAR-16, PAR-6	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-10	The system shall notify the patient when an updated care plan is published to the patient.	PEP-1.6 Update active care plan	PAR-15, PAR-16, PAR-6	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-11	The system shall set an active care plan as inactive when a PEP Client System notifies that the active care plan has been closed.	PEP-1.7 Mark active care plan as finished	None	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-12	The system shall support measurement device assignment to the patient when the patient care plan includes prescribed remote monitoring.	PEP-2.1 Measure and collect patient-observation data according the timings defined in care plan	PAR-35, PAR-47	Proposed	Functional	H	MEDIXINE	PEP

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
PEP-FR-13	The system shall support upload of patient measurement data from connected devices.	PEP-2.1 Measure and collect patient-observation data according the timings defined in care plan	PAR-35, PAR-47	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-14	The system shall send a notification to the patient when a prescribed questionnaire activity becomes active.	PEP-2.2 Complete patient questionnaires according the timings defined in care plan	PAR-46	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-15	The system shall send a notification to the patient if the prescribed questionnaire activity end time is reached before the activity has been completed.	PEP-2.2 Complete patient questionnaires according the timings defined in care plan	PAR-46	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-16	The patient or another PEP User on behalf of the patient shall be able to start any time during the prescribed activity's active period to answer and complete the questionnaire.	PEP-2.2 Complete patient questionnaires according the timings defined in care plan	PAR-46	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-17	The patient or another PEP User on behalf of the patient may interrupt and return later to complete the questionnaire.	PEP-2.2 Complete patient questionnaires according the timings defined in care plan	PAR-46	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-18	The system shall enable the patient to send messages to health professionals.	PEP-3.1 Communicate via Safe messaging	PAR-22, PAR-41, PAR-49, PAR-50	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-19	The system shall enable the health professionals to send messages to patients.	PEP-3.1 Communicate via Safe messaging	PAR-22, PAR-41, PAR-49, PAR-50	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-20	The system shall enable the patient and health professionals to reply to received messages and thus continue an ongoing conversation.	PEP-3.1 Communicate via Safe messaging	PAR-22, PAR-41, PAR-49, PAR-50	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-21	The system shall enable the communication between a health professional and a patients using video.	PEP-3.2 Communicate via Video appointment	PAR-51	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-22	Health professional and/or a PEP Client System shall be able to create a future video appointment between a health professional and a patient.	PEP-3.2 Communicate via Video appointment	PAR-51	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-23	The patient and the health professional shall be able to join the video appointment when it is due.	PEP-3.2 Communicate via Video appointment	PAR-51	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-24	The system shall support the configuration of links to self-management material published to patients.	PEP-5.1: Access self-management material	PAR-1, PAR-2, PAR-21	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-25	Any PEP User shall be able to access the self-management material via the system.	PEP-5.1: Access self-management material	PAR-1, PAR-2, PAR-21	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-26	The system shall support patients or PEP Users acting on behalf of the patient to subscribe to health coaching programs for the selected patient.	PEP-5.2: Manage health coaching subscriptions	PAR-52	Proposed	Functional	M	MEDIXINE	PEP

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
PEP-FR-27	The health coaching engine shall monitor coaching program subscriptions and generate coaching messages to be delivered to a patient.	PEP-5.2: Manage health coaching subscriptions	PAR-52	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-28	The system shall receive messages from the health coaching engine and deliver the messages to the patient.	PEP-5.3: Generate and deliver health coaching messages	PAR-52	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-29	The system shall display sent coaching messages to PEP users.	PEP-5.3: Generate and deliver health coaching messages	PAR-52	Proposed	Functional	M	MEDIXINE	PEP
PEP-FR-30	PEP Users shall be able to invite the patient to access the patient's own record.	PEP-4.4 Invite patient to access own patient workspace	PAR-17	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-31	PEP Users shall be able to invite an informal caregiver to access the selected patient's workspace.	PEP-4.7 Invite personal caregiver to access related patient's workspace	PAR-17	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-32	The system shall send the patient access invitation to the invited person (patient or informal caregiver) by email.	PEP-4.4 Invite patient to access own patient workspace PEP-4.7 Invite personal caregiver to access related patient's workspace	PAR-17	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-33	The invited person (patient or informal caregiver) shall be able to register to the C3 Cloud solution using the information contained in the invitation and an additional invitation code. The additional invitation code shall be delivered separately from the invitation email.	PEP-4.4 Invite patient to access own patient workspace PEP-4.7 Invite personal caregiver to access related patient's workspace	PAR-17	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-34	Any patient access user shall be able to log in to PEP System using their login credentials.	PEP-4.5 Authenticate patient access user to use PEP functionality	None	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-35	Any health professional user shall be able to log in to PEP System using their login credentials.	PEP-4.6 Authenticate health professional user to use PEP functionality	None	Proposed	Functional	H	MEDIXINE	PEP
PEP-FR-36	A logged in PEP User shall be able to select and open the record of any of the patient's the user is authorized to access and act on behalf of.	PEP-4.8 Access selected patient's workspace	None	Proposed	Functional	H	MEDIXINE	PEP
PEP-IR-1	The care plan shall contain information needed to automatically guide, control, and monitor the execution and progress of the care plan activities and interventions.	PEP-1.1 Publish active care plan to patient PEP-1.6 Update active care plan	PAR-15, PAR-16	Proposed	Information	H	MEDIXINE	PEP
PEP-IR-2	The care plan shall contain all information needed to display the care plan to PEP Users.	PEP-1.2 View active care plan	PAR-18, PAR-19	Proposed	Information	H	MEDIXINE	PEP
PEP-IR-3	An updated care plan shall contain the change information needed to highlight changes in updated care plan versions.	PEP-1.6 Update active care plan	PAR-15, PAR-16	Proposed	Information	H	MEDIXINE	PEP
PEP-IR-4	The care plan shall contain the information needed to schedule and generate the treatment intervention reminder messages.	PEP-1.3 Send care plan related treatment intervention reminders	PAR-20	Proposed	Information	H	MEDIXINE	PEP

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
PEP-IR-5	The care plan information shall support the inclusion of prescribed remote monitoring information (measurement types, timings and goal/limit values).	PEP-1.1 Publish active care plan to patient PEP-1.6 Update active care plan	PAR-15, PAR-16	Proposed	Information	H	MEDIXINE	PEP
PEP-IR-6	The care plan information shall support the inclusion of prescribed questionnaire activities.	PEP-1.1 Publish active care plan to patient PEP-1.6 Update active care plan	PAR-15, PAR-16	Proposed	Information	H	MEDIXINE	PEP
PEP-SIR-1	All essential PEP Client System interfaces used by PEP shall support synchronous use.	All PEP Use cases	All PEP related	Proposed	System Interface	H	MEDIXINE	PEP
PEP-SIR-2	A PEP Client System shall publish the care plans in a machine processable format to PEP System.	PEP-1.1 Publish active care plan to patient PEP-1.6 Update active care plan	PAR-15, PAR-16	Proposed	System Interface	H	MEDIXINE	PEP
PEP-SIR-3	A PEP Client System shall publish updated versions of an active care plan in a machine processable format to PEP System.	PEP-1.6 Update active care plan	PAR-15, PAR-16	Proposed	System Interface	H	MEDIXINE	PEP
PEP-SIR-4	A PEP Client System shall notify PEP System when a care plan is closed.	PEP-1.7 Mark active care plan as finished	None	Proposed	System Interface	H	MEDIXINE	PEP
PEP-SIR-5	The system shall notify PEP Client Systems when the care plan has been accessed by the patient or by an informal caregiver.	PEP-1.2 View active care plan	PAR-18, PAR-19	Proposed	System Interface	H	MEDIXINE	PEP
PEP-SIR-6	The system shall notify PEP Client Systems when a PEP User changes manually the status of a treatment intervention goal.	PEP-1.4 Flag care plan treatment interventions and the corresponding goals as achieved PEP-1.5 Flag care plan treatment interventions and the corresponding goals as not achieved	None	Proposed	System Interface	M	MEDIXINE	PEP
PEP-SIR-7	The system shall notify PEP Client Systems when a new patient observation is stored.	PEP-2.3 Notify connected systems of new and changed patient-observed data	PAR-8, PAR-34, PAR-36, PAR-37, PAR-39, PAR-48, PAR-6	Proposed	System Interface	H	MEDIXINE	PEP
PEP-SIR-8	The system shall notify PEP Client Systems when a questionnaire has been completed.	PEP-2.3 Notify connected systems of new and changed patient-observed data	PAR-8, PAR-34, PAR-36, PAR-37,	Proposed	System Interface	H	MEDIXINE	PEP

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
			PAR-39, PAR-48, PAR-6					
PEP-SIR-9	The Health coaching engine shall send coaching messages via PEP System.	PEP-5.3: Generate and deliver health coaching messages	PAR-52	Proposed	System Interface	M	MEDIXINE	PEP
PEP-SIR-10	A PEP Client System shall manage the care team and the health professional information in PEP System.	PEP-4.1 Manage care teams and health professionals	None	Proposed	System Interface	H	MEDIXINE	PEP
PEP-SIR-11	A PEP Client System shall create a unique record in PEP System for each enrolled patient.	PEP-4.2 Create patient record for individual patient	None	Proposed	System Interface	H	MEDIXINE	PEP
PEP-SIR-12	A PEP Client System shall manage which patients have a relationship with which care teams.	PEP-4.2 Create patient record for individual patient	None	Proposed	System Interface	H	MEDIXINE	PEP
PEP-UIR-1	The system shall provide user interfaces for PEP Users to view the active, published care plan of the selected patient.	PEP-1.2 View active care plan	PAR-18, PAR-19	Proposed	User Interface	H	MEDIXINE	PEP
PEP-UIR-2	The system shall provide user interfaces for PEP Users to manage the patient contact information.	All PEP-1.x use cases PEP-2.1 Measure and collect patient-observation data according the timings defined in care plan	PAR-15, PAR-16, PAR-18, PAR-19, PAR-20, PAR-35, PAR-47	Proposed	User Interface	H	MEDIXINE	PEP
PEP-UIR-3	The system shall provide user interfaces for patient access users to access and use care plan related functionalities.	All PEP-1.x use cases	PAR-15, PAR-16, PAR-18, PAR-19, PAR-20	Proposed	User Interface	H	MEDIXINE	PEP
PEP-UIR-4	The system shall provide user interfaces for PEP Users to access and manage collected data of a patient (observations and completed questionnaires).	PEP-2.1 Measure and collect patient-observation data according the timings defined in care plan PEP-2.2 Complete patient questionnaires according the timings defined in care plan	PAR-35, PAR-47, PAR-46	Proposed	User Interface	H	MEDIXINE	PEP
PEP-UIR-5	The system shall provide user interfaces for patient access users to communicate with health professionals.	All PEP-3.x use cases	PAR-22, PAR-41, PAR-49, PAR-50, PAR-51	Proposed	User Interface	H	MEDIXINE	PEP

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
PEP-UIR-6	The system shall provide user interfaces for patient access users to access self-management material.	PEP-5.1: Access self-management material	PAR-1, PAR-2, PAR-21	Proposed	User Interface	M	MEDIXINE	PEP
PEP-UIR-7	The system shall provide user interfaces for PEP Users to manage health coaching subscriptions and view received coaching messages.	PEP-5.2: Manage health coaching subscriptions PEP-5.3: Generate and deliver health coaching messages	PAR-52	Proposed	User Interface	M	MEDIXINE	PEP
PEP-UIR-8	The system shall provide user interfaces to manage patient and informal caregiver access to a patient's workspace.	PEP-4.4 Invite patient to access own patient workspace PEP-4.7 Invite personal caregiver to access related patient's workspace	PAR-17	Proposed	User Interface	H	MEDIXINE	PEP
PEP-NFR-1	All system functions shall respond within reasonable time.	All PEP Use cases		Proposed	Non-Functional	M	MEDIXINE	PEP
PEP-NFR-2	All essential PEP Client System interfaces shall respond within reasonable time.	All PEP Use cases		Proposed	Non-Functional	M	MEDIXINE	PEP
PEP-NFR-3	All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.	All PEP Use cases		Proposed	Non-Functional	M	MEDIXINE	PEP
PEP-NFR-4	All system user interfaces should be designed in such manner that the user understands and knows what to do on each screen. All screens should include additional instructions and help text whenever needed.	All PEP Use cases		Proposed	Non-Functional	M	MEDIXINE	PEP
PEP-NFR-5	All error messages should explain how to recover from the error and propose a fallback mechanism	All PEP Use cases		Proposed	Non-Functional	M	MEDIXINE	PEP
PEP-NFR-6	The system shall not fail if an unsupported format of care plan is returned or pushed by PEP Client Systems.	All PEP Use cases		Proposed	Non-Functional	M	MEDIXINE	PEP
PEP-NFR-7	The system shall provide a role based user access control mechanism	All PEP Use cases		Proposed	Non-Functional	H	MEDIXINE	PEP
PEP-NFR-8	The system shall provide a log-in screen for users	All PEP Use cases		Proposed	Non-Functional	H	MEDIXINE	PEP
PEP-NFR-9	The system shall check the authorization of users to perform the operations supported by the system.	All PEP Use cases		Proposed	Non-Functional	H	MEDIXINE	PEP
PEP-NFR-10	All operations shall be audited.	All PEP Use cases		Proposed	Non-Functional	H	MEDIXINE	PEP
TIS-FR-1	The system shall send queries to local care system for patient records	TIS-1: Query Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
TIS-FR-2	The system shall send queries to local care system for clinical documents	TIS-1: Query Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-3	The system shall receive queries for patient records from PCPDP or C3DP	TIS-1: Query Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-4	The system shall receive queries for clinical documents from PCPDP or C3DP	TIS-1: Query Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-5	The system shall subscribe to clinical events generated by local care system	TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-6	The system shall receive patient records from local care system	TIS-1: Query Patient Data TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-7	The system shall receive clinical documents from local care system	TIS-1: Query Patient Data TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-8	The system shall send patient records to PCPDP or C3DP	TIS-1: Query Patient Data TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-9	The system shall send clinical documents to PCPDP or C3DP	TIS-1: Query Patient Data TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-10	The system shall receive care plan from PCPDP or C3DP	TIS-2: Share Care Plan	PAR-15	Proposed	Functional	M	WARWICK	TIS
TIS-FR-11	The system shall send care plan to local care system	TIS-2: Share Care Plan	PAR-15	Proposed	Functional	M	WARWICK	TIS
TIS-FR-12	The system shall receive patient measurements from tele-monitoring device or PHR	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	Functional	H	WARWICK	TIS
TIS-FR-13	The system shall send patient measurements to C3DP	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	Functional	H	WARWICK	TIS

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
TIS-FR-14	The system shall send patient measurements to PEP	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	Functional	H	WARWICK	TIS
TIS-FR-15	The system shall send patient records in source format to SIS	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-16	The system shall send clinical documents in source format to SIS	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-17	The system shall send patient measurements in source format to SIS	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-18	The system shall receive patient records in converted format from SIS	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-19	The system shall receive clinical documents in converted format from SIS	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-FR-20	The system shall receive patient measurements in converted format from SIS	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	WARWICK	TIS
TIS-IR-1	Patient records or clinical documents received from local care system shall comply with the clinical data requirements listed in Appendix III: Clinical Data Requirements	TIS-1: Query Patient Data TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Information	H	WARWICK	TIS
TIS-IR-2	Patient measurements received from tele-monitoring systems or PHR shall comply with the clinical data requirements listed in Appendix III: Clinical Data Requirements	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	Information	H	WARWICK	TIS
TIS-IR-3	The converted patient records or clinical documents received from SIS shall conform to C3-Cloud FHIR profile	TIS-1: Query Patient Data TIS-4: Map Information Models and Terminologies TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Information	H	WARWICK	TIS
TIS-IR-4	The care plan received from PCPDP or C3DP shall conform to C3-Cloud FHIR profile	TIS-2: Share Care Plan	PAR-15	Proposed	Information	M	WARWICK	TIS

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
TIS-SIR-1	The system shall provide FHIR-based API for PCPDP or C3DP to query and extract patient records and clinical documents	TIS-1: Query Patient Data	PAR-5 PAR-29 PAR-32	Proposed	System Interface	H	WARWICK	TIS
TIS-SIR-2	Local care system shall provide API to query and extract patient records and clinical documents	TIS-1: Query Patient Data	PAR-5 PAR-29 PAR-32	Proposed	System Interface	H	WARWICK	TIS
TIS-SIR-3	Local care system shall provide API to subscribe clinical events	TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	System Interface	H	WARWICK	TIS
TIS-SIR-4	Local care system shall send patient records or clinical documents when subscribed clinical events are triggered	TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	System Interface	H	WARWICK	TIS
TIS-SIR-5	PCPDP or C3DP shall provide FHIR-based API to receive patient records or clinical documents	TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	System Interface	H	WARWICK	TIS
TIS-SIR-6	Tele-monitoring device or PHR shall send patient measurements at regular intervals or when pre-defined events are triggered	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	System Interface	H	WARWICK	TIS
TIS-SIR-7	C3DP shall provide FHIR-based API to receive patient measurements	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	System Interface	H	WARWICK	TIS
TIS-SIR-8	PEP shall provide FHIR-based API to receive patient measurements	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	System Interface	H	WARWICK	TIS
TIS-SIR-9	SIS shall provide API to convert patient records or clinical documents into C3-Cloud FHIR format	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	System Interface	H	WARWICK	TIS
TIS-NFR-1	The call to local care system API should return results in reasonable time (such as less than 10 sec)	TIS-1: Query Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Performance	M	WARWICK	TIS

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
TIS-NFR-2	The call to PCPDP or C3DP API should return in reasonable time (such as less than 10 sec)	TIS-3: Push Patient Observations TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32 PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	Performance	M	WARWICK	TIS
TIS-NFR-3	The call to PEP API should return in reasonable time (such as less than 10 sec)	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	Performance	M	WARWICK	TIS
TIS-NFR-4	The call to SIS API should return in reasonable time (such as less than 10 sec)	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	Performance	M	WARWICK	TIS
TIS-NFR-5	The system shall not fail if local care system fails to respond. The failure should be logged and appropriate error messages should be produced.	TIS-1: Query Patient Data TIS-2: Share Care Plan	PAR-5 PAR-29 PAR-32 PAR-15	Proposed	Reliability	H	WARWICK	TIS
TIS-NFR-6	The system shall not fail if PCPDP or C3DP fail to respond. The failure should be logged and appropriate error messages should be produced.	TIS-3: Push Patient Observations TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32 PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	Reliability	H	WARWICK	TIS
TIS-NFR-7	The system shall not fail if PEP fails to respond. The failure should be logged and appropriate error messages should be produced.	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	Reliability	H	WARWICK	TIS

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
TIS-NFR-8	The system shall not fail if SIS fails to respond. The failure should be logged and appropriate error messages should be produced	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	Reliability	H	WARWICK	TIS
TIS-NFR-9	The Technical Interoperability Suite's Mean Time To Repair (MTTR) shall not exceed 24 hours	All TIS use cases	PAR-5 PAR-29 PAR-32 PAR-8 PAR-15	Proposed	Maintainability	M	WARWICK	TIS
TIS-NFR-10	The system shall establish a secure communication channel when transporting patient records or clinical documents from local care system to PCPDP or C3DP	TIS-1: Query Patient Data TIS-5: Push Patient Data	PAR-5 PAR-29 PAR-32	Proposed	Security	H	WARWICK	TIS
TIS-NFR-11	The system shall establish a secure communication channel when transporting patient care plan from PCPDP or C3DP to local care system	TIS-2: Share Care Plan	PAR-15	Proposed	Security	H	WARWICK	TIS
TIS-NFR-12	The system shall establish a secure communication channel when transporting patient measurements from tele-monitoring device or PHR to PEP or C3DP	TIS-3: Push Patient Observations	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	Security	H	WARWICK	TIS
TIS-NFR-13	The system shall establish a secure communication channel when transporting patient records or clinical documents to and from SIS	TIS-4: Map Information Models and Terminologies	PAR-5 PAR-29 PAR-32	Proposed	Security	H	WARWICK	TIS
TIS-NFR-14	All communications with local care system, tele-monitoring device or PHR, PCPDP, C3DP, PEP and SIS shall be audited	All TIS use cases	PAR-5 PAR-29 PAR-32 PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41 PAR-15	Proposed	Security	M	WARWICK	TIS
SIS-FR-1	The system shall receive patient records in source format from TIS	SIS-1: Map specific input data to C3-Cloud format and codes SIS-3: Map specific input data to other specific output format and codes	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	INSERM	SIS
SIS-FR-2	The system shall receive clinical documents in source format from TIS	SIS-1: Map specific input data to C3-Cloud format and codes SIS-3: Map specific input data	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	INSERM	SIS

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
		to other specific output format and codes						
SIS-FR-3	The system shall receive patient measurements in source format from TIS	SIS-1: Map specific input data to C3-Cloud format and codes SIS-3: Map specific input data to other specific output format and codes	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	INSERM	SIS
SIS-FR-4	The system shall send patient records in converted format from TIS	SIS-2: Map C3-Cloud formatted data to specific output format and codes SIS-3: Map specific input data to other specific output format and codes	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	INSERM	SIS
SIS-FR-5	The system shall send clinical documents in converted format from TIS	SIS-2: Map C3-Cloud formatted data to specific output format and codes SIS-3: Map specific input data to other specific output format and codes	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	INSERM	SIS
SIS-FR-6	The system shall send patient measurements in converted format from TIS	SIS-2: Map C3-Cloud formatted data to specific output format and codes SIS-3: Map specific input data to other specific output format and codes	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	INSERM	SIS
SIS-FR-7	The system shall receive information model specifications from Administrator	SIS-5: Create mapping between specific data format and C3-cloud format SIS-6: Register new data information model	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	INSERM	SIS
SIS-FR-8	The system shall receive terminology definitions from Administrator	SIS-5: Create mapping between specific data format and C3-cloud format SIS-6: Register new data information model	PAR-5 PAR-29 PAR-32	Proposed	Functional	H	INSERM	SIS
SIS-SIR-1	The system shall provide API to perform mapping query.	SIS-4: Query terminology server for mapping	PAR-5 PAR-29 PAR-32	Proposed	System Interface	H	INSERM	SIS
SIS-UIR-1	The system shall provide user interfaces for Administrator for register new information model of data source.	SIS-6: Register new data information model	PAR-5 PAR-29 PAR-32	Proposed	User Interface	H	INSERM	SIS

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
SIS-UIR-2	The system shall provide user interfaces for Administrator for register new terminology mapping.	SIS-5: Create mapping between specific data format and C3-cloud format	PAR-5 PAR-29 PAR-32	Proposed	User Interface	H	INSERM	SIS
SIS-NFR-1	The call to SIS API should return in reasonable time	All SIS use cases.	PAR-5 PAR-29 PAR-32	Proposed	performance	H	INSERM	SIS
SIS-NFR-2	The system shall not fail if a mapping is impossible to achieve. The failure should be logged and appropriate error messages should be produced.	All SIS use cases.	PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41	Proposed	reliability	H	INSERM	SIS
SIS-NFR-3	The Semantic Interoperability Suite's Mean Time To Repair (MTTR) shall not exceed 24 hours	All SIS use cases.	PAR-5 PAR-29 PAR-32 PAR-8 PAR-15	Proposed	maintainability	H	INSERM	SIS
SIS-NFR-4	The system shall establish a secure communication channel when receiving requested and transmitting output.	SIS-1: Map specific input data to C3-Cloud format and codes SIS-2: Map C3-Cloud formatted data to specific output format and codes SIS-3: Map specific input data to other specific output format and codes	PAR-5 PAR-29 PAR-32	Proposed	security	H	INSERM	SIS
SIS-NFR-5	SIS-NFR-5. All communications of SIS shall be audited	All SIS use cases.	PAR-5 PAR-29 PAR-32 PAR-8 PAR-35 PAR-36 PAR-37 PAR-38 PAR-40 PAR-41 PAR-15	Proposed	Security	H	INSERM	SIS
SPS-FR-1	Whenever available, the system should integrate with the existing organisational identity provider systems (e.g. LDAP, Active Directory) and allow associated Care Team Members to continue using their regular business user accounts in C3-Cloud software components such as PCPDP and C3DP.	SPS-1: Create Care Team Member Account	PAR-57	Proposed	Functional	H	SRDC	SPS

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
SPS-FR-2	For any Care Team Member without a business user account or whose organisation's identity provider system cannot be integrated with C3-Cloud SPS somehow, the system shall support user account creation in the internal Identity Provider System.	SPS-1: Create Care Team Member Account	PAR-57	Proposed	Functional	H	SRDC	SPS
SPS-FR-3	The system shall support new user account creation with approval of both parties for enhanced security; i.e. the Care Team Member and the Administrator of the regional/institutional setting.	SPS-1: Create Care Team Member Account	PAR-57	Proposed	Functional	H	SRDC	SPS
SPS-FR-4	The system shall enable rejection of new user account creation request by the Administrator.	SPS-1: Create Care Team Member Account	PAR-57	Proposed	Functional	H	SRDC	SPS
SPS-FR-5	The system shall enable single sign-on mechanism; i.e. the users shall be able to use C3-Cloud applications by using a single account.	SPS-2: Authenticate User	PAR-57	Proposed	Functional	H	SRDC	SPS
SPS-FR-6	The system shall display a list of integrated identity providers on the log on page and allow the user to select his/her associated identity provider.	SPS-2: Authenticate User	PAR-57	Proposed	Functional	H	SRDC	SPS
SPS-FR-7	The system shall automatically forward the user to the selected identity provider's sign in page, and upon providing of the necessary credentials and authentication by the selected identity provider, the authentication response shall be forwarded to the C3-Cloud application of interest (i.e. PCPDP and C3DP) and the authenticated user be navigated to the user interface of the C3-Cloud application.	SPS-2: Authenticate User	PAR-57	Proposed	Functional	H	SRDC	SPS
SPS-FR-8	In case of authentication failure, the user shall be informed about the outcome appropriately.	SPS-2: Authenticate User	PAR-57	Proposed	Functional	H	SRDC	SPS
SPS-FR-9	The system shall provide the Administrator with the ability to manage access control policies through the Authorisation Manager subcomponent of the SPS.	SPS-4: Manage Access Control Policies	PAR-59	Proposed	Functional	H	SRDC	SPS
SPS-FR-10	The Authorisation Manager subcomponent shall support permission definitions based on roles (e.g. nurse, GP, specialist) that can be assigned to types of resources (e.g. care plan, referral note, calendar) and operations (e.g. create, read, update, delete).	SPS-4: Manage Access Control Policies	PAR-59	Proposed	Functional	H	SRDC	SPS
SPS-FR-11	The Authorisation Manager subcomponent shall enable definition of new policies/rules or update of existing policies/rules at any time.	SPS-4: Manage Access Control Policies	PAR-59	Proposed	Functional	H	SRDC	SPS
SPS-FR-12	The Authorisation Manager subcomponent shall store machine processable permission definitions in a repository.	SPS-4: Manage Access Control Policies	PAR-59	Proposed	Functional	H	SRDC	SPS
SPS-FR-13	When a Care Team Member tries to perform a CRUD operation on a specific resource via PCPDP or C3DP, these applications shall provide the user attributes and information about the requested resource and operation to the Authorisation Manager.	SPS-3: Authorise User	PAR-58	Proposed	Functional	H	SRDC	SPS
SPS-FR-14	PCPDP or C3DP should be able to request additional attributes of the user from the associated identity provider when necessary.	SPS-3: Authorise User	PAR-58	Proposed	Functional	H	SRDC	SPS
SPS-FR-15	The Authorisation Manager acting as the Policy Decision Point shall check the user attributes and requested resource and operation against the access control policies in its repository, and shall either approve or deny the operation.	SPS-3: Authorise User	PAR-58	Proposed	Functional	H	SRDC	SPS
SPS-FR-16	The system shall have an Audit Record Repository (ARR) that accepts and stores standards based audit trail records.	SPS-5: Log Audit	PAR-60	Proposed	Functional	H	SRDC	SPS

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
SPS-FR-17	Whenever a clinical data exchange is done between a data provider system and data requestor system, each system acting as the Secure Node shall create corresponding audit trail records and send them to the ARR.	SPS-5: Log Audit	PAR-60	Proposed	Functional	H	SRDC	SPS
SPS-FR-18	Audit Record Repository shall inform the Secure Node about the result of the save operation.	SPS-5: Log Audit	PAR-60	Proposed	Functional	H	SRDC	SPS
SPS-IR-1	User identity data including the secrets (password, authentication/authorization tokens) shall be stored in encrypted secure storage.	SPS-1: Create Care Team Member Account	PAR-57	Proposed	Information	H	SRDC	SPS
SPS-IR-2	The authentication request, response and user attributes shall all be represented in widely recognised industrial standards such as OpenID Connect.	SPS-2: Authenticate User	None	Proposed	Information	H	SRDC	SPS
SPS-IR-3	The access control policies shall be represented in widely recognised machine processable formats such as OASIS XACML and XSPA.	SPS-4: Manage Access Control Policies	None	Proposed	Information	H	SRDC	SPS
SPS-IR-4	Audit trail records shall be based on widely accepted standards and profiles such as IHE ATNA and shall at least include information on timestamp, user requesting access/update to record(s), subsystem that the user is using to access/update to record(s), operation, details of query if it is a query, the identifiers(s) of the accessed/updated records.	SPS-5: Log Audit	None	Proposed	Information	H	SRDC	SPS
SPS-SIR-1	All identity providers shall provide a software interface to accept authentication requests by C3-Cloud applications, and pass back the authentication tokens and user identity attributes to client C3-Cloud systems in a secure way after authenticating the user.	SPS-2: Authenticate User	PAR-57	Proposed	System Interface	H	SRDC	SPS
SPS-SIR-2	The Authorisation Manager subcomponent of the SPS shall provide a software interface to receive resource access requests (user identity attributes, the resource to be accessed and the operation to be performed) for ensuring authorised access.	SPS-3: Authorise User	PAR-58	Proposed	System Interface	H	SRDC	SPS
SPS-SIR-3	The Audit Record Repository (ARR) subcomponent of the SPS shall provide a standards-based software interface for all C3-Cloud components acting as Secure Nodes to submit their audit trail records.	SPS-5: Log Audit	PAR-60	Proposed	System Interface	H	SRDC	SPS
SPS-UIR-1	The system shall provide a sign-in interface for Care Team Members and Administrators to authenticate users into C3-Cloud applications (PCPDP, C3DP and SPS components).	SPS-2: Authenticate User	PAR-57	Proposed	User Interface	H	SRDC	SPS
SPS-UIR-2	The system shall provide a user interface for account creation for Care Team Members without a business user account or whose organisation's identity provider system cannot be integrated with C3-Cloud SPS for a reason.	SPS-1: Create Care Team Member Account	PAR-57	Proposed	User Interface	H	SRDC	SPS
SPS-UIR-3	The system shall provide user interface on top of the Authorisation Manager for Administrators to define/update access control policies.	SPS-4: Manage Access Control Policies	PAR-59	Proposed	User Interface	H	SRDC	SPS
SPS-UIR-4	The system shall have an Audit Record Repository (ARR) User Interface for Administrators to monitor, query and filter all the audit trail records in the ARR.	SPS-5: Log Audit	PAR-60	Proposed	User Interface	H	SRDC	SPS
SPS-NFR-1	After authentication, the identity providers should pass the authentication tokens and user identity attributes to client C3-Cloud systems in a reasonable time (less than 3 seconds).	SPS-2: Authenticate User	None	Proposed	Performance	H	SRDC	SPS

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SPS-NFR-2	The policy decision making of the Authorisation Manager should be completed in a reasonable time (less than 2 seconds).	SPS-3: Authorise User	None	Proposed	Performance	H	SRDC	SPS
SPS-NFR-3	The call to audit trail record submission interface of the Audit Record Repository should return in less than 2 seconds.	SPS-5: Log Audit	None	Proposed	Performance	H	SRDC	SPS
SPS-NFR-4	All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.	All SPS Use Cases	None	Proposed	Usability	H	SRDC	SPS
SPS-NFR-5	All screens should have a help button.	All SPS Use Cases	None	Proposed	Usability	H	SRDC	SPS
SPS-NFR-6	All error messages should explain how to recover from the error and propose a fallback mechanism	All SPS Use Cases	None	Proposed	Usability	H	SRDC	SPS
SPS-NFR-7	The system shall not fail if authentication tokens or user identity attributes are invalid or in an unsupported format; appropriate error messages should be returned and the user shall not be authenticated.	SPS-2: Authenticate User	PAR-57	Proposed	Reliability	H	SRDC	SPS
SPS-NFR-8	The system shall not fail when the Authorisation Manager cannot be reached (e.g. is down); the users shall be informed and invited to try again later.	SPS-3: Authorise User	PAR-58	Proposed	Reliability	H	SRDC	SPS
SPS-NFR-9	The system shall not fail if an unsupported audit trail record is tried to be submitted; appropriate error messages should be returned.	SPS-5: Log Audit	PAR-60	Proposed	Reliability	H	SRDC	SPS
SPS-NFR-10	The Security and Privacy Suite's Mean Time To Repair (MTTR) shall not exceed 24 hours.	All SPS Use Cases	None	Proposed	Maintainability	H	SRDC	SPS
SPS-NFR-11	All software interfaces shall be secured by node-to-node authentication (SSL/TLS)	SPS-5: Log Audit	PAR-60	Proposed	Security	H	SRDC	SPS
SPS-NFR-12	All operations (create, read, delete, update, execute) shall be audited	SPS-5: Log Audit	PAR-60	Proposed	Security	H	SRDC	SPS
CDSM-FR-1	The system shall allow to create a new knowledge module	CDSM-1: Create or Update Knowledge Modules	None	Proposed	Functional	H	WARWICK	CDS M
CDSM-FR-2	The system shall allow to update an old knowledge module	CDSM-1: Create or Update Knowledge Modules	None	Proposed	Functional	H	WARWICK	CDS M
CDSM-FR-3	The system shall allow to validate a knowledge module	CDSM-2: Validate Knowledge Modules	None	Proposed	Functional	H	WARWICK	CDS M
CDSM-FR-4	The system shall list all knowledge modules	CDSM-1: Create or Update Knowledge Modules CDSM-2: Validate Knowledge Modules	None	Proposed	Functional	M	WARWICK	CDS M
CDSM-FR-5	The system shall display metadata of a knowledge module	CDSM-1: Create or Update Knowledge Modules CDSM-2: Validate Knowledge Modules	None	Proposed	Functional	M	WARWICK	CDS M
CDSM-FR-6	The system shall evaluate patient data using a knowledge module	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy	PAR-7 PAR-8 PAR-9 PAR-10 PAR-37	Proposed	Functional	H	WARWICK	CDS M

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		Management CDSM-5: Risk Assessment	PAR-38 PAR-39 PAR-40 PAR-44 PAR-46					
CDSM-FR-7	The system shall have knowledge modules to provide clinical guideline based diagnosis and treatment suggestions	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions	PAR-7 PAR-9 PAR-10 PAR-44 PAR-46	Proposed	Functional	H	WARWICK	CDS M
CDSM-FR-8	The system shall have knowledge modules to provide polypharmacy management suggestions	CDSM-4: Polypharmacy Management	PAR-7 PAR-9	Proposed	Functional	H	WARWICK	CDS M
CDSM-FR-9	The system shall have knowledge modules to provide risk assessment	CDSM-5: Risk Assessment	PAR-8 PAR-37 PAR-38 PAR-39 PAR-40	Proposed	Functional	H	WARWICK	CDS M
CDSM-IR-1	The patient data for CDS evaluation shall conform to C3-Cloud FHIR profile	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management CDSM-5: Risk Assessment	PAR-7 PAR-8 PAR-9 PAR-10 PAR-37 PAR-38 PAR-39 PAR-40 PAR-44 PAR-46	Proposed	Information	H	WARWICK	CDS M
CDSM-IR-2	The system shall support the clinical guidelines that will be agreed upon in Task 7.1.	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions	PAR-7 PAR-9 PAR-10 PAR-44 PAR-46	Proposed	Information	H	WARWICK	CDS M
CDSM-IR-3	The system shall support the following polypharmacy criteria: 1. Beer's list 2. FORTA 3. Drug Burden Index 4. START 5. STOPP	CDSM-4: Polypharmacy Management	PAR-7 PAR-9	Proposed	Information	H	WARWICK	CDS M
CDSM-IR-4	The system shall support the risk assessment algorithms listed as a part of clinical guidelines that will be agreed upon in Task 7.1.	CDSM-5: Risk Assessment	PAR-8 PAR-37	Proposed	Information	H	WARWICK	CDS M

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			PAR-38 PAR-39 PAR-40					
CDSM-SIR-1	The system shall provide web service API conforming to HL7 DSS standard	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management CDSM-5: Risk Assessment	PAR-7 PAR-8 PAR-9 PAR-10 PAR-37 PAR-38 PAR-39 PAR-40 PAR-44 PAR-46	Proposed	System Interface	H	WARWICK	CDS M
CDSM-UI-1	The system shall provide user interface for knowledge engineers to create or update knowledge modules	CDSM-1: Create or Update Knowledge Modules	None	Proposed	User Interface	H	WARWICK	CDS M
CDSM-UI-2	The system shall provide user interface for care team members to validate knowledge modules	CDSM-2: Validate Knowledge Modules	None	Proposed	User Interface	H	WARWICK	CDS M
CDSM-NFR-1	The operations to create or update knowledge modules should return in reasonable time (such as less than 10 sec)	CDSM-1: Create or Update Knowledge Modules	None	Proposed	Performance	M	WARWICK	CDS M
CDSM-NFR-2	The operation to list and display knowledge module metadata should return in reasonable time (such as less than 5 sec)	CDSM-1: Create or Update Knowledge Modules CDSM-2: Validate Knowledge Modules	None	Proposed	Performance	M	WARWICK	CDS M
CDSM-NFR-3	The operation to evaluate patient using a knowledge module should return results in reasonable time (such as less than 20 sec)	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management CDSM-5: Risk Assessment	PAR-7 PAR-8 PAR-9 PAR-10 PAR-37 PAR-38 PAR-39 PAR-40 PAR-44 PAR-46	Proposed	Performance	H	WARWICK	CDS M
CDSM-NFR-4	All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.	CDSM-1: Create or Update Knowledge Modules CDSM-2: Validate Knowledge Modules	None	Proposed	Usability	M	WARWICK	CDS M
CDSM-NFR-5	All error messages should explain how to recover from the error and propose a fallback mechanism	CDSM-1: Create or Update Knowledge Modules	None	Proposed	Usability	M	WARWICK	CDS M

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		CDSM-2: Validate Knowledge Modules						
CDSM-NFR-6	The system shall not fail if wrong knowledge modules are referenced. The failure should be logged and appropriate error messages should be produced.	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management CDSM-5: Risk Assessment	PAR-7 PAR-8 PAR-9 PAR-10 PAR-37 PAR-38 PAR-39 PAR-40 PAR-44 PAR-46	Proposed	Reliability	H	WARWICK	CDS M
CDSM-NFR-7	The system shall not fail if input patient data are invalid. The failure should be logged and appropriate error messages should be produced.	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management CDSM-5: Risk Assessment	PAR-7 PAR-8 PAR-9 PAR-10 PAR-37 PAR-38 PAR-39 PAR-40 PAR-44 PAR-46	Proposed	Reliability	H	WARWICK	CDS M
CDSM-NFR-8	The Clinical Decision Support System's Mean Time To Repair (MTTR) shall not exceed 24 hours	All CDSM use cases	PAR-7 PAR-8 PAR-9 PAR-10 PAR-37 PAR-38 PAR-39 PAR-40 PAR-44 PAR-46	Proposed	Maintainability	M	WARWICK	CDS M
CDSM-NFR-9	The system shall provide a login screen to knowledge engineers and care team members	CDSM-1: Create or Update Knowledge Modules CDSM-2: Validate Knowledge Modules	None	Proposed	Security	M	WARWICK	CDS M
CDSM-NFR-10	The system shall check authorizations of knowledge engineers to create or update knowledge modules	CDSM-1: Create or Update Knowledge Modules	None	Proposed	Security	M	WARWICK	CDS M
CDSM-NFR-11	The system shall check authorizations of care team members to validate knowledge modules	CDSM-2: Validate Knowledge Modules	None	Proposed	Security	M	WARWICK	CDS M
CDSM-NFR-12	All operations to create, update or validate knowledge modules and evaluate patients shall be audited	All CDSM use cases	PAR-7 PAR-8	Proposed	Security	M	WARWICK	CDS M

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			PAR-9 PAR-10 PAR-37 PAR-38 PAR-39 PAR-40 PAR-44 PAR-46					
PCPDP-FR-1	The system shall maintain a repository of machine processable care plans	PCPDP-1: Create Care Plan	PAR-28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-2	PCPDP-FR-2. The system shall utilize Clinical Decision Support Modules that suggests treatment goals and interventions based on clinical guidelines to create core care plans targeting selected health concerns	PCPDP-2: Add new Care Plan from a Core Care Plan	PAR-28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-3	The system shall communicate with Technical Interoperability Suite (TIS) to access clinical data of a selected Patient	PCPDP-1: Create Care Plan	PAR-28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-4	The system shall support the capability to define a care plan from scratch	PCPDP-3: Define new Care Plan	PAR-28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-5	The system shall support the capability to define care plans by adopting core care plans (based on the suggestions provided by clinical decision support modules)	PCPDP-2: Add new Care Plan from a Core Care Plan	PAR-28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-6	The system shall support selecting the targeted health concerns from patient's medical history as the target of care plan	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	M	SRDC	PCPD P
PCPDP-FR-7	The system shall support utilization of Clinical Decision Support Modules (CDSM) features to calculate risk factors for the patient that can be added as health concerns	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-8	The system shall support editing the details of health concerns such as editing the priority for patient or for the health professional.	PCPDP-4: Update Existing Care Plan	PAR-6	Proposed	Functional	M	SRDC	PCPD P
PCPDP-FR-9	The system shall support visualization of the details of care plan templates	PCPDP-2: Add new Care Plan from a Core Care Plan	PAR-28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-10	The system shall support the capability to personalize core care plans as care plans for a specific patient by updating the core care plan definition accordingly	PCPDP-2: Add new Care Plan from a Core Care Plan	PAR-28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-11	The system shall enable definition of a new care team	PCPDP-1: Create Care Plan	PAR-28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-12	The system shall enable invitation of new care team members	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-13	The system shall enable removal of care team members from the care team	PCPDP-4: Update Existing Care Plan	PAR-6	Proposed	Functional	H	SRDC	PCPD P

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PCPDP-FR-14	The system shall inform PEP about Care Team Member updates	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	M	SRDC	PCPD P
PCPDP-FR-15	The system shall support the capability to utilize the clinical decision support modules that suggest goals and interventions given a health concern to be addressed based on clinical guidelines	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-16	The system shall enable the definition of new goals for the care plan	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-17	The system shall enable linking care plan goals with health concerns set as the target of the care plan	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-18	The system shall enable reviewing the details of existing goals in the care plan definition and updating them if necessary.	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-19	The system shall enable the definition of new interventions in the care plan	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-20	The system shall enable linking interventions with goals set as the target of the care plan	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-21	The system shall enable reviewing the status of the existing 'planned' interventions in the care plan definition, and based on the information received from the EHRs and the PHR of the patient, provide support to mark the ones that have been achieved.	PCPDP-4: Update Existing Care Plan	PAR-6	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-22	The system shall enable noting outcome observations to indicate the progress of patient to achieve these goals by linking them with the previously added goals and interventions	PCPDP-4: Update Existing Care Plan	PAR-6	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-23	The system shall enable setting planned care plan review meeting dates	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-27	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-24	The system shall support utilization of CDSM services to review the care plan definition and the existing EHR of the patient to identify missing relevant interventions in the care plan given the demographics and current conditions of the patient	PCPDP-5: Review Care Plan for Reconciliation	PAR-7	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-25	The system shall support utilization of CDSM services to review the care plan definition and the existing EHR of the patient to identify contraindicating interventions	PCPDP-5: Review Care Plan for Reconciliation	PAR-7	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-26	The system shall mark the missing missing relevant interventions and contraindicating interventions visually to present to the Care Team Member (s).	PCPDP-5: Review Care Plan for Reconciliation	PAR-7	Proposed	Functional	H	SRDC	PCPD P

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PCPDP-FR-27	The system shall enable utilization of C3DP and TIS functionalities to associate supportive documents (such as consultation note, progress note, diagnostic reports) with the newly updated care plan	PCPDP-4: Update Existing Care Plan	PAR-6	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-28	The system shall enable utilization of C3DP functionalities to share the defined care plan with Care Team Members including the patients via PEP	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-14	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-29	The system shall enable utilization of C3DP functionalities to invite care team members to virtual care plan review meetings to collaboratively define, personalize, update and reconcile care plan definitions	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-30	The system shall enable utilization of C3DP functionalities to initiate an asynchronous negotiation with care team members to discuss a new proposal for updating a care plan item	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28, PAR 33	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-31	The system shall support the capability to share the exported care plan with local care systems via TIS functionalities	PCPDP-9: Export Care Plan	PAR-15	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-32	The system can open up multiple care plans in case of multimorbid conditions and enable the care team members to review the goals, and interventions proposed by individual care plans and to select and prioritize them.	PCPDP-6: Reconcile Care Plans for Multiple Conditions	PAR-7	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-33	The system shall support utilization of the related CDSM services to review the care plan definition and the existing EHR of the patient to identify missing relevant interventions in the integrated care plan given the demographics and current conditions of the patient	PCPDP-6: Reconcile Care Plans for Multiple Conditions	PAR-7	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-34	The system shall support utilization of the related CDSM services to review the integrated care plan definition and the existing EHR of the patient to identify contraindicating interventions	PCPDP-6: Reconcile Care Plans for Multiple Conditions	PAR-7	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-35	The system shall mark the identified inconsistencies visually to present to the care team member (s) while reconciling multiple care plans	PCPDP-6: Reconcile Care Plans for Multiple Conditions	PAR-7	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-36	The system shall support review of the identified problems and to resolve them by updating the care plan definition. It shall support reviewing, selecting and prioritizing health concerns, goals and interventions	PCPDP-6: Reconcile Care Plans for Multiple Conditions	PAR-7	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-37	The system shall enable discovery of existing plans for a patient by the authorized care team members in order to make the plan accessible for reading, reviewing and changing	PCPDP-7: Find Care Plan	None	Proposed	Functional	M	SRDC	PCPD P
PCPDP-FR-38	The system shall enable tagging care plan items (i.e. health concerns, goals, interventions, outcome assessments) requiring review or follow-up.	PCPDP-8: Tag Care Plan Items	None	Proposed	Functional	L	SRDC	PCPD P
PCPDP-FR-39	The system support export operation to create a care plan snapshot and share it as a machine processable Care Plan document	PCPDP-9: Export Care Plan	PAR-15	Proposed	Functional	H	SRDC	PCPD P
PCPDP-FR-40	The system shall support importing an existing care plan document represented in a machine processable format to the system	PCPDP-10: Import Care Plan	None	Proposed	Functional	L	SRDC	PCPD P

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PCPDP-FR-41	The system shall enable to ascertain who the lead clinician and care plan manager would be	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-56	Proposed	Functional	H	SRDC	PCPD P
PCPDP-IR-1	Care plan to be imported shall be in a machine processable format, such as C-CDA Care Plan Document template, HL7 FHIR Care Plan Resource	PCPDP-10: Import Care Plan	None	Proposed	Information	L	SRDC	PCPD P
PCPDP-IR-2	The system shall export the care plan snapshot in the machine processable formats supported by C3-Cloud pilot sites	PCPDP-9: Export Care Plan	PAR-15	Proposed	Information	H	SRDC	PCPD P
PCPDP-IR-3	The input and output to Clinical Decision Support Modules shall be through FHIR resources	PCPDP-5: Review Care Plan for Reconciliation, PCPDP-6: Reconcile Care Plans for Multiple Conditions	None	Proposed	Information	H	SRDC	PCPD P
PCPDP-IR-4	The patient data retrieved from TIS services shall be in the format of FHIR resources	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	None	Proposed	Information	H	SRDC	PCPD P
PCPDP-SIR-1	The CDSM services shall be accessible through a standardized API such as HL7 DSS SFM	PCPDP-5: Review Care Plan for Reconciliation, PCPDP-6: Reconcile Care Plans for Multiple Conditions	None	Proposed	System Interface	M	SRDC	PCPD P
PCPDP-SIR-2	Separate CDSM services shall be accessible for (a) calculating risk factors for the patient (b) identifying missing relevant interventions in the care plan given the demographics and current conditions of the patient (c) identifying contraindicating interventions in the care plan definition considering the poly-pharmacy indices, drug-to-drug & drug-to-condition contraindications.	PCPDP-5: Review Care Plan for Reconciliation, PCPDP-6: Reconcile Care Plans for Multiple Conditions	PAR-7, PAR-44, PAR-8, PAR-9, PAR-10, PAR-38, PAR-39, PAR-40, PAR-44, PAR-46	Proposed	System Interface	H	SRDC	PCPD P
PCPDP-SIR-3	TIS services for retrieving patient data shall be accessible through a standardized API such as FHIR services	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	None	Proposed	System Interface	H	SRDC	PCPD P
PCPDP-SIR-4	C3DP shall provide an interface to PCPDP for inviting care team members to virtual care plan review meetings	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-33	Proposed	System Interface	H	SRDC	PCPD P
PCPDP-SIR-5	C3DP shall provide an interface to PCPDP for sharing the defined care plan with Care Team Members	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-14	Proposed	System Interface	H	SRDC	PCPD P
PCPDP-SIR-6	C3DP shall provide an interface to PCPDP for retrieving patient data from local care systems	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-5, PAR-29, PAR-32	Proposed	System Interface	H	SRDC	PCPD P

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PCPDP-SIR-7	C3DP shall provide an interface to PCPDP for initiating an asynchronous negotiation with Care Team Members	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-33	Proposed	System Interface	H	SRDC	PCPD P
PCPDP-SIR-8	PEP shall provide an interface to PCPDP for sharing the care plan with the patient and her informal care givers	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-14	Proposed	System Interface	H	SRDC	PCPD P
PCPDP-UIR-1	The system shall provide user interfaces for authorized Care Team Members for creating, deleting and updating care plan Items i.e. health concerns, goals, interventions, outcome assessments	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	PAR-6, PAR 28	Proposed	User Interface	H	SRDC	PCPD P
PCPDP-UIR-2	The system shall provide menu items for importing care plans	PCPDP-10: Import Care Plan	None	Proposed	User Interface	L	SRDC	PCPD P
PCPDP-UIR-3	The system shall provide menu items for exporting care plans	PCPDP-9: Export Care Plan	PAR-15	Proposed	User Interface	H	SRDC	PCPD P
PCPDP-UIR-4	The system shall provide menu items for finding care plans for a given patient	PCPDP-7: Find Care Plan	None	Proposed	User Interface	M	SRDC	PCPD P
PCPDP-UIR-5	The system shall provide menu items for locating clinical guidelines for a given health concern	PCPDP-2: Add new Care Plan from a Core Care Plan	PAR-6, PAR 28	Proposed	User Interface	M	SRDC	PCPD P
PCPDP-NFR-1	The call to CDSM services should return a result in reasonable time (such as less than 10 sec)	PCPDP-5: Review Care Plan for Reconciliation, PCPDP-6: Reconcile Care Plans for Multiple Conditions	None	Proposed	Performance	H	SRDC	PCPD P
PCPDP-NFR-2	The call to TIS services for retrieving patient data should return a result in reasonable time (such as less than 15 sec)	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	None	Proposed	Performance	H	SRDC	PCPD P
PCPDP-NFR-3	All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.	All PCPDP use cases	None	Proposed	Usability	H	SRDC	PCPD P
PCPDP-NFR-4	All screens should have a help button.	All PCPDP use cases	None	Proposed	Usability	H	SRDC	PCPD P
PCPDP-NFR-5	All error messages should explain how to recover from the error and propose a fallback mechanism	All PCPDP use cases	None	Proposed	Usability	H	SRDC	PCPD P
PCPDP-NFR-6	The system shall not fail if an unsupported care plan format is tried to be imported, appropriate error messages should be displayed	PCPDP-10: Import Care Plan	None	Proposed	Reliability	H	SRDC	PCPD P
PCPDP-NFR-7	The system shall not fail if an unsupported format of patient data is returned by TIS, it should be saved as a non-machine processable supporting clinical data	PCPDP-1: Create Care Plan, PCPDP-4: Update Existing Care Plan	None	Proposed	Reliability	H	SRDC	PCPD P
PCPDP-NFR-8	The system shall return to a stable state when care plan definition, and update operations are failed to be completed due to inappropriate user input	PCPDP-4: Update Existing Care Plan	None	Proposed	Reliability	H	SRDC	PCPD P

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PCPDP-NFR-9	The Personalized Care Plan Definition platform's Mean Time To Repair (MTTR) shall not exceed 24 hours	All PCPDP use cases	None	Proposed	Maintainability	H	SRDC	PCPD P
PCPDP-NFR-10	The system shall provide a role based user access control mechanism	All PCPDP use cases	PAR-59	Proposed	Security	H	SRDC	PCPD P
PCPDP-NFR-11	The system shall provide a log-in screen for care team members	All PCPDP use cases	PAR-57	Proposed	Security	H	SRDC	PCPD P
PCPDP-NFR-12	The system shall check the authorization of care team members to access/create/update a care plan for a specific patient	All PCPDP use cases	PAR-58	Proposed	Security	H	SRDC	PCPD P
PCPDP-NFR-13	All operations (such as create, delete, update of care plan items) shall be audited	All PCPDP use cases	PAR-60	Proposed	Security	H	SRDC	PCPD P
C3DP-FR-1	The system shall support closing a care plan that is no longer in use and archive it	C3DP-1: Close Care Plan	None	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-2	The system shall send a notification to care team members whenever a care plan is marked as closed	C3DP-1: Close Care Plan	None	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-3	The system shall notify PEP whenever a care plan is marked as closed	C3DP-1: Close Care Plan	None	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-4	The system shall enable an authorized care team member to invite another individual to a care team.	C3DP-2: Invite a Care Team Member	PAR-25, PAR-30, PAR-31	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-5	The system shall prepare a communication with the details of the request to join the specific patient's care team, and send it through the channel specified.	C3DP-2: Invite a Care Team Member	PAR-25, PAR-30, PAR-31	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-6	The system shall provide an interface to the invitee to indicate whether s/he wants to be a part of the care team.	C3DP-2: Invite a Care Team Member	PAR-25, PAR-30, PAR-31	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-7	When the invitee accepts to be a part of the care team, the system shall provide the access details about the C3DP and PCPDP	C3DP-2: Invite a Care Team Member	PAR-25, PAR-30, PAR-31	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-8	The system shall notify the care team members about the new care team member added	C3DP-3: Add Care Team Member	PAR-30, PAR-31	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-9	The system shall notify PEP whenever a new care team member is added	C3DP-3: Add Care Team Member	PAR-30, PAR-31	Proposed	Functional	M	SRDC	C3DP
C3DP-FR-10	The system shall enable an authorized care team member to inactivate the membership of another care team member	C3DP-4: Remove Care Team Member	None	Proposed	Functional	M	SRDC	C3DP
C3DP-FR-11	The system shall notify the inactivated member about the inactivation/termination of his membership	C3DP-4: Remove Care Team Member	None	Proposed	Functional	M	SRDC	C3DP
C3DP-FR-12	The system shall notify PEP whenever a care team member's membership is inactivated/terminated	C3DP-4: Remove Care Team Member	None	Proposed	Functional	M	SRDC	C3DP
C3DP-FR-13	The system shall enable the authorized care team members to explore the details of (such as contact points, specialties) of the other care team members	C3DP-5: Discover Care Team	None	Proposed	Functional	M	SRDC	C3DP

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C3DP-FR-14	The system shall enable an authorized care team member to send asynchronous messages to one or more care team member(s)	C3DP-6: Send Message to Care Team Member(s)	PAR-33	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-15	The system shall support the capability to link the messages with care plan items, when necessary by tagging them as “proposal”, “reject”, “counter proposal” or “accept”.	C3DP-6: Send Message to Care Team Member(s)	PAR-33	Proposed	Functional	M	SRDC	C3DP
C3DP-FR-16	The system shall support care team members to view their messages, tag them, list them based on the tags	C3DP-7: Manage Messages	PAR-33, PAR-54, PAR-55	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-17	The system shall support care team members to list the messages s/he received from a specific Care Team/ Care Team Member	C3DP-7: Manage Messages	PAR-33	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-18	The system shall support care team members to list the messages s/he received from a specific Patient/Informal Care Giver	C3DP-7: Manage Messages	PAR-33	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-19	The system shall support care team members to list the messages s/he received related with a specific patient	C3DP-7: Manage Messages	PAR-33	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-20	The system shall support care team members to list the messages sent by the C3DP system as notifications (which are automatically tagged as “System Notifications”) such as “New Care Team Member Invitation”, “Update in the Shared Care Plan”, “New Shared Care Plan”, “Reminder for Care Plan Interventions to be carried out”	C3DP-7: Manage Messages	PAR-33, PAR-54, PAR-55	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-21	The system shall support care team members to send an invitation to organize a joint virtual Care Plan Review Meeting	C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting	PAR-33	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-22	The system shall provide an interface to invited care team members to accept/reject virtual care plan review meeting invitations	C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting	PAR-33	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-23	The system shall support organizing virtual care plan review meetings where an audio connection is established and where care team members follow the updates performed by an editor via web based PCPDP tool	C3DP-9: Organize Virtual Care Review Meeting	PAR-33	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-24	The system shall notify care team members whenever a new care plan is defined or an existing care plan is updated by making the care plan available via C3DP along with all the supporting clinical documents (if any)	C3DP-10: Share Care Plan with Care Team Members	PAR-14, PAR-45	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-25	The system shall notify PEP that a new care plan is defined or an existing care plan is updated	C3DP-10: Share Care Plan with Care Team Members	PAR-14	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-26	The system shall provide an interface to capture the patient made observations/assessments from PEP. These include readings from personal medical devices, results of assessment scales and instruments (e.g. for activities of daily living), results of forms or questionnaires as instructed by the care plan, or notes from the patients about the realization of the interventions needed to be carried out by the patient or about the patient set goals.	C3DP-11: Record Patient Observations	PAR-8, PAR-35, PAR-37, PAR-38, PAR-39, PAR-40, PAR-41, PAR-49	Proposed	Functional	H	SRDC	C3DP

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
C3DP-FR-27	Whenever a new patient recorded data is received from the PEP, the system shall check care team members' subscriptions to receive notifications about these events and if necessary shall send system notifications via messaging platform	C3DP-11: Record Patient Observations	PAR-8, PAR-35, PAR-37, PAR-38, PAR-39, PAR-40, PAR-41, PAR-49	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-28	The system shall support manually importing clinical documents of the patients in to the system and associating them with the active care plan	C3DP-12: Associate Supportive Content	PAR-5, PAR-29, PAR-32	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-29	Upon manual import of clinical documents, the system shall utilize TIS features to mediate the unsupported clinical document formats in to the formats supported by C3DP	C3DP-12: Associate Supportive Content	PAR-5, PAR-29, PAR-32	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-30	The system shall support the capability to manually initiate the retrieval of patient data from local care systems by utilizing TIS services in pull mode	C3DP-12: Associate Supportive Content	PAR-5, PAR-29, PAR-32	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-31	The system shall provide an interface to accept the patient data from local care systems via TIS services in push mode	C3DP-12: Associate Supportive Content	PAR-5, PAR-29, PAR-32	Proposed	Functional	M	SRDC	C3DP
C3DP-FR-32	Whenever new patient data is retrieved from local care systems or from PEP, the system shall invoke the CDSM services (poly pharmacy management, provide diagnostic and treatment suggestions, risk assessment) to see whether there are any inconsistencies in the care plan, missing or duplicate treatment interventions, contraindicating treatment interventions, new risks and these are notified to the care team members.	C3DP-12: Associate Supportive Content	PAR-5, PAR-8	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-33	As a result of the notifications received upon the retrieval of new patient data and execution of CDSM services, the system shall provide the capability to update the care plan via the PCPDP	C3DP-12: Associate Supportive Content, PCPDP-4: Update Existing Care Plan	PAR-5, PAR-8, PAR-41	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-34	The system shall provide mechanisms to subscribe to events in the lifetime of care plan execution (predefined set of events corresponding to changes in the care plan, associated patient data from local care systems and PEP, and patient feedback)	C3DP-13: Monitor Change	PAR-37, PAR-38, PAR-39, PAR-40, PAR-41	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-35	Whenever a subscribed event is detected by the system, the system shall send notifications about these events via messaging platform	C3DP-13: Monitor Change	PAR-37, PAR-38, PAR-39, PAR-40, PAR-41	Proposed	Functional	H	SRDC	C3DP

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
C3DP-FR-36	Whenever a subscribed event is detected by the system, if the patient needs to be notified, the system shall send notifications about these events to PEP to be delivered to the patient	C3DP-13: Monitor Change	PAR-37, PAR-38, PAR-39, PAR-40, PAR-41	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-37	The system shall provide a dashboard through which the authorized care team members can see/monitor the activities carried out during the care delivery process for a selected patient; see the previous care plans defined/updated for the patient, patient encounters during the life time of the multi-disciplinary care delivery process, the clinical documents/patient data created in this process such as transfer of care summary, discharge summary, referral note; see a brief overview of the patient's medical summary including recent encounters, lab results, conditions, vital sign measurements, risk assessment results, patient reported data and feedback from PEP.	C3DP-14: Care Plan Dashboard	PAR-3, PAR-6, PAR-26, PAR-35, PAR-49	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-38	The system shall clearly mark the responsible editors of different sections of care plan	C3DP-14: Care Plan Dashboard	PAR-11	Proposed	Functional	H	SRDC	C3DP
C3DP-FR-39	The system shall provide access to educational materials for care team members based on their roles and needs via web based interfaces	C3DP-15: Access Educational Material	PAR-34	Proposed	Functional	H	SRDC	C3DP
C3DP-IR-1	The patient data retrieved from TIS services shall be in the format of FHIR resources	C3DP-12: Associate Supportive Content	None	Proposed	Information	H	SRDC	C3DP
C3DP-IR-2	The patient reported observations to be retrieved from PEP shall be in the format of FHIR resources	C3DP-11: Record Patient Observations	None	Proposed	Information	H	SRDC	C3DP
C3DP-IR-3	The input and output to Clinical Decision Support Modules shall be through FHIR resources	C3DP-11: Record Patient Observations, C3DP-12: Associate Supportive Content	None	Proposed	Information	H	SRDC	C3DP
C3DP-SIR-1	The CDSM services shall be accessible through a standardized API such as HL7 DSS SFM	C3DP-11: Record Patient Observations, C3DP-12: Associate Supportive Content	None	Proposed	System Interface	M	SRDC	C3DP
C3DP-SIR-2	Separate CDSM services shall be accessible for (a) calculating risk factors for the patient (b) identifying missing relevant interventions in the care plan given the demographics and current conditions of the patient (c) identifying contraindicating interventions in the care plan definition considering the poly-pharmacy indices, drug-to-drug & drug-to-condition contraindications.	C3DP-11: Record Patient Observations, C3DP-12: Associate Supportive Content	PAR-7, PAR-44, PAR-8, PAR-9, PAR-10, PAR-38, PAR-39, PAR-40, PAR-44, PAR-46	Proposed	System Interface	H	SRDC	C3DP
C3DP-SIR-3	TIS services for retrieving patient data shall be accessible through a standardized API such as FHIR services	C3DP-12: Associate Supportive Content	None	Proposed	System Interface	H	SRDC	C3DP

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
C3DP-SIR-4	C3DP shall provide an interface to TIS to receive patient data in push mode from local care systems as FHIR resources	C3DP-12: Associate Supportive Content	None	Proposed	System Interface	H	SRDC	C3DP
C3DP-SIR-5	C3DP shall provide interfaces to PEP to receive patient recorded data as FHIR resources	C3DP-11: Record Patient Observations	None	Proposed	System Interface	H	SRDC	C3DP
C3DP-SIR-6	PEP shall provide an interface to receive notifications about new/updated/closed care plans	C3DP-10: Share Care Plan with Care Team Members	PAR-14	Proposed	System Interface	H	SRDC	C3DP
C3DP-SIR-7	PEP shall provide an interface to receive notifications about new/updated/terminated care team members	C3DP-3: Add Care Team Member, C3DP-4: Remove Care Team Member	PAR-12, PAR-16	Proposed	System Interface	H	SRDC	C3DP
C3DP-UIR-1	The system shall provide user interfaces for authorized Care Team Members for managing messages from care team members	C3DP-7: Manage Messages	PAR-33	Proposed	User Interface	H	SRDC	C3DP
C3DP-UIR-2	The system shall provide user interfaces for authorized Care Team Members for managing system notifications	C3DP-7: Manage Messages	PAR-33, PAR-54, PAR-55	Proposed	User Interface	H	SRDC	C3DP
C3DP-UIR-3	The system shall provide user interfaces for organizing virtual care plan review meetings	C3DP-9: Organize Virtual Care Review Meeting	PAR-33	Proposed	User Interface	H	SRDC	C3DP
C3DP-UIR-4	The system shall provide user interfaces for defining subscription rules to receive care plan event notifications	C3DP-13: Monitor Change	PAR-37, PAR-38, PAR-39, PAR-40, PAR-41	Proposed	User Interface	H	SRDC	C3DP
C3DP-UIR-5	The system shall provide a dashboard for visualizing the events in care plan lifecycle	C3DP-14: Care Plan Dashboard	PAR-6, PAR-26, PAR-35, PAR-49	Proposed	User Interface	H	SRDC	C3DP
C3DP-UIR-6	The system shall provide a dashboard for visualizing the patient's medical summary	C3DP-14: Care Plan Dashboard	PAR-3	Proposed	User Interface	H	SRDC	C3DP
C3DP-UIR-7	The system shall provide user interfaces for accessing educational material	C3DP-15: Access Educational Material	PAR-34	Proposed	User Interface	H	SRDC	C3DP
C3DP-NFR-1	The call to CDSM services should return a result in reasonable time (such as less than 10 sec)	C3DP-11: Record Patient Observations, C3DP-12: Associate Supportive Content	None	Proposed	Performance	H	SRDC	C3DP
C3DP-NFR-2	The call to TIS services for retrieving patient data should return a result in reasonable time (such as less than 15 sec)	C3DP-12: Associate Supportive Content	None	Proposed	Performance	H	SRDC	C3DP
C3DP-NFR-3	The audio connection to be supported for organizing virtual care plan review meetings shall provide acceptable voice quality	C3DP-9: Organize Virtual Care Review Meeting	None	Proposed	Performance	H	SRDC	C3DP

<i>Req ID</i>	<i>Description</i>	<i>Associated Use case</i>	<i>Associated User Requirement</i>	<i>Status</i>	<i>Type</i>	<i>Priority</i>	<i>Assigned To</i>	<i>System Component(s)</i>
C3DP-NFR-4	The patient dashboard shall be available for review within seconds	C3DP-14: Care Plan Dashboard	None	Proposed	Performance	H	SRDC	C3DP
C3DP-NFR-5	All system user interfaces should be designed in such manner that the system functions can be achieved with as few clicks as possible.	All C3DP Use cases	None	Proposed	Usability	H	SRDC	C3DP
C3DP-NFR-6	All screens should have a help button.	All C3DP Use cases	None	Proposed	Usability	H	SRDC	C3DP
C3DP-NFR-7	All error messages should explain how to recover from the error and propose a fallback mechanism	All C3DP Use cases	None	Proposed	Usability	H	SRDC	C3DP
C3DP-NFR-8	The system shall not fail if an unsupported format of patient data is returned or pushed by TIS, it should be saved as a non-machine processable supporting clinical data	C3DP-12: Associate Supportive Content	None	Proposed	Reliability	H	SRDC	C3DP
C3DP-NFR-9	The system shall not fail if an unsupported format of patient recorded observation is pushed by PEP, it should be saved as a non-machine processable supporting data	C3DP-11: Record Patient Observations	None	Proposed	Reliability	H	SRDC	C3DP
C3DP-NFR-10	The system shall return to a stable state when the virtual care plan review meeting is interrupted due to system failure (power, internet connection failure)	C3DP-9: Organize Virtual Care Review Meeting	None	Proposed	Reliability	H	SRDC	C3DP
C3DP-NFR-11	The C3DP Mean Time To Repair (MTTR) shall not exceed 24 hours	All C3DP Use cases	None	Proposed	Maintainability	H	SRDC	C3DP
C3DP-NFR-12	The system shall provide a role based user access control mechanism	All C3DP Use cases	PAR-59	Proposed	Security	H	SRDC	C3DP
C3DP-NFR-13	The system shall provide a log-in screen for care team members	All C3DP Use cases	PAR-57	Proposed	Security	H	SRDC	C3DP
C3DP-NFR-14	The system shall check the authorization of care team members to perform the operations supported by C3DP	All C3DP Use cases	PAR-58	Proposed	Security	H	SRDC	C3DP
C3DP-NFR-15	All operations shall be audited	All C3DP Use cases	PAR-60	Proposed	Security	H	SRDC	Coordinated Care and Cure Delivery Platform

6.2 Appendix II: Information Exchange Matrix

The information exchange matrix defines the information items being exchanged between C3-Cloud system actors including both the high-level components and human users. The matrix is derived from the information flow and interaction scenarios as defined in C3-Cloud use cases (section 3), and links the exchange items to its source use cases where the context information can be found. The definition of the exchange is directional, where an information item is specifically communicated from its producer to its consumer. The information exchange matrix consists of the following columns:

- **ID:** This column represents the unique identifier of the information exchange item, so each item can be referenced and trace in related documents.
- **Producer:** The column represents the information producer, i.e. the sender of the information item.
- **Consumer:** The column represents the information consumer, i.e. the receiver of the information item.
- **Content:** This column describes the information item being exchanged between the producer and the consumer.
- **xRef:** The column links to the use cases or other related documents where the information exchange item is derived, so the provenance of the information exchange item can be traced.
- **Notes:** This column provides additional information about the context, usage or open issues of the information item.

ID	Producer	Consumer	Content	xRef	Notes
IE2	C3DP	PCPDP	Care plan	PCPDP-1 Create Care Plan PCPDP-2: Add New Care Plan from a Core Care Plan PCPDP-3: Define New Care Plan PCPDP-4: Update Existing Care Plan	
IE2	C3DP	PCPDP	Patient data and	PCPDP-1 Create Care Plan PCPDP-3: Define New Care Plan PCPDP-4: Update Existing Care Plan	
IE3	C3DP	PCPDP	Clinical documents (SIS transformed format)	PCPDP-1 Create Care Plan PCPDP-3: Define New Care Plan	

ID	Producer	Consumer	Content	xRef	Notes
				PCPDP-4: Update Existing Care Plan	
IE4	PCPDP	C3DP	Care plan	PCPDP-1 Create Care Plan PCPDP-3: Define New Care Plan PCPDP-4: Update Existing Care Plan	
IE5	PCPDP	SPS	User attributes, requested operation and resource of interest	SPS-1: Create Care Team Member Account	For policy decision making
IE6	PCPDP	SPS	Audit trail record	SPS-5: Log Audit	
IE7	PCPDP	CDSM	Patient data	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions CDSM-4: Polypharmacy Management CDSM-5: Risk Assessment	
IE8	PCPDP	CDSM	Care plan	PCPDP-6: Reconcile Care Plans for Multiple Conditions	For evaluation
IE9	PCPDP	CTM	Care plan templates	PCPDP-2: Add New Care Plan from a Core Care Plan	
IE10	PCPDP	CTM	Care team membership invitation	C3DP-2: Invite a Care Team Member	
IE11	PCPDP	CTM	Virtual care plan review meeting invitation	C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting	
IE12	PCPDP	CTM	Shared care plan	C3DP-10: Share Care Plan with Care Team Members	
IE13	PCPDP	CTM	Care plan	PCPDP-9: Export Care Plan	Exported
IE14	C3DP	PEP	Care plan	PEP-1.1: Publish active care plan to patient PEP-1.6: Update care plan	

ID	Producer	Consumer	Content	xRef	Notes
IE15	C3DP	PEP	Care team member data	PEP-4.1: Manage care teams and health professionals	
IE16	C3DP	TIS	Patient demographics	TIS-1: Query Patient Data	To query patient data Shouldn't be just patient id?
IE17	C3DP	TIS	Care plan	TIS-2: Share Care Plan	To be shared with local systems
IE18	C3DP	SPS	User attributes, requested operation and resource of interest	SPS-1: Create Care Team Member Account	For policy decision making
IE19	C3DP	SPS	Audit trail record	SPS-5: Log Audit	
IE20	C3DP	CDSM	Patient data	CDSM-5: Risk Assessment	
IE21	C3DP	CDSM	Tele-monitoring measurements	CDSM-5: Risk Assessment	For evaluation
IE22	C3DP	CTM	Virtual care plan review meeting invitation	C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting	
IE23	C3DP	CTM	Care team membership invitation	C3DP-2: Invite a Care Team Member	
IE24	C3DP	CTM	Shared care plan	C3DP-10: Share Care Plan with Care Team Members	
IE25	C3DP	CTM	Notifications about subscribed patient data and care plan	C3DP-13: Monitor Change	
IE26	C3DP	CTM	Patient reported observations	C3DP-11: Record Patient Observations	
IE27	C3DP	CTM	Overall summary of patient's medical history and care plan progress	C3DP-14: Care Plan Dashboard	Via dashboard?
IE28	C3DP	CTM	New care team member notification	C3DP-2: Invite a Care Team Member	
IE29	C3DP	CTM	Messages from other CTM/Patients/Informal care givers	C3DP-7: Manage Messages	
IE30	C3DP	CTM	Educational material	C3DP-15: Access Educational Material	
IE31	PEP	C3DP	Patient observations, questionnaire responses and assessments	PEP-2.3: Notify connected systems of new and	

ID	Producer	Consumer	Content	xRef	Notes
				changed patient-observed data C3DP-11: Record Patient Observations PEP-2.2: Complete patient questionnaires according the timings defined in care plan	
IE32	PEP	TIS	Patient demographics	PEP-4.2: Create patient record for individual patient TIS-1: Query Patient Data	To query patient data TBD (preferred to synchronize patient data with C3DP)
IE33	PEP	SPS	Audit trail record	SPS-5: Log Audit	
IE34	PEP	CDSM	Patient data, questionnaire responses and telemonitoring measurements	CDSM-5: Risk Assessment	For evaluation
IE35	PEP	PIC	Care plan	PEP-1.1: Publish active care plan to patient PEP-1.2: View active care plan	
IE36	PEP	PIC	Patient data	PEP-4.8: Access selected patient's workspace	
IE37	PEP	PIC	Reminders	PEP-1.3: Send care plan related treatment intervention reminder	Treatment, intervention, questionnaires
IE38	PEP	PIC	Treatment intervention status	Error! Reference source not found. Error! Reference source not found.	
IE39	PEP	PIC	Questionnaire	PEP-2.2: Complete patient questionnaires according the timings defined in care plan	

ID	Producer	Consumer	Content	xRef	Notes
IE40	PEP	PIC	Self-management material	PEP-5.1: Access self-management material	PEP provides access to information (links to) but does not necessarily contain/host the information.
IE41	PEP	PIC	Registration invitation	PEP-4.4: Invite patient to access own patient workspace PEP-4.7: Invite personal caregiver to access related patient's workspace	
IE42	TIS	C3DP	Patient data	TIS-1: Query Patient Data TIS-5: Push Patient Data	
IE43	TIS	C3DP	Clinical documents	TIS-1: Query Patient Data TIS-5: Push Patient Data	In SIS transformed format
IE44	TIS	C3DP	Tele-monitoring measurements	TIS-3: Push Patient Observations	In SIS transformed format
IE45	TIS	PEP	Patient data	TIS-1: Query Patient Data TIS-5: Push Patient Data	TBD (preferred to synchronize patient data with C3DP)
IE46	TIS	PEP	Tele-monitoring measurements	TIS-3: Push Patient Observations	In SIS transformed format
IE47	TIS	SIS	Patient data	TIS-4: Map Information Models and Terminologies TIS-1: Query Patient Data TIS-5: Push Patient Data	
IE48	TIS	SIS	Clinical documents	TIS-4: Map Information Models and Terminologies TIS-1: Query Patient Data TIS-5: Push Patient Data	In source format
IE49	TIS	SIS	Tele-monitoring measurements	TIS-4: Map Information Models and Terminologies TIS-3: Push Patient Observations	In source format
IE50	TIS	SPS	Audit trail record	SPS-5: Log Audit	

ID	Producer	Consumer	Content	xRef	Notes
IE51	TIS	LCS	Care plan	TIS-2: Share Care Plan	
IE52	SIS	TIS	Patient data	TIS-4: Map Information Models and Terminologies TIS-1: Query Patient Data TIS-5: Push Patient Data	
IE53	SIS	TIS	Clinical documents	TIS-4: Map Information Models and Terminologies TIS-1: Query Patient Data TIS-5: Push Patient Data	In SIS transformed format
IE54	SIS	TIS	Tele-monitoring measurements	TIS-4: Map Information Models and Terminologies TIS-3: Push Patient Observations	In SIS transformed format
IE55	SIS	SPS	Audit trail record	SPS-5: Log Audit	
IE56	SIS	CDSM	Patient data	SIS-2: Map C3-Cloud formatted data to specific output format and codes	In target format
IE57	SIS	CDSM	CDSM results	SIS-2: Map C3-Cloud formatted data to specific output format and codes	In target format
IE58	SPS	PCPDP	User authentication response	SPS-2: Authenticate User	
IE59	SPS	PCPDP	Access control decision	SPS-3: Authorise User	
IE60	SPS	C3DP	User authentication response	SPS-2: Authenticate User	
IE61	SPS	C3DP	Access control decision	SPS-3: Authorise User	
IE62	SPS	LCS	Login credentials	SPS-1: Create Care Team Member Account	
IE63	CDSM	PCPDP	Diagnosis/treatment suggestion	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions	Based on clinical guidelines
IE64	CDSM	PCPDP	Medication reconciliation suggestion	CDSM-4: Polypharmacy Management	Based on reconciliation guidelines Based on polypharmacy criteria

ID	Producer	Consumer	Content	xRef	Notes
IE65	CDSM	PCPDP	Risk prediction	CDSM-5: Risk Assessment	
IE66	CDSM	C3DP	Diagnosis/treatment suggestion	CDSM-3: Guideline-based Diagnosis and Treatment Suggestions	Based on clinical guidelines
IE67	CDSM	C3DP	Medication reconciliation suggestions	CDSM-4: Polypharmacy Management	Based on polypharmacy criteria
IE68	CDSM	C3DP	Risk prediction	CDSM-5: Risk Assessment	
IE69	CDSM	PEP	Risk prediction	CDSM-5: Risk Assessment	
IE70	CDSM	SIS	Patient data	SIS-1: Map specific input data to C3-Cloud format and codes	Source format
IE71	CDSM	SIS	CDSM result data	SIS-1: Map specific input data to C3-Cloud format and codes	Source format
IE72	CDSM	SPS	Audit trail record	SPS-5: Log Audit	
IE73	LCS	PEP	Patient data	PEP-4.2: Create patient record for individual patient	
IE74	LCS	TIS	Patient data	TIS-1: Query Patient Data TIS-5: Push Patient Data	
IE75	LCS	TIS	Clinical documents	TIS-1: Query Patient Data TIS-5: Push Patient Data	Source format
IE76	LCS	SPS	Audit trail record	SPS-5: Log Audit	
IE77	PHR/TM	TIS	Tele-monitoring measurements	TIS-3: Push Patient Observations	Source format
IE78	CTM	PCPDP	Care plan	PCPDP-1 Create Care Plan PCPDP-3: Define New Care Plan PCPDP-4: Update Existing Care Plan PCPDP-5: Review Care Plan for Reconciliation	

ID	Producer	Consumer	Content	xRef	Notes
				PCPDP-10: Import Care Plan PCPDP-9: Export Care Plan	
IE79	CTM	PCPDP	Patient data	C3DP-12: Associate Supportive Content from Care Systems	
IE80	CTM	PCPDP	Clinical documents	C3DP-12: Associate Supportive Content from Care Systems	
IE81	CTM	C3DP	Care plan	C3DP-1: Close Care Plan C3DP-10: Share Care Plan with Care Team Members C3DP-13: Monitor Change	
IE82	CTM	C3DP	Care team member information	C3DP-3: Add Care Team Member C3DP-4: Remove Care Team Member C3DP-5: Discover Care Team	
IE83	CTM	C3DP	Text message	C3DP-6: Send Message to Care Team Member(s)	
IE84	CTM	C3DP	Virtual care plan review meeting	C3DP-9: Organize Virtual Care Review Meeting	
IE85	CTM	PEP	Text message	PEP-3.1: Communicate via Safe messaging	
IE86	CTM	PEP	Video appointment	Error! Reference source not found.	
IE87	CTM	PEP	Login credentials	PEP-4.6: Authenticate health professional user to use PEP functionality	
IE88	CTM	SPS	Login credentials	SPS-2: Authenticate User	

ID	Producer	Consumer	Content	xRef	Notes
IE89	KE	CDSM	Knowledge modules	CDSM-1: Create and Update Knowledge Modules	
IE90	KM	CDSM	Knowledge modules	CDSM-2: Validate Knowledge Modules	
IE91	PIC	PEP	Text message	PEP-3.1: Communicate via Safe messaging	
IE92	PIC	PEP	Care plan review/goal intervention assessment/symptoms	PEP-2.1: Measure and collect patient observation data according to the timings defined in care plan PEP-2.2: Complete patient questionnaires according to the timings defined in care plan	
IE93	PIC	PEP	Video appointment	PEP-3.2: Communicate via Video appointment	
IE94	PIC	PEP	Login credentials	PEP-4.5: Authenticate patient access user to use PEP functionality	
IE95	CSA	SIS	Clinical data format mappings	SIS-5: Create mapping between specific data format and C3-cloud format	
IE96	CSA	SIS	Terminology mappings	SIS-4: Query terminology server for mapping	
IE97	CSA	SPS	Login credentials	SPS-1: Create Care Team Member Account	
IE98	CSA	SPS	Access control policy	SPS-4: Manage Access Control Policies	

6.3 Appendix III: Clinical Data Requirements

Appendix III presents a candidate clinical data set based on the conceptual data elements identified in the US ONC 2014 Edition Standards and Certification Criteria related to Meaningful Use Stage 2, which have been used by the US ONC Data Access Framework (DAF) initiative to design the query stack for data sharing. ONC DAF offers a good practice, starting point for the design of the data elements, also offering a well peer reviewed implementation profile in FHIR (which has been adopted as a preferred design approach in C3-Cloud). It also presents candidate clinical documents that are based on HL7 C-CDA IG. The candidate list will be reviewed by the project partners as part of tasks 3.3, 3.4 and 4.1. The consolidated table will inform subsequent design of C3-Cloud. C3-Cloud will contribute to the definition of data elements when these are not covered by suggested standards.

Data Elements
Patient (s) Identification includes attributes necessary to enable effective patient matching to retrieve specific patient records
Provider Identification
Facility / Source
Encounter Type
Date (Date Range)
Patient name
Sex
Date of birth
Race
Ethnicity
Preferred language
Smoking status
Problems
Medications
Medication allergies
Laboratory test(s)
Laboratory value(s)/result(s)
Vital signs (height, weight, BP, BMI)
Care plan field(s), including goals and instructions
Procedures
Care team members
Immunizations
Confidentiality Information
Clinical Instructions
Cognitive Status
Date and Location of Visit
Dates and Location of Admission and Discharge- Inpatient Only
Diagnostic Tests Pending
Discharge Instructions- Inpatient Only
Functional Status
Future Appointments
Future Scheduled Tests
Immunizations Administered during the Visit
Medication List
Medications Administered during the Visit

Provider Name and Office Contact Information
Reason for Hospitalization- Inpatient Only
Reason for Referral- Ambulatory Only
Reason for Visit
Recommended Patient Decision Aids
Referrals to other Providers

The following list of clinical documents is based on the HL7 Consolidated CDA (C-CDA) Implementation Guide Release 2.1.

Clinical Documents
Care Plan
Consultation Note
Continuity of Care Document (CCD)
Diagnostic Imaging Report (DIR)
Discharge Summary
History and Physical (H&P) Note
Operative Note
Procedure Note
Progress Note
Referral Note
Transfer Summary
Unstructured Document (UD)