



# 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**

## D3.3 Conceptual Design of the C3-Cloud Architecture

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## EXECUTIVE SUMMARY

The purpose of deliverable D3.3 is to provide a description of the design of C3-Cloud architecture, at a conceptual level, in order for project stakeholders to have a technical reference to continue the implementation work for each subsystem in subsequent work packages. Based on a detailed analysis of the system requirements and use cases from deliverable D3.2, this deliverable derives key communication interfaces among system components and their interaction workflow, in order to fulfil the requirements. As an information intensive system, extensive information modelling has also taken place as part of the design activities.

The content of D3.3 is prepared in accordance with the IEEE Standard 1016-2009 (IEEE Standard for Information Technology -- Systems Design -- Software Design Descriptions). As required by IEEE 1016-2009, D3.3 is organised into design views. Five design views have been selected for use in the document. The *composition* view identifies communication interfaces between system components. The *logical* view analyses key business concepts and domain logic. The *information* view models key information items exchanged through the interfaces. Using the data models from the information view, the *interface* view defines operations for each interface identified in the composition view. The *interaction* view demonstrates how the operations in the interface view should be executed in order to fulfil each use case defined in D3.2.

C3-Cloud architecture design is heavily based on the emerging HL7 FHIR (Fast Healthcare Interoperability Resources) standards and FHIR-based open specifications. Specifically, C3-Cloud adopts the FHIR RESTful paradigm as the architecture foundation. FHIR resource models are used as the basis for the definitions of information items to be exchanged between C3-Cloud subsystems, with a plan to create FHIR profiles in subsequent work packages. The provision of a terminology service follows FHIR terminology service specification. Clinical decision support modules are delivered through CDS hooks based services. SMART apps are considered as options to deliver user interface applications to the clinician's desktop, in order to integrate with the local electronic health record system workflow. OpenID/OAuth2 are chosen as the authentication mechanism for single-sign-on. A FHIR variant of IHE ATNA is designed for auditing. Additionally, XACML is consulted for access control, where well-accepted authorisation standards are missing in FHIR ecosystem.

The document is organised as follows:

Section 1 introduces the purpose, scope, context and methodology of this deliverable, and identifies the key design stakeholders having been involved in the design process. Section 1 also describes achievement of the description of action, and conformance to IEEE Standard 1016-2009.

Section 2 presents an overall composition view of C3-Cloud architecture, in terms of top-level subsystems, followed by a refined composition view for each subsystem. The design of the composition view uses UML component diagrams.

Section 3 presents an overall logical view followed by refined subsystem logical views, formulating main business concepts and domain logic at a conceptual level. Section 4 expands key business entities from the logical view into concrete information models using FHIR resource models. Both sections use UML class diagrams for the design.

Section 5 presents the interface view, in which concrete operations are defined for each interface identified in the composition view. Section 6 describes the realisation of D3.2 use cases in the form of execution flows of the operations from the interface view, using UML sequence diagrams.

Section 7 links the design elements in this document to D3.2 requirements through the Requirements Traceability Matrix and Information Exchange Matrix (a.k.a. Traceability to User Requirements). Finally, user interface mock-ups and screenshots are included in Appendix II.



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# 1. INTRODUCTION

## 1.1. Purpose

This deliverable is the software design description (SDD) of C3-Cloud architecture. An SDD is a representation of a software design to be used for recording design information and communicating that design information to key design stakeholders. The purpose of an SDD is to provide a description of the design of a system, fully enough, to allow software development to proceed with an understanding of what is to be built and how it is expected to be built. The C3-Cloud architecture SDD (D3.3) describes the details of C3-Cloud architecture and the critical parts of the system. D3.3 will be the primary reference for software development in the implementation phase.

## 1.2. Context

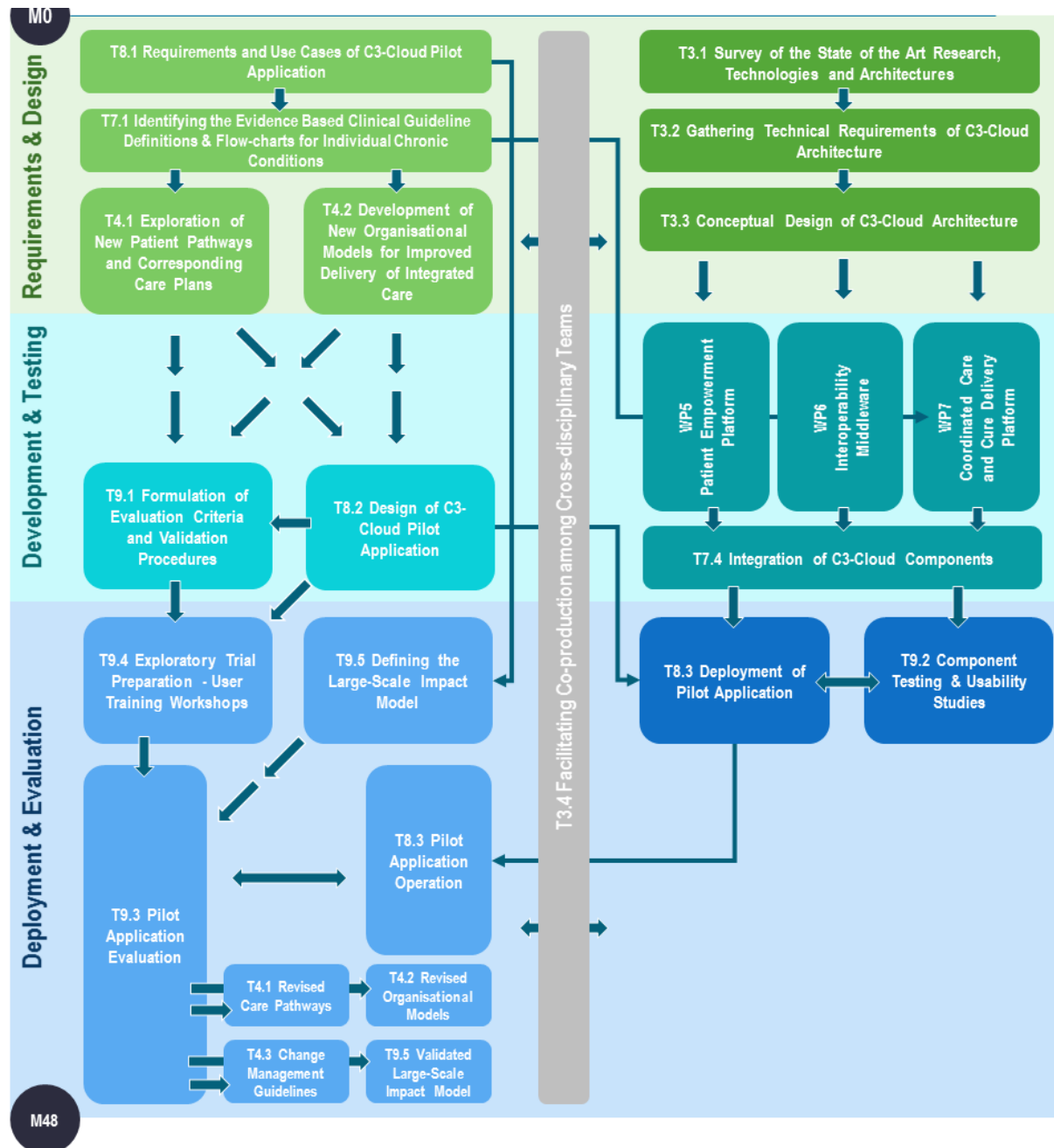
The software design is a process by which the software requirements, which have been captured in the software requirements specification (SRS) [D3.2], are translated into a representation of software components, interfaces, and data necessary for the implementation phase. SRS (D3.2) and SDD (D3.3) establish the technical basis for software implementation in other work packages 5, 6, 7; and pilot application design in work package 8. D3.2 and D3.3 also drive the development of testing and evaluation protocol in work package 9. D3.3 plays a role in project validation by providing: an overview necessary for understanding the implementation; the rationale justifying design decisions made; and traceability back to the requirements on the software under design.

## 1.3. Approach and Scope

This report documents the results of Task 3.3 of the C3-Cloud project. It presents a Software Description Document, in conformance with the IEEE 1016-2009 standard. All project partners contribute to the SDD. Task 3.3 uses information described in D8.1 and D3.3, and will be used to inform the implementation of the system, as described in the project's Description of Action (DoA), as in Figure 1.

C3-Cloud will establish an ICT infrastructure enabling a collaborative care and cure cloud to enable continuous coordination of patient-centred care activities by a multidisciplinary care team and patients/informal care givers. C3-Cloud will not replace pre-existing care systems but rather integrate them and enhance the overall care delivery process. Due to the diversity and complexity of pre-existing local care systems and local care delivery workflows, this SDD is focused on the conceptual design of a general system, which will be configured in local environments in conjunction with pre-existing local systems to implement specific pilot applications. Because it is targeted at the conceptual level, this SDD is organised to provide the design specification independent of implementation platforms. The focus is placed on precise and unambiguous communication of the design details regarding the architecture, data definitions, interfaces and interaction workflows. For this purpose, a generic modelling language, such as the Unified Modelling Language (UML), is chosen to present system models in a standard representation, which can be implemented by a wide range of technology platforms. Finally, this SDD is for building a system that provides the base level functionality, which will work as a proof of concept to show feasibility for large-scale production use.

Figure 1: C3-Cloud Phasing [DoA, Figure 11]



#### 1.4. Design stakeholders and concerns

Design stakeholders are individuals, organizations, or groups having an interest in, or design concerns relative to, the design of some software item [IEEE-1016]. A design concern is an area of interest with respect to a software design. C3-Cloud architecture SDD represent the collective contributions by all related project partners, who have design concerns relative to the design of software components in other work packages. Table 1 lists the partner organisations and their responsibilities in related work packages. The highlighted partner organisations (in bold text) are task leaders, who lead the design of their respective components. By analysing the use cases and requirements in D3.2, task members

identify the design concerns to be addressed in this architecture design phase. All the design concerns are addressed in relevant design views (Sections 2 to 6).

**Table 1 Design stakeholders and concerned components**

<b>WORK PACKAGE</b>	<b>COMPONENTS AND FUNCTIONS BY TASK</b>	<b>PARTNERS RESPONSIBILITIES</b>	<b>HIGH LEVEL COMPONENTS IDENTIFIED</b>	<b>DESIGN CONCERNS</b>
<b>Work package 5</b> Patient Empowerment Platform	Task 5.1 Development of Self-Management Training Materials for Increasing Patient Adherence to Care Plans	<b>SWFT</b> empirica, KG, ORU, RJH	<b>Patient Empowerment Platform</b>	Interaction, interface, shared/common information across components, UI design (mock ups)
	Task 5.2 Data Collection and Feedback Mechanism	<b>MEDIXINE</b> WARWICK		
	Task 5.3 Development of the Responsive Multi-Channel Patient Empowerment Platform	<b>MEDIXINE</b> WARWICK, SRDC, OSAKI		
<b>Work package 6</b> Interoperability Middleware	Task 6.1 Technical Interoperability Platform	<b>WARWICK</b> SRDC, OSAKI, CAMBIO	<b>Technical Interoperability Suite</b>	Functional components, clinical data models, service API and interactions
	Task 6.2 Semantic Interoperability Platform	<b>INSERM</b> WARWICK, SRDC, EuroRec	<b>Semantic Interoperability Suite</b>	Functional components, clinical data models, care plan data models, service API and interactions
	Task 6.3 Privacy Protection and Security within the C3-Cloud Architecture	<b>SRDC</b> WARWICK	<b>Security and Privacy Suite</b>	Functional components, audit trail data model, service API, authentication and authorisation workflow, UI for audit trail management
<b>Work package 7</b> Coordinated Care and Cure Delivery Platform	Task 7.2 Clinical Decision Support Modules for Personalised Care Plan Development and Execution	<b>WARWICK</b> INSERM, OSAKI, CAMBIO	<b>Clinical Decision Support Modules</b>	Functional components, clinical data models, service API, CDS evaluation workflow, UI for CDSM development
	Task 7.3 Personalised Care Plan Development Platform	<b>SRDC</b> MEDIXINE, CAMBIO	<b>Personalised Care Plan Development Platform</b>	Functional components, clinical data models, care plan data model, UI

WORK PACKAGE	COMPONENTS AND FUNCTIONS BY TASK	PARTNERS RESPONSIBILITIES	HIGH LEVEL COMPONENTS IDENTIFIED	DESIGN CONCERNS
				for personalised care plan development
	Task 7.4 Development of Coordinated Care and Cure Delivery Platform through Integration of C3-Cloud Components	SRDC WARWICK, INSERM, EuroRec, MEDIXINE, OSAKI, CAMBIO	<b>Coordinated Care and Cure Delivery Platform</b>	Functional components, FHIR repository, clinical data models, care plan data model, service API, UI for personalised care plan execution

## 1.5. Activities Based on Description of Action

Task 3.3 has provided the conceptual design for C3-Cloud. This encompasses how the main components in C3-Cloud, identified in the concept description (proposal and Task 3.2), as well as the early design (Task 3.2), will be structured and interact to satisfy the requirements identified in D3.2. This task focuses on architectural decisions and has made provisional technical decisions where necessary and appropriate to define the architecture (e.g., decision on interfaces), following architecture oriented development best practice. Design decisions will be under constant evaluation, as the design progresses, and potential changes will be documented and traced back to D3.3 and D3.2. A well-defined software engineering process has been followed by means of following the quality assurance plan, skill of the staff involved (partners have provided staff with appropriate software engineering training, and D3.3 owners have stipulated the skills necessary for development of the material in the deliverable), and by using appropriate standards, namely IEEE-1016 (Recommended Practice for Software Design Descriptions), as stipulated in the description of action of the project. User centred-design has been incorporated in the design by means of a) review by partners, b) by identifying best practice in the domain's literature and by c) reviewing user related decisions in previous tasks (Task 8.1). Review by partners with experience in the use of such systems by users (clinicians, healthcare professionals as well as patients), identified potential user-centred implications of the architectural decisions made. Previous tasks focusing on the healthcare service side of C3-Cloud identified a number of user-centred scenarios (these were discussed at on-site C3-Cloud meetings, for all clinical partners). Literature review has identified good practice in user-centred design, which has been considered (e.g., user interfaces).

## 1.6. Conformance Statement

The development of C3-Cloud architecture SDD follows IEEE Standard 1016-2009 - IEEE Standard for Information Technology -- Systems Design -- Software Design Descriptions. Conformance with IEEE 1016-2009 is captured in Appendix I. Some of the clauses of IEEE are discharged to subsequent C3-Cloud tasks, as part of detail design of each of the C3-Cloud components (e.g., a deployment diagram is expected within the scope of D8.2 and not D3.3).

## 1.7. Views and Viewpoints declaration

As specified by IEEE 1016-2009, the content of this document is organised into design views. Each design view is governed by a design viewpoint formally defined in IEEE 1016-2009. Based on the design concerns identified in Section 1.4, five design viewpoints are selected for use in this SDD:

- Composition Viewpoint (IEEE 1016-2009 clause 5.3)
- Logical Viewpoint (IEEE 1016-2009 clause 5.4)
- Information Viewpoint (IEEE 1016-2009 clause 5.6)
- Interface Viewpoint (IEEE 1016-2009 clause 5.8)
- Interaction Viewpoint (IEEE 1016-2009 clause 5.10)



Design views will be implemented using UML (v2), as implemented by the Modelio tool (v3.5) [MODELIO].

IEEE 1016-2009 provides developers with flexibility in selecting viewpoints according to the needs of the project. The above viewpoints were selected using the following criteria: a) Selection of viewpoints that provided detailed view of conceptual design at the appropriate level for the stage of the project. The project partners will further refine decisions in subsequent tasks, based on their expertise. This was considered the most suitable approach given the high technology maturity levels of the constituent components of project, as well as the expertise of each partner. b) Adoption of activity based development process, which is discharged to components by means of traceability matrices (i.e. deliverables D3.2 and D3.3 establish traceability among use cases, specific requirements and component design). The aforementioned viewpoints were considered the appropriate subset, allowing an unambiguous description of architecture whilst maintaining the desired traceability at this level.

## **1.8. Abbreviations and Acronyms**

Table 2 lists the abbreviations and acronyms used in this document.

**Table 2 List of Abbreviations and Acronyms**

<b>Abbreviation/ Acronym</b>	<b>DEFINITION</b>
AAA	Authentication, Authorization and Auditing
API	Application programming interface
C3DP	Coordinated Care and Cure Delivery Platform
CAMBIO	Cambio Healthcare Systems AB
CDS	Clinical Decision Support
CDSM	Clinical Decision Support Modules
CDSS	Clinical Decision Support Service
DoA	Description of Action
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
GDL	Guideline Definition Language
GUI	Graphical User Interface
IdP	Identity Provider
IEEE	Institute of Electrical and Electronics Engineers
INSERM	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE
MDT	Multidisciplinary Care Team
MEDIXINE	MEDIXINE OY
ORU	OREBRO UNIVERSITY
OSAKI	Servicio Vasco de Salud Osakidetza
PCPDP	Personalized Care Plan Development Platform
PEP	Patient Empowerment Platform
PHR	Personal Health Record
RJH	REGION JAMTLAND HARJEDALEN
SDD	Software design description
SIS	Semantic Interoperability Suite
SPS	Security and Privacy Suite
SRDC	SRDC YAZILIM ARASTIRMA VE GELISTIRME VE DANISMANLIK TICARET ANONIM SIRKETI
STU	Standard for Trial Use
SWFT	SOUTH WARWICKSHIRE NHS FOUNDATION TRUST
TIS	Technical Interoperability Suite
TS	Terminology Service
UI	User Interface
UML	Unified Modelling Language
WARWICK	THE UNIVERSITY OF WARWICK

## 2. COMPOSITION VIEW

The composition view identifies the major design constituents of C3-Cloud architecture, localizes and allocates functionality, responsibilities, or other design roles to these constituents. The view provides the design stakeholders with a high-level, architectural view of the system on the level of reusable subsystems and large-grained components. Components are considered autonomous, encapsulated units within a system or subsystem that provide one or more interfaces. This view is governed by the composition viewpoint declared in Section 1.7. The design is represented by UML2 component diagram. Section 2.1 presents an overall composition view of the whole C3-Cloud system. Sections 2.2-2.8 present detailed design of the composition view for each subsystem.

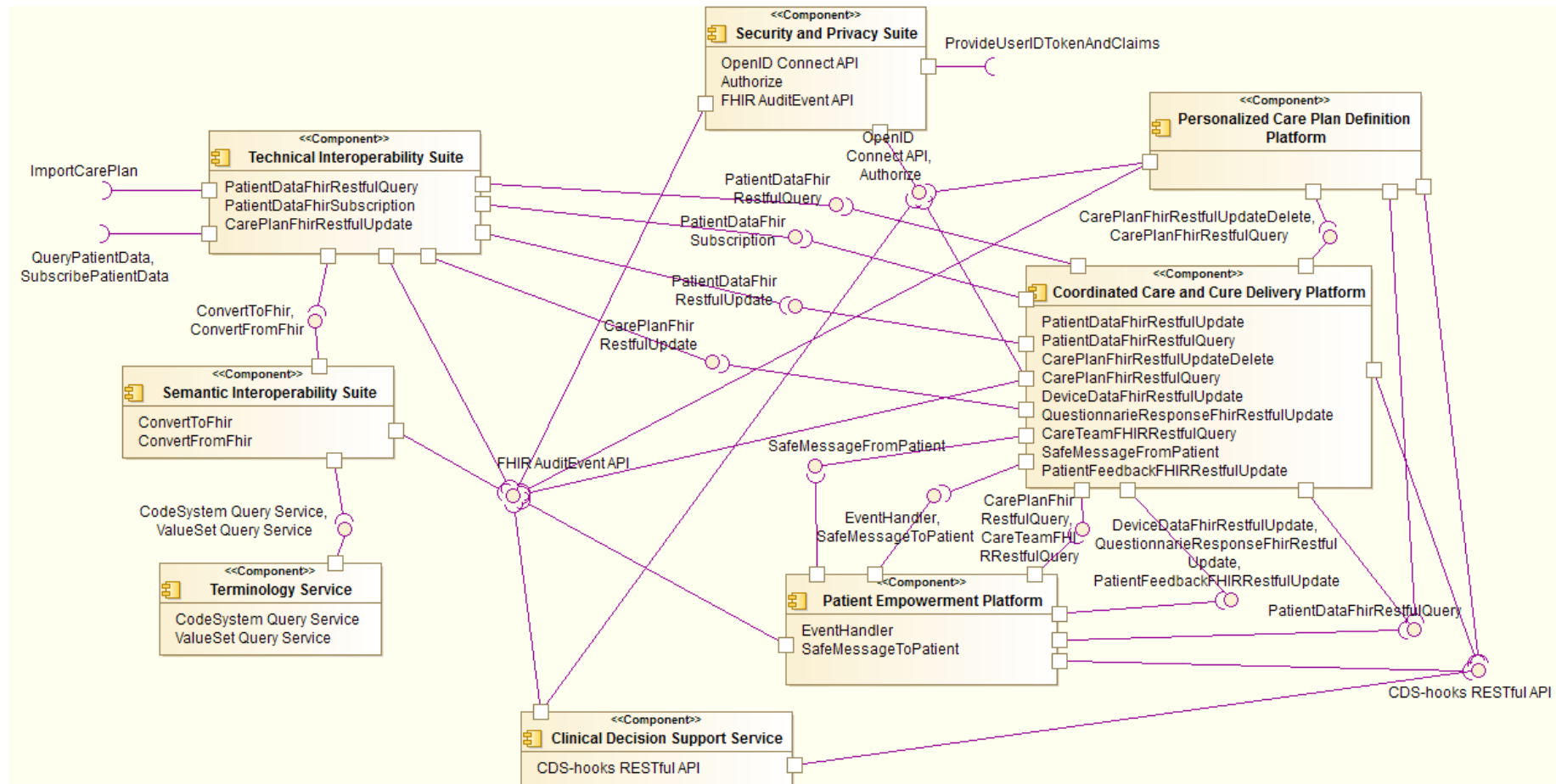
### 2.1. Overall Composition View

As investigated in D3.1 Survey of the State of the Art [D3.1], HL7 moves towards the next generation of standards framework, i.e. FHIR [FHIR]. FHIR leverages the latest web standards and applies a tight focus on how implementation is achieved. With support in a wide range of implementation platforms, FHIR is suitable for use in a wide variety of contexts – mobile phone apps, cloud communications, electronic health record (EHR)-based data sharing, and server communication in large institutional healthcare providers. With interoperability as a key focus, FHIR is evolutionary from existing standards such as HL7 Version 2, V3 and CDA, and can co-exist and leverage each other. More importantly, FHIR enables innovative ways of integrating with EHR systems. Typical examples include the SMART App platform for healthcare [SMART] and CDS-hooks, a hook-based pattern for invoking decision support from within a clinician's EHR workflow [CDS-HOOKS].

The architecture design of C3-Cloud takes advantage of FHIR and related open specifications to establish a consistent technology stack. FHIR supports multiple architecture paradigms: RESTful, service, messaging and documents. C3-Cloud chooses the RESTful architecture, because RESTful is the mostly widely supported paradigm in the community and FHIR resources are primarily designed for RESTful HTTP-based implementation. The design presented in this document is based on FHIR 1.6.0, which was the latest version of the standard at the time when this document was prepared. As FHIR is a standard for trial use (STU) in fast evolution, the design contained in D3.3 needs to keep track of the progress of FHIR development and align to new versions of the standard in subsequent work packages.

This section presents the design of an overall composition view based on the analysis of the use cases and information exchanges in D3.2. A UML2 component diagram (Figure 1) shows the C3-Cloud architecture on the level of top-level subsystems and their interdependencies (SDD-CMP-OVERALL). The following paragraphs present brief introduction to each of the subsystems and their interfaces and discuss related design rationales.

Figure 1: SDD-CMP-OVERALL: Top Level C3-Cloud Component Diagram



❖ **Patient Empowerment Platform (PEP)**

<b>Type</b>	Top-level subsystem
<b>Purpose</b>	The objective of 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 computerised means to improve the interaction between patients and health professionals and provide computerised means to collect relevant data and information to enable monitoring of care plan related activity status and progress.
<b>Definition</b>	PEP System provides RESTful services for PEP Client System components to exchange information related to PEP functionalities (care plan and patient-originated data related to the care plan). The information will be exchanged using FHIR STU3 standard. PEP System will further provide browser-based user interface to its functionalities. The user interface can be used on all modern desktop and mobile browsers. PEP supports data collection from connected self-monitoring devices.
<b>Provided Interfaces</b>	
<u>EventHandler</u>	Interface and event processor to process C3DP and PEP Events.  The C3DP events include updates to care teams, care plans and the safe messages from professionals to patients.  The PEP events handled internally by PEP Interface include pushing patient-originated observations and questionnaire responses to the central C3 FHIR repository (via PEP Gateway).
<u>SafeMessageToPatient</u>	A FHIR RESTful endpoint for client (C3DP) to post safe messages created by the multidisciplinary care team (MDT) for the patient. The interface should support the FHIR RESTful API type level <b>create</b> interaction for Communication resource.
<b>Required Interfaces</b>	
<u>PatientDataFHIRRestfulQuery</u>	PEP requires C3DP to provide a FHIR RESTful endpoint for PEP to retrieve patient data from C3DP patient data repository. The interface should support the FHIR RESTful API instance level interactions: <b>read</b> , <b>vread</b> , and <b>history</b> and type level interaction <b>search</b> .
<u>CarePlanFHIRRestfulQuery</u>	PEP requires C3DP to provide a FHIR RESTful endpoint for PEP to retrieve care plans from C3DP care plan FHIR repository. The interface should support the FHIR RESTful API instance level interactions: <b>read</b> , <b>vread</b> , and <b>history</b> and type level interaction <b>search</b> .
<u>PatientFeedbackFHIRRestfulUpdate</u>	PEP requires C3DP to provide a FHIR RESTful endpoint for PEP to push patient provided feedback for care plan activities and goals. The interface should support the FHIR

	RESTful API type level <i>create</i> interaction for PatientFeedback Observation (a C3-Cloud profile on top of Observation resource).
<u>DeviceDataFHIRRestful Update</u>	PEP requires C3DP to provide a FHIR RESTful endpoint for PEP to upload tele-monitoring device data to its FHIR repository. The interface should support the FHIR RESTful API type level <i>create</i> interaction for Observation resource, indeed a profile on top of Observation.
<u>QuestionnaireResponseFHIR RestfulUpdate</u>	PEP requires C3DP to provide a FHIR RESTful endpoint for PEP to upload questionnaire responses to its FHIR repository. The interface should support the FHIR RESTful API type level <i>create</i> interaction for QuestionnaireResponse resource.
<u>SafeMessageFromPatient</u>	PEP requires C3DP to provide a FHIR RESTful endpoint for PEP to upload safe messages to its FHIR repository. The interface should support the FHIR RESTful API type level <i>create</i> interaction for Communication resource.
<u>CareTeamFHIRRestfulQuery</u>	PEP requires C3DP to provide a FHIR RESTful endpoint for PEP to retrieve care team updates from C3DP FHIR repository. The interface should support the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> , and <i>history</i> and type level interaction <i>search</i> .
<u>EventAPI</u>	CarePlanRead and MessageRead PEP events are sent to C3DP through this API, based on event subscription configuration.
<u>CDS-hooks RESTful API</u>	PEP requires the CDS service to provide CDS hooks interface, so PEP can invoke CDS service for risk assessment.
<u>FHIR AuditEvent API</u>	PEP requires SPS's audit facility to manage audit trail.

❖ **Technical Interoperability Suite (TIS)**

<b>Type</b>	Top-level subsystem
<b>Purpose</b>	TIS enables seamless data exchange between C3-Cloud subsystems and pre-existing EHR, Social Care Records, personal health records (PHR) and home devices. The information systems utilised in local care settings are well known for their heterogeneity in data exchange protocols and clinical data representations. TIS implements standards based data exchange protocol to establish connections between C3-Cloud software components and local care information systems.
<b>Definition</b>	TIS is a RESTful service, which enables C3-Cloud subsystems to access patient data and share care plans with local care information systems through FHIR-based RESTful interface. TIS connects local systems through their native APIs.
<b>Provided Interfaces</b>	

<u>PatientDataFhirRestfulQuery</u>	A FHIR RESTful endpoint for client (e.g., C3DP) to retrieve patient data from a local care record system. This interface implements the FHIR RESTful API type level <i>search</i> interaction.
<u>PatientDataFhirSubscription</u>	A FHIR RESTful endpoint for client (e.g., C3DP) to subscribe for updates on patient data from a local care information system. The clients can set criteria on the data (e.g., type, source) that they want to receive. This interface supports the FHIR RESTful API instance level <i>update</i> interaction on FHIR subscription resource. On successful subscription, TIS will push subscribed data to client through client provided FHIR RESTful interface, when an update is available.
<u>CarePlanFhirRestfulUpdate</u>	A FHIR RESTful endpoint for client (e.g., C3DP) to send care plan to a local care information system. This interface implements the FHIR RESTful API instance level <i>update</i> interaction.
<b>Required Interfaces</b>	
<u>PatientDataFhirRestfulUpdate</u>	TIS requires subscription client (e.g., C3DP), which has subscribed to receive data, to provide a FHIR RESTful endpoint for TIS to upload subscribed patient data. The interface should support the FHIR RESTful API instance level <i>update</i> interaction.
<u>ConvertToFhir</u>	TIS requires SIS to provide a RESTful interface to convert patient data from the source representation to FHIR-based representation.
<u>ConvertFromFhir</u>	TIS requires SIS to provide a RESTful interface to convert care plan from FHIR-based representation to the source representation.
<u>QueryPatientData</u>	TIS requires local care information systems (e.g., EHR, Social Care Records, PHR) to provide an interface for TIS to query and retrieve patient data.
<u>SubscribePatientData</u>	TIS requires local care information systems (e.g., EHR, Social Care Records, PHR) to provide an interface for TIS to subscribe for updates on patient data. This interface should define the protocol for TIS to submit subscriptions and receive subscribed updates.
<u>ImportCarePlan</u>	TIS requires local care information systems (e.g., EHR, Social Care Records, PHR) to provide an interface for TIS to share care plan generated by C3-Cloud with local care information systems.
<u>FHIR AuditEvent API</u>	TIS requires SPS's audit facility to manage audit trail.

❖ **Semantic Interoperability Suite (SIS)**

<b>Type</b>	Top-level subsystem
<b>Purpose</b>	The objective of SIS is to address content level interoperability challenges. SIS semantically mediates different clinical information representations between C3-Cloud platform and local care information systems. As part of the semantic mediation process, SIS uses terminology service for terminology mappings. SIS together with TIS provides the essential support to enable seamless data exchange between clinical information systems.

<b>Definition</b>	SIS provides a RESTful service to Technical Interoperability Suite, which enables it to convert patient data from their local representation to FHIR-based representation, and care plans from C3-Cloud to this local representation.
<b>Provided Interfaces</b>	
<u><i>ConvertToFhir</i></u>	A RESTful interface to convert patient data from the source representation to FHIR-based representation.
<u><i>ConvertFromFhir</i></u>	A RESTful interface to convert care plan from FHIR-based representation to the source representation.
<b>Required Interfaces</b>	
<u><i>Terminology Service Interface</i></u>	SIS requires the terminology service to provide a RESTful interface for terminology concept look up and value set expansions. The interface should conform to FHIR Terminology Service standard [FHIR-TS].
<u><i>FHIR AuditEvent API</i></u>	SIS requires SPS's audit facility to manage audit trail.

❖ *Terminology Service (TS)*

<b>Type</b>	Top-level subsystem
<b>Purpose</b>	Terminology service supports semantic interoperability by providing concept look up and value set expansions.
<b>Definition</b>	Terminology service is a RESTful service based on FHIR Terminology Service Specification for representing, accessing and disseminating terminological content.
<b>Provided Interfaces</b>	
<u><i>CodeSystem Query Service</i></u>	A FHIR RESTful endpoint for client (e.g., SIS) to get and search FHIR <i>CodeSystem</i> resources. This interface implements the FHIR RESTful API instance level <i>read</i> interaction, type level <i>search</i> interaction, and <i>CodeSystem \$lookup</i> operation.
<u><i>ValueSet Query Service</i></u>	A FHIR RESTful endpoint for client (e.g., SIS) to get and search FHIR <i>ValueSet</i> resources. This interface implements the FHIR RESTful API instance level <i>read</i> interaction, type level <i>search</i> interaction, and <i>ValueSet \$expand</i> operation.
<b>Required Interfaces</b>	
None.	

❖ *Security and Privacy Suite (SPS)*

<b>Type</b>	Top-level subsystem
<b>Purpose</b>	SPS 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 are encrypted and audited properly. All of the C3-Cloud components utilise its audit logging feature, which 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 a local care system (when integration with local care sites' identity provider sites is possible).
<b>Definition</b>	SPS provides RESTful services for user (i.e. Care Team Member) authentication, user authorisation and audit trail management purposes. These services are based on open standards wherever possible, such as OpenID Connect authentication layer that is designed to fit web applications, as well as native / mobile apps. SPS will integrate with local Identity Providers (IdP) for enabling single sign-on with existing user accounts.
<b>Provided Interfaces</b>	
<u>OpenID Connect API</u>	A RESTful endpoint for user authentication according to OpenID Connect authentication layer, which is based on OAuth 2.0 protocol and enables single sign-on and identity provision on the Internet. Specifically, <i>Authorization</i> , <i>ID Token</i> and <i>UserInfo</i> endpoints of OpenID Connect specification will be implemented. User ID tokens and claims (user info) will be exchanged in JSON Web Token (JWT) format. This endpoint will be used by C3-Cloud components that need to authenticate non-patient users; i.e. PCPDP, C3DP and CDSM. IHE ATNA profile will be used for secure node (i.e. C3-Cloud components) authentication.
<u>Authorize</u>	A RESTful endpoint for client systems to ensure that a user (e.g., a GP) is authorised to perform a specific operation (e.g., update) on a specific resource (e.g., care plan of a specific patient). The RESTful endpoint will expect user claims (in JWT format) and information about the requested resource and operation, and after checking against the access control policies (represented in XACML) in its database, will return a positive or negative decision.
<u>FHIR AuditEvent API</u>	A FHIR RESTful endpoint for all C3-Cloud components to persist their audit trail records in the Audit Record Repository component of SPS. The interface will implement the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> , <i>update</i> , <i>delete</i> , and <i>history</i> on FHIR AuditEvent resource, which is based on IHE-ATNA audit record definitions. The interface will also be used by the Audit Trail User Interface to retrieve and display audit trail records.
<b>Required Interfaces</b>	
<u>ProvideUserIDTokenAndClaims</u>	SPS requires local Identity Provider (IdP) systems to provide ID tokens and claims for their registered users. If a local IdP is already OpenID Connect compliant, then the <i>Authenticate</i> interface of SPS will be directly bound to its interface. Otherwise, OpenID Connect aware interfaces will need to be implemented on top of the local IdP.

❖ **Clinical Decision Support Service (CDS Service)**

<b>Type</b>	Top-level subsystem
<b>Purpose</b>	A CDS service provides health professionals with clinical decision support, which is assistance with clinical decision-making tasks. The clinical decision support modules (CDSM) delivered by the CDS service in C3-Cloud include clinical guideline based diagnosis and treatment suggestions, risk stratification and prediction, and polypharmacy management guidance. The service is extensively used by other C3-Cloud components, especially C3DP and PCPDP, during the process of creation and update of care plans and in the context of monitoring patients.
<b>Definition</b>	The CDS service is a RESTful service that provides a hook-based pattern for invoking decision support from within a client's (e.g., a clinician's EHR) workflow.
<b>Provided Interfaces</b>	
<u>CDS-hooks RESTful API</u>	A "hook"-based pattern for invoking decision support from within a clinician's EHR workflow. The API supports: Synchronous, workflow-triggered CDS calls returning information and suggestions; Launching a user-facing SMART app when CDS requires deeper interaction; Long-running, non-modal CDS sessions that observe EHR activity in progress.
<b>Required Interfaces</b>	
<u>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</u>	The CDS service requires SPS's AAA facilities to authenticate users, authorise access and manage audit trail.

❖ **Personalized Care Plan Development Platform (PCPDP)**

<b>Type</b>	Top-level subsystem
<b>Purpose</b>	PCPDP enables online collaboration for a care team to collaboratively create and update a care plan specialized for a specific patient. PCPDP is delivered as a sub module of C3DP.
<b>Definition</b>	A Web application and internal business logic for MDT members to browse, create, update, reconcile, import, export, share personalised care plan definitions, by using the functionalities exposed by the underlying C3DP Engine.
<b>Provided Interfaces</b>	
None.	
<b>Required Interfaces</b>	
<u>CarePlanFhirRestfulUpdate Delete</u>	PCPDP requires C3DP to provide a FHIR RESTful endpoint for PCPDP to update care plans in C3DP care plan FHIR repository.

	The interface should support the FHIR RESTful API instance level interactions: <i>update</i> and <i>delete</i> ; and type level interactions: <i>create</i> .
<u>CarePlanFhirRestfulQuery</u>	PCPDP requires C3DP to provide a FHIR RESTful endpoint for PCPDP to retrieve care plans from C3DP care plan FHIR repository. The interface should support the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> , and <i>history</i> .
<u>PatientDataFhirRestfulQuery</u>	PCPDP requires C3DP to provide a FHIR RESTful endpoint for PCPDP to retrieve patient data from C3DP patient data repository. The interface should support the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> , and <i>history</i> .
<u>CDS-hooks RESTful API</u>	PCPDP requires the CDS service to provide CDS hooks interface so PCPDP can invoke CDS service for clinical guideline based diagnosis and treatment suggestions, polypharmacy management, or risk assessment.
<u>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</u>	PCPDP requires SPS's AAA facilities to authenticate users, authorise access and manage audit trail.

❖ **Coordinated Care and Cure Delivery Platform (C3DP)**

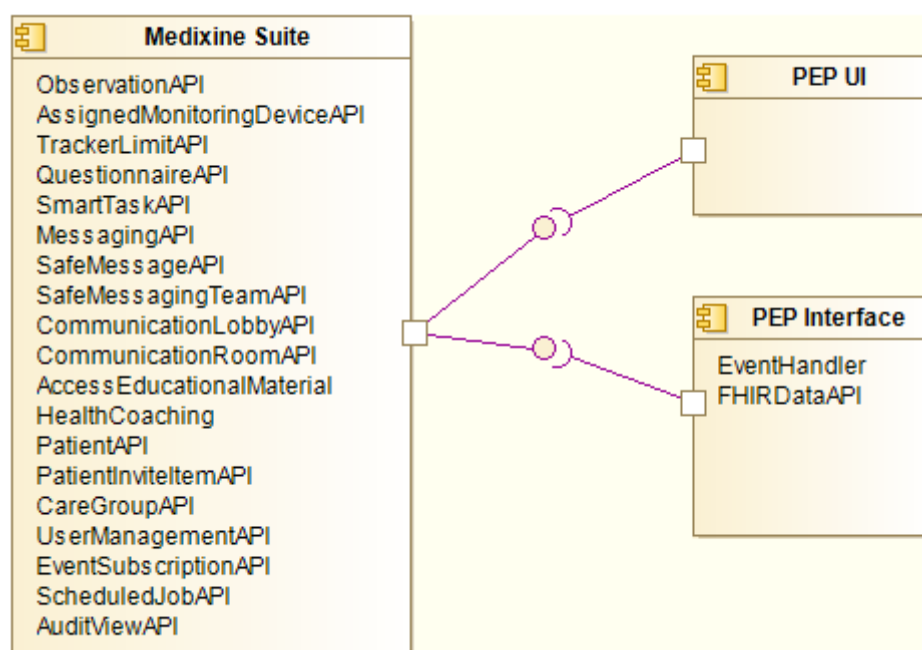
<b>Type</b>	Top-level subsystem
<b>Purpose</b>	C3DP facilitates collaborative management of care of patients with multi-morbid conditions. With the help of CDSM, it provides care team members with the capability to define, update, reconcile and share care plans, and organise online meetings for care plan review. It also allows care team members to navigate a patient's medical history along with his/her care plan history.
<b>Definition</b>	A Web application and internal business logic for MDT members to collaboratively manage the integrated care of patients around personalised care plans. C3DP is the core top-level component of C3-Cloud, integrating most functions provided by other components.
<b>Provided Interfaces</b>	
<u>CarePlanFhirRestfulUpdate Delete</u>	A FHIR RESTful endpoint for client (e.g., PCPDP) to create, update and delete care plans in its care plan FHIR repository. The interface implements the FHIR RESTful API instance level interactions: <i>update</i> and <i>delete</i> and type level interaction <i>create</i> on FHIR care plan resource.
<u>CarePlanFhirRestfulQuery</u>	A FHIR RESTful endpoint for client (e.g., PCPDP and PEP) to query care plans in its care plan FHIR repository. The interface implements the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> , and <i>history</i> on FHIR care plan resource.
<u>PatientDataFhirRestfulQuery</u>	A FHIR RESTful endpoint to its patient data repository for client (e.g., PCPDP, PEP) to retrieve patient data. The interface implements the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> , and <i>history</i> .

<u><i>PatientDataFhirRestfulUpdate</i></u>	A FHIR RESTful endpoint for client to upload subscribed patient data to its patient data repository. The interface implements the FHIR RESTful API type level <i>create</i> interaction.
<u><i>PatientFeedbackFHIRRestfulUpdate</i></u>	A FHIR RESTful endpoint for client (PEP) to push patient provided feedback for care plan activities and goals. The interface implements the FHIR RESTful API type level <i>create</i> interaction for PatientFeedback Observation; a C3-Cloud profile on top of Observation resource.
<u><i>DeviceDataFhirRestfulUpdate</i></u>	A FHIR RESTful endpoint for client to upload tele-monitoring device data to its FHIR repository. The interface implements the FHIR RESTful API type level <i>create</i> interaction for Observation resource, indeed a profile on top of Observation.
<u><i>QuestionnaireResponseFhirRestfulUpdate</i></u>	A FHIR RESTful endpoint for client to upload questionnaire responses to its FHIR repository. The interface implements the FHIR RESTful API type level <i>create</i> interaction for QuestionnaireResponse resource.
<u><i>SafeMessageFromPatient</i></u>	A FHIR RESTful for client to upload safe messages to its FHIR Repository. The interface implements the FHIR RESTful API type level <i>create</i> interaction for Communication resource.
<u><i>CareTeamFHIRRestfulQuery</i></u>	A FHIR RESTful endpoint for client (PEP) to retrieve care team updates from C3DP FHIR repository. The interface should support the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> , and <i>history</i> .
<u><i>EventAPI</i></u>	A RESTful API for client (PEP) to post CarePlanRead and MessageRead PEP events. This event API is used whenever an event is satisfactory enough to inform about updates; i.e. no need to upload a payload, such as questionnaire response.
<b>Required Interfaces</b>	
<u><i>PatientDataFhirRestfulRead</i></u>	C3DP requires TIS to provide a FHIR RESTful endpoint for C3DP to retrieve patient data from a local care information system. This interface should support the FHIR RESTful API instance level <i>read</i> interaction.
<u><i>PatientDataFhirSubscription</i></u>	C3DP requires TIS to provide a FHIR RESTful endpoint for C3DP to subscribe for updates on patient data from a local care information system. The interface should support the FHIR RESTful API instance level <i>update</i> interaction on FHIR subscription resource. On successful subscription, TIS will push subscribed patient data to PEP.
<u><i>CarePlanFhirRestfulUpdate</i></u>	C3DP requires TIS to provide a FHIR RESTful endpoint for C3DP to upload care plan for a patient. This interface should support the FHIR RESTful API instance level <i>update</i> interaction on FHIR care plan resource.
<u><i>EventHandler</i></u>	C3DP requires PEP to provide interface to process C3DP events; e.g., updates to care teams and care plans from professionals to patients.

<u>SafeMessageToPatient</u>	C3DP requires PEP to provide a FHIR RESTful endpoint for C3DP to post safe messages created by MDT for the patient. The interface should support the FHIR RESTful API type level <i>create</i> interaction for Communication resource.
<u>CDS-hooks RESTful API</u>	C3DP requires the CDS service to provide CDS hooks interface so C3DP can invoke CDS service for clinical guideline based diagnosis and treatment suggestions, polypharmacy management, or risk assessment.
<u>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</u>	C3DP requires SPS's AAA facilities to authenticate users, authorise access and manage audit trail.

## 2.2. Patient Empowerment Platform

Figure 2: SDD-CMP-PEP: PEP Component Diagram



### ❖ PEP Interface

<b>Type</b>	Subsystem component
<b>Purpose</b>	Providing a single interface for the communication between Patient Empowerment Platform and connected PEP Client Systems.
<b>Definition</b>	PEP Interface is the component facilitating the choreography of the communication with the other C3 components (mainly C3DP). This includes the exchange of care plans, observations, questionnaire responses and all messaging and communication related information exchange.
<b>Provided Interfaces</b>	
<i>EventHandler</i>	Interface and event processor to process C3DP and PEP Events.

	<p>The C3DP events include updates to care teams, care plans and the safe messages from professionals to patients.</p> <p>The PEP events handled internally by PEP Interface include pushing patient-originated observations and questionnaire responses to the central C3 FHIR repository (via PEP Gateway).</p>
FHIRDataAPI	Make observations and questionnaire responses (PEP Engine ObservationAPI and QuestionnaireAPI information) available to other components in FHIR format/syntax.
<b>Required Interfaces</b>	
<b>C3DP</b>	
<i>CarePlanFHIRRestfulQuery</i>	Called on C3DP Event <b>CarePlanUpdate</b> ; when changes are made to a care plan, PEP is informed by the C3DP event, and then PEP pulls the care plan via this interface.
<i>PatientFeedback-FHIRRestfulUpdate</i>	Called on PEP Event CareplanRead, CareplanActivityEdited or CareplanGoalEdited; when patient reads care plan or marks goal/activity status as achieved/not achieved.
<i>DeviceData-FHIRRestfulUpdate</i>	Called on PEP Event <b>ObservationCreated</b> ; when new measurement or other relevant observation stored in PEP.
<i>QuestionnaireResponse-FHIRRestfulUpdate</i>	Called on PEP Event <b>QuestionnaireAnswerCompleted</b> ; when completed questionnaire response stored in PEP.
<i>SendMessageToPatient</i>	Called on C3DP Event <b>SafeMessageCreated</b> ; when MDT member professional sends message to patient.
<i>ReceiveMessageFromPatient</i>	Called on PEP Event <b>SafeMessageCreated</b> ; when patient sends new message to MDT care team.
<i>CareTeamFHIRRestfulQuery</i>	Called on C3DP Event <b>CareTeamUpdate</b> ; when changes are made to care team (team info and team person assignments).
<i>EventAPI</i>	<b>CarePlanRead</b> and <b>MessageRead</b> PEP events are sent to this API (based on event subscription configuration).

❖ Medicine Suite

<b>Type</b>	Subsystem component
<b>Purpose</b>	Providing the business logic of the functionalities to be carried out for PEP User Interfaces and connected PEP Client Systems.
<b>Definition</b>	PEP Engine is the core sub-component of PEP component coordinating the internal business logic of the functionalities provided by PEP. It is the main component providing interfaces to the PEP UI component.
<b>Provided Interfaces</b>	
ObservationAPI	Operations for managing and querying observations and observation items. Observations use a dynamic data model and can represent various different observations about a person, such as weight, blood pressure or smoking habits.

AssignedMonitoringDeviceAPI	API for monitoring device assignment. Assigned monitoring devices are individual monitoring devices assigned to people.
TrackerLimitAPI	Enables querying and managing tracker limits.
QuestionnaireAPI	API for querying questionnaires and questionnaire answers.
SmartTaskAPI	Functionality to manage patient tasks and guide the patient to task activities at the right time.
MessagingAPI	Messaging API for sending messages and managing sent and received messages (SMS, email).
SafeMessageAPI	API to send and manage safe messages between patient and care team/professional.
SafeMessagingTeamAPI	This API allows the management of SafeMessagingTeams and Members of the teams (i.e. who participates and communicates with whom).
CommunicationLobbyAPI	Functionality to manage access to communication rooms (i.e. the video, audio, chat communication between patient and professional).
CommunicationRoomAPI	Functionality for video, audio and chat communication between patient and professional.
AccessEducationalMaterial	Functionality to access relevant patient educational material.
HealthCoaching	Functionality to subscribe to coaching programs and receive relevant non-personalised health educational messages from subscribed programs.
PatientAPI	API to query and manage patient (customer) records.
PatientInviteItemAPI	This API allow the management of invites to access patient (customer) profiles.
CareGroupAPI	Patient-professional relationships can be managed through this API.
UserManagementAPI	Allows the management and query of users.
EventSubscriptionAPI	Enables the query and management of event subscriptions. Event subscriptions are event listeners attached to EventSubscriptions.
ScheduledJobAPI	Enables the query and management of scheduled jobs.
AuditViewAPI	Patients' audit history can be queried using this API.
<b>Required Interfaces</b>	
None.	

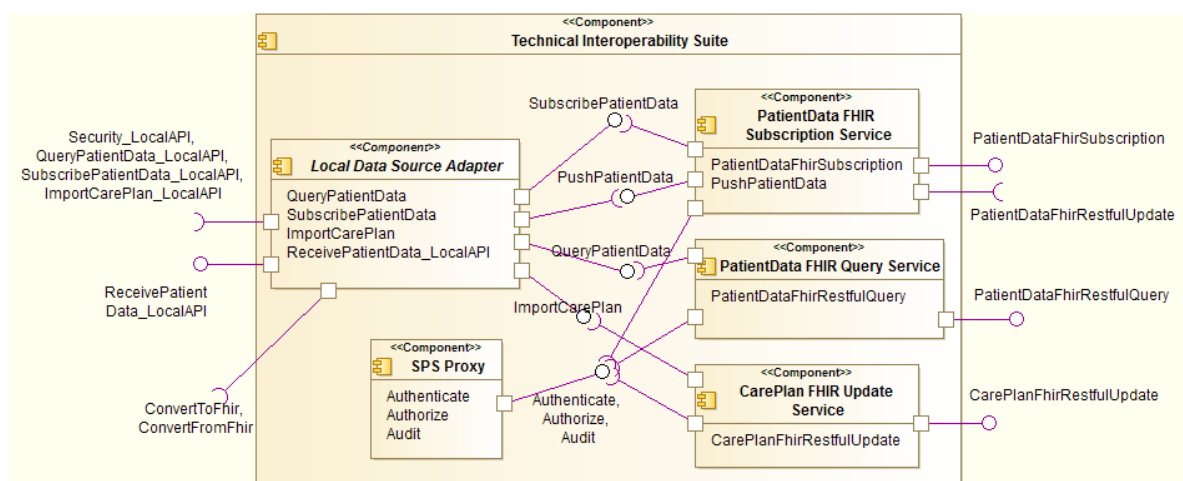
❖ **PEP UI**

<b>Type</b>	Subsystem component
<b>Purpose</b>	Provides access for patient access users to view their care plan and the related goals and activities. They can also enter and view follow-up data (including measurements and questionnaires),

	communicate with their MDT team (safe messaging and real-time communication), and access educational material.
<b>Definition</b>	A web application, based on Medixine Suite, for patient access users to view their care plan and the related goals and activities, to enter and view their follow-up data (including measurements and questionnaires), to communicate with their MDT team (safe messaging and real-time communication), and to access educational material.
<b>Provided Interfaces</b>	
<u>HTML5 based user interface</u>	UI for the patient access users of the C3-Cloud solution to access relevant information and functionality.

## 2.3. Technical Interoperability Suite

Figure 3: SDD-CMP-TIS: TIS Component Diagram



The Technical Interoperability Suite enables data exchange between the information systems in local care settings and C3-Cloud. The design of TIS is based on the emerging FHIR standard for interoperability. TIS extends local information systems with FHIR endpoints to present a uniform interface for the exchange of patient data and care plan. TIS uses the security and privacy suite to integrate into the local system's security environment.

### ❖ PatientData FHIR Subscription Service

<b>Type</b>	Subsystem component
<b>Purpose</b>	Provides a subscription-based push mechanism for client to receive patient data updates. Updates are pushed by the local information system to the client.
<b>Definition</b>	A FHIR RESTful service for client to create and update FHIR subscription resource.
<b>Provided Interfaces</b>	



<u>PatientDataFhirSubscription</u>	A FHIR RESTful endpoint for client (e.g., C3DP) to subscribe for updates on patient data from a local care information system. The clients can set criteria on the data (e.g., type, source) that they want to receive. This interface supports the FHIR RESTful API instance level <b>update</b> interaction on FHIR <b>Subscription</b> resource. On successful subscription, TIS will push subscribed data to client through client provided FHIR RESTful interface, when an update is available.
<u>PushPatientData</u>	A Callback API for local data source adapter to push patient data to the service component.
<b>Required Interfaces</b>	
<u>SubscribePatientData</u>	The service requires the local data source adapter to provide API for subscribing patient data.
<u>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</u>	The service requires SPS's AAA facilities to authenticate users, authorise access and manage audit trail.

❖ PatientData FHIR Query Service

<b>Type</b>	Subsystem component
<b>Purpose</b>	Provides a pull mechanism for client to retrieve patient data.
<b>Definition</b>	A FHIR RESTful service for client to query patient data related FHIR resources.
<b>Provided Interfaces</b>	
<u>PatientDataFhirRESTfulQuery</u>	A FHIR RESTful endpoint for client (e.g., C3DP) to retrieve patient data from a local care record system. This interface implements the FHIR RESTful API type level <b>search</b> interaction.
<b>Required Interfaces</b>	
<u>QueryPatientData</u>	The service requires the local data source adapter to provide API for querying patient data.
<u>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</u>	The service requires SPS's AAA facilities to authenticate users, authorise access and manage audit trail.

❖ CarePlan FHIR Update Service

<b>Type</b>	Subsystem component
<b>Purpose</b>	Shares care plan created by C3-Cloud to local care systems.
<b>Definition</b>	A FHIR RESTful service for client to create and update FHIR CarePlan resources.
<b>Provided Interfaces</b>	

<u>CarePlanFhirRestfulUpdate</u>	A FHIR RESTful endpoint for client (e.g. C3DP) to send care plan to a local care information system. This interface implements the FHIR RESTful API instance level <b>update</b> interaction on FHIR <b>CarePlan</b> resource.
<b>Required Interfaces</b>	
<u>ImportCarePlan</u>	The service requires the local data source adapter to provide API for importing care plans.
<u>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</u>	The service requires SPS's AAA facilities to authenticate users, authorise access and manage audit trail.

❖ SPS Proxy

<b>Type</b>	Subsystem component
<b>Purpose</b>	Integrates with local care site security system
<b>Definition</b>	A software proxy from SPS to provide authentication, authorisation and auditing functions.
<b>Provided Interfaces</b>	
<u>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</u>	Proxy interfaces to connect to SPS remote systems.
<b>Required Interfaces</b>	
None.	

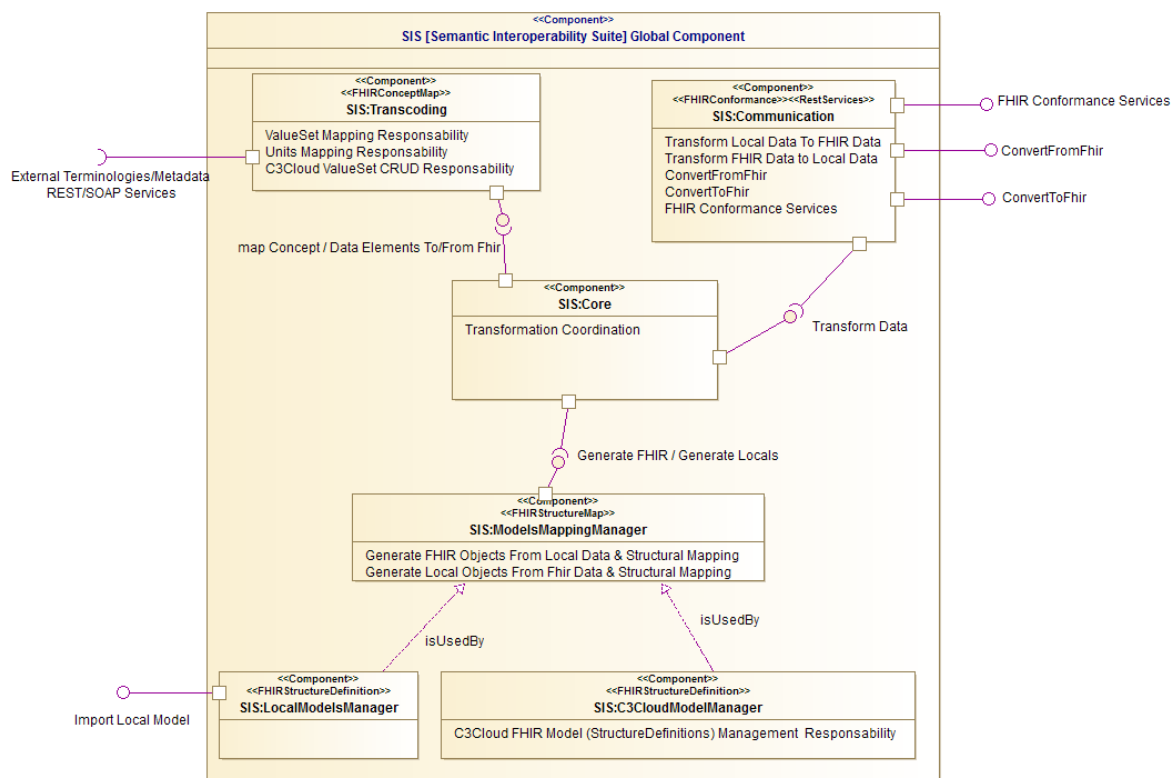
❖ Local Data Source Adapter

<b>Type</b>	Subsystem component
<b>Purpose</b>	Provides a plugin mechanism to connect each local information system through its native API.
<b>Definition</b>	A software module created for each local care information system to adapt the native API to a uniform internal API for the FHIR endpoint components to use.
<b>Provided Interfaces</b>	
<u>SubscribePatientData</u>	A uniform internal API to subscribe patient data updates.
<u>QueryPatientData</u>	A uniform internal API to query patient data.
<u>ImportCarePlan</u>	A uniform internal API to import care plan into local care system.
<u>ReceivePatientData LocalAPI</u>	A local callback API for the local care record system to push patient data updates.

Required Interfaces	
<u><i>PushPatientData</i></u>	The component requires a callback API to push patient data.
<u><i>SubscribePatientData LocalAPI</i></u>	The local system API to subscribe patient data updates.
<u><i>QueryPatientData LocalAPI</i></u>	The local system API to query patient data.
<u><i>ImportCarePlan LocalAPI</i></u>	The local system API to import care plan.
<u><i>Security LocalAPI</i></u>	The local system security API.
<u><i>ConvertToFhir</i></u>	SIS API to convert patient data in local format to FHIR format.
<u><i>ConverFromFhir</i></u>	SIS API to convert care plan in FHIR format to local format.

## 2.4. Semantic Interoperability Suite

Figure 4: SDD-CMP-SIS: SIS Component Diagram



The Semantic Interoperability Suite addresses content level interoperability challenges between the information systems in local care information systems and C3-Cloud platform, by semantically mediating different clinical information representations. The design of SIS is based on FHIR. As part of the semantic mediation process, SIS uses a terminology service for terminology mappings and a semantic metadata registry to process interoperability.

### ❖ SIS:Communication

Type	Subsystem component, FHIR:Conformance, FHIR:RestServices
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<b>Purpose</b>	Share C3-Cloud FHIR care plans in local care system formats, and local patient data to C3-Cloud FHIR format.
<b>Definition</b>	A FHIR RESTful service for client to convert care plans and patient data from and to C3-Cloud FHIR format.
<b>Provided Interfaces</b>	
<u><i>ConvertFromFhir</i></u>	A RESTful endpoint for TIS to convert FHIR-format care plan from C3-Cloud into local care information system formats and codes.
<u><i>ConvertToFhir</i></u>	A FHIR RESTful endpoint for TIS to convert patient data from local care information system to C3-Cloud FHIR.
<u><i>FHIR Conformance Services</i></u>	Information about capabilities of the FHIR Implementation.
<b>Required Interfaces</b>	
<u><i>Transform Data</i></u>	The service requires the transformation of the provided data.

❖ *SIS:Core*

<b>Type</b>	Subsystem component
<b>Purpose</b>	Ensures the data transformation workflow between all subsystem components of the SIS.
<b>Definition</b>	The central subsystem of SIS, coordinating mappings and communications.
<b>Provided Interfaces</b>	
<u><i>TransformData</i></u>	The local system API to query data conversion.
<b>Required Interfaces</b>	
<u><i>Generate FHIR / Generate Locals</i></u>	The service requires the generation of local or FHIR objects, based on the provided input data.
<u><i>Map Concept / Data Element to/from FHIR</i></u>	The service requires the mapping of internal concepts / data elements of the provided input data.

❖ *SIS:Transcoding*

<b>Type</b>	Subsystem component, FHIR:ConceptMap
<b>Purpose</b>	Transcodes Concepts or Data Elements among distinct terminologies and formats.
<b>Definition</b>	A software client to ask external terminology or metadata mapping from the remote FHIR RESTful service.
<b>Provided Interfaces</b>	

<u>Map Concept / Data Element to/from FHIR</u>	The local system API to query mappings.
<b>Required Interfaces</b>	
<u>External Terminologies/Metadata REST/SOAP Services</u>	A FHIR RESTful and SOAP client to access to external terminology and metadata repository services.

❖ SIS:ModelMappingManager

<b>Type</b>	Subsystem component, FHIR:StructureMap
<b>Purpose</b>	Handles structural format mapping between local care information system and C3-Cloud.
<b>Definition</b>	A software client to handle structural conversion between local data model and C3-Cloud.
<b>Provided Interfaces</b>	
<u>Generate FHIR / Generate Locals</u>	The local system API to query format generation.
<b>Required Interfaces</b>	
None.	

❖ SIS:LocalMappingManager

<b>Type</b>	Subsystem component, FHIR:StructureDefinition
<b>Purpose</b>	Provides the definition of the current local care information system format.
<b>Definition</b>	A subsystem to provide the definition of the current local care information system data model.
<b>Provided Interfaces</b>	
<u>Import Local Model</u>	A FHIR RESTful endpoint to provide local data model definition.
<b>Required Interfaces</b>	
None.	

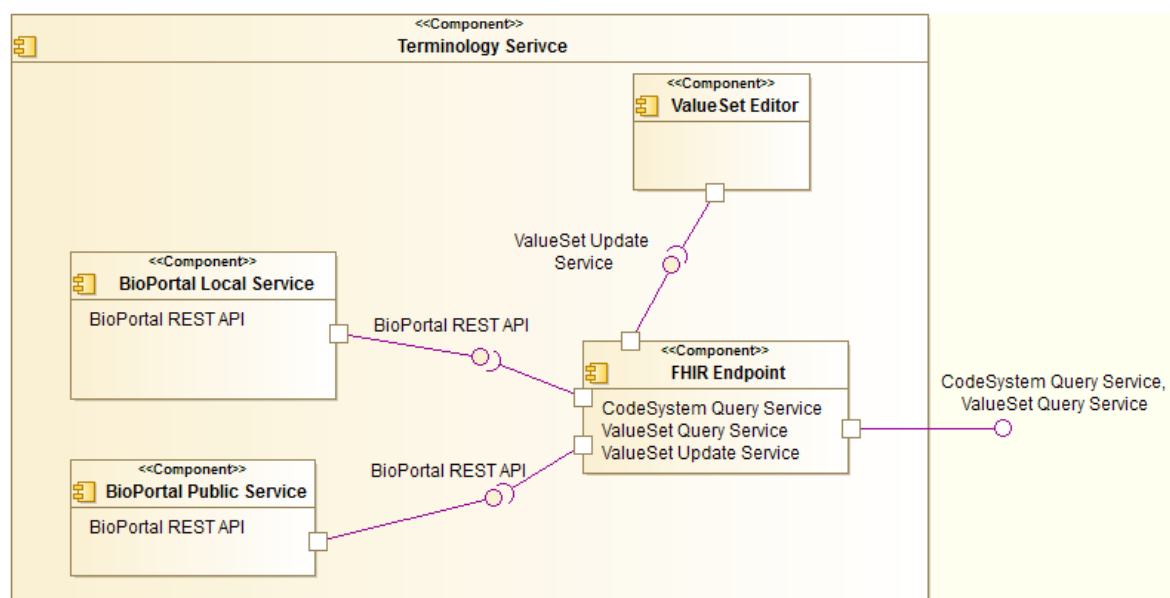
❖ SIS:C3CloudModelManager

<b>Type</b>	Subsystem component, FHIR:StructureDefinition
<b>Purpose</b>	Provides the definition of the C3-Cloud FHIR format.

<b>Definition</b>	A subsystem to provide the definition of the C3-Cloud FHIR data model.
<b>Provided Interfaces</b>	None.
<b>Required Interfaces</b>	None.

## 2.5. Terminology Service

Figure 5: SDD-CMP-TS: TS Component Diagram



The C3-Cloud terminology service builds on previous development of integrated vocabulary service at WARWICK [VS], which was based on the BioPortal REST service infrastructure [BIOPORTAL]. BioPortal is the largest repository of biomedical ontologies with over 300 ontologies. It hosts ontologies developed in OWL, OBO and other formats, as well as a large number of medical terminologies from UMLS Metathesaurus. The most commonly used code systems, such as ICD10, SNOMEDCT, LOINC, ICPC, ATC, etc. are available through the BioPortal public service. Users can publish their ontologies to BioPortal, submit new versions, browse the ontologies, and access the ontologies and their components through a set of RESTful services, SPARQL and dereferenceable URIs. The C3-Cloud terminology service integrates BioPortal via its public REST service API. A local instance is used to manage code systems not available in the public service. On top of BioPortal, C3-Cloud TS exposes a FHIR-based RESTful endpoint following FHIR Terminology Service standard [FHIR-TS]. C3-Cloud TS supports FHIR *CodeSystem* and *ValueSet* resources and related operations which SIS requires.

### ❖ BioPortal Public Service

<b>Type</b>	Subsystem component
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<b>Purpose</b>	BioPortal is the largest repository of biomedical ontologies and provides open access to over 300 ontologies including the mostly commonly used medical terminologies from UMLS Metathesaurus.
<b>Definition</b>	The latest version of BioPortal (v4) provides a rich set of RESTful APIs, which includes pagination and search suggestions, on a triple store based online repository.
<b>Provided Interfaces</b>	
<i>BioPortal REST API</i>	The public REST service is available at <a href="http://data.bioontology.org">http://data.bioontology.org</a>
<b>Required Interfaces</b>	
None.	

❖ **BioPortal Local Service**

<b>Type</b>	Subsystem component
<b>Purpose</b>	A local instance to serve license protected content or code systems not available from the public service.
<b>Definition</b>	The open source BioPortal REST service software is replicated in a local site.
<b>Provided Interfaces</b>	
<i>BioPortal REST API</i>	The same REST API as the public service.
<b>Required Interfaces</b>	
None.	

❖ **FHIR Endpoint**

<b>Type</b>	Subsystem component
<b>Purpose</b>	The component integrates BioPortal public and local services and maps to FHIR TS API.
<b>Definition</b>	FHIR TS compliant service for C3-Cloud components; e.g., SIS to access code systems and value sets.
<b>Provided Interfaces</b>	
<i>CodeSystem Query Service</i>	A FHIR RESTful service for client (e.g., SIS) to get and search FHIR <i>CodeSystem</i> resources. This interface implements the FHIR RESTful API instance level <i>read</i> interaction, type level <i>search</i> interaction, and <i>CodeSystem \$lookup</i> operation.
<i>ValueSet Query Service</i>	A FHIR RESTful service for client (e.g., SIS) to get and search FHIR <i>ValueSet</i> resources. This interface implements the FHIR RESTful API instance level <i>read</i> interaction, type level <i>search</i> interaction, and <i>ValueSet \$expand</i> operation.

<u><i>ValueSet Update Service</i></u>	A FHIR RESTful service to update FHIR <i>ValueSet</i> resources. This interface implements the FHIR RESTful API instance level <i>update</i> interaction.
<b>Required Interfaces</b>	
<u><i>BioPortal REST API</i></u>	The FHIR Endpoint requires BioPortal REST API.

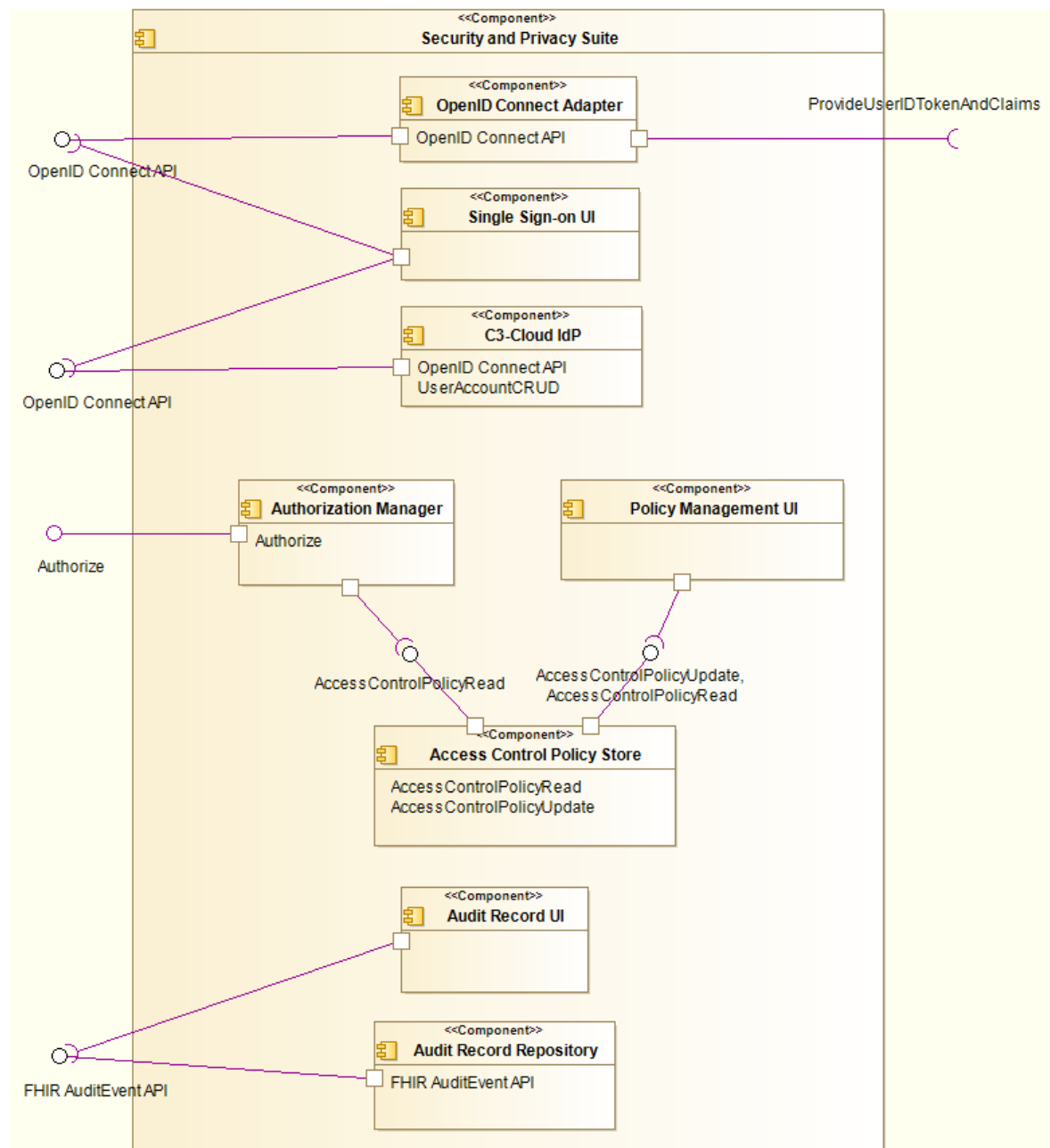
❖ *ValueSet Editor*

<b>Type</b>	Subsystem component
<b>Purpose</b>	The editor provides GUI for users to create value sets.
<b>Definition</b>	The component is a web application for users to browse, create, and update value set definitions.
<b>Provided Interfaces</b>	
<u><i>HTML5 based user interface</i></u>	A web interface for user to view and update value set definitions.
<b>Required Interfaces</b>	
<u><i>ValueSet Update Service</i></u>	The web app requires FHIR RESTful <i>update</i> interaction on FHIR <i>ValueSet</i> resources.



## 2.6. Security and Privacy Suite

**Figure 6: SDD-CMP-SPS: SPS Component Diagram**



Security and Privacy Suite is composed of three main sets of components focused on three security and privacy measures:

- User Authentication:
  - OpenID Connect Adapter
  - C3-Cloud Identity Provider (IdP)
  - Single Sign-on UI
- User Authorisation:
  - Authorization Manager
  - Policy Management UI

- Access Control Policy Store
- Audit Trail Logging:
  - Audit Record Repository
  - Audit Record UI

Security and Privacy Suite builds on widely-adopted open standards. User (non-patient users specifically, as patient / informal care giver authentication and authorisation is within the scope of PEP) authentication will be implemented according to OpenID Connect 1.0 specifications [OPENIDCONNECT]. OpenID Connect is a simple authentication layer, built on top of the OAuth 2.0 protocol [OAUTH]. It enables clients to verify the identity of a user, as well as to obtain basic profile information about the user in an interoperable and REST-like manner. User ID tokens and claims (user info) are represented and exchanged in the JSON Web Token (JWT) format. OpenID Connect adapters will be implemented on top of the local Identity Provider (IdP) systems that are not already OpenID Connect compliant.

SPS will also act as a Policy Decision Point by exposing a RESTful authorisation interface for C3-Cloud client systems to verify a specific user is authorised to access a specific resource, by checking against access control policy definitions represented in OASIS eXtensible Access Control Markup Language 3.0 standard [XACML].

Audit trails will be represented in FHIR AuditEvent resource [AUDITEVENT], which is based on the IHE Audit Trail and Node Authentication integration profile [ATNA] audit definitions, and exchanged with other C3-Cloud components according to FHIR RESTful API.

IHE ATNA profile will also be used to implement secure node authentication between the C3-Cloud components.

#### ❖ OpenID Connect Adapter

Type	Subsystem component
<b>Purpose</b>	Establishing authentication of Care Team Members based on modern open standards, while they are managing personalised care plans of patients and accessing sensitive personal data through C3-Cloud components (specifically PCPDP, C3DP and CDSM). Enabling Care Team Members to continue using their already existing business accounts for authentication to C3-Cloud components as well, via establishing integration with the local Identity Provider (IdP) systems.
<b>Definition</b>	As the name implies, OpenID Connect Adapter is an adapter on top of local IdP systems (e.g., LDAP, Active Directory) to make them compliant with the OpenID Connect authentication layer specification, which is based on OAuth 2.0 protocol and enables single sign-on and identity provision on the Internet. If a local IdP is already OpenID Connect compliant, then there will be no need to use this adapter.
<b>Provided Interfaces</b>	
<u>OpenID Connect API</u>	A RESTful endpoint for user authentication according to OpenID Connect authentication layer, which is based on OAuth 2.0 protocol. Specifically, <i>Authorization</i> , <i>ID Token</i> and <i>UserInfo</i> endpoints of OpenID Connect specification will be implemented. User ID tokens and claims (user info) will be exchanged in JSON Web Token (JWT) format. This endpoint will be used by C3-

	Cloud components that need to authenticate non-patient users; i.e. PCPDP, C3DP and CDSM.
<b>Required Interfaces</b>	
<u>ProvideUserIDTokenAndClaims</u>	OpenID Connect Adapter requires local IdP systems (e.g., LDAP, Active Directory) to provide ID tokens and claims for their registered users in the format that they support. The adapter will handle the conversion between OpenID Connect specification and local formats.

❖ C3-Cloud IdP

<b>Type</b>	Subsystem component
<b>Purpose</b>	Establishing authentication of Care Team Members based on modern open standards, while they are managing personalised care plans of patients and accessing sensitive personal data through C3-Cloud components (specifically PCPDP, C3DP and CDSM). Establishing a default C3-Cloud IdP system that will act as the identity provider of a Care Team Member, who does not have a business user account, or his/her organisation's identity provider system is somehow not integrated with C3-Cloud.
<b>Definition</b>	An open source OpenID Connect compliant Identity Provider system to be employed as the fall-back identity provider system in a pilot site. C3-Cloud IdP will provide both RESTful OpenID Connect endpoints for user authentication, and graphical user interfaces for user account management.
<b>Provided Interfaces</b>	
<u>OpenID Connect API</u>	A RESTful endpoint for user authentication according to OpenID Connect authentication layer, which is based on OAuth 2.0 protocol. Specifically, <i>Authorization</i> , <i>ID Token</i> and <i>UserInfo</i> endpoints of OpenID Connect specification will be implemented. User ID tokens and claims (user info) will be exchanged in JSON Web Token (JWT) format. This endpoint will be used by C3-Cloud components that need to authenticate non-patient users; i.e. PCPDP, C3DP and CDSM.
<u>UserAccountCRUD</u>	UI for user account management by the non-patient users and the Administrator.
<b>Required Interfaces</b>	
None.	

❖ Single Sign-on UI

<b>Type</b>	Subsystem component
<b>Purpose</b>	Redirecting non-patient users to a single location for authentication.

<b>Definition</b>	An HTML5 based user interface component that facilitates authentication of non-patient users through a single location by communicating with the actual IdPs in the background in compliance with the OpenID Connect specifications. The user will be able to select her identity provider in this page, which are pre-configured for all integrated IdPs in C3-Cloud, and then provide the necessary credentials (e.g., username, password, etc.) for authentication.
<b>Provided Interfaces</b>	
<u>HTML5 based user interface</u>	
<b>Required Interfaces</b>	
<u>OpenID Connect API</u>	Interface of OpenID Connect Adapter and C3-Cloud IdP.

❖ Authorization Manager

<b>Type</b>	Subsystem component
<b>Purpose</b>	Ensuring that no unauthorised user can access or modify sensitive data in the overall C3-Cloud environment.
<b>Definition</b>	Authorization Manager corresponds to the Policy Decision Point actor in the widely-adopted access control management architectures. It will expose a RESTful API to get user authorisation decision requests from C3-Cloud components (e.g., PCPDP, C3DP), which will enforce these decisions in their workflows, and to return a binary decision. Decisions will be taken by checking against the access control policies available in the Access Control Policy Store.
<b>Provided Interfaces</b>	
<u>Authorize</u>	A RESTful endpoint for client systems to ensure that a user (e.g., a GP) is authorised to perform a specific operation (e.g., update) on a specific resource (e.g., care plan of a specific patient). The RESTful endpoint will expect user claims (in JWT format) and information about the requested resource and operation, and after checking against the access control policies (represented in XACML) in the Access Control Policy Store, will return a positive or negative decision.
<b>Required Interfaces</b>	
<u>AccessControlPolicyRead</u>	interface of the Access Control Policy Store

❖ Policy Management UI

<b>Type</b>	Subsystem component
<b>Purpose</b>	Providing a GUI for Administrators to manage access control policy definitions.

<b>Definition</b>	A Web application for Administrators to browse, create, update or delete access control policy definitions applied in their settings.
<b>Provided Interfaces</b>	
<u>HTML5 based user interface</u>	UI for Administrators to browse, create, update or delete access control policy definitions.
<b>Required Interfaces</b>	
<u>AccessControlPolicyUpdate</u>	interface of the Access Control Policy Store

❖ Access Control Policy Store

<b>Type</b>	Subsystem component
<b>Purpose</b>	Maintaining access control policy definitions in a secure location and exposing interfaces to manipulate these definitions.
<b>Definition</b>	This component provides a secure database storing the access control policy definitions in the XACML standard, and exposes RESTful interfaces to read or update these policies.
<b>Provided Interfaces</b>	
<u>AccessControlPolicyRead</u>	A RESTful endpoint for read-only access to access control policy definitions kept in the Store in the XACML standard, to be utilised by the Authorization Manager to check user claims against the policies and make a decision.
<u>AccessControlPolicyUpdate</u>	A RESTful endpoint for unlimited access (i.e. create, read, update, delete) to access control policy definitions kept in the Store in the XACML standard, to be utilised by the Policy Management UI to update updating of policies by the Administrators.
<b>Required Interfaces</b>	
None.	

❖ Audit Record Repository

<b>Type</b>	Subsystem component
<b>Purpose</b>	Keeping audit trail records of all kinds of interactions in/out any data provider system and data requester system in the overall C3-Cloud environment.
<b>Definition</b>	Audit Record Repository is indeed a FHIR STU3 Repository, implementing RESTful FHIR API to manage AuditEvent resource, which is based on IHE-ATNA and hence DICOM audit record definitions.
<b>Provided Interfaces</b>	
<u>FHIR AuditEvent API</u>	A FHIR RESTful endpoint to store the audit trail records sent by all C3-Cloud components, and for Audit Record UI to retrieve and

	display audit trail records. This interface will implement the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> , <i>update</i> , <i>delete</i> , and <i>history</i> and type level interactions: <i>create</i> and <i>search</i> on FHIR AuditEvent resource.
<b>Required Interfaces</b>	
None.	

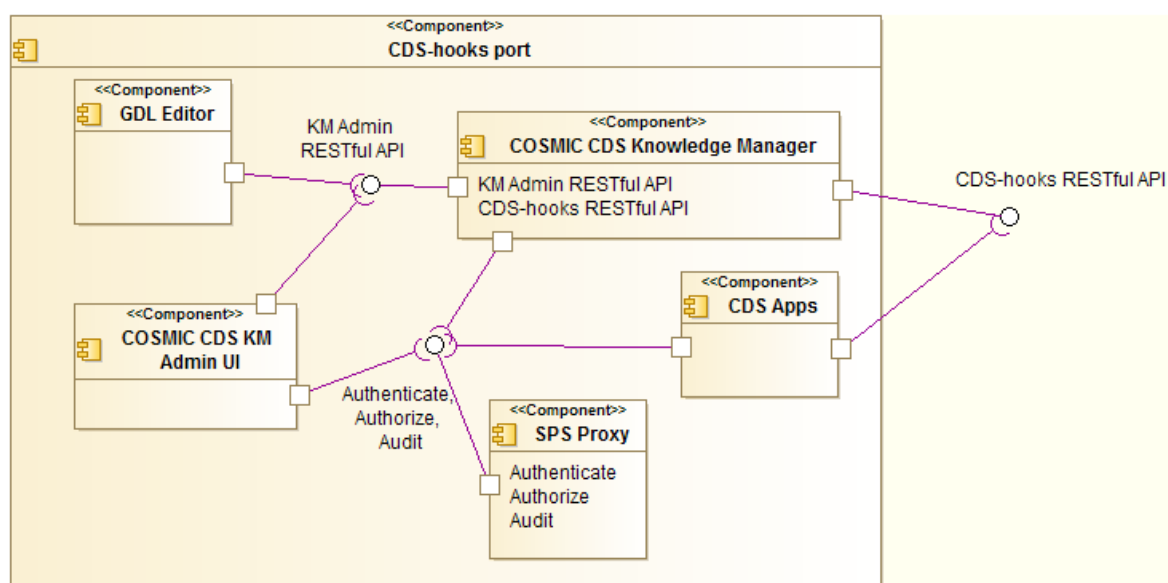
❖ **Audit Record UI**

<b>Type</b>	Subsystem component
<b>Purpose</b>	Displaying audit trail records of all kinds of interactions in/out any data provider system and data requester system in the overall C3-Cloud environment.
<b>Definition</b>	This component is a web application for Administrators to query, list, browse and see the details of all audit trail records that are available in the Audit Record Repository.
<b>Provided Interfaces</b>	
<i>HTML5 based user interface</i>	UI for Administrators to query, filter and display audit trail records.
<b>Required Interfaces</b>	
<i>FHIR AuditEvent API</i>	Audit Record Repository API

## 2.7. Clinical Decision Support Service

The exact content of clinical decision support modules to be implemented in C3-Cloud depends on the output of Work Task 7.1, which identifies and localises the evidence based clinical guidelines for individual chronic conditions that are targeted in the project, and the output of Work Task 4.1, which develops guidance on how individual clinical guidelines can be reconciled for the automation of personalised care plan development. Because the output of both tasks are not available by the time this SDD is developed, the conceptual architecture design for clinical decision support in this document focuses on the design of a generic CDS service, independent of any content specific CDS modules. Task 7.2 will develop concrete C3-Cloud CDS modules on a unified CDS platform and deliver them as CDS services based on the designed architecture in this SDD.

The core of C3-Cloud CDS service is COSMIC CDS, a CDS product from one of the project partners, Cambio Healthcare Systems. COSMIC CDS provides a computerised clinical decision support service combining information that is specific to an individual patient, with regulations based on medical evidence, to provide guidance on compliance or advice on what is the best treatment for the patient. COSMIC CDS is based on international standards and has been designed for easy integration with underlying, local medical records. The product supports a learning organisation, where new knowledge in the form of medical rules can continuously be added and quickly put to use in everyday clinical practice. COSMIC CDS can be used in all areas of healthcare, regardless of clinical specialty and organisational affiliation. COSMIC CDS provides comprehensive RESTful API for integration with other systems. In C3-Cloud, COSMIC CDS will provide FHIR-based CDS-hooks interface and integrates with the C3-Cloud SPS.

**Figure 7: SDD-CMP-CDSS: CDSS Component Diagram**❖ **COSMIC CDS Knowledge Manager**

<b>Type</b>	Subsystem component
<b>Purpose</b>	COSMIC CDS Knowledge Manager is a knowledge database and rules engine for managing medical regulations and clinical information models. Clinical knowledge is broken down into machine-readable rules, based on international standards and reference terminologies, so that decision support rules can easily be shared between different decision support applications, regardless of the vendor. These rules can be used to build a powerful and flexible clinical decision support system.
<b>Definition</b>	COSMIC CDS Knowledge Manager is a repository of standard-based, fully structured clinical models for advanced clinical applications. The content of the repository is neutral in terms of language and it can be used as building blocks to construct flexible and powerful clinical applications. Additionally, it enables sharing of clinical models between healthcare institutions and across country borders. Clinical models can be developed via international collaborations, as well as through local work. Clinical models are based on openEHR archetypes and Guideline Definition Language (GDL) [GDL].
<b>Provided Interfaces</b>	
<i>KM Admin RESTful API</i>	A RESTful API to deploy and manage CDS rules, guidelines and archetype templates, etc.
<i>CDS-hooks RESTful API</i>	A RESTful service API based on CDS-hooks API specification, for evaluation of patient information specific to an individual patient in order to provide guidance or advice. The API provides a “hook”-based pattern for invoking decision support from within a clinician’s EHR workflow. User activity inside the EHR triggers CDS hooks in real-time. When a triggering activity occurs, the EHR notifies each CDS service registered for the activity. These services must then provide near-real-time feedback about the triggering event. Each service gets basic details about the EHR context and whatever service-specific data

	are required. Each CDS service can return any number of cards in response to the hook. Cards convey some combination of text ( <i>information card</i> ), alternative suggestions ( <i>suggestion card</i> ), and links to apps or reference materials ( <i>app link card</i> ). In addition to cards, a CDS service may also return decisions - but only after a user has interacted with the service via an app link card. Returning a decision allows the CDS service to communicate the user's choices to the EHR without displaying an additional card.
<b>Required Interfaces</b>	
<i>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</i>	The component integrates SPS's AAA functions.

❖ **COSMIC CDS KM Admin UI**

<b>Type</b>	Subsystem component
<b>Purpose</b>	Performs administrative tasks, i.e. manage rules, guidelines and archetype templates, etc.
<b>Definition</b>	An HTML5 App based on the popular AngularJS JavaScript framework, utilising REST APIs to communicate with the Knowledge Manager Server.
<b>Provided Interfaces</b>	
<i>HTML5 based user interface</i>	UI to manage rules, guidelines and archetype templates, etc.
<b>Required Interfaces</b>	
<i>KM Admin RESTful API</i>	Requires COSMIC CDS Knowledge Manager Admin API to manage rules, guidelines and archetype templates, etc.
<i>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</i>	The component integrates SPS's AAA functions.

❖ **GDL Editor**

<b>Type</b>	Subsystem component
<b>Purpose</b>	The GDL editor is multiplatform application that allows users to create, edit and run GDL files. GDL is a formal language designed to represent clinical knowledge for decision support. It is designed to be natural language - and reference terminology- agnostic by leveraging the designs of openEHR Reference Model and Archetype Model. The tool provides an editing and testing environment capable of generating forms based on the elements defined in the GDL.
<b>Definition</b>	A Java desktop application for authoring and executing GDL rules [GDL-EDITOR]



<b>Provided Interfaces</b>	
<i>Java desktop graphical user interface</i>	GUI for authoring and executing GDL rules.
<b>Required Interfaces</b>	
<i>KM Admin RESTful API</i>	Requires COSMIC CDS Knowledge Manager Admin API to deploy GDL rules.
<i>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</i>	The component integrates SPS's AAA functions.

❖ CDS Apps

<b>Type</b>	Subsystem component
<b>Purpose</b>	CDS apps are substitutable modular applications designed to capture specific user input required to execute relevant CDS rules. C3-Cloud will develop CDS apps for each decision support module
<b>Definition</b>	A CDS app is a web application consisting of HTML, CSS and some Javascript calling the CDS-Service.
<b>Provided Interfaces</b>	
<i>HTML5 based user interface</i>	Each app will present a web form type of UI to capture patient information required by the backend CDS rules.
<b>Required Interfaces</b>	
<i>CDS-hooks RESTful API</i>	Requires the CDS-hooks API to call the backend CDS service, provided by COSMIC CDS Knowledge Manager.
<i>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</i>	The component integrates SPS's AAA functions.

❖ SPS Proxy

<b>Type</b>	Subsystem component
<b>Purpose</b>	Single-sign-on, access control and audit.
<b>Definition</b>	A software proxy from SPS to provide authentication, authorisation and auditing functions.
<b>Provided Interfaces</b>	
<i>OpenID Connect API, Authorize, FHIR AuditEvent API (AAA)</i>	Proxy interfaces to connect to SPS remote systems.
<b>Required Interfaces</b>	

None.
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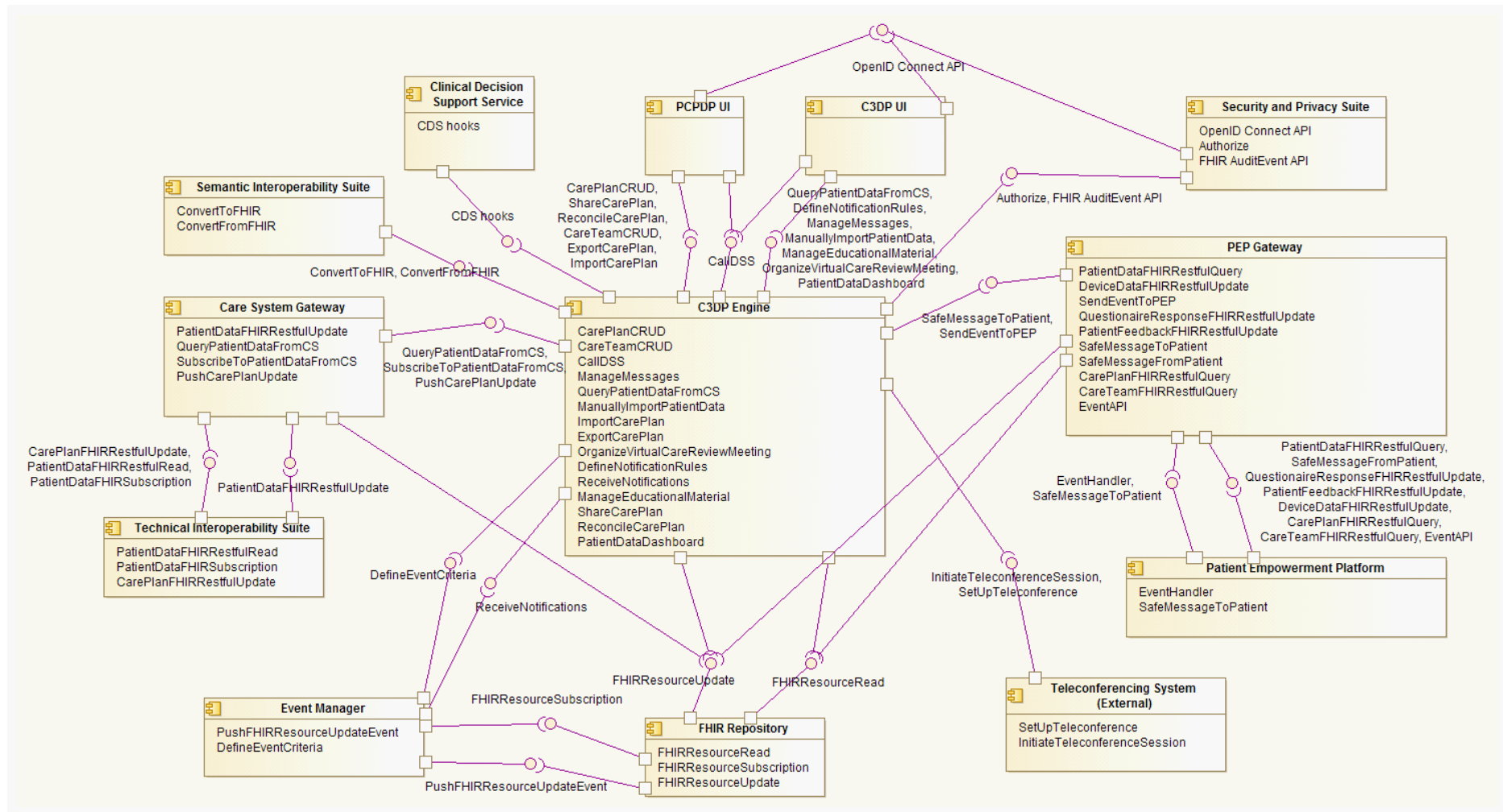
## 2.8. Coordinated Care and Cure Delivery Platform

Coordinated Care and Cure Delivery Platform is composed of nine components:

- C3DP Engine
- FHIR Repository
- Event Manager
- Care System Gateway
- PEP Gateway
- PCPDP UI
- C3DP UI
- Educational Material Registry
- [External] Teleconferencing System

It should be noted that Personalised Care Plan Development Platform (PCPDP), which has been analysed as an individual component in the requirements analysis phase, is indeed a sub-component of and deeply integrated with the Coordinated Care and Cure Delivery Platform. Therefore, now in the design phase, it is merged with the overall C3DP design.

Figure 8: SDD-CMP-C3DP: C3DP Component Diagram



❖ **C3DP Engine**

<b>Type</b>	Subsystem component
<b>Purpose</b>	Coordinating the choreography of the communication between other subcomponents within C3DP component. Providing the business logic of the functionalities to be carried out for PCPDP and C3DP User Interfaces.
<b>Definition</b>	C3DP Engine is the core sub-component of C3DP component coordinating the internal business logic of the functionalities provided by C3DP, facilitating the choreography of the communication between other subcomponents within C3DP component. It is the main interface to the two main graphical interfaces of C3DP, i.e. PCPDP UI and C3DP UI.
<b>Provided Interfaces</b>	
<u>CarePlanCRUD</u>	This interface is served to PCPDP UI, enabling the creation, update, view and deletion of care plan and its constituting entities managed within C3DP.
<u>ReconcileCarePlan</u>	This interface is served to PCPDP UI, enabling checking the inconsistencies within the care plan definition by calling the necessary clinical decision support modules when necessary.
<u>ImportCarePlan</u>	This interface is served to PCPDP UI, to import an existing care plan definition to be managed within C3DP.
<u>ExportCarePlan</u>	This interface is served to PCPDP UI, to export the care plan snapshot in a standard based format.
<u>ShareCarePlan</u>	This interface is served to PCPDP UI, to share the care plan snapshot with all care team members, local care systems and Patient Empowerment Platform.
<u>CareTeamCRUD</u>	This interface is served to PCPDP UI, enabling editing, viewing care team member list, and also inviting, adding, removing care team members.
<u>CallDSS</u>	This interface is served to PCPDP UI and C3DP UI to call specific clinical decision support modules for risk calculation, retrieving suggestions for interventions based on clinical guidelines, and polypharmacy management.
<u>QueryPatientDataFromCS</u>	This interface is served to C3DP UI, to enable the MDT member to manually initiate the query to local care systems to retrieve most recent patient data.
<u>ManuallyImportPatientData</u>	This interface is served to C3DP UI, to enable the MDT member to manually import existing patient data to C3DP.
<u>ManageMessages</u>	This interface is served to C3DP UI, to enable the MDT members to view, read, write, tag, send messages.
<u>DefineNotificationRules</u>	This interface is served to C3DP UI, to enable the MDT members to define the notification rules for receiving custom notifications about the different milestones in the care plan lifecycle, patient data received from local care systems and PEP and patient feedback received from PEP.

<u>ReceiveNotifications</u>	This interface is served to EventManager component to receive notifications about the events fired based on the pre-defined event subscriptions.
<u>ManageEducationalMaterial</u>	This interface is served to C3DP UI, to enable the MDT members to register, and access educational material for health professionals.
<u>OrganizeVirtualCareReviewMeeting</u>	This interface is served to C3DP UI, to enable the MDT members to set-up, initiate and run virtual care review meetings supported with a teleconferencing facility.
<u>PatientDataDashboard</u>	This interface is served to C3DP UI, to enable the MDT members to view patient summary overview.
<b>Required Interfaces</b>	
<u>QueryPatientDataFromCS</u> <u>SubscribeToPatientDataFromCS</u> <u>PushCarePlanUpdate</u>	interfaces of Care System Gateway
<u>CDS-hooks RESTful API</u>	interface of Clinical Decision Support Service
<u>DefineEventCriteria</u>	interface of Event Manager
<u>FHIRResourceRead</u> <u>FHIRResourceUpdate</u>	interfaces of FHIR Repository
<u>SendEventToPEP</u> <u>SendMessageToPatient</u>	interfaces of PEP Gateway
<u>Authorize</u> <u>FHIR AuditEvent API</u>	interfaces of Security and Privacy Suite
<u>InitiateTeleconferenceSession</u> <u>SetupTeleconference</u>	interfaces of Teleconferencing System (External)
<u>ConvertToFHIR</u> <u>ConvertFromFHIR</u>	interfaces of Semantic Interoperability Suite

❖ **FHIR Repository**

<b>Type</b>	Subsystem component
<b>Purpose</b>	Safe storage of data from various disconnected source systems required for personalised care planning and execution in a unified manner, and exchange of these data with authorized C3-Cloud components.
<b>Definition</b>	This component is a safe data repository implementing HL7 FHIR STU3 specifications. There will be support for tens of FHIR resource types including clinical (Condition, Observation, Procedure), care plan related (CarePlan, CareTeam, Goal), administrative (Patient, AuditEvent) and further (e.g., Questionnaire) resources. FHIR RESTful API will be implemented for exchange of FHIR resources with other

	components. Resources will also be stored as JSON files inside a MongoDB database for fast access and manipulation.
<b>Provided Interfaces</b>	
<u><i>FHIRResourceRead</i></u>	A read-only FHIR RESTful endpoint to access available FHIR resources in the repository. This interface will implement the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> and <i>history</i> and type level interaction: <i>search</i> on all supported FHIR resource types (Condition, Observation, CarePlan, AuditEvent, QuestionnaireResponse ...).
<u><i>FHIRResourceUpdate</i></u>	A FHIR RESTful for unlimited access (i.e. create, update, delete) to FHIR resources in the repository. This interface will implement the FHIR RESTful API instance level interactions: <i>update</i> and <i>delete</i> and type level interaction: <i>create</i> on all supported FHIR resource types (Condition, Observation, CarePlan, AuditEvent, QuestionnaireResponse ...).
<u><i>FHIRResourceSubscription</i></u>	A FHIR RESTful endpoint for subscribing to a resource according to a criterion (e.g., any update, or upon update of a specific attribute) by utilizing the FHIR Subscription resource type. The preferred “channels” for sending updates to subscribed systems is rest-hook and websocket.
<b>Required Interfaces</b>	
<u><i>PushFHIRResourceUpdateEvent</i></u>	Interface of the Event Manager

❖ **Event Manager**

<b>Type</b>	Subsystem component
<b>Purpose</b>	Management of subscriptions to specific resources or events, and generation of notifications based on subscription criteria to be forwarded to addressed actors.
<b>Definition</b>	This component provides a RESTful API for management of the subscriptions to specific resources or events (e.g., notify a Care Team Member, when a received patient device measurement is above a specific value, or notify all Care Team Members when a new patient feedback is received). After receiving an event criteria from C3DP Engine, it will adjust and realize the actual subscription to the FHIR Repository. Some detailed criteria might not be handled by the FHIR Repository subscription mechanism, so the Event Manager will be able to perform criteria matching as well. In case of match, necessary notifications will be created and sent back to the subscribed component, which is again the C3DP Engine.
<b>Provided Interfaces</b>	
<u><i>DefineEventCriteria</i></u>	A RESTful endpoint for accepting from the C3DP Engine the detailed event criteria for subscription.

<u><i>PushFHIRResourceUpdateEvent</i></u>	A RESTful endpoint for receiving an update from the FHIR Repository. This interface will be provided as a rest-hook while subscribing to the FHIR Repository for updates.
<b>Required Interfaces</b>	
<u><i>FHIRResourceSubscription</i></u>	Interface of the FHIR Repository
<u><i>ReceiveNotifications</i></u>	Interface of the C3DP Engine

❖ *Care System Gateway*

<b>Type</b>	Subsystem component
<b>Purpose</b>	Providing a single interface to local care systems through Technical Interoperability Suite.
<b>Definition</b>	Care System Gateway is the interface of C3DP to Technical Interoperability Suite to communicate with local care systems. It will communicate with Technical Interoperability Suite through its RESTful FHIR interfaces to query and subscribe patient data, and will open up a RESTful interface to receive subscribed patient data from local care systems. It will in turn store these patient data to the FHIR Repository of C3DP via its FHIR RESTful API.
<b>Provided Interfaces</b>	
<u><i>PatientDataFhirRestfulUpdate</i></u>	A FHIR RESTful endpoint for client (Technical Interoperability Suite) to upload subscribed patient data. The interface implements the FHIR RESTful API instance level <i>update</i> interaction. The received data is stored to the FHIR Repository of C3DP.
<u><i>QueryPatientDataFromCS</i></u>	A RESTful API for the C3DP Engine to query patient data from local care systems.
<u><i>SubscribeToPatientDataFromCS</i></u>	A RESTful API for the C3DP Engine to subscribe to patient data from local care systems.
<u><i>PUSHCarePlanUpdate</i></u>	A RESTful API for the C3DP Engine to push care plan updates to local care systems.
<b>Required Interfaces</b>	
<u><i>PatientDataFhirRestfulRead</i></u> <u><i>PatientDataFhirSubscription</i></u> <u><i>CarePlanFhirRestfulUpdate</i></u>	interfaces from Technical Interoperability Suite
<u><i>FHIRResourceUpdate</i></u>	interface from FHIR Repository

❖ *PEP Gateway*

<b>Type</b>	Subsystem component
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<b>Purpose</b>	Providing a single interface to Patient Empowerment Platform.
<b>Definition</b>	PEP Gateway is the interface of C3DP to Patient Empowerment Platform to exchange patient data, care plan, patient feedback, questionnaire results, device data and messages between MDT members and patients. It will communicate with Patient Empowerment Platform through RESTful FHIR API.
<b>Provided Interfaces</b>	
<i>CarePlanFHIRRestfulQuery</i>	A FHIR RESTful endpoint for PEP to query care plans in the FHIR repository. The interface implements the FHIR RESTful API instance level <i>read</i> , <i>vread</i> , and <i>history</i> interactions. The query will be passed to the FHIR Repository of C3DP.
<i>CareTeamFHIRRestfulQuery</i>	A FHIR RESTful endpoint for PEP to retrieve care team updates from C3DP FHIR repository. The interface implements the FHIR RESTful API instance level interactions: <i>read</i> , <i>vread</i> , and <i>history</i> . The query will be passed to the FHIR Repository of C3DP.
<i>PatientDataFHIRRestfulQuery</i>	A FHIR RESTful endpoint for PEP to query patient data. The interface implements the FHIR RESTful API instance level <i>read</i> , <i>vread</i> , and <i>history</i> interactions and type level interaction <i>search</i> . The query will be passed to the FHIR Repository of C3DP.
<i>QuestionnaireResponseFHIRRestfulUpdate</i>	A FHIR RESTful endpoint for PEP to upload questionnaire results of the patients to C3DP FHIR repository. The interface implements the FHIR RESTful API type level <i>create</i> interaction for QuestionnaireResponse resource, and passes this update request to C3DP FHIR Repository <i>FHIRResourceUpdate</i> interface.
<i>DeviceDataFHIRRestfulUpdate</i>	A FHIR RESTful endpoint for PEP to upload the subscribed device data of the patients to C3DP FHIR repository. The interface implements the FHIR RESTful API type level <i>create</i> interaction for Observation resource (indeed a profile on top of Observation), and passes this update request to C3DP FHIR Repository's <i>FHIRResourceUpdate</i> interface.
<i>PatientFeedbackFHIRRestfulUpdate</i>	A FHIR RESTful endpoint for PEP to upload the feedback of the patients for care plan activities and goals to C3DP FHIR repository. The interface implements the FHIR RESTful API type level <i>create</i> interaction for PatientFeedback Observation (a C3-Cloud profile on top of Observation resource), and passes this update request to C3DP FHIR Repository's <i>FHIRResourceUpdate</i> interface.
<i>SafeMessageFromPatient</i>	A RESTful endpoint to receive the messages sent by the patient to MDT members. The interface implements the FHIR RESTful API type level <i>create</i>



	interaction for Communication resource, and stores the received message to C3DP FHIR Repository via the <i>FHIRResourceUpdate</i> interface. This will trigger a notification to C3DP Engine via the Event Manager to notify the MDT member about the message received from the patient.
<i>SafeMessageToPatient</i>	A RESTful API for the C3DP Engine to pass the messages sent by MDT members to the Patient Empowerment Platform to be delivered to the patient.
<i>SendEventToPEP</i>	A RESTful API for the C3DP Engine to notify PEP about CarePlanUpdate and CareTeamUpdate events.
<i>EventAPI</i>	A RESTful API for PEP to post CarePlanRead and MessageRead PEP events. This event API is used whenever an event is satisfactory enough to inform about updates; i.e. no need to upload a payload such as questionnaire response.
<b>Required Interfaces</b>	
<i>EventHandler</i> <i>SafeMessageToPatient</i>	interfaces from Patient Empowerment Platform
<i>FHIRResourceRead</i> <i>FHIRResourceUpdate</i>	interfaces from FHIR Repository

❖ PCPDP UI

<b>Type</b>	Subsystem component
<b>Purpose</b>	Providing a GUI for MDT members to collaboratively create, update, share, and export personalised care plan definitions.
<b>Definition</b>	A Web application for MDT members to browse, create, update, reconcile, import, export, share personalised care plan definitions.
<b>Provided Interfaces</b>	
<i>HTML5 based user interface</i>	UI for MDT members to collaboratively create, update, share, and export personalised care plan definitions.
<b>Required Interfaces</b>	
<i>CarePlanCRUD</i> <i>CareTeamCRUD</i> <i>ReconcileCarePlan</i> <i>ShareCarePlan</i> <i>ImportCarePlan</i> <i>ExportCarePlan</i> <i>CallDSS</i>	interfaces of C3DP Engine
<i>OpenID Connect API</i>	interface of Security and Privacy Suite

❖ **C3DP UI**

<b>Type</b>	Subsystem component
<b>Purpose</b>	Providing a GUI for MDT members to retrieve patient data from local care systems (either by querying, or by manually importing existing clinical documents); manage messages from other MDT members, patients and system notifications; register/access educational material linked with personalised care plans; organise virtual care review meetings and define notification rules for receiving personalised system notifications.
<b>Definition</b>	A Web application for MDT members to manage messages and system notifications, manage educational material, associate supportive clinical data from care systems to care plan, organise virtual care review meetings.
<b>Provided Interfaces</b>	
<u>HTML5 based user interface</u>	UI for MDT members to collaboratively to manage the workflow of personalised care plan execution; e.g. manage messages, educational materials, virtual care review meetings.
<b>Required Interfaces</b>	
<i>QueryPatientDataFromCS DefineNotificationRules ManageMessages ManuallyImportPateintData ManageEducationalMaterial OrganizeVirtualCareReview-Meeting</i>	interfaces of C3DP Engine
<i>OpenID Connect API</i>	interface of Security and Privacy Suite

❖ **Teleconferencing System (External)**

<b>Type</b>	Subsystem component
<b>Purpose</b>	Set up and realisation of teleconferences among Care Team Members as periodic or spontaneous virtual care review meetings, involving the patient and/or informal care giver whenever necessary.
<b>Definition</b>	An external teleconferencing system will be utilised to organise teleconferences. In case a teleconferencing system is already in use in a pilot site, it will be reused. In the opposite case, an appropriate free solution will be integrated.
<b>Provided Interfaces</b>	
<u>SetUpTeleconference</u>	Ideally a programmable API to set up in advance a teleconference session and get the coordinates for connection (e.g., URL,

	participation code). If an API is not provided by the teleconferencing system, then graphical user interfaces will be used.
<u><i>InitiateTeleconferenceSession</i></u>	Ideally a programmable API to initiate a previously arranged teleconference session by using the coordinates for connection (e.g., URL, participation code). If an API is not provided by the teleconferencing system, then graphical user interfaces will be used.
<b>Required Interfaces</b>	
None.	

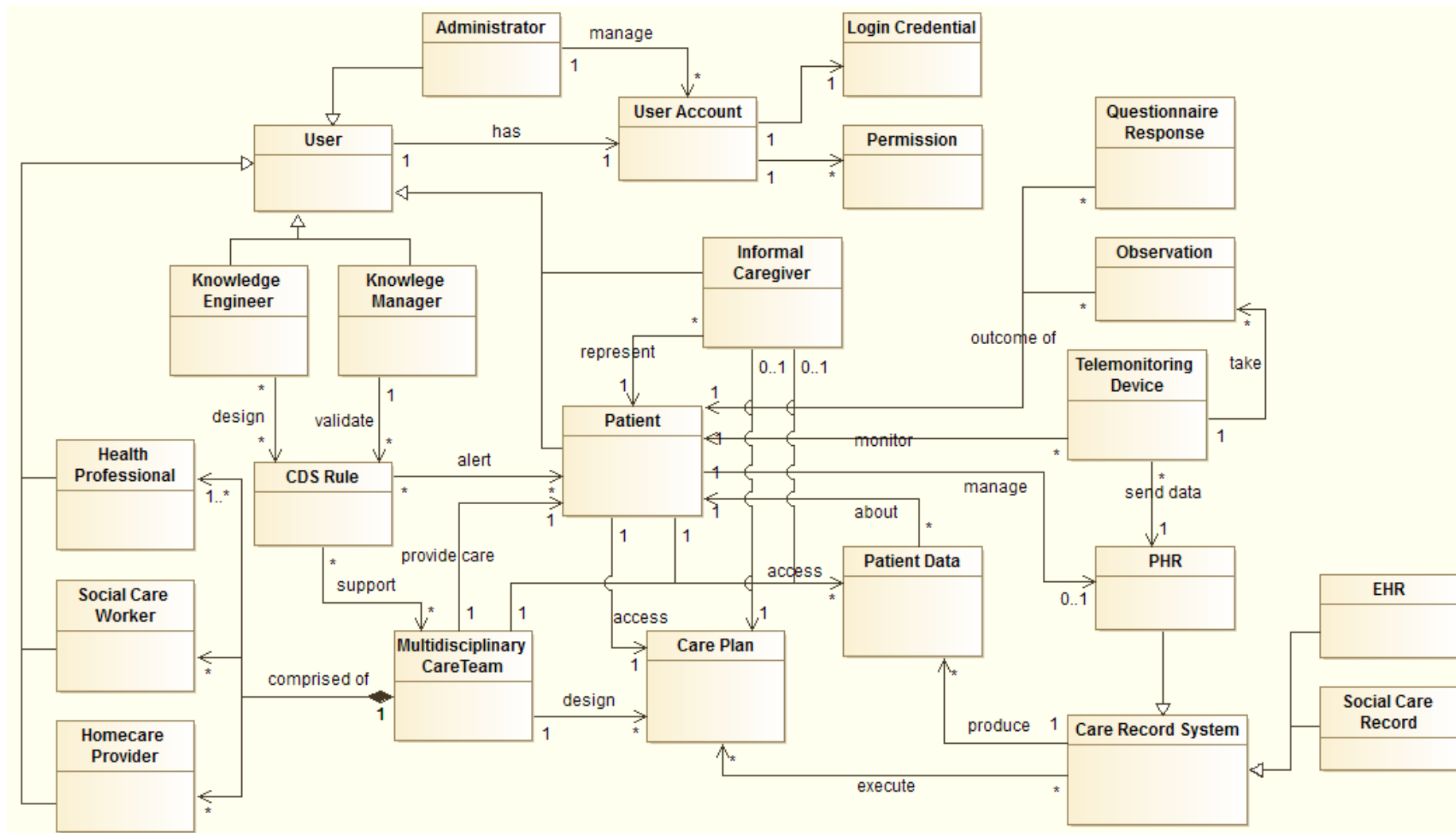
### 3. LOGICAL VIEW

The logical view focuses on domain models of C3-Cloud system. A domain model is a conceptual model of the problem domain that a system is designed to solve. The objective of the model is to identify key actors and domain entities, and their logical relationships in the system, in order to formally model the problem and establish a common vocabulary to describe the problem and solutions. This view is governed by the logical viewpoint declared in Section 1.7, and represented by UML2 class diagram. Section 3.1 presents an overall logical view of the whole C3-Cloud system. Sections 3.2-3.8 present detailed design of the logical view for each subsystem.

#### 3.1. Overall Logical View

SDD-LGC-OVERALL (Figure 9) presents the overall logical view in a UML class diagram, which captures the most important actors and information entities that are involved in the system, identified from the project description in DoA and use cases in D3.2. The model is intended to be abstract and high-level. The focus is to delineate the business context and to communicate with non-technical stakeholders. Part of the model will be extended and refined for each subsystem in subsequent sections. Models of each subsystem, being described using a coherent set of classes, are able to combine into an elaborated version of the top view.

**Figure 9: SDD-LGC-OVERALL: Top Level C3-Cloud Logical View**

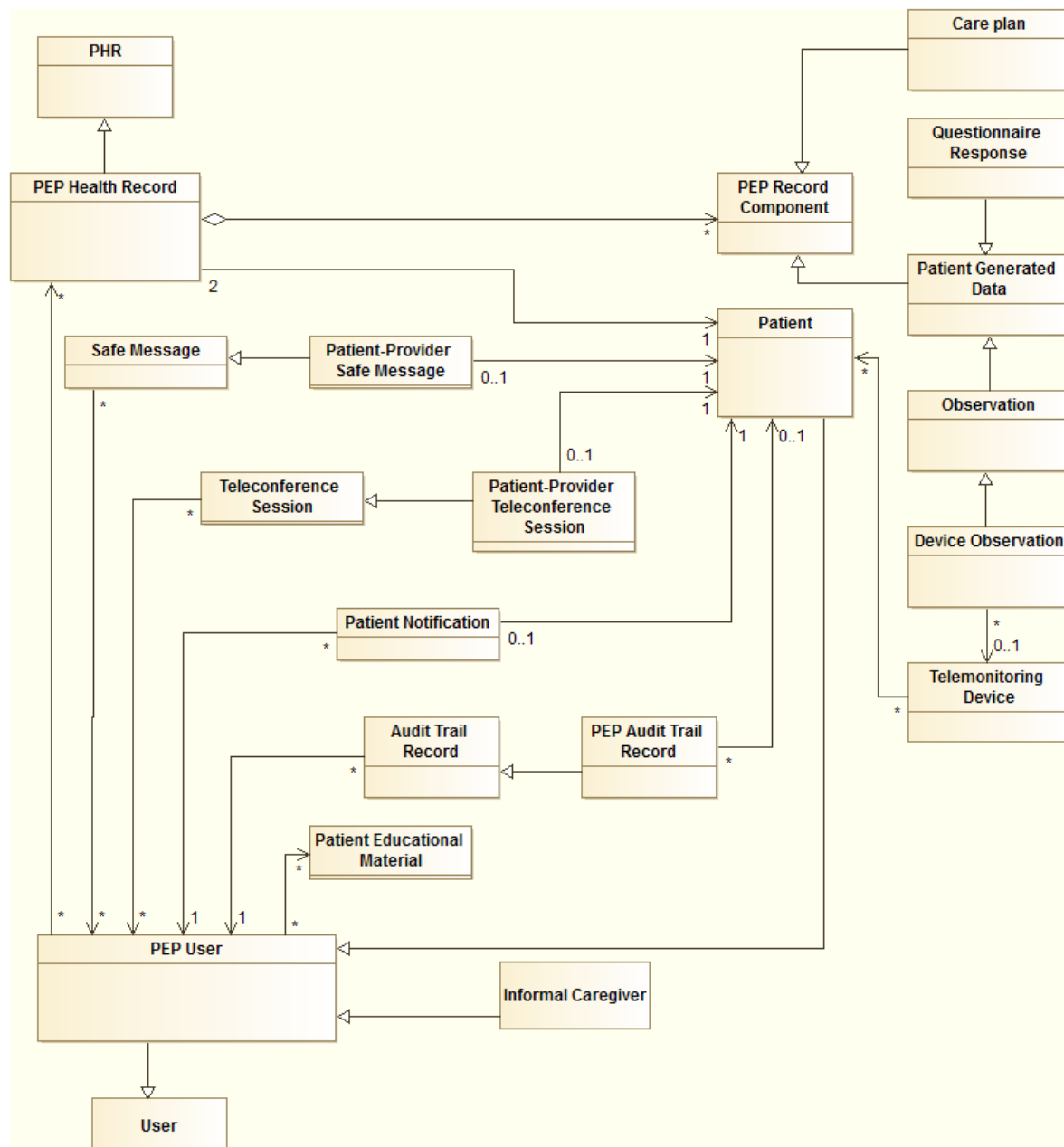


Domain Entity	Description
Administrator	System super user who can create user accounts and manage permissions.
Care Record System	The information technology system that captures, stores, manages or transmits information related to the health of individuals in a care sector.
Care Plan	Dynamic, personalised plan for a patient to tackle health issues, achieve health goals, and coordinate healthcare activities, collaboratively designed by MDT and executed by the systems in all involved care sectors.
CDS Rule	CDS rules encode clinical knowledge and provide health professionals with clinical decision support. CDS rules can also generate alerts to patients in the context of remote monitoring.
EHR	The information systems that manage patient electronic health records (EHR) in primary care and secondary care sectors. C3-Cloud aims to help provide an integrated view of patient data distributed over local EHR systems.
Health Professional	GPs, specialists, study nurses, pharmacists, physiotherapists, geriatricians, nutritionists, who comprise a multidisciplinary care team to provide care to a patient.
Homecare Provider	Home care, (also referred to as domiciliary care, social care, or in-home care), is supportive care provided in the home. Care may be provided by licensed healthcare professionals who provide medical treatment needs or by professional caregivers who provide daily assistance to ensure the activities of daily living (ADLs) are met. Homecare services help adults, seniors, and paediatric clients who are recovering after a hospital or facility stay, or need additional support to remain safely at home and avoid unnecessary hospitalisation. The services may include short-term nursing, rehabilitative, therapeutic, and assistive home health care.
Informal Caregiver	A person acting on behalf of the patient, who will have access to the patient's data and care plan. The informal care giver will have the same access permissions as the patient.
Knowledge Engineer	A user who can translate clinical knowledge (e.g., clinical guidelines, polypharmacy criteria, risk stratification models) into clinical decision support rules.
Knowledge Manager	A clinical expert who can validate CDS rules and approve the rules are safe to use.
Login Credential	The identity data used to authenticate a user; e.g., a combination of User ID and password.
Multidisciplinary Care Team (MDT)	Comprised of members from various care sectors, the MDT collaboratively designs an integrated and personalised care plan for the patient. The MDT has access to patient data generated in all care settings.
Observation	Measurements and simple assertions made about a patient, device or other subject. Observations are a central element in healthcare, used to support diagnosis, monitor progress, determine baselines and patterns and even capture demographic characteristics.
Patient	Patients with two or more of these chronic conditions: diabetes, heart failure, renal failure and depression who can access the integrated care plan and their health data through C3-Cloud.
Patient Data	Patient health information generated by information systems in various care settings. Patient data are sensitive and protected. In general, only the patient,

Domain Entity	Description
	informal caregivers on behalf of the patient, and MDT members who provide care to the patient can access the data of the patient.
Permission	User privileges to access C3-Cloud applications or protected data.
PHR	A personal health record (PHR) is an electronic application used by patients to maintain and manage their health information in a private, secure, and confidential environment.
Questionnaire Response	A structured set of questions and their answers. The questions are ordered and grouped into coherent subsets, corresponding to the structure of the grouping of the underlying questions. Questionnaire response provides a complete or partial list of answers to a set of questions filled when responding to a questionnaire. Questionnaires cover the need to communicate data originating from forms used in medical history examinations, research questionnaires and sometimes full clinical specialty records.
Social Care Record	The information systems that manage patient electronic records in social care sectors.
Social Care Worker	Social care workers support the needs of communities, families and individuals. They provide services for children, families, older people and those with mental and physical health problems.
Tele-monitoring Device	Remote monitoring devices continuously take measurements from patient and send to PHR. The data is shared to health professionals through C3-Cloud integration.
User	Human users of C3-Cloud system. Each user has one user account to access the system.
User Account	Each user account is associated with login credentials and a set of permissions.

### 3.2. Patient Empowerment Platform

**Figure 10: SDD-LGC-PEP: PEP Logical View**



Domain Entity	Description
Audit Trail Record	Logical model for long term persistence of proof for any data access or exchange transaction within the overall architecture. C3-Cloud implements audit trail records as FHIR AuditEvent resource instances.
Care plan	Dynamic, personalised plan including identified needed healthcare activity, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process.



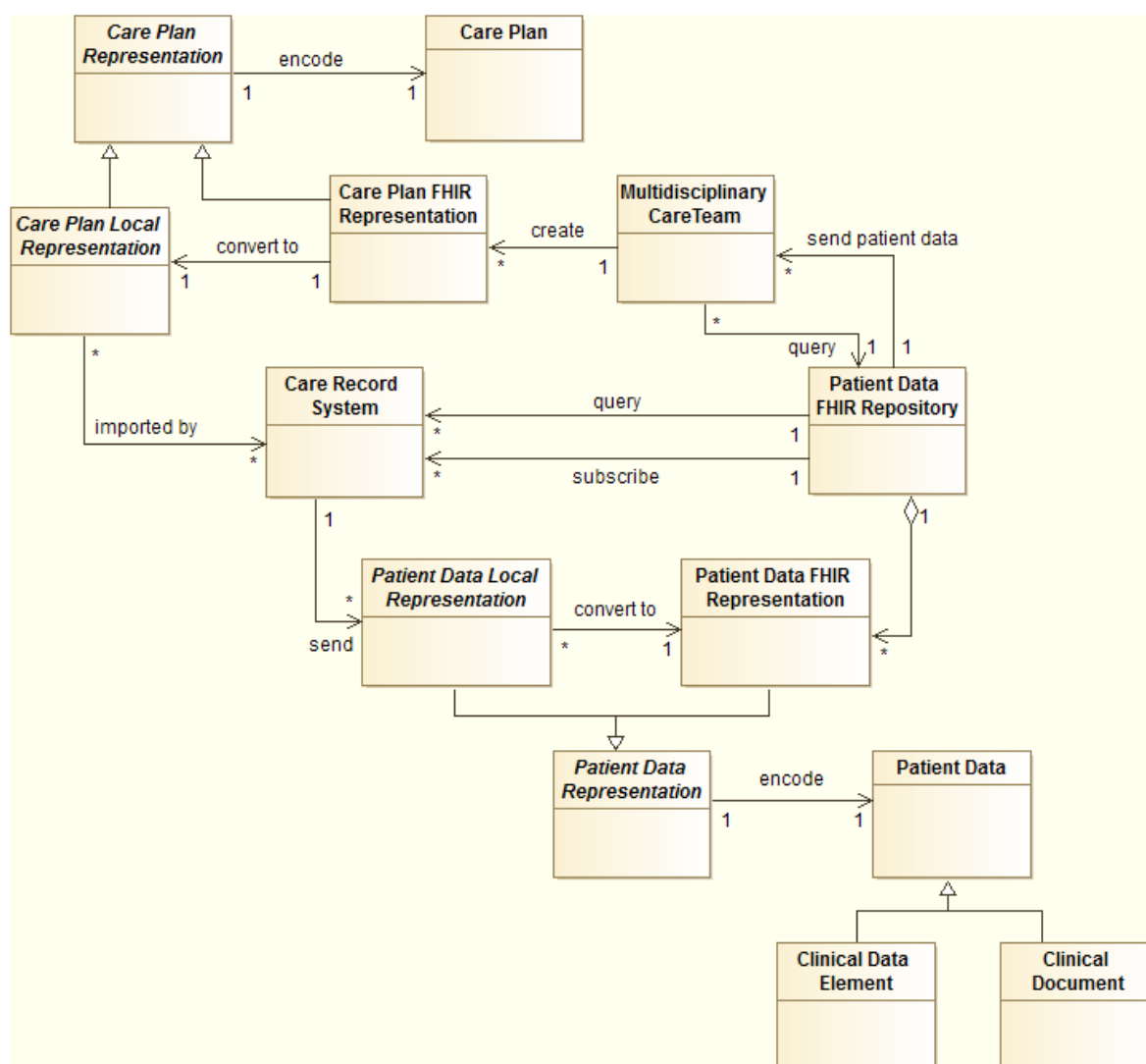
Domain Entity	Description
Device Observation	Observation (i.e. measurement) made using a device. For instance a blood glucose or blood pressure measurement.
Informal Caregiver	A person acting on behalf of the patient, who will have access to the patient's data and care plan in PEP. Also known as subject of care proxy.
Observation	Measurements and simple assertions made about a patient, device or other subject. Observations are a central element in healthcare, used to support diagnosis, monitor progress, determine baselines and patterns and even capture demographic characteristics.
Patient	Also known as subject of care. Patient is a PEP system user.
Patient Generated Data	Superclass of all types of data that can be generated and provided by the patient (or her informal care giver on behalf of the patient) related with the execution and update of her care plan.
Patient Educational Material	Logical pointers to locations of educational material (e.g., multi-morbidity guidelines, chronic disease management guidelines, etc.) for patients.
Patient Notification	Notification or reminder message related to a specific patient (i.e. subject of care). The notification message is sent to a patient access user (the patient self or an informal caregiver acting on behalf of the patient) typically via email or SMS.
Patient-provider Safe Message	Safe electronic messages exchanged between MDT and the patient. MDT members use C3DP and patients / informal care givers use PEP for interfacing safe messages. These messages are never sent, accessed or read via unsecure communication channels like email or SMS. Supportive notifications can be sent via email or SMS. A specialisation of the general Safe Message.
Patient-provider Teleconference Session	Teleconference sessions organised between MDT and the patient for discussing the recent progress of the patient and any issues she might have with the care plan. A specialisation of the general Teleconference Session.
PEP Audit Trail Record	Logical model for long term persistence of proof for any data access or exchange transaction within the PEP component.
PEP Health Record	PEP platform allows a patient (i.e. a subject of care) or an informal caregiver (i.e. a subject of care proxy) on behalf of the patient to access and maintain a health record regarding the health and healthcare of a patient. PEP is an extension to ordinary PHR. PEP provides a health data repository and additional services.
PEP Record Component	Information stored in electronic format in the PEP health record.
PEP User	The primary users of PEP system, including the patient and informal caregivers acting on behalf of the patient. The informal care giver has the same access permissions as the patient.
PHR	An electronic application used by patients to maintain and manage their health information in a private, secure, and confidential environment.
Questionnaire Response	A structured set of questions and their answers. The questions are ordered and grouped into coherent subsets, corresponding to the structure of the grouping of the underlying questions. Questionnaire response provides a complete or partial list of answers to a set of questions filled when responding to a questionnaire. Questionnaires cover the need to communicate data originating from forms used

Domain Entity	Description
	in medical history examinations, research questionnaires and sometimes full clinical specialty records.
Safe Message	Safe electronic messages exchanged among MDT members or between MDT and the patient. These messages are usually created and exchanged within the scope of a specific care plan. MDT members use C3DP and patients / informal care givers use PEP for interfacing safe messages. Supportive notifications can be sent via email or SMS.
Teleconference Session	Teleconference sessions organised among MDT members as planned or spontaneous virtual care review meetings, or between MDT and the patient for discussing the recent progress of the patient and any issues she might have with the care plan.
Tele-monitoring Device	Monitoring devices are manufactured items used by patient (i.e. subject of care) in the provision of healthcare without being substantially changed through that activity. The devices are used to record device observations related to the patient and store these in the personal health record. The device may be a medical or non-medical device. Medical devices include durable (reusable) medical equipment, implantable devices, as well as disposable equipment used for diagnostic, treatment, and research for healthcare and public health. Non-medical devices may include items such as a machine, cell phone, computer, application, etc.
User	Human users of C3-Cloud system. Each user has one user account to access the system. Each user is associated with authentication credentials and a set of permissions.

### 3.3. Technical Interoperability Suite

The logical view of technical interoperability suite extends and refines the patient data and care plan entities in the top-level logical view by introducing the concept of data representations to model the logical structure of the TIS subsystem.

Figure 11: SDD-LGC-TIS: TIS Logical View

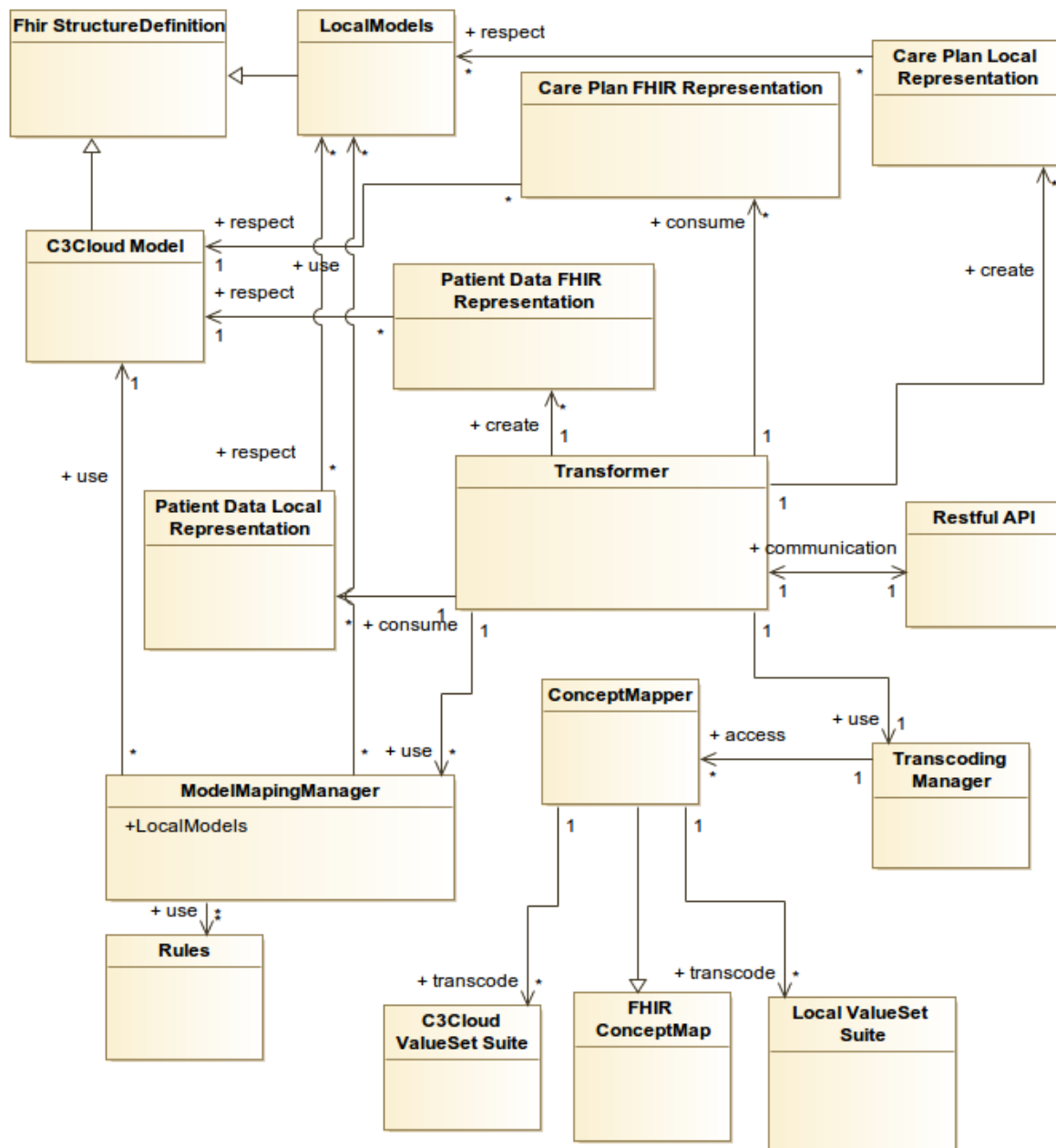


Domain Entity	Description
Care Plan	Conceptual entity of care plan which has a physical encoding format in a concrete system implementation.
Care Plan FHIR Representation	C3-Cloud implements care plans as FHIR resources.
Care Plan Local Representation	The physical representation of care plans in a local care record system.
Care Plan Representation	Abstract class of care plan representation, which has physical implementations in each system.
Care Record System	A care record system processes patient data and care plan encoded in concrete representations.
Clinical Data Element	Discrete clinical data items; e.g., gender, blood pressure, medical conditions, medication, lab test results, etc.

Domain Entity	Description
Clinical Document	Documents generated during the clinical workflow; e.g., discharge summary, referral note, transfer summary, continuity of care document, etc.
Multidisciplinary Care Team (MDT)	MDT accesses patient data in the patient data FHIR repository and designs care plans using C3-Cloud system. Both patient data and care plans are implemented as FHIR resources.
Patient Data	Conceptual entity of patient data, which have physical encoding format in a concrete system implementation.
Patient Data FHIR Representation	C3-Cloud implements patient data as FHIR resources.
Patient Data Local Representation	The physical representation of patient data in a local care record system.
Patient Data Representation	Abstract class of patient data representation, which has physical implementations in each system.
Patient Data FHIR Repository	Unified FHIR repository of patient data to support MDT access. Could be either a physical repository where copies of all patient data are stored as FHIR resources within C3-Cloud, or a virtual repository that presents as FHIR endpoints but gets data from source system on the fly.

### 3.4. Semantic Interoperability Suite

Figure 12: SDD-LGC-SIS: SIS Logical View



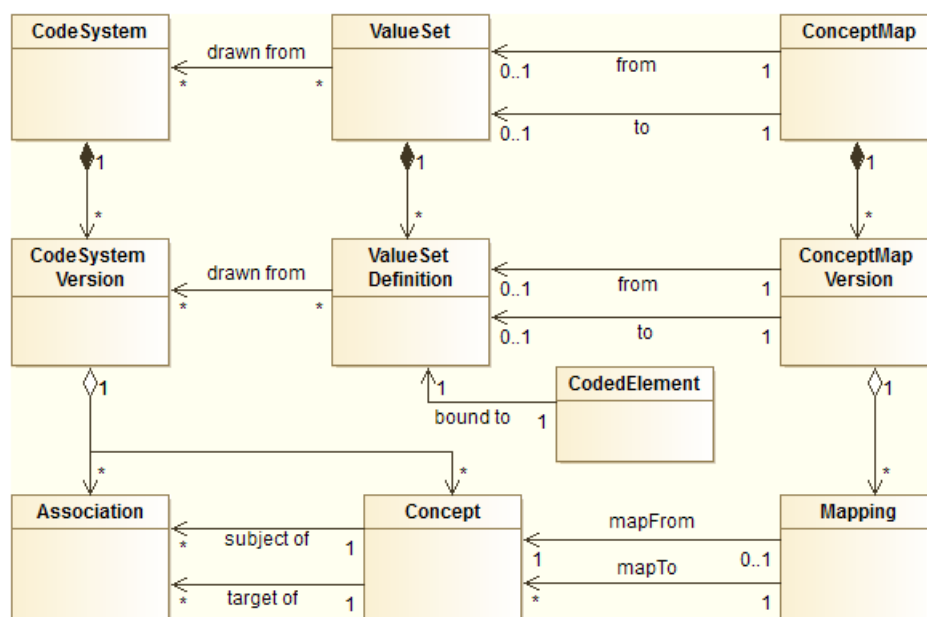
Domain Entity	Description
C3Cloud Model	FHIR StructureDefinition Instances of C3-Cloud resources (profiles).
C3Cloud ValueSet Suite	Physical representation of C3-Cloud ValueSets.
Care Plan FHIR Representation	Care Plan Instance as an FHIR Profile Instance.
Care Plan Local Representation	Care Plan Instance as a local care record system Instance.

Domain Entity	Description
ConceptMapper	Concepts Mapper Instance respecting a FHIR ConceptMap Implementation. Responsible of Mapping between one of C3Cloud ValueSet and one of local ValueSet.
Local ValueSet Suite	Physical representation of local care record system ValueSets.
LocalModels	FHIR StructureDefinition Instances of Locals resources (profiles).
ModelMappingManager	Supervision of mapping between C3-Cloud and local care record system data models.
Patient Data FHIR Representation	Patient Data Instance as a FHIR Profile Instance.
Patient Data Local Representation	Patient data representation as a local care record system Instance.
Restful API	Interfaces for SIS consumption.
Rules	Model Mapping rules, local care system specifics.
Transcoding Manager	ConceptMappers Manager Singleton.
Transformer	Full Transformation Manager Singleton (requester of the transformation process)

### 3.5. Terminology Service

The logical view of terminology service is based on the FHIR Terminology Service specification and other related standards; e.g., OMG CTS2 [CTS2]. The standards defined a comprehensive set of information classes and support data types aimed for implementation on specific platforms. The model presented in this view has abstracted away many such implementation details. The objective of the model is to highlight the key business concepts behind the implementation classes that a terminology service should be designed to support. More concrete implementation details are developed in other design views.

Figure 13: SDD-LGC-TS: TS Logical View

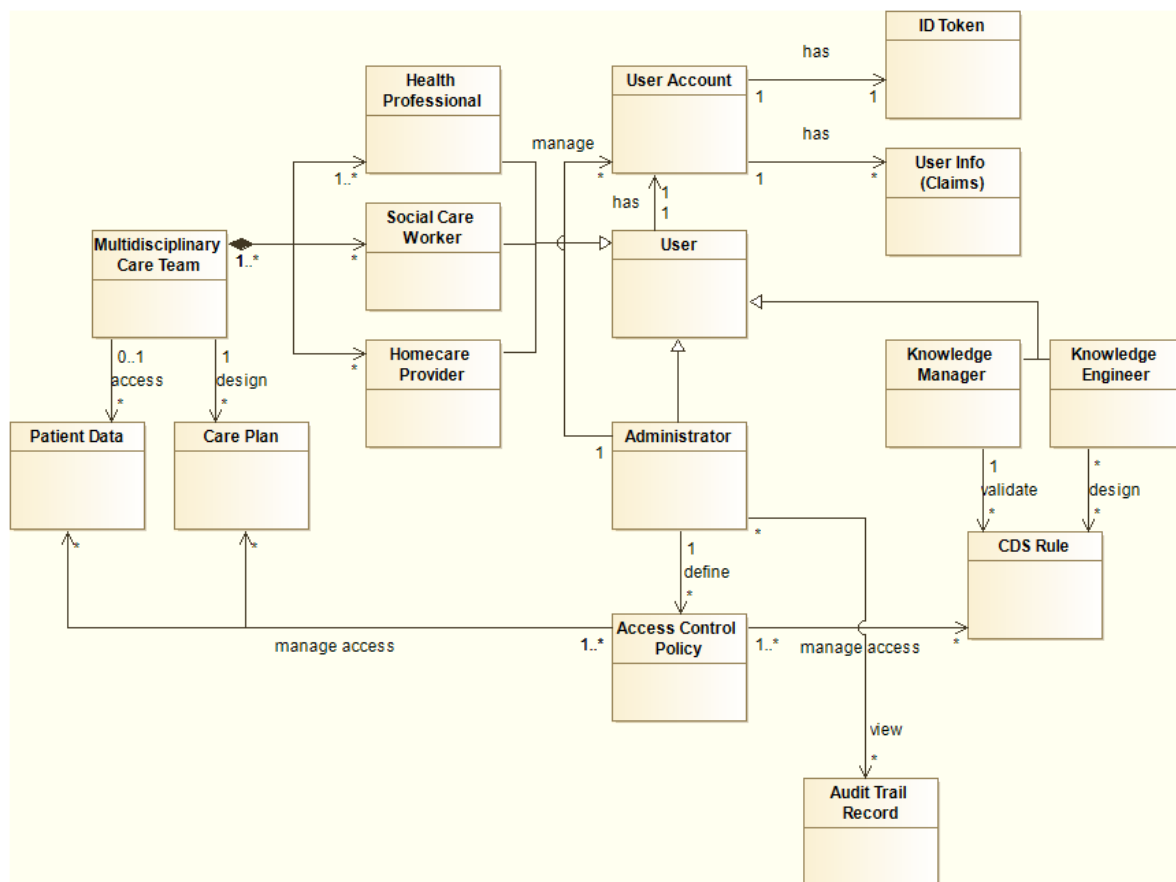


Domain Entity	Description
Association	A formal semantic assertion about the relationship between concepts, in the form of subject, relationship, and target. A concept can participate in multiple associations as either subject or target.
CodedElement	A data element that has a coded value. The set of coded values that is allowed to be used in the element is defined by a value set definition.
CodeSystem	A code system is defined as a collection of codes with associated designations and meanings. Examples of code systems include ICD-10, SNOMED CT, LOINC, and ATC.
CodeSystem Version	A specific version of a code system that contains the content of the codes. A code system may have multiple versions.
Concept	A representation unit defined in a code system associated with a code, descriptions and relationships with other concepts.
ConceptMap	A set of rules for transforming a set of concepts from a value set into a second set of concepts from another value set.
ConceptMap Version	A specific version or release of ConceptMap. ConceptMap Version is bound to specific value set definitions, and carries the actual content of the particular version, i.e. a set of mapping entries.
Mapping	A map entry is a set of rules that identify how a single <i>mapFrom</i> concept maps to zero or more <i>mapTo</i> target concepts.
ValueSet	A value set represents a uniquely identifiable set of valid concept representations, where any concept representation can be tested to determine whether it is a member of the value set. Value set complexity may range from a simple flat list of concept codes drawn from a single code system, to an unbounded hierarchical set of possibly post-coordinated expressions drawn from multiple code systems.
ValueSet Definition	A value set definition describes the rules that determine which entity references or value meanings belong to a value set at a given point in time. The definition of what belongs in a value set can evolve over time, and it is possible for there to be multiple definitions active at any given point in time.

### 3.6. Security and Privacy Suite

The logical view of security and privacy suite presents the logical models that are needed for establishment of the overall security and privacy architecture, and highlights their relationship with the responsible human actors.

**Figure 14: SDD-LGC-SPS: SPS Logical View**



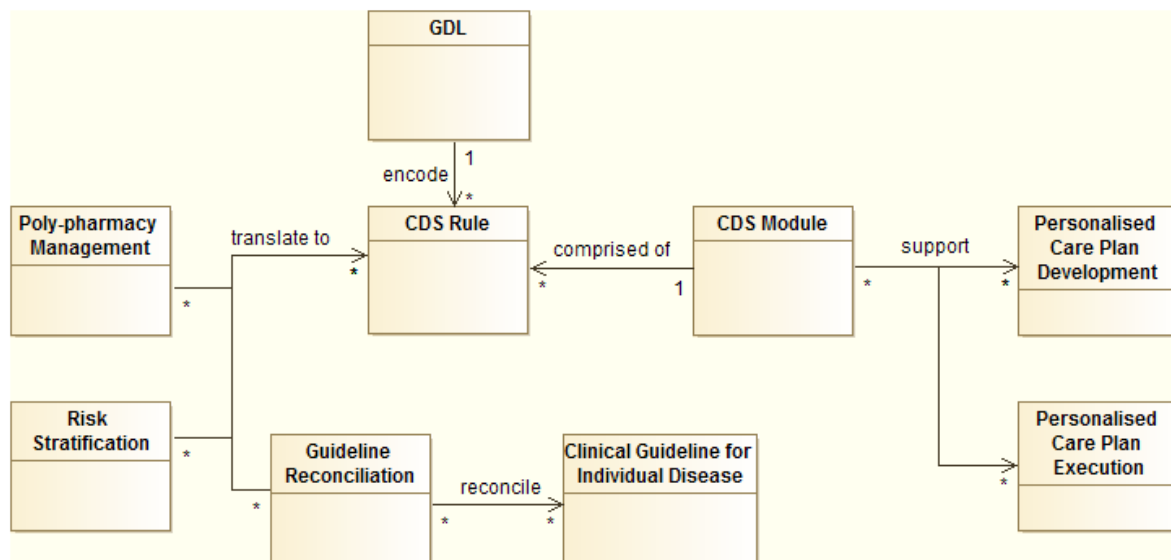
Domain Entity	Description
Access Control Policy	Access control policies are defined by the Administrator at the regional level and are composed of access control rules that specify who can and cannot access/update which kind of patient data. C3-Cloud implements access control policies as OASIS XACML 3.0 instances.
Administrator	System super user who can create user accounts, manage access control policies and view audit trail records.
Audit Trail Record	Logical model for long term persistence of proof for any data access or exchange transaction within the overall architecture. C3-Cloud implements audit trail records as FHIR AuditEvent resource instances.
Care Plan	Personalised, integrated care plan of a patient. C3-Cloud implements care plans as FHIR CarePlan resource instances. Access to a care plan must be permitted by access control policy definitions.
CDS Rule	CDS rules encode clinical knowledge and provide health professionals with clinical decision support. Access to a CDS rule must be permitted by access control policy definitions.
ID Token	Logical representation of user identity attributes such as name, surname, username, identifier, email address. An ID token is provided by the Identity Provider of a user upon successful authentication. C3-Cloud represents user ID token in JSON Web Token (JWT) format according to OpenID Connect and OAuth 2.0 specifications.



Domain Entity	Description
Health Professional	<i>As defined in Section 3.1.</i>
Homecare Provider	<i>As defined in Section 3.1.</i>
Knowledge Engineer	A user who can translate clinical knowledge (e.g., clinical guidelines, polypharmacy criteria, risk stratification models) into clinical decision support rules.
Knowledge Manager	A clinical expert who can validate CDS rules and approve the rules are safe to use.
Multidisciplinary Care Team (MDT)	Comprised of members from various care sectors, the MDT collaboratively designs an integrated and personalised care plan for the patient. The MDT has access to patient data generated in all care settings.
Patient Data	Any type of clinical or administrative patient data that is relevant in the context of care planning. If structured, represented as FHIR resources in the FHIR repository of the C3DP component. Non-structured data, such as imaging reports as PDF files, are also relevant. Access to patient data must be permitted by access control policy definitions.
Social Care Worker	<i>As defined in Section 3.1.</i>
User	In the SPS context, any non-patient or non-informal care giver human user of the overall C3-Cloud system; i.e. Care Team Member, Knowledge Engineer, Knowledge Manager.
User Account	Each user is associated with a user account for authentication and authorisation in the C3-Cloud components.
User Info (Claims)	Attributes of a user account that are complementing the user ID, such as role of a health professional (GP, cardiologist, nurse, etc.). C3-Cloud represents user info in JSON Web Token (JWT) format according to OpenID Connect and OAuth 2.0 specifications.

### 3.7. Clinical Decision Support Service

The CDS logic view extends the CDS rule part in the top-level logic view to illustrate the focus and scope of CDS functions in the project context.

**Figure 15: SDD-LGC-CDSS: CDSS Logical View**

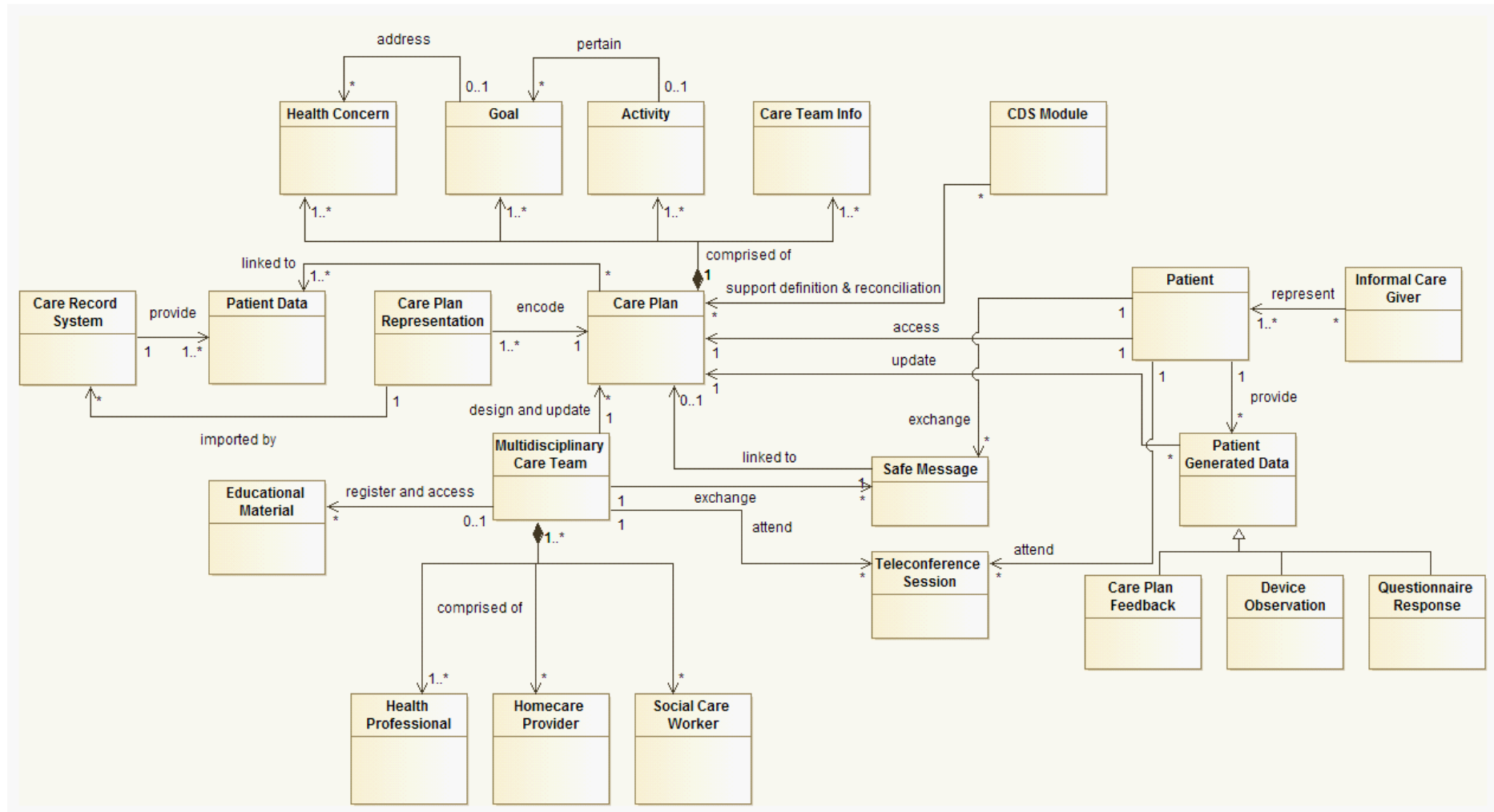
Domain Entity	Description
CDS Module	A self-contained clinical knowledge base that encapsulates a set of coherent CDS rules to provide a specific CDS function, such as patient risk stratification; treatment suggestion according to evidence based guidelines for individual chronic conditions; reconcile multiple treatment plans to create an integrated care plan; monitor and detect duplicate drugs; monitor and detect contraindications across multiple treatment plans due to drug-drug, drug-disease and drug-body part interactions; measure the burden of exposure to multiple drugs; suggestion risk factors based on the current conditions of the patient; identify disease stage; monitor and detect deviations from the outcome goals; monitor treatment continuously to realize benefit-risk assessment of drugs.
CDS Rule	Clinical logic in the form of if-then statement, by which characteristics of individual patients are used to generate patient specific interventions, assessments, recommendations, or other forms of guidance that are then presented to a decision making recipient or recipients that can include clinicians, patients, and others involved in care delivery.
Clinical Guideline for Individual Disease	The evidence based clinical guidelines for individual chronic conditions. C3-Cloud targets diabetes, heart failure, renal failure and depression. D7.1 will identify the clinical guidelines for use in C3-Cloud.
GDL	Guideline Definition Language is a formal language for expressing decision support logic. It is designed to be agnostic to natural languages and reference terminologies by leveraging the designs of openEHR Reference Model and Archetype Model. GDL expresses clinical logic as production rules. Discrete GDL rules, each containing if-then statements, can be combined together as building blocks to support single decision making and more complex decision making process. The GDL rules can be used to drive at-point-of-care decision support applications, as well as retrospective population analytics.
Guideline Reconciliation	Interlink individual clinical guidelines in various combinations depending on the number and type of the targeted co-existing chronic conditions, and reconcile them for the automation of personalised care plan development.

Domain Entity	Description
Personalised Care Plan Development	The process of developing integrated care plans, by both formal care givers from a multidisciplinary care team and informal care givers, for individual patients with chronic conditions where patients are more involved in decisions about their care.
Personalised Care Plan Execution	The process of executing the care plans developed for individual patients with collaboration between formal care givers from a multidisciplinary care team and informal care givers or patients.
Poly-pharmacy Management	Polypharmacy refers to the effects of taking multiple medications concurrently to manage coexisting health problems, such as diabetes and hypertension. Examples of risk assessment models and screening tools to address poly-pharmacy include Beer's list, FORTA, Drug Burden Index, START and STOPP criteria.
Risk Stratification	Models or algorithms to help the process of identifying the relative risk of patients in a population by analysing their medical history.

### 3.8. Coordinated Care and Cure Delivery Platform

The logical view of Coordinated Care and Cure Delivery Platform presents the logical models that are needed for the collaborative care planning process, and highlights their relationship with the responsible human actors.

Figure 16: SDD-LGC-C3DP: C3DP Logical View



Domain Entity	Description
Activity	Activity is a logical entity to represent the actions planned to be taken to maximise the prospects of the goals set within the care plan. C3-Cloud implements activities as activity definitions within the FHIR Care Plan resource instances.
Care Plan	Personalised, integrated care plan of a patient. C3-Cloud implements care plans as FHIR CarePlan resource instances. Access to a care plan must be permitted by access control policy definitions.
Care Plan Feedback	Patient or Informal Care Giver provided feedback to activities or goals defined in the care plan of the patient; e.g., progress update on the nutrition programme.
Care Plan Representation	Abstract class of care plan representation, which has physical implementations in each system. C3-Cloud imports different care plan representations utilized by local care systems to FHIR CarePlan resource instances. C3-Cloud can export FHIR CarePlan resource instances to the respective care plan representations utilized by local care systems.
Care Professional	Health care professionals and social care workers who comprise a multidisciplinary care team to provide care to a patient.
Care Record System	A care record system processes and produces patient data and receives care plan definition encoded in concrete representations from C3DP.
Care Team Info	A logical entity to represent the care team members' identity and contact information for a given care plan. C3-Cloud implements care teams as FHIR CareTeam resource instances.
CDS Module	A self-contained clinical knowledge base that encapsulates a set of coherent CDS rules to provide a specific CDS function. CDS Module supports (1) definition of goals and activities within a care plan by suggesting treatment options based on evidence based guidelines for individual chronic conditions; (2) reconciliation of multiple care plans, and also multiple goal, activity definitions within a care plan by monitoring and detecting duplicate drugs; monitoring and detecting drug-drug, drug-disease and drug-body part interactions and measuring the burden of exposure to multiple drugs; (3) identification of health concerns to be targeted by the care plan by detecting risk factors.
Device Observation	Medical device measurement, such as blood glucose or heart rate.
Educational Material	Logical pointers to locations of educational material (e.g., multimorbidity guidelines, chronic disease management guidelines, etc.) for the MDT members.
Goal	Goal is a logical entity that defines outcome or condition to be achieved as a result of care plan. C3-Cloud implements goals as FHIR Goal resource instances.
Health Concern	Health Concern is a logical entity that represents the health related matter (condition or risk) that is targeted by the care plan. C3-Cloud implements health concerns as FHIR Condition resource instances.
Health Professional	<i>As defined in Section 3.1.</i>
Homecare Provider	<i>As defined in Section 3.1.</i>
Informal Care Giver	A person acting on behalf of the patient, who will have access to the patient's data and care plan.

Domain Entity	Description
Multidisciplinary Care Team (MDT)	Comprised of members from various care sectors, the MDT collaboratively designs an integrated and personalised care plan for the patient. The MDT has access to patient data generated in all care settings.
Patient	Patients with two or more of these chronic conditions: diabetes, heart failure, renal failure and depression who can access the integrated care plan and their health data through C3-Cloud.
Patient Data	Any type of clinical or administrative patient data that is relevant in the context of care planning. If structured, represented as FHIR resources in the FHIR repository of the C3DP component. Non-structured data such as imaging reports as PDF files are also relevant.
Patient Generated Data	Superclass of all types of data that can be generated and provided by the patient (or her informal care giver on behalf of the patient) related with the execution and update of her care plan. Subclasses include Care Plan Feedback, Device Observation and Questionnaire Response. Collected through the Patient Empowerment Platform and provided to the C3DP for access of MDT members and update of care plan.
Questionnaire Response	Patient provided responses to a questionnaire that was introduced by the MDT within the scope of a care plan.
Safe Message	Safe electronic messages exchanged among MDT members or between MDT and the patient. These messages are usually created and exchanged within the scope of a specific care plan. MDT members use C3DP and patients / informal care givers use PEP for interfacing safe messages. Supportive notifications can be sent via email or SMS.
Social Care Worker	<i>As defined in Section 3.1.</i>
Teleconference Session	Teleconference sessions organised among MDT members as planned or spontaneous virtual care review meetings, or between MDT and the patient for discussing the recent progress of the patient and any issues she might have with the care plan.

## 4. INFORMATION VIEW

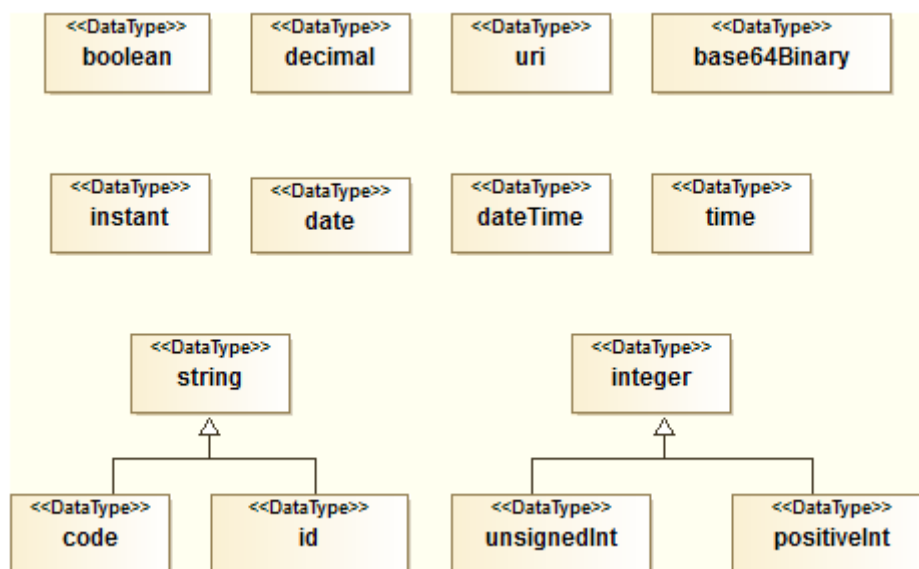
C3-Cloud processes, persists and exchanges a substantial information content concerning care plan, patient administrative and health information, and patient generated health outcomes (e.g., through questionnaires and tele-monitoring devices). D3.2 identified the conceptual information items being exchanged between C3-Cloud subsystems. The logic view analysed key domain entities being processed by C3-Cloud and its components. The central focus of the information view is to design data models with a greater level of details for the important information entities. The information models presented in this view form the basis for the development of database schema and messaging format in the implementation phase of the project. The content of this view relies heavily on FHIR models including both FHIR base data types and its resource definitions. Specifically the design is based on FHIR v1.6 (STU3), which is the latest version at the time of the writing. As FHIR is in development stage, new releases are frequently published. The models will align to new versions of FHIR when they are available. This view is governed by the information viewpoint declared in Section 1.7. A UML2 class diagram is used to represent the models.

### 4.1. Common Data Types

This section describes a set of common reusable data types that are used for the information models throughout the information view and the API specification in the interface view. The data types presented in this section are based on the FHIR STU3 data types. There are two categories of data types: simple / primitive types, which are single elements, and complex types, which are re-usable clusters of elements. Brief description is included for each type following the data type models specified using UMLS class diagrams. Please refer to FHIR STU3 Data Types specification for formal definition [FHIR-DATATYPES].

#### 4.1.1. Primitive Data Types

Figure 17: SDD-INF-DT-1: Primitive Data Types



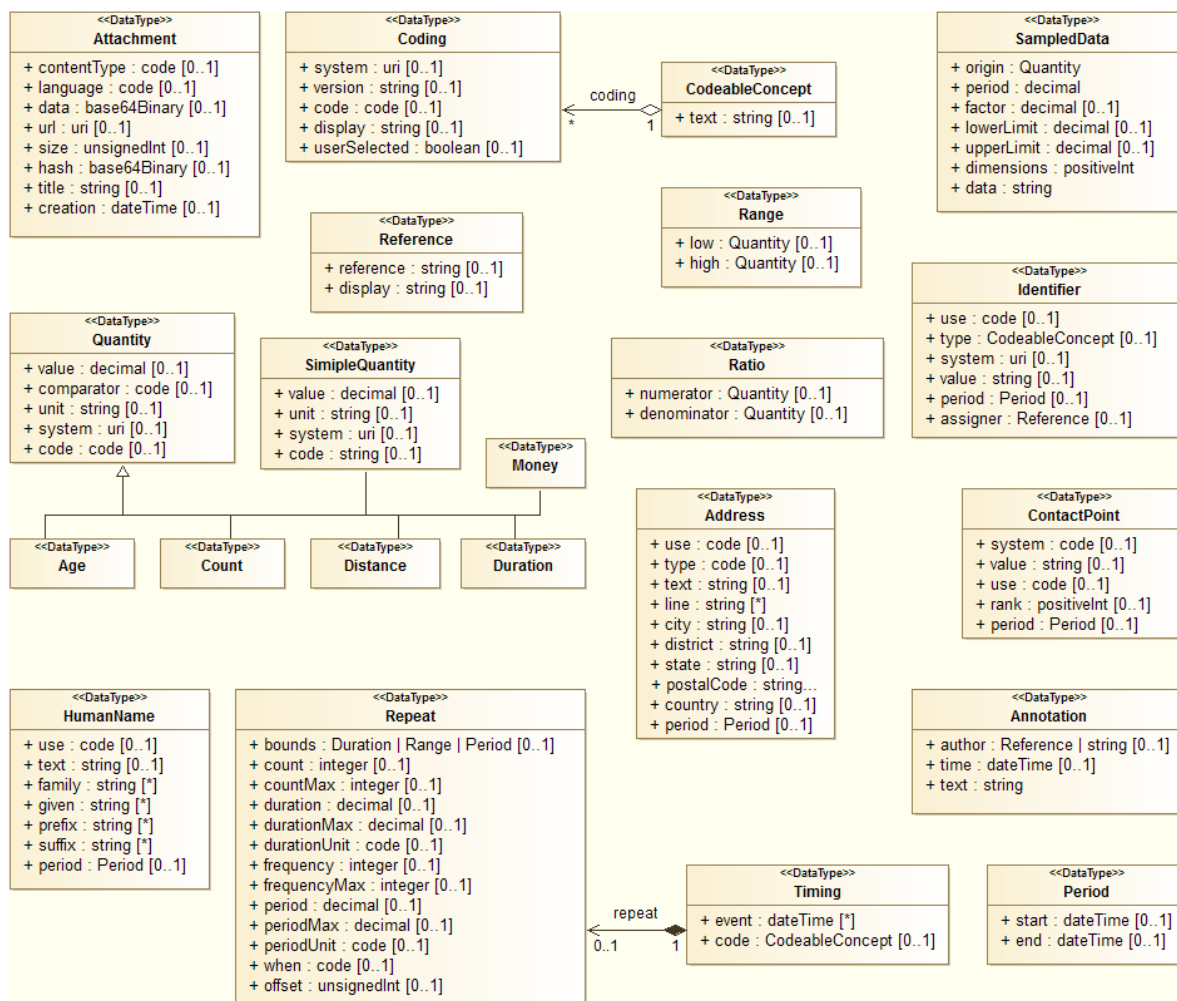
Data Type	Description
base64Binary	A stream of bytes, base64 encoded (RFC 4648, <a href="http://tools.ietf.org/html/rfc4648">http://tools.ietf.org/html/rfc4648</a> )
boolean	true   false

Data Type	Description
code	Indicates that the value is a coded value taken from a set of controlled strings defined elsewhere that identifies some defined "concept".
date	A date, or partial date (e.g., just year or year + month) as used in human communication. There is no time zone.
dateTime	A date, date-time or partial date (e.g., just year or year + month) as used in human communication. If hours and minutes are specified, a time zone SHALL be populated. Seconds must be provided due to schema type constraints but may be zero-filled and may be ignored. The time "24:00" is not allowed.
decimal	Rational numbers that have a decimal representation
id	Any combination of upper or lower case ASCII letters ('A'..'Z', and 'a'..'z', numerals ('0'..'9'), '-' and '.', with a length limit of 64 characters. This might be an integer, an un-prefixed OID, UUID or any other identifier pattern that meets these constraints.
instant	An instant in time - known at least to the second and always includes a time zone. This type is for system times, not human times (see date and dateTime).
integer	A signed 32-bit integer.
positiveInt	Any positive integer (e.g. >= 1).
string	A sequence of Unicode characters.
time	A time during the day, with no date specified. Seconds must be provided due to schema type constraints but may be zero-filled and may be ignored. The time "24:00" is not allowed, and neither is a time zone.
unsignedInt	Any non-negative integer (e.g. >= 0).
uri	A Uniform Resource Identifier Reference (RFC 3986, <a href="http://tools.ietf.org/html/rfc3986">http://tools.ietf.org/html/rfc3986</a> ). URIs can be absolute or relative, and may have an optional fragment identifier.



## 4.1.2. Complex Data Types

Figure 18: SDD-INF-DT-2: Complex Data Types



Data Type	Description
Address	An address expressed using postal conventions, as opposed to GPS or other location definition formats. The <i>text</i> element specifies the entire address, as it should be represented. This may be provided instead of or as well as the specific parts.
Annotation	Details for all kinds of technology-mediated contact points for a person or organization, including telephone, email, etc.
Attachment	This type is for containing or referencing attachments - additional data content defined in other formats. The most common use of this type is to include images or reports in some report format such as PDF. However, it can be used for any data that has a MIME type. The actual content of an <i>Attachment</i> can be conveyed directly using the <i>data</i> element or a <i>URL</i> reference can be provided. The <i>contentType</i> element SHALL always be populated when an Attachment contains <i>data</i> , and MAY be populated when there is a <i>url</i> . The <i>hash</i> is included so that applications can verify that the content returned by the URL has not changed.
CodeableConcept	A <i>CodeableConcept</i> represents a value that is usually supplied by providing a reference to one or more terminologies or ontologies, but may also be defined by the

Data Type	Description
	provision of <i>text</i> . Whether or not <i>coding</i> elements are present, the <i>text</i> is the representation of the concept as entered or chosen by the user, and which most closely represents the intended meaning of the user or concept.
Coding	<i>Coding</i> is a representation of a defined concept using a symbol from a defined code system. The meaning of the <i>Coding</i> is defined by the <i>code</i> . The <i>system</i> provides the source of the definition of the code, along with an optional <i>version</i> reference. The <i>display</i> is a human display for the text defined by the system. A coding may be marked as a " <i>userSelected</i> " if a user selected the particular coded value in a user interface (e.g., the user selects an item in a pick-list). If a user selected coding exists, it is the preferred choice for performing translations etc.
ContactPoint	Details for all kinds of technology-mediated contact points for a person or organization, including telephone, email, etc.
HumanName	A name of a human with text, parts and usage information.
Identifier	A numeric or alphanumeric string that is associated with a single object or entity within a given system. Typically, identifiers are used to connect content in resources to external content available in other frameworks or protocols. Identifiers are associated with objects, and may be changed or retired due to human or system process and errors. The <i>value</i> SHALL be unique within the defined <i>system</i> and have a consistent meaning wherever it appears. The <i>system</i> referred to by means of a URI defines how the identifier is defined (i.e. how the value is made unique).
Period	A time period defined by a <i>start</i> and <i>end</i> date/time.
Quantity	A measured amount, or an amount that can potentially be measured. The <i>value</i> contains the numerical value of the quantity, including an implicit precision. If no <i>comparator</i> is specified, the value is a point value (i.e. '='). The <i>comparator</i> element represents '<', '<=', '>=', and '>'. The <i>unit</i> element contains a displayable unit that defines what is measured. The <i>unit</i> may additionally be coded in some formal way using the <i>code</i> and the <i>system</i> . If the <i>unit</i> is able to be coded in UCUM and a code is provided, it SHOULD be a UCUM code.  <i>Age</i> , <i>Count</i> , <i>Distance</i> , <i>Duration</i> and <i>Money</i> are specialisations of <i>Quantity</i> that only introduce new restrictions on the existing elements defined as part of the <i>Quantity</i> data type. SimpleQuantity is a profile on Quantity where <i>comparator</i> is not used.
Range	A set of ordered <i>Quantity</i> values defined by a <i>low</i> and <i>high</i> limit.
Ratio	A relationship between two <i>Quantity</i> values expressed as a <i>numerator</i> and a <i>denominator</i> . Common factors in the numerator and denominator are not automatically cancelled out.
Reference	References to other resources. References are represented with a <i>reference</i> and a <i>text</i> description. The <i>reference</i> is the key element - resources are identified and addressed by their URL that is either an absolute URL, a relative URL, or an internal fragment reference.
SampledData	Data that comes from a series of measurements taken by a device, with upper and lower limits. There may be more than one dimension in the data. A <i>SampledData</i> provides a concise way to handle the data produced by devices that sample a physical particular state at a high frequency. A typical use for this is for the output of an ECG device.
Timing	Specifies an event that may occur multiple times. Timing schedules are not used for recording when things did happen, but when they are expected or requested to occur. A Timing schedule can be a list of events and/or criteria for when the event is to

Data Type	Description
	happen, which can be expressed in a structured form and/or as a code. When both event and a repeating specification are provided, the list of events should be understood as an interpretation of the information in the repeat structure. If the timing schedule has repeating criteria, the repeat can occur a given number of times per the specified duration or in relation to some real world event. If no end condition is specified, the schedule will terminate on some criteria that are expressed elsewhere.

## D3.3 Version 1.0, dated 29 December 2016

D3.3 Version 1.0, dated 29 December 2016



Class: CarePlan			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this CarePlan instance.
status	1..1	code	Indicates whether the plan is currently being acted upon, represents future intentions or is now a historical record. Selected from CarePlanStatus value set (see below).
category	0..*	CodeableConcept	Identifies what "kind" of plan this is to support differentiation between multiple co-existing plans; e.g. "Home health", "psychiatric", "asthma", "disease management", "wellness plan", etc. Can include codes from Snomed-CT UK Clinical Edition (April 2016) where concept is-a 325661000000106 (Care plan). Other value sets can be selected by pilot sites.
description	1..1	string	A description of the scope and nature of the plan. Provides more detail than conveyed by category.
subject	1..1	Patient	Identifies the patient whose intended care is described by the plan. A Reference to the Patient instance will be provided.
context	0..1	Encounter	Identifies the Encounter in which this particular CarePlan was created. A Reference to the Encounter instance will be provided.
period	0..1	Period	Indicates when the plan did (or is intended to) come into effect and end.
modified	1..1	dateTime	Identifies the most recent date on which the plan has been revised.
author	1..*	Patient   Practitioner   RelatedPerson	Identifies the individual(s) who is responsible for the content of the care plan. A Reference to the respective Patient, Practitioner, RelatedPerson instance will be provided.
careTeam	1..1	CareTeam	Identifies all people and organizations who are expected to be involved in the care envisioned by this plan. A Reference to the CareTeam instance will be provided.
addresses	1..*	Condition	Identifies the conditions/ problems/ concerns/ diagnoses/ risks whose management and/or mitigation are handled by this care plan. A Reference to the Condition instance will be provided.

Class: CarePlan			
Name	Cardinality	Type	Description
support	0..*	Observation   CareGiverCharacteristics-Observation   CharacteristicsOfHome-EnvironmentObservation   PersonalBelief-Observation   FunctionalStatus-Observation   MentalStatusObservation   AssessmentScale-Observation   RiskAssessment   AllergyIntolerance	Identifies barriers, risk factors, recent patient status assessments and other considerations, which are represented as portions of the patient's record and which are associated with the care plan.
relatedPlan	0..*	RelatedPlan	Identifies CarePlans linked with this CarePlan instance (e.g., replaces, includes)
goal	1..*	Goal	Describes the intended objective(s) of carrying out the care plan. A Reference to the Goal instance will be provided.
activity	0..*	Activity	Identifies a planned action to occur as part of the plan. For example, a medication to be used, lab tests to perform, self-monitoring, education, etc. Activity definitions are defined inline within a CarePlan instance.
note	0..*	Annotation	General notes about the care plan not covered elsewhere. Care Team members can use this part to exchange ideas while collaboratively managing the care plan definition and updates, as notes to each other.
title	1..1	string	Short descriptive title of the care plan
carePlanReviewDate	0..*	date	Identifies the dates of care plan review meeting dates. If the date is in the past, then this review has already taken place. If the date is in the future, then this is the date of the next scheduled review.
mdtEducational-Material	0..*	EducationalMaterial	Link to Educational Materials for MDT members.
patientEducational-Material	0..*	EducationalMaterial	Link to Educational Materials set by the MDT members to be accessed by patients.

Class: RelatedPlan			
Name	Cardinality	Type	Description
code	0..1	code	Identifies the type of relationship this plan has to the target plan.
plan	1..1	CarePlan	A reference to the CarePlan instance to which a relationship is asserted.

Class: EducationalMaterial			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier of the EducationalMaterial resource.
link	1..1	string	Link to the external educational material instance.
title	1..1	string	Title of the educational material.
topic	1..*	CodeableConcept	Coded category of the educational material.

Class: Activity			
Name	Cardinality	Type	Description
outcome	0..1	CodeableConcept	Coded representation of the results of the activity.
progress	0..*	Annotation	Notes about the adherence/status/progress of the activity, or concerns from patient or health professional. Feedback received from the patient about the activities will also be noted here.
detail	1..1	Activity Detail	Description of the care plan activity planned.

Class: ActivityDetail			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this ActivityDetail instance.
category	0..1	CodeableConcept	High-level categorization of the type of activity in a care plan. Selected from CarePlanActivityCategory value set (see below, can be extended).
definition	0..1	Questionnaire	Identifies the questionnaire that the patient (or practitioner) should fill in to fulfil the care plan activity. A Reference to the Questionnaire instance will be provided.
code	0..1	CodeableConcept	Detailed description of the type of planned activity; e.g., What lab test, what procedure, what kind of encounter. Codes can be selected from <a href="http://snomed.info/sct">http://snomed.info/sct</a> where concept is-a 71388002 (Procedure). Other value sets can be selected by pilot sites.

Class: ActivityDetail			
Name	Cardinality	Type	Description
reasonCode	0..*	CodeableConcept	Provides the rationale that drove the inclusion of this particular activity as part of the plan or the reason why the activity was prohibited. This could be a diagnosis code. If a full condition record exists or additional detail is needed, use reasonCondition instead. Codes can be selected from <a href="http://snomed.info/sct">http://snomed.info/sct</a> where concept is-a 404684003 (Clinical finding (finding)). Other value sets can be selected by pilot sites.
reasonReference	0..*	Condition	Provides the health condition(s) that drove the inclusion of this particular activity as part of the plan. A Reference to the Condition instance will be provided.
goal	0..*	Goal	Internal reference that identifies the goals that this activity is intended to contribute towards meeting. A Reference to the Goal instance will be provided.
status	1..1	code	Identifies what progress is being made for the specific activity. Selected from CarePlanActivityStatus value set (see below).
statusReason	0..1	CodeableConcept	Provides reason why the activity isn't yet started, is on hold, was cancelled, etc. Selected from GoalStatusReason value set (see below, can be extended).
prohibited	0..1	boolean	If true, indicates that the described activity is one that must NOT be engaged in when following the plan. If false, indicates that the described activity is one that should be engaged in when following the plan.
scheduledTiming	0..1	Timing	The timing upon which the described activity is to occur.
scheduledPeriod	0..1	Period	The period upon which the described activity is to occur.
ScheduledString	0..1	string	The frequency upon which the described activity is to occur.
location	0..1	Location	Identifies the facility where the activity will occur; e.g. home, hospital, specific clinic, etc. A Reference to the Location instance will be provided.
performer	0..*	Practitioner   Organization   RelatedPerson   Patient	Identifies who's expected to be involved in the activity. A Reference to the Practitioner, Organization, RelatedPerson or Patient instance will be provided.



Class: ActivityDetail			
Name	Cardinality	Type	Description
productCodeableConcept	0..1	CodeableConcept	Identifies the food, drug or other product to be consumed or supplied in the activity. Codes can be selected from <a href="http://snomed.info/sct">http://snomed.info/sct</a> where concept is-a 410942007 (Drug or medicament (substance)), a 373873005 (Pharmaceutical / biologic product (product)); or a 106181007 (Immunologic substance). Other value sets can be selected by pilot sites.
productReference	0..1	Medication   Substance	Identifies the food, drug or other product to be consumed or supplied in the activity by referencing the respective Medication or Substance instances.
dailyAmount	0..1	SimpleQuantity	Identifies the quantity expected to be consumed in a given day.
quantity	0..1	SimpleQuantity	Identifies the quantity expected to be supplied, administered or consumed by the subject.
description	0..1	String	This provides a textual description of constraints on the intended activity occurrence, including relation to other activities. It may also include objectives, pre-conditions and end-conditions. Finally, it may convey specifics about the activity such as body site, method, route, etc.
note	0..*	Annotation	General notes about the activity not covered elsewhere. Care Team members can use this part to exchange ideas while collaboratively managing the care plan definition and updates, as notes to each other.
title	1..1	string	Short descriptive title of the activity.

Class: CareTeam			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this CareTeam instance.
name	0..1	string	A label for human use intended to distinguish the teams.
subject	1..1	Patient	Identifies the patient whose intended care is handled by the team. A Reference to the Patient instance will be provided.
participant	1..*	Participant	Identifies all people and organizations who are expected to be involved in the care team.

Class: Participant			
Name	Cardinality	Type	Description
role	0..1	CodeableConcept	Code that identifies the role of the Care Team Member. Codes can be selected from <a href="http://snomed.info/sct">http://snomed.info/sct</a> where concept is-a 125676002 (Person), a 223366009 (Healthcare professional) or a 394730007 (Healthcare related organisation). Other value sets can be selected by pilot sites.
Member	1..1	Practitioner   RelatedPerson   Patient   Organization	The specific person or organization who is participating/expected to participate in the care team. A Reference to the Practitioner, Organization, RelatedPerson or Patient instance will be provided.
period	0..1	Period	Indicates when the specific member or organization did (or is intended to) come into effect and end.
isManager	1..1	Boolean	Indicates whether the participant is the care team manager.

Class: Goal			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this Goal instance.
status	1..1	code	Indicates whether the goal has been reached and is still considered relevant. Selected from GoalStatus value set (see below).
category	0..*	CodeableConcept	Indicates a category the goal falls within. Selected from GoalCategory value set (see below, can be extended).
priority	0..1	CodeableConcept	Identifies the mutually agreed level of importance associated with reaching/sustaining the goal. Selected from GoalPriority value set (see below).
description	1..1	CodeableConcept	Code and/or human-readable description of a specific desired objective of care. If no code is available, use CodeableConcept.text.
subject	1..1	Patient	Identifies the patient for whom the goal is being established. A Reference to the Patient instance will be provided.
startDate	0..1	date	The date after which the goal should begin being pursued.
startCodeableConcept	0..1	CodeableConcept	The event after which the goal should begin being pursued. Example event codes can be: 32485007 Admission to hospital 308283009 Discharge from hospital

Class: Goal			
Name	Cardinality	Type	Description
			442137000 Completion time of procedure 386216000 Childbirth
targetDate	0..1	date	Indicates the date after start by which the goal should be met.
targetDuration	0..1	Duration	Indicates the duration after start by which the goal should be met.
statusDate	0..1	date	Identifies the date when the current status is set; i.e. when initially created, when achieved, when cancelled, etc.
statusReason	0..*	CodeableConcept	Captures the reason for the current status. Selected from GoalStatusReason value set (see below, can be extended).
expressedBy	0..1	Patient   Practitioner   RelatedPerson	Indicates whose goal this is - patient goal, practitioner goal, etc. A Reference to the respective Patient, Practitioner, RelatedPerson instance will be provided.
addresses	0..*	Condition   RiskAssesment	The identified conditions and other risks that are intended to be addressed by the goal. A Reference to the respective Condition or RiskAssesment instance will be provided.
note	0..*	Annotation	General notes about the goal not covered elsewhere. Care Team members can use this part to exchange ideas while collaboratively managing the care plan definition and updates, as notes to each other.
title	1..1	string	Short descriptive title of the goal.
outcome	0..*	GoalOutcome	Identifies the change (or lack of change) at the point where the goal was deemed to be cancelled or achieved.

Class: GoalOutcome			
Name	Cardinality	Type	Description
resultReference	0..1	Observation	Details of what's changed (or not changed) expressed as an Observation instance (e.g. "25% increase in shoulder mobility", "Anxiety reduced to moderate levels". "15 kg weight loss sustained over 6 months"). A Reference to the Observation instance will be provided.
resultCodeableConcept	0..1	CodeableConcept	Details of what's changed (or not changed) expressed as a coded concept.

Class: CareGiverCharacteristicsObservation			
Name	Cardinality	Type	Description

identifier	1..1	Identifier	Unique identifier associated with this Observation instance.
code	1..1	CodeableConcept	One code which must have a fixed coding.system= '2.16.840.1.113883.5.4' a fixed code=ASSERTION).
status	1..1	code	The status of the feedback observation. It can be set as 'final' from the ObservationStatus value set ( <a href="http://hl7.org/fhir/observation-status">http://hl7.org/fhir/observation-status</a> ).
subject	1..1	Patient	Identifies the patient the assessment is being provided about. A Reference to the Patient instance will be provided.
effectiveDateTime	1..1	dateTime	The time the observation is asserted as being true.
performer	1..1	Practitioner	The Practitioner recording this assessment. A Reference to the Practitioner instance will be provided.
valueCodeableConcept	0..1	CodeableConcept	A coded representation of the barrier related with the care giver characteristics. Codes can be selected from <a href="http://snomed.info/sct">http://snomed.info/sct</a> where concept is-a 25622003 (Support system deficit (finding)). Other value sets can be selected by pilot sites.
valueString	0..1	string	A textual description of the barrier related with the characteristics of the home environment.

Class: CharacteristicsOfHomeEnvironmentObservation			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this Observation instance.
code	1..1	CodeableConcept	One code which must have a fixed coding.system= '2.16.840.1.113883.6.1' and a fixed code=75274-1).
status	1..1	code	The status of the feedback observation. It can be set as 'final' from the ObservationStatus value set ( <a href="http://hl7.org/fhir/observation-status">http://hl7.org/fhir/observation-status</a> ).
subject	1..1	Patient	Identifies the patient the assessment is being provided about. A Reference to the Patient instance will be provided.
effectiveDateTime	1..1	dateTime	The time the observation is asserted as being true.
performer	1..1	Practitioner	The Practitioner recording this assessment. A Reference to the Practitioner instance will be provided.
valueCodeableConcept	0..1	CodeableConcept	A coded representation of the barrier related with the characteristics of the home

Class: CharacteristicsOfHomeEnvironmentObservation			
Name	Cardinality	Type	Description
			environment. Codes can be selected from <a href="http://snomed.info/set">http://snomed.info/set</a> where concept is-a 365512000 (Finding of characteristics of home environment). Other value sets can be selected by pilot sites.
valueString	0..1	string	A textual description of the barrier related with the care giver characteristics.

Class: PersonalBeliefObservation			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this Observation instance.
code	1..1	CodeableConcept	One code which must have a fixed coding.system= '2.16.840.1.113883.6.1' and a fixed code= 75281-6" Personal belief).
status	1..1	code	The status of the feedback observation. It can be set as 'final' from the ObservationStatus value set ( <a href="http://hl7.org/fhir/observation-status">http://hl7.org/fhir/observation-status</a> ).
subject	1..1	Patient	Identifies the patient the assessment is being provided about. A Reference to the Patient instance will be provided.
effectiveDateTime	1..1	dateTime	The time the observation is asserted as being true.
performer	1..1	Practitioner	The Practitioner recording this assessment. A Reference to the Practitioner instance will be provided.
valueString	0..1	string	A textual description of the barrier related with the personal beliefs (such as 'Refuses all blood transfusion and administration of primary blood components and minor fractions').

Class: FunctionalStatusObservation			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this Observation instance.
code	1..1	CodeableConcept	One code which must have a fixed coding.system= '2.16.840.1.113883.6.1' and a fixed code= 54522-8" Functional status).

Class: FunctionalStatusObservation			
Name	Cardinality	Type	Description
status	1..1	code	The status of the feedback observation. It can be set as 'final' from the ObservationStatus value set ( <a href="http://hl7.org/fhir/observation-status">http://hl7.org/fhir/observation-status</a> ).
subject	1..1	Patient	Identifies the patient the assessment is being provided about. A Reference to the Patient instance will be provided.
effectiveDateTime	1..1	dateTime	The time the observation is asserted as being true.
performer	1..1	Practitioner	The Practitioner recording this assessment. A Reference to the Practitioner instance will be provided.
valueCodeableConcept	0..1	CodeableConcept	A coded representation of the functional status assessment observation. Codes can be selected from <a href="http://snomed.info/sct">http://snomed.info/sct</a> where concept is-a 118233009 (Finding of activity of daily living (finding)). Other value sets can be selected by pilot sites.
valueString	0..1	string	A textual description of the functional status assessment observation.

Class: MentalStatusObservation			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this Observation instance.
code	1..1	CodeableConcept	One code which must have a fixed coding.system= '2.16.840.1.113883.6.1' and a fixed code= 75275-8" Cognitive Function).
status	1..1	code	The status of the feedback observation. It can be set as 'final' from the ObservationStatus value set ( <a href="http://hl7.org/fhir/observation-status">http://hl7.org/fhir/observation-status</a> ).
subject	1..1	Patient	Identifies the patient the assessment is being provided about. A Reference to the Patient instance will be provided.
effectiveDateTime	1..1	dateTime	The time the observation is asserted as being true.
performer	1..1	Practitioner	The Practitioner recording this assessment. A Reference to the Practitioner instance will be provided.
valueCodeableConcept	0..1	CodeableConcept	A coded representation of the mental status assessment observation. Codes can be selected from <a href="http://snomed.info/sct">http://snomed.info/sct</a> where concept is-a 373930000 (Cognitive function finding). Other value sets can be selected by pilot sites.

Class: MentalStatusObservation			
Name	Cardinality	Type	Description
valueString	0..1	string	A textual description of the cognitive function status assessment observation.

Class: AssesmentScaleObservation			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this Observation instance.
code	1..1	CodeableConcept	A code from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) identifying the assessment scale.
status	1..1	code	The status of the feedback observation. It can be set as 'final' from the ObservationStatus value set ( <a href="http://hl7.org/fhir/observation-status">http://hl7.org/fhir/observation-status</a> ).
subject	1..1	Patient	Identifies the patient the assessment is being provided about. A Reference to the Patient instance will be provided.
effectiveDateTime	1..1	dateTime	The time the observation is asserted as being true.
performer	1..1	Practitioner	The Practitioner recording this assessment. A Reference to the Practitioner instance will be provided.
valueQuantity	1..1	Quantity	Decimal representation of the final score.
referenceRange	0..1		
referenceRange.text	0..1	string	A description of the observation scale (e.g., for a Pain Scale 1 to 10: 1 to 3 = little pain, 4 to 7= moderate pain, 8 to 10 = severe pain).
referenceRange.high	0..1		The highest possible value of the scale assessment.
component	0..*	BackboneElement	Observations representing the components of a scale used in an Assessment Scale Observation. See Observation.component for details.

ValueSet: CarePlanStatus ( <a href="http://hl7.org/fhir/ValueSet/care-plan-status">http://hl7.org/fhir/ValueSet/care-plan-status</a> )		
code	Display	Definition
proposed	Proposed	The plan has been suggested but no commitment to it has yet been made.
draft	Pending	The plan is in development or awaiting use but is not yet intended to be acted upon.

**ValueSet: CarePlanStatus**

(http://hl7.org/fhir/ValueSet/care-plan-status)

code	Display	Definition
active	Active	The plan is intended to be followed and used as part of patient care.
suspended	Suspended	The plan has been temporarily stopped but is expected to resume in the future.
completed	Completed	The plan is no longer in use and is not expected to be followed or used in patient care.
entered-in-error	Entered In Error	The plan was entered in error and voided.
cancelled	Cancelled	The plan has been terminated prior to reaching completion (though it may have been replaced by a new plan).
unknown	Unknown	The authoring system doesn't know the current state of the care plan.

**ValueSet: CarePlanActivityCategory**

(http://hl7.org/fhir/ValueSet/care-plan-activity-category)

code	Display	Definition
diet	Diet	Plan for the patient to consume food of a specified nature.
drug	Drug	Plan for the patient to consume/receive a drug, vaccine or other product.
encounter	Encounter	Plan to meet or communicate with the patient (in-patient, out-patient, phone call, etc.).
observation	Observation	Plan to capture information about a patient (vitals, labs, diagnostic images, etc.).
procedure	Procedure	Plan to modify the patient in some way (surgery, physiotherapy, education, counseling, etc.).
supply	Supply	Plan to provide something to the patient (medication, medical supply, etc.).
other	Other	Some other form of action.

**ValueSet: CarePlanActivityStatus**

(http://hl7.org/fhir/ValueSet/care-plan-activity-status)

code	Display	Definition
not-started	Not Started	Activity is planned but no action has yet been taken.
scheduled	Scheduled	Appointment or other booking has occurred but activity has not yet begun.
in-progress	In Progress	Activity has been started but is not yet complete.
on-hold	On Hold	Activity was started but has temporarily ceased with an expectation of resumption at a future time.
completed	Completed	The activities have been completed (more or less) as planned.
cancelled	Cancelled	The activities have been ended prior to completion (perhaps even before they were started).
unknown	Unknown	The authoring system doesn't know the current state of the activity.



<b>ValuSet: GoalStatusReason</b> (http://hl7.org/fhir/ValueSet/goal-status-reason)		
code	Display	Definition
surgery	surgery	Goal suspended or ended because of a surgical procedure.
life-event	life event	Goal suspended or ended because of a significant life event (marital change, bereavement, etc.).
replaced	replaced	Goal has been superseded by a new goal.
patient-request	patient request	Patient wishes the goal to be set aside, at least temporarily.
temp-not-attainable	Goal not attainable temporarily	Goal cannot be reached temporarily.
permanent-not-attainable	Goal not attainable permanently	Goal cannot be reached permanently.
financial-barrier	Financial reason	Goal cannot be reached due to financial barrier or reason.
lack-of-transportation	Lack of transportation	Goal cannot be reached due to a lack of transportation.
lack-of-social-support	Lack of social support	Goal cannot be reached due to a lack of social support.

<b>ValuSet: GoalStatus</b> (http://hl7.org/fhir/ValueSet/goal-status)		
code	Display	Definition
proposed	Proposed	A goal is proposed for this patient.
planned	Planned	A goal is planned for this patient.
accepted	Accepted	A proposed goal was accepted.
rejected	Rejected	A proposed goal was rejected.
in-progress	In Progress	The goal is being sought but has not yet been reached. (Also applies if goal was reached in the past but there has been regression and goal is being sought again).
achieved	Achieved	The goal has been met and no further action is needed.
sustaining	Sustaining	The goal has been met, but ongoing activity is needed to sustain the goal objective.
on-hold	On Hold	The goal remains a long term objective but is no longer being actively pursued for a temporary period of time.
cancelled	Cancelled	The goal is no longer being sought.
on-target	On Target	The goal is on scheduled for the planned timelines.
ahead-of-target	Ahead of Target	The goal is ahead of the planned timelines.
behind-target	Behind Target	The goal is behind the planned timelines.
entered-in-error	Entered In Error	The goal was entered in error and voided.

<b>ValuSet: GoalCategory</b> (http://hl7.org/fhir/ValueSet/goal-category)		
code	Display	Definition
dietary	dietary	Goals related to the consumption of food and/or beverages.
safety	safety	Goals related to the personal protection of the subject.
behavioral	behavioral	Goals related to the manner in which the subject acts.

<b>ValuSet: GoalPriority</b> (http://hl7.org/fhir/ValueSet/goal-priority)		
code	Display	Definition
high	high	Indicates that the goal is of considerable importance and should be a primary focus of care delivery.
medium	medium	Indicates that the goal has a reasonable degree of importance and that concrete action should be taken towards the goal. Attainment is not as critical as high-priority goals.
low	low	The goal is desirable but is not sufficiently important to devote significant resources to. Achievement of the goal may be sought when incidental to achieving other goals.

### 4.3. Patient Data

D3.2 listed clinical data elements from US ONC Common Clinical Data Set (CCDS) as a possible candidate patient data set for C3-Cloud to consider support through its interoperable platform integrating local care record systems. This section presents information models for those clinical data elements relevant for the scope of the project. The care plan related models are covered by Section 4.2. This section focuses on essential clinical data elements while leaving supporting models for administrative entities (e.g., Practitioner, Organisation, Location, Group, RelatedPerson) and workflow (e.g., Appointment, Schedule) to official FHIR specification. The information models of clinical data elements are based on the base FHIR specification. Models from the US Data Access Framework (DAF) FHIR implementation guide are also consulted where applicable [DAF-CORE]. Specifically, Observation-Vitalsigns and Patient are based on the DAF models. Note that the DAF Patient model includes Ethnicity, which is considered not appropriate for use in European countries and so is removed from the original definition to ensure the models compliant with EU data protection regulations.

The models in this section are presented in UML class diagrams. Note that the UML class diagrams are not verbatim copies of the FHIR specification. While UML classes are presented as one of the representations of a FHIR resource, the formal definition of a FHIR resource is not based on UML but rather XML schema. Moreover, FHIR profiling uses a custom syntax to further restrict or extend the base resource definition. The UML representation is auto-generated by tools from the underlying definition and uses many non-standard symbols and syntax. While the UML class models presented in this section try to match as precisely as possible FHIR formal specification, the focus of the models is to provide a logical view and therefore has abstracted away some technical nuances of FHIR syntax.

Note that the patient data models presented here are not finalised. They serve as basis to facilitate communication and discussion between project partners. The models will be refined or extended following the project progress. The finalisation of the models together with development of concrete FHIR profiles for C3-Cloud will take place in Work Package 6.

This section includes the following clinical data models:

Clinical Data Model	Description
AllergyIntolerance	Risk of harmful or undesirable, physiological response which is unique to an individual and associated with exposure to a substance.
ClinicalImpression	A record of a clinical assessment performed to determine what problem(s) may affect the patient and before planning the treatments or management strategies that are best to manage a patient's condition. Assessments are often 1:1 with a clinical consultation / encounter, but this varies greatly depending on the clinical workflow. This resource is called "ClinicalImpression" rather than "ClinicalAssessment" to avoid confusion with the recording of assessment tools such as Apgar score.

Clinical Data Model	Description
Condition	Use to record detailed information about conditions, problems or diagnoses recognized by a clinician. There are many uses including: recording a diagnosis during an encounter; populating a problem list or a summary statement, such as a discharge summary.
Device	This resource identifies an instance or a type of a manufactured item that is used in the provision of healthcare without being substantially changed through that activity. The device may be a medical or non-medical device. Medical devices includes durable (reusable) medical equipment, implantable devices, as well as disposable equipment used for diagnostic, treatment, and research for healthcare and public health. Non-medical devices may include items such as a machine, cellphone, computer, application, etc.
DiagnosticReport	The findings and interpretation of diagnostic tests performed on patients, groups of patients, devices, and locations, and/or specimens derived from these. The report includes clinical context such as requesting and provider information, and some mix of atomic results, images, textual and coded interpretations, and formatted representation of diagnostic reports.
Encounter	An interaction between a patient and healthcare provider(s) for the purpose of providing healthcare service(s) or assessing the health status of a patient.
EpisodeOfCare	An association between a patient and an organisation / healthcare provider(s) during which time encounters may occur. The managing organisation assumes a level of responsibility for the patient during this time.
FamilyMemberHistory	Significant health events and conditions for a person related to the patient relevant in the context of care for the patient.
Immunization	Describes the event of a patient being administered a vaccination or a record of a vaccination as reported by a patient, a clinician or another party and may include vaccine reaction information and what vaccination protocol was followed.
Medication	This resource is primarily used for the identification and definition of a medication. It covers the ingredients and the packaging for a medication.
MedicationOrder	An order for both supply of the medication and the instructions for administration of the medication to a patient. The resource is called "MedicationOrder" rather than "MedicationPrescription" to generalise the use across inpatient and outpatient settings as well as for care plans, etc. Both the <i>MedicationOrder</i> and <i>MedicationStatement</i> resources can be used to record a patient's medication.
MedicationStatement	A record of a medication that is being consumed by a patient. A MedicationStatement may indicate that the patient may be taking the medication now, or has taken the medication in the past or will be taking the medication in the future. The source of this information can be the patient, significant other (such as a family member or spouse), or a clinician. A common scenario where this information is captured is during the history taking process during a patient visit or stay. The medication information may come from e.g. the patient's memory, from a prescription bottle, or from a list of medications the patient, clinician or other party maintains. Both <i>MedicationOrder</i> and <i>MedicationStatement</i>

Clinical Data Model	Description
	can be used to record a patient's medication. The primary difference is that a medication statement is not a part of the Prescribe → Dispense → Administer sequence but is a report that such a sequence (or at least a part of it) did take place resulting in a belief that the patient has received a particular medication.
Observation	Measurements and simple assertions made about a patient, device or other subject.
Observation-Vitalsigns	A profile on Observation to record vital signs associated with a patient.
Patient	Demographics and other administrative information about an individual receiving care or other health-related services.
Procedure	This resource is used to record the details of procedures performed on a patient. A procedure is an activity that is performed with or on a patient as part of the provision of care. Examples include surgical procedures, diagnostic procedures, endoscopic procedures, biopsies, counselling, physiotherapy, exercise, etc. Procedures may be performed by a healthcare professional, a friend or relative or in some cases by the patient themselves.
Specimen	A sample to be used for analysis. Any material sample: taken from a biological entity, living or dead; taken from a physical object or the environment.
Substance	A homogeneous material with a definite composition. The resource can be used to represent either a kind of a substance - e.g. a formulation commonly used for treating patients, or it can be used to describe a particular package of a known substance (e.g., bottle, jar, packet).

Clinical documents are often generated during clinical workflow; e.g., transition of care. FHIR resources can be used to build documents that represent a composition: a set of coherent information that is a statement of healthcare information, particularly including clinical observations and services. A document is an immutable set of resources with a fixed presentation that is authored and/or attested by humans, organizations and devices. All documents have the same structure: a Bundle resource of type "document" that has a Composition resource as the first resource in the bundle, followed by a series of other resources, referenced from the Composition resource that provide supporting evidence for the document. Unstructured documents can be encoded by a Binary resource.

In addition to the models for the fine-grained discrete clinical data elements, this section also includes the relevant FHIR models which can be used to build clinical documents:

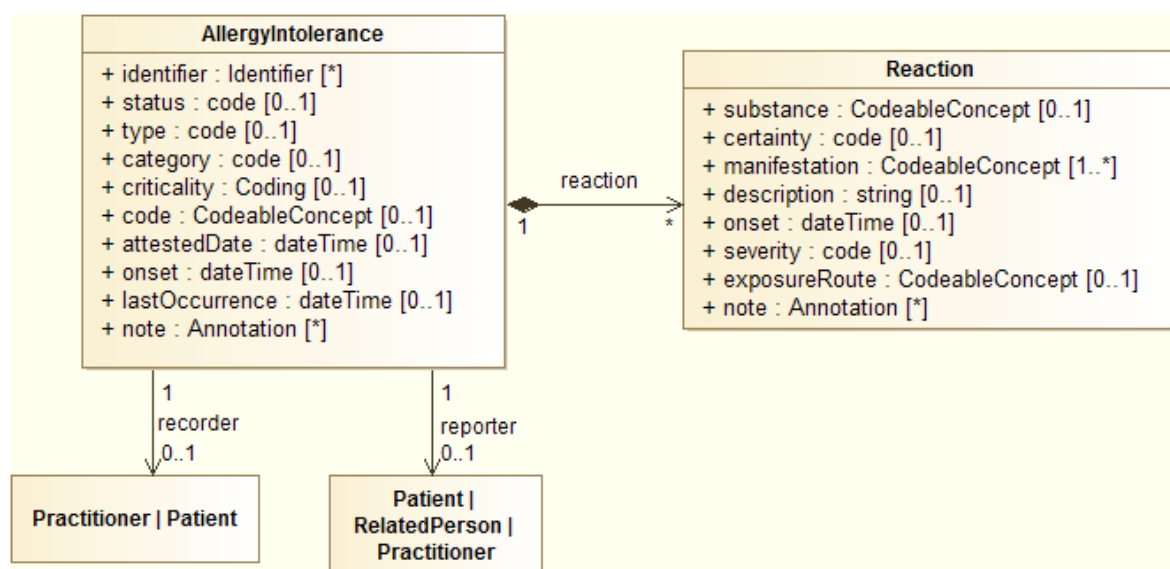
FHIR Models	Description
Binary	A binary resource can contain any content, whether text, image, pdf, zip archive, etc.
Bundle	A container for a collection of resources. One common operation performed with resources is to gather a collection of resources into a single instance with containing context. In FHIR this is referred to as "bundling" the resources together. These resource bundles are useful for a variety of different reasons, including: returning a set of resources that meet some criteria as part of a server operation, e.g., RESTful Search; returning a set of versions of resources as part of the history operation on a server; sending a set of resources as part of a message exchange; grouping a self-contained set of resources to act as an exchangeable and

FHIR Models	Description
	persistable collection with clinical integrity, e.g., a clinical document; creating/updating/deleting a set of resources on a server as a single operation (including doing so as a single atomic transaction); storing a collection of resources.
Composition	A set of healthcare-related information that is assembled together into a single logical document that provides a single coherent statement of meaning, establishes its own context and that has clinical attestation with regard to who is making the statement. While a Composition defines the structure, it does not actually contain the content: rather the full content of a document is contained in a Bundle, of which the Composition is the first resource contained.

Each of the models is detailed below.

- AllergyIntolerance**

Figure 20: SDD-INF-AI: FHIR Allergy or Intolerance Model



#### Class: AllergyIntolerance

Risk of harmful or undesirable, physiological response which is unique to an individual and associated with exposure to a substance.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	External IDs for this item.
status	0..1	code	<a href="#">AllergyIntoleranceStatus</a> : active   active-confirmed   inactive   resolved   refuted   entered-in-error.
type	0..1	code	<a href="#">AllergyIntoleranceType</a> : allergy   intolerance - Underlying mechanism (if known).
category	0..1	code	<a href="#">AllergyIntoleranceCategory</a> : food   medication   biologic   environment.

criticality	0..1	Coding	<a href="#">AllergyIntoleranceCriticality</a> : low   high   unable-to-assess.
code	0..1	CodeableConcept	Allergy or intolerance code. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-allergyintolerance-code.html">http://www.hl7.org/fhir/2016Sep/valueset-allergyintolerance-code.html</a>
patient	1..1	Patient	Who the sensitivity is for.
attestedDate	0..1	dateTime	Date record was believed accurate.
recorder	0..1	Practitioner   Patient	Who recorded the sensitivity.
reporter	0..1	Patient   RelatedPerson   Practitioner	Source of the information about the allergy.
onset	0..1	dateTime	Date(/time) when manifestations showed.
lastOccurrence	0..1	dateTime	Date(/time) of last known occurrence of a reaction.
note	0..*	Annotation	Additional text not captured in other fields.

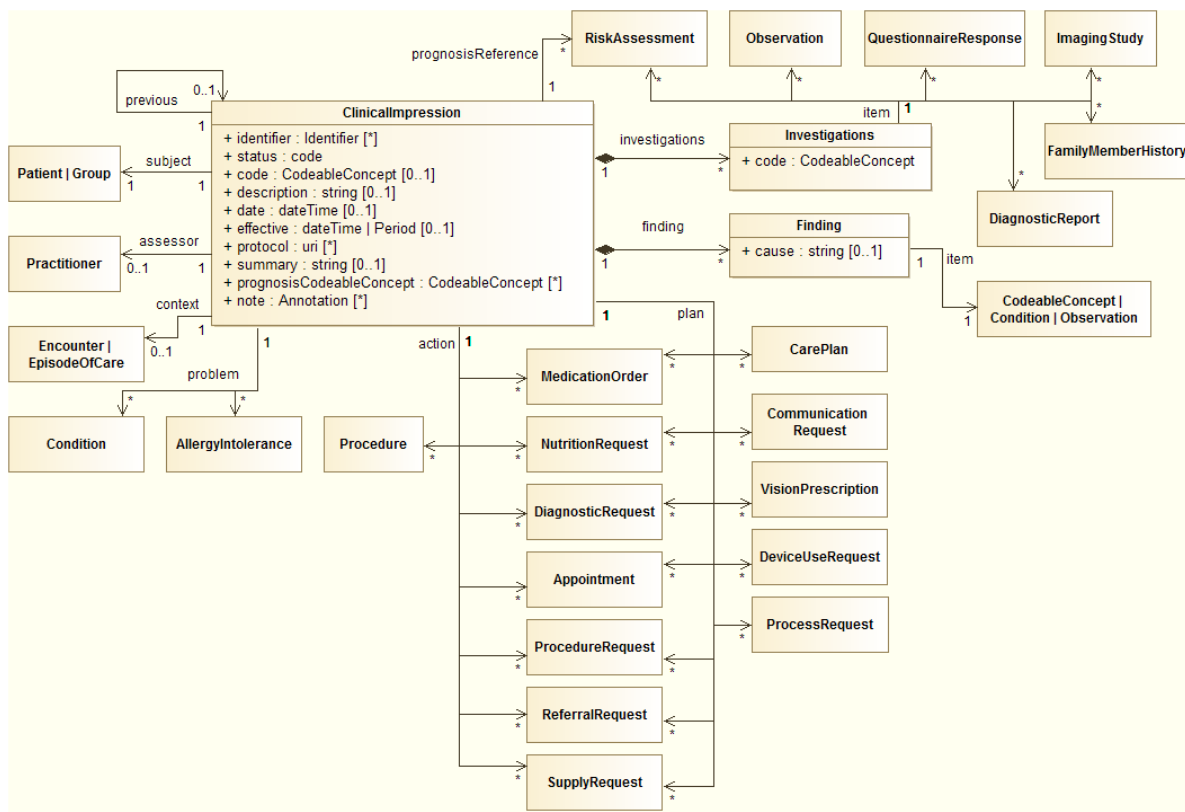
**Class: Reaction**

Adverse Reaction Events linked to exposure to substance.

Name	Cardinality	Type	Description
substance	0..1	CodeableConcept	Specific substance or pharmaceutical product considered to be responsible for event. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-substance-code.html">http://hl7.org/fhir/2016Sep/valueset-substance-code.html</a>
certainty	0..1	code	unlikely   likely   confirmed - clinical certainty about the specific substance.
manifestation	1..*	CodeableConcept	Clinical symptoms/signs associated with the Event. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-manifestation-codes.html">http://hl7.org/fhir/2016Sep/valueset-manifestation-codes.html</a>
description	0..1	string	Description of the event as a whole.
onset	0..1	dateTime	Date(/time) when manifestations showed.
severity	0..1	code	mild   moderate   severe (of event as a whole).
exposureRoute	0..1	CodeableConcept	How the subject was exposed to the substance. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-route-codes.html">http://hl7.org/fhir/2016Sep/valueset-route-codes.html</a>
note	0..*	Annotation	Text about event not captured in other fields.

- **ClinicalImpression**

Figure 21: SDD-INF-CI: FHIR Clinical Assessment Model

**Class: ClinicalImpression**

A record of a clinical assessment performed to determine what problem(s) may affect the patient and before planning the treatments or management strategies that are best to manage a patient's condition. Assessments are often 1:1 with a clinical consultation / encounter, but this varies greatly depending on the clinical workflow. This resource is called "ClinicalImpression" rather than "ClinicalAssessment" to avoid confusion with the recording of assessment tools such as Apgar score.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	Business identifier.
status	1..1	code	draft   completed   entered-in-error.
code	0..1	CodeableConcept	Kind of impression performed.
description	0..1	string	Why/how the assessment was performed.
subject	1..1	Patient   Group	Patient or group assessed.
assessor	0..1	Practitioner	The clinician performing the assessment.
date	0..1	dateTime	When the assessment was documented.
effective	1..1	dateTime   Period	Time of assessment.
context	0..1	Encounter   EpisodeOfCare	Encounter or Episode created from.
previous	0..1	ClinicalImpression	Reference to last assessment.
problem	0..*	Condition   AllergyIntolerance	Relevant impressions of patient state.

protocol	0..*	uri	Clinical Protocol followed.
summary	0..1	string	Summary of the assessment.
prognosisCodeableConcept	0..*	CodeableConcept	Estimate of likely outcome. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-clinicalimpression-prognosis.html">http://www.hl7.org/fhir/2016Sep/valueset-clinicalimpression-prognosis.html</a>
prognosisReference	0..*	RiskAssessment	RiskAssessment expressing likely outcome.
plan	0..*	CarePlan   Appointment   CommunicationRequest   DeviceUseRequest   DiagnosticRequest   MedicationOrder   NutritionRequest   ProcedureRequest   ProcessRequest   ReferralRequest   SupplyRequest   VisionPrescription	Plan of action after assessment.
action	0..*	ReferralRequest   ProcedureRequest   Procedure   MedicationOrder   DiagnosticRequest   NutritionRequest   SupplyRequest   Appointment	Actions taken during assessment.
note	0..*	Annotation	Comments made about the ClinicalImpression.

**Class: investigations**

One or more sets of investigations (signs, symptoms, etc.).

Name	Cardinality	Type	Description
code	1..1	CodeableConcept	A name/code for the set. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-investigation-sets.html">http://www.hl7.org/fhir/2016Sep/valueset-investigation-sets.html</a>
item	0..*	Observation   QuestionnaireResponse   FamilyMemberHistory   DiagnosticReport   RiskAssessment   ImagingStudy	Record of a specific investigation.

**Class: Finding**

Possible or likely findings and diagnoses.

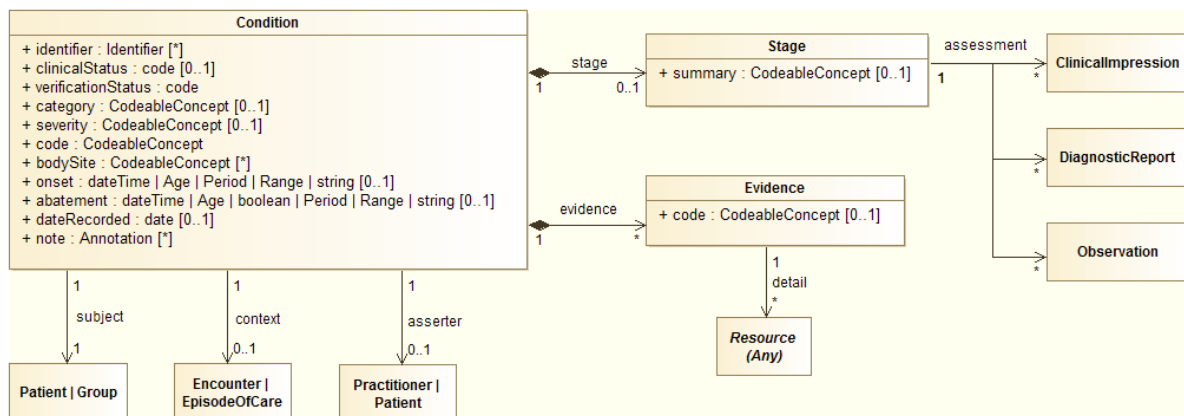
Name	Cardinality	Type	Description
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item	1..1	CodeableConcept   Condition   Observation	What was found. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-condition-code.html">http://www.hl7.org/fhir/2016Sep/valueset-condition-code.html</a>
cause	0..1	string	Which investigations support finding.

- Condition**

**Figure 22: SDD-INF-CN: FHIR Condition/Problem/Diagnosis Model**



### Class: Condition

Use to record detailed information about conditions, problems or diagnoses recognized by a clinician. There are many uses including: recording a diagnosis during an encounter; populating a problem list or a summary statement, such as a discharge summary.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	External Ids for this condition.
clinicalStatus	0..1	code	<a href="#">Condition Clinical Status Codes</a> : active   relapse   remission   resolved.
verificationStatus	0..1	code	<a href="#">Condition Verification Status</a> : provisional   differential   confirmed   refuted   entered-in-error   unknown.
category	0..1	CodeableConcept	<a href="#">Condition Category Codes</a> (Preferred): complaint   symptom   finding   diagnosis.
severity	0..1	CodeableConcept	Subjective severity of condition. Preferred value set: <a href="http://hl7.org/fhir/2016Sep/valueset-condition-severity.html">http://hl7.org/fhir/2016Sep/valueset-condition-severity.html</a>
code	1..1	CodeableConcept	Identification of the condition, problem or diagnosis. Example value set: <a href="http://hl7.org/fhir/us/daf/2016Sep/valueset-daf-problem.html">http://hl7.org/fhir/us/daf/2016Sep/valueset-daf-problem.html</a>
bodySite	0..*	CodeableConcept	Anatomical location, if relevant. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-body-site.html">http://hl7.org/fhir/2016Sep/valueset-body-site.html</a>
subject	1..1	Patient   Group	Who has the condition?
context	0..1	Encounter   EpisodeOfCare	Encounter when condition first asserted.

onset	0..1	dateTime   Age   Period   Range   string	Estimated or actual date, date-time, or age.
abatement	0..1	dateTime   Age   boolean   Period   Range   string	If/when in resolution/remission.
dateRecorded	0..1	date	When first entered.
asserter	0..1	Practitioner   Patient	Person who asserts this condition.
note	0..*	Annotation	Additional information about the Condition.

**Class: Stage**

Stage/grade, usually assessed formally.

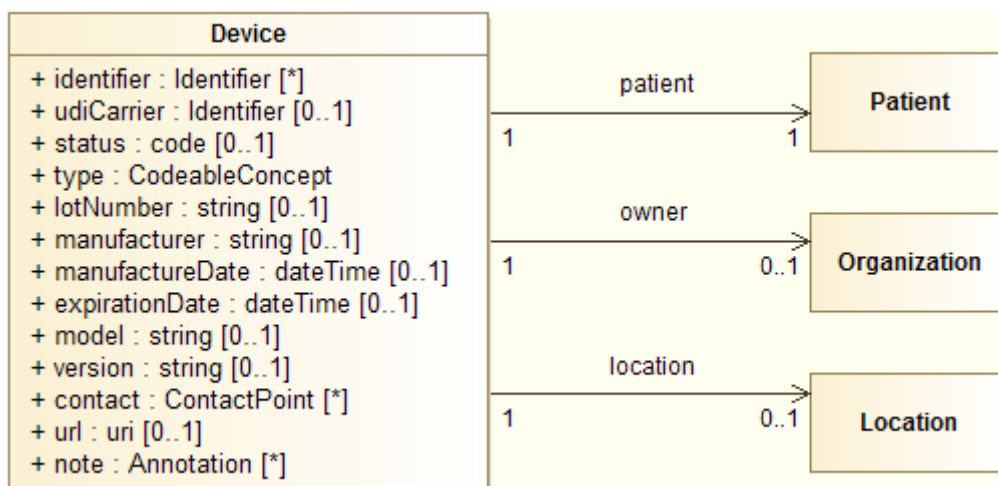
Name	Cardinality	Type	Description
summary	0..1	CodeableConcept	Simple summary (disease specific). Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-condition-stage.html">http://hl7.org/fhir/2016Sep/valueset-condition-stage.html</a>
assessment	0..*	ClinicalImpression   DiagnosticReport   Observation	Formal record of assessment.

**Class: Evidence**

Link to another patient resource that concerns the same actual person.

Name	Cardinality	Type	Description
code	0..1	CodeableConcept	Manifestation/symptom. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-manifestation-or-symptom.html">http://hl7.org/fhir/2016Sep/valueset-manifestation-or-symptom.html</a>
detail	0..*	Resource (Any)	Supporting information found elsewhere.

- *Device*

**Figure 23: SDD-INF-DV: FHIR Device Model****Class: Device**

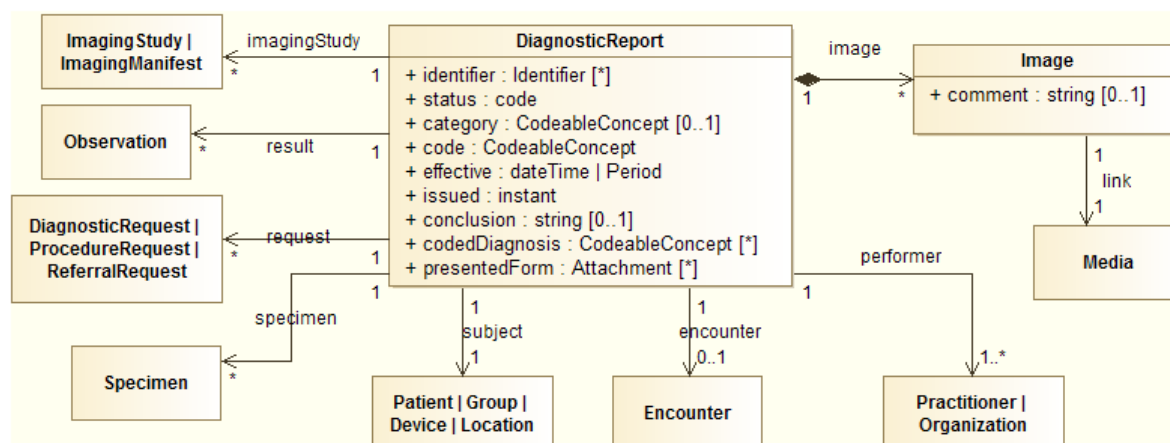
This resource identifies an instance or a type of a manufactured item that is used in the provision of healthcare without being substantially changed through that activity. The device may be a medical or non-medical device. Medical devices includes durable (reusable) medical equipment, implantable devices, as well as disposable equipment used for diagnostic, treatment, and research for healthcare and public health. Non-medical devices may include items such as a machine, cellphone, computer, application, etc.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	Instance identifier.
udiCarrier	0..1	Identifier	Unique Device Identifier (UDI) Barcode string.
status	0..1	code	<a href="#">DeviceStatus</a> : available   not-available   entered-in-error.
type	1..1	CodeableConcept	What kind of device this is. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-device-kind.html">http://hl7.org/fhir/2016Sep/valueset-device-kind.html</a>
lotNumber	0..1	string	Lot number of manufacture.
manufacturer	0..1	string	Name of device manufacturer.
manufactureDate	0..1	dateTime	Date when the device was made.
expirationDate	0..1	dateTime	Date and time of expiry of this device (if applicable).
model	0..1	string	Model ID assigned by the manufacturer.
version	0..1	string	Version number (i.e. software).
patient	1..1	Patient	Patient to whom Device is affixed.
owner	0..1	Organization	Organisation responsible for device.
contact	0..*	ContactPoint	Details for human/organisation for support.
location	0..1	Location	Where the resource is found.
url	0..1	uri	Network address to contact device.

note	0..*	Annotation	Device notes and comments.
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- **DiagnosticReport**

**Figure 24: SDD-INF-DR: FHIR Diagnostic Report Model**



#### Class: DiagnosticReport

The findings and interpretation of diagnostic tests performed on patients, groups of patients, devices, and locations, and/or specimens derived from these. The report includes clinical context such as requesting and provider information, and some mix of atomic results, images, textual and coded interpretations, and formatted representation of diagnostic reports.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	ID for external references to this report.
status	1..1	code	registered   partial   final   corrected   appended   cancelled   entered-in-error.
category	0..1	CodeableConcept	Service category. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-diagnostic-service-sections.html">http://www.hl7.org/fhir/2016Sep/valueset-diagnostic-service-sections.html</a>
code	1..1	CodeableConcept	Name/Code for this diagnostic report. LOINC codes preferred.
subject	1..1	Patient   Group   Device   Location	The subject of the report, usually, but not always, the patient.
encounter	0..1	Encounter	Health care event when test ordered.
effective	1..1	dateTime   Period	Clinically Relevant time/time-period for report.
issued	1..1	instant	Date/Time this version was released.
performer	1..*	Practitioner   Organization	Responsible Diagnostic Service.
request	0..*	DiagnosticRequest   ProcedureRequest   ReferralRequest	What was requested.
specimen	0..*	Specimen	Specimens this report is based on.

result	0..*	Observation	Observations - simple, or complex nested groups.
imagingStudy	0..*	ImagingStudy   ImagingManifest	Reference to full details of imaging associated with the diagnostic report.
conclusion	0..1	string	Clinical Interpretation of test results.
codedDiagnosis	0..*	CodeableConcept	Codes for the conclusion. Example value set – SNOMED CT Clinical Findings.
presentedForm	0..*	Attachment	Entire report as issued.

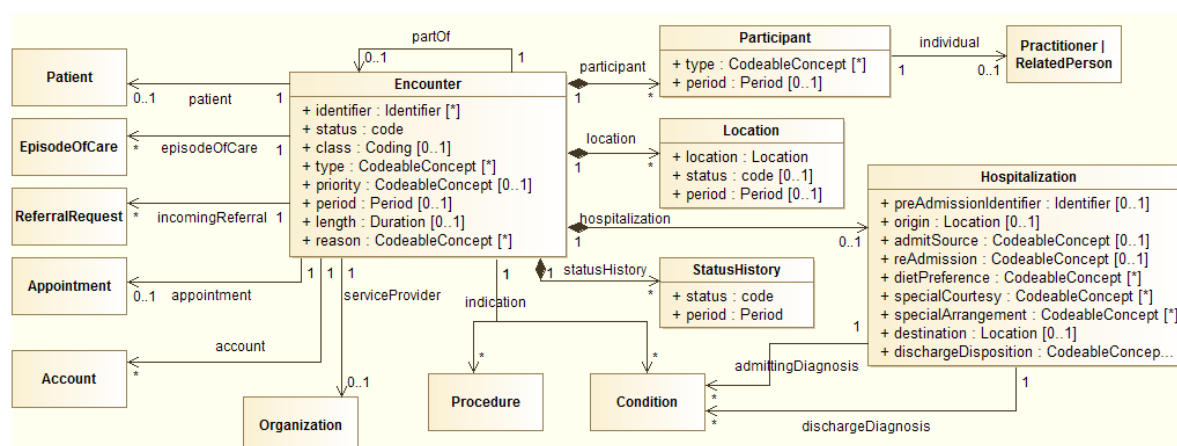
**Class: Image**

Key images associated with this report.

Name	Cardinality	Type	Description
comment	0..1	string	Comment about the image (e.g. explanation).
link	1..1	Media	Reference to the image source.

- Encounter**

**Figure 25: SDD-INF-ENC: FHIR Encounter Model**

**Class: Encounter**

An interaction between a patient and healthcare provider(s) for the purpose of providing healthcare service(s) or assessing the health status of a patient.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	Identifier(s) by which this encounter is known.
status	1..1	code	planned   arrived   in-progress   onleave   finished   cancelled   entered-in-error.
class	0..1	Coding	Reference value set: inpatient   outpatient   ambulatory   emergency.

type	0..*	CodeableConcept	Specific type of encounter. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-encounter-type.html">http://hl7.org/fhir/2016Sep/valueset-encounter-type.html</a>
priority	0..1	CodeableConcept	Indicates the urgency of the encounter. Example value set: <a href="http://hl7.org/fhir/2016Sep/v3/ActPriority/vs.html">http://hl7.org/fhir/2016Sep/v3/ActPriority/vs.html</a>
patient	0..1	Patient	The patient present at the encounter.
episodeOfCare	0..*	EpisodeOfCare	Episode(s) of care that this encounter should be recorded against.
incomingReferral	0..*	ReferralRequest	The ReferralRequest that initiated this encounter.
appointment	0..1	Appointment	The appointment that scheduled this encounter.
period	0..1	Period	The start and end time of the encounter.
length	0..1	Duration	Quantity of time the encounter lasted (less time absent).
reason	0..*	CodeableConcept	Reason the encounter takes place (code). Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-encounter-reason.html">http://hl7.org/fhir/2016Sep/valueset-encounter-reason.html</a>
indication	0..*	Condition   Procedure	Reason the encounter takes place (resource).
account	0..*	Account	The set of accounts that may be used for billing for this Encounter.
serviceProvider	0..1	Organization	The custodian organisation of this Encounter record.
partOf	0..1	Encounter	Another Encounter this encounter is part of

**Class: StatusHistory**

List of past encounter statuses.

Name	Cardinality	Type	Description
status	1..1	code	planned   arrived   in-progress   onleave   finished   cancelled   entered-in-error.
period	1..1	Period	The time that the episode was in the specified status.

**Class: Participant**

List of participants involved in the encounter.

Name	Cardinality	Type	Description
type	0..*	CodeableConcept	Role of participant in encounter. Reference value set: <a href="http://hl7.org/fhir/2016Sep/valueset-encounter-participant-type.html">http://hl7.org/fhir/2016Sep/valueset-encounter-participant-type.html</a>
period	0..1	Period	Period of time during the encounter participant was present.
individual	0..1	Practitioner   RelatedPerson	Persons involved in the encounter other than the patient.

**Class: Location**

List of locations where the patient has been.

Name	Cardinality	Type	Description
location	1..1	Location ( <i>Resource</i> )	Location the encounter takes place. Reference to FHIR Location resource.
status	0..1	code	planned   active   reserved   completed.
period	0..1	Period	Time period during which the patient was present at the location.

### Class: Hospitalization

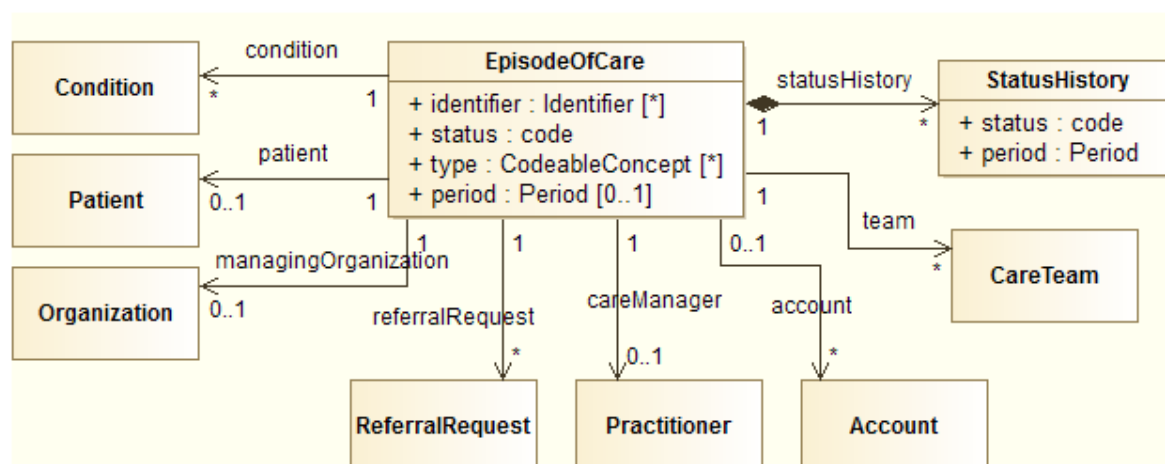
Details about the admission to a healthcare service.

Name	Cardinality	Type	Description
preAdmissionIdentifier	0..1	Identifier	Pre-admission identifier.
origin	0..1	Location ( <i>Resource</i> )	The location from which the patient came before admission. Reference to FHIR Location resource.
admitSource	0..1	CodeableConcept	From where patient was admitted (physician referral, transfer). Value set: <a href="http://hl7.org/fhir/2016Sep/valueset-encounter-admit-source.html">http://hl7.org/fhir/2016Sep/valueset-encounter-admit-source.html</a>
admittingDiagnosis	0..*	Condition	The admitting diagnosis as reported by admitting practitioner.
reAdmission	0..1	CodeableConcept	The type of hospital re-admission that has occurred (if any). If the value is absent, then this is not identified as a readmission. Example value set: <a href="http://hl7.org/fhir/2016Sep/v2/0092/index.html">http://hl7.org/fhir/2016Sep/v2/0092/index.html</a>
dietPreference	0..*	CodeableConcept	Diet preferences reported by the patient. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-encounter-diet.html">http://hl7.org/fhir/2016Sep/valueset-encounter-diet.html</a>
specialCourtesy	0..*	CodeableConcept	Special courtesies (VIP, board member). Value set: <a href="http://hl7.org/fhir/2016Sep/valueset-encounter-special-courtesy.html">http://hl7.org/fhir/2016Sep/valueset-encounter-special-courtesy.html</a>
specialArrangement	0..*	CodeableConcept	Wheelchair, translator, stretcher, etc. value set: <a href="http://hl7.org/fhir/2016Sep/valueset-encounter-special-arrangements.html">http://hl7.org/fhir/2016Sep/valueset-encounter-special-arrangements.html</a>
destination	0..1	Location ( <i>Resource</i> )	Location to which the patient is discharged. Reference to FHIR Location resource.
dischargeDisposition	0..1	CodeableConcept	Category or kind of location after discharge. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-encounter-discharge-disposition.html">http://hl7.org/fhir/2016Sep/valueset-encounter-discharge-disposition.html</a>
dischargeDiagnosis	0..*	Condition	The final diagnosis given a patient before release from the hospital after

			all testing, surgery, and workup are complete.
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- *EpisodeOfCare*

Figure 26: SDD-INF-EOC: FHIR Episode of Care Model

**Class: EpisodeOfCare**

An association between a patient and an organization / healthcare provider(s) during which time encounters may occur. The managing organization assumes a level of responsibility for the patient during this time.

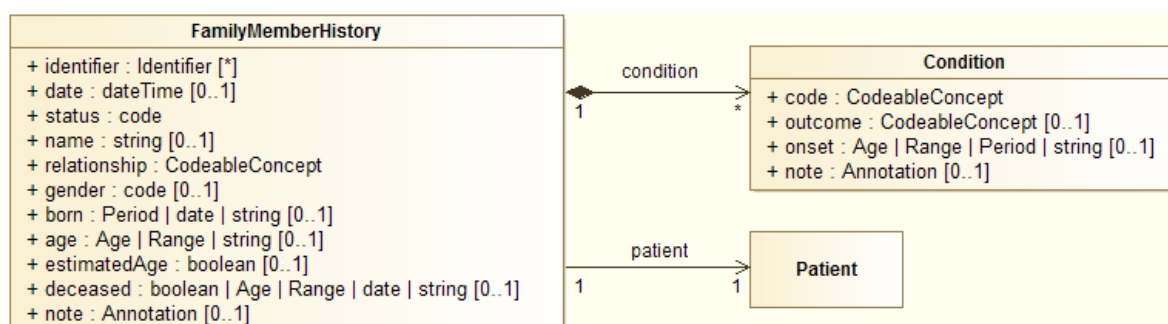
Name	Cardinality	Type	Description
identifier	0..*	Identifier	Identifier(s) for the EpisodeOfCare.
status	1..1	code	planned   waitlist   active   onhold   finished   cancelled   entered-in-error,
type	0..*	CodeableConcept	Type/class - e.g., specialist referral, disease management,
condition	0..*	Condition	Conditions/problems/diagnoses this episode of care is for,
patient	1..1	Patient	Patient for this episode of care,
managingOrganization	0..1	Organization	Organisation that assumes care.
period	0..1	Period	Interval during responsibility is assumed.
referralRequest	0..*	ReferralRequest	Originating Referral Request(s).
careManager	0..1	Practitioner	Care manager/care co-ordinator for the patient.
team	0..*	CareTeam	Other practitioners facilitating this episode of care.
account	0..*	Account	The set of accounts that may be used for billing for this EpisodeOfCare.



Class: StatusHistory			
Past list of status codes.			
Name	Cardinality	Type	Description
status	1..1	code	planned   waitlist   active   onhold   finished   cancelled   entered-in-error.
period	1..1	Period	Period for the status.

- **FamilyMemberHistory**

Figure 27: SDD-INF-FMH: FHIR Family Member History Model



Class: FamilyMemberHistory			
Significant health events and conditions for a person related to the patient relevant in the context of care for the patient.			
Name	Cardinality	Type	Description
identifier	0..*	Identifier	External ID(s) for this record.
patient	1..1	Patient	Patient history is about.
date	0..1	dateTime	When history was captured/updated.
status	1..1	Code	<a href="#">FamilyHistoryStatus</a> : partial   completed   entered-in-error   health-unknown.
name	0..1	string	The family member described.
relationship	1..1	CodeableConcept	Relationship to the subject. Example value set: <a href="http://hl7.org/fhir/2016Sep/v3/FamilyMember/vs.html">http://hl7.org/fhir/2016Sep/v3/FamilyMember/vs.html</a>
gender	0..1	code	<a href="#">AdministrativeGender</a> : male   female   other   unknown.
born	0..1	Period   date   string	(approximate) date of birth.
age	0..1	Age   Range   string	(approximate) age.
estimatedAge	0..1	boolean	Age is estimated?

deceased	0..1	boolean   Age   Range   date   string	Dead? How old/when?
note	0..1	Annotation	General note about related person.

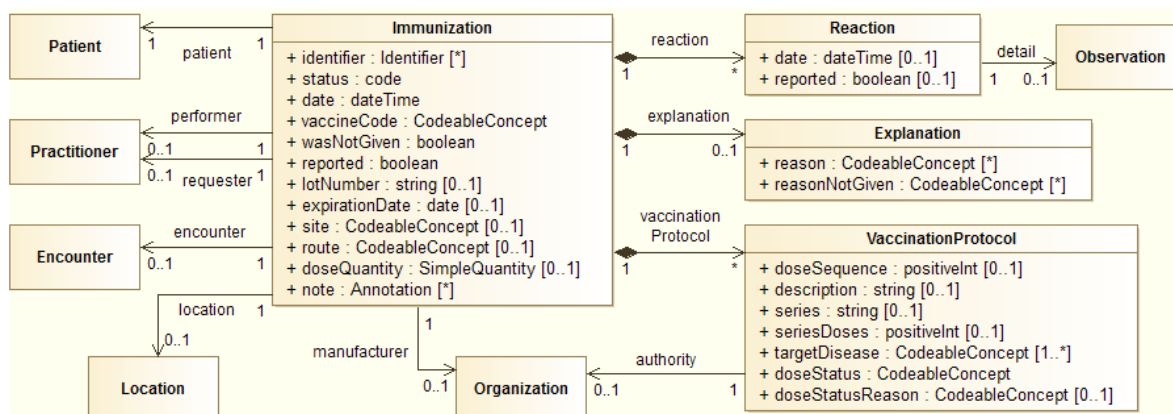
**Class: Condition**

Condition that the related person had.

Name	Cardinality	Type	Description
code	1..1	CodeableConcept	Condition suffered by relation. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-condition-code.html">http://hl7.org/fhir/2016Sep/valueset-condition-code.html</a>
outcome	0..1	CodeableConcept	Example value set: deceased   permanent disability   etc.
onset	0..1	Age   Range   Period   string	When condition first manifested.
note	0..1	Annotation	Extra information about condition.

- Immunization**

**Figure 28: SDD-INF-IMU: FHIR Immunization Model**

**Class: Immunization**

Describes the event of a patient being administered a vaccination or a record of a vaccination as reported by a patient, a clinician or another party and may include vaccine reaction information and what vaccination protocol was followed.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	Business identifier.
status	1..1	code	<a href="#">MedicationAdministrationStatus</a> : in-progress   on-hold   completed   entered-in-error   stopped.
date	0..1	dateTime	Vaccination administration date.

vaccineCode	1..1	CodeableConcept	Vaccine product administered. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-vaccine-code.html">http://hl7.org/fhir/2016Sep/valueset-vaccine-code.html</a>
patient	1..1	Patient	Who was immunised.
wasNotGiven	1..1	boolean	Flag for whether immunisation was given.
reported	1..1	boolean	Indicates a self-reported record.
performer	0..1	Practitioner	Who administered vaccine.
requester	0..1	Practitioner	Who ordered vaccination.
encounter	0..1	Encounter	Encounter administered as part of.
manufacturer	0..1	Organization	Vaccine manufacturer.
location	0..1	Location	Where vaccination occurred.
lotNumber	0..1	string	Vaccine lot number.
expirationDate	0..1	date	Vaccine expiration date.
site	0..1	CodeableConcept	Body site vaccine was administered. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-immunization-site.html">http://hl7.org/fhir/2016Sep/valueset-immunization-site.html</a>
route	0..1	CodeableConcept	How vaccine entered body. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-immunization-route.html">http://hl7.org/fhir/2016Sep/valueset-immunization-route.html</a>
doseQuantity	0..1	SimpleQuantity	Amount of vaccine administered.
note	0..1	Annotation	Vaccination notes.

**Class: Explanation**

Administration/non-administration reasons

Name	Cardinality	Type	Description
reason	0..*	CodeableConcept	Why immunization occurred. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-immunization-reason.html">http://hl7.org/fhir/2016Sep/valueset-immunization-reason.html</a>
reasonNotGiven	0..*	CodeableConcept	Why immunization did not occur. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-no-immunization-reason.html">http://hl7.org/fhir/2016Sep/valueset-no-immunization-reason.html</a>

**Class: Reaction**

Details of a reaction that follows immunization.

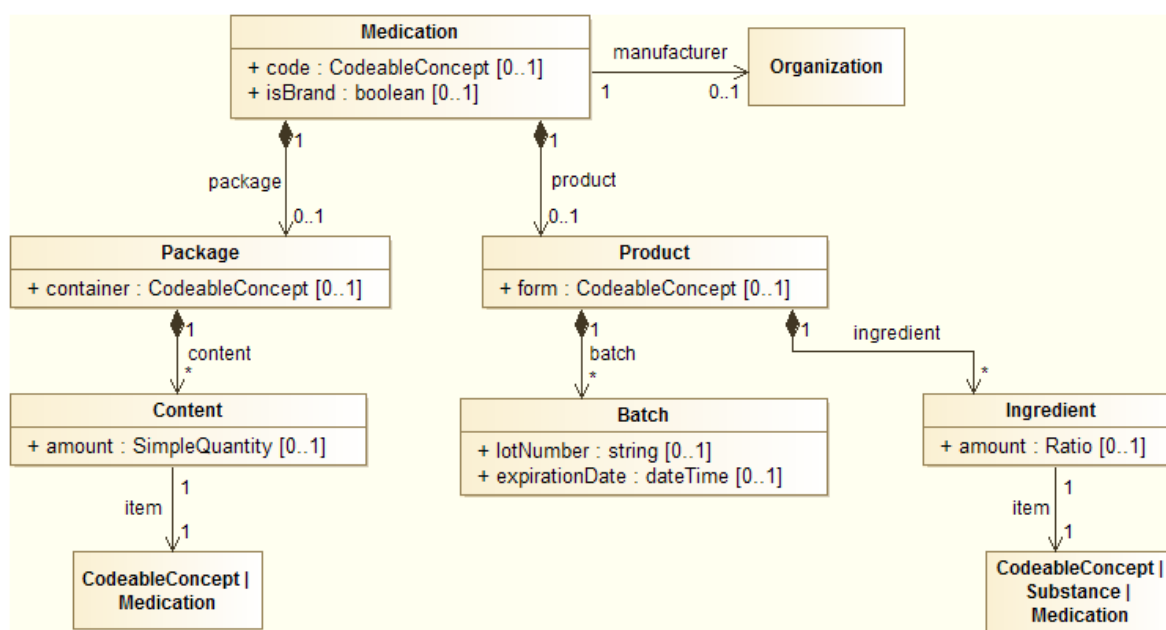
Name	Cardinality	Type	Description
date	0..1	dateTime	When reaction started.
detail	0..1	Observation	Additional information on reaction.
reported	0..1	boolean	Indicates self-reported reaction.

**Class: Reaction**

Details of a reaction that follows immunization.			
Name	Cardinality	Type	Description
date	0..1	dateTime	When reaction started.
detail	0..1	Observation	Additional information on reaction.
reported	0..1	boolean	Indicates self-reported reaction.

Class: VaccinationProtocol			
What protocol was followed			
Name	Cardinality	Type	Description
doseSequence	0..1	positiveInt	Dose number within series.
description	0..1	string	Details of vaccine protocol.
authority	0..1	Organization	Who is responsible for protocol.
series	0..1	string	Name of vaccine series.
seriesDoses	0..1	positiveInt	Recommended number of doses for immunity.
targetDisease	1..*	CodeableConcept	Disease immunised against. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-vaccination-protocol-dose-target.html">http://hl7.org/fhir/2016Sep/valueset-vaccination-protocol-dose-target.html</a>
doseStatus	1..1	CodeableConcept	Indicates if dose counts towards immunity. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-vaccination-protocol-dose-status.html">http://hl7.org/fhir/2016Sep/valueset-vaccination-protocol-dose-status.html</a>
doseStatusReason	0..1	CodeableConcept	Why dose does (not) count. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-vaccination-protocol-dose-status-reason.html">http://hl7.org/fhir/2016Sep/valueset-vaccination-protocol-dose-status-reason.html</a>

- **Medication**

**Figure 29: SDD-INF-MED: FHIR Medication Model****Class: Medication**

This resource is primarily used for the identification and definition of a medication. It covers the ingredients and the packaging for a medication.

Name	Cardinality	Type	Description
code	0..1	CodeableConcept	Codes that identify this medication. Example value set: <a href="#">SNOMED CT Medication Codes</a> .
isBrand	0..1	boolean	True if a brand,
manufacturer	0..1	Organization	Manufacturer of the item,

**Class: Product**

Administrable medication details

Name	Cardinality	Type	Description
form	0..1	CodeableConcept	E.g. powder, tablets, carton. Example value set: <a href="#">SNOMED CT Form Codes</a> .

**Class: Ingredient**

Active or inactive ingredient

Name	Cardinality	Type	Description
item	1..1	CodeableConcept   Substance   Medication	The product contained.
amount	0..1	Ratio	Quantity of ingredient present.

**Class: Batch**

Information about a group of medication produced or packaged from one production run.

Name	Cardinality	Type	Description
lotNumber	0..1	string	The assigned lot number of a batch of the specified product.
expirationDate	0..1	dateTime	When this specific batch of product will expire.

### Class: Package

Details about packaged medications.

Name	Cardinality	Type	Description
container	0..1	CodeableConcept	E.g. box, vial, blister-pack. Example value set: <a href="#">SNOMED CT Form Codes</a> .

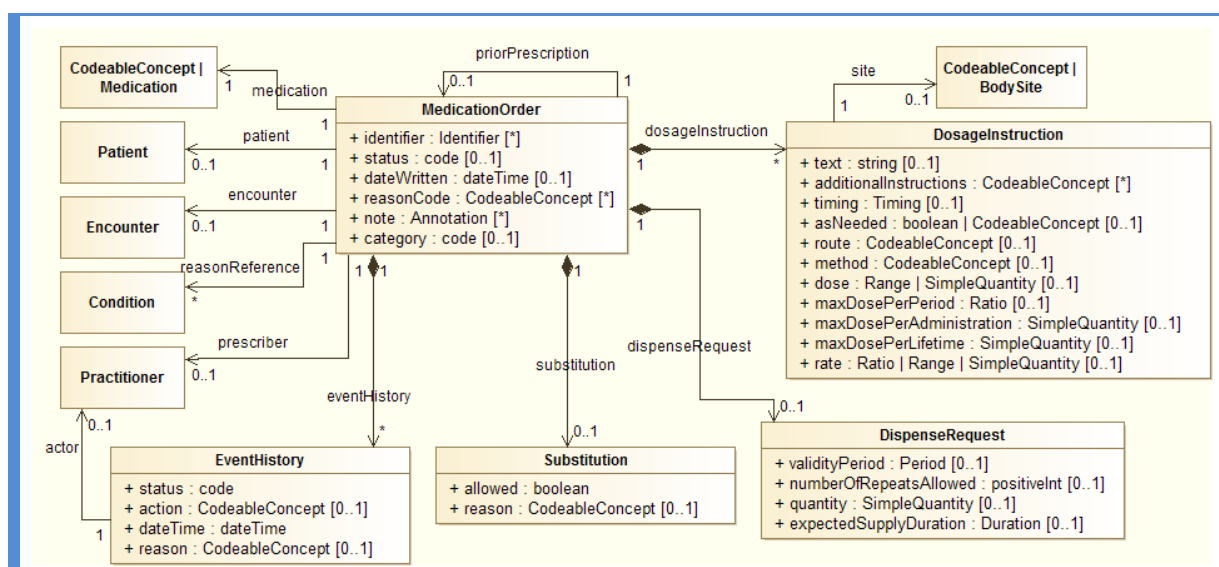
### Class: Content

What is in the package.

Name	Cardinality	Type	Description
item	1..1	CodeableConcept   Medication	The item in the package.
amount	0..1	SimpleQuantity	Quantity present in the package.

## • MedicationOrder

Figure 30: SDD-INF-MO: FHIR Medication Order Model



### Class: MedicationOrder

An order for both supply of the medication and the instructions for administration of the medication to a patient. The resource is called "MedicationOrder" rather than "MedicationPrescription" to generalize the use across inpatient and outpatient settings as well as for care plans, etc.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	External identifier.

status	0..1	code	<a href="#">MedicationOrderStatus</a> : active   on-hold   completed   entered-in-error   stopped   draft.
medication	1..1	CodeableConcept   Medication	Medication to be taken. Example value set: <a href="#">SNOMED CT Medication Codes</a> .
patient	0..1	Patient	Who prescription is for.
encounter	0..1	Encounter	Created during encounter/admission/stay.
dateWritten	0..1	dateTime	When prescription was initially authorised.
prescriber	0..1	Practitioner	Who ordered the initial medication(s).
reasonCode	0..*	CodeableConcept	Reason or indication for writing the prescription. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-condition-code.html">http://www.hl7.org/fhir/2016Sep/valueset-condition-code.html</a>
reasonReference	0..*	Condition	Condition that supports why the prescription is being written.
note	0..*	Annotation	Information about the prescription.
category	0..1	code	Type of medication usage. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-medication-order-category.html">http://www.hl7.org/fhir/2016Sep/valueset-medication-order-category.html</a>
priorPrescription	0..1	MedicationOrder	An order/prescription that this supersedes.

**Class: DosageInstruction**

Indicates how the medication is to be used by the patient.

Name	Cardinality	Type	Description
text	0..1	string	Free text dosage instructions, e.g. SIG.
additionalInstructions	0..*	CodeableConcept	Supplemental instructions - e.g. "with meals". Example value set: <a href="#">SNOMED CT Additional Dosage Instructions</a> .
timing	0..1	Timing	When medication should be administered.
asNeeded	0..1	boolean   CodeableConcept	Take "as needed". Example value set: <a href="#">SNOMED CT Medication As Needed Reason Codes</a> .
site	0..1	CodeableConcept   BodySite	Body site to administer to. Example value set: <a href="#">SNOMED CT Anatomical Structure for Administration Site Codes</a> .
route	0..1	CodeableConcept	How drug should enter body. Example value set: <a href="#">SNOMED CT Route Codes</a> .
method	0..1	CodeableConcept	Technique for administering medication. Example value set: <a href="#">SNOMED CT Administration Method Codes</a> .
dose	0..1	Range   SimpleQuantity	Amount of medication per dose.

maxDosePerPeriod	0..1	Ratio	Upper limit on medication per unit of time.
maxDosePerAdministration	0..1	SimpleQuantity	Upper limit on medication per administration.
maxDosePerLifetime	0..1	SimpleQuantity	Upper limit on medication per lifetime of the patient.
rate	0..1	Ratio   Range   SimpleQuantity	Amount of medication per unit of time.

**Class: DispenseRequest**

Indicates the specific details for the dispensing or medication supply part of a medication order (also known as a Medication Prescription). Note that this information is NOT always sent with the order. There may be in some settings (e.g., hospitals) institutional or system support for completing the dispense details in the pharmacy department.

Name	Cardinality	Type	Description
validityPeriod	0..1	Period	Time period supply is authorized for. Indicates when the Prescription becomes valid, and when it ceases to be a dispensable Prescription.
numberOfRepeatsAllowed	0..1	positiveInt	Number of refills authorized. This integer does NOT include the original order dispense.
quantity	0..1	SimpleQuantity	Amount of medication to supply per dispense,
expectedSupplyDuration	0..1	Duration	Number of days' supply per dispense. This attribute may be used instead of quantity, but when possible, it is always better to specify quantity.

**Class: Substitution**

Indicates whether or not substitution can or should be part of the dispense. In some cases substitution must happen, in other cases substitution must not happen, and in others it does not matter. This block explains the prescriber's intent. If nothing is specified substitution may be done.

Name	Cardinality	Type	Description
allowed	1..1	boolean	True if the prescriber allows a different drug to be dispensed from what was prescribed.
reason	0..1	CodeableConcept	Why should (not) substitution be made. Example value set: <a href="#">SubstanceAdminSubstitutionReason</a> .

**Class: EventHistory**

A summary of the events of interest that have occurred as the request is processed; e.g., when the order was verified or when it was completed.

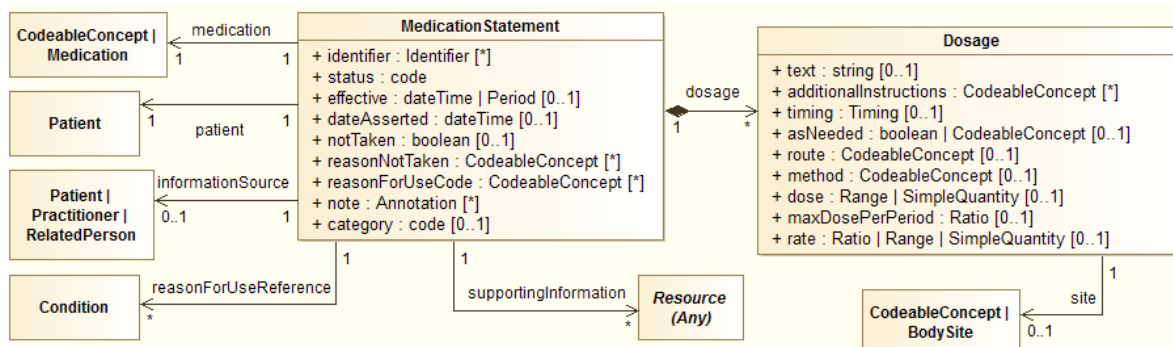
Name	Cardinality	Type	Description
status	1..1	code	<a href="#">MedicationOrderStatus</a> : active   on-hold   completed   entered-in-error   stopped   draft.
action	0..1	CodeableConcept	Why should (not) substitution be made? Example value set: <a href="#">SubstanceAdminSubstitutionReason</a> .
dateTime	1..1	dateTime	The date at which the event happened.



actor	0..1	Practitioner	Who took the action.
reason	0..1	CodeableConcept	Reason the action was taken.

- MedicationStatement**

**Figure 31: SDD-INF-MS: FHIR Medication Statement Model**



### Class: MedicationStatement

A record of a medication that is being consumed by a patient. A MedicationStatement may indicate that the patient may be taking the medication now, or has taken the medication in the past or will be taking the medication in the future. The source of this information can be the patient, significant other (such as a family member or spouse), or a clinician. A common scenario where this information is captured is during the history taking process during a patient visit or stay. The medication information may come from e.g. the patient's memory, from a prescription bottle, or from a list of medications the patient, clinician or other party maintains. Both *MedicationOrder* and *MedicationStatement* can be used to record a patient's medication. The primary difference is that a medication statement is not a part of the Prescribe → Dispense → Administer sequence but is a report that such a sequence (or at least a part of it) did take place resulting in a belief that the patient has received a particular medication.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	External identifier.
status	1..1	code	<a href="#">MedicationStatementStatus</a> : active   completed   entered-in-error   intended   stopped   on-hold.
medication	1..1	CodeableConcept   Medication	What medication was taken. Example value set: <a href="#">SNOMED CT Medication Codes</a> .
patient	1..1	Patient	Who is/was taking the medication.
effective	0..1	dateTime   Period	Over what period was medication consumed?

informationSource	0..1	Patient   Practitioner   RelatedPerson	Person who provided the information about the taking of this medication.
supportingInformation	0..*	Resource (Any)	Additional supporting information.
dateAsserted	0..1	dateTime	When the statement was asserted?
notTaken	0..1	boolean	True if medication is/was not being taken.
reasonNotTaken	0..*	CodeableConcept	A code indicating why the medication was not taken.
reasonForUseCode	0..*	CodeableConcept	Reason for why the medication is being/was taken. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-condition-code.html">http://www.hl7.org/fhir/2016Sep/valueset-condition-code.html</a>
reasonForUseReference	0..*	Condition	Condition that supports why the medication is being/was taken.
note	0..*	Annotation	Further information about the statement.
category	0..1	code	Type of medication usage. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-medication-statement-category.html">http://www.hl7.org/fhir/2016Sep/valueset-medication-statement-category.html</a>

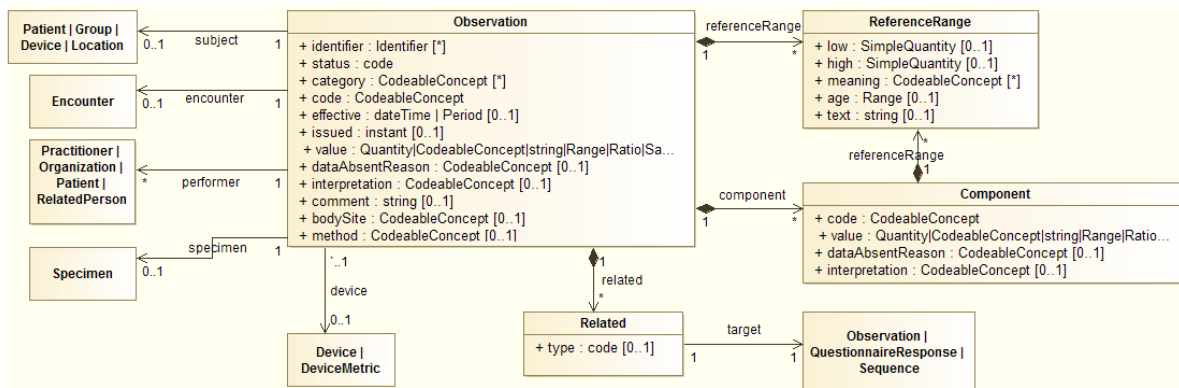
**Class: Dosage**

Details of how medication was taken.

Name	Cardinality	Type	Description
text	0..1	string	Free text dosage instructions as reported by the information source.
additionalInstructions	0..*	CodeableConcept	Supplemental instructions - e.g., "with meals". Example value set: <a href="#">SNOMED CT Additional Dosage Instructions</a> .
timing	0..1	Timing	When/how often was medication taken
asNeeded	0..1	boolean   CodeableConcept	Take "as needed". Example value set: <a href="#">SNOMED CT Medication As Needed Reason Codes</a> .
site	0..1	CodeableConcept   BodySite	Where (on body) medication is/was administered. Example value set: <a href="#">SNOMED CT Anatomical Structure for Administration Site Codes</a> .
route	0..1	CodeableConcept	How the medication entered the body. Example value set: <a href="#">SNOMED CT Route Codes</a> .
method	0..1	CodeableConcept	Technique used to administer medication. Example value set: <a href="#">SNOMED CT Administration Method Codes</a> .
dose	0..1	Range   SimpleQuantity	Amount of medication per dose.
maxDosePerPeriod	0..1	Ratio	Maximum dose that was consumed per unit of time.
rate	0..1	Ratio   Range   SimpleQuantity	Amount of medication per unit of time.

- Observation**

Figure 32: SDD-INF-OBS: FHIR Observation Model

**Class: Observation**

Measurements and simple assertions made about a patient, device or other subject.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	Unique ID for this particular observation
status	1..1	code	<a href="#">ObservationStatus</a> : registered   preliminary   final   amended   cancelled   entered-in-error   unknown.
category	0..*	CodeableConcept	Classification of type of observation. Example value set: <a href="#">Observation Category Codes</a> .
code	1..1	CodeableConcept	Type of observation (code / type). Example value set: <a href="#">LOINC Codes</a> .
subject	0..1	Patient   Group   Device   Location	Who and/or what this is about.
encounter	0..1	Encounter	Healthcare event during which this observation is made.
effective	0..1	dateTime   Period	Clinically relevant time/time-period for observation.
issued	0..1	instant	Date/Time this was made available.
performer	0..*	Practitioner   Organization   Patient   RelatedPerson	Who is responsible for the observation.
value	0..1	Quantity   CodeableConcept   string   Range   Ratio   SampledData   Attachment   time   dateTime   Period	Actual result. UCUM units should be used for Quantity value. SNOMED CT codes are preferred for CodeableConcept value.

dataAbsentReason	0..1	CodeableConcept	Why the result is missing. Reference value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-observation-valueabsentreason.html">http://www.hl7.org/fhir/2016Sep/valueset-observation-valueabsentreason.html</a>
interpretation	0..1	CodeableConcept	High, low, normal, etc. Reference value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-observation-interpretation.html">http://www.hl7.org/fhir/2016Sep/valueset-observation-interpretation.html</a>
comment	0..1	string	Comments about result.
bodySite	0..1	CodeableConcept	Observed body part. Example value set: SNOMED CT Body Structures.
method	0..1	CodeableConcept	How it was done. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-observation-methods.html">http://www.hl7.org/fhir/2016Sep/valueset-observation-methods.html</a>
specimen	0..1	Specimen	Specimen used for this observation.
device	0..1	Device   DeviceMetric	(Measurement) Device.

**Class: ReferenceRange**

Provides guide for interpretation. Must have at least a low or a high or text.

Name	Cardinality	Type	Description
low	0..1	SimpleQuantity	Low Range, if relevant.
high	0..1	SimpleQuantity	High Range, if relevant.
meaning	0..*	CodeableConcept	Reference range qualifier. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-referencerrange-meaning.html">http://www.hl7.org/fhir/2016Sep/valueset-referencerrange-meaning.html</a>
age	0..1	Range	Applicable age range, if relevant.
text	0..1	string	Text based reference range in an observation.

**Class: Related**

Resource related to this observation.

Name	Cardinality	Type	Description
type	0..1	code	<a href="#">ObservationRelationshipType</a> : has-member   derived-from   sequel-to   replaces   qualified-by   interfered-by.
target	1..1	Observation   QuestionnaireResponse   Sequence	Resource that is related to this one.

**Class: Component**

Component results.

Name	Cardinality	Type	Description
code	1..1	CodeableConcept	Type of component observation (code / type). Example value set: <a href="#">LOINC Codes</a> .

value	0..1	Quantity   CodeableConcept   string   Range   Ratio   SampledData   Attachment   time   dateTime   Period	Actual component result.
dataAbsentReason	0..1	CodeableConcept	Why the component result is missing. Reference value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-observation-valueabsentreason.html">http://www.hl7.org/fhir/2016Sep/valueset-observation-valueabsentreason.html</a>
interpretation	0..1	CodeableConcept	High, low, normal, etc. Reference value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-observation-interpretation.html">http://www.hl7.org/fhir/2016Sep/valueset-observation-interpretation.html</a>
referenceRange	0..*	ReferenceRange	Provides guide for interpretation of component result.

- **Observation-Vitalsigns**

**SDD-INF-VS: FHIR DAF Vital Signs Model**

(Class diagram: same as the Observation class diagram)

Class: Observation			
A profile on Observation for vital signs associated with a patient.			
Name	Cardinality	Type	Description
identifier	0..*	Identifier	See Observation.
status	1..1	code	See Observation.
category	1..1	CodeableConcept	Fixed value: vital-signs.
code	1..1	CodeableConcept	Example value set: <a href="http://hl7.org/fhir/us/daf/2016Sep/valueset-daf-observation-CCDAVitalSignResult.html">http://hl7.org/fhir/us/daf/2016Sep/valueset-daf-observation-CCDAVitalSignResult.html</a>
subject	1..1	Patient	Who this is about.
encounter	0..1	Encounter	See Observation.
effective	1..1	dateTime   Period	Date/time must be at least to day.
issued	0..1	instant	See Observation.
performer	0..*	Practitioner   Organization   Patient   RelatedPerson	See Observation.
value	0..1	Quantity	Vital Signs Units: <a href="http://hl7.org/fhir/2016Sep/valueset-ucum-vitals-common.html">http://hl7.org/fhir/2016Sep/valueset-ucum-vitals-common.html</a>
dataAbsentReason	0..1	CodeableConcept	See Observation.

interpretation	0..1	CodeableConcept	See Observation.
comment	0..1	string	See Observation.
bodySite	0..1	CodeableConcept	See Observation.
method	0..1	CodeableConcept	See Observation.
specimen	0..1	Specimen	See Observation.
device	0..1	Device   DeviceMetric	See Observation.

**Class: ReferenceRange**

See Observation.

**Class: Related**

Resource related to this observation.

Name	Cardinality	Type	Description
type	1..1	code	Fixed value: has-member.
target	1..1	Observation- Vitalsigns	Resource that is related to this one.

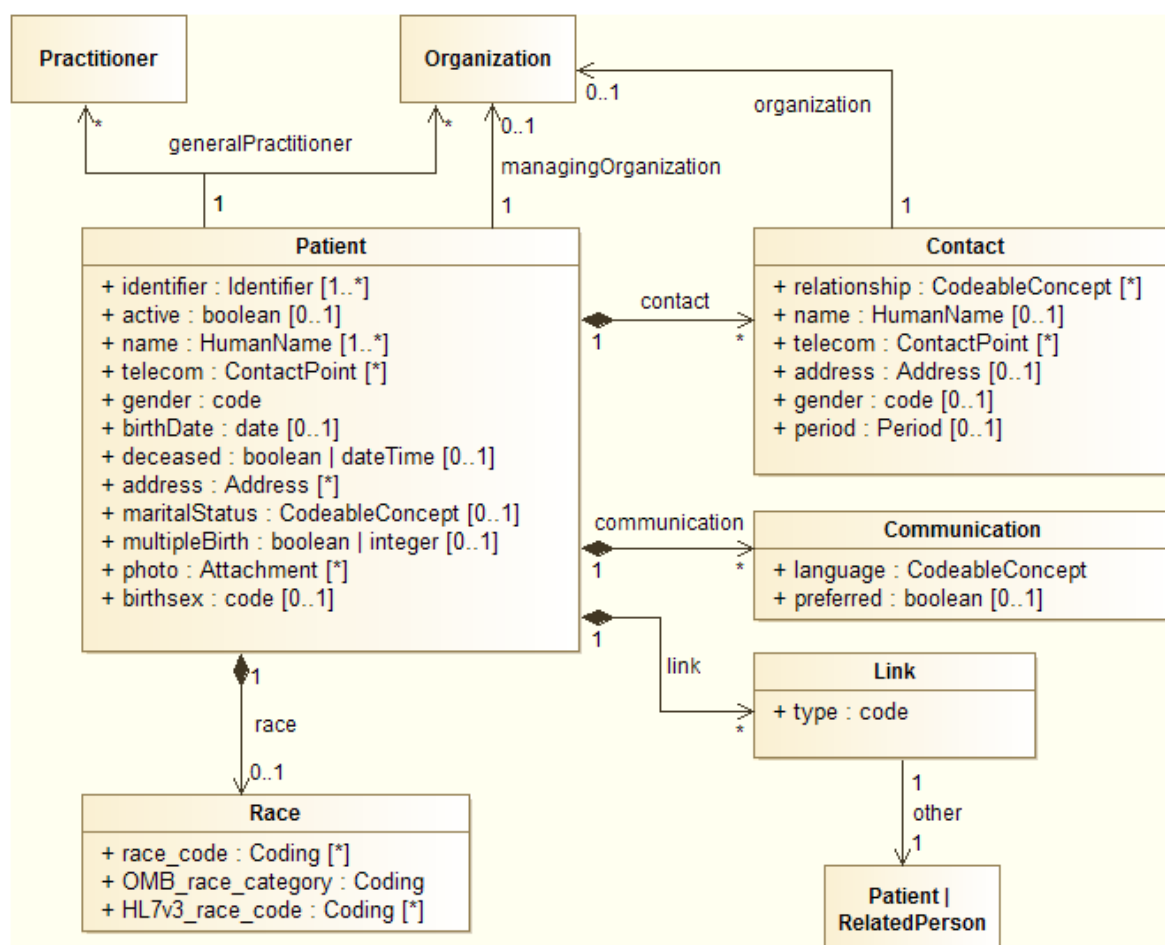
**Class: Component**

Component results.

Name	Cardinality	Type	Description
code	1..1	CodeableConcept	Reference value set: <a href="http://hl7.org/fhir/us/daf/2016Sep/valueset-daf-observation-CCDAVitalSignResult.html">http://hl7.org/fhir/us/daf/2016Sep/valueset-daf-observation-CCDAVitalSignResult.html</a>
value	0..1	Quantity	Vital Signs Units: <a href="http://hl7.org/fhir/2016Sep/valueset-ucum-vitals-common.html">http://hl7.org/fhir/2016Sep/valueset-ucum-vitals-common.html</a>
dataAbsentReason	0..1	CodeableConcept	See Observation.
interpretation	0..1	CodeableConcept	See Observation.
referenceRange	0..*	ReferenceRange	See Observation.

- *Patient*

Figure 33: SDD-INF-PAT: FHIR DAF Patient Model

**Class: Patient**

Demographics and other administrative information about an individual receiving care or other health-related services.

Name	Cardinality	Type	Description
identifier	1..1	Identifier	Business identifiers for this patient.
active	0..1	boolean	Whether this patient's record is in active use.
telecom	0..*	ContactPoint	Contact details for the individual.
gender	1..1	code	<a href="#">AdministrativeGender</a> : male   female   other   unknown.
birthDate	0..1	date	The date of birth for the individual.
deceased	0..1	boolean, dateTime	Indicates if the individual is deceased or not.
address	0..*	Address	Addresses for the individual.
maritalStatus	0..1	CodeableConcept	Marital (civil) status of a patient. The value set is available at <a href="http://hl7.org/fhir/2016Sep/valueset-marital-status.html">http://hl7.org/fhir/2016Sep/valueset-marital-status.html</a>

multipleBirth	0..1	boolean, integer	Indicates whether the patient is part of a multiple (boolean) or indicates the actual birth order (integer).
photo	0..*	Attachment	Image of the patient.
generalPractitioner	0..*	Organization   Practitioner	Patient's nominated primary care provider.
managingOrganization	0..1	Organization	Organisation that is the custodian of the patient record.
birthsex	0..1	code	The person's sex assigned at birth. Value set: <a href="http://hl7.org/fhir/2016Sep/valueset-usrealm-birthsex.html">http://hl7.org/fhir/2016Sep/valueset-usrealm-birthsex.html</a>

**Class: Contact**

A contact party (e.g. guardian, partner, friend) for the patient

Name	Cardinality	Type	Description
relationship	0..*	CodeableConcept	The kind of relationship. The reference value set can be found at: <a href="http://hl7.org/fhir/2016Sep/v2/0131/index.html">http://hl7.org/fhir/2016Sep/v2/0131/index.html</a>
name	0..1	HumanName	A name associated with the contact person.
telecom	0..*	ContactPoint	A contact detail for the person.
address	0..1	Address	Address for the contact person.
gender	0..1	code	<a href="#">AdministrativeGender</a> : male   female   other   unknown.
organization	0..1	Organization	Organisation that is associated with the contact.
period	0..1	Period	The period during which this contact person or organization is valid to be contacted relating to this patient.

**Class: Communication**

A list of Languages which may be used to communicate with the patient about his or her health.

Name	Cardinality	Type	Description
language	1..1	CodeableConcept	The language which can be used to communicate with the patient about his or her health. The common languages value set can be found at: <a href="http://hl7.org/fhir/2016Sep/valueset-languages.html">http://hl7.org/fhir/2016Sep/valueset-languages.html</a>
preferred	0..1	boolean	Indicates whether or not the patient prefers this language (over other languages he masters up a certain level).

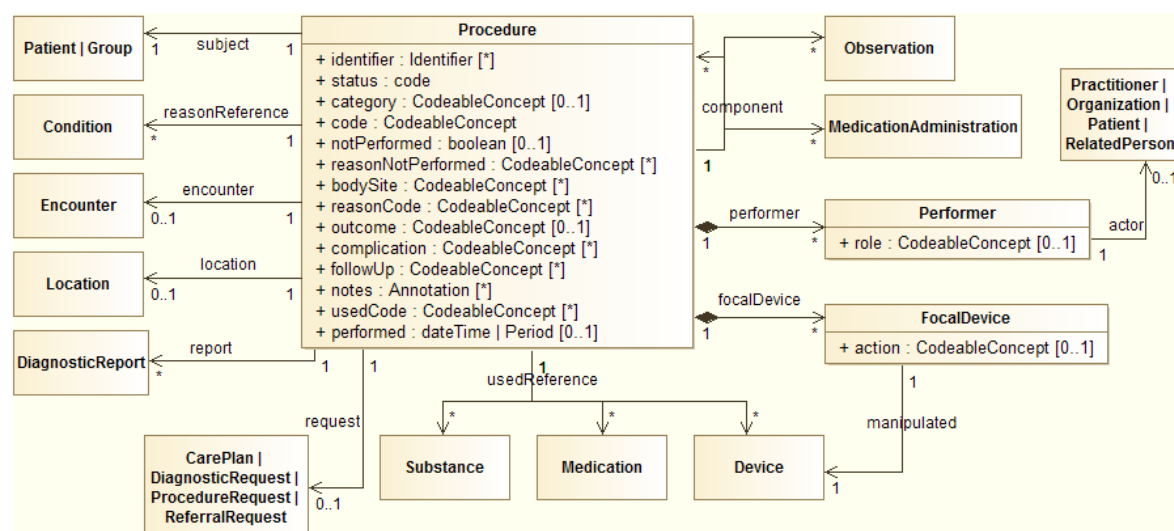


Class: Link			
Link to another patient resource that concerns the same actual person.			
Name	Cardinality	Type	Description
other	1..1	Patient   RelatedPerson	The other patient or related person resource that the link refers to.
type	1..1	code	Type of link. Value set: <a href="#">LinkType</a> .

Class: Race			
A category of humans sharing history, origin or nationality			
Name	Cardinality	Type	Description
race_code	0..*	Coding	Code defined by a terminology system.
OMB_race_category	1..1	Coding	OMB Race Categories, <a href="http://hl7.org/fhir/us/daf/2016Sep/value-set-daf-race.html">http://hl7.org/fhir/us/daf/2016Sep/value-set-daf-race.html</a>
HL7v3_race_code	0..*	Coding	HL7 v3 Code System Race, <a href="http://hl7.org/fhir/2016Sep/v3/Race/vs.html">http://hl7.org/fhir/2016Sep/v3/Race/vs.html</a>

- Procedure**

Figure 34: SDD-INF-PRC: FHIR Procedure Model



Class: Procedure			
This resource is used to record the details of procedures performed on a patient. A procedure is an activity that is performed with or on a patient as part of the provision of care. Examples include surgical procedures, diagnostic procedures, endoscopic procedures, biopsies, counseling, physiotherapy, exercise, etc. Procedures may be performed by a healthcare professional, a friend or relative or in some cases by the patient themselves.			
Name	Cardinality	Type	Description
identifier	0..*	Identifier	External Identifiers for this procedure.

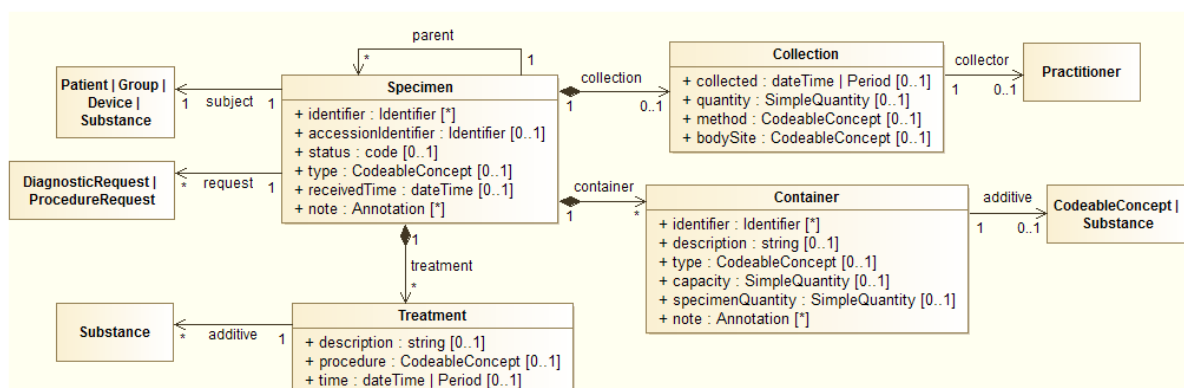
subject	1..1	Patient   Group	Who the procedure was performed on.
status	1..1	code	<a href="#">ProcedureStatus</a> : in-progress   aborted   completed   entered-in-error.
category	0..1	CodeableConcept	Classification of the procedure. Example value set: <a href="#">Procedure Category Codes (SNOMED CT)</a> .
code	1..1	CodeableConcept	Identification of the procedure. Example value set: <a href="#">Procedure Codes (SNOMED CT)</a> .
notPerformed	0..1	boolean	True if procedure was not performed as scheduled.
reasonNotPerformed	0..*	CodeableConcept	Reason procedure was not performed. Example value set: <a href="#">Procedure Not Performed Reason (SNOMED-CT)</a> .
bodySite	0..*	CodeableConcept	Target body sites. Example value set: <a href="#">SNOMED CT Body Structures</a> .
reasonReference	0..*	Condition	Condition that is the reason the procedure performed.
performed	0..1	dateTime   Period	Date/Period the procedure was performed.
encounter	0..1	Encounter	The encounter associated with the procedure.
location	0..1	Location	Where the procedure happened.
outcome	0..1	CodeableConcept	The result of procedure. Example value set: <a href="#">Procedure Outcome Codes (SNOMED CT)</a> .
report	0..*	DiagnosticReport	Any report resulting from the procedure.
complication	0..*	CodeableConcept	Complication following the procedure. Example value set: <a href="http://www.hl7.org/fhir/2016Sep/valueset-condition-code.html">http://www.hl7.org/fhir/2016Sep/valueset-condition-code.html</a> .
followUp	0..*	CodeableConcept	Instructions for follow up. Example value set: <a href="#">Procedure Follow up Codes (SNOMED CT)</a> .
request	0..1	CarePlan   DiagnosticRequest   ProcedureRequest   ReferralRequest	A request for this procedure.
note	0..*	Annotation	Additional information about the procedure.
usedReference	0..*	Device   Substance   Medication	Items used during procedure.
usedCode	0..*	CodeableConcept	Coded items used during the procedure.
component	0..*	MedicationAdministration   Procedure   Observation	Events related to the procedure.

Class: Performer			
The people who performed the procedure.			
Name	Cardinality	Type	Description
actor	0..1	Practitioner   Organization   Patient   RelatedPerson	The reference to the practitioner.
role	0..1	CodeableConcept	The role the actor was in. Example value set: <a href="#">Procedure Performer Role Codes</a> .

Class: FocalDevice			
Device changed in procedure.			
Name	Cardinality	Type	Description
action	0..1	CodeableConcept	Kind of change to device. Value set: <a href="#">Procedure Device Action Codes</a> .
manipulated	1..1	Device	Device that was changed.

- Specimen**

Figure 35: SDD-INF-SPC: FHIR Specimen Model



Class: Specimen			
A sample to be used for analysis. Any material sample: taken from a biological entity, living or dead; taken from a physical object or the environment.			
Name	Cardinality	Type	Description
identifier	0..*	Identifier	External Identifier.
accessionIdentifier	0..1	Identifier	Identifier assigned by the lab.
status	1..1	code	<a href="#">SpecimenStatus</a> : available   unavailable   unsatisfactory   entered-in-error.
type	0..1	CodeableConcept	Kind of material that forms the specimen. Example value set: <a href="#">v2 Specimen Type</a> .

subject	1..1	Patient   Group   Device   Substance	Where the specimen came from. This may be from the patient(s) or from the environment or a device.
receivedTime	0..1	dateTime	The time when specimen was received for processing.
parent	0..*	Specimen	Specimen from which this specimen originated.
request	0..*	DiagnosticRequest   ProcedureRequest	Why the specimen was collected.
note	0..*	Annotation	Comments.

**Class: Collection**

Details concerning the specimen collection.

Name	Cardinality	Type	Description
collector	0..1	Practitioner	Who collected the specimen.
collected	0..1	dateTime   Period	Collection time.
quantity	0..1	SimpleQuantity	The quantity of specimen collected.
method	0..1	CodeableConcept	Technique used to perform collection. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-specimen-collection-method.html">http://hl7.org/fhir/2016Sep/valueset-specimen-collection-method.html</a>
bodySite	0..1	CodeableConcept	Anatomical collection site. Example value set: <a href="#">SNOMED CT Body Structures</a> .

**Class: Container**

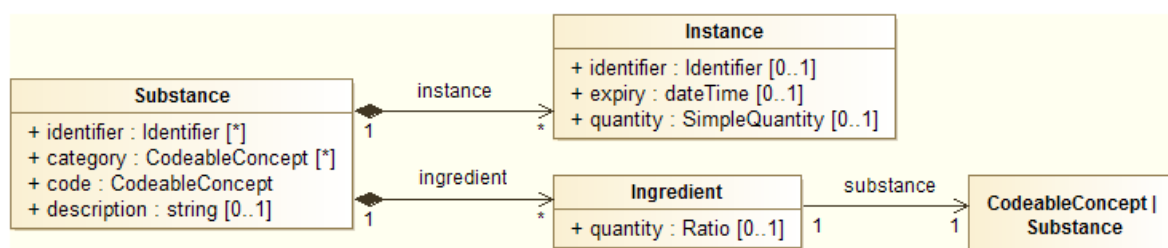
The container holding the specimen. The recursive nature of containers; i.e. blood in tube in tray in rack is not addressed here.

Name	Cardinality	Type	Description
identifier	0..*	Identifier	ID for the container.
description	0..1	string	Textual description of the container.
type	0..1	CodeableConcept	Kind of container directly associated with specimen. Example value set: <a href="http://hl7.org/fhir/2016Sep/valueset-specimen-container-type.html">http://hl7.org/fhir/2016Sep/valueset-specimen-container-type.html</a>
capacity	0..1	SimpleQuantity	Container volume or size.
specimenQuantity	0..1	SimpleQuantity	Quantity of specimen within container.
additive	0..1	CodeableConcept   Substance	Additive associated with container. Example value set: <a href="http://hl7.org/fhir/2016Sep/v2/0371/index.html">http://hl7.org/fhir/2016Sep/v2/0371/index.html</a>

Class: Treatment			
Details concerning treatment and processing steps for the specimen.			
Name	Cardinality	Type	Description
description	0..1	string	Textual description of procedure.
procedure	0..1	CodeableConcept	Indicates the treatment or processing step applied to the specimen. Example value set: <a href="#">SpecimenTreatmentProcedure</a> .
additive	0..*	Substance	Material used in the processing step.
time	0..1	dateTime   Period	Date and time of specimen treatment.

- Substance**

Figure 36: SDD-INF-SUB: FHIR Substance Model



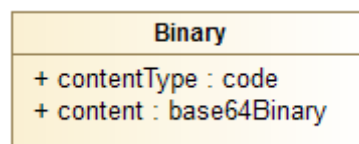
Class: Substance			
A homogeneous material with a definite composition. The resource can be used to represent either a kind of a substance - e.g., a formulation commonly used for treating patients, or it can be used to describe a particular package of a known substance (e.g., bottle, jar, packet).			
Name	Cardinality	Type	Description
identifier	0..*	Identifier	Unique identifier,
category	0..*	CodeableConcept	What class/type of substance this is. (Extensible) value set: <a href="#">Substance Category Codes</a> .
code	1..1	CodeableConcept	What substance this is. Example value set: <a href="#">Substance Code</a> .
description	0..1	string	Textual description of the substance, comments,

Class: Instance			
Substance may be used to describe a kind of substance, or a specific package/container of the substance: an instance. If this element is present, it describes a specific package/container of the substance. If this element is not present, then the substance resource describes a kind of substance.			
Name	Cardinality	Type	Description
identifier	0..1	Identifier	Identifier of the package/container,
expiry	0..1	dateTime	When no longer valid to use,
quantity	0..1	SimpleQuantity	Amount of substance in the package,

Class: Ingredient			
Composition information about the substance. A substance can be composed of other substances.			
Name	Cardinality	Type	Description
quantity	0..1	Ratio	The amount of the ingredient in the substance - a concentration ratio.
substance	1..1	CodeableConcept   Substance	A component of the substance. Example value set: <a href="#">Substance Code</a> .

- Binary**

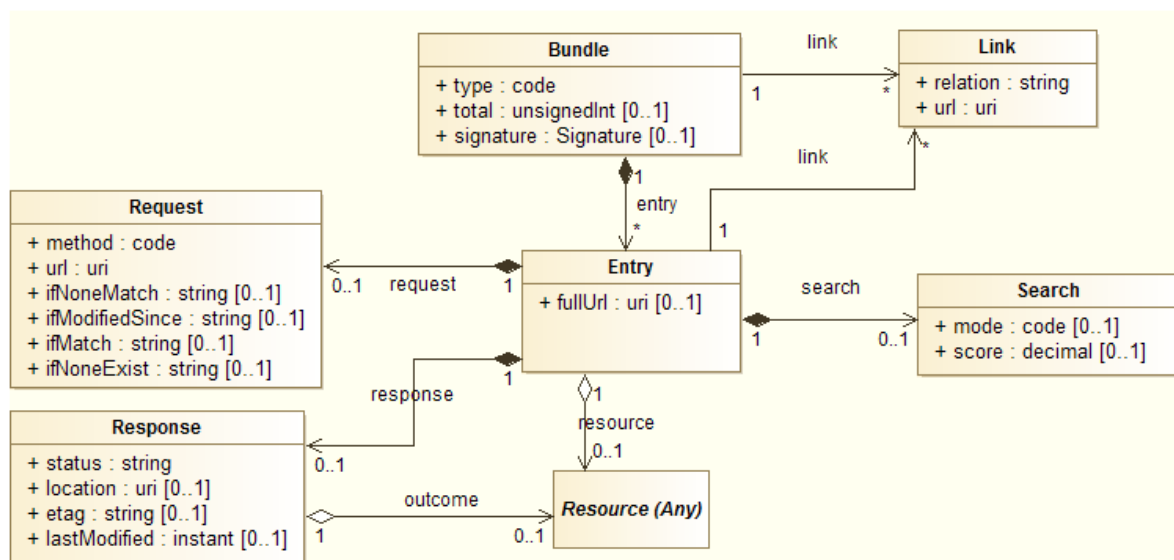
Figure 37: SDD-INF-BIN: FHIR Binary Model



Class: Binary			
A binary resource can contain any content, whether text, image, pdf, zip archive, etc.			
Name	Cardinality	Type	Description
contentType	1..1	code	MimeType of the binary content. Value set: <a href="#">MimeType</a>
content	1..1	base64Binary	The actual content, base64 encoded.

- Bundle**

Figure 38: SDD-INF-BUN: FHIR Bundle Model



**Class: Bundle**

A container for a collection of resources. One common operation performed with resources is to gather a collection of resources into a single instance with containing context. In FHIR this is referred to as "bundling" the resources together. These resource bundles are useful for a variety of different reasons, including: returning a set of resources that meet some criteria as part of a server operation e.g., RESTful Search; returning a set of versions of resources as part of the history operation on a server; sending a set of resources as part of a message exchange; grouping a self-contained set of resources to act as an exchangeable and persistable collection with clinical integrity e.g., a clinical document; creating /updating/deleting a set of resources on a server as a single operation (including doing so as a single atomic transaction); storing a collection of resources.

Name	Cardinality	Type	Description
type	1..1	code	Indicates the purpose of this bundle- how it was intended to be used. <a href="#">BundleType</a> value set: document   message   transaction   transaction-response   batch   batch-response   history   searchset   collection.
total	0..1	unsignedInt	If search, the total number of matches.
signature	0..1	Signature	Digital Signature.

**Class: Link**

A series of links that provide context to this bundle or bundle.entry.

Name	Cardinality	Type	Description
relation	1..1	string	<a href="http://www.iana.org/assignments/link-relations/link-relations.xhtml">http://www.iana.org/assignments/link-relations/link-relations.xhtml</a>
url	1..1	uri	Reference details for the link.

**Class: Entry**

An entry in a bundle resource - will either contain a resource, or information about a resource (transactions and history only).

Name	Cardinality	Type	Description
link	0..*	Link	Links related to this entry.
fullUrl	0..1	uri	Absolute URL for resource (server address, or UUID/OID).
resource	0..1	Resource	A resource in the bundle.

**Class: Search**

Information about the search process that lead to the creation of this entry.

Name	Cardinality	Type	Description
mode	0..1	code	<a href="#">SearchEntryMode</a> : match   include   outcome - why this is in the result set.
score	0..1	decimal	Search ranking (between 0 and 1).

**Class: Request**

Transaction related information about how this entry should be processed as part of a transaction.

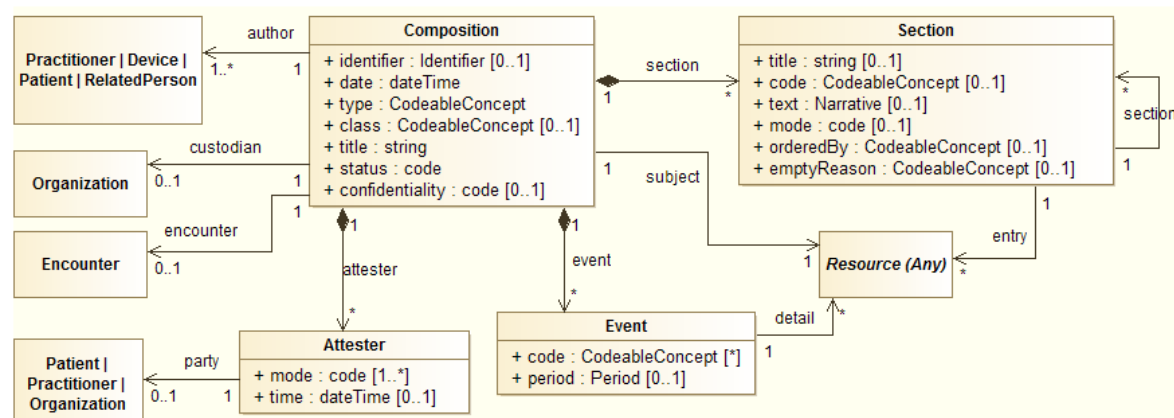
Name	Cardinality	Type	Description
method	1..1	code	<a href="#">HTTPVerb</a> : GET   POST   PUT   DELETE.
url	1..1	uri	URL for HTTP equivalent of this entry.
ifNoneMatch	0..1	string	If the ETag values match, return a 304 Not modified status.
ifModifiedSince	0..1	instant	Only perform the operation if the last updated date matches.
ifMatch	0..1	string	Only perform the operation if the Etag value matches.
ifNoneExist	0..1	string	Instruct the server not to perform the create if a specified resource already exists.

**Class: Response**

Transaction related information about how this entry should be processed as part of a transaction.

Name	Cardinality	Type	Description
status	1..1	string	The status code returned by processing this entry. The status SHALL start with a 3 digit HTTP code (e.g. 404) and may contain the standard HTTP description associated with the status code.
location	0..1	uri	The location header created by processing this operation.
etag	0..1	string	The etag for the resource (if relevant).
lastModified	0..1	instant	The date/time that the resource was modified on the server.
outcome	0..1	Resource	An OperationOutcome containing hints and warnings produced as part of processing this entry in a batch or transaction.

- Composition**

**Figure 39: SDD-INF-CMP: FHIR Composition Model**



**Class: Composition**

A set of healthcare-related information that is assembled together into a single logical document that provides a single coherent statement of meaning, establishes its own context and that has clinical attestation with regard to who is making the statement. While a Composition defines the structure, it does not actually contain the content: rather the full content of a document is contained in a Bundle, of which the Composition is the first resource contained.

Name	Cardinality	Type	Description
identifier	0..1	Identifier	Logical identifier for the composition, assigned when created. This identifier stays constant as the composition is changed over time.
date	1..1	dateTime	Composition editing time.
type	1..1	CodeableConcept	Kind of composition (LOINC if possible). Preferred value set: <a href="#">FHIR Document Type Codes</a>
class	0..1	CodeableConcept	Categorization of Composition. Example value set: <a href="#">FHIR Document Class Codes</a> .
title	1..1	string	Human Readable name/title.
status	1..1	code	<a href="#">CompositionStatus</a> : preliminary   final   amended   entered-in-error.
confidentiality	0..1	code	As defined by affinity domain. Value set: <a href="https://www.hl7.org/fhir/2016Sep/v3/ConfidentialityClassification/vs.html">https://www.hl7.org/fhir/2016Sep/v3/ConfidentialityClassification/vs.html</a>
subject	1..1	Resource (Any)	Who and/or what the composition is about.
author	1..*	Practitioner   Device   Patient   RelatedPerson	Who and/or what authored the composition.
custodian	0..1	Organization	Organisation which maintains the composition.
encounter	0..1	Encounter	Context of the Composition.

**Class: Attester**

A participant who has attested to the accuracy of the composition/document.

Name	Cardinality	Type	Description
mode	1..*	code	<a href="#">CompositionAttestationMode</a> : personal   professional   legal   official.
time	0..1	dateTime	When composition attested.
party	0..1	Patient   Practitioner   Organization	Who attested the composition.

**Class: Event**

The clinical service, such as a colonoscopy or an appendectomy, being documented.

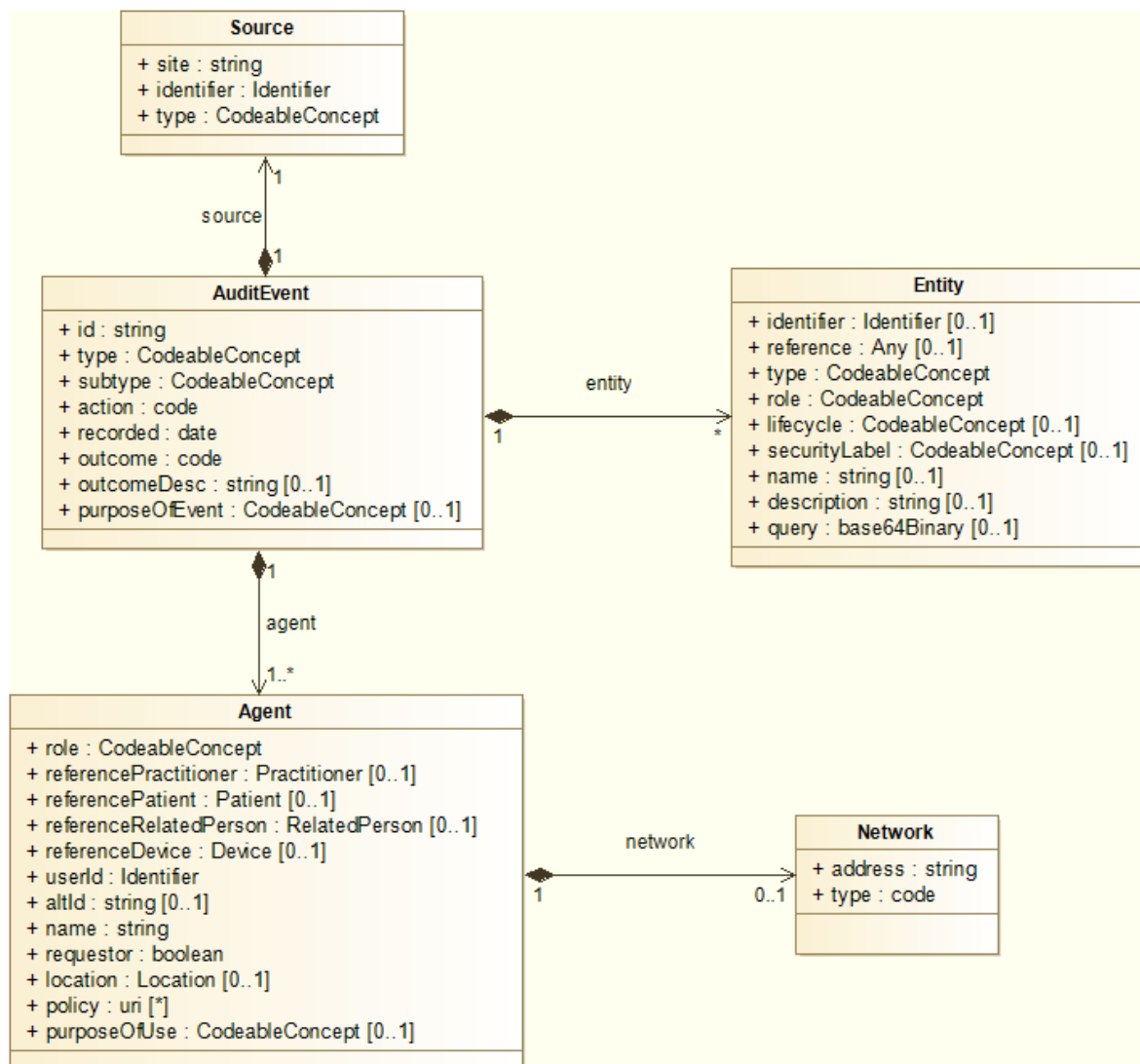
Name	Cardinality	Type	Description
code	0..*	CodeableConcept	Code(s) that apply to the event being documented. Example value set: <a href="#">v3 Code System ActCode</a> .

period	0..1	Period	The period covered by the documentation.
detail	0..*	Resource (Any)	The event(s) being documented.

Class: Section			
Composition is broken into sections. A section must have at least one of text, entries, or sub-sections. A section can only have an emptyReason if it is empty.			
Name	Cardinality	Type	Description
title	0..1	string	Label for section (e.g., for ToC).
code	0..1	CodeableConcept	Classification of section. Example value set: <a href="https://www.hl7.org/fhir/2016Sep/valueset-doc-section-codes.html">https://www.hl7.org/fhir/2016Sep/valueset-doc-section-codes.html</a>
text	0..1	Narrative	Text summary of the section, for human interpretation.
Mode	0..1	code	<a href="#">ListMode</a> : working   snapshot   changes.
orderedBy	0..1	CodeableConcept	Order of section entries. Preferred value set: <a href="#">List Order Codes</a> .
entry	0..*	Resource (Any)	A reference to data that supports this section.
emptyReason	0..1	CodeableConcept	Why the section is empty. Preferred value set: <a href="#">List Empty Reasons</a> .
section	0..*	Section	A nested sub-section within this section.

## 4.4. Audit Trail Record

C3-Cloud Audit Trail Record information model is based on the FHIR STU3 AuditEvent Resource model [AUDITEVENT]. C3-Cloud will have its own AuditEvent profile, which is a specialization of the generic AuditEvent resource for use in the C3-Cloud context. In FHIR, profiling basically involves changing cardinality of attributes, removing some optional attributes and adding some new attributes to existing resources according to the needs of a specific context. In this section, the information view of AuditEvent as it will be used in the C3-Cloud project, i.e. C3-Cloud AuditEvent Profile, is presented.

**Figure 40: SDD-INF-ATR: Audit Trail Record Model**

Class: AuditEvent			
Name	Cardinality	Type	Description
id	1..1	string	Unique identifier of the AuditEvent instance.
type	1..1	CodeableConcept	Type of event. Selected from Audit Event ID value set (e.g. RESTful operation, User Authentication).
subtype	1..1	CodeableConcept	More specific type of the event. Selected from Audit Event Sub-Type value set (e.g. vread, update, login, logout).
action	1..1	code	Type of action performed during the event. Selected from AuditEventAction value set (e.g. create, update, delete).
recorded	1..1	date	Exact time when the event occurred on source.
outcome	1..1	code	Whether the event succeeded or failed. Selected from AuditEventOutcome value set (e.g., success, minor failure, serious failure).

outcomeDesc	0..1	string	Description of the event outcome.
purposeOfEvent	0..1	CodeableConcept	The reason that was used during the event being recorded. Selected from PurposeOfUse value set (e.g. legal, records management).
source	1..1	Source	Audit event reporter.
agent	1..*	Agent	Any system or human user actor involved in the event.
entity	0..*	Entity	Data or objects used / accessed as the subject of the event.

Class: Source			
Name	Cardinality	Type	Description
site	1..1	string	Logical source location within the enterprise.
identifier	1..1	Identifier	The identity of source detecting the event.
type	1..1	CodeableConcept	The type of source where event originated. Selected from Audit Event Source Type value set (e.g. User Device, Application Server).

Class: Agent			
Name	Cardinality	Type	Description
role	1..1	CodeableConcept	The role of the agent in the event. Selected from Audit agent Role ID Code value set (e.g. Source Role ID, Application Launcher).
referencePractitioner	0..1	Practitioner	Direct reference to the agent itself, when the agent is a Practitioner.
referencePatient	0..1	Patient	Direct reference to the agent itself, when the agent is a Patient.
referenceRelatedPerson	0..1	RelatedPerson	Direct reference to the agent itself, when the agent is a RelatedPerson.
referenceDevice	0..1	Device	Direct reference to the agent itself, when the agent is a Device (including both medical and non-medical devices such as software).
userId	1..1	Identifier	Unique identifier of the agent.
altId	0..1	string	Alternative user identifier of the agent (e.g. authentication name).
name	1..1	string	Human-meaningful name of the agent.
requestor	1..1	boolean	Indicator that the user is or is not the requestor, or initiator, for the event being audited. There can only be one initiator.
location	0..1	Location	Where the event occurred.
policy	0..*	uri	The policy or plan that authorized the activity being recorded. For example, where a policy engine (e.g. XACML) holds policy logic, the unique policy identifier is placed into this attribute.
purposeOfUse	0..1	CodeableConcept	The reason, specific to this agent that was used during the event being

			recorded. Selected from PurposeOfUse value set (e.g., legal, records management).
network	0..1	Network	Logical network location for application activity, if the activity has a network location.

Class: Network			
Name	Cardinality	Type	Description
address	1..1	string	An identifier for the network access point of the user device for the audit event. This datum identifies the user's network access point, which may be distinct from the server that performed the action. The value could be an IP address or a device ID.
type	1..1	code	The type of network access point. Selected from AuditEventAgentNetworkType value set (e.g. IP Address, Machine Name).

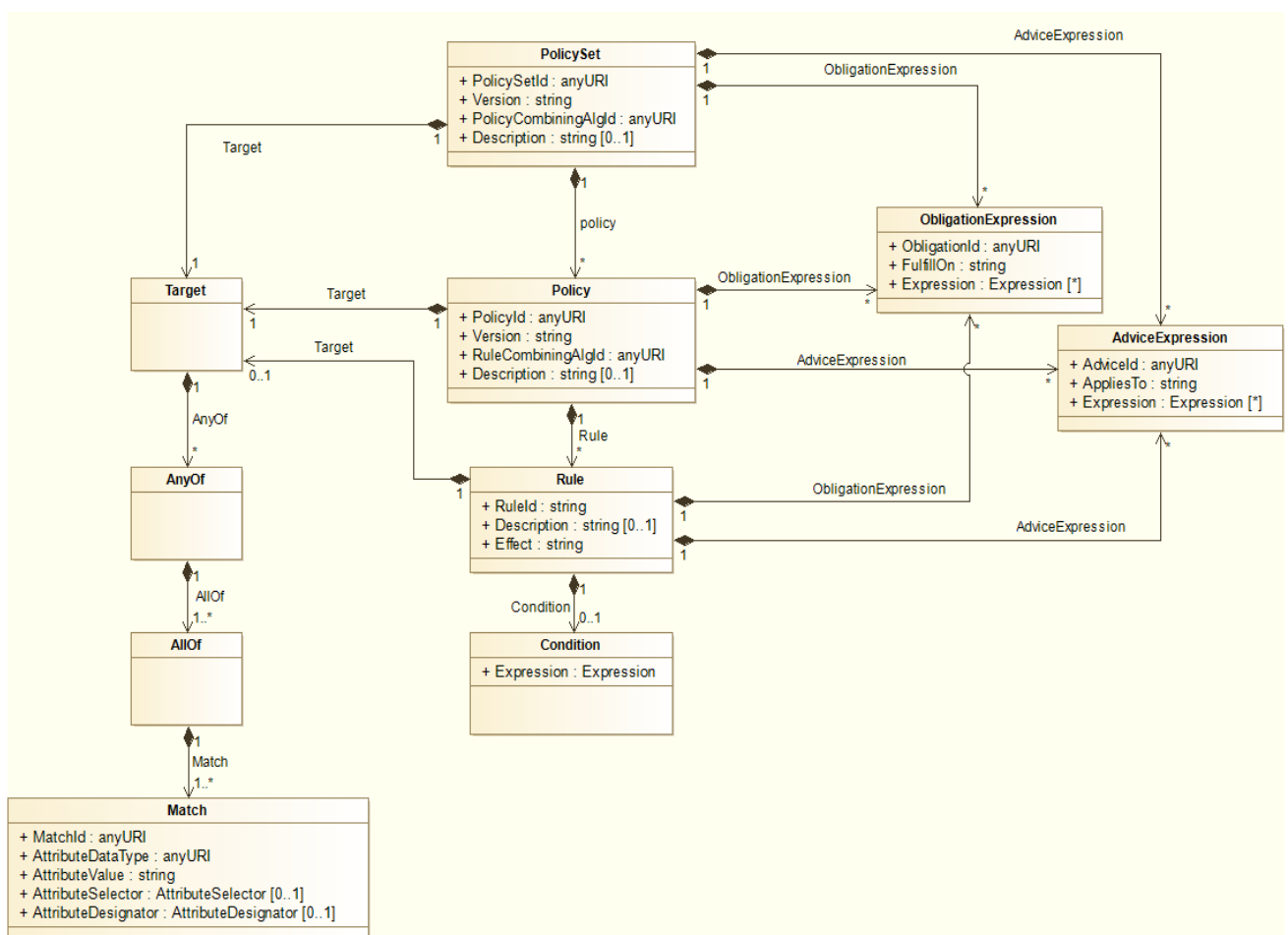
Class: Entity			
Name	Cardinality	Type	Description
identifier	0..1	Identifier	The identifier of the specific instance of entity.
reference	0..1	Any	If the entity being used/accessed is a FHIR resource, the reference of the entity is provided. It can be a CarePlan, Condition, Patient, Procedure ... instance. The reference should be version specific.
type	1..1	CodeableConcept	The type of the entity. Selected from AuditEventEntityType value set (e.g., Person, System Object).
role	1..1	CodeableConcept	The role the entity played in the event. Selected from AuditEventEntityRole value set (e.g., Patient, Domain Resource).
lifecycle	0..1	CodeableConcept	Data life-cycle stage for the entity. Selected from AuditEventEntityLifecycle value set (e.g., Access / Use, Amendment, Export).
securityLabel	0..1	CodeableConcept	Identifies the security label for a specific instance of an object. Selected from All Security Labels value set (e.g., low, moderate, very restricted).
name	0..1	string	A name of the entity in the audit event. Either a name or query shall exist.
description	0..1	string	Additional text that describes the entity in more detail.
query	0..1	base64Binary	Base64 encoded query parameters for query-type entities. For query events, it may be necessary to capture the actual query input to the query process in order to identify the specific event. Either a name or query shall exist.

## 4.5. Access Control Policy

In C3-Cloud, access control policies will be represented in OASIS Access Control Markup Language Version 3.0 [XACML]. Some important terms that will be used in the attribute descriptions are explained below:

- Policy administration point: The system entity that creates a policy or policy set.
- Policy decision point: The system entity that evaluates applicable policy and renders an authorisation decision.
- Policy enforcement point: The system entity that performs access control, by making decision requests and enforcing authorisation decisions.

**Figure 41: SDD-INF-ACP: Access Control Policy Model**



Class: Policy			
Name	Cardinality	Type	Description
PolicyId	1..1	anyURI	A unique identifier for the policy instance.
Version	1..1	string	Version of the policy instance.
RuleCombiningAlgId	1..1	anyURI	Specifies the procedure by which the results of evaluating the component

			rules are combined when evaluating the policy. Normative rule combining algorithms defined in the XACML specification (e.g., deny-overrides, deny-unless-permit) will be used.
Description	0..1	string	Free text description of the policy instance.
Rule	0..*	Rule	The set of component rules in the policy.
Target	1..1	Target	Specifies the set of requests to which the policy applies.
ObligationExpression	0..*	ObligationExpression	When a PDP evaluates a policy containing obligation expressions, it evaluates the obligation expressions into obligations and returns certain of those obligations to the PEP in the response context.
AdviceExpression	0..*	AdviceExpression	When a PDP evaluates a policy containing advice expressions, it evaluates the advice expressions into advice and returns certain of those advice to the PEP in the response context. In contrast to obligations, advice may be safely ignored by the PEP.

Class: PolicySet			
Name	Cardinality	Type	Description
PolicySetId	1..1	anyURI	A unique identifier for the policy set instance.
Version	1..1	string	Version of the policy set instance.
PolicyCombiningAlgId	1..1	anyURI	Specifies the procedure by which the results of evaluating the component policies are combined when evaluating the policy set. Normative policy combining algorithms defined in the XACML specification (e.g. deny-overrides, deny-unless-permit) will be used.
Description	0..1	string	Free text description of the policy set instance.
Policy	0..*	Policy	The set of component policies in the policy set.
Target	1..1	Target	Specifies the set of requests to which the policy set applies.
ObligationExpression	0..*	ObligationExpression	As described in Policy.
AdviceExpression	0..*	AdviceExpression	As described in Policy.

Class: Rule			
Name	Cardinality	Type	Description
RuleId	1..1	string	A unique identifier for the rule instance.
Description	0..1	string	Free text description of the rule instance.
Effect	1..1	string	The effect of the rule indicates the rule-writer's intended consequence of a "True" evaluation for the rule. Two values are allowed: "Permit" and "Deny".
Target	0..1	Target	Defines the set of requests to which the rule is intended to apply in the form of a logical expression on attributes in the request. If it is absent, then the target of the Rule is the same as that of the parent Policy element.
Condition	0..1	Condition	Represents a Boolean expression that refines the applicability of the rule beyond the predicates implied by its target. Therefore, it may be absent.
ObligationExpression	0..*	ObligationExpression	As described in Policy.
AdviceExpression	0..*	AdviceExpression	As described in Policy.

Class: Condition			
Name	Cardinality	Type	Description
Expression	1..1	Expression	A Boolean function over attributes or functions of attributes. There are several sub-classes to define the expression, e.g. AttributeDesignator, AttributeValue, AttributeSelector.

Class: Match			
Name	Cardinality	Type	Description
MatchId	1..1	anyURI	Specifies a matching function; e.g. name-match, xpath-node-match.
AttributeDataType	1..1	anyURI	The data type of the attribute being defined; e.g., xs:string.
AttributeValue	1..1	string	The exact value of the attribute being defined.
AttributeDesignator	0..1	AttributeDesignator	Used for retrieving a bag of values for a named attribute (e.g., patient-number, subject-id) from the request context. Either AttributeSelector or AttributeDesignator shall be present; not both.
AttributeSelector	0..1	AttributeSelector	Used for producing a bag of unnamed and uncategorised attribute values. The values shall be constructed from the node(s) selected by applying the XPath expression defined in Path



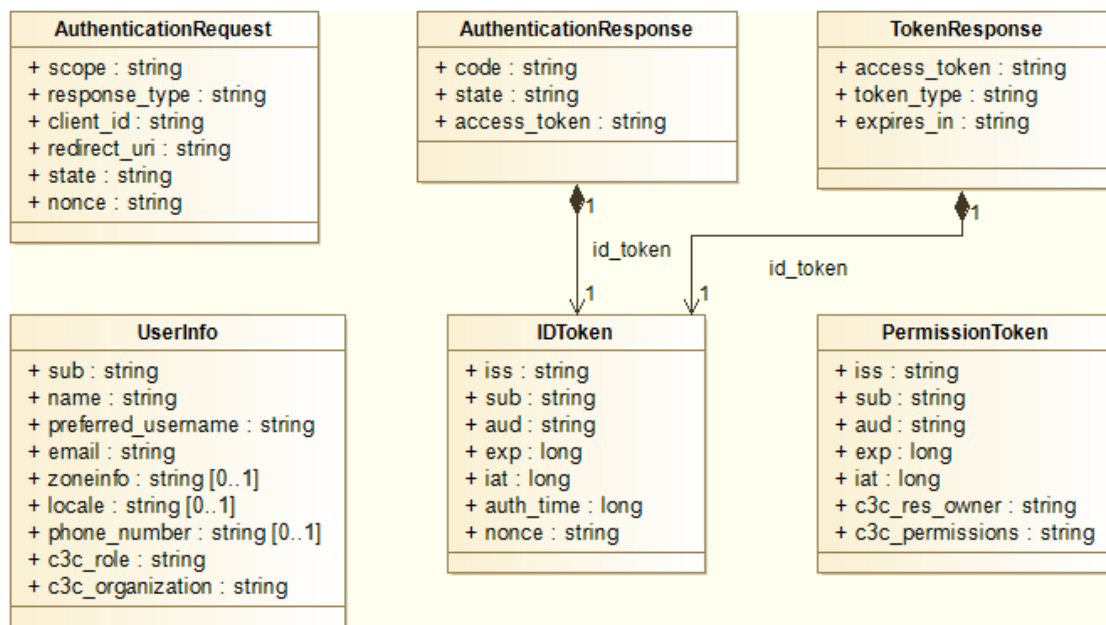
			attribute to the XML content indicated by the Category attribute. Either AttributeSelector or AttributeDesignator shall be present; not both.
--	--	--	---

Class: ObligationExpression			
Name	Cardinality	Type	Description
ObligationId	1..1	anyURI	Obligation identifier. This value shall be interpreted by the PEP.
FulfillOn	1..1	string	The effect for which this obligation must be fulfilled by the PEP. Two values are allowed: "Permit" and "Deny".
Expression	0..*	Expression	A set of expressions that form arguments of the action defined by the obligation. The expressions SHALL be evaluated by the PDP to constant AttributeValue elements or bags, which shall be the attribute assignments in the Obligation returned to the PEP.

Class: AdviceExpression			
Name	Cardinality	Type	Description
AdviceId	1..1	anyURI	Advice identifier. This value may be interpreted by the PEP.
AppliesTo	1..1	string	The effect for which this advice must be provided to the PEP. Two values are allowed: "Permit" and "Deny".
Expression	0..*	Expression	A set of expressions that form that form arguments of the supplemental information defined by the advice. The expressions SHALL be evaluated by the PDP to constant AttributeValue elements or bags, which shall be the attribute assignments in the Advice returned to the PEP.

## 4.6. Authentication & Authorization

In this section, information models that will be used in authentication and authorisation of all non-patient users in the C3-Cloud architecture are explained in detail. These models are all based on OpenID Connect 1.0 and OAuth 2.0 standards, with some extensions when necessary.

**Figure 42: SDD-INF-AUN: Authentication Model**

Class: AuthenticationRequest			
Name	Cardinality	Type	Description
scope	1..1	string	OpenID Connect requests MUST contain the “openid” scope value.
response_type	1..1	string	OAuth 2.0 Response Type value that determines the authorization processing flow to be used, including what parameters are returned from the endpoints used. It will be “code id_token token” in our case.
client_id	1..1	string	Identifier assigned to the client in C3-Cloud. Clients for C3-Cloud will be registered at deployment via a configuration file.
redirect_uri	1..1	string	Redirection URI to which the response will be sent.
state	1..1	string	Opaque value used to maintain state between the request and the callback.
nonce	1..1	string	String value used to associate a Client session with an ID Token, and to mitigate replay attacks. The value is passed through unmodified from the Authentication Request to the ID Token.

Class: AuthenticationResponse			
Name	Cardinality	Type	Description
code	1..1	string	Authorisation code to be used to access the Token Endpoint. The code will expire in 10 minutes and can only be used once, therefore it is expected to be used immediately.
state	1..1	string	The same value in Authentication Request. Client will verify this for Cross-Site Request Forgery (CSRF) mitigation.
access_token	1..1	string	OAuth 2.0 Access Token, which is needed for sending a request to User Info endpoint.

id_token	1..1	IDToken	ID Token that identity information of user is embedded in.
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Class: IDToken (a JSON Web Token [JWT])			
Name	Cardinality	Type	Description
iss	1..1	string	Issuer Identifier for the Issuer of the response. The iss value is a case sensitive URL using the https scheme that contains scheme, host, and optionally, port number and path components.
sub	1..1	string	Subject Identifier. A locally unique and never reassigned identifier within the Issuer for the subject (end-user), which is intended to be consumed by the Client.
aud	1..1	string	Audience that this ID Token is intended for. It MUST contain the OAuth 2.0 client_id of the Relying Party as an audience value.
exp	1..1	long	Expiration time on or after which the ID Token MUST NOT be accepted for processing.
iat	1..1	long	Time at which the JWT was issued. Its value is a JSON number representing the number of seconds from 1970-01-01T0:0:0Z as measured in UTC until the date/time.
auth_time	1..1	long	Time when the End-User authentication occurred.
nonce	1..1	string	String value used to associate a Client session with an ID Token, and to mitigate replay attacks. The value is passed through unmodified from the Authentication Request to the ID Token.

Class: TokenResponse			
Name	Cardinality	Type	Description
access_token	1..1	string	OAuth 2.0 Access Token, which is needed for sending a request to User Info endpoint.
token_type	1..1	string	“Bearer”
expires_in	1..1	string	The lifetime in seconds of the access token.
id_token	1..1	IDToken	ID Token that identity information of user is embedded in.

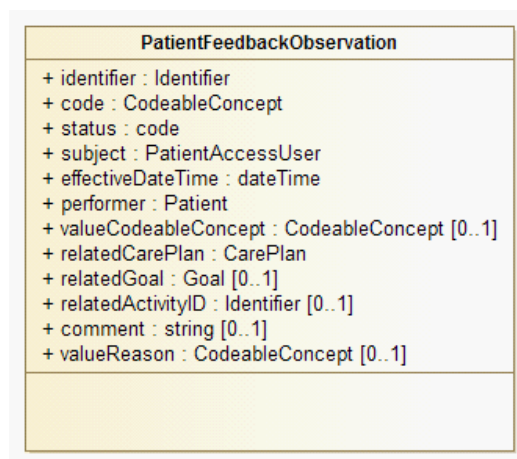
Class: UserInfo			
Name	Cardinality	Type	Description
sub	1..1	string	Subject (user) identifier.
name	1..1	string	Full name of user.
preferred_username	1..1	string	Username of user.
email	1..1	string	Email address of the user, which is linked with his identity at the issuer.
zoneinfo	0..1	string	Time zone of the user.
locale	0..1	string	User’s locale, represented as language tag (e.g. en-US, fr-CA).
phone_number	0..1	string	Preferred phone number of the user.

c3c_role	1..1	string	Structural role of the user (e.g., physician, nurse, social care worker). This is a C3-Cloud extension.
c3c_organization	1..1	string	The organization that the user is working for. This is a C3-Cloud extension.

Class: PermissionToken (a JSON Web Token [JWT])			
Name	Cardinality	Type	Description
iss	1..1	string	Issuer Identifier for the Issuer of the response.
sub	1..1	string	Subject Identifier. A locally unique and never reassigned identifier within the Issuer for the subject (end-user).
aud	1..1	string	The identifier assigned to client that this token is given to.
exp	1..1	long	Expiration time on or after which this token MUST NOT be accepted for processing.
iat	1..1	long	Time at which this JWT was issued.
c3c_res_owner	1..1	string	The owner of resources represented as encrypted value of Anonymous Patient Identifier assigned to patient.
c3c_permissions	1..1	string	The list of permissions bounded to this permission token (e.g., read, write permissions expressed on top of specific resource types).

## 4.7. Patient Feedback Observation

Figure 43: SDD-INF-PFO: Patient Feedback Observation Model



Class: PatientFeedbackObservation			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this PatientFeedbackObservation instance.
code	1..1	CodeableConcept	One code which must have.

			a fixed coding.system='http://loinc.org' a fixed code= '51855-5' (Patient Note).
status	1..1	code	The status of the feedback observation. It can be set as 'final' from the ObservationStatus value set ( <a href="http://hl7.org/fhir/observation-status">http://hl7.org/fhir/observation-status</a> ).
subject	1..1	Patient	Identifies the patient whose care plan is being commented on. A Reference to the Patient instance will be provided.
effectiveDateTime	1..1	dateTime	The time the observation is asserted as being true.
performer	1..1	PatientAccessUser (Patient RelatedPerson)	The Patient or Informal Care Giver reporting the feedback observation. A Reference to the Patient or RelatedPerson instance will be provided.
valueCodeableConcept	0..1	CodeableConcept	A coded representation of the status feedback reported by the patient about the selected goal and/or activity of the care plan. Selected from PatientReportedGoalStatus value set (see below) when feedback is provided for a goal. Selected from PatientReportedActivityStatus value set (see below) when feedback is provided for an activity.
relatedCarePlan	1..1	CarePlan	The Care Plan about which the feedback is being reported.
relatedGoal	0..1	Goal	The specific goal instance in the selected care plan about which the feedback is being reported.
relatedActivityId	0..1	Identifier	The unique ID of the activity instance in the selected care plan about which the feedback is being reported.
Comment	0..1	string	Patient feedback being reported in free text format.
valueReason	0..1	CodeableConcept	Captures the reason for the current status feedback. Selected from PatientReportedStatusReason value set (see below).

ValueSet: PatientReportedGoalStatus		
code	Display	Definition
in-progress	In Progress	The goal is being sought but has not yet been reached. <i>Patient says 'I have started to achieve this goal'.</i>
achieved	Achieved	The goal has been met and no further action is needed. <i>Patient says: 'I have achieved this goal'.</i>
not-achievable	Not Achievable	The goal is no longer achievable by the patient. <i>Patient says: 'I cannot achieve this goal'.</i>
sustaining	Sustaining	The goal has been met, but ongoing activity is needed to sustain the goal objective. <i>Patient says: 'I have achieved the goal but I am keeping on with the activities to sustain it'.</i>
on-hold	On Hold	The goal remains a long term objective but is no longer being actively pursued for a temporary period of time. <i>Patient says: 'I want to put this goal on hold'.</i>
cancelled	Cancelled	The goal is no longer being sought. <i>Patient says: 'I want to cancel this goal'.</i>
on-target	On Target	The goal is on scheduled for the planned timelines. <i>Patient says ('I'm on target with this goal').</i>
ahead-of-target	Ahead of Target	The goal is ahead of the planned timelines. <i>Patient says ('I'm on ahead of the set schedule to achieve this goal').</i>
behind-target	Behind Target	The goal is behind the planned timelines. <i>Patient says ('I'm behind the set schedule to achieve this goal').</i>

ValueSet: PatientReportedActivityStatus		
code	Display	Definition
in-progress	In Progress	The activity is progressing as planned. <i>Patient says ('I'm carrying out the activity, it is in progress').</i>
achieved	Achieved	The activity is completed. <i>Patient says ('I have finished this activity').</i>
not-achievable	Not Achievable	The activity is no longer achievable by the patient. <i>Patient says ('I cannot achieve this activity').</i>
on-hold	On Hold	Activity was started but has temporarily ceased with an expectation of resumption at a future time. <i>Patient says ('I had to stop this activity, but I will continue afterwards').</i>
cancelled	Cancelled	The activities have been ended prior to completion (perhaps even before they were started). <i>Patient says: 'I had to stop this activity'.</i>
not-started	Not Started	Activity is planned but no action has yet been taken. <i>Patient says: 'I haven't started to carry out this activity yet'.</i>

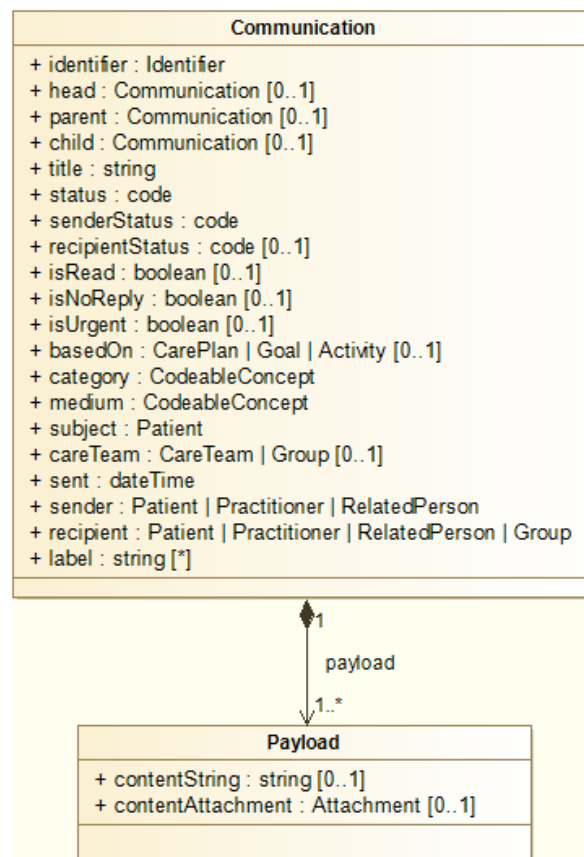
ValueSet: PatientReportedStatusReason		
code	Display	Definition
difficulty	Difficult	The patient is experiencing difficulty in carrying out the activity/achieving the goal.
financial-barrier	Financial reason	Goal cannot be reached due to financial barrier or reason.

		Activity cannot be carried out due to financial barrier or reason.
lack-of-transportation	Lack of transportation	Goal cannot be reached due to a lack of transportation. Activity cannot be carried out due to a lack of transportation.
lack-of-social-support	Lack of social support	Goal cannot be reached due to a lack of social support. Activity cannot be carried out due to a lack of social support.
life-event	life event	Goal suspended or ended because of a significant life event (marital change, bereavement, etc.). Activity cannot be carried out because of a significant life event (marital change, bereavement, etc.).

## 4.8. Safe Message

C3-Cloud Safe Message information model is based on FHIR Communication resource, with some extensions and further refinement.

**Figure 44: SDD-INF-SM: Safe Message Model**



Class: Communication			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier of the Communication instance.
head	0..1	Communication	Reference to the first Communication instance of a conversation.
parent	0..1	Communication	Reference to the parent Communication instance if this is a response.
child	0..1	Communication	Reference to the child (i.e. response) Communication instance in the conversation. In order to fill this attribute, when there is response to a message, that parent message needs to be updated retrospectively.
title	1..1	string	The title of the message in plain string.
status	1..1	code	Type of action performed during the event. Selected from CommunicationStatus value set (e.g., in-progress, completed, failed).
senderStatus	1..1	code	The status of the message from the sender's perspective. Selected from a locally defined CommunicationSenderStatus value set (e.g. draft, sent, deleted).
recipientStatus	0..1	code	The status of the message from the recipient's perspective. Selected from a locally defined CommunicationRecipientStatus value set (e.g. received, deleted).
isRead	0..1	boolean	Used to indicate whether the message is read by the recipient.
isNoReply	0..1	boolean	Used to indicate a message sent by a Health Professional can only be read but not replied by the Patient.
isUrgent	0..1	boolean	Used to express the urgency of a message. Default value is false.
basedOn	0..1	CarePlan   Goal   Activity	Reference to a specific Activity or Goal within the CarePlan, or directly the CarePlan itself, within the scope of which safe messaging takes place.
category	1..1	CodeableConcept	The type of message conveyed. Might be used to distinguish messages created by persons vs. by intelligent systems. Selected from a locally defined CommunicationCategory value set (e.g.,

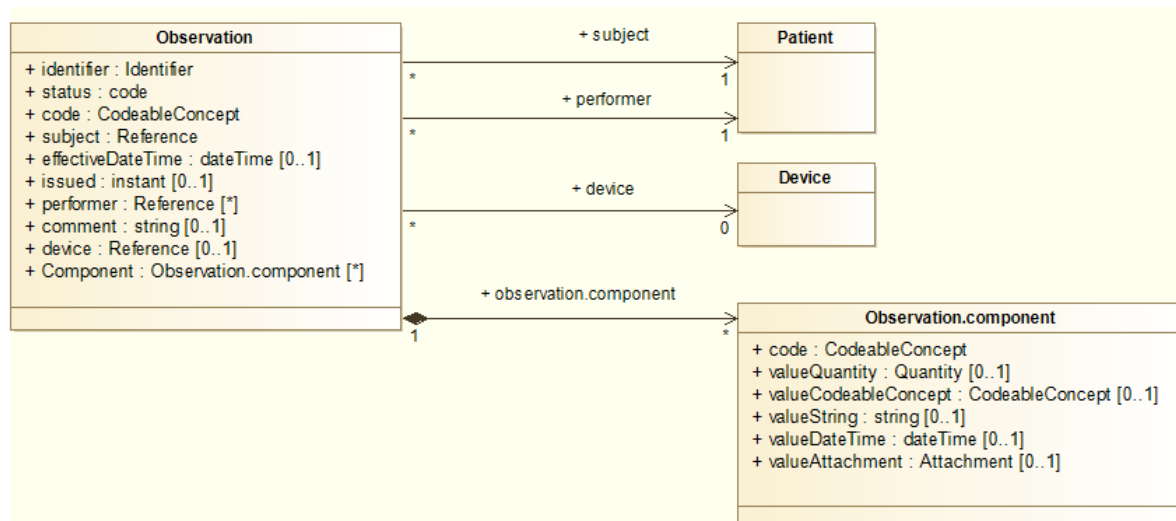


			human-message, system-notification, system-reminder).
medium	1..1	CodeableConcept	The channel of communication. In C3-Cloud case, might be fixed to “ONLINEWRIT: online written” code from the v3 ParticipationMode code system.
subject	1..1	Patient	Reference to the Patient who is the focus of this Communication.
careTeam	0..1	CareTeam   Group	Reference to the CareTeam or Group who is involved in this Communication, either directly (e.g. Patient sends a message to whole CareTeam) or indirectly (e.g. Practitioner as a part of the CareTeam sends a message to the Patient).
sent	1..1	dateTime	The time message is sent.
sender	1..1	Patient   Practitioner   RelatedPerson	Reference to the sender of the message.
recipient	1..1	Patient   Practitioner   RelatedPerson   Group	Reference(s) to the recipient(s) of the message. [Note: Ideally, instead of the Group resource, it is better to have CareTeam in C3-Cloud case, but it is not possible to do such an extension in FHIR]
payload	1..*	Payload	The actual message content that is communicated to the recipient(s).
label	0..*	string	Optional labels to categorize safe messages in the message box, just like in gmail. This attribute is not for exchange between systems, but for internal use.

Class: Payload			
Name	Cardinality	Type	Description
contentString	0..1	string	Text communicated in the message as payload.
contentAttachment	0..1	Attachment	Attachment (e.g., a PDF report) communicated in the message as payload.

## 4.9. Device Observation

Figure 45: SDD-INF-DVO: Device Observation Model



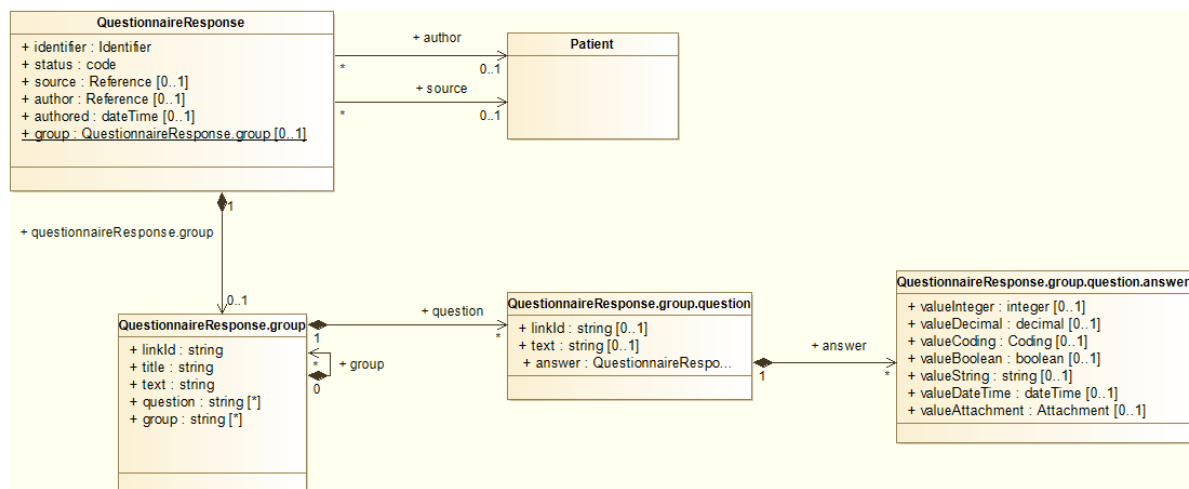
Class: Observation			
Name	Cardinality	Type	Description
identifier	1..1	Identifier	Unique identifier associated with this Observation instance. Example: "id":"143467".
status	1..1	code	From value set observation-status (registered   preliminary   final   amended). Example: "status":"final".
code	1..1	CodeableConcept	Type of observation (code / type). Example: "code":{ "coding":[{ "system":"http://loinc.org", "code":"55284-4", "display":"Blood pressure systolic & diastolic"}] }.
subject	0..1	Reference(Patient)	Who and/or what this is about. Example: "subject":{ "reference":"Patient/143258"}.
effectiveDateTime	0..1	dateTime	Clinically relevant time/time-period for observation. Example: "effectiveDateTime":"2016-08-25T13:28:23+00:00".
issued	0..1	instant	Date/Time this was made available. Example: "issued":"2016-08-25T13:31:14.074+00:00".
performer	0..*	Reference ( Practitioner   Organization   Patient   RelatedPerson)	Who is responsible for the observation. Example: "performer":[{ "reference":"Patient/143258"}].
comments		string	Comments about result. Example: "comments":"Source: Medixine BloodPressure observation gvbbn6daayzwrnfxs7plmrkq88u45cog"

device	0..1	Reference (Device)	(Measurement) Device. Example: "device":{"reference":"#5121000500", "display":"A&D UA-767PBT 5121000500"}.
Component	0..*	BackboneElement	Component results. See Observation.component for details.

Class: Observation.component			
Name	Cardinality	Type	Description
code	1..1	CodeableConcept	Unique identifier associated with this Observation instance. Example: "id":"143467".
valueQuantity	0..1		Actual component quantity result.
valueCodeableConcept	0..1	CodeableConcept	Actual component codable concept result.
valueString	0..1		Actual component string result.
valueDateTime	0..1		Actual component datetime result.
valueAttachment	0..1	Attachment	Actual component attachment result.

## 4.10. Questionnaire Response

Figure 46: SDD-INF-QR: Questionnaire Response Model



Class: QuestionnaireResponse			
Name	Cardinality	Type	Description
identifier	1..1	identifier	Unique ID for this set of answers. Example: "id":"122299".
status	1..1	code	From value set QuestionnaireResponseStatus (in-progress   completed   amended). Example: "status":"completed".
source	0..1	Reference (	The person who answered the questions.

		Patient   Practitioner   RelatedPerson)	Example: "subject":{"reference":"Patient/113634"}.
author	0..1	Reference ( Patient   Practitioner   RelatedPerson)	Person who received and recorded the answers. Example: "author":{"reference":"Patient/113634"}.
authored	0..1	datetime	Date this version was authored. Example: "authored":"2016-06-20".
group	0..1	BackboneElement	Grouped questions.Groups may either contain questions or groups but not both. See QuestionnaireResponse.group for details.

Class: QuestionnaireResponse.group			
Name	Cardinality	Type	Description
linkId	0..1	string	Corresponding question within Questionnaire Example: "linkId":"y8y3vah8vo6az3wcmjfv0q4w8oq0z6ja".
title	0..1	string	Name for this group.
text	0..1	string	Additional text for the group.
question	0..*	BackboneElement	Questions in this group. See QuestionnaireResponse.group.question for details.
group	0..*	BackboneElement	Nested questionnaire response group.

Class: QuestionnaireResponse.group.question			
Name	Cardinality	Type	Description
linkId	0..1	string	Corresponding question within Questionnaire.
text	0..1	string	Text of the question as it is shown to the user.
answer	0..*	BackboneElement	The response(s) to the question. QuestionnaireResponse.group.question.answer for details.

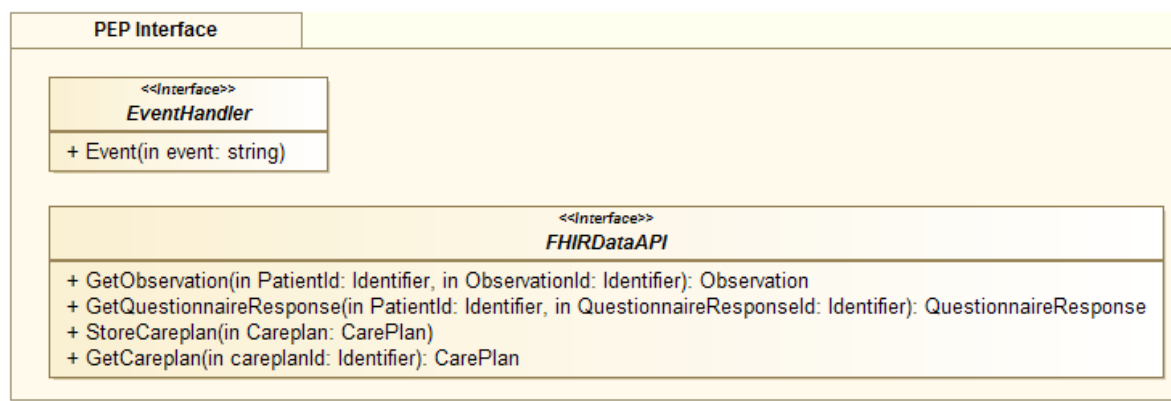
Class: QuestionnaireResponse.group.question.answer			
Name	Cardinality	Type	Description
valueInteger	0..1	integer	integer type answer to the question.
valueDecimal	0..1	decimal	Decimal type answer to the question.
valueCoding	0..1	Coding	Coding type answer to the question.
valueBoolean	0..1	boolean	Boolean type answer to the question.
valueString	0..1	string	String type answer to the question.
valueDateTime	0..1	datetime	Datetime type answer to the question.
valueAttachment	0..1	Attachment	Attachment type answer to the question.

## 5. INTERFACE VIEW

The Interface view provides design stakeholders the details of external and internal interfaces provided by the system and its components. This view consists of a set of interface specifications for each interface identified in the composition view (Section 2). The interface specifications serve as binding contracts between subsystems and subsystem components. The view also includes screen mock-ups to describe user interface design. The Interaction view (Section 6) will use the interfaces defined in this section to describe the dynamic interactions between different components in order to demonstrate how use cases defined in D3.2 can be realized. This view is governed by the interface viewpoint declared in Section 1.7, and represented by UML2 class diagram.

### 5.1. Patient Empowerment Platform

Figure 47: SDD-ITF-PEP: PEP Interface



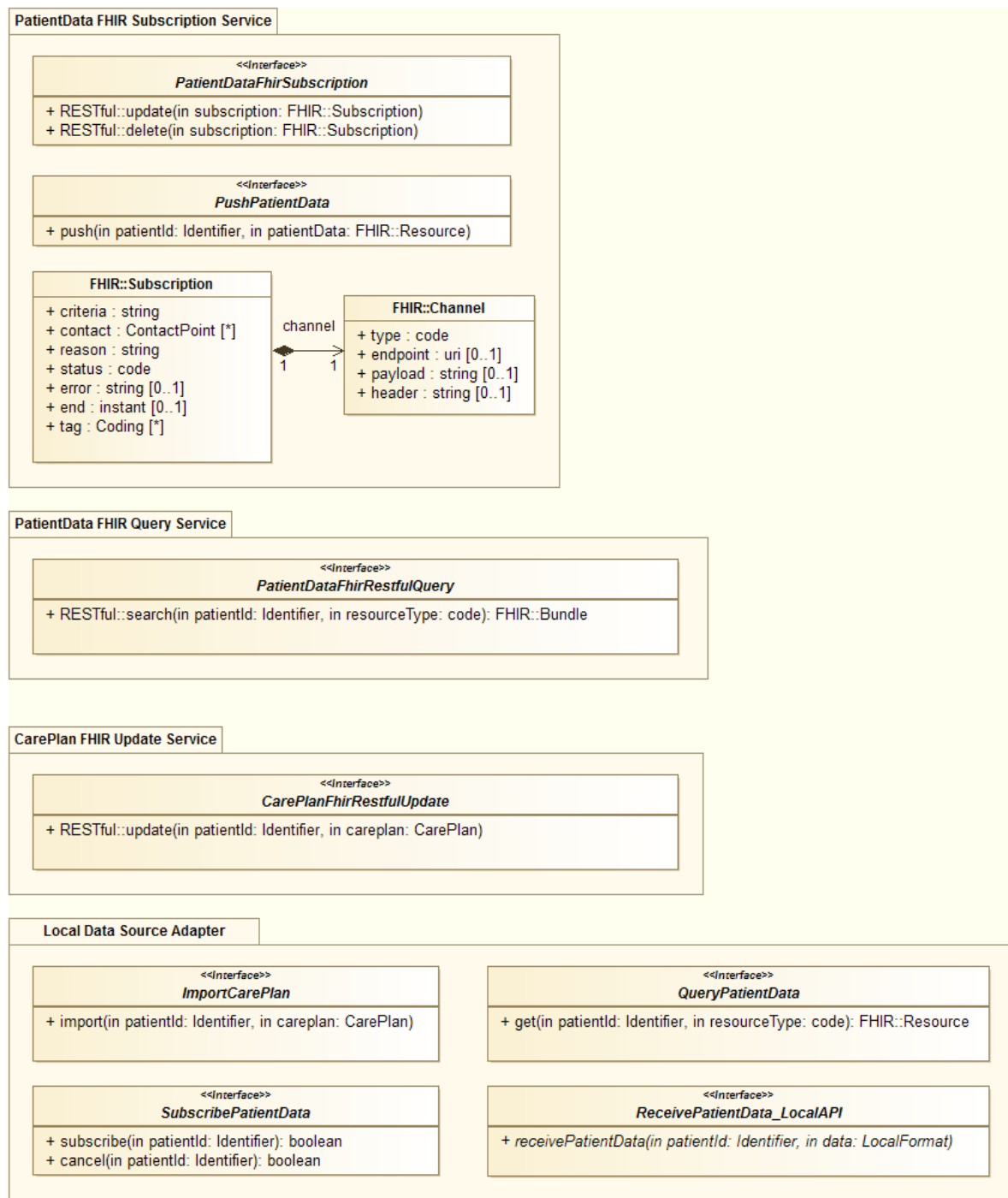
Interface: EventHandler		
<b>Operation</b>	Event	Operation to receive notification of new event from Medixine Suite or another connected component. When you receive the notification, you call the appropriate interface to fetch the actual data.
<b>Parameters</b>	event	Info of the event that occurred. The received data is only an indication that new data with the given ID exists.
<b>Return</b>	void	

Interface: FHIRDataAPI		
<b>Operation</b>	GetObservation	Get a single observation with the given id.
<b>Parameters</b>	PatientId	ID belonging to the patient whose data is requested.
	ObservationId	ID of the Observation.
<b>Return</b>	Observation	
<b>Operation</b>	GetQuestionnaireResponse	Get a single questionnaire response with the given id
<b>Parameters</b>	PatientId	ID belonging to the patient whose data is requested.
	QuestionnaireResponseId	ID of the QuestionnaireResponse.
<b>Return</b>	QuestionnaireResponse	
<b>Operation</b>	StoreCareplan	Process and store a published FHIR Careplan.

Interface: FHIRDataAPI		
<b>Parameters</b>	Careplan : CarePlan	
<b>Return</b>	void	
<b>Operation</b>	GetCareplan	Query a Careplan by ID for display.
<b>Parameters</b>	careplanId	ID of the Careplan.
<b>Return</b>	CarePlan	

## 5.2. Technical Interoperability Suite

Figure 48: SDD-ITF-TIS: TIS Interfaces



### Interface: PatientDataFhirSubscription

Operation	RESTful::update		FHIR RESTful instance level <i>update</i> , to register subscription for patient data.
Parameters	subscription	Subscription	FHIR Subscription resource, used to define a push based subscription. Patient ID is used as the criteria.

<b>Return</b>	HTTP status codes	
<b>Operation</b>	RESTful::delete	FHIR RESTful instance level <i>delete</i> , to unregister previous subscription.
<b>Parameters</b>	subscription	FHIR Subscription resource.
<b>Return</b>	HTTP status codes	

Class: Subscription			
Name	Cardinality	Type	Description
criteria	1..1	string	Rule for server push criteria.
contact	0..*	ContactPoint	Contact details for source (e.g., troubleshooting)
reason	1..1	string	Description of why this subscription was created.
status	1..1	code	requested   active   error   off.
error	0..1	string	Latest error note.
end	0..1	instant	When to automatically delete the subscription.
tag	0..*	Coding	A tag to add to matching resources.

Class: Channel			
Name	Cardinality	Type	Description
type	1..1	code	rest-hook   websocket   email   sms   message.
endpoint	0..1	uri	Where the channel points to.
payload	1..1	string	Mimetype to send, or blank for no payload.
header	0..1	string	Usage depends on the channel type.

Interface: PushPatientData			
<b>Operation</b>	push		Push patient data to remote FHIR endpoint.
<b>Parameters</b>	patientId	Identifier	Patient identifier.
	patientData	FHIR::Resource	Patient data in FHIR representation.
<b>Return</b>	void		

Interface: PatientDataFhirRESTfulQuery		
<b>Operation</b>	RESTful::search	FHIR RESTful type level <i>search</i> , to search for patient data resources for a specific patient.



<b>Parameters</b>	patientId	Identifier	Patient identifier.
	resourceType	code	FHIR resource type; e.g., AllergyIntolerance, Condition, DiagnosticReport, etc.
<b>Return</b>	FHIR::Bundle		Returning patient data resources wrapped in FHIR Bundle,

#### Interface: CarePlanRESTfulUpdate

<b>Operation</b>	RESTful::update		FHIR RESTful instance level <i>update</i> .
<b>Parameters</b>	patientId	Identifier	Patient identifier, same as or linked to patient identifier within local care record systems.
	careplan	CarePlan	CarePlan in FHIR representation.
<b>Return</b>	HTTP status codes		

#### Interface: ImportCarePlan

<b>Operation</b>	import		Import care plan into a local care record system.
<b>Parameters</b>	patientId	Identifier	Patient identifier.
	careplan	CarePlan	CarePlan in FHIR representation.
<b>Return</b>	void		

#### Interface: QueryPatientData

<b>Operation</b>	get		Retrieve patient data from a local care record system.
<b>Parameters</b>	patientId	Identifier	Patient identifier.
	resourceType	code	FHIR resource type.
<b>Return</b>	FHIR::Resource		Returning patient data in FHIR representation.

#### Interface: SubscribePatientData

<b>Operation</b>	subscribe		Register to receive patient data from a local care record system.
<b>Parameters</b>	patientId	Identifier	Patient identifier.
<b>Return</b>	boolean		True if subscription is accepted, False otherwise.
<b>Operation</b>	cancel		Cancel previous subscription.
<b>Parameters</b>	patientId		Patient identifier.

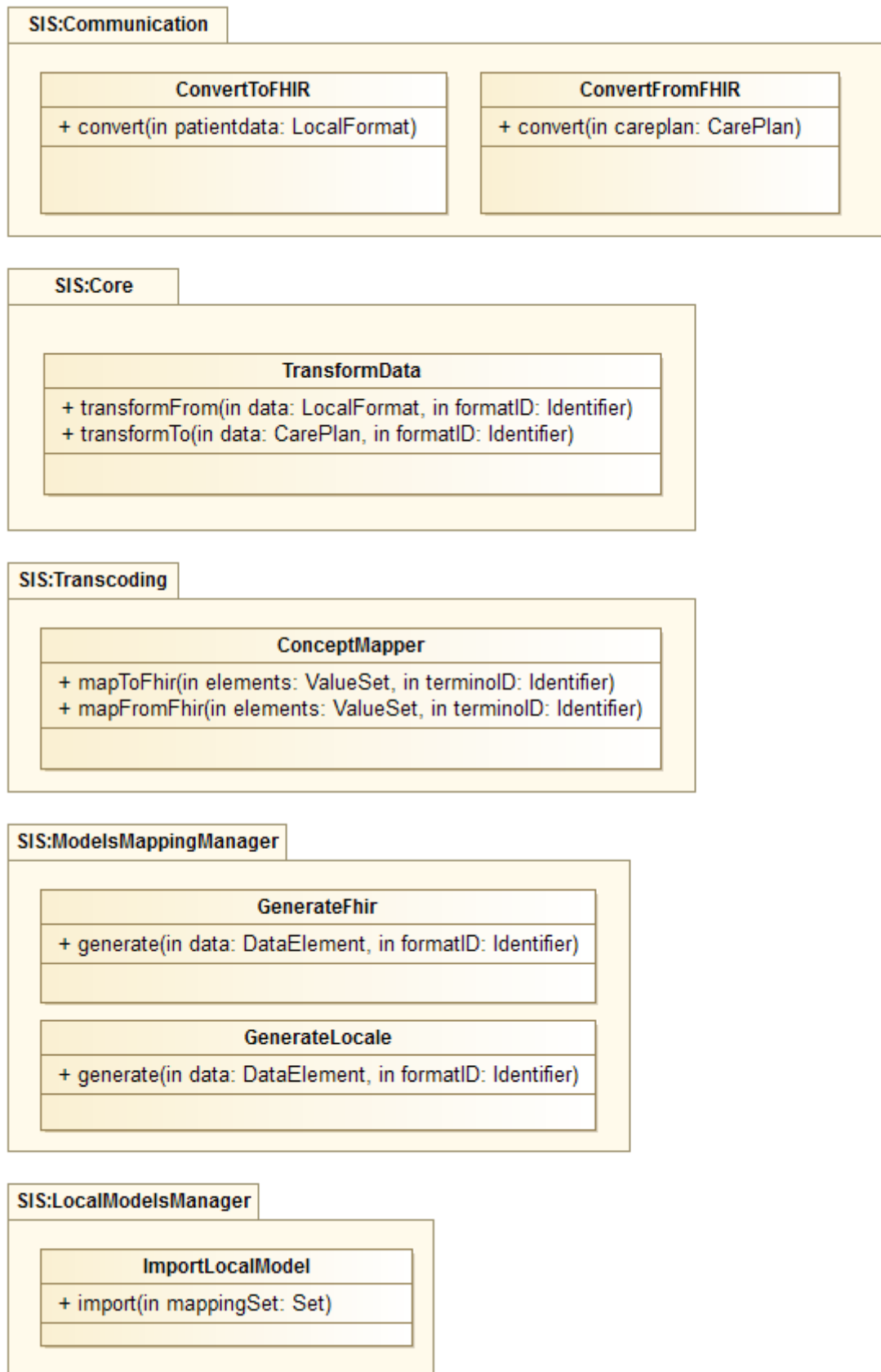
<b>Return</b>	boolean	True if cancelled successfully, False otherwise.
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#### Interface: ReceivePatientData\_LocalAPI

Operation	receivePatientData		Callback API for a local care record system to push patient data.
Parameters	patientId	Identifier	Patient identifier.
	data	LocalFormat	Patient data in local system specific format.
Return	void		Asynchronous one-way notification.

### 5.3. Semantic Interoperability Suite

Figure 49: SDD-ITF-SIS: SIS Interfaces



Interface:ConvertToFHIR			
<b>Operation</b>	convert		Convert patient data from a local care record system to FHIR representation.
<b>Parameters</b>	patentdata	LocalFormat	Patient data in local format.
<b>Return</b>	FHIR::Resource		Returning patient data in FHIR representation.

Interface:ConvertFromFHIR			
<b>Operation</b>	convert		Convert a FHIR care plan into local format.
<b>Parameters</b>	careplan	CarePlan	CarePlan in FHIR representation.
<b>Return</b>	data		Returning care plan in local format.

Interface:TransformData			
<b>Operation</b>	transformFrom		Transform patient data from a local care record system to FHIR representation.
<b>Parameters</b>	data	LocalFormat	Patient data in local format.
	formatID	Identifier	Local format identifier.
<b>Return</b>	FHIR::Resource		Returning patient data in FHIR representation.
<b>Operation</b>	transformTo		Cancel previous subscription.
<b>Parameters</b>	data	CarePlan	CarePlan in FHIR representation.
	formatID	Identifier	Local format identifier.
<b>Return</b>	Data		Returning care plan in local format.

Interface:ConceptMapper			
<b>Operation</b>	mapToFhir		Perform terminological concept mapping to FHIR representation.
<b>Parameters</b>	elements	ValueSet	Elements to map.
	terminoID	Identifier	Used terminology Identifier.
<b>Return</b>	ValueSet		FHIR representation.
<b>Operation</b>	mapFromFhir		Perform terminological concept mapping to local representation.
<b>Parameters</b>	elements	ValueSet	Elements to map.
	terminoID	Identifier	Used terminology Identifier.
<b>Return</b>	ValueSet		Local format representation.

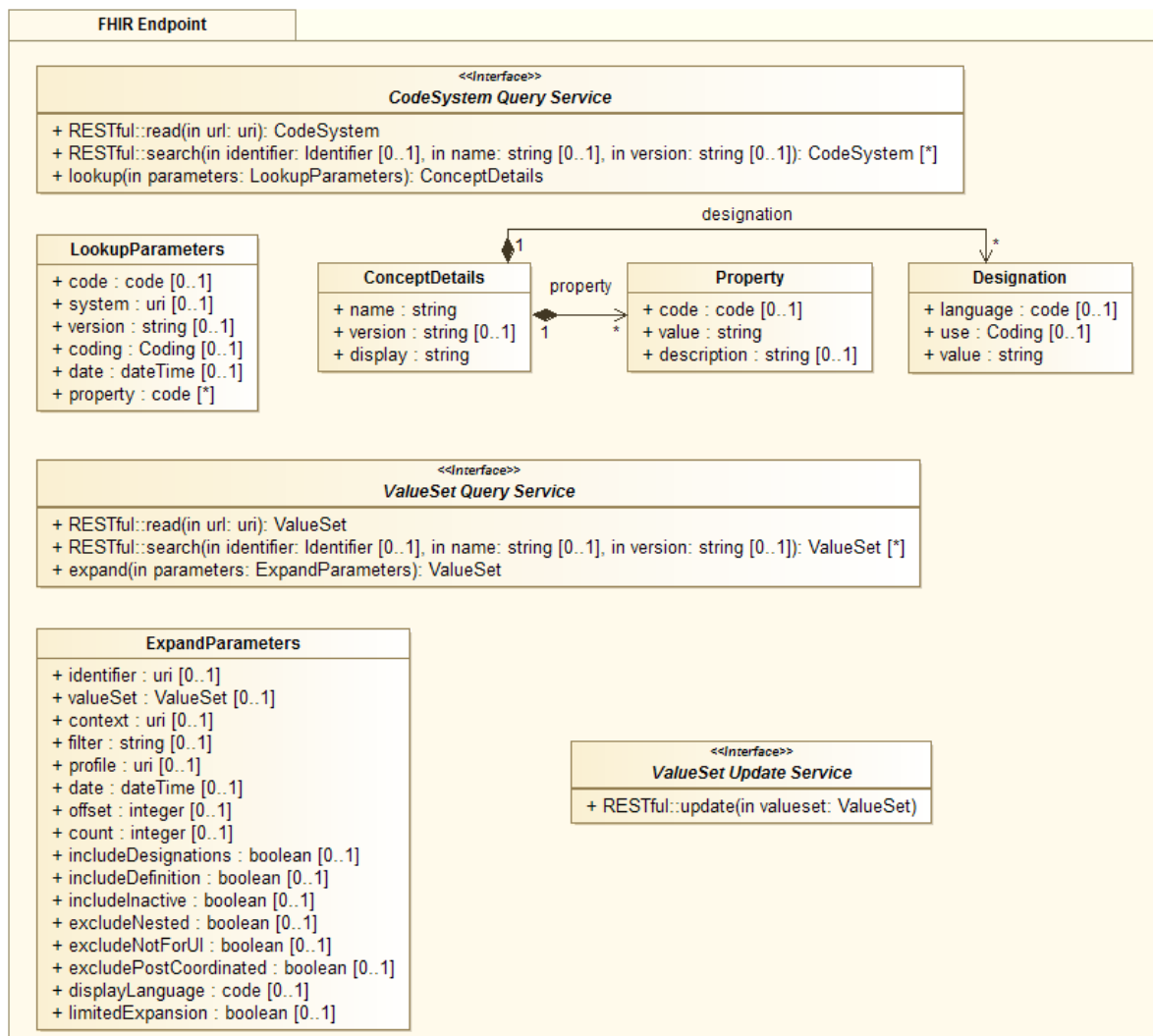
Interface:GenerateFhir			
<b>Operation</b>	generate		Generate FHIR DataElement form local format DataElement.
<b>Parameters</b>	data	DataElement	DataElement in local format.
	formatID	Identifier	Local format identifier.
<b>Return</b>	DataElement		FHIR representation.

Interface:GenerateLocale			
<b>Operation</b>	generate		Generate local format DataElement from FHIR DataElement.
<b>Parameters</b>	data	DataElement	DataElement in FHIR.
	formatID	Identifier	Local format identifier.
<b>Return</b>	DataElement		Local format representation.

Interface:ImportLocalModel			
<b>Operation</b>	Import		Import and register a local model for FHIR mapping.
<b>Parameters</b>	mappingSet	Set	Model definition.
<b>Return</b>	void		

## 5.4. Terminology Service

Figure 50: SDD-ITF-TS: Terminology Service Interfaces



### Interface: CodeSystem Query Service

<b>Operation</b>	RESTful::read		FHIR RESTful instance level <i>read</i> , to get a CodeSystem resource.
<b>Parameters</b>	url	uri	Globally unique identifier for code system.
<b>Return</b>	CodeSystem		FHIR CodeSystem resource.
<b>Operation</b>	RESTful::search		FHIR RESTful type level <i>search</i> , to find CodeSystem resources.
<b>Parameters</b>	identifier	Identifier	Identifier for the code system.
	name	string	Code system name.
	version	string	Code system version.
<b>Return</b>	CodeSystem [*]		0 or more FHIR CodeSystem resources.

Operation	lookup		Concept look up. Given a code/system, or a Coding, get additional details about the concept.
Parameters	parameters	LookupParameters	In parameters for lookup.
Return	ConceptDetails		Look up response.

#### Interface: ValueSet Query Service

Operation	RESTful::read		FHIR RESTful instance level <i>read</i> , to get a ValueSet resource.
Parameters	url	uri	Globally unique identifier for value set.
Return	ValueSet		FHIR ValueSet resource.
Operation	RESTful::search		FHIR RESTful type level <i>search</i> , to find ValueSet resources.
Parameters	identifier	Identifier	Identifier for the value set.
	name	string	Value set name.
	version	string	Value set version.
Return	ValueSet [*]		0 or more FHIR ValueSet resources.
Operation	expand		Value set expansion. The definition of a value set is used to create a simple collection of codes suitable for use for data entry or validation.
Parameters	parameters	ExpandParameters	In parameters for expand.
Return	ValueSet		An expanded value set will be returned.

#### Interface: ValueSet Update Service

Operation	RESTful::update		FHIR RESTful instance level <i>update</i> , to update a ValueSet resource.
Parameters	valueset	ValueSet	FHIR ValueSet resource.
Return	HTTP status codes		

#### Class: LookupParameters

Name	Cardinality	Type	Description
code	0..1	code	The code that is to be validated. If a code is provided, a system must be provided.
system	0..1	uri	The system for the code that is to be validated.
version	0..1	string	The version of the system, if one was provided in the source data.
coding	0..1	Coding	A coding to look up.
date	0..1	dateTime	The date for which the information should be returned. Normally, this is the current

			conditions (which is the default value) but under some circumstances, systems need to access this information as it would have been in the past. A typical example of this would be where code selection is constrained to the set of codes that were available when the patient was treated, not when the record is being edited. Note that which date is appropriate is a matter for implementation policy.
property	0..*	code	A property that the client wishes to be returned in the output. If no properties are specified, the server chooses what to return. The following properties are defined for all code systems: system, version, display, definition, designation, parent, child, and lang.X where X is a language code in a designation. These properties refer to the directly return parameters documented for the operation.

Class: ConceptDetails			
Name	Cardinality	Type	Description
name	1..1	string	A display name for the code system.
version	0..1	string	The version that these details are based on.
display	1..1	string	The preferred display for this concept.
property	0..*	Property	Concept properties as requested by the client.
designation	0..*	Designation	Additional representations for this concept.

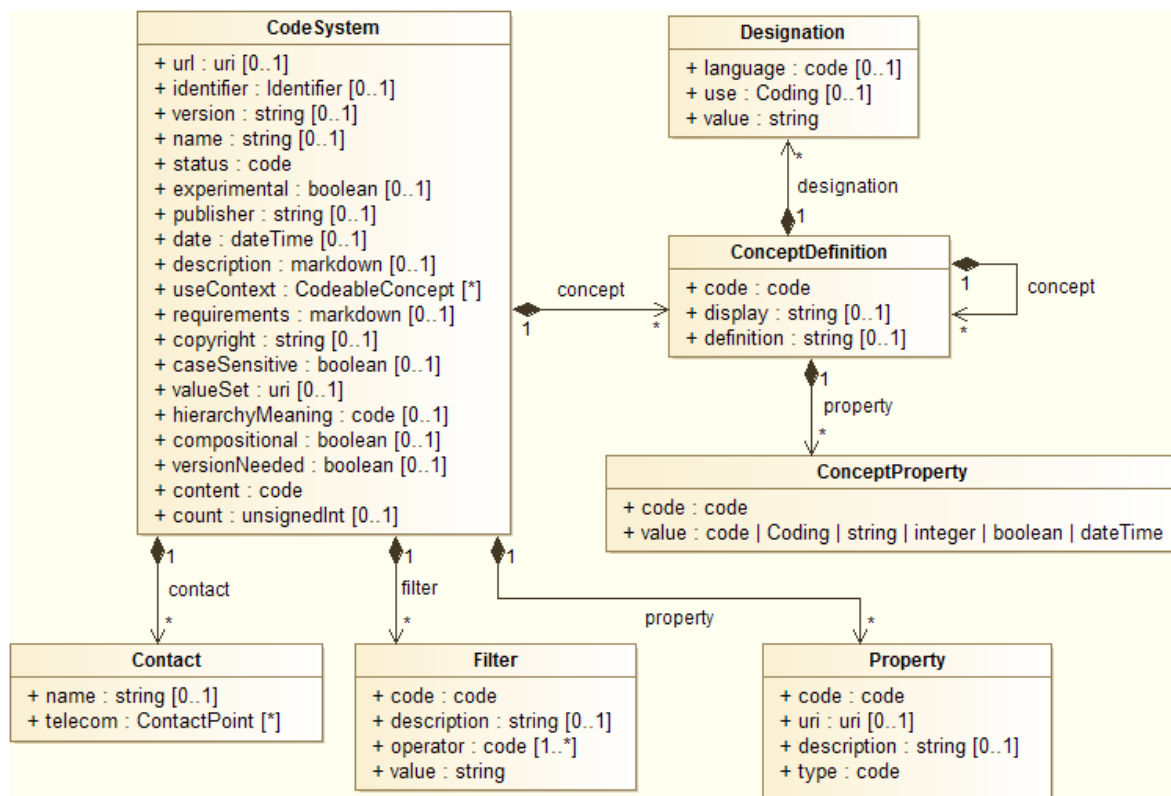
Class: Property			
Name	Cardinality	Type	Description
code	0..1	code	Property code.
value	1..1	string	Property value.
description	0..1	string	Human Readable representation of the property value.

Class: Designation			
Name	Cardinality	Type	Description
language	0..1	code	The language this designation is defined for. Value set: <a href="#">Common Languages</a> or <a href="#">All Languages</a> .
use	0..1	Coding	A code that details how this designation would be used. Extensible value set: <a href="#">Designation Use</a> .
value	1..1	string	The text value for this designation.



Class: ExpandParameters			
Name	Cardinality	Type	Description
identifier	0..1	uri	A logical value set identifier (i.e. ValueSet.url). The server must know the value set (e.g., it is defined explicitly in the server's value sets, or it is defined implicitly by some code system known to the server.
valueSet	0..1	ValueSet	The value set is provided directly as part of the request. Servers may choose not to accept value sets in this fashion.
context	0..1	uri	The context of the value set, so that the server can resolve this to a value set to expand. The recommended format for this URI is [Structure Definition URL]#[name or path into structure definition] e.g., <a href="http://hl7.org/fhir/StructureDefinition/observation-hspc-height-hspcheight#Observation.interpretation">http://hl7.org/fhir/StructureDefinition/observation-hspc-height-hspcheight#Observation.interpretation</a> . Other forms may be used but are not defined. This form is only useable if the terminology server also has access to the profile registry that the server is using, but can be used to delegate the mapping from an application context to a binding at run-time.
filter	0..1	string	A text filter that is applied to restrict the codes that are returned (this is useful in a UI context). The interpretation of this is delegated to the server in order to allow to determine the most optimal search approach for the context.
profile	0..1	uri	A reference to an external definition that provides additional control information about how the expansion is performed. At this time, there is no agreed format or functionality for the target of this URI.
date	0..1	dateTime	The date for which the expansion should be generated. If a date is provided, it means that the server should use the value set / code system definitions as they were on the given date, or return an error if this is not possible. Normally, the date is the current conditions (which is the default value) but under some circumstances, systems need to generate an expansion as it would have been in the past. A typical example of this would be where code selection is constrained to the set of codes that were available when the patient was treated, not when the record is being edited. Note that which date is appropriate is a matter for implementation policy.

offset	0..1	integer	Paging support - where to start if a subset is desired (default = 0) .
count	0..1	integer	Paging support - how many codes should be provided in a partial view. Paging only applies to flat expansions - servers ignore paging if the expansion is not flat. If count = 0, the client is asking how large the expansion is. Servers <b>SHOULD</b> honor this request for hierarchical expansions as well, and simply return the overall count.
includeDesignations	0..1	boolean	Controls whether concept designations are to be included or excluded in value set expansions. Overrides the value in the expansion profile if there is one.
includeDefinition	0..1	boolean	Controls whether the value set definition is included or excluded in value set expansions. Overrides the value in the expansion profile if there is one.
includeInactive	0..1	boolean	Controls whether inactive concepts are included or excluded in value set expansions. Overrides the value in the expansion profile if there is one.
excludeNested	0..1	boolean	Controls whether or not the value set expansion includes nested codes (i.e. ValueSet.expansion.contains.contains). Overrides the value in the expansion profile if there is one.
excludeNotForUI	0..1	boolean	Controls whether or not the value set expansion includes codes which cannot be displayed in user interfaces. Overrides the value in the expansion profile if there is one.
excludePostCoordinated	0..1	boolean	Controls whether or not the value set expansion includes post coordinated codes. Overrides the value in the expansion profile if there is one.
displayLanguage	0..1	code	Specifies the language to be used for description in the expansions i.e. the language to be used for ValueSet.expansion.contains.display. Overrides the value in the expansion profile if there is one.
limitedExpansion	0..1	boolean	If the value set being expanded is incomplete (because it is too big to expand), return a limited expansion (a subset) with an indicator that expansion is incomplete. Overrides the value in the expansion profile if there is one.

**Figure 51: SDD-ITF-TS-CS: FHIR CodeSystem model****Class: CodeSystem**

A set of codes drawn from one or more code systems. Within a code system definition, all the codes SHALL be unique.

Name	Cardinality	Type	Description
url	0..1	uri	Globally unique logical identifier for code system (Coding.system) .
identifier	0..1	Identifier	Additional identifier for the code system (e.g. HL7 v2 / CDA) .
version	0..1	string	Logical identifier for this version (Coding.version) .
name	0..1	string	Informal name for this code system.
status	1..1	code	Value set <a href="#">ConformanceResourceStatus</a> : draft   active   retired.
experimental	0..1	boolean	If for testing purposes, not real usage.
publisher	0..1	string	Name of the publisher (organisation or individual) .
contact	0..*	Contact	Contact details of the publisher.
date	0..1	dateTime	Date for given status.

description	0..1	markdown	Human language description of the code system.
useContext	0..*	CodeableConcept	Content intends to support these contexts. Extensible value set: <a href="#">Context of Use ValueSet</a> .
requirements	0..1	markdown	Why needed.
copyright	0..1	string	Use and/or publishing restrictions.
caseSensitive	0..1	boolean	If code comparison is case sensitive.
valueSet	0..1	uri	Canonical URL for value set with entire code system.
hierarchyMeaning	0..1	code	<a href="#">CodeSystemHierarchyMeaning</a> : grouped-by   subsumes   part-of   classified-with.
compositional	0..1	boolean	If code system defines a post-composition grammar.
versionNeeded	0..1	boolean	If definitions are not stable.
content	1..1	code	<a href="#">CodeSystemContentMode</a> : not-present   exemplar   fragment   complete.
count	0..1	unsignedInt	Total concepts in the code system.
filter	0..*	Filter	A filter that can be used in a value set compose statement when selecting concepts using a filter.
property	0..*	Property	Additional information supplied about each concept.
concept	0..*	ConceptDefinition	Concepts in the code system.

Class: Contact			
Name	Cardinality	Type	Description
name	0..1	string	Name of an individual to contact.
telecom	0..*	ContactPoint	Contact details for individual or publisher.

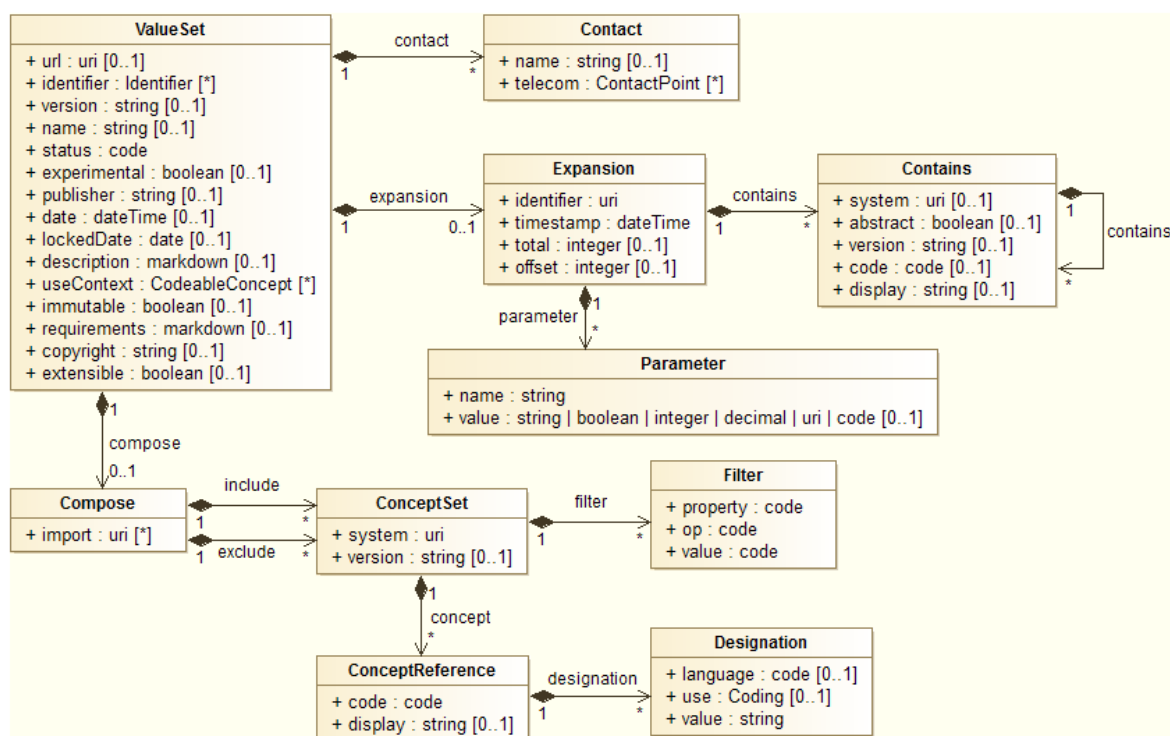
Class: Filter			
Name	Cardinality	Type	Description
code	1..1	code	Code that identifies the filter.
description	0..1	string	How or why the filter is used.
operator	1..*	code	Operators that can be used with filter. Value set: <a href="#">FilterOperator</a> .
value	1..1	string	What to use for the value.

Class: Property			
Name	Cardinality	Type	Description
code	1..1	code	Identifies the property on the concepts, and when referred to in operations.
uri	0..1	uri	Formal identifier for the property.
description	0..1	string	Why the property is defined, and/or what it conveys.
type	1..1	code	<a href="#">PropertyType</a> : code   Coding   string   integer   boolean   dateTime.

Class: ConceptDefinition			
Name	Cardinality	Type	Description
code	1..1	code	Code that identifies concept.
display	0..1	string	Text to display to the user.
definition	0..1	string	Formal definition.
designation	0..*	Designation	Additional representations for the concept.
property	0..*	ConceptProperty	Property value for the concept.
concept	0..*	ConceptDefinition	Child Concepts (is-a/contains/categorises) .

Class: ConceptProperty			
Name	Cardinality	Type	Description
code	1..1	code	Reference to CodeSystem.property.code
value	1..1	code   Coding   string   integer   boolean   dateTime	Value of the property for this concept.

Figure 52: SDD-ITF-TS-VS: FHIR ValueSet model

**Class: ValueSet**

A set of codes drawn from one or more code systems. A value set with only one import SHALL also have an include and/or an exclude. Value set SHALL contain at least one of a compose, or an expansion element.

Name	Cardinality	Type	Description
url	0..1	uri	Globally unique logical identifier for value set.
identifier	0..*	Identifier	Additional identifier for the value set (e.g., HL7 v2 / CDA) .
version	0..1	string	Logical identifier for this version of the value set.
name	0..1	string	Informal name for this value set.
status	1..1	code	<a href="#">ConformanceResourceStatus</a> : draft   active   retired.
experimental	0..1	boolean	If for testing purposes, not real usage.
publisher	0..1	string	Name of the publisher (organisation or individual)
contact	0..*	Contact	Contact details of the publisher.
date	0..1	dateTime	Date for given status.
lockedDate	0..1	date	Fixed date for all referenced code systems and value sets.
description	0..1	markdown	Human language description of the value set.

useContext	0..*	CodeableConcept	Content intends to support these contexts. Extensible value set: <a href="#">Context of Use ValueSet</a>
immutable	0..1	boolean	Indicates whether or not any change to the content logical definition may occur.
requirements	0..1	markdown	Why needed.
copyright	0..1	string	Use and/or publishing restrictions.
extensible	0..1	boolean	Whether this is intended to be used with an extensible binding.
compose	0..1	Compose	A set of criteria that provide the content logical definition of the value set by including or excluding codes from outside this value set. When value set includes codes from elsewhere. A value set composition SHALL have an include or an import.
expansion	0..1	Expansion	A value set can also be "expanded", where the value set is turned into a simple collection of enumerated codes. This element holds the expansion, if it has been performed.

Class: Compose			
Name	Cardinality	Type	Description
import	0..*	uri	Import the contents of another value set.
include	0..*	ConceptSet	Include one or more codes from a code system. Cannot have both concept and filter.
exclude	0..*	ConceptSet	Explicitly exclude codes.

Class: ConceptSet			
Name	Cardinality	Type	Description
system	1..1	uri	The system the codes come from.
version	0..1	string	Specific version of the code system referred to.
concept	0..*	ConceptReference	A concept defined in the system.
filter	0..*	Filter	Select codes/concepts by their properties (including relationships).

Class: ConceptReference			
Name	Cardinality	Type	Description
code	1..1	code	Code or expression from system.
display	0..1	string	Text to display for this code for this value set.
designation	0..*	Designation	Additional representations for this value set.

Class: Filter			
Name	Cardinality	Type	Description
property	1..1	code	A property defined by the code system.
op	1..1	code	<a href="#">FilterOperator</a> : =   is-a   is-not-a   regex   in   not-in   generalizes
value	1..1	code	Code from the system, or regex criteria.

Class: Expansion			
Name	Cardinality	Type	Description
identifier	1..1	uri	Uniquely identifies this expansion.
timestamp	1..1	dateTime	Time ValueSet expansion happened.
total	0..1	integer	Total number of codes in the expansion.
offset	0..1	integer	Offset at which this resource starts.
parameter	0..*	Parameter	Parameter that controlled the expansion process.
contains	0..*	Contains	The codes that are contained in the value set expansion. Codes in the value set SHALL have a code or a display. Must have a code if not abstract. Must have a system if a code is present.

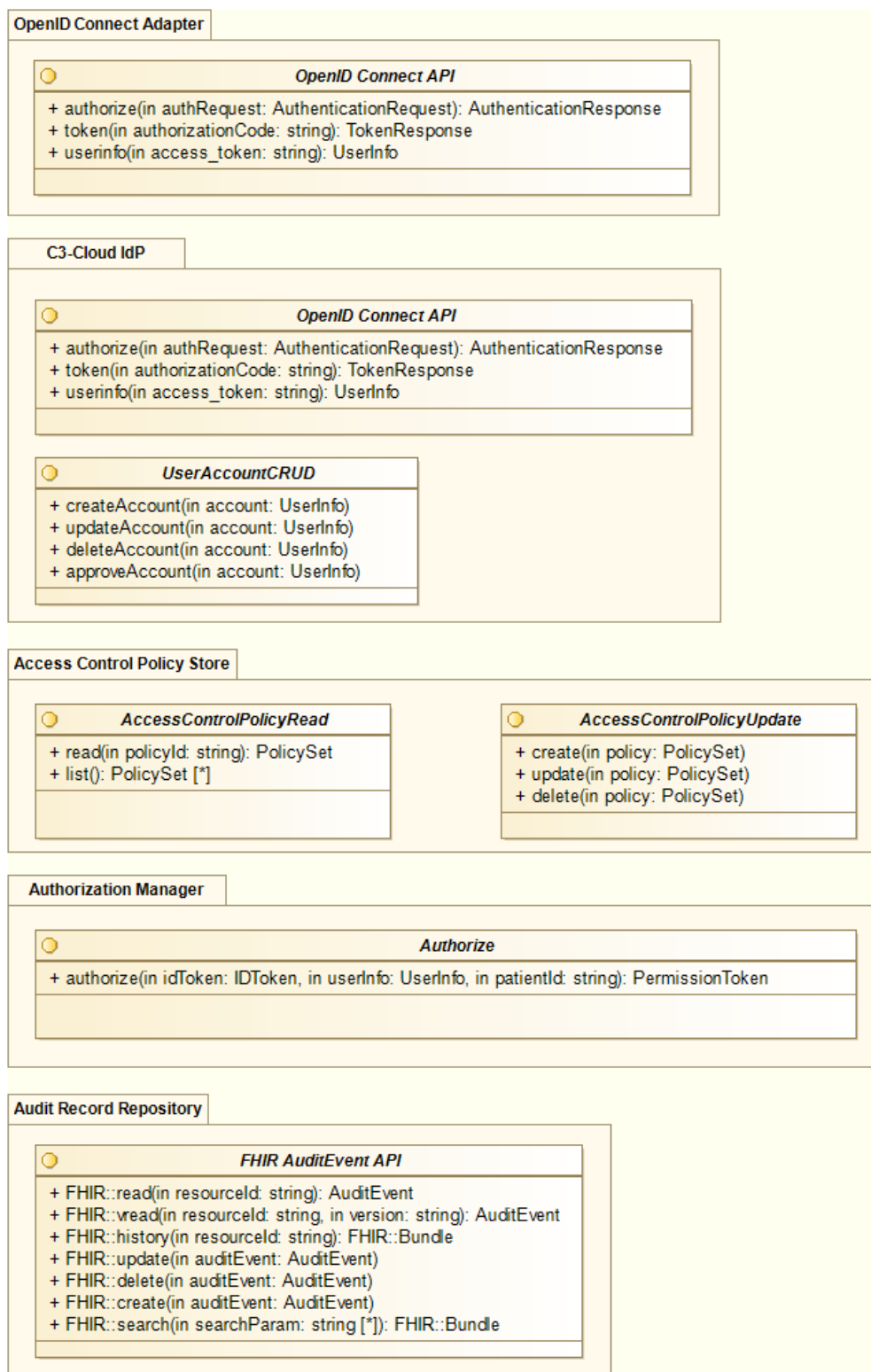
Class: Parameter			
Name	Cardinality	Type	Description
name	1..1	string	Name as assigned by the server.
value	0..1	string   boolean   integer   decimal   uri   code	Value of the named parameter.

Class: Contains			
Name	Cardinality	Type	Description
system	0..1	uri	System value for the code.
abstract	0..1	boolean	If user cannot select this entry.
version	0..1	string	Version in which this code/display is defined.
code	0..1	code	Code - if blank, this is not a selectable code.
display	0..1	string	User display for the concept.
contains	0..*	Contains	Codes contained under this entry.



## 5.5. Security and Privacy Suite

Figure 53: SDD-ITF-SPS: SPS Interfaces



❖ **OpenID Connect Adapter & C3-Cloud IdP**

Interface: OpenID Connect API			
<b>Operation</b>	authorize		Authorization endpoint of the OpenID Connect 1.0 specification, through which non-patient user authentication takes place.
<b>Parameters</b>	authRequest	AuthenticationRequest	The authentication request, as described in Section 4.
<b>Return</b>	AuthenticationResponse		The authentication response containing the IDToken of the user, as described in Section 4.
<b>Operation</b>	token		Token endpoint of the OpenID Connect 1.0 specification.
<b>Parameters</b>	authorizationCode	string	The authorisation code that is obtained within the authentication response.
<b>Return</b>	TokenResponse		The token response, as described in Section 4.
<b>Operation</b>	userinfo		UserInfo endpoint of the OpenID Connect 1.0 specification
<b>Parameters</b>	access_token	string	The access token that is obtained either via authentication response or token response.
<b>Return</b>	UserInfo		The user info including claims of the user (e.g., email address, role, organisation), as described in Section 4.

❖ **C3-Cloud IdP**

Interface: UserAccountCRUD			
<b>Operation</b>	createAccount		Operation for creating a new user account in C3-Cloud IdP.
<b>Parameters</b>	account	UserInfo	User account data.
<b>Return</b>	void		
<b>Operation</b>	updateAccount		Operation for updating an existing user account in C3-Cloud IdP.
<b>Parameters</b>	account	UserInfo	User account data.
<b>Return</b>	void		
<b>Operation</b>	deleteAccount		Operation for deleting an existing user account in C3-Cloud IdP.
<b>Parameters</b>	account	UserInfo	User account data.

<b>Return</b>	void		
<b>Operation</b>	approveAccount		Operation for Administrator to approve a newly created user account by the user himself.
<b>Parameters</b>	account	UserInfo	User account data.
<b>Return</b>	void		

❖ Access Control Policy Store

Interface: AccessControlPolicyRead			
<b>Operation</b>	list		Operation for getting the complete list of access control policies represented as XACML PolicySet instances.
<b>Return</b>	PolicySet [*]		
<b>Operation</b>	read		Read a specific access control policy represented as an XACML PolicySet.
<b>Parameters</b>	policyId	string	Unique identifier of the PolicySet.
<b>Return</b>	PolicySet		

Interface: AccessControlPolicyUpdate			
<b>Operation</b>	create		Create a new access control policy represented as an XACML PolicySet.
<b>Parameters</b>	policy	PolicySet	The access control policy.
<b>Return</b>	void		
<b>Operation</b>	update		Update an existing access control policy represented as an XACML PolicySet.
<b>Parameters</b>	policy	PolicySet	The access control policy.
<b>Return</b>	void		
<b>Operation</b>	delete		Delete an existing access control policy represented as an XACML PolicySet.
<b>Parameters</b>	policy	PolicySet	The access control policy.
<b>Return</b>	void		

❖ Authorization Manager

Interface: Authorize		
<b>Operation</b>	authorize	The authorization endpoint of the Authorization Manager, which acts as

			the Policy Decision Point (PDP) in the C3-Cloud architecture. It does not directly return an allow-deny decision as initially planned, but instead the complete list of permissions that the user has.
<b>Parameters</b>	token	IDToken	The IDToken of the user.
	userInfo	UserInfo	The user info including claims of the user (e.g., email address, role, organization), as described in Section 4.
	patientId	string	The identifier of the patient, as the owner of the resource that the user is trying to access / modify.
<b>Return</b>	PermissionToken		The JSON Web Token (JWT) that encapsulates all the permissions of the user for different types of resources, as described in Section 4. This token will be passed by the client to the policy enforcement point (PEP).

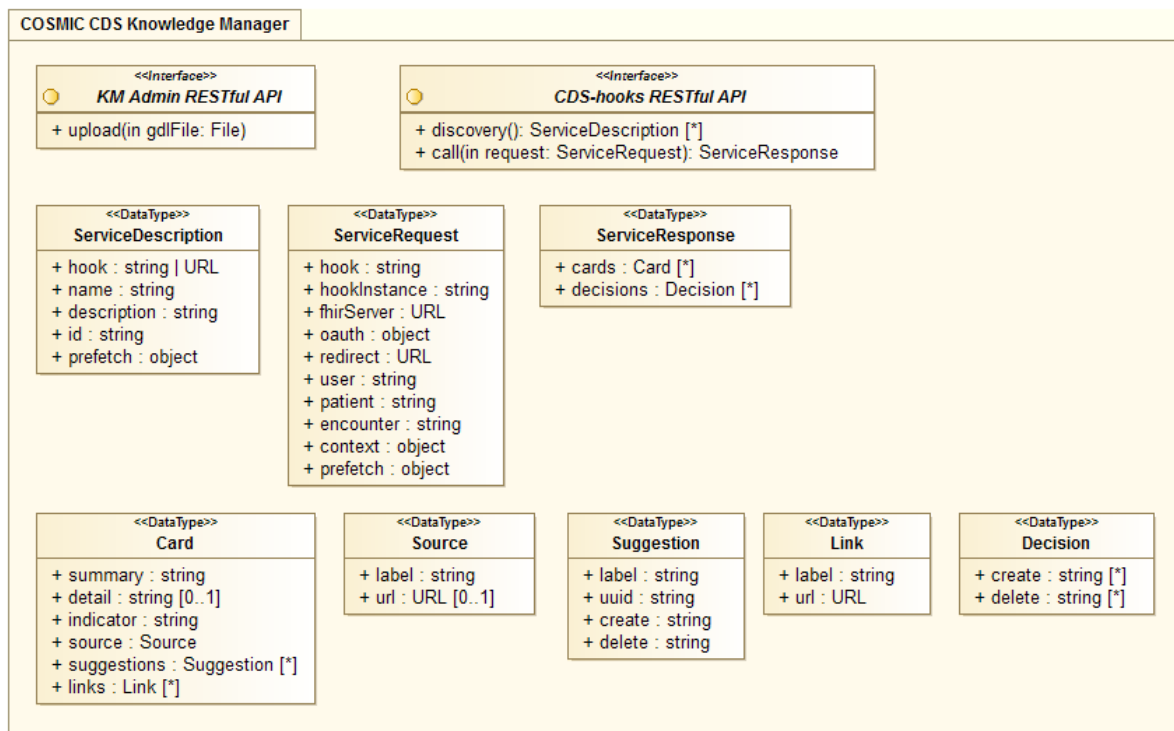
❖ **Audit Record Repository**

Interface: FHIR AuditEvent API			
<b>Operation</b>	FHIR::read		FHIR RESTful instance level <i>read</i> , to read the latest version of an AuditEvent instance.
<b>Parameters</b>	resourceId	string	Identifier of the AuditEvent to be read.
<b>Return</b>	AuditEvent		The FHIR AuditEvent, as described in Section 4.
<b>Operation</b>	FHIR::vread		FHIR RESTful instance level <i>vread</i> , to read a specific version of an AuditEvent instance.
<b>Parameters</b>	resourceId	string	Identifier of the AuditEvent to be read.
	version	string	Specific version of the resource.
<b>Return</b>	AuditEvent		The AuditEvent.
<b>Operation</b>	FHIR::history		FHIR RESTful instance level <i>history</i> , to retrieves the history of a particular AuditEvent resource.
<b>Parameters</b>	resourceId	string	Identifier of the AuditEvent.

<b>Return</b>	FHIR::Bundle		A FHIR Bundle of type history, containing the specified version history.
<b>Operation</b>	FHIR::search		FHIR RESTful type level <i>search</i> , to search AuditEvent instances based on some filter criteria.
<b>Parameters</b>	searchParam [*]	string	Filter criteria for search operation.
<b>Return</b>	FHIR::Bundle		A FHIR Bundle containing AuditEvent resources matching the filter criteria.
<b>Operation</b>	FHIR::create		FHIR RESTful type level <i>create</i> , to create a new AuditEvent resource. This operation will be used by Secure Nodes in C3-Cloud to save their audit trail records in the C3-Cloud Audit Record Repository.
<b>Parameters</b>	auditEvent	AuditEvent	FHIR AuditEvent to be created.
<b>Return</b>	HTTP status codes		
<b>Operation</b>	FHIR::update		FHIR RESTful instance level <i>update</i> , to update an existing AuditEvent resource.
<b>Parameters</b>	auditEvent	AuditEvent	FHIR AuditEvent to be updated.
<b>Return</b>	HTTP status codes		
<b>Operation</b>	FHIR::delete		FHIR RESTful instance level <i>delete</i> , to delete an existing AuditEvent resource.
<b>Parameters</b>	auditEvent	AuditEvent	FHIR AuditEvent to be deleted.
<b>Return</b>	HTTP status codes		

## 5.6. Clinical Decision Support Service

Figure 54: SDD-ITF-CDSS: CDSS Interfaces



### Interface: KM Admin RESTful API

<b>Operation</b>	upload		Upload guideline files onto COSMIC CDS Knowledge Manager.
<b>Parameters</b>	gdlFile	File	The guideline file encoded in GDL format.
<b>Return</b>	HTTP status codes		

### Interface: CDS-hooks RESTful API

Operation	discovery		A RESTful operation allowing to discover all available CDS Services, including information such as the purpose of the CDS Service, when it should be invoked, and any data that is requested to be prefetched. The discovery endpoint is always available at {baseUrl}/cds-services.
Parameters	None		
Return	A list of CDS ServiceDescription		A list of CDS service descriptions.
Operation	call		The RESTful operation calling a CDS service.

<b>Parameters</b>	ServiceRequest	A JSON document POSTed to the service endpoint.
<b>Return</b>	ServiceResponse	Each CDS service can return any number of cards and/or decisions in response to the hook.

Class: ServiceDescription			
Name	Cardinality	Type	Description
hook	1..1	string or URL	The hook this service should be invoked on.
name	1..1	string	The name of this service.
description	1..1	string	The description of this service.
id	1..1	string	The {id} portion of the URL to this service which is available at {baseUrl}/cds-services/{id}.
prefetch	1..1	object	An object containing key/value pairs of FHIR queries to data that this service would like the client to prefetch and provide on each service call. The key is a string that describes the type of data being requested and the value is a string representing the FHIR query.

Class: ServiceRequest			
Name	Cardinality	Type	Description
hook	1..1	string or URL	The hook that triggered this CDS Service call.
hookInstance	1..1	string	A UUID for this particular hook call.
fhirServer	1..1	URL	The base URL of the FHIR server. The scheme should be https.
oauth	1..1	object	The OAuth2 authorization providing access to the FHIR server.
redirect	1..1	URL	The URL an app link card should redirect to upon completion of user interaction.
user	1..1	string	The FHIR resource type + ID representing the current user. The type is one of: Practitioner, Patient, or RelatedPerson. For example, Practitioner/123.
patient	1..1	string	The FHIR Patient.id of the current patient in context.
encounter	1..1	string	The FHIR Encounter.id of the current encounter in context.
context	1..1	object	Hook-specific contextual data that the CDS service will need. For example, with the medication-prescribe hook this will include MedicationOrder being prescribed.
prefetch	1..1	object	The FHIR data that was prefetched by the client.

Class: ServiceResponse			
Name	Cardinality	Type	Description
cards	0..*	Card	An array of Cards. Cards can provide a combination of information (for reading), suggested actions (to be applied if a user selects them), and links (to launch an app if the user selects them). The client decides how to display cards, but it is recommended displaying suggestions using buttons, and links using underlined text.
decisions	0..*	Decision	An array of Decisions. A decision should only be generated after interacting with the user through an app link. Decisions are designed to convey any choices the user made in an app session.

Class: Card			
Name	Cardinality	Type	Description
summary	1..1	string	One-sentence, less than 140-character summary message for display to the user inside of this card.
detail	0..1	string	Optional detailed information to display, represented in Markdown. (For non-urgent cards, the client may hide these details until the user clicks a link like “view more details...”).
indicator	1..1	string	Urgency/importance of what this card conveys. Allowed values, in order of increasing urgency, are: success, info, warning, hard-stop. The client can use this field to help make UI display decisions such as sort order or colouring. The value hard-stop indicates that the workflow should not be allowed to proceed.
source	1..1	Source	The source of the information displayed on this card.
suggestions	0..*	Suggestion	Array of Suggestions, which allow a service to suggest a set of changes in the context of the current activity (e.g., changing the dose of the medication currently being prescribed, for the medication-prescribe activity).
links	0..*	Link	Array of Links, which allow a service to suggest a link to an app that the user might want to run for additional information or to help guide a decision.

Class: Source			
Name	Cardinality	Type	Description
label	1..1	string	A short, human-readable label to display for the source of the information displayed on this card. If a url is also specified, this may be the text for the hyperlink.



url	0..1	URL	An optional URL to load (via GET, in a browser context) when a user clicks on this link to learn more about the organization or data set that provided the information on this card. Note that this URL should not be used to supply a context-specific “drill-down” view of the information on this card. For that, use link.url instead.
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**Class: Suggestion**

Name	Cardinality	Type	Description
label	1..1	string	Human-readable label to display for this suggestion (e.g., the EHR might render this as the text on a button tied to this suggestion).
uuid	1..1	string	Unique identifier for this suggestion.
create	1..1	string	New resource that this suggestion applies within the current activity (e.g., for medication-prescribe, this holds the updated prescription as proposed by the suggestion).
delete	1..1	string	ID of any resources to remove from the current activity (e.g., for the order-review activity, this would provide a way to remove orders from the pending list). In activities like medication-prescribe where only one “content” resource is ever relevant, this field may be omitted.

**Class: Link**

Name	Cardinality	Type	Description
label	1..1	string	Human-readable label to display for this link (e.g. the client might render this as the underlined text of a clickable link).
url	1..1	URL	URL to load (via GET, in a browser context) when a user clicks on this link. Note that this may be a “deep link” with context embedded in path segments, query parameters, or a hash. In general this URL should embed enough context for the app to determine the hookInstance, and redirect url upon downstream launch, because the client will simply use this url as-is, without appending any parameters at launch time.

**Class: Decision**

Name	Cardinality	Type	Description
create	0..*	string	Array of strings, id(s) of new resource(s) that the client should create within the current activity (e.g. for medication-prescribe, this would be the updated prescription that a user had authored in an app session).
delete	0..*	string	Array of strings, id(s) of any resources to remove from the current activity (e.g., for the order-review activity, this would provide a way

		to remove orders from the pending list). In activities like medication-prescribe where only one “content” resource is ever relevant, this field may be omitted.
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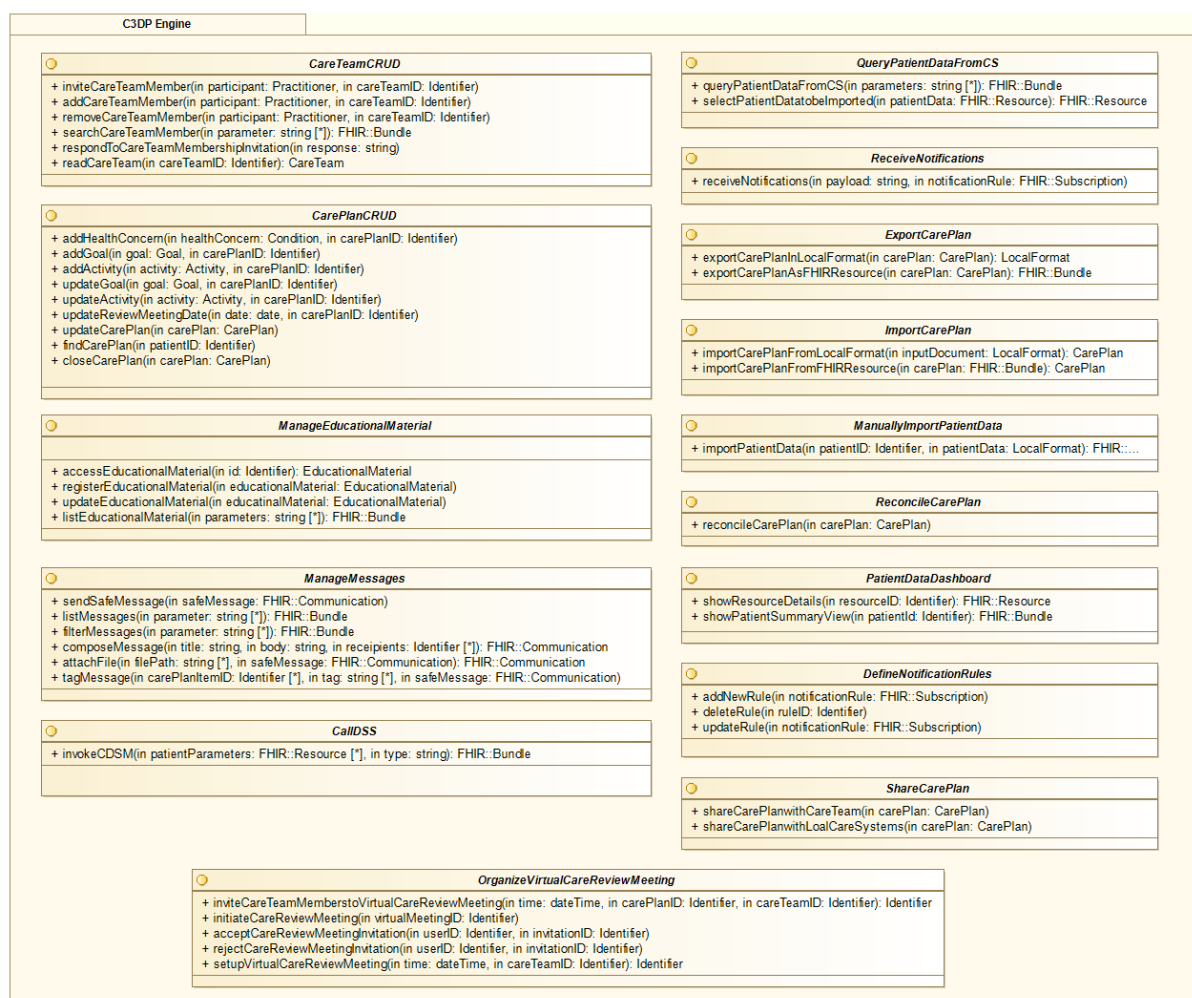
## 5.7. Coordinated Care and Cure Delivery Platform

Interfaces provided by C3DP are grouped under 5 main packages:

- C3DP Engine
- FHIR Repository
- Care System Gateway
- PEP Gateway
- Event Manager

### ❖ C3DP Engine

**Figure 55: SDD-ITF-C3DP-1: C3DP Engine Interfaces**



Interface: CareTeamCRUD			
<b>Operation</b>	inviteCareTeamMember		A RESTful operation for inviting new practitioners to care team.
<b>Parameters</b>	participant	Practitioner	Practitioner instance to be invited to the care team.
	careTeamID	Identifier	Unique identifier of the CareTeam instance to which the new participant is invited as a member.
<b>Return</b>	void		
<b>Operation</b>	addCareTeamMember		A RESTful operation for adding new care team members to the care team.
<b>Parameters</b>	participant	Practitioner	Parameters.
	careTeamID	Identifier	Unique identifier of the CareTeam instance to which the new participant is added as a member.
<b>Return</b>	void		
<b>Operation</b>	removeCareTeamMember		A RESTful operation for removing new care team members to the care team.
<b>Parameters</b>	participant	Practitioner	Practitioner instance to be removed to the care team.
	careTeamID	Identifier	Unique identifier of the CareTeam instance from which the participant will be detached.
<b>Return</b>	void		
<b>Operation</b>	searchCareTeamMember		A RESTful operation for searching care team members based on the specified parameters.
<b>Parameters</b>	parameter	String[*]	Parameters to be passed as FHIR CareTeam resource search criteria.
<b>Return</b>	FHIR::Bundle		
<b>Operation</b>	respondToCareTeamMembershipInvitation		A RESTful operation for responding care team membership invitation.
<b>Parameters</b>	response	string	‘Accept’ or ‘Reject’ response.
<b>Return</b>	void		
<b>Operation</b>	readCareTeam		A RESTful operation for retrieving the details of a CareTeam given the id.
<b>Parameters</b>	careTeamID	Identifier	The unique identifier of the CareTeam instance to be retrieved.
<b>Return</b>	CareTeam		

Interface: CarePlanCRUD			
<b>Operation</b>	addHealthConcern		A RESTful operation for adding a condition definition as a health concern to the care plan definition.
<b>Parameters</b>	healthConcern	Condition	The Condition instance to be added as a health concern to the care plan definition.
	carePlanID	Identifier	The unique identifier of the care plan to be edited.
<b>Return</b>	void		
<b>Operation</b>	addGoal		A RESTful operation for adding a goal to the care plan definition.
<b>Parameters</b>	goal	Goal	The Goal instance to be added as a goal to the care plan definition.
	carePlanID	Identifier	The unique identifier of the care plan to be edited.
<b>Return</b>	void		
<b>Operation</b>	addActivity		A RESTful operation for adding an activity to the care plan definition.
<b>Parameters</b>	activity	Activity	The Activity instance to be added as a new activity to the care plan definition.
	carePlanID	Identifier	The unique identifier of the care plan to be edited.
<b>Return</b>	void		
<b>Operation</b>	updateGoal		A RESTful operation for updating the goal definition within a care plan definition.
<b>Parameters</b>	goal	Goal	The Goal instance to be updated within the care plan definition.
	carePlanID	Identifier	The unique identifier of the care plan to be edited.
<b>Return</b>	void		
<b>Operation</b>	updateActivity		A RESTful operation for updating an activity definition within a care plan definition.
<b>Parameters</b>	activity	Activity	The Activity instance to be updated within the care plan definition.
	carePlanID	Identifier	The unique identifier of the care plan to be edited.
<b>Return</b>	void		

<b>Operation</b>	updateReviewMeetingDate		A RESTful operation for updating the date of the next care plan review meeting within a care plan definition.
<b>Parameters</b>	date	Date	The date of the next care plan review meeting planned.
	carePlanID	Identifier	The unique identifier of the care plan to be edited.
<b>Return</b>	void		
<b>Operation</b>	updateCarePlan		A RESTful operation for updating the care plan instance as a whole.
<b>Parameters</b>	carePlan	CarePlan	The CarePlan instance to be updated.
<b>Return</b>	void		
<b>Operation</b>	findCarePlan		A RESTful operation for listing all care plans for a given patient.
<b>Parameters</b>	patientID	Identifier	The unique identifier of the Patient.
<b>Return</b>	void		
<b>Operation</b>	closeCarePlan		A RESTful operation for updating the status of the care plan as closed.
<b>Parameters</b>	carePlan	CarePlan	The CarePlan instance to be updated.
<b>Return</b>	void		

#### Interface: ShareCarePlan

<b>Operation</b>	shareCarePlanwithCareTeam		A RESTful operation for sharing the latest version of the care plan with the care team members listed within the care plan definition.
<b>Parameters</b>	carePlan	CarePlan	The CarePlan instance to be shared.
<b>Return</b>	Void		
<b>Operation</b>	shareCarePlanwithLocalCaresystems		A RESTful operation for sharing a snapshot of the care plan with local care systems
<b>Parameters</b>	carePlan	LocalFormat	The CarePlan instance exported as a document in the local format to be shared.
<b>Return</b>	void		

#### Interface: ManageEducationalMaterial

<b>Operation</b>	accessEducationalMaterial		A RESTful operation to retrieve in the EducationMaterial instance given the unique identifier.
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<b>Parameters</b>	Id	Identifier	The unique ID of the educational material.
<b>Return</b>	EducationMaterial		
<b>Operation</b>	registerEducationalMaterial		A RESTful operation to register an EducationMaterial instance to the C3DP system together with its metadata in its definition.
<b>Parameters</b>	educationMaterial	EducationMaterial	EducationMaterial instance to be registered.
<b>Return</b>	void		
<b>Operation</b>	updateEducationalMaterial		A RESTful operation to update an EducationMaterial instance registered to the C3DP system.
<b>Parameters</b>	educationMaterial	EducationMaterial	EducationMaterial instance to be updated.
<b>Return</b>	void		
<b>Operation</b>	listEducationalMaterial		A RESTful operation to list the EducationMaterial instances matching the search parameters.
<b>Parameters</b>	parameters	String [*]	Search criteria to be passed to the FHIR Repository to retrieve the matching EducationMaterial instances.
<b>Return</b>	FHIR::Bundle		

#### Interface: ManageMessages

<b>Operation</b>	sendSafeMessage		A RESTful operation to send messages to care team members.
<b>Parameters</b>	safeMessage	FHIR::Communication	FHIR::Communication instance representing the message content and receivers.
<b>Return</b>	void		
<b>Operation</b>	composeMessage		A RESTful operation to compose a message.
<b>Parameters</b>	title	String	Title of the message.
	Body	String	Body of the message.
	recipients	Identifier [*]	Unique identifiers of the Care Team Members to receive the message.
<b>Return</b>	FHIR::Communication		

<b>Operation</b>	attachFile		A RESTful operation to attach a file to message.
<b>Parameters</b>	filePaths	String[*]	List of paths of the files to be attached.
	safeMessage	FHIR::Communication	FHIR::Communication instance to which the files will be attached to.
<b>Return</b>	FHIR::Communication		
<b>Operation</b>	listMessages		A RESTful operation to list the Messages matching the search parameters.
<b>Parameters</b>	parameters	String	Search criteria to be passed to the FHIR Repository to retrieve the matching Communication instances.
<b>Return</b>	FHIR::Bundle		
<b>Operation</b>	filterMessages		A RESTful operation to filter the Messages listed matching the filter parameters.
<b>Parameters</b>	parameters	String	Criteria to be used to filter the matching Communication instances listed.
<b>Return</b>	FHIR::Bundle		
<b>Operation</b>	tagMessages		A RESTful operation to tag the Messages with custom tags, and to optionally associate it with carePlan activity and goals.
<b>Parameters</b>	carePlanItemID	Identifier[*]	Unique identifier of the goals/activities wished to be associated with message.
	tag	String[*]	Labels wished to be associated with the message.
	safeMessage	FHIR::Communication	FHIR::Communication instance to be tagged.
<b>Return</b>	FHIR::Communication		

#### Interface: QueryPatientDataFromCS

<b>Operation</b>	queryPatientDataFromCS		A RESTful operation to query patient data from local care systems via the TIS.
<b>Parameters</b>	parameters	String[*]	The FHIR Resource search parameters to query patient data.
<b>Return</b>	FHIR::Bundle		

<b>Operation</b>	selectPatientDataTobeImported		A RESTful operation to select the patient data instances to be imported among the patient data list returned by 'queryPatientDataFromCS' query.
<b>Parameters</b>	patientData	FHIR::Resource	The FHIR::Resource instance selected to be imported.
<b>Return</b>	FHIR::Resource		

#### Interface: DefineNotificationRules

<b>Operation</b>	addNewRule		A RESTful operation to add a new notification rule.
<b>Parameters</b>	notificationRule	FHIR::Subscription	The FHIR Subscription instance representing the notification rule defining event criteria and communication channels to be used to deliver the notification.
<b>Return</b>	void		
<b>Operation</b>	addNewRule		A RESTful operation to update an existing notification rule.
<b>Parameters</b>	notificationRule	FHIR::Subscription	The updated FHIR Subscription instance representing the notification rule defining event criteria and communication channels to be used to deliver the notification.
<b>Return</b>	Void		
<b>Operation</b>	deleteRule		A RESTful operation to delete an existing notification rule.
<b>Parameters</b>	ruleID	Identifier	The unique ID of the FHIR Subscription instance representing the notification rule to be deleted.
<b>Return</b>	void		

#### Interface: ReceiveNotifications

<b>Operation</b>	receiveNotifications		The Restful endpoint to receive the notifications fired as a result of a defined notification rule.
<b>Parameters</b>	payload	String	The notification payload received.
	notificationRule	FHIR::Subscription	The notification rule fired.
<b>Return</b>	void		



Interface: ReconcileCarePlan			
<b>Operation</b>	reconcileCarePlan		A RESTful operation to initiate the reconciliation process, by communicating with the respective clinical decision support modules when necessary. A list of warning and error messages will be returned as a result.
<b>Parameters</b>	carePlan	CarePlan	The CarePlan instance to be reconciled.
<b>Return</b>	String[*]		The list of warning and error messages returned as a result of reconciliation.

Interface: OrganizeVirtualCareReviewMeeting			
<b>Operation</b>	inviteCareTeamMembersToVirtualCareReviewMeeting		A RESTful operation to invite Care Team Members to a created virtual.
<b>Parameters</b>	time	dateTime	Planned time of the virtual meeting.
	carePlanID	Identifier	CarePlan as the scope of the meeting.
	careTeamID	Identifier	Invited participants of the meeting.
<b>Return</b>	Identifier		Unique identifier assigned to the invitation.
<b>Operation</b>	acceptCareReviewMeetingInvitation		A RESTful operation to allow the invited Care Team Member to accept the invitation.
<b>Parameters</b>	userId	Identifier	Care Team Member accepting the invitation.
	invitationID	Identifier	Virtual meeting invitation identifier.
<b>Return</b>	void		
<b>Operation</b>	rejectCareReviewMeetingInvitation		A RESTful operation to allow the invited Care Team Member to reject the invitation.
<b>Parameters</b>	userId	Identifier	Care Team Member rejecting the invitation.
	invitationID	Identifier	Virtual meeting invitation identifier.
<b>Return</b>	void		
<b>Operation</b>	setupVirtualCareReviewMeeting		A RESTful endpoint to forward virtual meeting setup request to the external Teleconferencing System and get back the session identifier.
<b>Parameters</b>	time	dateTime	Actual time of the virtual meeting.

	careTeamID	Identifier	Actual participants of the virtual meeting.
<b>Return</b>	Identifier		The unique identifier assigned to the newly setup virtual meeting session.
<b>Operation</b>	initiateVirtualCareReviewMeeting		A RESTful endpoint to forward start request for a previously setup virtual meeting session to the external Teleconferencing System.
<b>Parameters</b>	virtualMeetingID	Identifier	Virtual meeting session identifier.
<b>Return</b>	void		

#### Interface: CalIDSS

<b>Operation</b>	invokeCDSM		A RESTful endpoint to accept CDSM call requests from the C3DP and forward to CDS-hooks RESTful API of the CDSM, and then get back the results from the CDSM.
<b>Parameters</b>	patientParameters [*]	FHIR::Resource	Patient data that are necessary for executing the CDSM.
	type	string	The type of the CDSM to be executed.
<b>Return</b>	FHIR::Bundle		Outcome of the CDSM execution.

#### Interface: PatientDataDashboard

<b>Operation</b>	showPatientSummaryView		A RESTful operation to collect the summary of all patient data (e.g., conditions, procedures, medications) available in the FHIR Repository.
<b>Parameters</b>	patientID	Identifier	Identifier of the patient as the subject of data.
<b>Return</b>	FHIR::Bundle		Patient data represented as FHIR resources and collected in a FHIR Bundle.
<b>Operation</b>	showResourceDetails		A RESTful operation to retrieve the full details of a specific resource (e.g., Condition, Procedure, Medication) requested by the Care Team Member.
<b>Parameters</b>	resourceID	Identifier	Identifier of the resource to be retrieved.
	resourceType	string	The type of resource to be retrieved (e.g., Condition, Procedure).
<b>Return</b>	FHIR::Resource		The requested FHIR Resource with all details present.

**Interface: ManuallyImportPatientData**

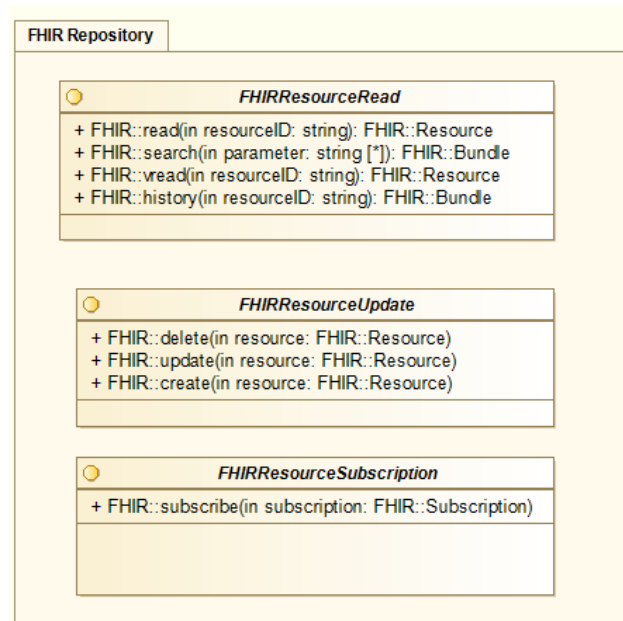
<b>Operation</b>	importPatientData		A RESTful operation to transform manually imported patient data in local format to FHIR resources via SIS and then store them in the FHIR Repository.
<b>Parameters</b>	patientID	Identifier	Identifier of the patient as the subject of patient data.
	patientData	LocalFormat	Patient data in local format (e.g., CDA document).
<b>Return</b>	HTTP status codes		

**Interface: ImportCarePlan**

<b>Operation</b>	importCarePlanFromLocalFormat		A RESTful operation to transform manually imported care plan in local format to FHIR::CarePlan via SIS and then store it in the FHIR Repository.
<b>Parameters</b>	inputDocument	LocalFormat	Care plan in local format (e.g., CDA document).
<b>Return</b>	CarePlan		
<b>Operation</b>	importCarePlanFromFHIRResource		A RESTful operation to store a manually imported FHIR::CarePlan (e.g. might be a CarePlan instance exported from C3DP earlier in a file system) in the FHIR Repository.
<b>Parameters</b>	carePlan	FHIR::Bundle	CarePlan and contained resources in a FHIR::Bundle.
<b>Return</b>	CarePlan		

**Interface: ExportCarePlan**

<b>Operation</b>	exportCarePlanInLocalFormat		A RESTful operation to transform the care plan in FHIR::CarePlan format to a local format (e.g., CDA document) via SIS.
<b>Parameters</b>	carePlan	CarePlan	Care plan in FHIR::CarePlan format.
<b>Return</b>	LocalFormat		
<b>Operation</b>	exportCarePlanAsFHIRResource		A RESTful operation to transform the care plan in FHIR::CarePlan format to a FHIR::Bundle including the CarePlan and contained resources.
<b>Parameters</b>	carePlan	CarePlan	Care plan in FHIR::CarePlan format.
<b>Return</b>	FHIR::Bundle		

❖ **FHIR Repository****Figure 56: SDD-ITF-C3DP-2: C3DP FHIR Repository Interfaces**

Interface: FHIRResourceRead			
<b>Operation</b>	FHIR::read		FHIR RESTful instance level <i>read</i> , to read a FHIR resource (e.g. Condition, CarePlan, Procedure) instance from the FHIR Repository.
<b>Parameters</b>	resourceId	string	Identifier of the resource instance.
<b>Return</b>	FHIR::Resource		The requested FHIR resource instance.
<b>Operation</b>	FHIR::vread		FHIR RESTful instance level <i>vread</i> , to read a specific version of a FHIR resource instance.
<b>Parameters</b>	resourceId	string	Identifier of the resource instance.
	version	string	Specific version of the resource.
<b>Return</b>	FHIR::Resource		The requested FHIR resource instance.
<b>Operation</b>	FHIR::history		FHIR RESTful instance level <i>history</i> , to retrieve the history of a particular FHIR resource instance.
<b>Parameters</b>	resourceId	string	Identifier of the resource instance.
<b>Return</b>	FHIR::Bundle		A FHIR Bundle of type history, containing the specified version history.

<b>Operation</b>	FHIR::search		FHIR RESTful type level <i>search</i> , to search FHIR resource instances based on some filter criteria.
<b>Parameters</b>	searchParam [*]	string	Filter criteria for search operation.
<b>Return</b>	FHIR::Bundle		A FHIR Bundle containing FHIR resource instances matching the filter criteria.

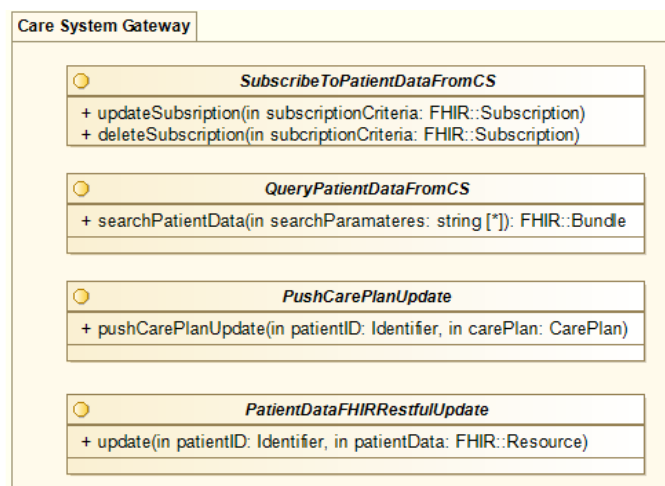
#### Interface: FHIRResourceUpdate

<b>Operation</b>	FHIR::create		FHIR RESTful type level <i>create</i> , to create a new FHIR resource instance.
<b>Parameters</b>	resource	FHIR::Resource	FHIR resource instance to be created.
<b>Return</b>	HTTP status codes		
<b>Operation</b>	FHIR::update		FHIR RESTful instance level <i>update</i> , to update an existing FHIR resource instance.
<b>Parameters</b>	resource	FHIR::Resource	FHIR resource instance to be updated.
<b>Return</b>	HTTP status codes		
<b>Operation</b>	FHIR::delete		FHIR RESTful instance level <i>delete</i> , to delete an existing FHIR resource instance.
<b>Parameters</b>	resource	FHIR::Resource	FHIR resource instance to be deleted.
<b>Return</b>	HTTP status codes		

#### Interface: FHIRResourceSubscription

<b>Operation</b>	FHIR::subscribe		FHIR RESTful subscription / push interface to subscribe to specific resources / resource types and receive the updates.
<b>Parameters</b>	subscription	FHIR::Subscription	FHIR Subscription resource, used to define a push based subscription. It contains the criteria for subscription and the channel to receive the updates.
<b>Return</b>	HTTP status codes		

#### ❖ Care System Gateway

**Figure 57: SDD-ITF-C3DP-3: C3DP Care System Gateway Interfaces****Interface: QueryPatientDataFromCS**

<b>Operation</b>	searchPatientData	A RESTful operation to query local care systems for patient data via TIS PatientDataFHIRRestfulRead FHIR API.
<b>Parameters</b>	searchParameters [*]	string Search parameters.
<b>Return</b>	FHIR::Bundle	FHIR resources matching the search criteria, collected in a Bundle.

**Interface: SubscribeToPatientDataFromCS**

<b>Operation</b>	updateSubscription	A RESTful operation to subscribe to local care systems via TIS for specific patient data represented as FHIR resources.
<b>Parameters</b>	subscriptionCriteria	FHIR::Subscription FHIR Subscription resource, used to define a push based subscription.
<b>Return</b>	HTTP status codes	
<b>Operation</b>	deleteSubscription	A RESTful operation to cancel an existing patient data subscription on TIS.
<b>Parameters</b>	subscriptionCriteria	FHIR::Subscription FHIR subscription to be deleted.
<b>Return</b>	HTTP status codes	

**Interface: PatientDataFHIRRestfulUpdate**

<b>Operation</b>	update	A RESTful endpoint to receive the patient data updates pushed from TIS according to existing subscriptions.
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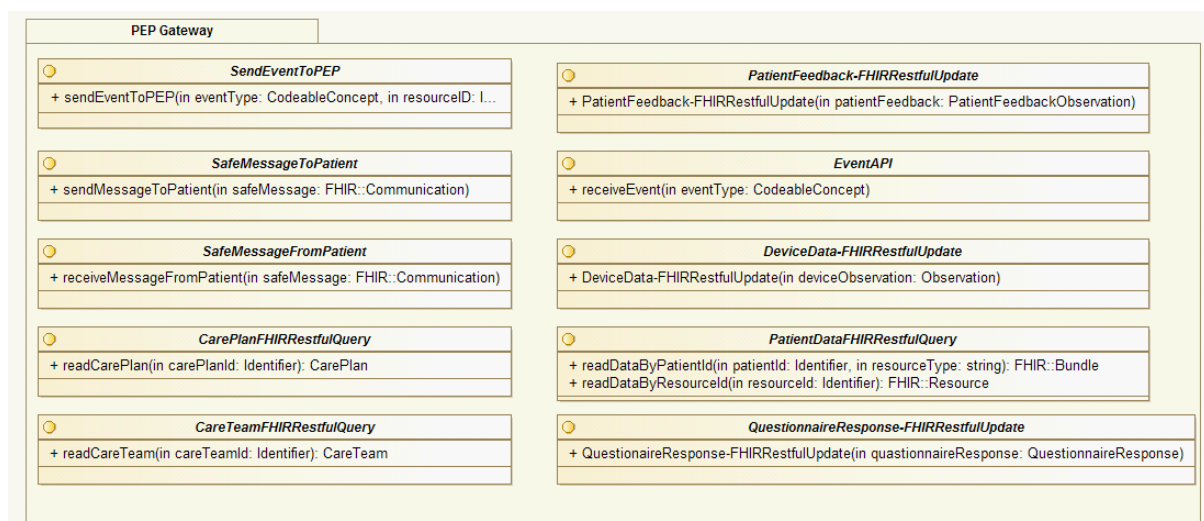
<b>Parameters</b>	patientID	Identifier	Identifier of the patient as the subject of patient data.
	patientData	FHIR::Resource	Patient data updates pushed from TIS as FHIR resources.
<b>Return</b>	HTTP status codes		

#### Interface: PushCarePlanUpdate

<b>Operation</b>	pushCarePlanUpdate	A RESTful operation to push the care plan of a patient from C3DP to local care system via TIS.	
<b>Parameters</b>	patientID	Identifier	Identifier of the patient as the subject of the care plan.
	carePlan	CarePlan	Personalised care plan of the patient in FHIR::CarePlan format.
<b>Return</b>	HTTP status codes		

### ❖ PEP Gateway

Figure 58: SDD-ITF-C3DP-4: C3DP PEP Gateway Interfaces



#### Interface: DeviceData-FHIRRestfulUpdate

<b>Operation</b>	deviceData-FHIRRestfulUpdate	A RESTful endpoint to receive the medical device measurements pushed from PEP according to existing subscriptions, and store them in the FHIR Repository.	
<b>Parameters</b>	deviceObservation	DeviceObservation	Medical device measurements represented in a specialized FHIR::Observation.
<b>Return</b>	HTTP status codes		

Interface: PatientFeedback-FHIRRestfulUpdate			
<b>Operation</b>	patientFeedback-FHIRRestfulUpdate		A RESTful endpoint to receive patient feedback (e.g., for a specific goal or activity) pushed from PEP, and store them in the FHIR Repository. These subscriptions are automatically created when a care plan is shared with PEP.
<b>Parameters</b>	patientFeedback	PatientFeedbackObservation	Patient feedback represented in a specialized FHIR::Observation.
<b>Return</b>	HTTP status codes		

Interface: QuestionnaireResponse-FHIRRestfulUpdate			
<b>Operation</b>	questionnaireResponse-FHIRRestfulUpdate		A RESTful endpoint to receive questionnaire responses provided by the patient and pushed from PEP, and store them in the FHIR Repository. These subscriptions are automatically created when a care plan is shared with PEP.
<b>Parameters</b>	questionnaireResponse	QuestionnaireResponse	Questionnaire response represented in FHIR::QuestionnaireResponse.
<b>Return</b>	HTTP status codes		

Interface: CarePlanFHIRRestfulQuery			
<b>Operation</b>	readCarePlan		FHIR RESTful instance level <i>read</i> to read a specific FHIR CarePlan instance from the FHIR Repository.
<b>Parameters</b>	carePlanId	Identifier	Identifier of the CarePlan instance. This ID is notified to PEP earlier via event API.
<b>Return</b>	CarePlan		The complete CarePlan instance.

Interface: CareTeamFHIRRestfulQuery			
<b>Operation</b>	readCareTeam		FHIR RESTful instance level <i>read</i> to read a specific FHIR CareTeam instance from the FHIR Repository.
<b>Parameters</b>	careTeamId	Identifier	Identifier of the CareTeam instance. This ID is notified to PEP earlier via event API.



<b>Return</b>	CareTeam	The complete CareTeam instance.
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#### Interface: PatientDataFHIRRestfulQuery

<b>Operation</b>	readDataByPatientId		FHIR RESTful instance level <i>read</i> to read patient data represented as FHIR resources (e.g., Condition, Procedure, Observation) from the FHIR Repository.
<b>Parameters</b>	patientId	Identifier	Identifier of the patient as the subject of data.
	resourceType	string	The type of FHIR resources to be read.
<b>Return</b>	FHIR::Bundle		Requested patient data collected in a FHIR Bundle.
<b>Operation</b>	readDataByResourceId		FHIR RESTful instance level <i>read</i> to read a specific patient data represented as a FHIR resource from the FHIR Repository.
<b>Parameters</b>	resourceId	Identifier	Identifier of the specific FHIR resource instance to be read.
<b>Return</b>	FHIR::Resource		Requested FHIR resource instance.

#### Interface: SafeMessageToPatient

<b>Operation</b>	sendMessageToPatient		A RESTful operation to push safe messages created by the MDT through C3DP to the patient through PEP.
<b>Parameters</b>	safeMessage	FHIR::Communication	The safe message represented in a FHIR::Communication resource.
<b>Return</b>	HTTP status codes		

#### Interface: SafeMessageFromPatient

<b>Operation</b>	receiveMessage		A RESTful operation to receive safe messages sent by the patient via PEP, and store them in the FHIR Repository.
<b>Parameters</b>	safeMessage	FHIR::Communication	The safe message represented in a FHIR::Communication resource.
<b>Return</b>	HTTP status codes		

#### Interface: SendEventToPEP

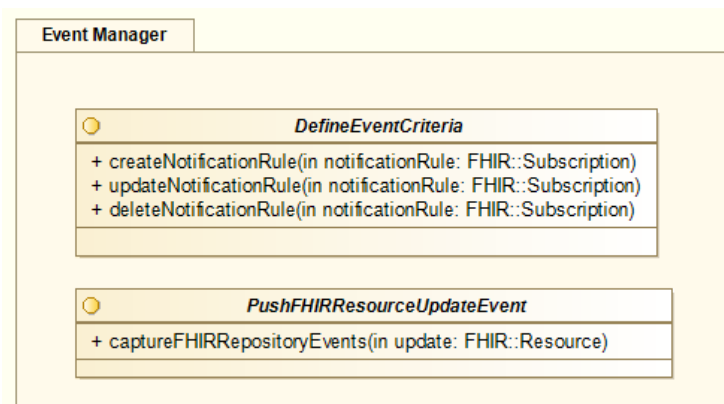
<b>Operation</b>	sendEventToPEP		A RESTful operation to push C3DP events (e.g. CarePlanUpdate, CareTeamUpdate) to PEP.
<b>Parameters</b>	eventType	CodeableConcept	The event expressed in a coded manner.
	resourceID	Identifier[*]	The list of unique ID of the resources affected by the event.
<b>Return</b>	HTTP status codes		

#### Interface: EventAPI

<b>Operation</b>	receiveEvent		A RESTful operation to receive events (e.g., CarePlanRead, MessageRead) pushed by PEP.
<b>Parameters</b>	eventType	CodeableConcept	The event expressed in a coded manner.
<b>Return</b>	HTTP status codes		

### ❖ Event Manager

**Figure 59: SDD-ITF-C3DP-5: C3DP Event Manager Interfaces**



#### Interface: DefineEventCriteria

<b>Operation</b>	createNotificationRule		A RESTful operation to create a new notification rule in the Event Manager.
<b>Parameters</b>	notificationRule	FHIR::Subscription	Notification rule expressed in a FHIR::Subscription instance.
<b>Return</b>	HTTP status codes		
<b>Operation</b>	updateNotificationRule		A RESTful operation to update an existing notification rule in the Event Manager.

<b>Parameters</b>	notificationRule	FHIR::Subscription	Notification rule expressed in a FHIR::Subscription instance.
<b>Return</b>	HTTP status codes		
<b>Operation</b>	deleteNotificationRule		A RESTful operation to delete an existing notification rule in the Event Manager.
<b>Parameters</b>	notificationRule	FHIR::Subscription	Notification rule expressed in a FHIR::Subscription instance.
<b>Return</b>	HTTP status codes		

#### Interface: PushFHIRResourceUpdateEvent

<b>Operation</b>	captureFHIRRepositoryEvents		A RESTful endpoint for receiving an update from the FHIR Repository related with existing subscriptions. Depending on the complexity of notification rule, the event can be directly generated by the FHIR Repository or data can be pushed to the Event Manager, which can then check the existence of the notification.
<b>Parameters</b>	update	FHIR::Resource	The event expressed in a coded manner.
<b>Return</b>	HTTP status codes		

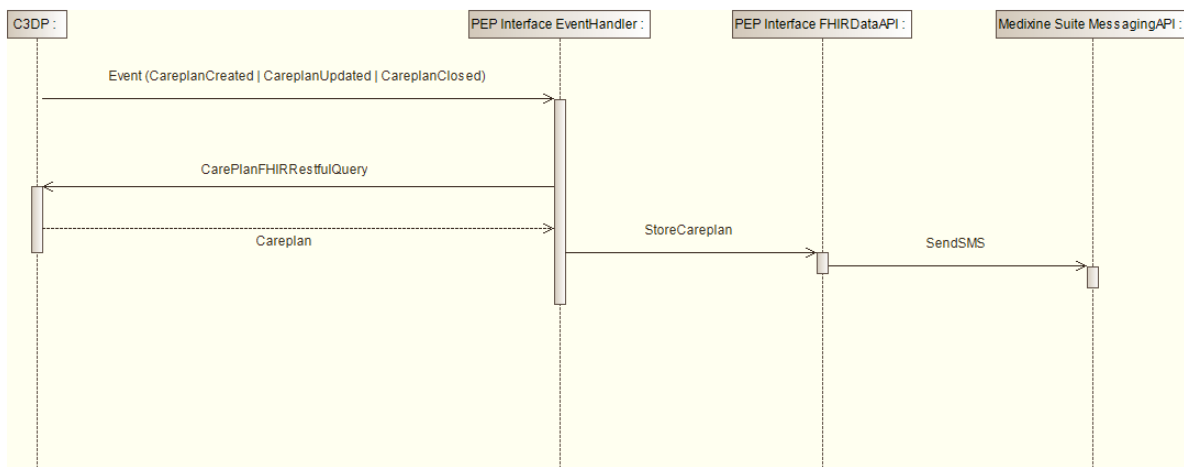
## 6. INTERACTION VIEW

The Interaction view describes interactions among the different system components to capture the dynamic aspect of a system. This view is governed by the interaction viewpoint declared in Section 1.7, and represented by UML2 sequence diagram. Sequence diagrams are used to capture the time sequence of messages flow from one component to another. One sequence diagram is created for each use case defined in D3.2 to describe the flow of logic how the use case is fulfilled.

### 6.1. Patient Empowerment Platform

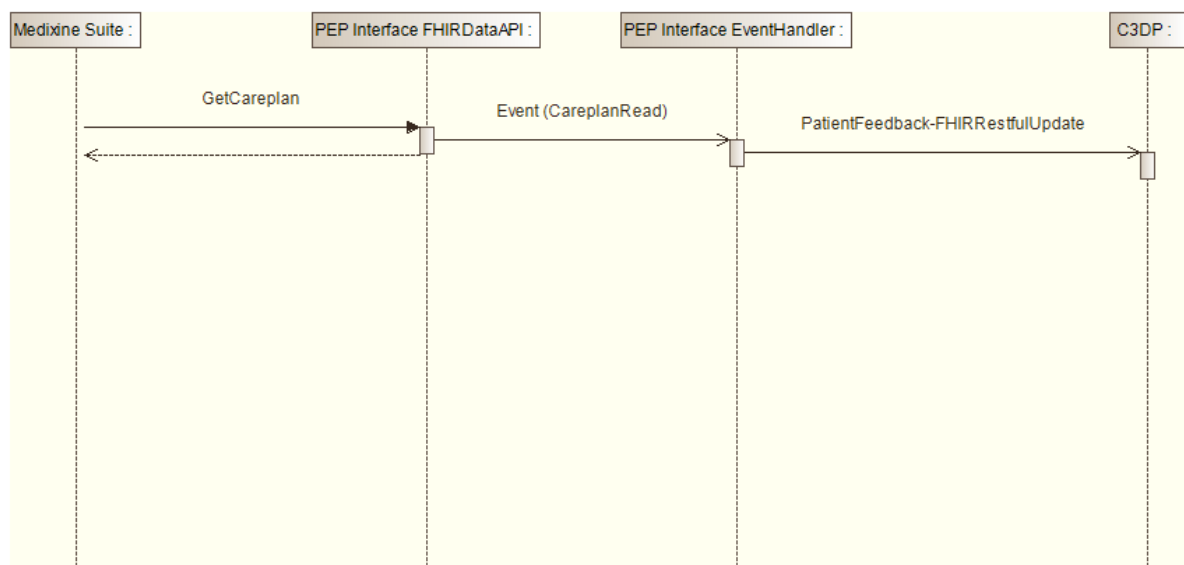
- PEP-1.1: Publish active care plan to patient,
- PEP-1.6: Update active care plan
- PEP-1.7: Mark active care plan as finished

**Figure 60: SDD-SEQ-PEP-1: Use Cases PEP-1.1/1.6/1.7 Sequence Diagram**



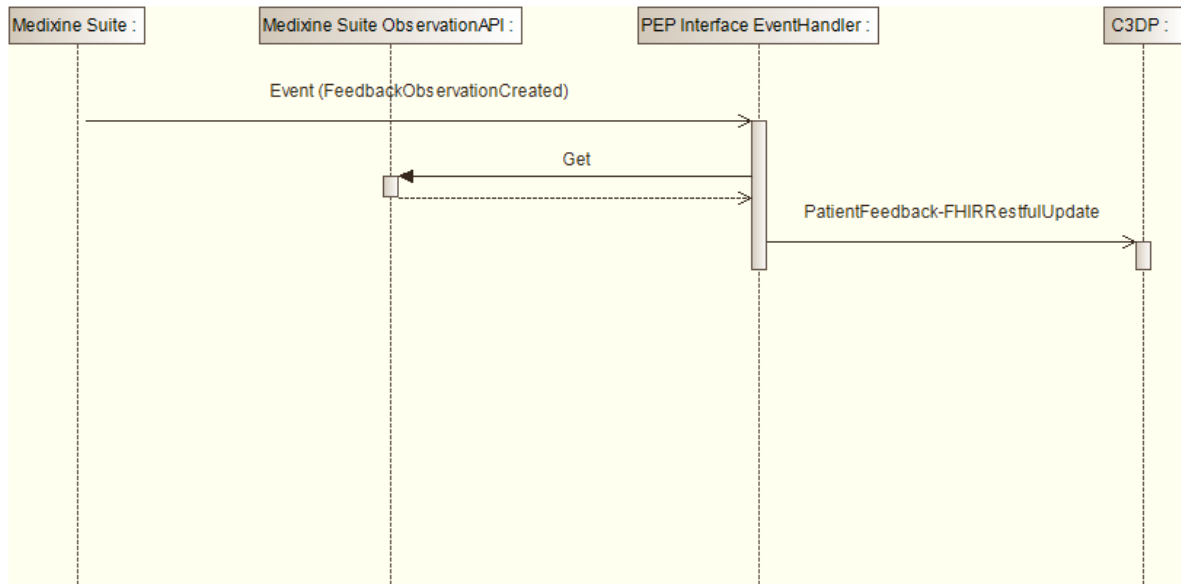
- PEP-1.2: View active care plan

**Figure 61: SDD-SEQ-PEP-2: Use Case PEP-1.2 Sequence Diagram**



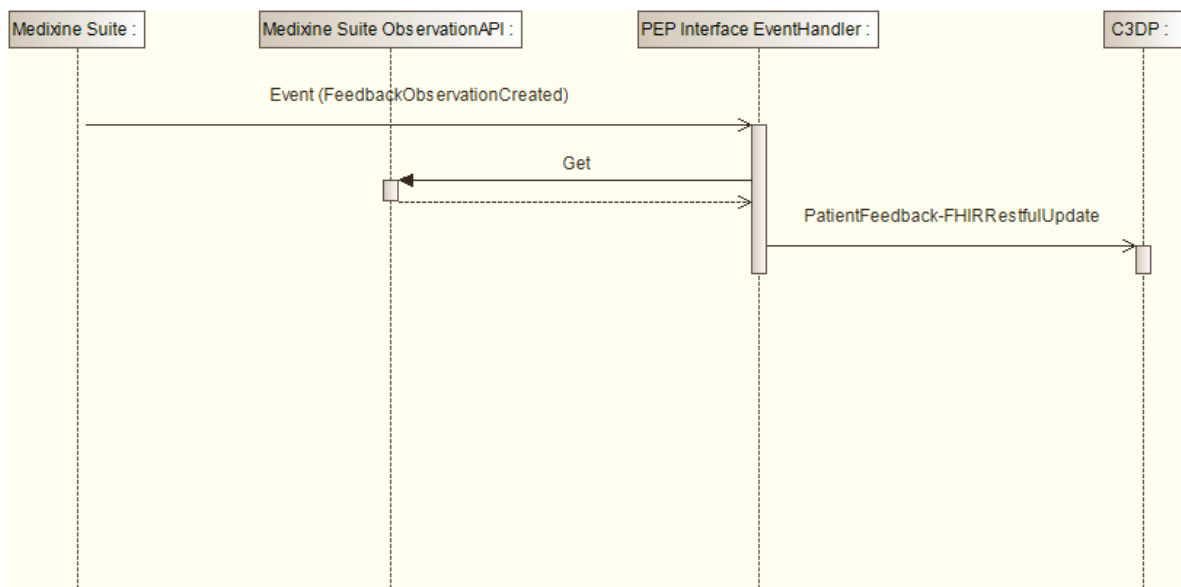
- PEP-1.4: Flag care plan treatment interventions and the corresponding goals as achieved

**Figure 62: SDD-SEQ-PEP-3: Use Case PEP-1.4 Sequence Diagram**



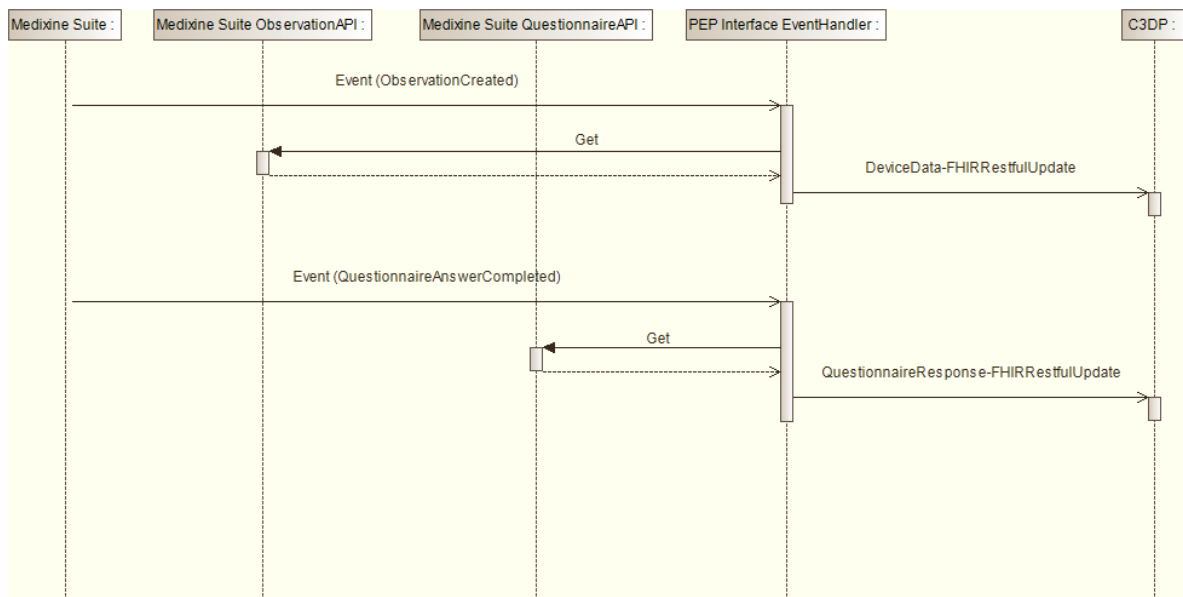
- PEP-1.5: Flag care plan treatment interventions and the corresponding goals as not achieved

**Figure 63: SDD-SEQ-PEP-4: Use Case PEP-1.5 Sequence Diagram**



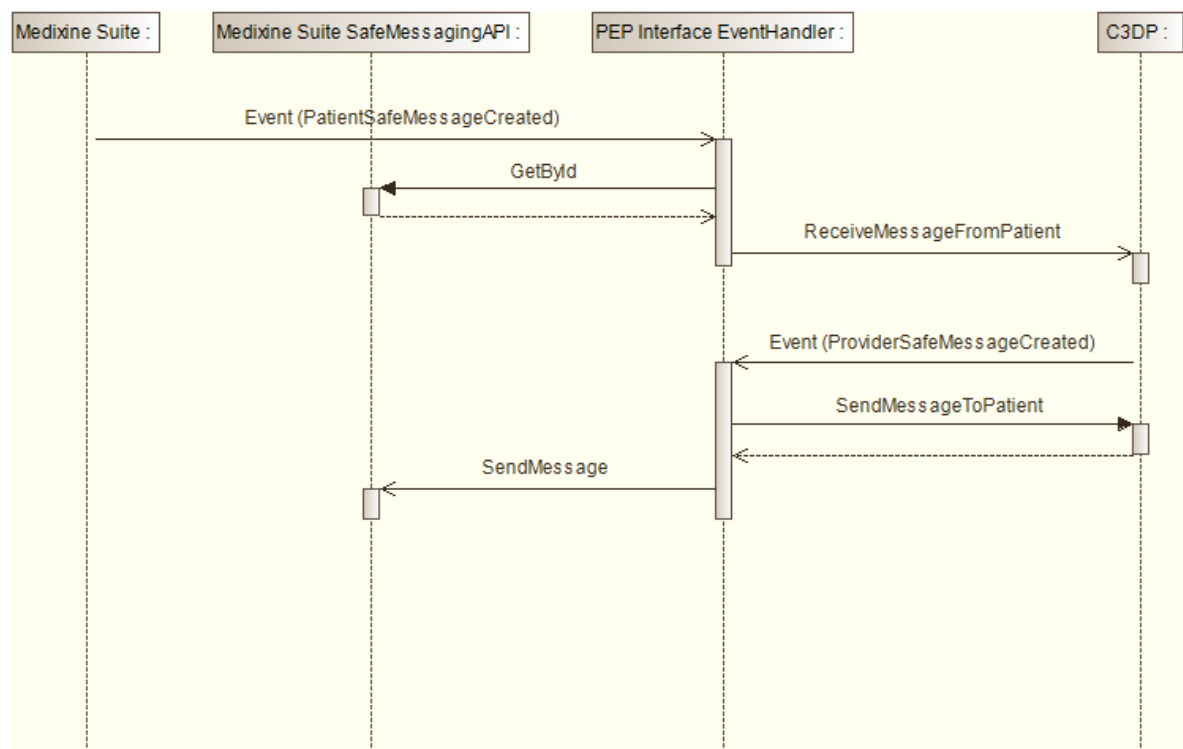
- PEP-2.3: Notify connected systems of new and changed patient-observed data

**Figure 64: SDD-SEQ-PEP-5: Use Case PEP-2.3 Sequence Diagram**



- PEP-3.1: Communicate via Safe messaging

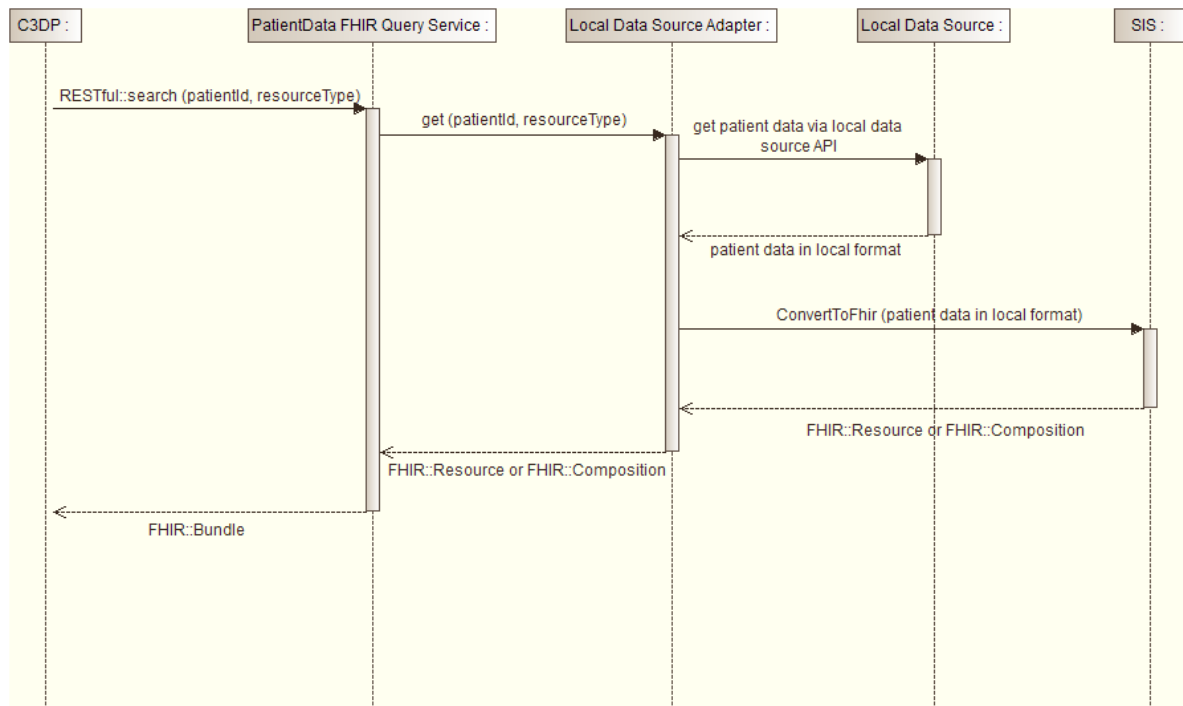
**Figure 65: SDD-SEQ-PEP-6: Use Case PEP-3.1 Sequence Diagram**



## 6.2. Technical Interoperability Suite

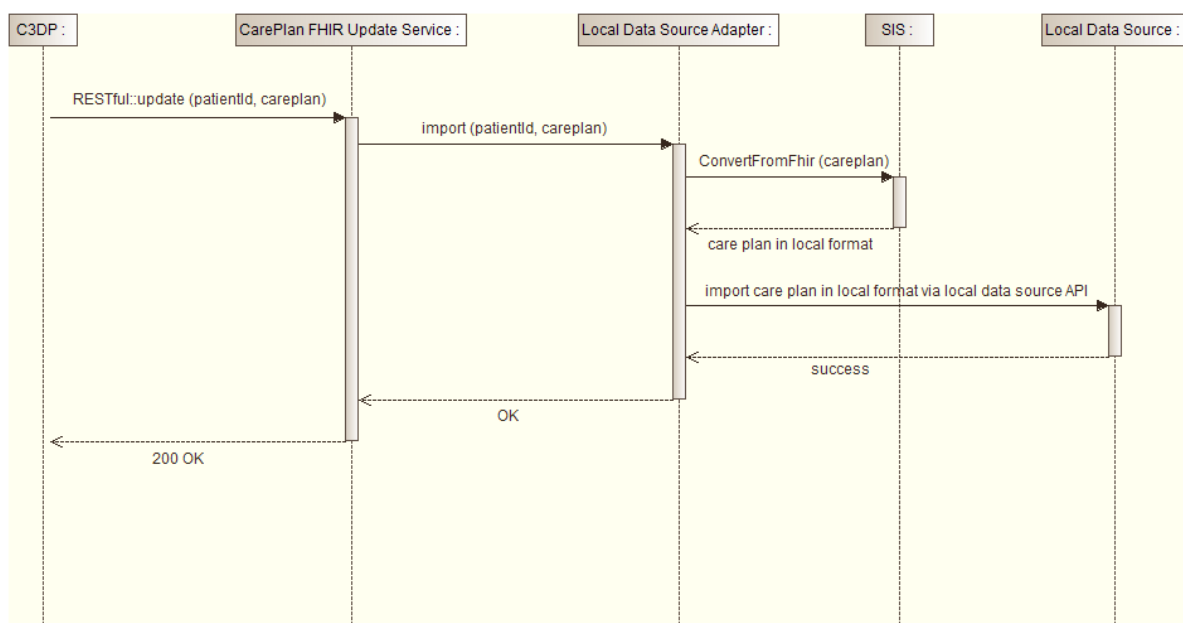
- TIS-1 Query Patient Data

**Figure 66: SDD-SEQ-TIS-1: Use Case TIS-1 Sequence Diagram**



- TIS-2 Share Care Plan

**Figure 67: SDD-SEQ-TIS-2: Use Case TIS-2 Sequence Diagram**



- TIS-3 Push Patient Observations

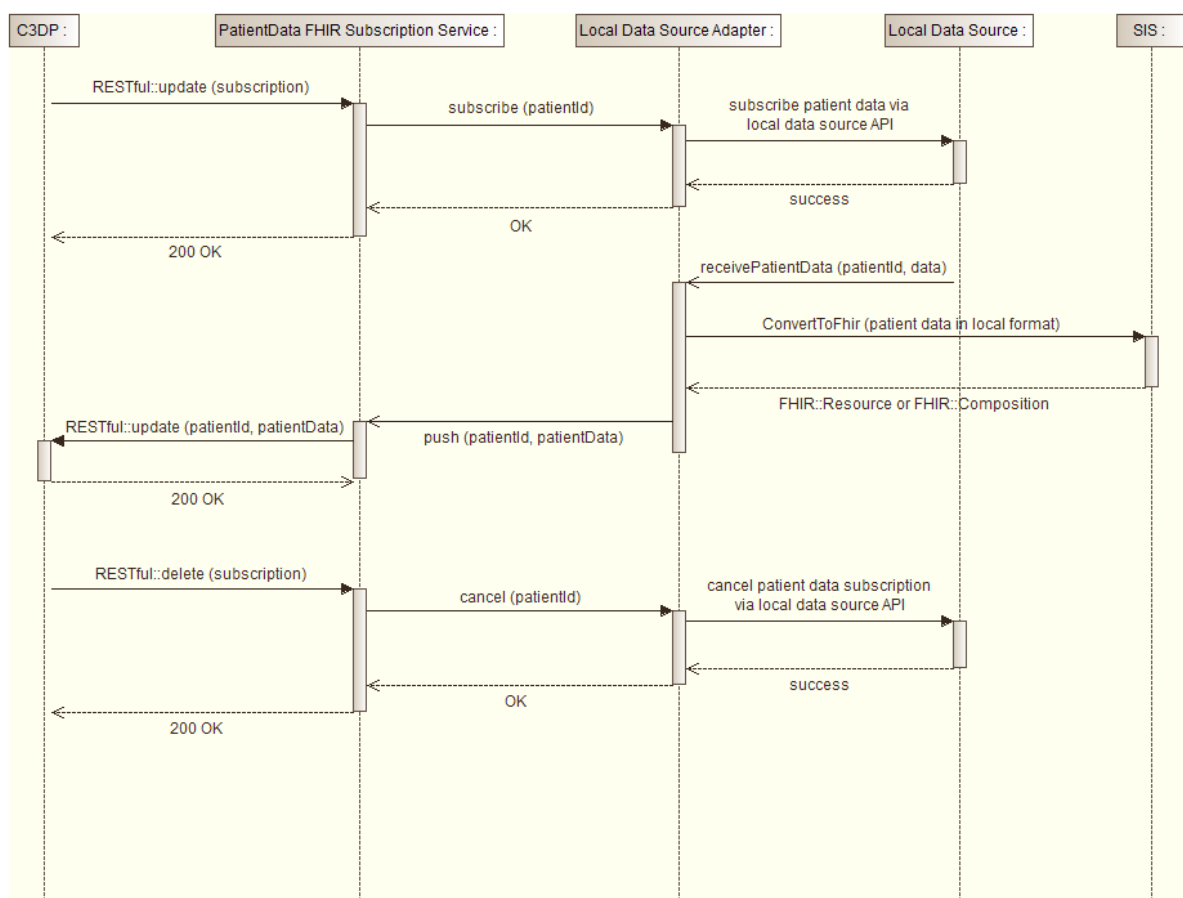
This use case has become obsolete. Patient generated data including both device observations and questionnaire responses are collected by PEP and pushed to C3DP through the interfaces between PEP and C3DP.

- TIS-4 Map Information Models and Terminologies

TIS-4 is a sub use case to support other use cases. Its flow of operation has been described in the context of other use cases.

- TIS-5 Push Patient Data

**Figure 68: SDD-SEQ-TIS-3: Use Case TIS-5 Sequence Diagram**

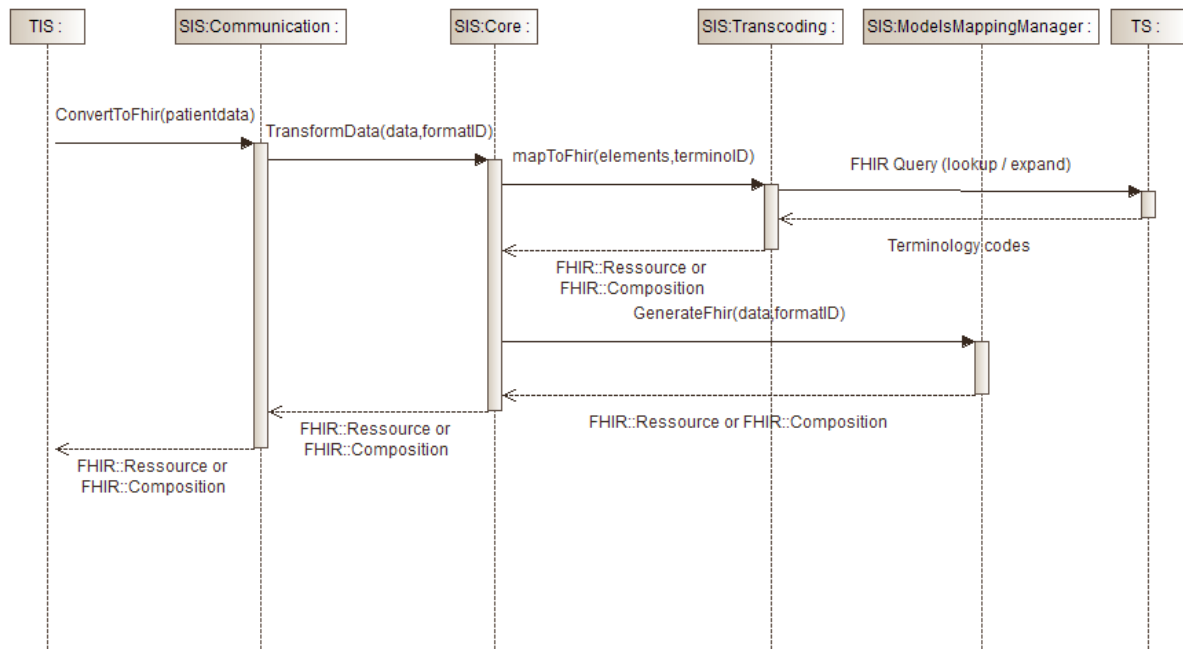




### 6.3. Semantic Interoperability Suite

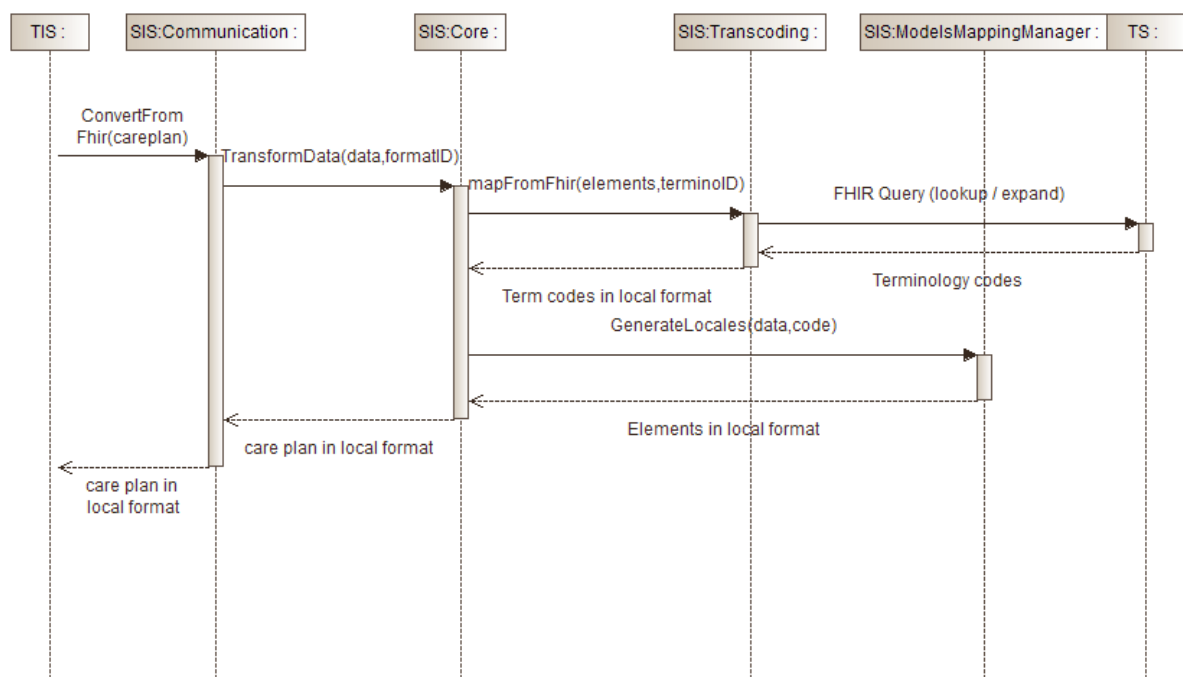
- SIS-1: Map specific input data to C3-Cloud format and codes

**Figure 69: SDD-SEQ-SIS-1: Use Case SIS-1 Sequence Diagram**



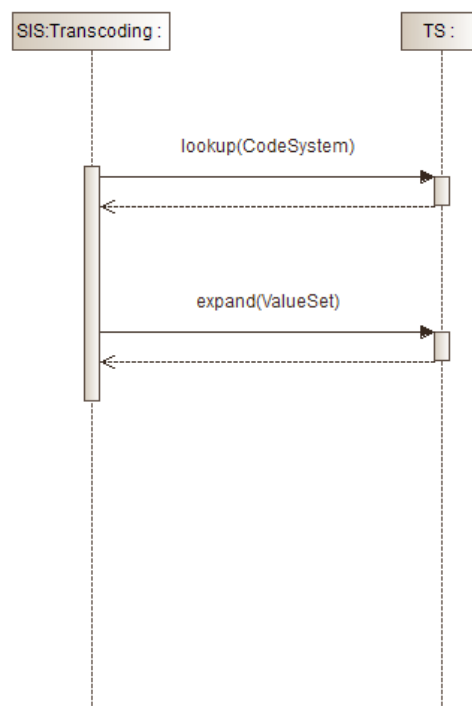
- SIS-2: Map C3-Cloud formatted data to specific output format and codes

**Figure 70: SDD-SEQ-SIS-2: Use Case SIS-2 Sequence Diagram**



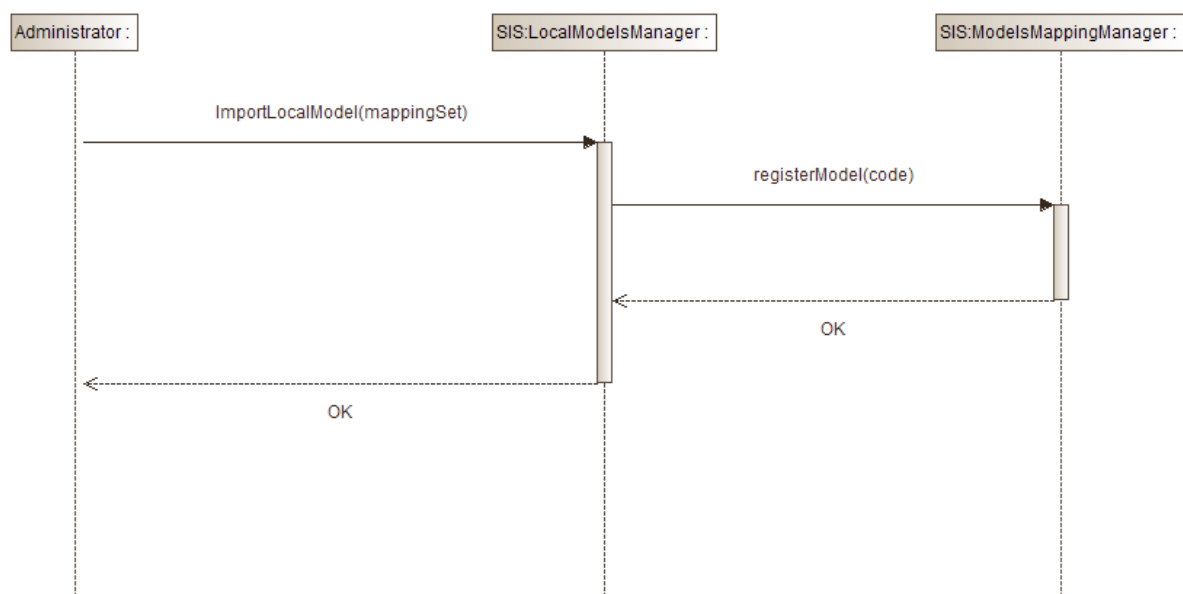
- SIS-3: Map specific input data to other specific output format and codes: is the combination of use of SIS-1 first and SIS-2 then. As local care record system does not share data, SIS-3 is no more needed in C3-Cloud implementation.
- SIS-4: Query terminology server for mapping: is part of SIS-1 and SIS-2.

**Figure 71: SDD-SEQ-SIS-3: Use Case SIS-4 Sequence Diagram**



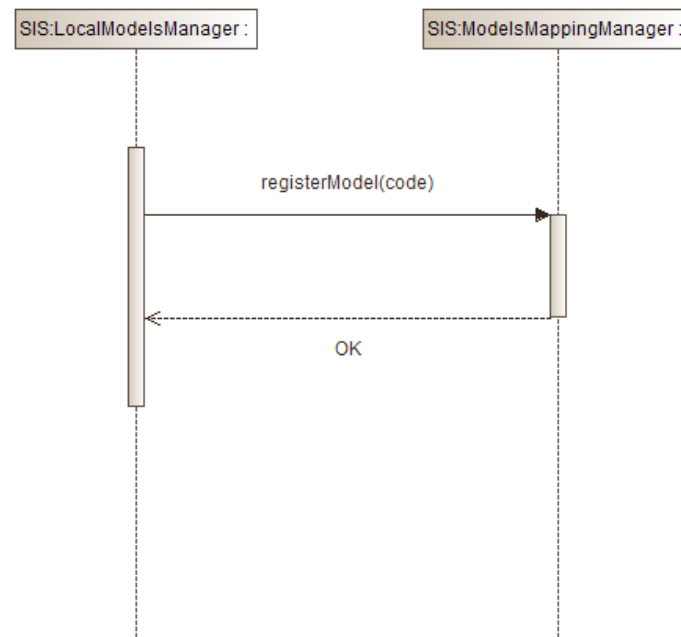
- SIS-5: Create mapping between specific data format and C3-cloud format

**Figure 72: SDD-SEQ-SIS-4: Use Case SIS-5 Sequence Diagram**



- SIS-6: Register new data information model: is part of SIS-5.

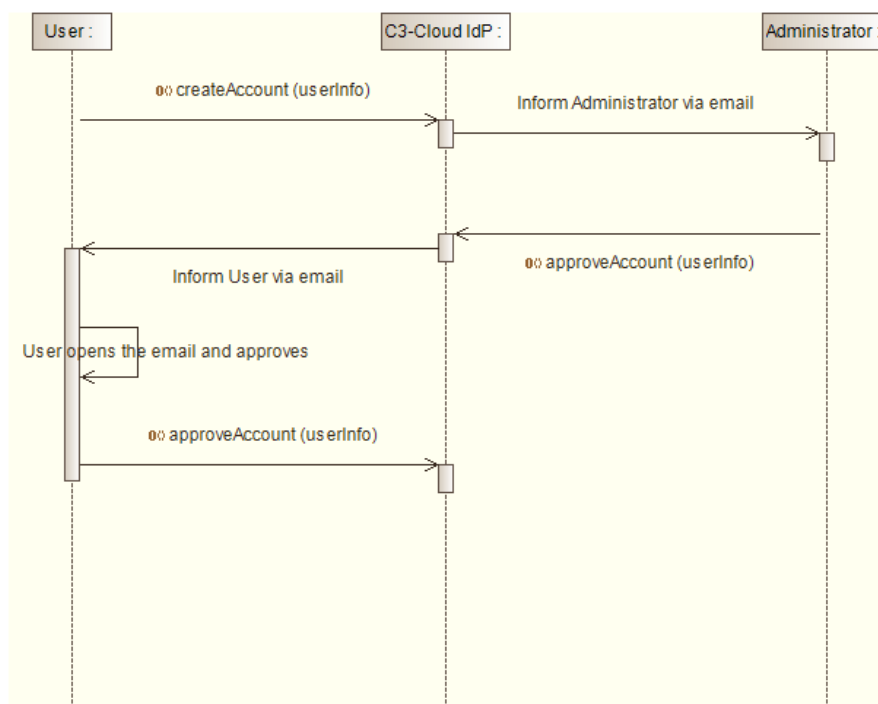
**Figure 73: SDD-SEQ-SIS-5: Use Case SIS-6 Sequence Diagram**



## 6.4. Security and Privacy Suite

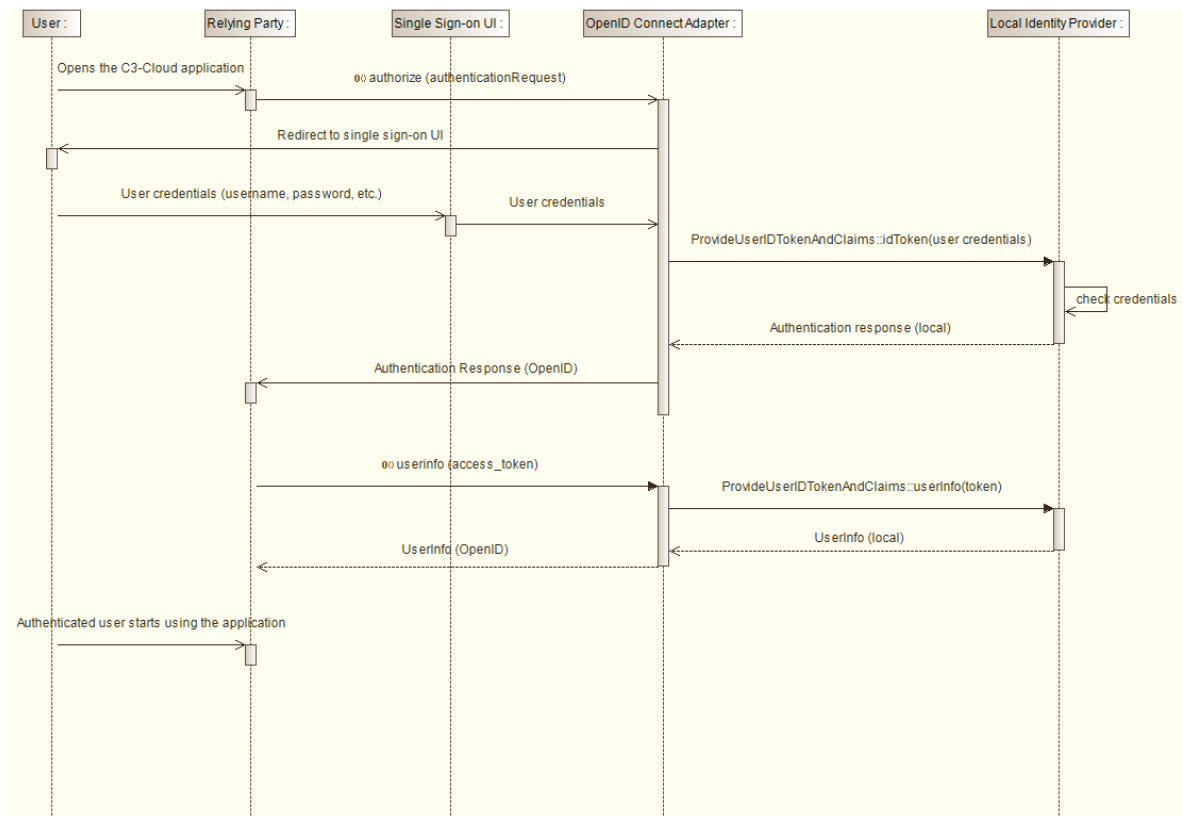
- SPS-1: Create Care Team Member Account

**Figure 74: SDD-SEQ-SPS-1: Use Case SPS-1 Sequence Diagram**



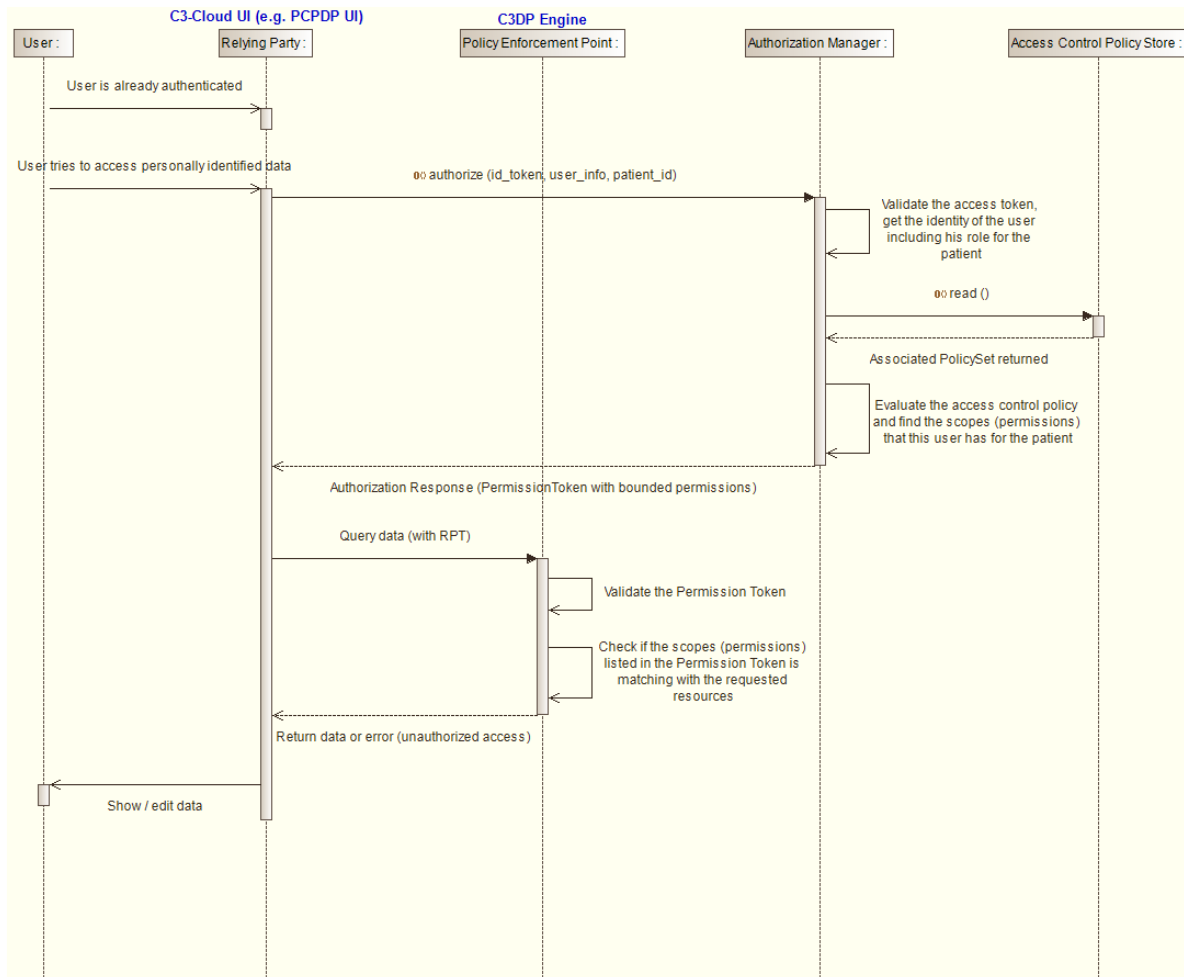
- **SPS-2: Authenticate User:** The Relying Party is any C3-Cloud Web-based UI component that needs to authenticate and authorize non-patient users (e.g., PCPDP UI, C3DP UI, CDSM Admin UI). In this flow, the case with local Identity Provider (IdP) is represented. The interaction with the C3-Cloud IdP is exactly the same with OpenID Connect Adapter. The Authentication subsystem will be implemented based on the OpenID Connect 1.0 protocol with Hybrid Flow [OPENID-HYBRID].

**Figure 75: SDD-SEQ-SPS-2: Use Case SPS-2 Sequence Diagram**



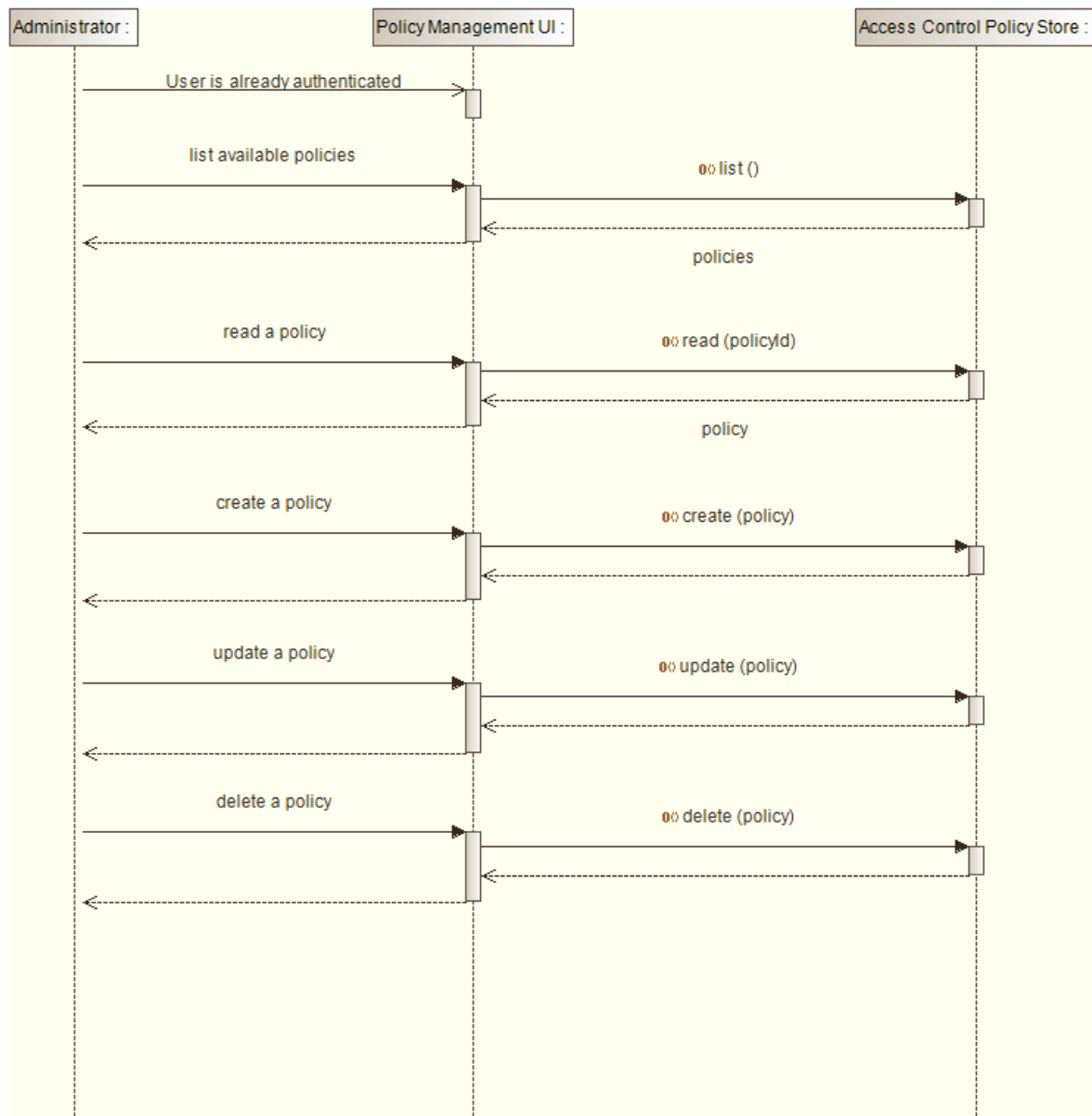
- SPS-3: Authorise User: The Relying Party is as explained above in SPS-2. In the regular care plan management transactions, the Policy Enforcement Point is decided as C3DP Engine in this conceptual design phase; however, there is a possibility that (some) policy enforcement functionality can be shifted further down below to the FHIR Repository.

**Figure 76: SDD-SEQ-SPS-3: Use Case SPS-3 Sequence Diagram**



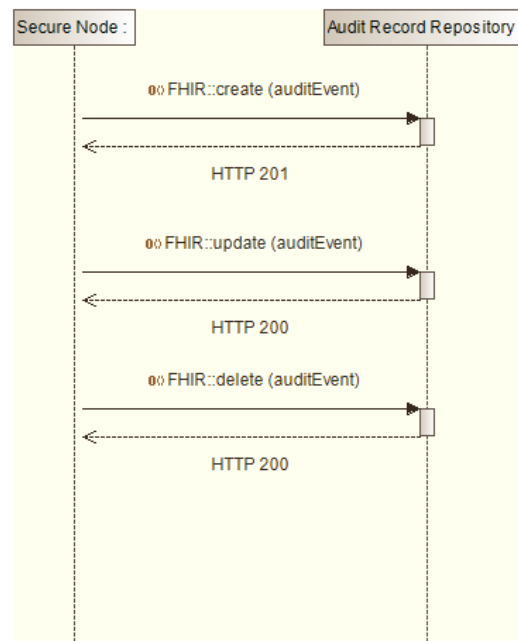
- SPS-4: Manage Access Control Policies

**Figure 77: SDD-SEQ-SPS-4: Use Case SPS-4 Sequence Diagram**



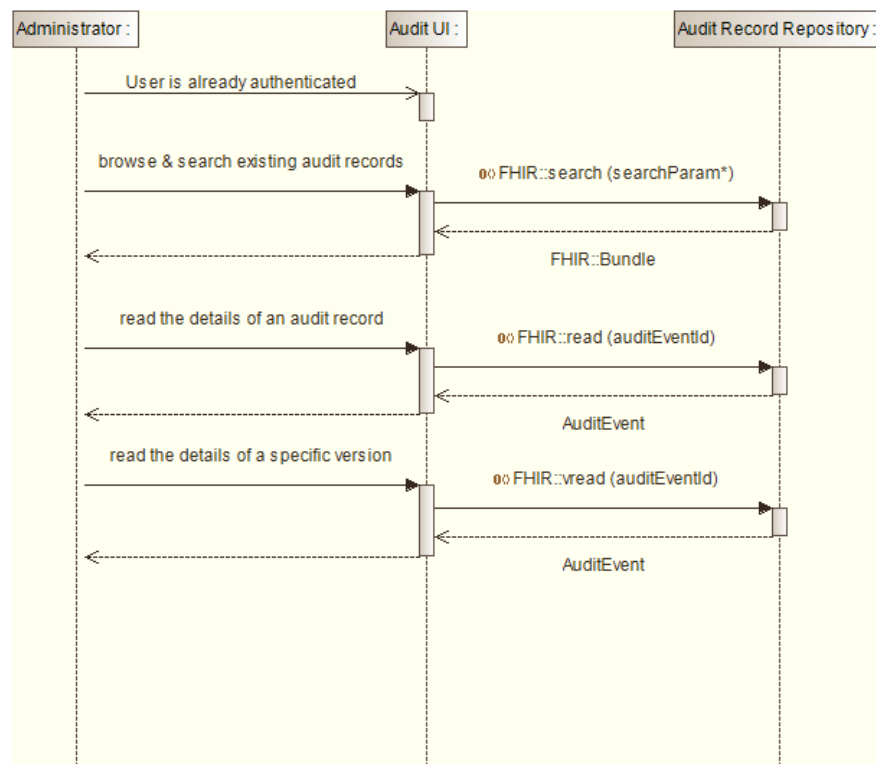
- SPS-5: Log Audit: Secure Node corresponds to all C3-Cloud applications and external data sources communicating with each other.

**Figure 78: SDD-SEQ-SPS-5: Use Case SPS-5 Sequence Diagram**



- Manage Audit Trail Records: This is a supplementary interaction on top of SPS-5 to allow Administrators to manage the existing audit trail records collected in the Audit Record Repository via SPS-5 interactions.

**Figure 79: SDD-SEQ-SPS-6: Manage Audit Trail Record Sequence Diagram**



## 6.5. Clinical Decision Support Service

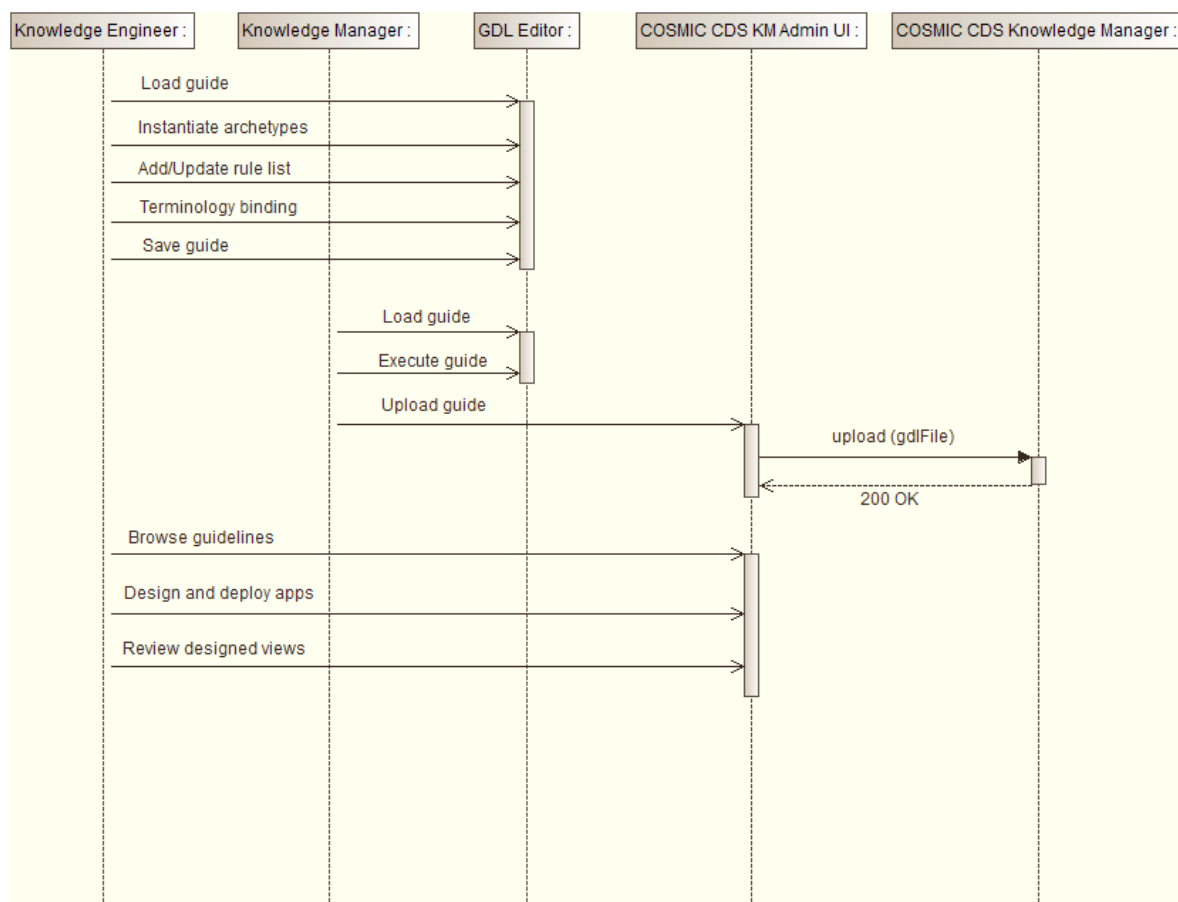
- CDSM-1: Create and Update Knowledge Modules
- CDSM-2: Validate Knowledge Modules

The sequence diagram below has covered both CDSM-1 and CDSM-2 use cases, which describes the whole cycle of CDSM development. Generally the process divides into three stages: CDS rule development, rule validation and deployment, CDS apps development and deployment.

- Knowledge Engineer uses the GDL editor to create/update CDS rules.
- Knowledge Manager validates the rules by executing the rules within the GDL editor. Once rules validated, Knowledge Manager uploads the rule set (as GDL files) to COSMIC CDS Knowledge Manager through the KM Admin UI.
- Knowledge Engineer can then browse the guidelines and related content (e.g. data models) in the KM Admin UI, design CDS apps when necessary and preview the app UI. The apps are available from the CDS Knowledge Manager ready for execution.

Appendix II includes screenshots of COSMIC CDS products to demonstrate every step of the above process.

**Figure 80: SDD-SEQ-CDSS-1: Use Cases CDSM-1 & CDSM-2 Sequence Diagram**



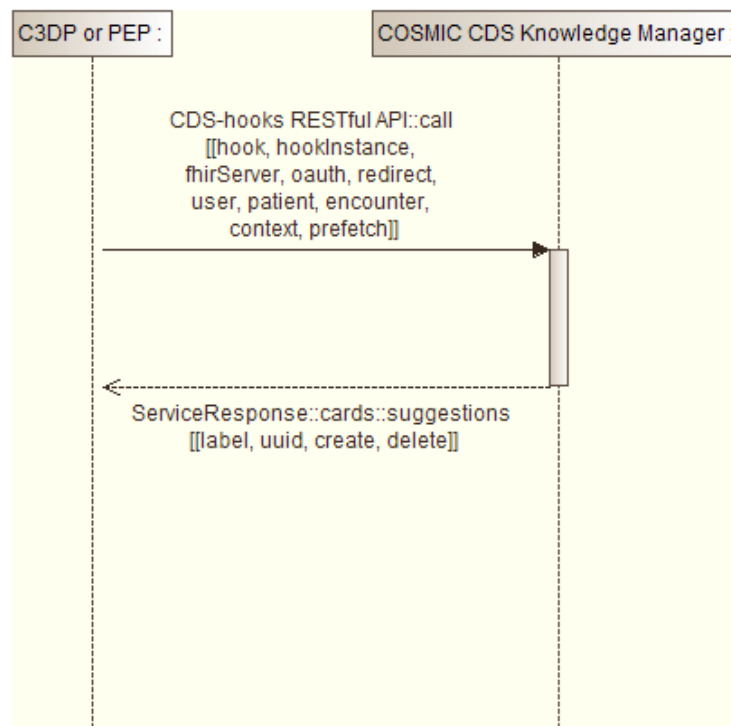
- CDSM-3: Guideline-based Diagnosis and Treatment Suggestions
- CDSM-4: Polypharmacy Management
- CDSM-5: Risk Assessment



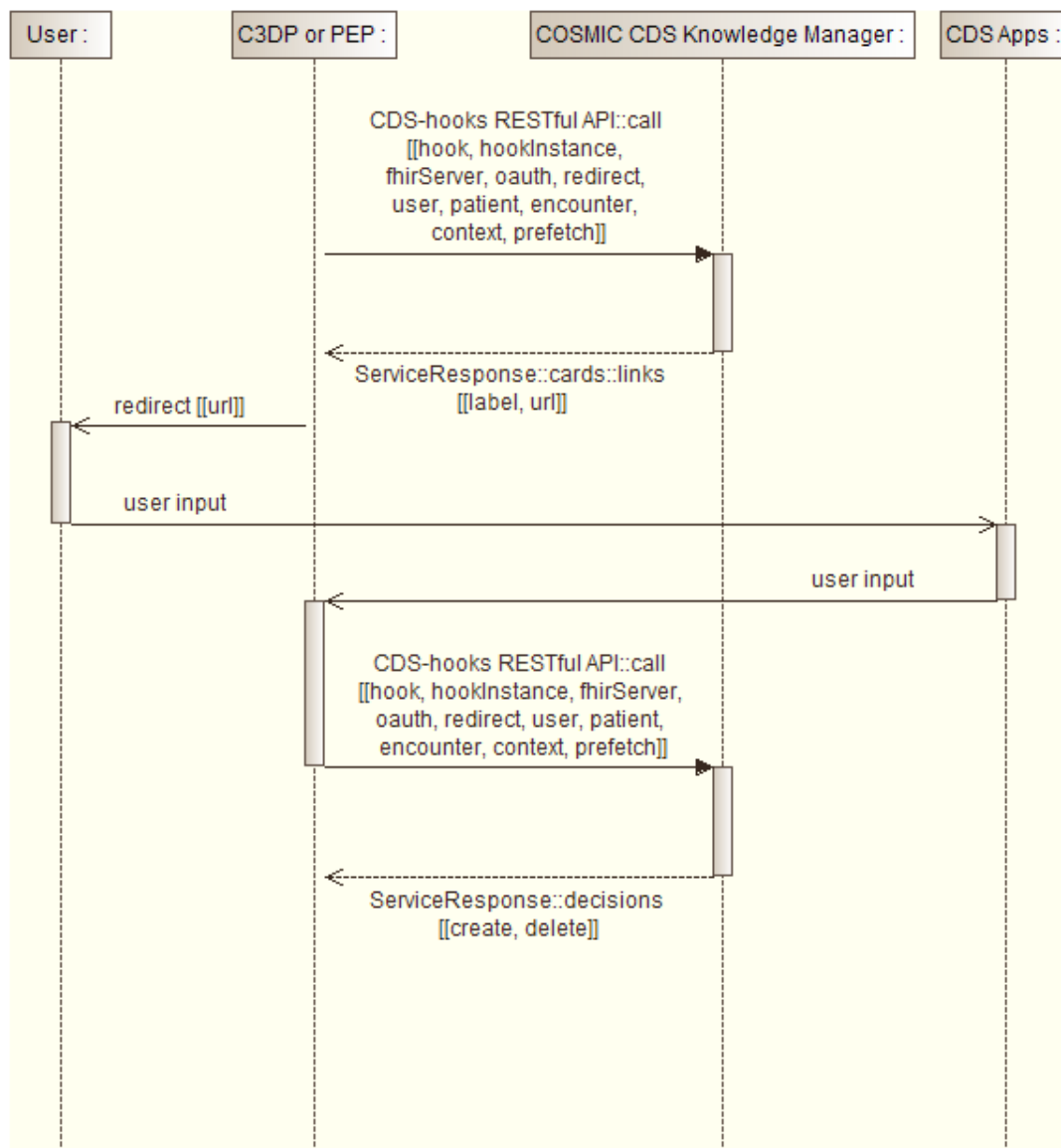
CDSM-3, CDSM-4 and CDSM-5 follow the same service execution pattern. The CDS-hooks based workflow supports two scenarios, which are described below.

- a) Automated decision support without user interaction  
In this scenario, the client calls the CDS service through CDS-hooks API. The service returns any number of information cards or suggestion cards.

**Figure 81: SDD-SEQ-CDSS-2: Use Case CDSM-3/4/5 Scenario A Sequence Diagram**



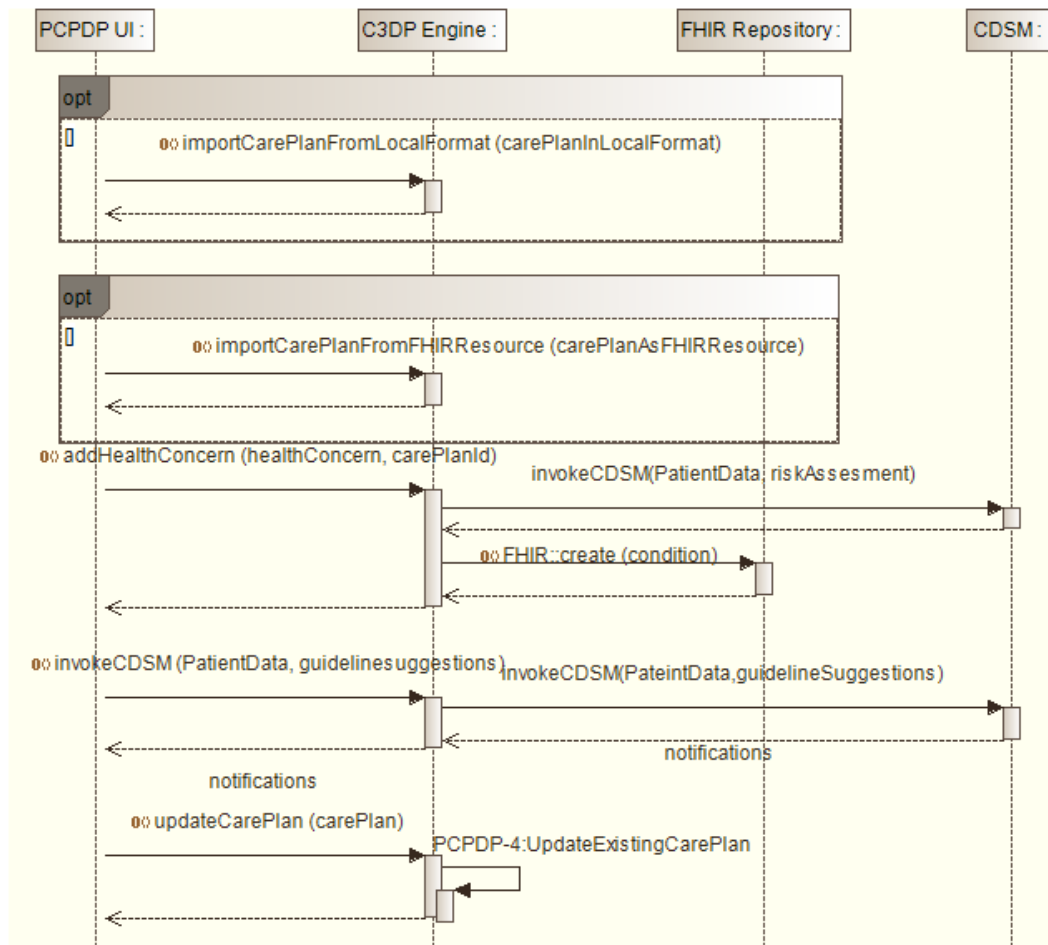
- b) Decision support with user interaction through CDS apps  
In this scenario,
1. The client invokes CDS hook
  2. CDS service returns app link card
  3. User clicks app link and interacts with app
  4. Upon completion of user interaction, flow returns to client, which re-invokes CDS hook
  5. CDS service returns decision with user's choice

**Figure 82: SDD-SEQ-CDSS-3: Use Case CDSM-3/4/5 Scenario B Sequence Diagram**

## 6.6. Coordinated Care and Cure Delivery Platform

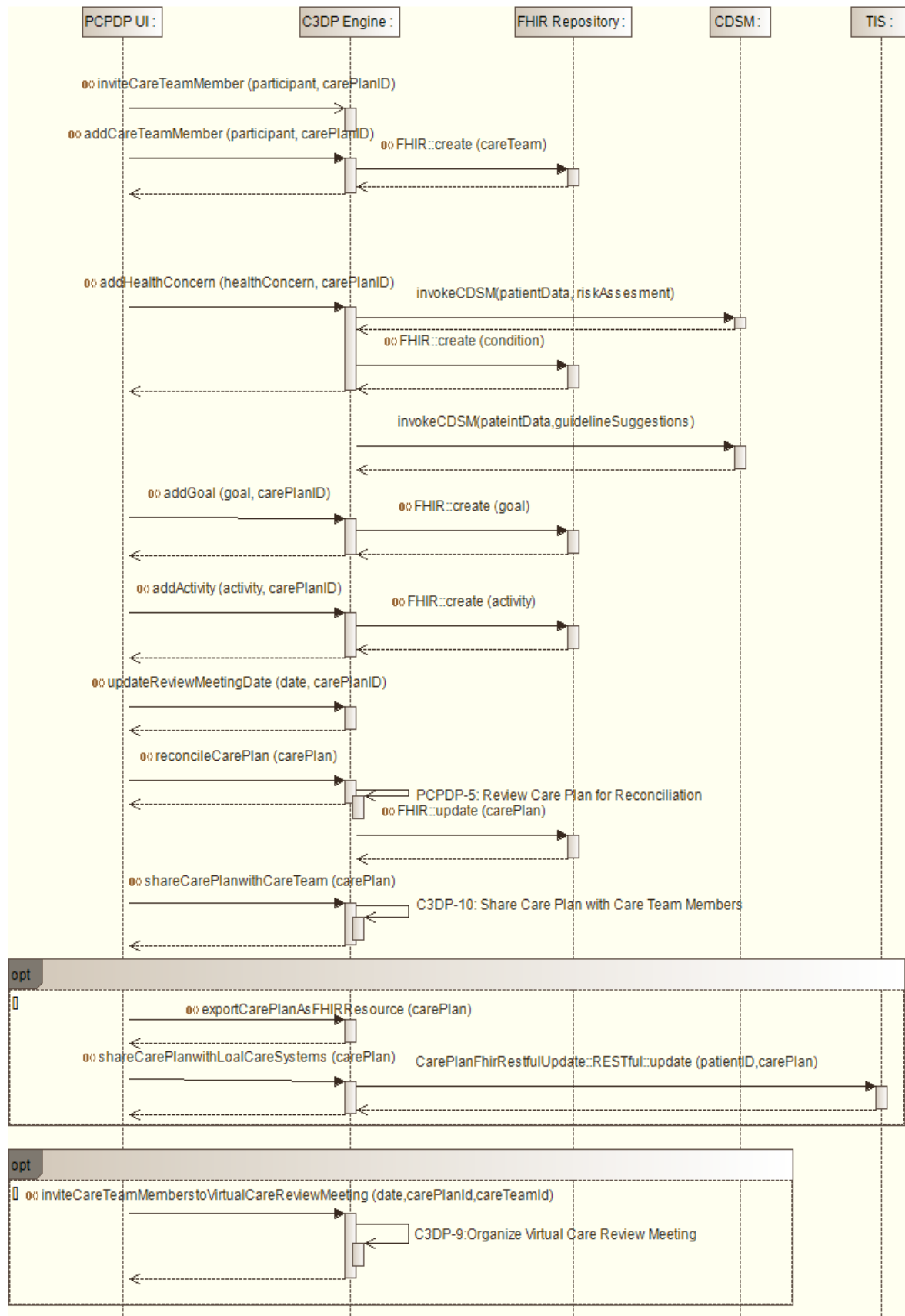
- PCPDP-1: Create Care Plan: This is an abstract use case realized by PCPDP-2, PCPDP-3 and PCPDP-6.
- PCPDP-2: Add New Care Plan from a Core Care Plan

Figure 83: SDD-SEQ-PCPDP-1: Use Case PCPDP-2 Sequence Diagram



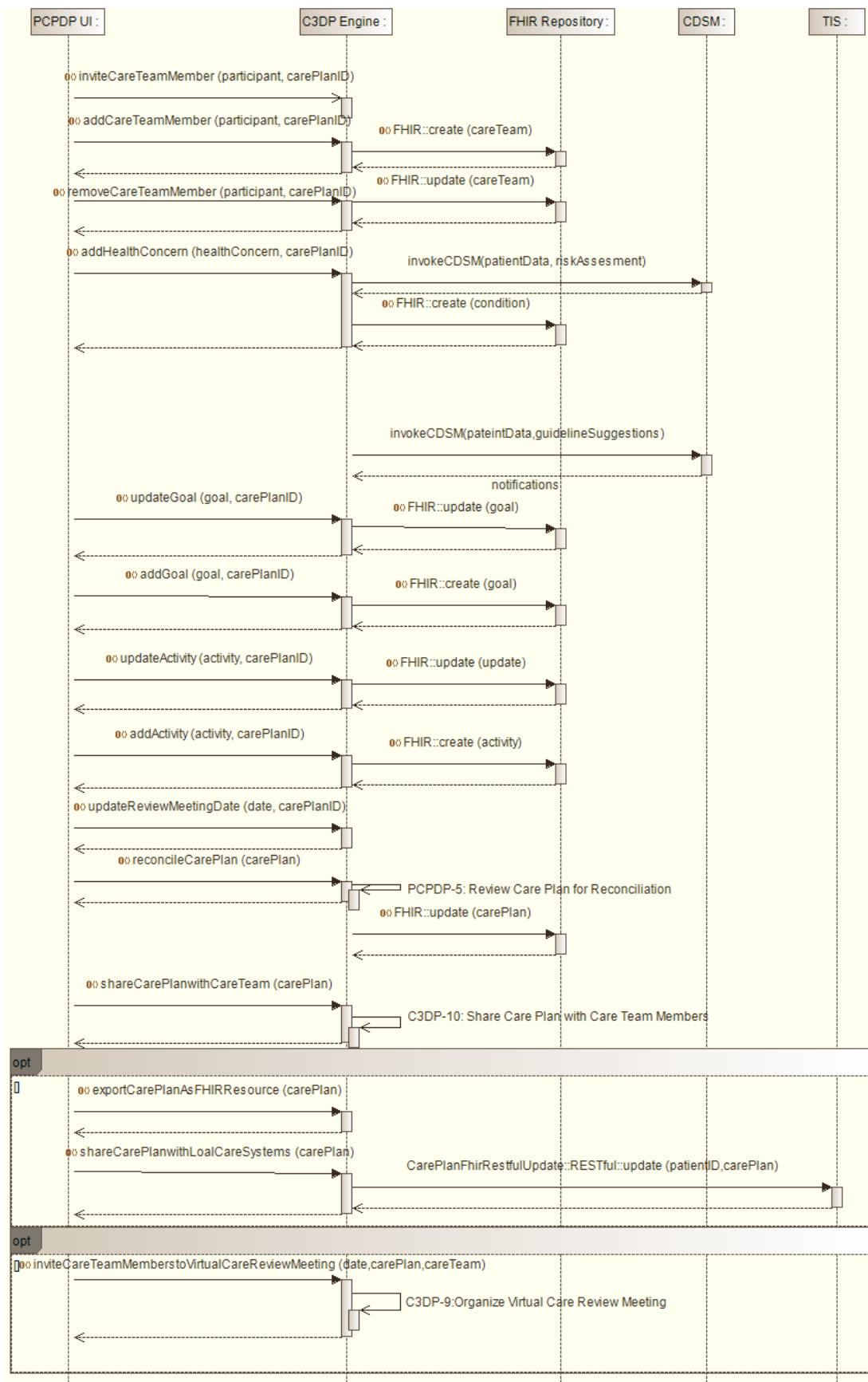
- PCPDP-3: Define New Care Plan

**Figure 84: SDD-SEQ-PCPDP-2: Use Case PCPDP-3 Sequence Diagram**



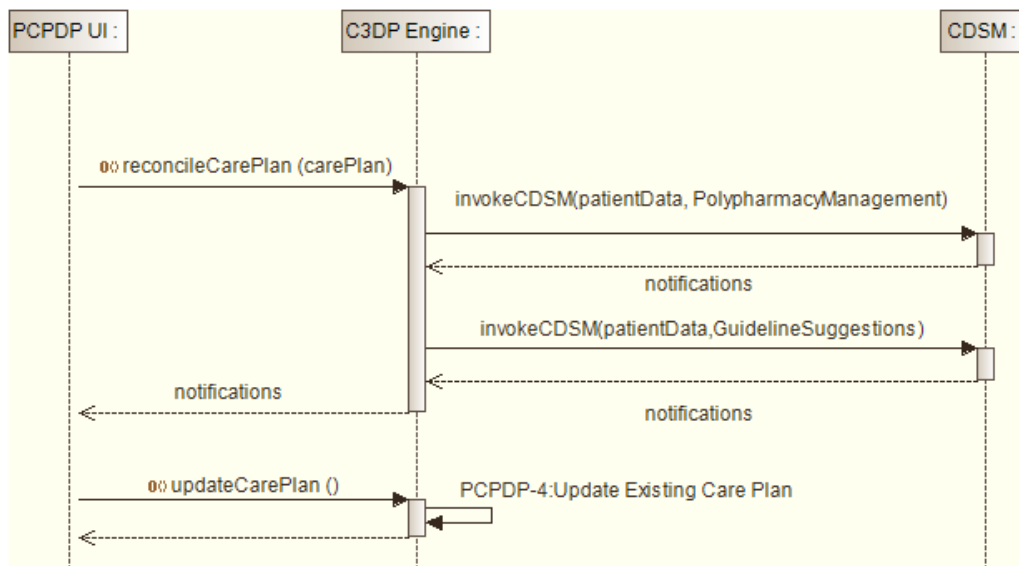
- PCPDP-4: Update Existing Care Plan

**Figure 85: SDD-SEQ-PCPDP-3: Use Case PCPDP-4 Sequence Diagram**



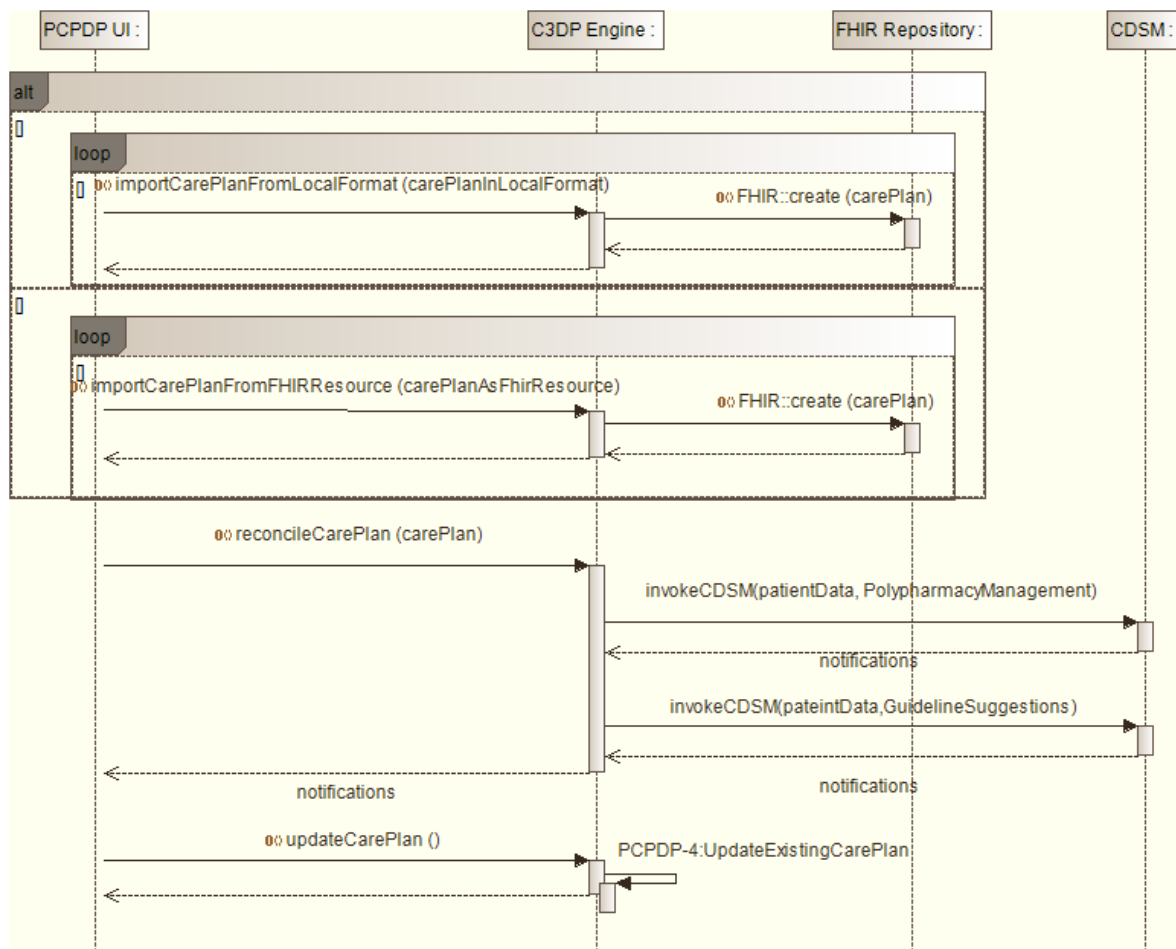
- PCPDP-5: Review Care Plan for Reconciliation

**Figure 86: SDD-SEQ-PCPDP-4: Use Case PCPDP-5 Sequence Diagram**



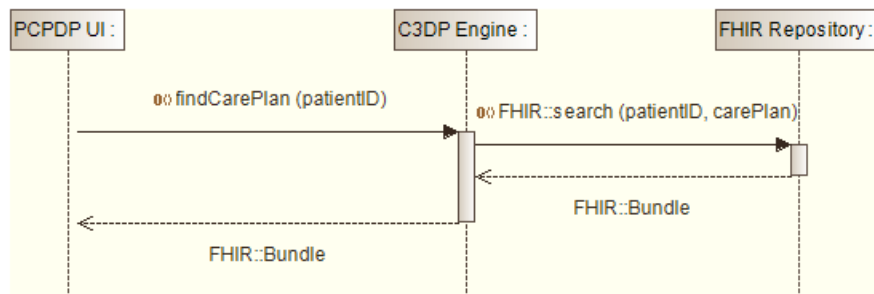
- PCPDP-6 Reconcile Care Plans for Multiple Conditions

**Figure 87: SDD-SEQ-PCPDP-5: Use Case PCPDP-6 Sequence Diagram**



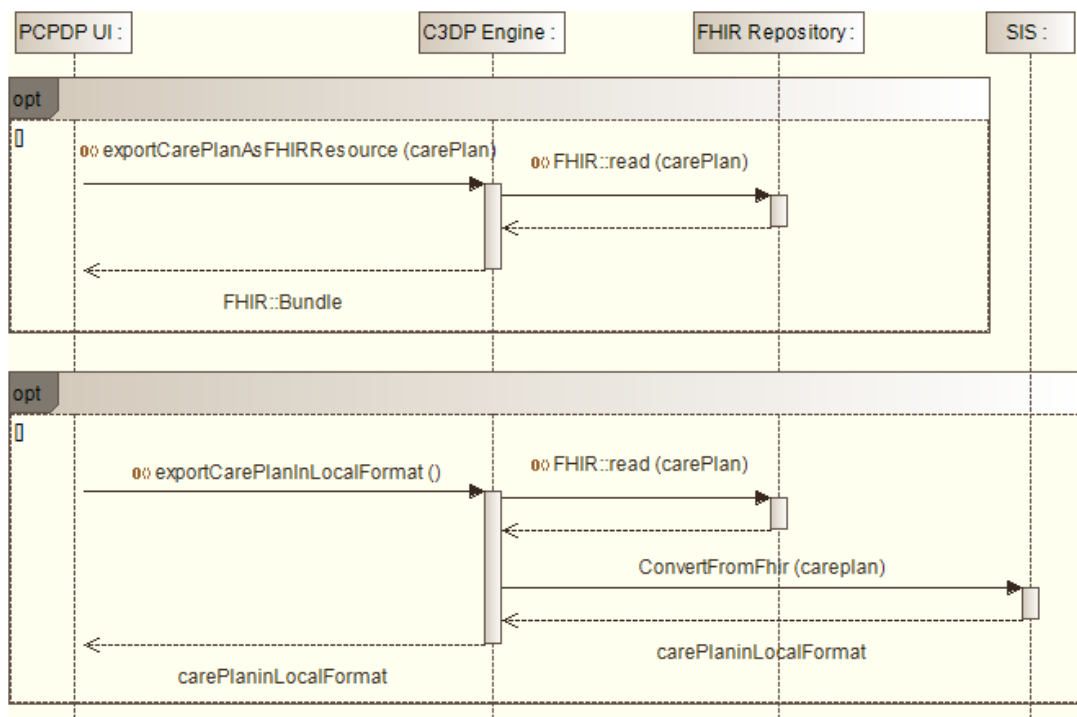
- PCPDP-7 Find Care Plan

**Figure 88: SDD-SEQ-PCPDP-6: Use Case PCPDP-7 Sequence Diagram**



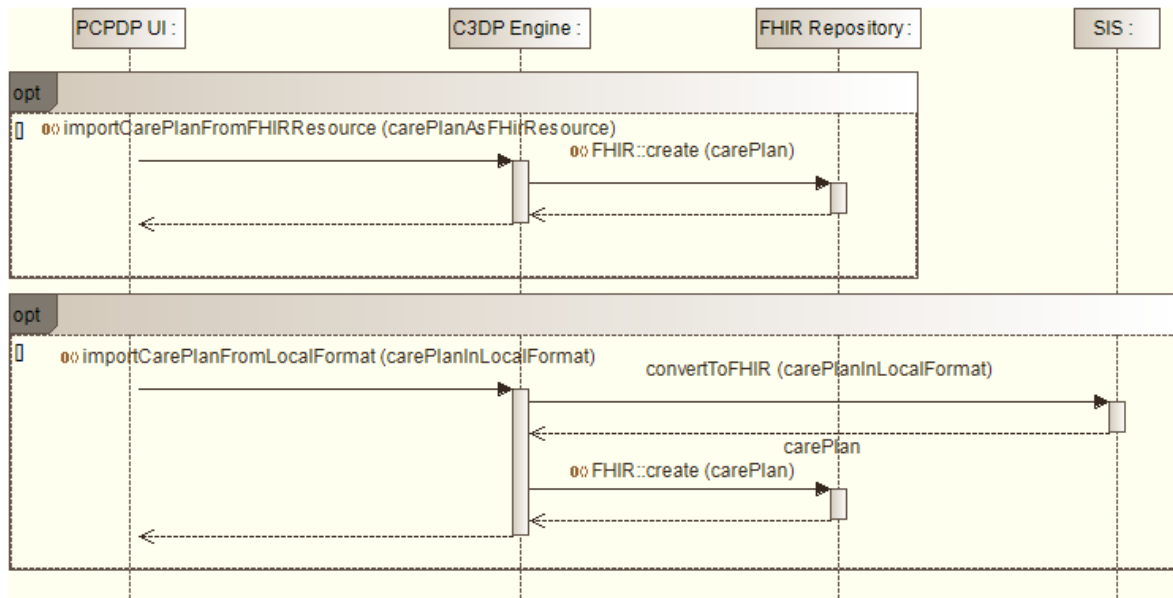
- PCPDP-8 Tag Care Plan Items: Handled within PCPDP-4: Update Care Plan use case.
- PCPDP-9 Export Care Plan: Two alternatives are possible where (1) care plan is exported as a FHIR Resource, (2) care plan is exported in local format.

**Figure 89: SDD-SEQ-PCPDP-7: Use Case PCPDP-9 Sequence Diagram**



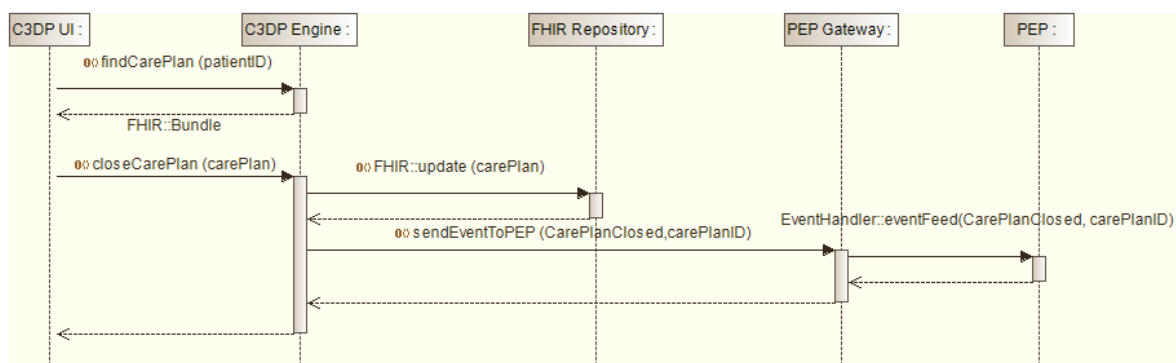
- PCPDP-10 Import Care Plan: Two alternatives are possible where (1) care plan is imported from a FHIR Resource (2) care plan is imported from a local format.

**Figure 90: SDD-SEQ-PCPDP-8: Use Case PCPDP-10 Sequence Diagram**



- C3DP-1: Close Care Plan

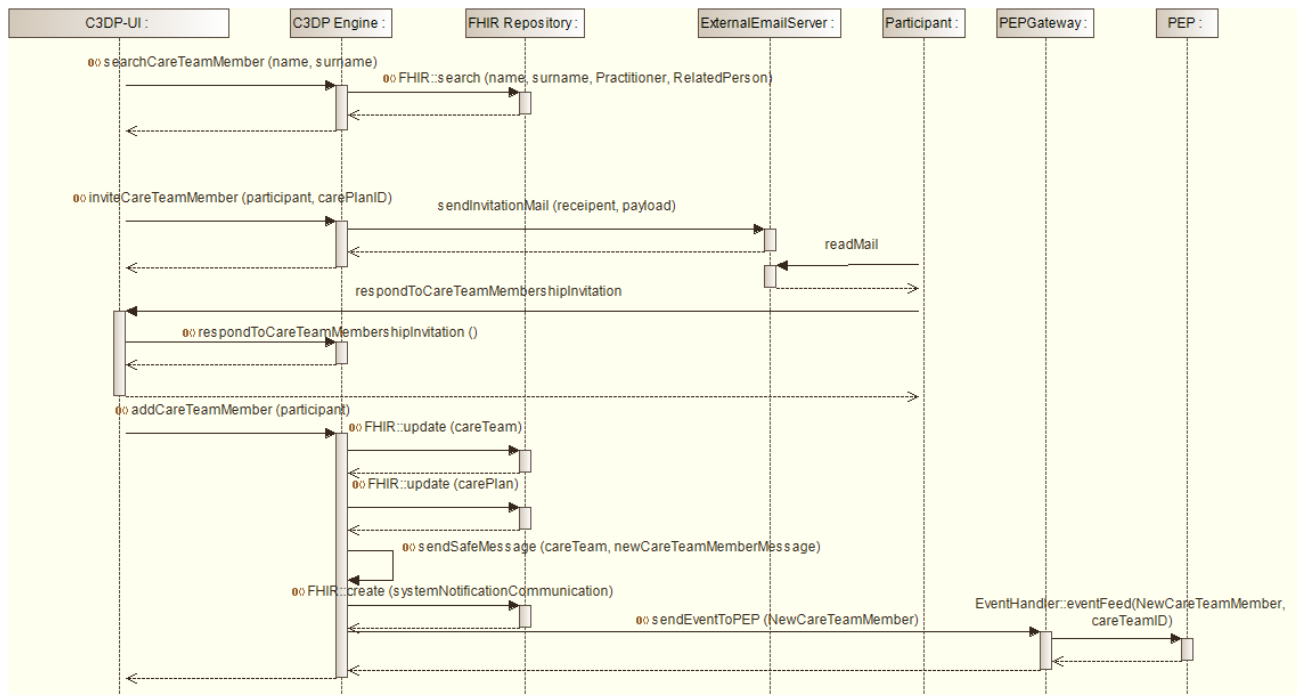
**Figure 91: SDD-SEQ-C3DP-1: Use Case C3DP-1 Sequence Diagram**





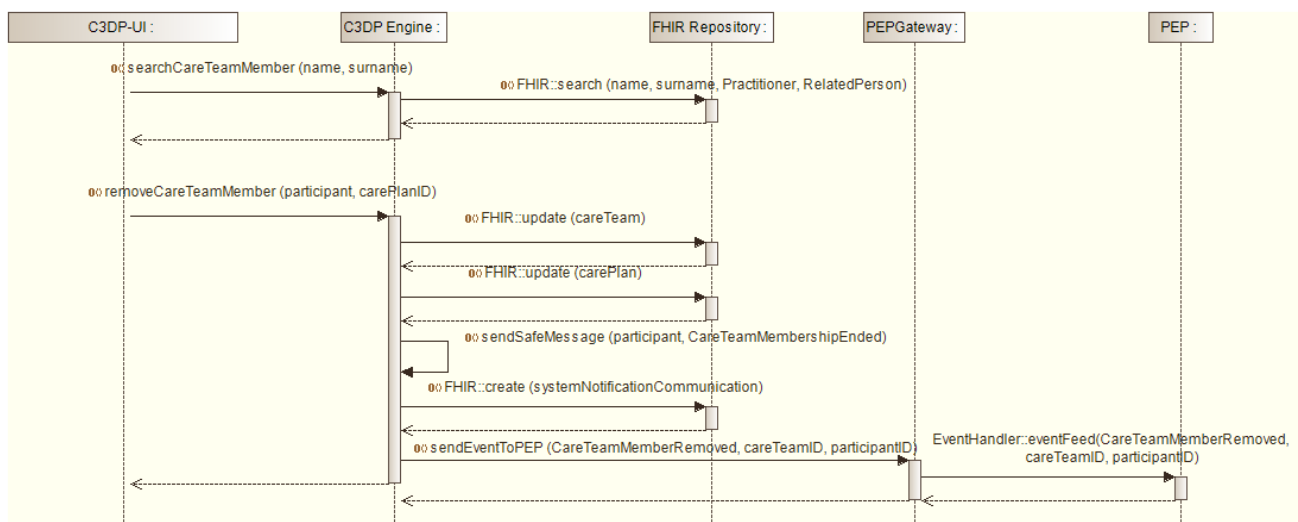
- C3DP-2: Invite a Care Team Member & C3DP-3: Add Care Team Member

**Figure 92: SDD-SEQ-C3DP-2: Use Cases C3DP-2 & C3DP3 Sequence Diagram**



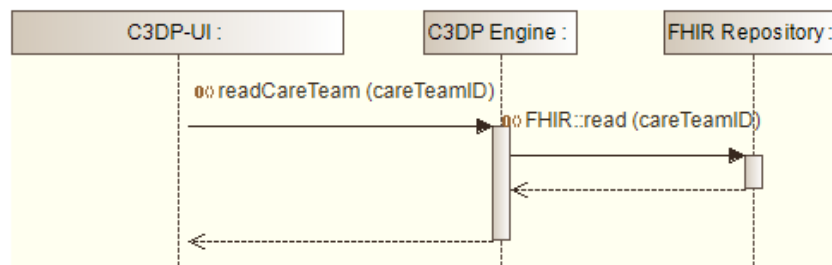
- C3DP-4: Remove Care Team Member

**Figure 93: SDD-SEQ-C3DP-3: Use Case C3DP-4 Sequence Diagram**



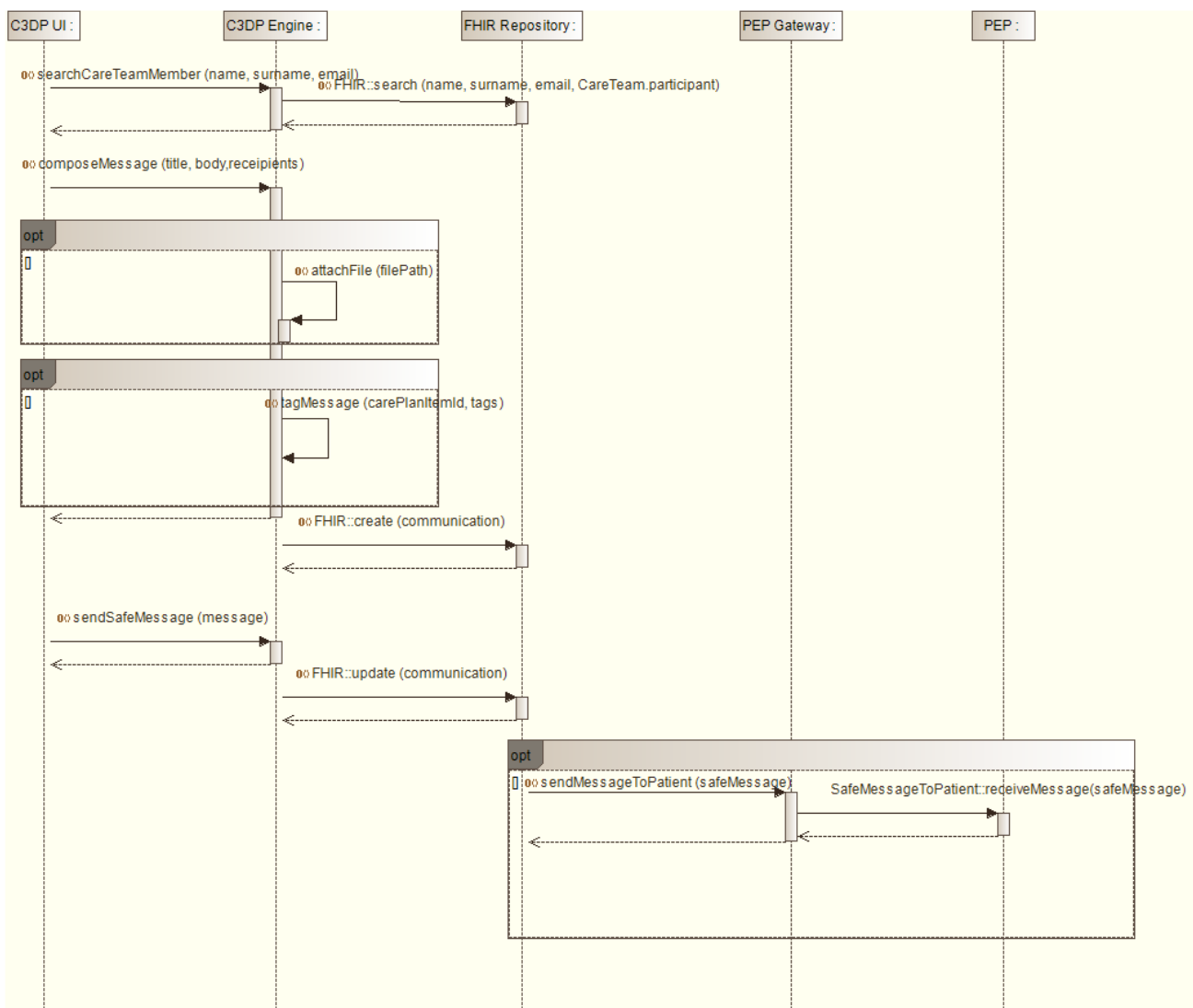
- C3DP-5: Discover Care Team

**Figure 94: SDD-SEQ-C3DP-4: Use Case C3DP-5 Sequence Diagram**



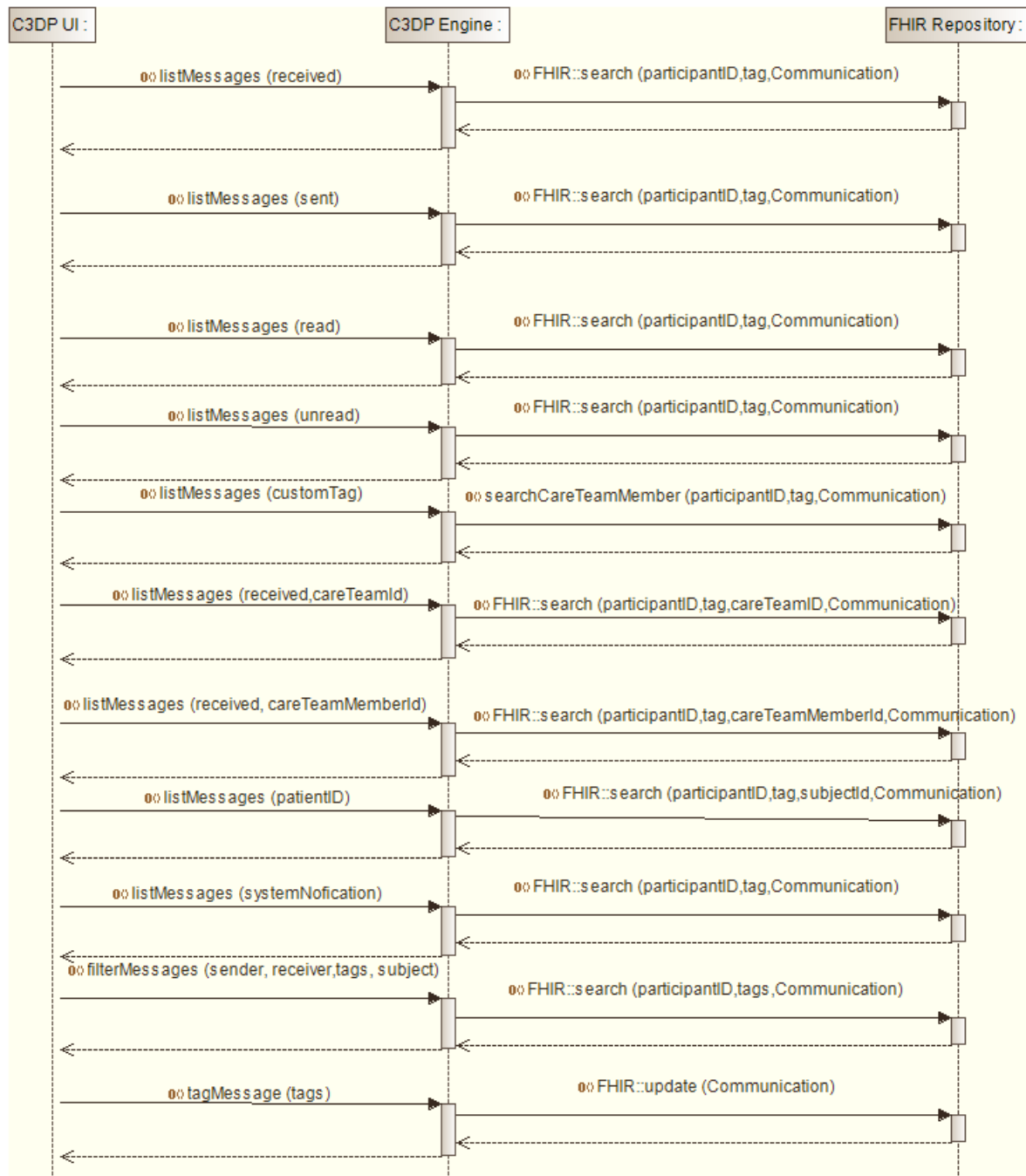
- C3DP-6: Send Message to Care Team Member(s)

**Figure 95: SDD-SEQ-C3DP-5: Use Case C3DP-6 Sequence Diagram**



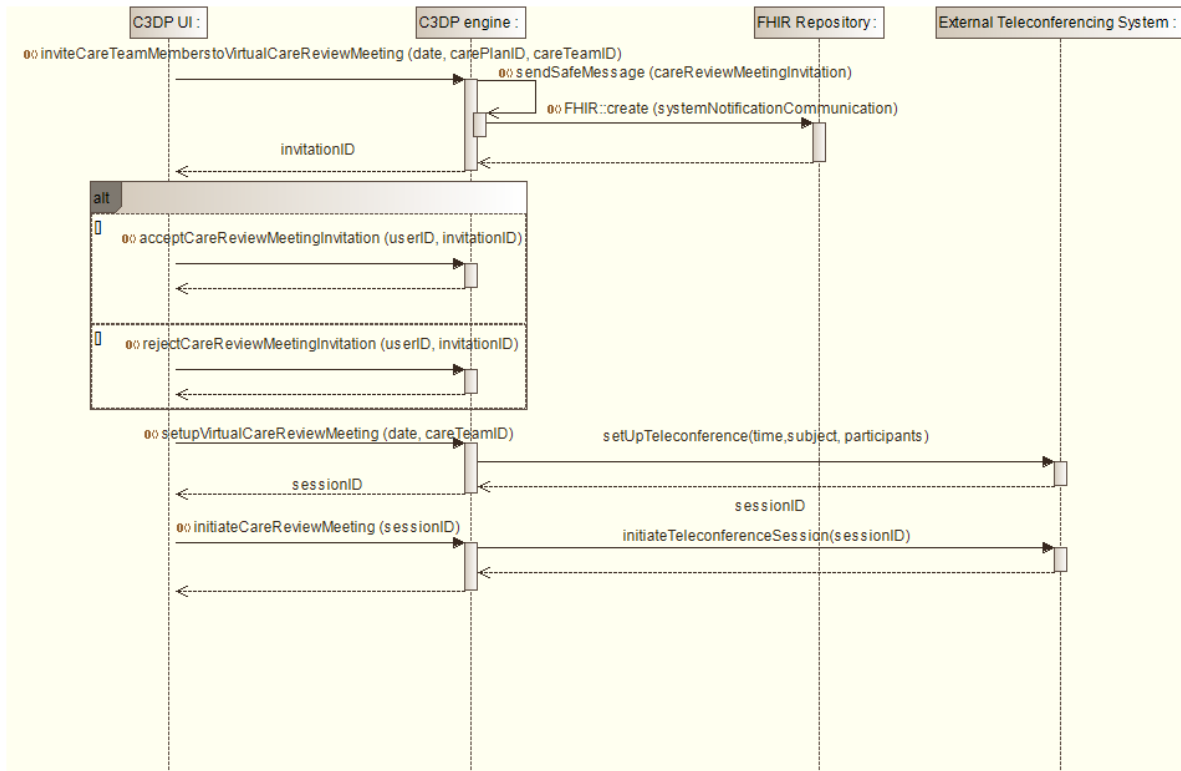
- C3DP-7: Manage Messages

**Figure 96: SDD-SEQ-C3DP-6: Use Case C3DP-7 Sequence Diagram**



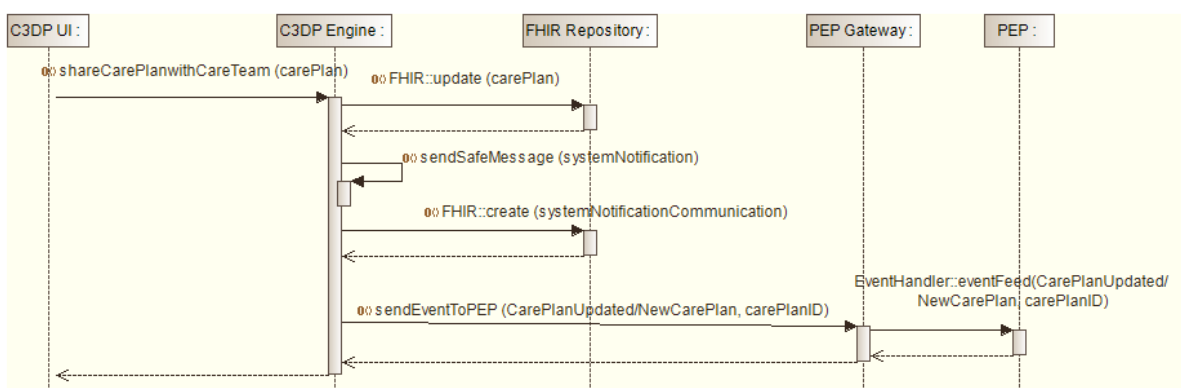
- C3DP-8: Invite Care Team Members to a Virtual Care Review Meeting & C3DP-9: Organise Virtual Care Review Meeting

**Figure 97: SDD-SEQ-C3DP-7: Use Cases C3DP-8 & C3DP-9 Sequence Diagram**



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

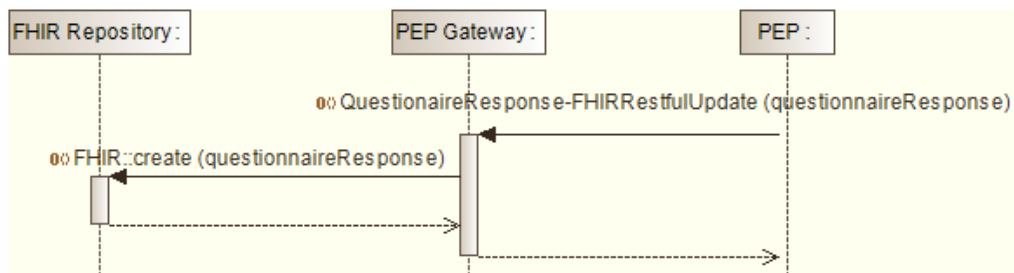
**Figure 98: SDD-SEQ-C3DP-8: Use Case C3DP-10 Sequence Diagram**



- C3DP-11: Record Patient Observations: Three separate sequence diagrams are provided for (1) Recording questionnaire responses filled by the patient; (2) Recording patient feedback about the goal and activity status prescribed within the care plan and (3) Recording device observations.

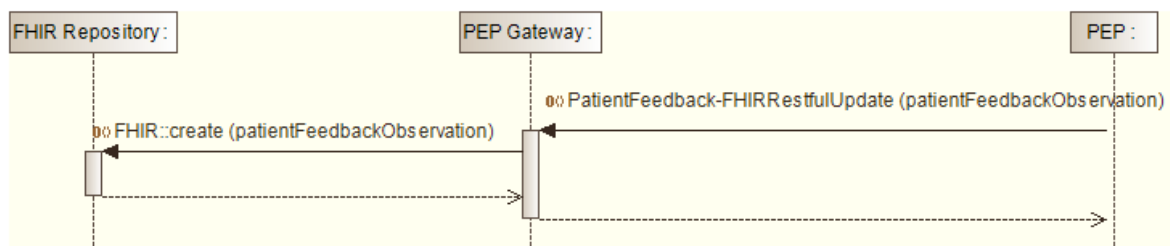
C3DP-11-a: Recording questionnaire responses filled by the patient:

**Figure 99: SDD-SEQ-C3DP-9: Use Case C3DP-11 Scenario A Sequence Diagram**



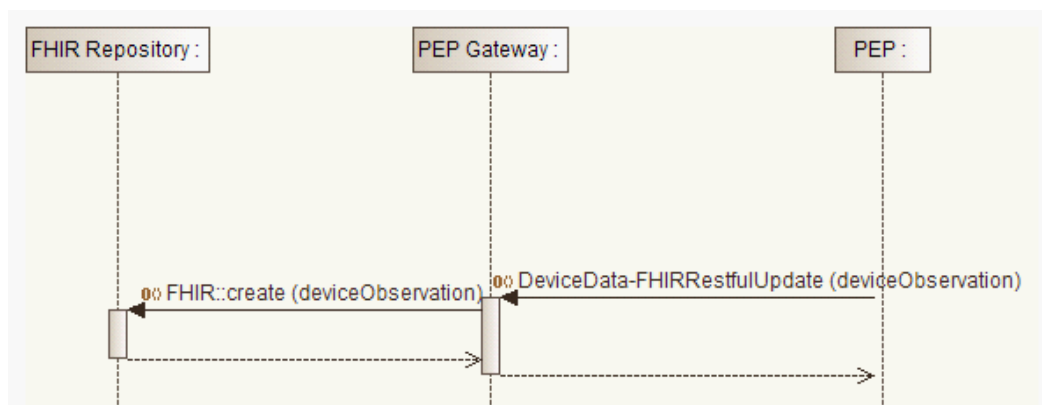
C3DP-11-b: Recording patient feedback about the goal and activity status prescribed within the care plan:

**Figure 100: SDD-SEQ-C3DP-10: Use Case C3DP-11 Scenario B Sequence Diagram**



C3DP-11-c: Recording device observations:

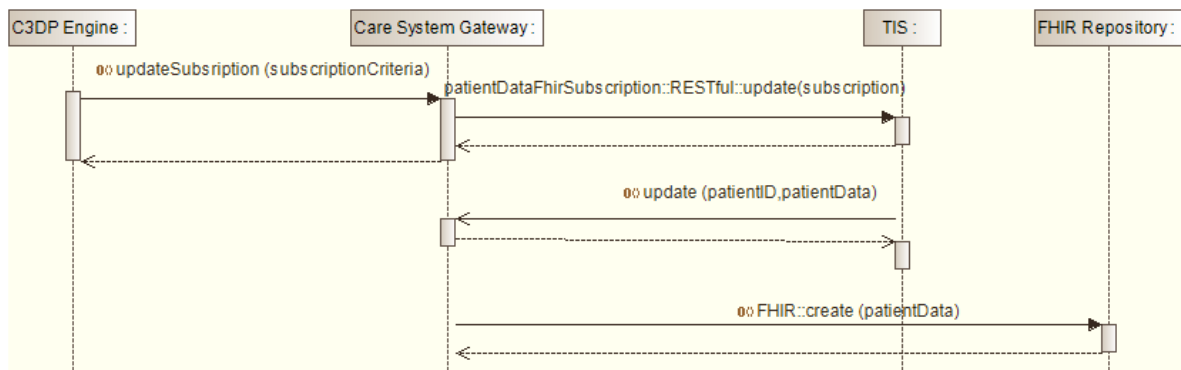
**Figure 101: SDD-SEQ-C3DP-11: Use Case C3DP-11 Scenario C Sequence Diagram**



- C3DP-12: Associate Supportive Content: Three separate sequence diagrams are provided for (1) Receiving patient data via subscription; (2) Manually uploading patient data and (3) Querying patient data

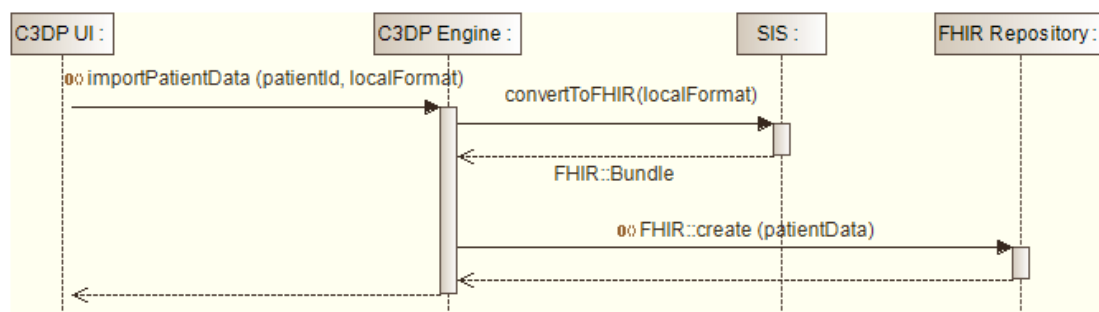
C3DP-12-a: Receiving patient data via subscription:

**Figure 102: SDD-SEQ-C3DP-12: Use Case C3DP-12 Scenario A Sequence Diagram**



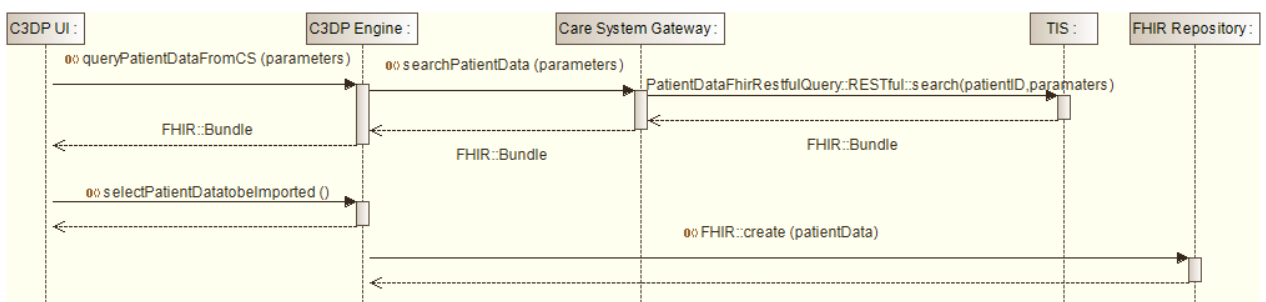
C3DP-12-b: Manually uploading patient data:

**Figure 103: SDD-SEQ-C3DP-13: Use Case C3DP-12 Scenario B Sequence Diagram**



C3DP-12-c: Querying patient data:

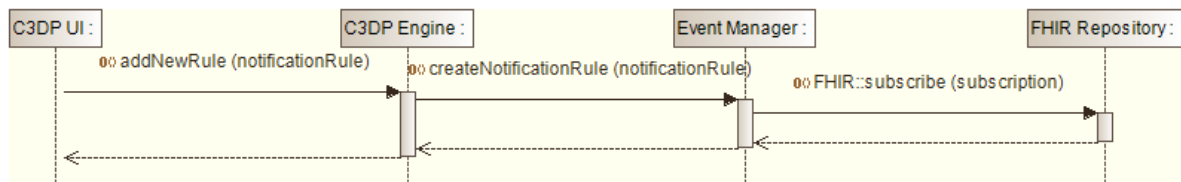
**Figure 104: SDD-SEQ-C3DP-14: Use Case C3DP-12 Scenario C Sequence Diagram**



- C3DP-13: Monitor Change: Two separate sequence diagrams are provided for (1) Definition of notification rules and (2) Receiving notifications as a result of notification subscriptions

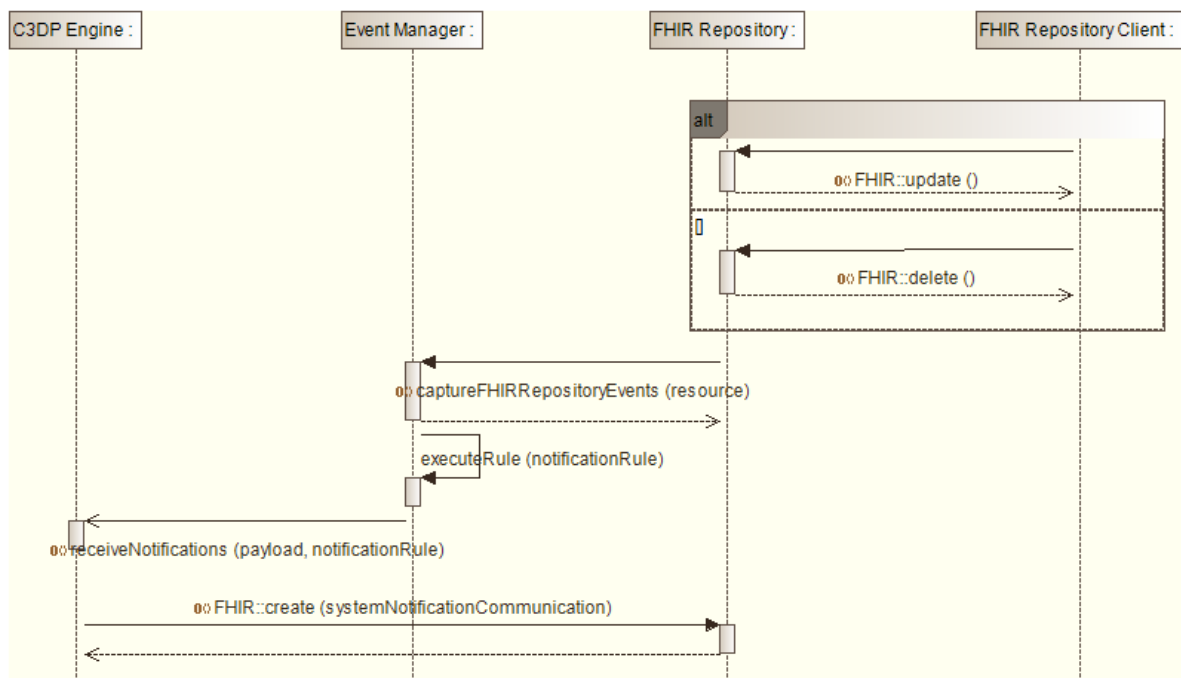
C3DP-13-a: Definition of notification rules:

**Figure 105: SDD-SEQ-C3DP-15: Use Case C3DP-13 Scenario A Sequence Diagram**



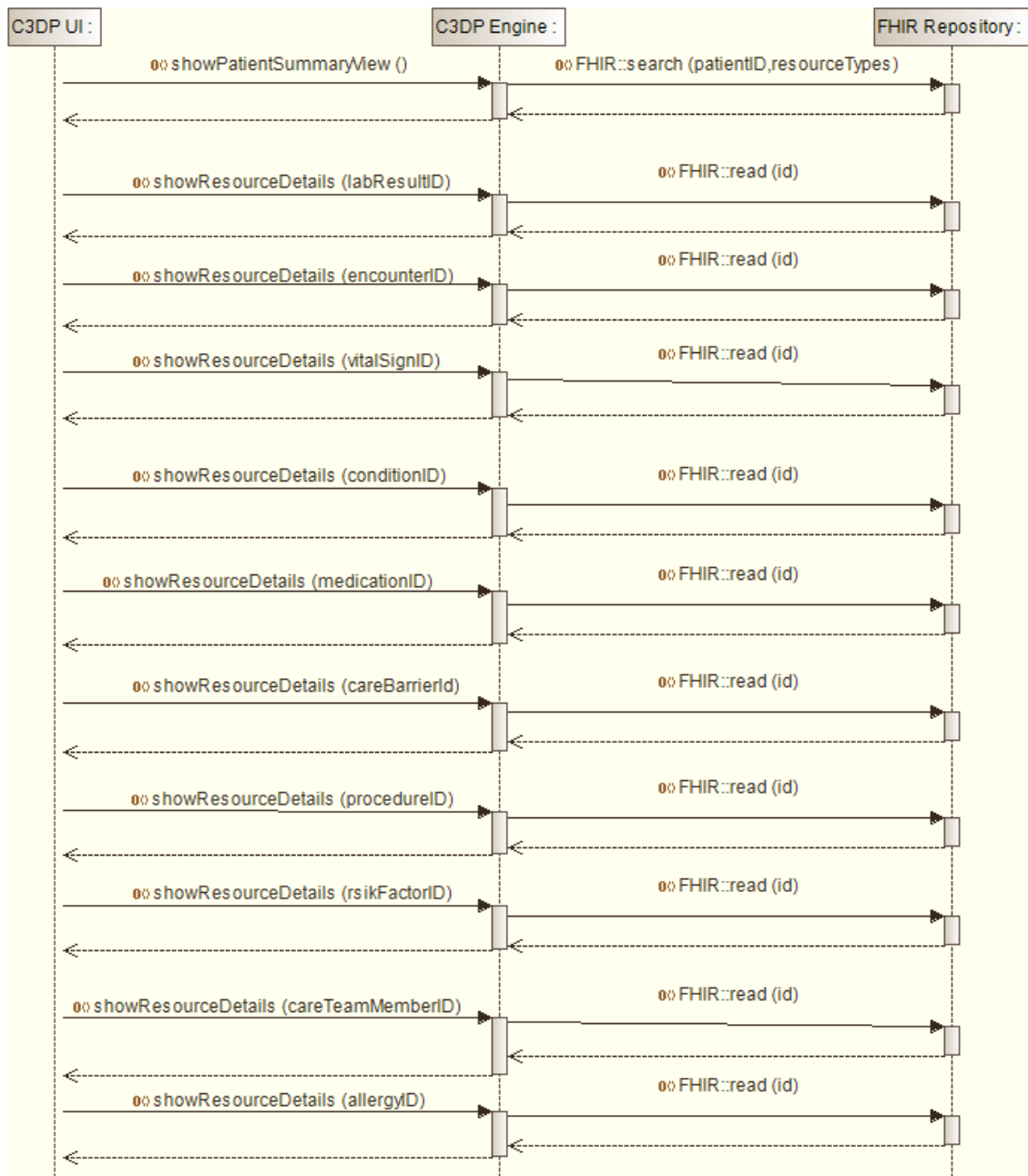
C3DP-13-b: Receiving notifications as a result of notification subscriptions:

**Figure 106: SDD-SEQ-C3DP-16: Use Case C3DP-13 Scenario C Sequence Diagram**



- C3DP-14: Care Plan Dashboard

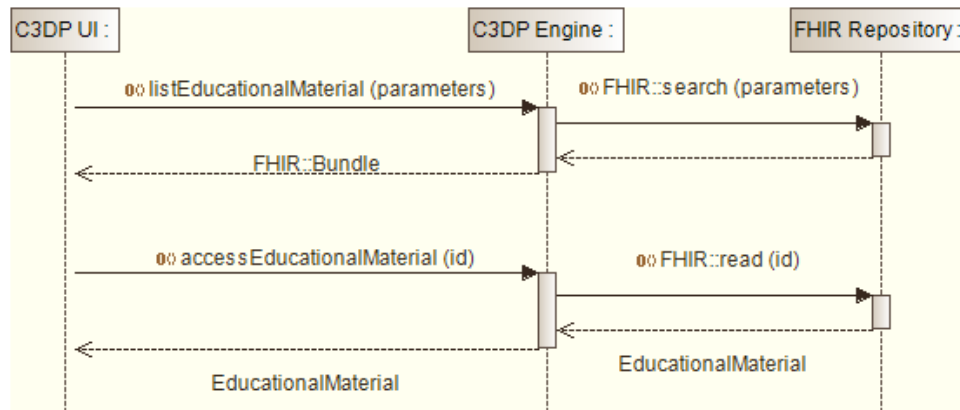
**Figure 107: SDD-SEQ-C3DP-17: Use Case C3DP-14 Sequence Diagram**





- C3DP-15: Access Educational Material

**Figure 108: SDD-SEQ-C3DP-18: Use Case C3DP-15 Sequence Diagram**



## 7. REQUIREMENTS TRACEABILITY

This section links the SDD design elements to the requirement traceability matrix and information exchange matrix in D3.2. A description of the achievement of each requirement is demonstrated in the matrix by means of references to SDD model ids. If a requirement has not been addressed by this SDD, an estimate of which deliverable will describe its implementation is indicated instead.

A definition of the template for the requirement traceability matrix is available in D3.2 Appendix I. this deliverable includes the following columns for complete reference and updates the status and the architecture design columns:

- **Requirement ID:** This column contains the unique identifier of the requirement.
- **Description:** A brief description of the requirement.
- **Status:** This column is populated with the current status of the requirement. (Proposed, Validated, Obsolete, Designed, Implemented, Tested)
- **Assigned To:** Identifies the C3-Cloud Partner responsible for fulfilling this requirement.
- **System Component(s):** This column indicates the high-level system component(s) linked to the requirement (PEP, TIS, SIS, SPS, CDSM, PCPDP, C3DP).
- **Architecture Design:** This column contains references to the design model IDs in deliverable D3.3 linked to the requirement. (a.k.a. "Trace To Design")

**Table 3: Requirements Traceability Matrix**

<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</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.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-1
PEP-FR-2	The system shall notify the patient when a new care plan is published to the patient.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-1
PEP-FR-3	The system shall display the published, active care plan to PEP Users (the patient, authorized informal caregivers and health professionals).	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-2
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.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-2
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.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-6	The system shall send treatment intervention reminder messages to patients according the timings defined in the patient's active care plan.	Proposed	MEDIXINE	PEP	To be addressed in D5.3

<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</i>
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.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-3
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.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-4
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.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-1
PEP-FR-10	The system shall notify the patient when an updated care plan is published to the patient.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-1
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.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-1
PEP-FR-12	The system shall support measurement device assignment to the patient when the patient care plan includes prescribed remote monitoring.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-13	The system shall support upload of patient measurement data from connected devices.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-14	The system shall send a notification to the patient when a prescribed questionnaire activity becomes active.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
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.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
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.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-17	The patient or another PEP User on behalf of the patient may interrupt and return later to	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product

<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</i>
	complete the questionnaire.				
PEP-FR-18	The system shall enable the patient to send messages to health professionals.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-6, SDD-INF-SM
PEP-FR-19	The system shall enable the health professionals to send messages to patients.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-6, SDD-INF-SM
PEP-FR-20	The system shall enable the patient and health professionals to reply to received messages and thus continue an ongoing conversation.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-6, SDD-INF-SM
PEP-FR-21	The system shall enable the communication between a health professional and a patients using video.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
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.	Proposed	MEDIXINE	PEP	To be addressed in D5.3
PEP-FR-23	The patient and the health professional shall be able to join the video appointment when it is due.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-24	The system shall support the configuration of links to self-management material published to patients.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-25	Any PEP User shall be able to access the self-management material via the system.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
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.	Obsolete	MEDIXINE	PEP	
PEP-FR-27	The health coaching engine shall monitor coaching program subscriptions and generate coaching messages to be delivered to a patient.	Obsolete	MEDIXINE	PEP	
PEP-FR-28	The system shall receive messages from the health coaching engine and deliver the messages to the patient.	Obsolete	MEDIXINE	PEP	

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PEP-FR-29	The system shall display sent coaching messages to PEP users.	Obsolete	MEDIXINE	PEP	
PEP-FR-30	PEP Users shall be able to invite the patient to access the patient's own record.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-31	PEP Users shall be able to invite an informal caregiver to access the selected patient's workspace.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-32	The system shall send the patient access invitation to the invited person (patient or informal caregiver) by email.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
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.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-34	Any patient access user shall be able to log in to PEP System using their login credentials.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-FR-35	Any health professional user shall be able to log in to PEP System using their login credentials.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
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.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
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.	Proposed	MEDIXINE	PEP	To be addressed in D7.4 and D5.3
PEP-IR-2	The care plan shall contain all information needed to display the care plan to PEP Users.	Designed	MEDIXINE	PEP	SDD-INF-CP
PEP-IR-3	An updated care plan shall contain the change information needed to highlight changes in updated care plan versions.	Proposed	MEDIXINE	PEP	To be addressed in D7.4 and D5.3

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PEP-IR-4	The care plan shall contain the information needed to schedule and generate the treatment intervention reminder messages.	Proposed	MEDIXINE	PEP	To be addressed in D7.4 and D5.3
PEP-IR-5	The care plan information shall support the inclusion of prescribed remote monitoring information (measurement types, timings and goal/limit values).	Proposed	MEDIXINE	PEP	To be addressed in D7.4 and D5.3
PEP-IR-6	The care plan information shall support the inclusion of prescribed questionnaire activities.	Designed	MEDIXINE	PEP	SDD-INF-CP
PEP-SIR-1	All essential PEP Client System interfaces used by PEP shall support synchronous use.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-1
PEP-SIR-2	A PEP Client System shall publish the care plans in a machine processable format to PEP System.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-1
PEP-SIR-3	A PEP Client System shall publish updated versions of an active care plan in a machine processable format to PEP System.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-1
PEP-SIR-4	A PEP Client System shall notify PEP System when a care plan is closed.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-1
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.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-2
PEP-SIR-6	The system shall notify PEP Client Systems when a PEP User changes manually the status of a treatment intervention goal.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-3, SDD-SEQ-PEP-4
PEP-SIR-7	The system shall notify PEP Client Systems when a new patient observation is stored.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-5
PEP-SIR-8	The system shall notify PEP Client Systems when a questionnaire has been completed.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP, SDD-ITF-PEP, SDD-SEQ-PEP-5
PEP-SIR-9	The Health coaching engine shall send coaching messages via PEP System.	Obsolete	MEDIXINE	PEP	

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PEP-SIR-10	A PEP Client System shall manage the care team and the health professional information in PEP System.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP
PEP-SIR-11	A PEP Client System shall create a unique record in PEP System for each enrolled patient.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP, SDD-LGC-OVERALL, SDD-LGC-PEP
PEP-SIR-12	A PEP Client System shall manage which patients have a relationship with which care teams.	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-PEP
PEP-UIR-1	The system shall provide user interfaces for PEP Users to view the active, published care plan of the selected patient.	Proposed	MEDIXINE	PEP	To be addressed in D5.3
PEP-UIR-2	The system shall provide user interfaces for PEP Users to manage the patient contact information.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-UIR-3	The system shall provide user interfaces for patient access users to access and use care plan related functionalities.	Proposed	MEDIXINE	PEP	To be addressed in D5.3
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).	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-UIR-5	The system shall provide user interfaces for patient access users to communicate with health professionals.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-UIR-6	The system shall provide user interfaces for patient access users to access self-management material.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-UIR-7	The system shall provide user interfaces for PEP Users to manage health coaching subscriptions and view received coaching messages.	Obsolete	MEDIXINE	PEP	
PEP-UIR-8	The system shall provide user interfaces to manage patient and informal caregiver access to a patient's workspace.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-NFR-1	All system functions shall respond within reasonable time.	Proposed	MEDIXINE	PEP	To be addressed in D5.3
PEP-NFR-2	All essential PEP Client System interfaces shall	Proposed	MEDIXINE	PEP	To be addressed in D5.3

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	respond within reasonable time.				
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.	Proposed	MEDIXINE	PEP	To be addressed in D5.3
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.	Proposed	MEDIXINE	PEP	To be addressed in D5.3
PEP-NFR-5	All error messages should explain how to recover from the error and propose a fallback mechanism	Proposed	MEDIXINE	PEP	To be addressed in D5.3
PEP-NFR-6	The system shall not fail if an unsupported format of care plan is returned or pushed by PEP Client Systems.	Proposed	MEDIXINE	PEP	To be addressed in D5.3
PEP-NFR-7	The system shall provide a role based user access control mechanism	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-NFR-8	The system shall provide a log-in screen for users	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-NFR-9	The system shall check the authorization of users to perform the operations supported by the system.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
PEP-NFR-10	All operations shall be audited.	Implemented	MEDIXINE	PEP	Native function supported by Medixine Suite product
TIS-FR-1	The system shall send queries to local care system for patient records	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1
TIS-FR-2	The system shall send queries to local care system for clinical documents	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1
TIS-FR-3	The system shall receive queries for patient records from PCPDP or C3DP	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1
TIS-FR-4	The system shall receive queries for clinical documents from PCPDP or C3DP	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1
TIS-FR-5	The system shall subscribe to clinical events generated by local care system	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-5
TIS-FR-6	The system shall receive patient records from local care system	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS,



<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</i>
					SDD-ITF-TIS, SDD-SEQ-TIS-5
TIS-FR-7	The system shall receive clinical documents from local care system	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-5
TIS-FR-8	The system shall send patient records to PCPDP or C3DP	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1, SDD-SEQ-TIS-5,  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
TIS-FR-9	The system shall send clinical documents to PCPDP or C3DP	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1, SDD-SEQ-TIS-5,  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP
TIS-FR-10	The system shall receive care plan from PCPDP or C3DP	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-2,  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-CP
TIS-FR-11	The system shall send care plan to local care system	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-2
TIS-FR-12	The system shall receive patient measurements from tele-monitoring device or PHR	Obsolete	WARWICK	TIS	TIS will not collect tele-monitoring device measurements. PEP will collect instead.
TIS-FR-13	The system shall send patient measurements to C3DP	Obsolete	WARWICK	TIS	TIS will not collect and upload tele-monitoring device measurements. PEP will directly send C3DP.
TIS-FR-14	The system shall send patient measurements to PEP	Obsolete	WARWICK	TIS	TIS will not collect tele-monitoring device measurements. PEP will collect directly.
TIS-FR-15	The system shall send patient records in source format to SIS	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1, SDD-SEQ-TIS-5
TIS-FR-16	The system shall send clinical documents in source format to SIS	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1, SDD-SEQ-TIS-5
TIS-FR-17	The system shall send patient measurements in source format to SIS	Obsolete	WARWICK	TIS	PEP will collect and convert tele-monitoring device measurements.
TIS-FR-18	The system shall receive patient records in	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS,

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	converted format from SIS				SDD-ITF-TIS, SDD-SEQ-TIS-1, SDD-SEQ-TIS-5,  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
TIS-FR-19	The system shall receive clinical documents in converted format from SIS	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1, SDD-SEQ-TIS-5,  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP
TIS-FR-20	The system shall receive patient measurements in converted format from SIS	Obsolete	WARWICK	TIS	PEP will convert tele-monitoring device measurements.
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	Proposed	WARWICK	TIS	To be addressed in D6.1
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	Obsolete	WARWICK	TIS	Not a requirement for TIS any more.
TIS-IR-3	The converted patient records or clinical documents received from SIS shall conform to C3-Cloud FHIR profile	Proposed	WARWICK	TIS	To be addressed in D6.1
TIS-IR-4	The care plan received from PCPDP or C3DP shall conform to C3-Cloud FHIR profile	Proposed	WARWICK	TIS	To be addressed in D6.1
TIS-SIR-1	The system shall provide FHIR-based API for PCPDP or C3DP to query and extract patient records and clinical documents	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1
TIS-SIR-2	Local care system shall provide API for TIS to query and extract patient records and clinical documents	Proposed	WARWICK	TIS	To be addressed in D6.1
TIS-SIR-3	Local care system shall provide API for Tis to subscribe clinical events	Proposed	WARWICK	TIS	To be addressed in D6.1
TIS-SIR-4	Local care system shall send TIS patient records or clinical documents	Proposed	WARWICK	TIS	To be addressed in D6.1

<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</i>
	when subscribed clinical events are triggered				
TIS-SIR-5	PCPDP or C3DP shall provide FHIR-based API to receive patient records or clinical documents	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-ITF-C3DP, SDD-SEQ-TIS-5
TIS-SIR-6	Tele-monitoring device or PHR shall send TIS patient measurements at regular intervals or when pre-defined events are triggered	Obsolete	WARWICK	TIS	Patient measurements are sent to PEP directly.
TIS-SIR-7	C3DP shall provide FHIR-based API to receive patient measurements	Obsolete	WARWICK	TIS	C3DP will provide interface to PEP to receive patient measurements
TIS-SIR-8	PEP shall provide FHIR-based API to receive patient measurements	Obsolete	WARWICK	TIS	PEP will not use TIS to collect patient measurements.
TIS-SIR-9	SIS shall provide API to convert patient records or clinical documents into C3-Cloud FHIR format	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-CMP-SIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-LGC-SIS, SDD-ITF-TIS, SDD-ITF-SIS, SDD-SEQ-TIS-1, SDD-SEQ-TIS-5
TIS-NFR-1	The call to local care system API should return results in reasonable time (such as less than 10 sec)	Proposed	WARWICK	TIS	To be addressed in D6.1
TIS-NFR-2	The call to PCPDP or C3DP API should return in reasonable time (such as less than 10 sec)	Proposed	WARWICK	TIS	To be addressed in D7.4
TIS-NFR-3	The call to PEP API should return in reasonable time (such as less than 10 sec)	Obsolete	WARWICK	TIS	No interface between TIS and PEP any more.
TIS-NFR-4	The call to SIS API should return in reasonable time (such as less than 10 sec)	Proposed	WARWICK	TIS	To be addressed in D6.2
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.	Proposed	WARWICK	TIS	To be addressed in D6.1
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.	Proposed	WARWICK	TIS	To be addressed in D6.1
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.	Obsolete	WARWICK	TIS	No interface between TIS and PEP any more.

<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</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	Proposed	WARWICK	TIS	To be addressed in D6.1
TIS-NFR-9	The Technical Interoperability Suite's Mean Time To Repair (MTTR) shall not exceed 24 hours	Proposed	WARWICK	TIS	To be addressed in D6.1
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	Proposed	WARWICK	TIS	To be addressed in D6.3
TIS-NFR-11	The system shall establish a secure communication channel when transporting patient care plan from PCPDP or C3DP to local care system	Proposed	WARWICK	TIS	To be addressed in D6.3
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	Obsolete	WARWICK	TIS	
TIS-NFR-13	The system shall establish a secure communication channel when transporting patient records or clinical documents to and from SIS	Proposed	WARWICK	TIS	Obsolete
TIS-NFR-14	All communications with local care system, tele-monitoring device or PHR, PCPDP, C3DP, PEP and SIS shall be audited	Proposed	WARWICK	TIS	To be addressed in D6.3
SIS-FR-1	The system shall receive patient records in source format from TIS	Designed	INSERM	SIS	SDD-CMP-OVERALL, SDD-CMP-SIS, SDD-LGC-OVERALL, SDD-LGC-SIS, SDD-ITF-SIS, SDD-SEQ-SIS-1
SIS-FR-2	The system shall receive clinical documents in source format from TIS	Proposed	INSERM	SIS	SDD-CMP-OVERALL, SDD-CMP-SIS, SDD-LGC-OVERALL, SDD-LGC-SIS, SDD-ITF-SIS, SDD-SEQ-SIS-1
SIS-FR-3	The system shall receive patient measurements in source format from TIS	Proposed	INSERM	SIS	SDD-CMP-OVERALL, SDD-CMP-SIS, SDD-LGC-OVERALL, SDD-LGC-SIS, SDD-ITF-SIS, SDD-SEQ-SIS-1
SIS-FR-4	The system shall send patient records in converted format from TIS	Proposed	INSERM	SIS	SDD-CMP-OVERALL, SDD-CMP-SIS, SDD-LGC-OVERALL, SDD-LGC-SIS, SDD-ITF-SIS, SDD-SEQ-SIS-1

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SIS-FR-5	The system shall send clinical documents in converted format from TIS	Proposed	INSERM	SIS	SDD-CMP-OVERALL, SDD-CMP-SIS, SDD-LGC-OVERALL, SDD-LGC-SIS, SDD-ITF-SIS, SDD-SEQ-SIS-1
SIS-FR-6	The system shall send patient measurements in converted format from TIS	Proposed	INSERM	SIS	SDD-CMP-OVERALL, SDD-CMP-SIS, SDD-LGC-OVERALL, SDD-LGC-SIS, SDD-ITF-SIS, SDD-SEQ-SIS-1
SIS-FR-7	The system shall receive information model specifications from Administrator	Proposed	INSERM	SIS	SDD-CMP-OVERALL, SDD-CMP-SIS, SDD-LGC-OVERALL, SDD-LGC-SIS, SDD-ITF-SIS, SDD-SEQ-SIS-4, SDD-SEQ-SIS-5
SIS-FR-8	The system shall receive terminology definitions from Administrator	Proposed	INSERM	SIS	SDD-CMP-OVERALL, SDD-CMP-SIS, SDD-LGC-OVERALL, SDD-LGC-SIS, SDD-ITF-SIS, SDD-SEQ-SIS-4, SDD-SEQ-SIS-5
SIS-SIR-1	The system shall provide API to perform mapping query.	Proposed	INSERM	SIS	To be addressed in D6.2
SIS-UIR-1	The system shall provide user interfaces for Administrator for register new information model of data source.	Proposed	INSERM	SIS	To be addressed in D6.2
SIS-UIR-2	The system shall provide user interfaces for Administrator for register new terminology mapping.	Proposed	INSERM	SIS	To be addressed in D6.2
SIS-NFR-1	The call to SIS API should return in reasonable time	Proposed	INSERM	SIS	To be addressed in D6.2
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.	Proposed	INSERM	SIS	To be addressed in D6.2
SIS-NFR-3	The Semantic Interoperability Suite's Mean Time To Repair (MTTR) shall not exceed 24 hours	Proposed	INSERM	SIS	To be addressed in D6.2
SIS-NFR-4	The system shall establish a secure communication channel when receiving requested and transmitting output.	Proposed	INSERM	SIS	To be addressed in D6.3
SIS-NFR-5	All communications of SIS shall be audited	Proposed	INSERM	SIS	To be addressed in D6.3
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	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS, SDD-LGC-OVERALL, SDD-LGC-SPS, SDD-INF-AUN, SDD-ITF-SPS, SDD-SEQ-SPS-2

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	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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-1
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-1
SPS-FR-4	The system shall enable rejection of new user account creation request by the Administrator.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-1
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-2, SDD-SEQ-SPS-3
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-2
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-2

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SPS-FR-8	In case of authentication failure, the user shall be informed about the outcome appropriately.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-2
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-4
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).	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-4
SPS-FR-11	The Authorisation Manager subcomponent shall enable definition of new policies/rules or update of existing policies/rules at any time.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-4
SPS-FR-12	The Authorisation Manager subcomponent shall store machine processable permission definitions in a repository.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-4
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-3
SPS-FR-14	PCPDP or C3DP should be able to request additional attributes of the user from the associated identity provider when necessary.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-2, SDD-SEQ-SPS-3
SPS-FR-15	The Authorisation Manager acting as the Policy Decision Point shall check the user attributes and requested resource and operation	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN, SDD-INF-ACP

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	against the access control policies in its repository, and shall either approve or deny the operation.				SDD-ITF-SPS SDD-SEQ-SPS-3
SPS-FR-16	The system shall have an Audit Record Repository (ARR) that accepts and stores standards based audit trail records.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ATR SDD-ITF-SPS SDD-SEQ-SPS-5, SDD-SEQ-SPS-6
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ATR SDD-ITF-SPS SDD-SEQ-SPS-5
SPS-FR-18	Audit Record Repository shall inform the Secure Node about the result of the save operation.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ATR SDD-ITF-SPS SDD-SEQ-SPS-5
SPS-IR-1	User identity data including the secrets (password, authentication/authorization tokens) shall be stored in encrypted secure storage.	Proposed	SRDC	SPS	To be addressed in D6.3.
SPS-IR-2	The authentication request, response and user attributes shall all be represented in widely recognised industrial standards such as OpenID Connect.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-2, SDD-SEQ-SPS-3
SPS-IR-3	The access control policies shall be represented in widely recognised machine processable formats such as OASIS XACML and XSPA.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-4
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)	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ATR SDD-ITF-SPS SDD-SEQ-SPS-5, SDD-SEQ-SPS-6



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	of the accessed/updated records.				
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.	Proposed	SRDC	SPS	To be addressed in D6.3.
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-3
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ATR SDD-ITF-SPS SDD-SEQ-SPS-5
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).	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-2
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.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-1
SPS-UIR-3	The system shall provide user interface on top of the Authorisation Manager for Administrators to define/update access control policies.	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-4
SPS-UIR-4	The system shall have an Audit Record Repository (ARR) User Interface for Administrators to monitor, query and filter	Designed	SRDC	SPS	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ATR SDD-ITF-SPS

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	all the audit trail records in the ARR.				SDD-SEQ-SPS-6
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).	Proposed	SRDC	SPS	To be addressed in D6.3.
SPS-NFR-2	The policy decision making of the Authorisation Manager should be completed in a reasonable time (less than 2 seconds).	Proposed	SRDC	SPS	To be addressed in D6.3.
SPS-NFR-3	The call to audit trail record submission interface of the Audit Record Repository should return in less than 2 seconds.	Proposed	SRDC	SPS	To be addressed in D6.3.
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.	Proposed	SRDC	SPS	To be addressed in D6.3.
SPS-NFR-5	All screens should have a help button.	Proposed	SRDC	SPS	To be addressed in D6.3.
SPS-NFR-6	All error messages should explain how to recover from the error and propose a fallback mechanism	Proposed	SRDC	SPS	To be addressed in D6.3.
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.	Proposed	SRDC	SPS	To be addressed in D6.3.
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.	Proposed	SRDC	SPS	To be addressed in D6.3.
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.	Proposed	SRDC	SPS	To be addressed in D6.3.
SPS-NFR-10	The Security and Privacy Suite's Mean Time To Repair (MTTR) shall not exceed 24 hours.	Proposed	SRDC	SPS	To be addressed in D6.3.
SPS-NFR-11	All software interfaces shall be secured by node-	Proposed	SRDC	SPS	To be addressed in D6.3.

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	to-node authentication (SSL/TLS)				
SPS-NFR-12	All operations (create, read, delete, update, execute) shall be audited	Proposed	SRDC	SPS	To be addressed in D6.3.
CDSM-FR-1	The system shall allow to create a new knowledge module	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-LGC-OVERALL, SDD-LGC-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-1
CDSM-FR-2	The system shall allow to update an old knowledge module	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-LGC-OVERALL, SDD-LGC-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-1
CDSM-FR-3	The system shall allow to validate a knowledge module	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-LGC-OVERALL, SDD-LGC-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-1
CDSM-FR-4	The system shall list all knowledge modules	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-LGC-OVERALL, SDD-LGC-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-1
CDSM-FR-5	The system shall display metadata of a knowledge module	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-LGC-OVERALL, SDD-LGC-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-1
CDSM-FR-6	The system shall evaluate patient data using a knowledge module	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-LGC-OVERALL, SDD-LGC-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-2
CDSM-FR-7	The system shall have knowledge modules to provide clinical guideline based diagnosis and treatment suggestions	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-LGC-OVERALL, SDD-LGC-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-2
CDSM-FR-8	The system shall have knowledge modules to provide polypharmacy management suggestions	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-LGC-OVERALL, SDD-LGC-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-2
CDSM-FR-9	The system shall have knowledge modules to provide risk assessment	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-LGC-OVERALL, SDD-LGC-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-2
CDSM-IR-1	The patient data for CDS evaluation shall conform to C3-Cloud FHIR profile	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D6.1
CDSM-IR-2	The system shall support the clinical guidelines that will be agreed upon in Task 7.1.	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
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	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2

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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.	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
CDSM-SIR-1	The system shall provide web service API conforming to HL7 DSS standard	Obsolete	WARWICK, CAMBIO	CDSM	CDS-hooks is adopted instead
CDSM-SIR-1a	The system shall provide web service API conforming to CDS-hooks	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-ITF-CDSS
CDSM-UI-1	The system shall provide user interface for knowledge engineers to create or update knowledge modules	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-1
CDSM-UI-2	The system shall provide user interface for care team members to validate knowledge modules	Designed	WARWICK, CAMBIO	CDSM	SDD-CMP-OVERALL, SDD-CMP-CDSS, SDD-ITF-CDSS, SDD-SEQ-CDSS-1
CDSM-NFR-1	The operations to create or update knowledge modules should return in reasonable time (such as less than 10 sec)	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
CDSM-NFR-2	The operation to list and display knowledge module metadata should return in reasonable time (such as less than 5 sec)	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
CDSM-NFR-3	The operation to evaluate patient using a knowledge module should return results in reasonable time (such as less than 20 sec)	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
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.	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
CDSM-NFR-5	All error messages should explain how to recover from the error and propose a fallback mechanism	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
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.	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
CDSM-NFR-7	The system shall not fail if input patient data are invalid. The failure should be logged and appropriate error	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2

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	messages should be produced.				
CDSM-NFR-8	The Clinical Decision Support System's Mean Time To Repair (MTTR) shall not exceed 24 hours	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
CDSM-NFR-9	The system shall provide a login screen to knowledge engineers and care team members	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
CDSM-NFR-10	The system shall check authorizations of knowledge engineers to create or update knowledge modules	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D6.3
CDSM-NFR-11	The system shall check authorizations of care team members to validate knowledge modules	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D6.3
CDSM-NFR-12	All operations to create, update or validate knowledge modules and evaluate patients shall be audited	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D6.3
PCPDP-FR-1	The system shall maintain a repository of machine processable care plans	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-2, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-SEQ-PCPDP-4, SDD-SEQ-PCPDP-5, SDD-INF-CP
PCPDP-FR-3	The system shall communicate with Technical Interoperability Suite (TIS) to access clinical data of a selected Patient	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-3, SDD-SEQ-C3DP-12, SDD-SEQ-C3DP-13, SDD-SEQ-C3DP-14  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
PCPDP-FR-4	The system shall support the capability to define a care plan from scratch	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-2, SDD-INF-CP
PCPDP-FR-5	The system shall support the capability to define care plans by adopting core care plans (based on the suggestions provided	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP,

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	by clinical decision support modules)				SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-INF-CP
PCPDP-FR-6	The system shall support selecting the targeted health concerns from patient's medical history as the target of care plan	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-SEQ-PCPDP-4, SDD-SEQ-PCPDP-5, SDD-INF-CP
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.	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-9	The system shall support visualization of the details of care plan templates	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-INF-CP
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-INF-CP
PCPDP-FR-11	The system shall enable definition of a new care team	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-12	The system shall enable invitation of new care team members	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-SEQ-C3DP-2, SDD-INF-CP
PCPDP-FR-13	The system shall enable removal of care team members from the care team	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-SEQ-C3DP-3, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-14	The system shall inform PEP about Care Team Member updates	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-SEQ-C3DP-3, SDD-SEQ-C3DP-2, SDD-INF-CP
PCPDP-FR-15	The system shall support the capability to utilize the clinical decision support modules that suggest goals and	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP,

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	interventions given a health concern to be addressed based on clinical guidelines				SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-SEQ-PCPDP-4, SDD-SEQ-PCPDP-5
PCPDP-FR-16	The system shall enable the definition of new goals for the care plan	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-17	The system shall enable linking care plan goals with health concerns set as the target of the care plan	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-18	The system shall enable reviewing the details of existing goals in the care plan definition and updating them if necessary.	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-19	The system shall enable the definition of new interventions in the care plan	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-20	The system shall enable linking interventions with goals set as the target of the care plan	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
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.	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-3, SDD-INF-CP
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-23	The system shall enable setting planned care plan review meeting dates	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-4, SDD-INF-CP

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	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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-4, SDD-SEQ-PCPDP-5, SDD-INF-CP
PCPDP-FR-26	The system shall mark the missing relevant interventions and contraindicating interventions visually to present to the Care Team Member (s).	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-4, SDD-SEQ-PCPDP-5
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-3, SDD-SEQ-C3DP-12, SDD-SEQ-C3DP-13, SDD-SEQ-C3DP-14
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-SEQ-C3DP-8, SDD-INF-CP
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-6, SDD-INF-SM
PCPDP-FR-31	The system shall support the capability to share the exported care plan with local care systems via TIS functionalities	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-3, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-32	The system can open up multiple care plans in case of multimorbid conditions and enable the care team members to	Proposed	SRDC	PCPDP	To be addressed in D7.3



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	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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-4, SDD-SEQ-PCPDP-5, SDD-INF-CP
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-5, SDD-INF-CP
PCPDP-FR-35	The system shall mark the identified inconsistencies visually to present to the care team member (s) while reconciling multiple care plans	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-4, SDD-SEQ-PCPDP-5
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-4, SDD-SEQ-PCPDP-5, SDD-SEQ-PCPDP-3, SDD-INF-CP
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-6, SDD-INF-CP
PCPDP-FR-38	The system shall enable tagging care plan items (i.e. health concerns, goals, interventions, outcome assessments) requiring review or follow-up.	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-FR-39	The system support export operation to create a care plan snapshot and share it as a machine processable Care Plan document	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-9, SDD-INF-CP
PCPDP-FR-40	The system shall support importing an existing care plan document	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP,

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	represented in a machine processable format to the system				SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-10, SDD-INF-CP
PCPDP-FR-41	The system shall enable to ascertain who the lead clinician and care plan manager would be	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-10
PCPDP-IR-2	The system shall export the care plan snapshot in the machine processable formats supported by C3-Cloud pilot sites	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-9, SDD-INF-CP
PCPDP-IR-3	The input and output to Clinical Decision Support Modules shall be through FHIR resources	Proposed	WARWICK, CAMBIO	PCPDP	To be addressed in D6.1
PCPDP-IR-4	The patient data retrieved from TIS services shall be in the format of FHIR resources	Proposed	WARWICK	PCPDP	To be addressed in D6.1
PCPDP-SIR-1	The CDSM services shall be accessible through a standardized API such as HL7 DSS SFM	Proposed	WARWICK, CAMBIO	PCPDP	To be addressed in D7.2
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.	Proposed	WARWICK, CAMBIO	PCPDP	To be addressed in D7.2
PCPDP-SIR-3	TIS services for retrieving patient data shall be accessible through a standardized API such as FHIR services	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
PCPDP-SIR-4	C3DP shall provide an interface to PCPDP for inviting care team	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP,

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	members to virtual care plan review meetings				SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3
PCPDP-SIR-5	C3DP shall provide an interface to PCPDP for sharing the defined care plan with Care Team Members	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-9
PCPDP-SIR-6	C3DP shall provide an interface to PCPDP for retrieving patient data from local care systems	Obsolete	SRDC	PCPDP	This feature is handled directly from C3DP now.
PCPDP-SIR-7	C3DP shall provide an interface to PCPDP for initiating an asynchronous negotiation with Care Team Members	Obsolete	SRDC	PCPDP	This feature is handled directly from C3DP now.
PCPDP-SIR-8	PEP shall provide an interface to PCPDP for sharing the care plan with the patient and her informal care givers	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-8, SDD-INF-CP
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	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
PCPDP-UIR-2	The system shall provide menu items for importing care plans	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-8
PCPDP-UIR-3	The system shall provide menu items for exporting care plans	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-7
PCPDP-UIR-4	The system shall provide menu items for finding care plans for a given patient	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-6, SDD-INF-CP
PCPDP-UIR-5	The system shall provide menu items for locating clinical guidelines for a given health concern	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3
PCPDP-NFR-1	The call to CDSM services should return a result in reasonable time (such as less than 10 sec)	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
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)	Proposed	WARWICK	TIS	To be addressed in D6.1
PCPDP-NFR-3	All system user interfaces should be designed in such manner that the system functions can be	Proposed	SRDC	PCPDP	To be addressed in D7.3.

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	achieved with as few clicks as possible.				
PCPDP-NFR-4	All screens should have a help button.	Proposed	SRDC	PCPDP	To be addressed in D7.3.
PCPDP-NFR-5	All error messages should explain how to recover from the error and propose a fallback mechanism	Proposed	SRDC	PCPDP	To be addressed in D7.3.
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	Proposed	SRDC	PCPDP	To be addressed in D7.3.
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	Proposed	SRDC	PCPDP	To be addressed in D7.3.
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	Proposed	SRDC	PCPDP	To be addressed in D7.3.
PCPDP-NFR-9	The Personalized Care Plan Definition platform's Mean Time To Repair (MTTR) shall not exceed 24 hours	Proposed	SRDC	PCPDP	To be addressed in D7.3.
PCPDP-NFR-10	The system shall provide a role based user access control mechanism	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN, SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-3
PCPDP-NFR-11	The system shall provide a log-in screen for care team members	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-2
PCPDP-NFR-12	The system shall check the authorization of care team members to access/create/update a care plan for a specific patient	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-2, SDD-SEQ-SPS-3
PCPDP-NFR-13	All operations (such as create, delete, update of care plan items) shall be audited	Designed	SRDC	PCPDP	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ATR SDD-ITF-SPS

<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</i>
					SDD-SEQ-SPS-5
C3DP-FR-1	The system shall support closing a care plan that is no longer in use and archive it	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-1, SDD-INF-CP
C3DP-FR-2	The system shall send a notification to care team members whenever a care plan is marked as closed	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-5, SDD-SEQ-C3DP-1, SDD-SEQ-C3DP-16, SDD-INF-CP, SDD-INF-SM
C3DP-FR-3	The system shall notify PEP whenever a care plan is marked as closed	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-1, SDD-INF-CP
C3DP-FR-4	The system shall enable an authorized care team member to invite another individual to a care team.	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-2
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.	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-2
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.	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-2
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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-2
C3DP-FR-8	The system shall notify the care team members about the new care team member added	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-5, SDD-SEQ-C3DP-2, SDD-INF-SM
C3DP-FR-9	The system shall notify PEP whenever a new care team member is added	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-1, SDD-INF-SM
C3DP-FR-10	The system shall enable an authorized care team member to inactivate the membership of another care team member	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-3
C3DP-FR-11	The system shall notify the inactivated member about the inactivation/termination of his membership	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-5, SDD-SEQ-C3DP-3, SDD-INF-SM
C3DP-FR-12	The system shall notify PEP whenever a care team member's	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP,

<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</i>
	membership is inactivated/terminated				SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-3, SDD-INF-CP
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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-4, SDD-INF-CP
C3DP-FR-14	The system shall enable an authorized care team member to send asynchronous messages to one or more care team member(s)	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-SM
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”.	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-5, SDD-INF-SM, SDD-INF-CP
C3DP-FR-16	The system shall support care team members to view their messages, tag them, list them based on the tags	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-6, SDD-INF-SM
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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-6, SDD-INF-SM
C3DP-FR-18	The system shall support care team members to list the messages s/he received from a specific Patient/Informal Care Giver	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-6, SDD-INF-SM
C3DP-FR-19	The system shall support care team members to list the messages s/he received related with a specific patient	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-6, SDD-INF-SM
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”	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-6, SDD-INF-SM
C3DP-FR-21	The system shall support care team members to send an invitation to organize a joint virtual Care Plan Review Meeting	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-5, SDD-SEQ-C3DP-7

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C3DP-FR-22	The system shall provide an interface to invited care team members to accept/reject virtual care plan review meeting invitations	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-7
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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-7
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)	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-5, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-SEQ-C3DP-16, SDD-INF-SM
C3DP-FR-25	The system shall notify PEP that a new care plan is defined or an existing care plan is updated	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
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.	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-9, SDD-SEQ-C3DP-10, SDD-SEQ-C3DP-11, SDD-INF-DVO, SDD-INF-QR, SDD-INF-PFO
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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-ITF-C3DP-5, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-SEQ-C3DP-16, SDD-SEQ-C3DP-9, SDD-SEQ-C3DP-10, SDD-SEQ-C3DP-11, SDD-INF-SM
C3DP-FR-28	The system shall support manually importing clinical documents of the patients in to the system	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP,

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	and associating them with the active care plan				SDD-ITF-C3DP-1, SDD-ITF-C3DP-3, SDD-INF-CP, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-13,
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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-3, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-13, SDD-SEQ-SIS-1  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB  SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP
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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-3, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-14, SDD-SEQ-TIS-1  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
C3DP-FR-31	The system shall provide an interface to accept the patient data from local care systems via TIS services in push mode	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-3, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-12, SDD-SEQ-TIS-3  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
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	Proposed	SRDC	C3DP	To be further addressed in D7.3 and 7.4



<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</i>
	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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-5, SDD-ITF-C3DP-3, SDD-SEQ-PCPDP-3, SDD-INF-CP
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)	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-5, SDD-ITF-C3DP-3, SDD-SEQ-C3DP-15, SDD-INF-CP
C3DP-FR-35	Whenever a subscribed event is detected by the system, the system shall send notifications about these events via messaging platform	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-5, SDD-ITF-C3DP-3, SDD-SEQ-C3DP-16, SDD-INF-SM
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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-ITF-C3DP-5, SDD-ITF-C3DP-3, SDD-SEQ-C3DP-16, SDD-SEQ-C3DP-5, SDD-INF-SM
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.	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-17, SDD-INF-CP  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB

<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</i>
C3DP-FR-38	The system shall clearly mark the responsible editors of different sections of care plan	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-INF-CP
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	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-18, SDD-INF-CP
C3DP-IR-1	The patient data retrieved from TIS services shall be in the format of FHIR resources	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1
C3DP-IR-2	The patient reported observations to be retrieved from PEP shall be in the format of FHIR resources	Designed	MEDIXINE	PEP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-9, SDD-SEQ-C3DP-10, SDD-SEQ-C3DP-11, SDD-ITF-C3DP-4, SDD-INF-PFO SDD-INF-DVO SDD-INF-QR
C3DP-IR-3	The input and output to Clinical Decision Support Modules shall be through FHIR resources	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
C3DP-SIR-1	The CDSM services shall be accessible through a standardized API such as HL7 DSS SFM	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
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.	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
C3DP-SIR-3	TIS services for retrieving patient data shall be accessible through a standardized API such as FHIR services	Designed	WARWICK	TIS	SDD-CMP-OVERALL, SDD-CMP-TIS, SDD-LGC-OVERALL, SDD-LGC-TIS, SDD-ITF-TIS, SDD-SEQ-TIS-1  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB  SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP

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C3DP-SIR-4	C3DP shall provide an interface to TIS to receive patient data in push mode from local care systems as FHIR resources	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-TIS-3, SDD-SEQ-C3DP-12  SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
C3DP-SIR-5	C3DP shall provide interfaces to PEP to receive patient recorded data as FHIR resources	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-C3DP-9, SDD-SEQ-C3DP-10, SDD-SEQ-C3DP-11, SDD-ITF-C3DP-4, SDD-INF-PFO, SDD-INF-DVO, SDD-INF-QR
C3DP-SIR-6	PEP shall provide an interface to receive notifications about new/updated/closed care plans	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-SEQ-C3DP-1, SDD-INF-CP
C3DP-SIR-7	PEP shall provide an interface to receive notifications about new/updated/terminated care team members	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-4, SDD-SEQ-PCPDP-1, SDD-SEQ-PCPDP-2, SDD-SEQ-PCPDP-3, SDD-SEQ-C3DP-2, SDD-SEQ-C3DP-3, SDD-INF-CP
C3DP-UIR-1	The system shall provide user interfaces for authorized Care Team Members for managing messages from care team members	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-6, SDD-INF-SM
C3DP-UIR-2	The system shall provide user interfaces for authorized Care Team Members for managing system notifications	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-6, SDD-INF-SM
C3DP-UIR-3	The system shall provide user interfaces for organizing virtual care plan review meetings	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-7
C3DP-UIR-4	The system shall provide user interfaces for defining subscription rules to receive care plan event notifications	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-ITF-C3DP-5, SDD-ITF-C3DP-3, SDD-SEQ-C3DP-15, SDD-INF-CP
C3DP-UIR-5	The system shall provide a dashboard for visualizing the events in care plan lifecycle	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-17, SDD-INF-CP
C3DP-UIR-6	The system shall provide a dashboard for visualizing the patient's medical summary	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP,

<i>Requirement ID</i>	<i>Description</i>	<i>Status</i>	<i>Assigned To</i>	<i>System Component(s)</i>	<i>Architecture Design (D3.3)</i>
					SDD-ITF-C3DP-1, SDD-SEQ-C3DP-17, SDD-INF-CP
C3DP-UIR-7	The system shall provide user interfaces for accessing educational material	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-C3DP, SDD-LGC-OVERALL, SDD-LGC-C3DP, SDD-ITF-C3DP-1, SDD-SEQ-C3DP-18, SDD-INF-CP
C3DP-NFR-1	The call to CDSM services should return a result in reasonable time (such as less than 10 sec)	Proposed	WARWICK, CAMBIO	CDSM	To be addressed in D7.2
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)	Proposed	WARWICK	TIS	To be addressed in D6.1
C3DP-NFR-3	The audio connection to be supported for organizing virtual care plan review meetings shall provide acceptable voice quality	Proposed	SRDC	C3DP	To be addressed in D7.3.
C3DP-NFR-4	The patient dashboard shall be available for review within seconds	Proposed	SRDC	C3DP	To be addressed in D7.3.
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.	Proposed	SRDC	C3DP	To be addressed in D7.3.
C3DP-NFR-6	All screens should have a help button.	Proposed	SRDC	C3DP	To be addressed in D7.3.
C3DP-NFR-7	All error messages should explain how to recover from the error and propose a fallback mechanism	Proposed	SRDC	C3DP	To be addressed in D7.3.
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	Proposed	SRDC	C3DP	To be addressed in D7.3.
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	Proposed	SRDC	C3DP	To be addressed in D7.3.
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)	Proposed	SRDC	C3DP	To be addressed in D7.3.

<i><b>Requirement ID</b></i>	<i><b>Description</b></i>	<i><b>Status</b></i>	<i><b>Assigned To</b></i>	<i><b>System Component(s)</b></i>	<i><b>Architecture Design (D3.3)</b></i>
C3DP-NFR-11	The C3DP Mean Time To Repair (MTTR) shall not exceed 24 hours	Proposed	SRDC	C3DP	To be addressed in D7.3.
C3DP-NFR-12	The system shall provide a role based user access control mechanism	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN, SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-3
C3DP-NFR-13	The system shall provide a log-in screen for care team members	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-AUN SDD-ITF-SPS SDD-SEQ-SPS-2
C3DP-NFR-14	The system shall check the authorization of care team members to perform the operations supported by C3DP	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ACP SDD-ITF-SPS SDD-SEQ-SPS-2, SDD-SEQ-SPS-3
C3DP-NFR-15	All operations shall be audited	Designed	SRDC	C3DP	SDD-CMP-OVERALL, SDD-CMP-SPS SDD-LGC-OVERALL, SDD-LGC-SPS SDD-INF-ATR SDD-ITF-SPS SDD-SEQ-SPS-5

A definition of the information exchange matrix is available in D3.2 Appendix II. This deliverable includes the following columns from D3.2 for complete reference and adds an architecture design column to link the information items to its design model IDs. The matrix consists of the following columns:

- **ID**: This column represents the unique identifier of the information exchange item.
- **Producer**: The information producer, i.e. the sender of the information item.
- **Consumer**: The information consumer, i.e. the receiver of the information item.
- **Content**: A description of the information item being exchanged between the producer and the consumer.
- **Architecture Design**: The column links to SDD design model IDs in this deliverable.

(Abbreviations: CTM – Care Team Member, PIC – Patient/Informal Care Giver,

LCS – Local Care System, CSA – C3-Cloud System Administrator)

**Table 4: Information Exchange Matrix**

ID	Producer	Consumer	Content	Architecture Design (D3.3)
IE1	C3DP	PCPDP	Care plan	SDD-INF-CP
IE2	C3DP	PCPDP	Patient data	SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
IE3	C3DP	PCPDP	Clinical documents (SIS transformed format)	SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP
IE4	PCPDP	C3DP	Care plan	SDD-INF-CP
IE5	PCPDP	SPS	User attributes, requested operation and resource of interest	SDD-INF-AUN (Process is slightly modified; all the user permissions per resource will be made available in each request)
IE6	PCPDP	SPS	Audit trail record	SDD-INF-ATR
IE7	PCPDP	CDSM	Patient data	SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
IE8	PCPDP	CDSM	Care plan	SDD-INF-CP
IE9	PCPDP	CTM	Care plan templates	SDD-INF-CP

ID	Producer	Consumer	Content	Architecture Design (D3.3)
IE10	PCPDP	CTM	Care team membership invitation	SDD-INF-CP (CareTeam resource)
IE11	PCPDP	CTM	Virtual care plan review meeting invitation	SDD-INF-CP (Activity resource)
IE12	PCPDP	CTM	Shared care plan	SDD-INF-CP
IE13	PCPDP	CTM	Care plan	SDD-INF-CP
IE14	C3DP	PEP	Care plan	SDD-INF-CP
IE15	C3DP	PEP	Care team member data	SDD-INF-CP (CareTeam resource)
IE16	C3DP	TIS	Patient demographics	SDD-INF-PAT
IE17	C3DP	TIS	Care plan	SDD-INF-CP
IE18	C3DP	SPS	User attributes, requested operation and resource of interest	SDD-INF-AUN (Process is slightly modified; all the user permissions per resource will be made available in each request)
IE19	C3DP	SPS	Audit trail record	SDD-INF-ATR
IE20	C3DP	CDSM	Patient data	SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB, SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP
IE21	C3DP	CDSM	Tele-monitoring measurements	SDD-INF-DVO
IE22	C3DP	CTM	Virtual care plan review meeting invitation	SDD-INF-CP (Activity resource)
IE23	C3DP	CTM	Care team membership invitation	SDD-INF-CP (CareTeam resource)
IE24	C3DP	CTM	Shared care plan	SDD-INF-CP
IE25	C3DP	CTM	Notifications about subscribed patient data and care plan	SDD-INF-SM
IE26	C3DP	CTM	Patient reported observations	SDD-INF-DVO
IE27	C3DP	CTM	Overall summary of patient's medical history and care plan progress	SDD-INF-CP, SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-

ID	Producer	Consumer	Content	Architecture Design (D3.3)
				OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB, SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP, SDD-INF-DVO
IE28	C3DP	CTM	New care team member notification	SDD-INF-SM
IE29	C3DP	CTM	Messages from other CTM/Patients/Informal care givers	SDD-INF-SM
IE30	C3DP	CTM	Educational material	SDD-INF-CP (EducationalMaterial resource)
IE31	PEP	C3DP	Patient observations, questionnaire responses and assessments	SDD-INF-DVO, SDD-INF-QR
IE32	PEP	TIS	Patient demographics	Obsolete
IE33	PEP	SPS	Audit trail record	SDD-INF-ATR
IE34	PEP	CDSM	Patient data, questionnaire responses and telemonitoring measurements	SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB, SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP, SDD-INF-DVO, SDD-INF-QR
IE35	PEP	PIC	Care plan	SDD-INF-CP
IE36	PEP	PIC	Patient data	SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB, SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP
IE37	PEP	PIC	Reminders	Native function supported by Medixine Suite product
IE38	PEP	PIC	Treatment intervention status	SDD-INF-CP



ID	Producer	Consumer	Content	Architecture Design (D3.3)
IE39	PEP	PIC	Questionnaire	Native function supported by Medixine Suite product
IE40	PEP	PIC	Self-management material	Native function supported by Medixine Suite product
IE41	PEP	PIC	Registration invitation	Native function supported by Medixine Suite product
IE42	TIS	C3DP	Patient data	SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
IE43	TIS	C3DP	Clinical documents	SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP
IE44	TIS	C3DP	Tele-monitoring measurements	Obsolete
IE45	TIS	PEP	Patient data	Obsolete
IE45a	C3DP	PEP	Patient data	SDD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
IE46	TIS	PEP	Tele-monitoring measurements	Obsolete
IE47	TIS	SIS	Patient data	To be addressed in D6.1
IE48	TIS	SIS	Clinical documents	To be addressed in D6.1
IE49	TIS	SIS	Tele-monitoring measurements	Obsolete
IE50	TIS	SPS	Audit trail record	SDD-INF-ATR
IE51	TIS	LCS	Care plan	To be addressed in D6.1
IE52	SIS	TIS	Patient data	DD-INF-DT-1, SDD-INF-DT-2, SDD-INF-AI, SDD-INF-CI, SDD-INF-CN, SDD-INF-DV, SDD-INF-DR, SDD-INF-ENC, SDD-INF-EOC, SDD-INF-FMH, SDD-INF-IMU, SDD-INF-MED, SDD-INF-MO, SDD-INF-

ID	Producer	Consumer	Content	Architecture Design (D3.3)
				MS, SDD-INF-OBS, SDD-INF-VS, SDD-INF-PAT, SDD-INF-PRC, SDD-INF-SPC, SDD-INF-SUB
IE53	SIS	TIS	Clinical documents	SDD-INF-BIN, SDD-INF-BUN, SDD-INF-CMP
IE54	SIS	TIS	Tele-monitoring measurements	Obsolete
IE55	SIS	SPS	Audit trail record	SDD-INF-ATR
IE56	SIS	CDSM	Patient data	Obsolete
IE57	SIS	CDSM	CDSM results	Obsolete
IE58	SPS	PCPDP	User authentication response	SDD-INF-AUN
IE59	SPS	PCPDP	Access control decision	SDD-INF-ACP
IE60	SPS	C3DP	User authentication response	SDD-INF-AUN
IE61	SPS	C3DP	Access control decision	SDD-INF-ACP
IE62	SPS	LCS	Login credentials	SDD-INF-AUN
IE63	CDSM	PCPDP	Diagnosis/treatment suggestion	To be addressed in D7.2
IE64	CDSM	PCPDP	Medication reconciliation suggestion	To be addressed in D7.2
IE65	CDSM	PCPDP	Risk prediction	To be addressed in D7.2
IE66	CDSM	C3DP	Diagnosis/treatment suggestion	To be addressed in D7.2
IE67	CDSM	C3DP	Medication reconciliation suggestions	To be addressed in D7.2
IE68	CDSM	C3DP	Risk prediction	To be addressed in D7.2
IE69	CDSM	PEP	Risk prediction	To be addressed in D7.2
IE70	CDSM	SIS	Patient data	Obsolete
IE71	CDSM	SIS	CDSM result data	Obsolete
IE72	CDSM	SPS	Audit trail record	SDD-INF-ATR
IE73	LCS	PEP	Patient data	Obsolete
IE74	LCS	TIS	Patient data	To be addressed in D6.1
IE75	LCS	TIS	Clinical documents	To be addressed in D6.1
IE76	LCS	SPS	Audit trail record	SDD-INF-ATR
IE77	PHR/TM	TIS	Tele-monitoring measurements	Obsolete
IE78	CTM	PCPDP	Care plan	SDD-INF-CP
IE79	CTM	PCPDP	Patient data	To be addressed in D6.1 and D7.3
IE80	CTM	PCPDP	Clinical documents	To be addressed in D6.1 and D7.3
IE81	CTM	C3DP	Care plan	SDD-INF-CP
IE82	CTM	C3DP	Care team member information	SDD-INF-CP (CareTeam resource)

ID	Producer	Consumer	Content	Architecture Design (D3.3)
IE83	CTM	C3DP	Text message	SDD-INF-SM
IE84	CTM	C3DP	Virtual care plan review meeting	SDD-INF-CP (Activity resource)
IE85	CTM	PEP	Text message	Obsolete
IE86	CTM	PEP	Video appointment	SDD-INF-CP (Activity resource)`
IE87	CTM	PEP	Login credentials	SDD-INF-AUN (To be further discussed in D5.3 and D6.3)
IE88	CTM	SPS	Login credentials	SDD-INF-AUN
IE89	KE	CDSM	Knowledge modules	openEHR GDL
IE90	KM	CDSM	Knowledge modules	openEHR GDL
IE91	PIC	PEP	Text message	SDD-INF-SM
IE92	PIC	PEP	Care plan review/goal intervention assessment/symptoms	SDD-INF-PFO
IE93	PIC	PEP	Video appointment	Native function supported by Medixine Suite product
IE94	PIC	PEP	Login credentials	Native function supported by Medixine Suite product
IE95	CSA	SIS	Clinical data format mappings	To be addressed in D6.2
IE96	CSA	SIS	Terminology mappings	To be addressed in D6.2
IE97	CSA	SPS	Login credentials	SDD-INF-AUN
IE98	CSA	SPS	Access control policy	SDD-INF-ACP

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## APPENDIX I – IEEE 1016-2009 CONFORMANCE TABLE

IEEE 1016-2009 Clause	Sub-Item	D3.3 Conformance	
4.1	Identification of SDD	Introductory pages (pp. 1-2)	
4.2	Identified design stakeholders	Section 1.4	
4.3	Identified design concerns	Section 1.5	
4.4	Design views	Section 1.7	
4.5	Design viewpoints	Section 1.7	
4.6	Design elements	Name, type, purpose, and attributes are specified during introduction of new design elements. Conformance of elements are inherited by D3.2 was checked during use in D3.3 and missing attributes added.	
4.7	Design overlays	Not applicable for this deliverable	
4.8	Design rationale	Rationale is identified as a distinct section in each diagram. Pedigree decision carried forward from documents such as the DoA are considered assumptions.	
4.9	Design languages	UML is used for all diagrams	
5	Design viewpoints	All selected viewpoints as declared for requirement 4.5 are described in UML	

## APPENDIX II – UI DESIGN

### COSMIC CDS UI

GDL Editor: open guide

**GDL Editor - CHA2DS2-VASc Score - (build 2016-11-17\_11-23)**

File Language Configuration Help

Load guide... Save guide Add rule Add binding Run

Description Definitions Rule list Preconditions Defaults Terminology Binding GDL HTML

**Name:** CHA2DS2-VASc Score

**Author details**

**Name:** Rong Chen

**Email:** rong.chen@cambio.se

**Organisation:** Cambio Healthcare Systems

**Date:** 2012-12-03

**Authorship lifecycle:** Author draft

**Copyright:** Cambio Healthcare Systems

**Keywords**

- atrial fibrillation
- stroke
- CHA2DS2-VASc
- diabetes
- hypertension
- congestive heart failure
- CHF
- vascular disease
- age
- gender

**Contributors**

- Dr Carlos Valladares

**Description**

CHA2DS2-VASc Score for estimating the risk for stroke in atrial fibrillation, possibly better than the CHADS2 score.

**Purpose**

To calculate the total CHA2DS2-VASc Score based on the guidelines of the European Society of Cardiology (ESC).

**Use**

Use for calculating the CHA2DS2-VASc Score in patients with atrial fibrillation.

**Misuse**

Do not use for calculating CHADS2 score. This should be a different guidelines as it relies on different parameters.

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GDL Editor: instantiate archetypes (in C3-Cloud FHIR resources will be supported)

**GDL Editor - CHA2DS2-VASc Score - (build 2016-11-17\_11-23)**

File Language Configuration Help

Load guide... Save guide Add rule Add binding Run

Description Definitions Rule list Preconditions Defaults Terminology Binding GDL HTML

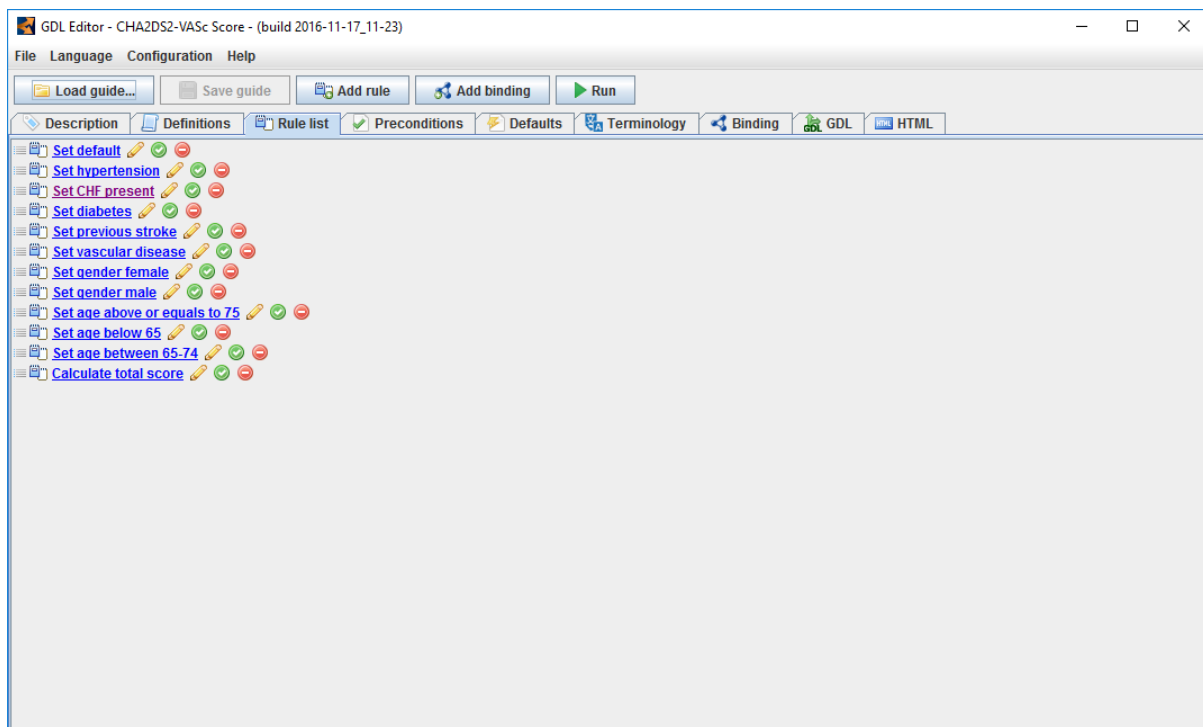
**Definitions**

- Instantiate archetype CDS openEHR-EHR-EVALUATION.chadsvas\_diagnosis\_review.v1
- Instantiate element Hypertension as Hypertension review
- Instantiate element Atrial fibrillation as Atrial fibrillation review
- Instantiate element Stroke/TIA/Thromboembolism as Stroke/TIA/Thromboembolism review
- Instantiate element Congestive Heart Failure as Congestive heart failure review
- Instantiate element Vascular disease as Vascular disease review
- Instantiate element Diabetes as Diabetes review
- Instantiate archetype EHR openEHR-EHR-OBSERVATION.basic\_demographic.v1
- Instantiate element Birthdate as Birthdate
- Instantiate element Gender as Gender
- Instantiate archetype CDS openEHR-EHR-OBSERVATION.chadsvas\_score.v1
- Instantiate element Diabetes as Diabetes
- Instantiate element Age as Age
- Instantiate element Congestive Heart Failure as Congestive Heart Failure
- Instantiate element Stroke/TIA/Thromboembolism as Stroke/TIA/Thromboembolism
- Instantiate element Vascular disease as Vascular disease
- Instantiate element Hypertension as Hypertension
- Instantiate element Gender as Gender
- Instantiate element Total score as Total score

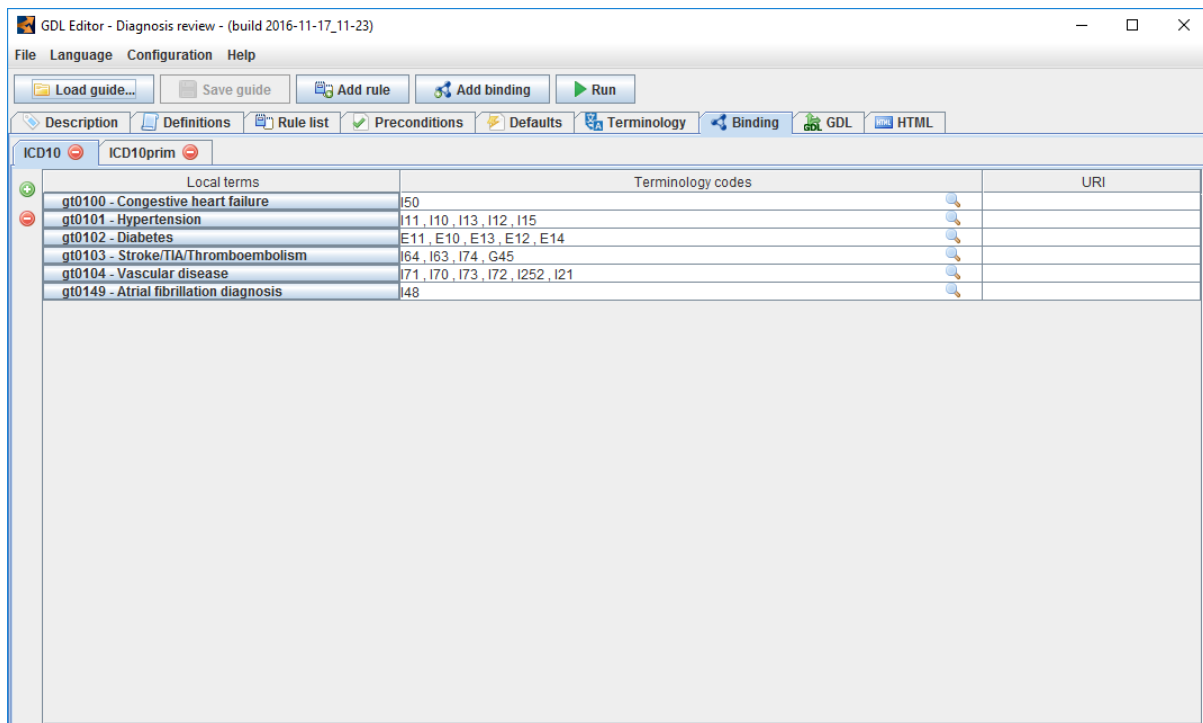
**Definitions**

- Archetype instantiation
- Element instantiation
- Predicate (DataValue)
- Predicate (Function)
- Predicate (Exists)
- Predicate (Expression)


## GDL Editor: update rule list




## GDL Editor: terminology binding




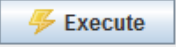
## GDL Editor: execute guide


Diagnosis review
×

**Input**

openEHR-EHR-EVALUATION.problem-diagnosis.v1  
EHR Diagnosis =  + -  
EHR Date of initial onset =  

openEHR-EHR-EVALUATION.chadsvas\_diagnosis\_review.v1  
EHR Atrial fibrillation review =  ▼  
EHR Diabetes review =  ▼  
EHR Stroke/TIA/Thromboembolism review =  ▼  
EHR Congestive heart failure review =  ▼ + -  
EHR Vascular disease review =  ▼  
EHR Hypertension review =  ▼  
EHR Date (time) of diagnosis review =  

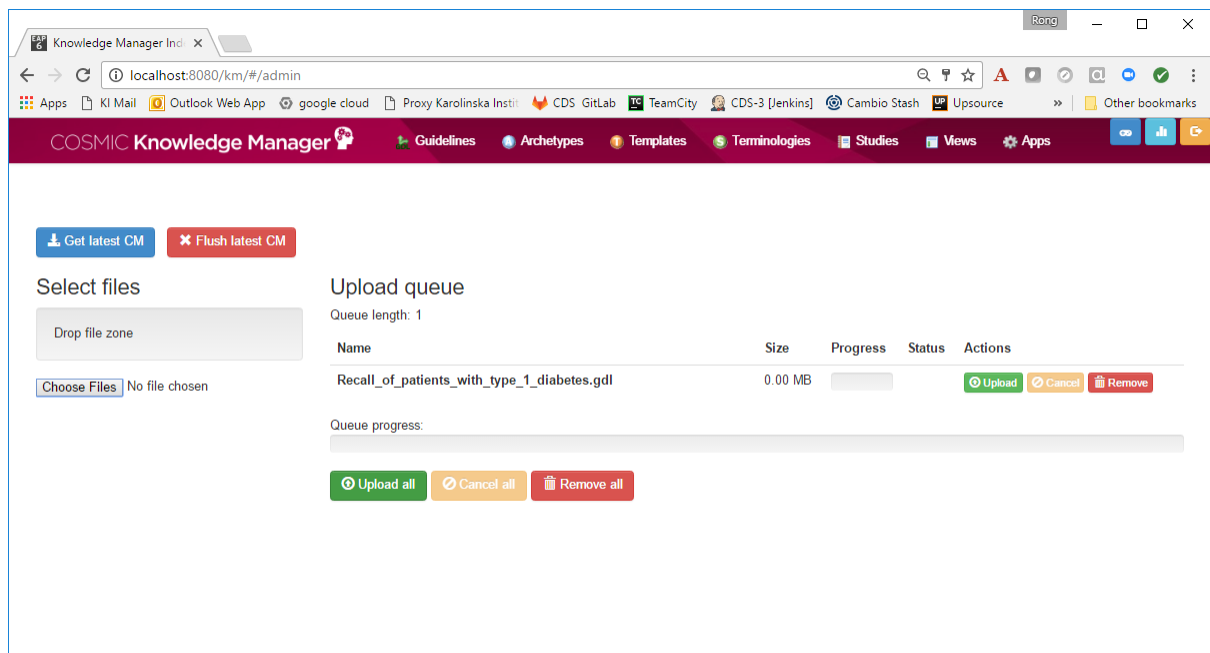

(6)

**Result**

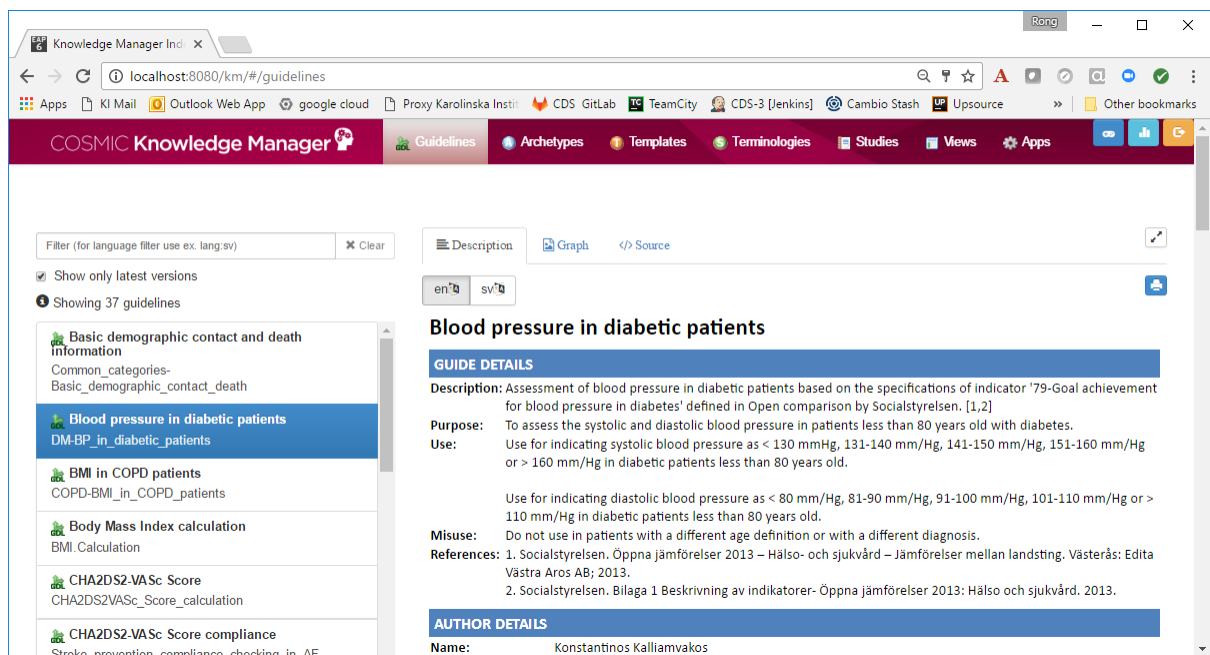
openEHR-EHR-EVALUATION.chadsvas\_diagnosis\_review.v1  
CDS Atrial fibrillation = 1 - Present  
CDS Diabetes = 1 - Present  
CDS Stroke/TIA/Thromboembolism = 0 - Absent  
CDS Congestive heart failure = 1 - Present  
CDS Vascular disease = 1 - Present  
CDS Hypertension = 1 - Present  
CDS Date (time) of diagnosis review = 08/12/2016 22:17:23



## COSMIC CDS KM Admin UI: upload guidelines



## COSMIC CDS KM Admin UI: browse guidelines



## COSMIC CDS KM Admin UI: browse guideline related archetype models

The screenshot shows the COSMIC Knowledge Manager Admin UI. The top navigation bar includes links for Guidelines, Archetypes, Templates, Terminologies, Studies, Views, and Apps. The main content area is titled 'Archetypes' and shows a list of archetypes on the left and details for the 'Blood Pressure' archetype on the right.

**Archetype List:**

- Alert: openEHR-EHR-EVALUATION.alert
- Antibiotic treatment study: openEHR-EHR-OBSERVATION.antibiotic\_treatment\_case\_study
- Basic demographic: openEHR-EHR-OBSERVATION.basic\_demographic
- Blood Pressure: openEHR-EHR-OBSERVATION.blood\_pressure**
- Body mass index: openEHR-EHR-OBSERVATION.body\_mass\_index
- Body weight: openEHR-EHR-OBSERVATION.body\_weight

**Blood Pressure Archetype Details:**

- Description:** Blood Pressure
- Purpose:** To record the systemic arterial blood pressure of an individual.
- Use:** Use to record all representations of systemic arterial blood pressure measurement, no matter which method or body location is used to record it. The archetype is intended to capture blood pressure measurements in all clinical scenarios - for example, self-measurement with a home blood pressure machine; an emergency assessment of systolic using palpation and a sphygmomanometer; measurements taken in clinical consultations or during exercise stress testing; and a series of measurements made by a machine in Intensive Care. There is a rich state model that supports interpretation of measurements through identifying patient position, exercise, confounding factors and angle of a tilt table in research. Named events have been limited to average over a 24 hour period, however templates can further constrain the default 'any event' to cater for specific requirements for blood pressure measurements such as recording Blood Pressure against specific points in time, or over a range of intervals (+/- mathematical functions).
- Misuse:** Not to be used for intravenous pressure. Not to be used for the measurement of arterial blood pressure which is NOT a surrogate for arterial pressure in the systemic circulation eg specific measurement of right Pulmonary artery pressure.

## COSMIC CDS KM Admin UI: guideline views

The screenshot shows the COSMIC Knowledge Manager Admin UI. The top navigation bar includes links for Guidelines, Archetypes, Templates, Terminologies, Studies, Views, and Apps. The main content area is titled 'Views' and shows a list of views on the left and details for the 'Stroke Prevention for Atrial Fibrillation' view on the right.

**View List:**

- Stroke Prevention for Atrial Fibrillation: CHA2DS2-VASc-COSMIC**

**Stroke Prevention for Atrial Fibrillation View Details:**

- Description:** Compliance to the ESC guidelines for stroke prevention in patients with atrial fibrillation.
- Purpose:** Estimates the compliance to the ESC guidelines for stroke prevention in patients with atrial fibrillation.
- Use:** Use to assess if a treatment is compliant to the ESC guidelines in patients with atrial fibrillation.
- Misuse:**
- References:**
  - Lip GY, Nieuwlaat R, Pisters R, Lane DA, Crijns HJ. Refining clinical risk stratification for predicting stroke and thromboembolism in atrial fibrillation using a novel risk factor-based approach: the euro heart survey on atrial fibrillation. Chest. 2010 Feb;137(2):263-72.
  - Camm a J, Kirchhof P, Lip GYH, Schotten U, Savelieva I, Ernst S, et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). Eur Heart J. 2010 Oct;31(19):2369-429.
  - Lip GY, Frison L, Halperin JL, Lane DA. Identifying patients at high risk for stroke despite anticoagulation: a comparison of contemporary stroke risk stratification schemes in an anticoagulated atrial fibrillation cohort. Stroke. 2010 Dec;41(12):2731-8.

## COSMIC CDS KM Admin UI: preview CDS apps

The screenshot shows the COSMIC Knowledge Manager Admin UI. The top navigation bar includes links for Guidelines, Archetypes, Templates, Terminologies, Studies, Views, and Apps. The main content area displays a preview of the 'Stroke Prevention for Atrial Fibrillation' app. The app interface includes a filter for language (en, sv), a 'Show only latest versions' checkbox, and a 'Showing 1 views' indicator. The app content is divided into several sections: 'CHA2DS2-VASc Diagnosis review', 'CHA2DS2-VASc Score', 'Alerts', 'Prescription', and 'Medical Decision'. The 'Diagnosis review' section contains a table for clinical assessment with columns for Diagnosis and Clinical assessment (Present/Absent). The 'Score' section shows a table with categories and scores. The 'Alerts' section displays the CHA2DS2-VASc Score and Stroke risk. The 'Prescription' section includes a medication list and a 'Prescribe' button. The 'Medical Decision' section has a 'Make a decision now' button and a 'Follow-CDS Recommendation' section.

Diagnosis	Clinical assessment
Atrial fibrillation	<input checked="" type="radio"/> Present <input type="radio"/> Absent
Congestive Heart Failure	<input type="radio"/> Present <input type="radio"/> Absent
Hypertension	<input type="radio"/> Present <input type="radio"/> Absent
Diabetes	<input type="radio"/> Present <input type="radio"/> Absent
Stroke/TIA/Thromboembolism	<input type="radio"/> Present <input type="radio"/> Absent
Vascular disease	<input type="radio"/> Present <input type="radio"/> Absent

Category	Score
C Congestive Heart Failure	1
H Hypertension	1
A <sub>2</sub> Age ≥ 75	0
D Diabetes	1
S <sub>2</sub> Stroke/TIA/Thromboembolism	0
V Vascular disease	0
A Age between 65 and 74	0
Sc Sex Female	0
<b>Total score</b>	<b>3</b>

## COSMIC CDS KM Admin UI: CDS apps ready for execution

The screenshot shows the COSMIC Knowledge Manager Admin UI with the 'Stroke Prevention for Atrial Fibrillation' app in execution mode. The app interface is similar to the preview, but with updated data and execution controls. The 'Diagnosis review' section shows the same clinical assessment table. The 'Score' section shows the same category and score table. The 'Alerts' section displays a yellow banner indicating 'NON compliant with ESC guidelines'. The 'CHA2DS2-VASc Score' is 3, and the 'Stroke risk' is 3.2%. The 'Prescription' section shows a medication list with 'Eliquis (mock)' selected. The 'Medical Decision' section has a 'Make a decision now' button and a 'Follow-CDS Recommendation' section with 'Yes' selected. The bottom of the screen shows the 'Stroke Prevention CDS App' title and 'Sign' and 'Close' buttons.

Diagnosis	Clinical assessment
Atrial fibrillation	<input checked="" type="radio"/> Present <input type="radio"/> Absent
Congestive Heart Failure	<input type="radio"/> Present <input type="radio"/> Absent
Hypertension	<input type="radio"/> Present <input type="radio"/> Absent
Diabetes	<input type="radio"/> Present <input type="radio"/> Absent
Stroke/TIA/Thromboembolism	<input type="radio"/> Present <input type="radio"/> Absent
Vascular disease	<input type="radio"/> Present <input type="radio"/> Absent

Category	Score
C Congestive Heart Failure	1
H Hypertension	1
A <sub>2</sub> Age ≥ 75	0
D Diabetes	1
S <sub>2</sub> Stroke/TIA/Thromboembolism	0
V Vascular disease	0
A Age between 65 and 74	0
Sc Sex Female	0
<b>Total score</b>	<b>3</b>

## C3DP UI Mock-ups

The complete set of designed mock-up user interfaces for C3DP are available at <https://projects.invisionapp.com/share/BF9O8BO54#/> in an interactive manner. In this section, a summary of main screens is provided.

### C3DP My Patients – Main view

C3Cloud Care Management

























Welcome Anna Svensson

Home

My Patients

Inbox

Filter by Name:

	<b>Sven Karlsson</b> Age 67 Born on 23.06.1949 Male	 Kyrkgatan 18 Östersund, Sweden  0046 063-19 72 00  sven.karlsson@gmail.com	<b>Care Coordinator</b> Dr. Anna Svensson  0046 065-48 67 40  anna.svenson@regionjh.se	<b>Active Care Plans</b> Management of Diabetes & Hypertension Last updated: 02/06/2015
	<b>Anette Nilsson</b> Age 53 Born on 23.06.1963 Female	 Kyrkgatan 18 Östersund, Sweden  0046 063-19 72 00  anette.nilsson@gmail.com	<b>Care Coordinator</b> Dr. Anna Svensson  0046 065-48 67 40  anna.svenson@regionjh.se	<b>Active Care Plans</b> Management of Tye 2 Diabetes Last updated: 02/06/2015
	<b>Niklas Olsson</b> Age 78 Born on 23.06.1938 Male	 Kyrkgatan 18 Östersund, Sweden  0046 063-19 72 00  niklas.olsson@gmail.com	<b>Care Coordinator</b> Dr. Anna Svensson  0046 065-48 67 40  anna.svenson@regionjh.se	<b>Active Care Plans</b> Management of Renal Failure Last updated: 02/06/2015
	<b>Lisa Lindberg</b> Age 48 Born on 2.09.1968 Female	 Kyrkgatan 18 Östersund, Sweden  0046 063-19 72 00  lisa.lindberg@gmail.com	<b>Care Coordinator</b> Dr. Greta Holm  0046 065-48 67 40  greta.holm@regionjh.se	<b>Active Care Plans</b> Management of Heart Failure Last updated: 02/06/2015

## C3DP Summary view for a patient

C3Cloud Care Management


Welcome Anna Svensson

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SvenKarlsson





Sven Karlsson

Age 67

Born on 23.06.1949


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Östersund, Sweden
 


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Care Coordinator

Dr. Anna Svensson

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 anna.svenson@regionjh.se

QuickView

Care Plans



Clinical Documents

Conditions



Hypertension	11/10/2006	
Diabetes Mellitus-Type2	07/06/2015	
Bronchitis	23/04/2012-12/05/2012	

Show more





Medications

Metformin	07/06/2015	
Atorvastatin	07/06/2015	

Vitals


Blood Pressure	120/75 mmHg		12/07/2016.14:00	
----------------	-------------	---	------------------	---

Lab Results

Serum Creatinine	1,6 mg/dl		07/06/2016	
GFR	85		07/06/2016	




Show more

Allergies/Intolerances



Penicillin Allergy	11/08/1985	
--------------------	------------	--

Procedures










Risk Factors

Depression	mild (GDS)	07/06/2016	
Cognitive Impairment	mild (MMSE)	07/06/2016	
Stroke	12,5% (CHADS)	07/06/2016	

Care Barriers/Patient Status

Lives alone	
Does not accept blood transfusions, or donates	

Care Team Members

Dr. Anna Svensson	Care Coordinator	
 0046 065-48 67 40  anna.svenson@regionjh.se		
Erik Larsson	Diabetes Nurse	
 0046 065-48 67 40  erik.larsson@regionjh.se		
Dr. Anders Blom	Nephrologist	
 0046 065-48 67 40  anders.blom@regionjh.se		

Synchronize


Upload Document

## C3DP Care plan view for a patient




C3Cloud Care Management
Welcome Anna Svensson



Home
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SvenKarlsson



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 anna.svenson@regionjh.se

QuickView
Care Plans
Clinical Documents
Manage Notifications

Care Plans / Management of Hypertension & Diabetes
History
Reconcile
Save and Share
Export
Close

Status: Active  
Period: 21/05/2014-  
Last modified: 13/06/2015  
Description: Textual description of the Care Plan.. Next Review:

Authors: Dr. Anna Svensson  
Erik Larsson

Related Encounters: Hypertension-15/03/2013  
Diabetes-21/05/2014

Related Careplans: Hypertension-Replaced  
Related Educational Material (MDT): select  
Related Educational Material (Patient): select

Re-Use Care Plan Templates

Health Concerns Addressed

☒ Hypertension  
☒ Diabetes Mellitus, Type 2

Goals Targeted

☐ Increase Physical Activity  
☐ Improve Hemodynamic stability  
☐ Decrease HbA1c to ...

! View new patient feedback behind-target  
! View new results from care systems in-progress  
achieved

Activities

☐ Monitor Blood Pressure  
☐ Log daily insulin injection and medication intake  
☐ Daily exercise, mild

Monitor results  
Monitor results  
View recent patient feedback

Care Team

Care Barriers/Patient Status

Notes

## C3DP Add new health concern screen

**C3Cloud Care Management** Welcome Anna Svensson

Home **My Patients** Inbox

---

**Sven Karlsson**

**Sven Karlsson**

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---

**QuickView** **Care Plans** Clinical Documents Manage Notifications

**Care Plans / Management of Hypertension & Diabetes** History Reconcile Save and Share Export Close

Status: Active
Authors: Dr. Anna Svensson
Related Encounters: Hypertension-15/03/2013
Related Careplans: Hypertension-Replaced

**Health Concerns Addressed**

☐ Hypertension

☐ Diabetes Mellitus, Type 2

**Goals Targeted**

☐ Increase Physical Activity

☐ Improve Hemodynamic stability

☐ Decrease HbA1c to ...

**Activities**

☐ Monitor Blood Pressure

☐ Log daily insulin injection and

☐ Daily exercise, mild

**Care Team**

**Care Barriers/Patient Status**

**Notes**

Add new Health Concern

Choose among existing records

- ▶ **Conditions**
  - ☒ Obesity
  - ☐ Migraine
  - ☐ Bronchitis
- ▶ **Risk Factors**
  - ☒ Depression (mild)
  - ☒ Stroke (12.5%)
  - ☐ Cognitive Impairment (mild)

➔

Health Concerns addressed

- ☐ Hypertension
- ☐ Diabetes Mellitus, Type 2

Add

Delete

Save and close
Cancel

**Plan Templates** 🔍 ↶ + 🗑

**View new patient feedback** behind-target

in-progress

**new results from care systems** achieved

🔍 ↶ + 🗑

Monitor results

Monitor results

View recent patient feedback

## C3DP Add new goal screen

Add New Goal

Title:

start date..

Goal definition:

Describe the target aimed to be achieved here..

Targeted parameter:

Type ahead search from terminology server to choose the parameter whose value is being tracked, e.g. body weight

Targeted value:

☒ value

☐ low

☐ high

☐ choose from term. server

Category:

Behavioral

Treatment

Dietary

Status:

proposed

planned

accepted

in-progress

achieved

Priority:  
(Healthcare professional)

high

medium

low

Status Reason:

Select from GoalStatusReason ValueSet

ExpressedBy:

Select from Care Team Members

Start Date:

start date..

When to be achieved:

target date..

Addressed Health Concerns:

Obesity, Stroke

Save and close

Cancel



## C3DP Add new activity screen

### Add New Activity

Title:

Title of the Activity

Description:

Textual description of the Activity

Status:

Select from CarePlanActivityStatus Value Set (e.g. Planned)

Status Reason:

Select from GoalStatusReason Value Set (e.g. patient request)

Category:

Select from CarePlanActivityCategory Value Set (e.g. Diet)

Code:

Typeahead search from code list

Is Prohibited?:

☐ Yes
 ☒ No

Link to a Condition:  
(Reason)

Select from the conditions of the patient (e.g. Obesity)

Related Goal:

Select from existing goals (e.g. Weight Loss)

Questionnaire to  
be performed:

Select from the existing Questionnaires if needed

Add New

Timing:

once at:

30/08/2016: 09:30

/

start:

30/08/2016: 09:30

end:

30/08/2016: 09:30

advanced timing constraints

Performers

Actor:

Sven Karlsson (Patient)

+

Location

Name:

Name of the Location

Type:

Select from ServiceDeliveryLocationRoleType Value Set (e.g. Planned)

Address:

Address

Notes

Dr. Anna Svensson, 23/06/2016.14:55

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam.....

Dr. Eriksson, 24/06/2016.09:45

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam.....

[See all](#)
[Reply](#)

See all

Reply

Save and close

Cancel

## C3DP Add new Care Team Member screen

### Add New Care Team Member

Name, Surname:

Dr. Kim West

Role:

Physician

Specialty:

Dietitian

Phone:

0046 065-48 67 53

e-Mail:

kim.west@regionjh.se

Address:

Region of Jaamlandt, Sweden

Organisation:

RJH

Is Care Coordinator:

☐

Send a new invitation

Cancel

## C3DP Add new care barrier / patient status screen

### Add New Assessment Observation

**Choose the type of observation:**

☐ Care Giver Characteristics
 ☐ Functional Status Observation

☐ Characteristics of Home Environment
 ☒ Mental Status Observation

☐ Personal Beliefs
 ☐ Other

**Observation:**

Describe the barrier (optional):

Select from list (optional) :

[Add new Assessment Scale](#)


[Save and close](#) [Cancel](#)

## C3DP Care plan timeline screen




**C3Cloud Care Management**
Welcome Anna Svensson



[Home](#)
[My Patients](#)
[Inbox](#)

**Sven Karlsson**



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 anna.svenson@regionjh.se

[QuickView](#)
[Care Plans](#)
[Clinical Documents](#)
[Manage Notifications](#)

**Care Plans / Management of Hypertension & Diabetes/ Dashboard**

NEW

15/12/2013, Care plan created, by Anna Svensson, Primary Care Physician Visit

21/12/2013, Life Style questionnaire & new photos received from Patient

30/12/2013, Weekly Blood Pressure Measurement Results received from Patient

03/02/2014, new lab results received from EHR

23/12/2013, Care plan updated, by Erik Larsson, Diabetes Nurse Visit

04/02/2014, Care plan updated, by Anna Svensson, Primary Care Physician Visit

05/03/2014, New MDT member, Referral to Anders Blom, by Anna Svensson, Primary Care Physician Visit

05/03/2014, Care plan updated, by Anders Blom, Hospital Specialist Visit

05/03/2014, New MDT member, Referral to Stina Ek, by Anders Blom, Hospital Specialist Visit

[See Upcoming Activities](#)

## C3DP Care plan reconciliation screen

C3Cloud Care Management


Welcome Anna Svensson

Home

My Patients

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SvenKarlsson



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QuickView

Care Plans

Clinical Documents

Manage Notifications

Care Plans / Management of Hypertension & Diabetes / Reconciliation Results

Current Care Plan

Health Concerns Addressed

☐ Hypertension
 ☐ Diabetes Mellitus, Type 2

Goals Targeted

☐ Increase Physical Activity
 ☐ Improve Hemodynamic stability
 ☐ Decrease HbA1c to ...

Activities

☐ Monitor Blood Pressure
 ☐ Log daily medication intake
 ☐ Daily exercise, mild

Care Team

Care Barriers/Patient Status

Notes

Reconciliation Results

Decision Support Modules Utilized

Clinical Guidelines

1 NG 28: Type 2 diabetes in adults: management

2 CG 127: Hypertension in adults: diagnosis and management

Risk Assessment Tools

Polypharmacy Tools

Notifications

This patient has type 2 diabetes. Recent lab results show renal renal function deterioration. Consider stopping Metformin and starting insulin therapy.

This patient is already on first-line antihypertensive drug treatment yet the person's blood pressure is not reduced to the individually agreed target. Consider adding a calcium-channel blocker or a diuretic.

This patient has type 2 diabetes. 70 days has passed since the last follow-up. Consider arranging the routine 3 monthly follow-up appointment.

Save and Close Reconciliation View

## C3DP Clinical documents provided by MDT screen

C3Cloud Care Management


Welcome Stina Ek

Home

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Inbox

SvenKarlsson



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QuickView

Care Plans

Clinical Documents

Manage Notifications

Title	Type	Date	Source	Health Professional
SvenKarlsson_DischargeReport_15-05-2015	Discharge Summary	15/06/2015	Hospital A	Dr. A. Bates
Referral_to_Nephrologist	Referral Document	21/08/2015	GP Office	Dr. Anna Svensson
EncounterNotes_SvekKarlsson_02-09-2015	Consult Note	02/09/2015	Hospital B	Dr. Anders Blom
Referral_to_Dietitian	Referral Document	23/09/2015	GP Office	Dr. Anna Svensson <span>! New</span>

Synchronize

Upload Document

## C3DP Care Team Member message inbox screen

**C3Cloud Care Management** Welcome Anna Svensson

Home My Patients **Inbox**

**Compose**

**Inbox**  
 Tags  
   MDT Members  
     Erik Larsson  
     Anders Blom  
     Stina Ek  
   Patients  
     Sven Karlsson  
     Anette Nilsson  
     Niklas Olsson  
     Lisa Lindberg  
   Custom  
     To be discussed  
     Follow-up

**Care Team Members** **SystemNotifications**

	From	Subject	Date
<input type="checkbox"/>	Erik Larsson	New Intervention for Sven Karlsson	04/09/16 12:46
<input type="checkbox"/>	Anette Nilsson	My Exercise Plan	04/09/16 09:30
<input type="checkbox"/>	Anders Blom	Requesting your Opinion...	28/08/16 14:34
<input type="checkbox"/>	Erik Larsson	New Intervention for Sven Karlsson	04/09/16 12:46
<input type="checkbox"/>	Anette Nilsson	My Exercise Plan	04/09/16 09:30
<input type="checkbox"/>	Anders Blom	Requesting your Opinion...	28/08/16 14:34