A Personalised Integrated Care Platform

(Grant Agreement No. 689209)

D2.3 The PICASO Architecture Specification

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1 Executive Summary

This deliverable defines the initial PICASO architecture based on the current version of use cases, vision scenarios and requirements. The architecture targets at reaching a common understanding of all the involved stakeholders and provides a bridge between the users' requirements and the design of the PICASO platform. Given that the project follows an iterative approach, while the requirements will be changing the architecture will need to be updated in order to ensure the good transformation of user requirement to system's features.

In order to achieve its critical goal, the architecture has been developed following well established methodologies and standards adapted to the needs of PICASO. The architecture has been established through a number of face to face and remote dedicated workshops. Through the involvement of both technical and clinical partners, a logical architecture has been developed based on different perspectives and incorporating different types of concerns. This will be translated for every site to a physical architecture as per IEEE 1471 "Recommended Practice for Architectural Description for Software-Intensive Systems.

The PICASO develops a service oriented, ICT based integration platform that will support collaborative sharing of care plans across sectors based on dynamic and personalised orchestration of care services. It will further provide a method for sharing patient information across all relevant formal and informal care providers using trust federated solution to the problem of data privacy in cloud based health systems. Different architectural views are discussed in this deliverable in order to face challenges from different perspectives.

The context view describes the relationships, dependencies, and interactions between the system and its environment (the people, systems, and external entities with which it interacts). The logical view describes the end users' concerns about the functionality of the system and provides a list with the primary components of the PICASO architecture following a layered approach including application, service, data access and persistence layers. The information view includes information about the data models, data transformations, data storage, and data flows. The data landscape will be documented in a separate deliverable - D5.1 Data Models & Shared Memory Objects. The Environment and Deployment view discusses the three different environments in the PICASO project: one for developing, one for testing and one for production. These environments need different levels of security and privacy to correspond with the data management plan implementation. The Infrastructure view provides information about the physical infrastructure in the patients' non-clinical environment and an example infrastructure (as foreseen for UDUS trials) of the care system private cloud effectively demarcates the hospital/clinical information systems at PICASO user sites, from the surrounding PICASO environment. User Interaction view discusses the major concerns from a user interface perspective and provides some very first mock-ups of PICASO application components.

2 Introduction

This chapter outlines the purpose, background, and context of this deliverable as well as the structure of the remaining document.

2.1 Purpose, context and scope of this deliverable

This deliverable provides the initial architecture description for the PICASO system. The requirements for the architecture can change during the course of a project and some aspects of the architecture need verification during development, and therefore the architecture described here cannot be considered to be final or complete. There will be an updated version of the architecture description in deliverable D2.4 "First Updated Requirements and Architectural Report" due in month 14 and deliverable D2.5 "Second Updated Requirements and Architectural Report" due in month 26.
Within the PICASO work package structure, Work Package 2 “Domain Driven Requirements Engineering and Architecture” is responsible for defining requirements and specifying the system architecture design. An initial set of requirements has been defined and is documented in deliverable D2.2 Initial Requirements Report. This deliverable contains the PICASO Architecture Specification, preparing for prototypal implementation to be carried out by the technical work packages.
The architectural description includes aspects related to the identification of the major system components, how they should interact and how their external interfaces should be defined.
Finally, this architecture is designed to ensure compliance to constraints including the ones described in Consortium Agreement (Article 10.8):

> *“… Accordingly, each Party agrees that it will take all necessary steps to ensure that all Personal Data is removed from the Shared Information, made illegible, or otherwise made inaccessible (i.e. de-identify) to the other Parties prior to providing the Shared Information to such other Parties. For the avoidance of doubt, Parties shall be entitled to exchange and process Personal Data pertaining to the individuals directly involved in the implementation of the Action and/or Exploitation activities, for the purpose of such implementation or activities.”*

2.2 Content and structure of this deliverable

The first chapters give an overview of the deliverable and where it can be placed in the overall context: chapter 1 provides an executive summary of this deliverable, chapter 2 contains the introduction. Chapter 3 describes the methodology used to develop the architectural design of the software system developed in PICASO. Chapter 4 gives the overview of the PICASO Architecture from a solutions’ domain perspective. Chapter 5 to 10 include the different views used to describe the architecture.

3 Methodology

This section presents the key concepts related to the methodology used to develop the architectural design of the software system developed in PICASO.
We follow standards and best practices as described in the following subchapters. In addition, there have been several workshops to discuss, produce and refine the architecture design. There were two workshops with clinic personnel, an internal design workshop and two architecture workshops during consortium meetings.

3.1 Software Architecture Design Fundamentals

The process used is based on principles of IEEE 1471 "Recommended Practice for Architectural Description for Software-Intensive Systems" [IEEE1471, 2000] and ISO/IEC/IEEE 42010:2011 “Systems and software engineering - Architecture description” [IEEE 42010, 2011], by which it was superseded. The latter establishes a methodology for the architectural description (AD) of software-intensive systems. It implies a process which includes the following steps:

- Identify and record the stakeholders for the architecture and the system of interest
- Identify the architecture-related concerns of those stakeholders
- Select and document a set of architecture viewpoints which can address the stakeholder concerns
- Create architecture views (one view for each viewpoint) which contain the architectural models
- Analyse consistency of the views
- Record rationales for architectural choices taken

Viewpoints are collections of patterns, templates and conventions for constructing one type of view. One example is the functional viewpoint (and therefore a functional view) which contains all functions that the system should perform, the responsibilities and interfaces of the functional elements and the relationship between them. These functions can be described using UML diagrams. Moreover, it also describes which stakeholders need to be involved and how to apply their needs in the architecture as stated in the "architectural perspectives" chapter by Rozanski and Woods [Rozanski - Woods, 2005].

3.2 Definitions

The following definitions are on the basis of the ISO/IEC/IEEE 42010:2011 [IEEE 42010, 2011] standard and the definitions provided by Rozanski and Woods [Rozanski & Woods, 2005].

Architecture: Comprises of the”concepts or properties of a system in its environment embodied in its elements, relationships, and in the principles of its design and evolution”

Architectural Description: a collection of products to document an architecture

Stakeholder: an individual, group or organization that has at least one concern relating to the system-of-interest

Concern: an interest in a system which is relevant to one or more stakeholders. It might be a requirement (functional or non-functional) or an objective a stakeholder has regarding the system.

View: a set of models and descriptions representing a system or part of a system from the perspective of a related set of concerns

Viewpoint: collection of patterns, templates and conventions for constructing one type of view

Model: a simplified representation of an aspect of the architecture, could be in form of a UML diagram

The relationships between these concepts and the system-of-interests are shown in Figure 1.

According to the specification of the ISO/IEC/IEEE 42010:2011 standard the main concepts, architecture view and architecture viewpoint, are defined as follows.

- **Architecture viewpoint: “**work product establishing the conventions for the construction, interpretation and use of architecture views to frame specific system concerns”
- **Architecture view:** “A representation of a whole system from the perspective of a related set of concerns.”

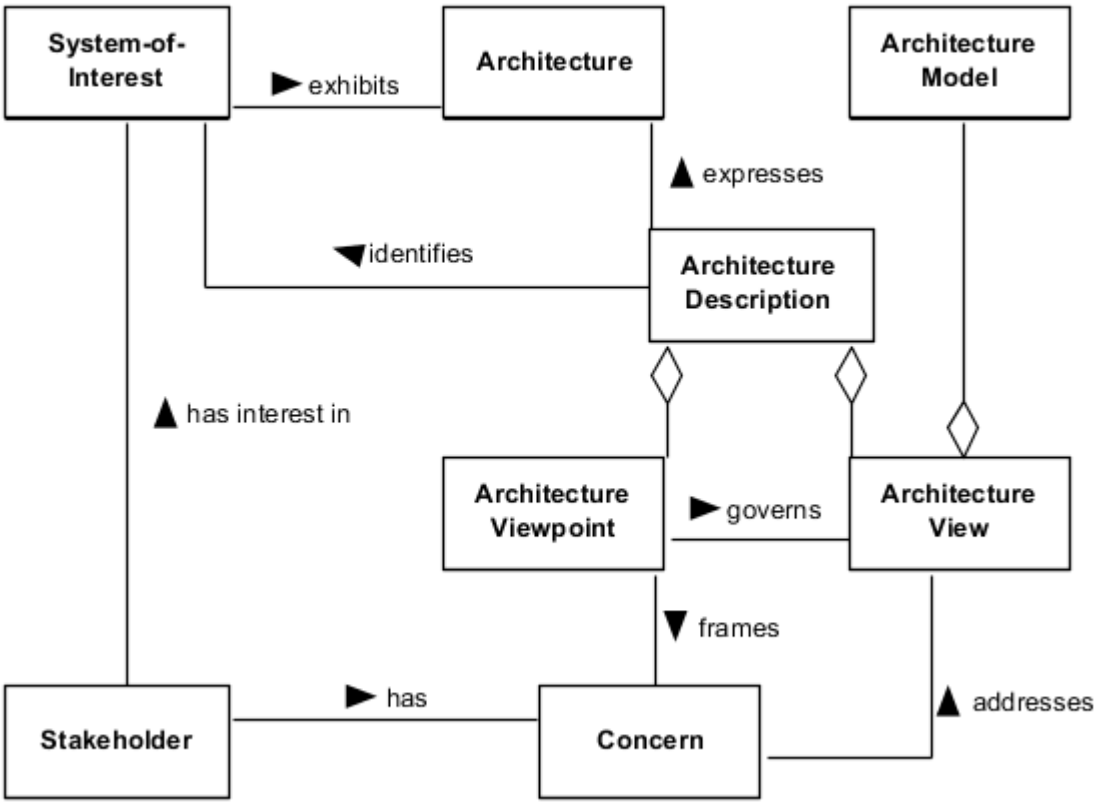


Figure 1 - Architecture description concepts (Adapted from ISO/IEC/IEEE 42010:2011 "Systems and software engineering - Architecture description" [IEEE 42010, 2011])

A viewpoint defines the aims, intended audience, and content of a class of views and defines the concerns that views of this class will address e.g. Functional viewpoint or Deployment Viewpoint. A view conforms to a viewpoint and so communicates the resolution of a number of concerns (and a resolution of a concern may be communicated in a number of views).

According to [Rozanski & Woods, 2005] using vision and point of view to describe the system architecture can bring many benefits such as:

- **Separation of concerns:** Separating different models of a system into distinct (but related) descriptions helps the design, analysis and communication processes by allowing designers to focus on each aspect separately.
- **Communication with stakeholder groups:** Different stakeholder groups can be guided quickly to different parts of the AD based on their particular concerns, and each view can be represented using language and notation appropriated to the knowledge, expertise, and concerns of the intended readership.
- **Managements of complexity:** Treat each significant aspect of the system separately, the architecture can focus on each in turn and so help conquer the complexity resulting from their combination.
- **Improved developer focus:** Separating into different views those aspects of the system that are particularly important to the development team, you help ensure that the right system gets built.

3.3 Software Architecture Design Process

In a software architecture design process there are several principles we should follow to ensure a high quality of the architecture design. The different stakeholders should be engaged and their concerns taken into account. There might be conflicting or incompatible concerns from different stakeholders which must be dealt with. Also an effective way to communicate decisions and solutions should be implemented and the whole

architecture design process should be flexible and pragmatic to be able to deal with the changing requirements and the iterative approach in this project. Also the process should be technology-neutral.

3.3.1 Architecture Definition Activities

Rozanski and Woods have based the architectural design process on the following definition:

> *"Architecture Definition is a process by which stakeholder needs and concerns are captured, an architecture to meet these needs is designed, and the architecture is clearly and unambiguously described via an architectural description."* [Rozanski & Woods, 2005] (p.56)

The foundation for our process is the IEEE 1471 standard and we have used the process proposed by Rozanski and Woods [Rozanski & Woods, 2005] which is aligned to this standard:

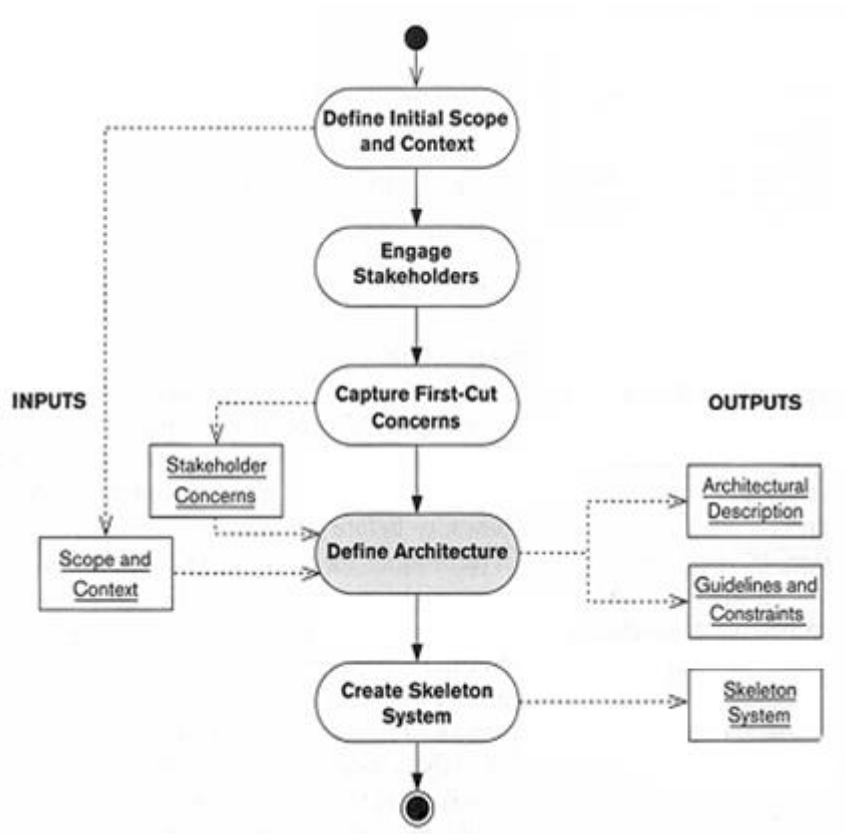


Figure 2 - Activities supporting architecture definition [Rozanski & Woods, 2005]

The process to be implemented in the PICASO project should reflect this approach. We start with the initial scope and context and the involvement of stakeholders in the process of the scenario development and use cases in WP2 and the subsequent requirements process. The stakeholders are included to express their needs and desires and capture quality properties that increase the success of the platform. The requirements from workshops, vision scenarios, as-is use cases and to-be use cases together with requirements from other sources are the input for the current architecture design phase where we create a first draft of the architectural description. Based on this architectural description, the first prototype should be created, which can be seen as a skeleton system with minimal functionality developed above that. These development efforts reveal some experiences and lessons learnt which in turn constitute a valuable source for the derivation of additional requirements and the revision of already existing ones.

3.3.2 Viewpoint Catalogue

The project decided on the following viewpoints from which the views of the architectural document are derived.

- **Context viewpoint**: The context viewpoint describes interactions, relationships and as well dependencies between the system-of-interest and its environment. The environment includes those external entities with which the system interacts, such as other systems, users, or developers.

- **Logical viewpoint**: The purpose of the Logical viewpoint is to elaborate existing and designed types and their implementations as classes and interfaces with their structural static relationships. This viewpoint also uses examples of instances of types in outlining design ideas.
- **Information viewpoint**: The information viewpoint describes the data models and the data flow as well as the distribution. The viewpoint also defines which data will be stored and where. The description of where data will be manipulated is also part of this viewpoint.
- **Environments and Deployment viewpoint**: This viewpoint describes how and where the system will be deployed in the different environments (development, testing and production) as and what dependencies exist, considering for example hardware requirements and physical restraints. If there are technology compatibility issues, these can be addressed in this viewpoint as well.
- **Infrastructure viewpoint**: This viewpoint contains information about the software and hardware elements which support the PICASO system.
- **User interaction viewpoint:** the system is viewed as a part that represents the user interface and a part that contains the application logic, associated with the user interface (Avgeriou & Zdun, 2005)

To address quality properties and cross-cutting concerns, architectural perspectives will be used. A typical example is security: it should be considered how the data is secured and which functional elements need to be protected. Another perspective which is interesting is availability, e.g. of the hardware, the functional elements or the data.

3.4 Design Principles

During the first PICASO architecture workshop the consortium came up with the following list of design principles:

- **Push-based transaction**: As new information becomes available, or whenever it deems appropriate, the source system sends the information to the destination. It expects the destination system to maintain and index the information on receipt. The source system must trust the destination system to manage access/security appropriately
- **Transaction-based consent**: Every transaction needs to obtain the consent of the involved stakeholders
- **Follow the law**: The system will allow for adaptation and deployment to different countries following different laws and regulations.
- **Need to know basis**: Every system will require data that is absolutely needed for the benefit of the user.
- **Role-based authorisation**: The authorization will be based on roles
- **Traceability and auditability**: Every transaction will be recorded for offering traceability and auditability
- **Emergency override**: For emergency situations PICASO will allow for skipping some of the procedures / mechanisms in order to respond fast to the situation.
- **No change to clinical systems**: No clinical system or data will be changed.
- **Classification System Agnostic**: PICASO will be capable of working with different classification systems if and when is necessary.
- **HL7 compliant**: Compliance to well established HL7 standards
- **End-to-end security**: All data transactions and hosts need to be secured
- **Privacy By Design**: Every component of PICASO will include Privacy during design time

4 Overview of PICASO Architecture

The PICASO project aims to research and demonstrate a service oriented, ICT based integration platform that will support collaborative sharing of care plans across sectors based on dynamic and personalised orchestration of care services. It will further provide a method for sharing patient information across all relevant formal and informal care providers using trust federated solution to the problem of data privacy in cloud based health systems.

The major technological objectives to be achieved are:

O1. Create a Care Management system based on dynamic design of complex care plans guided by *narratives* using goal-driven heuristic search and with secure authentication of patients and carers involved.

O2. Develop a robust, privacy compliant, cloud based Resource Management system that can perform *acquisition of physiological and behavioural data in non-clinically controlled care spaces,* taking into account the variability in the population in order to provide carers with realistic *situational awareness.*

O3. Develop a Service Orchestration framework that *orchestrates and executes care narratives* across a multitude of care platforms providing event detection and processing and incorporating risk assessment based on risk prediction models and contextual situation awareness, which can be used for decision support for professional and non-professional cares.

O4. Develop a Data Management framework for secure, privacy compliant, and role based information sharing based on *distributed shared memory* allowing carers to share patient information and exchange knowledge across care networks using intuitive, interactive ad-hoc information search.

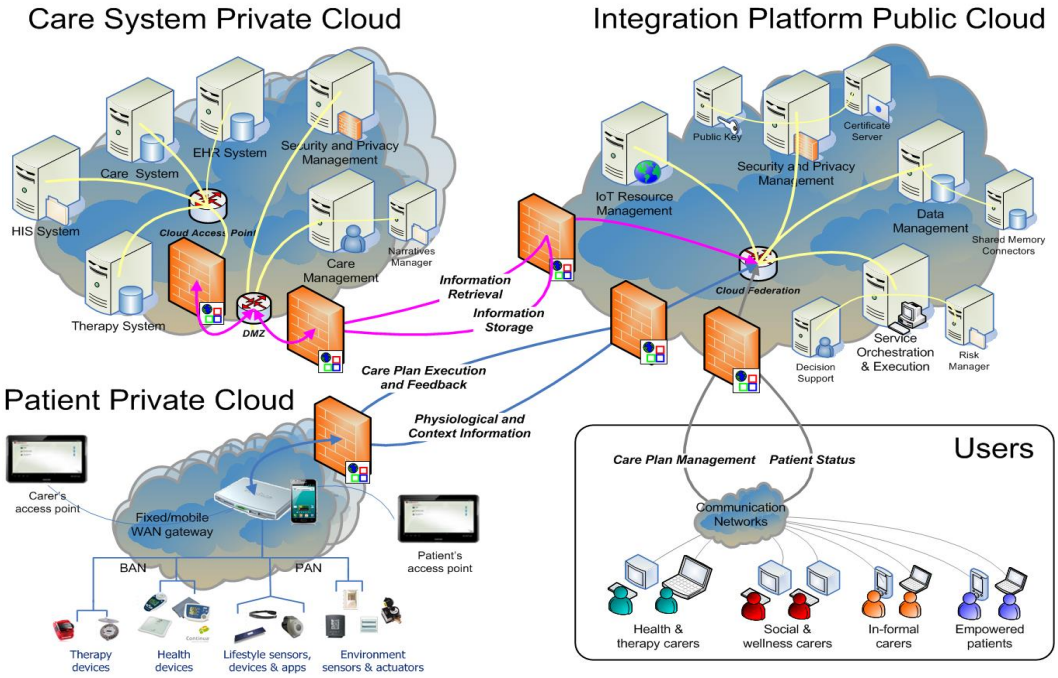


Figure 3: The envisioned PICASO distributed cloud concept

The PICASO integration platform is built on a federation of multiple external and internal cloud solutions in order to match the needs of future care provision, while still respecting the legacy structure of today's health care systems. Hence, the platform consists of three major cloud structure:

1) Multiple legacy care information systems, each operating as a private cloud or cloud-like internal business structure with strict access control and limited access rights including secure storage of patient data. The PICASO care management system (for creating the narratives for care plan execution) is located inside the secure private cloud due to the need for accessing multiple critical data repositories.

2) The PICASO integration platform operating as a public cloud solution providing the central integration service platform such as management of secure data exchange between the multi-disciplinary actors, secure data collections from patients' homes, and secure execution of care plan services.

3) Multiple patient and environment monitoring systems running in the patients' homes. Each of them exposes cloud web services; and is thus regarded as the patient's 'private cloud'.

The PICASO architecture is shown in Figure 4 below.

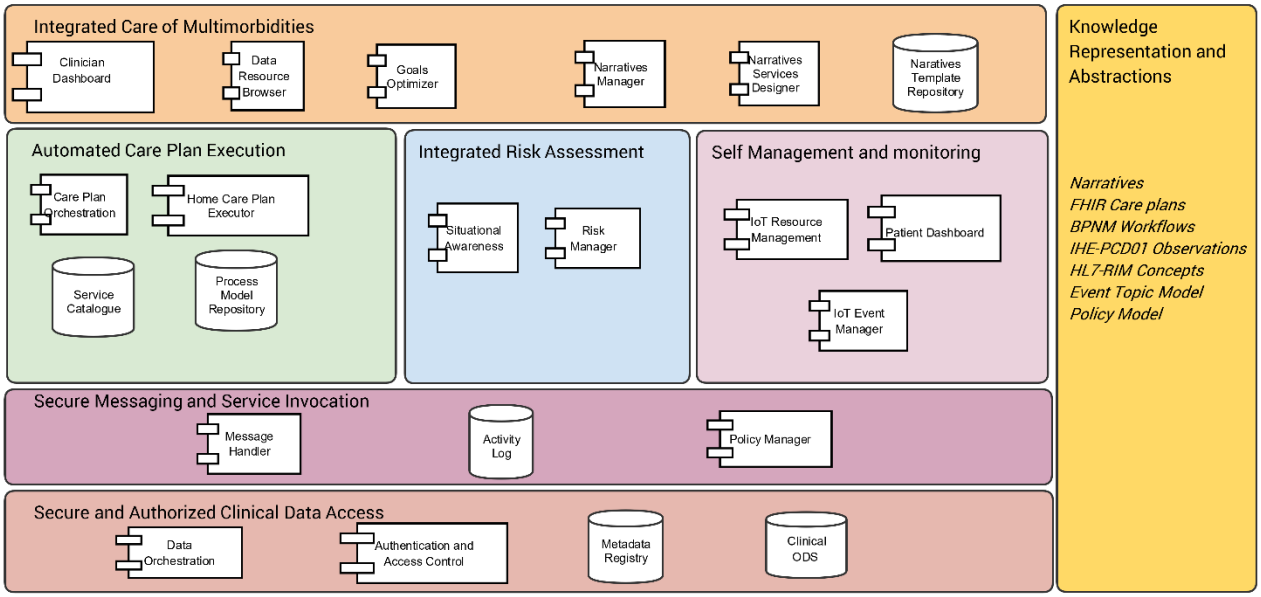


Figure 4 The PICASO Architecture

The PICASO platform provides 6 functionality blocks which all will be detailed in the coming chapters.

4.1 Mapping Components to Use Cases

The components that consist the PICASO architecture aim at fulfilling the requirements driven by the TO-BE use cases described in deliverable D2.1 Scenarios and Use Cases for Integrated Care. Table 1 provides the mapping between use cases and architectural components. As soon as the Use Cases will be revisited through the project iterative process, the architecture will need to adapt accordingly

Table 1: TO-BE use cases – Components mapping

UC ID	UC Title	Components
UC-1	Presenting symptoms	• ODS • Activity Log
UC-2	Information sharing during examination and diagnosis of new patients	• Data Resource Browser • Care Plan Orchestration • Patient Dashboard • Clinician Dashboard • Data Orchestration • Metadata Registry • ODS • Activity Log
UC-3	Information sharing during examination and diagnosis of new patients (UTV)	• Data Resource Browser • Care Plan Orchestration • Patient Dashboard • Clinician Dashboard • Data Orchestration • Metadata Registry

		• ODS • Activity Log
UC-4	Medication plan distribution	• Narratives Manager • Care Plan Orchestration • Service Catalogue • Process Model repository • Clinician Dashboard • Data Orchestration • Metadata Registry • ODS • Patient Dashboard
UC-5	Browsing for relevant data	• Data Resource Browser • Data Orchestration • Metadata Registry • ODS • Activity Log
UC-6	Authentication by users to share data	• Patient Dashboard • Authentication and Access Control • Activity Log
UC-10	Constructing care plans using narratives	• Narratives Manager • Narratives Services Designer • Narratives Template Repository • Care Plan Orchestration • Service Catalogue • Process Model repository • Situational Awareness • Goal Optimiser • Activity Log
UC-11	Monitoring and handling of events and alerts	• IoT Event Manager • Care Plan Orchestration • Message Handler • ODS • Activity Log
UC-12	Intervention strategies, definition and execution	• Narratives Manager • Narratives Services Designer • Narratives Template Repository • Care Plan Orchestration • Service Catalogue • Process Model repository • Metadata Registry • Clinician Dashboard
UC-13	Risk assessments during care plan execution	• Care Plan Orchestration • Risk Manager • Clinician Dashboard
UC-14	Monitoring for co-morbidities and handling of incidental findings	• Data Resource Browser • ODS • Activity Log
UC-15	Flexible informed consent	• Patient Dashboard • Policy Manager • Authentication and Access Control • Activity Log
UC-20	Home monitoring for self-management	• Home Care Plan Executor

		• IoT Event Manager • IoT Resource Manager • Patient Dashboard • Message Handler • Activity Log • ODS
UC-21	Handling non-connectivity of home monitoring platform	• IoT Event Manager • Patient Dashboard • Message Handler
UC-22	Filtering and sorting of data and events	• IoT Event Manager • IoT Resource Manager • Care Plan Orchestration • Data Orchestration • ODS • Activity Log
UC-23	Medication reminders and compliance monitoring	• Home Care Plan Executor • Patient Dashboard • Care Plan Orchestration • IoT Resource Manager • Activity Log
UC-24	Joint care – Patients and the informal carers	• Data Resource Browser • Patient Dashboard • IoT Event Manager • ODS • Activity Log
UC-25	Patient interaction modalities	• Patient Dashboard • IoT Event Manager • Home Care Plan Executor • Care Plan Orchestration • Situational awareness • ODS

4.2 Integrated Care of Multimorbidities

This layer consists of components and services which packages under lying functionalities towards the care organisation to enable them to implement new approaches to integrated care of multimorbidities:

- Clinician Dashboard
- Data Resource Browser
- Goals Optimiser
- Narratives Manager
- Narratives Service Designer
- Narratives Templates Repository

Most of these components have a User Interface and interacts directly with the clinicians.

4.3 Automated Care Plan Execution

This is an important cornerstone in the PICASO platform. Several enabling components collaborate to provide a mechanism to monitor individualised care plans for different patients and help them comply with medication and monitoring plans as well as automating tasks like booking next appointment for lab tests etc. The Care Plan Orchestration has the overall responsibility and delegates the self monitoring part to the Home Care Plan Executor. The Service Catalogue contains information about how to find and invoke different services. The Process Model Repository stores and retrieves the created narratives for the care plans.

4.4 Integrated Risk Assessment

The PICASO platform will provide both short term and long term risk assessments. The purpose of the Risk manager is to support the decision making process of clinicians by predicting the development of a patient's health status in the medium term. The situational awareness components fuses and aggregates data for various PICASO components for short term actions like creating alerts to informal carers. Such an alert could indicate high blood pressure readings in combination with an absence of confirmed medication intake.

4.5 Self Management and Monitoring

PICASO implements a number of services to allow for patients to be able to self-manage their diseases and monitor different vital signs under the supervision of formal as well as informal carers. This includes software for connecting home monitoring devices, accessing external cloud services and a Patient Dashboard for visualising vital signs and provide a diary for activities.

4.6 Secure Messaging and Service Invocation

All communication between services and components in PICASO will be secured and all access to services will be controlled through defined policies under the control of the Policy Manager. All activities will be logged in an Activity Log for traceability.

4.7 Secure and Authorised Clinical Data Access

One of the basic principles of PICASO is that sensitive clinical data is not transferred outside the clinical domains. A Meta Data register is keeping track of where different data items are stored but does not contain the actual data. All relevant clinical data is read out from clinical system and made available to PICASO components in a Clinical Operational Datastore (Clinical ODS). All access to data goes through a Data Orchestrator which is responsible to bring together the data needed to fulfil a request. All data access takes place under the control of a Authentication and Access Control Mechanism.

4.8 Knowledge Representation and Abstractions

Data and knowledge are being exchanged between the different components in the PICASO platform. Therefore we need a set of common object and data models for representing different aspects such as “Care Plan”, “Patient”, “Workflow”, “Narrative”, “Observations”, “Workflow” et c. PICASO builds on open standards as far as possible, and will adhere to HL7 standards like FHIR (Fast Healthcare Interoperability Resources), HL7 RIM and IHE-PCD01 where applicable.

5 Context view

Describes the relationships, dependencies, and interactions between the system and its environment (the people, systems, and external entities with which it interacts).

That context is defined by reference to actors that include users and other stakeholders, which interact with the PICASO system in its environment.

5.1 Stakeholders

In this first part of the PICASO project different stakeholders were identified, which are relevant for the platform definition and the trials. See also deliverable D2.1 Scenarios and Use Cases for Integrated Care, where the stakeholders for the two trials are listed. The definition used is from [Rozanski & Woods, 2005], derived from the ISO standard 42010:

"A stakeholder in the architecture of a system is an individual, team, organization, or classes thereof, having an interest in the realization of system."

Table 2 - Stakeholders in PICASO

Role	Description
Medical specialist	Medical doctor who is specialized in a certain field in medicine, such as General Practitioner, Rheumatologist, Cardiologist, Radiologist, Nuclear Medicine Physician, Neuropsychologist/ Psychiatrist, Clinical Neurologist, or Occupational Physician
General Practitioner (GP)	Medical doctor, who normally is the first point of contact with a patient and who works together with other medical specialists. [WONCA, 2011]
Occupational therapist/ Physiotherapist	Helps to recover or to maintain physical abilities and in case of occupational therapy also mental and cognitive abilities.
Laboratory	Institution which executes measurements in a controlled environment, such as a complete blood count. Results are given back to the requesting authority.
Health Insurance Company	Insurance company that pays certain medical expenses of a insured person, which include defined treatments by accredited medical doctors and certain medicines.
Patient	A person who suffers from an illness or injury and who is the recipient of health care services or treatments. In the PICASO trials patients are chosen who suffer either from rheumatoid arthritis and cardiovascular diseases or from Parkinson's disease and cardiovascular diseases.
Patient's Family	The family of the patient. This includes for example parents, children, grandchildren, nieces, and nephews. Help of family members can cover a wide range: doing little household tasks, helping with formalities such as appointments, driving to the doctors' appointments or in severe cases care for the patient at home.
Pharmacist	Distributes prescription and non-prescription drugs to patients and provides guidance as to take them. In some cases, the paying of invoices of prescription drugs is directly settled with the health insurance company instead of the patient.
Social and Health Services	Organisation providing formal support to patients, also outside the clinic.
Medical Records Technician	Responsible for entering information gained from extensive questionnaires (such as the questionnaires used for rheumatism patients) into a computer system.
IT-Administration hospital	Group of people who are responsible for configuration, maintenance and the reliable and secure operation of the hospital information systems.
IT-data security hospital	Group of people concerned with data security and privacy within the hospitals (Including lawyers, data security manager)
Developer	Software developers who design, implement, and integrate the different components PICASO system.

Installation supporter	Responsible for the installation of LinkWach and devices in the patient's home
1. level PICASO support team	The patient shall be able to get help in using PICASO and the LinkWatch system.

To include the stakeholders, there already were workshops in Düsseldorf and Rome respectively to come to get a mutual understanding with the clinic personnel, including personnel from the hospital's IT department and a representative of a German Health Insurance Company.

In addition, first patient interviews have been conducted in order to understand the problems that patient with multimorbidities have.

5.2 System scope and responsibilities

The PICASO system is envisaged as a set of multiple external and internal cloud solutions with well-defined interfaces to existing health information systems and services in today's health care environment.
The PICASO system and its immediate context consists of three major cloud structures:

1) Multiple existing care information systems, operating as a private cloud or cloud-like internal organisational ICT solutions with strict access controls and data protection policies. In the PICASO trials these correspond to the clinical systems at UDUS, Santa Lucia and UTV.
2) The PICASO Cloud platform, including the PICASO Private Patient Cloud, Public Cloud and Private Cloud.
3) External cloud services

Users in the PICASO context include the clinical stakeholders, patients and their informal carers, and ICT development and operating staff.

The PICASO system does not directly modify or update data in any existing clinical systems, these systems are regarded as external information sources.

5.3 Identity and characteristics of external entities, services and data used

5.3.1 External entities (users)

The following stakeholders for the clinical trials have been identified in the clinical workflows at UDUS and UTV (see D2.1).

Stake holders Trial 1 UDUS:

- Cardiologist
- Ergo-/physiotherapist
- GP
- Insurance Company
- Laboratory
- Occupational Physician
- Patient
- Patient's Family
- Pharmacy
- Radiology
- Rheumatologist
- Social Service

Stakeholders Trial 2 UTV:

- Cardiologist
- Clinical Neurologist
- Family
- GP
- Laboratory
- Neuropsychologist/Psychiatrist
- Nuclear Medicine Physician
- Patient
- Pharmacologist
- Pharmacy

5.3.2 External services and data

- Private Cloud Services
    - (FitBiT and other activity trackers) when possible based on Data protection
- eHealth services
    - National (e.g.," Hälsa för Mig")

5.4 Compliance to regulations

EU Medical Device Directive[1]

EU General Data Protection Regulation[2]

Data Security Policies at UDUS and UNITOV

5.5 Standards

- Device data:
    - IEEE11073 representation used for Continua, ANT+, and proprietary/legacy devices
- Observations:
    - IHE PCD01
- Messaging
    - HL7 Message subsets
- Vocabulary and Information Model
    - HL7 Reference Information Model (RIM) and vocabularies
    - HL7 FHIR[3]

[1] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

[2] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0679

[3] https://www.hl7.org/fhir/

6 Logical view

The logical view describes the end user's concerns about the functionality of the system.

6.1 The component model

Figure 5 gives a first graphical overview of the planned components and their connection to each other. Detailed descriptions can be found in following sub-chapters.

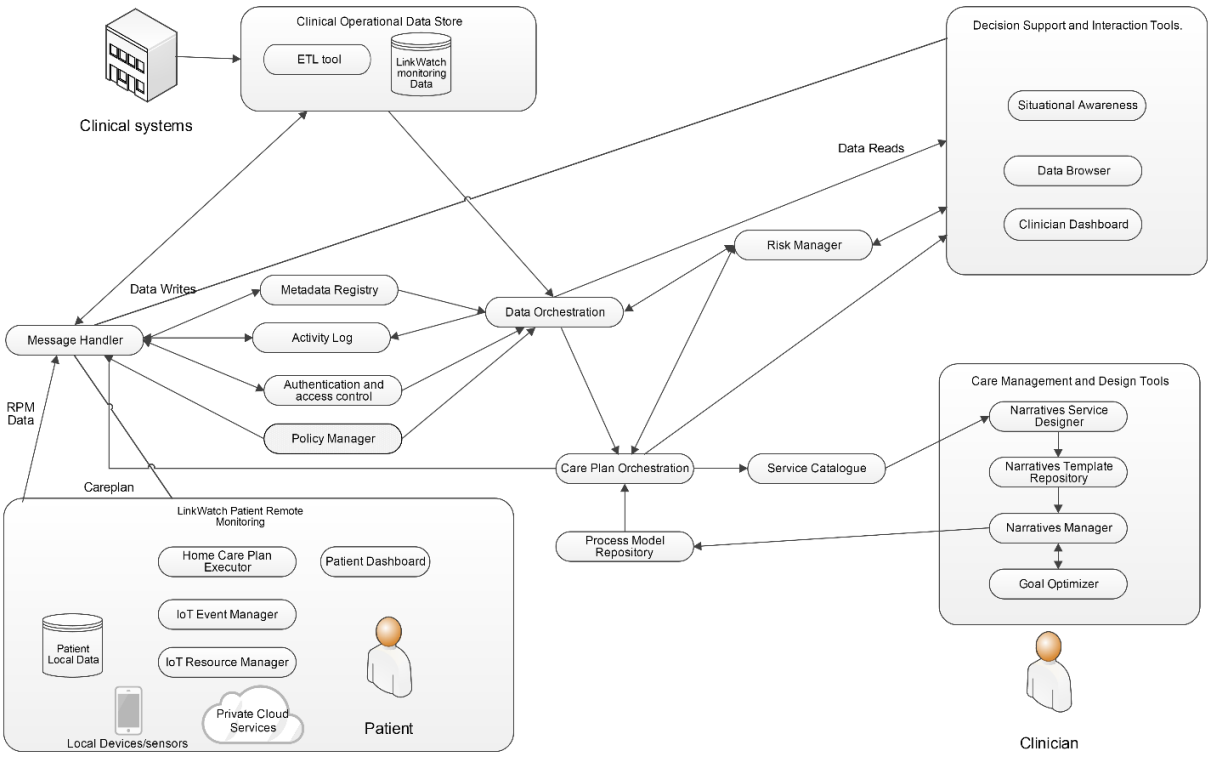


Figure 5: PICASO Component Model

Table 3 provides a list with the primary components of the PICASO architecture. Each component is assigned to an owner project partner, who is the main responsible for the design and the development in cooperation with the main contributors. Additionally in this table it is a preliminary mapping of every component to related project deliverables.

Table 3: List of architectural components including responsibilities and mapping to the GA descriptions

Component	Owner	Main Contributors	Deliverable
Message Handler	IBM	CNET, INUIT	D5.4 Integrated Data Management Subset
Metadata Registry	TUK	IBM	D5.2 Shared Memory Manager
Activity Log	IBM	TUK, INUIT	D5.4 Integrated Data Management Subset
Policy Manager	INUIT	IBM, TUK	D5.4 Integrated Data Management Subset
Authentication and Access Control	INUIT	IBM, TUK	D5.4 Integrated Data Management Subset
Data Orchestration	TUK	FIT, INUIT, CNET, IBM	D5.2 Shared Memory Manager
Situational Awareness	INUIT	CNET, TUK, FIT	D6.2 Decision Support & Interaction Tools

Data Resource Browser	FIT	TUK	D5.3 First Data Resource Browser (FIT, M10, OTHER) D5.5 Second Data Resource Browser (FIT, M22, OTHER)
Risk Manager	INUIT	TUK, IBM	D6.1 Risk Manager
Clinician Dashboard	TUK	FIT, INUIT, CNET	D6.2 First Decision Support and Interaction Tools
Care Plan Orchestration	CNET	INTUIT	D6.3 Service Orchestration & Execution
Clinical ODS (Operational Data Store)	IBM	UDUS, UTV, INUIT	D5.4, D5.1
Goal Optimiser	TUK		D7.3
Narratives Manager	FIT	CNET	D7.2 Narratives Manager and Service Catalogue
Narratives Services Designer	FIT	UDUS, UTV, CNET, IN-JET	D7.1: First Care Management and Design Tools (FIT, DEM, M14) D7.6: Second Care Management and Design Tools (FIT, DEM, M26)
Narratives Templates Repository	FIT	UDUS, UTV, CNET	D7.1: First Care Management and Design Tools (FIT, DEM, M14) D7.6: Second Care Management and Design Tools (FIT, DEM, M26)
Service Catalogue	CNET	FIT	D6.3 Service Orchestration & Execution D7.2 Narratives Manager and Service Catalogue
Process Model Repository	CNET/INUIT	FIT	D6.3 Service Orchestration & Execution
IoT Resource Manager	CNET	IN-JET	D4.1 Sensor Network & WAN Access Point D4.2 IoT Resource Management Subset D4.3 Patient Private Cloud
IoT Event Manager	CNET	IN-JET, IBM	D4.3 Patient Private Cloud
Home Care Plan Executor	CNET	IN-JET	D4.2 IoT Resource Management Subset
Patient Dashboard	CNET	IN-JET, FIT, TUK, UTV, UDUS	D4.3 Patient Private Cloud

Figure 6 provides a layered architecture for the systematic design and development of the components.

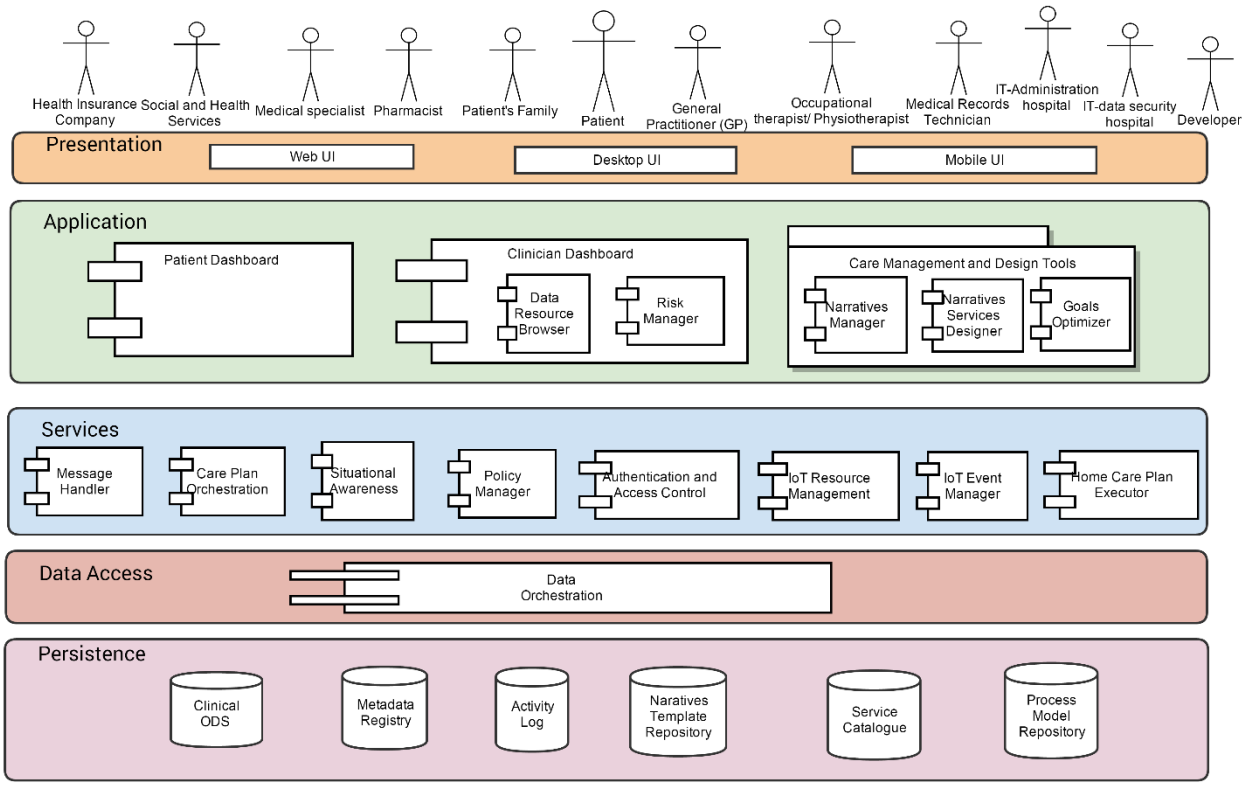


Figure 6: PICASO Layered Architecture

The following subsections provide a more detailed description of every component including its role in the architecture, its dependencies and its currently foreseen technologies for implementation. For the description of every component we follow the structure defined in the table below:

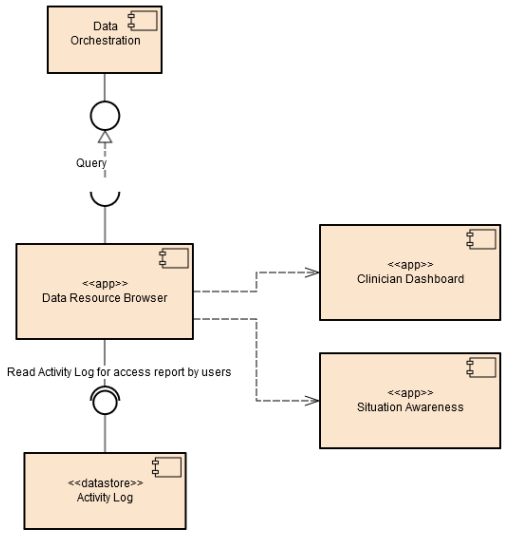
Table 4: The structure (table fields) of Components' description (table)

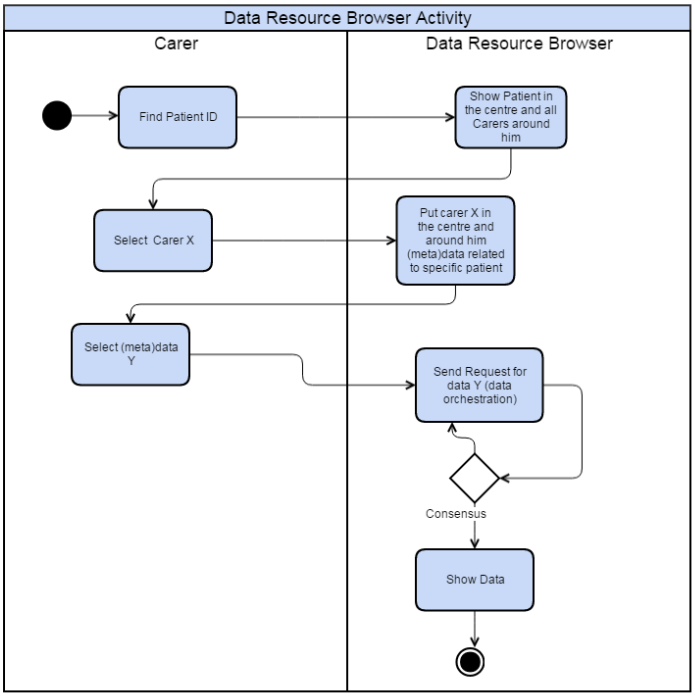
Type	The type of the component. It can be service, User Interface, Repository e.t.c.
Description	This gives in short the overview of components aims and scope
Dependencies	How this component interact with other PICASO components (IN/OUT)
Technologies	These are the foreseen technologies for the development of every component. This can still be changed.
Primary Technical Use Case(s)	During the design phase, use cases need to be translated to technical use cases. At this stage only a primary – abstract technical use case is illustrated using UML Activity Diagrams
Data	The main involved data and formats

6.2 Application Layer components

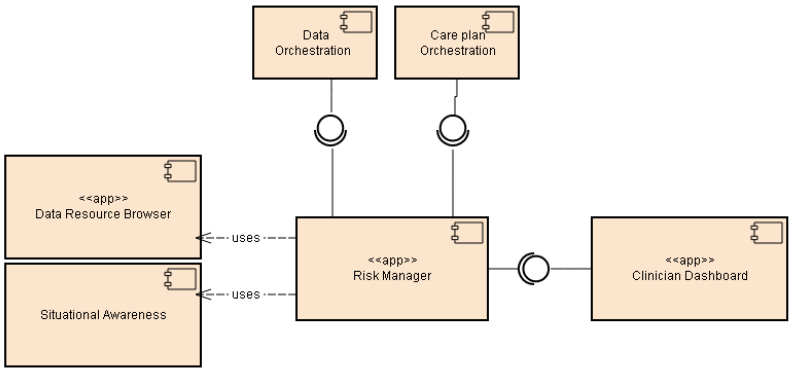
6.2.1 Data Resource Browser

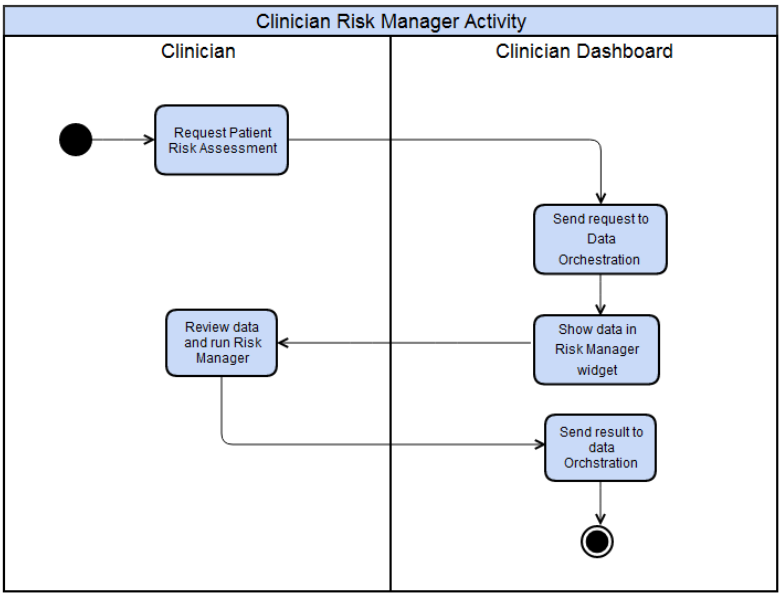
Type	Web based UI
Description	The Resource Data Browser is a web-based, interactive interface where clinicians (logged in) can search for combination of all the information stored in the shared memory such as patients, other cares, data and care plans. The user retrieves data by querying the Data Orchestration (Metadata Registry) for data relevant to a certain patient or a certain carer. The query provides a visual image

	of which data are found and what the user can retrieve. The relationship between the kind of data available and the data owner can be presented in the form of a mind map or Debategraph©. The graph is "live" and is dynamically updated, when the user clicks on the different nodes. If, for example, a general practitioner searches for data send by her patient, the graph will show the actual patient as the centre node together with all the carers that has requested data from the doctors patient shown as the surrounding nodes, provided that these carers has agreed to share this information with the doctor. By clicking on one of the carers, a new graph forms showing which data the carer has received from the patient (again provided that the doctor has been authorised to see this information. Finally, the doctor can click on a certain data type and see all the measurements performed (including contextual data and again, provided the proper authorisation is established. The doctor can click around the different branches and see other carers' interventions, the care plans executed, and dig further into the relevant data according to her access rights. The Data Browser is a read-only tool. It does not write any data within PICASO, other than to the Activity Log for logging access to data.
Dependencies	
Technologies	• NodeJS • Web technologies • vis.js visualization library

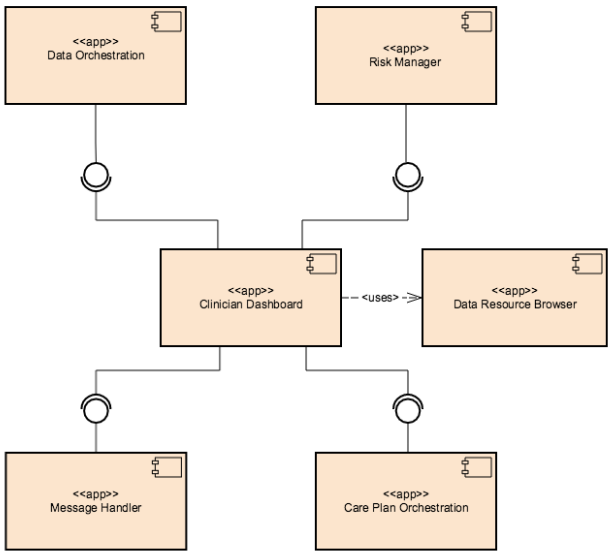
Primary Technical Use Case(s)	
Data	Common Information Model

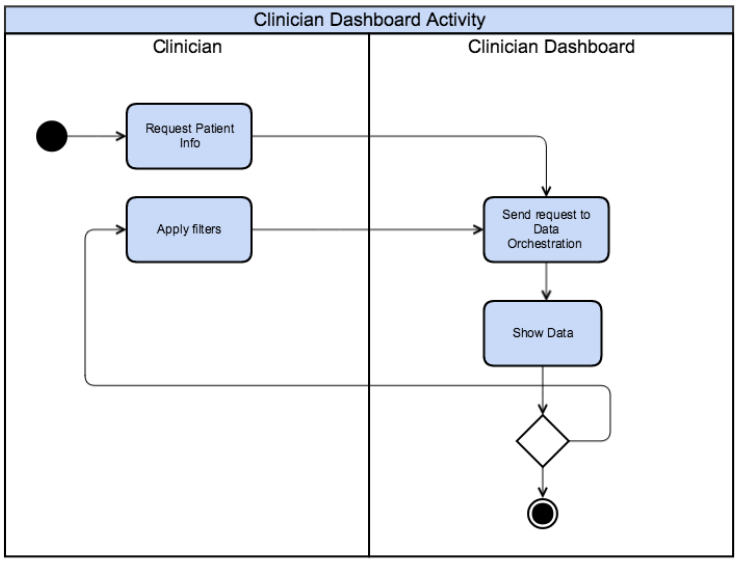
6.2.2 Risk Manager

Type	Application
Description	The purpose of the Risk manager is to support the decision making process of clinicians by predicting the development of a patient's health status in the medium term. Automated updates of risk profiles as new patient data become available and/or care plan and medication changes are implemented to support the situational awareness of clinicians.
Dependencies	
Technologies	TypeScript, jQuery, AngularJS for graphical interfaces

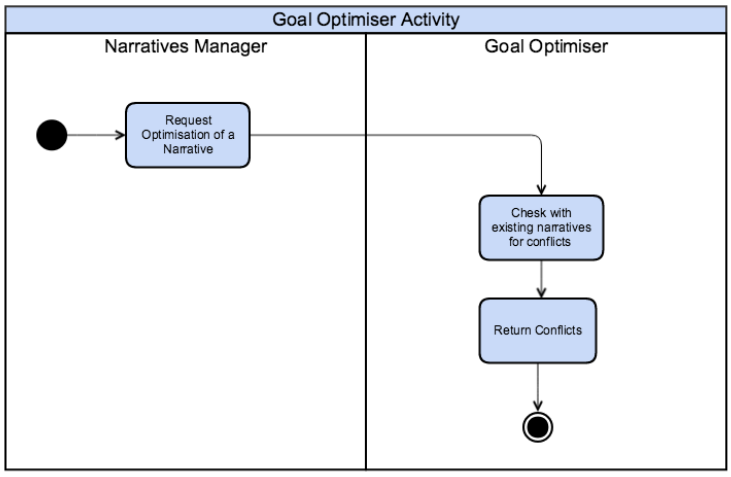
Primary Technical Use Case(s)	
Data	Clinical patient data as required for standard risk scores (based on risk tables), extended patient data for personalized risk scores

6.2.3 Clinician Dashboard

Type	Web based UI
Description	The Dashboard will probably be the first view of the patient that a clinician sees when wishing to interrogate a patient's data. The purpose of the Clinician Dashboard is to provide a tailored summary of the current status and history of different patients. The Clinician Dashboard also allows the clinician to register patients and their (remote) monitoring scheme, and to enter monitoring device and gateways and connect them to the different patients. It also allows entry of patient monitoring plans.
Dependencies	
Technologies	javascript based web portal

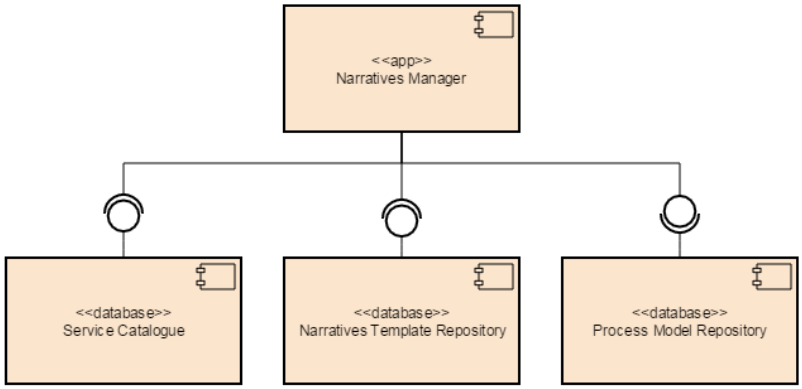
Primary Technical Use Case(s)	
Data	Any data available from other components for clinicians has to be supported. Structured texts, measurement data for graphs, time data, images, …

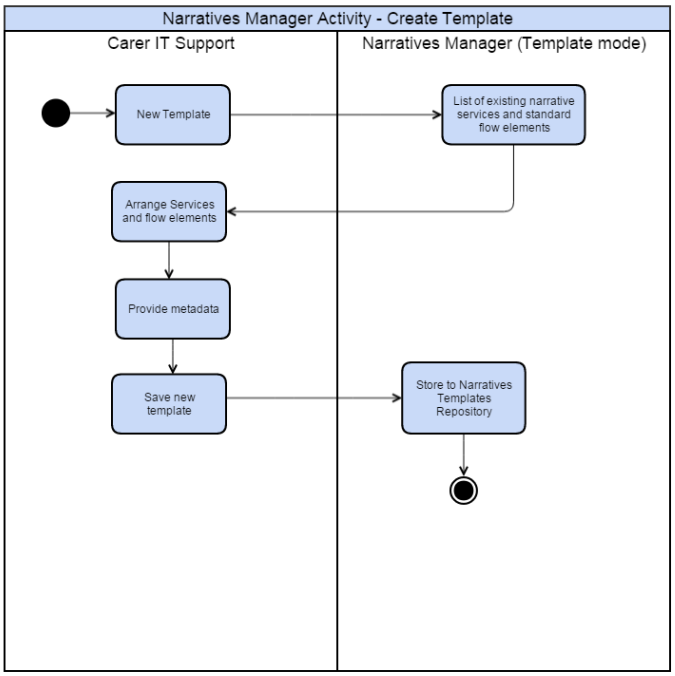
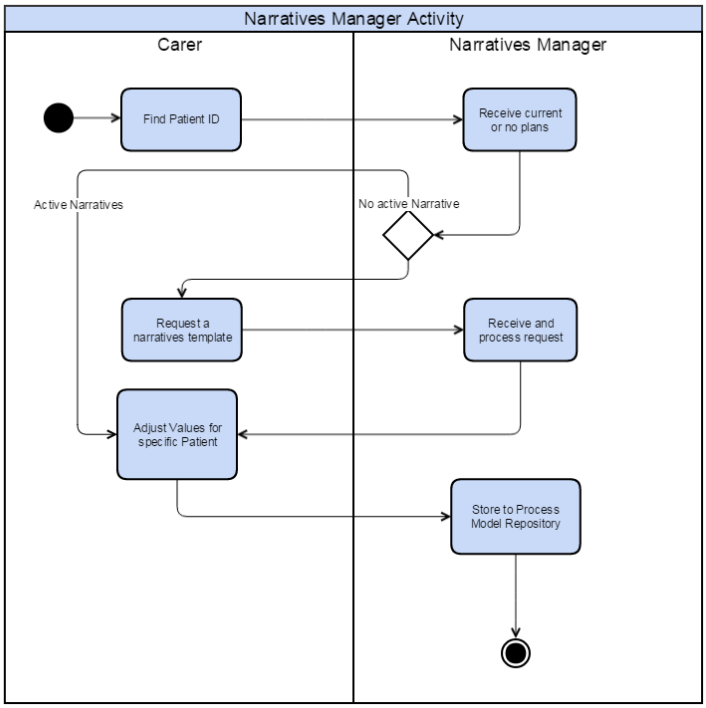
6.2.4 Goal Optimizer

Type	UI/service
Description	The purpose of the Goal Optimiser is to check, if one or more narratives are realizable. It has to handle the differences between the 2 narratives for each morbidity. Every narrative step of the narrative is validated and possible conflicts with other narratives or external information sources are detected. This component is used as a support when designing care plans or customizing narratives for specific patients.
Dependencies	Narratives Manager
Technologies	Constrain Satisfaction Algorithms
Primary Technical Use Case(s)	
Data	Narratives from Narratives Manager

6.2.5 Narratives Manager

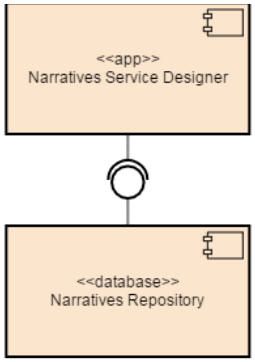
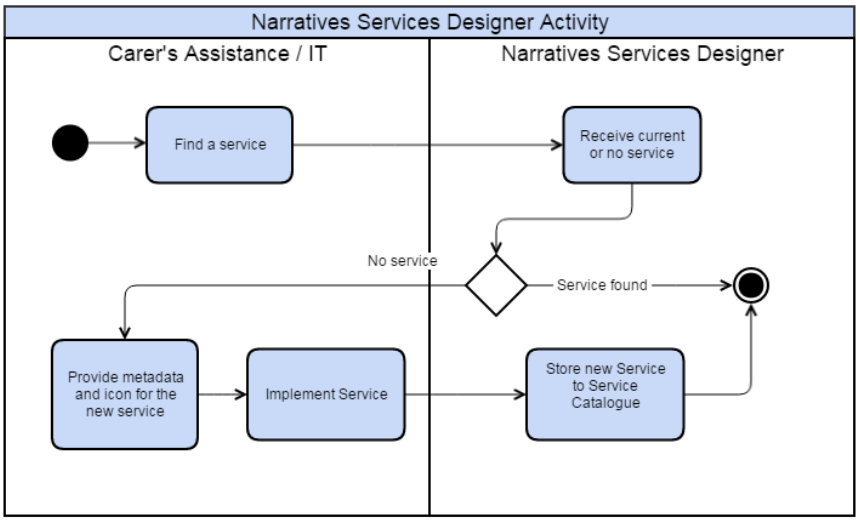
Type	Web based UI - Authoring
Description	The aim of this tool is to allow the creation, integration and effective sharing of a Patient pathway between all involved professional carers. Every

	organisation/physician uses a number of standard care plans for various diseases management actions. These care plans are expressed in a narrative form and are stored as Narrative templates in the Narratives Template Repository. A narrative template uses in a specific arrangement standard services stored in the service catalogue with open data fields for specific service parameters. To develop a Patient Pathway, a physician or an assistant instantiates one of the existing templates and fills the missing services' data for the specific patient. The resulting patient's pathway is then stored in the Process Model Repository for optimisation and service orchestration. A narrative should: • be easily created and configured by the carers • be shared between professional carers. The Narratives manager should also allow multiple clinicians to adjust and agree on a Patient's narrative / care plan • be exported to an appropriate machine readable format for optimisation (Optimisation Manager) and execution (Care Plan Orchestration) • be exported to human readable format (e.g. pdf/doc)
Dependencies	
Technologies	• Web technologies, nodejs, angularjs • Java / Drools.org / jBPM

Primary Technical Use Case(s)	 
Data	• IN: XML (narrative elements from Service Catalogue, FHIR Care Plan) • OUT: XML (narratives)

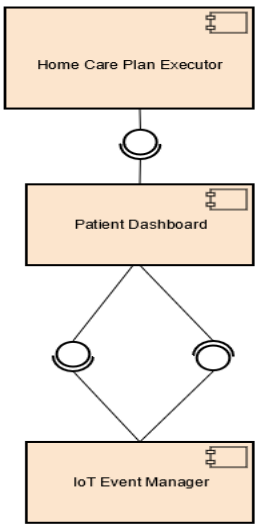
6.2.6 Narratives Services Designer

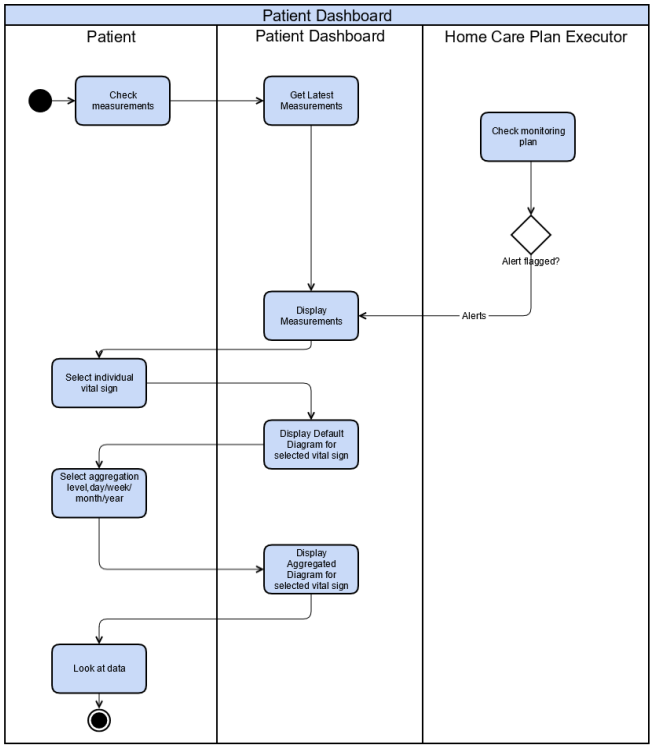
Type	Tool
Description	This is a tool for designing the standard Services for every care provider to be included in templates and used for automatic service execution anywhere that

	such a service needs to be executed including in clouds and in patient's homes –. This tool will be used by an assistant or IT staff who can implement in form of a service that needs to be executed during a care plan. The Narrative services designer bridge between the care plan designers (physicians), care provider IT stuff (develop and config) and final users (patients that will "run" the services as part of their care plan). The tool needs to support adaptive and dynamic processes by also providing the service control back to the end users for performing manual tasks / feedback.
Dependencies	
Technologies	• Web technologies • Eclipse • Java / Drools.org
Primary Technical Use Case(s)	
Data	• IN: XML (narrative elements from Service Catalogue, FHIR Care Plan) • OUT: XML (narratives)

6.2.7 Patient Dashboard

Type	UI
Description	The purpose of the Patient Dashboard is to provide a tailored summary of a patient's current status and history for the patient himself

	The sort of data which might be displayed includes: • Individual Care Plan • Current and historical clinical readings, including RPM data and patient's home self-assessments • Current medication plan • Appointments (past and future) • Links to educational material and different patient forums. • Report / Documentation history It should be possible to click through any of the various data types to see the detailed data behind it.
Dependencies	
Technologies	• Web technologies, node-js, Wordpress plug-ins, responsive design technologies et c. • SQL based storage • MQTT eventing • Android tools

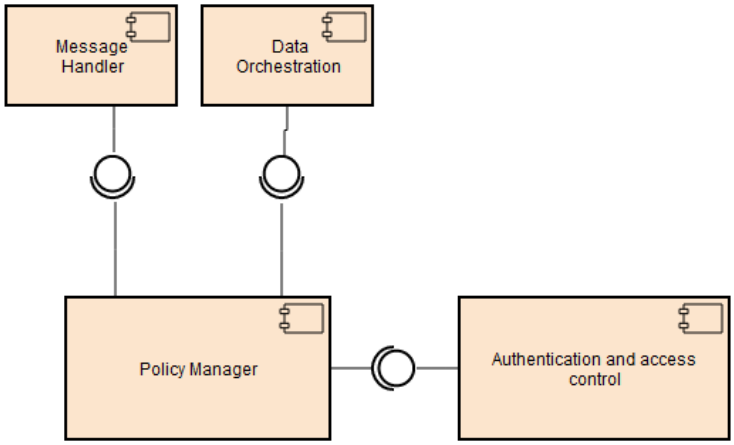
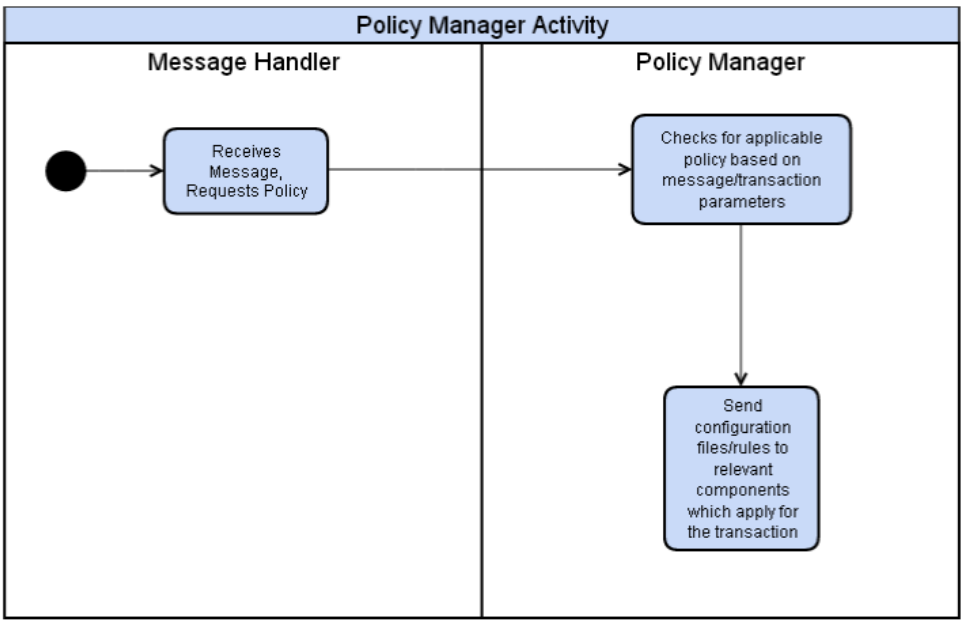
Primary Technical Use Case(s)	
Data	• IHE-PCD01 for patient observations • FHIR (Fast Healthcare Interoperability Resources) Care Plan https://www.hl7.org/fhir/careplan.html

6.3 Service Layer components

6.3.1 Message Handler

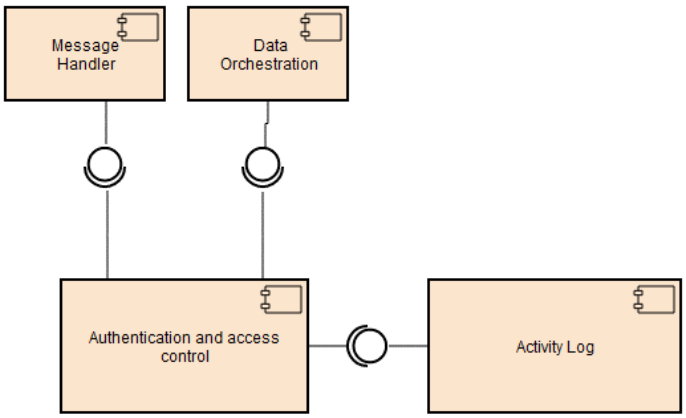
Type	Service
Description	This purpose of the Message Handler is to queue and process messages from the PICASO sources primarily the remote patient monitoring data. There will be a message handle instance in each clinic. Remote Patient Monitoring Data For patient home monitoring data, the LinkWatch device pushes the data to the Message Handler, where the data is then processed. The Message Handler checks first with the Policy Manager what it is supposed to do with the message type, then checks with the Authentication and Access Control component that the source is allowed to deliver data to the PICASO solution at this clinic. The Message Handler then loads the data in an agreed format. The message handler does not retain any of the data that passes through it.
Dependencies	• Clinical ODS (Operational Data Store) • Activity log • Authentication and Access Control component
Technologies	MQ (IBM Message Queue) for Transport and IBM (IBM Integration Broker) (with HL7 pack) for message processing. Or similar Open Source software which complies with UDUS and / or UTV/Santa Lucia standards.
Data	The data will consist of HL7 formatted messages.

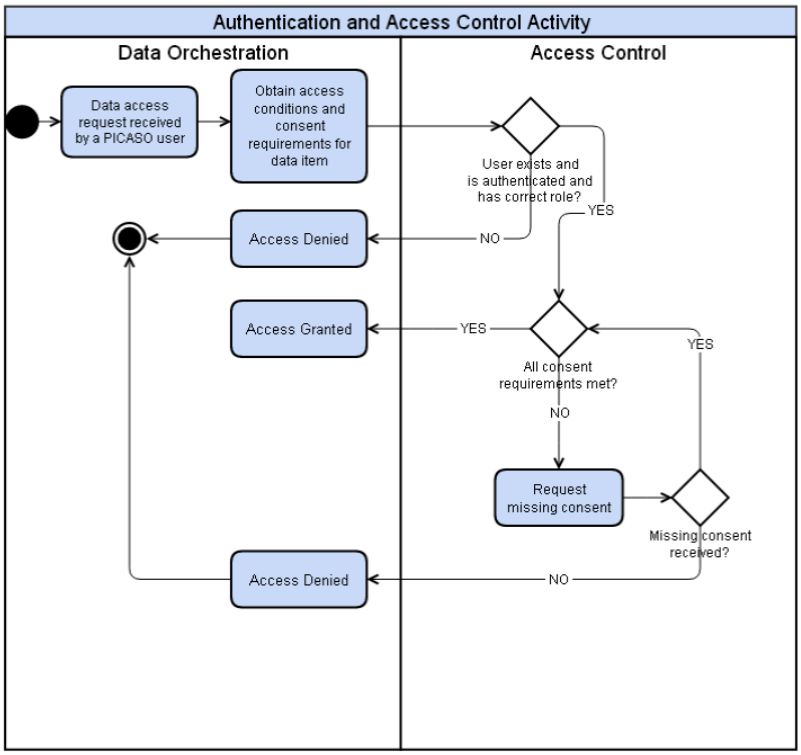
6.3.2 Policy Manager

Description	Implementations of the PICASO platform by different operators and/or in different jurisdictions in the EU could require the application of different policies regarding for example • security requirements • data protection requirements • consent requirements • privacy requirements • documentation requirements (Activity Log) The policy manager recognizes based on transaction parameters (user;country, transaction type) what policies should apply and provides the corresponding instructions/configuration files to the relevant PICASO components.
Dependencies	
Primary Technical Use Case(s)	
Technologies	

Data	All data required to infer the origin and type of a transaction so that the applicable policies can be identified.

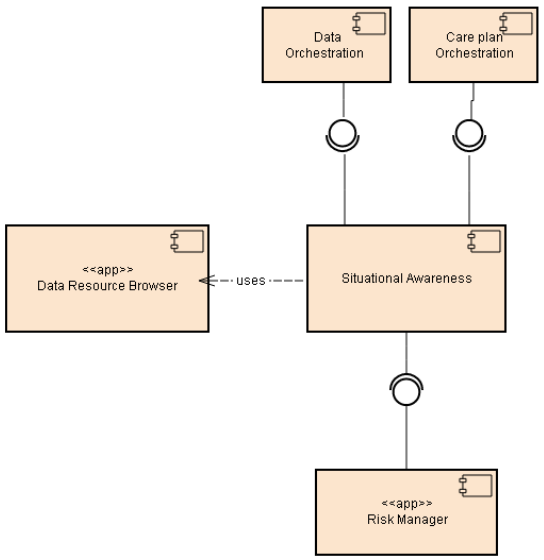
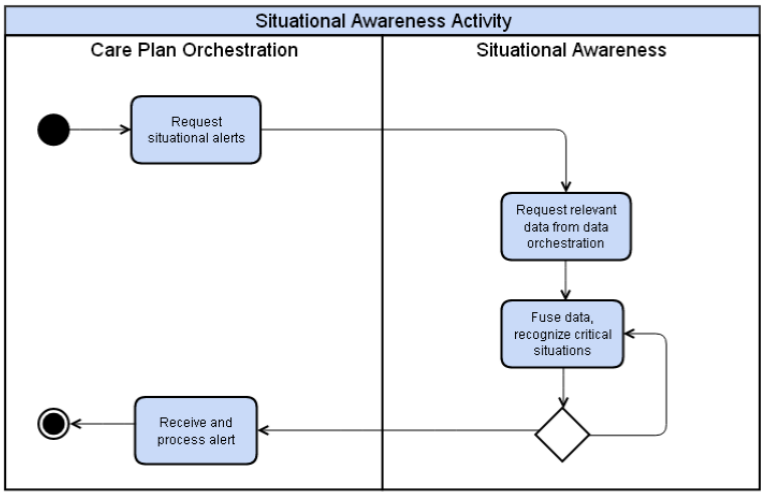
6.3.3 Authentication and Access Control

Type	Service
Description	The purpose of the Authentication and access control component of PICASO is to ensure that all actors are properly registered and access to data is only granted if all access requirements are met. In particular the Authentication and access control component is responsible for • PICASO user registration and user credential life-cycle management • Providing authentication means and credentials to all legitimate users • Verifying and controlling that all users meet the requirements for access to the PICASO platform and databases • Verify that the consent of all relevant parties has been obtained before access to data is granted • Provide all required information regarding PICASO system access to Activity Log • Apply configuration settings as received from policy manager
Dependencies	
Technologies	• To be decided based on UDUS and UTV, requirements, LinkWatch compatability etc. e.g. PKI

Primary Technical Use Case(s)	
Data	User authentication data, role data, consent data, consent policies

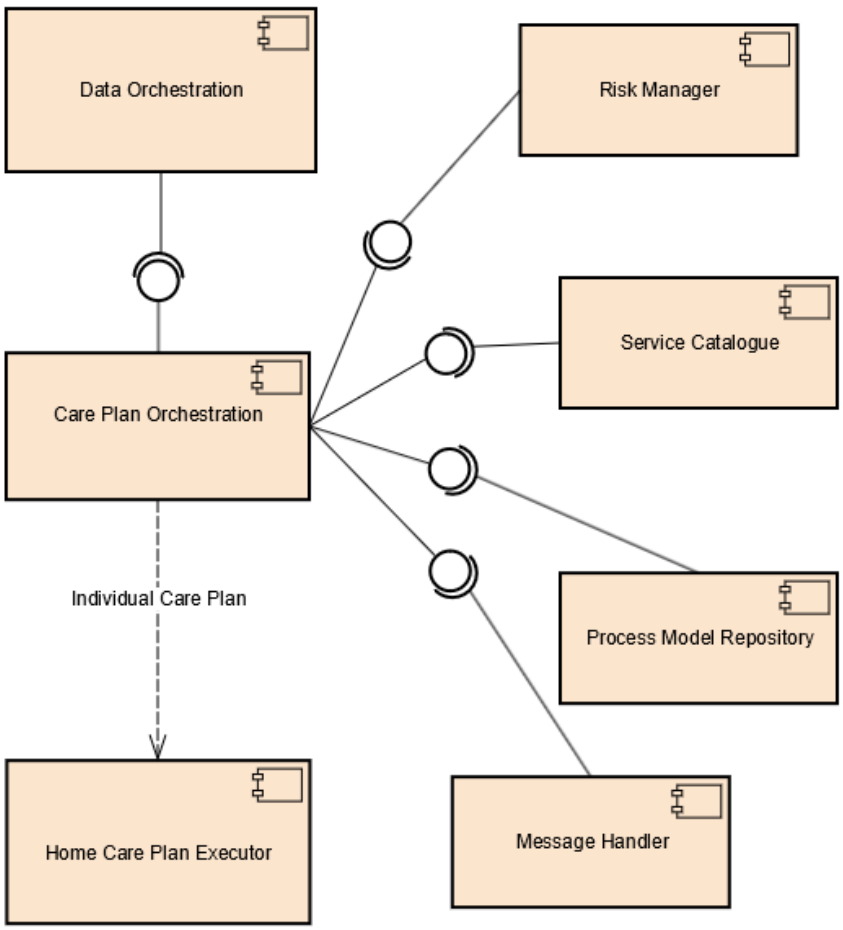
6.3.4 Situational awareness

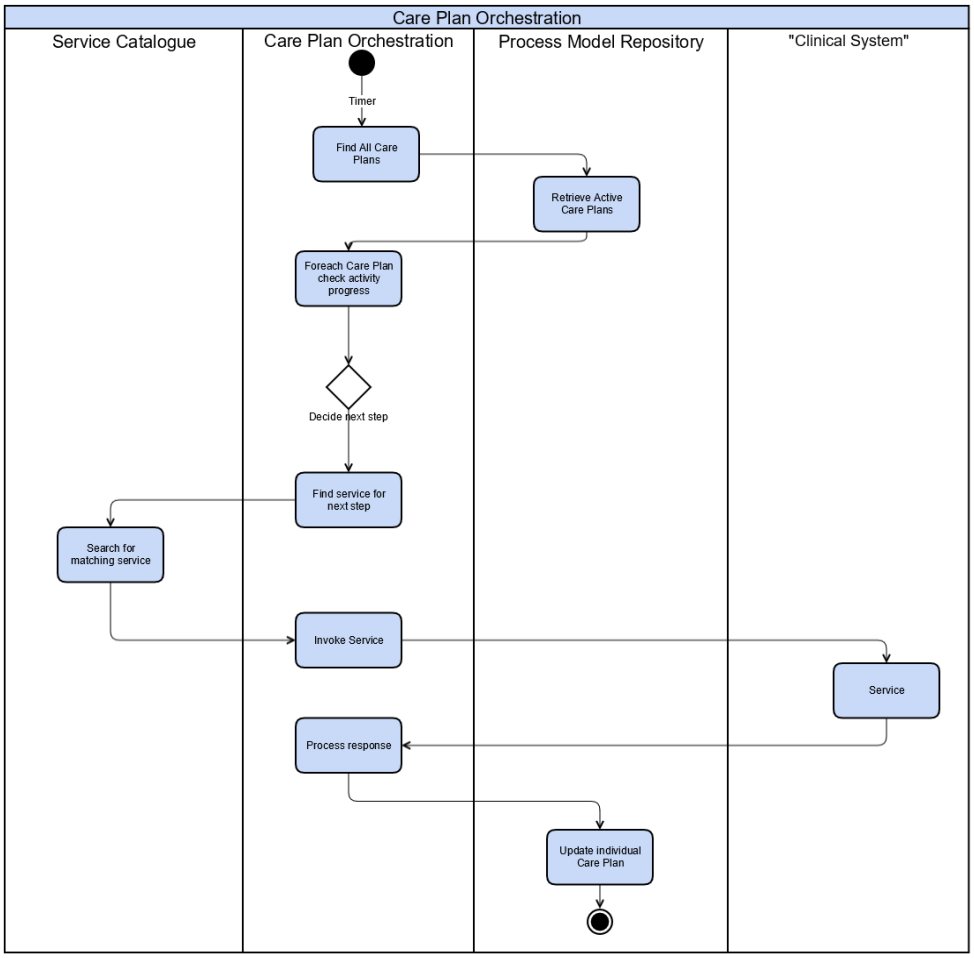
Type	Service
Description	The situational awareness components fuses and aggregates data for various PICASO components but also information indicating the patient state readable to human expert. The goal is to provide data in a format that it suitable for further analysis and display by components like • the risk manager • service orchestration • narrative execution • decision support • clinician dashboard Examples this component will aggregate LinkWatch data (IoT data from the patient's home) into a form that allows adequate display in the clinician dashboard. Situational awareness can also process LinkWatch data in order to create alerts to informal carers which are distributed via the Care Plan Orchestration component. Such an alert could indicate high blood pressure readings in combination with an absence of confirmed medication intake.

Dependencies	
Technologies	Data fusion
Primary Technical Use Case(s)	
Data	All data required to assess the situation of a patient or to raise specific alerts in particular IoT device data, clinical patient data

6.3.5 Care Plan Orchestration

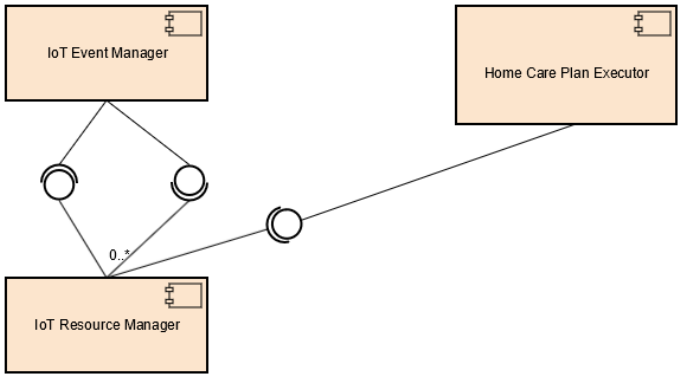
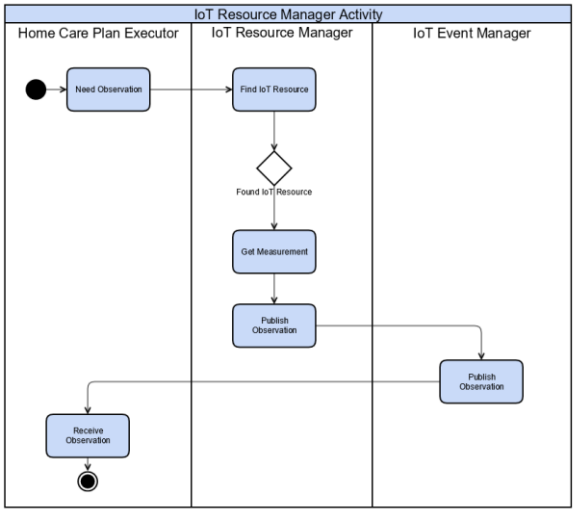
Type	Service with REST API
Description	The purpose of Care Plan Orchestration is to execute the care plan narrative. It therefore works closely with the Decision Support & Interaction Tools components to control the process flow in the PICASO application and aid the PICASO actors in logically stepping through the care plan. Care Plan orchestration will also work in a batch mode; processing RPM data to identify whether a clinical intervention is required when RPM data falls outside defined tolerances. Similarly Care Plan Orchestration may be used to ensure that the Patients' calendar at home has a replicated patient's Care Plan. Care Plan Orchestration will also have to address the two way updates of comments and updates from the Patient or Clinicians and synchronise the replicated patient care plan and patient master care plan. The replicated care plan is to ensure that Patient and

	RPM can operate, without an online connection, autonomously for a period of time e.g. at least 24hours.
Dependencies	
Technologies	• .net • HL7 Parser • MQTT eventing

Primary Technical Use Case(s)	
Data	FHIR (Fast Healthcare Interoperability Resources) Care Plan https://www.hl7.org/fhir/careplan.html

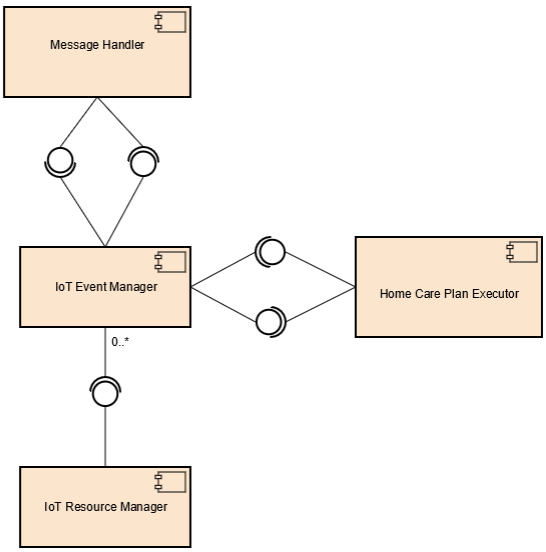
6.3.6 IoT Resource Manager

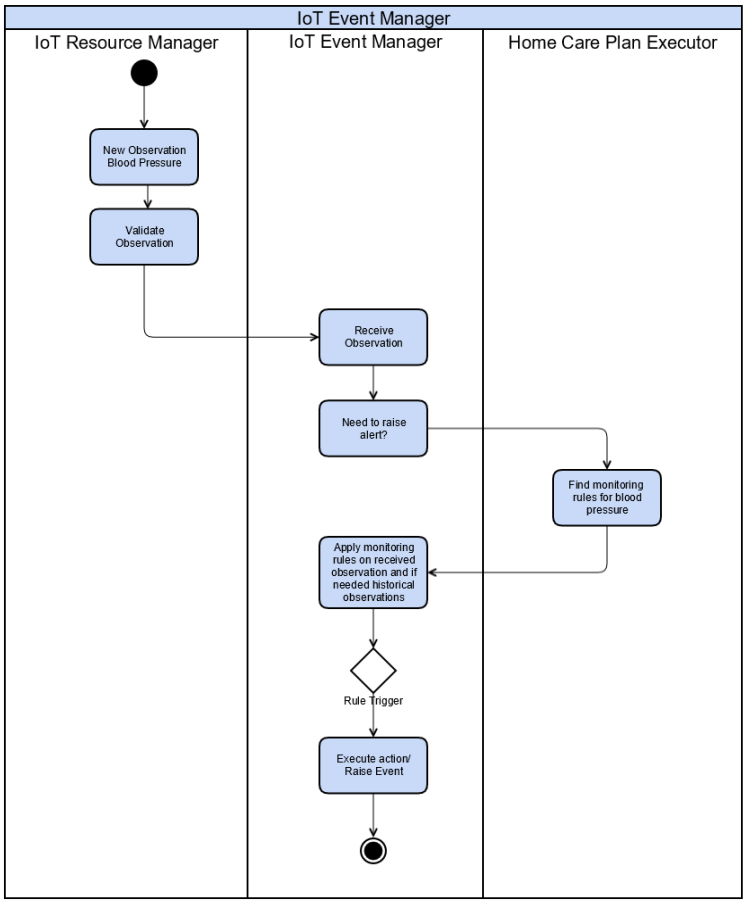
Type	Service with REST and MQTT API
Description	The IoT Resource Manager is a software defined gateway for the Patient Private Cloud. The purpose of the IoT Resource Manager is to provide interfaces for the different medical IoT resources supporting the patients self-monitoring, and to manage the local LinkWatch Patient Database. This includes interfaces for medical devices supplied to the patient by the clinician as well as lifestyle and behaviour monitoring sensors. It also provides access to patients own cloud-enabled devices like Fitbit, WiThings, MyFitnessPal. The IoT Resource Manager also provides local storage of monitoring data, including caching and functions for recovery/re-transmission of monitored data. The IoT Resource Manager intially supports the following devices and sensors: • Continua Enabled medical devices • Continua Enabled sensors for behaviour monitoring • Apple Health Kit compliant devices • Numerous Bluetooth, Zigbee and Enocean proprietary devices and sensors

	• OpenmHealth format for the ehealth cloud services. These type of devices exports data and stores it in their own cloud services where the user has an own account. Data export is done through OpenmHealth. The implementation or not of course needs to be based on the relative applied Data protections laws and regulations
Dependencies	
Technologies	• MQTT • .net • C++ • Observations in IHE-PCD01 format
Primary Technical Use Case(s)	
Data	Observations in IHE-PCD01 format

6.3.7 IoT Event Manager

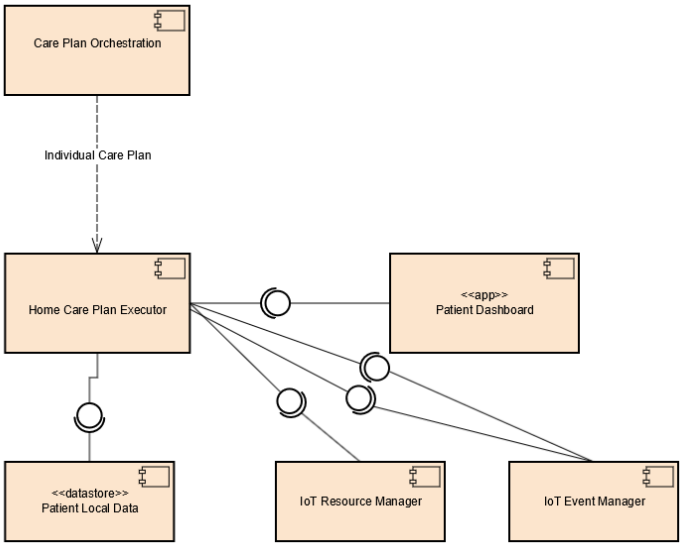
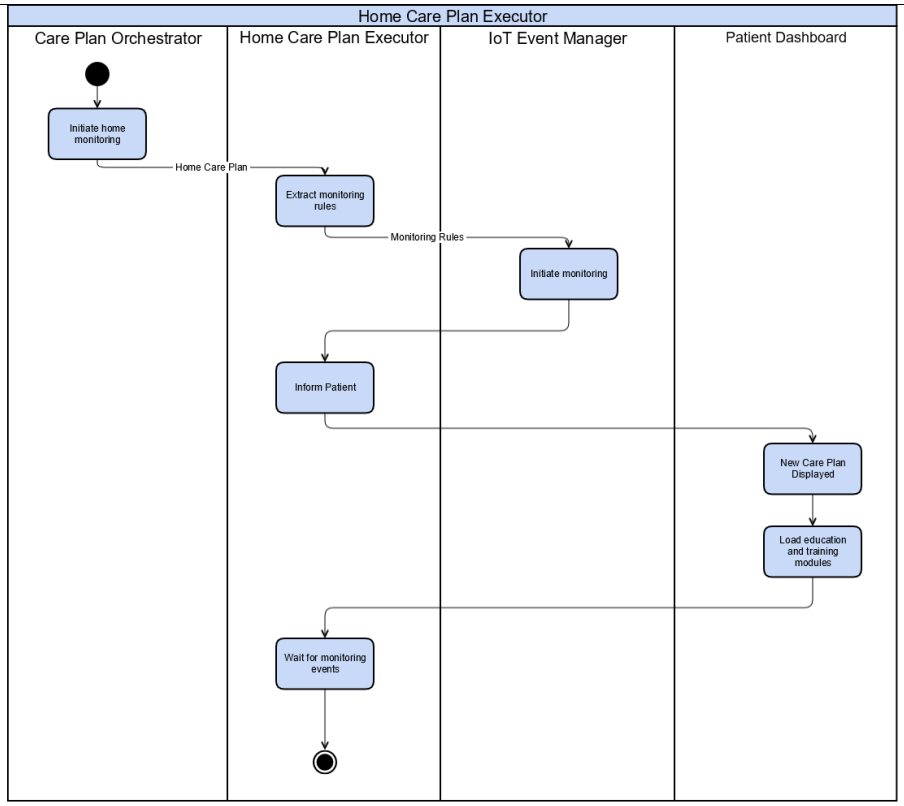
Type	Service with REST and MQTT API
Description	The Event Manager is part of the Patient Private Cloud and analyses measurements from the remote monitoring and takes actions depending on rules. The rules have been expressed by clinicians to provide a monitoring of a patient's ongoing health status. The IoT Event Manager is dealing with two type of events: ***Medical events***: A medical event is typically generated as a result of a complex logic algorithm or a query performed by the PICASO platform, but can also be created by a human. For example, if a patient is not performing the required blood pressure measurements, taking the required medication and is still in bed by 10 am for three consecutive days, it can be a sign of increasing depression and an event is raised. A fall sensor activated will also raise an event. And a patient feeling ill and needing help can also activate an event. Since most medical events are critical, there is no automatic processing. Rather, the event will go directly to the responsible professional carer for

	intervention. (It should be noted that PICASO is NOT handling critical events in this project. All participants in the trials must be explicitly informed about this fact). ***Process events***: The home gateway will be able to handle event monitoring and alarm handling during periods of non-connectivity. Events are either responded to at the local level, or they are stored and processed when connectivity is re-established. A part of the care plan can be downloaded to the gateway and will be executed there autonomously. The care plan may call for certain actions to be performed by the patient (measuring data, exercise, taking medication, calling the clinic). The event detection will monitor all data flows, including data from specific sensors whose only purpose is to monitor compliance, such as pill dispensers. When the patient or informal carer deviates from the care plan within a certain margin, an event is raised and recorded. An event may just trigger a closed loop interaction with the patient, e.g., reminders or dialogue about changes and reasons for changes). If possible, such changes will be automatically submitted to the care plan orchestration as requests for changes in care plan/pathway, subject to approval and/or adjustment by a physician. For example the patient is set to measure blood pressure every Monday before 10 am. If the patient for practical reasons changes this to every Tuesday, an event is raised that will automatically change the orchestrated care plan. If the patient changes it from once a week to once a month, the event may first trigger a request to the physician to approve to the request, it the event handling has been set up to require such approval. Finally, if blood pressure values are over predefined limits for an entire week, an event may be raised to the physician to take control of this patient (see UC-12 Intervention strategies, definition and execution).
Dependencies	
Technologies	• MQTT Eventing • .net

Primary Technical Use Case(s)	
Data	• FHIR (Fast Healthcare Interoperability Resources) Care Plan format: https://www.hl7.org/fhir/careplan.html • IHE-PCD01 Observation format

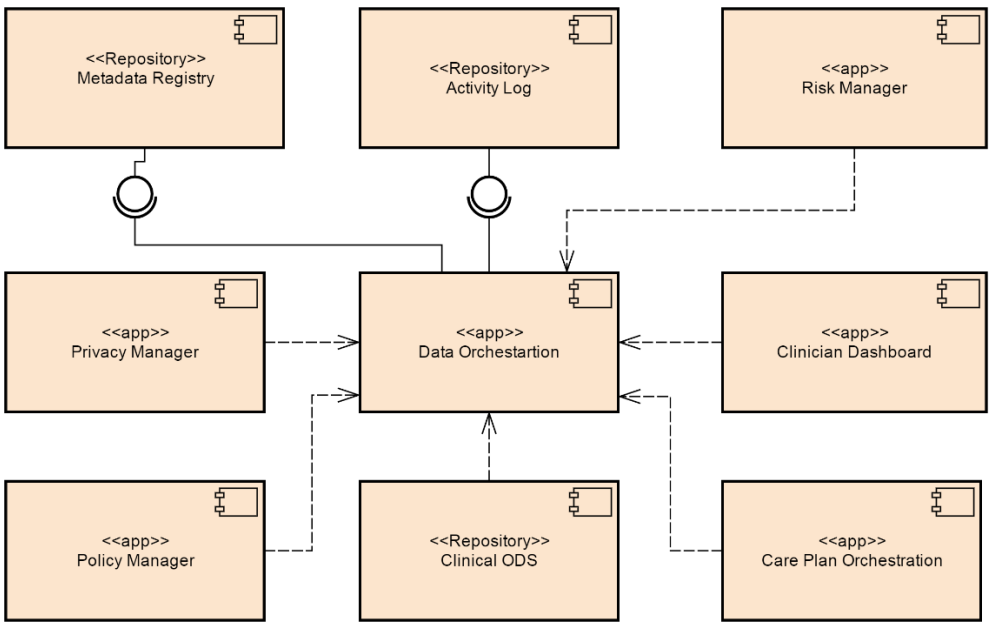
6.3.8 Home Care Plan Executor

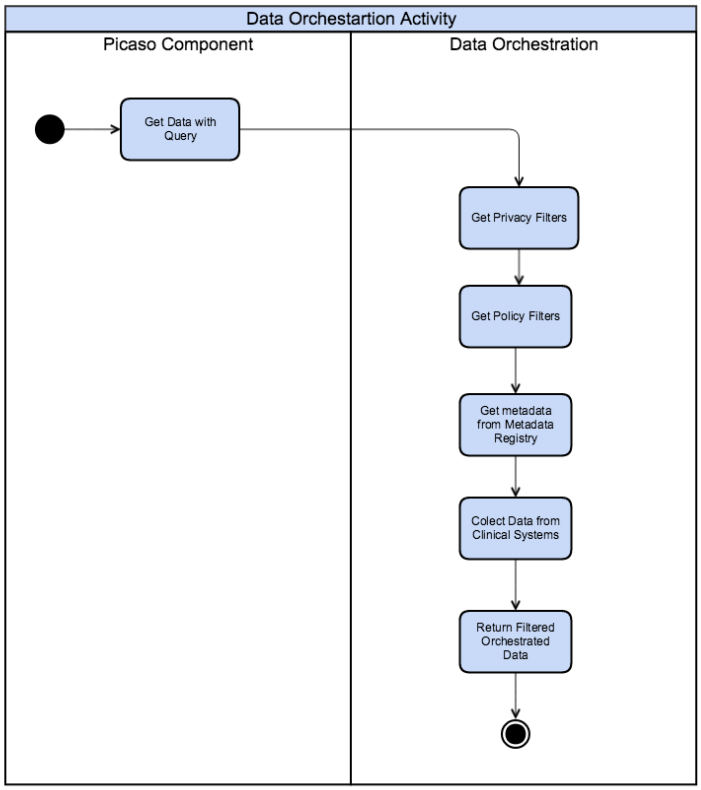
Type	Service
Description	This component is part of the Patient Private Cloud and is responsible for supervising that the patient complies with the self-monitoring plan, for instance: • The number of periodic measurements are taken • The measurement is taken at the right time of day • The monitoring devices are operational, battery levels etc. • The monitoring device connectivity is working It creates a notification or alert if the patient is non-compliant or if there are technical problems with devices or there are connectivity failures.

Dependencies	
Technologies	• MQTT • .net
Primary Technical Use Case(s)	
Data	• IHE-PCD01 for patient observations • FHIR (Fast Healthcare Interoperability Resources) Care Plan https://www.hl7.org/fhir/careplan.html

6.4 Data Access Layer components

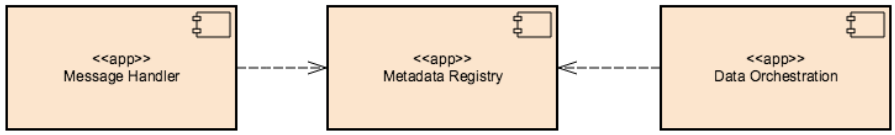
6.4.1 Data Orchestration

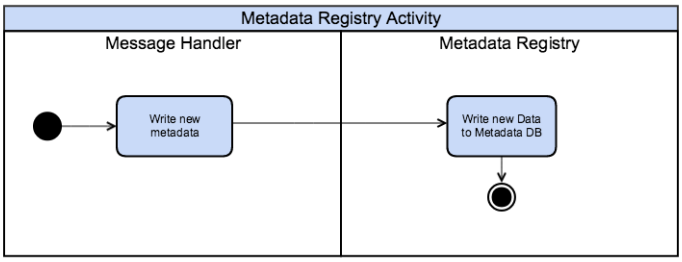
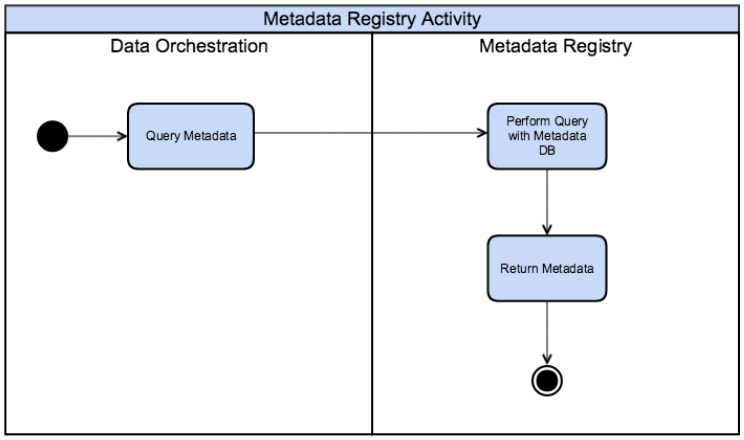
Type	Java based application with RESTful interface
Description	The Data Orchestration component serves as the data access layer for the PICASO application, interacting closely with the Decision Support and User Interaction Tools and also the Care Plan Orchestration component. Data Orchestration receives data requests from these other components, interrogates the Metadata Registry to determine whether the data exists and obtain the location of the actual data in the Clinical ODS. It then checks with the authentication and access control component for each item of data that the actual end user is allowed to know the data exist and is allowed to see the data. Based on rules defined with the Policy Manager, Data Orchestration may write an entry to the Activity Log for each data request; both successful and rejected. Data Orchestration then requests the actual data from the ODS and receives it via a push from the data source. The data is then returned to the requesting component; be it the Decision Support & Interaction Tools or the Care Plan Orchestration component.
Dependencies	
Technologies	RESTful

Primary Technical Use Case(s)	
Data	JSON

6.5 Persistence Layer

6.5.1 Metadata Registry

Type	Java based application accessible through RESTful services
Description	The purpose of the Metadata Registry is to hold a key, type and location information that is necessary to allow the Data Orchestration component to retrieve the specific data requested by the PICASO application. The sort of metadata held here will include: • A unique identifier for each metadata registry entry – so that the PICASO application can collate whole "reports" which consist of multiple data items • URLs for identifying specific documents in a document management system • Primary key attributes for structured data, together with which database and table locations allow the data to be uniquely identified Data types to identify whether the data item is a scan, report/letter or one of a wide range of structured data
Dependencies	
Technologies	NoSQL, Semantic Tripplestores

Primary Technical Use Case(s)	 
Data	N-Tuple, accepted serialisations from mesage handler (JSON, XML), translated into semantic format (e.g. N3)

6.5.2 Activity Log

Type	Service
Description	The activity log will not be a single file. It will be a journal of activity for the PICASO project. A separate data store is needed in each clinic to hold any patient data and transaction data for the PICASO project at an individual clinic. Another Activity log will exist as a central data store in the IBM public Cloud, this activity log will not hold any patient data, it will only hold transaction data, A patient token will be held and an actor token will be held in this log. This is to ensure privacy of the patient and actor, The token will be a indirect lookup to the patient and actor actual ID's. The look table will be held within the Clinical DMZ so that only an application within the DMZ can decode it. The data store needs to be man and machine readable therefore an XML format will be used to ensure that any component that wished to write specific data for that component can write it in its own format. The data store will be a plain acsii data store The first 5 XML fields will be <DATETIME>2016-09-29Z18-06-03</DATETIME> <TRANSACTION>number</TRANSACTION><ACTOR>name</ACTOR><Patient>patient id or token</PATIENT><COMPONENT>name</Component> . The rest of the fields can be defined to suit the component that wishes to write the Activity Log.
Dependencies	None
Technologies	A flat ASCII file. (Assume file lock on Open, Write data to file, Release lock on close)
Primary Technical Use Case(s)	

Data	The data will consist of log message with any valid XML structure following the mandatory fields: . The data store will be a plain ASCII data store The first 5 XML fields will be <DATETIME>2016-09-29Z18-06-03</DATETIME> <TRANSACTION>number</TRANSACTION><ACTOR>name</ACTOR><Patient>patient id or token</PATIENT><COMPONENT>name</Component>. The rest of the fields can be defined to suit the component that wishes to write the Activity Log.

6.5.3 Clinical ODS (Operational Data Store)

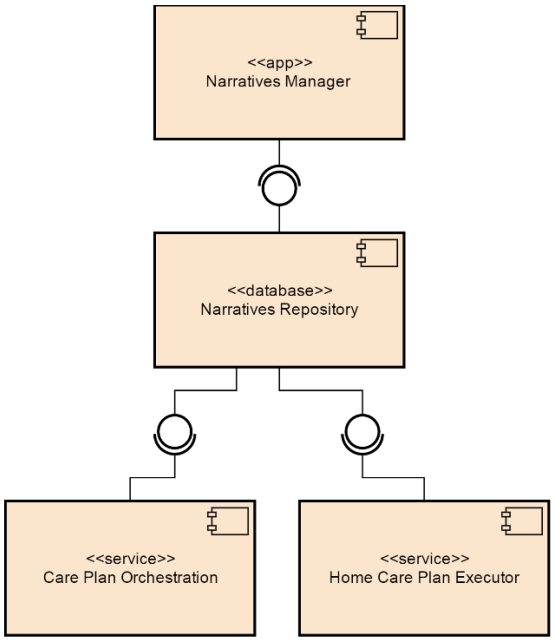
Description	The ODS (Operational Data Store). This component includes the ETL (Extract Transform and Load) tool. This component is where the CIM (Common Information Model) will be deployed. Please see D5.1 for details. The ODS will hold the data extracted from the clinical system that has been made available to the PICASO solution. This component differs from the GA (Grant Agreement) in so far as the original idea was to access a copy of the clinical IT systems. After a discussion with UDUS it became clear that a copy of UDUS IT systems which PICASO could access was not feasible. It was agreed between UDUS IT, UDUS data protection, IBM and TUK that an ODS was the best option for the PICASO project to get access to UDUS clinical data.Technology: MYSQL was suggested by UDUS since they have expertise in this are already and it is an open source product. However this needs to be agreed with UDUS and UTV/Santa Lucia. Dependencies: ETL tool, D5.1 Infrastructure as deployed at UDUS and UTV/Santa Lucia.Agreement with the clinics - since .
Dependencies	ETL tool
Technologies	MYSQL or any other RDMS that is acceptable to UDUS/UTV.
Primary Technical Use Case(s)	Data store for clincal data.
Data	Any data that can be held in a RDBMS.

6.5.3.1 ETL (Extract Transform and Load) tool

Type	ODS Support Tool
Description	This component will extract the data from the clinical system under the guidance of the clinical IT department. Transform the data content into a format and structure that is compatible with the ODS structure and content. (It may create and load additional tables which are not part of the PICASO ODS, to assist in the forward and backward translations
Dependencies	ODS
Technologies	IBM would recommend IBM DataStage but this component needs to be chosen by the clinic who will have to run and administer the component.
Data	

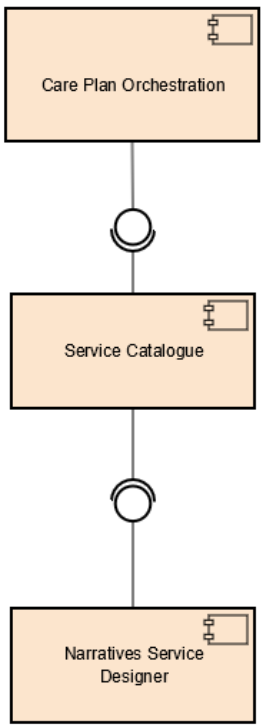
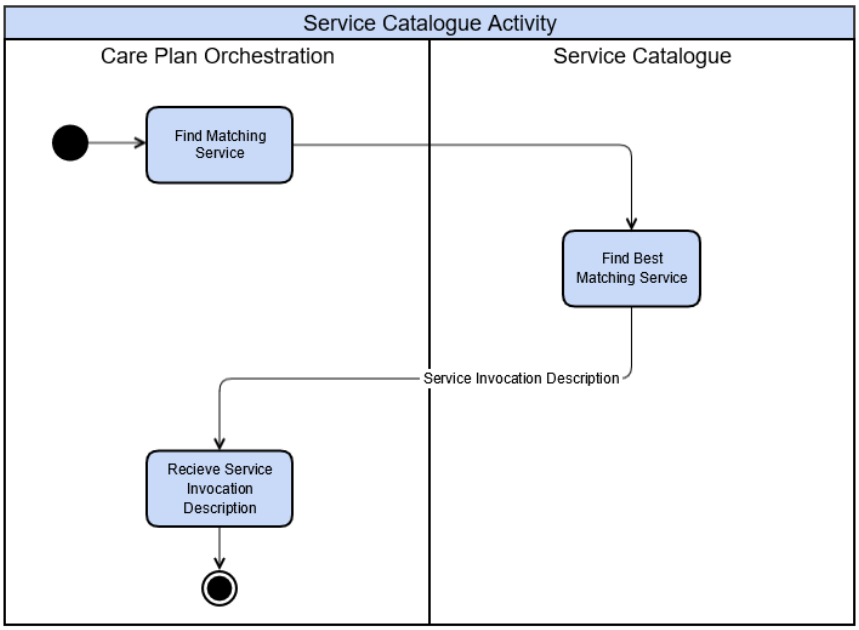
6.5.4 Narratives Template Repository

Description	The purpose of the Narrative Template Repository is to store the template narratives for the different car plan activities inside a clinic based on clinics' standard guidelines.

Dependencies	
Technologies	XML Database
Primary Technical Use Case(s)	see Narratives Manager
Data	see Narratives Manager

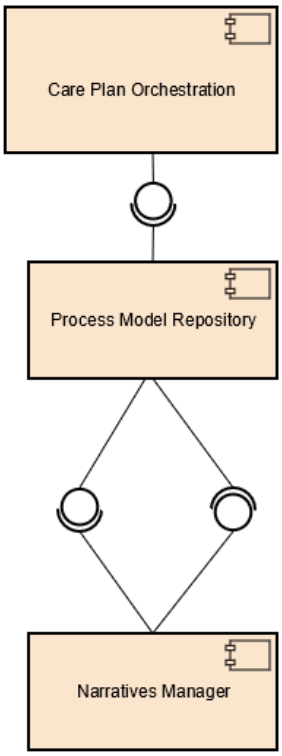
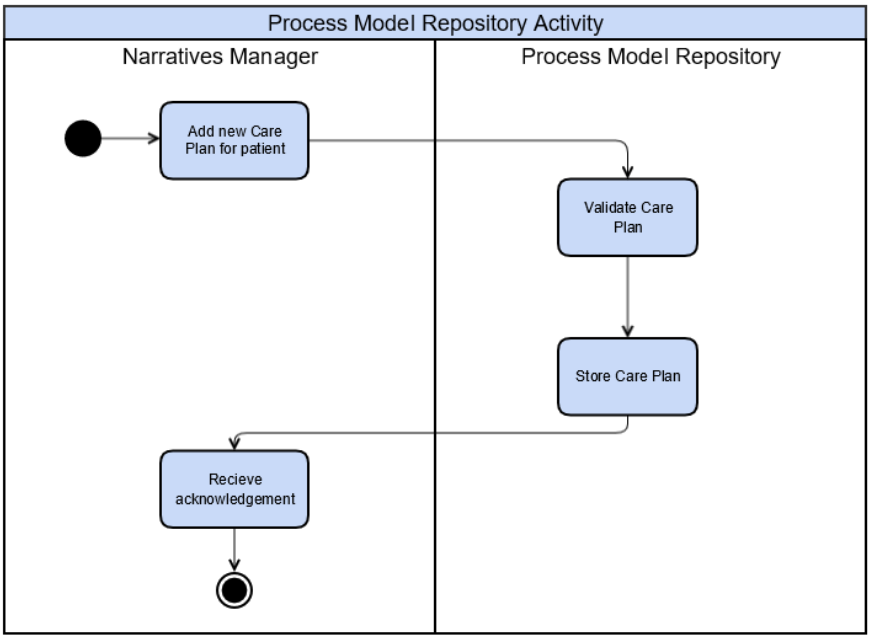
6.5.5 Service Catalogue

Type	.Net JSON RESTful interface
Description	Services are individual, reusable clinical process steps and elements which can be grouped together to form complete Narratives. The Service Catalogue contains semantic descriptions of these services and the necessary information needed for activating and consuming such as service. The services described might be executed automatically by a computer system or might require manual execution by humans. Example of services are “take blood pressure”, “book appointment with clinician”, “get medication”, et c. The service catalogue serves both the Narratives Manager with available services to choose from as well as the Care Plan Orchestrator with runtime data on how to initiate and execute services.

Dependencies	
Technologies	• .net • Brightstar/MongoDB
Primary Technical Use Case(s)	
Data	Service Descriptions

6.5.6 Process Model Repository

Type	Service with REST API
Description	The database where tailored patient Narratives are stored by the Narrative Manager. Each tailored narrative includes numerous calls to the Service Catalogue to invoke specific process steps. The Care Plan Orchestration component interrogates these Narratives to determine the next step(s) in a patient's care plan execution.

Dependencies	
Technologies	MongoDB
Primary Technical Use Case(s)	
Data	FHIR (Fast Healthcare Interoperability Resources) Care Plan https://www.hl7.org/fhir/careplan.html

7 Information view

7.1 Introduction

This chapter includes information about the data models, data transformations, data storage, and data flows.

7.2 Data Landscape

The data landscape will be documented in a separate deliverable - D5.1 Data Models & Shared Memory Objects. This deliverable will deliver the following as input to the PICASO solution:

- Detailed Clinical Data Requirements, down to data attribute level
- Identification of the clinical systems data sources which will be input to the PICASO ODS (Operational Data Store)
- Data Models for the ODS, each of the Clinical Systems data sources will feed into the ODS to produce a Common Information source for the data orchestration to access at each clinic.
- A data model or set of message formats from the LinkWatch IoT Resource Manager
- A third normal form Common Information Model for PICASO covering the clinical data to be used by PICASO this will be implemented as the ODS.
- Source to Target mappings from IoT Resource Manager data sources to the Common Information Model. The Source to Target mapping from the clinical system to the Common Information Model will be performed by the clinical systems IT staff (since they will have knowledge of their IT systems).
- Work with the UDUS and UTV/Santa Lucia It teams to ensure that the needed clinical data will be extracted and made available to the PICASO ODS.
- The data management plan

In the following figure this data landscape is graphically depicted.

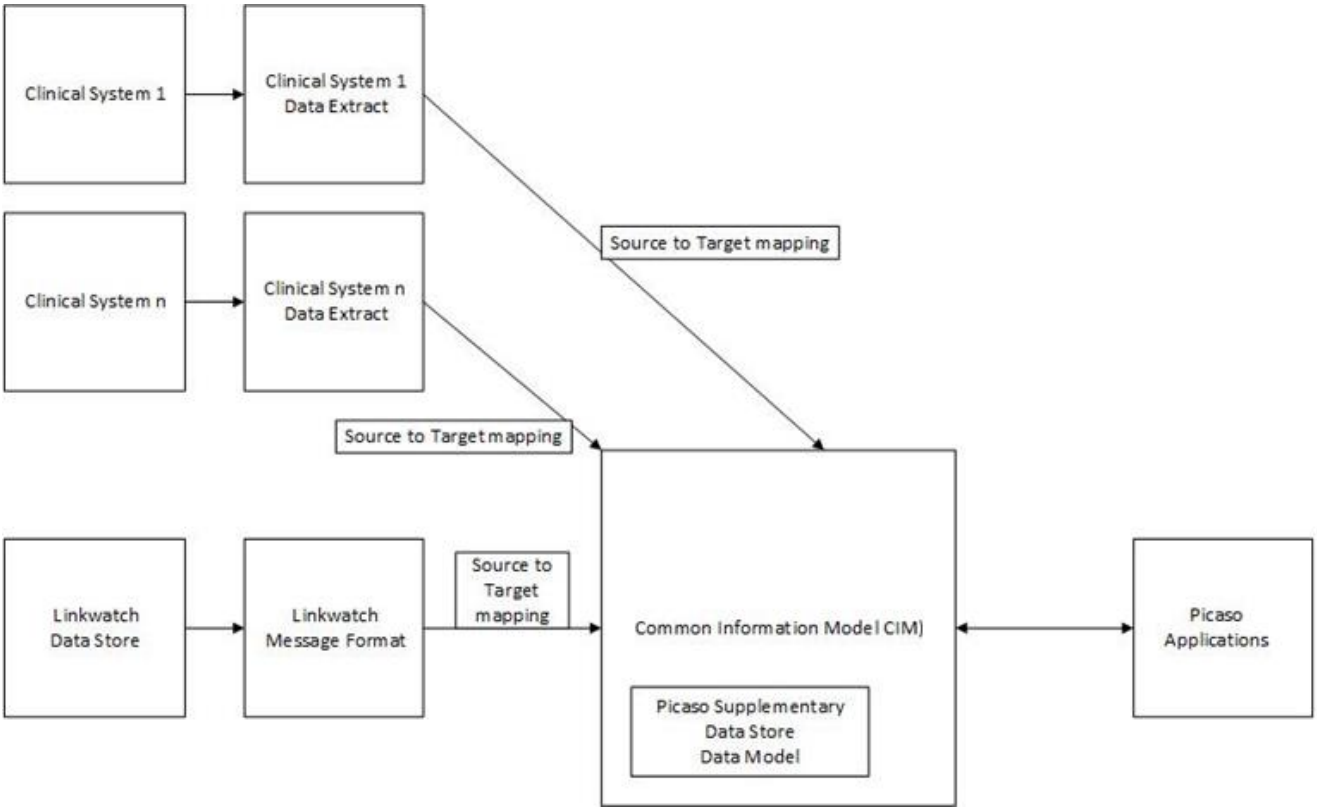


Figure 7 - Data Landscape Schematic

The work done in Task T5.1 Data Models and Shared Memory Objects will only consider data from the existing clinical systems and LinkWatch. Any data that is required internally by PICASO (such as actor tokenisation, events & alerts, care plans, etc.) will not be considered by this task.

7.2.1 Data Requirements

The D2.1 Initial Requirements documented high level data categories required by PICASO and task T2.4 Requirements Re-engineering will add further requirements.

These will be turned into detailed requirements at an attribute level. This will be done by investigating the data required to support the data exchanges contained in the To-Be Use Cases, together with detailed interviews with the clinicians on PICASO.

The data attributes will be validated against the data categories to ensure that all data categories have been considered by Data Investigation.

7.2.2 Data Sources

The project will work with the IT teams and clinicians from UDUS and UTV/Santa Lucia to identify where (if at all) the required data is held in their systems. Note that it is highly likely that there will be substantial gaps in these data sources. These gaps will be documented.

There will also be instances where the same data is available from more than one system. The preferred ("master") data source will be identified.

7.2.3 Source Data Models

The project will obtain the physical data models for all data sources identified. Where these do not exist, the project will endeavour to document the data models, adequate for the needs of PICASO.

Note that this will include both structured and unstructured data; the latter likely to include both imaging data and documents.

The project will obtain the data model or message formats from CNET, to be delivered by the LinkWatch component of PICASO.

7.2.4 Common Information Model

A third normal form "common information model" will be developed. This will compose the basis of the interaction between the Shared Memory Manager solution defined in Section 8.4 and the application elements of PICASO, documented in Section 9.

7.2.5 Source-to-Target Mappings

The mapping of source system data to the common information model will be mapped, to provide the input to the API design described in Section 8.4.

7.2.6 Source Databases

PICASO is not allowed to directly integrate with the operational clinical systems a UDUS and UTV / Santa Lucia.

Instead, the project will work with the various hospital IT teams to determine how and in what format, clinical source data will be extracted from the clinical systems for the participants in the clinical trials. This will include how frequently this data will be refreshed for use by PICASO.

The resulting data extracts will be held inside the respective hospital's DMZ and accessed by the Shared Memory Manager, as described in Section 7.4. The hospitals will provide the platforms within which these data extracts will be hosted, as documented in Section 8.

7.2.7 Data Management Plan

The requirement for "Privacy by Design" has a large impact on the data management plan. The main way that privacy is maintained is to ensure that the data cannot be read without the correct permissions being granted to the reader. Therefore the following rules apply:

Data at rest has to be either in a secure or encrypted storage. Data in transit must be encrypted since that data is passing over the public cloud including the internet.

Where data has multiple sources in PICASO (e.g. UTV and Santa Lucia both hold a patient record) a primary source has to be defined. For UTV the UTV record is the master and for Santa Lucia the Santa Lucia record is the master (No Patient data will be stored in Picaso system, only the metadata will be stored in the PICASO system). Hence the data displayed is dependent on the actor and which system is their primary source.

These data quality and data sources issues have rules sets to determine how data is handled in PICASO.

Each environment that is built (3 environments are assumed at present, as documented in Section 8: Development, Test and Production) needs to have a different data management plan implementation. Production will handle actual patient data which will need to be secured to ensure privacy either at rest or in transit. Test will be using actual data that has had a level of anonymization from actual patient data (to be agreed with each hospital's data security team, so that it has a production like quality). Development will be using both manually created data and sanitised data from actual patient data where the level of anonymization is sufficient to allow any developer to be able to build the solution. The Development environment will therefore not need to be encrypted in any way.

From Grant Agreement T8.4 an assumption has been made that PICASO will connect with demonstration servers and these demonstration servers will be refreshed with actual patient data on a daily or suitable periodic basis. After a meeting with UDUS IT they did not want to use a demonstration system. UDUS IT want to write a feed of the 30 patients records into an ODS.

7.3 Technical Data Integration

PICASO data integration core concepts can be divided into three parts (all additional details will be described in D5.2 Shared Memory Manager):

- Data Sources. All data producing components and their connected storages, where data is physically presented (Clinical Systems, LinkWatch measurements, Activity log, Services/Narrative Templates/Process Model Repositories, etc.)
- Meta-Data Registry Component responsible for holding the patient token and hospitals/locations that holds data on that patient. Every time when some of data sources produces new piece of information, this event is captured via Message Handler component, translated into meta-data format and recorded in meta-data registry. Meta data registry does not store whole information, only record, that information exists with core information needed to identify the information and its source, so it can be easily found and retrieved by data orchestration component.
- Data Orchestration Component responsible for searching, filtering, sorting of meta-data records and retrieval of physical data stored in data sources. Each request on data orchestration component is consulted with Authentication and Access Control component to check if requester is allowed to receive the information. Depending on Policy Manager rules, the record about the data request is stored in Activity Log.

7.3.1 Meta-data description

The meta-data record must be able to identify all aspects of information enabling the search and possibly, if additional meta-data are present, the filtering, aggregation and sorting of data. The key parts of meta-data record are:

- unique ID and type of information subject: in most cases, the subject of information is the patient. Generally thinking, the subject of information can be anything, e.g. patient independent action of clinician.
- unique ID of information source: the source can be any of components producing data
- optional additional meta-data extracted from original information, which may help in meta-data search, and result processing. The example of additional meta-data may be timestamp, information type or automatically extracted text annotations describing the semantics of document content.

All parts of meta-data description are standardized. We assume the use of semantic models providing all necessary vocabularies enabling the machine readable standardization. This covers the typology, taxonomies and structured vocabularies for precise description of subjects, actors, sources and contents, including formal descriptions, how the physical content will be retrieved from source.

The standardized description of meta-data enables wide range of possible searches, e.g. get all information about patient from particular source or particular clinician; get all information provided by concrete clinician (for particular patient or particular diagnosis or particular action (medicament prescription, diagnosis made, etc)) and many more. All data will be in constrained time intervals if needed.

Depending of type of recorded information, some parts of meta-data can be omitted as optional. This has the influence on search and result processing strategy, which must take into account the (in-) completeness of meta-data record content.

The tricky part of identification of meta-data parts is the anonymization of data and possible change of unique identifiers for the same subject or actor. For example:

- the same patient may have different identifiers in different clinical systems.
- the unique ID of patient may change over time (e.g. change of insurance number)

To handle the change of identifiers and their corresponding anonymizations must be solved via specific mappings representing relations between identifiers in same data sources and among all data sources.

7.3.2 Standardized communication

There are two main aspects enabling the standard communication and data exchange within PICASO platform:

- Data transformation into common machine-readable formats. To enable fully machine readable exchange of information, the several transformations in standard format must be performed during dataflow.
  - The ETL tool will translate from the original clinical system data to the ODS
  - The ETL tool will translate from the original clinical system data to the ODS. Thereby ensuring a uniform standard format and definition for clinical data.
- Each component in data flow must implement the common API for reading and writing of data. The common API implementation enables the communication with data components in uniform way, so the new data sources may be easily added into existing infrastructure. Another advantage of the common API is the possibility for replacement of underlying technical backend.

7.4 Privacy

Data storage and data flows must be designed according to “privacy by design” principles and permit the application of all local, national and EU wide data privacy and data protection requirements.

In meetings with the clinical partners the following principles were agreed in particular:

- Only once all requirements for consent, need to know (treatment case, role) etc. are fulfilled patient data can be exchanged between medical professionals.
- Informal carer access to patient data is solely initiated and controlled by the patient itself. Data must be grouped so that patients can grant granular access (e.g. medication plan, activity data, appointment reminders etc.).
- Patient can decide anytime which notifications/dashboard data she/he wants to receive and must be able to change preferences accordingly.
- Patient must be informed what data are held in what PICASO databases for how long and for what purpose. Consent must be obtained.
- The only persistent Picaso data store for clinical data will be the Clinical ODS
- PICASO applies the principle that patient data should be saved only at the clinical ODS of the originating hospital. However, the clinician at the receiving hospital must have the option to save selected data to the clinical record of the patient (for internal use only; this saved data will not become available within PICASO).
- Any patient-related data held outside the hospital DMZs will use tokenisation of the Patient identity
- For all stored patient related data, data retention policies need to be formulated. These policies must cover data retention during the trials, after the end of the trials as well as data retention in case of patient withdrawal from the trials.

7.5 Data Issues

In this subchapter issues related to data quality and data handling are listed, which might arise during the project and which need to be handled once they occur.

7.5.1 Data Quality

The data quality in the various clinical systems is outside the control of PICASO and may lead to issues in presenting and interpreting data shared between clinicians. The project needs to consider the implications of this during the clinical trials.

7.5.2 Joining Data across Clinical Systems

Note that where there are multiple sources of clinical data, PICASO expects to join this data to create a more complete patient record. There are likely to be different ways in which entities like patients are uniquely identified in these system, despite for example there being a National Health Identify Number in use across Italy.

Another example might be where systems do not use a common format and standard for medications, or medical conditions.

Such data issues that mean the data may not join easily, thereby making it difficult to recognise the same patient or data across these systems. In such circumstances, unless there is some form of manual intervention or considerable mapping of data values, PICASO may not be able to conform the data into a common standard. This might result in PICASO identifying a given patient as multiple patients; such as one per hospital.

PICASO is only considering a very small number of data sources in the trial at best (and may not extend beyond a single hospital), so this issue will not be as obvious as it will be when multiple hospitals are “integrated” in a future production PICASO solution.

The solution needs to consider the eventuality that such data quality issues will occur in a production solution and factor in ways to handle this situation. During the project it will be of significant interest to identify which data attributes are most likely to cause these issues – a unique patient identifier being the most obvious example.

7.5.3 Breadth of available clinical data

The clinical IT systems may not be able to provide a sufficiently complete set of clinical data needed to allow the PICASO Project to adequately support the objectives of the clinical trials and demonstrate the objectives stated in the Grant Agreement.

7.5.4 Data definitions

The data held in the clinical systems my not conform to consistent standards such as SNOMED. Standardising the data so that PICASO presents a consistent set of data that is acceptable to all clinicians may not be possible. However, the project needs to consider during the clinical trials whether this is a problem and what it would take to achieve such as standard.

8 Environments and Deployment view

8.1 Introduction

There will be three different environments in the PICASO project, one for developing, one for testing and one for production. These environments need different levels of security and privacy to correspond with the data management plan implementation.

8.2 Environments

All 3 environments require authentication and a record of any access is recorded to ensure that any changes can be tracked.

8.2.1 Development

Development will be using sanitised data from actual patient data where the level of anonymization is sufficient to allow any developer to be able to view it. The Development environment will therefore not need to be encrypted in any way. This environment has very little security and privacy. It is open for all authorised developers to work in a cooperative manner.

Development environments will be provided independently by the respective partners for their own separate development. An integrated development environment will be provided for the development of the integration.

8.2.2 Testing

The testing environment will be using actual data that has had a light touch anonymization from actual patient data so that it has a production like quality. This environment has tightest security and very little privacy. It is only open to testers to make changes but is open to all for read only access.

The testing environment will also be used for integration testing.

8.2.3 Production

Production will handle actual patient data which will need to be secured to ensure privacy either at rest or in transit. This environment has a reasonable level of security to allow the appropriate used to use the system effectively and has the highest level of privacy only authorised users can actually see patient data as authorised by the authentication and access control component.

8.3 Deployment

The development environment is available for any member of the consortium to deploy code and data into. This needs to be run in a cooperative manner to ensure that one developer does not overwrite the work of another developer.

When code and data is ready for deployment to test from development, the artefacts including deployment instructions need to be supplied to IBM who are responsible for integration and testing. IBM then will deploy to the testing environment and then test the PICASO System there.

When code and data is tested sufficiently, IBM will promote the code and data to production. After this, IBM will verify with specific data (e.g. the users own named patient details which may be entirely fictitious) that the PICASO system is working as intended for use by the clinicians.

After the code is released for the PICASO System to production, it is necessary to test the PICASO system with LinkWatch connected and all possible devises connected to LinkWatch. This will be performed by IN-JET. The test is carried out with a fictitious patient - a test patient. It is therefore necessary that the PICASO system can handle test patients. When the test is completed, the system is released for installation. Note that before each installation for a specific patient the LinkWatch system and the specific devices for that particular patient must be installed at a test bend and tested again together with PICASO system, to ensure that all components are working correct for that specific patient. This testing needs to be completed in the test environment. Testing has to be complete before code is released to the production system.

8.3.1 Code management

Given the nature of the small scale of the Picaso Project a manual code management process will be applied with version labelled directories being copied when agreed using the deployment management process. Manual copying of directories will provide the level of trust between partner and colleagues to ensure success.

8.3.2 Deployment Management

Given the nature of the small scale of the Picaso Project a manual coordinated agreement will be used with the authorisation and synchronisation being an email receipt. The process will be as follows: Manual stop of processes, followed by manual copying of directories and then manual start of processes.

When code and data need to be deployed, the partner will obtain email authorisation from the other partners with an agreed start time. The partners will then make the multiple changes to deploy code and data in a synchronised way. When each partner has completed their changes they will email the other partners stating the success or failure of their changes.

8.4 Concerns

8.4.1 Security and privacy of data during development

The objective of PICASO is to develop a solution which does not physically move clinical data outside of the hospitals' DMZs. Data will only be shared at runtime through PICASO and preferably not cached in the PICASO application.

Because the project involves some highly sensitive personal information, consideration needs to be paid to situations where that data is taken outside the clinical systems environments for development purposes and how that data is subsequently protected.

As stated in the Data Management Plans contained in Section 7.2.7, any data used for development purposes will need to be fully anonymised. Any data used during testing will need to be pseudonomised.

This will require the agreement of each hospital's data security officer. Without that, any development or testing using actual, sensitive patient data will need to be carried out within the hospital's DMZ on their own platforms.

8.4.2 Security and privacy during clinical trials

The public cloud solution will need to be compliant with each hospital's data security policies, since data will transit through this layer to get to the PICASO application hosted in each hospital's DMZ.

Lastly, the LinkWatch application and localised care solution operating at the patients' homes will inevitably hold sensitive patient data, such as device readings. These platforms will need to comply with the hospitals' data security policies.

8.4.3 Development environments usage

Each development partner in the consortium will have to decide on their use of a development environment and then communicate their requirements for a development environment to IBM and IN-JET so that the required Cloud or Hybrid Cloud can be provisioned to the partners' requirements.

9 Infrastructure view

9.1 Patient Private Cloud

The physical infrastructure in the patients' non-clinical environment includes:

- A set of medical and monitoring devices
- The LinkWatch Gateway running the LinkWatch software
    - PC, tablet, Smartphone
- A standard home broadband internet router with firewall

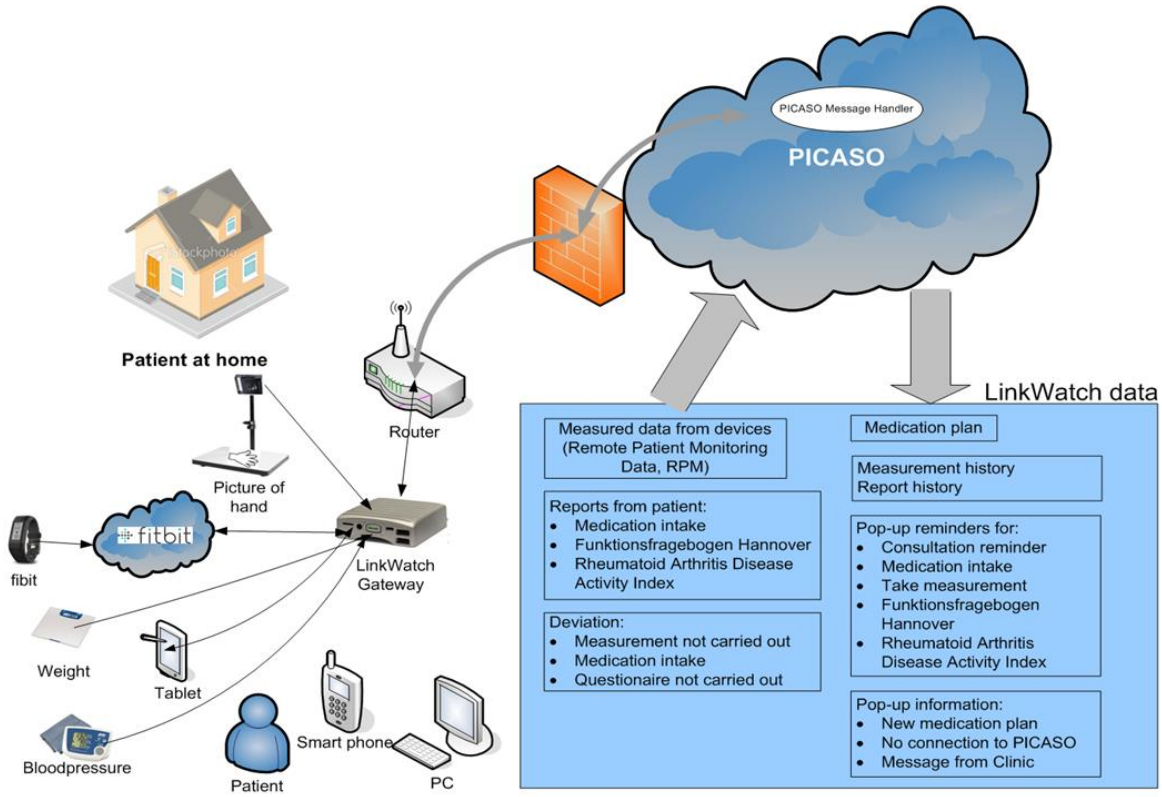


Figure 8 - Patient Private Cloud

When not at home or in transit, a patient may used

- medical devices/wearables, and
- a SmartPhone

to monitor values and interact with LinkWatch application.

The software infrastructure is that subset of PICASO components grouped in the LinkWatch Patient Remote Monitoring group (see Component diagram above). This includes an adaptation of the LinkWatch application with the necessary medical/sensor device driver protocols. The patient monitoring data is transferred to PICASO Care System private clouds following the IHE PCD01 standard. Depending on the actual deployment this message can be forwarded using a Web Service invocation, JSON RESTFUL call or as payload in a mqtt message.

For supported gateways and devices, see Appendix 1: Linkwatch Supported Devices.

9.2 Care System Private Cloud and PICASO Public Cloud

This care system private cloud effectively demarcates the hospital/clinical information systems at PICASO user sites, from the surrounding PICASO environment.

Strictly controlled clinical data is exposed to PICASO via interface ETL[4] modules which are used to extract, transform and load clinical data from the back-end HIS into the PICASO Clinical ODS (Operational Data Store).

The ODS is the only accessible clinical data source and sink for PICASO applications and is deployed isolated from all local clinical HIS, and behind the Care System Private Cloud firewall. Additional PICASO components deployed in this cloud sphere include Data Orchestration and the Activity Log

The Clinical ODS is updated with patient monitoring data from the from the LinkWatch application in the Patient Private Cloud.

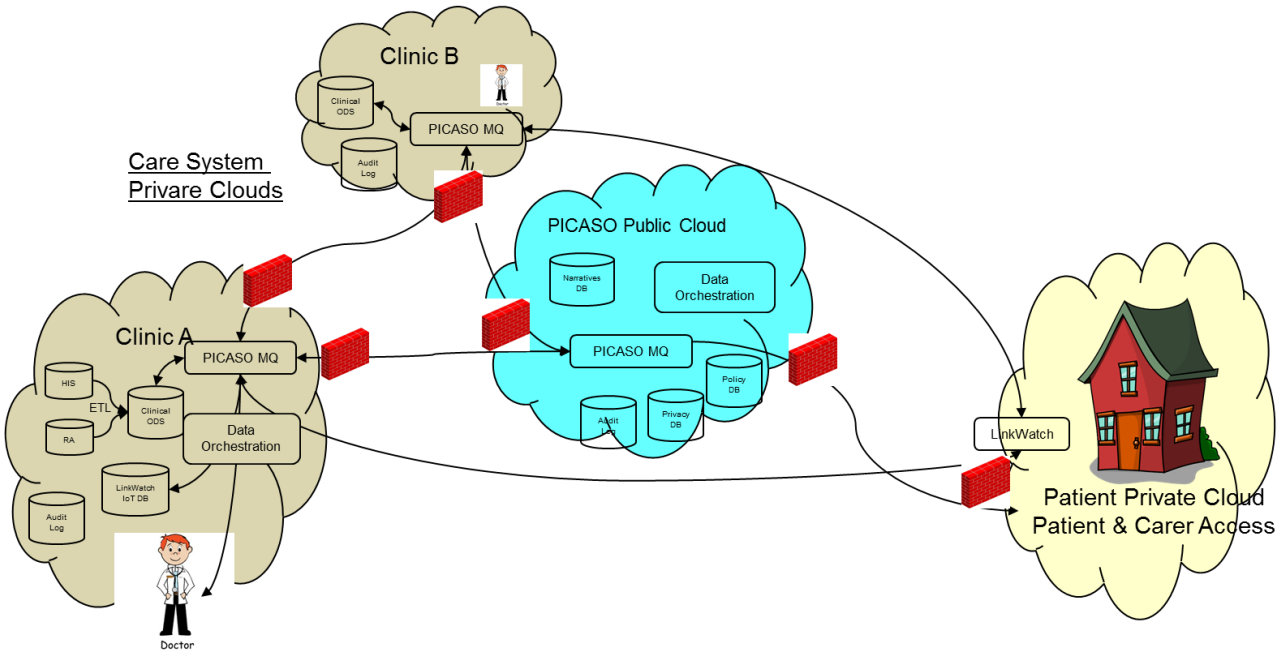


Figure 9: Example of deployment of PICASO components to the different cloud spheres (lines show principle data flows)

The public cloud infrastructure of PICASO is used to deploy the components that inter-connects the different cloud spheres into an integrated PICASO system.

Central components include the dictionary and look-up service for data distributed in the PICASO system, the Meta Data Registry. The message management in PICASO is based on the MQTT message broker principles, and is implemented the PICASO Message Handler component (PICASO MQ in the figure). **For** the initial PICASO trials, the technical infrastructure for the public cloud will be provided by partner IBM, including a standard solution for messaging (MQ).

[4] Extract Transform & Load

10 User Interaction View

In the User Interaction View the system is viewed as a part that represents the user interface and a part that contains the application logic, associated with the user interface (Avgeriou & Zdun, 2005). This section discusses the major concern related to this view and then provides some very first mock-ups of PICASO application components.

10.1 Interaction Concerns

Usability is a key aspect mostly to software and hardware systems in the eHealth domain. Usability is not only an important concern for the design of user interfaces, it is further directly linked to liability issues of a product. The European regulations are very strict especially for the devices that are consider as medical devices. The need to ensure that medical devices are designed, manufactured and also used in a way that does not lead to unnecessary risks to patients and users is not new. This need is addressed in a broad manner in the general Essential Requirements of medical device directives including: the Medical Devices Directive (MDD; 93/42/EEC), and In Vitro Diagnostic Medical Devices Directive (IVDD; 98/79/EC).

PICASO needs to follow well establish usability engineering methods and standards. ISO standard for usability (ISO 9241-11:1998) says that a product is usable if the people who are intended to use it can do so in a way that is effective for them, efficient in their terms, and satisfying them in terms of their own goals. ISO standard (ISO 9241-20:2008) simply defines accessibility as usability for a broader group of people – people with the widest range of capabilities. A more recent standard, ISO/IEC 40500:2012, provides a set of guidelines for accessibility coming from W3C Web Content Accessibility Guidelines (WCAG) 2.0.

For PICASO shall:

- Ensure the user-friendly design as well as accessibility in the design of the application.
- Ensure that its applications will be usable in everyday life of its users and support daily routines.
- Promote patient empowerment through effective user experience design allowing for patient control, participation and support.
- Ensure the quality of the outcome through usability tests.

10.2 Initial Mock-ups for PICASO Applications

This section presents the some initial mock-ups targeting at boosting the discussion on user requirements elicitations but also at ensuring common understanding of the vision of PICASO components and overall system.

10.2.1 Clinician Dashboard

The clinician dashboard will be a user interface for the doctor. It will consist of several configurable views, mainly presenting data relevant to the currently diagnosed patient.

Figure 10: Clinician Dashboard Mock-up

10.2.1.1 Risk Manager

The following screenshots display: some user interfaces of the risk manager. Figure 11 shows a possible standard patient data read which can be reviewed and adjusted by the clinician. Figure 12 shows a read of additional patient data which can be used for obtaining personalized risk scores (experimental). Figure 13 shows a possible output providing a comparison of the risk predicted based on the standard data read (traditional clinical risk) in comparison with the experimental score (integrated genetic risk).

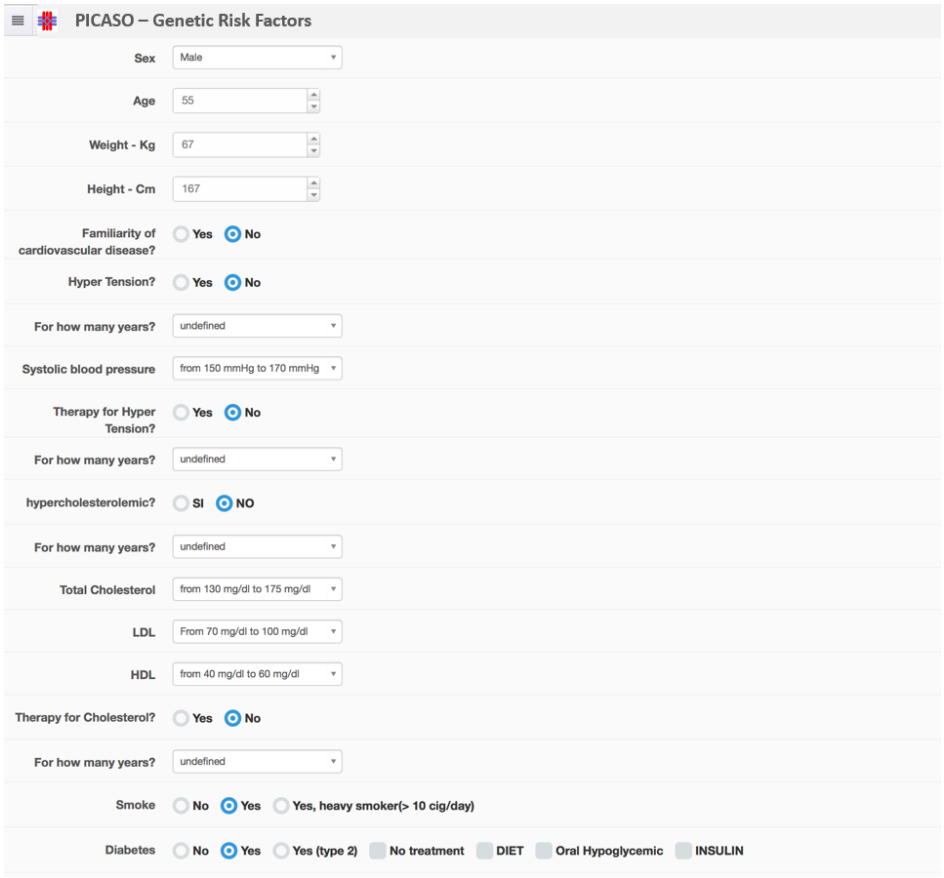


Figure 11: Risk Manager - Review/Adjust patient data read (for standard risk assessment)

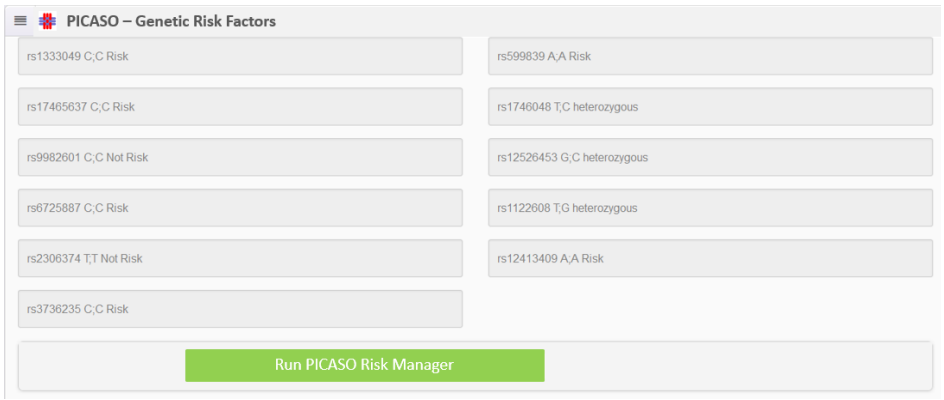


Figure 12: Risk Manager - Review/Intake of additional patient data for personalized risk assessment (here polymorphism)

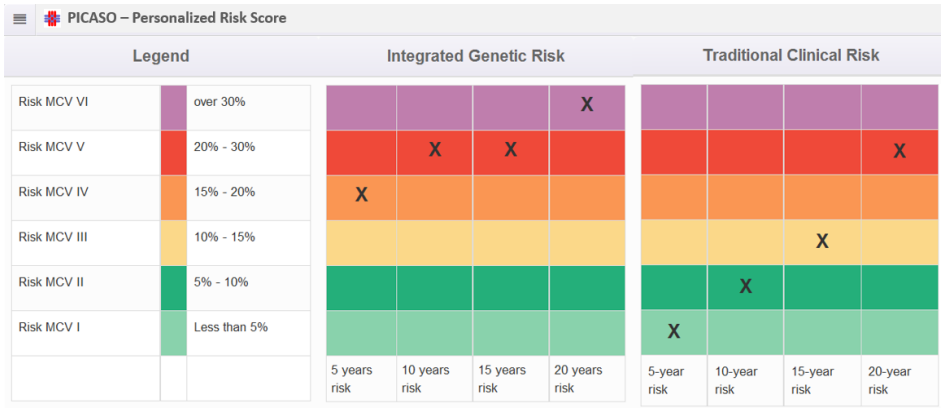


Figure 13: Risk Manager Output

10.2.1.2 Data Resource Browser

The Data Resource Browser will be an interactive visualization tool for browsing the PICASO shared data space. In the mock-up below, the clinician can search for a Patient, a care plan of any other type of primary information available in the shared data space. When this is found, a predefined related list of categories will appear around it allowing the clinician to have all information she needs in a structured way. Key aspect on the design of this browser will be the PICASO role based authorization and consent mechanism.

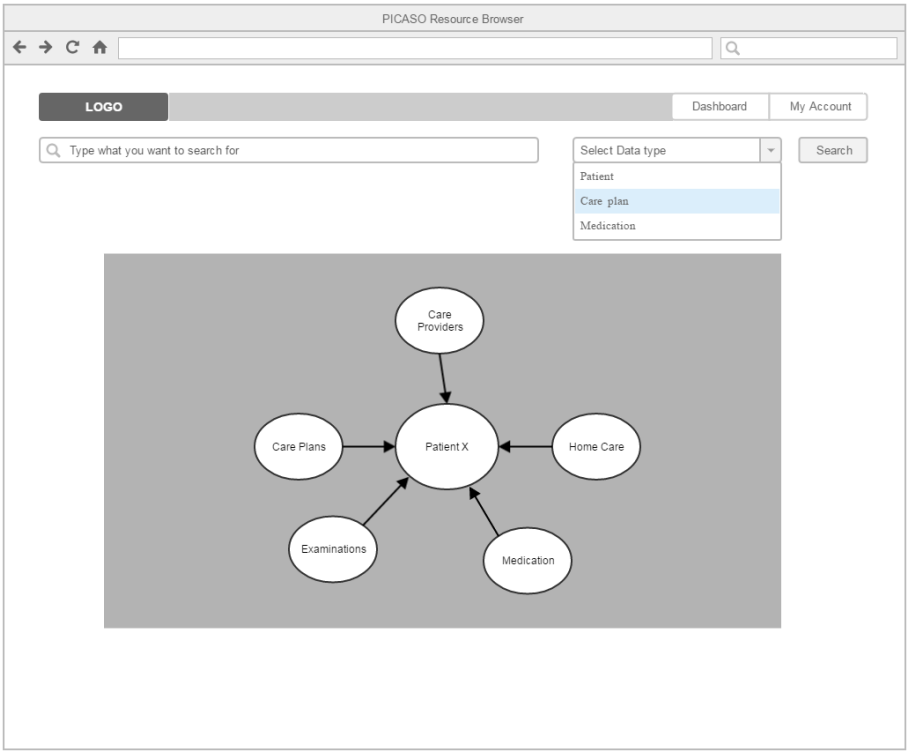


Figure 14: Data Resource Manager – Screen for searching data.

10.2.2 Care Management and Design tools

10.2.2.1 Narratives Manager

The Narrative Manager will consist of two sub design tools: The Narratives Template Designer (Figure 15: Narratives Manager: Create a new narrative template for an existing clinical guideline) and Patient Pathway

designer (Figure 16: Narratives Manager: Work an existing Patient pathway, based on an appropriate narrative template).

The Narrative Template Designer will allow a user to develop a template for a clinical guideline (e.g. for a specific treatment). This can be done for example graphically using existing services from the service catalogue and BPMN flow components.

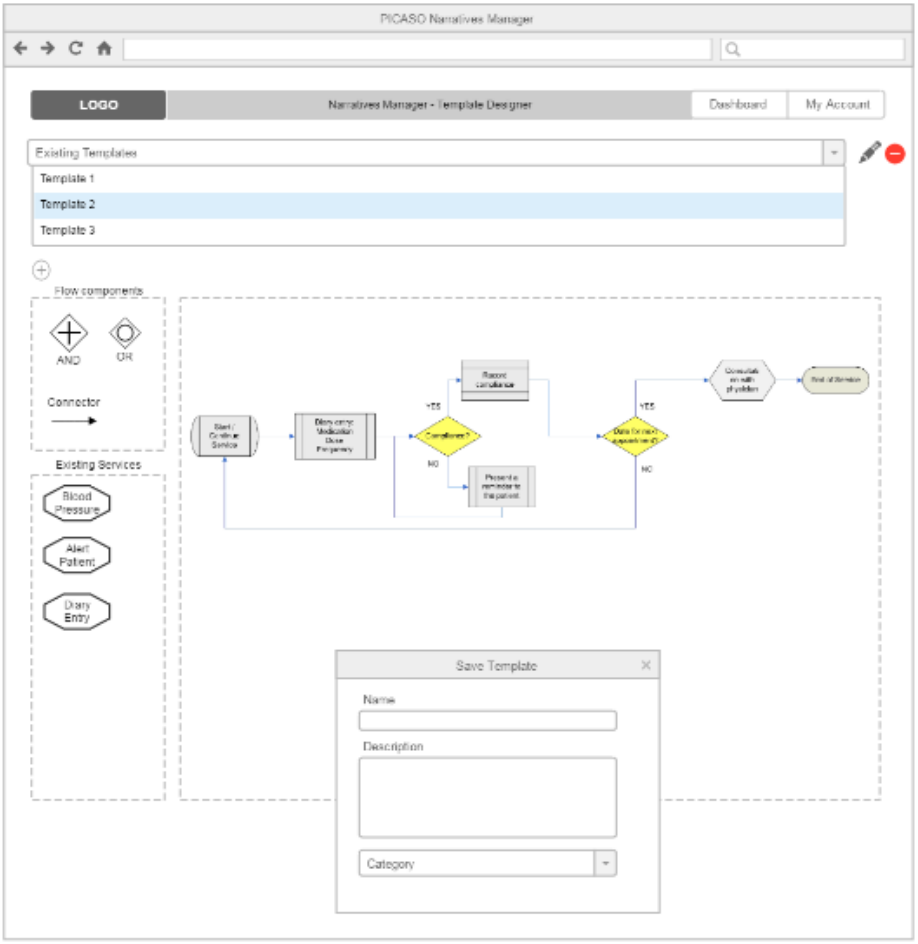


Figure 15: Narratives Manager: Create a new narrative template for an existing clinical guideline

The Patient Pathway designer will then instantiate an existing template and allow a clinician to specify a number of parameters for the specific situation of a patient. The clinician with the patient can also define with whom this information will be shared and what kind of alerts she will get.

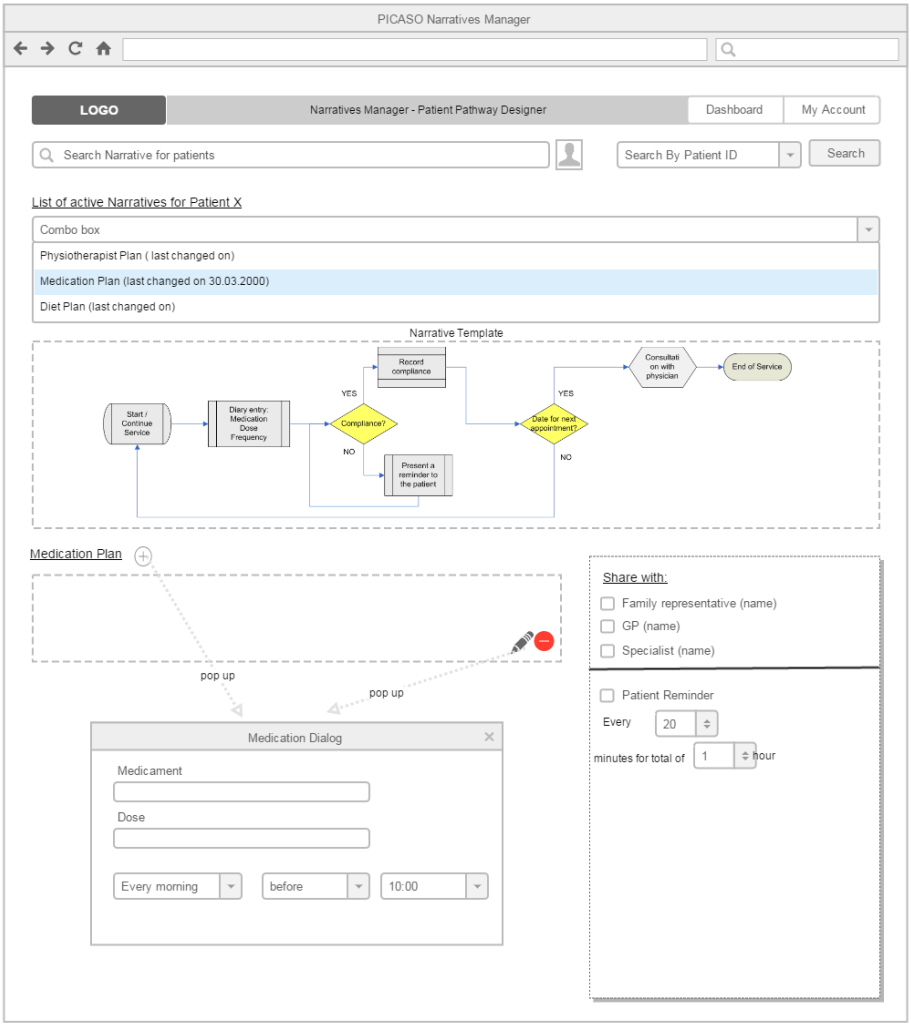


Figure 16: Narratives Manager: Work an existing Patient pathway, based on an appropriate narrative template

10.2.2.2 Narratives Services Designer

With this tool an IT staff in a clinic will be able to define new services that can be used by the Narratives Manager above. Doing this a user need both to implement an API (Figure 18) and then register this to the service catalogues by providing appropriate metadata (Figure 17).

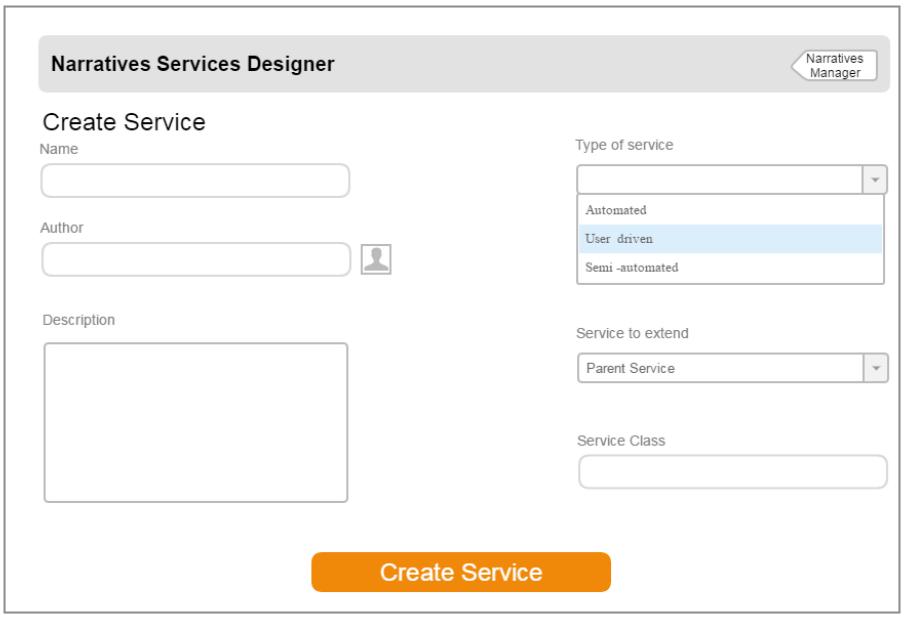


Figure 17 : Narratives Sercvices Designer: Service Description and Registry

```
public class HelloWorldService extends Service {
    public HelloWorldService() {
    }
```

Figure 18 Narratives Sercvices Designer: Service Implementation

10.2.2.3 Goal Optimizer

Goal optimiser is a special view for the Narrative Manager, where user can check the currently designed narrative for conflicts with other existing narratives. The result will be clearly displayed to the user.

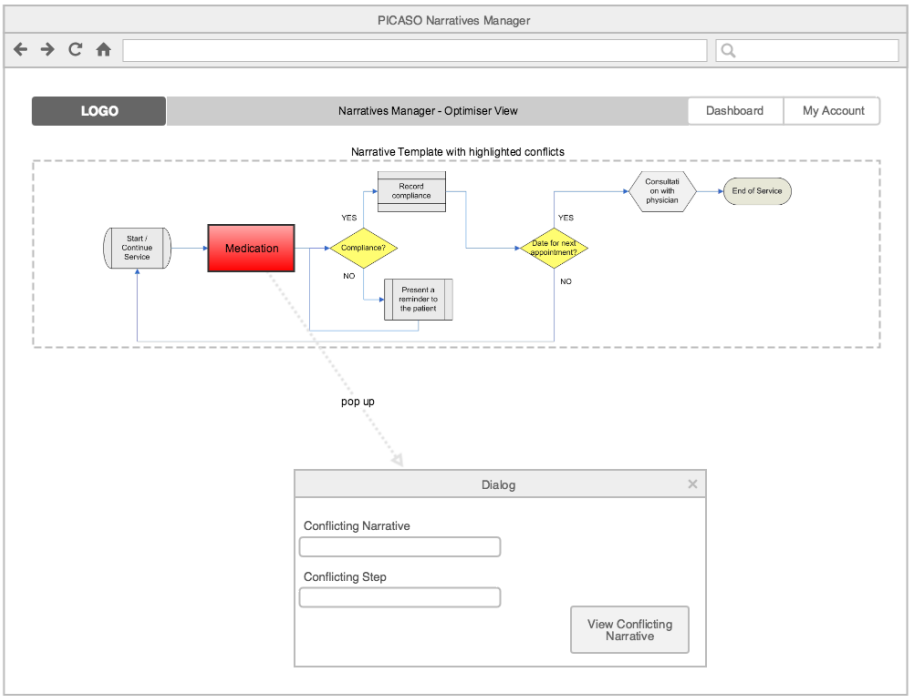


Figure 19: PICASO Goal optimizer

10.2.3 Patient Dashboard

The Patient Dashboard is the user main interface to the PICASO (LinkWatch) home monitoring application. The interface is provided in several languages, for PICASO trials this will be German, Italian and English.

The figures below shows (German) examples of Dashboard screens as displayed on a PC or tablet device.

Figure 20: Welcome screen

Summaries of monitored values are presented per type of signs depending on the current set of monitoring devices available to the patient. The sensing of values can be combined with manual entries (if required).

Figure 21: Summary of measurements from the monitoring devices

Monitored values can be combined to show variations over time. Alternative presentation styles (such as tables or graph) depending observation type and display device.

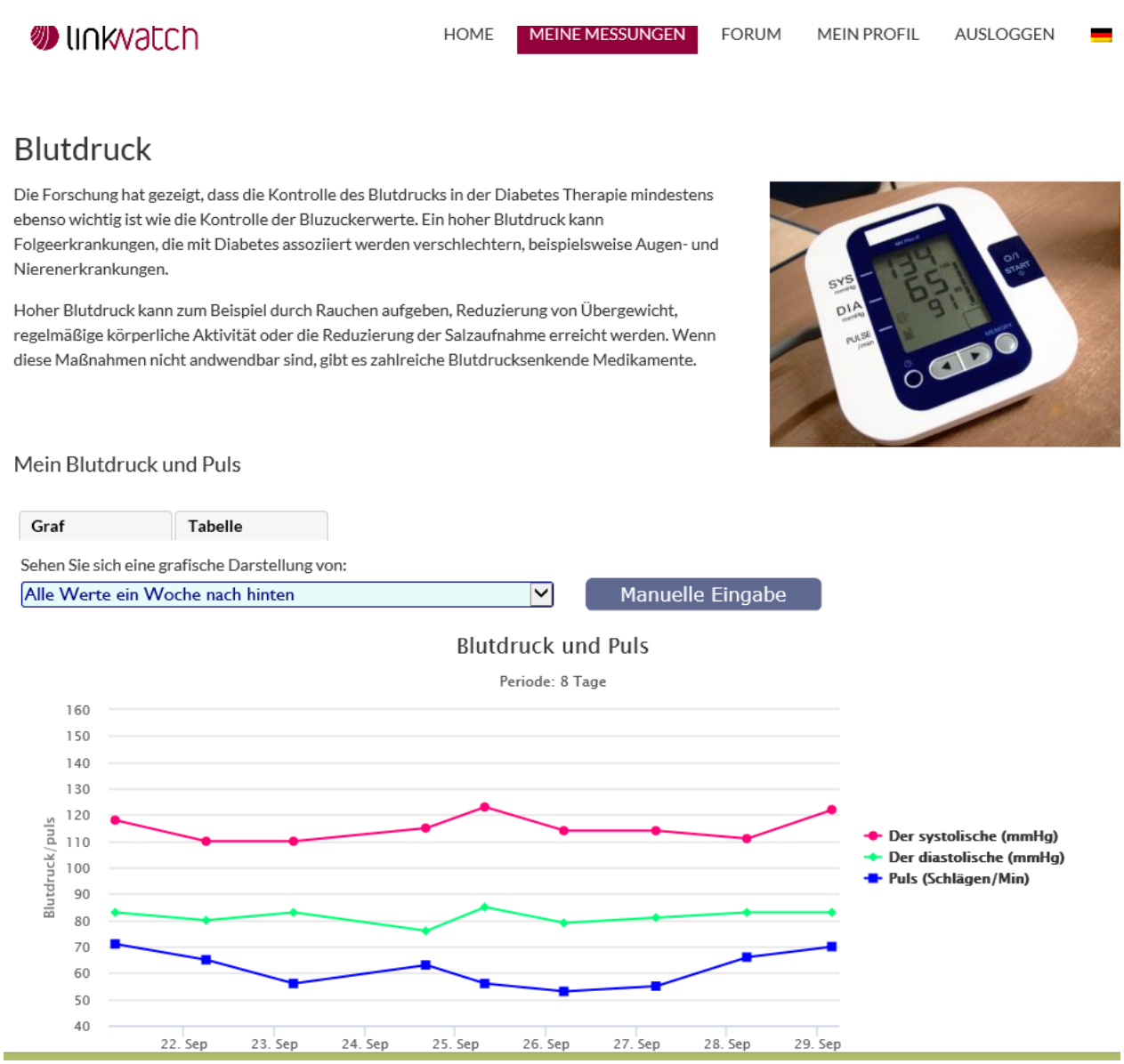


Figure 22: A detailed overview of combined measurements

11 List of Figures and Tables

11.1 Figures

11.2 Tables

12 References

(IEEE1471, 2000) IEEE Standard 1471-2000 (2000). IEEE Recommended Practice for Architectural Description of Software-Intensive Systems

(IEEE 42010, 2011) Standard ISO/IEC/IEEE 42010:2011. IEEE Systems and software engineering - Architecture description

(Rozanski & Woods, 2005) Rozanski, N., Woods, E. (2005), “Software Systems Architecture”, ISBN: 0321112296

(WONCA, 2011) http://www.woncaeurope.org/sites/default/files/documents/Definition%203rd%20ed%202011%20with%20revised%20wonca%20tree.pdf, World Organization of Family Doctors. 2011. Retrieved 09 August 2016.

(Avgeriou & Zdun, 2005) P. Avgeriou, U. Zdun, Architectural Patterns Revisited – A Pattern Language, the European Pattern Languages of Programming (EuroPLOP) 6–10 July 2005, Irsee, Germany..

Appendix 1: Linkwatch Supported Devices

Picaso

Four Hardware Platforms for Patient Gateway

- "Kiosk" style monitor with 20" Touch screen
  - Users: Frail patients with little or no ICT skills
  - Features: Touch screen, video and audio capabilities
  - Pro/con: Easy to use, powerful, rich features, relatively expensive

- "Laptop" style gateway on legacy equipment
  - Users: Patients with full ICT skills and own equipment
  - Features: Installs LinkWatch on the patients own equiment w PAN/LAN
  - Pro/Con: Low cost, not so easy to install, risk of platform related problems

- "Compute Stick" style gateway with build in Wifi webserver
  - Users: Patients with some ICT skills
  - Features: Embedded in home, plugs in TV, mobility at home, audio capability
  - Pro/con: Lower cost, easy to install, easy to operate, rich features.

- Mobile gateway for mobility (Android and iPhone)
  - Users: Patients with active work life and need for always-on feature
  - Features: Lightweight portable gateway on extisting smart phones
  - Pro/Con: Low cost, easy to install