Deliverable D1.1 R1

Technical Requirements and Architecture Report including Open Call Requirements

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Abstract

D1.1 R1 discusses the following achievements during M1-6: Specification of usage-specific requirements: use case scenario and experimentation site requirements, specification of technical solution-oriented requirements: solution deployment and non-functional requirements (including security and privacy requirements and previews on legislation, privacy, standards, and certification requirements), generic requirements that can be implemented through Generic Enablers: exemplary application architecture, initial FI-STAR platform architecture with consumer and provider edges, and status on selection and usage of FI-PPP Phase 1 Generic Enablers technology, completion of project scope: open call requirements, roll-out of FI-STAR technology: stakeholder board and open community.

Disclaimer

Impressum

Title: Future Internet Social and Technological Alignment Research

Acronym: FI-STAR

Work Package 1, Requirements Specification

Deliverable D1.1 R1 Technical Requirements and Architecture Report including Open Call Requirements

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Executive summary

FI-STAR innovates by evaluating and aligning FI-PPP technology with the needs and demands from the healthcare sector. To achieve such innovation FI-STAR needs to capitalize on existing Future Internet (FI) and domain specific knowledge and ensure shared values and subsequently optimal knowledge transfer and between technologists and the social environment. For reaching these goals, the deliverable D1.1 R1 reports of the following results that have been achieved during M1-6:

- Section I - specification of usage-specific requirements: use case scenario and experimentation site requirements. It describes seven FI-STAR solution with vision, stakeholders, value case, intended features for the seven FI-STAR experimentation sites.
- Section II - specification of technical solution-oriented requirements: solution deployment and non-functional requirements (including deployment, security, privacy requirements and previews on legislation, privacy, standards, and certification requirements).
- Section III - generic requirements that can be implemented through Generic Enablers: exemplary application architecture, initial FI-STAR platform architecture with consumer and provider edges, and status on selection and usage of FI-PPP Phase 1 Generic Enablers technology in Section III.
- Section IV - completion of project scope: open call requirements.
- Section V - roll-out of FI-STAR technology: stakeholder board and open community.

The deliverable is presented as a compilation of reports that have been produced for specific requirements engineering and architecture design objectives by the respective task forces.

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Glossary

Alert	It is a special type of notification. Alerts are generated based on event/rules processing.
Assessment questionnaire	It is a special type of questionnaire. This type of questionnaire aims at assessing the level of understating of the user. It includes a set of questions and each question has associated a set of potential answers where one or several of them are the right ones and the others are wrong. The expected input is the selection of the right answer(s).
Borg RPE Scale	Measures perceived exertion. In medicine this is used to document the patient's exertion during a test.It is especially used in clinical diagnosis of breathlessness and dyspnoea, chest pain, angina and muscular-skeletal pain.
Business Service Authority	NHS agency previously known as Prescription Pricing authority, responsible development and dissemination of the Drugs Tariff and reconciliation of all prescriptions dispensed.
Cardiac fitness	The ability of the heart and lungs to supply oxygen-rich blood to the working muscle tissues and the ability of the muscles to use oxygen to produce energy for movement.[1] This type of fitness is a health-related component of physical fitness that is brought about by sustained physical activity.[2]A person's ability to deliver oxygen to the working muscles is affected by many physiological parameters, including heart rate, stroke volume, cardiac output, and maximal oxygen consumption.
Cardiac Stress test	Test used in medicine and cardiology to measure the heart's ability to respond to external stress in a controlled clinical environment. It compares the coronary circulation while the patient is at rest with the same patient's circulation observed during maximum physical exertion, showing any abnormal blood flow to the heart's muscle tissue (the myocardium).
Condition (patient)	an overall state of patient with regard to his/her objective and subjective status.
Consultation (remote)	typically scheduled, remote audio-video meeting with a member of a hospital medical personnel, in order to seek advice, summarise period of a treatment, provide recommendation and share personal condition.
Data carrier	A means to represent data in a machine-readable form; used to enable automatic reading of data (element string) held within the carrier.
Data Matrix	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix ISO version ECC 200 is the only version that supports GS1 System identification numbers, including function 1 character. Data Matrix Symbols are read by two-dimensional imaging scanners or vision systems.
Global Trade Item Number (GTIN)®	The GS1 Identification Key for any pre-defined product or service that may be priced, ordered or invoiced at any point in the supply chain.
GS1 Check	The GS1 Identification Key for any pre-defined product or service that may be

Digit Calculation	priced, ordered or invoiced at any point in the supply chain.
GS1 Company Prefix	Part of the GS1 System identification number consisting of a GS1 Prefix and a Company Number, both of which are allocated by GS1 Member Organisation.
GS1 General Specifications	Defines the GS1 System data and application standards related to the marking and automatic identification of trade items, locations, logistic units, assets, and more using bar codes, RFID, and GS1 Identification Keys.
Human Readable	Characters that can be read by persons, such as letters and numbers, as opposed to symbol characters within bar code symbols, which are read by machines.
Identification Key	A numeric or alphanumeric character string to ensure the global, unambiguous uniqueness of the identifier in the open demand or supply chain.
Monitoring questionnaire	It is a special type of questionnaire. This type of questionnaire aims at collecting relevant parameters and information about the patient. It includes a set of parameters and/or questions. that could have or not associated a set of potential answers. In this case there are not right or wrong answers. The expected inputs can vary and could be a numeric value, text, a predefined answer, a picture.
Objective data or measurement	actual data/measurements obtained from biometric devices connected to TeleCare solution, not influenced by patient personal feelings or opinion in considering and representing his/her real condition (e.g. blood pressure, oxygen saturation, pulse rate)
Observation	Data item representing any patient biometric or external parameter important for diabetes treatment. Including but not limited to: blood glucose, insulin dosage, physical activity, carbohydrate intake, perceived stress level, sleep patterns, and notes.
OSAREAN	OSAREAN is the in place OSAKIDETZA's Multi-channel service platform. The proposed BPTM solution will interoperate with the OSAREAN Platform by exchanging relevant information. Some features will be supported by the OSAREAN platform. The OSAREAN platform includes both the CRM and PHR.
Parameter	It is a special type of questionnaire item. Parameter will have associated a numeric value, unit and value range.
PIP Codes	The PIP code is a unique coding system designed to allow the identification and efficient ordering of products supplied by UK pharmacies. It is used by the majority of UK pharmacies through their dispensary systems
Question	It is a special type of questionnaire item. Question could have or not associated a set of potential answers. In this case there are not right or wrong answers. The expected inputs can vary and could be text, a predefined answer, a picture.
Rehabilitation session (remote)	typically scheduled, remote audio-video session enabling physiotherapist to supervise rehabilitation process (of improving lungs efficiency) of patients discharged from a hospital, before thoracosurgical procedure.
Reminder	It is a special type of notification. Reminders are scheduled.

Scanner	An electronic device to read bar code symbols and convert them into electrical signals understandable by a computer device.
Sensor	a biometric device enabling objective measurement of the particular patient vital sign or condition indicator, connected to the TeleCare solution
Serial Number	(1) A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number. (2) Specific instance of the Object Class being tagged.
Subjective data	data about patients' perceived condition based on, or influenced by personal feelings and opinions (e.g. levels and nausea, level of fatigue).
Supplier	The party that produces, provides or furnishes an item or service
TeleCare	The FI-STAR solution for cancer rehabilitation enabling video consultations, supervising of remote rehabilitation sessions and gathering objective and subjective data about patient physiological and psychological condition.
Thoraco (thorax)	prefix meaning "the chest"; referring to the patient chest

Abbreviations

6MWT	Six-Minute Walk Test tests of functional exercise capacity and physical fitness. It is easy to administer, better tolerated, and more reflective of activities of daily living than other walking tests. This test measures the distance that a patient can walk quickly on a flat, hard surface in a period of 6 minutes (the 6MWD).
AIDC	Automatic Identification and Data Capture
API	Application Programming Interface
App	Application (software)
BAEH	Bagdasar Arseni Emergency Hospital
BNP	Brain Natriuretic Peptide secreted by the ventricles of the heart in response to excessive stretching of heart muscle cells.
BP	Blood pressure
BPM	Heart beats per minute
BPTM	The Bipolar Patient Treatment Manager is the FI STAR proposed solution to support telecare of mental disorders.
BT	Body temperature
ChemoDiary	Chemotherapy patient digital diary, TeleCare functionality (available also for cancer rehabilitation patients)
CR	Cardiac Rehabilitation
CRM	The Customer Relationship Management system manages the workflows to handle alerts and provides access to the electronic health record EHR. It is part of the OSAREAN platform that can be only accessible by authorised clinical personnel.
CRP	The FI-STAR solution for cardiac rehabilitation program.
CV	Cardio-vascular
D1.1	Deliverable D1.1
dm+d	Dictionary of Medicines and Devices
DoW	Description of Work
ECG	Electrocardiogram
EHR	Electronic Health Record. It includes all the clinically relevant information related to the patient/citizen and it is accessible by clinicians.
EI	External interface

FBB	Functional building block
FI	Future Internet
GE	Generic Enabler
GTIN	Global Trade Item Number
HR	Heart Rate
HIS	Hospital Information Systems; legacy IT systems
HW	Hardware
IF	Information flow
ISP	Internet Service Provider
ITTI	FI-STAR project member; main developer of the TeleCare solution
JP2	John Paul II Hospital in Krakow; FI-STAR project member; beneficiary of the TeleCare solution
NPA	National Pharmacy Association
MHRA	Medicines and Healthcare products Regulatory Agency (NHS)
NPSA	National Patient Safety Agency (NHS)
OSB	Osakidetza Service Bus (Oracle Service Bus).
PASA	Purchasing and Supply Agency (NHS)
PHR	The Personal Health Record includes a sub set of the information included in the Electronic Health Record that can be accessible by all the citizens. The PHR allows bidirectional information exchange and allows citizens to include information that could be included in the EHR. It is part of the OSAREAN Platform that can be accessed by citizens that possess a digital identity access.
PM	Person Months
PR	Pulse rate
PSA/SPN	Patient Safety Alert and Safer Practice Notice
RehCal	Rehabilitation Calendar (TeleCare functionality, entity)
RFID	Radio Frequency Identification
RPE	Rate of perceived effort
RSC	Romanian Society of Cardiology
SE	Specific Enabler

SpO2	Arterial oxyhemoglobin saturation. Oxygen saturation levels in blood.
T	Task
TC	TeleCare
UMFCD	University of Medicine and Pharmacy Carol Davila Bucharest
UC	Only in application design section: Use case (of information flow)
US	Only in application design section: User story
VO2 max	The maximum capacity of an individual's body to transport and use oxygen during incremental exercise, which reflects the physical fitness of the individual
WP	Work Package
GUI	Graphical User Interface

1 Introduction to FI-STAR Deliverable D1.1 Requirements Specification

Growing attention has been given to requirements analysis as part of development processes in almost all industrial domains over recent years. Strong evidence suggests that Requirements Engineering processes are likely to increase the effectiveness and efficiency of (product) development processes. On a more simplistic level it is crowd knowledge that carefully prepared approaches are likely to save time and money. There can be no surprise that already in the announcement of the call for proposals for FI-PPP phase II projects the relevance of a proper requirements analysis as integral part of the work-plan was highlighted.

With this in mind and in accordance with the guidance provided by the European Commission at information days and in the call text FI-STAR has been designed around a conceptually sound and professionally conducted requirements analysis.

1.1 Specifications of deliverable D 1.1

D 1.1 was completed by the end of month 6 while the actual delivery date was projected for end of months 3. The delays were caused through a variety of administrative delays and the late signing of the contract. However, it came naturally that authors made use of the progressed knowledge so that D 1.1 inevitably includes knowledge and facts, which were available to the authors and editors well beyond M3.

The deliverable D 1.1 is based on information retrieved from the outcomes of tasks T1.1, T1.2, T1.3, T1.4 und T1.6. The scope and content of D1.1 is following the subject heading the relevant section in the Description of Work.

Other important specification requirements for D1.1 result from the FI-STAR aims and objectives and the corresponding outcomes, which have been collected and analyzed.

Task 1.5 has slightly changed focus as it became clear that a strong legal input is required to oversee legal frameworks on European and national level. This has proven to be crucial in order to develop the architectural concept of FI-STAR. The internal contractual matters of FI-STAR parties seem less relevant as it would be regarded crucial for any party, which would enter the commercialization phase to establish a stable contractual base in their own responsibility.

1.2 Requirements Engineering Challenges

Approaching the challenge of a comprehensive requirements analysis for a variety of use cases and implementation and instantiation of Generic Enablers in the health domain it might not surprise that we soon came across complexities caused by the dichotomy of object and project specifications. On the one hand technical requirements are clearly at the very heart of any technological development process. Objects and processes are typically defined through their specifications, which need to be captured, mapped analysed and to be defined so that it can be shared and used by interested parties. Certainly, there will always be an argument regarding the question if the outcome of a Requirements analysis will ever be “complete” as the analysis depends on the available sources and the level of information the source is prepared to share. Also the analysis depends on the scope, which was set prior to the process with only limited knowledge of the revelations during the process. Therefore the requirements analysis has to allow for certain flexible changes depending on the developments during the process.

Requirements engineering clearly offers the skillset and the tools to do so. Processes can be explored by using sophisticated approaches involving, interviews, workshops, and other strategies. Questioners, recordings of interviews, pictures and video-images are well established tools which may be used to capture the scenes in order to proceed to a mapping of processes. Diagrams based on standardized approaches such as UML have been used under FI-STAR WP1 D 1.1 to

assess the use cases and to specify the requirements in a way that the information is readily available to the technical team.

However, it became evident pretty soon, that a sole focus on technicalities would distort the view of the technicians and could have led to a false interpretation of the actual needs and demands of the users. Sitting well with Tom Peter's theorem "soft is hard and hard is soft" it became clear that Requirements Engineering in healthcare has to go the extra mile to also capture crucial social dimensions which are likely to be overseen when using standard Requirements Engineering approaches. An experience from the Requirements Engineering process in FI-STAR is clearly that a purely technical approach by capturing data through distributing questioners and asking for local IT system specifications is doomed to fail and cannot be successful. Another important experience from the work on the requirements analysis under FI-STAR is clearly that the process of Requirements Engineering in human-technological hybrid systems is challenging for both, those who assess the system (researchers) and those who are part of the system under observation. The main challenges to the current FI-STAR requirement engineering process were identified as:

1.2.1 The "naivety" of the observer

Technologists seem to tend to idealize clinical approaches but underestimate the relevance of ethical/legal requirements. During the workshops and several project meetings we could observe that the ideas of local IT staff and managers in terms of privacy and trust differs significantly from the view point of FI-STAR engineers and researchers. One concrete example was the among technologists wide spread believe, that practitioners knew their IT system, its specifications and that healthcare IT systems would be more or less readily accessible if agreed by the clinicians. In reality clinicians have only limited say if it comes to access to the organizations IT system. While researchers were assuming that personal information could be easily accessed (for experimental purposes within FI-STAR), local managers rejected the idea of allowing direct access to the most secure data base which is commonly referred to as "Hot Zone" straight away and all together. Technologists struggle to accept the fact that health policies supersede technical knowledge. On the other hand we found that technologists sometimes overestimate the relevance of medical data or the accuracy of measurements in the context of the task at hand due to lack of understanding of physiology, biochemistry and medical processes. Typically an important part of requirements engineering is to develop a rough and high level understanding of the "hard" but also the "soft" factors of the process in question, whereby hard factors need to be understood as the measurable and visible elements which can be monitored, quantified and mapped and the soft factors as those elements determining the communication among staff, hidden agendas associated with the process (local variation, financial and political objectives) and hierarchical models.

1.2.2 The limitations of IT knowledge of medical professionals and patients

Medical professionals but also managers typically lack technical expertise and detailed knowledge about software and hardware of computers, network technologies and – the internet. Only very few people in medical organizations have detailed and comprehensive knowledge about the specifications of the organization's IT system. As an additional layer of complexity the detailed specifications of the Generic Enablers were not available by the time of the assessment. Therefore the requirements analysis had to be very broad but nevertheless had to go into relative detail to cover all potential requirements.

There was a strong feeling that it had been much easier to establish a requirements analysis based on the relevant facts, namely the needs and demands of the users and the requirements of prospective GEs.

Overall even for very experienced Requirements Engineers it proved to be a rather difficult and a more time consuming undertaking than expected to deal with all these uncertainties in a manner which still allows for a scientifically reasonable and stable outcome.

1.2.3 The Babel Phenomenon

Different stakeholders speak different languages (Social scientists, medical professionals, patients, Engineers, lawyers, managers). A reoccurring patter all through the assessment process was the problem of a shared language to ensure that there was an equal, multilateral understanding of the processes under discussion in the local sessions and the activities of the various bodies within FI-STAR. A virtual "ontology" could be build through the first 6 months of FI-STAR which still needs extension and improvement which will be an ongoing process all through the project. Therefore one of the achievements of T1.1 is clearly the establishment of awareness on all sides and the creation of a "ontology" which will be of use for the upcoming work in FI-STAR and FI-PPP phase III.

1.2.4 The "Problem of Observation"

The so called "problem of observation" is a classical dilemma in scientific observational processes from social science to Quantum Physics. By observing a system – especially by observing human or human-machine hybrid systems and in particular where the observation is evident to the system, effects analogue to quantum effects occur meaning that outcomes are already altered by the fact that the system is under observation (Schroedinger's Cat). It is important to understand that by conducting a Requirements Engineering process, especially in medical scenarios we alter the practice of professionals and their approach. In order to project the experience gained in the 7 FI-STAR use case scenarios onto future implementation and instantiation scenarios this effect has to be taken into consideration. It cannot be assumed that a proper Requirements Engineering process can be replaced by simply providing access to the documentation produced as part of FI-STAR D 1.1. The process of Requirements Engineering is not only informative but it creates changes in human-machine legacy systems, such as:

- Awareness ("A significant barrier lies in the lack of awareness of e-health opportunities and challenges for users (citizens, patients, health and social care professionals" [1])
- Enlightenment (better understanding of IT processes)
- Acceptance (reduction of the reluctance to change)
- Ownership (Important driver towards innovation)
- Capacity building (Building capacity in health care organizations among staff and subsequently in the community they serve)

All of these effects provoked by Requirements Engineering facilitates uptake and ensures wider deployment of e-health solutions and will ultimately lead to wider interoperability of e-health services in health care providing organizations on national and international level, which are important operational objectives of the European Commission's E-Health Action Plan 2012-2020 – Innovative healthcare for the 21st century [2].

1.2.5 Controversy

Researchers of different specialties do have different understandings regarding technical-social hybrid models and struggle to communicate with each other due to semantic incompatibilities despite a shared set of "values". This causes frustration and following the frustration – aggression model, tensions among the researchers [3]. The resulting debates do as such not display a problem due to a set of shared values – i.e. a common understanding on how the controversy can be resolved in a constructive manner. However these discussions require time, which is limited due to the projected duration of FI-STAR of only 24 months (with a projected 3 months extension)

1.2.6 Confounding

Answers depend on the questions – and whom you ask. The configuration of members of the workshop, which is typically controlled by the use case scenarios are likely to trigger distortion and outcomes of requirements analysis might be hampered by the fact who participates in the Requirements engineering workshop sessions, whereby the configuration of the workshop then would be the "confounder". During the Requirements Engineering leading to D 1.1 we could

observe and based on our experience correct unbalanced workshops by proposing extensions to the list of attendees. In some cases it seemed necessary to balance a lack of clinical input and in other scenarios we observed and corrected a lack in representation of IT experts. However, it seems noteworthy that imbalanced Requirements Engineering workshops may distort the analysis whereby the imbalanced configuration of the workshop would be the confounding factor.

1.3 Requirements Engineering under FI-STAR

The requirements specification approach under FI-STAR WP1 Task 1.1 chose a comprehensive approach, which was considering not only technical requirements but all the relevant factors in organizations as identified by Peters and Waterman in the 7s McKinsey Model [4]. This was regarded as mandatory to define the specifications of highly complex social-technological hybrid models. During the assessment it has become entirely clear that the highly sophisticated interdependencies between technologies, professionals and patients could have never been described sufficiently and comprehensive by using questioners or other observational techniques only. By de facto considering the 7s model processes and their interactive dynamics could be established as integrated models describing the social technological interface and focusing on the alignment of technological and social dynamics. This clearly contributes to the reliability of the specifications and is likely to reduce the complexities associated with upcoming implementation and instantiations. The integrative, multidimensional approach was realized in form of “vision documents” which were designed for each of the seven use case scenarios. In addition questioners were used to provide a maximum of technical information on the existing specifications of the local infrastructure.

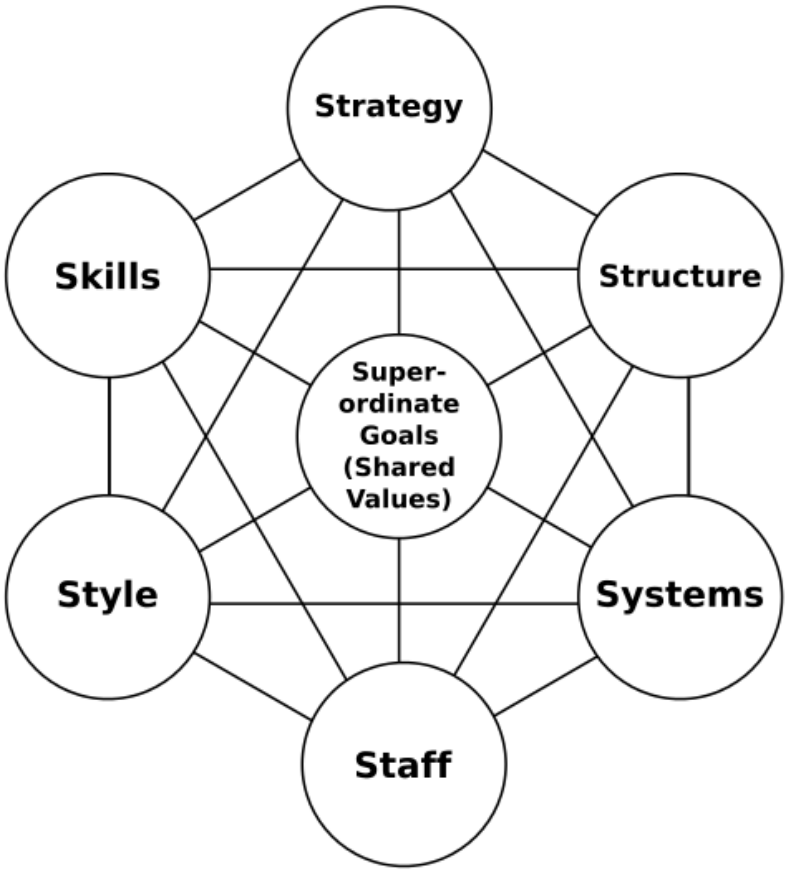


Figure 1: The 7S McKinsey Model (Peters, Waterman)

1.3.1 Extent of Requirements Engineering in FI-STAR Compared to Industrial Standards

FI-STAR stretches over a total of 1423.13 Person Months (PM). WP1, “Requirements Specification” counts a total of 201.68 PMs, occupying 14.2 % of the overall project effort. This is significantly below the average industrial effort spent on Requirements Analysis in commercial projects, which is typically more than 20%. It remains to be seen how the Requirements Analysis as integral part of FI-STAR will differ from industrial processes and what scientific prepositions might result from findings under FI-STAR with view towards new techniques. FI-STAR might come up with proposals for altered approaches and methodologies, which might save money in industrial, domain specific processes in the future. On the other hand industrial approaches seem to be more flexible than funded research as they allow for an extension of the allocated budget if this was regarded as necessary. Contrary to the relatively fuzzy information on external factors such as Generic Enablers and their specifications under FI-STAR in industrial set ups external factors are typically well defined to ensure effective financial monitoring and reliable outcomes.

1.3.2 FI-STAR Requirements Engineering: The Core Team

The Technical Requirements Analysis team has been led by a professional Requirements Engineer, Dr. Samuel A. Fricker who is based at Blekinge Institute of Technology, one of the leading institutions in the field in Europe. Dr. Fricker has extensive industrial experience and is we regarded on a global scale. He was supported by Professor Markus Fiedler, a senior Requirements Engineer, also based at BTH, Sweden, and by Niklas Andersson from Nasjonalt senter for samhandling og telemedisin in Norway.

Technical support with regards to Interactive Design has been provided by Professor David Benyon, an international regarded expert and Dr. Oli Mival from Edinburgh Napier University.

Security issues as far as they are part of the scope of FI-STAR which is exclusively state of the art of security rather than a mandate to develop new security technologies are covered by Professor Bill Buchanan an internationally regarded security expert and Dr. Elias Economou, both from Edinburgh Napier University.

Dr. Ing. Armin Schneider from Technical University Munich, Mr. Thomas Jell from Siemens and Mr. Altaf Sadique from Medichem Leeds were providing input around all aspects of medical equipment and smart devices, such as RFID readers, barcode scanners and others.

Support regarding general software technology was provided by Mr. Alois Paulin from Medichem Leeds, Dr. Mojca Volk from University of Ljubljana, Professor Christoph Thuemmler, Professor Hubertus Feussner, and Professor Crina Sinescu from "Carol Davila" University of Medicine and Pharmacy Bucharest.

Jonnie Turpie from MTV has been leading the digital illustration and dissemination activities.

Legal advice has been obtained from Eleni Kosta from Tilburg University.

Ethical advice has been obtained from Ioana Ispas from the Romanian Ministry of Education.

There has been ongoing exchange with our Chief Architect, Dr. Ing. Stefan Covaci, Technical University Berlin, Dr. Stelios Sotiriadis from TU Crete, and Dr. Alessandro Serbanati, Consorzio Roma Ricerche, as well as with the Coordinator Mr. Anastasius Gavras from Eurescom.

The Core Team has been heavily supported by all FI-STAR partners.

1.3.3 FI-STAR workshops over Europe

The requirements analysis and the subsequent requirements engineering process was based on 10 interactive uses case Workshops held in Munich, Bologna, Tromsø, Krakow, Bucharest, Bilbao, Leeds, Karlskrona, Chania, and Edinburgh between April and September 2013. Each of the workshops lasted up to 3 days. The workshops were typically attended by approximately 20 people or more, which where held on project level. All use case workshops are well documented and

illustrated and can be found at the FI-STAR dissemination web page www.fistarblog.com. The FI-STAR blog has proven to be very successful over recent month. Workshop experiences and outcomes have also be documented on www.fi-star.eu and on our YouTube channel.

1.4 Achievements Leading to Deliverable D1.1

The objective of deliverable D1.1 was to align FI-STAR technical solutions with stakeholders. The alignment has been established as follows. Each experimentation site has stakeholders with needs and demands on the FI-STAR solution. A FI-STAR solution integrates FI-STAR applications in an experimentation site-specific manner. A FI-STAR Application is software offered to a market, which has been composed with generic enablers, specific enablers, and other application-specific components.

1.4.1 Alignment of needs and demands of stakeholders and solutions

During the first cycle of FI-STAR and in the build up towards the deliverable D1.1 the alignment of needs and demands of stakeholders such as users and third party systems and project specific solutions could be demonstrated and described. The description is based on existing UML standards and the use of flow-charts.

1.4.2 Identification of features of solutions

Detailed designs for solutions could be created and isolated and systemic features could be described in detail.

1.4.3 Value case analysis

D 1.1 describes in detail how these features would be used in order to create value for the users and the stakeholders.

1.4.4 Scope specifications for alpha and beta versions

The scope of the planned FI-STAR solutions has been prioritized with four levels of priority. D 1.1 distinguishes the scope of the FI-STAR solutions with regards to alpha and beta versions, which will commence at different stages of the project, additional options, and features out of scope. D 1.1 shows the different requirements of alpha and beta versions and how these solutions are linked to each other.

1.4.5 Definition of deployment scenarios

The workshops in Blekinge, Chania, and Edinburgh where used to establish comprehensive definitions of deployment scenarios, which are integral part of deliverable D 1.1.

1.4.6 Architecture

Deliverable D 1.1 gives a detailed overview over the computing context, nodes and servers and smart, peripheral mobile devices required for each use case scenario. The initially anticipated architecture is clearly mapped and described, thus D 1.1 creates a high level initial overview of the FI-STAR Architecture which is expected to meet the requirements of the use use-case. D 1.1 also puts an emphasis on the information requirements of the architectural FI-STAR work packages WP2 and WP3 by providing information to the FI-STAR platform architects in a format chosen by the architects.

1.4.7 Applications and Solutions

Applications represent software products that are offered to a market, e.g. by being made available on an application store. Applications consist Generic Enablers, Usage Specific Enablers and other application-specific components. Applications are integrated into site-specific solutions. These

solutions are used by the end-users and thereby generate value in terms of economic and health impacts.

1.4.8 Definitions of Functionality

D1.1 clearly defines functionalities by describing inputs and outputs by use-case-scenario.

1.4.9 Social-Technological and Structural Vertical and Horizontal Alignment

We have identified generically applicable “applications” across the use cases (horizontals) and have depicted the local integration of innovative technologies in the local infrastructure and work-flow (verticals).

1.4.10 Security

We have analysed the deployment scenarios by use case with regards to security requirements on a high level. In keeping with the FI-STAR Description of Work we have specified the security requirements but not the implementation as this rests entirely with the use-cases from a governance perspective.

1.4.11 Legal Framework

We mapped the currently existing legal framework in terms of privacy, patient rights and associated legal aspects on European level.

1.4.12 Standardization and Certification

D 1.1 contains a roadmap towards standardization and certification which is important in the context of commercialization and further dissemination of FI-STAR outcomes.

1.5 D1.1 Chapter Overview

1.5.1 Section I - Use Case Scenario and Experimentation Site Requirements

The following chapters give an overview of the FI-STAR-based solutions intended to be developed for each of the respective FI-STAR use case scenarios. Each chapter includes a problem and solution positioning statement, an overview of the stakeholders and their interests and expectations, the value case delivered to the healthcare environment at the experimentation site, and an overview and summative specification of the features planned to be implemented. The solution features are prioritized for alpha development, beta development, options, and out of scope.

Chapter 2: Diabetes Share System for Diabetes Care in Tromsø, Norway

Chapter 3: TeleCare Solution for Rehabilitation and State Monitoring in Krakow, Poland

Chapter 4: Chronic Disease Treatment Assistance for COPD Treatment in Bologna, Italy

Chapter 5: Management Solution for Bipolar Patient Treatment in Bilbao, Spain

Chapter 6: CRP Solution for Cardiac Rehabilitation in Bucharest, Rumania

Chapter 7: Operating Theatre Monitor for Operation Consumables Tracking in Munich, Germany

Chapter 8: Drug Supply Manager for Reverse Drug Supply Chain in Leeds, United Kingdom

1.5.2 Section II - Solution Deployment and Non-Functional Requirements

The following chapters give an overview of deployment and non-functional requirements for each of the FI-STAR-based solutions. The deployment scenarios define the architecture of the deployed solutions in terms of nodes, applications to be developed and integrated, and essential information flows between these applications. The deployment and security requirements give constraints to

be respected by these deployment scenarios. The chapters about legislations and privacy requirements and about standards and certification requirements are previews of the corresponding future WP1 deliverables.

Chapter 9: Deployment Scenarios

Chapter 10: Deployment Requirements

Chapter 11: Security Requirements

Chapter 12: Preview on Legislation and Privacy Requirements

Chapter 13: Preview on Standards and Certification Requirements

1.5.3 Section III - Application and Platform Architecture (Architecture Report)

The following chapters give previews of application and platform architecture. For exemplifying the application architecture, the most representative use case scenario has been chosen: the Diabetes Share System. The FI-STAR platform architecture describes how FI-STAR technology intends to support the development of FI-STAR applications and solutions. The last of the three chapters describes current state and next steps of GE selection and usage.

Chapter 14: Application Architecture – Diabetes Share System Example

Chapter 15: FI-STAR Platform Architecture

Chapter 16: Selection and Usage of Generic Enablers (GE)

1.5.4 Section IV - Completion of Project Scope

The following chapter describes the technical requirements, eligibility requirements, and evaluation criteria for FI-STAR open call proposals.

Chapter 17: Open Call Requirements

1.5.5 Section V - Roll-Out of FI-STAR Technology

The following chapters describe current status and plan for roll-out of FI-STAR technology. These include the stakeholder board and the open community. Excluded are the digital dissemination activities, which are reported as part of WP8 deliverables.

Chapter 18: Stakeholder Board

Chapter 19: Open Community

1.5.6 Annexes

The following annexes are peer-reviewed papers that cover materials reported in this deliverable D1.1 and have been accepted at important scientific conferences.

Annex A: Norms and Standards in Modular Medical Architectures

Annex B: Active Protection of Patient Data by Reverse Cloud Approach

Annex C: Aktiver Schutz von Patientendaten in mobilen e-Health Clouds

Annex D: Applying the Software-to-Data Paradigm in Next Generation E-Health Hybrid Clouds

1.6 D1.1 Scope

Deliverable D1.1 has the following relationships with work packages and tasks specified in the description of work.

D1.1 Section/Chapter	DoW WP/Tasks

Section I, Chapters 2-8	WP1 T1.1
Section II, Chapters 9-11	WP1 T1.1
Section II, Chapter 12	WP1 T1.3
Section II, Chapter 13	WP1 T1.2
Section III, Chapter 14	WP4
Section III, Chapter 15	WP2 and WP3
Section III	-
Section IV, Chapter 17	WP1 T1.6
Section V, Chapter 18	WP8 and WP9
Section V, Chapter 19	WP7

1.7 References

[1] European Commission 2011, eHealth Action Plan 2012 – 2020 – public consultation – results report

[2] European Commission 2012, Communication of the European Commission to the European Parliament, The Council, The European Economic and Social Committee and The Committee of Regions, eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century

[3] Dollard, J., Doob, L.W., Miller, N.E., Mowrer, O.H. & Sears, R.R. (1939). Frustration and Aggression. New Haven: Yale University-Press.

[4] Peters T, Waterman R H, 1982, In Search of Excellence.

SECTION I – Use Case and Experimentation Site Requirements

The following chapters give an overview of the FI-STAR-based solutions intended to be developed for each of the respective FI-STAR use case scenarios. Each chapter includes a problem and solution positioning statement, an overview of the stakeholders and their interests and expectations, the value case delivered to the healthcare environment at the experimentation site, and an overview and summative specification of the features planned to be implemented. The solution features are prioritized for alpha development, beta development, options, and out of scope.

Chapter 2: Diabetes Share System for Diabetes Care in Tromsö, Norway

Chapter 3: TeleCare Solution for Rehabilitation and State Monitoring in Krakow, Poland

Chapter 4: Chronic Disease Treatment Assistance for COPD Treatment in Bologna, Italy

Chapter 5: Management Solution for Bipolar Patient Treatment in Bilbao, Spain

Chapter 6: CRP Solution for Cardiac Rehabilitation in Bucharest, Rumania

Chapter 7: Operating Theatre Monitor for Operation Consumables Tracking in Munich, Germany

Chapter 8: Drug Supply Manager for Reverse Drug Supply Chain in Leeds, United Kingdom

2 Diabetes Share System for Diabetes Care in Tromsö, Norway

The FI-STAR solution Diabetes Share System (DSS) addresses the problem of inadequate blood glucose levels of Diabetes I patients, which affects the patients, next-of-kin (e.g. relatives), doctors, and nurses. The impact of this problem are sever complications for the patient and high treatment costs. A successful solution enables the patient in effectively balancing intake of insulin and carbohydrate, physical activity, and stress.

DSS is intended for patients, next-of-kin (e.g. relatives), physicians, and nurses who train, monitor, and consult an empowered Diabetes patient. DSS is a FI-STAR cloud solution that enables mobile recording of health and biometrical parameters, remote counselling, and comparison with other patients' anonymous observations. Unlike in-clinic treatment based upon manually recorded or lacking health parameters, DSS increases evidence to support treatments, increases the patient's knowledge base, assists in maintaining a healthy lifestyle, reduces the number of in-person appointments, and improves the patient's diabetes condition, wellbeing, and health.

This chapter gives an overview of a FI-STAR solution that is intended to be built to support the FI-STAR use case. The chapter covers the goal/purpose of the FI-STAR solution, stakeholders and their interests/expectations, the application and their features that are integrated into the FI-STAR solution to support these interests/expectations, and the FI-STAR solution-wide requirements and constraints. The appendix can be used to capture any other material, including business processes, glossary, description of the as-is situation, problems with current solutions, storyboards, and examples of artefacts and photographs of usage context.

The vision chapter is intended as a starting point for subsequent detailed requirement engineering. The features are used to establish an overview of the FI-STAR solution's requirements that then will be engineered just-in-time before the relevant development starts. The features should be specified by explaining how the concerned FI-STAR application will support the corresponding FI-STAR stakeholders' interests and expectations. The vision chapter should be updated as the understanding of the FI-STAR solution and of its aims and objectives evolve.

Future uses of this vision chapter will be to establish personas for target user segmentation and user experience engineering, traceability to release and project planning, application and enabler design and development, and quantification of quality requirements and testing, definition/monitoring of KPI, and analyzing commonality/variability across applications. In addition, this vision chapter will refer to relevant specialty requirements.

2.1 FI-STAR Solution Positioning

The following captures the essence of the FI-STAR solution, including the problem it addresses and the key idea of solving the problem.

2.1.1 Problem Statement

The problem of	inadequate blood glucose levels of Diabetes I patients
affects	patients, next-of-kin (e.g. relatives), doctors, and nurses
the impact of which is	severe complications for the patient and high treatment costs
a successful solution would be	to enable the patient in effectively balancing intake of insulin and carbohydrate, physical activity, and stress

2.1.2 Position Statement

For	patients, next-of-kin (e.g. relatives), physicians, and nurses
Who	train, monitor, and consult an empowered Diabetes patient
The (product name)	Diabetes Share System (DSS) is a FI-STAR cloud solution
That	enables mobile recording of health and biometrical parameters, remote counselling, and comparison with other patients' anonymous observations
Unlike	in-clinic treatment based upon manually recorded or lacking health parameters
Our product	increases evidence to support treatments, increases the patient's knowledge base, assists in maintaining a healthy lifestyle, reduces the number of in-person appointments, and improves the patient's diabetes condition, wellbeing, and health

2.2 FI-STAR Use Case Stakeholders

The following users, interfacing systems, and other stakeholders are affected by the solution.

2.2.1 Users

Figure 2 gives an overview of the diabetes share system users. These are the patients, the nurses and physicians (both special cases of clinicians), and next-of-kin.

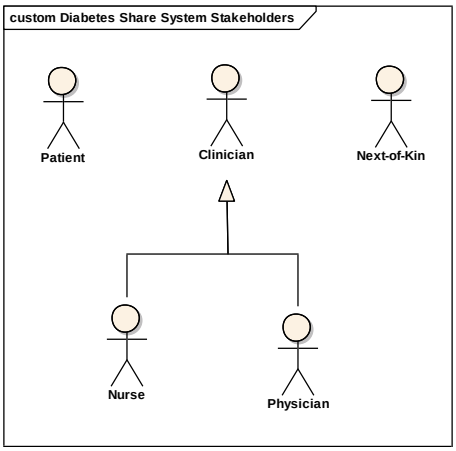


Figure 2: Users of the Diabetes Share System solution

Figure 3 gives an overview of the diabetes treatment workflow.

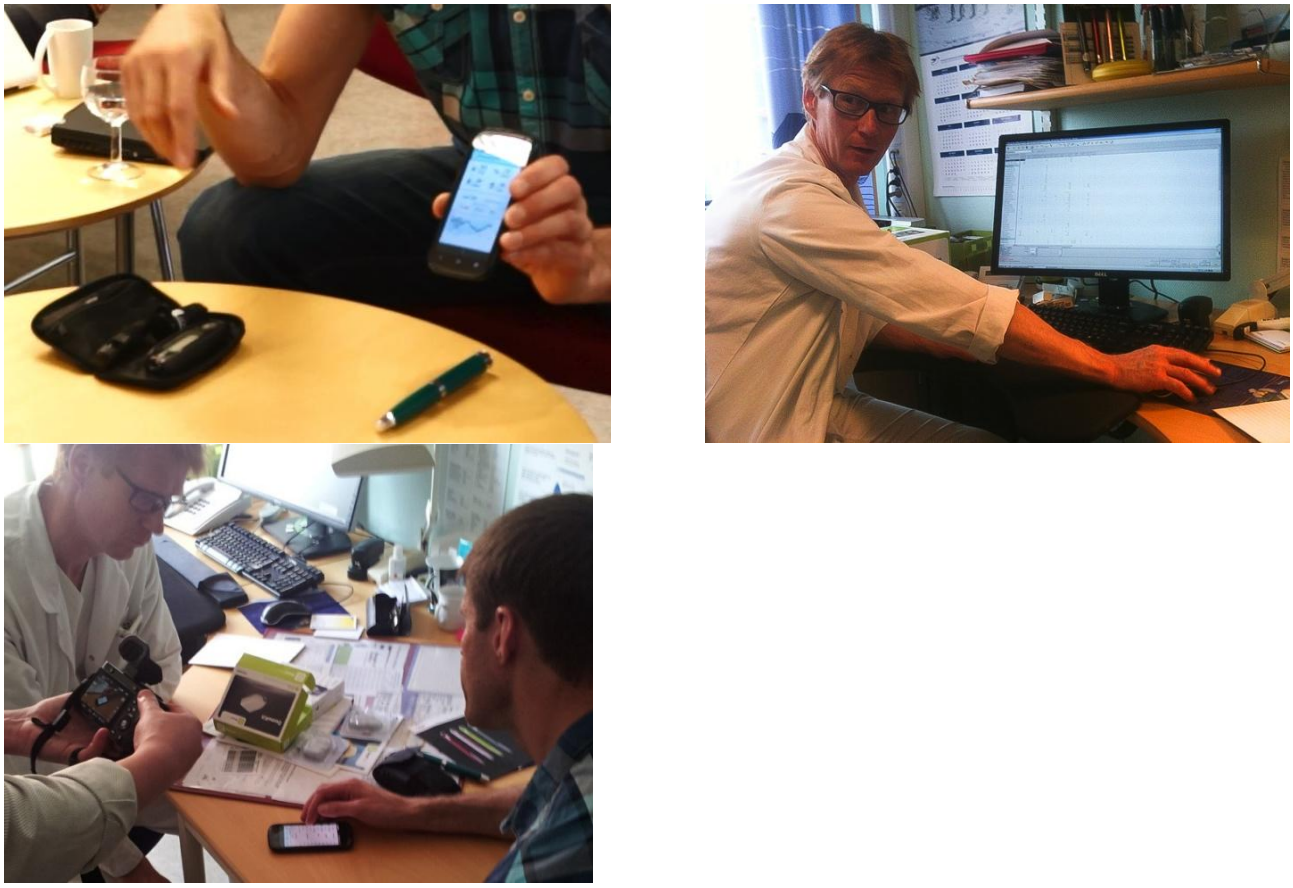


Figure 3: Patient plans insulin injection with blood glucose measurement and the Diabetes Diary or DeSA application out of hospital (left). Clinician PC showing patient's health records ahead of consultation (with patient's consent) (upper right). Patient uses blood glucose and other observation history in consultation with diabetes specialist (physician) (lower left).

Figure 4-Figure 5 give an overview of how the diabetes share system is intended to be used in the diabetes treatment workflow.

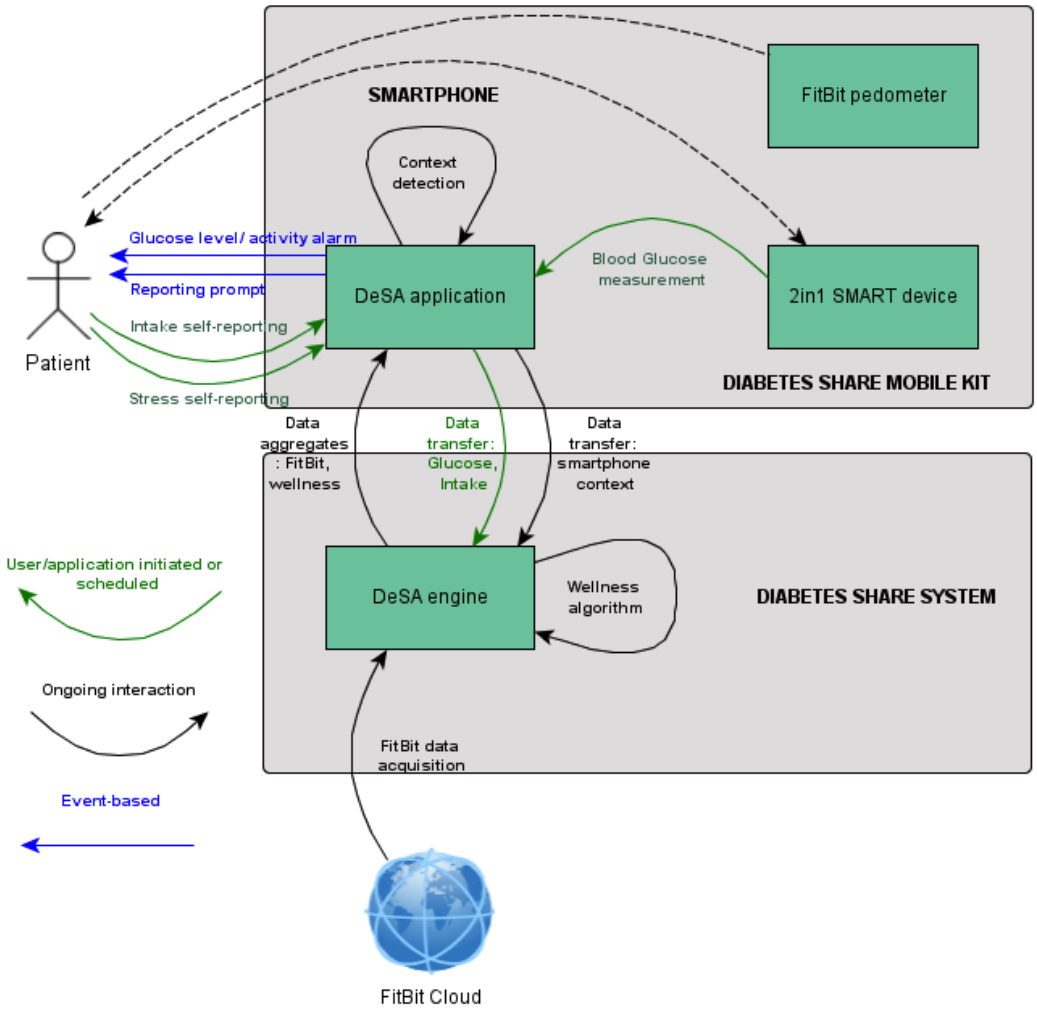


Figure 4: DeSA Mobile Application workflow (basic steps).

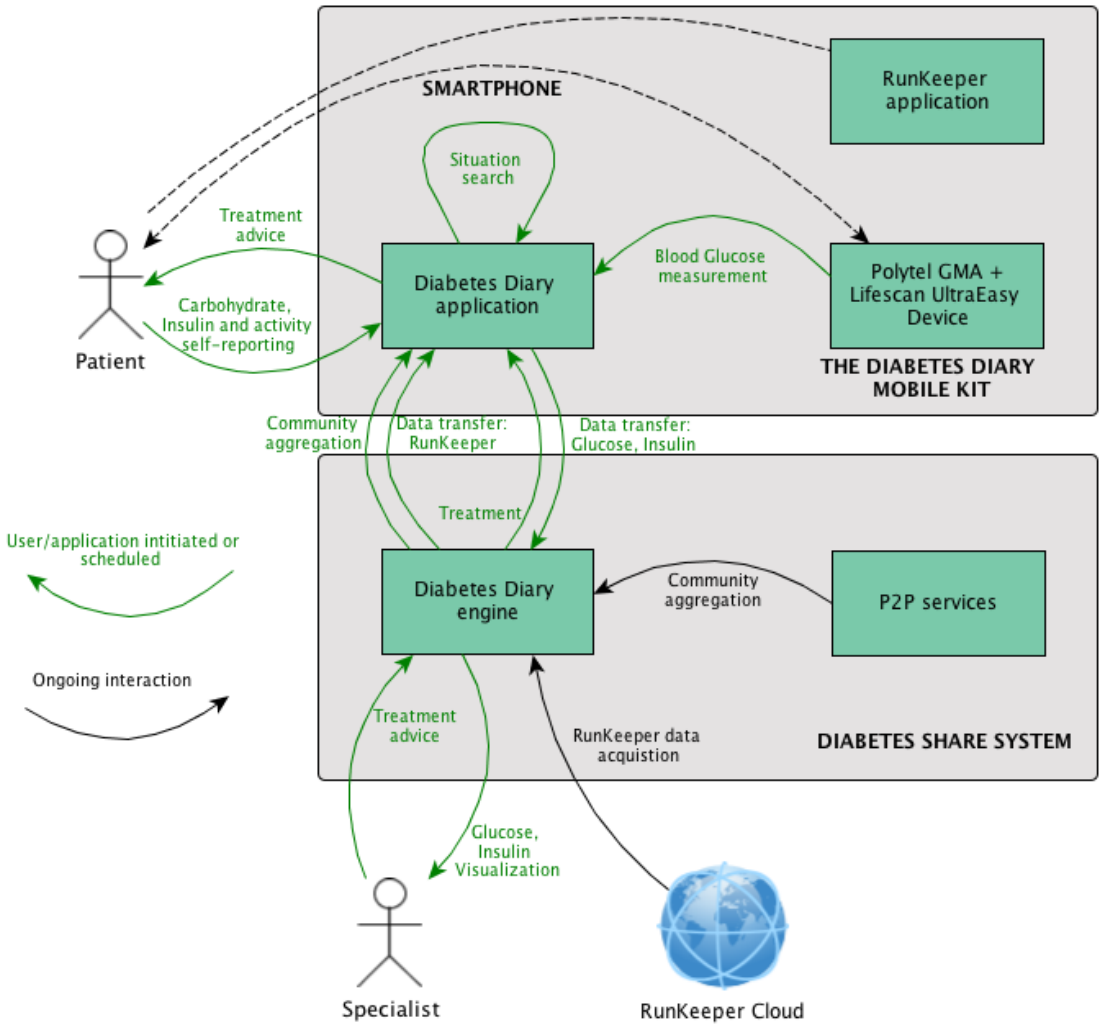


Figure 5: Diabetes Diary mobile application workflow (basic steps).

The following table describes the users, including their background, role, and expectations.

Name	Description	Expectations on Solution
Patient 30 Dr. Eirik Årsand (UNN) eirik.arsand@telemed.no Robert Galicic (VPD) Yeon Sik. Lee (VPD)	Diabetes patient. Uses smartphone applications (DeSA and The Diabetes Diary) to register observations and biometrics as part of their self-help treatment. Consumes counselling and treatment advice and wellbeing guidelines available through smartphone application. Consumes anonymous peer and community experiences through comparative features in smartphone application.	Effectiveness: consistent observation (blood glucose, insulin, carbohydrate intake, physical activity, sleepless pattern, and perceived stress) logs with timestamps and context information for personal use. Safety: automatic patient alerting in case of serious diabetes condition Safety: automatic monitoring by next-of-kin Satisfaction: diabetes community group strengthening/creation, improved social involvement. Efficiency: closer follow-up from clinician Satisfaction: novel sensor gadgets and

		a smartphone application, easy-to-use. Effectiveness: mobile solution Efficiency: reduce number of in-person appointments
Clinician (physician or nurse) (1+3) Dr. Ragnar Joakimsen (UNN) ragnar.joakimsen@unn.no	Diabetes clinician Uses clinical PC to access EHR system for patient data during counselling.	Efficiency: improved patient adherence Effectiveness: motivator/awareness raiser of the importance of a healthy lifestyle. Effectiveness: access to patient observation logs with timestamps just before (up to 1 day) and during counselling session. Effectiveness: ability to correlate and compare observation types visually for configurable time intervals on clinic pc. Efficiency: effortless interoperability with EHR Efficiency: closer follow-up of patient in initial phase of disease Efficiency: reduce number of in-person appointments Usefulness: methods for printing patient data
Physician 1 Dr. Ragnar Joakimsen (UNN) ragnar.joakimsen@unn.no	Diabetes physician Responsible for treatment of the patient. Wants to improve patient's diabetes condition by providing personalized treatment and training based on an in-depth and contextualized record of patients' diabetes-related parameters.	Efficiency: improved level of personalized treatment and training
Nurse 3 Mona Iren Torsteinsen (UNN) mona.iren.torsteinsen@unn.no Solrunn Coucheron (UNN) solrunn.coucheron@unn.no	Diabetes nurse. Manages, trains and distributes (glucose and insulin) equipment to patient. Helps physician treat the patient. Manages many practical details regarding patients' day-to-day issues with disease management.	Effectiveness: integration of data from clinical devices for continuous glucose monitors with patient observation logs.
Next-of-kin OUT OF SCOPE	Family member, close friend or partner. Uses smartphone to passively monitor the patient for following up on treatment continuity and alarming values.	Safety: automatic monitoring of patient Safety: satisfactory self-help treatment continuity

2.2.2 Interfacing Systems

Figure 6 gives an overview of the system boundary of the DSS solution. The connectivity to the FI-STAR cloud is a concern of the solution architecture, hence omitted from the overview.

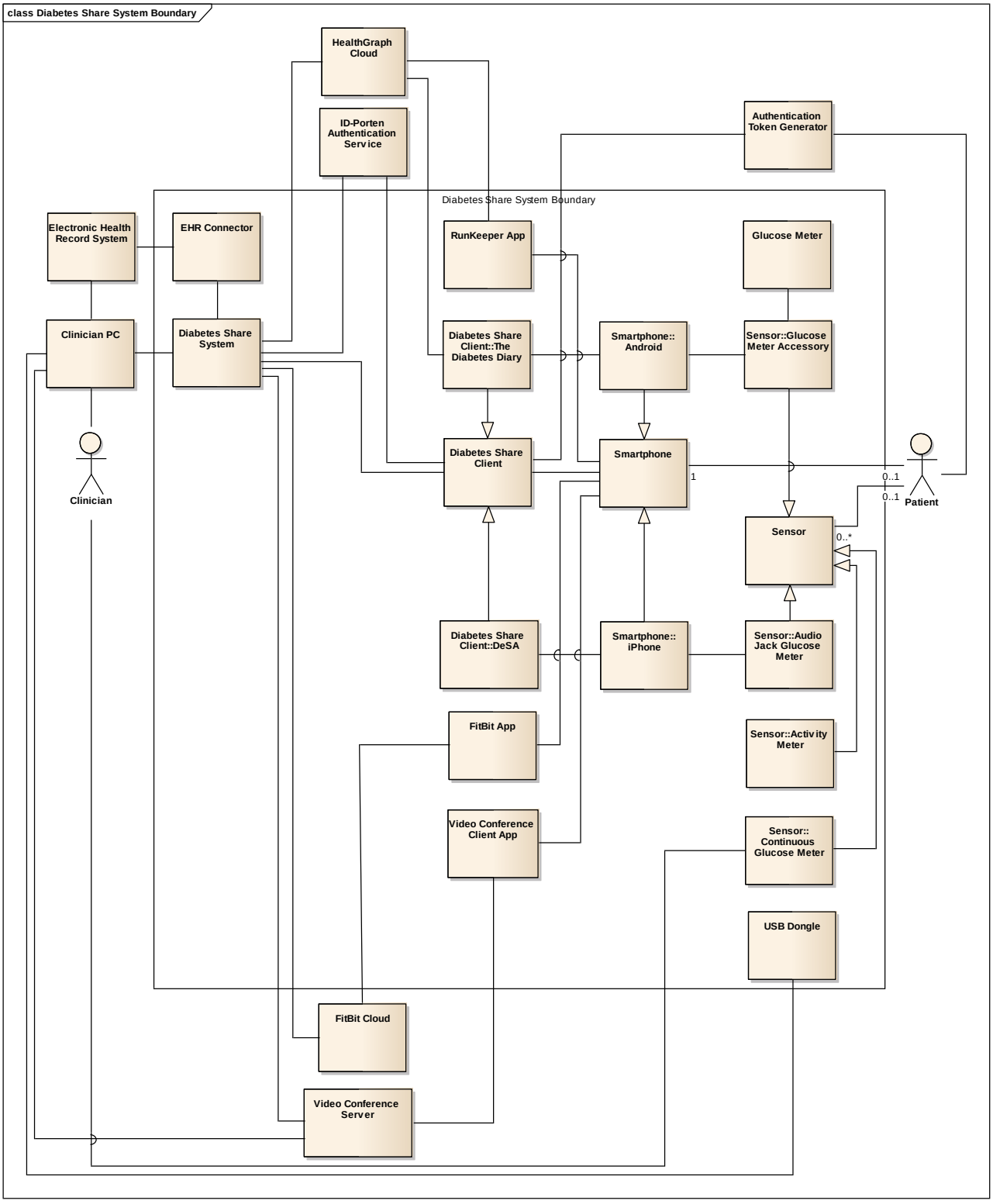


Figure 6: Diabetes Share solution, comprising Diabetes Share System on the FI-STAR Consumer Cloud implemented in hospital environment, and patient domain with the Diabetes Share Mobile Kit.

Figure 7-Figure 12 show the user interfaces and sensors that are planned to be integrated into the Diabetes Share System solution.

Figure 7: Left: Patient's Diabetes Diary application summary screen. Middle: Patient's Diabetes Diary application showing situation search screen. Right: Patient's Diabetes Diary application showing periodicity graph.

Figure 8: Smartphone with 2in1SMART application (left), a FitBit pedometer (middle), a 2in1SMART glucose meter (right)

Figure 9: Smartphone with Diabetes Diary application (left) Lifescan UltraEasy glucose meter with a Polytel Glucose Meter Accessory (GMA) (middle), an Activ ID Entity authenticator device for generation of one time passwords (right).

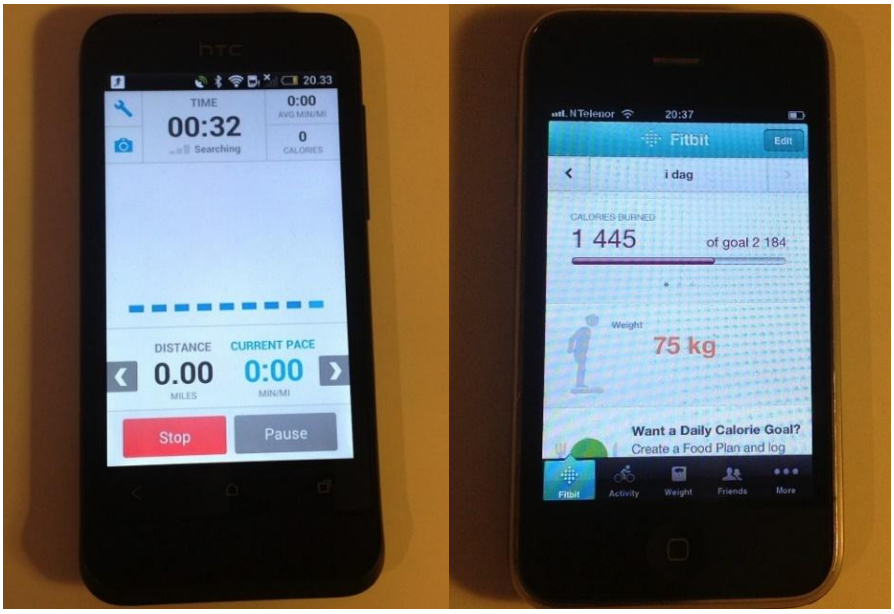


Figure 10: Android with RunKeeper app (left) iPhone with FitBit app (right)

Figure 11: Medtronic Continuous Glucose Meter (left), a Medtronic wearable sensor (white) with charger (blue) (middle), a Medtronic USB communication-dongle (right).

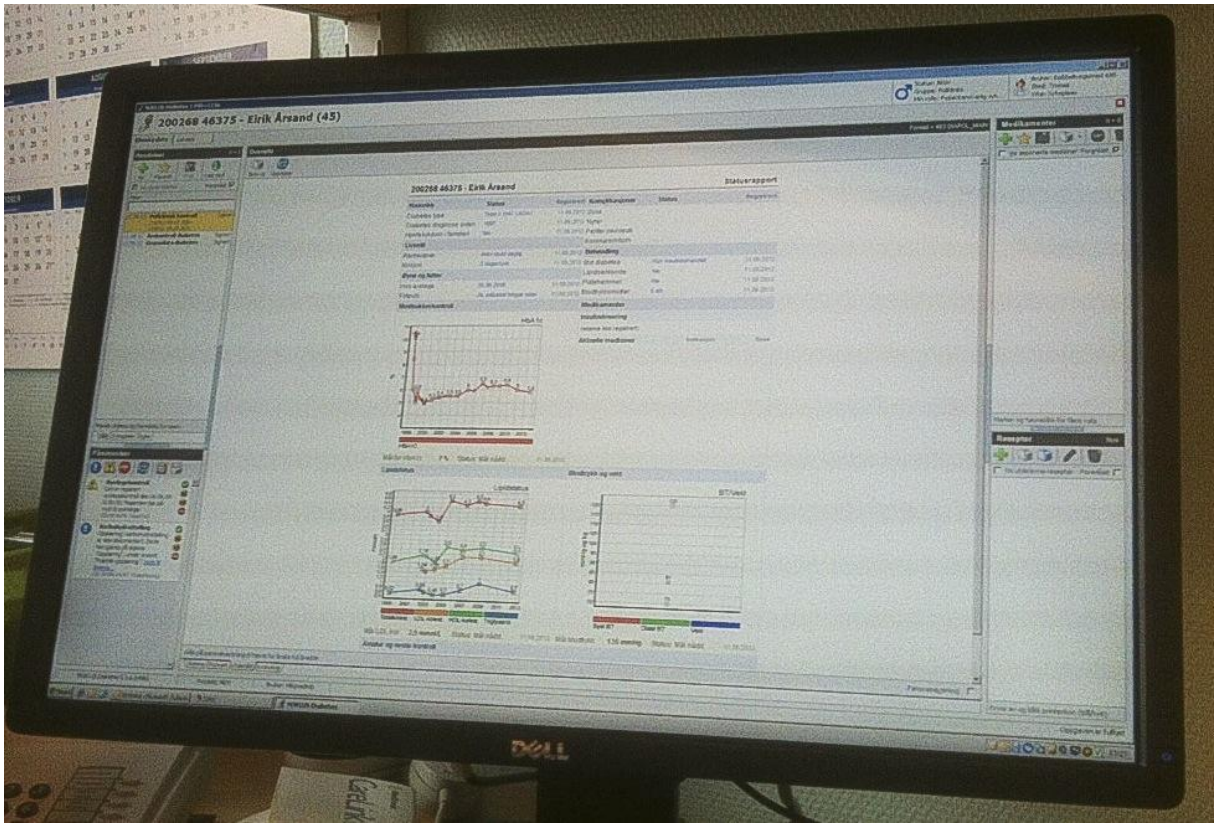


Figure 12: Clinician PC showing patient's Medtronic glucose value summary. Photographed with consent from patient.

The following table describes the interfacing systems and artefacts and related expectations on the solution.

Name	Description	Expectations on Solution
Smartphone (e.g. Android, iPhone) 30 (15+15) Niklas Andersson (UNN) niklas.andersson@telemed.no	Aggregator and gateway for biometrics and health observations originating from sensors or created manually using its installed applications. Patient's primary tool for interfacing to the system. Sends data using Wifi/4G/LTE to the Diabetes Share System.	Lightweight integration protocols (to minimize costly traffic) for accessing the Diabetes Share System features. Autonomous operation: Sensor integration and application useful in offline mode.
Android Smartphone 15 Niklas Andersson (UNN) niklas.andersson@telemed.no	Smartphone running Android OS 2.3 or later. Installed Diabetes Diary application, and potentially, RunKeeper.	
iPhone Smartphone 15 Dr. Urban Sedlar (UL) urban.sedlar@ltfe.org	Smartphone (iPhone 4S or newer) running iOS 6 or more (required for BLE compatibility). Installed DeSA and FitBit application.	
Glucose meter	Radio device to enable Bluetooth	Presence of Bluetooth 2.1 interface in

accessory (GMA) 15 Niklas Andersson (UNN) niklas.andersson@telemed.no	communication between compatible glucose meters and smartphone.	smartphone.
Lifescan UltraEasy Glucose Monitor 15 Niklas Andersson (UNN) niklas.andersson@telemed.no	Personal glucose meter for measuring blood glucose levels.	Compatible Glucose Meter Accessory (Polymap Polytel® Wireless Glucose Meter Accessory (GMA) PWR-08-06) for enabling Bluetooth communication with smartphone.
2in1 SMART glucose meter 15 VPD, Bled, d.o.o. Pot na Lisice 4 4260 BLED	Glucose meter that plugs into smartphone's audio jack. It is produced by VPD, a company specialized in manufacturing glucose level meters. NOTE: Pending official approval for Norwegian use.	Presence of audio jack interface in smartphone. Requires a specific range of output voltage in audio jack; device is iPhone compatible.
Medtronic Continuous Glucose Meter (CGM) Niklas Andersson (UNN) niklas.andersson@telemed.no	Device for continuously monitoring a patient's glucose values over limited time intervals (days). MWT1 is the brand name for the Medtronic MiniMed proprietary RF telemetry protocol.	USB connector on clinic PC for connecting Medtronic USB-dongle. Support for inclusion of downloaded glucose data documents in PDF-format in presentation solution on clinic PC.
FitBit pedometer 15 Dr. Urban Sedlar (UL) urban.sedlar@ltfe.org http://fitbit.com	Physical activity sensor that downloads data to FitBit smartphone app. Sensor will be able to store activity data locally. When coming near to the sensor node (either smartphone with Bluetooth BLE, or a PC with BLE dongle), data will be automatically uploaded to the device provider's cloud service. DSS will be able to connect to the service via open APIs and obtain gathered data	Presence of Bluetooth (BLE) interface and FitBit app in smartphone.
FitBit Cloud 1 Dr. Urban Sedlar (UL) urban.sedlar@ltfe.org http://dev.fitbit.com	Web service for storing physical activity data aaS. Integrates with FitBit app on smartphone and proxy service in DSS.	Requires Diabetes Share services and apps interfacing with FitBit APIs to use REST over HTTP and OAuth 1.0 to authenticate users. Supports pubsub mechanism to deliver data to subscribers as it appears.
Health Graph Cloud 1 Niklas Andersson (UNN) niklas.andersson@telem	Cloud services for storing fitness data, e.g. physical activity, diet, sleep patterns and so on. Open APIs with over 100 integrating partners providing apps and widgets.	Requires Diabetes Share services and apps interfacing with Health Graph APIs to use REST over HTTP and OAuth 2.0 to authenticate users.

ed.no http://runkeeper.com		
Clinician PC 4 Dr. Ragnar Joakimsen (UNN) ragnar.joakimsen@unn.no	PC used by nurse and specialist to access patient data in the EHR system and give treatment advice to patient. Client for Diabetes Share internal services will reside here and integrate with EHR client.	Presence of pertinent patient data for diabetes treatment in the EHR system. Access to video conferencing server for remote counselling.
DIPS Arena (Electronic Health Record System - EHR and Patient Administrative System - PAS). 1 Chief Technical Lead Yngve H. Nyheim (DIPS ASA) yny@dips.no	Hospital-wide electronic health record system. Stores health observations per patient. DIPS is the leading vendor of the EHR system used in Norwegian hospitals and the system used locally at the use case site. Today it is possible to store blood glucose and other biometrics as KITH-XML lab and HL7 version 2 messages. DIPS however, is currently developing support for interoperability through OpenEHR archetypes, IHE XDS and HL7 CDA, expected to be available within the project time frame.	EHR connector component. Interface not implemented yet. DIPS provides services for communicating with the EHR using OpenEHR archetypes, IHE XDS, HL7 CDA and/or KITH-XML lab defined here: http://bit.ly/10kojvP
ID-Porten Authentication Service TBD Daniel Hallgren (UNN) daniel.hallgren@telemed.no	Officially approved service for authenticating citizens at “level 4” (highest authentication level) required by Norwegian legislation. Web application (web page) for authentication that public services can integrate with. Integrates with client browser, client back-end service and chosen authentication organization. NOTE: Still under investigation. Assuming Android support in some months.	Client browser: • HTTPS v3.0 or TLS v1.0 • Javascript support Smartphone: • BankID app installed Diabetes Share Server: • SAML2 • SOAP • HTTPS v3.0 or TLS v1.0 • AES encryption with 128 bit key • Signing with SHA1 with RSA (1024 bit modulo) • Secure public/private key management of a private/public key pair, for communication with ID-Porten.
Activ ID Entity Authenticator Device Niklas Andersson (UNN) niklas.andersson@telemed.no	Device for generating one-time passwords for authentication procedures.	Presence of authentication client mechanisms in smartphone. See ID-Porten Authentication service above.
CISCO Jabber Video Conference Service	Approved and risk assessed service for video conferencing in Norwegian	TBD

Daniel Hallgren (UNN) daniel.hallgren@telemed.no	health domain based on XMPP, SIP and H.323 At the moment there are clients for Windows, OS X and iOS on iPad. But no smartphone support. The service is located in The Norwegian Health Network. http://nhn.no Data sheet http://www.cisco.com/en/US/prod/collateral/ps7060/ps11303/ps11310/ps11328/data_sheet_c78-628609.html	

2.2.3 Other Stakeholders

The following list describes other stakeholders that do not directly interact with the solution.

Name	Description	Expectations on Solution
The Norwegian Directorate of Health. 1 Per Bruvold, Data protection officer at UNN. per.bruvold@unn.no http://helsedirektoratet.no/	The Norwegian Directorate of Health is an executive agency to the Norwegian Ministry of Health and Care Services. The data protection officer is responsible for patients' privacy in relation to UNN operations and fulfilment of requirements defined in legislation and through the «Code of Conduct for information security in the healthcare, care, and social services sector» The Code of Conduct is describing best practises and policies and is recommended as a guide for implementing systems according to legislation. It is available here: http://bit.ly/11FbwlJ Relevant legislation is: "Act of 14 April 2000 No. 31 relating to the processing of personal data (Personal Data Act)" "Act of 18 May 2001 No. 24 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) And regulation: "Regulations on the processing of personal data (Personal Data Regulations)." Found at the site of the Data Protection office: http://www.datatilsynet.no,	Security: The Diabetes Share system should provide protocols and mechanisms for secure communication in compliance with Norwegian legislation as well as local network topology requirements Included but not limited to: • Communication needs to be encrypted and messages signed • Two-Factor Authentication with non-copyable tokens, one of which is dynamic • Supplier of PKI-certificates needs official approval • Patient needs to initially show up physically to establish identity • Access log needs to be stored 5 years Access to The Diabetes Share system needs to be initiated internally via a polling scheme comprising two firewalled servers in different security zones. Security: Proper Risk Analysis needs to be performed and shared with The Norwegian Data Protection Authority

	http://bit.ly/11tFp4j	
Helsenord IKT (HN-IKT) 1 TBD	Local hospital network and equipment maintenance unit.	The Diabetes Share system should comply with local network topology and have approval from hospital data protection officer. Server hardware needs to be approved and possibly maintained by HN-IKT Expects HTTP-based traffic through security barriers.
Regional Committee for Medical and Health Research Ethics (REC) 1 Dr. Ragnar Joakimsen (UNN) http://helseforskning, http://etikkom.no	Approves medical and health research projects. REC carries out an assessment as to whether research is undertaken in an acceptable manner. This entails the consideration of benefit versus risk and whether data protection is assured. List of relevant legislation: http://bit.ly/12DUM1u	The Diabetes Share system complies with requirements defined in Norwegian law on research ethics and medical research.
Northern Norway Regional Health Authority (Helse Nord RHF) 1 Dr. Ragnar Joakimsen (UNN) http://www.helse-nord.no	Helse-Nord is responsible for the public hospitals in northern Norway. Has a Regional Action Plan for Diabetes, available here in Norwegian: http://bit.ly/11FeXcc	Effectiveness: Improved quality of diabetes treatment. Effectiveness: Improved diabetes quality management. Effectiveness: Improved training of patients. (All of above from section 2.5.2 in Regional Action Plan for Diabetes)

2.3 FI-STAR Solution: Value Case

The Diabetes Share System creates value by reducing the number of in-person/doctors appointments and improving patients' health through an increased evidence base for decision support and increased motivation for healthy living.

The reduction of in-person appointments is achieved through providing decision-support to the clinician by integrating the clinic PC with clinical sensors and by providing effortless interoperability with the electronic health record.

The improvement of the patient's diabetes condition, health and well-being is achieved by 1) improving patient adherence through improved personalized treatment and training, 2) providing motivation for a healthy lifestyle through novel gadgets, a mobile solution, and a sense of community involvement, 3) increasing the patient's knowledge base through holistic observation interpretation, automatic patient alerts, report printing, and advanced operation views, 4) prohibiting harmful habits, and 5) providing a healthy lifestyle assistance.

Figure 13 summarizes the value case.

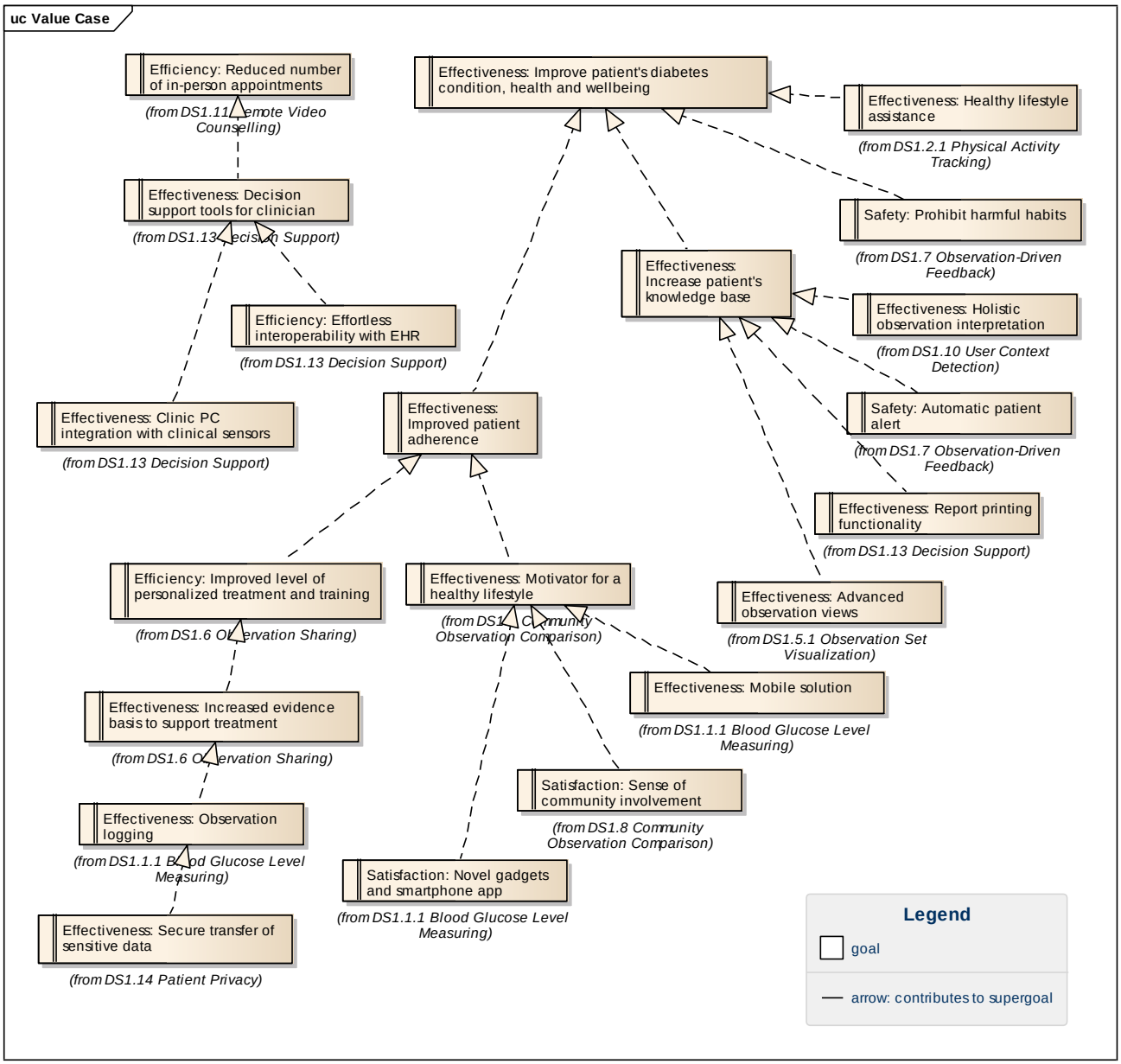


Figure 13: Goal tree for The Diabetes Share System indicating sub goals and their origins (system features) supporting the main objective.

2.4 FI-STAR Solution Overview

The Diabetes Share System provides a set of features (groups of requirements that belong together) to support the use case stakeholders. The solution comprises a base system, the Diabetes Share System, and two mobile applications; The Diabetes Diary and DeSA.

Figure 14 gives an overview and defines priorities in terms of minimal scope (alpha prototype for month 12), target scope (beta prototype for month 24), and enhanced scope (options) of the solution. Each feature is specified in more detail in the following subsections. Figure 15 and Figure 16 illustrate features related to The Diabetes Diary and DeSA applications respectively.

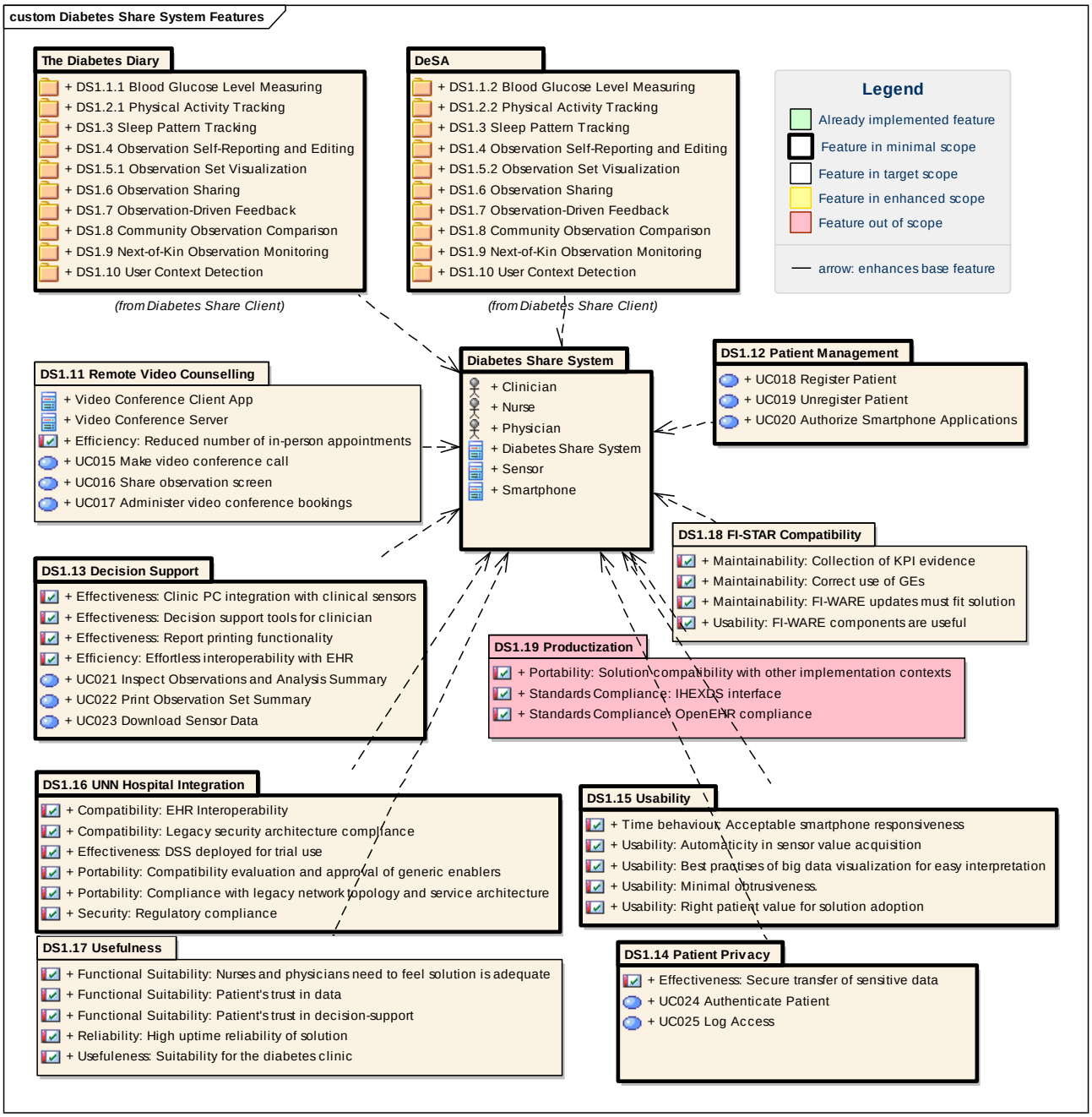


Figure 14: Feature tree of the Diabetes Share System

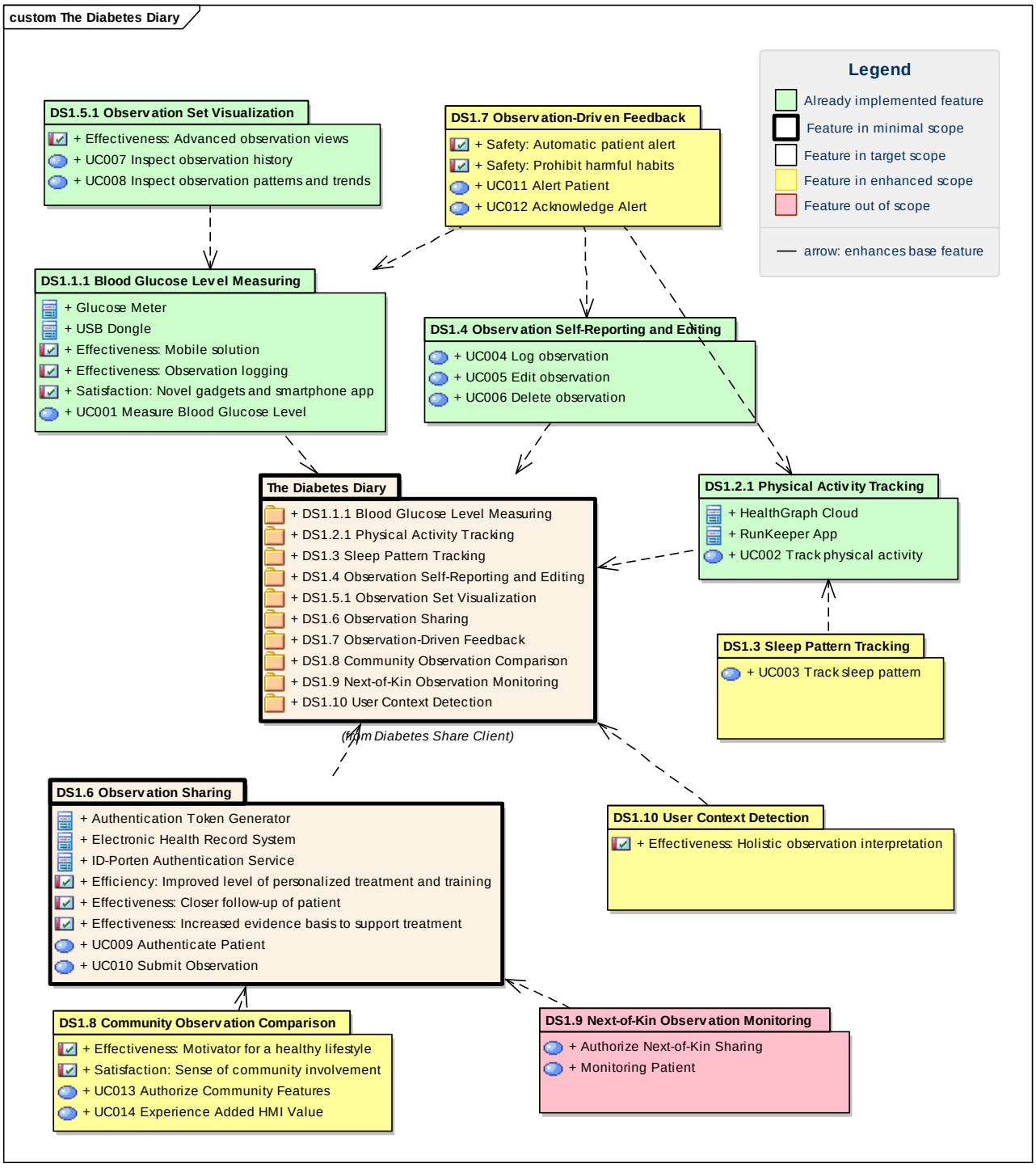


Figure 15: Feature tree of The Diabetes Diary smartphone application

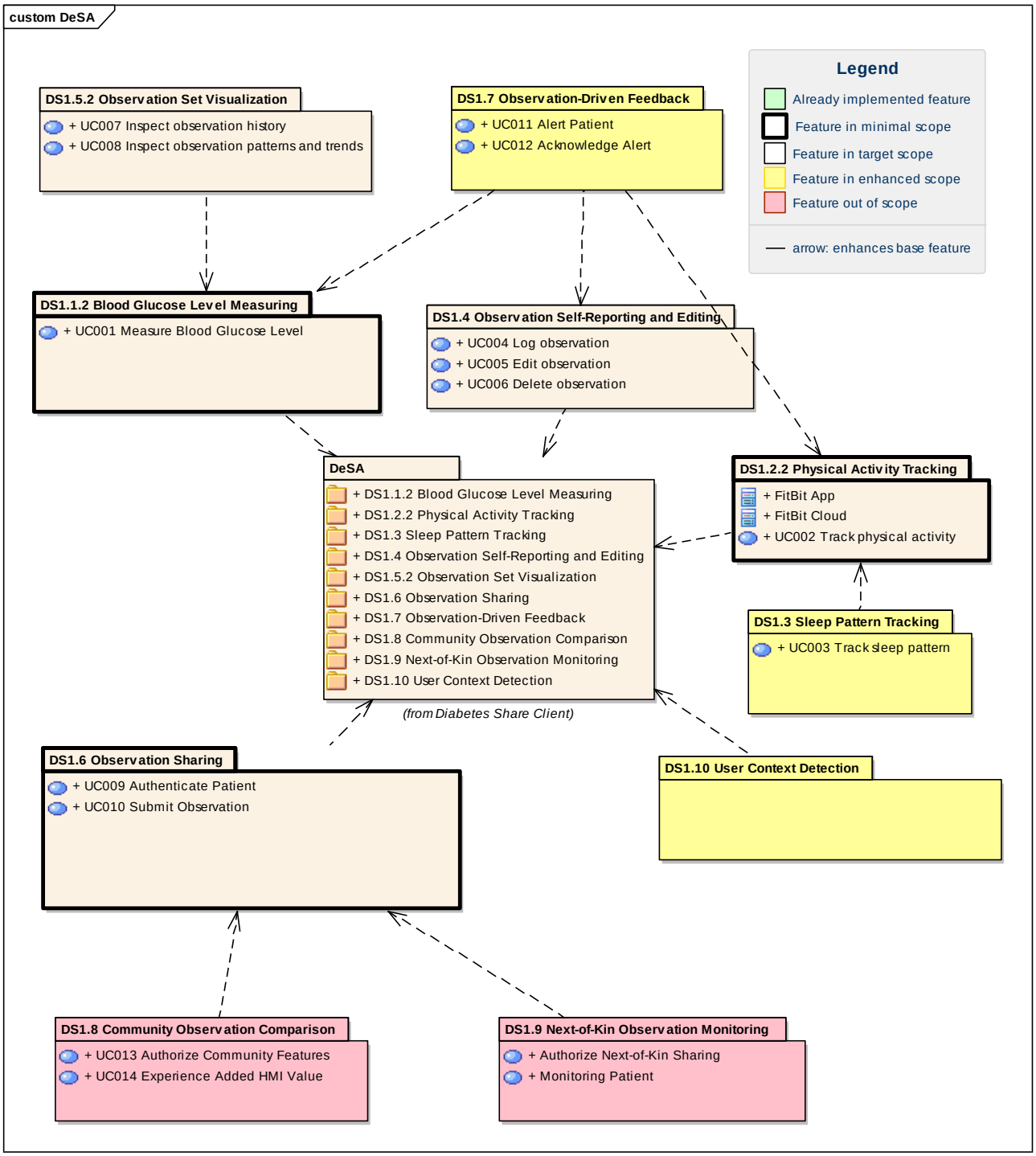


Figure 16: Feature tree of the DeSA smartphone application

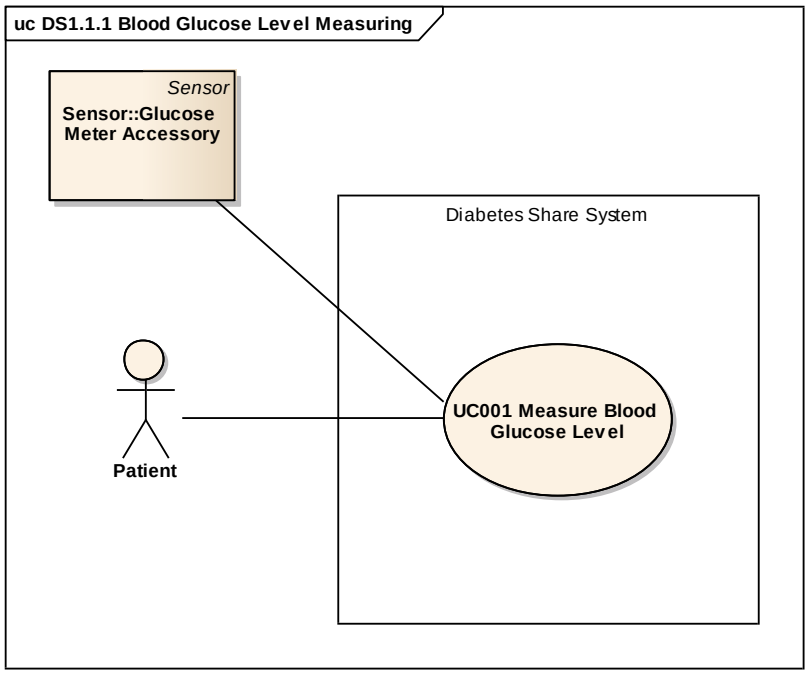
2.4.1 Diabetes Share System Features

2.4.1.1 Feature DS1.1 Blood Glucose Level Measuring

The Blood Glucose Level Measuring feature provides patients with the ability to acquire information on current blood glucose level from a Diabetes Share client app on a smartphone connected to a glucose sensor.

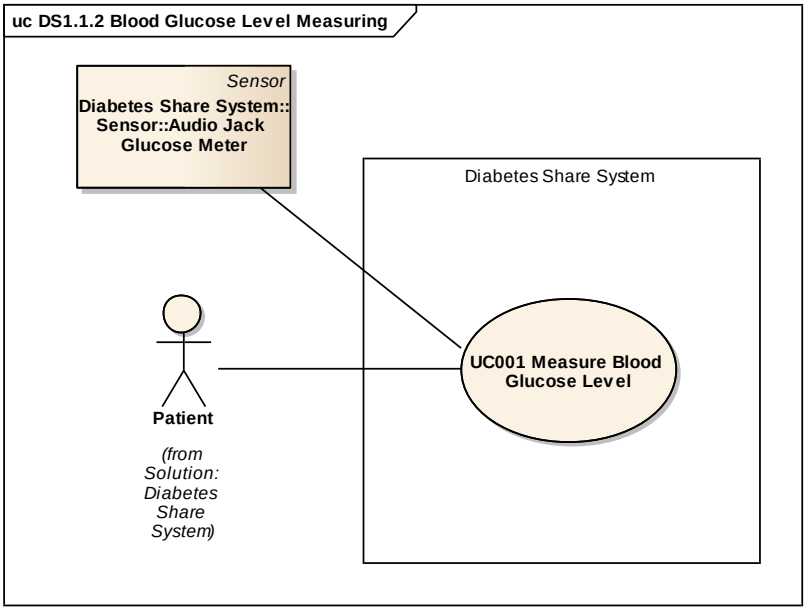
2.4.1.2 Feature DS1.1.1 Blood Glucose Level Measuring

This is the Diabetes Diary version of the feature.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: mobile solution • Effectiveness: observation logging • Satisfaction: novel gadgets and smartphone app External interfaces: • Smartphone HMI to patient • Smartphone M2M to sensor • Sensor HMI to patient Use cases: • Measure blood glucose level 
Key ideas for implementation	Already implemented
Notes	The patient smartphone is an Android and the sensor will be one compatible and connected to the Polymap Glucose Meter Accessory communicating over Bluetooth.

2.4.1.3 Feature DS1.1.2 Blood Glucose Level Measuring

This is the DeSA version of the feature.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: mobile solution • Effectiveness: observation logging • Satisfaction: novel gadgets and smartphone app External interfaces: • Smartphone HMI to patient • Smartphone M2M to sensor • Sensor HMI to patient Use cases: • Measure blood glucose level 
Notes	The patient smartphone is an iPhone and the sensor will be 2in1 Smart plugged into audio jack. NOTE: This is pending Norwegian approval of the Smart sensor.

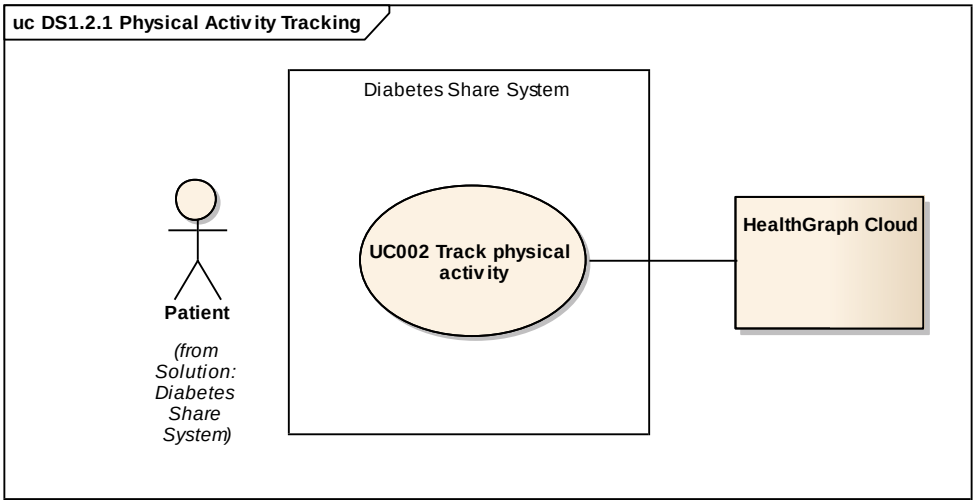
2.4.1.4 Feature DS1.2 Physical Activity Tracking

The Physical Activity Tracking feature provides patients with the ability to acquire information on their physical activity from a Diabetes Share client app on a smartphone.

2.4.1.5 Feature DS1.2.1 Physical Activity Tracking

This is the Diabetes Diary version of the feature.

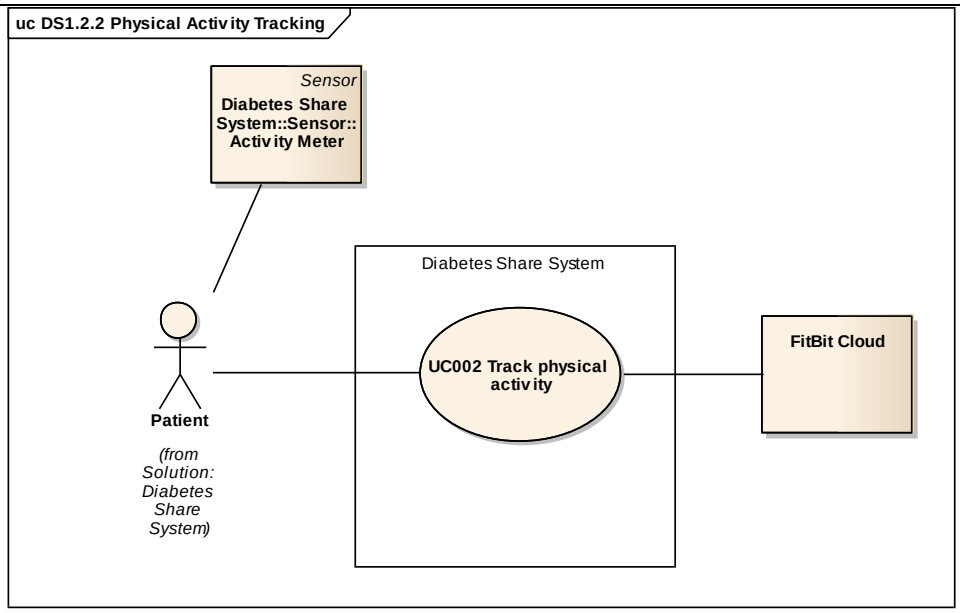
Addressed stakeholder interests and expectations	Goals to be achieved: • From DS1.1 Effectiveness: mobile solution • From DS1.1 Effectiveness: observation logging • From DS1.1 Satisfaction: novel gadgets and smartphone app • Effectiveness: Healthy lifestyle assistance External interfaces: • From DS1.1 Smartphone HMI to patient

	• From DS1.1 Smartphone M2M to sensor • From DS1.1 Sensor HMI to patient Use cases: • Track physical activity 
Notes	The patient smartphone is an Android and internal sensors will used.

2.4.1.6 Feature DS1.2.2 Physical Activity Tracking

This is the DeSA version of the feature.

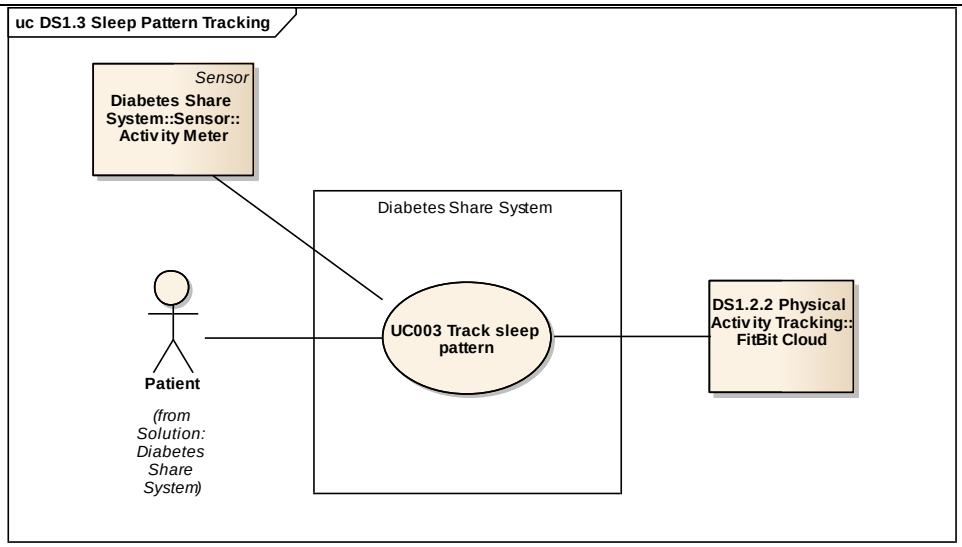
Addressed stakeholder interests and expectations	Goals to be achieved: • From DS1.1 Effectiveness: mobile solution • From DS1.1 Effectiveness: observation logging • From DS1.1 Satisfaction: novel gadgets and smartphone app • From DS1.2 Effectiveness: Healthy lifestyle assistance Quality requirement: • Durability: sensor must be splash and vibration resistant External interfaces: • From DS1.1 Smartphone HMI to patient • From DS1.1 Smartphone M2M to sensor • From DS1.1 Sensor HMI to patient Use cases: • Track physical activity

	
Notes	The patient smartphone is an iPhone and the sensor will be FitBit One.

2.4.1.7 Feature DS1.3 Sleep Pattern Tracking

The Sleep Pattern Tracking feature provides patients with the ability to acquire information on their sleep activity from a Diabetes Share client app on a smartphone.

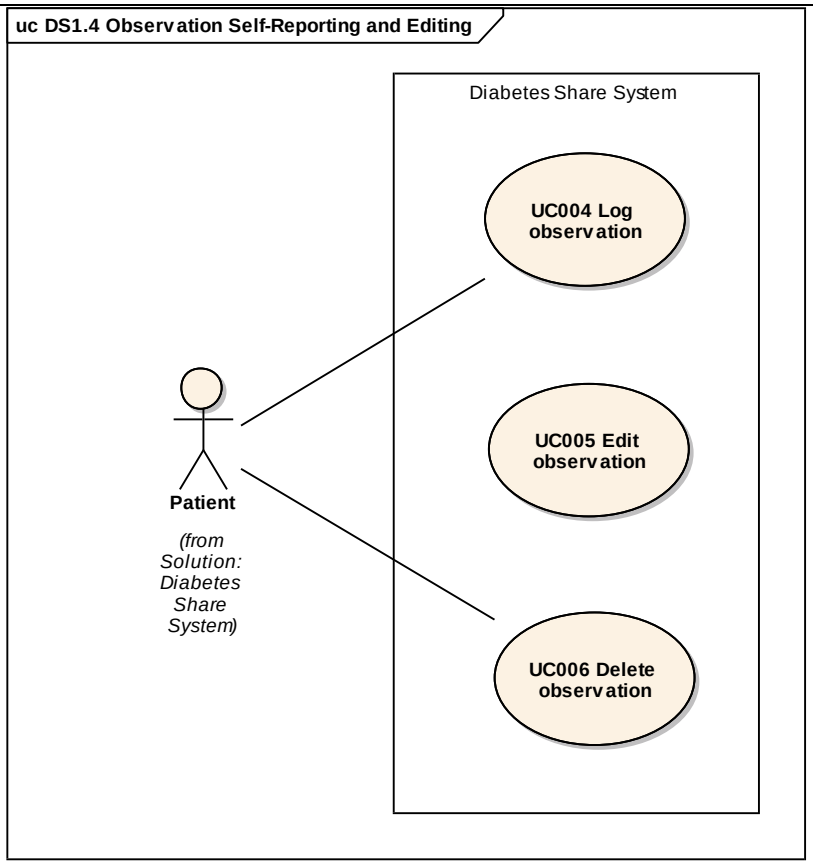
Addressed stakeholder interests and expectations	Goals to be achieved: • From DS1.1 Effectiveness: mobile solution • From DS1.1 Effectiveness: observation logging • From DS1.1 Satisfaction: novel gadgets and smartphone app Quality requirement: • Durability: sensor must be splash and vibration resistant External interfaces: • From DS1.1 Smartphone HMI to patient • From DS1.1 Smartphone M2M to sensor • From DS1.1 Sensor HMI to patient Use cases: • Track sleep pattern

	
Assumptions	Use of appropriate sensor. (FitBit at time of writing)

2.4.1.8 Feature DS1.4 Observation Self-Reporting and Editing

The Observation Self-Reporting and Editing feature provides patients with the ability to self-report and edit biometric and wellness observations.

Addressed stakeholder interests and expectations	Goals to be achieved: • From DS1.1 Effectiveness: mobile solution • From DS1.1 Effectiveness: observation logging • From DS1.1 Satisfaction: novel gadgets and smartphone app • From DS1.2 Effectiveness: Healthy lifestyle assistance Quality requirements: • Usability: intuitive graphical interface; minimum effort for the patient to log and edit observation External interfaces: • From DS1.1 Smartphone HMI to patient Use cases: • Log observation • Edit observation • Delete observation

	
Comments or drawings	The observation concept is defined in the Glossary chapter.

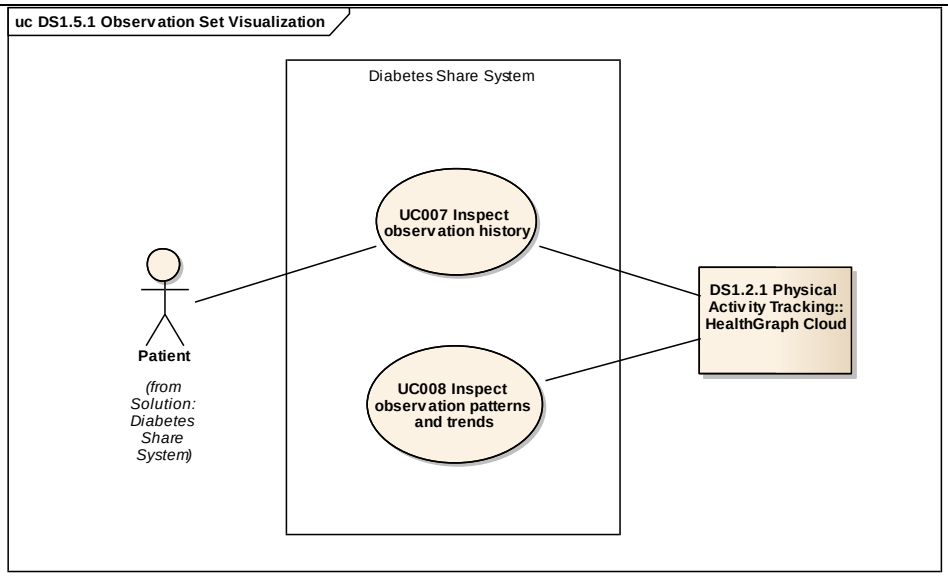
2.4.1.9 Feature DS1.5 Observation Set Visualization

The Observation Set Visualization feature provides advanced smartphone application views on sets of observations with indicators showing abnormal values.

2.4.1.10 Feature DS1.5.1 Observation Set Visualization

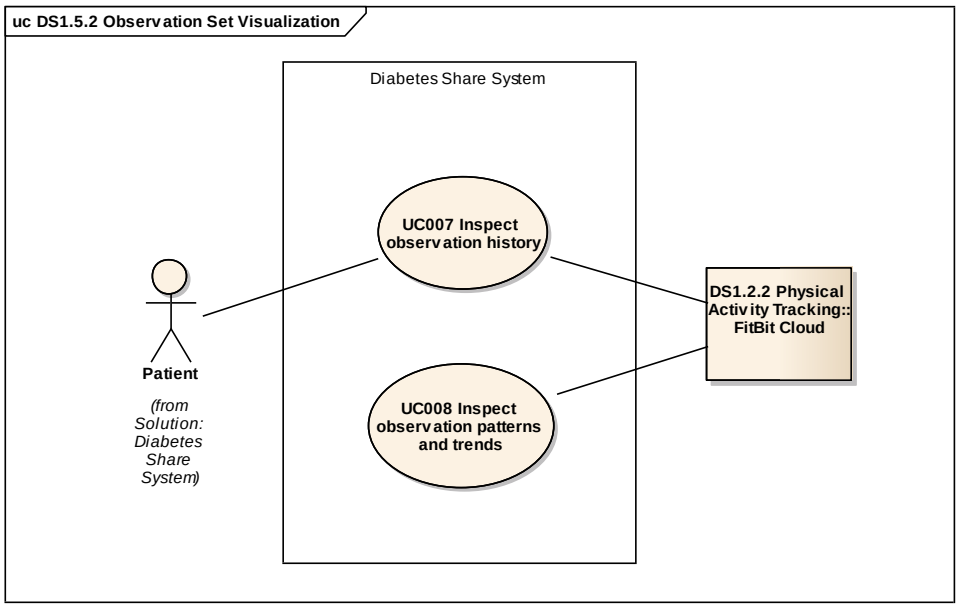
This is the Diabetes Diary version of the feature.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: advanced observation views • From DS1.1 Satisfaction: novel gadgets and smartphone app External interfaces: • From DS1.1 Smartphone HMI to patient • Diabetes Share M2M to Activity tracking cloud Use cases: • Inspect observations history • Inspect observations patterns and trends

	
Notes	The patient smartphone is an Android and will be integrated with the HealthGraph cloud service.

2.4.1.11 Feature DS1.5.2 Observation Set Visualization

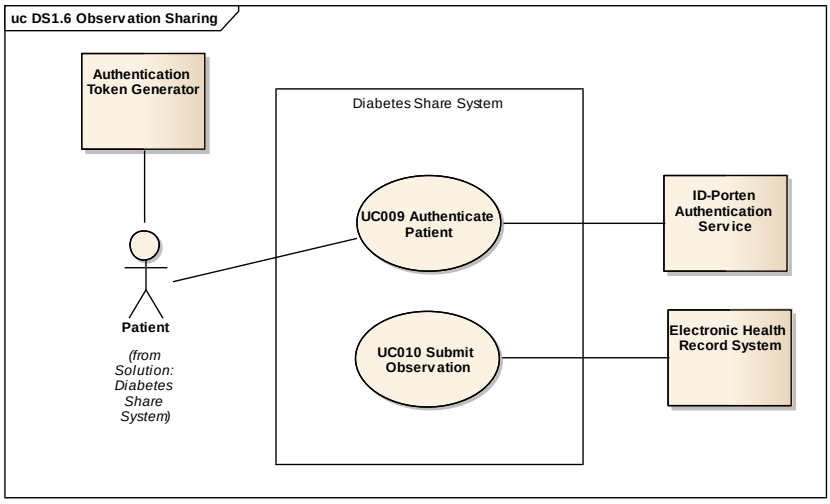
This is the DeSA version of the feature.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: advanced observation views • From DS1.1 Satisfaction: novel gadgets and smartphone app External interfaces: • From DS1.1 Smartphone HMI to patient • Diabetes Share M2M to Activity tracking cloud Use cases: • Inspect observations history • Inspect observations patterns and trends 

Notes	The patient smartphone is an iPhone and will be integrated with the FitBit cloud service.

2.4.1.12 Feature DS1.6 Observation Sharing

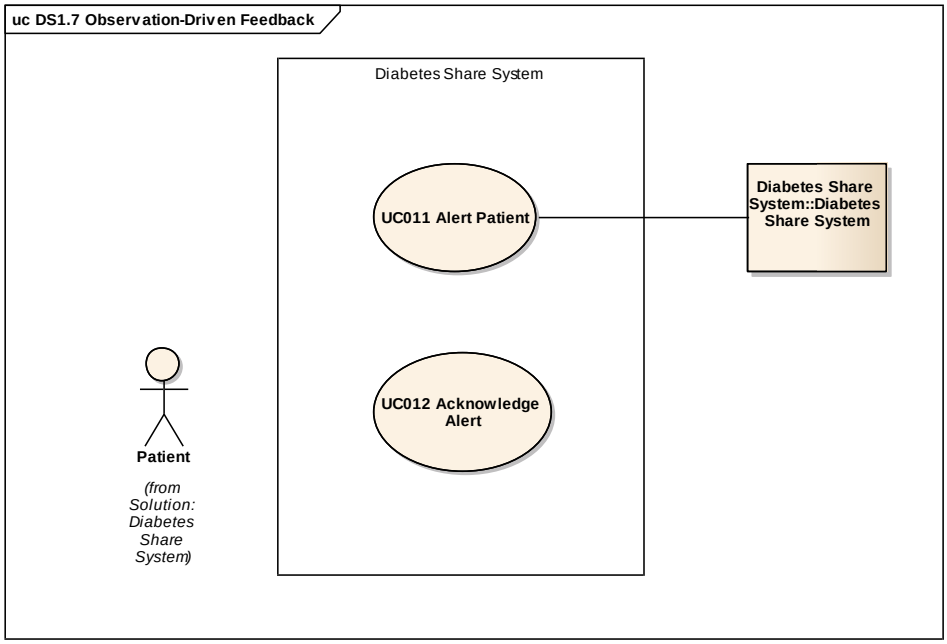
The Observation Sharing feature provides a service for mediating observations from Diabetes Share client smartphone applications into an EHR system to provide clinicians with patient observations.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: increased evidence basis for treatment • Effectiveness: closer follow-up of patient • Efficiency: improved level of personalized treatment and training External interfaces: • EHR Connector to Electronic Health Record system • From DS1.1 Smartphone HMI to patient • Diabetes Share External service to ID-Porten Authentication Service • Token generator HMI to patient Use cases: • Authenticate • Submit observation 
Assumptions	It is assumed that the EHR-system to integrate with will be supporting document sharing over IHE-XDS and HL7 CDA at time of integration. If this is not the case, a KITH-XML standard for lab responses may be used.

2.4.1.13 Feature DS1.7 Observation-Driven Feedback

The Data-driven Feedback feature provides functionality for notifying the patient on harmful habits through smartphone application.

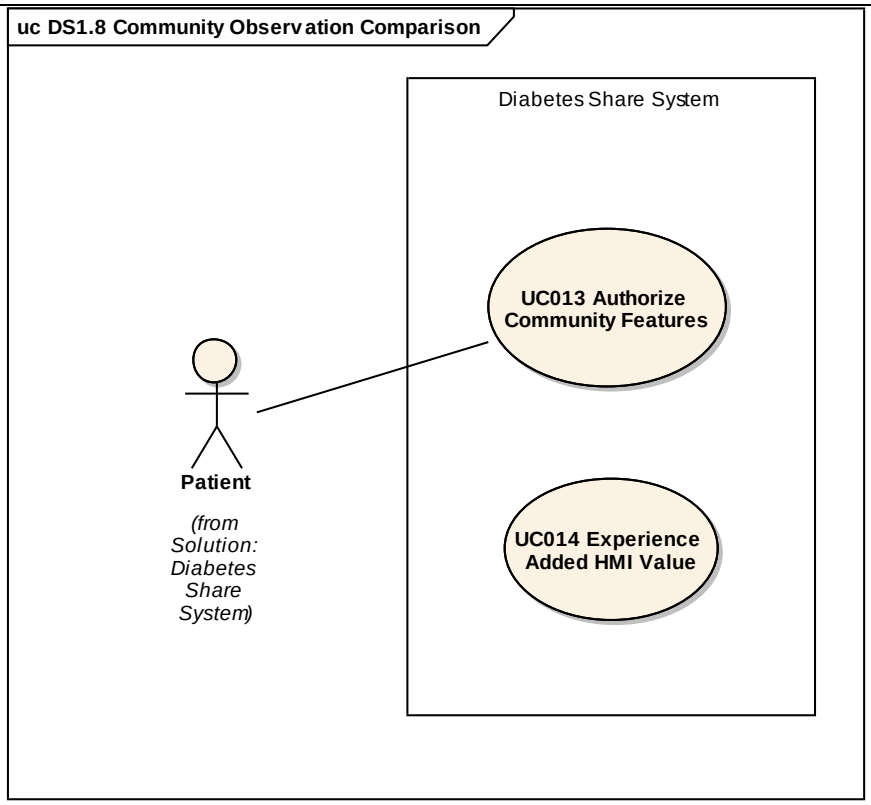
Addressed stakeholder interests and expectations	Goals to be achieved: • Safety: automatic patient alerts External interfaces: • From DS1.1 Smartphone HMI to patient

	Use cases: • alert patient • acknowledge alert 
Key ideas for implementation	A Diabetes Share cloud component will provide feedback by employing push notifications mechanism, which is well defined within various smartphone platforms.

2.4.1.14 Feature DS1.8 Community Observation Comparison

The Community Observation Comparison feature provides statistical aggregations of observations and matched peer experiences devoid of identifiable content. Supporting functionality in smartphone applications for patients to add comparative value with respect to peer experiences. Requires explicit sharing of own observations to gain access to feature.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: Motivator for a healthy lifestyle • Satisfaction: Sense of community involvement External interfaces: • From DS1.1 Smartphone HMI to patient Use cases: • Authorize community features • Experience added HMI value



2.4.1.15 Feature DS1.9 Next-of-Kin Observation Monitoring

The Next-of-Kin Observation Monitoring feature provides functionality for sharing observations with trusted peer or next-of-kin.

Addressed stakeholder interests and expectations	Goals to be achieved: - Safety: Monitoring by next-of-kin External interfaces: - From DS1.1 Smartphone HMI to patient - Smartphone HMI to next-of-kin Use cases: • Authorize next-of-kin sharing • Monitor patient
Key ideas for implementation	Potentially a read-only version of the Diabetes Share client can be set up to receive patient observations for monitoring by next-of-kin.
Comments or drawings	OUT OF SCOPE

2.4.1.16 Feature DS1.10 User Context Detection

The User Context Detection feature provides functionality of current user context assessment.

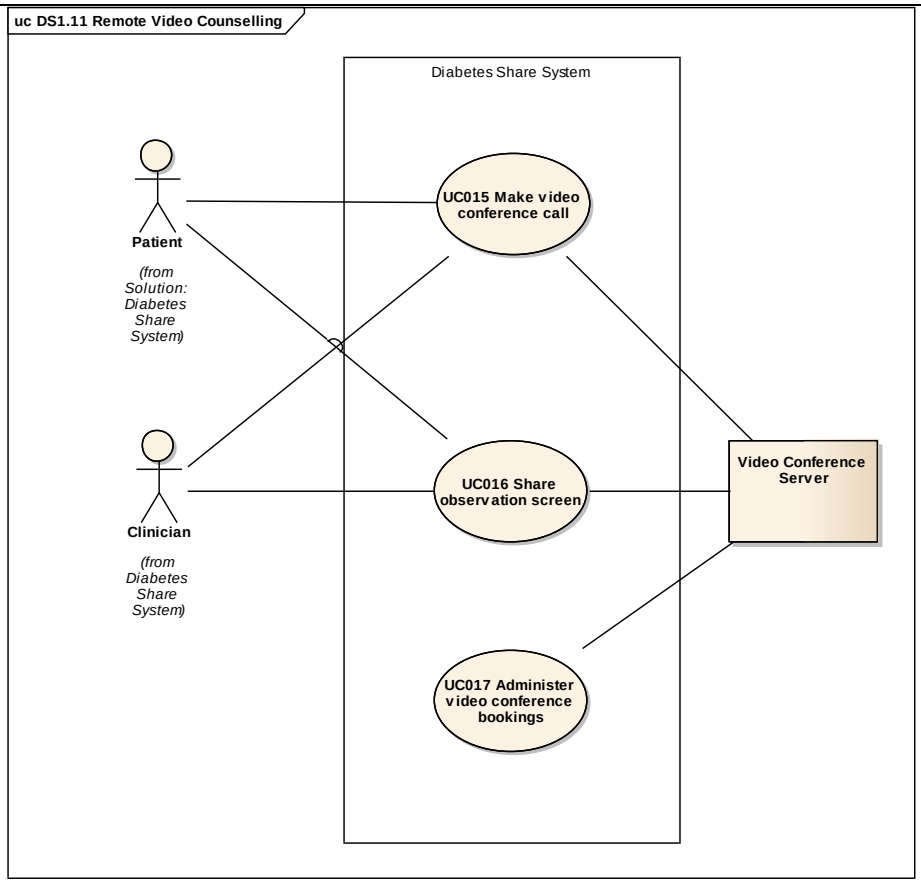
Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: holistic observation interpretation External interfaces: • From DS1.1 Smartphone HMI to patient

	Quality requirements: • Performance efficiency: low power consumption is strongly required • Usability: data will be gathered in the background without user intervention • Mobility: smart phone application will be able to provide data for user context assessment Data acquired: • Time • Geolocation and/or micro location • Ambiental volume • Phone accelerometer and gyroscope data • Calendar events
Key ideas for implementation	Smart phone application will acquire contextual data by obtaining various sensors and resources available within the smart phone platform. Data will be gathered in the background inside predefined time intervals and processed in a Diabetes Share System component.

2.4.1.17 Feature DS1.11 Remote Video Counselling

The Remote Video Counselling feature provides a service for remote real-time video counseling and treatment sessions between clinician and patient.

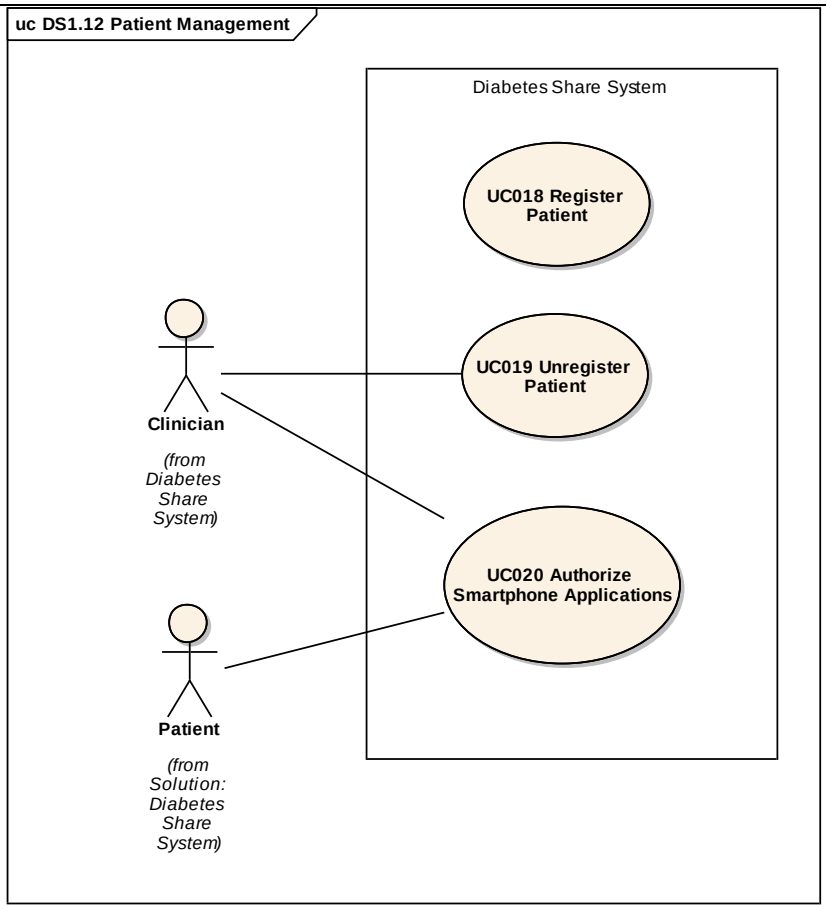
Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: reduced number of in-person appointments • From DS1.6 Efficiency: closer follow-up of patients External interfaces: • Diabetes Share service M2M to video conference server • From DS1.1 Smartphone HMI to patient Use cases: • Make video conference call • Share screen from smartphone app over video • Administration of video conference bookings

	
Key ideas for implementation	CISCO Jabber has previously been used with success in other projects at NST. Norsk Helsenett plan to have a Jabber server available for uses cases like this.
Assumptions	Risk analysis shows that security at level 2 is enough, so no integration with external 3PTY Authentication Service is needed. Smartphone HMI not available yet.

2.4.1.18 Feature DS1.12 Patient Management

The Patient Management feature administers patients' access to the Diabetes Share services.

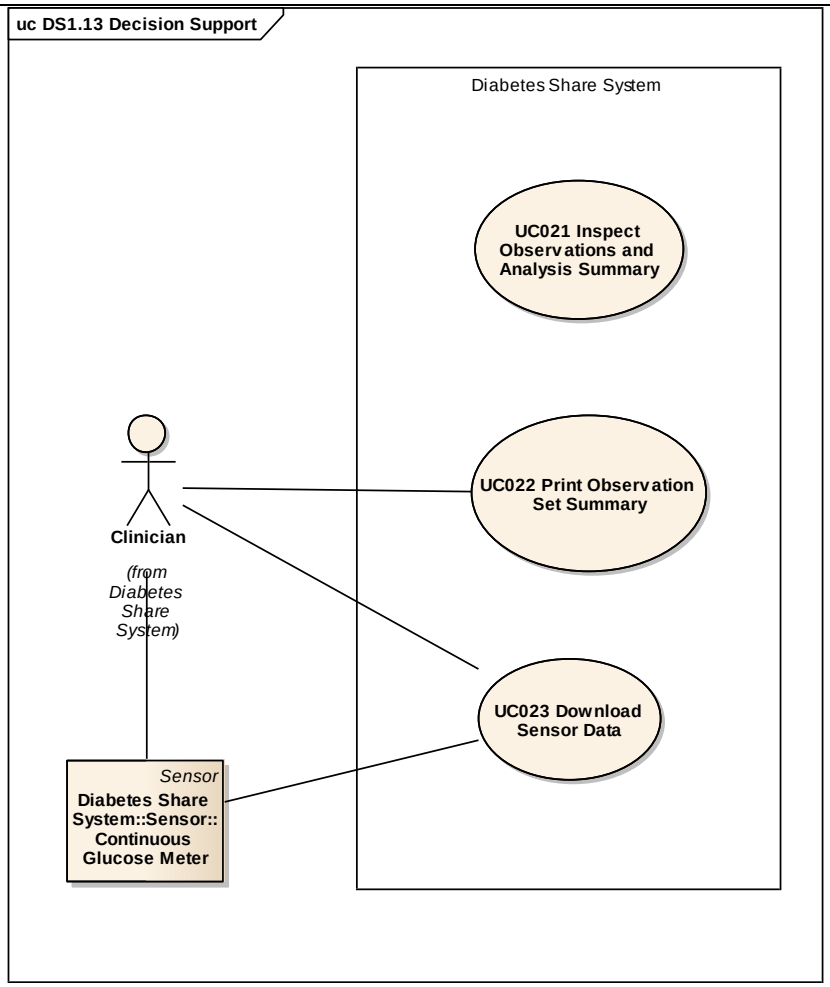
Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: Secure transfer of sensitive data Quality requirements: • Security: Regulatory compliance External interfaces: • Clinician PC to Clinician • From DS1.1 Smartphone HMI to patient Use cases: • Register patient • Unregister patient • Authorize smartphone & mobile apps



2.4.1.19 Feature DS1.13 Decision Support

The Decision Support feature provides an enhanced visualization of diabetes patients' status for clinicians on clinician's PC.

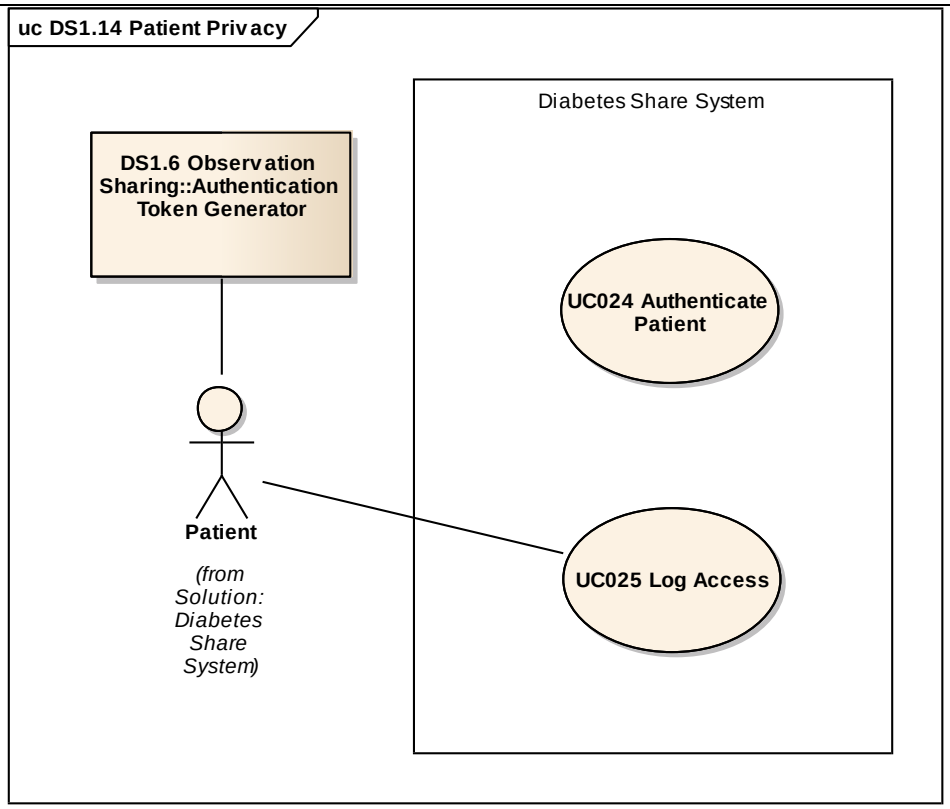
Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: effortless interoperability with EHR • Effectiveness: report printing functionality • Effectiveness: analytics tools for clinician • Effectiveness: clinic PC integration with clinical sensors External interfaces: • Clinician PC to Clinician • Sensor to clinician PC Use cases: • Inspect observations and summary • Print observation set summary • Download sensor data



2.4.1.20 Feature DS1.14 Patient Privacy

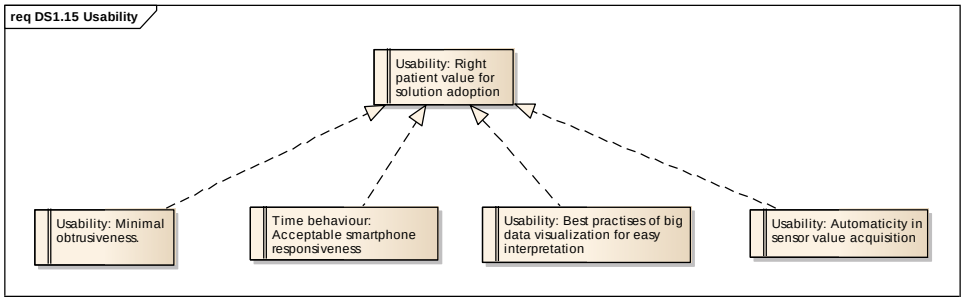
The Patient Privacy feature ensures protection of the patient's interests.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: Secure transfer of sensitive data Quality requirements: • Security: Regulatory compliance External interfaces: • From DS1.6 Diabetes Share External service to ID-Porten Authentication Service • From DS1.1 Smartphone HMI to patient • From DS1.6 Token generator HMI to patient Use cases: • From DS1.1: Authenticate patient • Log access



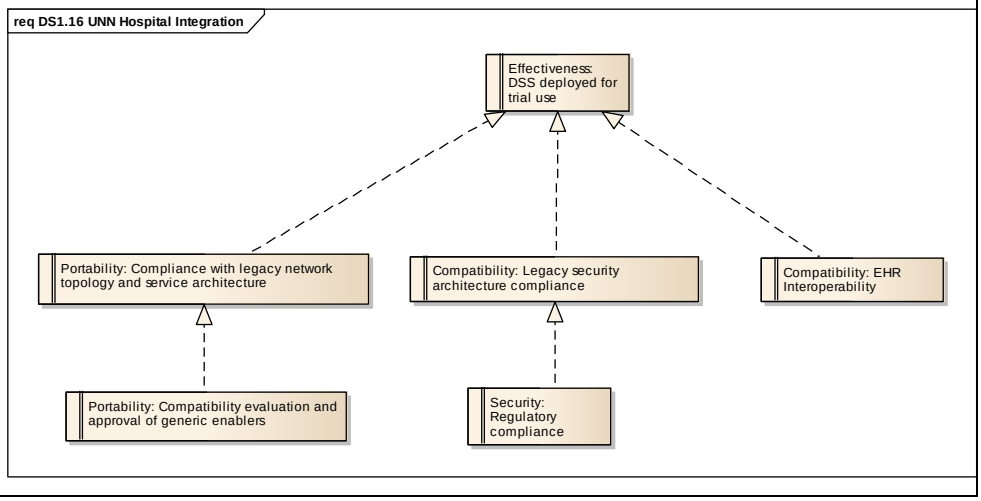
2.4.1.21 Feature DS1.15 Usability

The Usability feature defines the minimal criteria for the solution to be usable for patients.

Addressed stakeholder interests and expectations	Goals to be achieved: • Usability: Right patient value for solution adoption Quality requirements: • Time behaviour: Acceptable smartphone responsiveness • Usability: Automaticity in sensor value acquisition • Usability: Best practices of big data visualization for easy interpretation • Usability: Minimal obtrusiveness 
Notes	Automaticity for value acquisition means the user should not have to perform any extra steps (i.e. in addition to necessary handling of sensor for measuring) to get the value from the sensor to the smartphone.

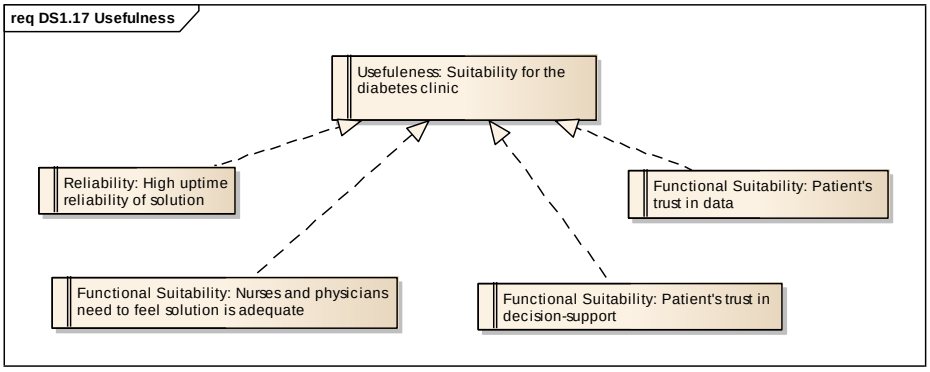
2.4.1.22 Feature DS1.16 UNN Hospital Integration

The UNN Hospital Integration feature defines the minimal criteria for the solution to be deployable and useful in the hospital network.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: DSS deployed for production use Quality requirements: • Compatibility: Legacy security architecture compliance • Compatibility: EHR interoperability • Portability: Compatibility evaluation and approval of generic enablers • Portability: Compatibility with legacy network topology and service architecture • Security: Regulatory compliance 

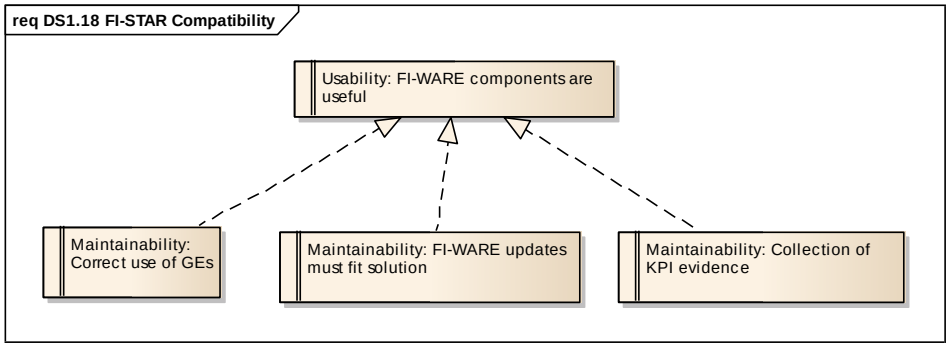
2.4.1.23 Feature DS1.17 Usefulness

The Usefulness feature defines the minimal criteria for the solution to be useful for the FI-STAR use case.

Addressed stakeholder interests and expectations	Goals to be achieved: • Usefulness: Suitability for the diabetes clinic Quality requirements: • Functional Suitability: Nurses and physicians need to feel solution is adequate • Functional Suitability: Patient's trust in decision support • Functional Suitability: Patient's trust in data • Reliability: High uptime reliability of solution 

2.4.1.24 Feature DS1.18 FI-STAR Compatibility

The FI-STAR Compatibility feature defines the minimal criteria for the solution to prove FI-WARE usefulness.

Addressed stakeholder interests and expectations	Goals to be achieved: • Usability: FI-WARE components are useful Quality requirements: • Maintainability: Collection of KPI evidence • Maintainability: Correct use of GEs • Maintainability: FI-WARE updates must fit solution 

2.4.1.25 Feature DS1.19 Productization

Out of scope

3 TeleCare Solution for Rehabilitation and State Monitoring in Krakow, Poland

The FI-STAR solution TeleCare addresses the problem of inefficient preoperative rehabilitation in thoracosurgical treatment and patient state monitoring (physical and psychological) during the chemotherapy treatment, which affects cancer patients at the hospital and at home. The impacts of this problem for the patients are low lung efficiency, high rescheduling rate of planned clinical procedures, and bad overall physical and psychological condition. A successful solution would improve the patient's lung efficiency before the thoracosurgical procedure, the chemotherapy patient's well-being, and generally patient's psychological state.

TeleCare is intended for cancer patients who are planned for a thoracosurgical treatment (scenario A) or are under chemotherapy treatment (scenario B) and for medical personnel (oncological nurses, physiotherapists, and medical doctors) who treat lung cancer. TeleCare is a FI-STAR cloud solution that enables conducting remote lung cancer rehabilitation sessions that prepare for thoracosurgical procedure and enables online remote patient monitoring based on health parameters provided by a local sensor platform as well as provides possibility to perform live video observations. Unlike the current lack of supervision of chemotherapy patients at home and lung cancer patients rehabilitation sessions at home, TeleCare improves the general quality of care for targeted lung cancer treatment, increases treatment efficiency, and helps patients to maintain better communication with medical personnel through improved consultancy capabilities.

This chapter gives an overview of a FI-STAR solution that is intended to be built to support the FI-STAR use case. The chapter covers the goal/purpose of the FI-STAR solution, stakeholders and their interests/expectations, the application and their features that are integrated into the FI-STAR solution to support these interests/expectations, and the FI-STAR solution-wide requirements and constraints. The appendix can be used to capture any other material, including business processes, glossary, description of the as-is situation, problems with current solutions, storyboards, and examples of artefacts and photographs of usage context.

The vision chapter is intended as a starting point for subsequent detailed requirement engineering. The features are used to establish an overview of the FI-STAR solution's requirements that then will be engineered just-in-time before the relevant development starts. The features should be specified by explaining how the concerned FI-STAR application will support the corresponding FI-STAR stakeholders' interests and expectations. The vision chapter should be updated as the understanding of the FI-STAR solution and of its aims and objectives evolve.

Future uses of this vision chapter will be to establish personas for target user segmentation and user experience engineering, traceability to release and project planning, application and enabler design and development, and quantification of quality requirements and testing, definition/monitoring of KPI, and analyzing commonality/variability across applications. In addition, this vision chapter will refer to relevant specialty requirements.

3.1 FI-STAR Solution Positioning

The following section captures the essence of the FI-STAR TeleCare solution, including the problem it addresses and the key idea of solving the problem.

3.1.1 Problem statement

The problem of	inefficient preoperative rehabilitation in thoracosurgical treatment and patients at home state (physical and psychological) monitoring at home during chemotherapy treatment
affects	cancer patients at home, respectively the hospital

the impact of which is	lower patients' lungs efficiency and high rescheduling rate of planned procedures; bad overall physical and psychological patient's condition; unnecessary patients visits in hospital; overloaded medical personnel; high costs of a treatment
a successful solution would be	to improve patients' lungs efficiency before thoracosurgical procedure; wellbeing, and psychological state of chemotherapy patients'

3.2 Position statement

For	cancer patients; medical personnel (e.g. oncological nurses, physiotherapists and medical doctors)
Who	are going to qualify for a thoracosurgical treatment (scenario[1] A) or are under chemotherapy treatment (scenario B); treat lung cancer
The (solution name)	TeleCare (TC) is a FI-STAR cloud solution
That	enables scheduled and on-demand video consultations capabilities; online, remote patient monitoring based upon vital signs measurements provided by a local sensor platform and patient subjective condition reporting; conducting remote lung cancer telerehabilitation sessions preparing for thoracosurgical procedure.
Unlike	currently not supervised chemotherapy patients at home and not supervised rehabilitation sessions at home
Our solution	reduces needed effort for care of cancer patients in particular by: reducing unnecessary visits in hospital through improved consultancy capabilities; improving decision support effectiveness of a treatment through continuous acquisition of patients vital signs and subjective condition reports; lowering rescheduling rate of planned thoracosurgical procedures through supervised telerehabilitation sessions

3.3 FI-STAR Use Case Stakeholders

The following users, interfacing systems, and other stakeholders are affected by the solution.

3.3.1 User Roles

Figure 17 provides an overview of the user roles the TeleCare solution supports. These are the ontological nurse, the physiotherapist, the medical doctor, and the psychologist (all four special cases of medical personnel), the TeleCare system administrator and the hospital information system HIS administrator (both special cases of administrator), and the patient. The thoracic surgeon and the medical oncologist are special cases of the medical doctor.

[1] The TeleCare solution is intended to support two medical treatment scenarios for different groups of patients and with different needs. Scenario A addresses preoperative remote rehabilitation in thoracosurgical treatment while scenario B covers video consultations for chemotherapy patients. Both scenarios will use common TeleCare features.

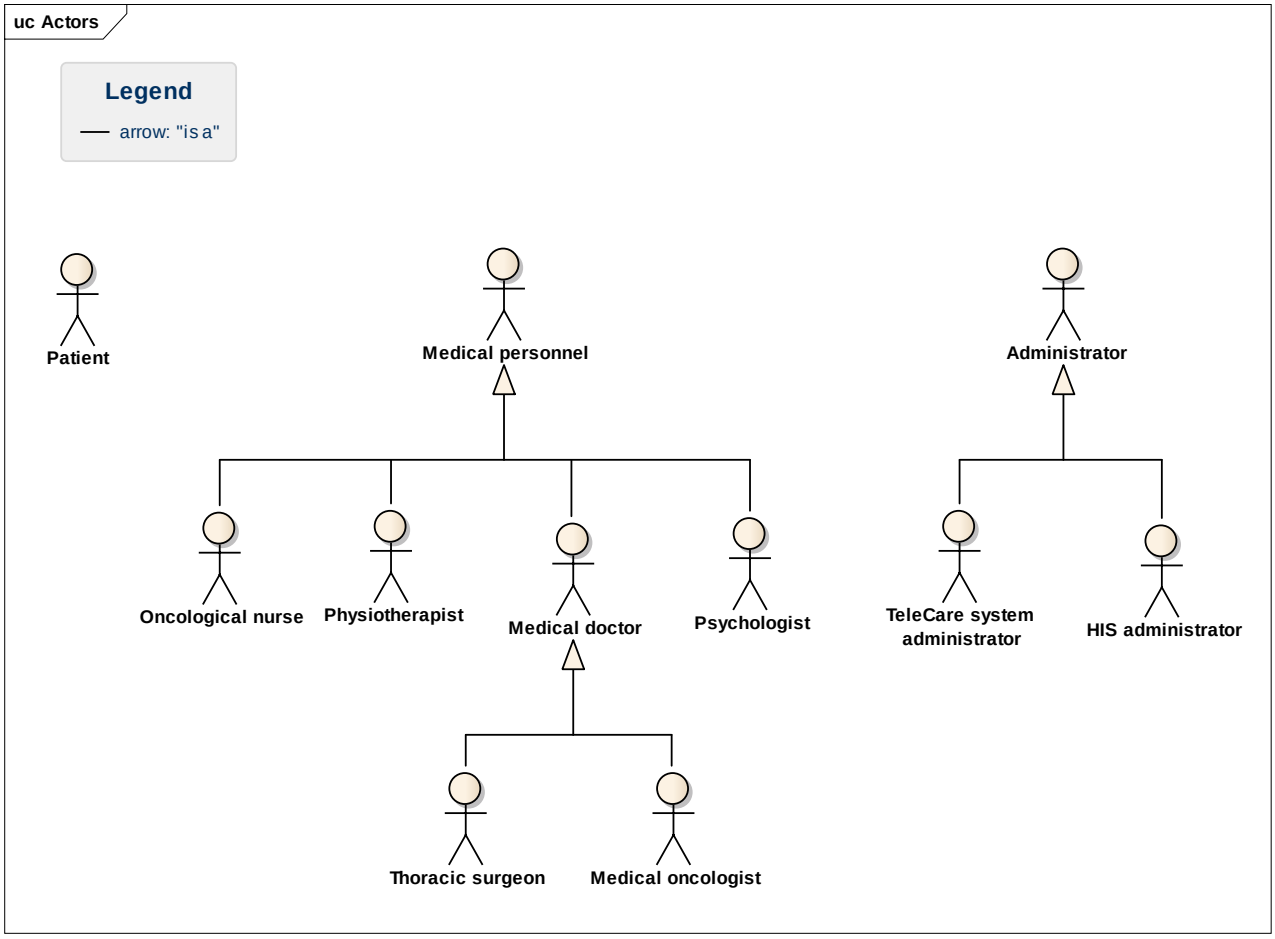


Figure 17: Users of the TeleCare solution

The TeleCare solution supports two scenarios: rehabilitation that prepares lung cancer patients for thoracosurgery (Scenario A) and care of patients that undergo chemotherapy (Scenario B).

3.3.1.1 Scenario A - preoperative remote rehabilitation in thoracosurgical treatment:

Figure 18 - Figure 20 give an overview of the lung cancer patient treatment workflow related to thoracosurgical treatment. Initially, patient is admitted for a 3-day stay at the hospital for thoracosurgery qualification tests and rehabilitation training. Before starting the TeleCare rehabilitation trial program at home, the patient will perform at the hospital: spirometry tests to evaluate pulmonary function parameters, the type of pulmonary dysfunction (Figure 19) and 6-minute walk test (6MWT) assessing the patient's functional status (Figure 18). Moreover, before and after the test the following measures will be taken: oxygen saturation, blood pressure, heart rate, level of dyspnea and level of fatigue on the Borg scale (Figure 19). All these test are performed to evaluate whether the patient qualifies for thoracosurgery and will be performed using a current hospital equipment. After the trail in the hospital, patient receives the TeleCare set (hardware and software) together with a set of exercises to do at home. Medical staff give patient an instruction how to perform such exercises (Figure 20) and how to use the TeleCare solution. After discharge from the hospital the patient is asked to use the TeleCare solution for his rehabilitation at home. Once being instructed in the hospital, patient should make exercises daily twice a day at home, receive video consultations according to the prepared schedule, measure vital signs before and after exercises and assess his or her subjective condition. Currently, the medical staff does not have the ability to control the patient whether and how he performs the exercises as well as have no information about patients' condition at home. Therefore, TeleCare solution could improve significantly quality of care and efficiency of preoperative rehabilitation due

to a possibility to perform supervised, remote video rehabilitation sessions and capturing most recent patient condition data.

At home, at the beginning and at the end of each rehabilitation session using the TeleCare, the patient measures blood pressure, heart rate, oxygen saturation, temperature and level of dyspnea and fatigue using provided biometric sensors and a dedicated TeleCare application functionality for assessing subjective patient condition. All results are stored locally within the patients' TeleCare application and can be transferred to the hospital TeleCare domain for further analysis. These parameters indicate a patient's well-being before and after rehabilitation session, as well as inform the medical personnel of any contraindications to take exercises such as high blood pressure or high temperature. In case of malaise during exercise the patient should perform additional measurements of the parameters referred to above on medical staff request. Data about patient current condition will be available remotely in hospital, provided by a local patient sensor platform and live video observations. According to the patient rehabilitation plan, exercises are performed and sometimes supervised by the medical personnel (via video sessions). Supervised video rehabilitation session is initiated either by a physiotherapist or by the patient. At the end of two-three weeks of exercises, these studies are compared with the results of pre-rehabilitation. The patient regularly visits the hospital for the thoracosurgery qualification tests until he/she is admitted for thoracosurgery.

It is assumed that the remote rehabilitation TeleCare scenario will include about 30 patients. After the experiment comparison might be made between patients from the experimental group and from control group (patients who practice independently and do not exercise at all before the surgery).

In general to support thoracosurgery preparation, the TeleCare solution: captures required measurements related to the thoracosurgery rehabilitation programme, enables supervision of the rehabilitation exercises, monitors the patient's condition by collecting health parameters, and establishes video communication between patient and medical personnel.

Figure 18: The 6MWT (Six Minute Walk Test) is used to evaluate the patient's tolerance to fatigue and risk of perioperative complications coming from the artificial respiratory system. Left: Patient walks over a total of six minutes on a hard, flat surface. Total distance travelled by patient is measured. Right: Physiotherapist monitors the procedure and counts down required walking time. During 6MWT procedure the physiotherapist asks the patient about any difficulties with breathing (shortness of breath). The patient is allowed to self-pace and rest as needed.

Figure 19: The following measurements are taken before and after the 6MWT (Six Minute Walk Test). Left: measurement of blood pressure and heart rate. Middle Left: measurement of arterial oxyhemoglobin saturation (SpO2) and pulse rate. Middle Right: Spirometry for evaluating pulmonary function parameters and the type of pulmonary dysfunction. Right: In addition to the objective measurements, subjective data about the patient's exertion is captured with the 1-10 Borg scale.

Figure 20: To prepare the patient for thoracosurgery and to increase the patient's breathing efficiency, preoperative rehabilitation is performed. Left: Physiotherapist instructs patient for how to perform rehabilitation exercises. These exercises are later performed by the patient at home according to a specified regime. Middle: Patient performs exercises according to given instructions. Right: Paper instruction of how to perform exercises at home given to patient.

3.3.1.2 Scenario B – Chemotherapy care

Regarding the TeleCare chemotherapy scenario, patients who are discharged form hospital (staying at home in between chemo doses in hospital) will have a possibility to consult their physical and psychological condition due to possibility of receiving scheduled and unscheduled video consultations with oncological nurses, medical oncologists and psychologists.

Medical personnel will qualify patient to the scenario B trials according to their overall condition. Initially, patient is admitted for a 1-2 day stay at the hospital for receiving a chemotherapy dose. Patient after receiving a chemotherapy dose in hospital, will be discharged and will receive the TeleCare set (hardware and software) for a period of either until receiving next dose (approx. 1 month) or for the whole treatment (approx. 3-6 months) depending on medical oncologist decision.

At home, patients according to the prepared schedule of consultations, will provide to the medical personnel feedback about their condition (subjective, objective). This feedback will be received via TeleCare video consultations, typically initiated by an oncological nurse (Figure 21) and by local sensor platform being a part of the TeleCare solution. Patients using the TeleCare solution at home, will be asked to journalise a treatment process using provided TeleCare ChemoDiary functionality. Each day patient should follow a very short process of collecting his or her condition related data including: measuring requested vital signs: pulse rate, blood pressure, body temperature and optionally arterial oxyhemoglobin saturation (SpO2) and assessing his or her subjective condition (e.g. using standardized LCSS scales). All these ChemoDiary results will be available in the hospital domain for medical staff to analyze the chemotherapy treatment efficiency, effectiveness and influence on patient physical and psychological state.

It is planned to organize a team dedicated to the experiment including 3 doctors, 4 nurses and 1 psychologist. Contact with patient will be scheduled (once per week) or as additional video session on the patient request. Primary contact will be held by a nurse, and if necessary, a doctor or psychologist will be assisting. Request for additional “remote visits” will be possible 24/7 but video consultations will be held normally on weekdays from 08.00 to 15.30. It is assumed that 15 patients will participate in chemotherapy TeleCare scenario.

In general to support chemotherapy care, the TeleCare solution monitors the patient’s condition by collecting health parameters, subjective patient’s condition and establishes video communication between patient and medical personnel.

Figure 21: Left: Oncological nurses take care of their patients on chemotherapy ward on daily basis. Middle: All information about the patient treatment history is stored in integrated IT system available for medical personnel. Right: Patients during their stay in hospital can consult with medical oncologists in dedicated rooms.

The general TeleCare workflow:

The proposed general TeleCare workflow starts while discharging form the hospital and is described in the following steps:

1) (**Delivery**) For both TeleCare scenarios (A and B), during discharging from the hospital patient receives TeleCare hardware set (Biometric devices, Tablet with TeleCare application installed and optionally external video camera for patients qualified for scenario A). The TeleCare hospital workstation(s) to be used by medical personnel during the pilot TeleCare trials should be already operational by this time and the personnel should be properly trained how to use the proposed solution. The TeleCare workstations in hospital will be deployed probably in the oncological nurses room for chemotherapy scenario and in physiotherapists room for the rehabilitation scenario.
2) (**Deployment**) Depending on patient technology knowledge, he/she is instructed how to use the solution (in terms of operating provided software application and hardware biometric devices) and the TeleCare solution deployment in patient home is possible by qualified technicians. The broadband internet connection in patient home is required to

deploy the solution and enable its main features. Nevertheless, some of the features might be used offline by a patient, and send results (e.g. vital signs data) whenever the solution is back online.

3) (**Scheduling**) Additionally, for each patient a schedule of video consultations/rehabilitation sessions is prepared and available for both patient and medical personnel using the TeleCare solution (calendar like functionality). Patients or medical personnel can request for additional consultation sessions and adjust the schedule using the TeleCare solution during the trial, if needed.
4) (**Treatment support**) According to the schedule, patients at home consult remotely using the TeleCare with a medical personnel, measure their vital signs using provided devices, assess their subjective condition and share results with a medical personnel on daily basis. For chemotherapy scenario, providing video consultation sessions enable fast feedback about a chemotherapy treatment influence on a particular patient condition. For a cancer rehabilitation scenario, patients additionally perform exercises sessions according to a provided rehabilitation plan. Such sessions can be supervised by physiotherapists using the TeleCare video consultation features (high quality video transmission available). Remote treatment cycle with a use of the TeleCare for supporting cancer rehabilitation (scenario A) is expected to last approx. 3-4 weeks for each patient, while for chemotherapy patients (scenario B) approx. 3 months. Nevertheless, patient may still visit the hospital during TeleCare trails, if needed (on a medical personnel request or basing on his/her personal decision).
5) (**Treatment analysis**) The history of patient subjective and objective condition is stored in the TeleCare solution (electronic health records for the TeleCare patients) and available for both medical personnel and patient for further analysis which may result as a change in the treatment process (recommendations for changing daily habits, lifestyle, prescribed drugs etc.). Moreover, a video consultancy features enable observation of chemotherapy patients and supervising rehabilitation sessions of patients preparing for thoracosurgical procedure.
6) (**Trial end**) After ending the assumed treatment cycles, each patient return to the hospital leased TeleCare set or a decision is made by a medical personnel to start next cycle (e.g. when patient still cannot qualify for thoracosurgical procedure or further chemotherapy cycles are needed).

The following table describes the user roles in detail, including their background, role and expectations.

Table 1: TeleCare user roles

Name / Count / Representative	**Description**	**Expectations on Solution**
Oncological nurse 12 Ewa Marczewska (JP2) Danuta Lachowska (JP2)	Responsible for first contact with patient in hospital. Looks after patients during patients' hospital stay. Supports communication between patients and medical doctors. Performs basic medical procedures.	More flexible contact with the patient (24/7). Supervision of patient's condition after discharging from hospital. Communication and feedback quality maintained despite the distance. Reduced number of unnecessary patients visits in the hospital
Physiotherapist 4 Anna Jarosz (JP2) Mirosław Janczura (JP2)	Responsible for rehabilitation process before thoracosurgical procedure. Supports the 6MWT procedure and spirometry during patients' first days trials. Measures basic patient's life	Increased treatment efficiency and reduced number of hospital visits. More efficient preoperative rehabilitation in thoracosurgical treatment Patient's condition data gathering on

Roksana Ryczek (JP2)	parameters shortness of breath and fatigue level on the Borg scale. Guides patients in how to perform rehabilitation exercises.	daily basis (faster reaction in case of major changes in patient's condition)
Thoracic surgeon 3 M.D. Jarosław Kużdżał (JP2)	Responsible for overall cancer treatment process, performs and leads thoracic operations and medical procedures. Decision maker.	Pilot tests results analysis Possibility of additional consultancy Increased treatment efficiency and reduced number of hospital visits. More efficient preoperative rehabilitation in thoracosurgical treatment Patients condition data gathering on daily basis (faster reaction in case of major changes in patients' condition)
Psychologist 2 M.D. Marta Skoczek (JP2)	Responsible for psychological support. Decreases patient's fear level Performs psychological sessions	Fast feedback about overall psychological state of a patient Psychological video consultations No video sessions recording
Administrator (Hospital IT resources management) 4 Małgorzata Rusin Roman Rogóż Tomasz Czeluśniak Marcin Deptuch	Responsible for managing hospital IT infrastructure (hardware and software). Provide access to hospital IT resources.	Easy to maintain and support Easy to adapt to new devices and medical domains
Medical oncologist 5 M.D. Grzegorz Czyżewicz (JP2) M.D. Marta Skoczek (JP2)	Responsible for overall cancer treatment process. Decision maker.	More flexible contact with the patient (24/7). Supervision of patients condition after discharging from hospital. Communication and feedback quality maintained despite the distance. Reduced number of unnecessary patients visits in the hospital
Patient approx. 30 for two scenarios trials	Patients at home in particular: Patients discharged from hospital preparing for thoracosurgical procedure at home (scenario A – remote rehabilitation) Patients discharged from hospital, staying at home in between taking chemo doses in hospital (scenario B – remote consultations). Mostly older people (>60);	Easy to learn and use, minimally disturbing at home, highly usable and responsive, simple and straightforward to use, attractive, invading the privacy in a minimal manner, trustful, not interfering to the one's privacy much

	Might be afraid of new technologies; Might require help form the family; Bad overall physical and psychological condition.	

3.3.2 Interfacing Systems and Artefacts

Figure 22 gives an overview of the system boundary of the TeleCare solution. The connectivity of the FI-STAR cloud (e.g. Provider Edge Cloud) is a concern of the solution architecture, hence omitted from the overview.

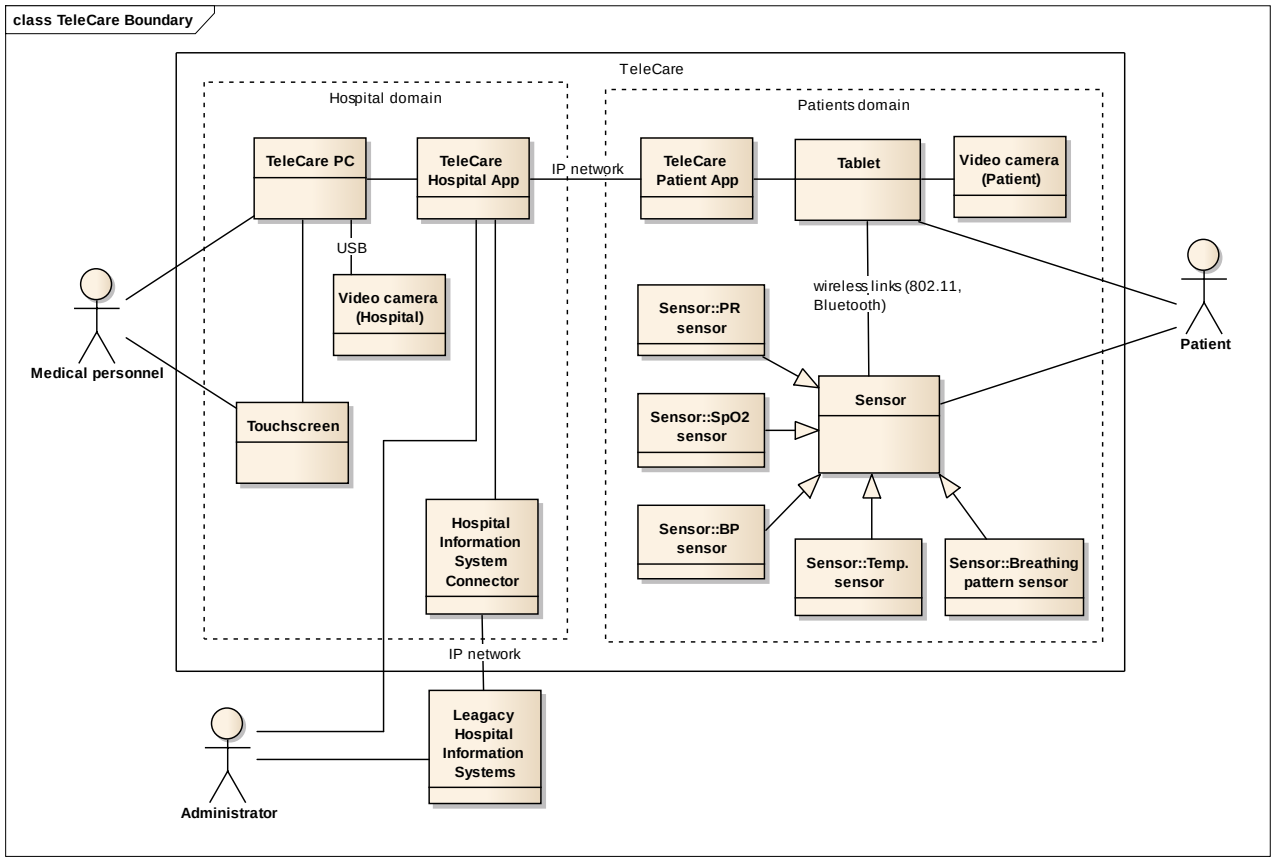


Figure 22: System boundary of the TeleCare solution, including all interfaces to users, systems, artefacts of the FI-STAR use case.

Figure 23-Figure 26 give an overview of the TeleCare solution interfaces and artefacts that are to be supported.

Figure 23: Possible sensors. Left: Wrist blood pressure (BP) monitor. Middle-left: Pulse Oximeter measuring pulse rate (PR) and arterial oxyhemoglobin saturation (SpO2). Middle-Right: Thermometer (BT sensor) Right: RIP belt - Respiratory Inductance Plethysmography belt – for measuring breathing patterns. The presented devices are examples only. The planned tender will determine the exact products to be used. More information: see annex.

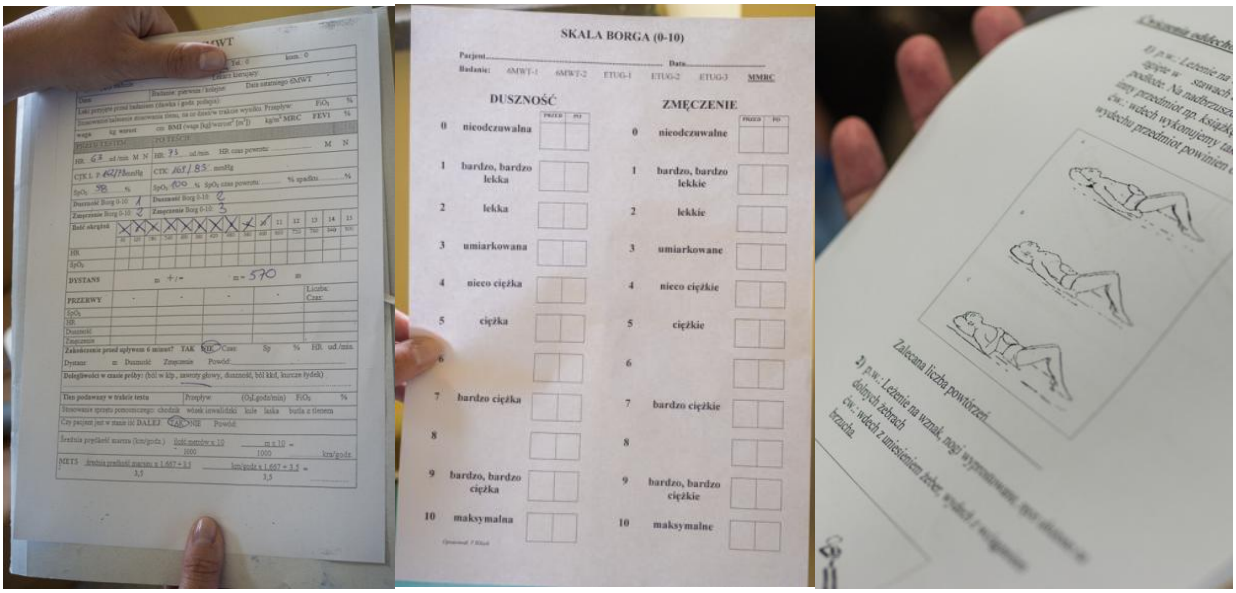


Figure 24: The TeleCare solution manages date remotely in electronic format. It collects patient data that today is recorded in the hospital on paper forms and manually inserted into the Hospital Information System and provides instructions to the patient that today are captured on paper. Left: 6MWT form including HR, blood pressure and SpO2 measures, perceived level of exertion. Middle: Borg scale form with perceived level of exertion and dyspnoea. Right: Rehabilitation exercise guide.

Figure 25: Possible end-user physical TeleCare interfaces. Left: TeleCare touchscreen - medical personnel user interface available in the hospital (TeleCare hospital workstation with the touchscreen). Right: patient 10'' tablet with the TeleCare application installed.

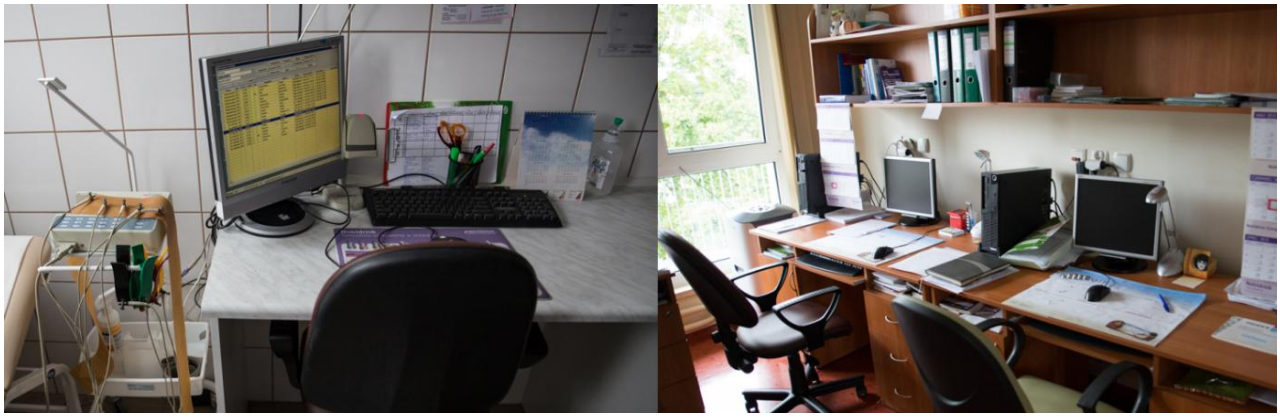


Figure 26: All information about a patient's treatment history, including tests results and x-ray photos, is managed in the integrated Hospital Information System HIS from InfoMedica. Left: HIS terminal in examination room. Right: HIS terminals in medical oncologist room.

The following table describes the interfacing systems, artefacts and related expectations on the solution.

For the reasons of public procurement procedures that the JP2 as a public administration institution has to follow in order to buy equipment, interfacing devices described below are presented only in a form of general specification. No vendors and devices models names are given to support fair competition.

Table 2: TeleCare interfacing systems and artefacts

Name	Description	Expectations on Solution
Patients' sensors (sensor platform, set of sensors)	Each patient will be equipped with a set of sensors enabling measurement of basic vital signs: blood pressure (BP), pulse rate (PR), body temperature (BT) and arterial oxyhemoglobin saturation (Sp02). Sensors should enable wireless transmission of measurements to the	The solution will enable daily monitoring of basic patients' vital signs after discharging from hospital, during chemotherapy periods at home and rehabilitation before thoracosurgical procedure at home. The solution will enable gathering locally

	patients' mobile device (tablet). Additionally, other sensors might be used for the TeleCare solution especially for monitoring remote rehabilitation process e.g. sensors for measuring shortness of breath or breathing patterns (e.g. Respiratory Inductance Plethysmography belts). Devices to be used: wireless, fingertip Pulse Oximeter (SpO2, PR), wireless, wrist/arm Blood Pressure monitor (BP), (optionally) Breathing pattern sensor (e.g. chest RIP belt stripes), wireless thermometer (BT) More detailed information about biometric devices can be found in the appendix to the present document.	(within patients domain) and transmitting gathered life parameters data to the hospital domain. The solution should enable user friendly data visualization and aggregation functions. The set of sensors should be easy to use for the patient (limited number of buttons, information on LCD screen etc.). The best solution would be to use one sensor platform (one device) enabling monitoring of all (or most of) required vital signs.
Tablet	Each patient will be equipped with a 10'' tablet (Android OS based). Min. req. for tablet: 1280x800 display resolution, LED backlight, 8 GB flash memory, 1 GB DDR2 RAM, 1Ghz processor clock speed, 802.11 b/g/n Bluetooth 2.0, 1 megapixels front facing camera, Android 4.0 supported, microphone, speaker, 6 hours run time on battery, USB interface. The tablet will be a hardware heart of the TeleCare solution within patient domain enabling bidirectional video communication with the medical personnel, gathering and transmission of life parameters measurements and subjective patient condition data.	Patients will receive tablets after discharging from hospital for the time needed for treatment (each patient in chemotherapy scenario for 3 months, and remote rehabilitation for 3 weeks). Will be used for video consolations and gathering patients' condition objective and subjective data. Will be connected to the Internet through patients' ISP.
TeleCare Patient App	FI-STAR TeleCare application for patients, installed on patient tablet	It will enable wireless communication with vital signs sensors, gathered data visualization and video teleconsultations. It will be an Android OS application installed on a Tablet.
TeleCare Hospital App	FI-STAR TeleCare application for hospital, installed on Medical personnel PC in hospital.	Is will enable video consultations, patients vital signs visualization and browsing patients remote treatment history record.
Video camera (Patient)	High definition (1920x1080), wide angle video camera enabling video streaming through mobile device (tablet).	TeleCare Patient App will be connected to the patient video camera enabling high definition video streaming.
TeleCare PC	Standard PC workstation (or laptop) provided by hospital. Currently used PC for accessing patients data through legacy IT systems (e.g. in oncological nurses room). Operating systems: Windows XP (or newer), Java VM installed, connection to	Hardware for TeleCare Hospital App. Hardware deployment environment

	the Internet.	
Touchscreen (optional)	Big (>24'') touchscreen enabling manipulation on TeleCare Hospital App	Hardware manipulation interface for TeleCare Hospital App.
Video camera (Hospital)	Standard USB Web video camera	Enables patients to see medical personnel during video teleconsultations
Hospital Information Systems	Hospital legacy IT systems integrated by Asseco InfoMedica hospital central IT system. Integrated systems: CGM Computed tomography (CAT), Microbiology, ComPACS Echocardiography, Blood bank system, LIS laboratory, Oracle BI and CONTEC billing.	Possible TeleCare solution integration with current legacy hospital IT systems - InfoMedica (e.g. data gathered through TeleCare might enrich current patients history record). Integration possibilities to be discussed.

3.3.2.1 Data flow

The following section give an overview of how the TeleCare solution is intended to be used within the overall workflow. Diagram below (Figure 27) that describes the data flows across the system boundary and among the applications that the solution integrates.

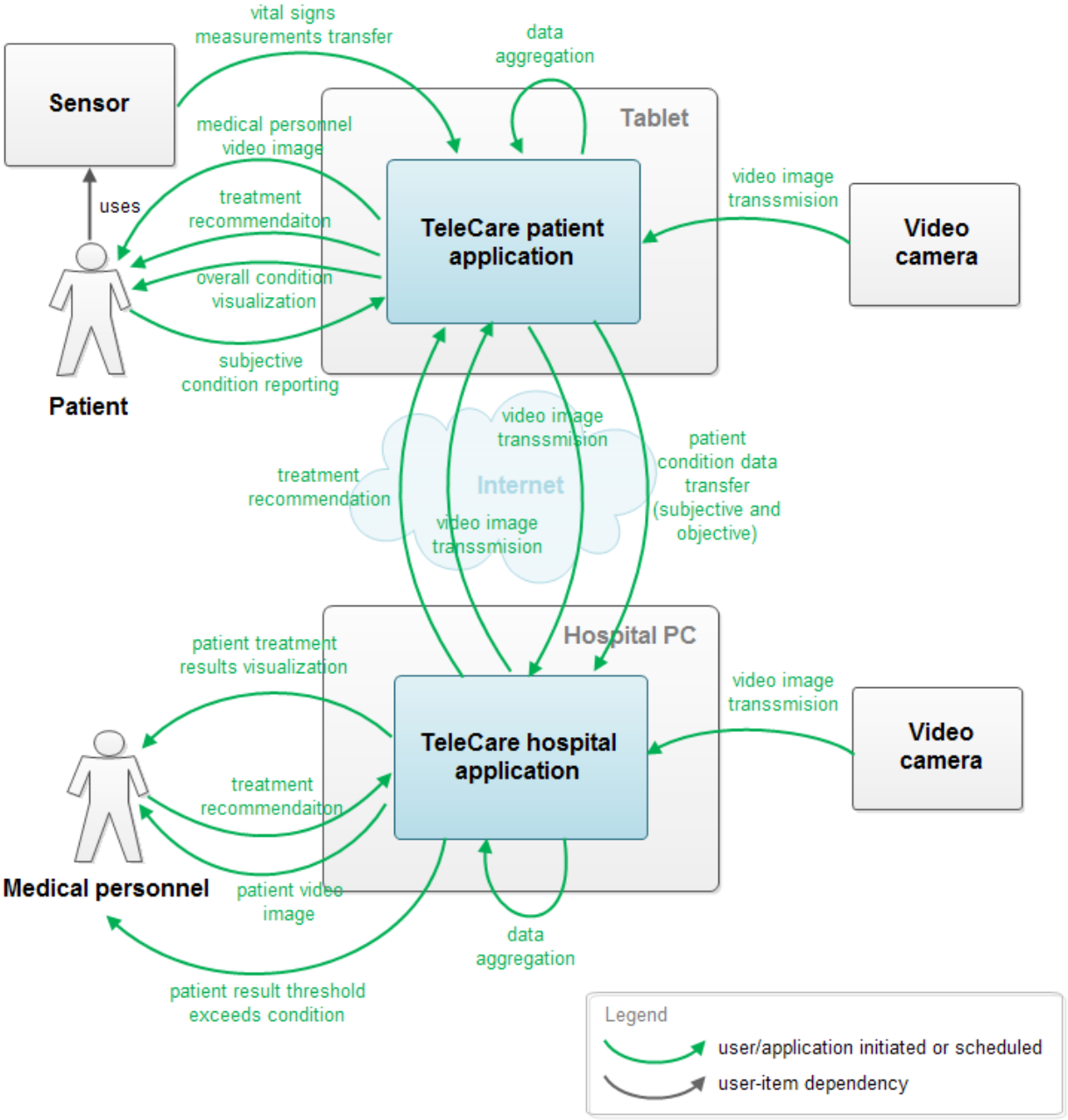


Figure 27: Overview of the TeleCare data flows

3.3.3 Other Stakeholders

Figure 28 and the following table describe stakeholders that affect, but do not directly interact with the solution. The description includes background and role of these stakeholders and their expectations on the solution.

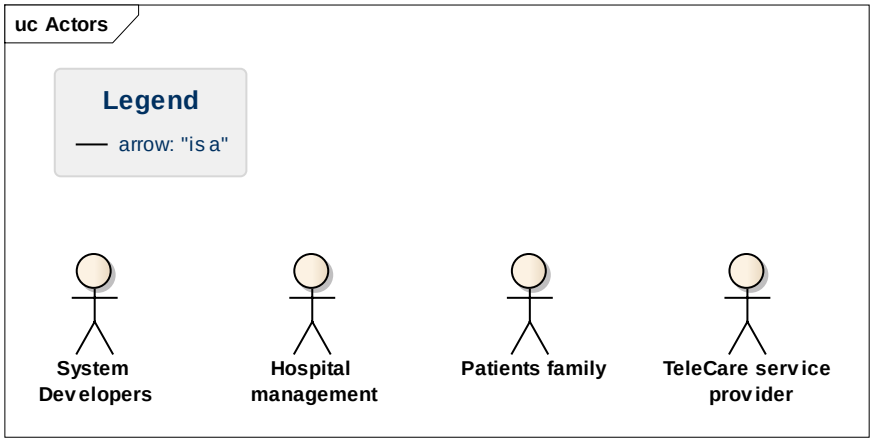


Figure 28: Other stakeholders of the TeleCare solution

The following table describes these stakeholders and their expectations on the solution in detail.

Table 3: TeleCare other stakeholders

Name / Representative	Description	Expectations on Solution
System developers ITTI developers team	TeleCare solution developers responsible for the implementation and technical testing of the TeleCare solution	Modular and easy to adapt to other devices – sensors. FI-STAR GEs supporting some functionalities already provided Coherent with other FI-STAR products.
Hospital management M.D. Anna Prokop-Staszecka (JP2 CEO)	Hospital management members responsible for the overall hospital management (financial, human resources, strategic planning, introducing innovations, acquiring contracts etc.) High level decision makers.	Measuring cost efficiency of telemedicine solutions (leading to possible law regulations changes and changing government policies towards funding eHealth domain in Poland) Innovative telemedicine solution deployed in JP2 hospital. Reduced number of unnecessary visits in hospital leading to reduced costs Possible extension of the solution for other types of treatment
Patients' family	Patients' family	Quality of care improved

3.4 FI-STAR Value Case

3.4.1 Value provided for thoracosurgical rehabilitation

At the Department of Thoracic Surgery in the John Paul II Hospital in Krakow, there is no possibility for a daily or ambulatory rehabilitation. Currently, a patient who is qualified for thoracic surgery is provided with a set of exercises to practice at home. Initial results of our research shows that after two weeks of independent practice only a part of those patients can achieve better results in the test. Results of the other part of them remains the same or even becomes worse. During the interviews with patients it has been found out that most of them do not practice regularly or not practice at all. The reasons mentioned by patients are: lack of motivation, malaise, and difficulty in

the implementation of the training. Also, they do not remember how to correctly perform each exercise.

The new TeleCare system of telerehabilitation creates the possibility to the analyse the patient well-being, to mobilize and motivate him to exercise, to monitor and possibly to improve the way in which the exercises are performed, and the frequency of their use. Supervised, high quality video rehabilitation sessions transmission should improve the correctness of performed exercises what as a result can improve patient lungs efficiency before thoracosurgical procedure. This, in combination with daily gathering data of the patient's objective and subjective condition improves the quality of patients care at home and further treatment decisions.

3.4.2 Value provided for Chemotherapy

Currently, chemotherapy patients in between visits in the clinic are not supervised anyhow. This leads to either unnecessary visits in hospital which may cause further complications of vulnerable patients or to a delay in diagnosis of patients condition change during their home stay. Additionally, target group of chemotherapy patients often suffer from various physical and psychological conditions which affects overall effectiveness of the chemotherapy treatment.

Therefore the capability of video consultations with oncological nurses and medical doctors enable fast feedback about the patient's overall condition, provide recommendations about further treatment and the patient's lifestyle, and provide psychological support. The TeleCare will enable medical personnel to analyse patient's daily vital signs (objective data) and perceived condition (subjective data) between chemotherapy doses taken in the hospital. It is assumed that the program will limit the admission of patients in clinic by solving the patient problems by video consultations. On the other hand, the purpose of the program is to improve the safety of patients during treatment and early detection of symptoms requiring prior contact with the physician. An additional benefit will be better evaluation of the patient during chemotherapy which allows improving treatment decisions.

3.4.3 Combined Value Case of the TeleCare Solution

Figure 29 gives a graphical overview of the combined value case for the overall TeleCare solution within two assumed scenarios of use. The TeleCare solution creates a major value by improving general quality of care through reducing needed treatment effort for both medical personnel and patients. In particular a value will be created by 1) reducing the unnecessary admission of patients in a clinic by solving the patient problems through video consultations (TC.1), 2) improving patients' wellbeing and psychological state by the possibility of on-demand access to medical advices and additional consultancy capabilities, 3) improving treatment decision support through continuous acquisition of patient vital signs (TC.2) and assessment of patient subjective condition (TC.3) what provides better preoperative diagnosis, 4) reducing rescheduling rate of planned thoracosurgery procedures through patients empowerment due to supervised rehabilitation sessions (TC.4) and more rehabilitation exercises done properly. Additionally the TeleCare solution will improve safety of patients during treatment and early detection of symptoms requiring prior contact with the physician (TC.2, TC.3). An additional benefit will be a better evaluation of the patient during chemotherapy (TC.6) which improves treatment decisions (TC.8).

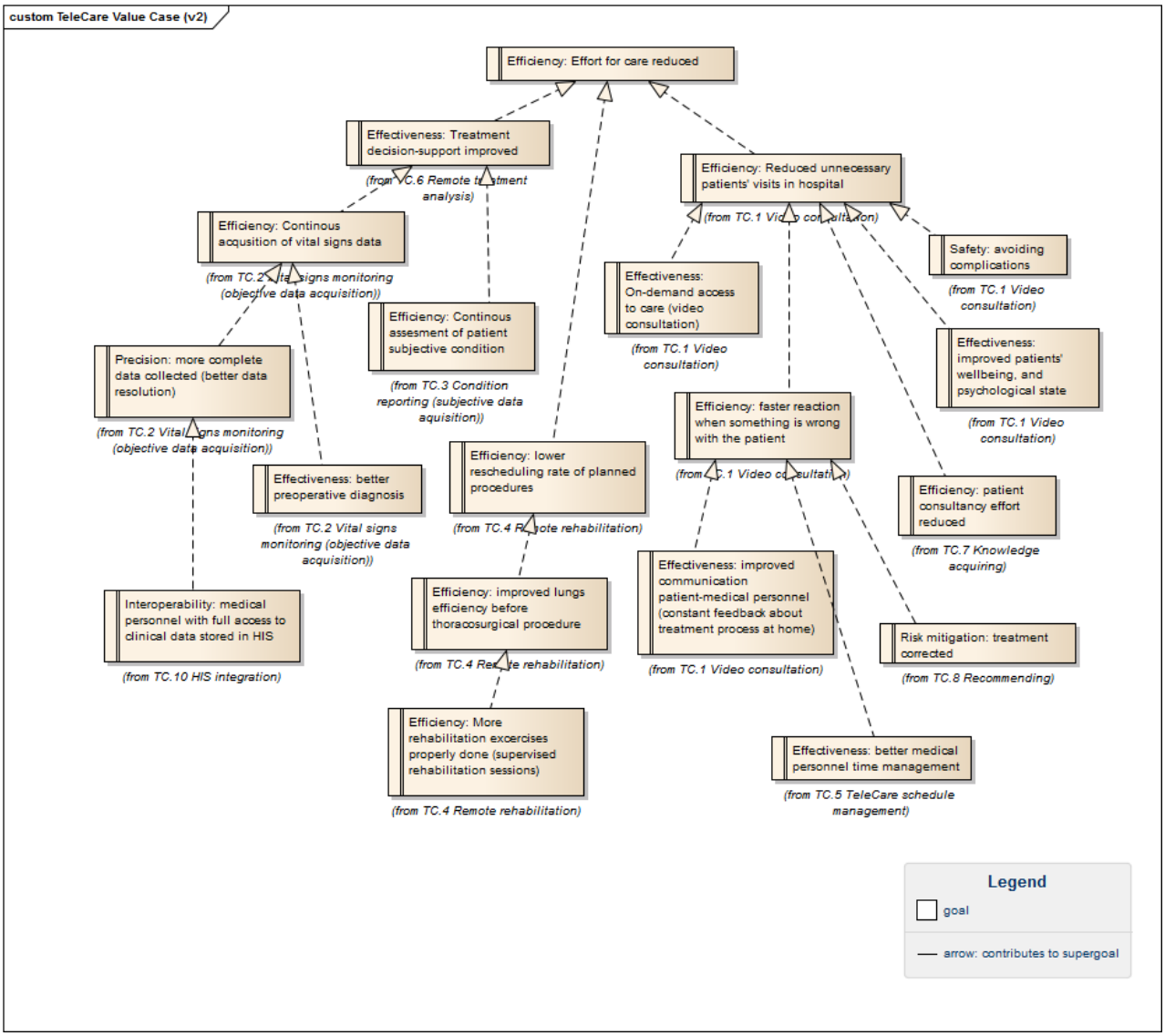


Figure 29: The combined goal tree explaining how the TeleCare solution creates major value for the FI-STAR use case stakeholders within two scenarios.

3.5 FI-STAR Solution Overview

The TeleCare solution will provide a set of features (groups of requirements that belong together) to support the use case stakeholders. Figure 30 gives an overview and defines priorities in terms of minimal scope (alpha prototype for month 12 – bold feature package border), target scope (beta prototype for month 24), and enhanced scope (options) of the solution. Each feature is specified in more detail in the following subsections.

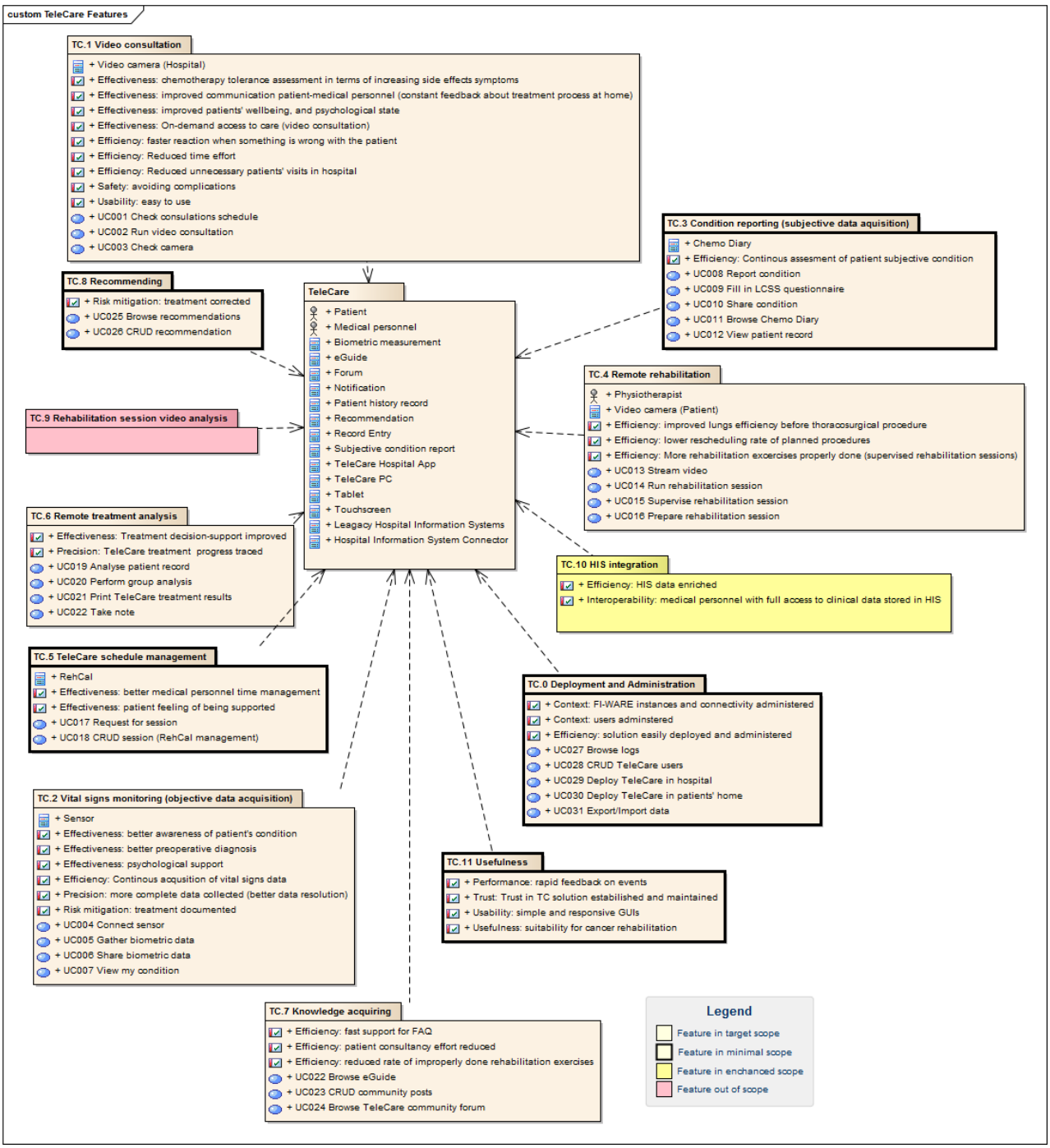


Figure 30: Feature tree of the TeleCare solution

3.5.1 Domain Model

Figure 31 gives an overview of the basic elements (entities) of the future solution data model.

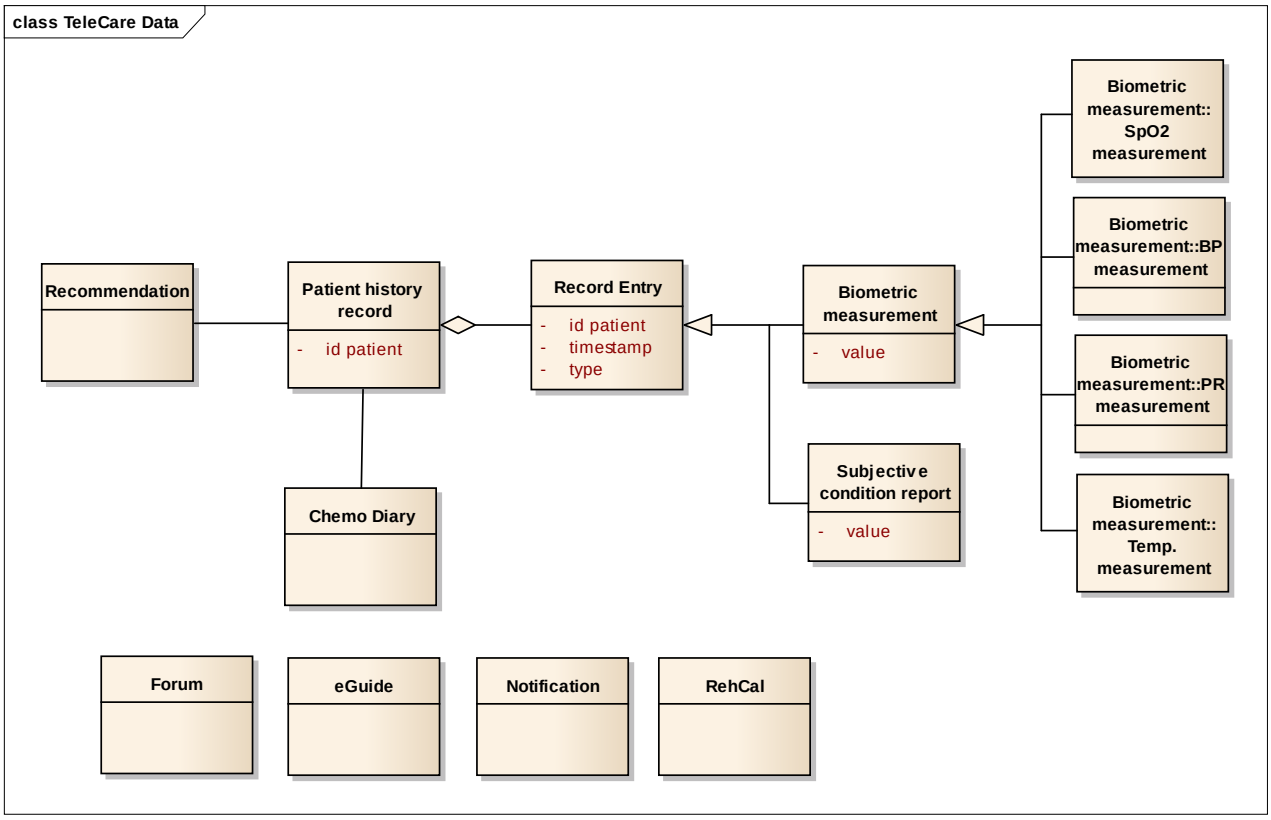


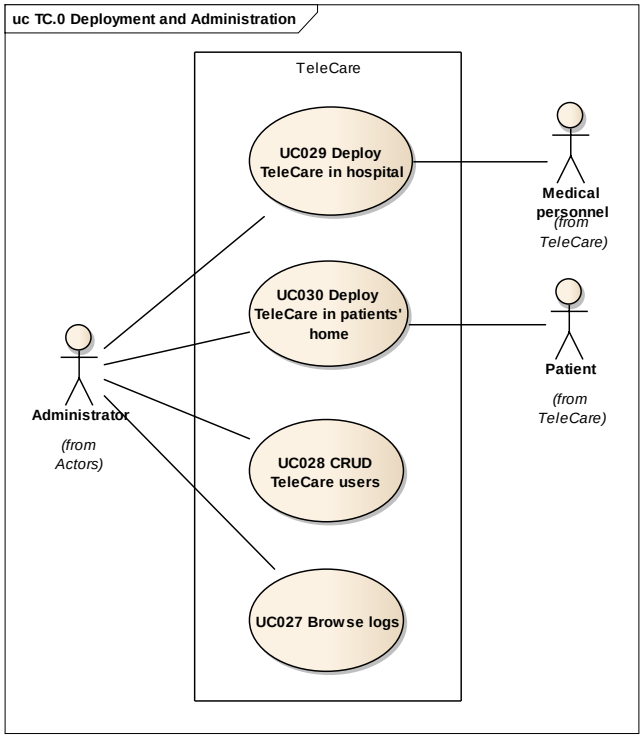
Figure 31: Main entities for the TeleCare solution data model

3.5.2 TeleCare Features

3.5.2.1 Feature TC.0 Deployment and Administration

The feature TC.0 Deployment and Administration provides the hospital IT Administrator with the ability to deploy the TeleCare solution and manage it. Moreover FI-STAR platform instances and connectivity is established.

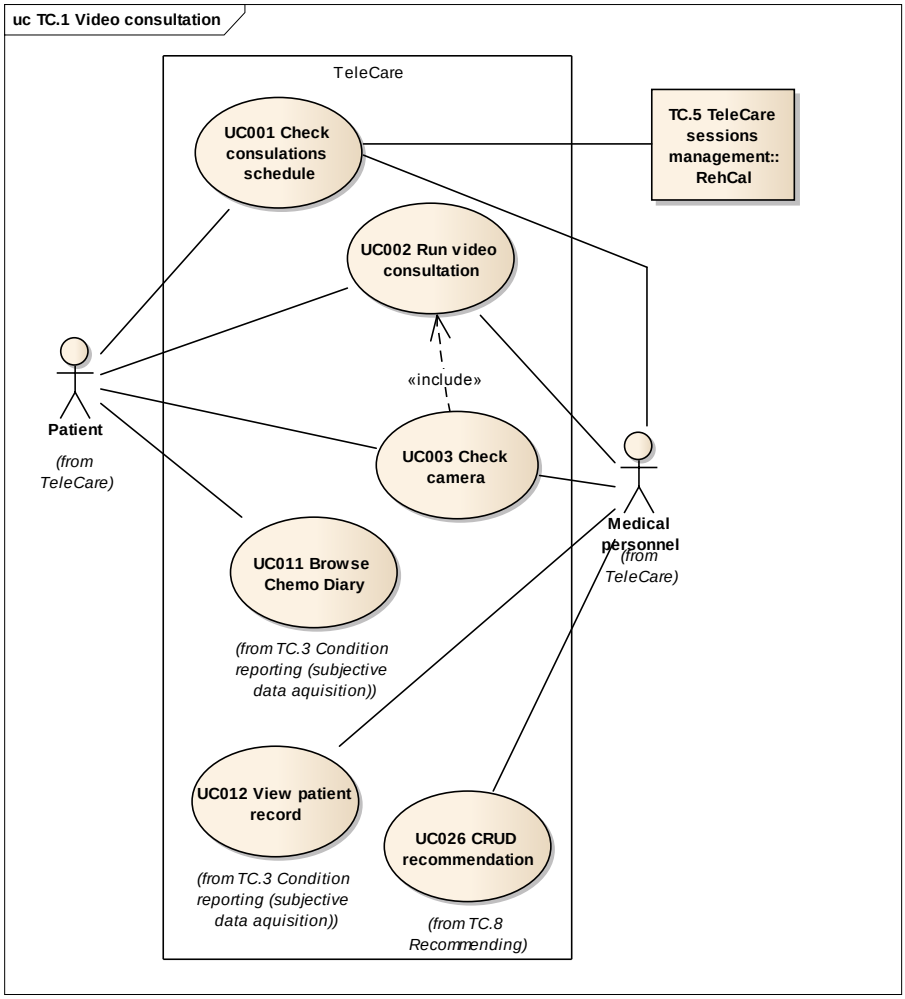
Addressed stakeholder interest and expectations	Goals to be achieved: • Efficiency: solution easily deployed and administered • Effectiveness: Solution maintained • Context: users administered • Context: FI-WARE instances and connectivity administered Sub-goals: • Effectiveness: FI-WARE instances and connectivity administered • Effectiveness: Solution users administered External interfaces: • From TeleCare Patient App (HMI) to Patient • From TeleCare Hospital App (HMI) to Medical personnel • From TeleCare Hospital App (HMI) to Administrator Use Cases: • Deploy TeleCare in hospital • Deploy TeleCare in patient's home

	• CRUD TeleCare users • Browse logs 
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.2 Feature TC.1 Video consultations

The feature TC.1 Video consultations provides the Medical personnel and Patients with the ability to perform video consultations (Skype like).

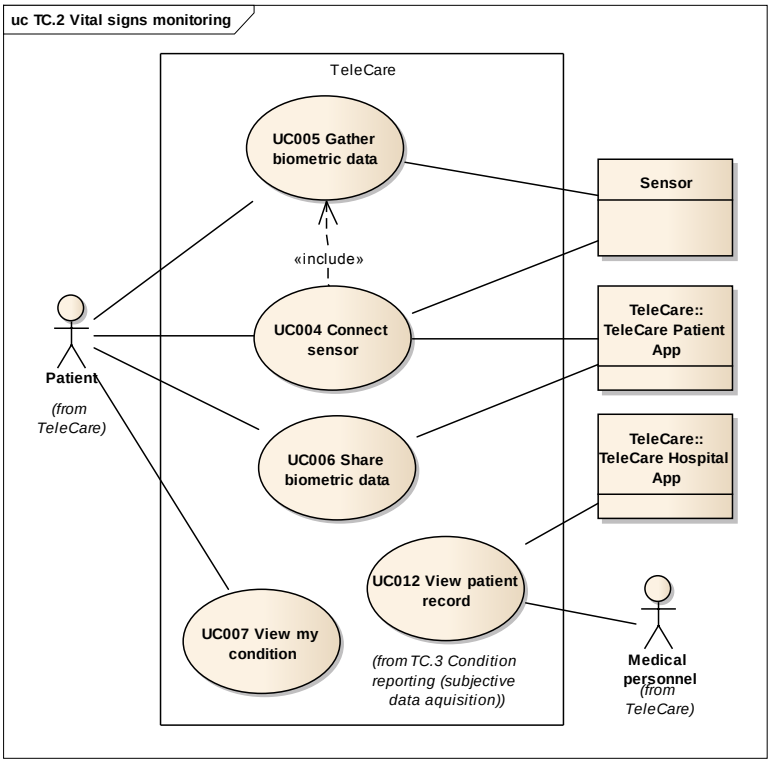
Addressed stakeholder interest and expectations	Goals to be achieved: • Effectiveness: improved patients' wellbeing, and psychological state • Effectiveness: improved communication patient-medical personnel (constant feedback about treatment process at home) • Efficiency: Reduced unnecessary patients' visits in hospital • Efficiency: faster reaction when something is wrong with the patient • Safety: avoiding complications coming from unnecessary visits in hospital • Effectiveness: chemotherapy tolerance assessment in terms of increasing side effects symptoms External interfaces: • From TeleCare Patient App (HMI) to Patient • From TeleCare Hospital App (HMI) to Medical personnel • From Video Camera to TeleCare Patient App • From Video Camera to TeleCare Hospital App Quality Requirements • Usability: easy to use Use Cases: • Check consultation schedule

	• Run video consultation • Check camera • Browse Chemo Diary • View patients' record • Create new recommendation 
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.3 Feature TC.2 Vital signs monitoring (objective data acquisition)

The feature TC.2 Vital signs monitoring provides the Medical personnel with the ability to obtain current, vital signs measurements incoming from remote sensors.

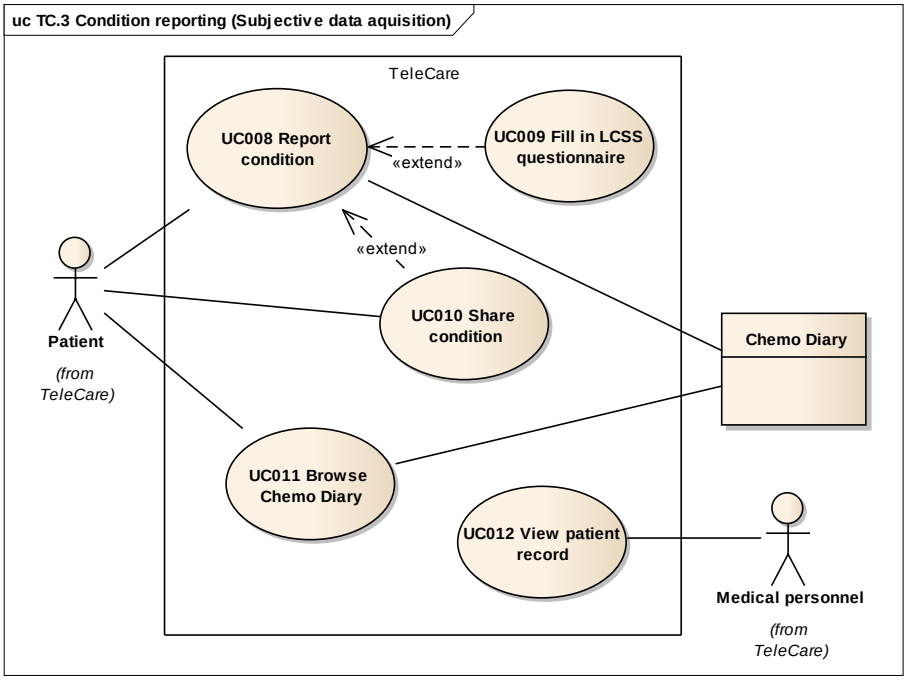
Addressed stakeholder interest and expectations	Goals to be achieved: • Effectiveness: better awareness of patient's condition • Efficiency: faster reaction when something is wrong with the patient • Precision: more complete data collected (better data resolution) • Risk mitigation: treatment documented • Effectiveness: chemotherapy tolerance assessment in terms of increasing side effects symptoms • Effectiveness: better preoperative diagnosis • Effectiveness: psychological support External interfaces:

	• From Sensor to Patient • From TeleCare Patient App (HMI) to Patient • From TeleCare Hospital App (HMI) to Medical personnel Use Cases: • Gather biometric data • Connect sensor • Share biometric data • View my condition • View patient record 
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.4 Feature TC.3 Condition reporting (subjective data acquisition)

The feature TC.3 Condition reporting provides the Medical personnel with the ability to obtain current, perceived by patient subjective condition (in form of values on analogue scales – LCSS or discrete scale – Borg scale).

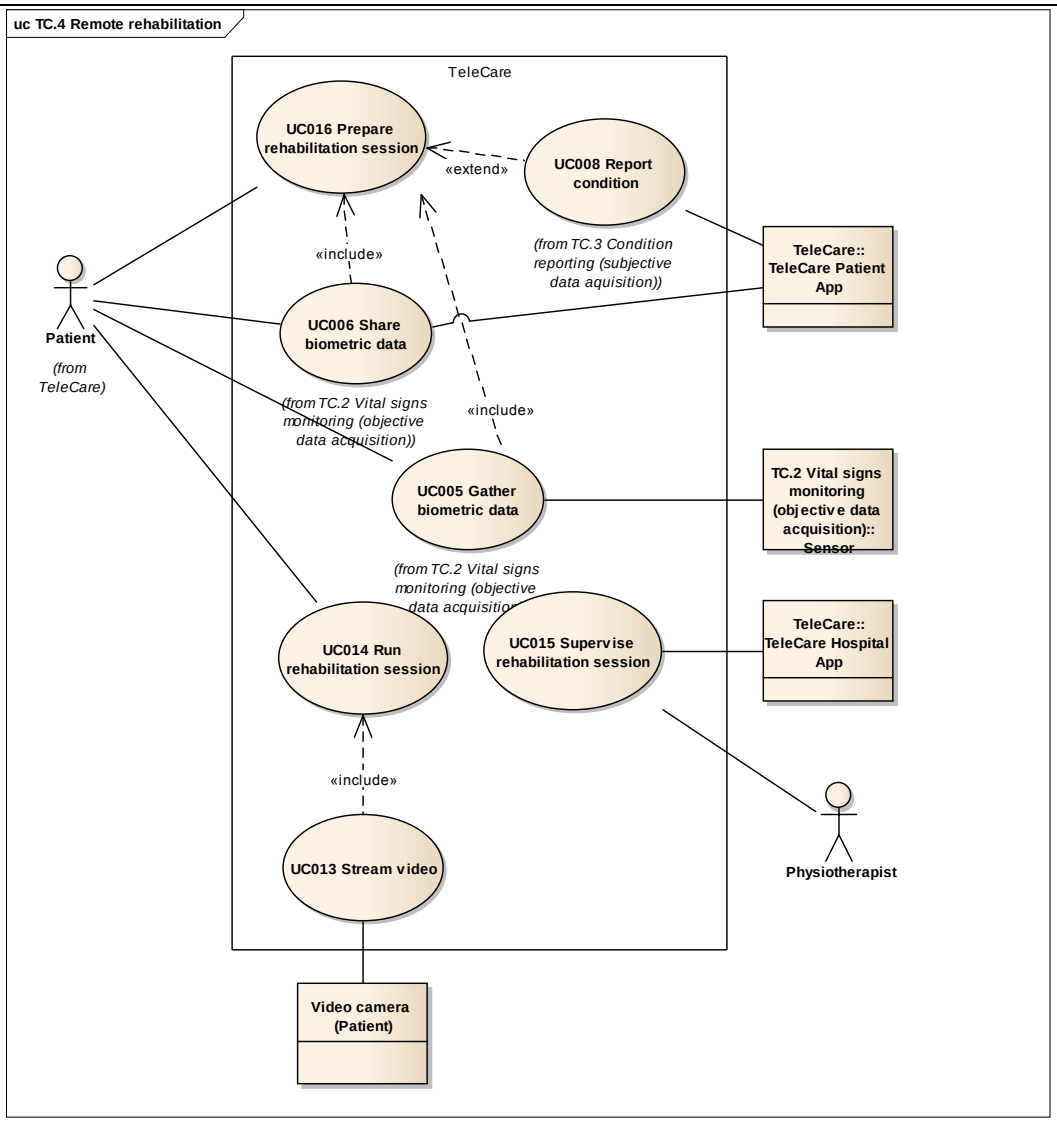
Addressed stakeholder interest and expectations	Goals to be achieved: • Effectiveness: better awareness of patient's condition • Risk mitigation: treatment documented • Effectiveness: chemotherapy tolerance assessment in terms of increasing side effects symptoms • Effectiveness: better preoperative diagnosis External interfaces: • From TeleCare Patient App (HMI) to Patient • From TeleCare Hospital App (HMI) to Medical personnel Use Cases:

	• Report condition • Fill in LCSS questionnaire • Share condition • Browse Chemo Diary • View patient record 
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.5 Feature TC.4 Remote rehabilitation

The feature TC.4 Remote rehabilitation provides the Medical personnel with the ability to remotely supervise patients at home rehabilitation sessions and view current patient condition (both perceived and objectively measured).

Addressed stakeholder interest and expectations	Goals to be achieved: • Efficiency: improved lungs efficiency before thoracosurgical procedure • Efficiency: lower rescheduling rate of planned procedures External interfaces: • From Sensor to Patient • From Video camera to TeleCare Patient App • From TeleCare Patient App (HMI) to Patient • From TeleCare Hospital App (HMI) to Medical personnel Use Cases: • Prepare rehabilitation session • Report condition • Share biometric data • Gather biometric data • Run rehabilitation session • Supervise rehabilitation session • Stream video

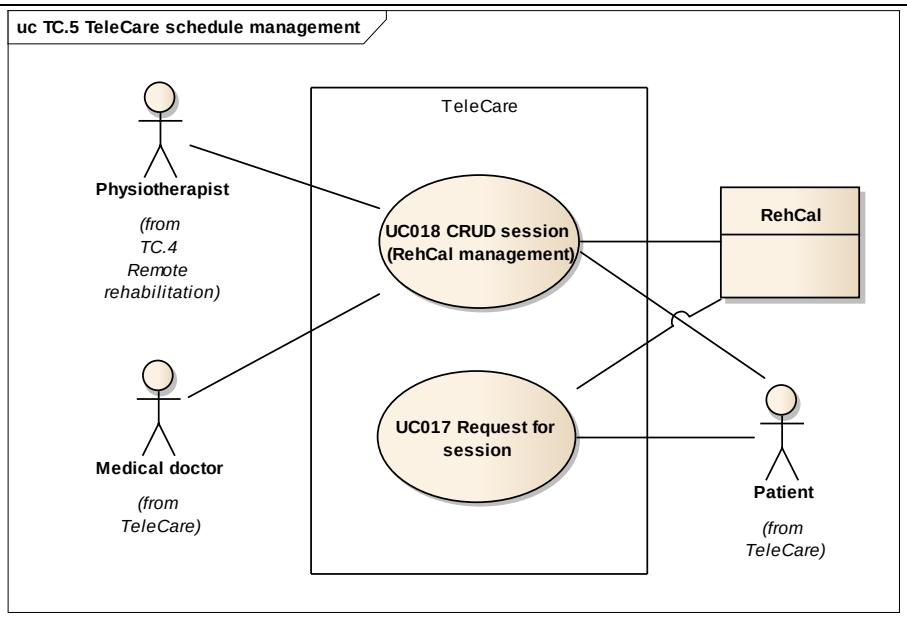


Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.6 Feature TC.5 TeleCare schedule management

The feature TC.5 TeleCare sessions management provides the Medical personnel with the ability to schedule remote rehabilitation and video teleconsultations sessions.

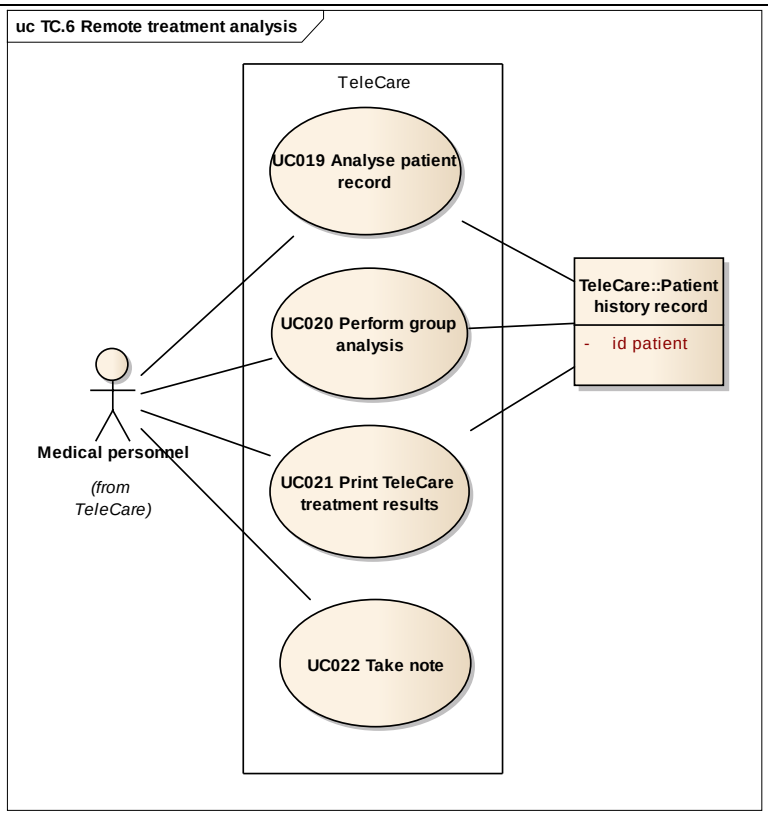
Addressed stakeholder interest and expectations	Goals to be achieved: • Effectiveness: better medical personnel time management • Effectiveness: patient feeling of being supported External interfaces: • From TeleCare Patient App (HMI) to Patient • From TeleCare Hospital App (HMI) to Medical personnel Use Cases: • CRUD session • Request for session

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.7 Feature TC.6 Remote treatment analysis

The feature TC.6 Remote treatment analysis provides the Medical personnel with the ability to analyse patients treatment with the use of TeleCare, compare patients results, visualize history of treatment (including trends in changing perceived patient condition as well as subjective vital signs measurements).

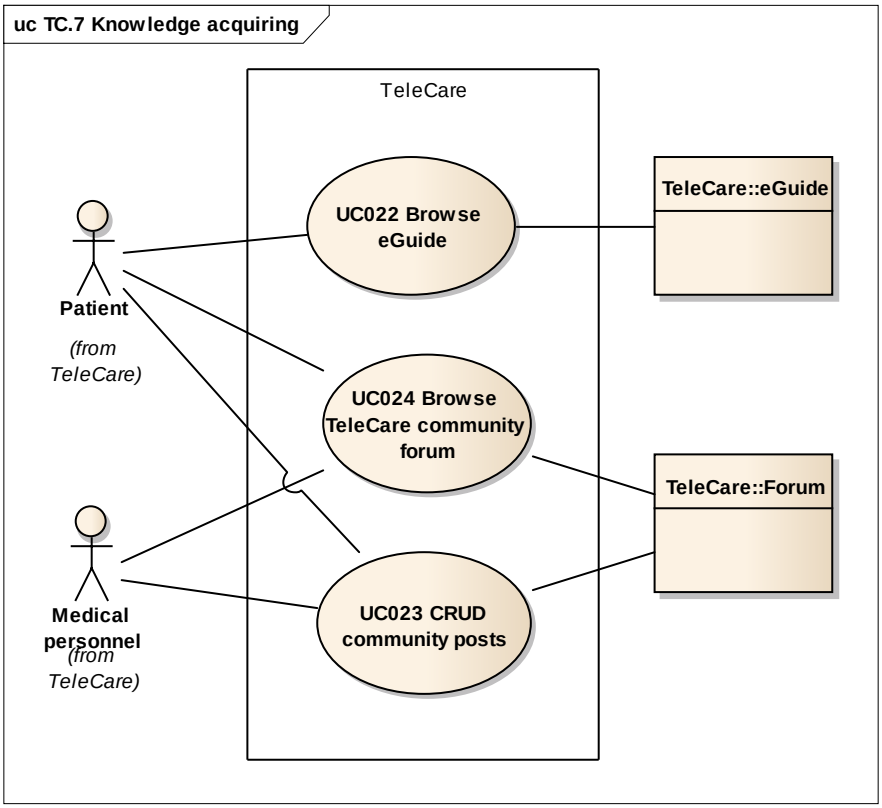
Addressed stakeholder interest and expectations	Goals to be achieved: • Effectiveness: better awareness of patient's condition • Precision: TeleCare treatment progress traced External interfaces: • From TeleCare Hospital App (HMI) to Medical personnel Use Cases: • Analyse patient record • Perform group analysis • Print TeleCare treatment results

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.8 Feature TC.7 Knowledge acquiring

The feature TC.7 Knowledge acquiring provides the Patient with the ability to get more knowledge about his or her condition (eGuide) as well as exchange knowledge and findings with TeleCare community and Medical doctors. Additionally, for remote rehabilitation a digital exercises guide will be provided.

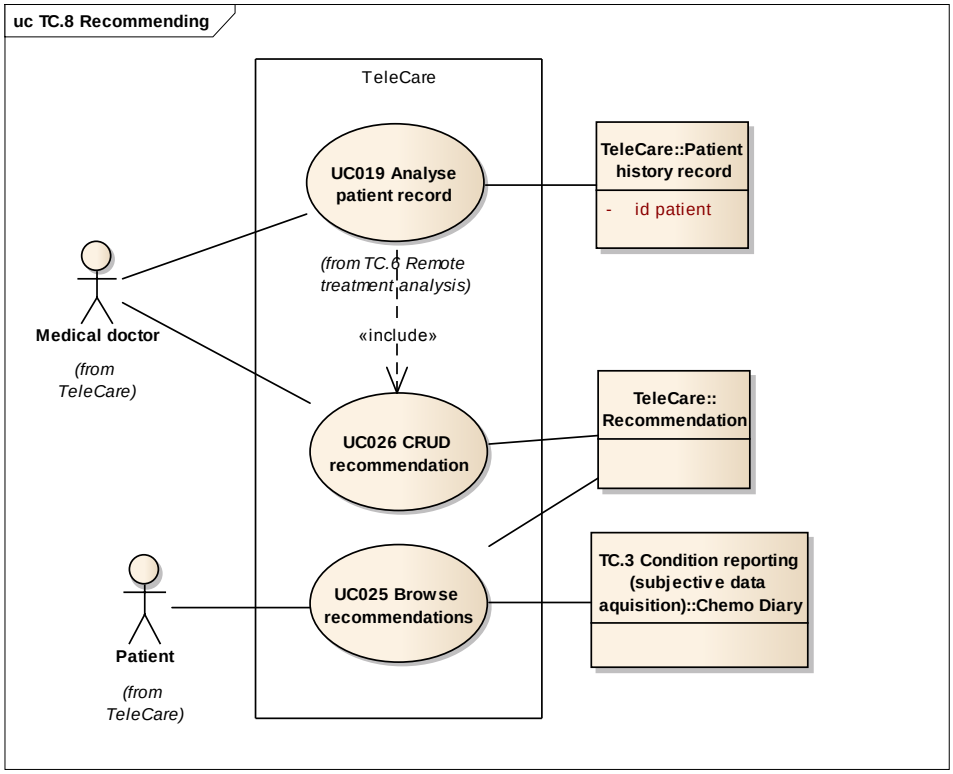
Addressed stakeholder interest and expectations	Goals to be achieved: • Efficiency: patient consultancy effort reduced • Efficiency: fast support for FAQ • Efficiency: reduced rate of improperly done rehabilitation exercises External interfaces: • From TeleCare Patient App (HMI) to Patient • From TeleCare Hospital App (HMI) to Medical personnel Use Cases: • Browse eGuide • Browse TeleCare community forum • CRUD community posts

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.9 Feature TC.8 Recommending

The feature TC.8 Recommending provides the Medical doctor with the ability to recommend changes in treatment or lifestyle based on video consultation observations and patients history record (including historical gathered data about patient condition).

Addressed stakeholder interest and expectations	Goals to be achieved: • Efficiency: faster reaction when something is wrong with the patient • Risk mitigation: treatment corrected External interfaces: • From TeleCare Patient App (HMI) to Patient • From TeleCare Hospital App (HMI) to Medical personnel Use Cases: • Analyse patient record • CRUD recommendation • Browse recommendations

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.10 Feature TC.9 Rehabilitation session video analysis

The feature TC.9 Rehabilitation session video analysis provides a Physiotherapist capability to assess correctness of the performed rehabilitation exercises based on automatic, live video stream analysis (patient movement analysis based on algorithms and devices similar to e.g. Microsoft Kinect).

Addressed stakeholder interest and expectations	Out of scope

3.5.2.11 Feature TC.10 HIS integration

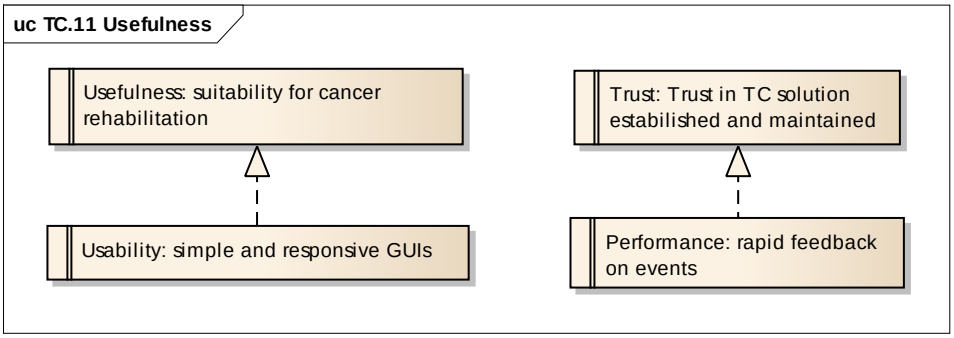
The feature TC.10 HIS integration provides capability to integrate TeleCare solution with legacy hospital IT systems in order to enrich currently gathered data. This feature is optional and it is going to be decided whether it is in scope of the solution. Implementation of this feature may require additional costs for JP2 related to the development of a dedicated/specific external interfaces/services to the current IT systems (e.g. InfoMedica).

Addressed stakeholder interest and expectations	Goals to be achieved: • Interoperability: medical personnel with full access to clinical data stored in HIS • Efficiency: HIS data enriched External interfaces: • From TeleCare Hospital App (HMI) to HIS connector (HIS system/services)

Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.2.12 Feature TC.11 Usefulness

The feature TC.11 Usefulness defines the minimal criteria for the solution to be useful.

Addressed stakeholder interest and expectations	Goals to be achieved: • Usefulness: suitability for cancer rehabilitation • Trust: Trust in TC solution established and maintained Quality requirements: • Usability: simple and responsive GUIs • Performance: rapid feedback on events 
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

3.5.3 FI-STAR Solution-wide Requirements and Constraints

3.5.3.1 Constraints towards Enablers and Technology

ID	Constraint	Rationale and comments
TC.CT.01	Google Android platform to be used for the implementation of the TeleCare Patient App forces biometric devices compatibility with such platform. Not all devices allow data exchange with Android solution.	Android is a free, lightweight and popular in Europe technology for mobile applications. ITTI has a background in implementation of Android based applications. Reusability of software components incoming from other FI-STAR use cases solutions.
TC.CT.02	Patients qualified for the use case trails (in both TeleCare scenarios) need to have a broadband Internet connection.	Video consultations feature require high speed internet connection in order to provide good image quality and frame rate. High quality GSM 3G networks (and better) are available only in the city centers, qualified patients might be far from city centers.
TC.CT.03	Integration with JP2 hospital legacy IT systems might not be possible.	High costs and effort needed to adapt legacy systems (e.g. exposing appropriate interfaces).

3.6 Validation

The remote rehabilitation TeleCare scenario will be validated with 30 patients by comparing the results from patients that use the TeleCare solution with those obtained by a control group of patients that follow today's practice.

The team dedicated to the chemotherapy scenario experiments includes 3 doctors, 4 nurses, and 1 psychologist. Contact with the patient will be once per week and additional video sessions performed on the patient's request. Primary contact will be held by a nurse. If necessary a doctor or psychologist will assist. Request for additional "remote visits" will be possible 24/7 but video consultations will be held normally on weekdays from 08.00 to 15.30. 15 patients will participate in chemotherapy TeleCare scenario.

4 Chronic Disease Treatment Assistance for COPD Treatment in Bologna, Italy

The FI-STAR solution for Chronic Disease Treatment Assistance (CDTA) addresses the problem of treating chronic patients with respiratory problems (COPD patients), which affects the COPD patients, COPD specialists, and the society in general. The impact of this problem are severe long-term complications and consequent high costs for society. A successful solution empowers patients and nurses for COPD treatment, collects and integrates patient health data into the electronic health record for analysis, and limits the physicians' effort for the consultancies.

CDTA integrates two applications, PAA and PeAA, intended for COPD patients, caregivers, nurses and medical personnel who manage and treat the chronic disease. PAA is a FI-STAR cloud application that allows the patient to measure vital parameters and report and understand his disease condition him-/herself. PeAA is a FI-STAR cloud application that allows the medical personnel to tele-monitor the patient's vital parameter and provide feedback and treatment support to the patient. Unlike the current infrequent controls (4-5 times per year) and in-clinic or ambulatory treatment of emergencies, CDTA enables the medical personnel to reduce the cost of chronic disease treatment and assures trust of the patients in the medical system.

This chapter gives an overview of a FI-STAR solution that is intended to be built to support the FI-STAR use case. The chapter covers the goal/purpose of the FI-STAR solution, stakeholders and their interests/expectations, the application and their features that are integrated into the FI-STAR solution to support these interests/expectations, and the FI-STAR solution-wide requirements and constraints. The appendix can be used to capture any other material, including business processes, glossary, description of the as-is situation, problems with current solutions, storyboards, and examples of artefacts and photographs of usage context.

The vision chapter is intended as a starting point for subsequent detailed requirement engineering. The features are used to establish an overview of the FI-STAR solution's requirements that then will be engineered just-in-time before the relevant development starts. The features should be specified by explaining how the concerned FI-STAR application will support the corresponding FI-STAR stakeholders' interests and expectations. The vision chapter should be updated as the understanding of the FI-STAR solution and of its aims and objectives evolve.

Future uses of this vision chapter will be to establish personas for target user segmentation and user experience engineering, traceability to release and project planning, application and enabler design and development, and quantification of quality requirements and testing, definition/monitoring of KPI, and analyzing commonality/variability across applications. In addition, this vision chapter will refer to relevant specialty requirements.

4.1 FI-STAR Solution Positioning

The following captures the essence of the FI-STAR solution, including the problem it addresses and the key idea of solving the problem.

4.1.1 Problem Statement

The problem of	treating chronic patients with respiratory problems
Affects	COPD patients, COPD specialists and society in general
the impact of which is	
a successful solution would be	to empower patients and nurses for COPD treatment by collecting and integrating patient health data into the electronic health record, with analysis features, while limiting the physicians' effort for the consultancies at the current level

4.1.2 Position Statement

For	COPD patients, caregivers, nurses and medical personnel
Who	manage and treat the chronic disease
The (solution name)	Chronic Disease Treatment Assistance (CDTA) is a FI-STAR cloud solution consisting of the Patient Assistance Application (PAA) and the Personnel Assistance Application (PeAA)
That	allows the patient to collect vital health/BIO parameters and report and understand his disease condition him-/herself, allows the medical personnel to tele-monitor the patient's vital parameter, and provides feedback and treatment support to the patient
Unlike	the current infrequent controls (4-5 times per year) and in-clinic or ambulatory treatment of emergencies
Our product	enables (i) the medical personnel to reduce the cost of chronic disease treatment and (ii) assure trust of the patients in the medical system.

4.2 FI-STAR Use Case Stakeholders

The following users, interfacing systems, and other stakeholders are affected by the solution.

4.2.1 User Roles

Figure 32 provides an overview of the user roles of the Chronic Disease Treatment Assistance solution. These are the PAA end users (patients and caregivers), the medical personnel (nurses and physicians) that use the PeAA, and back office operators (nurses, physicians, and technicians).

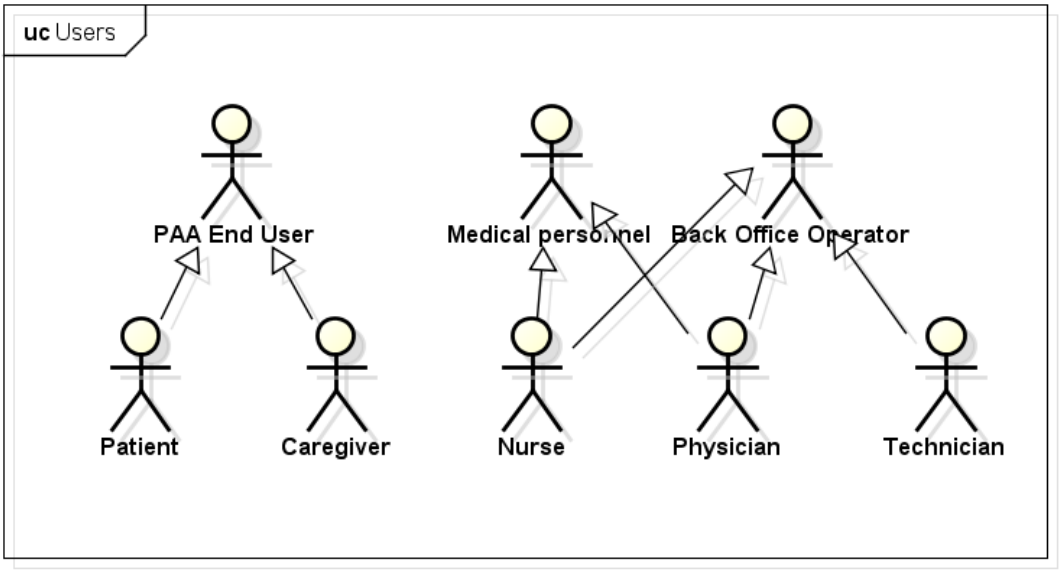


Figure 32: Users of the Chronic Disease Treatment Assistance solution

Following figures give an overview of the workflow of the patient self-monitoring process.

Figure 33: Patient, with help of caregivers, use (left) a tablet, and with a Pulsioxymeter connected via Bluetooth check her Hearth Rate and Blood Oxygenation (right).

Figure 34: She can answer on the tablet to questionnaires compiled by medical personnel (left) and check the history of health data on the screen (right)

The following figures give an overview of the workflow of the physicians and Nurses telemonitoring patients. Nurse access via SOLE portal to the Chronic Disease Treatment Assistance web application. Depending from monitoring results she follows protocol that physician have compiled, such as contacting the patient/caregiver, forwarding warning to the physician

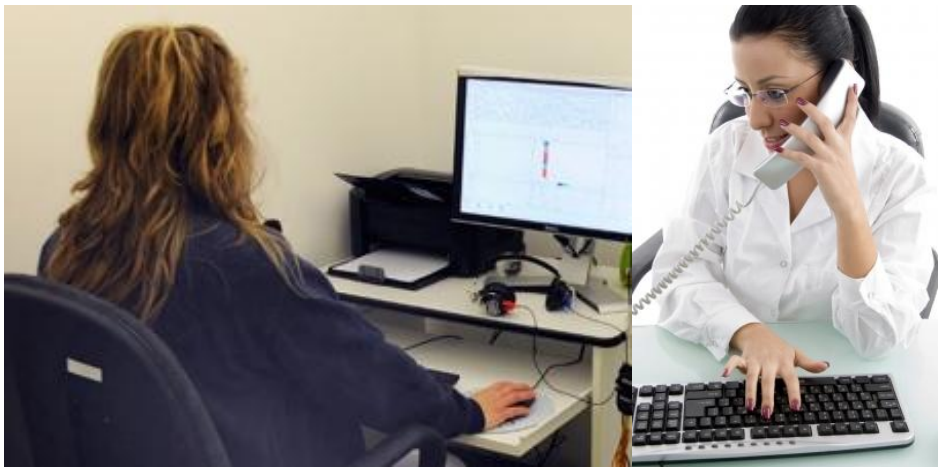


Figure 35: Nurse consults patient data on her PC (left); Nurse contacting patient /caregiver (right, Image courtesy of imagerymajestic / FreeDigitalPhotos.net)

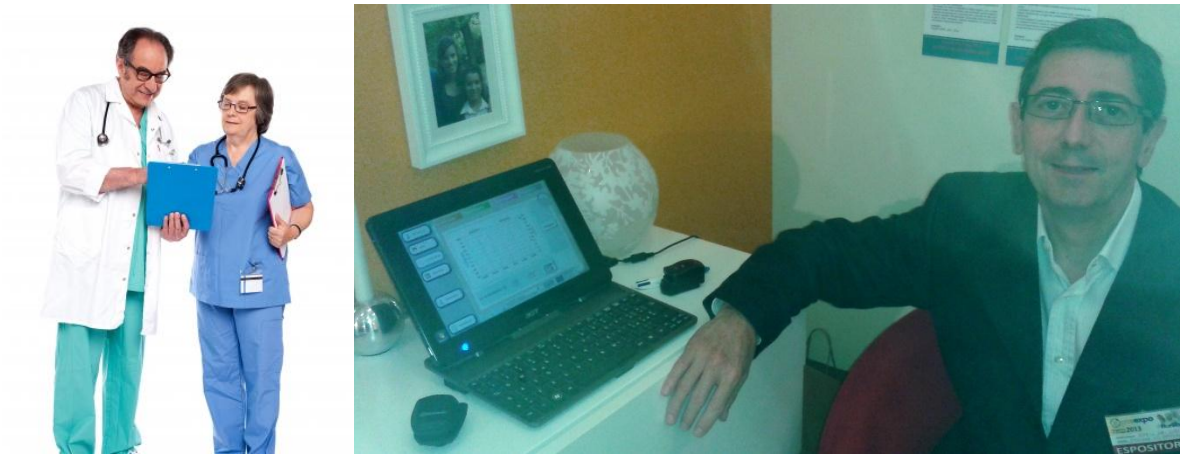


Figure 36: Nurse report to doctor criticalities (left; image courtesy of stockimages / FreeDigitalPhotos.net); Dr. Marco Lodi check patient data via Web

Figure 37: Patient treatment protocol can be manually or automatically adjusted (image courtesy of Stuart Miles / FreeDigitalPhotos.net)

The following table describes the users in detail, including their background, role, and expectations.

Name / Count	Description	Expectations on Solution
Patient 10 Patrizia Moro	Main End-User of PAA. Usually elderly and digitally illiterate. Does self-monitoring (use of measuring devices, answer to questionnaires), daily or less frequently.	[Briefly describe the user's expectations towards the artifact: functionality, qualities (security, reliability, usability, performance, experience, etc.) that if not implemented would discourage solution use, and constraints] The patient wants : easy to use solution to feel followed by medical personnel the system to assess their health status. If the system assesses they are in good health condition the feel more confident in their normal life not to use email help or information after system malfunctioning Send and receive communications to/from medical personnel Visualize his own data

Caregiver 10 TBD	Alternative End-User of PAA, i.e. may perform actions on the system when the patient is not able him/herself. Not all Patient need to be supported by caregiver in the use of SW solution.	Caregiver wants the system to be easy to use Caregiver are interested on forecasting exacerbation of the patient
Nurse 1-3 Simonetta Scaranello	Main End-User of PeAA. Assists the physician in remote monitoring by being the first contact with the patient. Being the front line of the monitoring process, the nurse is interested in detecting situations that need an intervention.	Contact the patient in a simple manner. Visualizes patient data. Receive warnings and alarms based on predefined data pattern and rules. Forward warnings to physicians. Configure reminders, alerts, and standard messages. Activity of nurses is based on protocols (triage style) defined by physicians that are out of scope of the application
Physician 2 Dr. Marco Lodi	Alternative End-User of PeAA. Monitors the patient remotely.	The physician wants • to have an overview of patients status • to have a clear view of health status and trends of parameter of the single patient. • support in highlight criticism • not to increase the effort in patient consultancy • They want to make patients feel more cared • They want to increase the data at their disposal without increasing the effort in consultancy • They do not want to appear always available to patient (e.g. through chat) • Receive warnings and alarms based on predefined data pattern and rules. • Configure reminders, alerts, and standard messages.
Technician 2 Alan Chiacchia	Remote back office administration: user management, app configuration	He need any easy management of the solution, minimizing the deployment and configuration effort.

4.2.2 Interfacing Systems

Figure 38 gives an overview of the system boundary of the Chronic Disease Treatment Assistance Solution. The connectivity to the FI-STAR cloud is a concern of the solution architecture, hence omitted from the overview. PeAA runs on the clinician PC that is used by clinicians. PAA runs on the PDA that is used by patients and care givers.

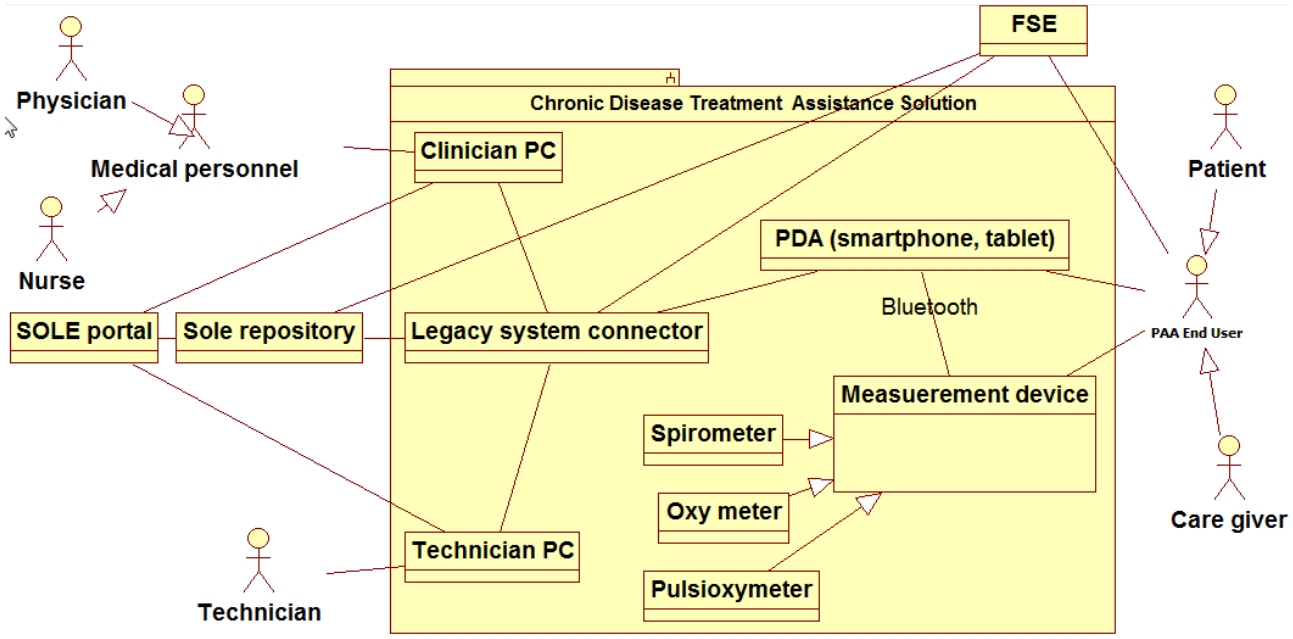


Figure 38: CDTA solution system boundaries

The following figures give an overview of the system, artifacts, and interfaces.

Figure 39: Interfaces - Left: tablet/smartpphone; Middle: Pulsioxymeter; Right: Spirometer

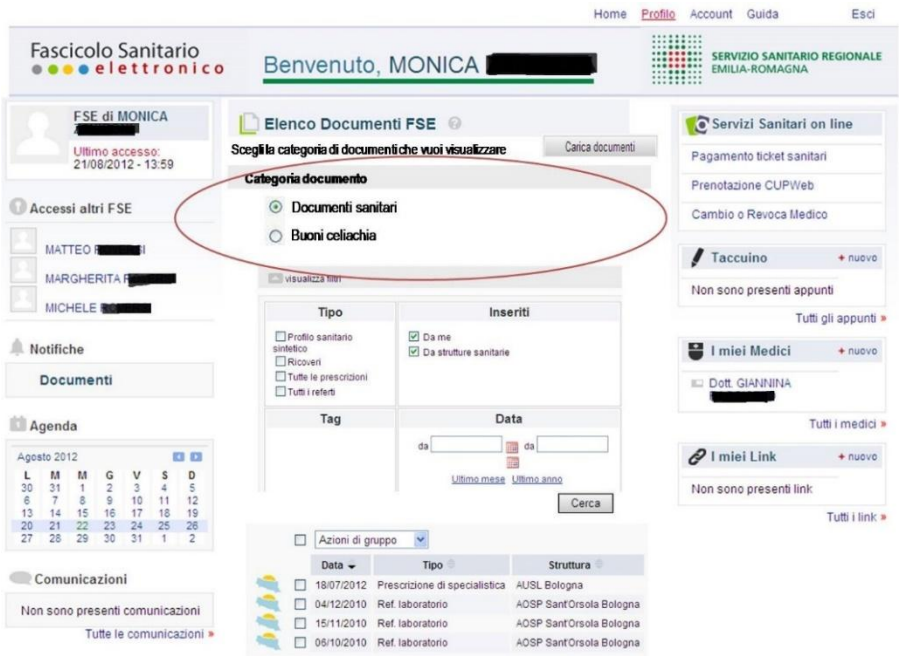


Figure 40: FSE citizen My page (vital parameter not yet included in current FSE)

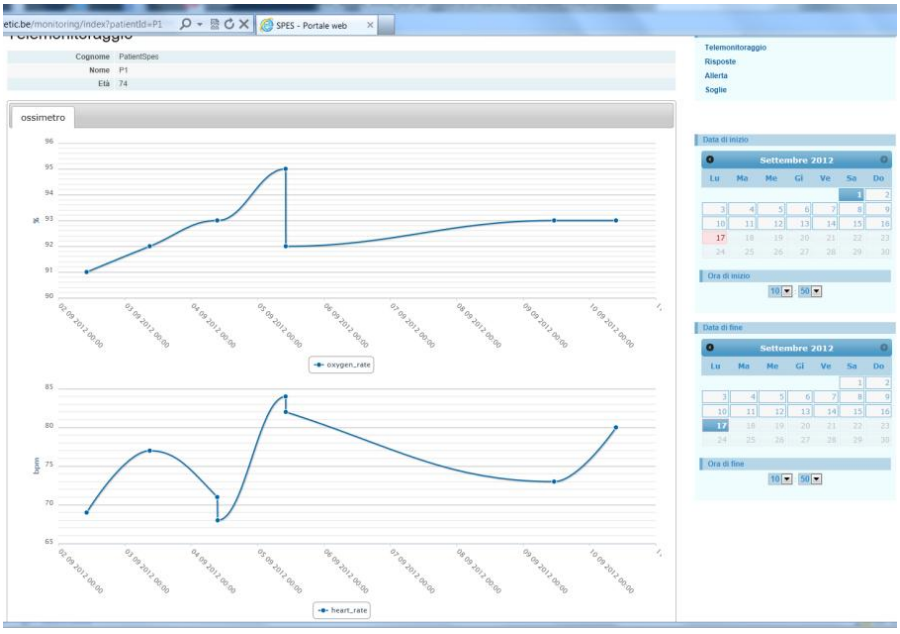


Figure 41: Medical personnel screen with graphic of Heart Rate and blood oxygenation parameter (former solution)

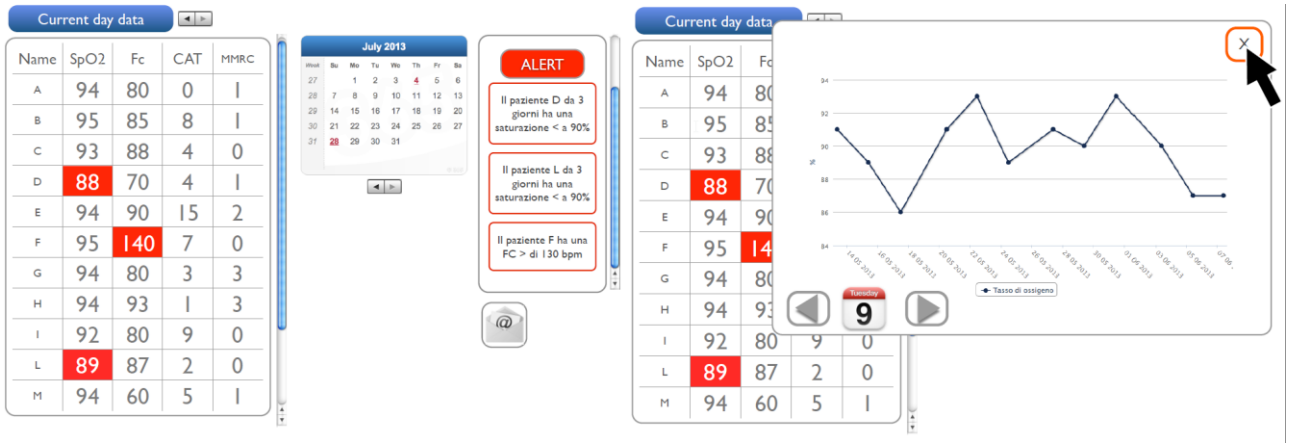


Figure 42: Examples of medical personnels screens Left: current day report of raw patient's raw data; Right: graphical representazion of one of the parameter

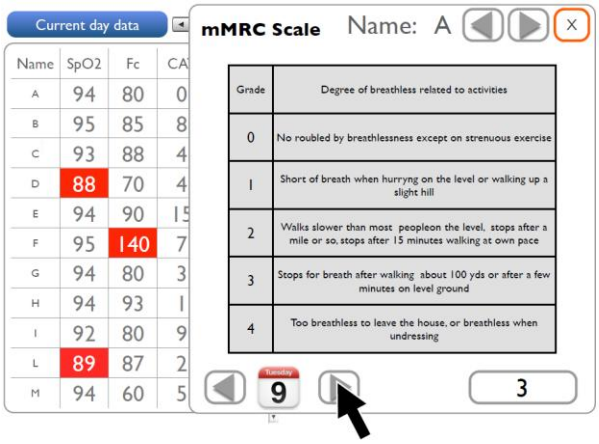


Figure 43: Example of mMRC questionaire

The following table describes the interfacing systems and artifacts and related expectations on the solution.

Name	Description	Expectations on Solution
Smartphone	Android (min ver 4.1) smartphone/tablet Patient Assistance Application on board	Aggregator for biometrics observations originating from sensors or created manually (questionnaire) using the applications. Connects via UMTS to internet, via Bluetooth with measurement devices.
FI-STAR Consumer Cloud sw modules	Backend System in SOLE domain. Provides backend logic for "Patient app" and "Personnel app".	Data analysis, aggregation and reasoning, data transmission, data translation, mobile app re-configuration, reasoning schemas re-configuration, user management
Legacy system connector	It allow legacy system and FISTAR solution work together	This connector allows FISTAR solution to interface with legacy system minimizing modifications of legacy system (one point of contact with SOLE

		legacy system)
SOLE repository	Repository where patient can upload his clinic information	Regional node assures: Routing towards LHA dB, capability of storing vital parameter
SOLE portal	Access point to SOLE system for actors of regional health system.	Personnel Application is installed as extension of SOLE Web Portal
FSE system	The Fascicolo Sanitario Elettronico is the electronic Health Record (eHR) of the region Emilia Romagna health system. It indexes and allow access to all the medical personnel information collected in SOLE. Authentication, Authorization, interoperability between local SOLE system, indexing, logging	As per other citizen health information, FSE will manage the access to patients vital paramenters
Pulsioxymeter Onyx ®. Model 9560	Measure Heart Rate and oxygen saturation (%SpO2) The user must equip the device.	Bluetooth communication between Pulsioxymeter and tablet/smartphone to transmit measurements. Proprietary protocol over BT
Spirometer MIR SPIRODOC (under evaluation)	Consumer device for measuring the volume of air inspired and expired by the lungs. FVC Forced vital capacity FEV1 Forced Exipratory Volume FEV1/FVC Tiffeneau-Pinelli index	Measurements of the volume of air inspired and expired by the lungs. Bluetooth communication between Spirometer and smartphone to transmit measurements. Proprietary protocol over BT
Oxymeter (Under Evaluation) (Out of scope)	Consumer device for measuring the consumption of Oxygen bottle	Oxygen level indicator Bluetooth communication with smartphone to transmit measurement

4.2.3 Data flow

Figure 44 gives an overview of how the CDTA system is intended to be used in the COPD treatment workflow.

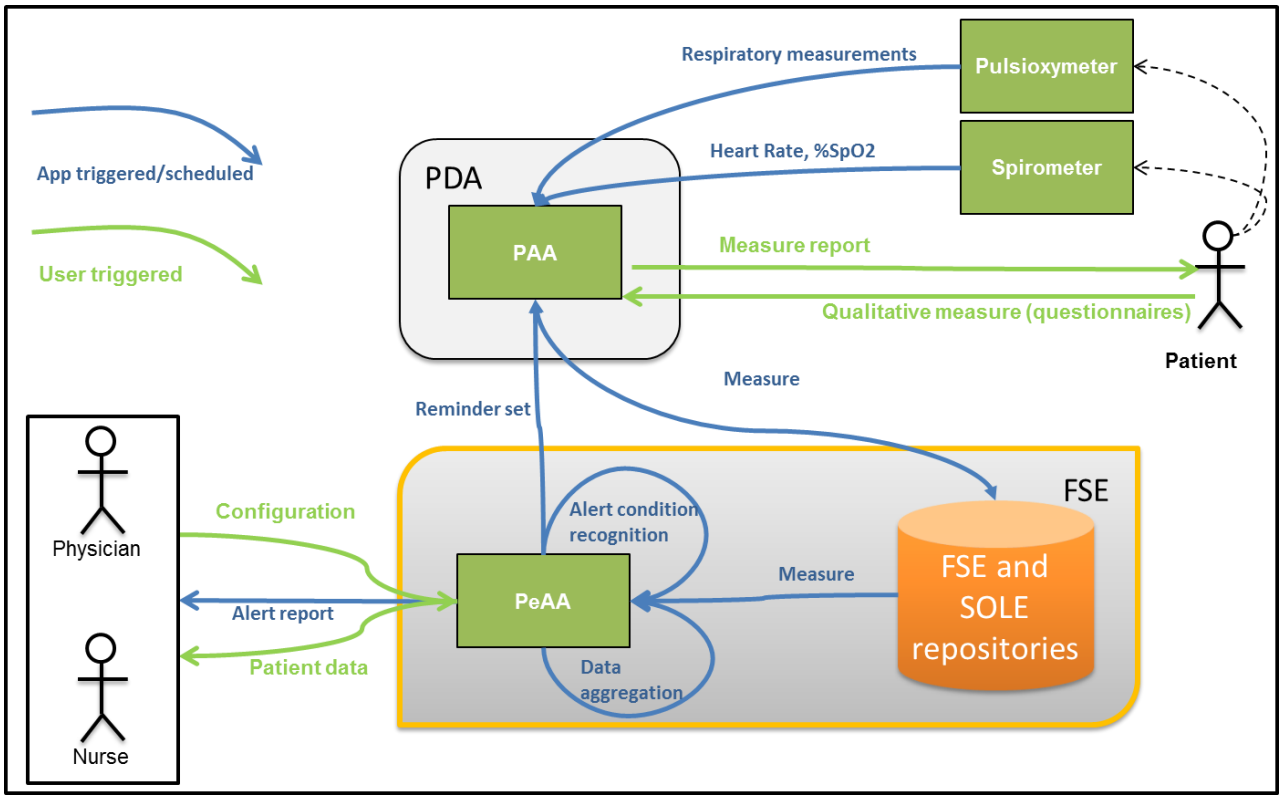


Figure 44: data flows over the system boundary of the solution and applications that are integrated.

4.2.4 Other Stakeholders

The following list describes other stakeholders that do not directly interact with the solution.

Name	Description	Expectations on Solution
Sole project leader Mr Leonardo Mariotti	SOLE system collects and manager clinic information of the Emilia Romagna citizens. With FI-STAR we want to enhance the system with the collection of monitored personal health related parameter.	Since SOLE is used by the 5Million citizen, and some thousand medical personnel, the interest is to build a system with a low cost of set up and maintenance, and taking advantage of the infrastructure already in place
FSE project leader Mr Stefano Micocci	Fascicolo Sanitario Elettronico (eHR) aims to collect all health information of the citizen during his whole life. Health parameter should be part of this information	wants to let patient and medical personnel be able to easily access to personal health parameter. wants to have a scalable system that can allow to add new parameter to monitor with a low cost of development
LHA Ferrara Dr Dario Pelizzola	Dr Dario Pelizzola is the director of the Presidio Unico Ospedaliero (FE). Leader of several e-health experimentations in region Emilia Romagna	The area of Copparo is highly interested in creating a system to telemonitoring chronic patient in order to improve their quality of life and reduce hospitalization

4.3 FI-STAR Value Case

The Chronic Disease Treatment Assistance solution creates value by reducing the cost for chronic desease treatment and by enabling patient trust in the medical system. Cost reduction is achieved by empowering the patient for independent disease treatment, improving decision-support for patient consultancy, reducing consultancy effort, and enabling the adaptation of the treatment support. Patient trust is achieved by empowering the patient for independent disease treatment, assuring patient safety, and assuring patient privacy improving patient empowerment.

Figure 45 gives a detailed overview of the value case in the form of a goal tree.

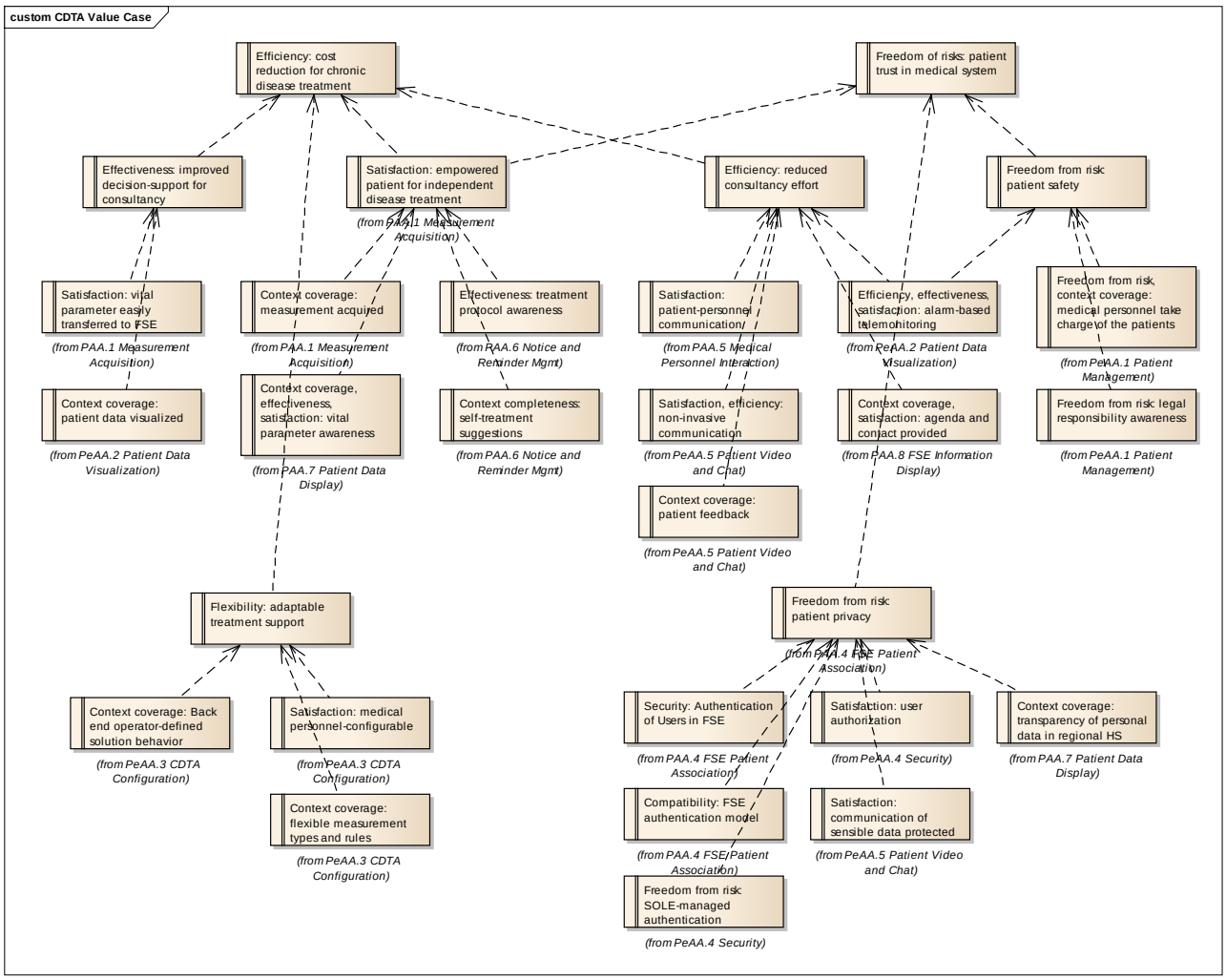


Figure 45: Goal tree of Chronic Disease Treatment Assistance Solution value case.

4.4 FI-STAR Solution Overview

The Chronic Disease Treatment Assistance solution provides a set of features (groups of requirements that belong together) to support the use case stakeholders. Figure 46 gives an overview and defines priorities in terms of minimal scope, target scope, and enhanced scope of the solution. Each feature is specified in more detail in the following subsections.

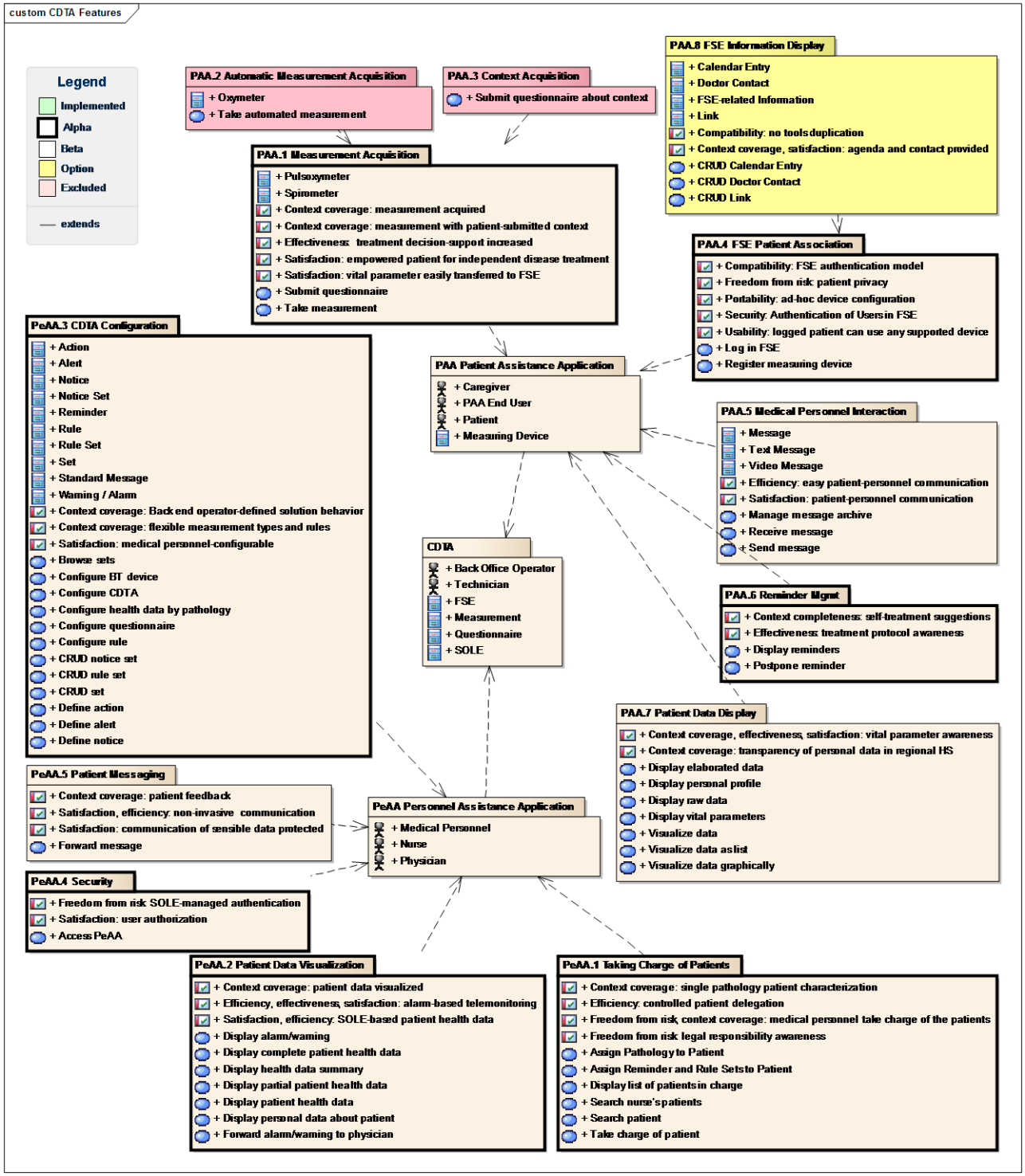
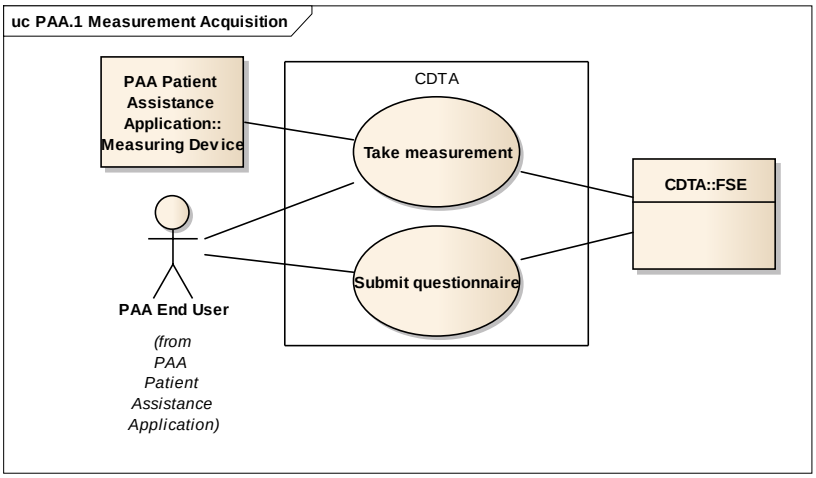


Figure 46: Feature tree of Chronic Disease Treatment Assistance Solution. (notation and method: Fricker (2012): "Release Planning with Feature Trees: Industrial Case", RefsQ)

4.4.1 Application A1 Patient Assistance Application (PAA)

4.4.1.1 Feature PAA.1 Measurement Acquisition

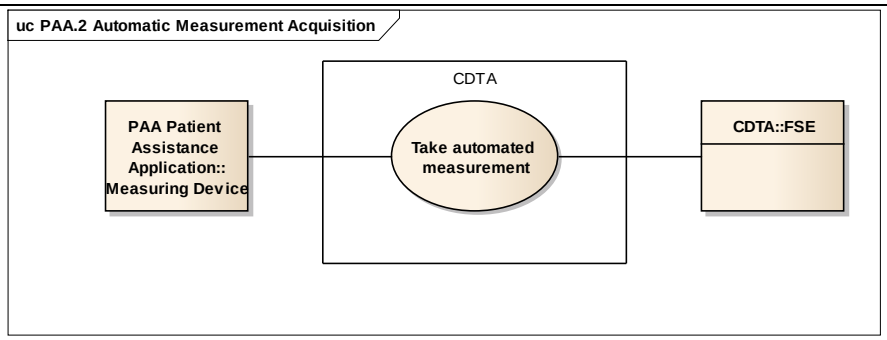
The Feature PAA.1 *Measurement Acquisition* provides the patient with the ability to take a measurement.

Addressed stakeholder interests and expectations	Goals to be achieved: • Satisfaction: Patient empowered to follow his health status • Context coverage: Measurement Acquired • Context coverage: Measurement can have context submitted by patient • Effectiveness: increase data for treatment, • Satisfaction: easiness to provide vital parameter to FSE External Interfaces • FSE • Measuring devices: Spirometer and Pusoxymeter • PAA end users, Patient and Caregiver Use cases: • UC01 Take measurement: take a measurement with a specific monitoring • UC02 Submit questionnaire: take a measurement by patient questionnaire 
Consequences of *not* implementing the feature	Core functionality of the solution would not be present
Comments or drawings	To be validated with prototype

4.4.1.2 Feature PAA.2 Automatic Measurement Acquisition

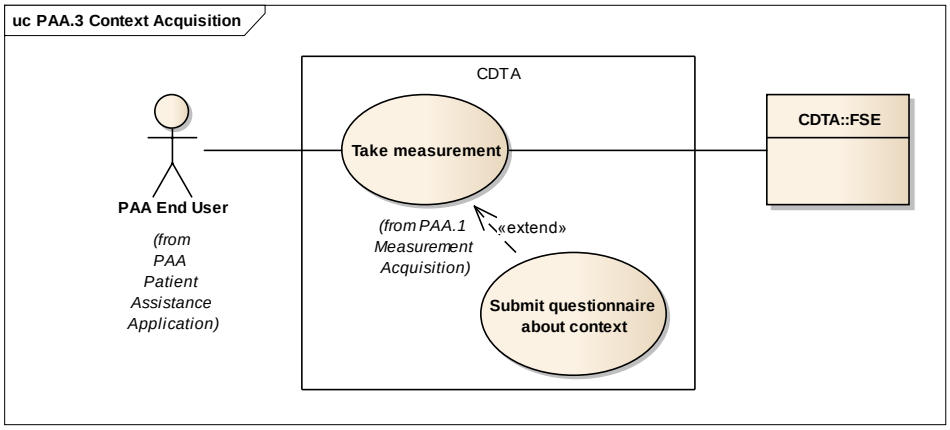
The Feature PAA.2 Automatic *Measurement Acuiqisiton* provides the patient with the ability to take a measurement without his intervention

Addressed stakeholder interests and expectations	Out of scope External Interfaces • FSE • Measuring device Oxymeter

4.4.1.3 Feature PAA.3 Context Acquistion

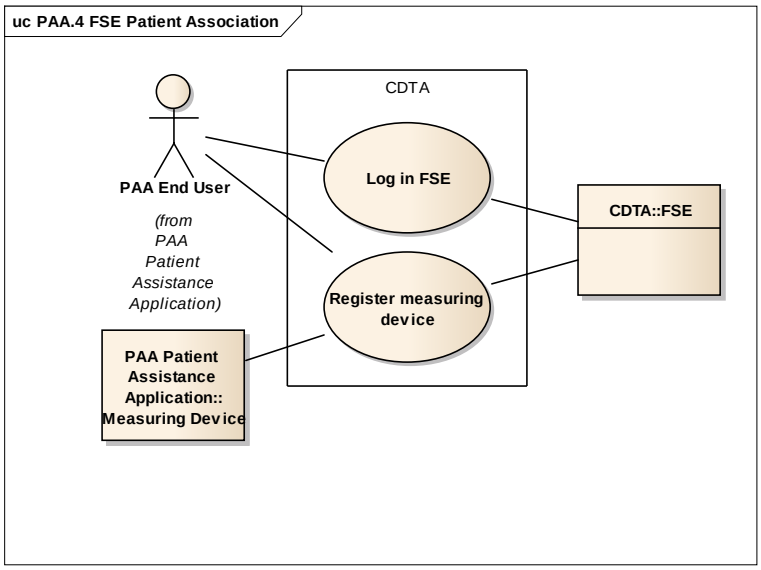
The Feature PAA.3 *Context Acquisition* provides the patient with the ability to report context information for his measurements.

Addressed stakeholder interests and expectations	• Out of scope 
Comments or drawings	The patient can answer to (max 4) questions when he take a measurement. These describe the context in which the measure have been taken. (e.g. What activities do you carried out over the past 15 minutes? (rest, walking, stairs, etc ...), how do you feel? (well, in anguish, in anxiety, cough, etc. ....)) It will be not developed: Pneumologist want the patient to be in a specific context when he take the measurement

4.4.1.4 Feature PAA.4 FSE Patient Association

The Feature PAA.4 *FSE Patient Associaiton* provides the patient with the ability to authorize information sharing with FSE.

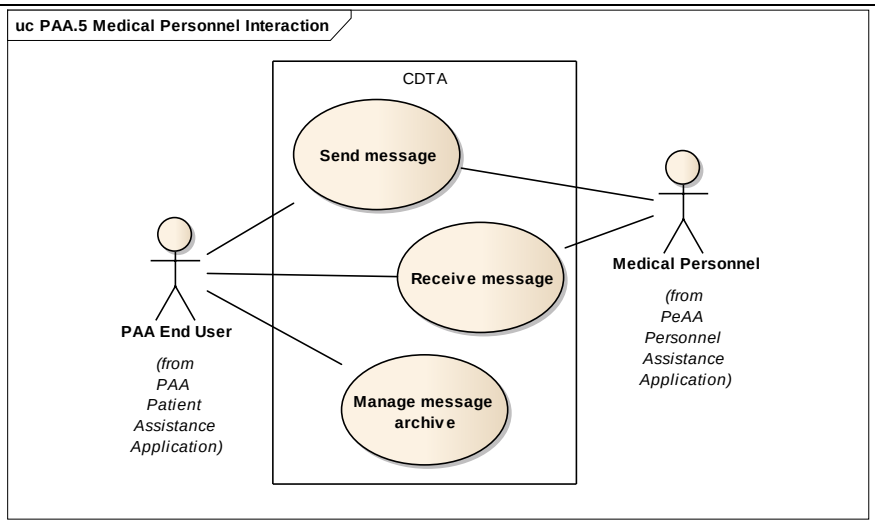
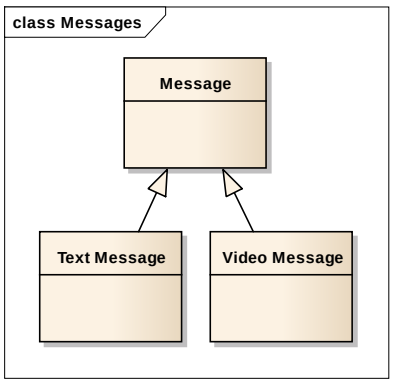
Addressed stakeholder interests and expectations	Goals to be achieved: • Freedom from risk: privacy assured • Security: Authentication of Users in FSE • Compatibility: FSE authentication model Sub Goals: • Usability: Logged patient can use any supported device • Portability: device do not need to be configured in advance External Interfaces

	• FSE • Measuring devices: Spirometer and Pusoxymeter • PAA end users: Patient and Caregiver Use cases: • UC03 Log in FSE • UC04 Register measuring device 
Assumptions	User must be already registered in FSE. Mobile device available to enable log in FSE.
Comments or drawings	The necessity of registration of device in the system depends on solution To be validated with prototype

4.4.1.5 Feature PAA.5 Medical Personnel Interaction

The Feature PAA.5 *Medical Personnel Interaction* provides the patient with the ability to communicate with their medical personnel and to receive feedbacks.

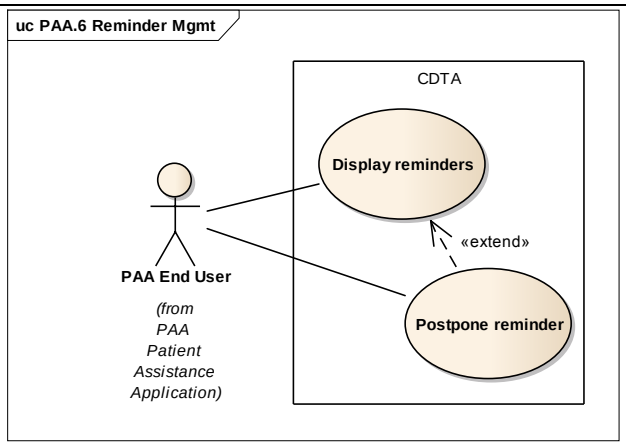
Addressed stakeholder interests and expectations	Goals to be achieved: • Satisfaction: Patient communicate with medical personnel • Efficiency: easiness of communication between medical personnel and patients Sub Goals: • satisfaction: Patient receive feedback from system and medical personnel External Interfaces • PAA end users: Patient and Caregiver • Medical personnel: Nurse, Physician Use cases: • UC05 Send message: text or video • UC06 Receive message: text or video • UC07 Manage message archive

	 Domain model 
Comments or drawings	Video message should be limited (< x Mb) To be validated with prototype

4.4.1.6 Feature PAA.6 Reminder Management

The Feature PAA.6 *Reminder Management* provides the patient with the ability to be informed about his treatment protocol.

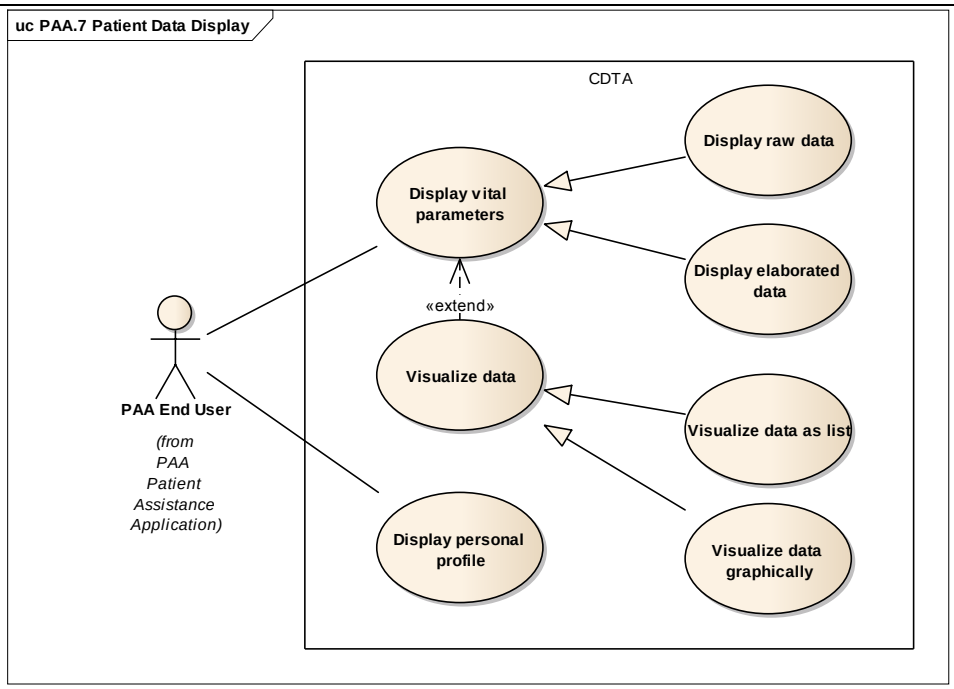
Addressed stakeholder interests and expectations	Goals to be achieved: • Context completeness: Patient receives suggestion on his self-treatment Sub Goals: • Effectiveness: Patient are aware of the treatment protocol External Interfaces • PAA end users: Patient and Caregiver Use cases: • UC08 Display reminders • UC09 Postpone reminder

	
Comments or drawings	Reminders' content and frequency are configured by back end operator To be validated with prototype

4.4.1.7 Feature PAA.7 Patient Data Display

The Feature PAA.7 *Patient Data Display* provides the patient with the ability to consult his own data.

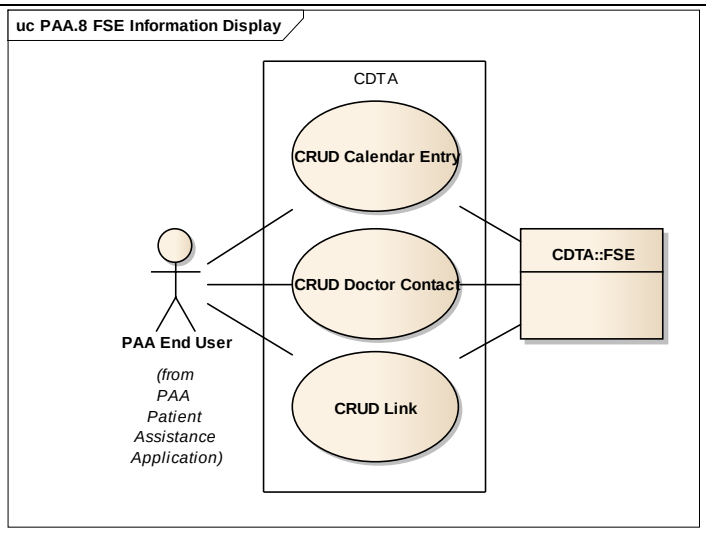
Addressed stakeholder interests and expectations	Goals to be achieved: • Context coverage, effectiveness, satisfaction: Patient are aware of their vital parameter • Context coverage: Patient can check their official personal data in regional HS External Interfaces • PAA end users: Patient and Caregiver Use cases: • UC10 Display personal profile • UC11 Displays vital parameters: measurements • UC12 Display raw data • UC13 Display elaborated data • UC14 Visualize data • UC15 Visualize data as list • UC16 Visualize data graphically

	
Comments or drawings	Personal data is not modifiable in the APP. They are formal patient personal data in FSE. To be validated with prototype

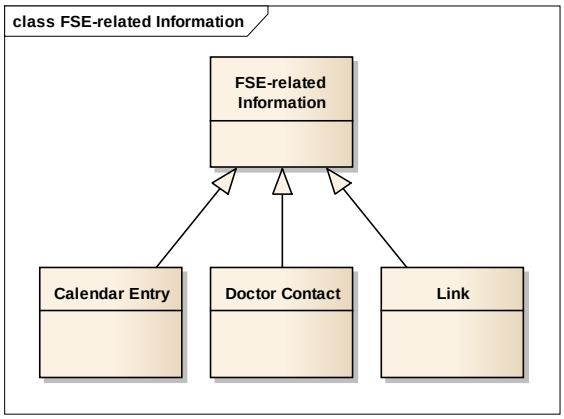
4.4.1.8 Feature PAA.8 FSE Information Display

The Feature PAA.8 *FSE Information Display* provides the patient with the ability to use FSE calendar, link and Doctor contact list.

Addressed stakeholder interests and expectations	Goals to be achieved: • Context coverage, satisfaction: Patient have agenda, contact list and link at their disposal Sub Goals: • Compatibility: FSE Tools are not duplicated in PAA External Interfaces • FSE PAA end users: Patient and CaregiverUse cases: • UC17 Create Read Update Delete Calendar Entry • UC18 Create Read Update Delete Doctor Contact • UC19 Create Read Update Delete Link



Domain model



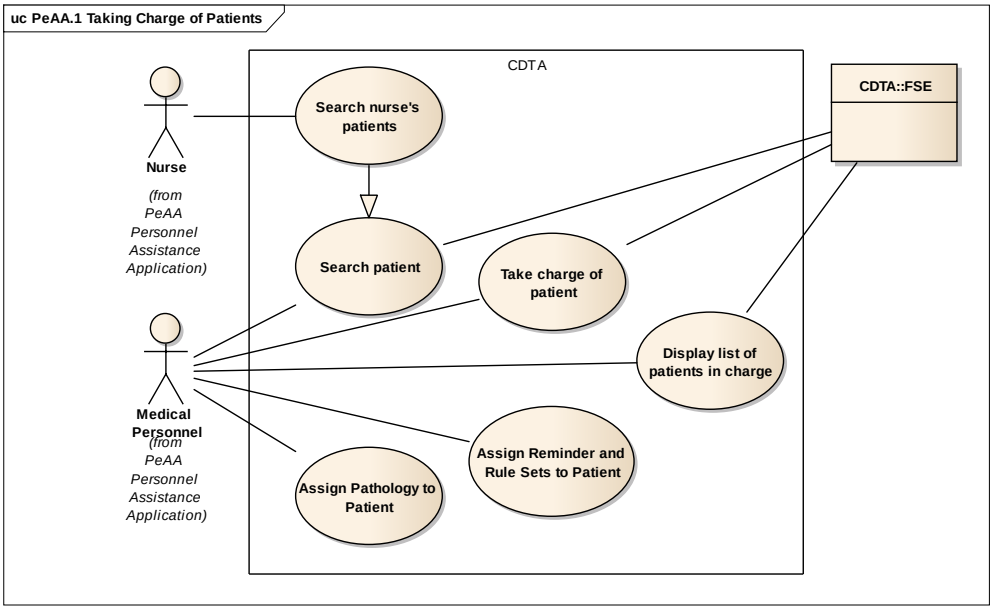
Comments or drawings	Agenda, link and doctor's contact are stored in FSE To be validated with prototype

4.4.2 Application A2 Personnel Assistance Application

4.4.2.1 Feature PeAA.1 Take charge of a patient

The Feature PeAA.1 *Take charge of a patient* provide the medical personnel with the ability to gain access to patient data and configure their treatment protocols.

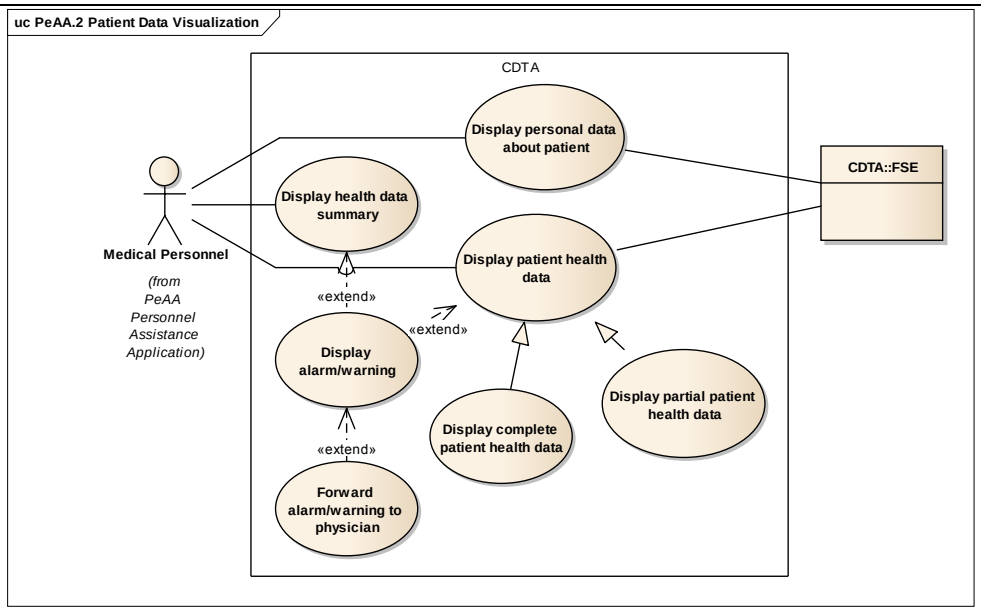
Addressed stakeholder interests and expectations	Goals to be achieved: • Freedom from risk, context coverage: medical personnel take charge of the patients • Freedom from risk: medical personnel are aware of legal responsibility Sub Goals: • Efficiency: nurse can take charge only the patient already in charge of the reference physician • Context coverage: patient are characterised with pathology, in case of this solution only one pathology is used External Interfaces • FSE

	Medical Personnel: Nurse, PhysicianUse cases: • UC20 Search nurse's patient • UC21 Search patient • UC22 Take charge of patient • UC23 Display list of patient in charge • UC24 Assign pathology to patient • UC25 Assign reminder set and rule set to patient 

4.4.2.2 Feature PeAA.2 Patient Data Visualization

The Feature PeAA.2 *Patient Data Visualization* provides the medical personnel with the ability to telemonitor patient health conditions.

Addressed stakeholder interests and expectations	Goals to be achieved: • Context coverage: core function of the solution • Efficiency, effectiveness, satisfaction: medical personnel take advantage of alarm/warning for the telemonitoring of the patients Sub Goals: • Satisfaction, efficiency: Patient health data derive from SOLE system External Interfaces • FSE • Medical Personnel Use cases: • UC26 Display complete set of patient health data • UC27 Display partial set of patient health data • UC28 Display patient health data • UC29 Display alarm/warning • UC30 Display health data summary • UC31 Forward warning to physician • UC32 Display patient personal data

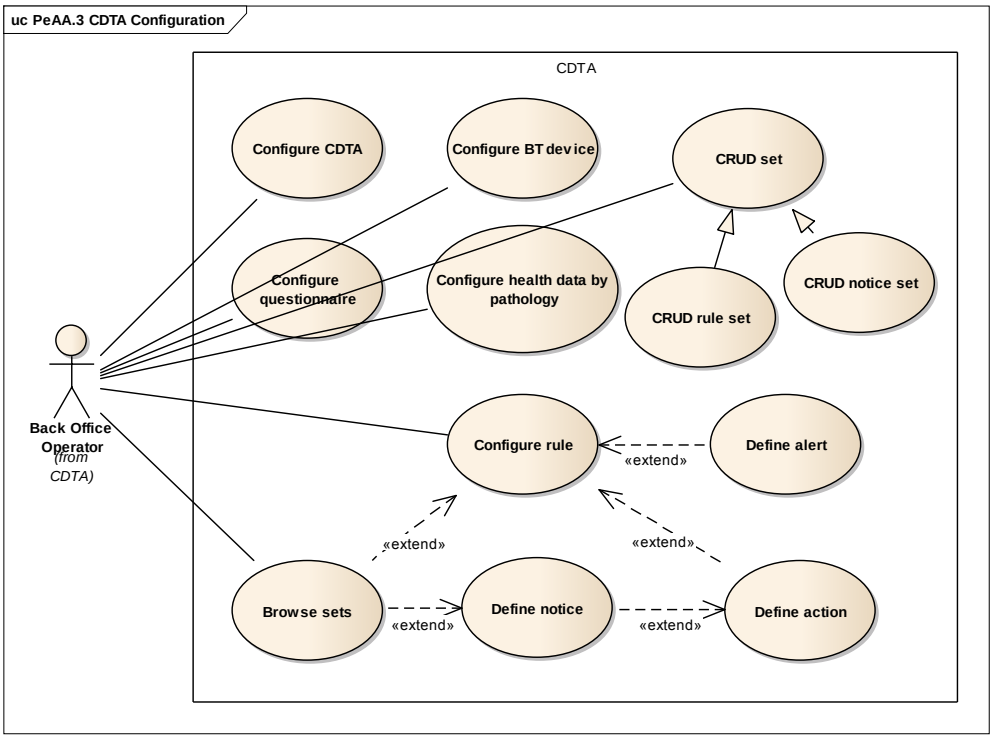
	
Comments or drawings	Set of patient data are configurable and based on pathology Assistants have a access to all information available and they display by default a wider set of information. Physician have access to all information available but they displays by default only a set of relevant information It must be possible to display raw and/or elaborated data in graphical and list format. Measurement with an associated context should be Highlighted To be validated with prototype

4.4.2.3 Feature PeAA.3 CDTA Configuration

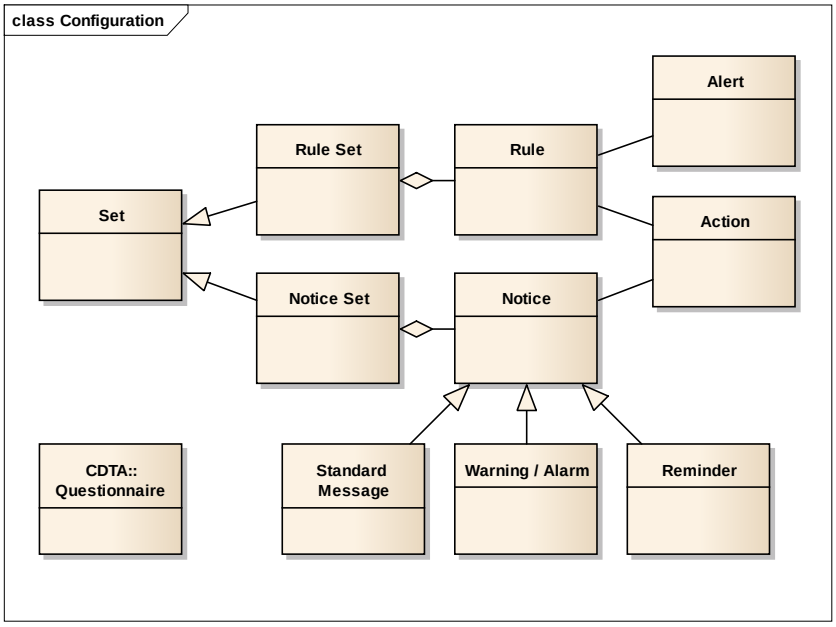
The Feature PeAA.3 *CDTA Configuration* provide the back office operator with the ability to configure the solution

Addressed stakeholder interests and expectations	Goals to be achieved: • Context coverage: Back end operator can define the behaviour of the solution • Satisfaction: configurable by non-technical user (medical personnel) • Context coverage: highly configurable solution for adding new types of measurement and rules External Interfaces • Back Office Operator: Nurse, Physician, Technician Use cases: • UC33 Configure CDTA (General Conf) • UC34 Configure health data by pathology • UC35 Configure BT Device • UC36 Configure Rule • UC37 Define Alert • UC38 Define Action • UC39 CRUD Set • UC40 CRUD Rule Set • UC41 CRUD Notice Set • UC42 Browse sets

- UC43 Define Notice
- UC44 Define Standard communication
- UC45 Define Reminder
- UC46 Define Alarm/warning
- UC47 Configure questionnaires



Domain model

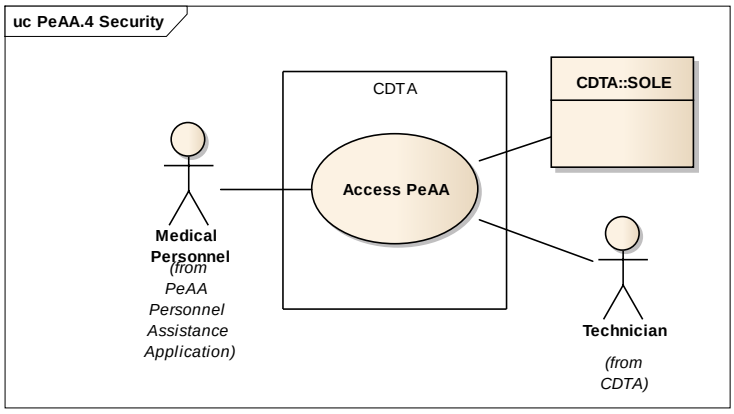


Key ideas for implementation	**Rule:** if alert then action1..actionN else action1..actionM **Alert**: the recognition of a pattern mono-multi parameter Action: • (de) assign rule set to patient • (de) assign reminder set to patient

	• Send standard communication to patient • Raise alarm/warning Notice: • Alarm/warning: text + photo (warning → nurse, alarm → nurse, physician) • Reminder: text + photo + frequency (→ any user) Standard communication: text + photo OR Video (→ Patient)
Comments or drawings	Configuration of BT devices need depend on solution

4.4.2.4 Feature PeAA.4 Security

The Feature PeAA.4 *Security* provide the PeAA users to gain authentication

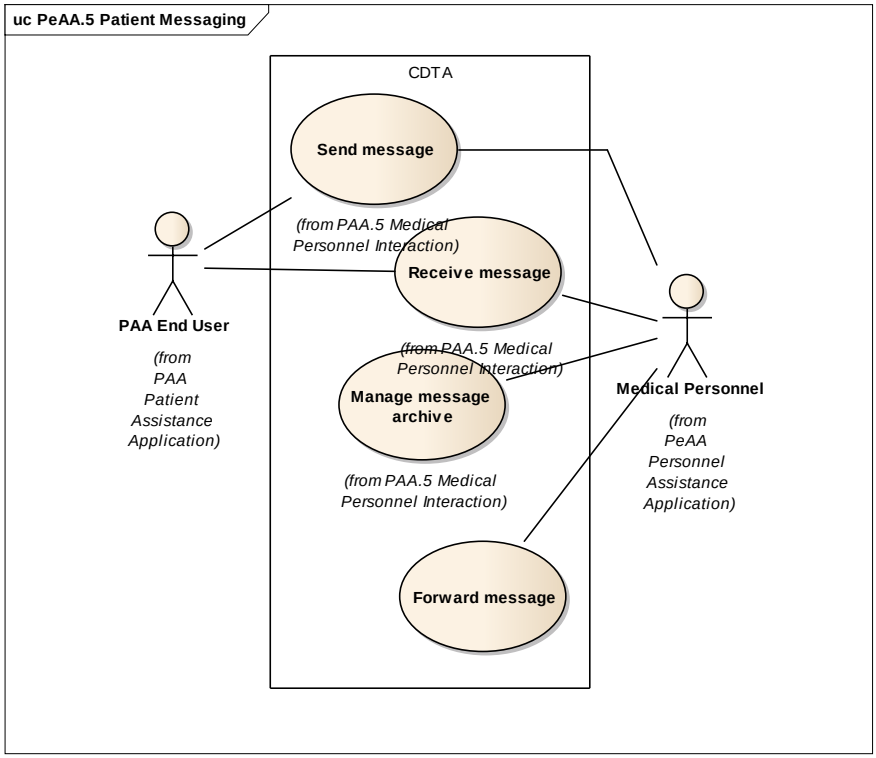
Addressed stakeholder interests and expectations	Goals to be achieved: • Satisfaction: Only authorised user can access • Freedom from risk: Authentication is managed by SOLE systems External Interfaces • SOLE portal Use cases: • UC48 Access to PeAA 
Comments or drawings	Roles need to be described The authentication phase is already managed by FSE and SOLE portal

4.4.2.5 Feature PeAA.5 Patient Messaging

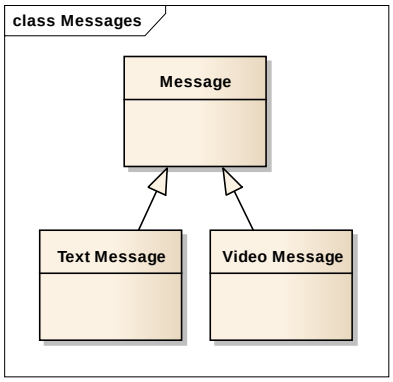
The Feature PeAA.5 *Patient Messaging* provides the medical personnel with the ability to communicate with the patient through asynchronous video and chat.

Addressed stakeholder interests and expectations	Goals to be achieved: • Context coverage: feedback to the patient is a core function • Satisfaction, efficiency:non invasive communication • Satisfaction: communication need to be protected if containing sensible data Use cases: • UC49 Send message: text and video • UC50 Receive message: text and video • UC51 Manage message archive

- UC52 Forward message



Domain model:



4.4.3 FI-STAR Solution-wide Requirements and Constraints

4.4.3.1 Quality Requirements

ID	Requirement (Title and Short Description)	Rationale and comments
	Quality requirement priority: Security, Suitability, Compatibility, Usability, Reliability, Maintainability, Performance, Portability	During Use case visit, CUP2000 stakeholder quality requirement
	Security	The collected data about patient and his/her health is sensible and must be protected
	Functional Suitability	The solution need to consider end user needs and to validate experimental experiences

	Usability	The solution need to be usable by elder, not digitally alphabetized The Medical personnel solution need to be usable for not technical people.
	Compatibility	A central goal for Cup2000 is the integration of the solution with the EHR
	Maintainability	The solution need to be scalable to other types of measurement
	Reliability	The collected data is vital and must not be lost. The solution is experimental, ie. not vital, but it should be as mature as possible Reliability affects user experience. Reliability problems can be mitigated by customer support provided by product manager.

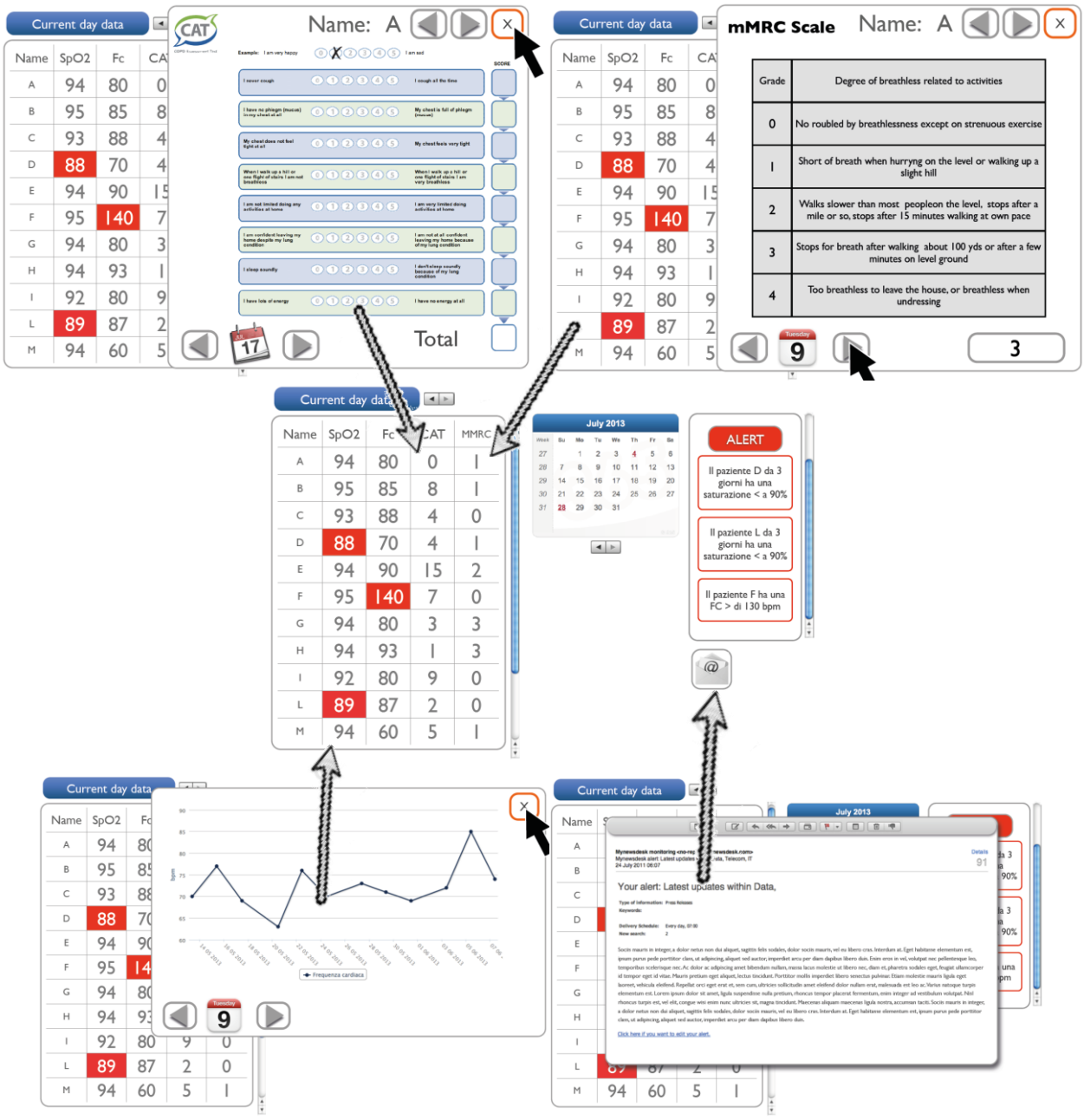
4.4.3.2 Constraints towards Platforms

ID	Constraint (Title and Short Description)	Rationale and comments
	Log of access of data is managed by FSE	
	Patient users are authenticated on FSE	
	Professional users are authenticated on SOLE portal	
	Touch and feel of PeAA must be compliant with SOLE standards	

4.4.3.3 Constraints towards Enablers and Technology

ID	Constraint (Title and Short Description)	Rationale and comments
	FISTAR platform is connected to legacy system with an unique point of contact (mediator GE)	
	PAA should be optimized for screen >4 inches	

4.4.4 Suggested PeAA Summary Screens



5 Management Solution for Bipolar Patient Treatment in Bilbao, Spain

The proposed FI-STAR solution aims at providing telecare for mental disorders. It specifically targets the bipolar disorder that is a chronic disorder with a 2.1% to 4.1% prevalence. The Bipolar Patient Treatment Manager (BPTM) focuses on patients' empowerment (i.e. person with mental disorders are the key actors of the proposed solution) by providing specific telecare capabilities and multi-channel interaction between the patients and the health service provider (i.e. OSAKIDETZA), using their preferred available devices and communication channels. The proposes use case trial aims to (1) improve the quality of care, enhance the patients evolution and reduces costs to the healthcare system by: (a) allowing patients to have a better knowledge about the disease and the related risk factors and providing them strategies to minimize its consequences,(b) allowing psychiatric professionals to identify symptoms and detect risks taking into account both patients and caregiver input. The psychiatric personnel will be able to better support and follow up patients, identify symptoms and risk or destabilization situations at early stages, and interact with both patients and caregivers, providing online individualized treatment according to the patient's needs and focused on improving the functionality and avoid the morbidity and therefore the disease worsening, (c) involving caregivers (e.g. relatives) in the treatment by providing them means to have a better knowledge about their relative's disease and be able to support them to manage it; (2) help healthcare professionals to address as many patients as possible and save time while complying with ethics and regulations by (a) enhancing the therapist's efficiency, and reducing the need of consultations by increasing the availability of psychological treatment though the provision of tele-services and (b) allowing call centre nurses to react to alarms (e.g. by calling patients and caregivers).

The proposed solution will (1) provide means to learn about how to manage the disease and how to identify symptoms and risk or destabilization situations; (2) provide means to register, share, and access relevant quantitative and qualitative status information, drugs intake, and potentially unwanted side effects; (3) provides feedback relevant for psychotherapy (i.e. information to the patient about the evolution of his/her disease, motivational messages, and comments of his/her therapist); (4) facilitates triggered and on-demand secure multi-channel interaction between patients and professionals (i.e. OSAKIDETZA),(5) allows the use of preferred available devices and communication channels; (6) ensures that the exchanged information is highly secured; (7) ensures that the clinical relevant information integrated within the existing personal health record PHR and electronic health record EHR by interoperating with existing infrastructures (OSAREAN Platform).

The FI STAR solution will interoperate with existing infrastructures (OSAREAN Platform) and will ensure that the exchanged information should be highly secured and the clinical relevant information will be integrated within the existing (PHR/EHR).

The main actors involved in the use case are: (1) treatment participants (i.e. patients and caregivers); psychiatric personnel (i.e. psychiatrics, psychologists, and psychiatric nurses), and call centre nurses.

The obtained results will be based on the FI architecture and will be tested with a group of 50 patients (25 will get tele-care support and the other 25 not) with bipolar disorders in a real environment.

This chapter gives an overview of a FI-STAR solution that is intended to be built to support the FI-STAR use case. The chapter covers the goal/purpose of the FI-STAR solution, stakeholders and their interests/expectations, the application and their features that are integrated into the FI-STAR solution to support these interests/expectations, and the FI-STAR solution-wide requirements and constraints. The appendix can be used to capture any other material, including business processes, glossary, description of the as-is situation, problems with current solutions, storyboards, and examples of artefacts and photographs of usage context.

The vision chapter is intended as a starting point for subsequent detailed requirement engineering. The features are used to establish an overview of the FI-STAR solution's requirements that then will be engineered just-in-time before the relevant development starts. The features should be specified by explaining how the concerned FI-STAR application will support the corresponding FI-STAR stakeholders' interests and expectations. The vision chapter should be updated as the understanding of the FI-STAR solution and of its aims and objectives evolve.

Future uses of this vision chapter will be to establish personas for target user segmentation and user experience engineering, traceability to release and project planning, application and enabler design and development, and quantification of quality requirements and testing, definition/monitoring of KPI, and analyzing commonality/variability across applications. In addition, this vision chapter will refer to relevant specialty requirements.

5.1 Introduction

5.1.1 The experimentation site

OSAKIDETZA is a Public Entity, the most important health service provider in the Basque Country (89%), entirely financed by the Basque Government. OSAKIDETZA covers 2.183.165 inhabitants (>=65 years 17.81%) and runs 320 Primary Health Centres, 12 acute hospitals, 4 chronic care hospitals, three regional networks with 4 psychiatric hospitals and 2 Long term Mental hospitals.

5.1.2 Background

The response to the needs of people suffering from chronic illnesses has become the principal challenge faced by the Basque Health System. These pathologies have a multiple impact: (1) they represent a considerable restraint on quality of life, productivity and the functional state of people who suffer from them; (2) they exert a strong influence on morbidity and mortality rates; (3) and they accelerate the increase in health and social costs, which compromises the medium term sustainability of the healthcare system.

To meet the challenge of chronicity the Basque Health System set up, in 2010, the "*Strategy to Tackle the Challenge of Chronicity in the Basque Country*[2] that provides a framework of action for the medium term transformation of the Basque Health System. This Chronic Patients Strategy aims to outline a new way of organizing care causing an impact on each and every aspect of the system (health results, satisfaction, patient and caregiver quality of life, and sustainability). This strategy is based on a *medium term vision***,** which defines and describes the desired future situation.

5.1.3 The Use Case

The aim of the proposed use case is to provide new, not available "Telecare service based on advanced communication channels to treat, monitor and support people with mental disorders and their relatives". The use-case includes new ICT-based services in a health area that until now was partially hidden, as far as the ICT is concern, by other "more popular" chronic pathologies. Mental health is important because of its prevalence in our society and the implementation of the use case in the Basque Country will be useful not only to generate evidence on the usability and clinical impact of the proposed solution but also to validate the proposed technological solution in addressing Mental Health. The importance of mental disorders is clear taking into account the epidemiological situation. Patients with mental disease represent between 15-20% of total population. The morbidity and mortality of patients with mental diseases is high, with a life expectancy of almost 10 years less than the general population, due especially to suicide, cardiovascular death and cancer. Cardiovascular risk is even higher in women with mental

2 »A Strategy to Tackle the Challenge of Chronicity in the Basque Country.« http://cronicidad.blog.euskadi.net/descargas/plan/ChronicityBasqueCountry.pdf

disorders. Mental disorders, especially the severe ones (schizophrenia, bipolar disorder and depression) begin usually in the adolescence and are chronic disorders. The diseases are associated also with cognitive symptoms, obesity and insomnia, and are related with difficulties in work, leisure and sexuality. Early and intensive treatment improves prognosis of mental disorders. psychoeducational-psychological treatments and relevant information are methods that have been associated with improved prognosis.

The use of telemedicine can be useful as a complement to the usual treatment, helping patients to control their diseases, and helping the health provider, and specially helping the health professionals, via feed-back. Therefore, telemedicine can help to improve functionality and quality of life, but what is most important, bringing different services together (Service aggregation) might double the impact of IT technologies on the quality of the service, patient safety, patient and professional satisfaction, treatment adherence, accessibility, and in the end quality of life.

In particular the use case targets patients with **Bipolar Disorders**. Bipolar disorder is a chronic disorder with a 2.1% to 4.1% prevalence. These patients have high rates of comorbidity with other disorders such as anxiety 60%, alcohol and drug dependence 50% and personality disorders 33-50%. The diagnosis of these patients is often very difficult because 30-50% of the patients start the disease with a depressive episode (40%) and these symptoms are similar to unipolar major depression. Thus, an appropriate treatment for these patients is often delayed until a correct diagnosis is made. There are also difficulties to diagnose bipolar disease in young people with psychotic symptoms, drug abuse, or in patients with mixed symptoms.

The typical pharmacotherapy bipolar disorder for the maintenance treatment is the mood stabilizers, alone or in combination with antipsychotics. These treatments are effective, however, the patients are not compliance with the medication, one third of patients leave the medication and usually the drop-off is associated with relapses. Previous studies have shown that early educational intervention increased knowledge and adherence reducing relapses and hospitalizations. During the early stages of the disease, critical period is usually the time where the subject and their families have a greater suffering for the disorder itself, partly because of the impact it diagnosis and lack of knowledge about the symptoms of the disease. Some psycho educational treatments have been specifically designed, some of them are only a collection of relevant information about the disorder and other psycho educational programs introduce some important cognitive-behavioural elements. There are also cognitive-behavioural treatments with proven efficacy. The addition of the cognitive-behaviour therapy in the Psychoeducation treatments provide some benefits in the depressive symptoms but this therapy did not show significant clinical benefits compared to psychoeducation therapy. Therefore, the effectiveness of both therapies are similar being cheaper the Psychoeducation than CBT and group format than individual. One of the biggest problems of the Psychoeducation groups is the fixed date and hour to go to the therapy and the complexity to get the agreement of all people of the group. Besides, this therapy is long over the time (6 months) and the patients must attend in the working hours at list one hour per week, so the consequence of these problems is a long number of dropouts, especially in functional patients. Currently the available psychological treatment for Bipolar patients in the OSAKIDETZA health system is quite rare due to the amount of time required to provide such treatments

There are many internet programs that has been demonstrated their efficacy. However, the number of the online treatments programs of bipolar disorder is reduced. The effectiveness of therapies online is variable, but there are indications that this efficacy is superior when online therapy is added additional support for clinicians. New technologies and especially the demo of Web 2.0 is a media opportunity. Using devices as support to psychological treatments could be very useful.

Refer to the value case section (section 3) for further details on the use case value proposition.

5.2 FI-STAR Solution Positioning

The following captures the essence of the FI-STAR solution, including the problem it addresses and the key idea of solving the problem.

5.2.1 Problem Statement

The following problem statement describes the current situation before the solution is available.

The problem of	treating and empowering patients with bipolar disorders
affects	patients, psychiatrics, psychologists, and psychiatric nurses
the impact of which is	• dependency on clinical staff who have insufficient capacity for giving all patients the necessary support for managing the patients' disease • patient anxiety and a difficulty family environment
a successful solution would	• empower patients and caregivers (e.g. relatives) to be actively involved in the management of the disease by allowing them to have a better knowledge about the disease and the related risk factors in order to minimize the consequences of their disease • support early detection and reduction of the patient's acute symptoms by involving the psychiatrics, psychologists, psychiatric nurses, and call center nurses in care provision and support • enhance the evolution of Bipolar Patients by providing high quality, efficient and accessible psychological treatment to all the users who need it • save time and costs to the healthcare system due to its quick accessibility and the possibility to use already in place interaction devices

5.2.2 Position Statement

The following statement describes the position and value of the solution.

For	patients, private caregivers (e.g. relatives), psychiatrics, psychologist, psychiatric nurses, and call centre nurses.
Who	teach, monitor, consult, and treat the patient
The solution	Bipolar Patient Treatment Manager (BPTM) is a FI-STAR **private** cloud solution.
That	• provides means to learn about how to manage the disease and how to identify symptoms and risk or destabilization situations, • provides means to register, share, and access relevant quantitative and qualitative status information, drugs intake, and potentially unwanted side effects, • provides feedback relevant for psychotherapy (i.e. information to the patient about the evolution of his/her disease, motivational messages, and comments of his/her therapist), • facilitates triggered and on-demand secure multi-channel interaction between patients and professionals (i.e. OSAKIDETZA), • allows the use of preferred available devices and communication channels, • ensures that the exchanged information is highly secured, • ensures that the clinical relevant information integrated within the existing personal health record PHR and electronic health record EHR by interoperating with existing infrastructures (OSAREAN Platform).
Unlike	a pure face-to-face process
Our product	• improves the quality of care, enhance the patients evolution and reduces costs to

	the healthcare system by ○ allowing patients to have a better knowledge about the disease and the related risk factors and providing them strategies to minimize its consequences, ○ allowing psychiatric professionals to identify symptoms and detect risks taking into account both patients and caregiver input. The psychiatric personnel will be able to better support and follow up patients, identify symptoms and risk or destabilization situations at early stages, and interact with both patients and caregivers, providing online individualized treatment according to the patient's needs and focused on improving the functionality and avoid the morbidity and therefore the disease worsening. ○ involving caregivers (e.g. relatives) in the treatment by providing them means to have a better knowledge about their relative's disease and be able to support them to manage it, • helps healthcare professionals to address as many patients as possible and save time while complying with ethics and legal regulations ○ enhancing the therapist's efficiency, and reducing the need of consultations by increasing the availability of psychological treatment though the provision of tele-services ○ allowing call centre nurses to react to alarms, e.g. by calling patients and caregivers.

5.3 FI-STAR Use Case Stakeholders

The following users, interfacing systems, and other stakeholders are affected by the solution.

5.3.1 User Roles

Figure 47 provides an overview of the user roles of the Bipolar Patient Treatment Manager solution. These are the clinical personnel, treatment participants, and technicians. The clinical personnel includes call centre nurses, psychiatric personnel including the psychiatric nurse and the two kinds of specialists psychiatrist and psychologist. Treatment participants are patients and caregivers. All roles use the BPTM solution except for the call centre nurse that interacts through the integrated OSAREAN platform.

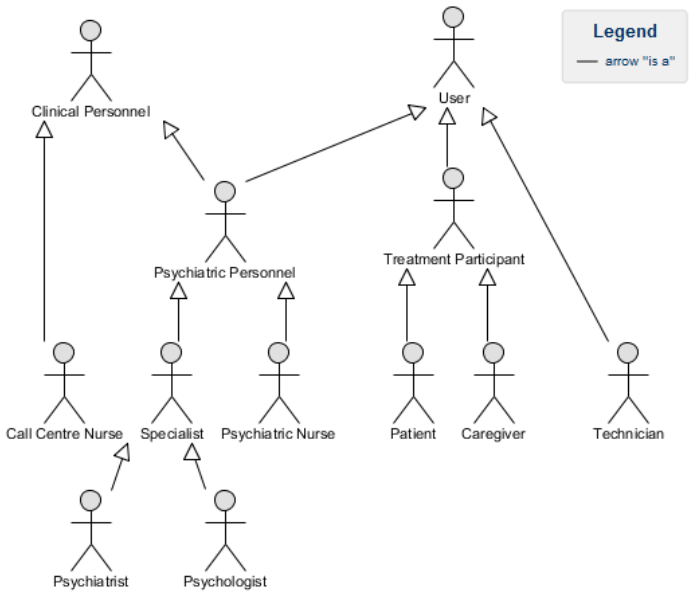


Figure 47: User roles of the Patient Treatment Manager solution.

The Bipolar Patient Treatment Manager (BPTM) solution will cover the key elements to provide a remote integrated treatment to patients with mental/ bipolar disorders.

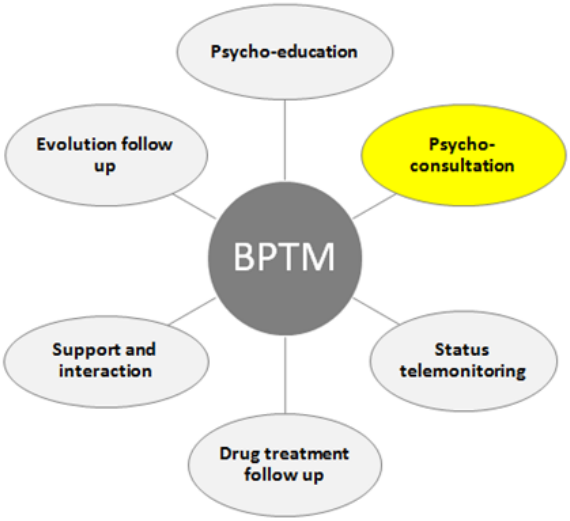


Figure 48: Key elements supported by the BPTM solution.

Table 4: Preliminary workflow overview

Target element	Preliminary workflow overview
Psychoeducation	The psychiatric personnel will define the learning modules, that include learning sessions (with associated assessment questionnaire) and related psychotherapy exercises, and assign them to the selected treatment participants (i.e. patients and caregivers). The treatment participants will be able to access the psychoeducation functionalities, whenever/wherever, by using their preferred interfacing devices (i.e. PC, tablet, smartphone). • **Learning sessions:** The treatment participants will be able to see the learning status of each assigned learning session and to access the related multimedia content. If they want they could download the associated pdf documents but the video content will only be available online. They will be allowed to include personal annotations related to the learning sessions that could be stored for further consultation. Once they have performed the learning session they will have to fulfil, online, a specific questionnaire to assess their level of understanding and send it. The system will send as well other relevant usage parameters (e.g. time spent in the learning session, etc.) that will be collected automatically. If the sending process fails the system should provide appropriate feedback (process failure - subsequent delivery attempt) to the user. If the process succeeds the system will evaluate the results of the assessment questionnaire, store them along with the usage parameters, provide feedback to the user on the success of the sending process and on the results of the questionnaire and update the learning status of the learning session (if all the answers are right → OK if any answer is wrong → NOK). The collected information will be kept in the BPTM environment. • **Psychotherapy exercises:** Psychotherapy exercises are ongoing activities that require previous knowledge from the related learning sessions. There are different types of exercises such as visual chart, social capabilities training, symptoms detection, problem resolution and relaxation follow up. Once the related learning session will be achieved the patients will be able to access the related psychotherapy exercises and update them. As it is an ongoing process so the patients should be able to access the psychotherapy exercises over time. The new updates will be sent and stored and the user will get feedback on the status of the information sending process (successful or not). The collected information will be kept

<table>
<tr><td></td><td>in the BPTM environment.
• Asynchronous messaging: If required the treatment participants could interact with the psychiatric personnel trough asynchronous messages to ask for clarifications related to learning sessions or psychotherapy exercises. The user will get feedback on the status of the information sending process (successful or not) and the messages should be kept in the BPTM environment.
• Multichannel notifications: The system could, automatically, identify potential Alerts. Some examples of alert's triggers could be: if the patient has not started the psychoeducation process after a certain period of time, if the patient fails more than one time the assessment questionnaire, etc. Treatment participants should get notifications based on their preferences (e.g. call centre call, sms, instant messaging, email – to be decided). The alerts regarding the Call centre will be sent to the OSAREAN platform that will manage them.
To allow a more user friendly interaction and avoid information loses due to a lack of connection, Information could be stored in a temporary local storage and synchronized with BPTM when connection is established.</td></tr>
<tr><td>Psycho-consultation
(optional)</td><td>The treatment participants should be able to access the psycho-consultation functionalities, whenever/wherever, by using their preferred interfacing devices (i.e. PC, tablet, smartphone). The psychiatric specialists should use their desktop PC.
Patients could get notifications (scheduled consultation reminder) based on their preferences (e.g. sms, instant messaging, email – to be decided).
On the scheduled data and time both the psychiatric personnel and the patients should access the system and interact on 1 to 1 basis by using video (video communication does not require a high quality it is just to see one each other) , audio or chat capabilities.
Psychiatric personnel should be able to record and store the communication for potential further analysis, to include relevant treatment annotations that should be stored for further consultation and to access patient's information that could be relevant during the Psychoconsultation session. This relevant info could come from the EHR/PHR.</td></tr>
<tr><td>Tele Monitoring</td><td>The psychiatric personnel will define the patient's baseline, assign the monitoring questionnaires with associated periodicity and evaluation rules to generate alerts.
The patients will receive reminders (scheduled depending on the data collection periodicity) based on their notification channel preferences.
The patients should be able to access the status telemonitoring functionalities, whenever/wherever, by using their preferred interfacing devices (i.e. PC, tablet, smartphone). They will register the required monitoring information either manually or automatically if they use biometric sensors. The patients could also use their mobile device to take and automatically send pictures related to status monitoring (e.g. skin problems).
As a preliminary approach, the following table includes an example of some of the key parameters/questions that have been identified.
<table>
<tr><th>Daily</th><th>Weekly/2 weeks</th><th>Monthly</th></tr>
<tr><td>Mood/emotional related parameters
Daily activity
Sleep hours
Daytime sleepiness
Nº of daily water</td><td>Weight
Body Mass Index (BMI)
Pulse rate
Blood Preassure
Tremor</td><td>Glucose
Body temperature,</td></tr>
</table>
</td></tr>
</table>

	<table><tr><td>glasses</td><td>Dizziness. Skin problems: eczema, rashes Extrapyramidal symptoms such as akinesia (inability to initiate movement) and akathisia (inability to remain motionless).</td><td></td></tr></table> The collected information will be sent to the system and stored. To allow a more user friendly interaction and avoid information loses due to a lack of connection, Information could be stored in a temporary local storage and synchronized with BPTM when connection is established. The patient will get feedback on the result of the information registering process. Clinically relevant information will be sent to the OSAREAN platform to be stored in the EHR/PHR. The collected parameters and values of the monitoring questions will be, automatically, evaluated by the system based on the rules defined by the psychiatric personnel to identify potential alerts. Optionally, other alert types based on other kind of events could be generated (e.g. the patient does not fulfil the monitoring questionnaires and it is necessary to contact him/her to know if there is any kind of problem, etc). The alerts will be notified by using the preferred channels. The alerts regarding the call centre will be sent to the OSAREAN platform that will manage them. If required the patients could interact with the psychiatric personnel trough asynchronous messages to ask for clarifications related to the status monitoring. The user will get feedback on the status of the information sending process (successful or not) and the messages should be kept in the BPTM environment.
Drug treatment follow up	The patients will be able to access the drug treatment follow up functionalities, whenever/wherever, by using their preferred interfacing devices (i.e. PC, tablet, smartphone). The patients will be able access the relevant information related to their medication prescription that is stored in the patient's EHR/PHR and will come from the OSAREAN platform and to self register medication intake (yes/no) and potential drug side effects by fulfilling the appropriate monitoring questionnaires. The collected information will be sent to the system and stored. Clinically relevant information will be sent to the OSAREAN platform to be stored in the EHR/PHR. The patient will get feedback on the result of the information registering process and if appropriate an alert could be generated (event processing/rule evaluation) and notify by using the preferred channels. The alerts regarding the call centre will be sent to the OSAREAN platform that will manage them. If required the patients could interact with the psychiatric personnel trough asynchronous messages to ask for clarifications related to the medication prescription or side effects. The user will get feedback on the status of the information sending process (successful or not) and the messages should be kept in the BPTM environment.
Support and interaction	The treatment participants (i.e. patients and caregivers) should be able to access the support and interaction functionalities, whenever/wherever, by using their preferred interfacing devices (i.e. PC, tablet, smartphone). The psychiatric specialists should use their desktop PC. • **FAQ repository**: The psychiatric specialists will be able to create/update or modify new FAQ items. The treatment participants will only be able to browse the repository. • **Asynchronous messaging** will support interaction between treatment participants and professionals. All of them will be able to browse, compose, send and archive messages.

Evolution follow up	Both psychiatric personnel and patients should be able to access evolution follow up information. Depending on his/her role the user should access a different scoreboard. • **Patient scoreboard:** The patients will access the patient scoreboard functionalities, whenever/wherever, by using their preferred interfacing devices (i.e. PC, tablet, smartphone). The available functionalities could depend on the selected interfacing device because of size limitations. The patient should be able to access his/her own treatment log in a user friendly manner including graphical information whenever possible. The patient's treatment history should include info such as education evolution, patients' notes, status monitoring parameters evolution, reported medication side effects, medication intake Follow Up evolution, Log, patient's alerts/notifications. • **Professional scoreboard:** The psychiatric specialists will access the professional scoreboard functionalities trough their desktop PC. The psychiatric specialists should be able to access, in a very easy (including colour code – green/yellow/red), an aggregated view of alerts related to the patients in their charge his/her own treatment. From this aggregate view they could select a specific patient and access his/her treatment history (include info such as education evolution, psychiatric personnel notes, status monitoring parameters evolution, reported medication side effects, medication intake Follow Up evolution, consultation records). The psychiatric specialists should also be able to access both aggregated and individual learning usage analytics.

The expected solution includes also a connector (i.e. OSAREAN Connector) to integrate the BPTM with the existing internal legacy systems in the current infrastructure of Osakidetza. The integration covers mainly aspects like exchange of clinically relevant data collected by the BPTM solution to the patients PHR/EHR, management of call centre alerts and authentication and will make use of available SOAP web services (exposed by the OSAREAN platform) by exchanging HL7 messages.

Figure 49 to Figure 54 give an overview of the BPTM-supported workflow related to bipolar disease treatment.

Figure 49: (1) The Psychiatric Personnel identifies the patients suitable to be involved in the telecare treatment and explains them its scope. Once the patients have agreed to be involved in the telecare process the Psychiatric Personnel associates them to the bipolar treatment telecare programme, assign them learning modules and monitoring questionnaires, identifies the patient baseline and explain them how to interact with the system (further details could be provided by technical staff. If caregivers are involved the Psychiatric Personnel associates them to the programme and assign them learning modules (2) The Psychiatric Personnel interacts with the Patient in face to face follow up interviews that are complementary to the telecare treatment.

Figure 50: The Treatment Participants (i.e. patients and caregivers) can configure some settings (e.g. the way they want to receive reminders, notifications, etc) and they interact with the BPTM system whenever/wherever they want by using their preferred available interfacing devices. (1) The patients access specific education contents, perform the psychotherapy exercises, provide relevant information about status monitoring and medication intake, follow up the evolution of their disease, access relevant support information, get reminders and notifications and interact with the Psychiatric Personnel through asynchronous messaging; (2) The caregivers access specific education contents relevant support information and interact with the Psychiatric Personnel through asynchronous messaging.

Figure 51: The patient could use his/her mobile device (i.e. smartphone or tablet) to take and automatically send pictures related to status monitoring (e.g. skin problems).

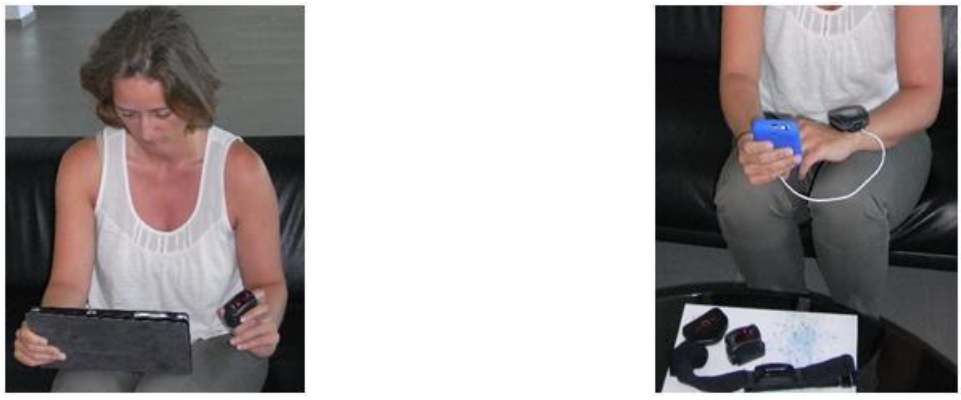


Figure 52: Optionally the patient uses biometric sensors to automatically collect and include biometric data (included for experimentation purposes)to their status monitoring data (biometric, activity). If the patients use biometric sensors they will receive the sensors set and appropriate technical support and training.

Figure 53: The Psychiatric Personnel uses the BPTM to follow up patients, and interact with both patients and caregivers through asynchronous messaging and FAQ repository

Figure 54: The call centre nurse reacts to alarms and calls from the patients and caregivers.

The following table describes the user roles in detail, including their background, role, and expectations.

Table 5: BPTM user roles

Name / Count	Description	Expectations on Solution
Psychiatrist 5-8 (estimated) Representative: Ana Gonzalez Pinto (anamaria.gonzalez-pintoarrillaga@osakidetza.net)	Designs and coordinates the treatments for a portfolio of patients. Offers consultations for the patients. Has unlimited access to the patient's history, monitoring data, symptoms, sleep, mood, drug treatment, results of evaluations, asynchronous mailing. Knows the OSAREAN platform. Possesses PC for interacting with BPTM through the browser.	Effectiveness • Personalised patient treatment. • Flexible assignment of treatment features (learning sessions, etc.). • Collection of information to detect potential problems to improve the definition learning modules. • Allow interactive treatment for doctor and patient and correct patient consultation. • Increased awareness of patient's condition • Availability of relevant information to support adequate treatment prescription. • Personalised and improved reaction to patients needs. Efficiency • Increased doctor's efficiency. • Effort for care contained for psychiatric personnel.

		• Teaching effort reduced for psychiatric personnel. • Creation of customisable evaluation rules to evaluate questionnaires. • Remote collection of patient related data. • Needs for F2F consultation reduced. • Faster support for treatment participant • Improved patient adherence to treatment. • Improved knowledge on strategies to minimize disease's consequences (i.e. psychotic, anxious, maniac and depressive symptoms) • Reduction of relapses, hospitalisation events, hospitalisation days and their related costs. • Keep a unique record. • Reduce/avoid transcription errors Usefulness • Increased availability of psychotherapy. Trust • Confidentially and privacy guaranteed. Comfort • Continuous patient status availability. • Better information and time to prepare for patient visit. Usability • Well-known interaction metaphors for user. • User friendly navigation. Risk mitigation • Care documented for doctor • Increased knowledge allows avoiding health risks. • Crisis situation handled for patient • Early response to crisis situation. • Early identification of potential side effects. Flexibility Patient handover enabled for doctor.
Psychologist 3-5 (estimated) Representative: Sonia Ruiz de Azua (SONIA.RUIZDEAZUAGARCIA@osakidetza.net)	Coordinates the treatments for a portfolio of patients. Offers consultations for the patients. Has unlimited access to the patient's history, monitoring data, symptoms, sleep, mood, drug treatment, results of evaluations, and asynchronous mailing. Knows the OSAREAN platform. Possesses PC for interacting with BPTM and could also interact with the system through the browser of a tablet.	Effectiveness • Personalised patient treatment. • Flexible assignment of treatment features (learning sessions, etc.). • Collection of information to detect potential problems to improve the definition learning modules. • Allow interactive treatment for doctor and patient and correct patient consultation. • Increased awareness of patient's condition • Personalised and improved reaction to patients needs. Efficiency • Increased doctor's efficiency. • Effort for care contained for psychiatric personnel. • Teaching effort reduced for psychiatric personnel. • Remote collection of patient related data.

		• Needs for F2F consultation reduced. • Faster support for treatment participant • Improved patient adherence to treatment. • Improved knowledge on strategies to minimize disease's consequences (i.e. psychotic, anxious, maniac and depressive symptoms) • Reduction of relapses, hospitalisation events, hospitalisation days and their related costs. • Keep a unique record • Reduce/avoid transcription errors Usefulness • Increased availability of psychotherapy. Trust • Confidentially and privacy guaranteed. Comfort • Continuous patient status availability. • Better information and time to prepare for patient visit. Usability • Well-known interaction metaphors for user. • User friendly navigation. Risk mitigation • Care documented for doctor • Increased knowledge allows avoiding health risks. • Crisis situation handled for patient • Early response to crisis situation. • Early identification of potential side effects. Flexibility • Patient handover enabled for doctor
Psychiatrist Nurse 1-3 (estimated) Representative: Yolanda Pérez	Supports the specialists in administering education to the treatment participants, status monitoring, and drug treatment follow up. Possesses PC for interacting with BPTM. Knows the OSAREAN platform	Effectiveness • Flexible assignment of treatment features (learning sessions, etc.). • Collection of information to detect potential problems to improve the definition learning modules. • Increased awareness of patient's condition • Personalised and improved reaction to patients needs. Efficiency • Teaching effort reduced for psychiatric personnel. • Remote collection of patient related data. • Reduce/avoid transcription errors Comfort • Continuous patient status availability. Usability • Well-known interaction metaphors for user. • User friendly navigation.

		Risk mitigation • Early response to crisis situation.
Patient 25 Patients will use the system (other 25 will be involved as control group) They will be kept anonymous. The psychiatric personnel will be in charge of involving the patients and validating the solution. Representative: Ana Gonzalez Pinto (anamaria.gonzalez-pintoarrillaga@osakidetza.net)	Suffers from bi-polar disorder. Receives care from doctor, nurses and can be supported by family/friends that act as caregivers. Is actively involved in the management of his/her disease. Target group age: 18-50 years old The goal of the patient is to be as self-managed as possible. Possesses PC and/or mobile device for interacting with BPTM.	Effectiveness • Personalised patient treatment. • Independent learning for treatment participant • Interactive treatment for doctor and patient • Interaction with clinical personnel. • Better awareness of personal condition • Adequate treatment prescription. • Personalised and improved reaction to patients needs. Efficiency • Improved knowledge on strategies to minimize disease's consequences (i.e. psychotic, anxious, maniac and depressive symptoms) • Improved motivation and awareness of risk factors (e.g. lifestyles, drugs, etc). • Patient participation increased (better control of his/her own disease). • Remote collection of patient's related data. • Needs for F2F consultation reduced. • Faster support • Reduction of relapses, hospitalisation events, hospitalisation days. Usefulness • Increased availability of psychotherapy. Trust • Confidentially and privacy guaranteed. Comfort • Psychotherapy in private. • Care for busy patients. • Continuous status availability. • Remote access whenever/wherever. Usability • Well-known interaction metaphors for user. • User friendly navigation. • Common ((as much as possible)) user experience by using any of the potential interfaces (PC, smartphone or tablet). • Multilanguage. Risk mitigation • Early Response to crisis situation.
Caregiver (e.g. a relative) Max 25 They will be kept anonymous. The psychiatric	Observes a patient and provides 1st-level support in physical proximity of the patient. Gets educational support and can be in contact with the Psychiatrist, Psychologist, Psychiatrist	The solution should provide means to be able to better support their relatives and interact with the health provider service. Effectiveness • Independent learning

personnel will be in charge of involving the caregivers of the patients participating in the validation of the solution. Representative: Ana Gonzalez Pinto (anamaria.gonzalez-pintoarrillaga@osakidetza.net)	nurses, and the call centre. Possesses PC and/or mobile device for interacting with BPTM.	• Interaction with clinical personnel. Efficiency • Private caregivers involved. • Improved knowledge on strategies to support patient to minimize disease's consequences (i.e. psychotic, anxious, maniac and depressive symptoms) • Improved awareness of risk factors (e.g. lifestyles, drugs, etc). Usefulness • Increased availability of psychoeducation. Trust • Confidentially and privacy guaranteed. Comfort • Remote access whenever/wherever. Usability • Well-known interaction metaphors for user. • User friendly navigation. • Common user experience by using any of the potential interfaces (PC, smartphone or tablet). • Multilanguage.
Call Center Nurse 3 (estimated) Representative: Ana Gonzalez Pinto	Specialised nurses serving the call centre. The call centre nurses will be in charge of supporting the patients (and caregiver) 24x7. Provides 1st-level support for patients from a call centre. Handles alerts when necessary (the alerts generated by BPTM are handled by the OSAREAN CRM). The nurses in the call centre are anonymous to the patient. They use the CRM application of the OSAREAN platform, and not BPTM, to interact with patients.	Transparent for the user. The BPTM solution generates alerts that will be managed by the OSAREAN CRM and showed to the Centre Nurses trough their usual system. Efficiency • Call center nurses involved Risk mitigation • Crisis situation handled for patient • Early response to crisis situation.
Technician (administrator) 1 Representatives: Josu Llano (jllano@osatek.net) and Angel Farias (ANGELJOSE.FARIARODRIGUEZ@osakidetza.net)	Provides 1st-level technical support to doctors and nurses when required. For example, assists in rule definition for alerts. Usually technical staff. A doctor can provide technical services as well.	Efficiency • Easy to maintain. Usability • Well-known interaction metaphors for user. • User friendly navigation.

5.3.2 Interfacing Systems and Artefacts

The following figure gives an overview of the system boundary of the BPTM solution. The connectivity to the FI-STAR cloud is a concern of the solution architecture, hence omitted from the overview.

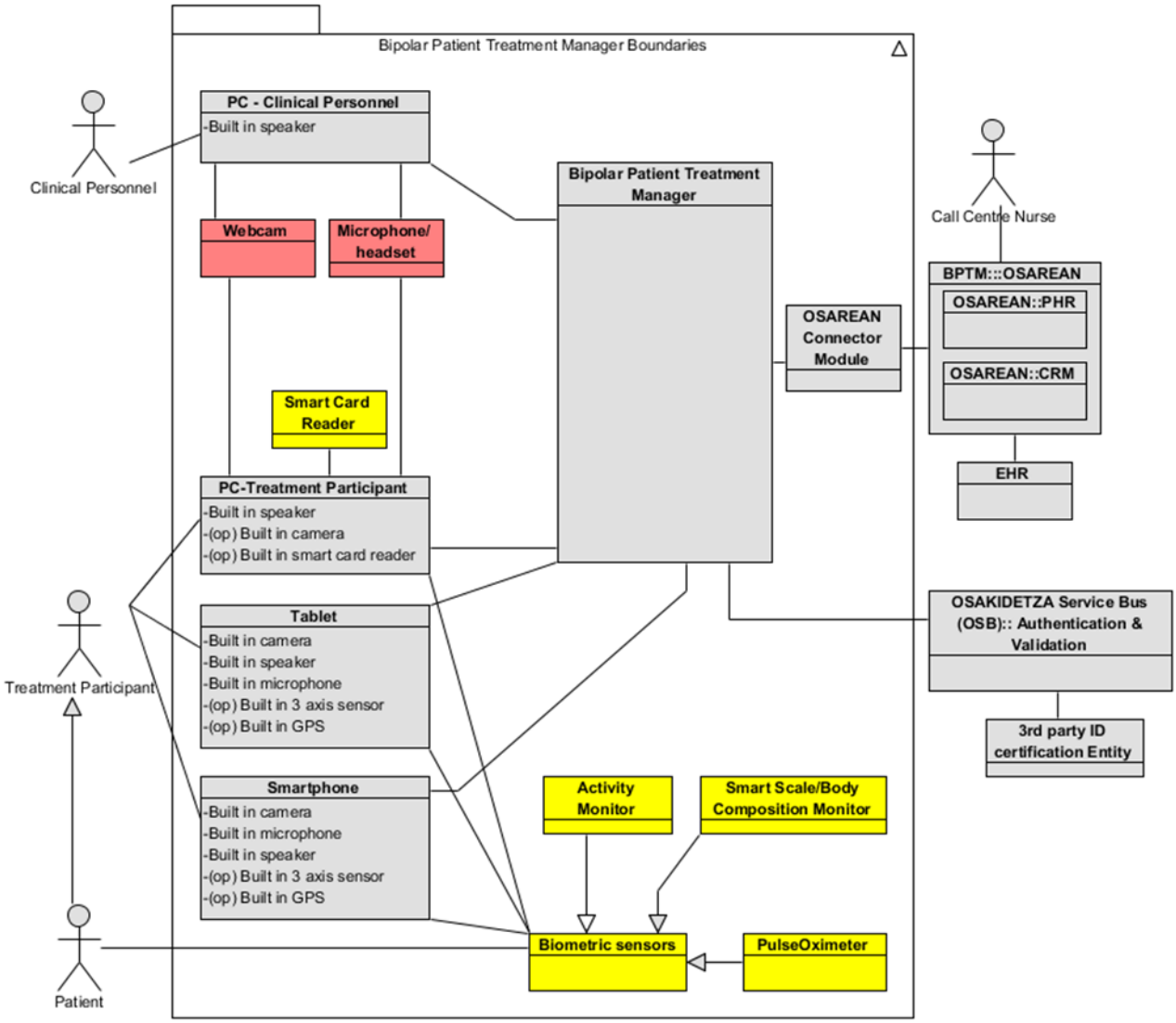


Figure 55: System boundary of Patient Treatment Manager Solution, including all interfaces to users, systems, and artifacts of the FI-STAR use case.

The following table describes the interfacing systems, artifacts and related expectations on the solution.

Table 6: BPTM interfacing systems and artefacts

Name	Description	Expectations on Solution
PC: Clinical personnel	Desktop PC with built in speaker The clinical personnel should be able to access the BPTM functionality via web browser.	Currently the standardised operating systems and explorer are: • Operating system: Windows 7 • Web browser: Internet Explorer 8

		Connectivity: LAN
PC: Treatment Participant	Desktop PC or laptop. It could include built camera , microphone and smart card reader The treatment participant should be able to access the BPTM functionality via web browser.	The operating system and explorer used in the patients' side are unknown (to reduce distribution costs and meet user preferences the aim is to use, whenever possible, user's own means). The solution should follow the most common O.S and web browsers. Connectivity: ADSL/WIFI
Tablet	Tablet includes built-in **camera** (that can be used to take pictures for status monitoring and video consultation)**,** microphone and speaker. The tablet can integrate other sensors such as: GPS, gyroscope. They will not be used in the pilot application but could (TBD) be used for experimentation The treatment participant could be able to access most of the BPTM functionality with a web mobile approach but a mobile app approach will be required to collect information from external biometric sensors (hybrid app approach)	The specific device used in the patients' side is unknown (to reduce distribution costs and meet user preferences the aim is to use, whenever possible, user's own devices). The solution should follow the most common devices and technologies (i.e. web browsers in case of web access or OS such as Android 4.0 or higher, IOS whenever an app is required in the mobile device for example to connect sensors to collect biometric parameters. Connectivity: WIFI, 3G/4G, Bluetooth (to connect biometric sensors)
Smartphone	Smartphone includes built-in **camera** (that can be used to take pictures for status monitoring and video consultation), microphone and speaker. The smartphones can integrate other sensors such as: GPS, gyroscope. They will not be used in the pilot application but could (TBD) be used for experimentation. The treatment participant could be able to access most of the BPTM functionality with a web mobile approach but a mobile app approach will be required to collect information from external biometric sensors (hybrid app approach)	The specific device used in the patients' side is unknown (to reduce distribution costs and meet user preferences the aim is to use, whenever possible, user's own devices). The solution should follow the most common devices and technologies (i.e. web browsers in case of web access or OS such as Android 4.0 or higher, IOS whenever an app is required in the mobile device for example to connect sensors to collect biometric parameters. Connectivity: WIFI, 3G/4G, Bluetooth (to connect biometric sensors)
Activity monitor	Biometric sensor that provides information about daily activity and sleep hours. The criteria to select the activity monitor are that they should either provide open specification/SDK or be + 11073 compliant. Under evaluation Jawbone Up, Zephyr BIOHARNESS 3 (backup).Data should be kept in a private environment, devices sending data	Optional. It will be used at least for experimentation. Connectivity: Bluetooth. It requires Bluetooth connection in mobile devices (i.e. smartphones and tablet) and PC (could be built in or using a BT USB dongle).

<table>
<tr><td></td><td colspan="2">to manufacturers external clouds are not eligible.

Depending on final sensor the data provided could require specific data processing services. Some device provide processed data such as daily activity or sleep time (e.g. jawbone up) while others (e.g. Zephyr BIOHARNESS 3) provide “raw data” that should be processed.</td><td></td></tr>
<tr><td></td><td>  </td><td>  </td><td></td></tr>
<tr><td></td><td>Jawbone Up[3] (under evaluation)</td><td>Zephyr BIOHARNESS 3[4] (selected as backup)</td><td></td></tr>
<tr><td>Pulsioximeter</td><td colspan="2">Biometric sensor that provides information about pulse and S02%

Nonin 9560/ Nonin Wrist OX2 3150 (open specification + 11073 compliant).</td><td>Optional. It will be used at least for experimentation.

Connectivity: Bluetooth. It requires Bluetooth connection in mobile devices (i.e. smartphones and tablet) and PC (could be built in or using a BT USB dongle).</td></tr>
<tr><td></td><td>  </td><td>  </td><td></td></tr>
<tr><td></td><td>Nonin 9560 (selected)[5]</td><td>Nonin Wrist OX2 - 3150[6] (selected)</td><td></td></tr>
<tr><td>Smart Scale/ Body Composition Monitor</td><td colspan="2">Biometric sensor that provides information about weight, IMC and in some cases Body Fat.

The criteria to select the Smart Scale/ Body Composition Monitor are that they should either provide open specification/SDK or comply with 11073. Data should be kept in a private environment, devices sending data to manufacturers external clouds are not eligible.</td><td>Optional. It can be optionally used for experimentation.

Connectivity: Bluetooth. It requires Bluetooth connection in mobile devices (i.e. smartphones and tablet) and PC (could be built in or using a BT USB dongle).</td></tr>
<tr><td></td><td>  </td><td>OMRON BF 206-BT [7](Under evaluation)</td><td></td></tr>
</table>

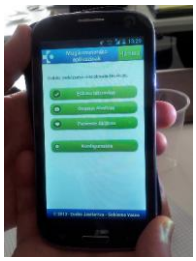
[3] Jawbone UP: https://jawbone.com/up

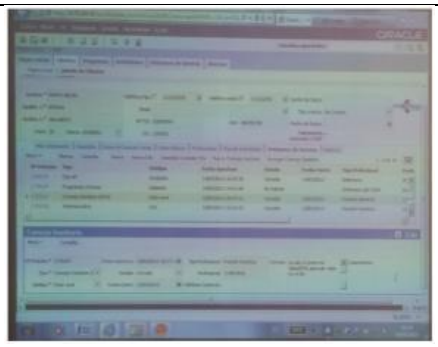
[4] Zephyr BIOHARNESS 3: http://www.zephyranywhere.com/products/bioharness-3/

[5] Nonin 9560: http://www.nonin.com/onyx9560

[6] Nonin Wrist OX: http://www.nonin.com/PulseOximetry/Wrist-Worn/WristOx3100

[7] OMRON BF 206-BT http://www.healthcare.omron.co.jp/bt/english/spec.html

Smart card reader	One of the potential ways to control the access of the treatment participant is through a smart ID card including valid digital certificates.	Optional. Should be used if the patient utilizes a smart ID to access the system through a PC. Connectivity: USB or “built in” in some PCs/laptops.
Webcam	External webcam connected to PC. Some webcams include built in microphones.	Optional. Only necessary if pchycho consultation functionality is included (currently optional–deferred features). Connectivity: USB.
Microphone/ Headset	External microphone/ headset webcam connected to PC.	Optional. Only necessary if pchycho consultation functionality is included (currently optional–deferred features). Connectivity: USB.
OSAREAN Platform (OSAKIDETZA) Representative: Josu Llano (jllano@osatek.net)	Already in place infrastructure. The BPTM solution will interoperate with it. Stores patient data: Personal Health Record PHR and provides citizens that possess a digital identity access to their Personal Health Record.  www.osanet.euskadi.net  https://play.google.com/store/apps/details?id=com.osakidetza Manages the workflows to handle alerts though its customer relationship management (CRM) application.	OSAREAN provides SOAP web-services interface based on HL7.25 information messages to exchange information. Clinically relevant data should be stored PHR/EHR.

	 Provides access to the electronic health record EHR.	
OSAKIDETZA Service BUS	Makes available services to authenticate users. Internally it connects to the 3º party Certification Entity.	
3º party Certification Entity	Is a third party company (i.e. http://www.izenpe.com/s15-12010/en/) that identifies the ID holder and checks the validity of the ID certificates),	

5.3.3 Data flow

The following gives a **preliminary** high level overview of how the BPTM solution is intended to be used within the overall workflow. The diagram below describes the main data flows across the system boundary and among the applications that the solution integrates.

As stated before the expected BPTM solution should allow to interact with the BPTM system whenever/wherever they want by using their preferred available interfacing devices (i.e. PC, smartphone or tablet) this. If the users utilize a PC they will access the BTMP solution though the web browser (web app). If they use a mobile device (i.e. PC, smartphone or tablet) they should be able to access most of the BPTM functionality with a web mobile approach but mobile app approach will be required to collect information from external biometric sensors (hybrid app approach).

To simplify the representation we have included several figures providing a partial view. All the figures will share the following legend.

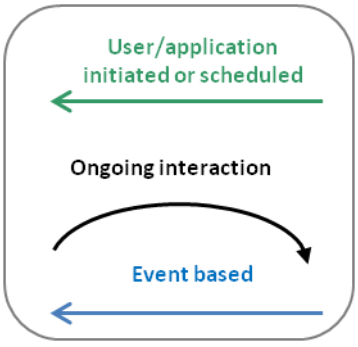


Figure 56: Data flow representation legend

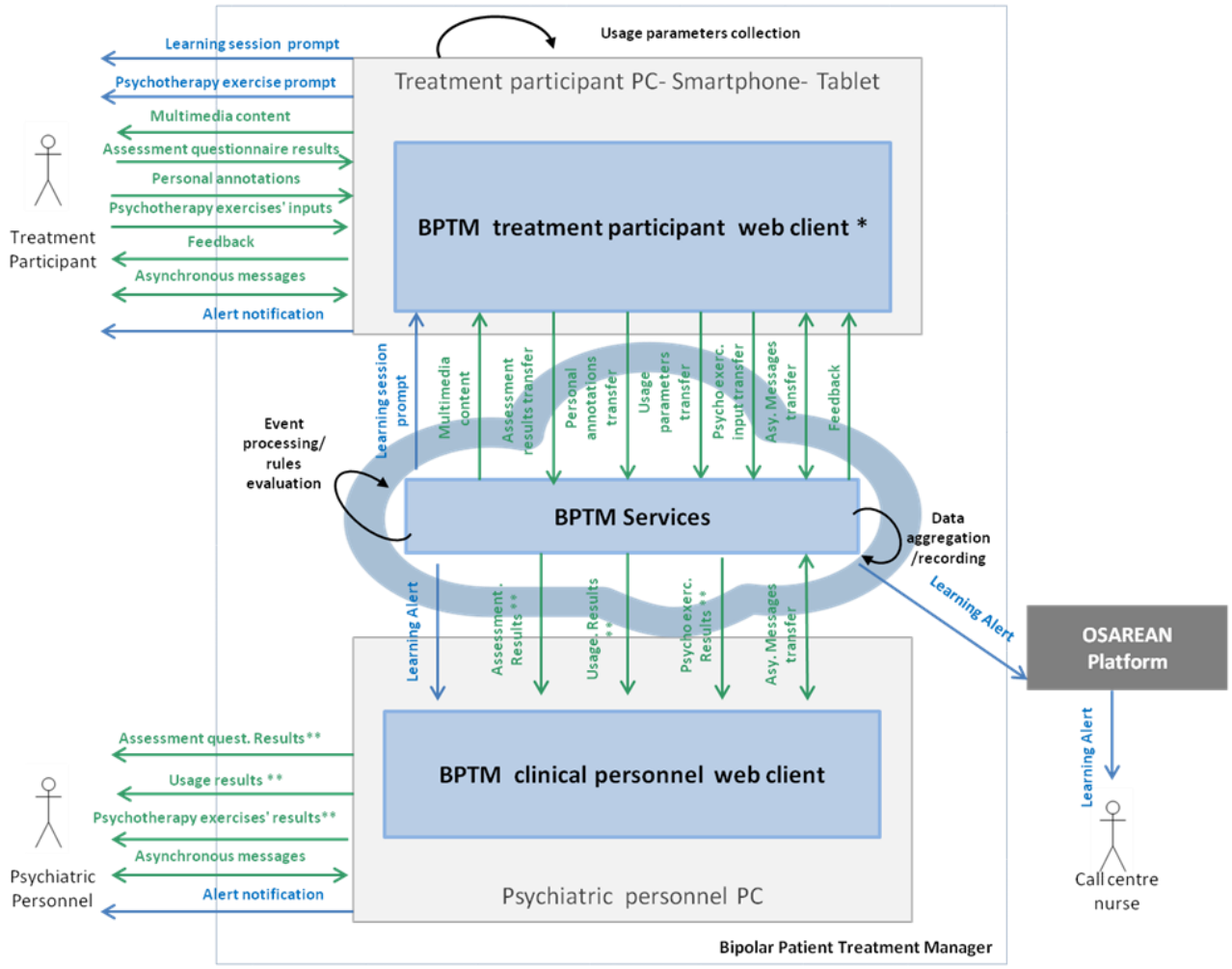


Figure 57: Psychoeducation dataflow (preliminary basic overview). * Optionally it could be a mobile app in mobile devices (hybrid app). ** This elements are related to psychoeducation but should be accessible through the Professional scorecards.

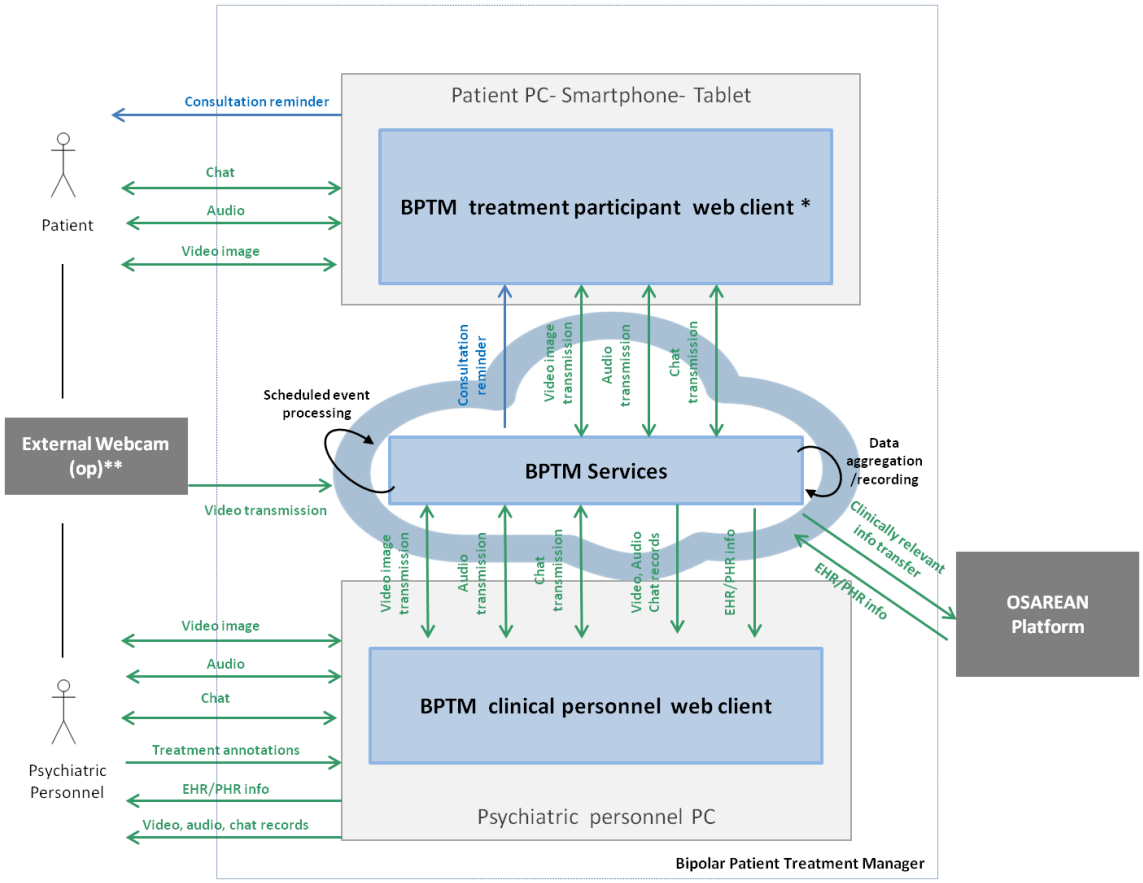


Figure 58: Optional-Deferred. Psycho-consultation dataflow (preliminary basic overview).* Optionally it could be a mobile app in mobile devices (hybrid app).

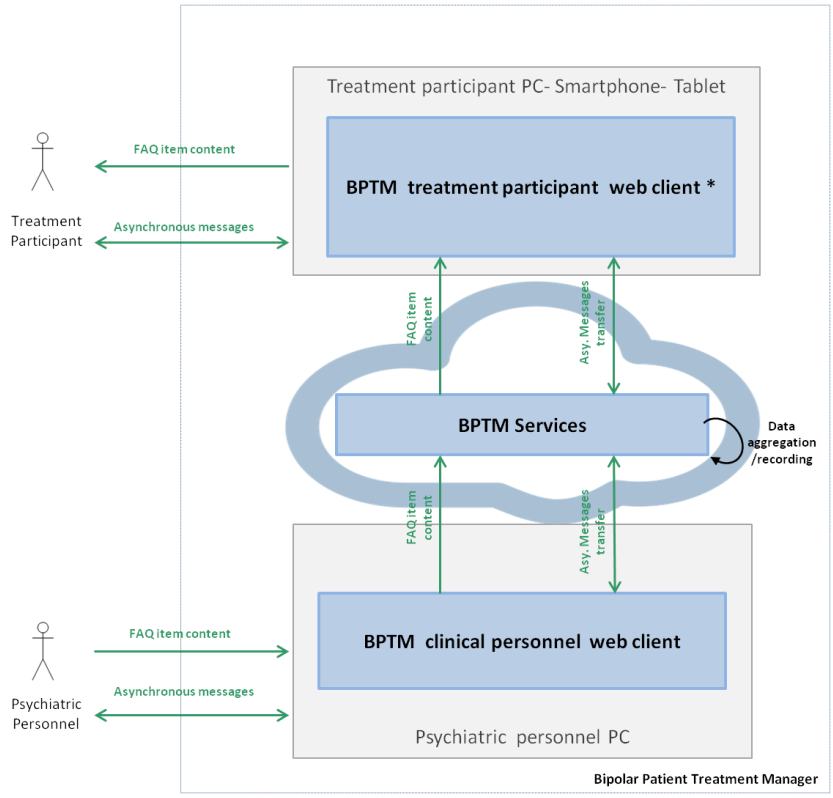


Figure 59: Support and iteration dataflow (preliminary basic overview). *Optionally it could be a mobile app if mobile devices are used (hybrid app).

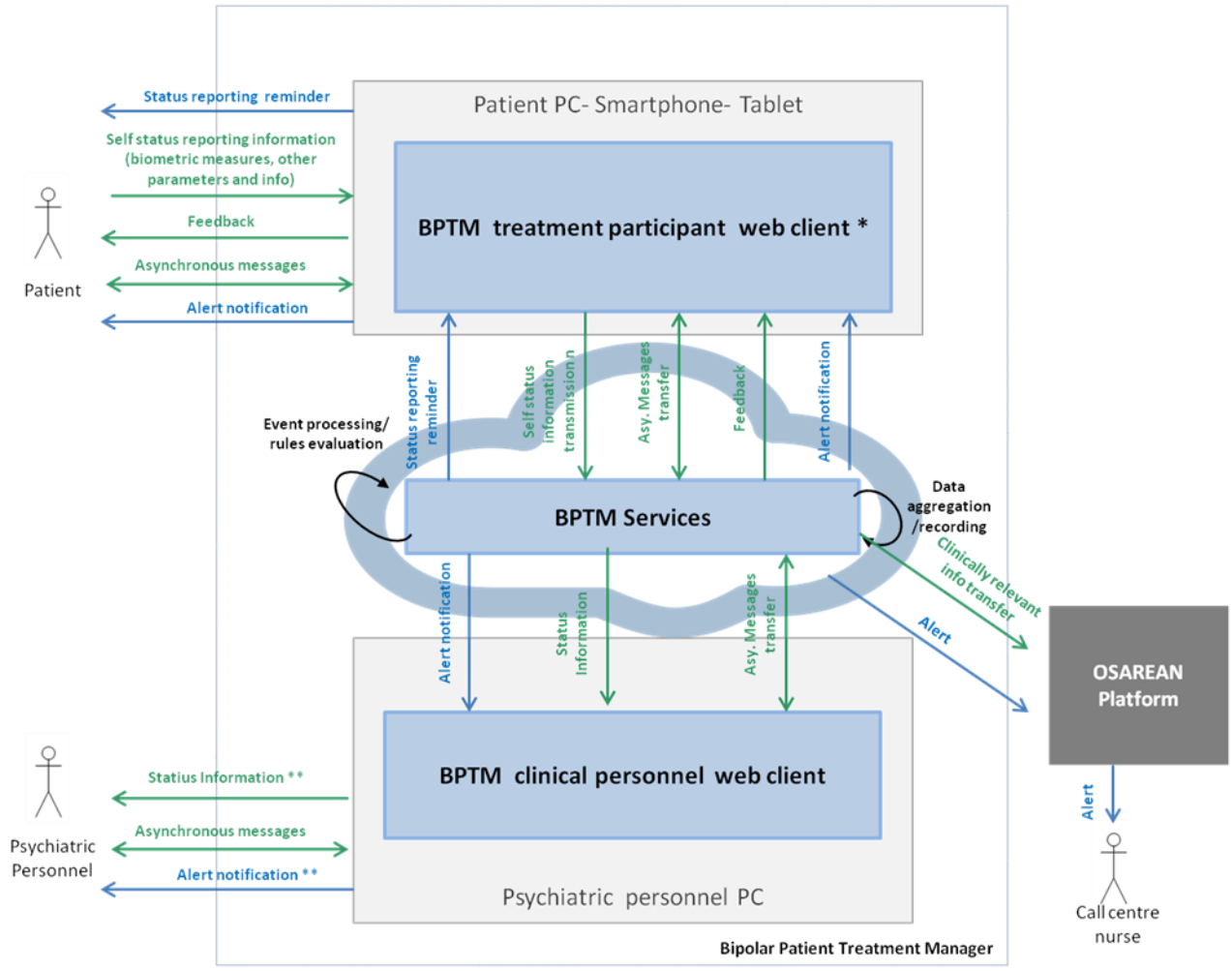


Figure 60: Status telemonitoring dataflow (preliminary basic overview) with manual status information input. * Optionally it could be a mobile app in mobile devices (hybrid app). ** This elements are related to status telemonitoring but should be accessible through the Professional scorecards.

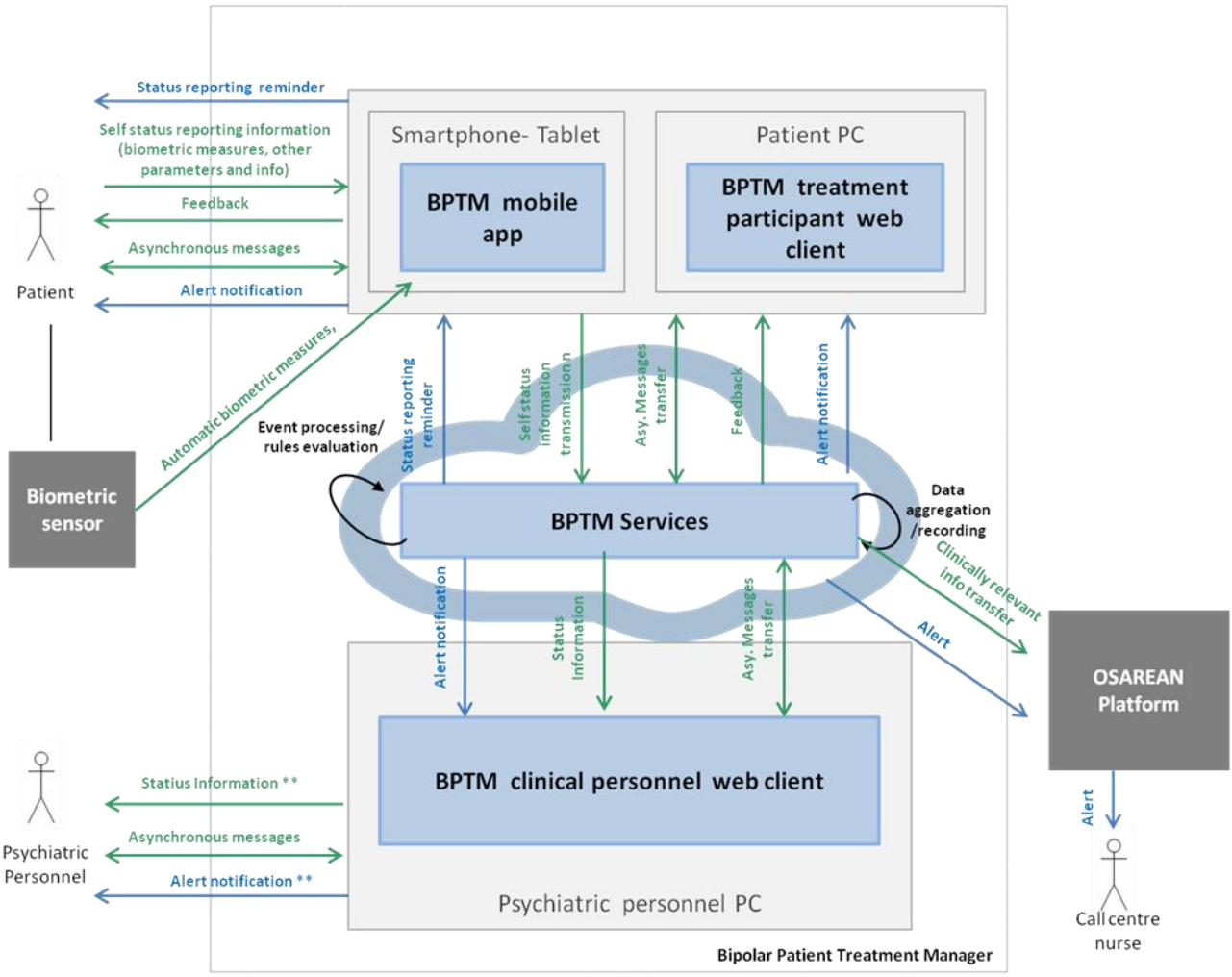


Figure 61: Status telemonitoring dataflow (preliminary basic overview) including automatic input of some biometric data using biometric sensors, the rest of the information will be included manually. * Automatic data collection requires a mobile app in the mobile devices (hybrid app) . ** This elements are related to status telemonitoring but should be accessible through the Professional scorecards.

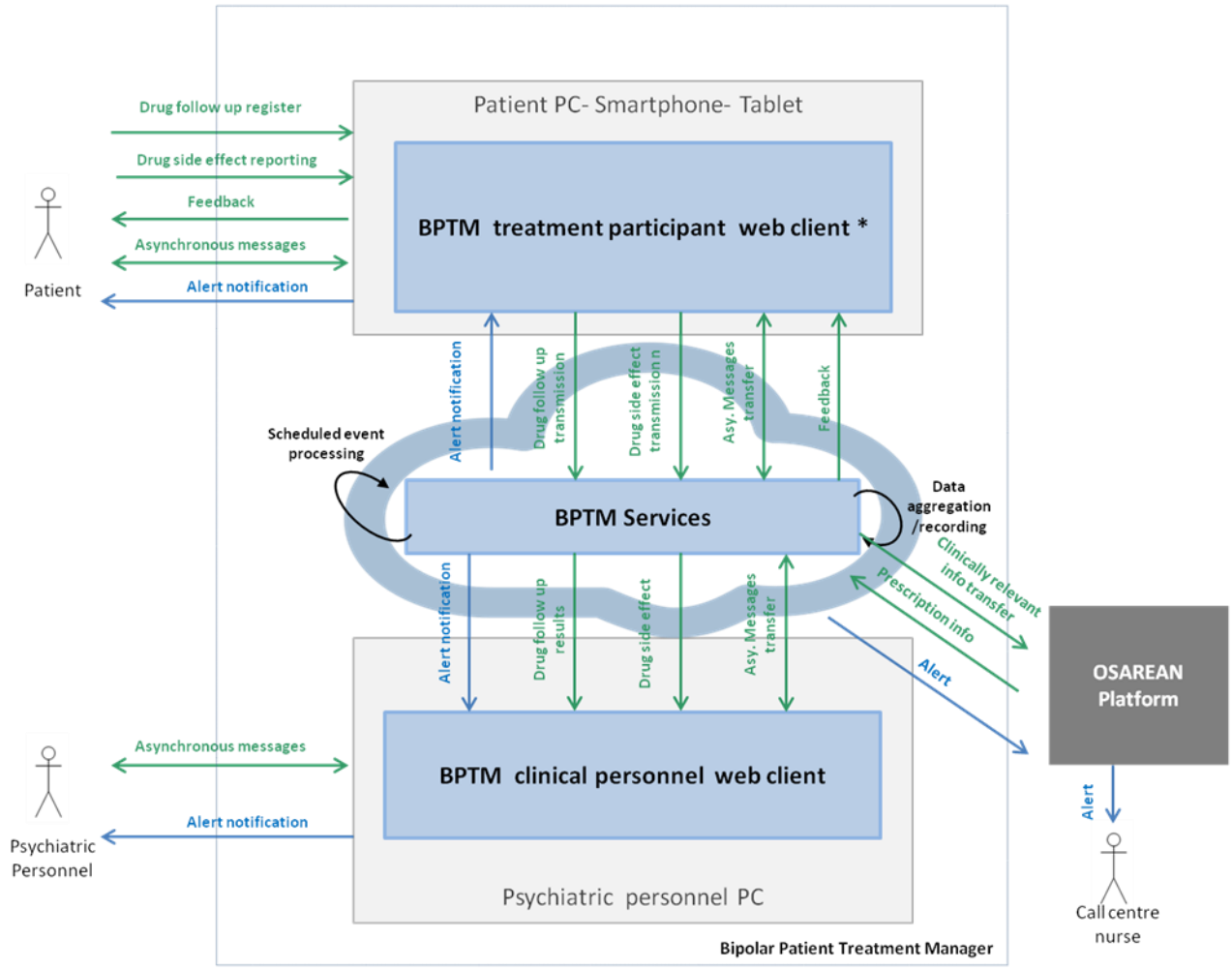


Figure 62: Drug follow up dataflow (preliminary basic overview). * Optionally it could be a mobile app in mobile devices (hybrid app).

5.3.4 Other Stakeholders

The following table describes the stakeholders that affect, but do not directly interact with the solution. The description includes background and role of these stakeholders and their expectations on the solution.

Table 7: Other stakeholders for BPTM

Name	Description	Expectations on Solution
Ethics committee The medical leader will prepare all the required information and submit it to the committee (Responsible of submitting the information to the Ethics committee: Ana Gonzalez Pinto)	Approves clinical trials and practice.	Description of the use case trial scope and methodology, informed consent and opt-out at any moment for patients, caregivers, and clinical personnel.

Name	Description	Expectations on Solution
Developer and owner of the application solution Representative: Patricia Casla patricia.casla@tekniker.es	Develops the BPTM solution.	Maintainability, modularity, and sustainability are key issues. Free/Low GEs licensing costs. Clear definition of potential GEs licensing costs.
OSAKIDETZA IT Services Representative: Angel Farias ANGELJOSE.FARIARODRIGUEZ@osakidetza.net	Manages EHR. Manages the private cloud for BPTM.	Compliant with regional privacy and data protection legislations (private environment, secure protocols to keep medical data exchange totally secured, etc.). Keep a unique record. Integrated with existing IT infrastructure (PHR/EHR) Easy to maintain. Scalable, reliable and cost efficient solution (low distribution costs). Free/Low GEs licensing costs. Clear definition of potential GEs licensing costs.

5.4 Value Case for the FI-STAR Use Case

The Bipolar Patient Treatment Manager (BPTM) shall:

1. help healthcare professionals to address as many patients as possible and save time (for both professionals and patients) and involve call centre nurses in the healthcare services provision process,
2. improve the quality of care, enhance the patients evolution and reduce costs to the healthcare system,
3. supply online personalised treatment according to the patients needs,
4. make available to patients means to enhance their knowledge about the management of their own disease and provide them strategies to minimize its consequences and to increase their treatment adherence,
5. enable patients to be actively involved in the treatment process and to increase treatment adherence,
6. allow caregivers to get more involved and increase their knowledge about the disease and interact with the clinicians to be able to better support their relatives,

while (7) guarantying confidentially and privacy and fulfilling all local regulations and (8) providing user friendly interfaces and personalised interaction capabilities.

Find below a summarised view on how BPTM aims to achieve the expected outcomes.

- To help healthcare professionals to address as many patients as possible and save time (for both professionals and patients) as well as to collect relevant data for research, BPTM shall increase the availability of psychological treatment by enabling the provision of tele-services (cheap, easy access), increase the therapist's efficiency, reduce the need of consultations, allow the involvement of the call centre nurses to react early to alarms (e.g. by calling patients and caregivers) and make easier patient handover from one doctor to the other;

- To improve quality of care enhance the patients evolution and reduce costs to the healthcare system, BPTM shall help clinical personnel to improve patients follow up (i.e. have a more detailed monitoring of symptoms, and more frequent contact with patients including online consultation), support early identification of risk factors to improve the reaction to patient needs (this will reduce relapses, hospitalizations and hospital days and their related costs) and provide means to interact with both patients and caregivers (e.g. secure asynchronous messaging);
- To supply online personalised treatment according to the patients needs BPTM shall allow psychiatric personnel to tailor patient's treatment (e.g. assignation of learning sessions to be achieved by the user, questionnaires, defining individual patient's baseline to allow personalised evaluation rules to identify notifications, etc.);
- To make available to patients means to enhance their knowledge about the management of their own disease and provide them strategies to minimize its consequences (e.g. reduce symptoms: psychotic, anxious, manic and depressive) and to increase their treatment adherence, BPTM shall provide psychoeducation and psychotherapy capabilities that will involve learning session (including multimedia content such as video tutorials, presentation, pdf documents and optionally audio) and specific psychotherapy exercises and can be performed whenever and wherever (i.e. psychotherapy in private, care for busy patients) the patient decides;
- To enable patients to be actively involved in their treatment process, BPTM will provide means to monitor remotely their status by making possible the collection of relevant physiological/biometric parameters (either manually or automatically using sensors), psychological parameters and pictures (e.g identify skin problems), follow up medication intake, collect potential medication side effects as well as follow up their evolution, by interacting with the system trough their preferred, available (allowing users to utilise their already available will reduce healthcare provision costs and promote sustainability) interaction devices (i.e. PC, smartphone, tablet). Optionally biometric data could be automatically gathered trough mobile devices by connecting to specifics biometric sensors (e.g. activity monitor, pulseoximeter, Smart Scale/ Body Composition Monitor);
- To allow caregivers to get more involved and increase their knowledge about the disease and interact with the clinicians to be able to better support their relatives, BPTM shall support their access to specific psychoeducation related contents and shall provide means to interact with the psychiatric personnel. The involvement of the caregivers and relatives in the treatment will reduce the patient's acute symptoms by preventing them or providing support for early detection. Improved patient adherence to treatment will be achieved by providing a better family environment and reduce patient anxiety caused by family disputes;
- To guaranty security, confidentially and privacy BPTM shall comply with all local regulations and implement secure protocols to keep medical data exchange totally secured.
- To supply user friendly interfaces and personalised interaction capabilities BPTM shall allow treatment participants (i.e. patients and caregivers) to use their preferred available interaction devices (i.e. PC, smartphone, tablet) and have a common user experience independently of it, allow them to select their preferred notification channels. BPTM shall also support well known interaction metaphors and usability criteria.

The use case will target patients with bipolar disorders being treated in OSAKIDETZA. The **use case** group will involve 50 patients with mental disorders (25 will get tele-care support and the other 25 not) and their caregivers or relatives.

In order to be able to evaluate the real impact of the proposed solution in the provision of telecare services, OSAKIDETZA will set up the validation phase as a clinical trial where the objectives will be:

i) To analyze the effectiveness of telemedicine in patients with mental health disorders,
ii) To evaluate the efficacy of psychological treatments (psycho education), information and communication through the Internet, added to the usual pharmacological treatment, in the functionality of patients, and in the patients and health professional satisfaction.

The process to be followed will be a randomized clinical trial simple blind evaluation. Patients will be assigned, in a randomized way, to usual treatment (pharmacological and visits to psychiatry) or to treatment supported by ICT. If, as expected, the results from the clinical trial support the positive impact of the introduction of the new Telehealth services for mental disorders, gradual scale up to the whole target population and scale up to other chronic diseases will be envisaged. Future potential steps could be:

1. Scale up to all the patients with the target mental disease (i.e. bipolar disorders).
2. Scale up to other mental diseases (e.g. depression, schizophrenia, etc.).
3. Scale up the other chronic diseases (e.g. COPD, Diabetes, HTA, etc.).

5.5 FI-STAR Solution Overview

The Bipolar Patient Treatment Management (BPTM) solution includes six key functional modules (i.e. psychoeducation, psycho-consultation, telemonitoring, drug treatment follow up, support and scoreboard) to cover the key elements to provide a remote integrated care identified in section 2.1. The solution includes well a support module aimed to integrate treatment administration functionalities.

The proposed solution provides a set of features (groups of requirements that belong together) to enable the FI-STAR Use Case stakeholders to deliver the value case. The use case features **have been prioritised** based on their relevance for achieving the BPTM goals specified in section 3 and the available and timing and resources. The figure below shows the related use case features identified and gives an overview on the relationships between them and defines the implementation priorities in terms of minimal scope (planned in α version), target scope (planned in β version), optional or enhanced scope of the solution and out of scope. The features representation complies with the following notation

	Dark grey shape groups the main **specific** features related to each functional module. Common features involved in different modules are represented outside the grey shapes.
	Light grey shape group the main specific features related to the support module aimed to integrate treatment administration functionalities.
<-	The arrows represent the relationships between the different features.
	Feature in minimal scope (planned in α version)
	Feature in the Use case target scope (planned in β version)
	Optional /enhanced scope. Includes features that will be implemented for experimentation purposes.
	Out of scope of the Use Case development either because they are supported by an external solution (OSAREAN platform) or they have been identified as lower priority and deferred.

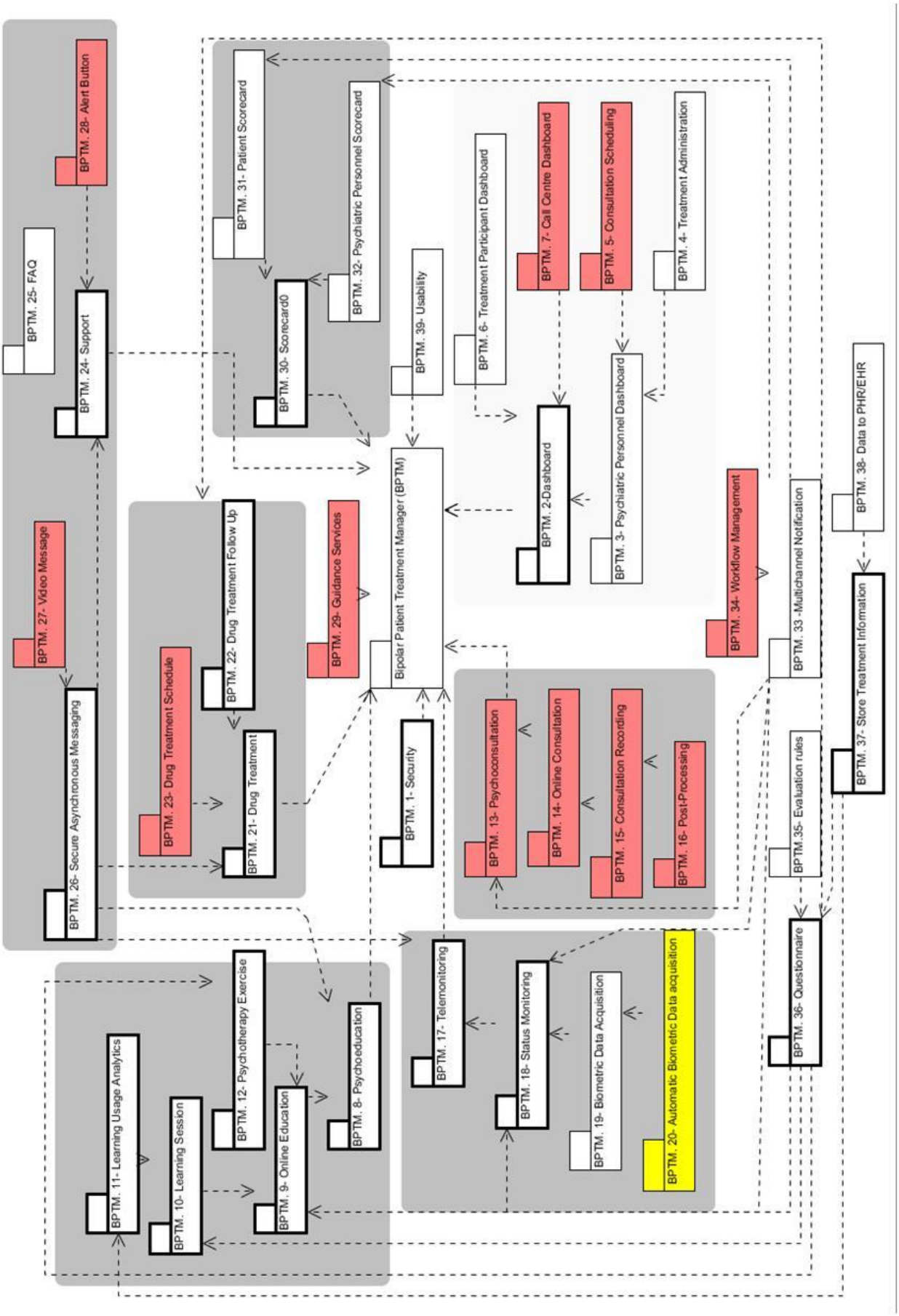


Figure 63: Features of the Patient Treatment Management solution.Domain Model

The Bipolar Patient Treatment Management solution manages a set of data entities that capture the interaction between medical personnel and the treatment participants along the treatment. Figure 64 gives an overview of some basic entities.

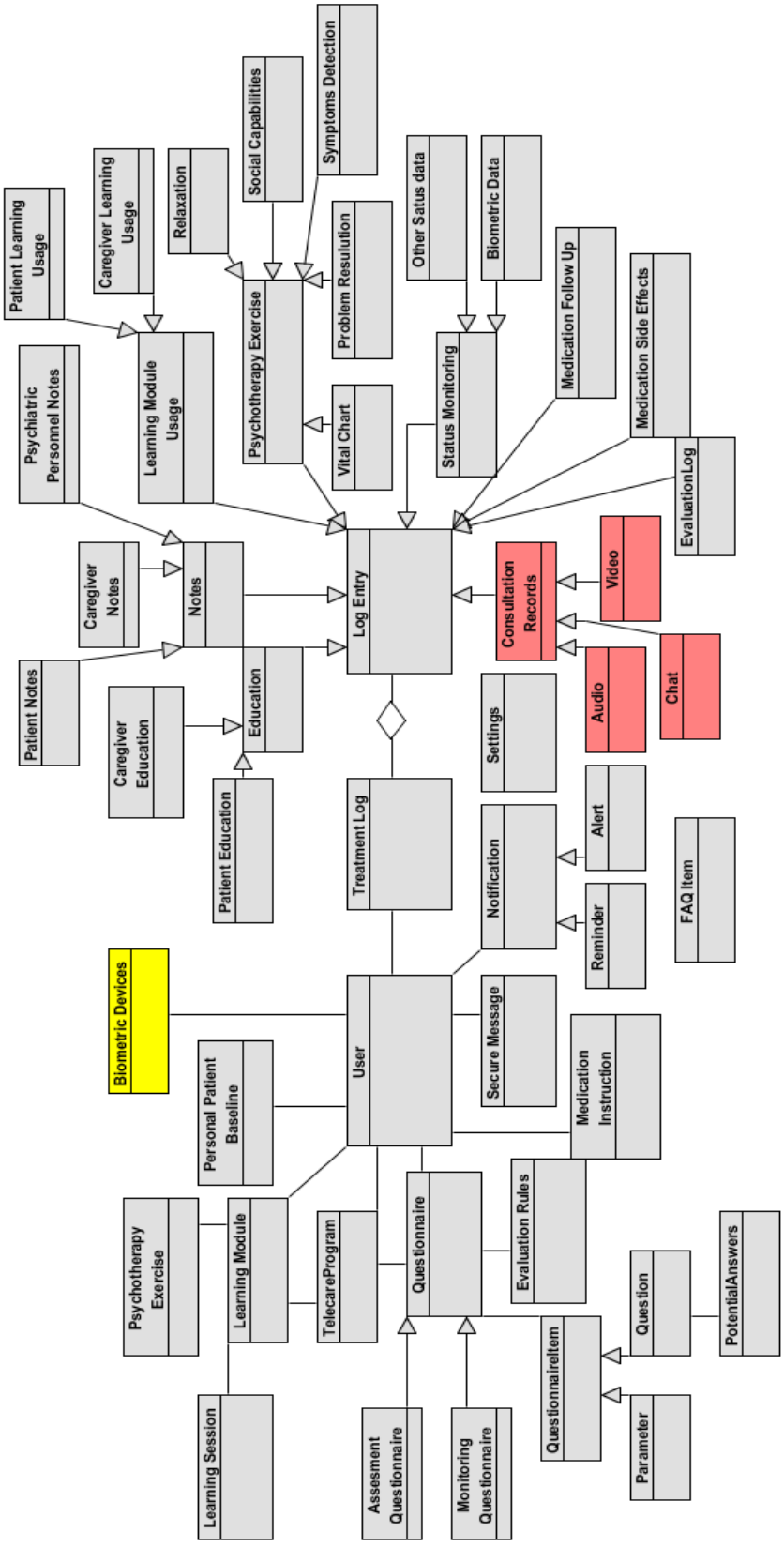
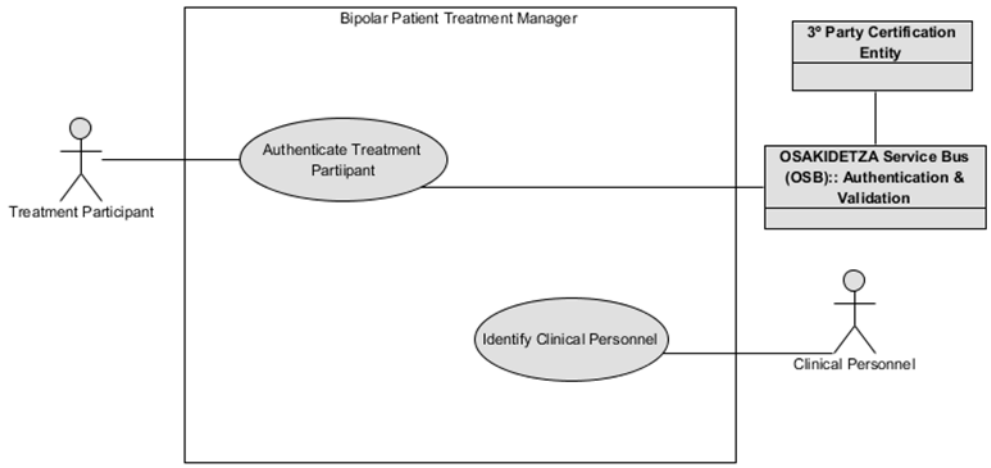


Figure 64: Coarse-grained data model of the Bipolar Patient Treatment Management solution.

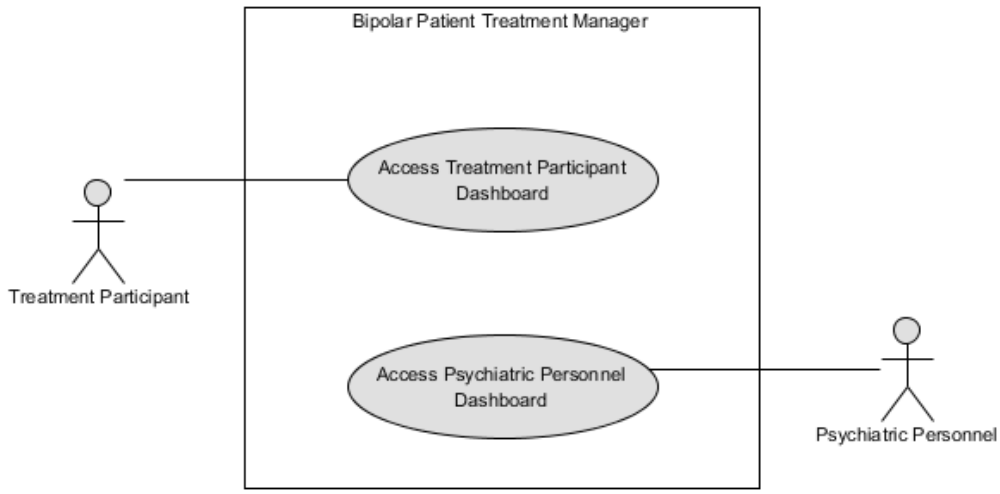
5.5.1 Features

5.5.1.1 Feature BPTM.1 Security

Addressed stakeholder interests and expectations	Goals to be achieved: • Trust: confidentially and privacy guaranteed. • Security: state-of-art authorization • Security: secure protocols to keep medical data exchange totally secured. • Security: manually triggered data sharing External interfaces: • From Clinical Personnel to PC. • From Treatment Participant to PC, Smart Phone, OR Tablet • From BTPM to OSAKIDETZA OSB (to 3rd party certification entity). Data entities involved • Treatment Participant. • Clinical Personnel. Use cases • Authenticate Treatment Participant • Clinical Personnel Identification 
Comments	To be validated with prototype

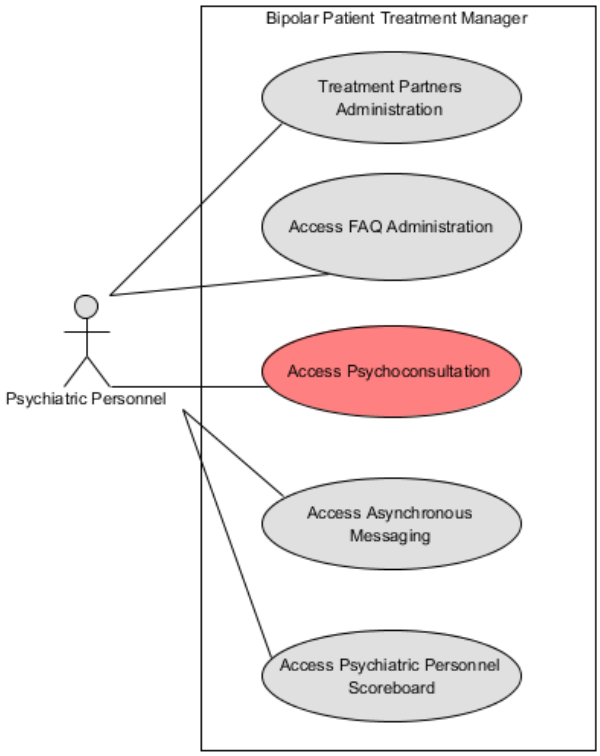
5.5.1.2 Feature BPTM.2 Dashboard

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: cheap, easy access to care for patient • Efficiency: needs for consultation reduced. • Efficiency: Patients participation increased. • Efficiency: Private caregivers involved. • Comfort: psychotherapy in private. • Comfort: care for busy patients. • Usefulness: Increased availability of psychotherapy.

	External interfaces: • From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet Use cases • Access Treatment Participant Dashboard • Access Psychiatric Personnel Dashboard 
Comments	To be validated with prototype

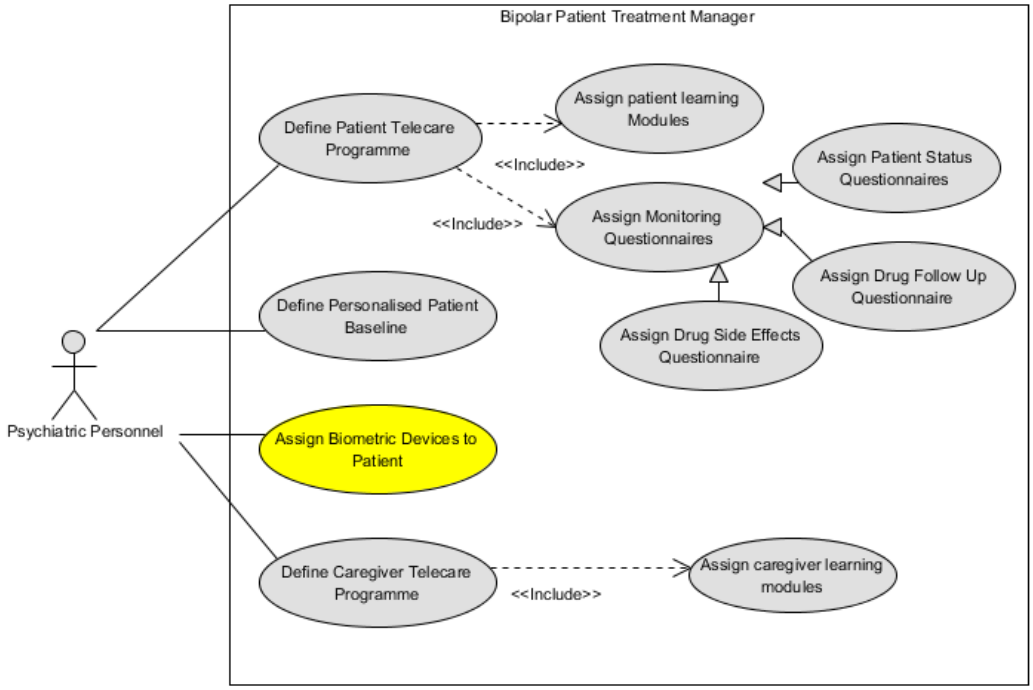
5.5.1.3 Feature BPTM.3 Psychiatric Personnel's Dashboard

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: cheap, easy access to care for patient • Efficiency: needs for consultation reduced. • Efficiency: Patients participation increased. • Efficiency: Private caregivers involved. External interfaces: • From Psychiatric Personnel to PC Use cases • Treatment Partners Administration • Access FAQ Administration • Access Asynchronous Messaging • Access Psychoconsultation (out of scope) • Access Psychiatric Personnel Scoreboard

	
Comments	To be validated with prototype

5.5.1.4 Feature BPTM.4 Treatment Administration

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: Personalised patient treatment. • Effectiveness: Flexible assignment of treatment features. External interfaces: • From Psychiatric Personnel to PC Data entities involved • Treatment Participant (patient, caregiver) • Telecare Programme • Learning Module • Questionnaire • Personal Patient Baseline • Biometric Devices Use cases • Define Patient Telecare Programme • Assign Patient Learning Modules. • Assign Monitoring questionnaires • Assign Patient Status Monitoring questionnaire (special case of Assign Monitoring questionnaires) • Assign Drug follow up questionnaire (special case of Assign Monitoring questionnaires) • Assign Drug side effects questionnaire (special case of Assign Monitoring questionnaires)

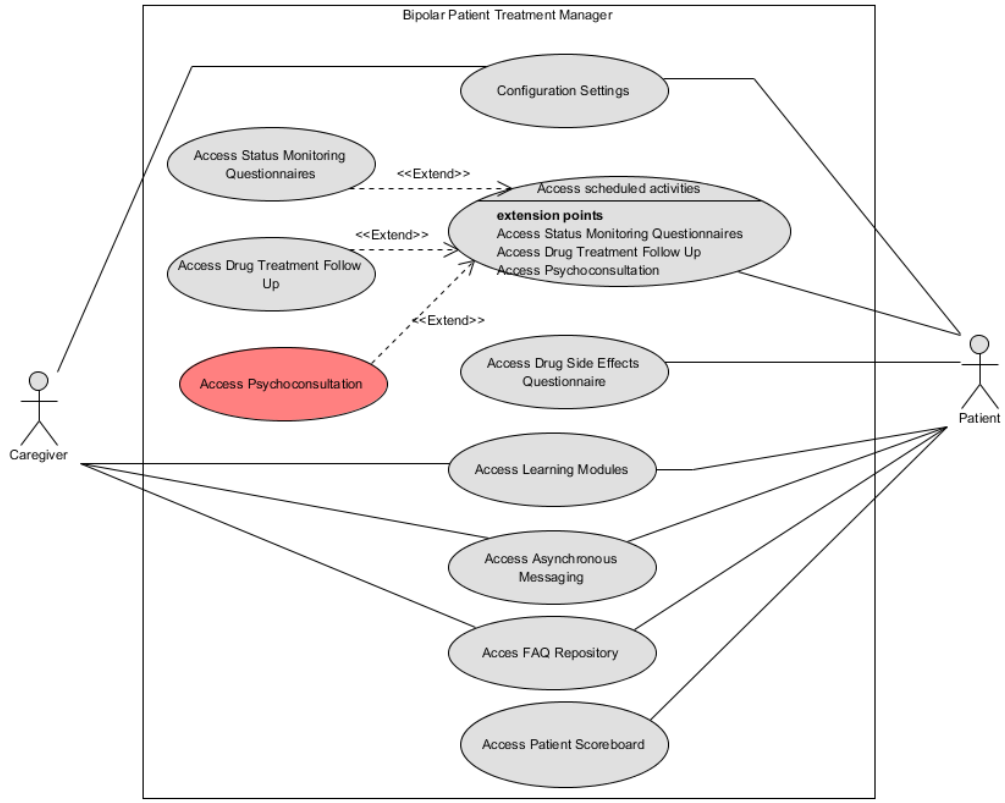
	• Define Personalised Patient Baseline • Assign Biometric Devices to Patient (Optional) • Define Caregiver Telecare Programme • Assign Caregiver Learning Modules. 
Comments	To be validated with prototype

5.5.1.5 Feature BPTM.5 Consultation Scheduling

It is achieved in the OSAREAN platform (out of scope).

5.5.1.6 Feature BPTM.6 Treatment Participant's Dashboard

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: cheap, easy access to care for patient • Efficiency: needs for consultation reduced. • Comfort: psychotherapy in private. • Comfort: care for busy patients. • Usefulness: Increased availability of psychotherapy. External interfaces: • From Treatment Participant to PC, Smart Phone, OR Tablet Use cases • Configuration settings. • Access Scheduled activities (extended by Access Status Monitoring Questionnaires, Access Drug Treatment Follow Up, and Access Psycho-consultation – out of scope). • Access Drug Side Effects Questionnaire. • Access Learn modules. • Access Asynchronous Messaging. • Access FAQ Repository. • Access Treatment Participant Scorecard.

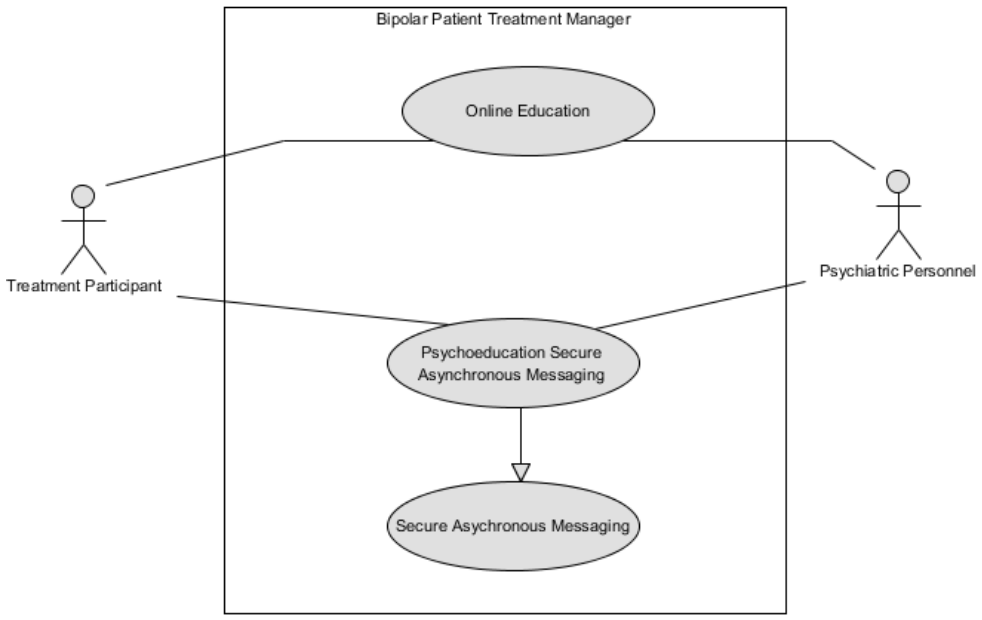
	
Comments	To be validated with prototype

5.5.1.7 Feature BPTM.7 Call Centre Dashboard

Implemented in the OSAREAN platform (out of scope).

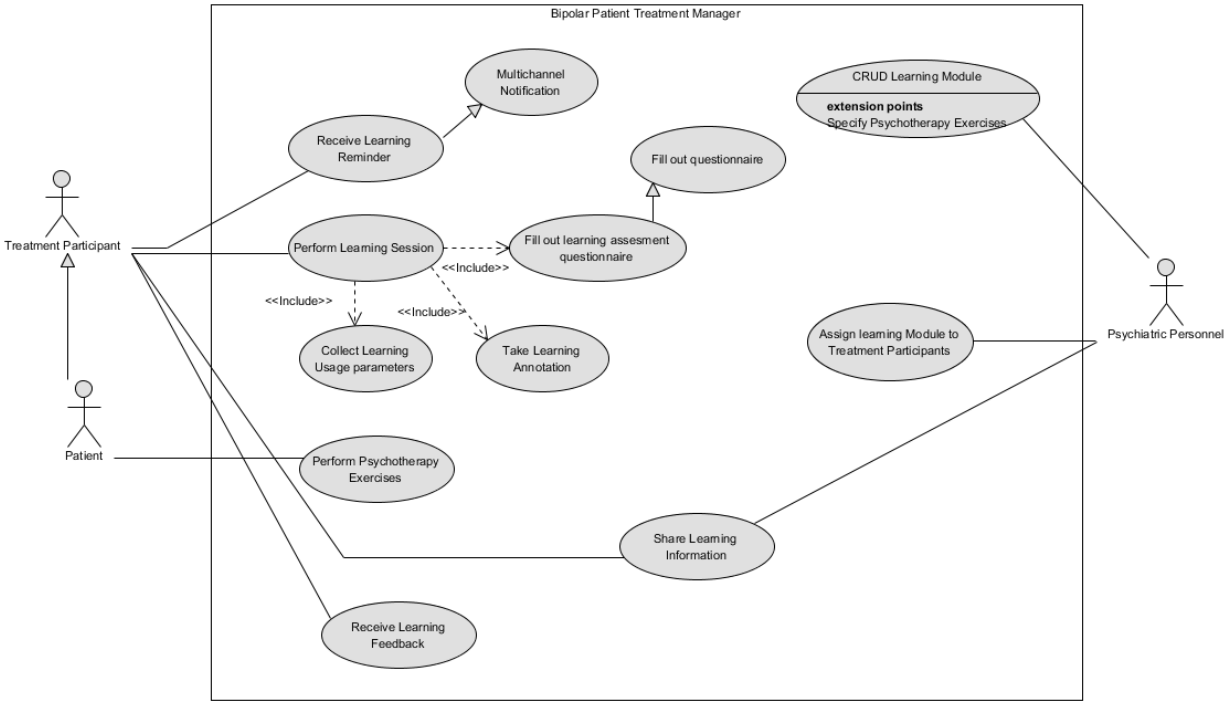
5.5.1.8 Feature BPTM.8 Psychoeducation

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: independent learning for treatment participant • Efficiency: Teaching effort reduced for psychiatric personnel. • Efficiency: Patients participation increased (better control of his/her own disease). • Efficiency: Private caregivers involved. • Efficiency: needs for consultation reduced. • Risk mitigation: Increased knowledge allows avoiding health risks. External interfaces: • From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet Data entities involved • Secure Mail Use cases • Online Education • Psychoeducation Secure Asynchronous Messaging (special case of Secure Asynchronous Messaging)

	
Comments	To be validated with prototype

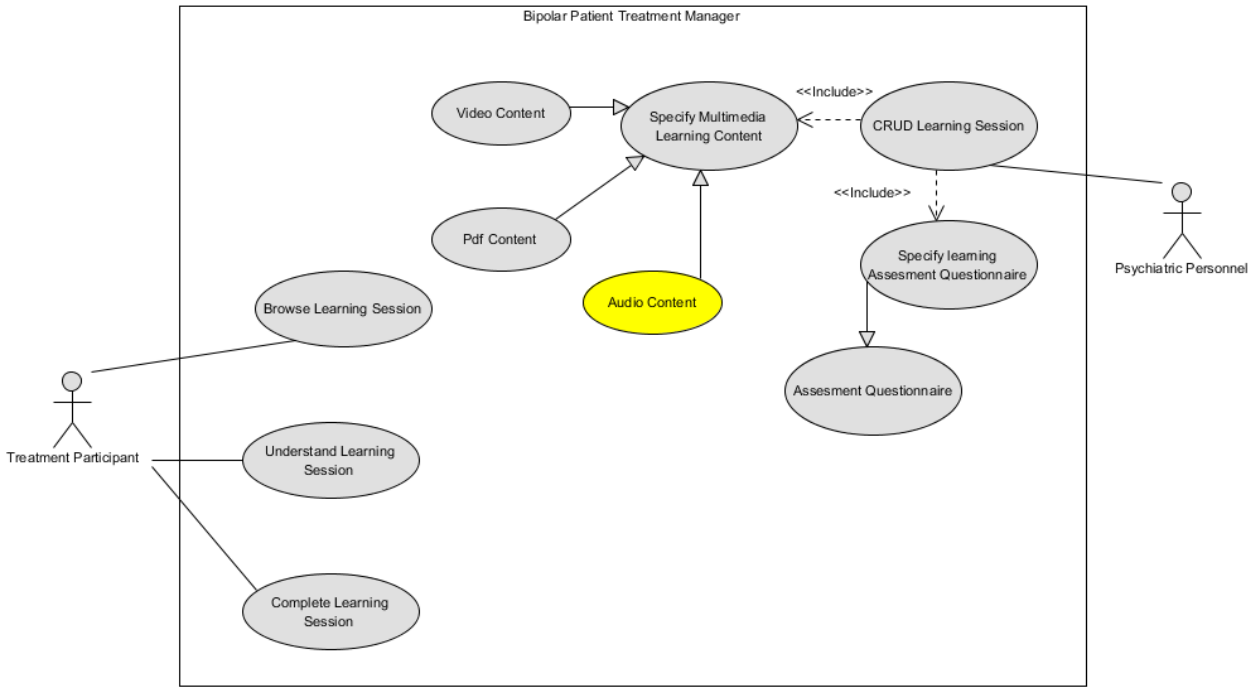
5.5.1.9 Feature BPTM.9 Online Education

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: teaching effort reduced for psychiatric personnel • Effectiveness: independent learning for treatment participant • Efficiency: Patients participation increased (better control of his/her own disease). • Efficiency: Private caregivers involved. • Efficiency: needs for consultation reduced. • Risk mitigation: Increased knowledge allows avoiding health risks. External interfaces: • From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet Data entities involved • Learning Module • Learning Session • Psychotherapy Exercise • Questionnaire • Notification • Treatment Log: Education Log, Notes, Learning Module Usage Log, Psychotherapy Exercise Log Use cases • CRUD Learning Module • Assign Learning Module to Treatment Participants • Receive Learning Reminder (special case of multichannel notification) • Perform Learning Session • Collect Learning Usage Parameter • Take Learning Note • Fill out Learning Assessment Questionnaire (special case of fill out

	questionnaire). • Perform Psychotherapy Exercise • Share Learning Information • Receive Learning Feedback
	
Comments	To be validated with prototype

5.5.1.10 Feature BPTM.10 Learning Session

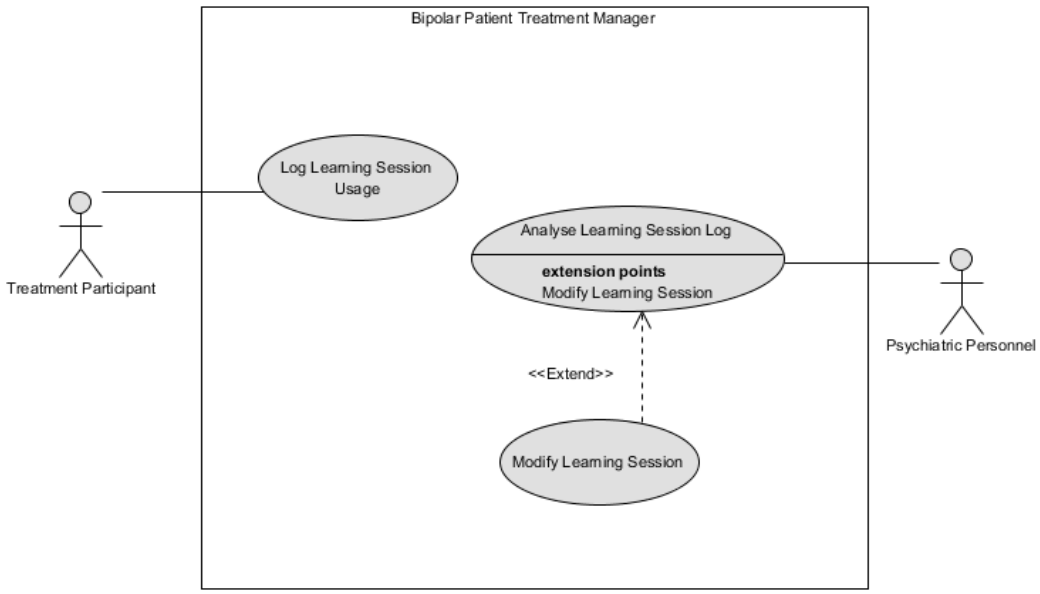
Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: teaching effort reduced for psychiatric personnel • Effectiveness: independent learning for treatment participant External interfaces: • From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet Data entities involved • Learning Session Use cases • CRUD Learning Session • Specify Multimedia Content • Video content (special case of Specify Multimedia Content) • Pdf content (special case of Specify Multimedia Content) • Audio content (special case of Specify Multimedia Content). Optional. • Specify Learning Assessment Questionnaire • Browse Learning Session • Understand Learning Session • Complete Learning Session



Comments	To be validated with prototype

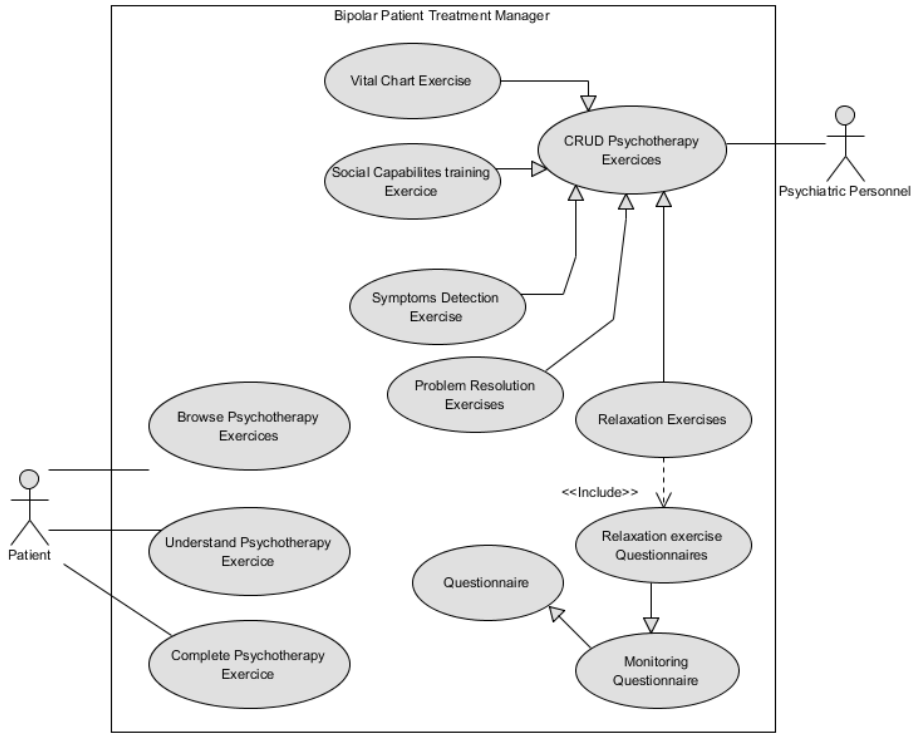
5.5.1.11 Feature BPTM.11 Learning Usage Analytics

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: Collect information to detect potential problems and improve the definition of the learning modules. External interfaces: • From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet Data entities involved • Treatment Log: Learning Session Usage Log Use cases • Log Learning Session Usage • Analyse Learning Session Log • Modify Learning Session

	
Comments	To be validated with prototype

5.5.1.12 Feature BPTM.12 Psychotherapy Exercises

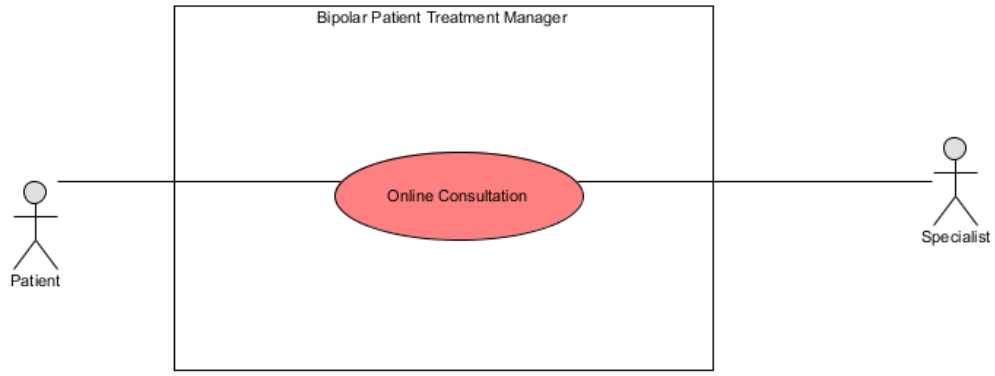
Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: independent learning for treatment participant • Efficiency: Patients participation increased (better control of his/her own disease). • Efficiency: needs for consultation reduced. • Risk mitigation: Increased knowledge allows avoiding health risks. External interfaces: • From Psychiatric Personnel to PC • From Patient to PC, Smart Phone, OR Tablet Data entities involved • Psychotherapy Exercises • Treatment Log: Psychotherapy Exercise Log Use cases • CRUD Psychotherapy Exercises • Visual Chart Exercise (special case of Psychotherapy Exercise) • Special Capability Training Exercise (special case of Psychotherapy Exercise) • Symtom Detection Exercise (special case of Psychotherapy Exercise) • Problem resolution Exercise (special case of Psychotherapy Exercise) • Relaxation Exercise (special case of Psychotherapy Exercise) • Browse Psychotherapy Exercises • Understand Psychotherapy Exercises • Complete Psychotherapy Exercises

	
Comments	To be validated with prototype

5.5.1.13 Feature BPTM.13 Psycho-consultation

Deferred (out of scope).

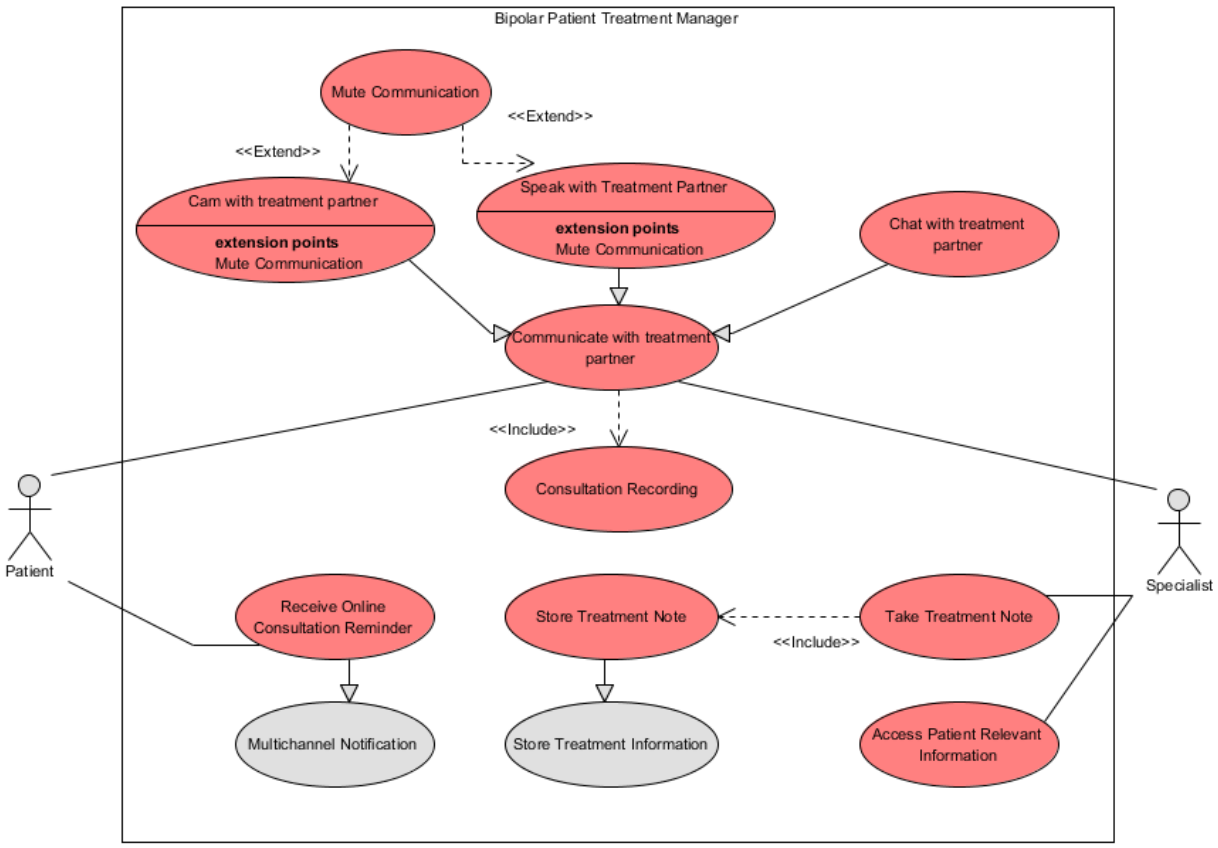
Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: increase doctor's efficiency • Comfort: care for busy patients • Comfort: psychotherapy in private for patients • Effectiveness: interactive treatment for doctor and patient • Performance: video as good as Skype for doctor and patient External interfaces: • From Psychiatric Personnel to PC • From Patient to PC, Smart Phone, OR Tablet Use cases • Online consultation (out of scope)

	
Comments	Deferred. Out of scope.

5.5.1.14 Feature BPTM.14 Online Consultation

Deferred (out of scope).

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: increase doctor's efficiency • Comfort: care for busy patients • Comfort: psychotherapy in private for patients • Effectiveness: interactive treatment for doctor and patient • Performance: video as good as Skype for doctor and patient External interfaces: • From Specialist to PC • From Patient to PC, Smart Phone, OR Tablet Data entities involved • Notification • Treatment Log: Consultation records, Notes Use cases • Communicate with treatment partner (out of scope) • Chat with treatment partner (special case of communicate with treatment partner) (out of scope) • Speak with treatment partner (special case of communicate with treatment partner) (out of scope) • Cam with treatment partner (special case of communicate with treatment partner) (out of scope) • Mute communication (extends speak with treatment partner, extends cam with treatment partner) (out of scope) • Take treatment notes (out of scope) • Access patient relevant information (out of scope) • Receive Online Consultation Reminder (out of scope)

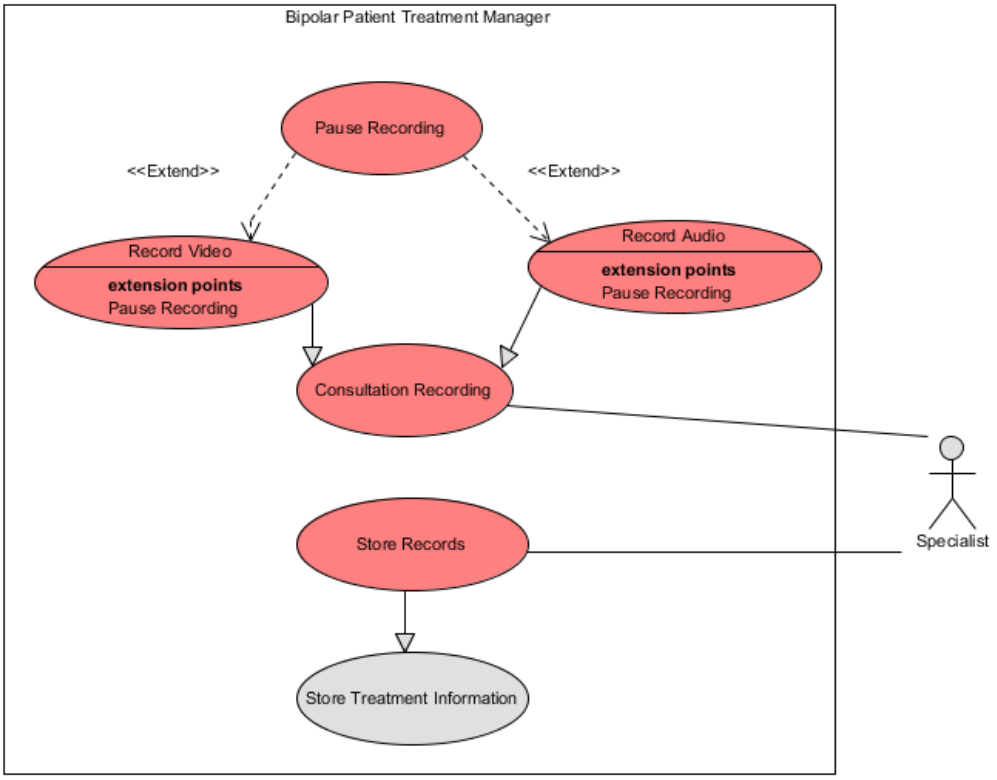


Comments	Deferred. Out of scope.

5.5.1.15 Feature BPTM.15 Consultation Recording

Deferred (out of scope).

Addressed stakeholder interests and expectations	Goals to be achieved: • Flexibility: patient handover enabled for doctor • Compliance: ethics committee approval for doctor • Precision: rich research data collected for doctor • Risk mitigation: care documented for doctor • Performance: big data supported External interfaces: • From Specialist to PC • From Patient to PC, Smart Phone, OR Tablet Data entities involved • Treatment Log: Consultation records Use cases • Record video (out of scope) • Record audio (out of scope) • Pause recording (extends record video and record audio) (out of scope) • Store records (special case of store treatment information) (out of scope)

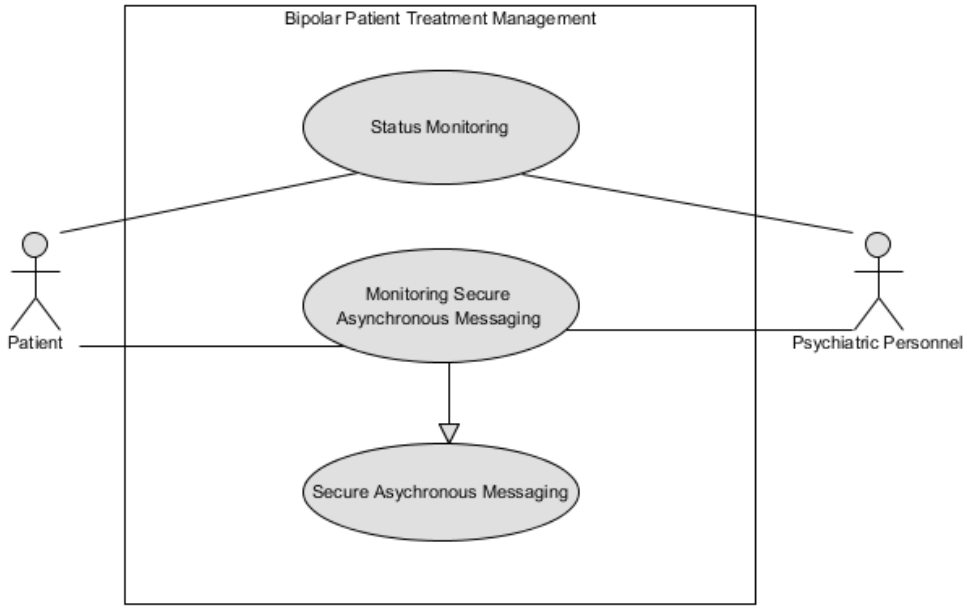
	
Comments	Deferred. Out of scope.

5.5.1.16 Feature BPTM.16 Research Data Post-Processing

Deferred (out of scope).

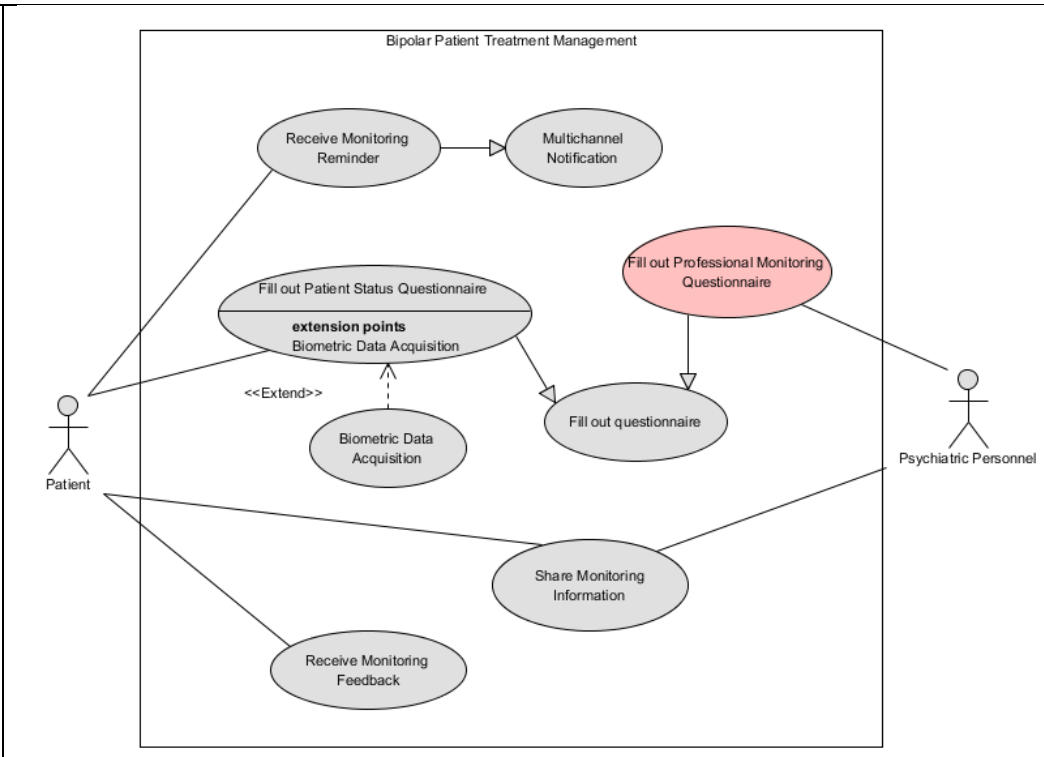
5.5.1.17 Feature BPTM.17 Telemonitoring

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: increased awareness of patient's condition • Effectiveness: adequate treatment prescribed. • Effectiveness: patient correctly consulted. • Effectiveness: Improved transparency on treatment effect. • Effectiveness: personalised and improved reaction to patients needs. • Efficiency: patient participation increased • Comfort: continuous patient status availability. • Comfort: better information and time to prepare for patient visit. External interfaces: • From Psychiatric Personnel to PC • From Patient to PC, Smart Phone, OR Tablet Data entities involved • Secure messaging Use cases • Status Monitoring • Monitoring Secure Asynchronous Messaging (special case of Secure Asynchronous Messaging)

	
Comments	To be validated with prototype

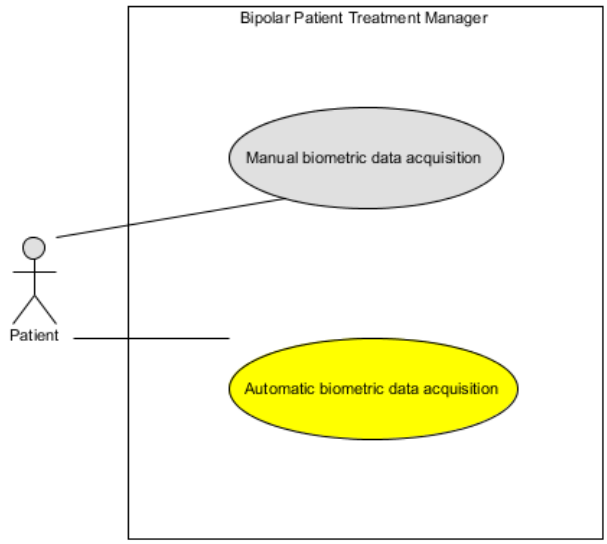
5.5.1.18 Feature BPTM.18 Status Monitoring

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: personalised and improved reaction to patients needs. • Effectiveness: increased awareness of patient's condition. • Effectiveness: Improved transparency on treatment effect. • Efficiency: patient participation increased • Comfort: continuous patient status availability. External interfaces: • From Psychiatric Personnel to PC • From Patient to PC, Smart Phone, OR Tablet Data entities involved • Notification • Questionnaire • Treatment Log: Status Monitoring Log (status data, biometric data, picture) Use cases • Receive monitoring reminder (special case of multichannel notification) • Fill out Patient status questionnaire (special case of fill out questionnaire, extended by Biometric Data Acquisition) • Receive monitoring feedback • Share Monitoring Information • Fill out Professional Monitoring questionnaire (special case of fill out questionnaire) (out of scope)

	
Comments	To be validated with prototype

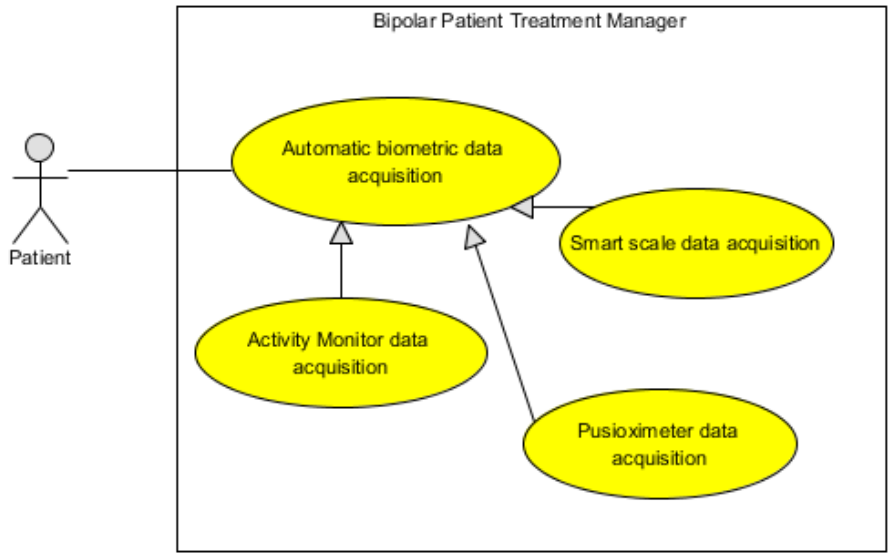
5.5.1.19 Feature BPTM.19 Biometric Data Acquisition

Addressed stakeholder interests and expectations	Goals to be achieved: • Precision: relevant data collected for doctor (for treatment prescription and research purposes). • Performance: big data supported External interfaces: • From Patient to PC, Smart Phone, OR Tablet • From Patient to Biometric Sensor Data entities involved • Treatment Log: Biometric Data Use cases • Manual Biometric Data Acquisition • Automatic Biometric Data Acquisition (Optional – for experimentation)

	
Comments	The Automatic Biometric Data Acquisition is an optional feature. It is to be defined if it is going to be piloted with real patients or only for experimentation but in any case it will be included in the application solution. To be validated with prototype.

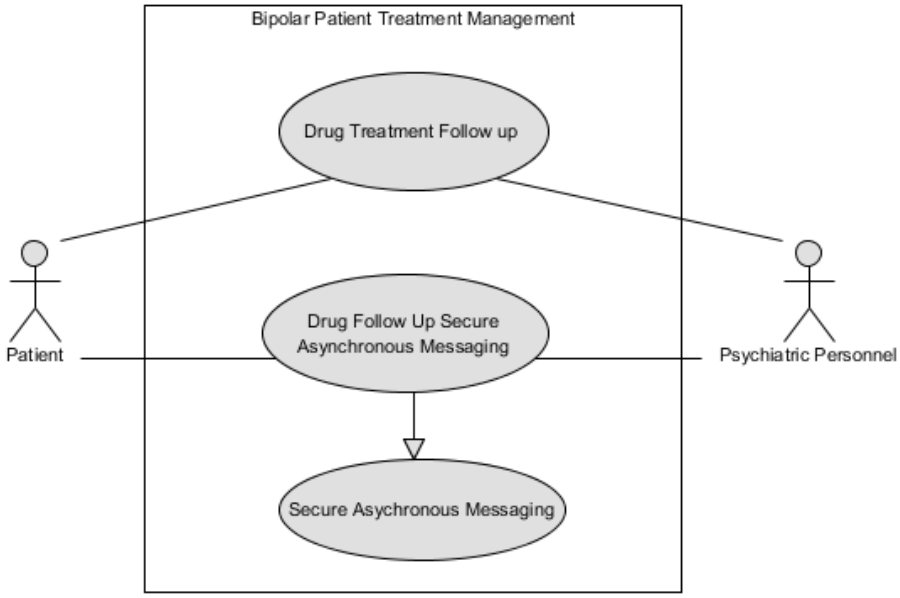
5.5.1.20 Feature BPTM.20 Automatic Biometric Data Acquisition

Addressed stakeholder interests and expectations	Goals to be achieved: • Trust: Avoid transcription errors External interfaces: • From Patient to Biometric Sensor Data entities involved • Treatment Log: Biometric Data Use cases • Automatic Biometric Data Acquisition (for experimentation) • Activity monitor data acquisition (specialisation of Automatic Biometric Data Acquisition) • pulsioximeter acquisition (specialisation of Automatic Biometric Data Acquisition) • Smart scale data acquisition (specialisation of Automatic Biometric Data Acquisition)

	
Comments	The Automatic Biometric Data Acquisition is an optional feature. It is to be defined if it is going to be piloted with real patients or only for experimentation but in any case it will be included in the application solution. To be validated with prototype

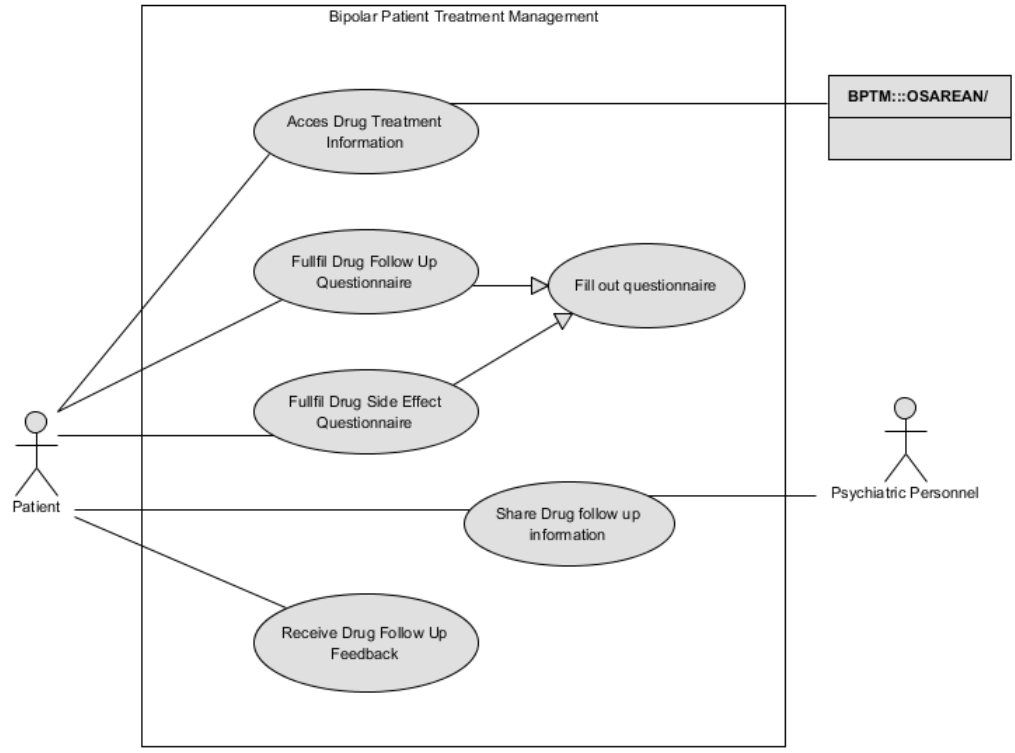
5.5.1.21 Feature BPTM.21 Drug Treatment

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: patient participation increased External interfaces: • From Psychiatric Personnel to PC • From Patient to PC, Smart Phone, OR Tablet Data entities involved • Secure messaging Use cases • Drug Treatment Follow Up • Drug Follow Up Secure Asynchronous Messaging (special case of Secure Asynchronous Messaging)

	
Comments	To be validated with prototype

5.5.1.22 Feature BPTM.22 Drug Treatment Follow Up

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: patient participation increased • Effectiveness: adequate treatment prescribed. • Risk mitigation: early identification of potential side effects. External interfaces: • From Psychiatric Personnel to PC • From Patient to PC, Smart Phone, OR Tablet • From OSAREAN to OSAREAN Connector Data entities involved • Medication Instruction • Treatment Log: Medication Follow Up, Medication Side Effects Use cases • Access Drug Treatment Information (Medication Information comes from OSAREAN::PHR) • Fulfil Drug Follow Up Questionnaire (special case of Fill Out Questionnaire) • Fulfil Drug Side Effects Questionnaire (special case of Fill Out Questionnaire) • Share Drug Follow Up Information • Receive Drug Follow Up Feedback

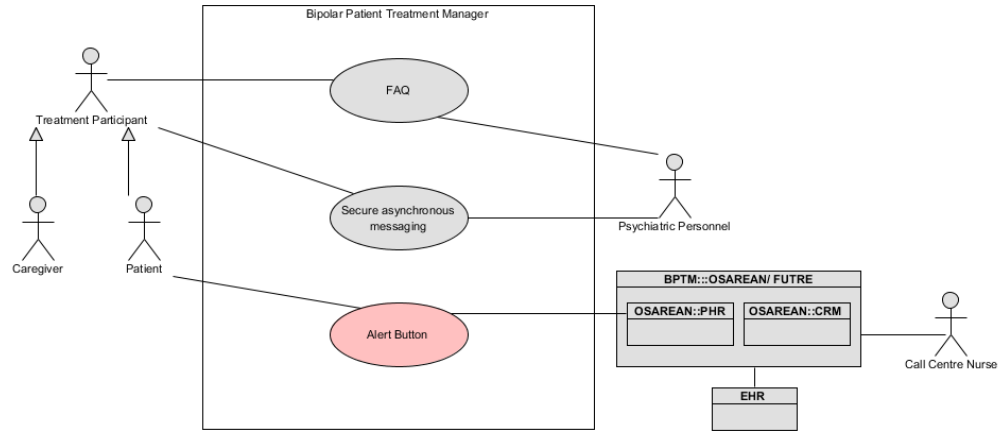
	
Comments	To be validated with prototype

5.5.1.23 Feature BPTM.23 Drug Treatment Schedule

It is achieved by OSAKIDETZAs internal services (out of scope).

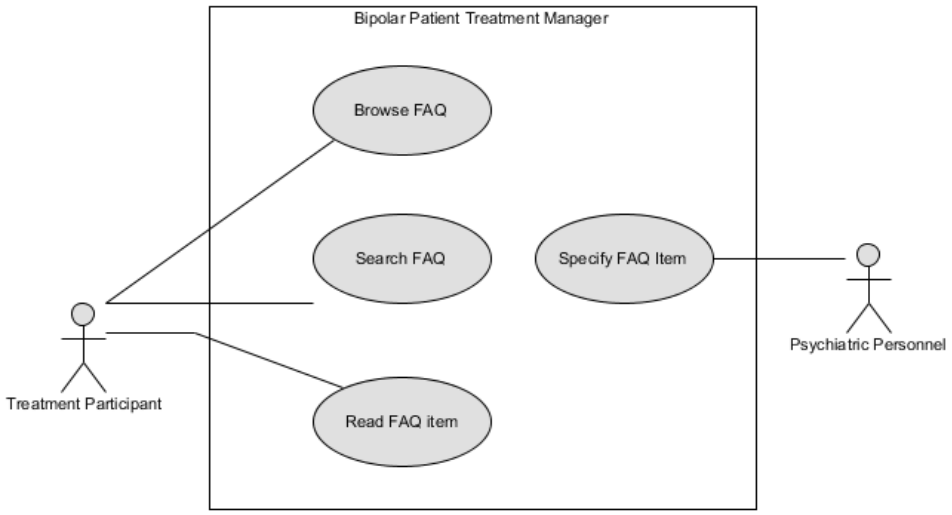
5.5.1.24 Feature BPTM.24 Support

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: fast support for treatment participant • Efficiency: need for F2F consultations reduced for treatment participant and psychiatric personnel • Efficiency: Private caregivers involved • Effectiveness: Interaction with clinical personnel. External interfaces: • From Psychiatric Personnel to PC • From Patient to PC, Smart Phone, OR Tablet • From OSAREAN to OSAREAN Connector Data entities involved • FAQ Item • Secure messaging Use cases • FAQ • Secure Asynchronous Messaging • Alert Button (out of scope)

	
Comments	To be validated with prototype

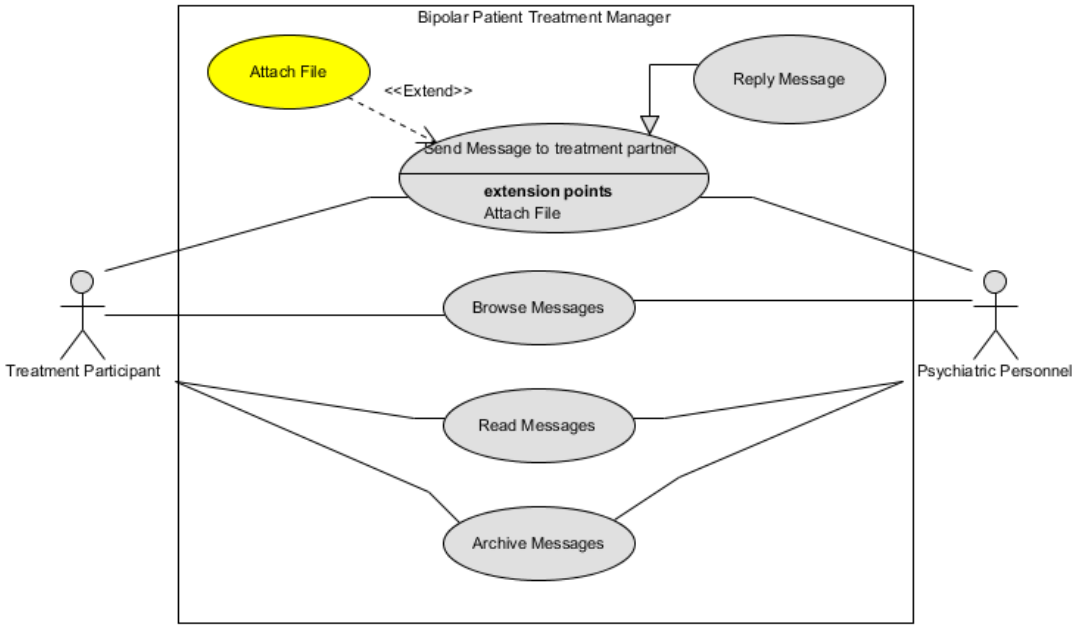
5.5.1.25 Feature BPTM.25 FAQ

Key ideas for to implement feature	Goals to be achieved: • Efficiency: fast support for treatment participant • Efficiency: need for consultations reduced for treatment participant and psychiatric personnel • Efficiency: Private caregivers involved External interfaces: • From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet Data entities involved • FAQ Item Use cases • Specify FAQ item • Browse FAQ • Search FAQ • Read FAQ Item

	
Comments	To be validated with prototype

5.5.1.26 Feature BPTM.26 Secure Asynchronous Messaging

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: availability of psychotherapy increased for patient • Efficiency: patient participation increased • Efficiency: Private caregivers involved External interfaces: • From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet Data entities involved • Secure Message Use cases • Send message to treatment partner • Attach file (extends send message to treatment partner) – Optional feature. • Reply to message (special case of send message to treatment partner) • Browse messages • Read messages • Archive message

	
Comments	To be validated with prototype

5.5.1.27 Feature BPTM.27 Video Mail

Deferred (out of scope).

5.5.1.28 Feature BPTM.28 Alert Button

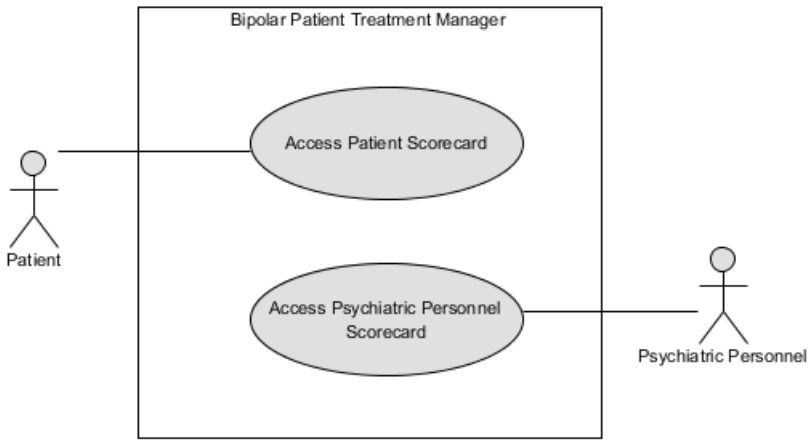
Deferred (out of scope).

5.5.1.29 Feature BPTM.29 Guidance Services

Deferred (out of scope).

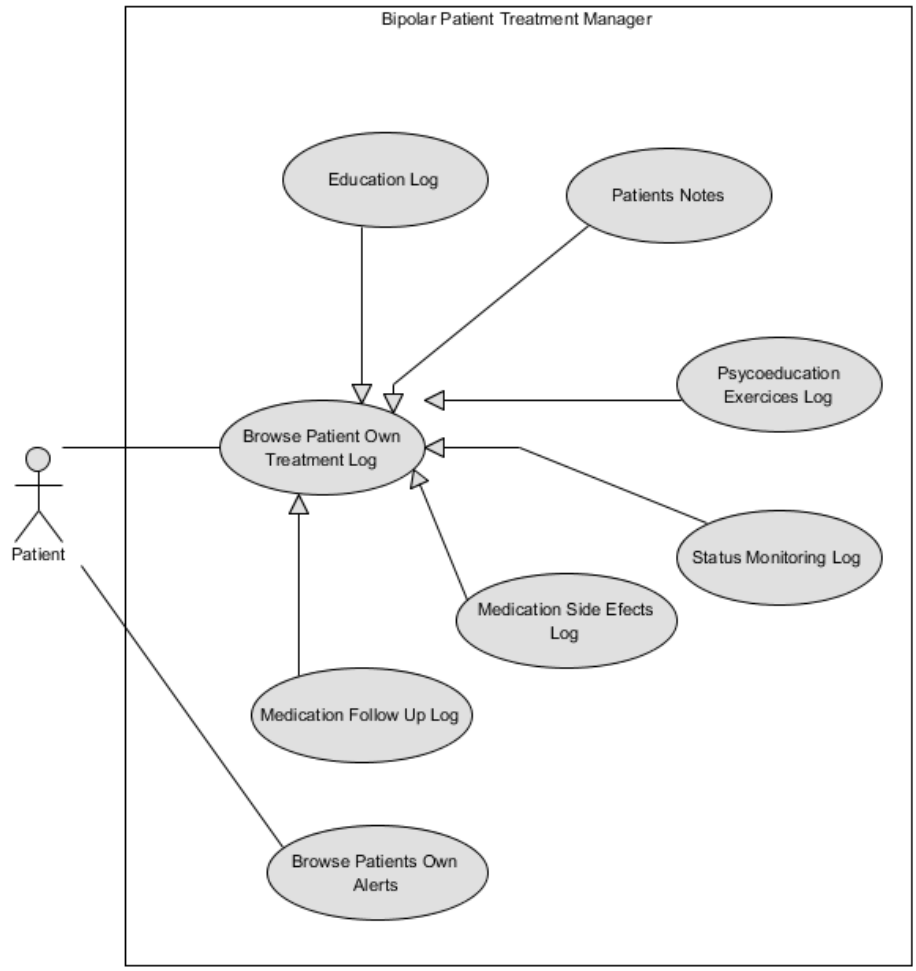
5.5.1.30 Feature BPTM.30 Scorecard

Addressed stakeholder interests and expectations	Goals to be achieved: • Comfort: continuous patient status availability for psychiatric personnel • Comfort: continuous status availability for patient • Efficiency: patient participation increased • Risk mitigation: crisis situation handled for patient • Effectiveness: increased awareness of patient's condition for patient and doctor External interfaces: • From Psychiatric Personnel to PC • From Patient to PC, Smart Phone, OR Tablet Use cases • Access Patient Scorecard • Access Psychiatric Personnel Scorecard

	
Comments	To be validated with prototype

5.5.1.31 Feature BPTM.31 Patient Scorecard

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: patient participation increased • Effectiveness: increased awareness of patient's condition for patient and doctor • Comfort: continuous status availability for patient External interfaces: • From Patient to PC, Smart Phone, OR Tablet Data entities involved • Treatment Log (Education Log, Notes, Learning Module Usage Log, Psychotherapy Exercise Log, status monitoring log, medication follow up log, medication side effects log) • Notification (alerts) Use cases • Browse Patient Own Treatment Log • Education Log (special case of Browse Patient Own Treatment Log) • Patients' notes (special case of Browse Patient Own Treatment Log) • Psychoeducation Exercises Log (special case of Browse Patient Own Treatment Log) • Status Monitoring Log (special case of Browse Patient Own Treatment Log) • Medication Side Effect Log (special case of Browse Patient Own Treatment Log) • Medication Follow Up Log (special case of Browse Patient Own Treatment Log) • Browse Patient's own alerts.

	
Comments	To be validated with prototype

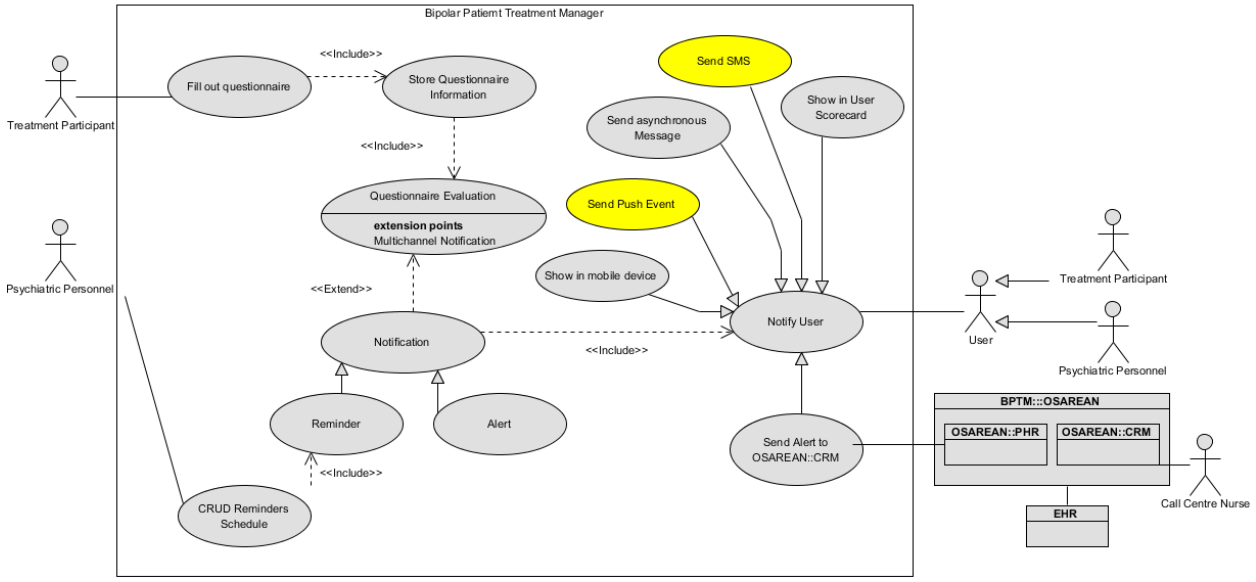
5.5.1.32 Feature BPTM.32 Psychiatric Personnel Scorecard

Addressed stakeholder interests and expectations	Goals to be achieved: • Comfort: continuous patient status availability for psychiatric personnel • Efficiency: patient participation increased • Risk mitigation: crisis situation handled for patient • Effectiveness: increased awareness of patient's condition for patient and doctor External interfaces: • From Psychiatric Personnel to PC Data entities involved • Treatment Log (Education Log, Notes, Learning Module Usage Log, Psychotherapy Exercise Log, status monitoring log, medication follow up log, medication side effects log) • Notification (Alerts) Use cases • Browse Aggregated Patients Alerts • Browse Aggregated Learning Usage Analytics • Browse Individual Patient Treatment Log. • Education Log (special case of Browse Individual Patient Treatment Log)

	• Patients' Learning Usage Log (special case of Browse Individual Patient Treatment Log) • Psychiatric Personnel Treatment Notes (special case of Browse Individual Patient Treatment Log) • Psychoeducation Exercises Log (special case of Browse Individual Patient Treatment Log) • Status Monitoring Log (special case of Browse Individual Patient Treatment Log) • Medication Side Effect Log (special case of Browse Individual Patient Treatment Log) • Medication Follow Up Log (special case of Browse Individual Patient Treatment Log) • Consultation records. Optional. (special case of Browse Individual Patient Treatment Log) – (out of scope) 
Comments	To be validated with prototype

5.5.1.33 Feature BPTM.33 Multi-Channel Notification

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: effort for care contained for psychiatric personnel • Efficiency: call center nurses involved • Risk mitigation: crisis situation handled for patient External interfaces:

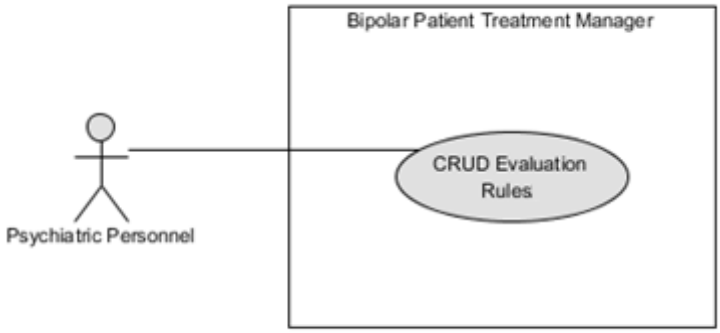
	• From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet • From OSAREAN to OSAREAN Connector • From Call Center Nurse to OSAREAN Connector through OSAREAN Data entities involved • Questionnaires • Evaluation Rules • Evaluation Log • Notification • Alert (special type of notification) • Reminder (special type of notification) Use cases • Create, read, update, delete reminder schedule • Notify user • Send SMS (special case of notify user). Optional. • Send message (special case of notify user) • Send Push event (special case of notify user). Optional • Show in mobile device (special case of notify user) • Show in user scorecard (special case of notify user) Send Alert to OSAREAN::CRM (special case of notify user)
	
Comments	To be validated with prototype

5.5.1.34 Feature BPTM.34 Workflow Management

Implemented in OSAREAN (out of scope).

5.5.1.35 Feature BPTM.33 Evaluation rules

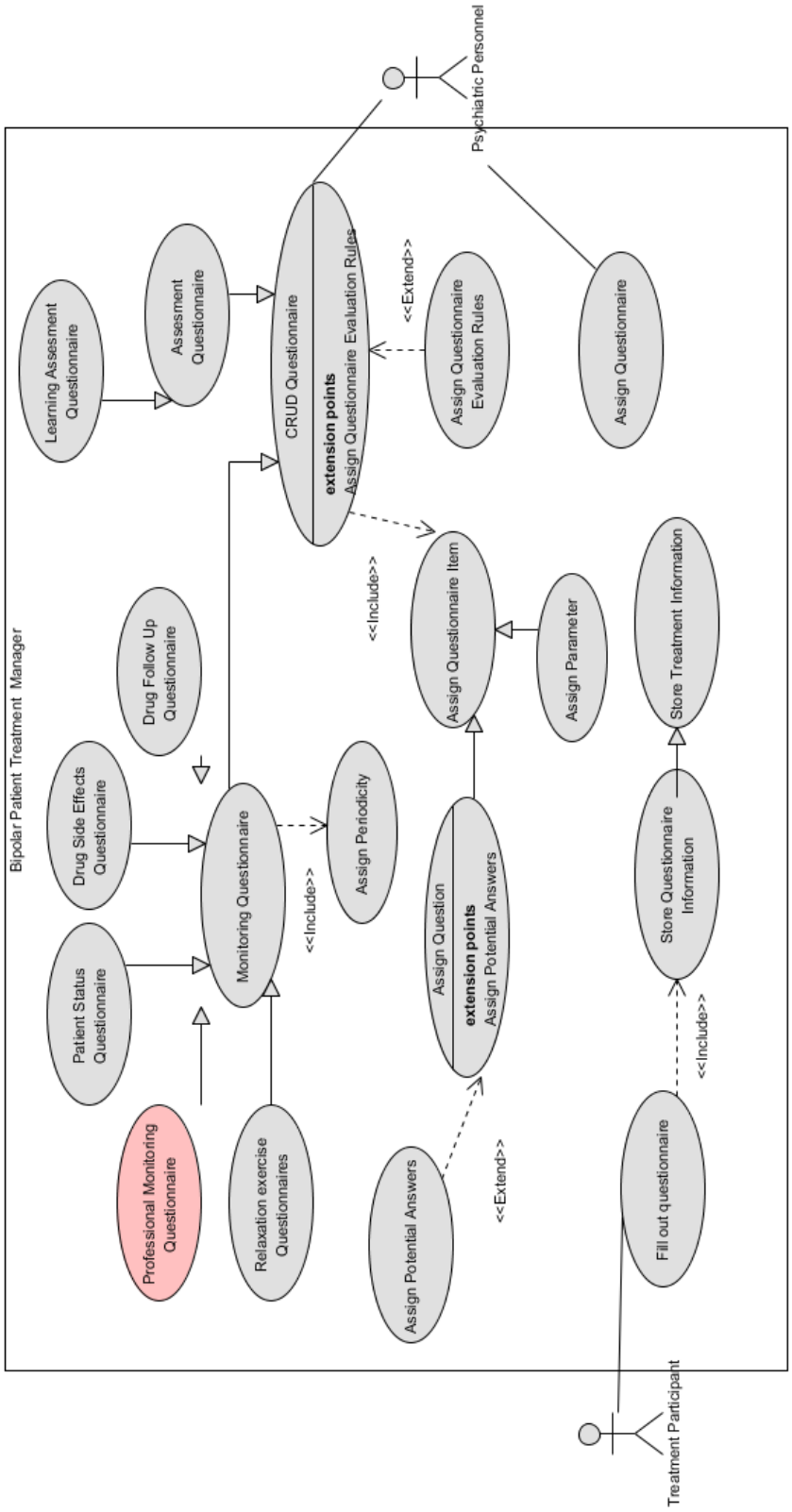
Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: Personalised patient treatment. • Effectiveness: Flexible assignment of treatment features (learning sessions, etc.). • Efficiency: fast support. • Risk mitigation: Early response to crisis situation.

	• Performance: creation of customisable evaluation rules to evaluate questionnaires. External interfaces: • From Psychiatric Personnel to PC Data entities involved • Evaluation Rules. Use cases • Create, read, update, delete evaluation rule 
Comments	To be validated with prototype

5.5.1.36 Feature BPTM.36 Questionnaires

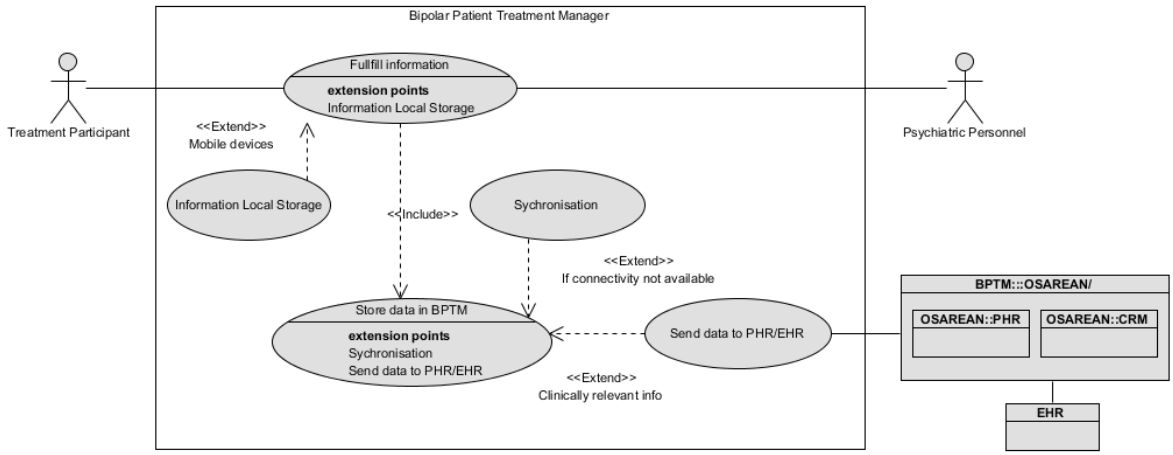
Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: remote collection of patient related data. External interfaces: • From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet Data entities involved • Questionnaire • Questionnaire item • Questions • Potential Answers • Parameter. • Personal Patient Baseline (the personal baseline is taken into account by evaluation rules-> personalisation) • Evaluation Rules • Treatment Log (Education Log, , Psychotherapy Exercise Log, status monitoring log, medication follow up log, medication side effects log, evaluation log) Use cases • Create, read, update, delete questionnaire • Assessment Questionnaire (special case of CRUD questionnaire) • Assign questionnaire items • Assign Parameters (special case of Assign questionnaire items) • Assign Questions (special case of Assign questionnaire items, extended by Assign set of potential answers) • Assign questionnaire evaluation rules

	• Learning Assessment Questionnaire (special case of Assessment Questionnaire) • Monitoring Questionnaire (special case of CRUD questionnaire) • Drug follow up Questionnaire (special case of Monitoring questionnaire) • Drug side effects Questionnaire (special case of Monitoring questionnaire) • Patients Status Questionnaire (special case of Monitoring questionnaire) • Relaxation exercises Questionnaire (special case of Monitoring questionnaire) • Professional Monitoring Questionnaire (special case of Monitoring questionnaire) – Out of scope. • Assign periodicity. • Assign Questionnaire • Fill out questionnaire



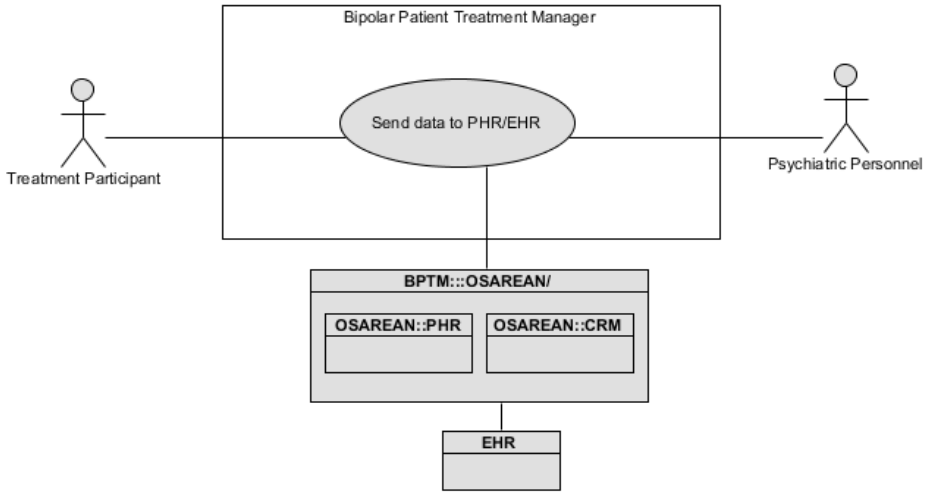
Comments	To be validated with prototype

5.5.1.37 Feature BPTM.37 Store Treatment Information

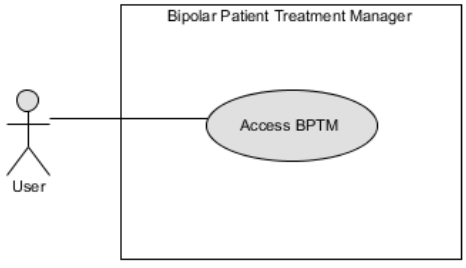
Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: Keep a unique record External interfaces: • From Psychiatric Personnel to PC • From Treatment Participant to PC, Smart Phone, OR Tablet • From OSAREAN to OSAREAN Connector Data entities involved • Treatment Log Use cases • Fulfil Information (extended by Local Storage (in mobile devices)) • Store data in BPTM. Extended by Synchronisation (if required, seamless when connectivity available) and Send data to PHR (clinically relevant information)
	
Comments	To be validated with prototype

5.5.1.38 Feature BPTM.38 Data to PHR/EHR

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: Keep a unique record External interfaces: • From OSAREAN to OSAREAN Connector Data entities involved • Treatment Log (Clinically relevant info from Monitoring Status, Notes, Medication Follow Up, Medication side Effects,..) Use cases • Send data to PHR/EHR Note: The OSAREAN Connector will provide mean to update Patients PHR/EHR by using the available web services provided by the OSAREAN Platform.

	
Comments	To be validated with prototype

5.5.1.39 Feature BPTM.39 Usability

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: low distribution costs • Usability: Multilanguage (the BPTM system should support the co-official languages). • Usability: well-known interaction metaphors for user. • Usability: Common (as much as possible) user (treatment participant) experience by using any of the potential interfaces (PC, smartphone or tablet) • Usability: User friendly navigation. External interfaces: • From User to PC • From Treatment Participant to smartphone • Form Treatment Participant to Tablet Use cases • Access BPTM 
Comments	To be validated with prototype

5.5.2 FI-STAR Solution-wide Requirements and Constraints

Define the priority of these other product requirements. Include, if useful, attributes such as stability, benefit, effort, and risk. Use the feature template given in §4 if appropriate.

5.5.2.1 Constraints towards Platforms

ID	Constraint (Title and Short Description)	Rationale and comments
1	Multilanguage	The BPTM system should support the co-official languages).
2	Multi device access	Allow multi-device access to the solution (PC, Smartphone, tablet) to allow patients to use they preferred, available devices (reducing distribution costs)
3	Interoperability	BPTM should interoperate with the OSAREAN platform by using available SOAP web services that exchange HL7 v2.5 messages. BPTM should be prepared to support 11073 (experimentation level)

5.5.2.2 Constraints towards Enablers and Technology

ID	Constraint	Rationale and comments
1	Secure information exchange	The exchanged information need to be highly secured and comply with local regulations.
2	Secure access control for the patient or carers	In a real working environment the solution should comply with the following access control (it could be reduced in the pilot solution). Clinical Personnel Professional access to the solution should require digital signature provides within Osakidetza´s professional ID-card.  Clinical personnel will use single sign on capabilities. Treatment participants The Secure access for the patient or carers should be defined based on: • Digital signature (by using Smart ID Card)  • User/password/number matrix http://www.izenpe.com/s15-12010/en/ Access to Authentication Service in the OSAKIDETZA Service BUS (OSB) that connect to the 3rd party Certification Entity and provides (or not) access.

3	Privacy	Data must be kept in a private environment (OSAKIDETZA's facilities). No data should be transferred to external/public sites. The data stored in the **temporary** local storage should be encrypted.
4	Communications	Communications should go through the OSAKIDETZA service bus (OSB). The OSB Internet is in the OSAKIDETZA DMZ and the OSB intranet OSAKIDETZA secure domain. The OSAKIDETZA's service bus uses Oracle Service Bus.
5	Usability	WCAG AA conformance (the level of constraint could be reduced in the pilot solution).

6 CRP Solution for Cardiac Rehabilitation in Bucharest, Rumania

The FI-STAR solution CRP for Cardiac Rehabilitation addresses the problem of reducing the costs and disabilities produced by cardiovascular diseases and produce an easier management of the cardiac patient, which affects the patient, family, health assurances, and society. The impact of this problem for patients is that he/she is unable to resume and maintain a place as normal as possible in the community because of the limitations that appear in terms of cardiac fitness and psychological stress and anxiety. The impact of this problem for the society is increased health system costs that appear from frequent rehospitalisation and therapeutical costs. A successful solution improves the outcomes in terms of improved cardiac fitness for the patient's diminished anxiety and fear for performing daily life activities, reduces the rehospitalisation rates and decreases the time needed for the caregiver to monitor a patient.

CRP is intended for medical doctors, nurses, and hospitals who conduct cardiac rehabilitation programs. CRP is a FI-STAR cloud solution that monitors heart rate, body temperature, consumed calories of the patient at home in real-time. Separate modules for arterial pressure measurement, pulse-oximetry, and electrocardiogram can be attached when needed. Unlike the current rehab done in rehabilitation centres, CRP reduces expenditure and personnel cost, accelerates reintegration of the patient in the community and economic circuit, and consequently decreases health-system costs.

This chapter gives an overview of a FI-STAR solution that is intended to be built to support the FI-STAR use case. The chapter covers the goal/purpose of the FI-STAR solution, stakeholders and their interests/expectations, the application and their features that are integrated into the FI-STAR solution to support these interests/expectations, and the FI-STAR solution-wide requirements and constraints. The appendix can be used to capture any other material, including business processes, glossary, description of the as-is situation, problems with current solutions, storyboards, and examples of artefacts and photographs of usage context.

The vision chapter is intended as a starting point for subsequent detailed requirement engineering. The features are used to establish an overview of the FI-STAR solution's requirements that then will be engineered just-in-time before the relevant development starts. The features should be specified by explaining how the concerned FI-STAR application will support the corresponding FI-STAR stakeholders' interests and expectations. The vision chapter should be updated as the understanding of the FI-STAR solution and of its aims and objectives evolve.

Future uses of this vision chapter will be to establish personas for target user segmentation and user experience engineering, traceability to release and project planning, application and enabler design and development, and quantification of quality requirements and testing, definition/monitoring of KPI, and analyzing commonality/variability across applications. In addition, this vision chapter will refer to relevant specialty requirements.

6.1 FI-STAR Solution Positioning

The following captures the essence of the FI-STAR solution, including the problem it addresses and the key idea of solving the problem.

6.1.1 Problem Statement

The problem of	reducing the costs and the disabilities produced by cardiovascular diseases
Affects	patient, family, assuranceand society
the impact of which is	patient : unable to resume and maintain as normal as possible a place in the community

	society:increased health-system costs family:decrease the income because of the work imposibility and increase the costs with hospitalization assurance: increase the health assurance costs
a successful solution would be	to improve the efficacy of the existing rehabilitation programs through reducing hospitalization time, decreased recovery time, increase the number of people who return to work and increase wellbeing.

6.1.2 Position Statement

For	medical doctors, nurses, and hospitals
Who	Conduct cardiac rehabilitation programs
The (product name)	Cardio Rehabilitation Program (CRP) is a FI-STAR cloud solution
That	monitors the patient at home in real-time: heart rate, body temperature, calories consumed. Small separate modules for arterial pressure measurement, pulse-oximetry and electrocardiogram can be attached to the device when needed.
Unlike	current rehab done in rehabilitation centres, which is more expensive and personal cost are higher
Our product	hospital: reduces expenditure and personnel cost, patient: accelerates reintegration in the community and economic circuit; society: decrease health-system costs

6.2 FI-STAR Use Case Stakeholders

The following users, interfacing systems, and other stakeholders are affected by the solution.

6.2.1 User Roles and Rehabilitation Process

Figure 65 provides an overview of the user roles of the Cardiac Rehabilitation Program. These are the patient, the doctor and nurse as professional caregivers, the call center agent, and the two types of administrator CRP administrator and IT administrator.

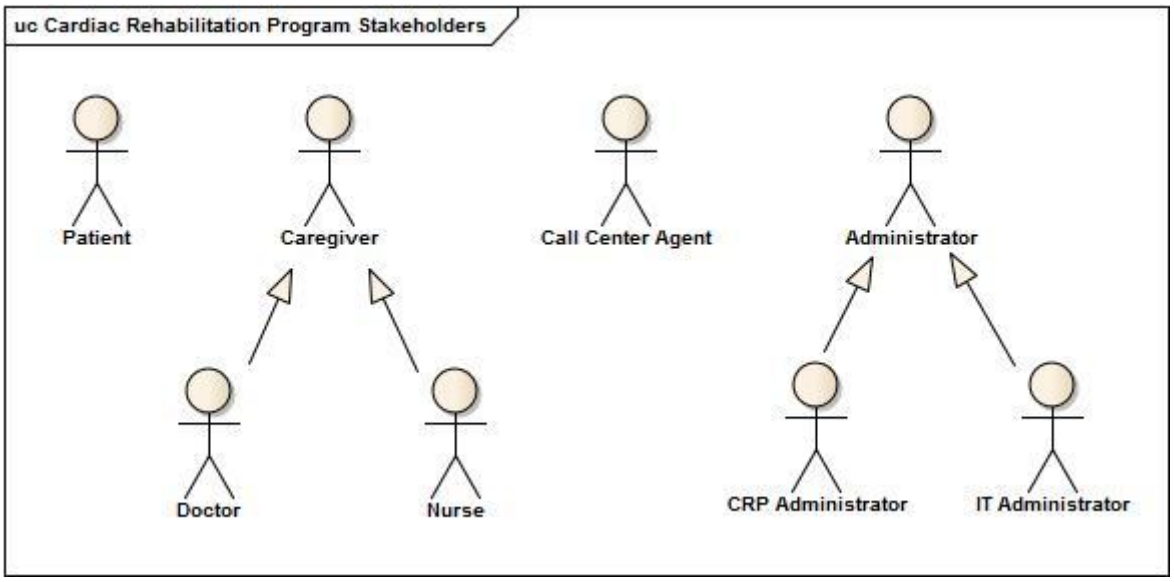


Figure 65: User roles of the Cardiac Rehabilitation Program solution.

Cardiac Rehabilitation (CR) is conventionally divided into three phases. Phase I, inpatient, involves the hospitalized period of the patient following an acute MI (it usually takes between 5 to 7 days of hospitalization). Phase II is the immediate post discharge period containing a structured therapy, exercise, and nutritional plan. Phase-3 is the maintenance phase.

CR has a set of core components that should be included into every cardiac rehabilitation plan. These components include baseline patient assessment, medication, nutritional counselling, risk factor modification, psychosocial interventions, physical activity counselling, and exercise training.

6.2.1.1 Structure of the process- Phase I, the inpatient period (hospitalization period)

The patient is brought to the ICU of the BAEH, where the medical team makes a complete clinical and paraclinical assessment (Figure 66). The patient is then monitored (Figure 67) using a system of Bluetooth sensors attached to him. The caregivers monitor in real-time the heart rate, pulse-oximetry, body temperature, arterial pressure and electrocardiogram. He is observed closely for any signs and symptoms during ambulation.

Figure 66: Clinical and paraclinical assessment

Figure 67: Patient monitoring

The patient is regularly visited by a member of the rehab team; the purpose of these visits is to:

- Offer medical treatment
- Give support and information to the patient and their families about heart disease.
- Assist the patient to identify personal risk factors and discuss modifications of these risk factors
- Provide patient with an individual plan for self-care and lifestyle change
- Assist the patient in accomplishing his exercise plan
- Encourage the patients to adhere to the outpatients activity program
- Inform patients regarding Phase 2 and Phase 3 programs, and encourage their attendance.

Education: During these visits, educational sessions are initiated. They comprise verbal information and the use of audio-visual materials regarding the cardiac event, psychological reactions to the event and cardiac pain/symptom management:

- Cardiac anatomy and physiology related to the cardiac event
- Cardiac pain and symptom management
- Risk factor management
- Benefits of physical activity
- Energy conservation/graded return to Activities of Daily Living
- Cardio protective healthy eating
- Medication
- Resumption of sexual activity
- Benefits and entitlements post-event

Educational units (EdU) stored in repository on the private cloud are available through CRP on Tablets or Smartphones (Figure 68) to the patients.

Figure 68: Educational sessions initiated in Phase I

Cardiac Rehabilitation Physical Exercise Protocol: At this stage the patient is provided with a personalized plan for self-care and lifestyle change. In addition, the psychosocial status of the patient is assessed using a validated structured interview or by self-report questionnaire.

Cardiac rehabilitation physical exercise protocols are individualized for each patient and tailored to the patient's condition. A generic protocol may be structured as follows.

6.2.1.1.1 Protocol Level 1 Day 0 (the day of admission)

The protocol at the day of admission consists of complete bed rest, relaxation, breathing exercises and active range of motion exercises (ankle foot, finger and wrist movements) performed five times, thrice daily. Educational sessions of half an hour, two times daily are initiated from the day of admission until the discharge day.

CRP allows the patient to record the measured parameters. Table 8 shows the parameters that have to be monitored, the devices to be used for monitoring, and the monitoring frequency.

Table 9 and Figure 69 show the timing and the training of the patient on how to use the devices for monitoring and educational purposes.

Table 8: Parameters that have to be monitored at admission with monitoring devices and timing

Parameter	**Device**	**Timing, Frequency**
Heart Rate, Calories Burned.	the BASIS watch	All the time.
ECG	ECG strap band	All the timeuntil day2.
Blood Pressure	Automatic-Bluetooth-Pressure-Monitor-HPL	Morning, Evening, Pre and Post Effort
Sp O_2	PulseOximeter	Morning, Evening, Pre and Post Effort
Weight	Weight Scale	Morning

Table 9: Educational sessions timing

Movies 1.heart pathology movie 2.secondary preventive measures movie/(s)	Tablet with educative movies	Two educational sessions per day of half an hour length 9.00-09:30 19.00-19:30

Figure 69: Monitoring initiated during Phase I (here with watch and pulse-oxymeter)

6.2.1.1.2 Protocol Level 2 (day 1 and 2)

During day 1 the following exercises are performed: sitting (1-2 hours / day), self-feeding, relaxation, breathing, and motion exercises to hip and knee (five repetitions, thrice day).

During day 2 the following exercises are performed: sitting-arm bending / stretching up / bending (five repetitions, thrice a day), increased sitting time (3-4 hours / day), independent toileting (bedside), alternate heel drags, static quadriceps and glutei (do not hold breath), and static and spinal extension (five repetitions, thrice a day).

CRP allows the patient to record the measured parameters. Table 10 shows the parameters that have to be monitored, the devices to be used for monitoring, and the monitoring frequency.

Table 10: Parameters that have to be monitored at admission with monitoring devices and timing

Parameter	Device	Timing, Frequency
Heart Rate, Calories Burned.	the BASIS watch	All the time.
ECG	ECG strap band	All the time until day2.
Blood Pressure(BP)	Automatic Bluetooth Pressure Monitor HPL	Morning, Evening, Pre and Post Effort
Sp O_2	Pulse-Oximeter	Morning, Evening, Pre and Post Effort

6.2.1.1.3 Protocol Level 3 (days 3to5)

During days 3 to 5 the following exercises are performed: progress exercises to 10 repetitions, walk within room (thrice a day), standing-upper limb flexion (five repetitions thrice a day), walk-standing-lower limb flexion (five repetitions thrice a day), stride-standing-hip and knee flexion (five repetitions thrice a day), walking outside the room (thrice a day), bend standing-elbow circling, trunk bending, walking outside the room with arm swings, and climbing one flight of step.

CRP allows the patient to record the measured parameters. Table 11 shows the parameters that have to be monitored, the devices to be used for monitoring, and the monitoring frequency.

Table 11: Parameters that have to be monitored at admission with monitoring devices and timing

Parameter	Device	Timing, Frequency
All watch-supported parameters.	the BASIS watch	All the time.
ECG	ECG strap	day2 until dismissal: exercise period 60 minutes/day, every day, (during exercise: warm-up, maximum workload, warm-down)
Blood Pressure	Automatic Bluetooth Pressure Monitor HPL	Morning, Evening, Pre and Post Effort
O_2 saturation	Pulse Oximeter	Morning, Evening, Pre and Post Effort

A symptom-induced cardiac stress test (6MWT or VO2max) is performed at the end of this phase: this initial evaluation is essential and serves as reference. A maximal test will be performed (17/20 Borg), during 10-15 minutes and the reference maximal heart rate will be noted; this will serve as reference for the next phases. Other medical parameters that are monitored during this evaluation: echocardiography parameters and BNP. If VO2 max is used, the anaerobic threshold will be determined. Figure 70 illustrates the stress test situation.

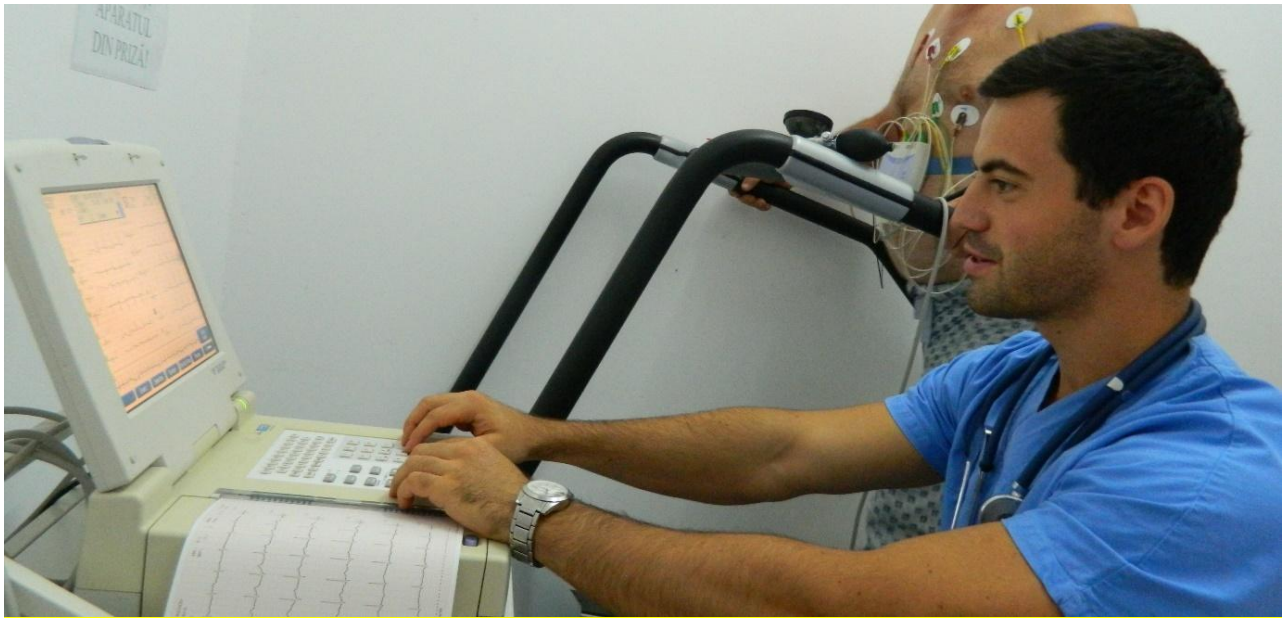


Figure 70: Patient performing a stress test.

6.2.1.2 Structure of the process- Phase II

Phase II of cardiac rehabilitation begins after discharge from the hospital. Phase II is a supervised and monitored out-patient program.

The objectives of phase II cardiac rehabilitation are to reinforce modification of risk factors, provide education to the patient and his/her family, and promote continuing adherence with lifestyle recommendations.

CRP supports phase II with a mobile device for the patient and a PC-based interface for the caregivers. Figure 71 shows the CRP main interfaces.

Figure 71: CRP support for outpatient monitoring.

After being instructed once in the hospital, the patient exercises daily 3-5 times per week at home. The caregiver has the ability to control the patient whether he performs the exercises during the day. From the monitoring centre the caregivers can change in real time the medical treatment and the nutritional plan according to the evolution of the patient vital parameters.

Phase II of the program has the two components IIa and IIb.

Phase IIa (6 weeks) consists of low to moderate exercise training and secondary prevention programs (therapeutical, nutritional, smoking cessation, and alcohol consumption reduction).

Phase IIb (6weeks) follows phase II2. It assesses the risk for cardiovascular complications for each patient. The patients at low and moderate risk will pass to a high intensity exercise training program. The patients at high risk will continue low to moderate exercise training. Both options will be doubled by secondary prevention programs (reducing blood lipid levels, smoking cessation,, waist size, psychological counselling). Patients with physically demanding work or leisure time activity achieve added benefit from high intensity exercise.

CRP allows the patient to record vital parameters at home during phase, show patterns of their evolution during the rehab, sound alarms when parameters are not normal parameters or subjective symptoms appear, and allows the caregiver to modify in real-time the medical, nutritional and physical exercise plan. This gives the patient a lot of trust and safety in performing his/her activities. II. Table 12 shows the parameters that have to be monitored and the timing or frequency of that monitoring.

Table 12: Daily monitored parameters during phase II with timing and frequency.

Parameter	Morning	Pre-Effort	Effort	Post-Effort	Evening	Alarm	24h
ECG			X				
HR							X
BP	X	X		X	X	X	
Calories							X
SpO2	X	X		X	X	X	

At the end of Phase 2 the patient will perform a cardiac stress test which will quantify how much his cardiac function has improved during the whole rehabilitation process and at what level of cardiac fitness he has reached. At the begging of the rehab trial there will also be chosen a witness group which won`t follow the home rehabilitation program but will perform the stress test at the end of the 12 weeks for assessing their cardiovascular fitness. This will serve as a comparison for the

rehabilitated patients. Also during the rehabilitation plan it will be monitored the rehospitalisation rates of rehab and the non-rehab patients.

6.2.2 User Roles with Interests and Expectations on Solution

The following table describes the users, including their background, role, and expectations.

Table 13: User roles with interests and expectations.

Name	Description	Expectations on Solution
Doctors (4) Prof. Crina Sinescu M.D. Stefan Busnatu M.D. Alexandru Mischie M.D. Chioncel Valentin M.D.	Responsible for patient safety. Creates personalized cardiac rehab protocols for each patient. Monitors the patient.	Give the patient a safe, monitored environment for exercise Increase the patient's exercise work capacity Teach the patient to monitor himself/herself during an exercise period Relieve fear and anxiety Patient Education
ICU Nurse(2) Bajenaru Florentina Dobrin Daniela	Responsible for patient safety. Monitors the patient.	Give the patient a safe, monitored environment for exercise Relieve fear and anxiety Patient Education
Call Center Agent (4) Emilian Dumitru M.D. Suzana Guberna M.D. Anamaria Avram M.D. Lucian Axente M.D.	Monitors the patients.	Monitor (24/7) the patients status. Analyse the importance of alarms. Realise an interaction with the patient, in order to clarify the alarm level. Relieve fear and anxiety
IT Team (2) Prof. Eng. Serban Petrescu Eng. Catalin Chera	Provides system administration and first level support.	Solution easy to deploy and manage
Patient (approx. 25) TBD	Responsible for following the doctors recommendations Responsible for the proper use of the sensors Might be afraid of new technologies; Might require help form the family; Most of them over 50 years old	Easy to learn and use Better quality of life Few rehospitalisation during lifetime

6.2.3 Interfacing Systems

Figure 72 gives an overview of the system boundary of the CRP solution. The connectivity to the FI-STAR cloud is a concern of the solution architecture, hence omitted from the overview.

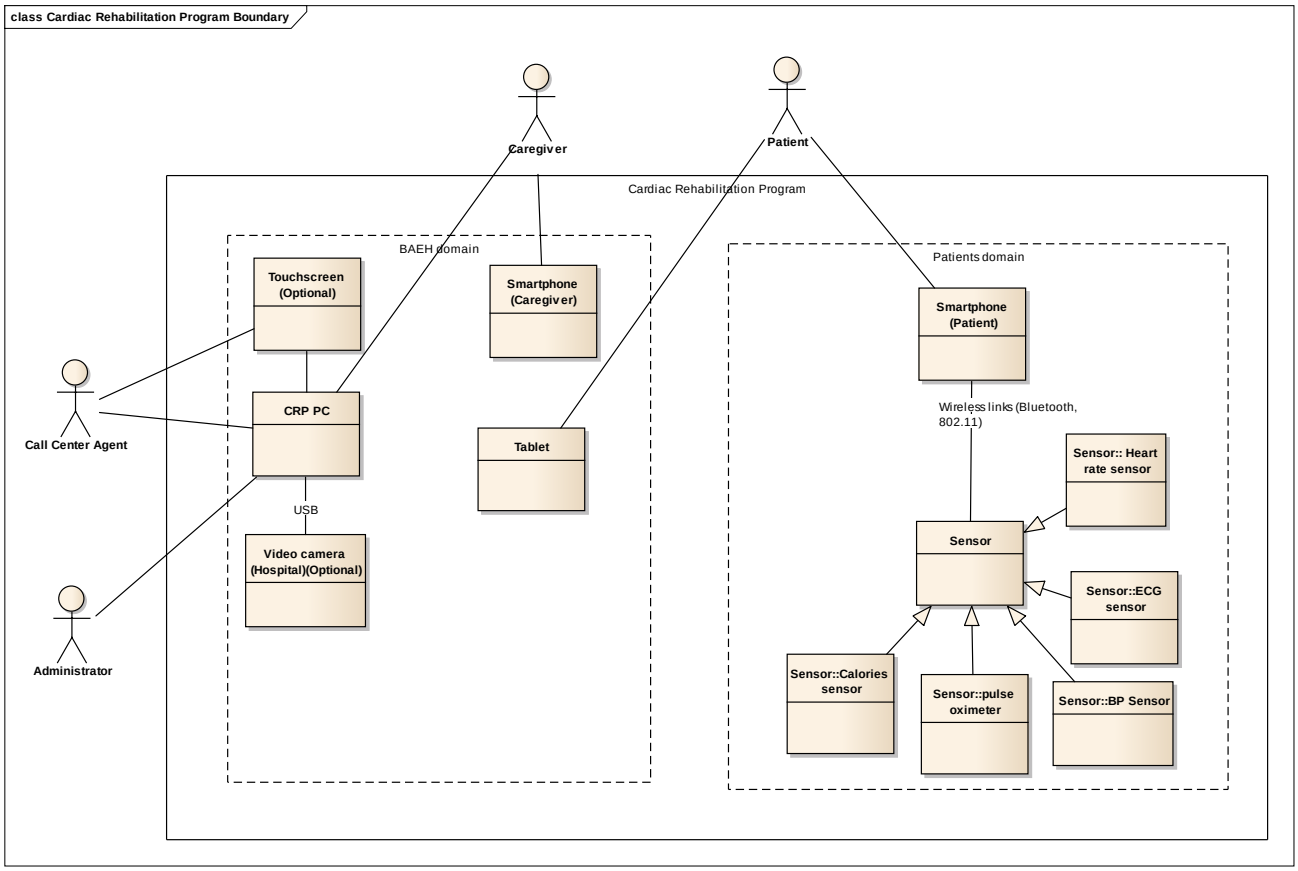


Figure 72: System boundary of the CRP solution.

The following figures and tables give an overview of the systems, artefacts, and interfaces that make up the system boundary of the CRP solution.

Figure 73: Sensors: BASIS watch, Nonin pulse oximeter, Zephyr Bioharness, A&D Blood Pressure Meter UA-767PBT-C40

Table 14: Measurements performed by devices

Device name	ECG	Heart rate	Blood pressure	Calories Burned	Pulse oxiometry
BASIS watch		x		x	
Nonin pulse oximeter					x

Zephyr Bioharness	x	x		x	
A&D Blood Pressure Meter UA-767PBT-C40			x		

Figure 74: Left: smart phone for Patient – CRP interaction. Right: tablet for patient – CRP interaction and CRP PC with CRP hospital app.

Table 15: Systems, artefacts, and interfaces that make up the system boundary of the CRP solution.

Name	Description	Expectations on Solution
Sensors	Each patient is equipped with a set of sensors for measuring vital life parameters: diastolic and systolic blood pressure (BP), heart rate (HR), Oxygen saturation (SpO2), ECG, caloric intake, weight. Sensors should enable wireless (Bluetooth) transmission of measurements to the patients' mobile device (Android Smartphone). Devices to be used: • BASIS wrist watch, capable of transmitting 24h the heart rate, burned calories • Pulse oximeter in order to determine the O2 saturation of the patient in the morning, in the evening, pre and post exercise or on alarms • Zephyr Bioharness chest strap band worn during effort with attached electrodes capable of transmitting real-time ECG, HR, RR, calories burned, with a built in accelerometer • A&D Blood Pressure Meter UA-767PBT-C40 in order to determine the BP of the patient in the morning, in the evening, pre and post exercise or on alarms	The solution will enable daily monitoring of basic patients' vital signs during inpatient period and after discharging from hospital. The solution will enable gathering locally (within patients' domain) and transmitting gathered life parameters data to the hospital domain. The solution should enable user friendly data visualization and aggregation functions. The set of sensors should be easy to use for the patient (limited number of buttons, information on LCD screen etc.). The best solution would be to use one sensor platform (one device) enabling monitoring of all (or most of) required vital signs.
Tablet	During the inpatient period each patient will be equipped with a 10'' tablet (Android OS based). Min. req. for tablet: 1280x800 display resolution, LED backlight, 8 GB flash memory, 1 GB DDR2 RAM, 1Ghz, 802.11 b/g/n Bluetooth 2.0, 1 megapixels front facing camera, Android 4.0 supported, microphone, speaker, 6 hours run time	The tablet will be used for viewing educational videos related to preventing and rehabilitation of cardiac diseases.

	on battery, USB interface.	
Smartphone	Each patient will be equipped with an Android operating smartphone. Also the doctors will have a smartphone with the same characteristics. Specifications: display ~4 inches; processor>1GHz; memory >512 RAM; secondary video camera; battery ~ 2000 mAh.	For patients the smartphone will be the connectivity solution within patient domain enabling bidirectional communication with the medical personnel, gathering and transmission of life parameters measurements and subjective patient condition data. Will be connected to the Internet. For doctors will be used to verify the stat of the patient and to be notified by alarms.
CRP Patient App	FI-STAR CRP application for patients, installed on patient's smartphone. It will be an Android OS application.	It will enable wireless communication with vital signs sensors, gathered data visualization.
CRP Doctors App	FI-STAR CRP application for doctors, installed on Medical personnel smartphones	It will enable patients' vital signs visualization, browsing patients' remote treatment history record, modifying medical or nutritional treatment plan, notifying the patient. It will be an Android OS application.
CRP Hospital App	FI-STAR CRP application for hospital, installed on Medical personnel PC.	It will enable patient's vital signs visualization, browsing patient's remote treatment history record, modifying medical or nutritional treatment plan, notifying the patient. It will be a Windows application.
CRP PC	Standard PC workstation (or laptop) provided for accessing and monitoring patient data through legacy IT systems.	Hardware for CRP Hospital App. Hardware deployment environment
CRP Server	Specialized server for hosting the cloud part of the system.	It will provide secured hosting of the patients data. It will offer secured access to patient data.
Touchscreen (optional)	Big (>24'') touchscreen enabling manipulation on CRP Hospital App	Hardware manipulation interface for CRP Hospital App.
Video camera	Standard USB Web video camera	Enables patients to see medical personnel during video tele-consultations or alarms.

6.2.4 Data Flow

The following section gives an overview of how the CRP solution is intended to be used within the overall workflow. Diagram below (Figure 75-Figure 76) that describes the data flows across the system boundary and among the applications that the solution integrates.

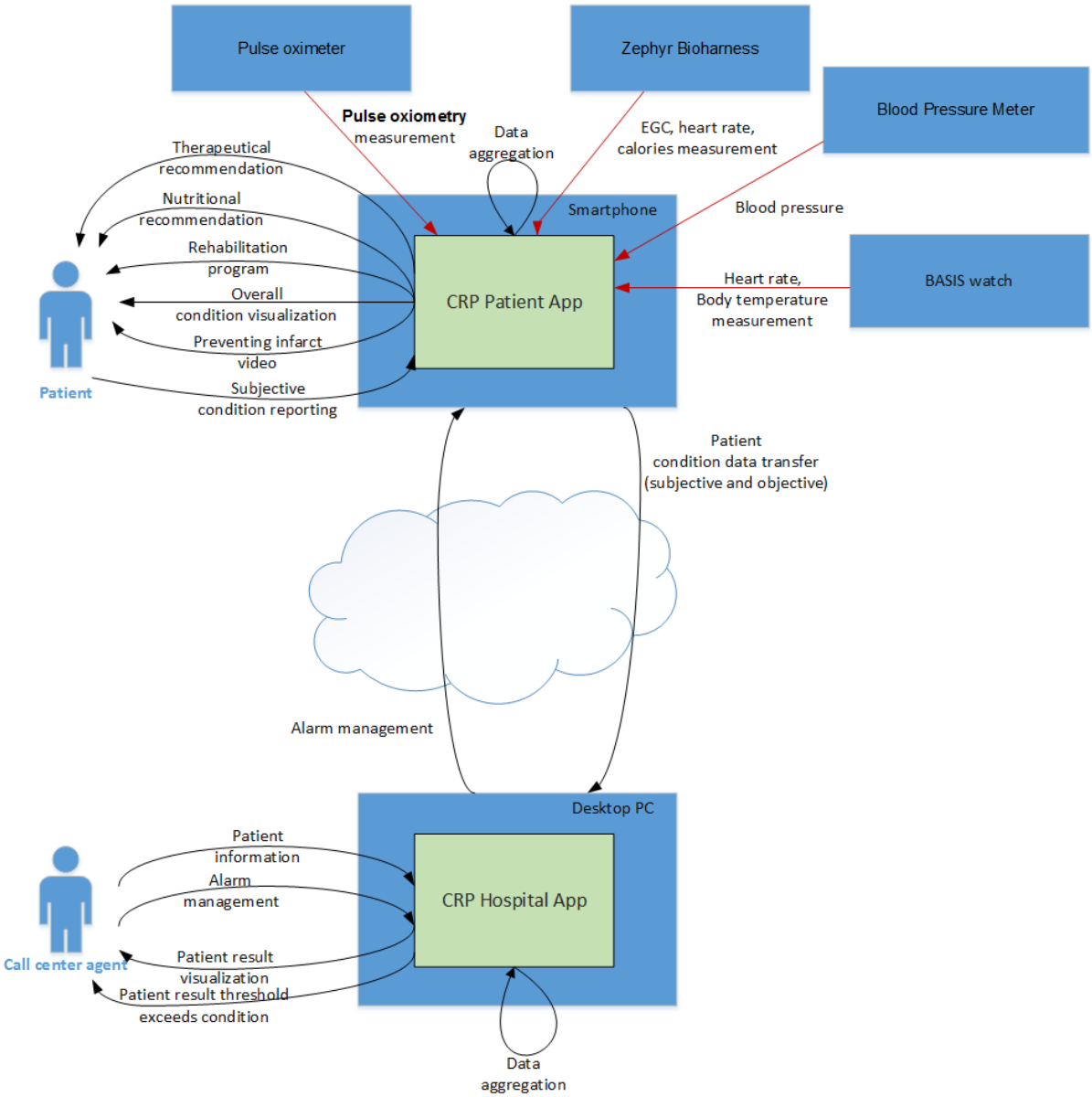


Figure 75: Overview of the patient-call center agent relation

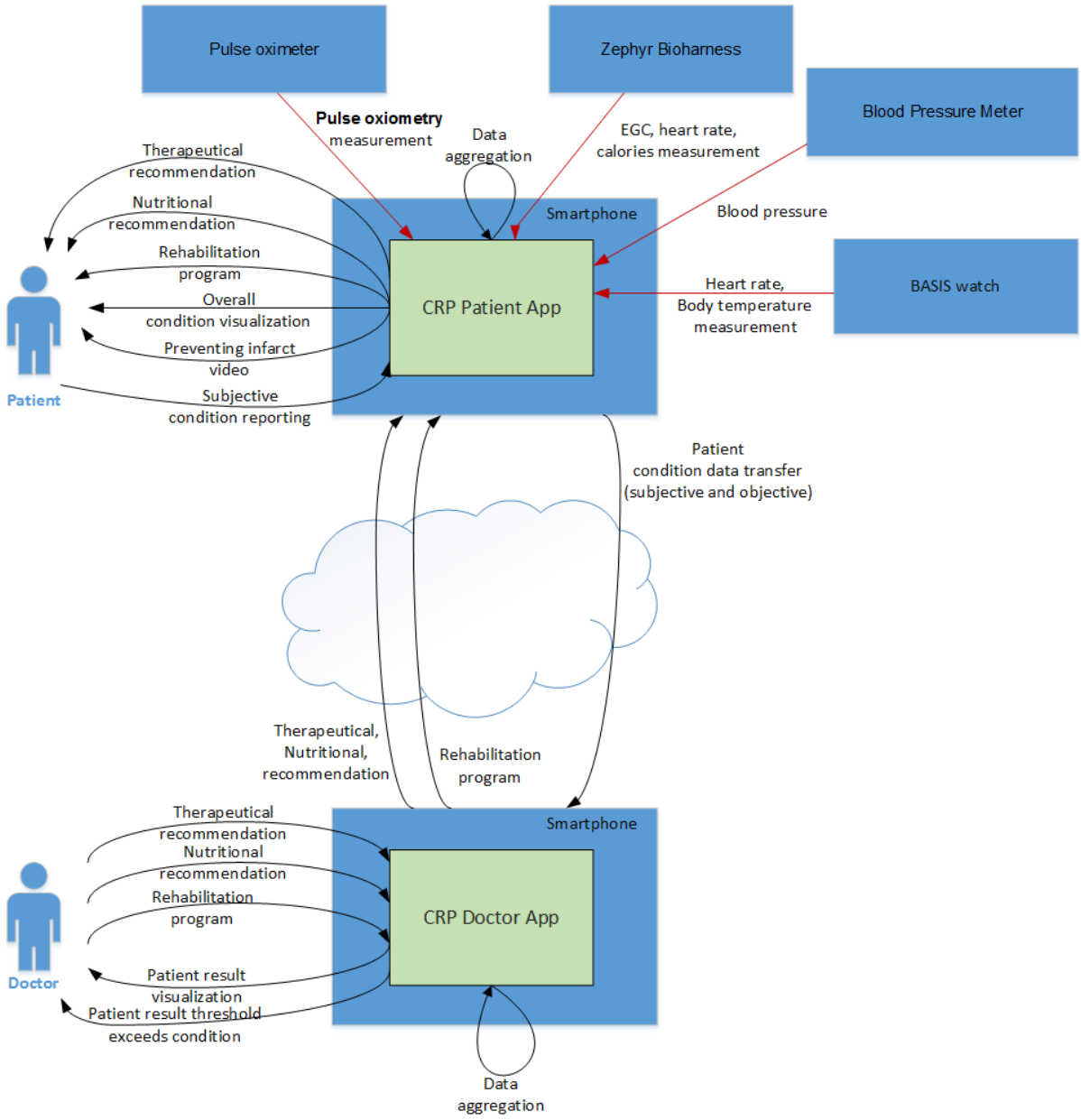


Figure 76: Overview of the patient-doctor relation

6.2.5 Other Stakeholders

The following table defines stakeholders who state requirements for the FI-STAR solution, but do not use it or interface with it.

Table 16: Other stakeholders

Name	Description	Expectations on Solution
Patient family TBD	The close relatives of the patient.	Easy to use and enjoyable. Increase the quality of life of the patient. Help him overcome his fears regarding his medical condition. Reintegrating the patient faster

		in the society.
Romanian Society of Cardiology TBD	Non-profit and apolitical professional and scientific association of cardiologists and physicians with other specialties, involved in cardiology practice and research. The aims of RSC are: • to improve cardiovascular prevention and therapy in Romania, • to promote valuable scientific research in basic, clinic and epidemiologic fields of cardiology, both within the country and abroad, • to disseminate the most recent scientific information, • to help public health authorities in elaborating health programs, based on epidemiologic data collected from national and European Registries, • to promote the training and scientific excellence of young cardiologists.	Increase the quality of life of the patient Reduce the rate of future cardiovascular (CV) events Reduce to medical costs of CV diseases Reintegrating the patient faster in the society
Romanian National Health Assurance Institution TBD	Ensures a consistent and coordinated health insurance system, monitors the effective collection and use of funds, and covers the health care needs of individuals through the availability of funds.	Reduce the rate of future CV events Reduce to medical costs of CV diseases

6.3 FI-STAR Value Case

Cardiovascular diseases are the main cause of mortality in almost all EU member states, accounting for 36% of all deaths in the region in 2010. They cover a range of diseases related to the circulatory system, including ischemic heart disease (known as IHD, or heart attack) and cerebro-vascular disease (or stroke). Together, IHD and stroke comprise 60% of all cardiovascular deaths, and caused more than one-fifth of all deaths in EU member states in 2010.

Ischemic heart disease is caused by the accumulation of fatty deposits lining the inner wall of a coronary artery, restricting blood flow to the heart. IHD alone was responsible for 13% of all deaths in EU member states in 2010.

Also another issue is that cardiovascular (CV) conditions consume the highest amounts of financial funds from every European National Health system.

So as many studies concluded: the best way to reduce the rate of CV diseases is throw efficient and rapid primary or secondary prevention.

UMFCD aims at developing new software, which, with the help of the existing hardware, could significantly improve the efficacy and outcomes of these secondary prevention programs.

The outcomes will be:

- significant reduction in the Europe-wide costs associated with cardiovascular disease
- reintegrate the patient faster in the work space and increased work productivity
- enable patients to return to activities of daily living within the limits imposed by their disease
- offset deleterious psychological and physiologic effects of CV diseases like anxiety of fear of performing daily life activities
- time management: medical personnel will be able to monitor patients vital signs and adjust treatment faster reducing the time necessary for face to face consultations and monitoring during physical activity.

Figure 77 gives an overview of these goals and how they are achieved with the CRP solution.

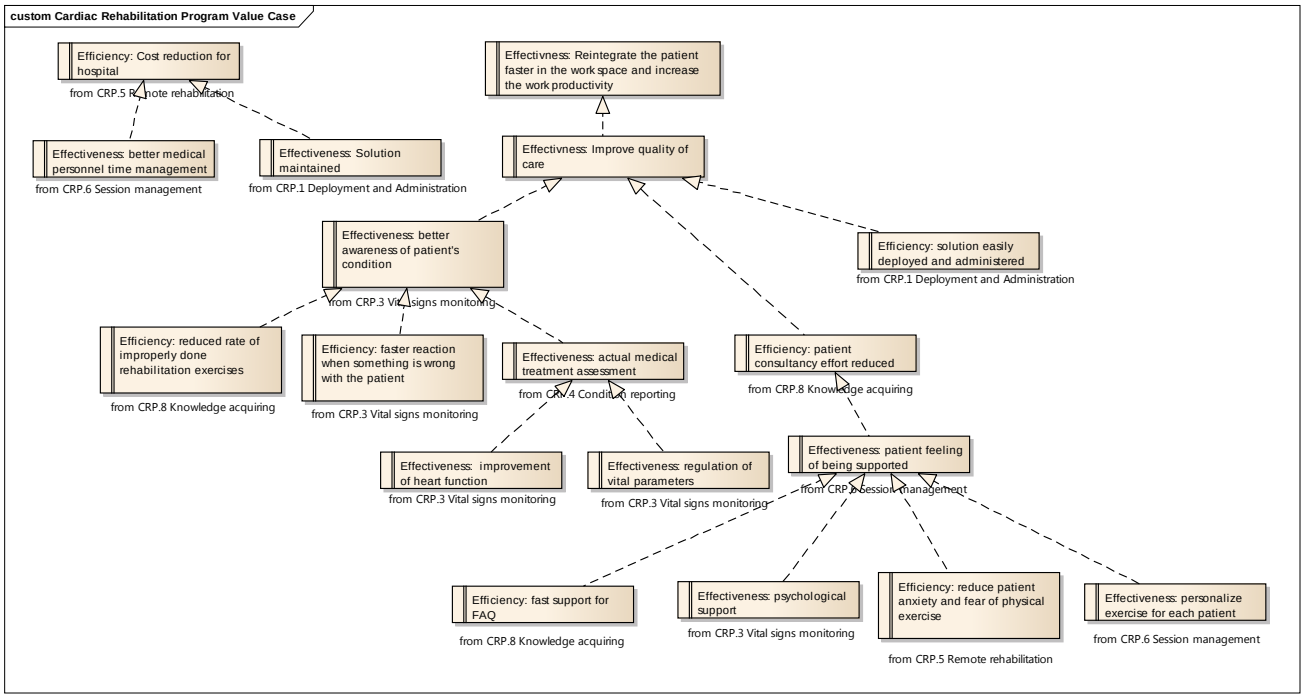


Figure 77: Goal forest explaining how the Cardiac Rehabilitation Program solution creates value for the FI-STAR use case stakeholders.

6.4 FI-STAR Solution Overview

The CRP will provide a set of features (groups of requirements that belong together) to support the use case stakeholders. Figure 78 gives an overview and defines priorities in terms of minimal scope (alpha prototype for month 12), target scope (beta prototype for month 24), and enhanced scope (options) of the solution. Each feature is specified in more detail in the following subsections.

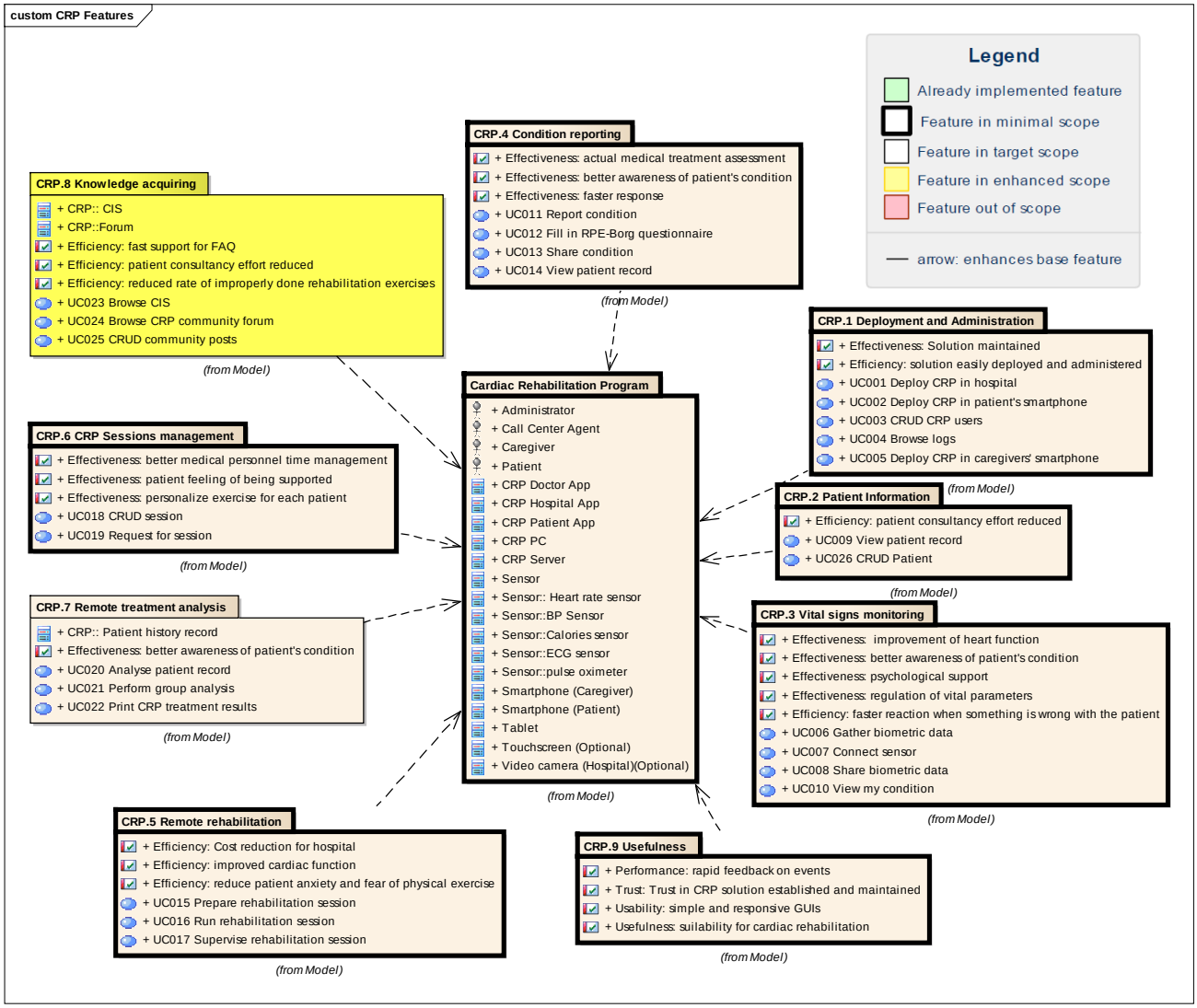


Figure 78: Feature tree of Cardiac Rehabilitation Program

6.4.1 Domain Model

Figure 79 gives an overview of the central elements of the data model.

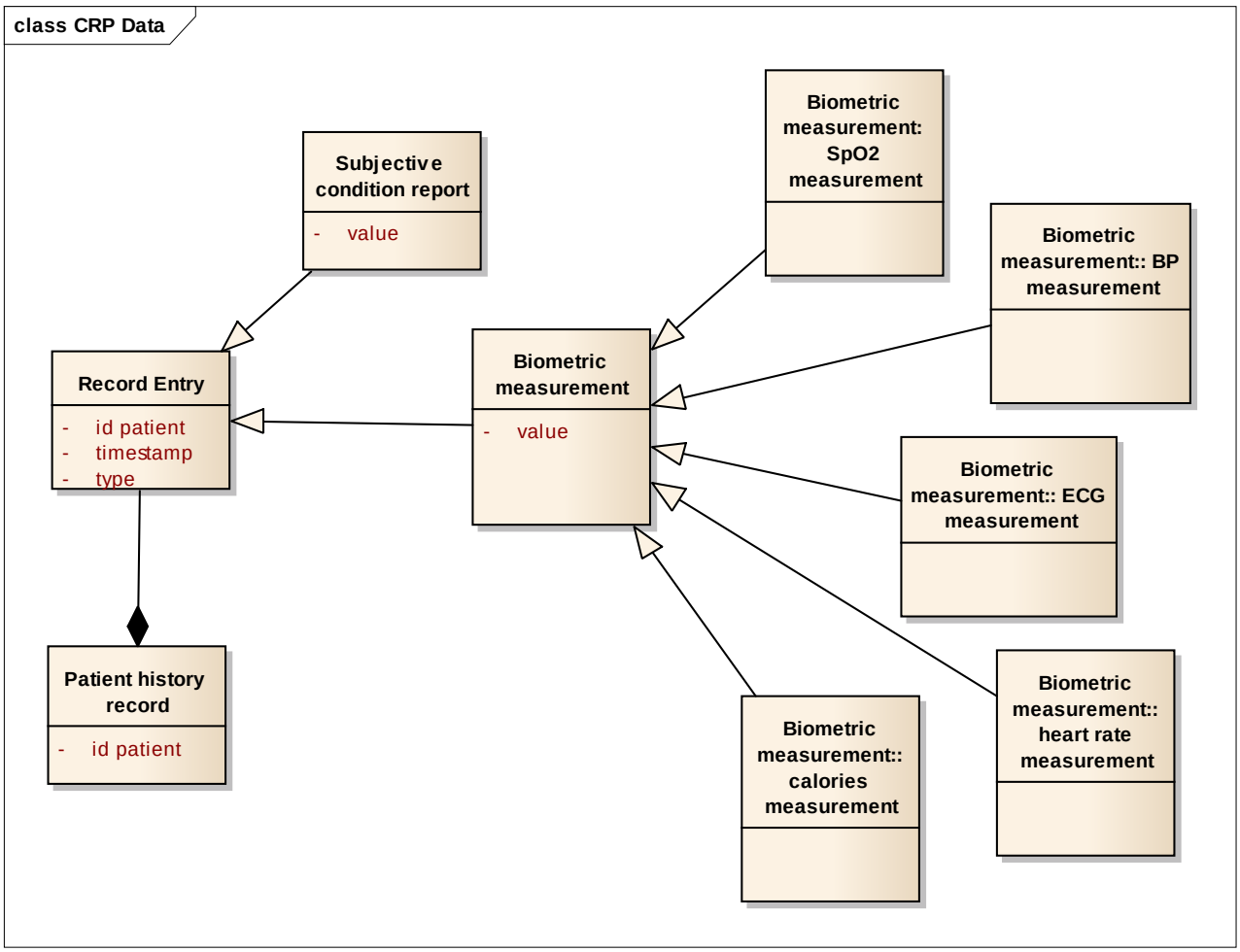
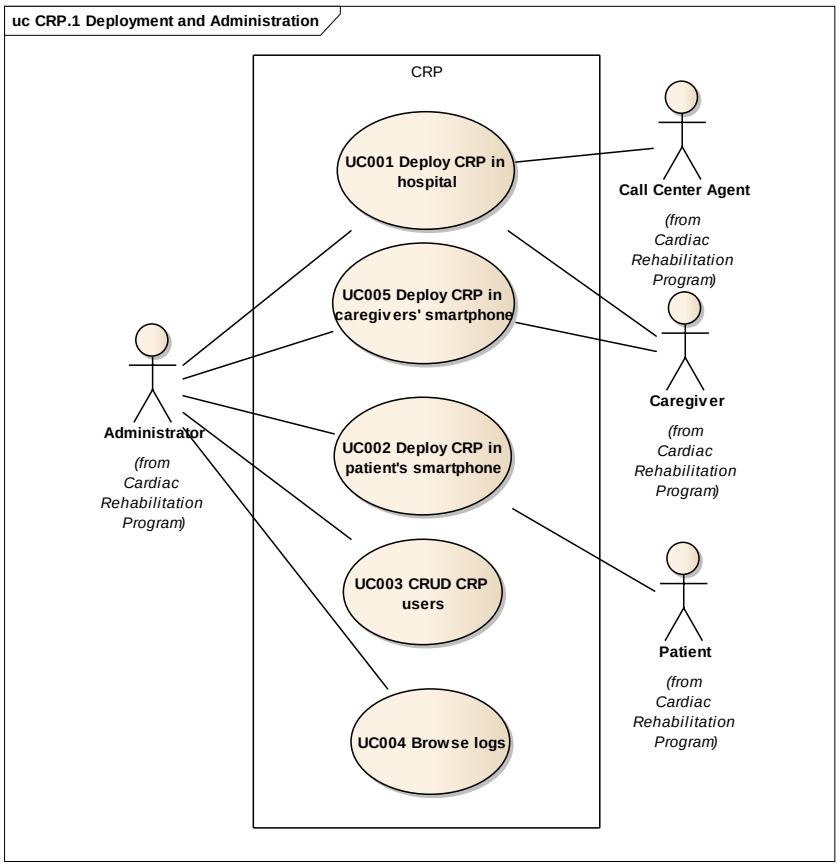


Figure 79: Central elements of the Cardiac Rehabilitation Program data model

6.4.2 Features

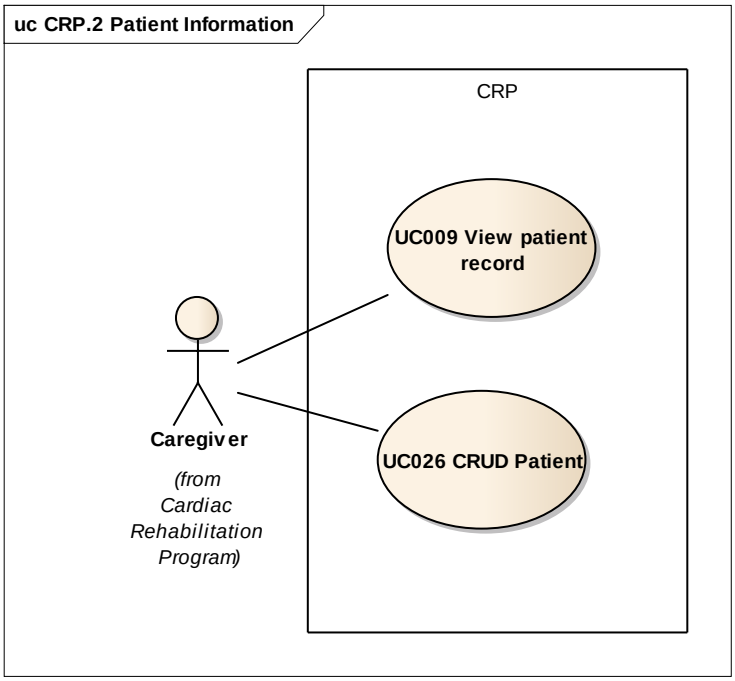
6.4.2.1 Feature CRP.1 Deployment and Administration

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: solution easily deployed and administered • Effectiveness: solution maintained • Context: users administered • Context: FI-WARE instances and connectivity administered Sub-goals: • Effectiveness: FI-WARE instances and connectivity administered • Effectiveness: solution users administered External interfaces: • From CRP Patient App (HMI) to Patient • From CRP Doctor App (HMI) to Medical personnel • From CRP Hospital App (HMI) to Medical personnel • From CRP Hospital App (HMI) to Administrator Use Cases:

	• Deploy CRP in hospital • Deploy CRP in caregivers' smartphone • Deploy CRP in patient's smartphone • CRUD CRP users • Browse logs 
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

6.4.2.2 Feature CRP.2 Patient Information

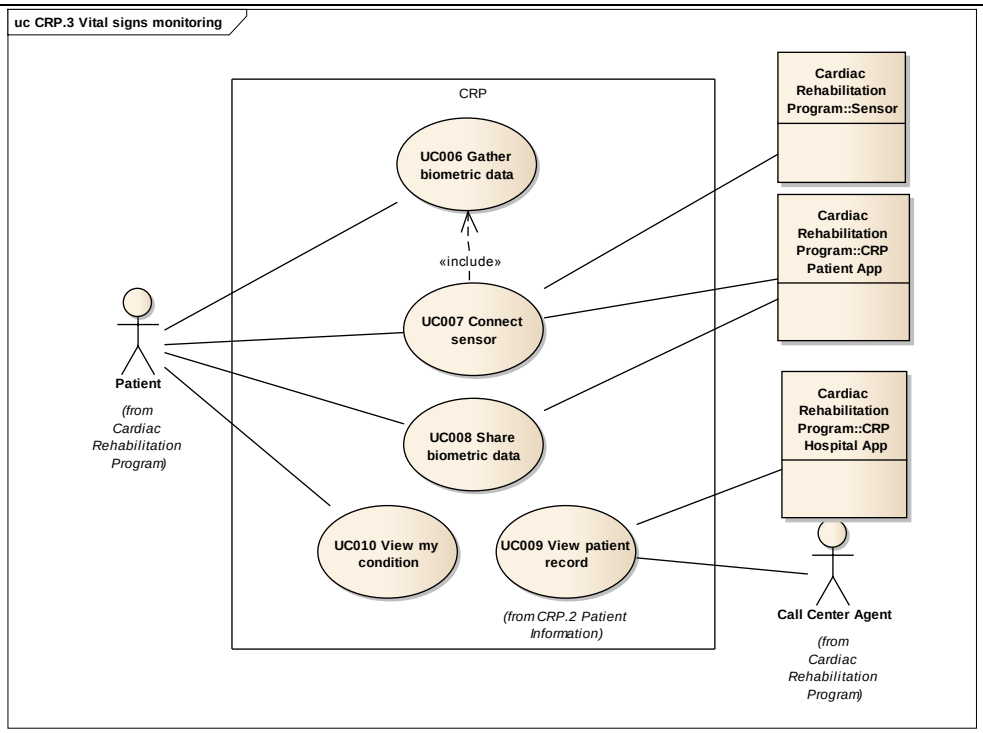
Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: patient consultancy effort reduced • Risk mitigation: patient safety • Risk mitigation: correct use of products • Risk mitigation: correct timing of drug use • Usability: easy to use External interfaces: • From Medical Personnel to CRP Hospital App Use cases • View patient record • CRUD Patient

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

6.4.2.3 Feature CRP.3 Vital signs monitoring (objective data acquisition)

The feature CRP.3 Vital signs monitoring provides the Medical personnel with the ability to obtain current, vital signs measurements incoming from remote sensors.

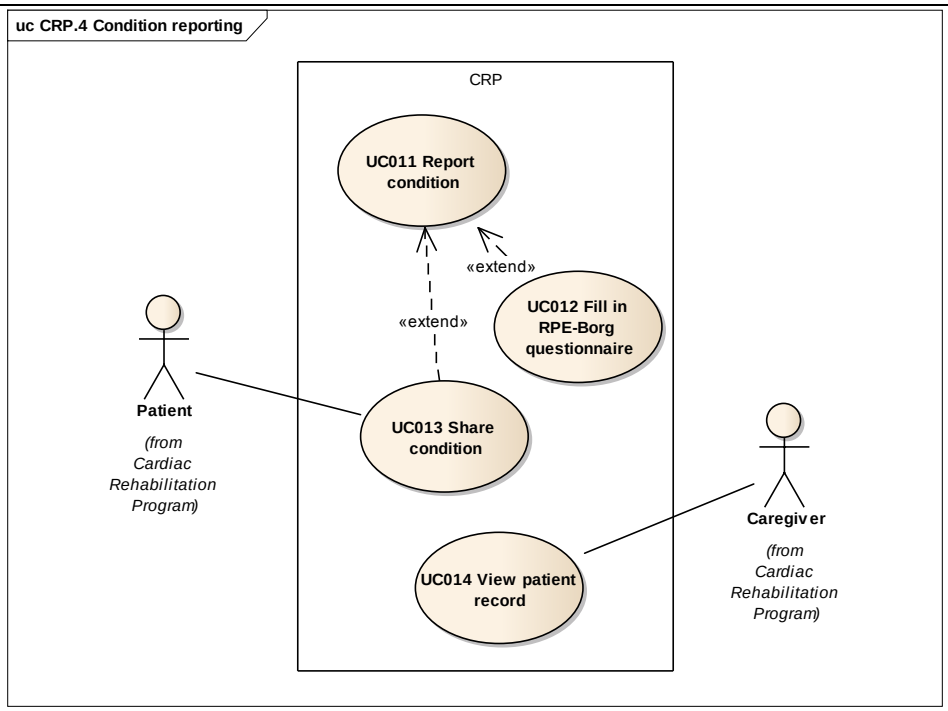
Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: better awareness of patient's condition • Efficiency: faster reaction when something is wrong with the patient • Precision: more complete data collected (better data resolution) • Risk mitigation: treatment documented • Effectiveness: improvement of heart function • Effectiveness: regulation of vital parameters • Effectiveness: psychological support External interfaces: • From Sensor to Patient • From CRP Patient App (HMI) to Patient • From CRP Hospital App (HMI) to Medicalpersonnel • From CRP Doctors App (HMI) to Medical personnel Use Cases: • Gather biometric data • Connect sensor • Share biometric data • View my condition • View patient record

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

6.4.2.4 Feature CRP.4 Condition reporting (subjective data acquisition)

Condition reporting provides the Medical personnel with the ability to obtain current, perceived by patient subjective condition (RPE-Borg scale) or alarm notifications regarding any particular symptoms felt.

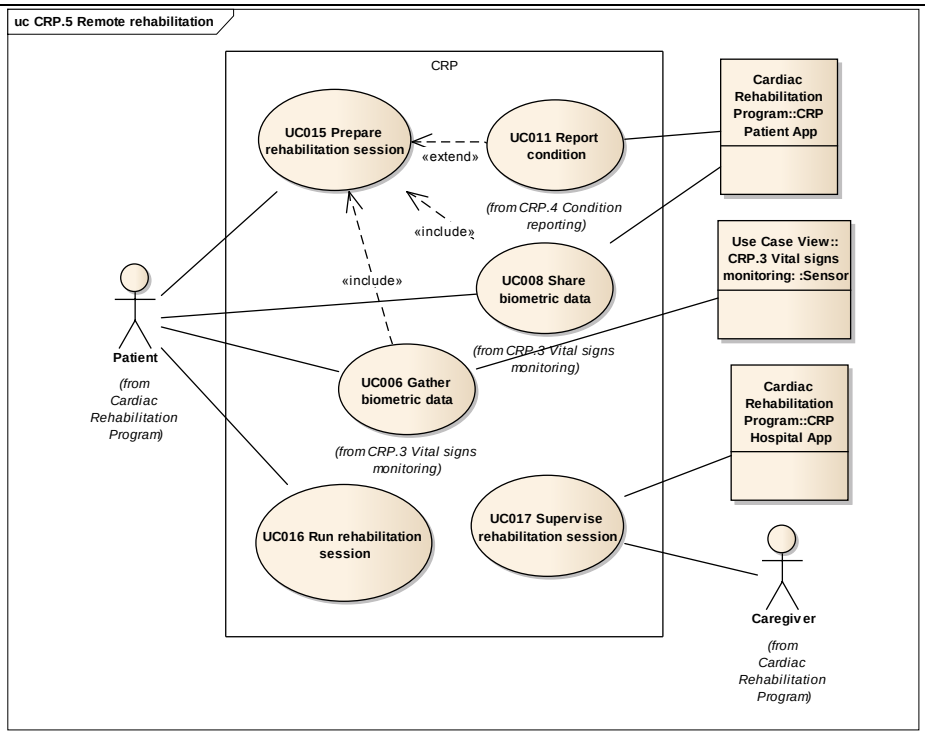
Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: better awareness of patient's condition • Risk mitigation: treatment documented • Effectiveness: actual medical treatment assessment • Effectiveness: faster response External interfaces: • From CRP Patient App (HMI) to Patient • From CRP Hospital App (HMI) to Medical personnel Use Cases: • Report condition • Fill in RPE-Borg questionnaire • Share condition • View patient record

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

6.4.2.5 Feature CRP.5 Remote rehabilitation

The feature CRP.5 Remote rehabilitation provides the Medical personnel with the ability to remotely supervise patients at home rehabilitation sessions and view current patient condition (both perceived and objectively measured).

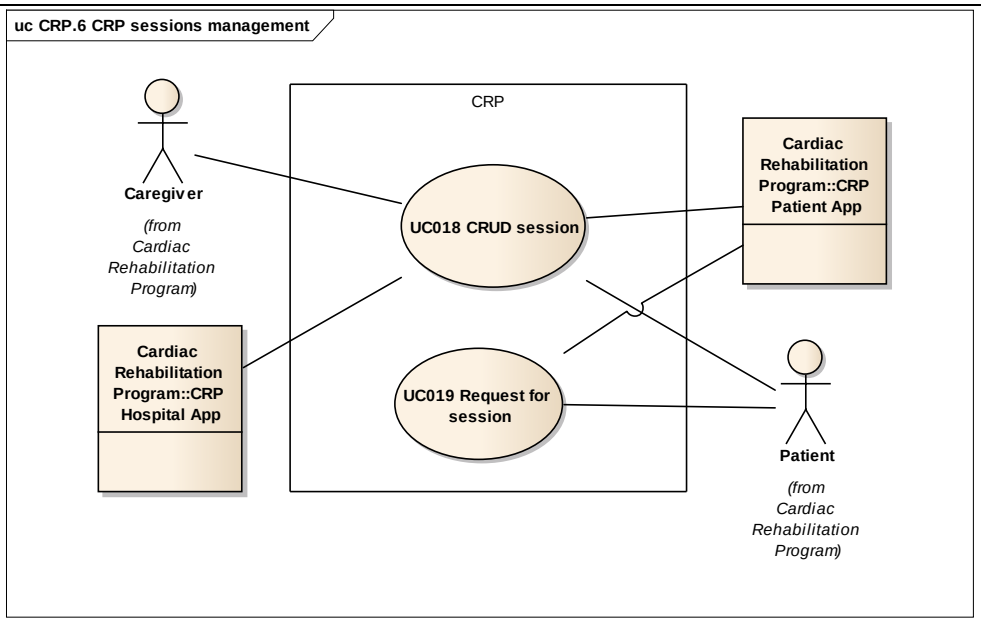
Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: improved cardiac function • Efficiency: reduce patient anxiety and fear of physical exercise • Efficiency: Cost reduction for hospital External interfaces: • From Sensor to Patient • From CRP Patient App (HMI) to Patient • From CRP Hospital App (HMI) to Medical personnel Use Cases: • Prepare rehabilitation session • Report condition • Share biometric data • Gather biometric data • Run rehabilitation session • Supervise rehabilitation session

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

6.4.2.6 Feature CRP.6 CRP sessions management

The feature CRP.6 sessions management provides the Medical personnel with the ability to schedule remote rehabilitation sessions.

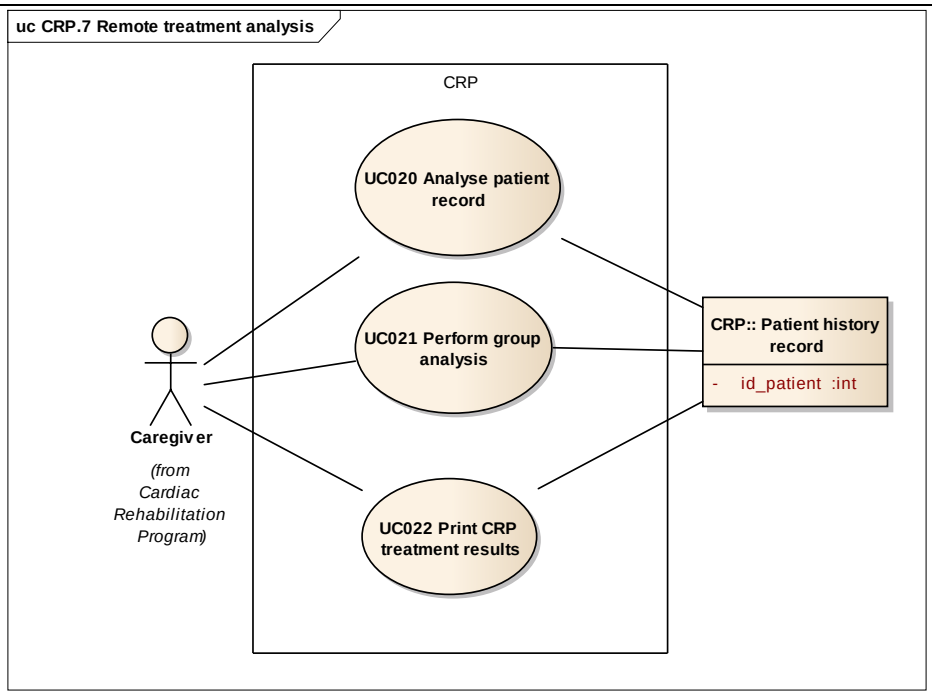
Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: better medical personnel time management • Effectiveness: patient feeling of being supported • Effectiveness: personalize exercise for each patient External interfaces: • From CRP Patient App (HMI) to Patient • From CRP Hospital App (HMI) to Medical personnel Use Cases: • CRP CRUD session • Request for session

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

6.4.2.7 Feature CRP.7 Remote treatment analysis

The feature CRP.7 Remote treatment analysis provides the Medical personnel with the ability to analyse patient's treatment with the use of CRP, compare patient results, and visualize history of treatment (including trends in changing perceived patient condition as well as subjective vital signs measurements).

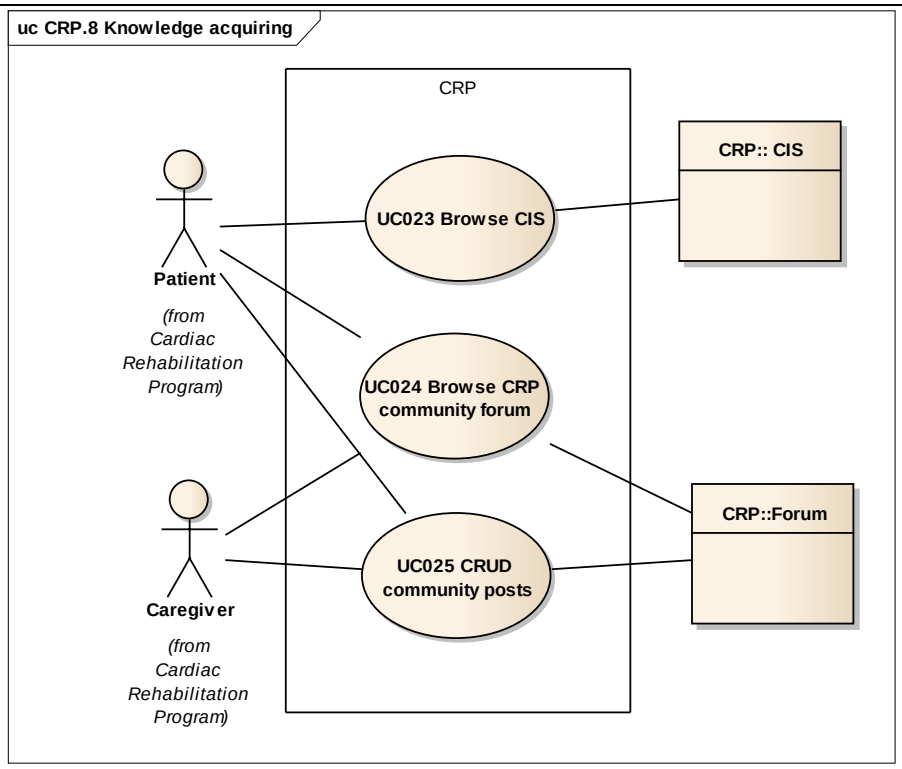
Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: better awareness of patient's condition • Precision: medical and nutritional treatment real-time control External interfaces: • From CRP Hospital App (HMI) to Medical personnel Use Cases: • Analyse patient record • Perform group analysis • Print CRP treatment results

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

6.4.2.8 Feature CRP.8 Knowledge acquiring

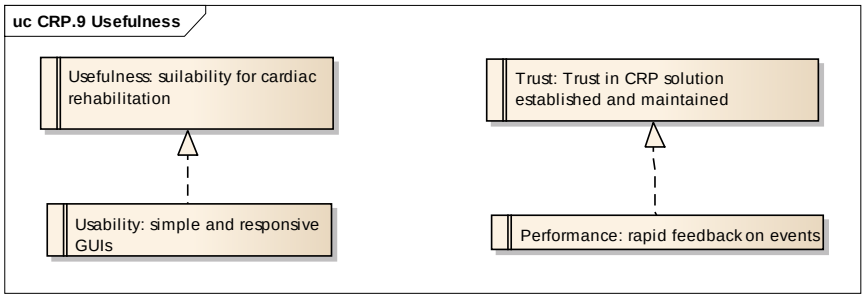
The feature CRP.8 Knowledge acquiring provides the Patient with the ability to get more knowledge about his or her condition through a database of video clips related prevention and management of CV diseases.

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: patient consultancy effort reduced • Efficiency: fast support for FAQ • Efficiency: reduced rate of improperly done rehabilitation exercises External interfaces: • From CRP Patient App (HMI) to Patient • From CRP Hospital App (HMI) to Medical personnel Use Cases: • Browse CIS (CRP Information System) • Browse CRP community forum • CRUD community posts

	
Comments	To be validated with prototype

6.4.2.9 Feature CRP.9 Usefulness

The feature CRP.9 Usefulness assures good-enough quality of the solution for cardiac rehabilitation.

Addressed stakeholder interests and expectations	Goals to be achieved: • Usefulness: suitability for cardiac rehabilitation • Trust: trust in CRP solution established and maintained Quality requirements: • Usability: simple and responsive GUIs • Performance: rapid feedback on events 
Comments	To be validated with prototype

6.4.3 FI-STAR Solution-wide Requirements and Constraints

6.4.3.1 Constraints towards Enablers and Technology

ID	Constraint (Title and Short Description)	Rationale and comments
CRP.01	Google Android platform to be used for the implementation of the Cardiac Rehabilitation Patient App forces biometric devices compatibility with such platform. Not all devices allow data exchange with Android solution.	Android is a free, lightweight and popular in Europe technology for mobile applications. Reusability of software components incoming from other FI-STAR use cases solutions.
CRP.02	Patients qualified for the use case trails need to have at least a GSM 3G connections.	The coverage of the GSM 3G networks is not country all wide.

7 Operating Theatre Monitor for Operation Consumables Tracking in Munich, Germany

This chapter gives an overview of a FI-STAR solution that is intended to be built to support the FI-STAR use case. The chapter covers the goal/purpose of the FI-STAR solution, stakeholders and their interests/expectations, the application and their features that are integrated into the FI-STAR solution to support these interests/expectations, and the FI-STAR solution-wide requirements and constraints. The appendix can be used to capture any other material, including business processes, glossary, description of the as-is situation, problems with current solutions, storyboards, and examples of artefacts and photographs of usage context.

The vision chapter is intended as a starting point for subsequent detailed requirement engineering. The features are used to establish an overview of the FI-STAR solution's requirements that then will be engineered just-in-time before the relevant development starts. The features should be specified by explaining how the concerned FI-STAR application will support the corresponding FI-STAR stakeholders' interests and expectations. The vision chapter should be updated as the understanding of the FI-STAR solution and of its aims and objectives evolve.

Future uses of this vision chapter will be to establish personas for target user segmentation and user experience engineering, traceability to release and project planning, application and enabler design and development, and quantification of quality requirements and testing, definition/monitoring of KPI, and analyzing commonality/variability across applications. In addition, this vision chapter will refer to relevant specialty requirements.

7.1 FI-STAR Solution Positioning

The following captures the essence of the FI-STAR solution, including the problem it addresses and the key idea of solving the problem.

7.1.1 Problem Statement

The problem of	forgetting consumables like towels in the operated patient body
affects	patients, respectively the clinic
the impact of which is	severe complications, respectively litigations and high insurance costs
a successful solution would be	to reduce the likelihood of consumable loss

7.1.2 Position Statement

For	surgeons and nurses
Who	operate patients
The (solution name)	Operating Theatre Monitor (OTM) is a FI-STAR cloud solution
That	tracks the use of consumables in an operation, enables its analysis, and automates reporting
Unlike	the current manual work
Our solution	increases the efficiency of the operation work, increases patient safety, and delivers decision-support for consumable planning and process improvement.

7.2 FI-STAR Use Case Stakeholders

The following users, interfacing systems, and other stakeholders are affected by the solution.

7.2.1 Users

Figure 80 provides an overview of the users of the Operating Theatre Monitor solution.

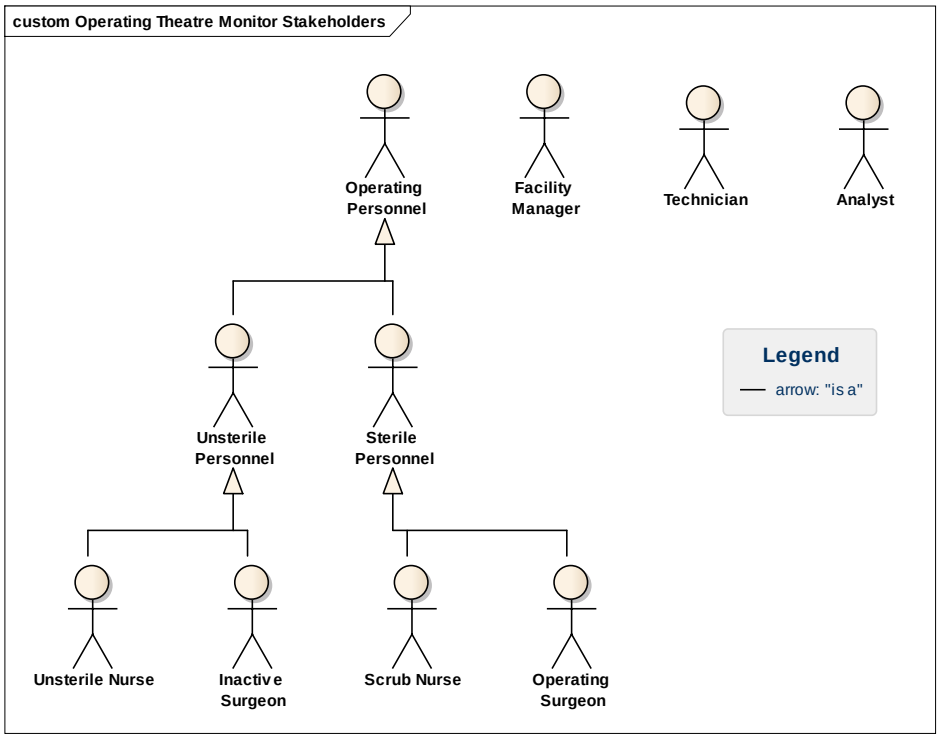


Figure 80: Users of the Operating Theatre Monitor solution

Figure 81 - Figure 83 give an overview of the workflow of the operating personnel from the preparation of consumables to operation to reporting.

Figure 81: Left: consumables prepared on instrument ray for the operation. Middle: consumables stock in the operation room and telephone handled by the unsterile nurse for outside communication. Right: stock of consumables in the anteroom of the operation room. All consumables have a bar code.

Figure 82: Left: 2 doctors and a scrub nurse in the sterile area during an operation. In front are the Mayo stands with the consumables ready for use in the operation. Right: hand-over of towels from the unsterile nurse to the sterile nurse. Operation reporting system is visible at the left border.

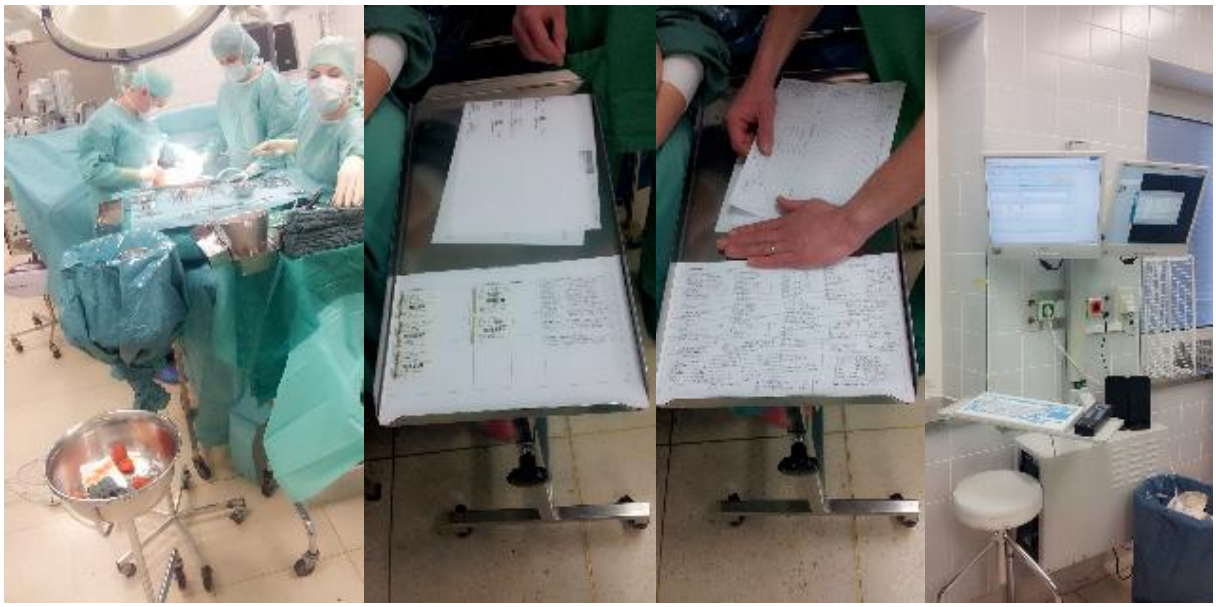


Figure 83: Left: wastebasket with used consumables. Middle-left and middle-right: sticker and tick-off lists for consumables used during operation. The lists are associated with the patient id and name. Right: reporting station with operation reporting system for electronic consumable reporting.

The following table describes the users in detail, including their background, role, and expectations.

Name Representative	**Description**	**Expectations on Solution**
Surgeon Dr. Michael Kranzfelder (TUM)	Works on the patient. Has overall responsibility for towels being removed from the patient. Wants to know that no consumable is left in the patient.	Safety: No consumables forgotten in patient. Efficiency: Reduced search for lost consumables. Safety: X-ray scanning avoided for consumable search. Effectiveness: decision-support for consumables planning. Safety: be alarmed when something is

		going wrong. Effectiveness: decision-support for consumables planning.
Scrub Nurse TBD	Does the logistics for surgeons in the sterile area of the operation. Requests more consumables from unsterile nurse.	Usefulness: suitability for operating theatre. Performance: rapid feedback on sensor events. Usefulness: suitability for operating theatre, including distance to monitor of up to 3 meters
Unsterile Nurse (anonymous nurse interviewed during operation at TUM) TBD	Sets up the equipment in the operation room. Does the logistics for the scrub nurse in the unsterile are of the operation and outside the operation room. Reports the consumables used during the operation, both on paper and in operation reporting system. The reports are double-checked by her supervisor. Has idle time during operation, where she does consumable reporting. Has very little time between operations. Is educated in the use of operation reporting system in and outside the operation room for consumable reporting. The nurse prefers to speak German, but is able to use English.	Efficiency: Total effort of an operation room engagement for the nurse to be reduced. • Efficiency: Rapid and easy setup of the equipment in the operation room. • Efficiency: Effort for counting all consumables to be reduced. Counting of towels alone not sufficient for efficiency gains. Trust: Trust in Machine is missing. How could a machine be more reliable than double-checked work performed by humans? • Performance: rapid feedback on sensor events. • Effectiveness, freedom from risk: correctness of recorded data assured. • Maturity: few faults. • Skills: ability to use OTM correctly. Clean room operability, including touch-screen use with gloves. Operability: Foolproof (erroneous use of dangerous commands avoided).
Technician Armin Schneider (TUM)	Adapts the equipment to the operation room. Does system administration and first-level support. Is educated in the clinical routines and the quality assurance checks for equipment used in the operation room.	Efficiency: Solution easily deployed and administered. Compliance: Standard operating procedures facilitated. Comfort: Fancy solution with Smart-Phones.
Analyst Armin Schneider (TUM)	Uses information generated by the operation room management system.	Effectiveness: information of relevance for process improvement to be collected. Effectiveness: decision-support for consumables planning.

7.2.2 Interfacing Systems and Artefacts

Figure 84 gives an overview of the system boundary of the OTM solution. The connectivity to the FI-STAR cloud is a concern of the solution architecture, hence omitted from the overview.

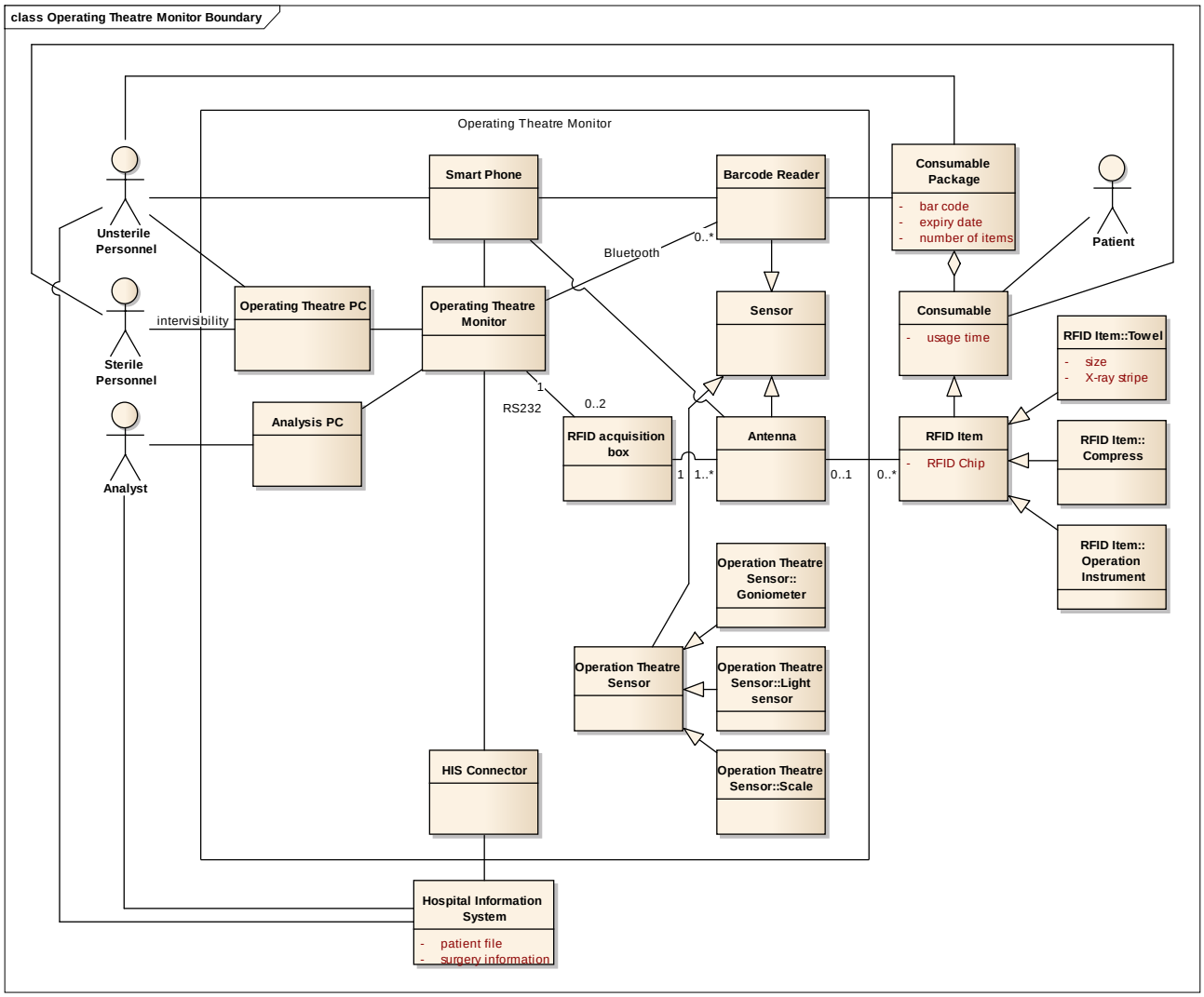


Figure 84: System boundary of Operating Theatre Monitor solution, including all interfaces to users, systems, and artifacts of the FI-STAR use case (notation inspired by Glinz et al (2002): "Object-oriented modeling with ADORA", Information Systems 27).

Figure 85-Figure 87 give an overview of the system, artifacts, and interfaces.

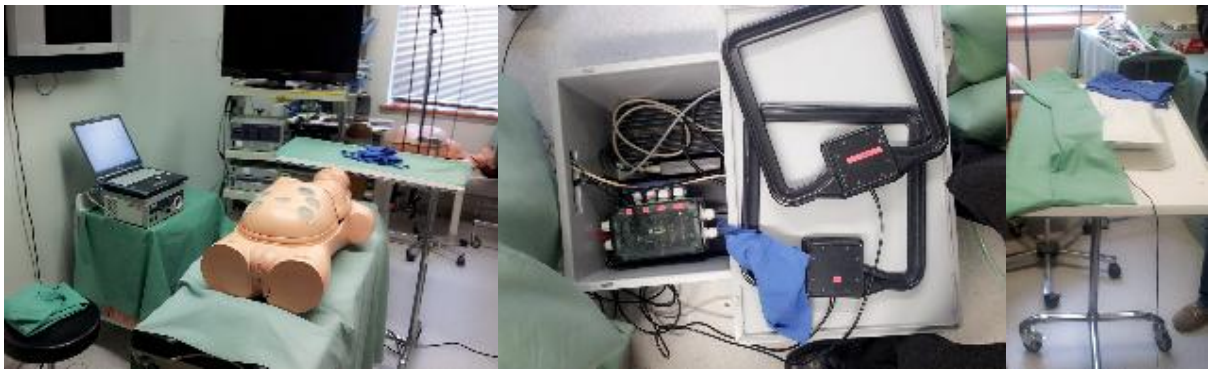


Figure 85: Left: OperationRoomManager laboratory with reporting station to the left, patient bed in the front, and Mayo stand to the back. Middle: data acquisition system to the left with 2 RFID antennas and one towel to the right. Right: RFID antenna on Mayo stand with towel and with towel package.

Figure 86: Left: Mayo stand fixture with integrated RFID antenna. Right: physical interface of RFID acquisition box for connecting antennas and the OTM PC.

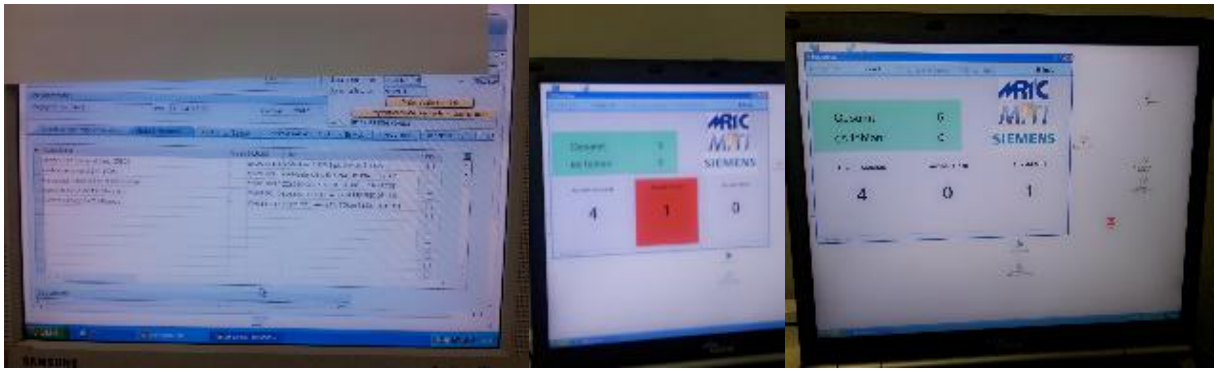


Figure 87: Left: extract of bill-of-materials used during operation (screenshot hospital information system SAP ISHR3). Middle: Towel Monitor reporting 4 towels on Mayo stand and one on patient bed. Right: Towel Monitor reporting 4 towels on Mayo stand and one in wastebasket.

The following table describes the interfacing systems and artifacts and related expectations on the solution.

Name Representative	**Description**	**Expectations on Solution**
RFID Acquisition Box with Antennas Thomas Jell (Siemens)	Prototype stage; not offered as a product yet. Connects 2-8 antennas to capture IDs of nearby RFID chips. The number of antennas needed grows with the size of the Mayo stand. Unclear whether regulations limit the emitted energy. Antennas emit maximum 12W. Each antenna can capture about 20 RFID tags per scan. The configurable scan cycle is currently set to 2 seconds. Optimal parameters to be determined. Distance measurement to RFID chips not possible today. 1-2 RS-232 interfaces to monitoring PC. Proprietary protocol. Readers, as well as Multiplexers and Antennas will be from FEIG, Germany. Documentation as well as an SDK are available. Data can also be provided via TCP/IP.	For each operation, the OTM is setup again. It would be good to have the antennas integrated into the Mayo stand. 3 seconds for RFID position update desirable.
Consumable	A consumable is used during the operation and then thrown away or recycled.	-

	Attributes: expiry date	
RFID Item (e.g. towel) Armin Schneider (TUM)	An RFID item is a consumable with an RFID chip. Contains an RFID chip for detection by an antenna. 1 cent per single-use transponder. 30 cents per washable transponder. Attributes: RFID chip with serial number, sterile status, and position. A towel is a RFID item. Rarely more than 100 towels needed per operation. The number of towels used during an operation gives an indication of operation complexity. A Towel is thrown away after use. Reuse by washing and sterilization is only relevant for research prototypes, but not clinical practice. A towel contains an X-ray stripe for detection by an X-ray scanner. Attributes: towel size.	An RFID chip may not be working or go blind: identify which one is not working and have audit possibility. TBD: towel producers have no business model established yet for towels with RFID chip.
Consumable Package (e.g. towel package) Armin Schneider (TUM)	Consumable packages have a bar code. Contained consumables are considered to be used as soon as the package is opened. Attributes: expiry date, bar code, number of items A towel package contains 3-5 towels.	-
Hospital Information System (HIS) SAP ISHR3 (TUM)	Documentation system for whole process of patient in clinic. Attributes: patient file with identification and record, surgery information with charge number of the instrument ray and consumables (e.g. “20 towels were used, then thrown away after operation”).	Interface not implemented yet. SAP provides connectors for connecting to an SAP solution. OTM should run on the same computer in the operation room as the hospital information system.
Barcode reader TBD	Patient wears voluntarily a barcode bracelet for identification	Identify patient with barcode and check whether barcode matches patient code stored in HIS.
Operation room sensors TBD	Types: Light sensor, Scales, Goniometer in patient bed TBD	TBD

7.2.3 Other Stakeholders

The following list describes other stakeholders that do not directly interact with the solution. The description includes background and role of these stakeholders and their expectations on the solution.

Name Representative	**Description**	**Expectations on Solution**
Patient TBD	Receives consumables applied by the surgeon during the operation. All consumable must have been removed after the operation.	Trust: information about patient is protected and access restricted. Safety: No consumables forgotten in patient. Safety: X-ray scanning avoided for consumable

	Carries a wrist band with a bar code.	search.
Developer Thomas Jell (Siemens)	Built the current solution with Microsoft Visual Studio. The rest was developed on project basis. RFID components were taken from another project. Current solution: • RFID is tracked. • Database keeps track of the RFID data.	Generic enabler should give access to antenna.
Product Manager Thomas Jell (Siemens)	Current solution is offered by ATOS.	Has many ideas how the current solution could be extended: Authentication, security, video streaming. We will do a system with much more functionality around operating theatre. See submitted use case proposal. • Focus first on towel use case, then expand to other use cases. • Patient flow in the clinic. Waiting times have to be analyzed and next functional department/operation room has to be informed if patient is in arrival. • Data must be in the private cloud. • Several iOS and Android devices as output devices. Major challenges: • Towels are more expensive (business case) • Reliability • Insurance fees are very high -> demonstrate that the system is avoiding accidents (reduce risk) • Insurance has interest of traceability for litigation of patients (audit trail). • Patient can demonstrate that operation team has done a failure (audit trail). • Sterilization/re-sterilization (how many times they can be re-use; how many times have they been used -> cleaning process). Only for research prototypes, not for normal operation, where consumables are thrown away. • KPIs that Armin formulated in the use case sheet (reduce time of patient in operation room, every 50th operation looks for towels takes 10'-30', uses X-ray which costs money and staff).
Solution Procurement Project Leader TBD	Responsible for procuring the solution for a hospital. Includes solution evaluation, integration, and migration work.	TBD
Regulation Armin Schneider	-	Compliance with following standards required: • MPG (medizinisches Produktegesetz):

(TUM)		hardware and software • VDE (Verein Deutscher Elektriker, VDE0600): elektrische Sicherheit für Medizingeräte • ISO80001: Application of Risk Management for IT-Networks Incorporating Medical Devices • ISO27000: Information Technology – Security Techniques – Information Security Management Systems • ISO/IEEE 11073: Health Informatics – Personal Health Device Comunication • DIN EN 62304: Medical Device Software – Software Life-cycle Processes • CEN/TC 251: Collection of Standards on Health Informatics for Health Interoperability • EN ISO 14971_ Medical Devices – Application of Risk Management to Medical Devices Each hospital has own Standard Operating Procedures that the solution needs to comply with.

7.3 FI-STAR Solution: Value Case

The Operating Theatre Monitor solution can create value by reducing the search for consumables (feature OTM.2), reducing the total effort of the nurses engaged in the operation (OTM.1, OTM.3, and OTM.5), avoiding patient complications (OTM.2 and OTM.5), enabling consumable planning (OTM.9), and enabling process improvement (OTM.4 and OTM.8). Figure 88 gives an overview of the value case in the form of a goal tree.

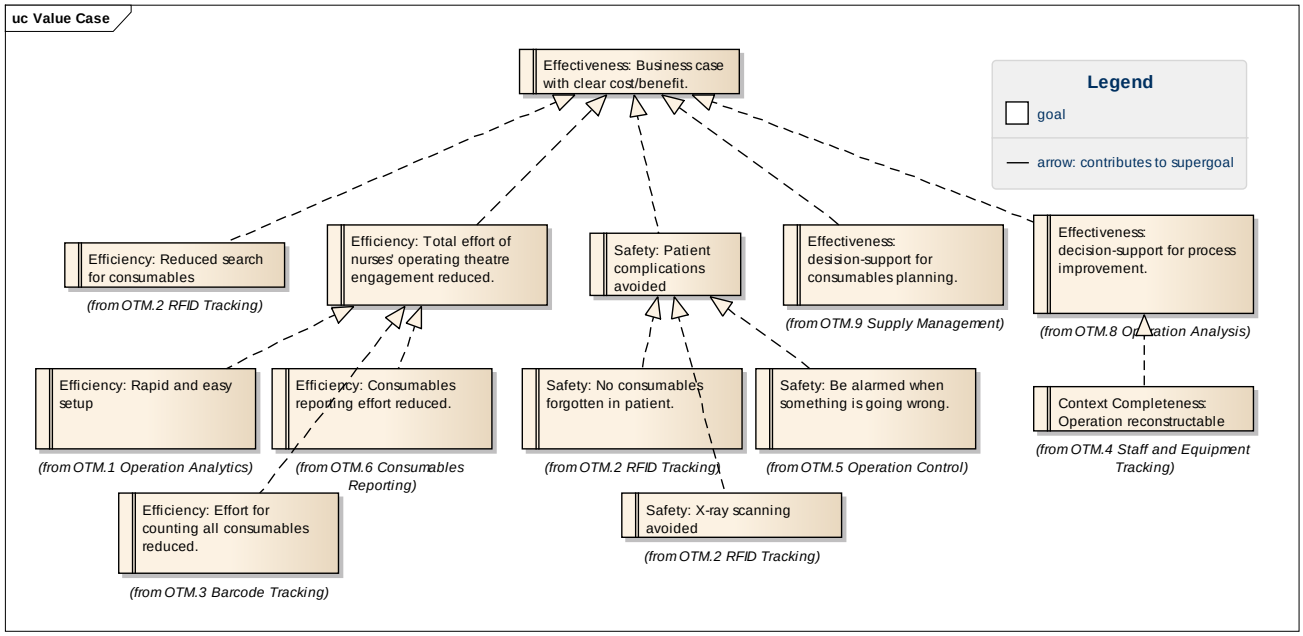


Figure 88: Goal tree explaining how the Operating Theatre Monitor solution creates value for the FI-STAR use case stakeholders (notation inspired by Chung et al (2000): Non-Functional Requirements in Software Engineering. Kluwer). The parentheses refer to features of the OTM solution.

7.4 FI-STAR Solution Overview

The Operating Theatre Monitor solution provides a set of features (groups of requirements that belong together) to support the use case stakeholders. Figure 89 gives an overview and defines

priorities in terms of minimal scope, target scope, and enhanced scope of the solution. Each feature is specified in more detail in the following subsections.

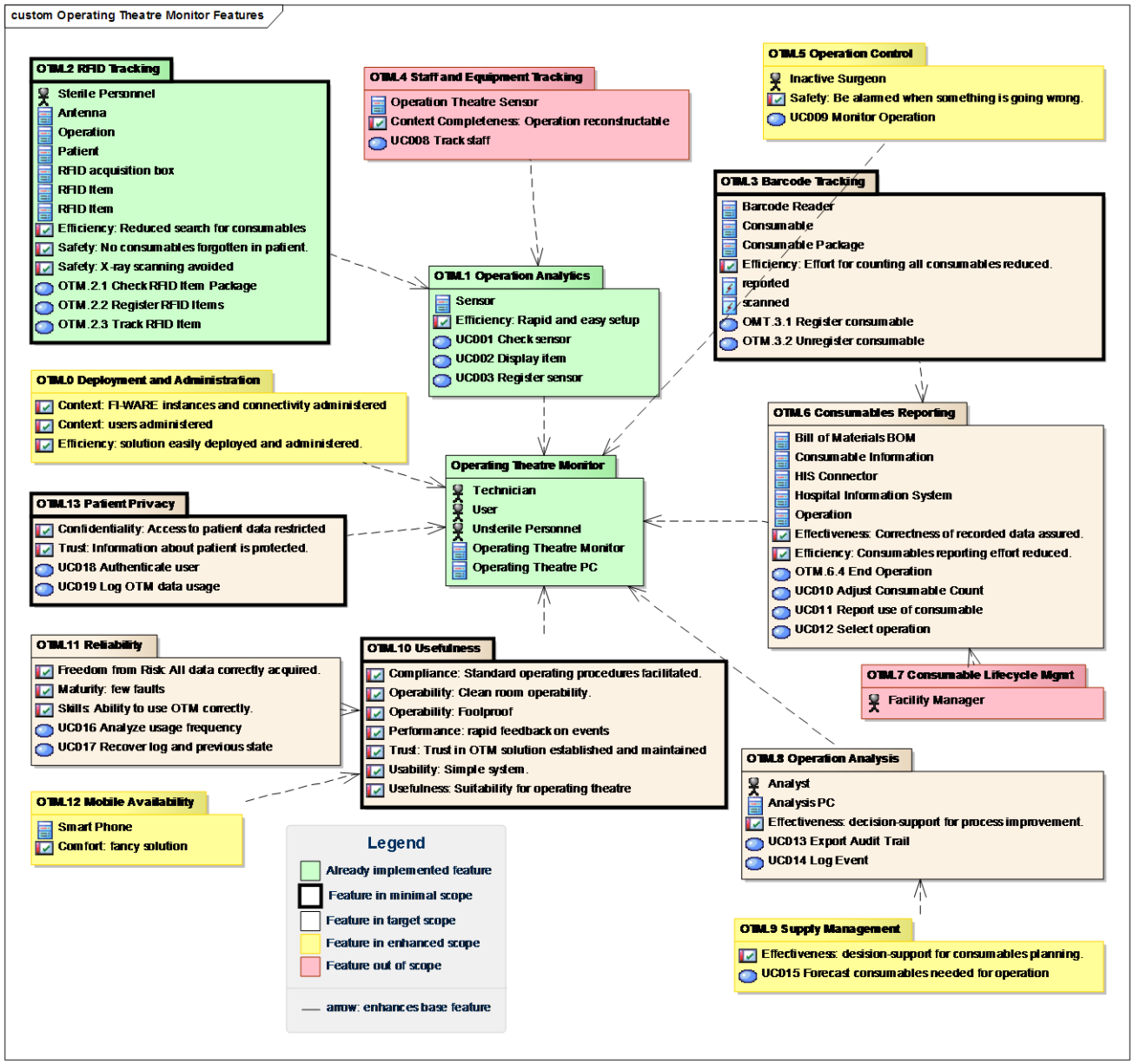
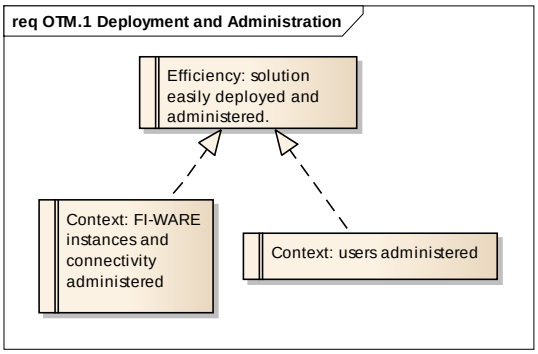


Figure 89: Feature tree of operating theatre monitor. (notation and method: Fricker (2012): "Release Planning with Feature Trees: Industrial Case", RefsQ)

7.4.1 Features

7.4.1.1 Feature OTM.0 Deployment and Administration

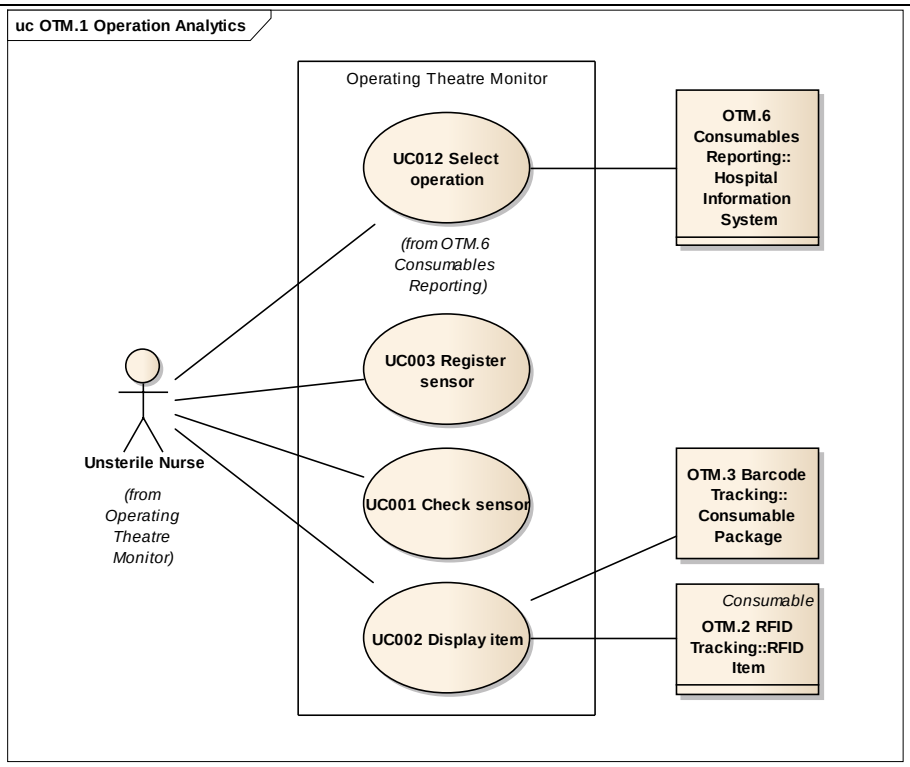
The feature OTM.0 Deployment and Administration provides a technician with the ability to deploy a solution by administering users, FI-WARE instances, and connectivity to these instances.

Addressed stakeholder interests and expectations	Goals to be achieved: • Solution deployed Sub-goals • FI-WARE instances and connectivity administered • Users administered 
Comments	Specific requirements to be identified based on architectural concepts. To be validated with prototype.

7.4.1.2 Feature OTM.1 Operation Analytics

The feature OTM.1 Operation Analytics provides the unsterile nurse with the ability to check the proper working of the solution, including sensors and connection to hospital information system.

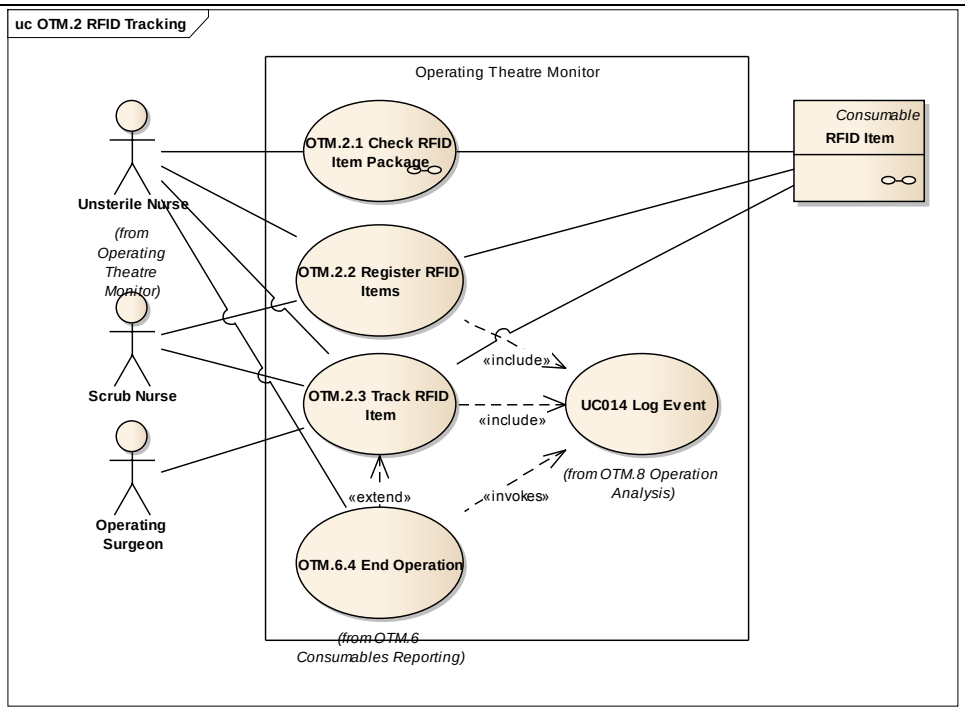
Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: Rapid and easy setup External interfaces • Operating Theatre PC HMI to Unsterile Nurse • From OTM.2: RFID Antenna to RFID Item • From OTM.3: Barcode Reader to Consumable Package • From OTM.6: HIS Connector to Hospital Information System (HIS) Use cases • Check sensor • Display item • From OTM.6: Select operation

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

7.4.1.3 Feature OTM.2 RFID Tracking

The feature OTM.2 RFID Tracking provides the operating staff with the ability to track consumables that are tagged with an RFID chip.

Addressed stakeholder interests and expectations	Goals to be achieved: • Safety: no consumables forgotten in patient. • Efficiency: reduced search for towels. • Safety: X-ray scanning avoided. • From OTM.10 Usefulness: Performance: rapid feedback on events External interfaces • Operating Theatre PC HMI to Unsterile Nurse, Scrub Nurse, and Operating Surgeon • RFID Antenna to RFID Item Use cases • Check RFID Item Package • Register RFID Item • Track RFID Item • From OTM.6: End Operation • From OTM.8: Log Event

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

Use Case	OTM.2.1 Check RFID Item Package
Goals	To have checked whether the IDs of all RFID chips supposed to be in the package can be detected by the antennas.
External Actors	Unsterile nurse, RFID items contained in a package.
Input Devices	Acquisition box with antenna, Operating Theatre PC (OT PC)
Output Devices	Operating Theatre PC (OT PC)
Assumptions	Acquisition box with antenna does self-monitoring.
Pre-conditions	Antenna is operational
Flow of Events	1. Unsterile nurse places RFID items on antenna 2. Antenna detects RFID items 3. OT PC displays count of RFID to unsterile nurse. 4. Unsterile nurse confirms count of RFID items on OT PC. 5. Unsterile nurse removes RFID items from antenna 6. Antenna detects no RFID items 7. 7. OT PC displays no RFID items to unsterile nurse
Post-conditions	RFID item package is checked
Alternatives and Exceptions	3a. Antenna not working: 3a1. Acquisition box sends no Antenna ID to OTM 3a2. OT PC displays broken Antenna to unsterile nurse

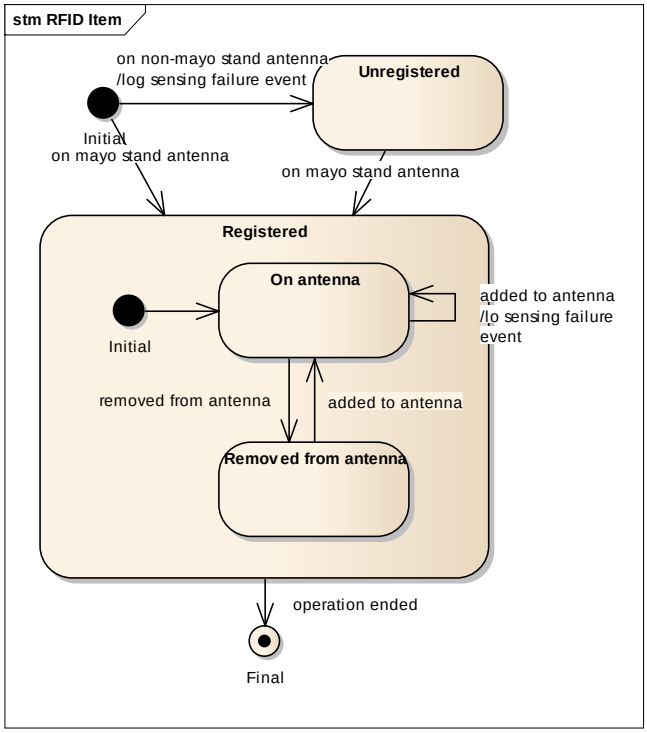
	3a3. END (antenna not operational) 3b. Wrong count of RIFD: 3b1. Unsterile nurse removes RFID items from antenna 3b2. -> 1. 3ba. Wrong count of RFID (2nd attempt): 3ba1. Unsterile nurse removed RFID items from antenna 3ba2. Unsterile nurse removes RFID items from operating theatre 3ba3. -> 1.

Use Case	OTM.2.2 Register RFID Items
Goals	To enable tracing of consumables that are used during the operation.
External Actors	Scrub nurse, unsterile nurse, RFID items
Input Devices	Acquisition box with antenna on Mayo stand, Operating Theatre PC (OT PC)
Output Devices	Operating Theatre PC (OT PC)
Assumptions	• Acquisition box with antenna does self-monitoring. • OTM does self-monitoring.
Pre-conditions	• Operation has been activated in OTM • Unsterile nurse has opened package
Flow of Events	1. Unsterile nurse hands opened package contents over to sterile nurse. 2. Sterile nurse places RFID items on Mayo-stand. 3. Antenna scans RFID of the RFID items. 4. OT PC displays count of new RFID items to operating personnel. 5. Unsterile nurse confirms correctness of number of RFID items on OT PC. 6. OTM stores RFID items. 7. 7. OTM logs association of RFID items to may-stand antenna (UC014)
Post-conditions	• RFID items are in use. • RFID items are associated with operation. • RFID items are located on Mayo stand. • Association of RFID items with mayo stand antenna added to operation log with time stamp. • OT PC displays count of RFID items for each antenna
Alternatives and Exceptions	2a: If RFID items placed on antenna other than mayo stand: 2a1. OTM logs sensing failure event (UC014) 2a2. -> 2. 4a: If OT PC displays wrong number of new RFID items: 4a1. Scrub nurse throws RFID Items into garbage. 4a2. Unsterile nurse marks sensing failure event on OT PC. 4a3. OTM logs sensing failure event (UC014) 4a4. -> 1.

Use Case	OTM.2.3 Track RFID Item
Goals	• consumables that are used during the operation are traced to minimize consumable search and incidents due to forgotten consumables • data obtained for operation process analysis improvement.
External Actors	Operating person (scrub nurse OR operating surgeon), RFID item
Input Devices	2 RFID antennas at different locations (Mayo stand, operating bed, OR trash), Operating Theatre PC (OT PC)
Output Devices	Operating Theatre PC (OT PC)
Assumptions	• Acquisition box with antenna does self-monitoring. • OTM does self-monitoring.
Pre-conditions	• RFID item is in use • RFID item is on first antenna • RFID item is not on second antenna • RFID items is associated with operation. • OT PC displays count of RFID items for each antenna
Flow of Events	1. Operating person takes consumable from first antenna. 2. OT PC displays change and new count of RFID items for first antenna. 3. OTM logs removed association of RFID items to first antenna (UC014) 4. Operating person places consumable on second antenna. 5. OT PC displays change and new count of RFID items for second antenna. 6. 6. OTM logs new association of RFID items to second antenna (UC014)
Post-conditions	• RFID item is in use. • RFID item is associated with operation. • Changes of associations of RFID item with antennas added to operation log with time stamp. • RFID item is located on second antenna.
Alternatives and Exceptions	2a: If OT PC displays wrong number of removed RFID items: 2a1. Unsterile nurse marks sensing failure event on OT PC. 2a2.. OTM logs sensing failure event (UC014) 2a3. -> 4. 4a: If operation finished: 4a1. OPERATION END 4a3. END 5a: If OT PC displays wrong number of added RFID items: 5a1. Unsterile nurse marks sensing failure event on OT PC. 5a2. OTM logs sensing failure event (UC014) 5a3. -> 4. 5b: If OTM believes RFID item has not been removed from first antenna (correction of 2a): 5b1a. If sensing failure event not yet marked by unsterile nurse:

	5b1a1. OTM logs sensing failure event (UC014) 5b1. -> 2, 3, 5, 6.

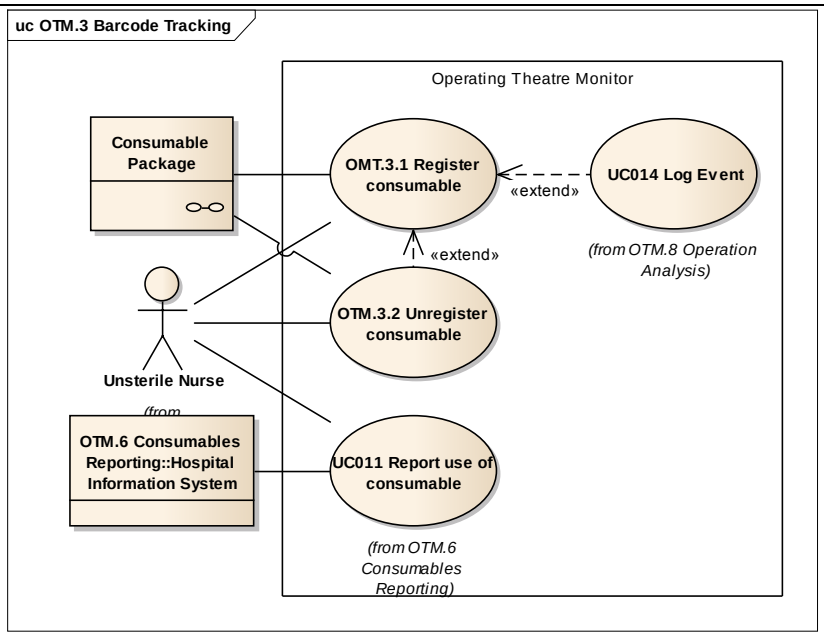
Lifecycle of RFID Item:



7.4.1.4 Feature OTM.3 Barcode Tracking

The feature OTM.3 Barcode Tracking provides the unsterile nurse with the ability to register consumables used for the operation.

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: Effort for counting all consumables reduced. External interfaces • Operating Theatre PC HMI to Unsterile Nurse • Barcode Reader to Consumable Package Use cases • Register consumable • From OTM.8: Log Event

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

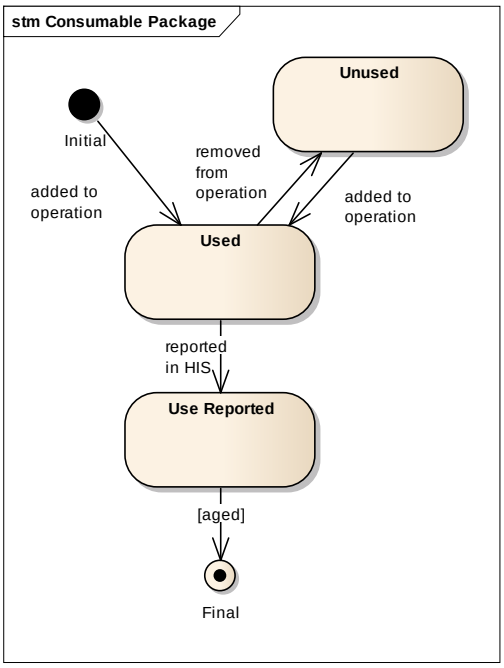
Use Case	OTM.3.1 Register consumable
Goals	• effort for registering consumables reduced. • error rate of consumables reporting reduced. • expired consumables avoided. • counting errors avoided. • - double-registration of consumables avoided.
External Actors	consumable packages, unsterile nurse
Input Devices	Barcode scanner
Output Devices	Barcode scanner
Assumptions	• Consumable package barcode is unique
Pre-conditions	• Operation has been activated in OTM
Flow of Events	1. Unsterile nurse sets barcode scanner mode to registration 2. Unsterile nurse scans barcode of consumable package 3. OTM adds the correct count of the contained consumables to Bill of Materials (BOM) 4. Barcode scanner displays consumable information (count, type, expiry date, and IDs)
Post-conditions (changes)	• consumable package added to Bill of Materials (BOM)
Alternatives and Exceptions	2a. Barcode is incompatible: 2a1. Barcode reader informs about incompatibility.. 2a2. END (-)

	2b. Barcode matches consumable package already registered in current operation: 2b1. Barcode reader informs about existing registration. 2b2. END (-) 2c. Barcode matches consumable package already registered in previous operation: 2c1. IF unsterile nurse wants to unregister consumable: 2c1.1 CONSUMABLE UNREGISTRATION. 2c1.2 -> 3. 2c2. Barcode reader informs about cancellation of registration. 2c3. END (-) 4a. Barcode scanner display unexpected information: 4a1. CONSUMABLE UNREGISTRATION. 4a2. END (-)

Use Case	OTM.3.2 Unregister consumable
Goals	• unused consumables re-entered into stock. • wrong registration of consumables avoided.
External Actors	consumable packages, unsterile nurse
Input Devices	Barcode scanner
Output Devices	Barcode scanner
Assumptions	-
Pre-conditions	-
Flow of Events	1. Unsterile nurse sets barcode scanner mode to unregistration 2. Unsterile nurse scans barcode of consumable package 3. OTM identifies operation that registered the consumables 4. Barcode scanner displays operation and consumable information (count, type, expiry date, and IDs) 5. Unsterile nurse confirms unregistration 6. OTM removes the correct count of the contained consumables from BOM
Post-conditions (changes)	• consumable package removed from BOM of correct operation
Alternatives and Exceptions	2a. Barcode is incompatible: 2a1. Barcode reader informs about incompatibility.. 2a2. END (-) 3a. Barcode does not match any consumable package already registered in an operation: 3a1. Barcode reader informs about missing registration. 3a2. END (-)

	5a. Unsterile nurse cancels unregistration: 5a1. Barcode informs about cancellation. 5a2. END (-)

Lifecycle of consumable package:



7.4.1.5 Feature OTM.4 Staff and Equipment Tracking

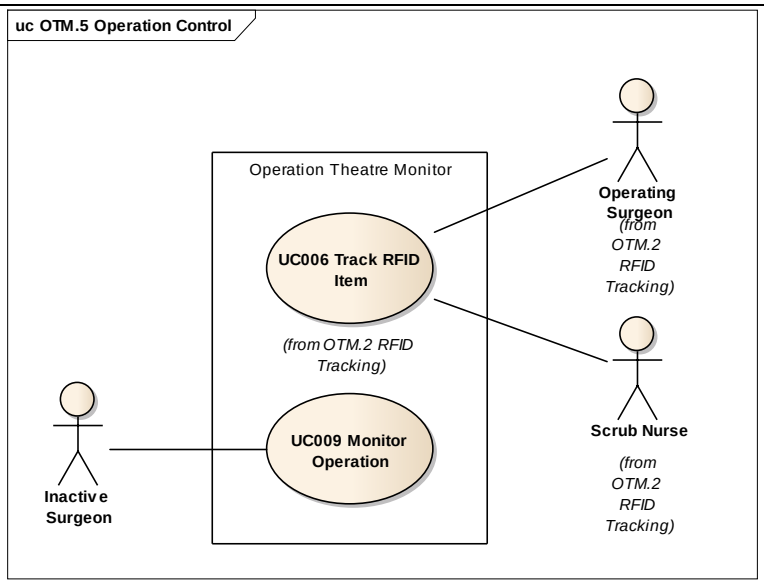
The feature OTM.4 Staff and Equipment Tracking provides the operating staff with the ability to track their movements and the use of equipment during the operation.

Addressed stakeholder interests and expectations	Out of scope

7.4.1.6 Feature OTM.5 Operation Control

The feature OTM.5 Operation Control provides the inactive surgeon outside the operating room with the ability to be alarmed when something goes wrong. This is achieved through transparency of RFID item statuses.

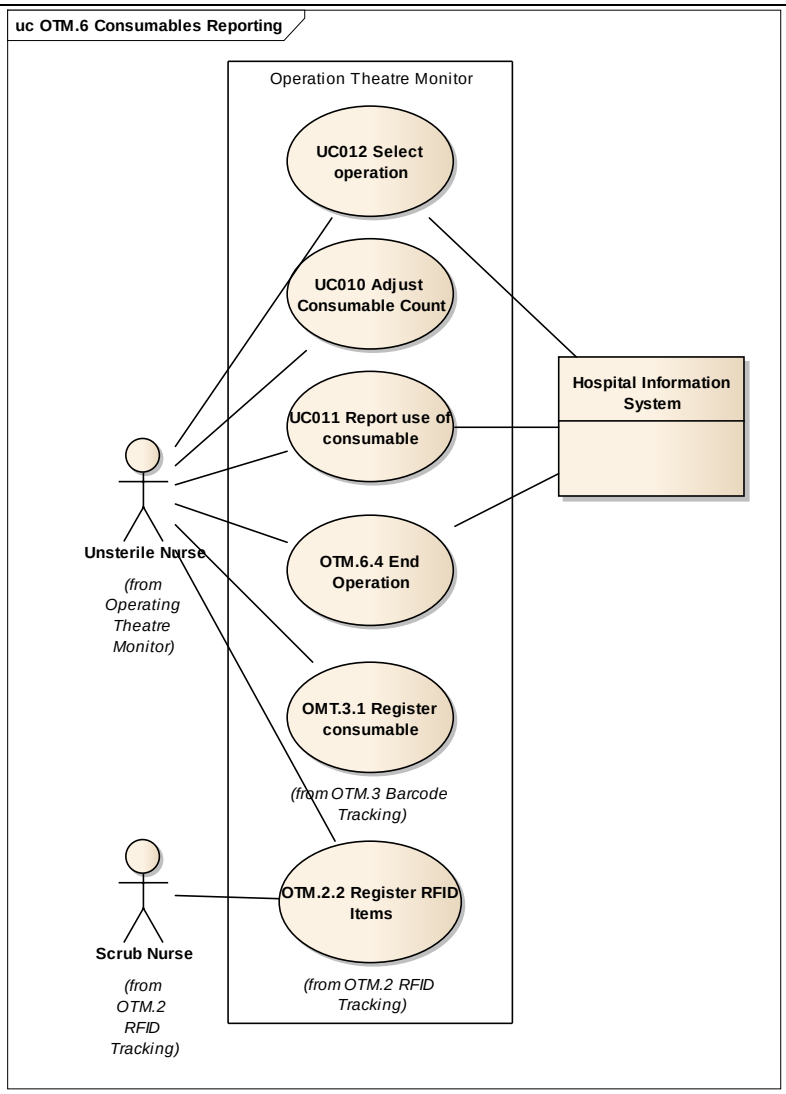
Addressed stakeholder interests and expectations	Goals to be achieved: • Safety: Be alarmed when something is going wrong. External interfaces • Operating Theatre PC HMI to Unsterile Nurse and Scrub Nurse • Station PC HMI to Inactive Surgeon Use cases • Monitor operation • From OTM.2: Track RFID item

	
Comments	To be validated with prototype Specification to be refined with mock-up

7.4.1.7 Feature OTM.6 Consumables Reporting

The feature OTM.6 Consumables Report provides the unsterile nurse with the ability to automate the reporting of the consumables used during the operation.

Addressed stakeholder interests and expectations	Goals to be achieved: • Efficiency: Consumables reporting effort reduced. • Effectiveness: Correctness of recorded data assured. External interfaces • Operating Theatre PC HMI to Unsterile Nurse and Scrub Nurse • HIS Connector to Hospital Information System (HIS) Use cases • Select operation • Adjust consumable count • Report consumables • End operation • From OTM.3: Register consumable • From OTM.2: Register RFID item



Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

7.4.1.8 Feature OTM.7 Consumable Lifecycle Management

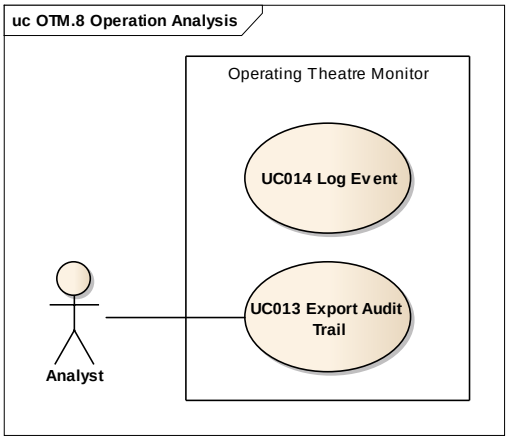
The feature OTM.7 Consumable Lifecycle Management provides the facility manager to decide on reuse of consumables.

Addressed stakeholder interests and expectations	Out of scope: consumables are thrown away after use. They may be reused only in the context of research.

7.4.1.9 Feature OTM.8 Operation Analysis

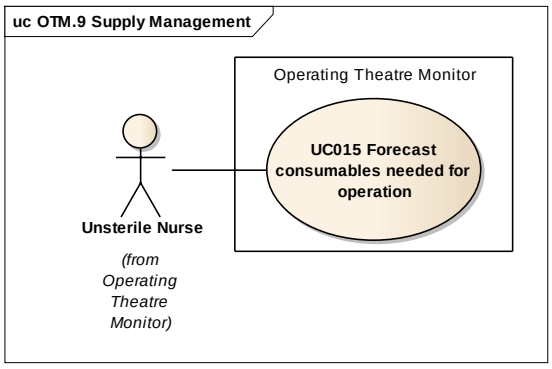
The feature OTM.8 Operation Analysis provides the analyst with the ability to study operation logs for process improvement purposes.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: Decision-support for process improvement. External interfaces

	• Analytics PC HMI to Analyst Use cases • Log event (from sensors) • Export audit trail 
Comments	To be validated with prototype Specification to be refined with mock-up

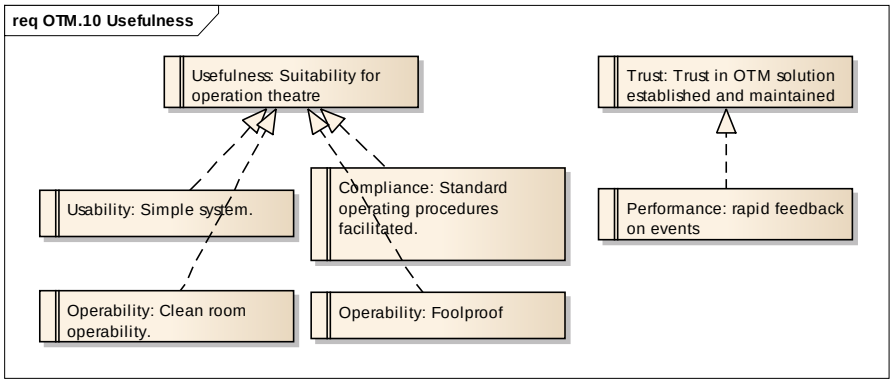
7.4.1.10 Feature OTM.9 Supply Management

The feature OTM.9 Supply Management provides the unsterile nurse with the ability to forecast consumables needed for an operation and the facility manager with the ability to determine stock replenishment needs.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: Decision-support for consumable planning. External interfaces • Analytics PC HMI to Unsterile Nurse Use cases • Forecast consumables needed for operation 
Comments	Stock management, both at clinic and hospital levels, are scope of HIM, not of the Operating Theatre Monitor. To be validated with prototype Specification to be refined with mock-up

7.4.1.11 Feature OTM.10 Usefulness

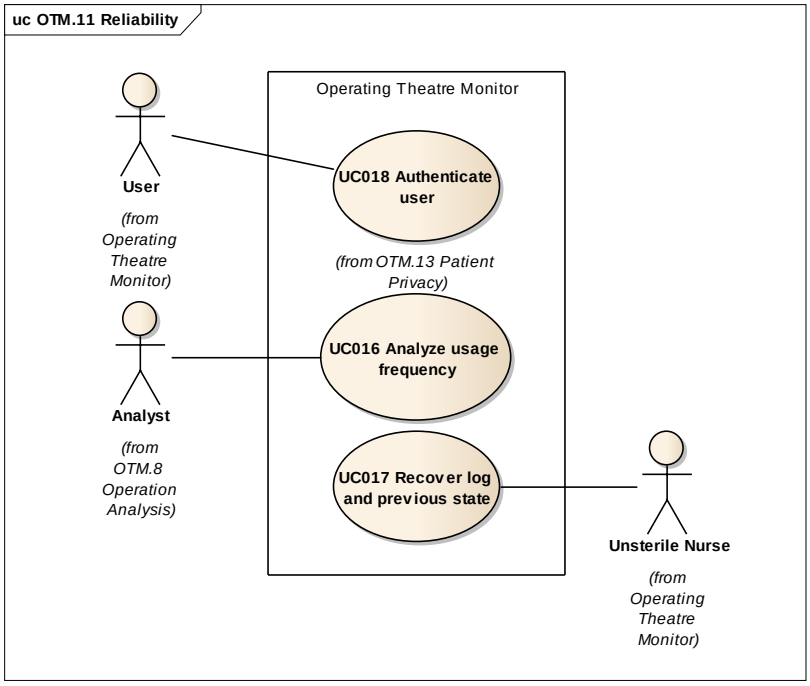
The feature OTM.10 defines the minimal criteria for the solution to be useful for the FI-STAR use case.

Addressed stakeholder interests and expectations	Goals to be achieved: • Usefulness: Suitability for operation theatre. • Trust: Trust in OTM solution established and maintained. Quality requirements: • Usability: Simple system (too complex system disrupts routine and generates work). • Compliance: Standard operating procedures facilitated (Each hospital has own standard operating procedures SOP). • Operability: Clean room operability (touchscreen use with gloves, GUI legible from 3m distance). • Operability: Foolproof (user is supported in avoiding erroneous commands that affect system operation, e.g. "stop" button) • Performance: Rapid feedback on events (3 seconds time to feedback to sensor events). 
Comments	To be validated with prototype Applicable regulations and standard operating procedures TBD.

7.4.1.12 Feature OTM.11 Reliability

The feature OTM.11 defines the reliability requirements to ensure that all analytics data is correctly acquired and that the OTM solution is correctly used (by training staff and monitoring OTM usage).

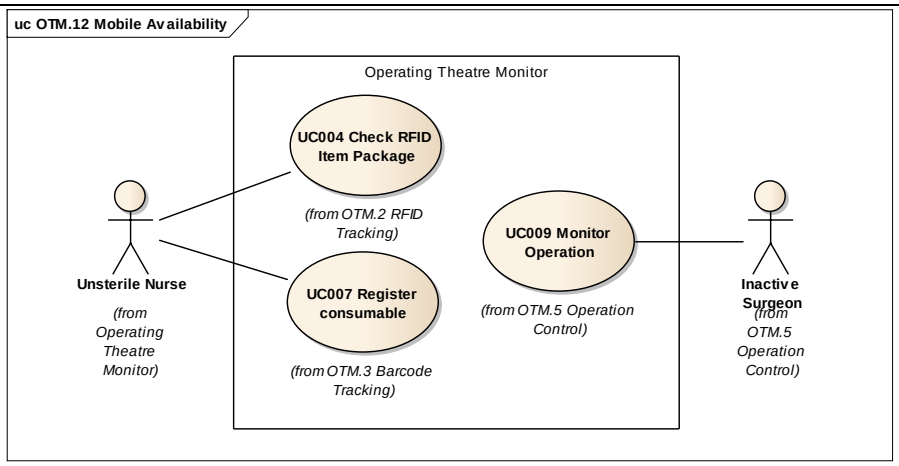
Addressed stakeholder interests and expectations	Goals to be achieved: • Freedom from Risk: All data correctly acquired. • Skills: Ability to use OTM correctly (ensure that operating staff knows the OTM solution and uses it frequently). Quality requirements: • Maturity: Few faults (less than 1 fault per 500 uses). External interfaces • Operating Theatre PC HMI to Unsterile Nurse • Analytics PC HMI to Analyst Use cases: • From OTM.14: Authenticate user • Analyze usage frequency

	• Recover log and previous state 
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

7.4.1.13 Feature OTM.12 Mobile Availability

The feature OTM.12 Mobile Availability provides access to the unsterile nurse and the inactive surgeon with a smart phone.

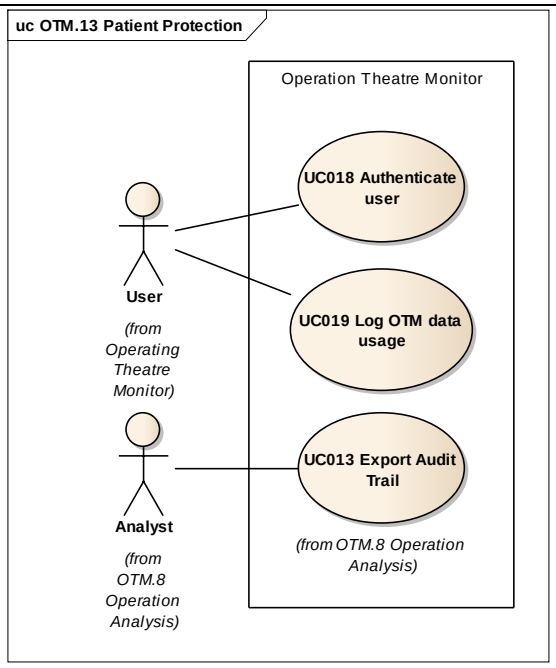
Addressed stakeholder interests and expectations	Goals to be achieved: • Comfort: Fancy solution External interfaces • Smart-Phone HMI to Unsterile Nurse and Inactive Surgeon (iPhone and Android) Use cases: • From OTM.2: Check RFID item package • From OTM.3: Register consumable • From OTM.5: Monitor operation

	
Comments	To be validated with prototype Specification to be refined with mock-up and interface protocols

7.4.1.14 Feature OTM.13 Patient Privacy

The feature OTM.13 Patient Privacy ensures protection of the patient's interests.

Addressed stakeholder interests and expectations	Goals to be achieved: • Effectiveness: Business case with clear cost/benefit. Quality requirements: • Confidentiality: Access to patient data restricted. External interfaces • Any HMI to any User • From OTM.8: Analytics PC HMI to Analyst Use cases: • Authenticate user • Log OTM data usage • From OTM.8: Export audit trail

	
Comments	To be validated with prototype Specification to be refined with mock-up Applicable regulations and standard operating procedures TBD.

7.4.2 FI-STAR Solution-wide Requirements and Constraints

7.4.2.1 Constraints towards Platforms

ID	Constraint (Title and Short Description)	Rationale and comments
CP01	The IT department in the TUM clinic mainly uses CISCO Switches. I would prefer to pass over these devices, but we will need some (not yet defined) in the operation room and on the ward	Source: Use-Case-Senario TUM-Siemens
CP02	Multiple different sensors in the operation room, since there´s analog electronic between, I can deliver from a dedicated acquisition computer every data you need, you can also install own software	Location: Operation room (fixed) Source: Use-Case-Senario TUM-Siemens
CP03	Data Output Computer which controls experimentally for the project several functions in the operation room. Software installation possible	Location: Operation room (fixed) Source: Use-Case-Senario TUM-Siemens
CP04	Operation room data, if analyzed somewhere, should be transferred with high priority, patient positions lower priority, exact details tbd	Source: Use-Case-Scenario TUM-Siemens
CP05	Highest Security for patient data in the private cloud at the clinic Moderate security for extracted user profile and user entered data (mobility profile) in the public cloud	Source: Use-Case-Scenario TUM-Siemens
CP06	Mobile Smartphones with installed internet connection	Source: Use-Case-Scenario TUM-Siemens

	(WLAN, 3G, (4G)	

7.4.2.2 Constraints towards Enablers and Technology

ID	Constraint (Title and Short Description)	Rationale and comments
CT01	Several RFID Readers, number not yet clear (5-10), eventually with Multiplexers to connect multiple Antennas. Readers, as well as Multiplexers and Antennas will be from FEIG, Germany. We have the documentation as well as a SDK, but we can provide you the data via TCP/IP or even simpler protocols (RS232)	Location: Several places hospital/operation room (fixed) Source: Use-Case-Scenario TUM-Siemens
CT02	Several iOS and Android devices as output devices. Software/App installation possible	Location: hospital (mobile, WLAN/3G) Source: Use-Case-Scenario TUM-Siemens
CT03	Integration of new or additional sensors should be possible • iOS/ Android devices (mobile), for demonstrator approx. 20 devices, all mobile • Sensors included in the device (GPS, Acceleration, …) • Additional (wearable) sensors (Heart rate, …)	Source: Use-Case-Scenario TUM-Siemens

8 Drug Supply Manager for Reverse Drug Supply Chain in Leeds, United Kingdom

This chapter gives an overview of a FI-STAR solution that is intended to be built to support the FI-STAR use case. The chapter covers the goal/purpose of the FI-STAR solution, stakeholders and their interests/expectations, the application and their features that are integrated into the FI-STAR solution to support these interests/expectations, and the FI-STAR solution-wide requirements and constraints. The appendix can be used to capture any other material, including business processes, glossary, description of the as-is situation, problems with current solutions, storyboards, and examples of artefacts and photographs of usage context.

The vision chapter is intended as a starting point for subsequent detailed requirement engineering. The features are used to establish an overview of the FI-STAR solution's requirements that then will be engineered just-in-time before the relevant development starts. The features should be specified by explaining how the concerned FI-STAR application will support the corresponding FI-STAR stakeholders' interests and expectations. The vision chapter should be updated as the understanding of the FI-STAR solution and of its aims and objectives evolve.

Future uses of this vision chapter will be to establish personas for target user segmentation and user experience engineering, traceability to release and project planning, application and enabler design and development, and quantification of quality requirements and testing, definition/monitoring of KPI, and analyzing commonality/variability across applications. In addition, this vision chapter will refer to relevant specialty requirements.

8.1 FI-STAR Solution Positioning

The following captures the essence of the FI-STAR solution, including the problem it addresses and the key idea of solving the problem.

8.1.1 Problem Statement

The problem of	distributing effective and safe drugs to patients
affects	pharmacists
the impact of which is	patient safety
a successful solution would be	to trace drug packages with a globally unique barcode and thereby enable a reverse supply chain

8.1.2 Position Statement

For	pharmacists, dispensers, drivers, producers, wholesalers, and patients
Who	package, distribute, receive, and consume drugs
The (product name)	Drug Supply Manager (DSM) is a FI-STAR cloud solution
That	supports drug packaging, procurement, location tracking, dispensing, and home delivery and provides product information to the patient
Unlike	current manual work with drugs that are identified by the producers and product type, but not uniquely identified packages
Our product	assures drug authenticity, helps pharmacists to avoid dispensing errors, helps patients to correctly use the drugs, helps dispensers to reduce patient consultancy

	and drug handling efforts

8.2 FI-STAR Use Case Stakeholders

The following users, interfacing systems, and other stakeholders are affected by the solution.

8.2.1 User Roles

Figure 90 provides an overview of the user roles of the Drug Supply Manager solution.

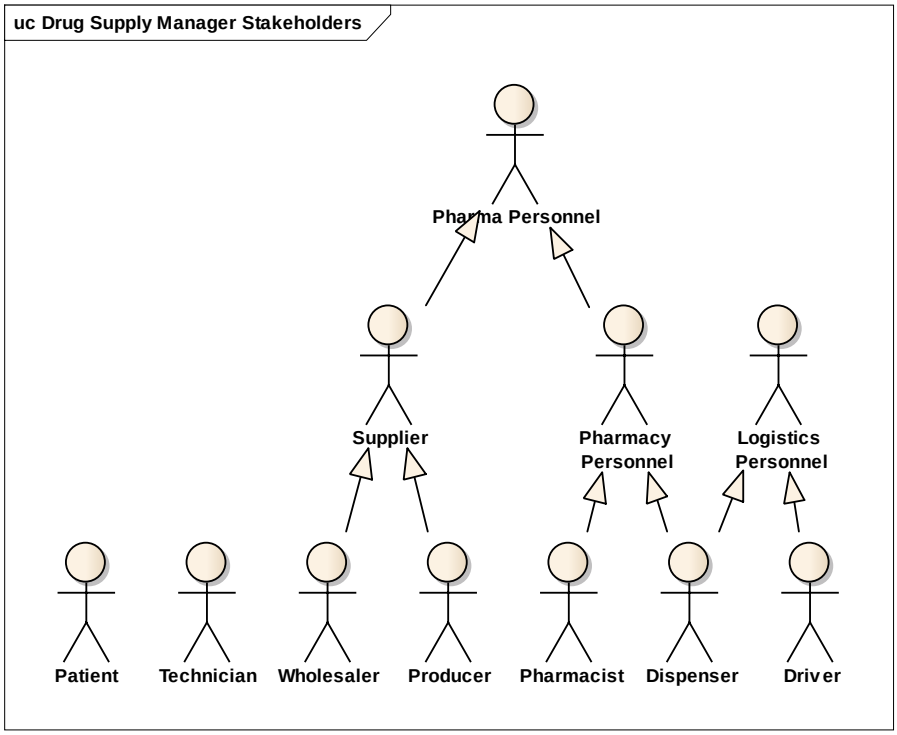


Figure 90: User roles of the Drug Supply Manager solution.

Figure 91-Figure 93 give an overview of the workflow of the pharmacy personnel from drug procurement to home delivery.

Figure 91: Left: Reception of drug delivery (ticking-off of items on the invoice and filling-out of an invoice for return of drugs). Middle: storage of drugs in the pharmacy stock. Right: storage of drugs in the pharmacy's customer area.

Figure 92: Left: Checking of the prescription by pharmacist and patient. Middle: Dispensing of medication and reporting of the dispense in the pharmacy management system. Right: Re-labelling of a drug with information about treatment-specific use of the drug.

Figure 93: Left: Preparation of a home delivery of drugs for a patient. Middle: Backlog of the home delivery driver. Right: driver with home delivery car.

The following table describes the users, including their background, role, and expectations.

Name / Count	Description	Expectations on Solution
Pharmacist 9 Sarah Armitage, Angela Goldsmith, Meena Dhand	Responsible for patient safety. Manage the operations of a pharmacy. Compliance: Legal and SOP Issue 600-700 prescriptions for patients every day. • 300-350 walk-in • 300-350 home delivery	Identify, withdraw, and disseminate information about counterfeit drugs from the pharmacy's stock and from the patients. Improved traceability, enabling authenticity checks for product recalls. Fewer adverse events and critical errors
Dispenser 3 Kelly Shaw	Check and receive medicines from wholesaler/producer. Confirm items received are as per requirements set by PO, Use by date >6 months Assemble and prepare medicines to patient prescription requirements ready for Pharmacist to check	More efficient dispensing Recording of information which is scanned at the point of use Simplification and enhanced accuracy of order processing and receipt Print 2D barcode labels for all packets of medicines received
Driver	Deliver prescription medications to patient home.	Electronic delivery details Recording of information which is

1 Mike Riley	Ensure correct environment is maintained throughout transportation, such as temperature regime and security.	scanned at the point of delivery Reduce delivery errors and improve traceability
Producer 1 Rajeev Dhand	Manufactures generic medicines for wholesalers and pharmacy chains.	Packaging to contain unique identifiers to enable traceability and reverse supply chain
Wholesaler 2 AAH & Alliance Healthcare	Provide medicines for stock and prescription fulfilment on a timely basis. Coded using GS1 GTIN or PIP codes	Greater transparency and visibility of product. Reduce delivery errors and improve traceability Improved recalls from pharmacy stocks and patient
Patient 50 TBD	Provides prescription to be dispensed by pharmacist.	Better medicine management Improved safety Better information on the use of medicines
Technician 1 Altaf Sadique	Provides system administration and first level support.	Solution easy to deploy and manage

8.2.2 Interfacing Systems

Figure 94 gives an overview of the system boundary of the OTM solution. The connectivity to the FI-STAR cloud is a concern of the solution architecture, hence omitted from the overview.

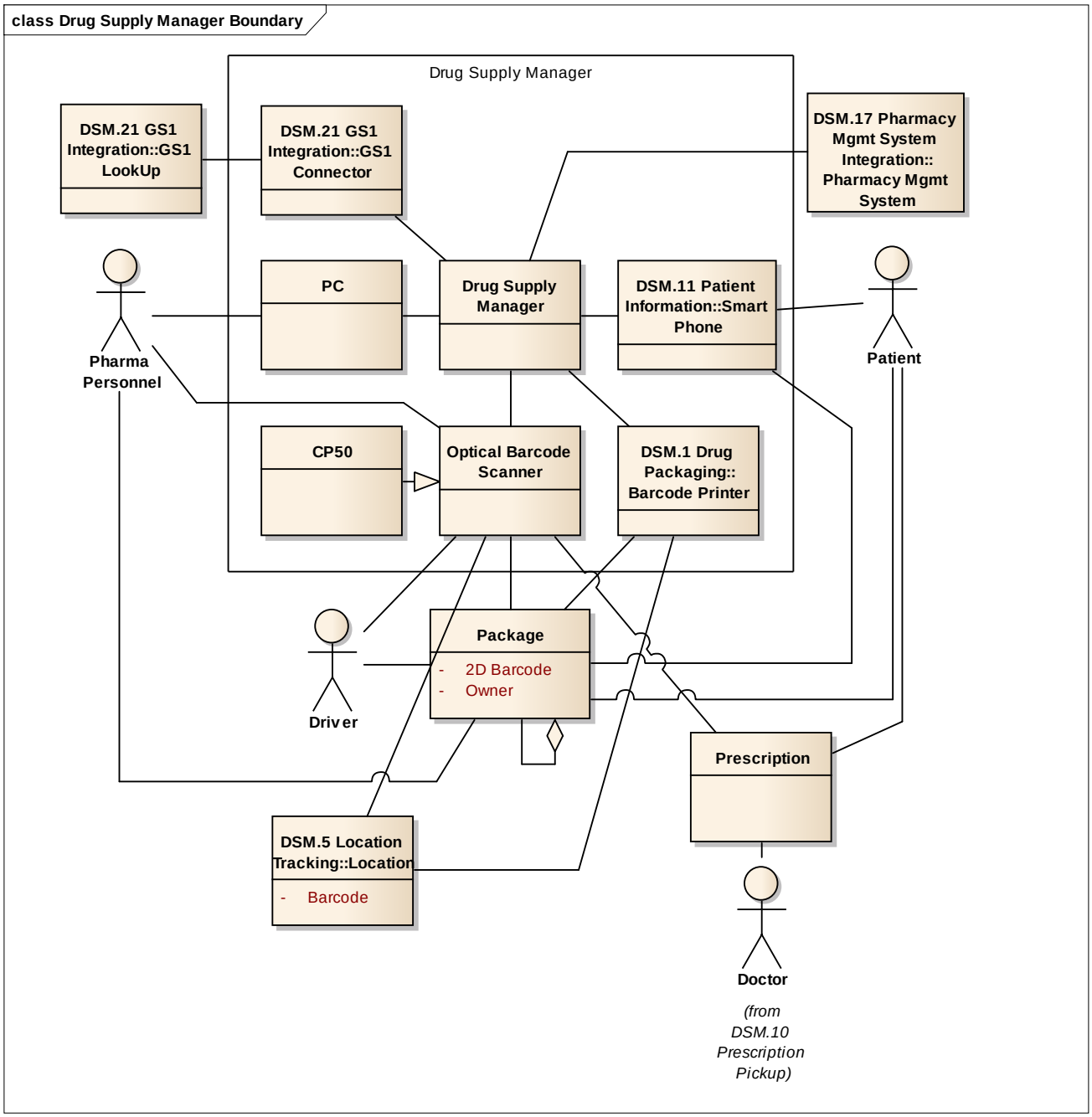


Figure 94: System boundary of Drug Supply Manager solution, including all interfaces to users, systems, and artifacts of the FI-STAR use case.

Figure 95 - Figure 98 give an overview of the system, artifacts, and interfaces.

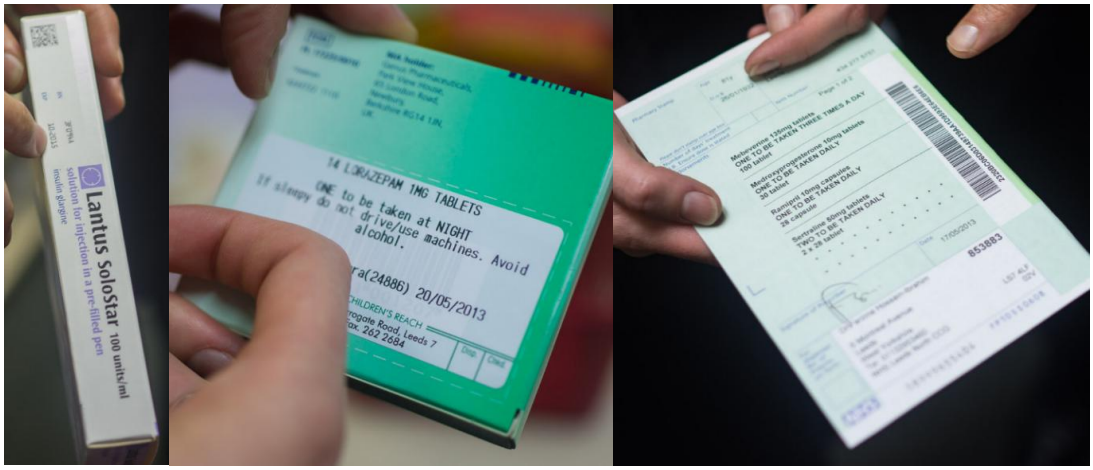


Figure 95: Left: Drug package information, including name, expiry date, lot number, and 2D-barcode (referencing the drug type here only). Middle: Re-labelled drug package, including name, use instructions, expiry date, and pharmacy contact information. Right: printed electronic prescription, including patient contact information, medication, barcode referencing the prescription, doctor contact information, and doctor's signature.

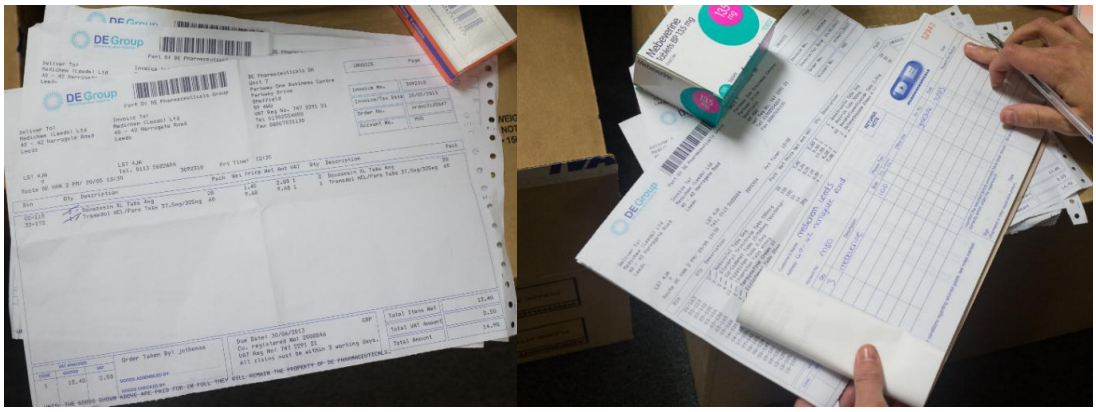


Figure 96: Left: Invoice declaring the shipment of drugs; controlled items have been ticked by the dispenser. Right: invoice for declaring drugs to be returned.

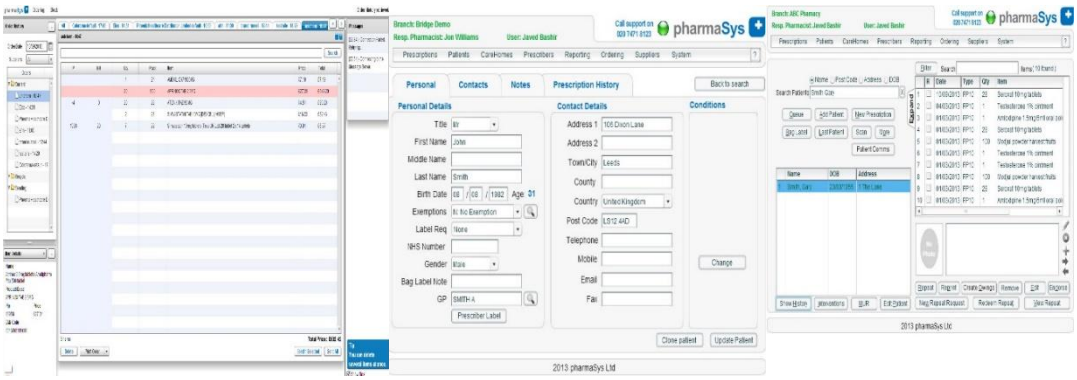


Figure 97: Pharmacy Manager system. Left: drug ordering. Middle: patient information. Right: prescriptions for patients.

Figure 98: Left: CP50 barcode scanner that supports various types of barcodes and photographing with OCR form recognition. Right: RT700i barcode printer.

The following table describes the interfacing systems and artifacts and related expectations on the solution.

Name	Description	Expectations on Solution
Package 10'000 items for FI-STAR (155'000 items per pharmacy during 1 year). 2'500 item types in a pharmacy. Altaf Sadique	Used to enclose or protect medical and appliances products for distribution, storage, sale, and use. Contains product information (GS1 GTIN code), expiry date, batch (lot) number, unique identifier (new). The GS1 Global Trade Item Number (GTIN) is a generic unique coding system for products at an item level.	New 2D barcode to be developed that contains unique package identifier, product information (GS1 GTIN code), and expiry date.
Location Altaf Sadique	Allocated site or place for storage of medicines & pharmacy inventory between delivery from supplier to dispensing event. Identifiable uniquely per site, provide appropriate environment and conditions for safe storage.	A location is tagged with a barcode that, together with the package barcode, is used to scan package location information and enable inventory management automation.
Prescription with 1-5 items, in average 2 items Rajeev Dhand	The paper form known as FP10 or Electronic Token based Prescriptions (ETP) may be issued by general practitioners GPs or nurse and pharmacist prescribers, and hospital doctors. Patients can receive a medicine paid for by the NHS, allows pharmacist to dispense error free and claim payment from PPA. FP10 prescriptions, electronically written, and hand-written prescriptions (<1%).	Prescriptions are to be photographed by the barcode scanner image capture feature only if data is not available from the PMR/N3 system. These will to be stored for track and trace purposes for those dispensed items. Hand-written prescriptions may be out of scope. Electronically written prescriptions may be read with OCR. FP10 prescriptions will be gathered from PMR/N3.
Optical Barcode	Barcode scanner with laser pointing, optical 1D and 2D barcode scanning, and	Will be used to capture barcodes, prescription forms, and delivery receipts

Scanner CipherLab CP50 Altaf Sadique	5M pixel photography. The scanner has a 3.5" QVGA LCD display. The scanner communicates with WLAN, 3.8G HSPA+, and USB 2.0. It has a GPS/AGPS option for real-time localization-based applications. The scanner has a Samsung S3C6410 CPU running at 800MHz, has 2 GB Flash memory, and supports micro SD cards. It runs applications developed with Windows Embedded Handheld 6.5.	(patient signs with a pen on the stylus-based touch screen on the barcode scanner: proof of delivery POD in the format of a bitmap).
Barcode Label Printer Godex RT700i Altaf Sadique	Desk top barcode label printer. The printer has Ethernet, USB 2.0, and RS232 connectivity.	Provides 2D barcode label print capability at the point of goods received and prescription dispensed.
Pharmacy Management System Pharmacy Manager Rajeev Dhand	Software to manage data concerning the treatment of patients, dispensing of prescriptions, billing of claims, compliance with laws and regulations, and communications with other health care professionals. N3 provides the network technology infrastructure for most NHS GP surgeries, hospitals and other small health sites across the UK including retail pharmacies.	Pharmacy Management System integration for the FI-STAR pilot will be executed via PharmaSys, a web based PRM solution. Direct integration to the N3 is out of scope.

8.2.3 Other Stakeholders

The following list describes other stakeholders that do not directly interact with the solution.

Name	Description	Expectations on Solution
NHS PPA	Its primary function is to determine the reimbursement and remuneration due when prescriptions are dispensed outside hospitals anywhere in England. Detailed information, collected when prescriptions are processed for payment, is then made available to organisations within the National Health Service NHS, to support management, planning and governance activities. NHS Prescription Services has previously been known as the Prescription Pricing Authority PPA, and as the Prescription Pricing Division.	Out of scope. Reporting of dispenses and billing will be done manually based on exports of captured dispensing data. However, PharmaSys will provide capabilities to provide all regulatory reporting.
GS1	A membership company that is responsible for administering the GS1 data carrier System in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 System, have access to education, training, promotion and implementation support and have access to play an active role in GSMP. A member of GS1 that is responsible for administering the GS1 System in its training, promotion and implementation support and have access to play an active role in GSMP.	GS1 provides a look-up service for GS1 barcodes, which is to be integrated.

8.3 FI-STAR Value Case

The Drug Supply Manager solution can create value by improving patient safety and increasing the profitability of the pharmacy. 3-5% of circulating drugs are fake medication, and a large number of prescriptions are inadequate for the concerned patient. DSM.6, DSM.11, DSM.14, and DSM.13 address patient safety. DSM.4, DSM.5, DSM.6, DSM.9, DSM.10, and DSM.16 address pharmacy profitability. DSM.1 is a prerequisite for both main goals. Figure 99 gives an overview of the value case in the form of a goal forest.

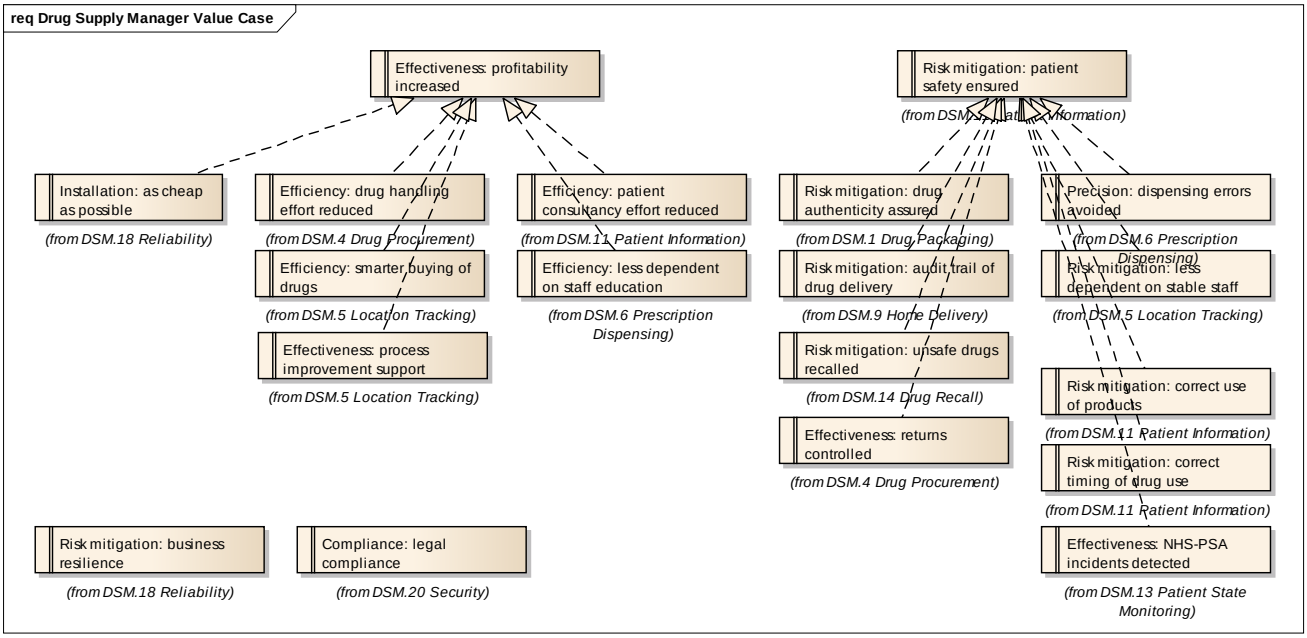


Figure 99: Goal forest explaining how the Drug Supply Manager solution creates value for the FI-STAR use case stakeholders. The parentheses refer to features of the DSM solution.

8.4 FI-STAR Solution Overview

The Drug Supply Manager solution provides a set of features (groups of requirements that belong together) to support the use case stakeholders. Figure 100 gives an overview and defines priorities in terms of minimal scope (alpha prototype for month 12), target scope (beta prototype for month 24), and enhanced scope (options) of the solution. Each feature is specified in more detail in the following subsections.

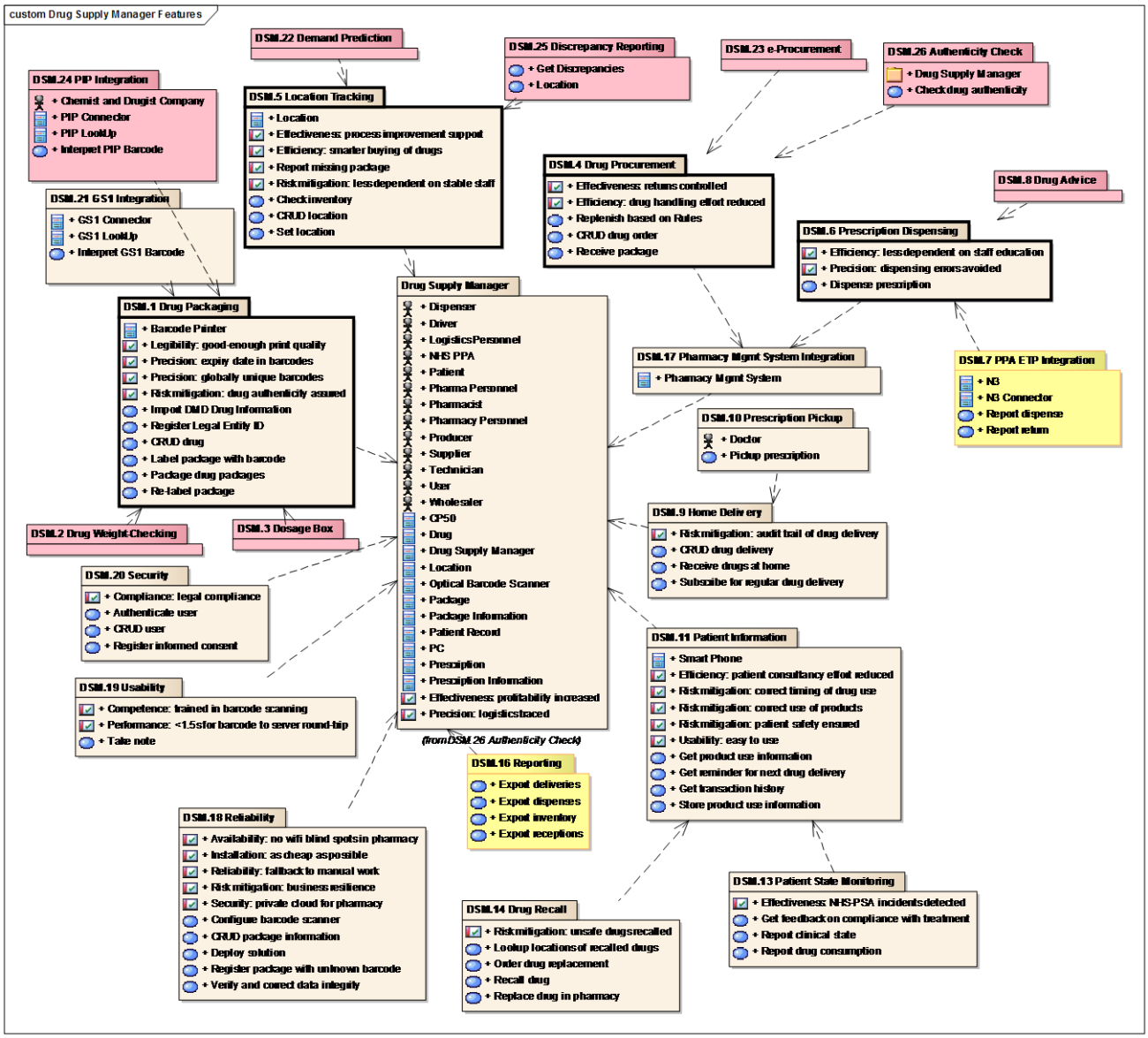


Figure 100: Feature tree of Drug Supply Manager.

8.4.1 Domain Model

Figure 101 gives an overview of the central elements of the data model.

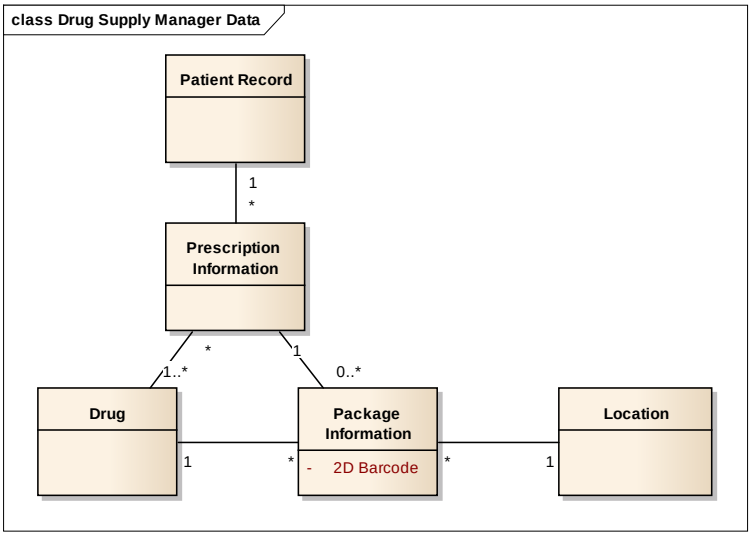
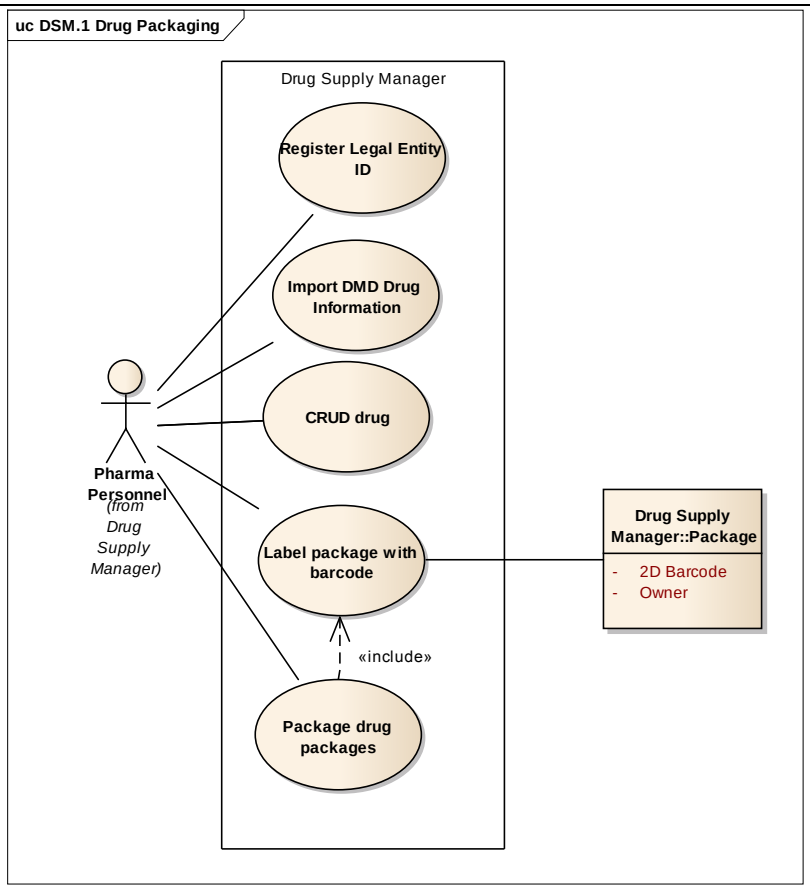


Figure 101: Central elements of the Drug Supply Manager data model

8.4.2 Features

8.4.2.1 Feature DSM.1 Drug Packaging

Addressed stakeholder interests and expectations	Goals to be achieved: 1) Risk mitigation: drug authenticity assured 2) Precision: globally unique barcodes 3) Precision: expiry date in barcode 4) Legibility: good-enough print quality External interfaces: 5) From Pharma Personnel to PC and Barcode Scanner 6) From Package to Barcode Printer 7) From Package to Barcode Scanner Use cases 8) Register legal identity ID 9) Import DMD drug information 10) Create, read, update delete drug 11) Label package with barcode 12) Package drug packages (includes label package with barcode)

	
Comments	To be validated with prototype

8.4.2.2 Feature DSM.2 Drug Weight Checking

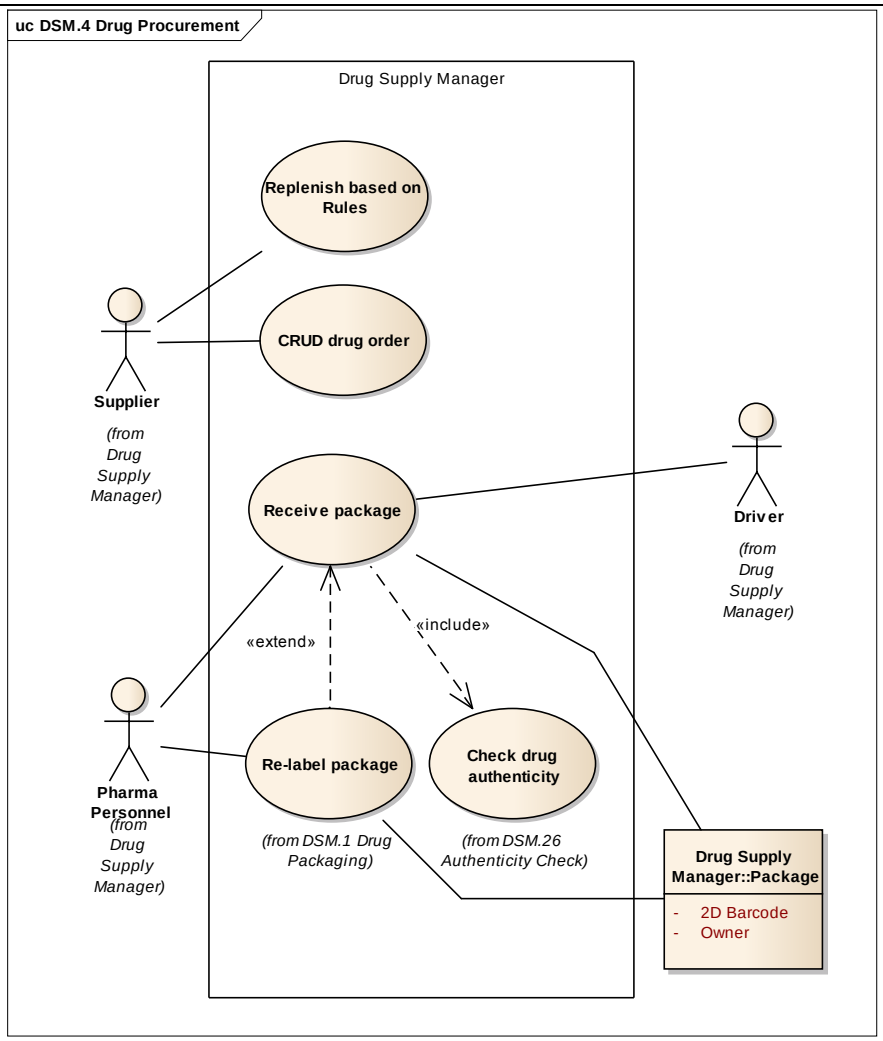
Out of scope

8.4.2.3 Feature DSM.3 Drug Dosage Box

Out of scope

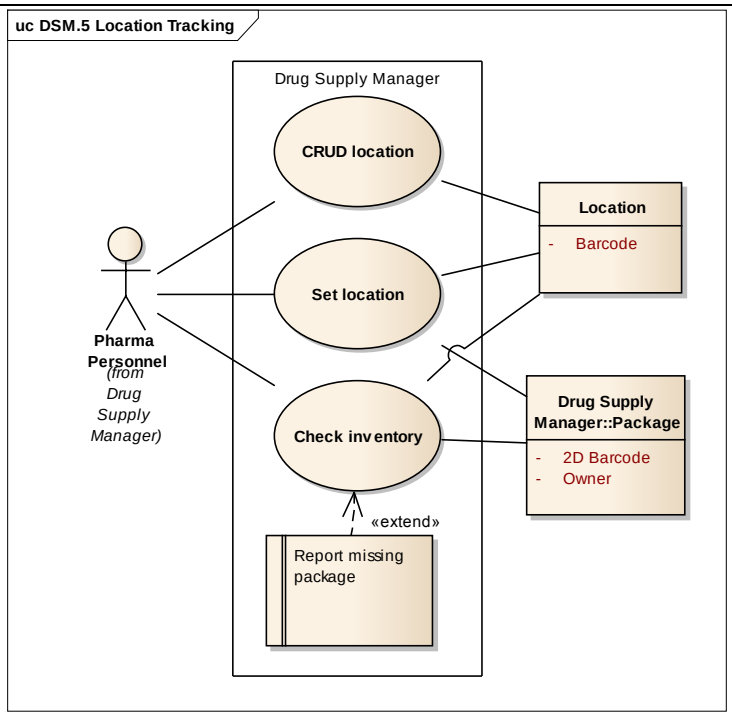
8.4.2.4 Feature DSM.4 Drug Procurement

Addressed stakeholder interests and expectations	Goals to be achieved: 13) Risk mitigation: drug authenticity assured 14) Effectiveness: returns controlled 15) Precision: logistics traced 16) Efficiency: drug handling effort reduced External interfaces: 17) From Pharma Personnel to PC and Barcode Scanner 18) From Package to Barcode Printer 19) From Package to Barcode Scanner Use cases 20) Replenish based on rules 21) Create, read, update, delete drug order 22) Receive package (includes check drug authenticity) 23) Re-label package (extends receive package) 24) Check drug authenticity

	
Key ideas for implementation	Drugs ordered via PharmaSys with existing supplier accounts, Drug returns to be handled in DSM or PharmaSys is to TBD
Comments	To be validated with prototype

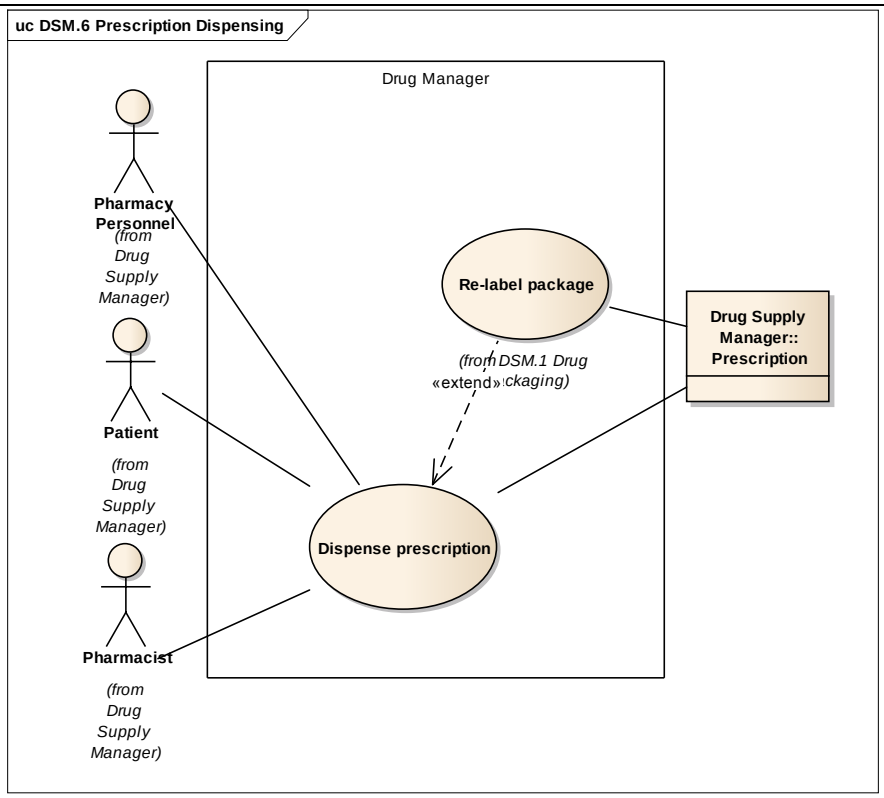
8.4.2.5 Feature DSM.5 Location Tracking

Addressed stakeholder interests and expectations	Goals to be achieved: 25) Risk mitigation: less dependent on stable staff 26) Efficiency: drug handling effort reduced 27) Efficiency: smarter buying of drugs 28) Effectiveness: process improvement support External interfaces: 29) From Pharma Personnel to PC and Barcode Scanner 30) From Package to Barcode Scanner 31) From Location to Barcode Scanner Use cases 32) Create, read, update, delete location 33) Set location 34) Check inventory 35) Report missing package (extends check inventory)

	
Key ideas for implementation	At point of delivery an order location can be determined (possibly prep 2D barcode before arrival).
Comments	To be validated with prototype

8.4.2.6 Feature DSM.6 Prescription Dispensing

Addressed stakeholder interests and expectations	Goals to be achieved: 36) Risk mitigation: patient safety 37) Precision: dispensing errors avoided 38) Precision: logistics traced 39) Efficiency: less dependent on staff education 40) Efficiency: drug handling effort reduced External interfaces: 41) From Pharma Personnel to PC and Barcode Scanner 42) From Package to Barcode Scanner 43) From Package to Barcode Printer Use cases 44) Dispense prescription (includes capture prescription image) 45) Re-label package (extends dispense prescription)

	
Comments	To be validated with prototype

8.4.2.7 Feature DSM.7 PPA ETP Integration

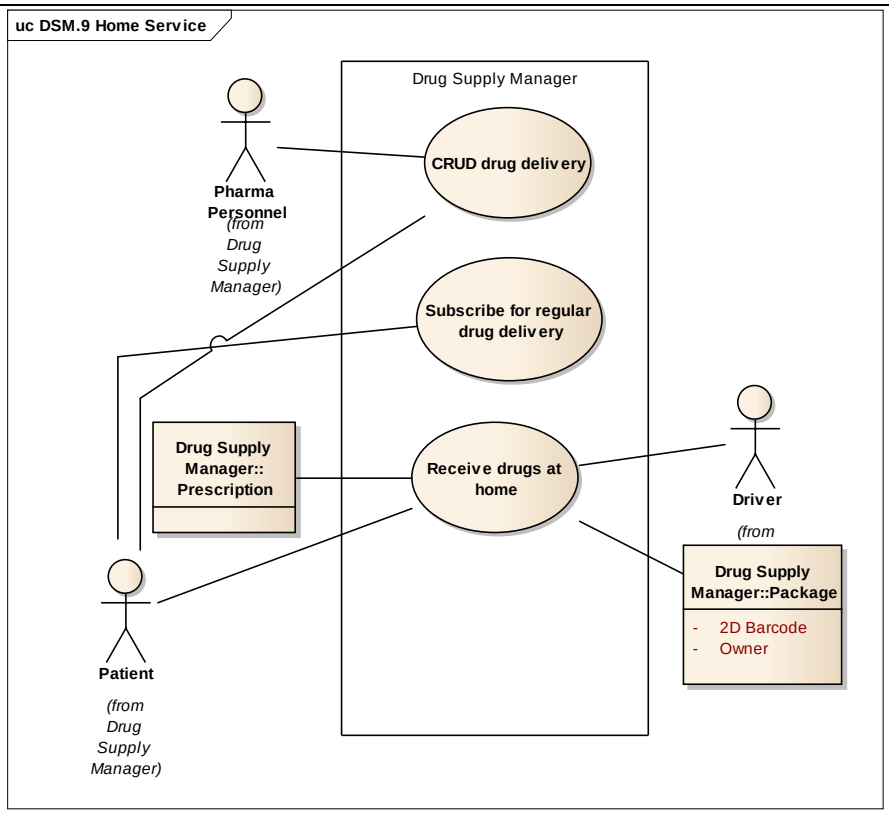
Out of scope [Is this now is scope as PharmaSys is to be integrated]

8.4.2.8 Feature DSM.8 Drug Advice

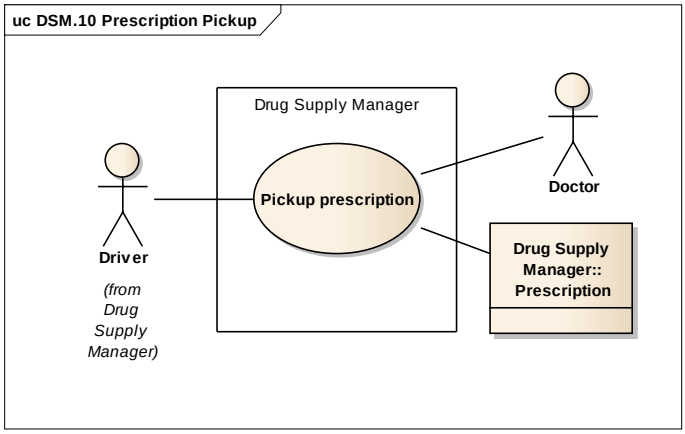
Out of scope

8.4.2.9 Feature DSM.9 Home Delivery

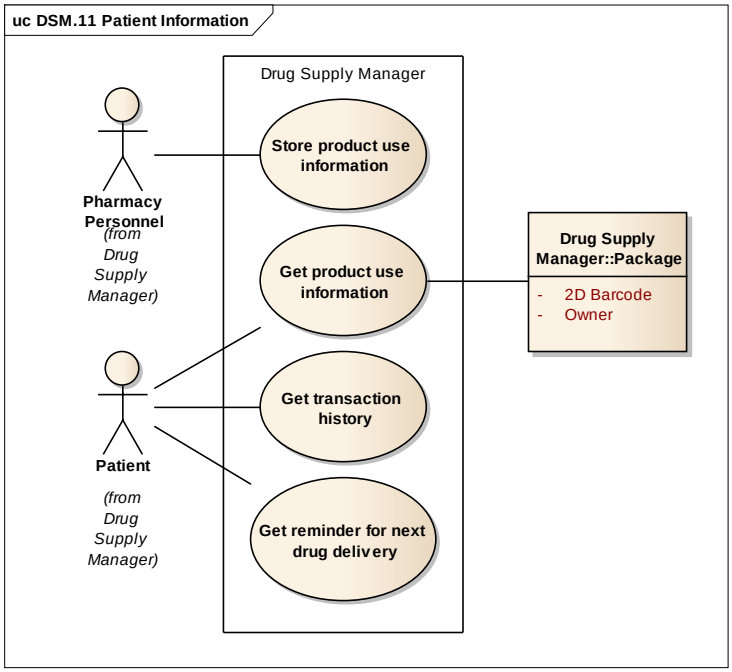
Addressed stakeholder interests and expectations	Goals to be achieved: 46) Risk mitigation: Audit trail of drug delivery 47) Precision: logistics traced External interfaces: 48) From Pharma Personnel to PC and Barcode Scanner 49) From Driver to Barcode Scanner 50) From Package to Barcode Scanner Use cases 51) CRUD drug delivery 52) Dispatch package 53) Receive drugs at home

	
Comments	To be validated with prototype

8.4.2.10 Feature DSM.10 Prescription Pickup

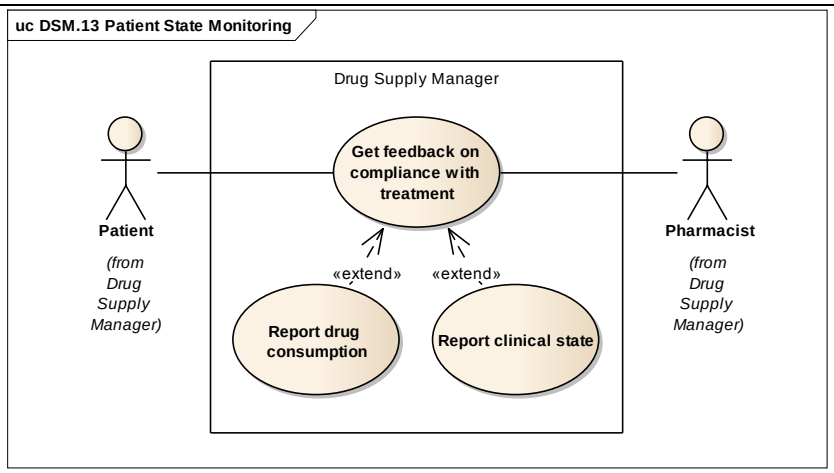
Addressed stakeholder interests and expectations	Goals to be achieved: 54) TBD External interfaces: 55) From Driver to Barcode Scanner 56) From Prescription to Barcode Scanner Use cases 57) Pickup prescription (includes capture prescription image) 58) Capture prescription image 
Comments	To be validated with prototype

8.4.2.11 Feature DSM.11 Patient Information

Addressed stakeholder interests and expectations	Goals to be achieved: 59) Efficiency: patient consultancy effort reduced 60) Risk mitigation: patient safety 61) Risk mitigation: correct use of products 62) Risk mitigation: correct timing of drug use 63) Usability: easy to use External interfaces: 64) From Pharmacy Personnel to PC 65) From Patient to Mobile Phone 66) From Package to Mobile Phone Use cases 67) Store product use information 68) Get product use information 69) Get transaction history 70) Get reminder for next drug delivery 
Comments	To be validated with prototype

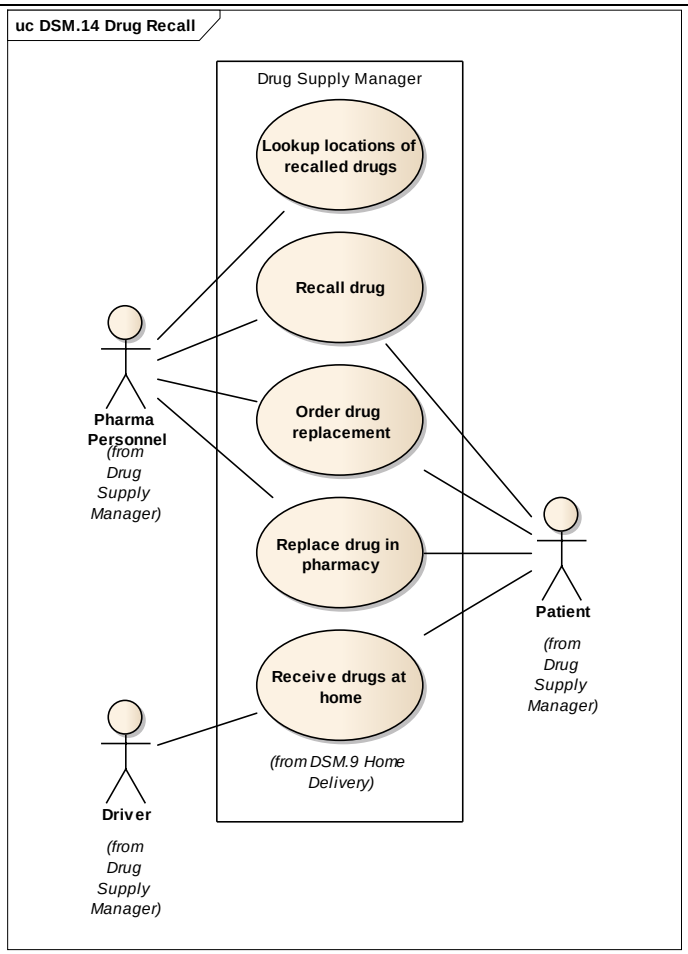
8.4.2.12 Feature DSM.13 Patient State Monitoring

Addressed stakeholder interests and expectations	Goals to be achieved: 71) Effectiveness: NHS-PSA incidents detected External interfaces: 72) From Patient to Mobile Phone Use cases 73) Get feedback on compliance with treatment 74) Report drug consumption 75) Report clinical state

	
Comments	To be validated with prototype

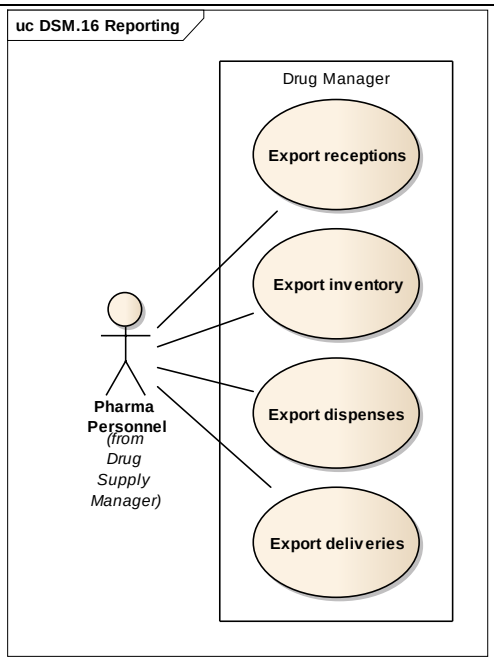
8.4.2.13 Feature DSM.14 Drug Recall

Addressed stakeholder interests and expectations	Goals to be achieved: 76) Risk mitigation: unsafe drugs recalled External interfaces: 77) From Pharma Personnel to PC and Barcode Scanner 78) From Driver to Barcode Scanner 79) From Package to Barcode Scanner Use cases 80) Lookup locations of recalled drugs 81) Recall drug 82) Order drug replacement 83) Replace drug in pharmacy 84) Receive drugs at home 85) Return drugs

	
Comments	To be validated with prototype

8.4.2.14 Feature DSM.16 Reporting

Addressed stakeholder interests and expectations	Goals to be achieved: 86) TBD External interfaces: 87) From Pharma Personnel to PC Use cases 88) Export receptions 89) Export inventory 90) Export dispenses 91) Export deliveries

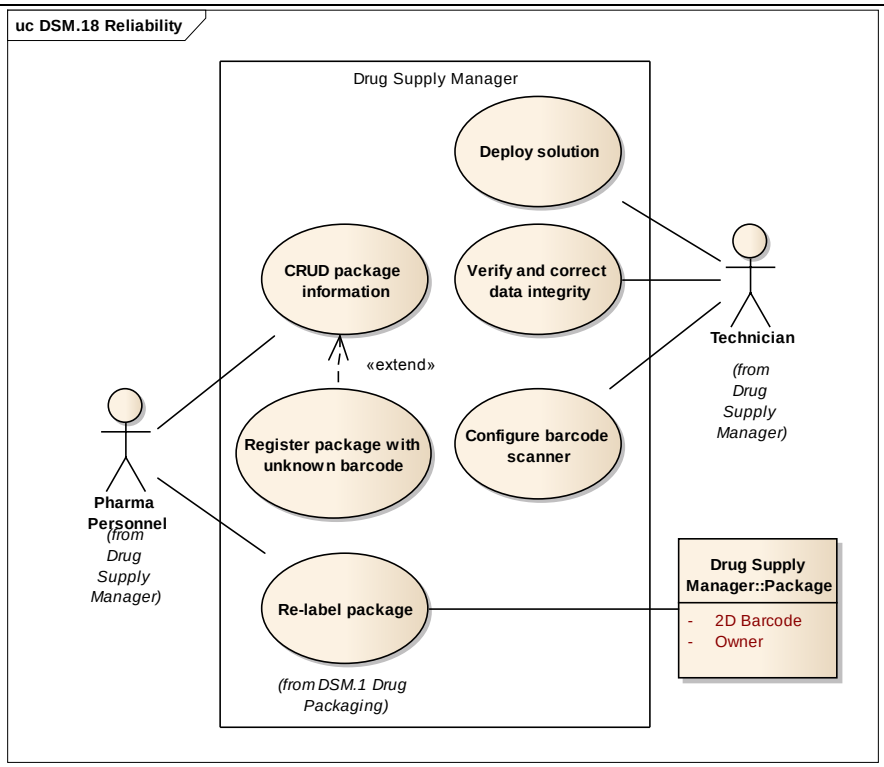
	
Comments	To be validated with prototype

8.4.2.15 Feature DSM.17 Pharmacy Management System Integration

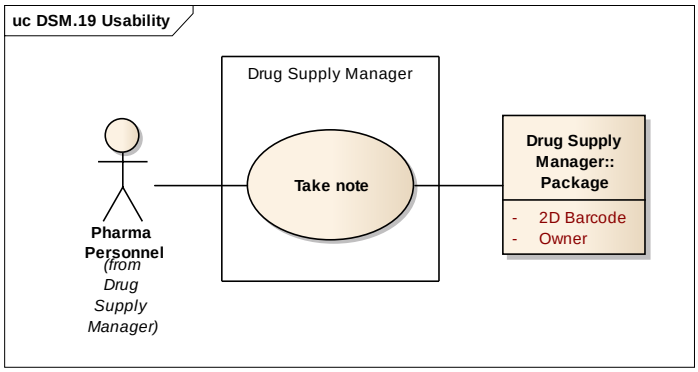
Out of scope

8.4.2.16 Feature DSM.18 Reliability

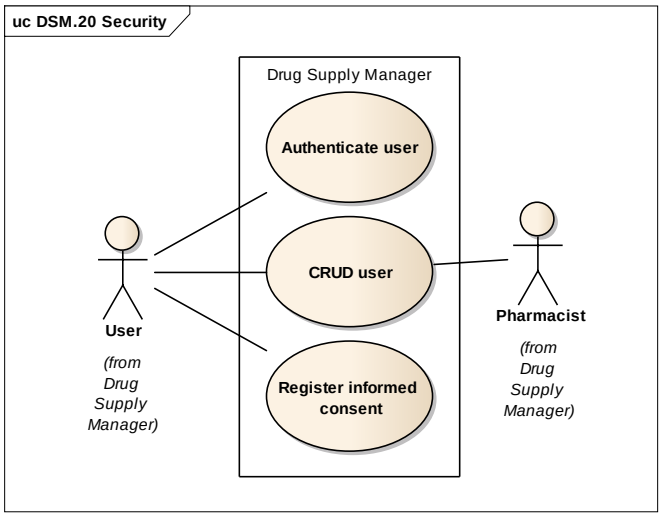
Addressed stakeholder interests and expectations	Goals to be achieved: 92) Risk mitigation: business resilience 93) Reliability: fallback to manual work 94) Security: private cloud for pharmacy 95) Availability: no wifi blind spots in pharmacy 96) Installation: as cheap as possible External interfaces: 97) From Pharma Personnel to PC 98) Technician: TBD 99) From Package to Barcode Printer Use cases 100) Create, read, update, delete package information 101) Register package with unknown barcode (extends create, read, update, delete package information) 102) Re-label package 103) Deploy solution 104) Verify and correct data integrity 105) Configure barcode scanner

	
Comments	To be validated with prototype

8.4.2.17 Feature DSM.19 Usability

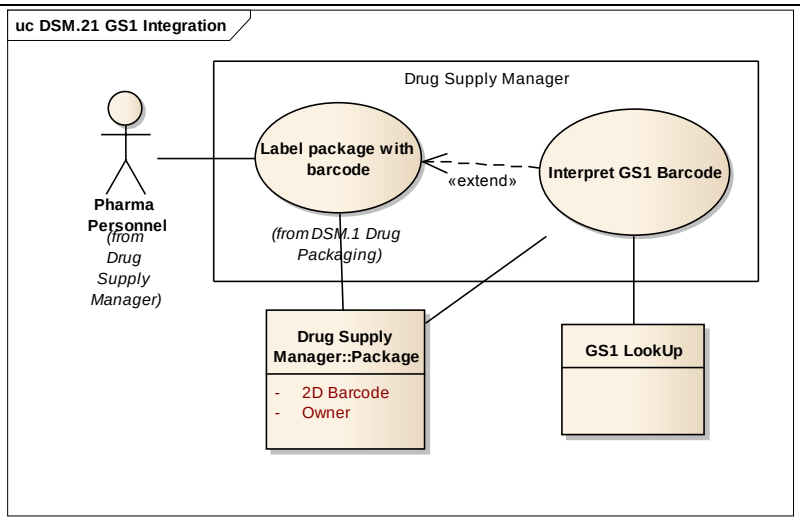
Addressed stakeholder interests and expectations	Goals to be achieved: 106) Competence: staff trained in barcode scanning 107) Performance: <1.5s for barcode to server round trip External interfaces: 108) From Pharma Personnel to PC Use cases 109) Take note 
Comments	To be validated with prototype

8.4.2.18 Feature DSM.20 Security

Addressed stakeholder interests and expectations	Goals to be achieved: 110) Compliance: legal compliance External interfaces: 111) From Pharmacist to PC 112) From User to PC or Smart Phone Use cases 113) Authenticate User 114) Create, read, update, delete User 115) Register informed consent 
Comments	To be validated with prototype

8.4.2.19 Feature DSM.21 GS1 Integration

Addressed stakeholder interests and expectations	Goals to be achieved: 116) Accelerate the creation of 2D barcodes. External interfaces: 117) From Pharma Personnel to PC and Barcode Scanner 118) From GS1 Connector to GS1 LookUp 119) From Barcode reader to Drug Package Use cases 120) Label package with barcode 121) Interpret GS1 Barcode (extends Label package with barcode)

	
Comments	To be validated with prototype GS1 has data gaps that need to be completed manually with the wholesale suppliers' CSV files.

8.4.2.20 Feature DSM.22 Demand Prediction

Out of scope

8.4.2.21 Feature DSM.23 e-Procurement

Out of scope

8.4.2.22 Feature DSM.24 PIP Integration

Out of scope

8.4.2.23 Feature DSM.25 Discrepancy Reporting

Out of scope

8.4.2.24 Feature DSM.26 Authenticity Check

Out of scope

SECTION II – Solution Deployment and Non-Functional Requirements

The following chapters give an overview of deployment and non-functional requirements for each of the FI-STAR-based solutions. The deployment scenarios define the architecture of the deployed solutions in terms of nodes, applications to be developed and integrated, and essential information flows between these applications. The deployment and security requirements give constraints to be respected by these deployment scenarios. The chapters about legislations and privacy requirements and about standards and certification requirements are previews of the corresponding future WP1 deliverables.

Chapter 9: Deployment Scenarios

Chapter 10: Deployment Requirements

Chapter 11: Security Requirements

Chapter 12: Preview on Legislation and Privacy Requirements

Chapter 13: Preview on Standards and Certification Requirements

9 Deployment Scenarios

The deployment scenarios describe how the FI-STAR solutions are structured. They describe the applications that are being integrated and how these applications interact to deliver end-to-end functionality. The deployment scenarios describe in addition the computing contexts and computation nodes that execute the applications. FI-STAR-enabled computation nodes are indicated explicitly, however without premature selection of Generic Enablers.

We chose to specify the deployment scenarios with UML deplyoment diagrams as a modeling notation. UML is a broadly adopted standard in the software industry. Two variants of UML deployment diagrams were created: runtime and deployment models. The runtime models describe the structure of a solution and the data flows between applications during runtime. The deployment models extend the runtime models by describing how the applications are sourced from application stores.

The deployment scenarios are used to enable:

- application design by determining the applications and their essential functionality in terms of inputs and outputs (WP4).
- platform design by describing examples of system structures and by providing a vocabulary for specification of deplyoment requirements and technological constraints (WP2 and WP3)
- application testing and end-to-end testing by describing the traces of end-to-end use cases (WP6)
- certification by describing the products that recide in application stores that may be equipped with certification processes and capabilities (WP6)

9.1 Diabetes Share System for Diabetes Care in Tromsö, Norway

The Diabetes Share System is deployed on both patient smartphones and hospital servers in an environment comprising legacy and third party systems.

Figure 102 gives a complete overview of the relationships between these and the origins of the Diabetes Share System artefacts. It is drawn according to UML deployment notation and shows nodes required to support features in minimal scope (alpha prototype for month 12) and target scope (beta prototype for month 24). Communication paths between nodes is also shown, indicating major data flow and corresponding data types

Figure 103 shows a simplified version of Figure 102 showing only the nodes affected by the Diabetes Share System.

Feature specific deployment diagrams are also included in the next section for the features in minimal and target scope.

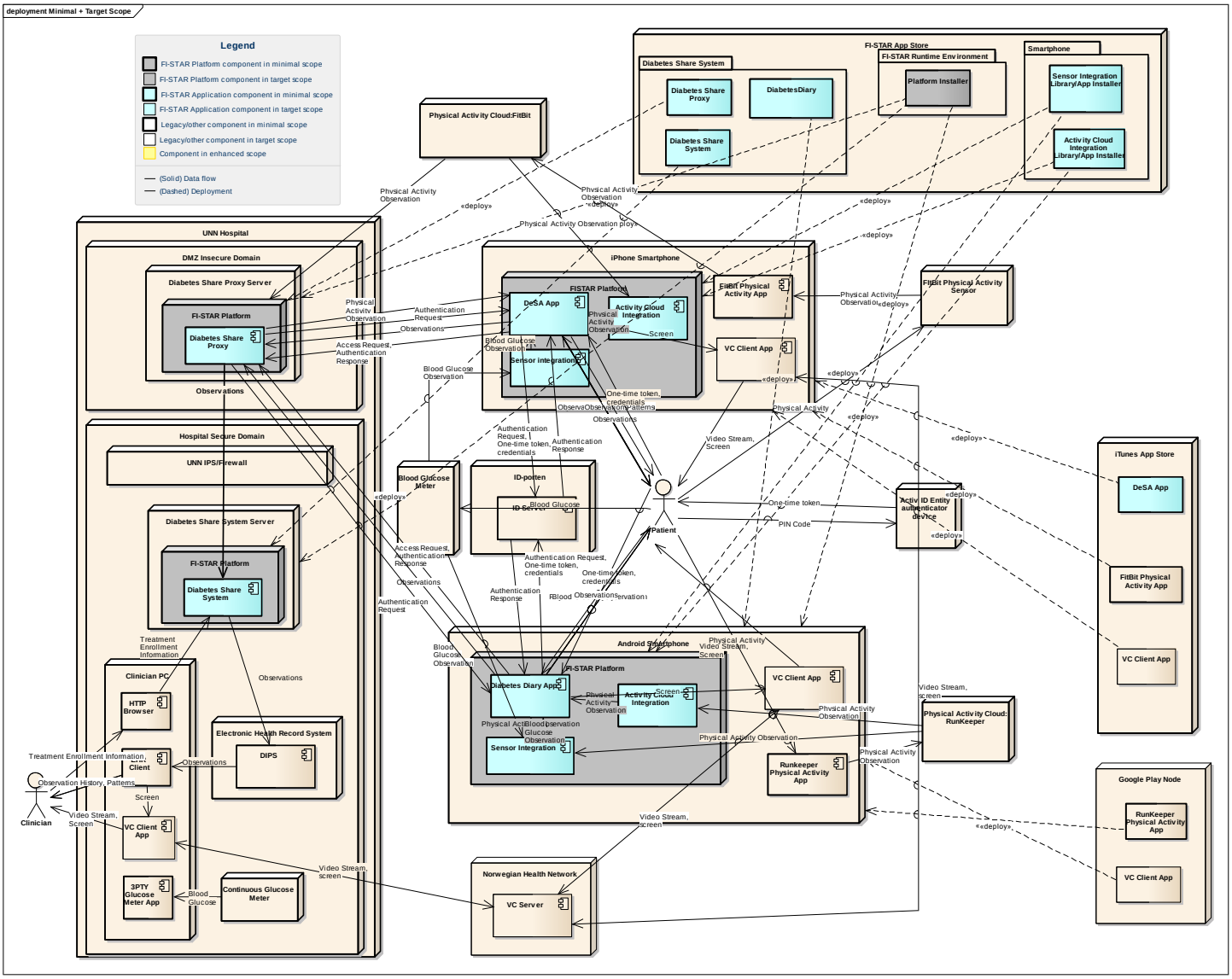


Figure 102: Complete deployment diagram for minimal and target scope.

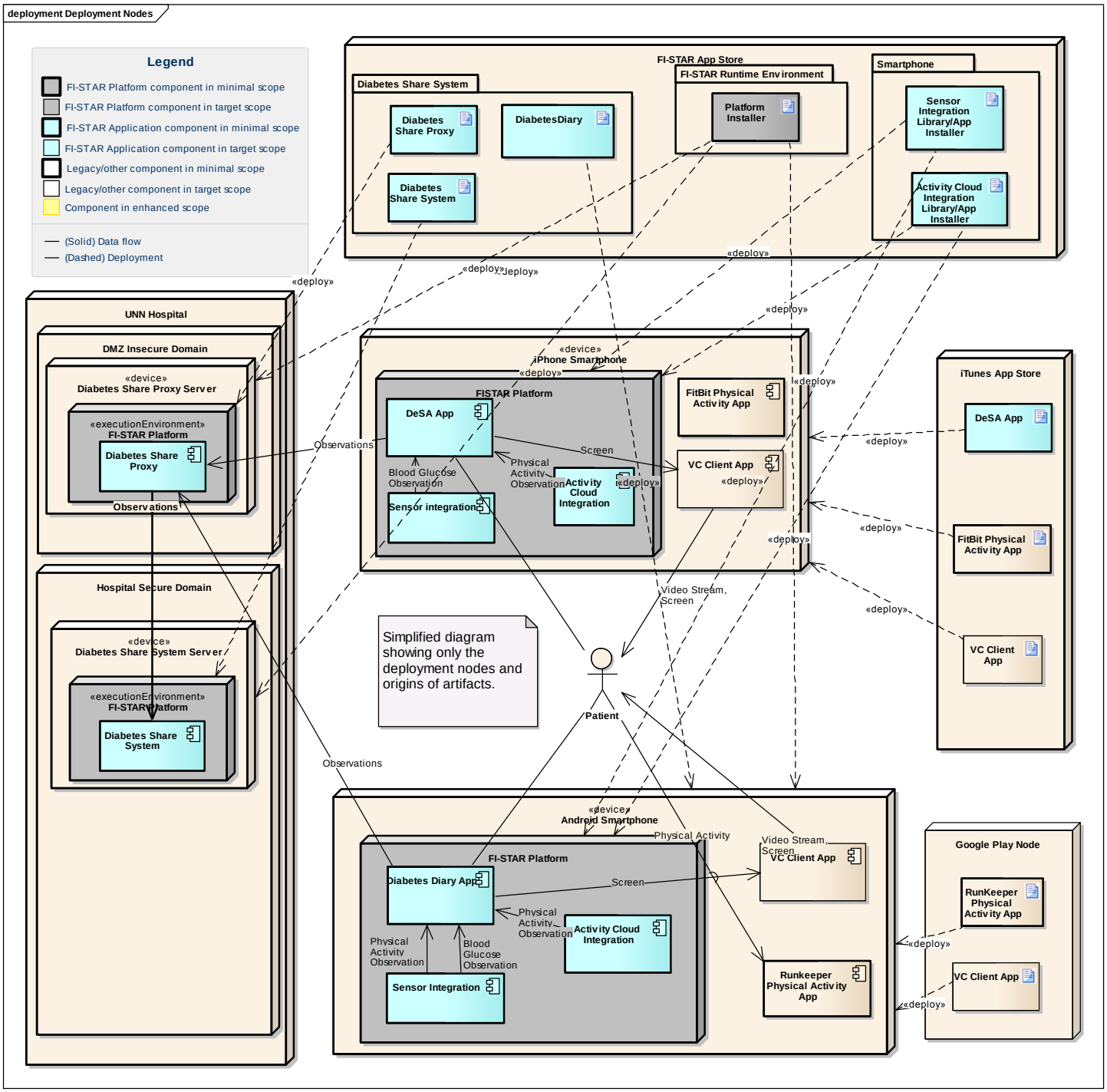


Figure 103: Simplified deployment diagram

9.2 TeleCare Solution for Rehabilitation and State Monitoring in Krakow, Poland.

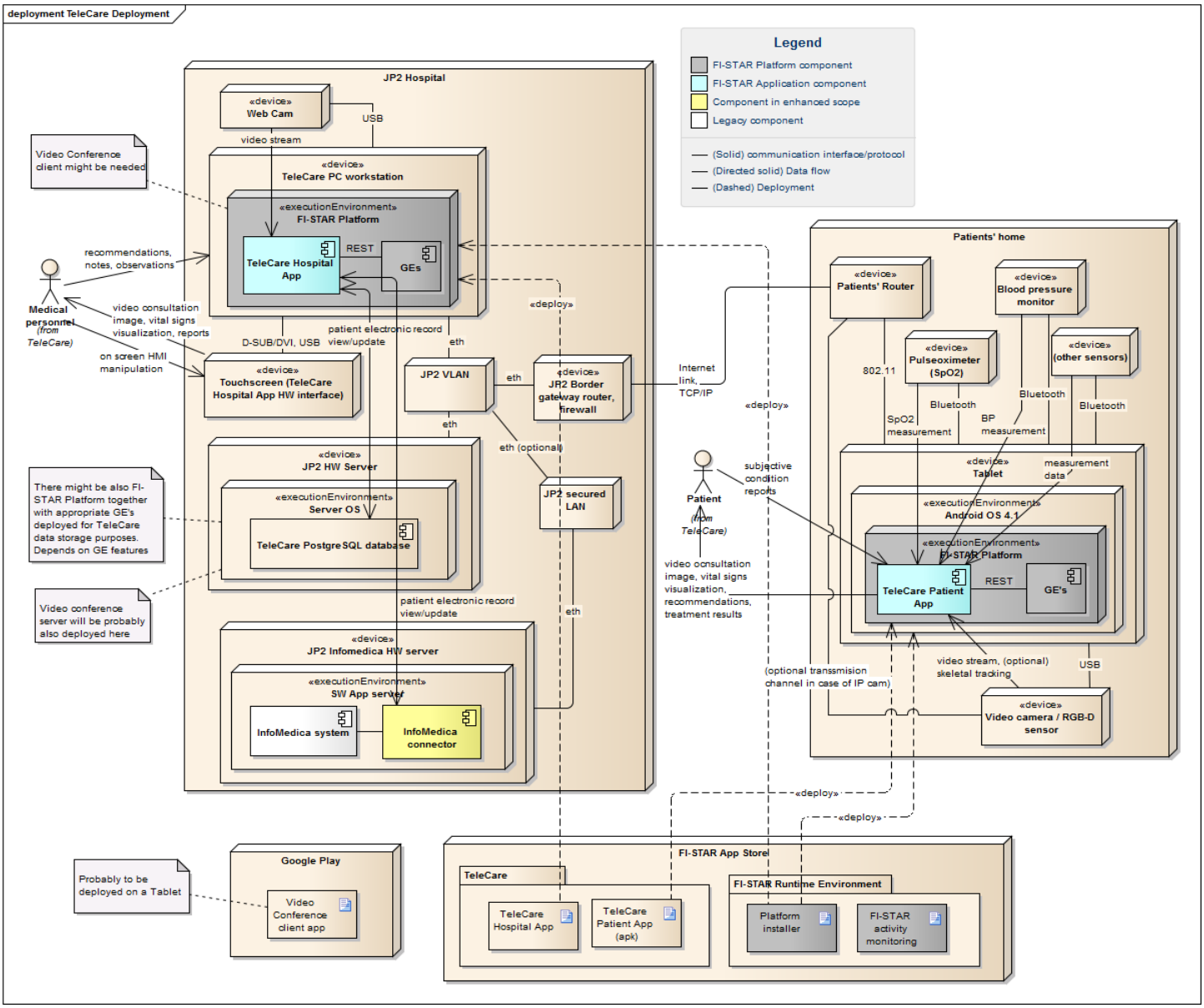


Figure 104: Complete deployment diagram for minimal and target scope.

9.3 Chronic Disease Treatment Assistance for COPD Treatment in Bologna, Italy

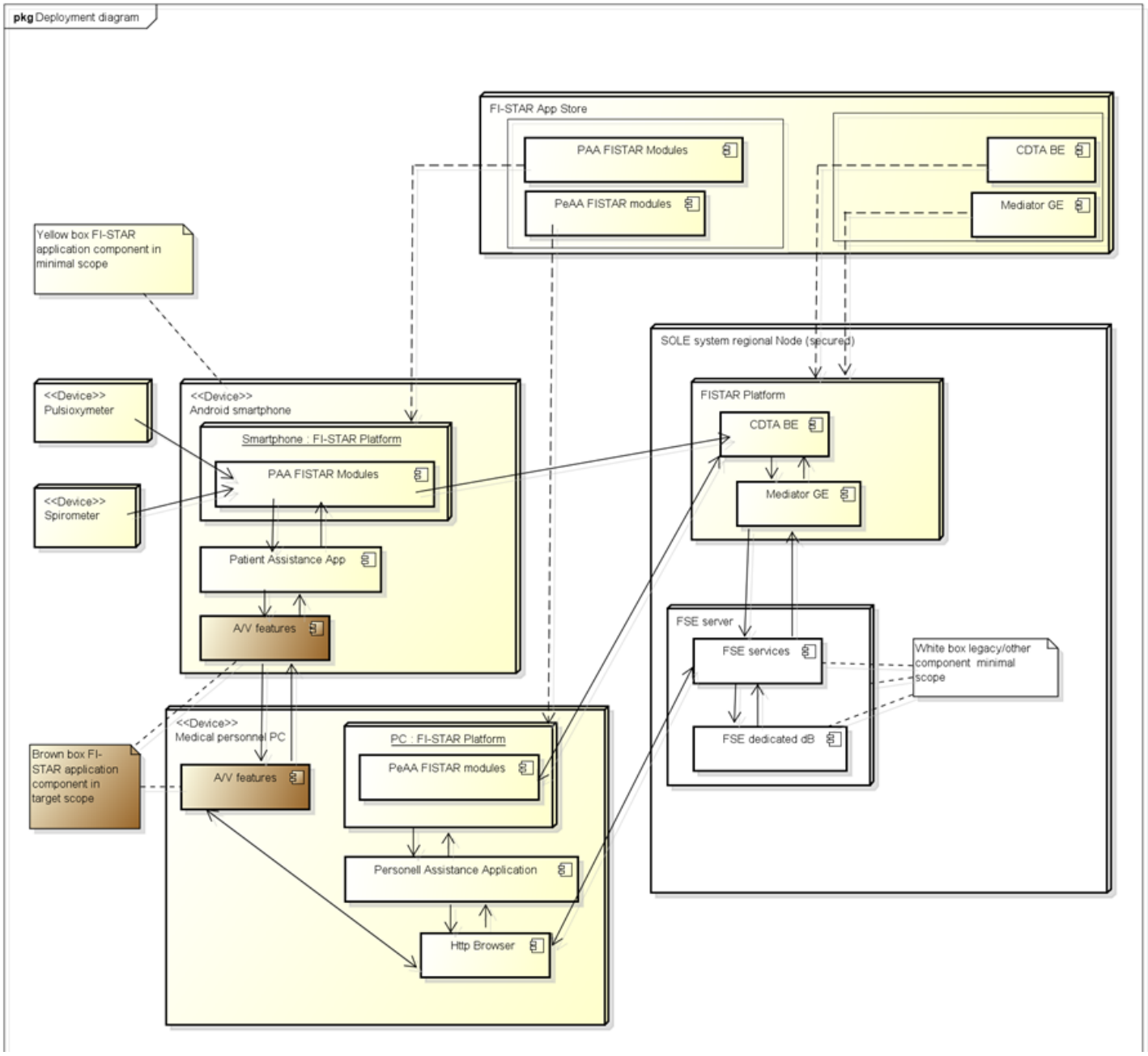


Figure 105: Complete deployment diagram for minimal and target scope.

9.4 Management Solution for Bipolar Patient Treatment in Bilbao, Spain

Notation

	FI STAR Platform in minimal scope (planned in α version)
	FI STAR Platform in target scope (planned in β version)
	FI STAR Application Component in minimal scope (planned in α version)
	FI STAR Application Component target scope (planned in β version)
	For experimentation in target scope
	Optional /enhanced scope.

<-· Deployment

← Data flow

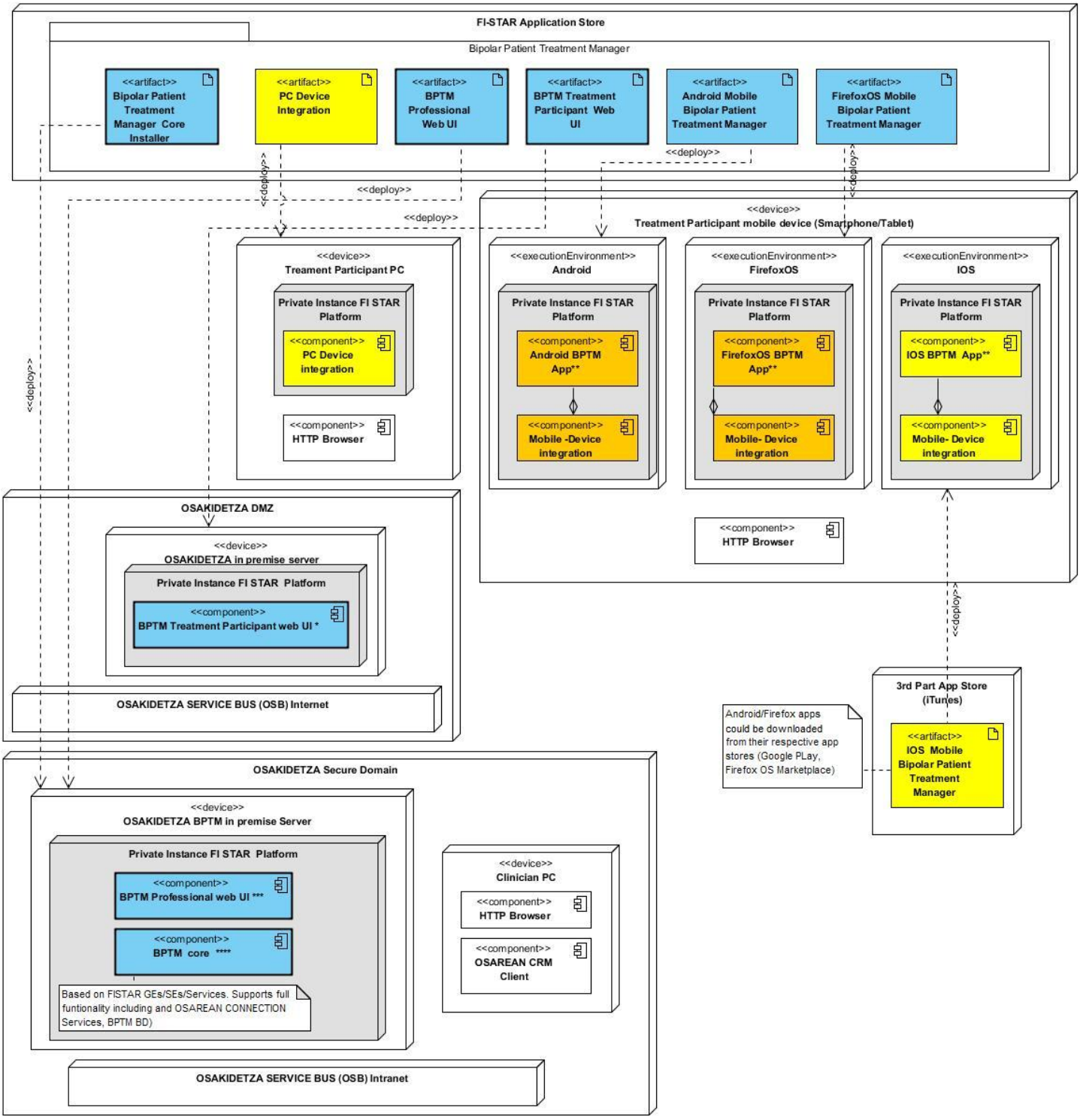


Figure 106: Deployment model

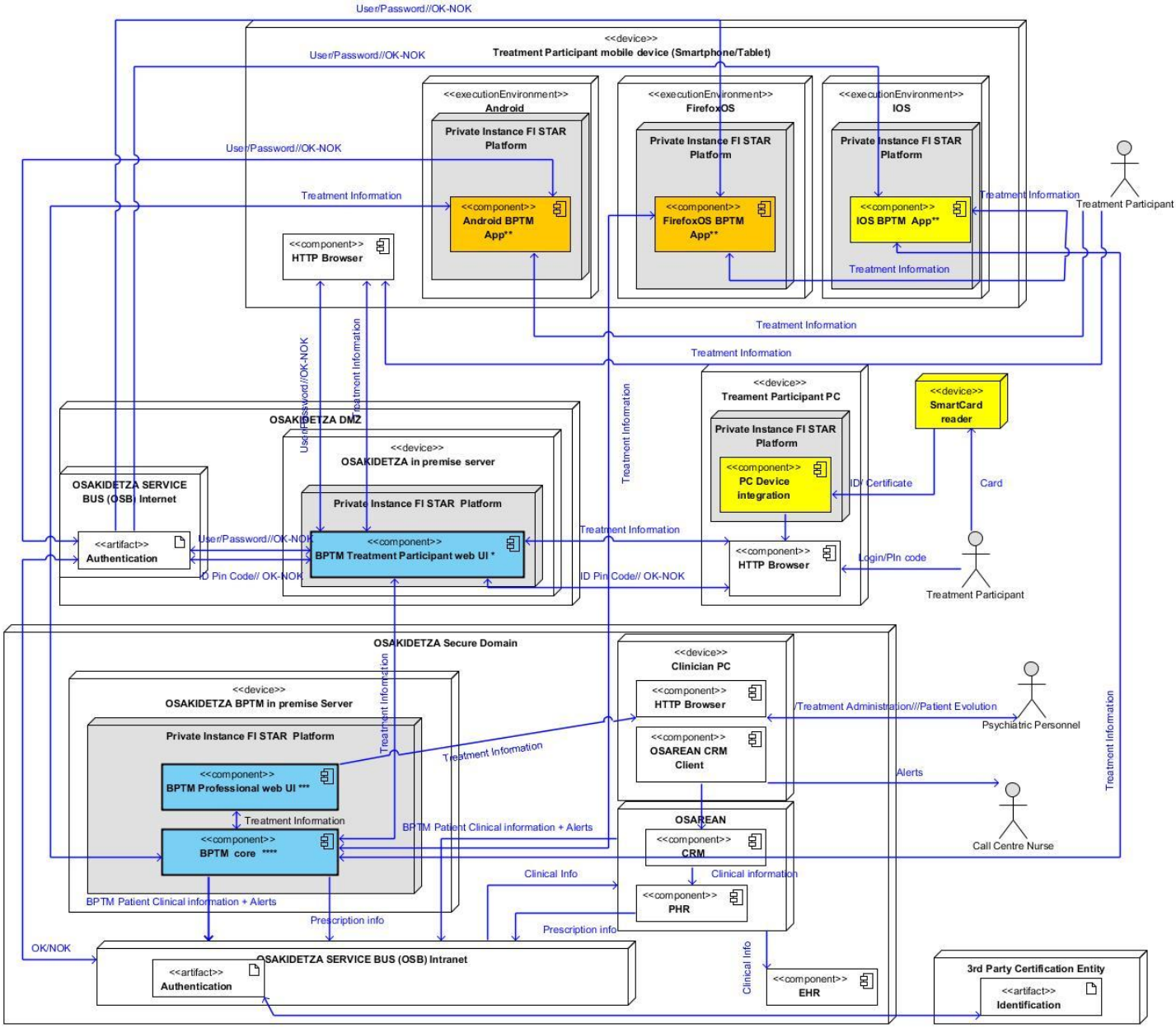


Figure 107: Runtime model with manual data input

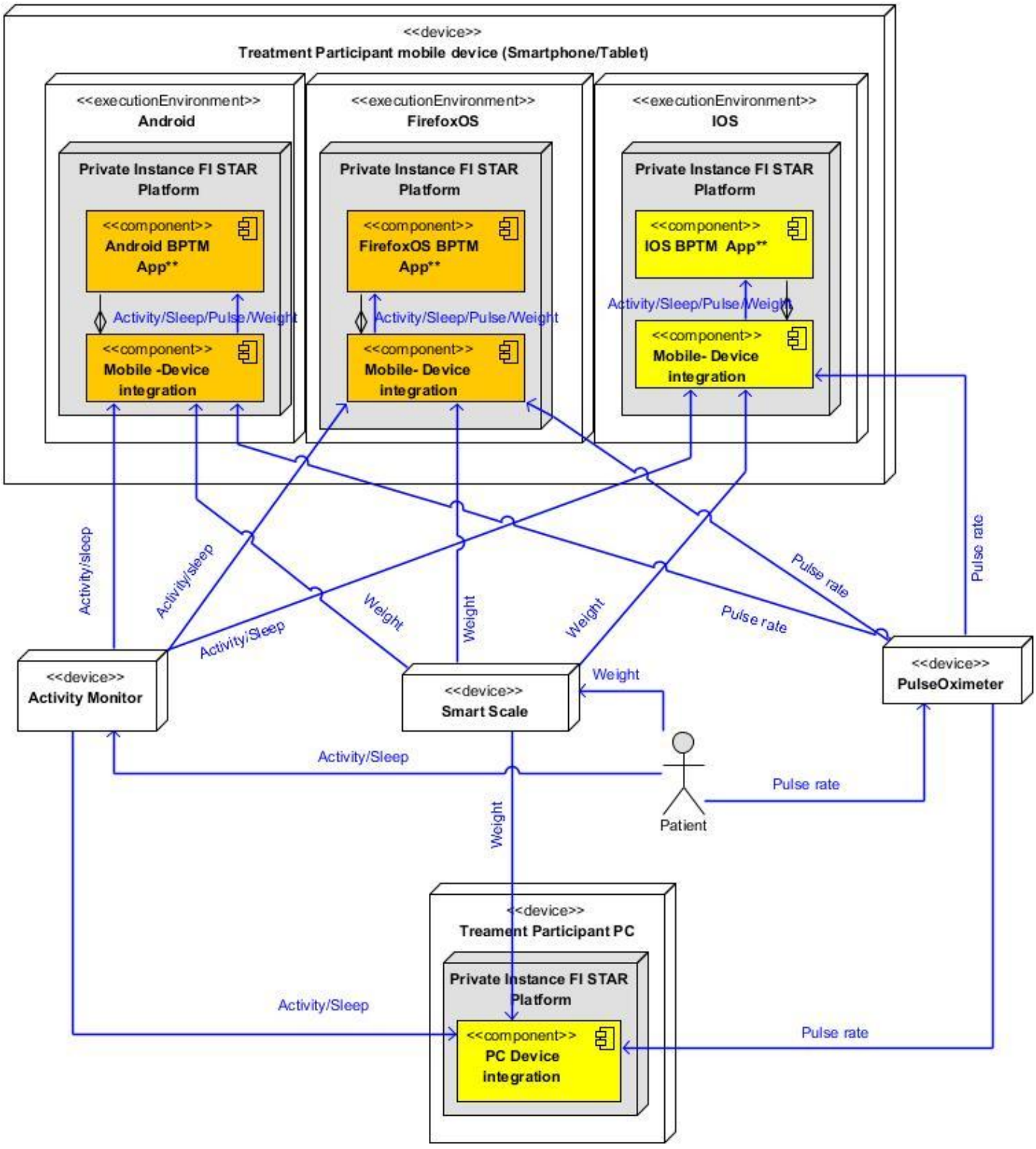


Figure 108: Runtime model automatic biometric input

9.5 CRP Solution for Cardiac Rehabilitation in Bucharest, Romania

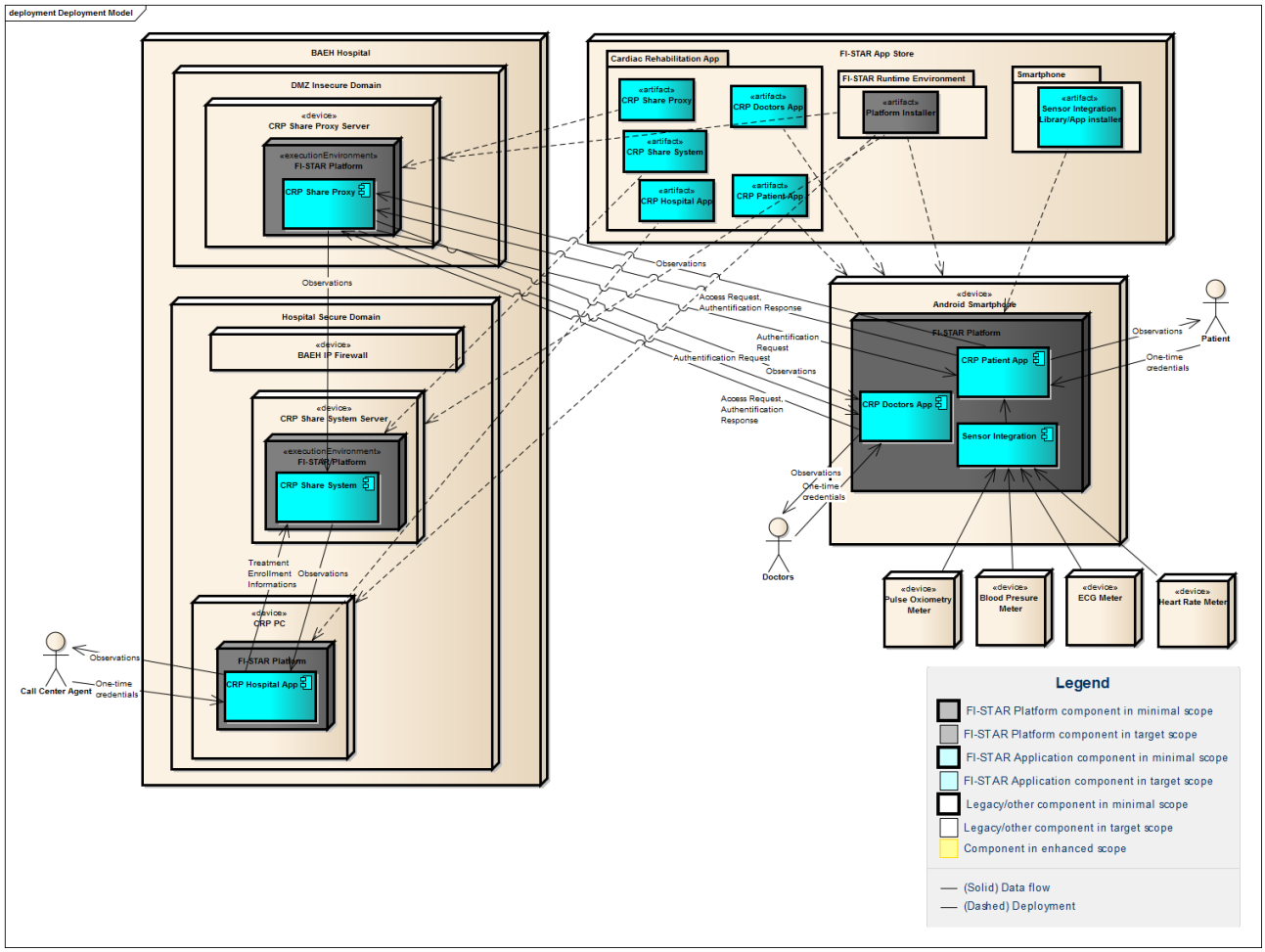


Figure 109: Deployment Model for Cardiac Rehabilitation Solution

9.6 Operating Theatre Monitor for Operation Consumables Tracking in Munich, Germany

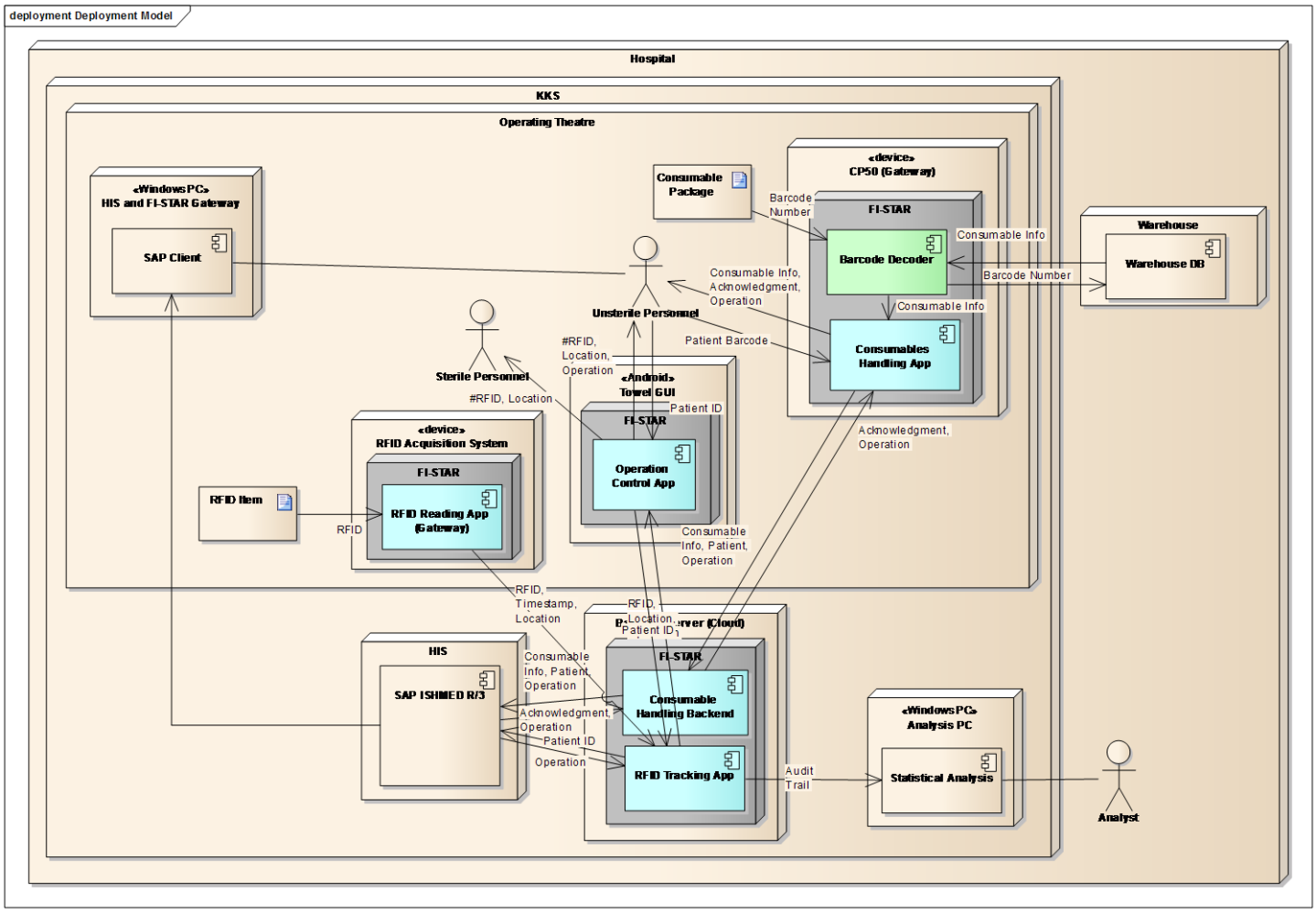


Figure 110: Runtime Model for Operating Theatre Monitor

9.7 Drug Supply Manager for Reverse Drug Supply Chain in Leeds, United Kingdom

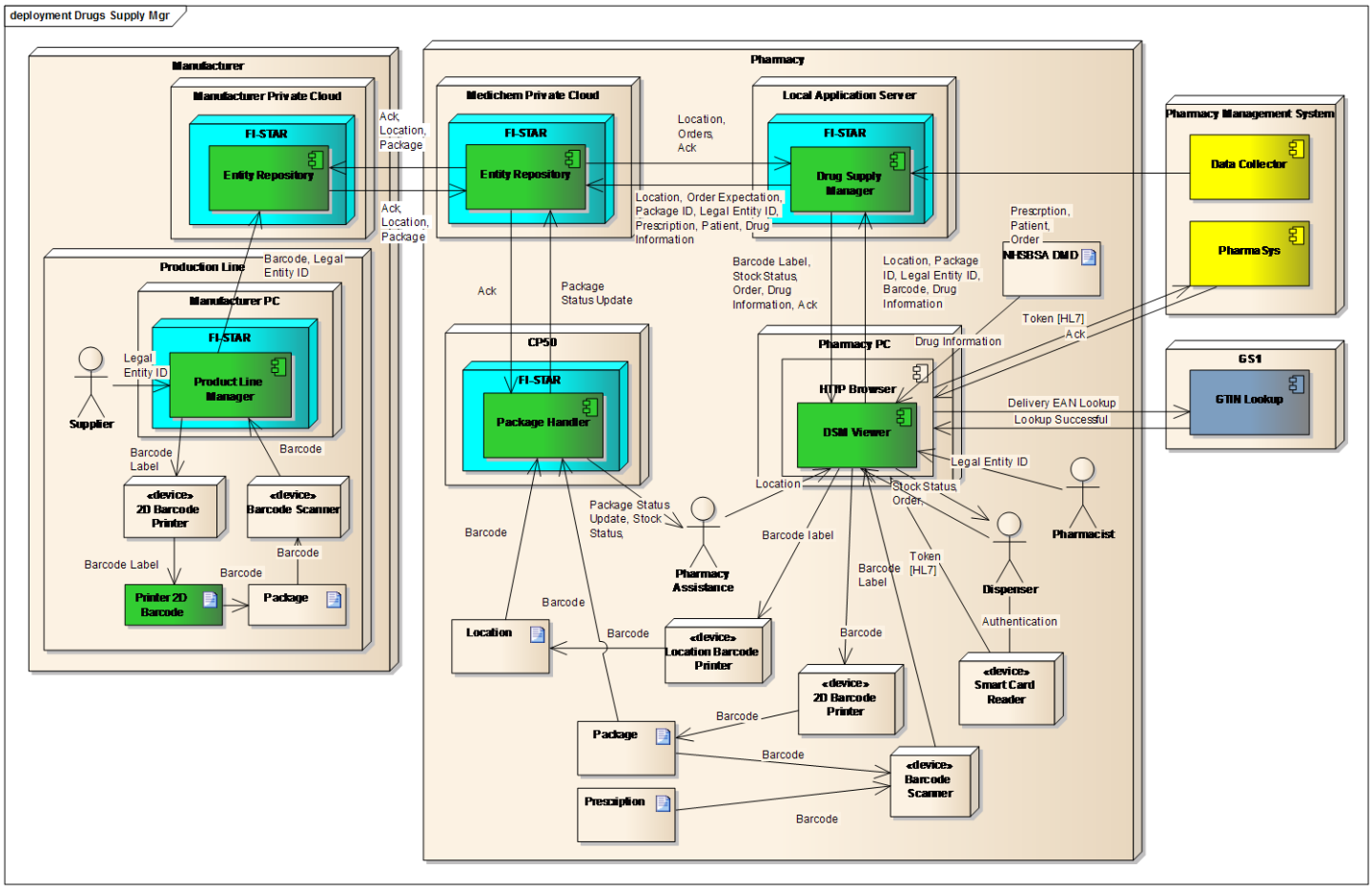


Figure 111: Runtime Model for Drug Supply Manager

10 Deployment Requirements for all Use Cases

10.1 Introduction

A questionnaire has been prepared in order to gather the requirements relevant to the deployment of the software components.

10.1.1 Questionnaire Structure

The requirements are organized in six main categories (i.e. the FI-STAR Applications Dimensions) which have an impact to the infrastructure specification of the back-end (provider platform) and the front-end (consumer platform) (see Figure 112).

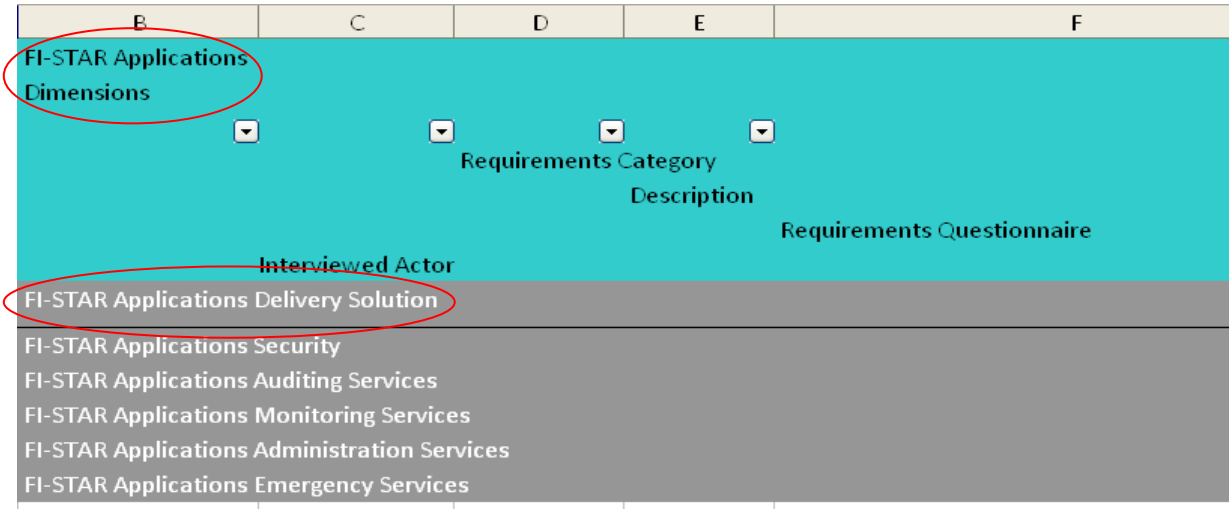


Figure 112: FI-STAR Applications Dimensions

In turn each dimension is further exploded in order to catch finer grained *requirements categories*. Below a snapshot about the questionnaire related to the system monitoring requirements category.

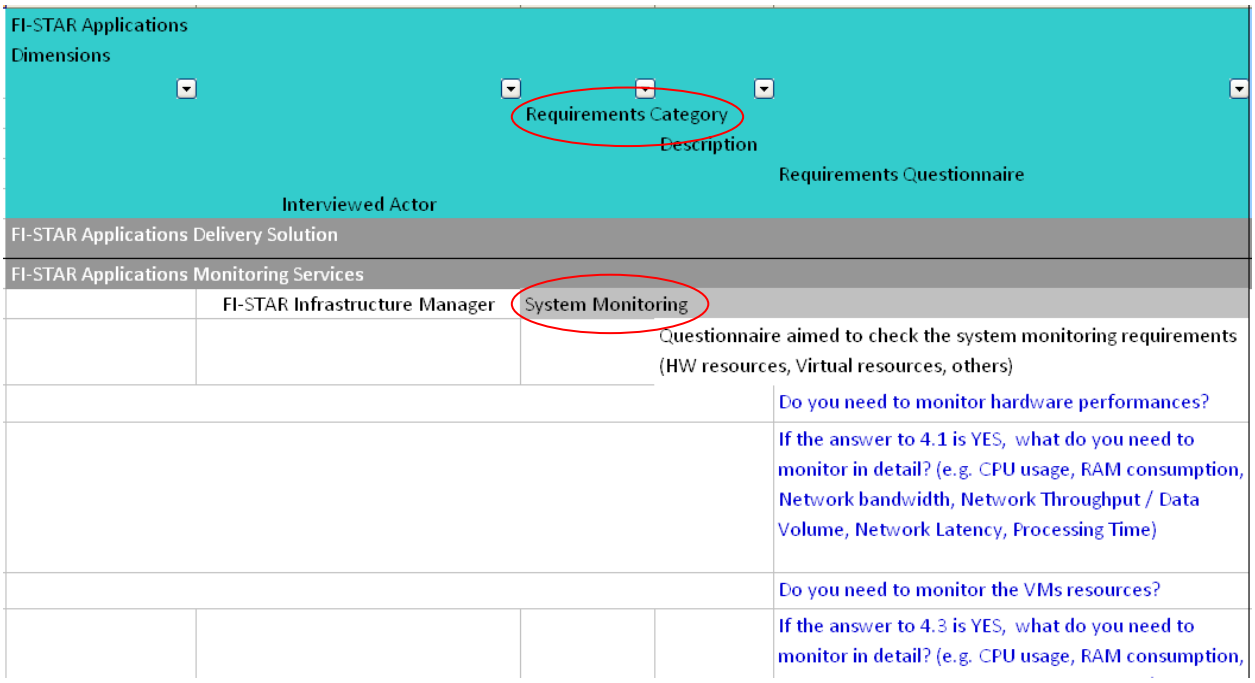
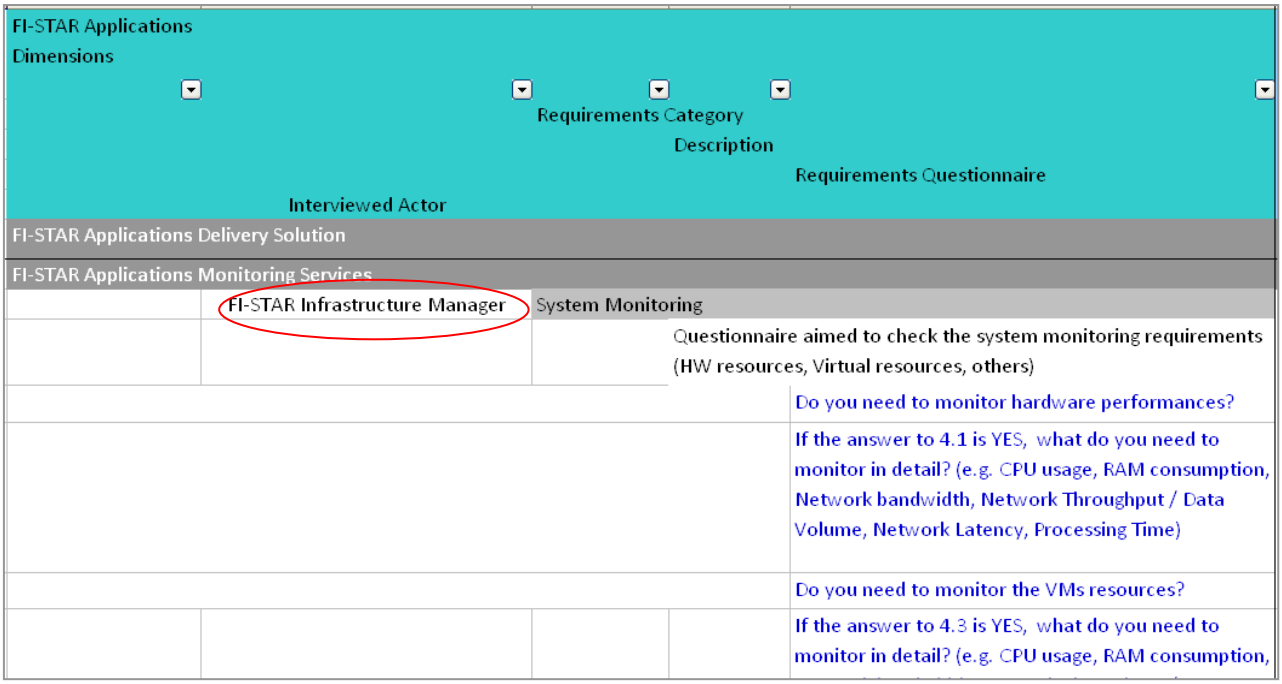


Figure 113: Requirements Categories

10.1.2 Viewpoints Addressed by the Questionnaire

In order to allow the use cases team to easier identify the actors to interview and involve in the requirements elicitation process, the *requirements categories* are linked to specific actors.



FI-STAR Applications Dimensions	Interviewed Actor	Requirements Category	Description	Requirements Questionnaire
FI-STAR Applications Delivery Solution				
FI-STAR Applications Monitoring Services				
	FI-STAR Infrastructure Manager	System Monitoring		
			Questionnaire aimed to check the system monitoring requirements (HW resources, Virtual resources, others)	
				Do you need to monitor hardware performances?
				If the answer to 4.1 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)
				Do you need to monitor the VMs resources?
				If the answer to 4.3 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption,

Figure 114: Interviewed Actors

FI-STAR Infrastructure Manager

responsible for taking decisions related to the needed infrastructure resources (servers, storage, network) and related to their deployment according to the: delivery model (client-server or cloud), performance (load, availability, response time), resilience, monitoring, auditing (governance and compliance requirements)

FI-STAR Security manager

responsible for the security requirements related to the applications access and data security requirements, data privacy requirements and requirements related to protection against cyber-attacks

FI-STAR Administrator

responsible for the requirements related to: Change and Release Management, Configuration, Test and Maintenance, Incident Management

FI-STAR Emergency Manager

responsible for requirements related to the management of an emergency situation that affects the FI-STAR Use-Case-Applications delivery.

10.2 Analysis

The analysis process started with a review of all submitted questionnaires in order to discover errors, inconsistencies or still empty fields which triggered a second step to fix the pending points by means of new iterations with the use cases teams.

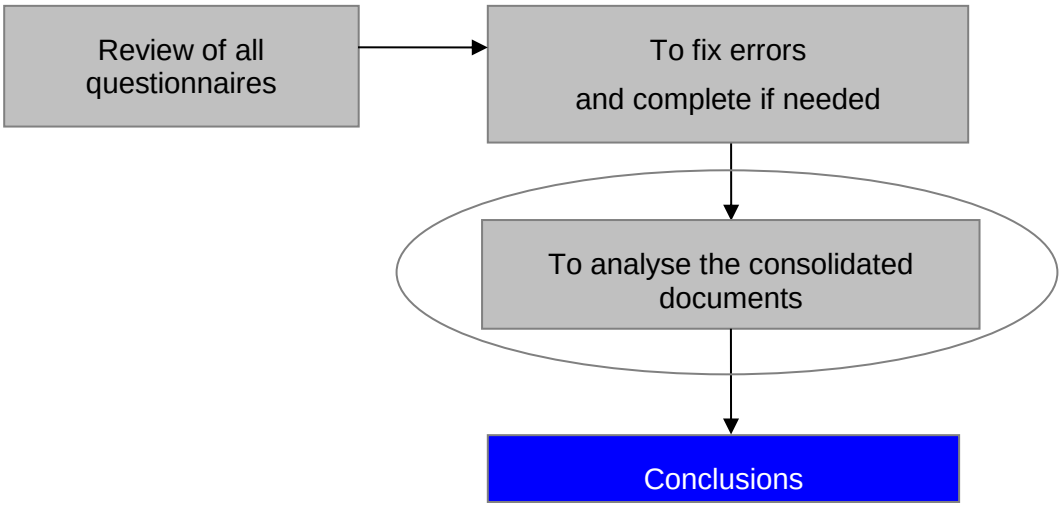


Figure 115: The Analysis Process

During the analysis step, the answers provided by the different use cases were fetched by each excel file and transferred in a common single file (see Figure 116) in order to facilitate the following step focused on aggregating the values trying to make a clustering.

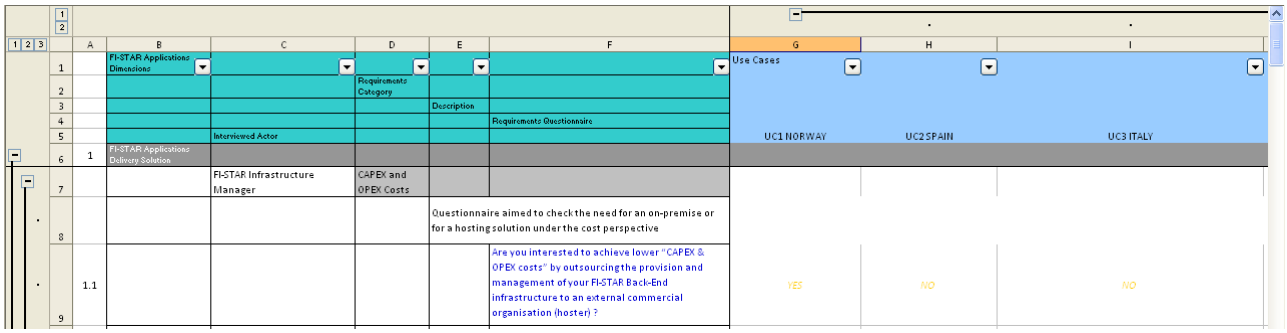
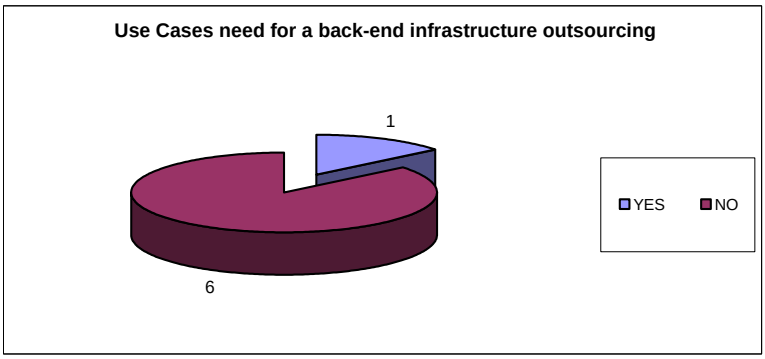


Figure 116: The file gathering all the answers

The applied logic was to extract those answers able to satisfy all the different needs coming from the seven use cases. With respect to this objective, different *strategies* were possible depending, in principle, by the nature of the requirements themselves. In some cases it would be possible, for instance, to organize the clusters around the average value of the provided values while in other cases the meaningful value could be the minimal one (e.g. bandwidth).

In case the nature of the requirements do not allow the application of such strategies, an approach based on the simple union of the answers can take place. In the figure below a simple example of such clustering attempt taken in to account within this work package (more complex analysis were reminded to the design work packages). The figure outlines that that the only one use case requires to outsource its back-end infrastructure.



10.3 Results

10.3.1 Diabetes Share System (Tromsö, Norway)

	FI-STAR Applications Dimensions / Requirements Category / Description / Requirements Questionnaire / Interviewed Actor			Diabetes Share System (Tromsö, Norway)	Clarifications
1	FI-STAR Applications Delivery Solution				
	FI-STAR Infrastructure Manager	CAPEX and OPEX Costs			
			Questionnaire aimed to check the need for an on-premise or for a hosting solution under the cost perspective		
1.1			Are you interested to achieve lower "CAPEX & OPEX costs" by outsourcing the provision and management of your FI-STAR Back-End infrastructure to an external commercial organisation (hoster) ?	*YES*	The UNN CIO has outsourced the UNN Hospital Node to Helsenord IKT for provision of all IT services. The UNN CIO has adopted the use of the Norwegian Health Network for video conferencing. The DeSA product manager decided to use the FitBit Physical Activity Cloud for storing data about physical activity. The Diabetes Diary product manager decided to use the Runkeeper Physical Activity Cloud for storing data about physical activity. The Diabetes Share System solution architect decided to use the ID-porten for patient authentication.
1.2			If the answer to 1.1 is NO, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in your existing data cente ? (NO means the FI-STAR Back-end infrastructure will be deployed in a new on-premise data center)	*NO*	Neither customer, product managers, nor solution architects deploy FI-STAR Back-End infrastructure in own data centres. However, all back-end infrastrcture is deployed into existing data centres (not the own ones, though).
1.3			If the answer to 1.2 is YES, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in a separate physical environment (YES means new CAPEX, NO means reuse of existing infrastructure resources)?	*NO*	No CAPEX for this from the customer, product mgmt, or solution architecture perspectives.
1.4			If the answer to 1.3 is NO, please describe the resources intended to be used for the deployment of your FI-STAR Back-End infrastructure	*NO*	UNN Hospital: Helsenord IKT (company owned by government)
1.4.1			Computing resources (server machines)		
			Hardware		(From here we just mention the nodes that are planned to host a FI-STAR platform instance.) Diabetes Share Proxy Server: Virtual machine. Diabetes Share System Server: Virtual machine. Deployment on existing server hardware hosting virtual machines is a requirement from infrastructure management.
			Operating System		TBD
1.4.2			Storage System		
			Hardware		Virtual Machine
			Data base System		TBD
1.4.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)		*Firewall: Hospital Secure System* *VPN concentrator/router: TBD* *Front-end LAN after VPN concentrator: TBD*
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)		*Firewall: ID-porten, Physical Activity Cloud: Fitbit, Physical Activity Cloud: Runkeeper, Hospital Secure System*
1.5			If the answer to 1.3 is YES, please describe the resources you intende to purchase		
1.5.1			Computing resources (server machines)		
			Hardware		
			Operating System		
1.5.2			Storage System		
			Hardware		
			Data base System		
1.5.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)		
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)		
			Questionnaire aimed to check the real need of a cloud solution under the resource utilisation perspective		
1.6			If the answer to 1.1 is NO, are you interested to achieve higer "resource utilisation" by adopting economies of scale in your FI-STAR Back-End infrastructure management, by means of a greater sharing of your infrastructure resources ?	*(YES/NO)*	
	FI-STAR Infrastructure Manager	Scalability			
			Questionnaire aimed to check the real need of a cloud solution under the scalability perspective		
1.7			Are you interested to offer an almost instantly "scalable" FI-STAR Applications Delivery solution ?	*YES*	The Diabetes Share System needs to support a trial with up to 40 diabetes patients. Stakeholders are interested in scalability to support a much larger user base and a variety of diagnoses upon productization.
	FI-STAR Infrastructure Manager	Performance			
			Questionnaire aimed to specify the performance requirements of the FI-STAR Applications services		
1.8		Response Time	What is the typical and maximum required Responce Time (Round Trip Time plus Processing Time) of your FI-STAR use-case-scenario applications / use cases requests ?		*Users: Applicattion reaction time TBD (Markus Fiedler?)* *Rountrips Android/iPhone - Diabetes Share Proxy: like SMS confirmation messages (a few seconds)* *DS1.11 Remote Video Counselling: TBD (Markus Fiedler?)*
1.9		Availability	What is the required availability of your FI-STAR use-case-scenario applications ?		
1.9.1			down-time pro month	*5 (0.1) hours*	alpha/beta prototyes (40 patients): 5h per month product (post-FI-STAR, 10'000 patients): 0.1h per month
1.9.2			mean time to repair	*5 minutes*	
1.10		Load	What are your parallel processing and load requirements ?		
1.10.1			Number of Simultaneous patient sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*5 simultaneous sessions/ 5 req pro day / TBD kB pro upload /TBD kB pro download*	*Product: <1000 simultaneous sessions*
1.10.2			Number of Simultaneous profesional users (GP, clinical specialist, pharmacist, call ctr .agent, ...) sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*3 simultaneous sessions/ 3 pro day / TBD kB)*	*Product: <50 simultaneous sessions*
1.10.3			How many peak-load situations do you expect?	*0 peaks / hour*	*Product: 1/hour*
1.11			Do you intend to provide to your end-users Application Performance Reports? If YES, please specify the reporting time-interval	*NO*	
1.12			Do you intend to provide to your end-users Application Delivery Incident Reports? If YES, please specify the time after incident occurance	*YES, 5 sec*	If submitting observations from Android or iPhone Smartphone fails, users should know in 5 seconds.
	FI-STAR Infrastructure Manager	Resilience			
			Questionnaire aimed to check the real need of a cloud solution under the reliability perspective		
1.13			Are you interested to offer an high level of "resilience" of the hosted applications by reducing, as much as possible, single points of hardware failure and offering, in such a way, an higher uptime?	*NO (YES)*	Most communication is infrequent asynch HTTP. Even so, a high level of resilience is of course benificial, but not critical.
	FI-STAR Applications Service Billing	Pricing			
			Questionnaire aimed to check the real need of a cloud solution under the pricing perspective		
1.14			Do you intend to offer a pricing model based on a fee (or a flat rate) ?	*(YES/NO)*	TBD
1.15			Do you intend to offer a pricing model based on a pay-per-use pricing mechanism (enabling, such a way, a real consumption service based "billing") ?	*(YES/NO)*	TBD

2	FI-STAR Applications Security					
	FI-STAR Applications Security Manager	Access Security				
				Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application services		
2.1				Which of your FI-STAR Use-Case-Scenario Application Services require a secured access?	*DS1.2.1, DS1.2.2, DS1.3, DS1.5.2, DS1.6, DS1.7, DS1.8, DS1.10, DS1.11, DS1.12, DS1.13, DS1.14, DS1.15, DS1.16, DS1.17*	
2.2				How many security zones do you foresee for your FI-STAR Infrastructure deployment? (please give detail about security perimeters in the FI-STAR Back-End and Front-End domains)	*2*	*Hospital Secure Domain* *DMZ Insecure Domain*
2.3				Which Certificate Types do you foresee (e.g. end-user certificates, signature certificates, encription certificates, gateway certificates,sensor certificates, FI-STAR Applications certificates, root certificates, certificattion authority,...) / Source of the certificates (FI-STAR Infrastructure or Internet) ?	*signature /internet, encryption/internet, root/internet*	*Rest TBD.*
2.4				Do you already have a Public Key Infrastructure (PKI) in place ?	*NO*	Keys for authentication are managed by ID-porten
2.5				If YES please give details (symetric / asymetric keys, Certificates, Certificate Authorities, ...); If NO please specify requirements on your new PKI		*Communication with IdP "ID-porten" should use SAML2 and SOAP over HTTPS (SSL >= v3.0 or TLS >= v1.0). Messages must be encrypted with AES (min 128 bit) and signed with SHA1 with RSA (min 1024 bit modulo). The Diabetes Share System must use a company certificate, the certificate authority must be authorized by the Government. There must be well defined and good procedures for handling the private key used for encryption, signing and transport protection. Subsequent communication of sensitive data between smartphone and Diabetes Share System must use HTTPS as well.*
2.6				Do you intend to provide to your end-users Application Access Security Incident Reports? If YES, please specify the time after incident occurance	*NO*	
	FI-STAR Applications Security Manager	Data Security				
				Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application data objects		
2.7				Which of your FI-STAR Use-Case-Scenario Application data objects require a secured access and which actors have (read / write) rights?	*observation/patient / R* *observation/clinician/R* *treatment enrollment information/clinician/R, W*	*Clinician's write access to observations is TBD* *Observations: (Blood glucose, physical activity and so on)*
2.8				Do you intend to provide to your end-users Application-Data Access Incident Reports? If YES, please specify the time after incident occurance	*(YES/NO) (time interval)*	TBD
	FI-STAR Applications Security Manager	Data Privacy				
				Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for anonymisation / pseudonimisation of application data objects		
2.9				Which of your FI-STAR Use-Case-Scenario Application data objects require anonymisation / pseudonimisation of the end-user?	*(data obj type)*	TBD: Possibly for feature DS1.2.x and DS1.8 (Enhanced scope)
	FI-STAR Applications Security Manager	Security Risks				
				Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for protection against cyber attacks		
2.10				Against which type of cyber atacks do you want to protect your FI-STAR Applications ?	*Sensitive data exposure and manipulation, DoS, viruses,Torjan Horses (on smartphone)*	
3	FI-STAR Applications Auditing Services					
	FI-STAR Infrastructure Manager	Auditing				
				Questionnaire aimed to check the need for providing auditing services related to the FI-STAR Use-Case-Scenario Applications Services		
		Governance				
3.1				Are you interested / obliged to offer the FI-STAR Applications end-users a service that enables them to see all accesses (including refused requests) to their data ?	*YES*	
		Compliance				
3.2				Are you obliged to offer to external auditors information regarding the FI-STAR applications provision and usage ? (please enumerate what kind of audit logs are you supposed to provide, e.g. service usage statistics, performance, security, ...)	*YES, 2 years storage of Access logs,* *5 years storage of Authorization registry.*	The Norwegian Data Protection Authority governs systems dealing with personal data. Service providers are required to keep this authority informed (submit risk analysis reports, system and responsibility descriptions) and/or apply for approval of running the service.
4	FI-STAR Applications Monitoring Services					
	FI-STAR Infrastructure Manager	System Monitoring				
				Questionnaire aimed to check the system monitoring requirements (HW resources, Virtual resources, others)		
4.1				Do you need to monitor hardware performances?	*(YES/NO)*	TBD
4.2				If the answer to 4.1 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)		
4.3				Do you need to monitor the VMs resources?	*YES*	This is likely a requirement from infrastructure management.
				If the answer to 4.3 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)		TBD
	FI-STAR Infrastructure Manager	Service Monitoring				
				Questionnaire aimed to check the FI-STAR Applications service monitoring requirements (responce time, availability,..)		
4.4				Do you have an SLA evaluation need ? (YES means that you intend to offer your end-users Service Reports)	*(YES/NO)*	Not relevant before productization.
4.5				If the answer to 4.4 is YES, please specify per use-case-scenario application / use-case the performance categories (response time, availability, load) and security categories (service access, data access) to be included in such service reports		*Not relevant before productization.*
4.6				Do you intend to offer to your custumers incentives for changing their SLA ? (YES means that you intend to optimise the performance of your applications by peak shaving mechanisms)	*NO*	Not relevant before productization.
4.7				Do you intend to offer to your custumers incentives for avoiding a penalty that would result from an SLA breach ? (YES means that you intend to manage the performance of your applications by pro-active service management mechanisms)	*NO*	Not relevant before productization.
4.8				If you have other monitoring needs please specify them (e.g. parameters related to the end-user Quality of Experience (QoE))	*YES*	Response time, errors, downtime, throughput, user attitude, feature use (see Fiedler, Fricker)
5	FI-STAR Applications Administration Services					
	FI-STAR Applications Administrator	Change and Release Management Services				
				Questionnaire aimed to check the FI-STAR Applications change & release management requirements		
5.1				How do you plan to manage the releases and changes of your FI-STAR Applications Services ?		Roadmap, release plan, release validation, release notes
5.2				How do you intend to deploy / roll-out your releases and changes ?		Submit to FI-STAR App store and orchestrate deployment
5.3				Do you need to adopt mechanisms to enable the distributed deployment of the software (i.e. the modules of the use-case-scenario applications)?	*YES*	Expect to use FI-STAR Appstore mechanisms for deployment and distribution to back-end and front-end.
5.4				Do you need to upload your own VM images?	*YES*	See above.
5.5				How do you prefer to upload your templates (SFTP, SCP...)	*SCP*	
5.6				Is the software to deploy in the VMs strictly dependent from the OS?	*YES*	Linux/Unix, plus Android and iOS for smartphone clients
5.6.1				If such software depends from a Linux OS, can you specify the distribution?		TBD
5.6.2				If such software depends from a not Linux based OS, can you specify such OS?	*see next sheet*	
5.7				Which software would you need to find pre-installed on the VM templates as required by the software to deploy?	*see next sheet*	TBD
5.8				Do you need to document the releases and inform your changes as a result of a compliance requirement ?		TBD
5.9				Do you have a releases and changes management system ?	*NO*	
5.10				If the anser to 5.4 is YES, please name the product		
	FI-STAR Applications Administrator	Configuration Services				
				Questionnaire aimed to check the FI-STAR Applications configuration management requirements		
5.11				What configuration items can you identify (application services, HW resources, Virtual resources, documentation, ...)		FitBit Physical Activity App, VC Client App, RunKeeper Physical Activity App, Diabetes Share System Product (Diabetes Share Proxy, Diabetes Diary, DeSA app, Diabetes Share System), FI-STAR Runtime Environment Product (Platform Installer), Smartphone Product (Sensor Integration Libary App Installer), Sensors (Blood Glucose, Physical Activity)
5.12				What configuration data can you identify ? (attributes of the configuration items)		Identifier, Name, Version, Description, Bluetooth Service name and PIN, rest TBD
5.13				Would you need VM images to customize with respect to already built VMs?		TBD
	FI-STAR Applications Administrator	Test & Maintenance Services				
				Questionnaire aimed to check theFI-STAR Applications test and maintenance requirements		
5.14				What test-services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	Test server for automatically running model based	
	FI-STAR Applications Administrator	Incident Management Services				
				Questionnaire aimed to check theFI-STAR Applications Incidents Management requirements		
5.15				What incident management services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	NO	Not for FI-STAR. Yes for productization.
5.16				Do you intend to build a KB for support in problem solving?	NO	Not for FI-STAR. Yes for productization.
6	FI-STAR Applications Emergency Services					
	FI-STAR Applications Emergency Manage	Emergency Management Services				
				Questionnaire aimed to check the FI-STAR Applicationsemergency management requirements		
6.1				How do you plan to manage an emergency situation affecting your FI-STAR Applications Services ?	Smartphone clients: crash reports optionally submitted by email to tech support team (probably responsible use case developers).	

10.3.2 TeleCare Solution (Krakow, Poland)

	FI-STAR Applications Dimensions Requirements Category Description Requirements Questionnaire Interviewed Actor			TeleCare Solution (Krakow, Poland)	Clarifications
1	FI-STAR Applications Delivery Solution				
	FI-STAR Infrastructure Manager	CAPEX and OPEX Costs			
			Questionnaire aimed to check the need for an on-premise or for a hosting solution under the cost perspective		
1.1			Are you interested to achieve lower "CAPEX & OPEX costs" by outsourcing the provision and management of your FI-STAR Back-End infrastructure to an external commercial organisation (hoster) ?	*NO*	
1.2			If the answer to 1.1 is NO, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in your existing data cente ? (NO means the FI-STAR Back-end infrastructure will be deployed in a new on-premise data center)	*YES*	
1.3			If the answer to 1.2 is YES, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in a separate physical environment (YES means new CAPEX, NO means reuse of existing infrastructure resources)?	*NO*	
1.4			If the answer to 1.3 is NO, please describe the resources intended to be used for the deployment of your FI-STAR Back-End infrastructure		
1.4.1			Computing resources (server machines)		
			Hardware	Virtual server(s); final specific configuration (incl. connections existing network) to be defined	
			Operating System		Linux
1.4.2			Storage System		
			Hardware		
			Data base System		TeleCare PostgreSQL database
1.4.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)	*JPII VLAN, Border gatawey, router + firewall; optional: secured LAN*	
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)	*JPII VLAN, Border gatawey, router + firewall; optional: secured LAN*	
1.5			If the answer to 1.3 is YES, please describe the resources you intende to purchase		
1.5.1			Computing resources (server machines)		
			Hardware	*NOT DUE: answer to 1.3 is NO*	
			Operating System		
1.5.2			Storage System		
			Hardware		
			Data base System		
1.5.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)		
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)		
			Questionnaire aimed to check the real need of a cloud solution under the resource utilisation perspective		
1.6			If the answer to 1.1 is NO, are you interested to achieve higer "resource utilisation" by adopting economies of scale in your FI-STAR Back-End infrastructure management, by means of a greater sharing of your infrastructure resources ?	*NO*	
	FI-STAR Infrastructure Manager	Scalability			
			Questionnaire aimed to check the real need of a cloud solution under the scalability perspective		
1.7			Are you interested to offer an almost instantly "scalable" FI-STAR Applications Delivery solution ?	*YES*	
	FI-STAR Infrastructure Manager	Performance			
			Questionnaire aimed to specify the performance requirements of the FI-STAR Applications services		
1.8		Response Time	What is the typical and maximum required Responce Time (Round Trip Time plus Processing Time) of your FI-STAR use-case-scenario applications / use cases requests ?		
1.9		Availability	What is the required availability of your FI-STAR use-case-scenario applications ?		
1.9.1			down-time pro month	*(# of hours)*	the system is not life critical and doesn not cover constant monitoring it is not a crucial factor; as a product in the future should not extend 15min/day however
1.9.2			mean time to repair	*(# of minutes)*	day
1.10		Load	What are your parallel processing and load requirements ?		
1.10.1			Number of Simultaneous patient sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*(# simultaneous sessions/ # req pro day / kB pro upload / kB pro download)*	*project: up to two sessions; for product up to 30*
1.10.2			Number of Simultaneous profesional users (GP, clinical specialist, pharmacist, call ctr .agent, ...) sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*# sessions/ #req pro day / kB)*	*project: up to 4; for product up to 60*
1.10.3			How many peak-load situations do you expect?	*(# of peaks / hour)*	
1.11			Do you intend to provide to your end-users Application Performance Reports? If YES, please specify the reporting time-interval	*(YES/NO) (# of days)*	weekly
1.12			Do you intend to provide to your end-users Application Delivery Incident Reports? If YES, please specify the time after incident occurance	*(YES/NO) (# of sec)*	an hour or 3-4 hours (i.e. before next session)
	FI-STAR Infrastructure Manager	Resilience			
			Questionnaire aimed to check the real need of a cloud solution under the reliability perspective		
1.13			Are you interested to offer an high level of "resilience" of the hosted applications by reducing, as much as possible, single points of hardware failure and offering, in such a way, an higher uptime?	*NO*	
	FI-STAR Applications Service Billing	Pricing			
			Questionnaire aimed to check the real need of a cloud solution under the pricing perspective		
1.14			Do you intend to offer a pricing model based on a fee (or a flat rate) ?	*YES*	
1.15			Do you intend to offer a pricing model based on a pay-per-use pricing mechanism (enabling, such a way, a real consumption service based "billing") ?	*NO*	

2	FI-STAR Applications Security				
	FI-STAR Applications Security Manager	Access Security			
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application services		
2.1			Which of your FI-STAR Use-Case-Scenario Application Services require a secured access?	*All with the connection to the hospital*	
2.2			How many security zones do you foresee for your FI-STAR Infrastructure deployment? (please give detail about security perimeters in the FI-STAR Back-End and Front-End domains)	*One Zone withinh the hospital, Most probably the second one in patients home*	
2.3			Which Certificate Types do you foresee (e.g. end-user certificates, signature certificates, encription certificates, gateway certificates,sensor certificates, FI-STAR Applications certificates, root certificates, certificattion authority,...) / Source of the certificates (FI-STAR Infrastructure or Internet) ?	*TBD*	
2.4			Do you already have a Public Key Infrastructure (PKI) in place ?	*NO*	
2.5			If YES please give details (symetric / asymetric keys, Certificates, Certificate Authorities, ...); If NO please specify requirements on your new PKI		
2.6			Do you intend to provide to your end-users Application Access Security Incident Reports? If YES, please specify the time after incident occurance	*NO*	
	FI-STAR Applications Security Manager	Data Security			
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application data objects		
2.7			Which of your FI-STAR Use-Case-Scenario Application data objects require a secured access and which actors have (read / write) rights?	*Write: patient, R: medical personnel + patient (restricted scope)*	
2.8			Do you intend to provide to your end-users Application-Data Access Incident Reports? If YES, please specify the time after incident occurance	*NO*	
	FI-STAR Applications Security Manager	Data Privacy			
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for anonymisation / pseudonimisation of application data objects		
2.9			Which of your FI-STAR Use-Case-Scenario Application data objects require anonymisation / pseudonimisation of the end-user?	*All patient data (video, sensor reading)*	
	FI-STAR Applications Security Manager	Security Risks			
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for protection against cyber attacks		
2.10			Against which type of cyber atacks do you want to protect your FI-STAR Applications ?	*data leakage*	
3	FI-STAR Applications Auditing Services				
	FI-STAR Infrastructure Manager	Auditing			
			Questionnaire aimed to check the need for providing auditing services related to the FI-STAR Use-Case-Scenario Applications Services		
3.1		Governance	Are you interested / obliged to offer the FI-STAR Applications end-users a service that enables them to see all accesses (including refused requests) to their data ?	*NO*	
3.2		Compliance	Are you obliged to offer to external auditors information regarding the FI-STAR applications provision and usage ? (please enumerate what kind of audit logs are you supposed to provide, e.g. service usage statistics, performance, security, ...)	*NO*	
4	FI-STAR Applications Monitoring Services				
	FI-STAR Infrastructure Manager	System Monitoring			
			Questionnaire aimed to check the system monitoring requirements (HW resources, Virtual resources, others)		
4.1			Do you need to monitor hardware performances?	*YES*	
4.2			If the answer to 4.1 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)	*esp. bandwith and latency*	
4.3			Do you need to monitor the VMs resources?	*YES*	
			If the answer to 4.3 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)	RAM, banwith	
	FI-STAR Infrastructure Manager	Service Monitoring			
			Questionnaire aimed to check the FI-STAR Applications service monitoring requirements (responce time, avalilability,..)		
4.4			Do you have an SLA evaluation need ? (YES means that you intend to offer your end-users Service Reports)	*NO*	
4.5			If the answer to 4.4 is YES, please specify per use-case-scenario application / use-case the performance categories (response time, availability, load) and security categories (service access, data access) to be included in such service reports	*(responce time, availability, load / service access log, data access log)*	
4.6			Do you intend to offer to your custumers incentives for changing their SLA ? (YES means that you intend to optimise the performance of your applications by peak shaving mechanisms)	*NO/TBD*	
4.7			Do you intend to offer to your custumers incentives for avoiding a penalty that would result from an SLA breach ? (YES means that you intend to manage the performance of your applications by pro-active service management mechanisms)	*NO/TBD*	
4.8			If you have other monitoring needs please specify them (e.g. parameters related to the end-user Quality of Experience (QoE))		
5	FI-STAR Applications Administration Services				
	FI-STAR Applications Administrator	Change and Release Management Services			
			Questionnaire aimed to check the FI-STAR Applications change & release management requirements		
5.1			How do you plan to manage the releases and changes of your FI-STAR Applications Services ?		
5.2			How do you intend to deploy / roll-out your releases and changes ?	remote updates; opt: when patients visit the hospital	
5.3			Do you need to adopt mechanisms to enable the distributed deployment of the software (i.e. the modules of the use-case-scenario applications)?	*YES*	
5.4			Do you need to upload your own VM images?	*NO*	
5.5			How do you prefer to upload your templates (SFTP, SCP...)	*TBD*	
5.6			Is the software to deploy in the VMs strictly dependent from the OS?	*YES*	
5.6.1			If such software depends from a Linux OS, can you specify the distribution?	*see next sheet*	
5.6.2			If such software depends from a not Linux based OS, can you specify such OS?	*Android, Windows*	
5.7			Which software would you need to find pre-installed on the VM templates as required by the software to deploy?	*TBD*	
5.8			Do you need to document the releases and inform your changes as a result of a compliance requirement ?	*YES*	
5.9			Do you have a releases and changes management system ?	*NO*	
5.10			If the anser to 5.4 is YES, please name the product		
	FI-STAR Applications Administrator	Configuration Services			
			Questionnaire aimed to check the FI-STAR Applications configuration management requirements		
5.11			What configuration items can you identify (application services, HW resources, Virtual resources, documentation, ...)		
5.12			What configuration data can you identify ? (attributes of the configuration items)		
5.13			Would you need VM images to customize with respect to already built VMs?		
	FI-STAR Applications Administrator	Test & Maintenance Services			
			Questionnaire aimed to check theFI-STAR Applications test and maintenance requirements		
5.14			What test-services do you foresee for your FI-STAR Use-Case-Scenario Applications ?		
	FI-STAR Applications Administrator	Incident Management Services			
			Questionnaire aimed to check theFI-STAR Applications Incidents Management requirements		
5.15			What incident management services do you foresee for your FI-STAR Use-Case-Scenario Applications ?		
5.16			Do you intend to build a KB for support in problem solving?		
6	FI-STAR Applications Emergency Services				
	FI-STAR Applications Emergency Manage	Emergency Management Services			
			Questionnaire aimed to check the FI-STAR Applicationsemergency management requirements		
6.1			How do you plan to manage an emergency situation affecting your FI-STAR Applications Services ?		

10.3.3 Chronic Disease Treatment Assistance (Bologna, Italy)

	FI-STAR Applications Dimensions / Requirements Category / Description / Requirements Questionnaire / Interviewed Actor			Chronic Disease Treatment Assistance (Bologna, Italy)	Clarifications
1	FI-STAR Applications Delivery Solution				
	FI-STAR Infrastructure Manager	CAPEX and OPEX Costs			
			Questionnaire aimed to check the need for an on-premise or for a hosting solution under the cost perspective		
1.1			Are you interested to achieve lower "CAPEX & OPEX costs" by outsourcing the provision and management of your FI-STAR Back-End infrastructure to an external commercial organisation (hoster) ?	*NO*	We are intrested to achieve lower "CAPEX & OPEX cost by adopting cloud technology for our own FISTAR back end infrastructure
1.2			If the answer to 1.1 is NO, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in your existing data cente ? (NO means the FI-STAR Back-end infrastructure will be deployed in a new on-premise data center)	*YES*	
1.3			If the answer to 1.2 is YES, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in a separate physical environment (YES means new CAPEX, NO means reuse of existing infrastructure resources)?	*NO*	
1.4			If the answer to 1.3 is NO, please describe the resources intended to be used for the deployment of your FI-STAR Back-End infrastructure		
1.4.1			Computing resources (server machines)		
			Hardware	*Virtual Machine on existing infrastructure*	
			Operating System	*Linux*	
1.4.2			Storage System		
			Hardware	*Existing Virtual Machine Storage Area Network*	
			Data base System	*Oracle 11g*	
1.4.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)	*Secure SSL Connections over Internet*	
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)	*Existing private network infrastructure connecting all Healthcare Structure*	
1.5			If the answer to 1.3 is YES, please describe the resources you intende to purchase		
1.5.1			Computing resources (server machines)		
			Hardware	*NOT DUE: answer to 1.3 is NO*	
			Operating System		
1.5.2			Storage System		
			Hardware		
			Data base System		
1.5.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)		
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)		
			Questionnaire aimed to check the real need of a cloud solution under the resource utilisation perspective		
1.6			If the answer to 1.1 is NO, are you interested to achieve higer "resource utilisation" by adopting economies of scale in your FI-STAR Back-End infrastructure management, by means of a greater sharing of your infrastructure resources ?	*No*	Existing infrastructure is already shared and resources are optimized
	FI-STAR Infrastructure Manager	Scalability			
			Questionnaire aimed to check the real need of a cloud solution under the scalability perspective		
1.7			Are you interested to offer an almost instantly "scalable" FI-STAR Applications Delivery solution ?	*YES*	experimentation will be on 10 patient and few medical personnel. Productiozation will need scalability
	FI-STAR Infrastructure Manager	Performance			
			Questionnaire aimed to specify the performance requirements of the FI-STAR Applications services		
1.8		Response Time	What is the typical and maximum required Responce Time (Round Trip Time plus Processing Time) of your FI-STAR use-case-scenario applications / use cases requests ?	*PeAA.5 - UC52 Forward message: 200 ms / 2 sec -PeAA.5 - UC51 Manage message archive : 500 ms / 3 sec -PeAA.5 - UC50 Receive message: text and video: 500 ms / 3 sec -PeAA.5 - UC49 Send message: text and video: 500 ms / 3 sec -PeAA.4 - UC48 Access to PeAA: 500 ms / 3 sec -PeAA.3 - UC47 Configure questionnaires : TBD -PeAA.3 - UC46 Define Alarm/warning: TBD -PeAA.3 - UC45 Define Reminder: TBD -PeAA.3 - UC44 Define Standard communication: TBD -PeAA.3 - UC43 Define Notice: TBD -PeAA.3 - UC42 Browse sets: 500 ms / 3 sec -PeAA.3 - UC41 CRUD Notice Set: 500 ms / 3 sec -PeAA.3 - UC40 CRUD Rule Set: 500 ms / 3 sec -PeAA.3 - UC39 CRUD Set: 500 ms / 3 sec -PeAA.3 - UC38 Define Action: TBD -PeAA.3 - UC37 Define Alert: TBD -PeAA.3 - UC36 Configure Rule: TBD -PeAA.3 - UC35 Configure BT Device: TBD - PeAA.3 - UC34 Configure health data by pathology: TBD -PeAA.3 - UC33 Configure CDTA (General Conf): TBD -PeAA.2 - UC32 Display patient personal data: 500 ms / 3 sec -PeAA.2 - UC31 Forward warning to physician: 200 ms / 2 sec -PeAA.2 - UC30 Display health data summary: 1 sec / 15 sec -PeAA.2 - UC29 Display alarm/warning: 500 ms / 3 sec -PeAA.2 - UC28 Display patient health data: 1 sec / 15 sec -PeAA.2 - UC27 Display partial set of patient health data: 1 sec / 15 sec -PeAA.2 - UC26 Display complete set of patient health data: 1 sec / 15 sec -PeAA.1 - UC25 Assign reminder set and rule set to patient: 200 ms / 2 sec -PeAA.1 - UC24 Assign pathology to patient: 200 ms / 2 sec -PeAA.1 - UC23 Display list of patient in charge: 1 sec / 15 sec -PeAA.1 - UC22 Take charge of patient: 1 sec / 15 sec -PeAA.1 - UC21 Search patient: 1 sec / 15 sec -PeAA.1 - UC20 Search nurse's patient : 1 sec / 15 sec -PAA.8 - UC19 Create Read Update Delete Link: 200 ms / 2 sec -PAA.8 - UC18 Create Read Update Delete Doctor Contact: 200 ms / 2 sec -PAA.8 - UC17 Create Read Update Delete Calendar Entry: 500 ms / 3 sec -PAA.7 - UC16 Visualize data graphically: 500 ms / 3 sec -PAA.7 - UC15 Visualize data as list: 500 ms / 3 sec -PAA.7 - UC14 Visualize data: 500 ms / 3 sec -PAA.7 - UC13 Display elaborated data: 500 ms / 3 sec -PAA.7 - UC12 Display raw data: 500 ms / 3 sec -PAA.7 - UC11 Displays vital parameters: measurements: 500 ms / 3 sec -PAA.7 - UC10 Display personal profile: 500 ms / 3 sec -PAA.6 - UC09 Postpone reminder: 200 ms / 2 sec -PAA.6 - UC08 Display reminders : 500 ms / 3 sec -PAA.5 - UC07 Manage message archive : -PAA.5 - UC06 Receive message: text or video: 500 ms / 3 sec -PAA.5 - UC05 Send message: text or video: 500 ms / 3 sec -PAA.4 - UC04 Register measuring device: 15 sec / 25 sec -PAA.4 - UC03 Log in FSE: 1 sec / 15 sec -PAA.1 - UC02 Submit questionnaire: take a measurement by patient questionnaire: few sec / 15 sec -PAA.1 - UC01 Take measurement: take a measurement with a specific monitoring: few sec / 15 sec*	
1.9		Availability	What is the required availability of your FI-STAR use-case-scenario applications ?		
1.9.1			down-time pro month	*No constraint on alpha and beta.*	Target for production enviroment is 8h
1.9.2			mean time to repair	*No constraint on alpha and beta.*	Target for production enviroment is 30m
1.10		Load	What are your parallel processing and load requirements ?		
1.10.1			Number of Simultaneous patient sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*5 simultaneous patient session / 2 req per day /TBD / TBD*	
1.10.2			Number of Simultaneous profesional users (GP, clinical specialist, pharmacist, call ctr .agent, ...) sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*3 session / 5 session per day /TBD /TBD*	
1.10.3			How many peak-load situations do you expect?	*0 peaks / hour*	
1.11			Do you intend to provide to your end-users Application Performance Reports? If YES, please specify the reporting time-interval	*NO*	
1.12			Do you intend to provide to your end-users Application Delivery Incident Reports? If YES, please specify the time after incident occurance	*No*	
	FI-STAR Infrastructure Manager	Resilience			
			Questionnaire aimed to check the real need of a cloud solution under the reliability perspective		
1.13			Are you interested to offer an high level of "resilience" of the hosted applications by reducing, as much as possible, single points of hardware failure and offering, in such a way, an higher uptime?	*YES*	The solution is experimental, ie. not vital, but it should be as mature as possible.
	FI-STAR Applications Service Billing	Pricing			Reliability affects user experience.
			Questionnaire aimed to check the real need of a cloud solution under the pricing perspective		Reliability problems can be mitigated by customer support provided by product manager
1.14			Do you intend to offer a pricing model based on a fee (or a flat rate) ?	*YES*	C2k is an in House company owned by principal actors of the Regional Health System. Our services are aimed only to our associates and are part of global service agreements
1.15			Do you intend to offer a pricing model based on a pay-per-use pricing mechanism (enabling, such a way, a real consumption service based "billing") ?	*NO*	

2	FI-STAR Applications Security					
	FI-STAR Applications Security Manager	Access Security				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application services			
2.1			Which of your FI-STAR Use-Case-Scenario Application Services require a secured access?	*PAA, PeAA*		
2.2			How many security zones do you foresee for your FI-STAR Infrastructure deployment? (please give detail about security perimeters in the FI-STAR Back-End and Front-End domains)	*1) Internet Zone for end user* *2) DMZ as gateway between Internet and Secure domain* *3) Secure SOLE domain*		
2.3			Which Certificate Types do you foresee (e.g. end-user certificates, signature certificates, encription certificates, gateway certificates,sensor certificates, FI-STAR Applications certificates, root certificates, certificattion authority,...) / Source of the certificates (FI-STAR Infrastructure or Internet) ?	*SSL Server certificates* *User client certificates* *Applications certificates* *All issued by existing SOLE Internal Certification Authority*		
2.4			Do you already have a Public Key Infrastructure (PKI) in place ?	*YES*		
2.5			If YES please give details (symetric / asymetric keys, Certificates, Certificate Authorities, ...); If NO please specify requirements on your new PKI	*We use an internal Certification Authority to issue all kinds of certificates using asymetric keys*		
2.6			Do you intend to provide to your end-users Application Access Security Incident Reports? If YES, please specify the time after incident occurance	*NO*		
	FI-STAR Applications Security Manager	Data Security				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application data objects			
2.7			Which of your FI-STAR Use-Case-Scenario Application data objects require a secured access and which actors have (read / write) rights?	*quantitative measurement / patient / R, W* *qualitative measurement / patient / R, W* *quantitative measurement / physician, nurse / R* *qualitative measurement / physician, nurse / R*		
2.8			Do you intend to provide to your end-users Application-Data Access Incident Reports? If YES, please specify the time after incident occurance	*NO*		
	FI-STAR Applications Security Manager	Data Privacy				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for anonymisation / pseudonimisation of application data objects			
2.9			Which of your FI-STAR Use-Case-Scenario Application data objects require anonymisation / pseudonimisation of the end-user?	*NO*		
	FI-STAR Applications Security Manager	Security Risks				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for protection against cyber attacks			
2.10			Against which type of cyber atacks do you want to protect your FI-STAR Applications ?	*Sensitive data exposure and manipulation, DoS, viruses,Torjan Horses*		
3	FI-STAR Applications Auditing Services					
	FI-STAR Infrastructure Manager	Auditing				
			Questionnaire aimed to check the need for providing auditing services related to the FI-STAR Use-Case-Scenario Applications Services			
3.1		Governance	Are you interested / obliged to offer the FI-STAR Applications end-users a service that enables them to see all accesses (including refused requests) to their data ?	*YES*		
3.2		Compliance	Are you obliged to offer to external auditors information regarding the FI-STAR applications provision and usage ? (please enumerate what kind of audit logs are you supposed to provide, e.g. service usage statistics, performance, security, ...)	*NO*		
4	FI-STAR Applications Monitoring Services					
	FI-STAR Infrastructure Manager	System Monitoring				
			Questionnaire aimed to check the system monitoring requirements (HW resources, Virtual resources, others)			
4.1			Do you need to monitor hardware performances?	*No*	Existing infrastructure is already monitored	
4.2			If the answer to 4.1 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)			
4.3			Do you need to monitor the VMs resources?	*No*	Existing infrastructure is already monitored	
			If the answer to 4.3 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)			
	FI-STAR Infrastructure Manager	Service Monitoring				
			Questionnaire aimed to check the FI-STAR Applications service monitoring requirements (responce time, availability,..)			
4.4			Do you have an SLA evaluation need ? (YES means that you intend to offer your end-users Service Reports)	*Not relevant before productization.* *Clarifications: in alpha and beta reports on services are needed anyway*		
4.5			If the answer to 4.4 is YES, please specify per use-case-scenario application / use-case the performance categories (response time, availability, load) and security categories (service access, data access) to be included in such service reports	*Not relevant before productization.* *Clarifications: in alpha and beta in general on response time, availability, service access, data access*		
4.6			Do you intend to offer to your custumers incentives for changing their SLA ? (YES means that you intend to optimise the performance of your applications by peak shaving mechanisms)	*Not relevant before productization.*		
4.7			Do you intend to offer to your custumers incentives for avoiding a penalty that would result from an SLA breach ? (YES means that you intend to manage the performance of your applications by pro-active service management mechanisms)	*Not relevant before productization.*		
4.8			If you have other monitoring needs please specify them (e.g. parameters related to the end-user Quality of Experience (QoE))	*Not relevant before productization.*		
5	FI-STAR Applications Administration Services					
	FI-STAR Applications Administrator	Change and Release Management Services				
			Questionnaire aimed to check the FI-STAR Applications change & release management requirements			
5.1			How do you plan to manage the releases and changes of your FI-STAR Applications Services ?	Roadmap, release plan, release validation, release notes		
5.2			How do you intend to deploy / roll-out your releases and changes ?	On end user devices using Google Play Store On server platform using our internal deployment infrastructure		
5.3			Do you need to adopt mechanisms to enable the distributed deployment of the software (i.e. the modules of the use-case-scenario applications)?	*not necessary for BE (few customers even on after productization) and medical FE (web based)*		
5.4			Do you need to upload your own VM images?	*No*		
5.5			How do you prefer to upload your templates (SFTP, SCP...)			
5.6			Is the software to deploy in the VMs strictly dependent from the OS?	*No*		
5.6.1			If such software depends from a Linux OS, can you specify the distribution?			
5.6.2			If such software depends from a not Linux based OS, can you specify such OS?			
5.7			Which software would you need to find pre-installed on the VM templates as required by the software to deploy?	*see next sheet*		
5.8			Do you need to document the releases and inform your changes as a result of a compliance requirement ?	*NO*		
5.9			Do you have a releases and changes management system ?	*NO*		
5.10			If the anser to 5.4 is YES, please name the product			
	FI-STAR Applications Administrator	Configuration Services				
			Questionnaire aimed to check the FI-STAR Applications configuration management requirements			
5.11			What configuration items can you identify (application services, HW resources, Virtual resources, documentation, ...)	PAA, PeAA, A/V service (TBD), CDTA BE, FISTAR platform, smartphone		
5.12			What configuration data can you identify ? (attributes of the configuration items)	Under study		
5.13			Would you need VM images to customize with respect to already built VMs?	Under study		
	FI-STAR Applications Administrator	Test & Maintenance Services				
			Questionnaire aimed to checkFI-STAR Applications test and maintenance requirements			
5.14			What test-services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	TBD		
	FI-STAR Applications Administrator	Incident Management Services				
			Questionnaire aimed to checkFI-STAR Applications Incidents Management requirements			
5.15			What incident management services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	NO		
5.16			Do you intend to build a KB for support in problem solving?	NO		
6	FI-STAR Applications Emergency Services					
	FI-STAR Applications Emergency Manage	Emergency Management Services				
			Questionnaire aimed to check the FI-STAR Applicationsemergency management requirements			
6.1			How do you plan to manage an emergency situation affecting your FI-STAR Applications Services ?	TBD		

10.3.4 Treatment Management Solution (Bilbao, Spain)

	FI-STAR Applications Dimensions / Requirements Category / Description / Requirements Questionnaire / Interviewed Actor			Treatment Management Solution (Bilbao, Spain)	Clarifications
1	FI-STAR Applications Delivery Solution				
	FI-STAR Infrastructure Manager	CAPEX and OPEX Costs			
			Questionnaire aimed to check the need for an on-premise or for a hosting solution under the cost perspective		
1.1			Are you interested to achieve lower "CAPEX & OPEX costs" by outsourcing the provision and management of your FI-STAR Back-End infrastructure to an external commercial organisation (hoster) ?	*NO*	
1.2			If the answer to 1.1 is NO, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in your existing data cente ? (NO means the FI-STAR Back-end infrastructure will be deployed in a new on-premise data center)	*YES*	
1.3			If the answer to 1.2 is YES, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in a separate physical environment (YES means new CAPEX, NO means reuse of existing infrastructure resources)?	*YES*	
1.4			If the answer to 1.3 is NO, please describe the resources intended to be used for the deployment of your FI-STAR Back-End infrastructure		
1.4.1			Computing resources (server machines)		
			Hardware		
			Operating System		
1.4.2			Storage System		
			Hardware		
			Data base System		
1.4.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)		
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)		
1.5			If the answer to 1.3 is YES, please describe the resources you intende to purchase	*YES*	
1.5.1			Computing resources (server machines)		
			Hardware	*. Servidor de Aplicaciones Internet Information Server (IIS) 7.5 Microsoft Windows Server 2008 R2/64 bits, Enterprise Edition 64-bit ODAC 11.2 Release 4 (11.2.0.3.0) for Windows x64 Unity 2.x - Released: May 5 2010 Microsoft .NET Framework 4.0 - 64 bits . Servidor Web Internet Information Server (IIS) 7.5 Microsoft Windows Server 2008 R2/64 bits, Enterprise Editio*	
			Operating System		
1.5.2			Storage System		
			Hardware	*1 TB*	
			Data base System	*Oracle 11g configured on High availability*	
1.5.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)	*In Study for It Subdepartment*	
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)	*paradigm o interoperability and integration is oriented to SOA architecture. We are using Oracle service Bus , and others tools included in SOA suite*	
			Questionnaire aimed to check the real need of a cloud solution under the resource utilisation perspective		
1.6			If the answer to 1.1 is NO, are you interested to achieve higer "resource utilisation" by adopting economies of scale in your FI-STAR Back-End infrastructure management, by means of a greater sharing of your infrastructure resources ?	*YES*	
	FI-STAR Infrastructure Manager	Scalability			
			Questionnaire aimed to check the real need of a cloud solution under the scalability perspective		
1.7			Are you interested to offer an almost instantly "scalable" FI-STAR Applications Delivery solution ?	*YES*	
	FI-STAR Infrastructure Manager	Performance			
			Questionnaire aimed to specify the performance requirements of the FI-STAR Applications services		
1.8		Response Time	What is the typical and maximum required Responce Time (Round Trip Time plus Processing Time) of your FI-STAR use-case-scenario applications / use cases requests ?	*Administration Fi-star platform: 15000 ms - Treatment Participant Pc: 10000 ms - Treatment Participant mobile device : 15000 ms*	
1.9		Availability	What is the required availability of your FI-STAR use-case-scenario applications ?		
1.9.1			down-time pro month	*8 hours*	
1.9.2			mean time to repair	*30 minutes*	
1.10		Load	What are your parallel processing and load requirements ?		
1.10.1			Number of Simultaneous patient sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*(25/ 40/in study / in study)*	
1.10.2			Number of Simultaneous profesional users (GP, clinical specialist, pharmacist, call ctr .agent, ...) sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*10/ 15 / in study)*	
1.10.3			How many peak-load situations do you expect?	*(1/ hour)*	
1.11			Do you intend to provide to your end-users Application Performance Reports? If YES, please specify the reporting time-interval	*NO*	
1.12			Do you intend to provide to your end-users Application Delivery Incident Reports? If YES, please specify the time after incident occurance	*NO*	
	FI-STAR Infrastructure Manager	Resilience			
			Questionnaire aimed to check the real need of a cloud solution under the reliability perspective		
1.13			Are you interested to offer an high level of "resilience" of the hosted applications by reducing, as much as possible, single points of hardware failure and offering, in such a way, an higher uptime?	*YES*	
	FI-STAR Applications Service Billing	Pricing			
			Questionnaire aimed to check the real need of a cloud solution under the pricing perspective		
1.14			Do you intend to offer a pricing model based on a fee (or a flat rate) ?	*YES*	the service is free for users , but public provider service needs to measure the maintenance costs of Fi-Star platform
1.15			Do you intend to offer a pricing model based on a pay-per-use pricing mechanism (enabling, such a way, a real consumption service based "billing") ?	*NO*	

2	FI-STAR Applications Security					
	FI-STAR Applications Security Manager	Access Security				
				Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application services		
2.1				Which of your FI-STAR Use-Case-Scenario Application Services require a secured access?	*All Scenarios (Treatment mobile device , Treatment participant device, BPTM treatment participant Web UI, BPTM Professional Web UI)*	
2.2				How many security zones do you foresee for your FI-STAR Infrastructure deployment? (please give detail about security perimeters in the FI-STAR Back-End and Front-End domains)	*We have several security zones 1/ DMZ , demilitarized Zone 2/ WAF . WEB APPLICATION FIREWALL Service Buss for Internet applcations Service Bus for Intranet Apllications*	
2.3				Which Certificate Types do you foresee (e.g. end-user certificates, signature certificates, encription certificates, gateway certificates,sensor certificates, FI-STAR Applications certificates, root certificates, certificattion authority,...) / Source of the certificates (FI-STAR Infrastructure or Internet) ?	*I will use x509 certificates: *user certificates for authentificate in BPTM to profesional on web UI and BPTM Treatment participant web UI *server certificates and gateway certificates for establish a secure channel of communication (SSL protocol and ws-s) *application certificates for the protection of transmitted messages(without encription) The source of certificates are both FI-star infrastructure and internet*	
2.4				Do you already have a Public Key Infrastructure (PKI) in place ?	*YES*	
2.5				If YES please give details (symetric / asymetric keys, Certificates, Certificate Authorities, ...); If NO please specify requirements on your new PKI	*we have asymetric keys, and personal, server and application certificates from CA of www.izenpe.com*	
2.6				Do you intend to provide to your end-users Application Access Security Incident Reports? If YES, please specify the time after incident occurance	*NO*	
	FI-STAR Applications Security Manager	Data Security				
				Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application data objects		
2.7				Which of your FI-STAR Use-Case-Scenario Application data objects require a secured access and which actors have (read / write) rights?	*TBD*	
2.8				Do you intend to provide to your end-users Application-Data Access Incident Reports? If YES, please specify the time after incident occurance	*NO*	
	FI-STAR Applications Security Manager	Data Privacy				
				Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for anonymisation / pseudonimisation of application data objects		
2.9				Which of your FI-STAR Use-Case-Scenario Application data objects require anonymisation / pseudonimisation of the end-user?	*TBD*	
	FI-STAR Applications Security Manager	Security Risks				
				Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for protection against cyber attacks		
2.10				Against which type of cyber atacks do you want to protect your FI-STAR Applications ?	*all applications*	
3	FI-STAR Applications Auditing Services					
	FI-STAR Infrastructure Manager	Auditing				
				Questionnaire aimed to check the need for providing auditing services related to the FI-STAR Use-Case-Scenario Applications Services		
3.1		Governance		Are you interested / obliged to offer the FI-STAR Applications end-users a service that enables them to see all accesses (including refused requests) to their data ?	*YES*	
3.2		Compliance		Are you obliged to offer to external auditors information regarding the FI-STAR applications provision and usage ? (please enumerate what kind of audit logs are you supposed to provide, e.g. service usage statistics, performance, security, ...)	*NO*	
4	FI-STAR Applications Monitoring Services					
	FI-STAR Infrastructure Manager	System Monitoring				
				Questionnaire aimed to check the system monitoring requirements (HW resources, Virtual resources, others)		
4.1				Do you need to monitor hardware performances?	*YES*	
4.2				If the answer to 4.1 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)	*CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time*	
4.3				Do you need to monitor the VMs resources?	*YES*	
				If the answer to 4.3 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)	CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time	
	FI-STAR Infrastructure Manager	Service Monitoring				
				Questionnaire aimed to check the FI-STAR Applications service monitoring requirements (responce time, avalilability,..)		
4.4				Do you have an SLA evaluation need ? (YES means that you intend to offer your end-users Service Reports)	*YES*	
4.5				If the answer to 4.4 is YES, please specify per use-case-scenario application / use-case the performance categories (response time, availability, load) and security categories (service access, data access) to be included in such service reports	*currently we are defining the SLA's*	
4.6				Do you intend to offer to your custumers incentives for changing their SLA ? (YES means that you intend to optimise the performance of your applications by peak shaving mechanisms)	*NO*	
4.7				Do you intend to offer to your custumers incentives for avoiding a penalty that would result from an SLA breach ? (YES means that you intend to manage the performance of your applications by pro-active service management mechanisms)	*NO*	
4.8				If you have other monitoring needs please specify them (e.g. parameters related to the end-user Quality of Experience (QoE))	*satisfaction surveys*	
5	FI-STAR Applications Administration Services					
	FI-STAR Applications Administrator	Change and Release Management Services				
				Questionnaire aimed to check the FI-STAR Applications change & release management requirements		
5.1				How do you plan to manage the releases and changes of your FI-STAR Applications Services ?	Basque public health service has a specific area for implement and deploy of systems and its versions. The Fi-Star application will install in two enviroments (Pre-Production for deploying and testing new versions and Production fo support the real activity of user)	
5.2				How do you intend to deploy / roll-out your releases and changes ?	By deploy in central server	
5.3				Do you need to adopt mechanisms to enable the distributed deployment of the software (i.e. the modules of the use-case-scenario applications)?	*NO*	
5.4				Do you need to upload your own VM images?	*TBD*	
5.5				How do you prefer to upload your templates (SFTP, SCP...)	*SFTP*	
5.6				Is the software to deploy in the VMs strictly dependent from the OS?	*YES*	
5.6.1				If such software depends from a Linux OS, can you specify the distribution?	*Red Hat 6,5*	
5.6.2				If such software depends from a not Linux based OS, can you specify such OS?	*see next sheet*	
5.7				Which software would you need to find pre-installed on the VM templates as required by the software to deploy?	*see next sheet*	
5.8				Do you need to document the releases and inform your changes as a result of a compliance requirement ?	*YES*	
5.9				Do you have a releases and changes management system ?	*NO*	
5.10				If the anser to 5.4 is YES, please name the product		
	FI-STAR Applications Administrator	Configuration Services				
				Questionnaire aimed to check the FI-STAR Applications configuration management requirements		
5.11				What configuration items can you identify (application services, HW resources, Virtual resources, documentation, ...)	TBD	
5.12				What configuration data can you identify ? (attributes of the configuration items)	TBD	
5.13				Would you need VM images to customize with respect to already built VMs?	TBD	
	FI-STAR Applications Administrator	Test & Maintenance Services				
				Questionnaire aimed to check theFI-STAR Applications test and maintenance requirements		
5.14				What test-services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	TBD	
	FI-STAR Applications Administrator	Incident Management Services				
				Questionnaire aimed to check theFI-STAR Applications Incidents Management requirements		
5.15				What incident management services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	TBD	
5.16				Do you intend to build a KB for support in problem solving?	TBD	
6	FI-STAR Applications Emergency Services					
	FI-STAR Applications Emergency Manage	Emergency Management Services				
				Questionnaire aimed to check the FI-STAR Applicationsemergency management requirements		
6.1				How do you plan to manage an emergency situation affecting your FI-STAR Applications Services ?	TBD	

10.3.5 CRP Solution (Bucharest, Romania)

	FI-STAR Applications Dimensions / Requirements Category / Description / Requirements Questionnaire / Interviewed Actor			CRP Solution (Bucharest, Romania)	Clarifications
1	FI-STAR Applications Delivery Solution				
	FI-STAR Infrastructure Manager	CAPEX and OPEX Costs			
			Questionnaire aimed to check the need for an on-premise or for a hosting solution under the cost perspective		
1.1			Are you interested to achieve lower "CAPEX & OPEX costs" by outsourcing the provision and management of your FI-STAR Back-End infrastructure to an external commercial organisation (hoster) ?	*NO*	
1.2			If the answer to 1.1 is NO, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in your existing data cente ? (NO means the FI-STAR Back-end infrastructure will be deployed in a new on-premise data center)	*NO*	
1.3			If the answer to 1.2 is YES, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in a separate physical environment (YES means new CAPEX, NO means reuse of existing infrastructure resources)?	*(YES/NO)*	
1.4			If the answer to 1.3 is NO, please describe the resources intended to be used for the deployment of your FI-STAR Back-End infrastructure		
1.4.1			Computing resources (server machines)		
			Hardware		CRP Share Proxy Server: Virtual machine. CRP Share System Server: Virtual machine.
			Operating System		TBD
1.4.2			Storage System		
			Hardware		Virtual machine
			Data base System		TBD
1.4.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)		*Firewall: TBD.* *VPN concentrator/router: TBD* *Front-end LAN after VPN concentrator: TBD*
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)		*Firewall: LAN Hospital* *Back-end LAN: TBD* *Network transport service: TBD*
1.5			If the answer to 1.3 is YES, please describe the resources you intende to purchase		
1.5.1			Computing resources (server machines)		
			Hardware		
			Operating System		
1.5.2			Storage System		
			Hardware		
			Data base System		
1.5.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)		
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)		
			Questionnaire aimed to check the real need of a cloud solution under the resource utilisation perspective		
1.6			If the answer to 1.1 is NO, are you interested to achieve higer "resource utilisation" by adopting economies of scale in your FI-STAR Back-End infrastructure management, by means of a greater sharing of your infrastructure resources ?	*NO*	
	FI-STAR Infrastructure Manager	Scalability			
			Questionnaire aimed to check the real need of a cloud solution under the scalability perspective		
1.7			Are you interested to offer an almost instantly "scalable" FI-STAR Applications Delivery solution ?	*YES*	
	FI-STAR Infrastructure Manager	Performance			
			Questionnaire aimed to specify the performance requirements of the FI-STAR Applications services		
1.8		Response Time	What is the typical and maximum required Responce Time (Round Trip Time plus Processing Time) of your FI-STAR use-case-scenario applications / use cases requests ?		*Users: Application reaction time TBD* *Doctors: Application reaction time TBD*
1.9		Availability	What is the required availability of your FI-STAR use-case-scenario applications ?		
1.9.1			down-time pro month	*1 hour*	alpha/beta prototypes: 1h per month product (post-FI-STAR): 99% availability
1.9.2			mean time to repair	*5 minutes*	
1.10		Load	What are your parallel processing and load requirements ?		
1.10.1			Number of Simultaneous patient sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*5 simultaneous sessions/ 3 req pro day/ TBD kB pro upload/ TBD kB pro download*	
1.10.2			Number of Simultaneous profesional users (GP, clinical specialist, pharmacist, call ctr .agent, ...) sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*5 simultanious sessions/ 3 req pro day / TBD kB)*	
1.10.3			How many peak-load situations do you expect?	*0 of peaks / hour*	
1.11			Do you intend to provide to your end-users Application Performance Reports? If YES, please specify the reporting time-interval	*NO*	
1.12			Do you intend to provide to your end-users Application Delivery Incident Reports? If YES, please specify the time after incident occurance	*YES, 5 sec*	If submitting observations from Android Smartphone fails, users should know in 5 seconds
	FI-STAR Infrastructure Manager	Resilience			
			Questionnaire aimed to check the real need of a cloud solution under the reliability perspective		
1.13			Are you interested to offer an high level of "resilience" of the hosted applications by reducing, as much as possible, single points of hardware failure and offering, in such a way, an higher uptime?	*NO*	
	FI-STAR Applications Service Billing	Pricing			
			Questionnaire aimed to check the real need of a cloud solution under the pricing perspective		
1.14			Do you intend to offer a pricing model based on a fee (or a flat rate) ?	*(YES/NO)*	TBD
1.15			Do you intend to offer a pricing model based on a pay-per-use pricing mechanism (enabling, such a way, a real consumption service based "billing") ?	*(YES/NO)*	TBD

2	FI-STAR Applications Security					
	FI-STAR Applications Security Manager	Access Security				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application services			
2.1			Which of your FI-STAR Use-Case-Scenario Application Services require a secured access?	*CRP.1, CRP. 2, CRP.3, CRP4, CRP.5, CRP.6, CRP.7, CRP.8*		
2.2			How many security zones do you foresee for your FI-STAR Infrastructure deployment? (please give detail about security perimeters in the FI-STAR Back-End and Front-End domains)	*2*		*Hospital Secure Domain* *DMZ Insecure Domain*
2.3			Which Certificate Types do you foresee (e.g. end-user certificates, signature certificates, encription certificates, gateway certificates,sensor certificates, FI-STAR Applications certificates, root certificates, certificattion authority,...) / Source of the certificates (FI-STAR Infrastructure or Internet) ?	*signature/internet, encryption/internet, root/internet*		*TBD*
2.4			Do you already have a Public Key Infrastructure (PKI) in place ?	*NO*		
2.5			If YES please give details (symetric / asymetric keys, Certificates, Certificate Authorities, ...); If NO please specify requirements on your new PKI			
2.6			Do you intend to provide to your end-users Application Access Security Incident Reports? If YES, please specify the time after incident occurance	*NO*		
	FI-STAR Applications Security Manager	Data Security				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application data objects			
2.7			Which of your FI-STAR Use-Case-Scenario Application data objects require a secured access and which actors have (read / write) rights?	*observation/patient R* *observation/caregiver R* *treatment enrollment information/caregiver/R,W*		
2.8			Do you intend to provide to your end-users Application-Data Access Incident Reports? If YES, please specify the time after incident occurance	*Yes*		TBD
	FI-STAR Applications Security Manager	Data Privacy				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for anonymisation / pseudonimisation of application data objects			
2.9			Which of your FI-STAR Use-Case-Scenario Application data objects require anonymisation / pseudonimisation of the end-user?	*(data obj type)*		TBD:
	FI-STAR Applications Security Manager	Security Risks				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for protection against cyber attacks			
2.10			Against which type of cyber atacks do you want to protect your FI-STAR Applications ?	*Sensitive data exposure and manipulation,*		
3	FI-STAR Applications Auditing Services					
	FI-STAR Infrastructure Manager	Auditing				
			Questionnaire aimed to check the need for providing auditing services related to the FI-STAR Use-Case-Scenario Applications Services			
3.1		Governance	Are you interested / obliged to offer the FI-STAR Applications end-users a service that enables them to see all accesses (including refused requests) to their data ?	*NO*		
3.2		Compliance	Are you obliged to offer to external auditors information regarding the FI-STAR applications provision and usage ? (please enumerate what kind of audit logs are you supposed to provide, e.g. service usage statistics, performance, security, ...)	*NO*		TBD
4	FI-STAR Applications Monitoring Services					
	FI-STAR Infrastructure Manager	System Monitoring				
			Questionnaire aimed to check the system monitoring requirements (HW resources, Virtual resources, others)			
4.1			Do you need to monitor hardware performances?	*NO*		TBD
4.2			If the answer to 4.1 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)			
4.3			Do you need to monitor the VMs resources?	*YES*		
			If the answer to 4.3 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)			TBD
	FI-STAR Infrastructure Manager	Service Monitoring				
			Questionnaire aimed to check the FI-STAR Applications service monitoring requirements (responce time, avalilability,..)			
4.4			Do you have an SLA evaluation need ? (YES means that you intend to offer your end-users Service Reports)	*(YES/NO)*		Not in this phase
4.5			If the answer to 4.4 is YES, please specify per use-case-scenario application / use-case the performance categories (response time, availability, load) and security categories (service access, data access) to be included in such service reports	*(responce time, availability, load / service access log, data access log)*		*Not in this phase*
4.6			Do you intend to offer to your custumers incentives for changing their SLA ? (YES means that you intend to optimise the performance of your applications by peak shaving mechanisms)	*(YES/NO)*		Not in this phase
4.7			Do you intend to offer to your custumers incentives for avoiding a penalty that would result from an SLA breach ? (YES means that you intend to manage the performance of your applications by pro-active service management mechanisms)	*(YES/NO)*		Not in this phase
4.8			If you have other monitoring needs please specify them (e.g. parameters related to the end-user Quality of Experience (QoE))	*YES*		From WP6
5	FI-STAR Applications Administration Services					
	FI-STAR Applications Administrator	Change and Release Management Services				
			Questionnaire aimed to check the FI-STAR Applications change & release management requirements			
5.1			How do you plan to manage the releases and changes of your FI-STAR Applications Services ?	Roadmap, plan, validation, notes		
5.2			How do you intend to deploy / roll-out your releases and changes ?	Automatically		
5.3			Do you need to adopt mechanisms to enable the distributed deployment of the software (i.e. the modules of the use-case-scenario applications)?	*YES*		FI-STAR Appstore mechanism
5.4			Do you need to upload your own VM images?	*Yes*		
5.5			How do you prefer to upload your templates (SFTP, SCP...)	*SCP*		
5.6			Is the software to deploy in the VMs strictly dependent from the OS?	*(YES/NO)*		TBD: Android for smartphone, Linux/Unix....
5.6.1			If such software depends from a Linux OS, can you specify the distribution?	*see next sheet*		TBD
5.6.2			If such software depends from a not Linux based OS, can you specify such OS?	*see next sheet*		TBD
5.7			Which software would you need to find pre-installed on the VM templates as required by the software to deploy?	*see next sheet*		TBD
5.8			Do you need to document the releases and inform your changes as a result of a compliance requirement ?	*(YES/NO)*		TBD
5.9			Do you have a releases and changes management system ?	*NO*		
5.10			If the anser to 5.4 is YES, please name the product			
	FI-STAR Applications Administrator	Configuration Services				
			Questionnaire aimed to check the FI-STAR Applications configuration management requirements			
5.11			What configuration items can you identify (application services, HW resources, Virtual resources, documentation, ...)	CRP Share System Product, FI-STAR Euntime Environment Product (Platform Installer), Smartphone Product (Sensor Integration Library App Installer), Sensors (Blood pressure, Heart rate, ECG, Calories,		
5.12			What configuration data can you identify ? (attributes of the configuration items)			TBD
5.13			Would you need VM images to customize with respect to already built VMs?			TBD
	FI-STAR Applications Administrator	Test & Maintenance Services				
			Questionnaire aimed to check theFI-STAR Applications test and maintenance requirements			
5.14			What test-services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	Test server for automatically running model based test		
	FI-STAR Applications Administrator	Incident Management Services				
			Questionnaire aimed to check theFI-STAR Applications Incidents Management requirements			
5.15			What incident management services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	NO		
5.16			Do you intend to build a KB for support in problem solving?	NO		
6	FI-STAR Applications Emergency Services					
	FI-STAR Applications Emergency Manage	Emergency Management Services				
			Questionnaire aimed to check the FI-STAR Applicationsemergency management requirements			
6.1			How do you plan to manage an emergency situation affecting your FI-STAR Applications Services ?			TBD

10.3.6 Operating Theatre Monitor (Munich, German)

	FI-STAR Applications Dimensions / Requirements Category / Description / Requirements Questionnaire / Interviewed Actor			Operating Theatre Monitor (Munich, Germany)	Clarifications
1	FI-STAR Applications Delivery Solution				
	FI-STAR Infrastructure Manager	CAPEX and OPEX Costs			
			Questionnaire aimed to check the need for an on-premise or for a hosting solution under the cost perspective		
1.1			Are you interested to achieve lower "CAPEX & OPEX costs" by outsourcing the provision and management of your FI-STAR Back-End infrastructure to an external commercial organisation (hoster) ?	*NO*	
1.2			If the answer to 1.1 is NO, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in your existing data cente ? (NO means the FI-STAR Back-end infrastructure will be deployed in a new on-premise data center)	*YES*	Yes, big datacenter in University as well as in hospital for patient data available
1.3			If the answer to 1.2 is YES, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in a separate physical environment (YES means new CAPEX, NO means reuse of existing infrastructure resources)?	*NO*	
1.4			If the answer to 1.3 is NO, please describe the resources intended to be used for the deployment of your FI-STAR Back-End infrastructure	*Hospital IT department/ TUM IT-department*	
1.4.1			Computing resources (server machines)		
			Hardware	*tbd*	not yet clear, but we can install own servers as well as use of VM
			Operating System	*tbd*	TBD
1.4.2			Storage System		
			Hardware	*tbd*	
			Data base System	*tbd*	
1.4.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)	*connection only necessary for barcode lookup --> firewall*	
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)	*connection only necessary for barcode lookup --> firewall*	
1.5			If the answer to 1.3 is YES, please describe the resources you intende to purchase		
1.5.1			Computing resources (server machines)		
			Hardware	*NOT DUE: answer to 1.3 is NO*	
			Operating System		
1.5.2			Storage System		
			Hardware		
			Data base System		
1.5.3			Network System		
			Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)		
			Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)		
			Questionnaire aimed to check the real need of a cloud solution under the resource utilisation perspective		
1.6			If the answer to 1.1 is NO, are you interested to achieve higer "resource utilisation" by adopting economies of scale in your FI-STAR Back-End infrastructure management, by means of a greater sharing of your infrastructure resources ?	*NO*	
	FI-STAR Infrastructure Manager	Scalability			
			Questionnaire aimed to check the real need of a cloud solution under the scalability perspective		
1.7			Are you interested to offer an almost instantly "scalable" FI-STAR Applications Delivery solution ?	*YES*	We would like to use the OTM also for other operations in more operating rooms. During the project only one operating room will be in use
	FI-STAR Infrastructure Manager	Performance			
			Questionnaire aimed to specify the performance requirements of the FI-STAR Applications services		
1.8		Response Time	What is the typical and maximum required Responce Time (Round Trip Time plus Processing Time) of your FI-STAR use-case-scenario applications / use cases requests ?	*OR sensor analysis: 5/30sec - RFID towel monitoring/counting: 5/10sec. - Barcode scanning response: 300/1000ms*	
1.9		Availability	What is the required availability of your FI-STAR use-case-scenario applications ?	*1*	the operating room team needs to trust the system, therfore it must be available
1.9.1			down-time pro month	*see comments*	during project test phase down always possible by request and information, for the product approx. 30min.
1.9.2			mean time to repair	*??*	no idea, ideally system should be covered by second parallel system
1.10		Load	What are your parallel processing and load requirements ?	*tbd*	
1.10.1			Number of Simultaneous patient sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*project: 3 simultanious/ max. 5day/ <20MB upload/ <20MB download; product 3 simultanious/operating room; 5/day; <20MB upload <20MB download/session*	
1.10.2			Number of Simultaneous profesional users (GP, clinical specialist, pharmacist, call ctr .agent, ...) sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*project: 2 simultanious/ max. 5day/ <20MB upload/ <20MB download; product (2 simultanious/ max. 5day/ <20MB upload/ <20MB download)/operating room*	
1.10.3			How many peak-load situations do you expect?	*none (no video, small data volume)*	
1.11			Do you intend to provide to your end-users Application Performance Reports? If YES, please specify the reporting time-interval	*NO*	
1.12			Do you intend to provide to your end-users Application Delivery Incident Reports? If YES, please specify the time after incident occurance	*YES, see comment*	Important during towel counting, if data transmission problems or ID get lost, system should report immediately
	FI-STAR Infrastructure Manager	Resilience			
			Questionnaire aimed to check the real need of a cloud solution under the reliability perspective		
1.13			Are you interested to offer an high level of "resilience" of the hosted applications by reducing, as much as possible, single points of hardware failure and offering, in such a way, an higher uptime?	*YES*	
	FI-STAR Applications Service Billing	Pricing			
			Questionnaire aimed to check the real need of a cloud solution under the pricing perspective		
1.14			Do you intend to offer a pricing model based on a fee (or a flat rate) ?	*???*	
1.15			Do you intend to offer a pricing model based on a pay-per-use pricing mechanism (enabling, such a way, a real consumption service based "billing") ?	*???*	

2	FI-STAR Applications Security					
	FI-STAR Applications Security Manager	Access Security				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application services			
2.1			Which of your FI-STAR Use-Case-Scenario Application Services require a secured access?	*NONE - patient data will not leave hospital*		
2.2			How many security zones do you foresee for your FI-STAR Infrastructure deployment? (please give detail about security perimeters in the FI-STAR Back-End and Front-End domains)	*tbd*		
2.3			Which Certificate Types do you foresee (e.g. end-user certificates, signature certificates, encription certificates, gateway certificates,sensor certificates, FI-STAR Applications certificates, root certificates, certificattion authority,...) / Source of the certificates (FI-STAR Infrastructure or Internet) ?	*informed consent from patient*		
2.4			Do you already have a Public Key Infrastructure (PKI) in place ?	*NO*	maybe TUM IT department (Leibniz-Rechenzentrum)	
2.5			If YES please give details (symetric / asymetric keys, Certificates, Certificate Authorities, ...); If NO please specify requirements on your new PKI			
2.6			Do you intend to provide to your end-users Application Access Security Incident Reports? If YES, please specify the time after incident occurance	*NO*		
	FI-STAR Applications Security Manager	Data Security				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application data objects			
2.7			Which of your FI-STAR Use-Case-Scenario Application data objects require a secured access and which actors have (read / write) rights?	*R/W for operating room team*		
2.8			Do you intend to provide to your end-users Application-Data Access Incident Reports? If YES, please specify the time after incident occurance	*NO*	better communication to the IT department	
	FI-STAR Applications Security Manager	Data Privacy				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for anonymisation / pseudonimisation of application data objects			
2.9			Which of your FI-STAR Use-Case-Scenario Application data objects require anonymisation / pseudonimisation of the end-user?	*none*	however during project, patient will be anonymized	
	FI-STAR Applications Security Manager	Security Risks				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for protection against cyber attacks			
2.10			Against which type of cyber atacks do you want to protect your FI-STAR Applications ?	*Intrusion in hospital network with patient data (hopefully done by IT department)*		
3	FI-STAR Applications Auditing Services					
	FI-STAR Infrastructure Manager	Auditing				
			Questionnaire aimed to check the need for providing auditing services related to the FI-STAR Use-Case-Scenario Applications Services			
3.1		Governance	Are you interested / obliged to offer the FI-STAR Applications end-users a service that enables them to see all accesses (including refused requests) to their data ?	*NO*		
3.2		Compliance	Are you obliged to offer to external auditors information regarding the FI-STAR applications provision and usage ? (please enumerate what kind of audit logs are you supposed to provide, e.g. service usage statistics, performance, security, ...)	*NO*		
4	FI-STAR Applications Monitoring Services					
	FI-STAR Infrastructure Manager	System Monitoring				
			Questionnaire aimed to check the system monitoring requirements (HW resources, Virtual resources, others)			
4.1			Do you need to monitor hardware performances?	*YES*	Correct function of RFID/Barcode reader/sensors has to be checked somewhere in software	
4.2			If the answer to 4.1 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)	*All software should not reach 100% CPU load to not produce delays*		
4.3			Do you need to monitor the VMs resources?	*???*		
			If the answer to 4.3 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)			
	FI-STAR Infrastructure Manager	Service Monitoring				
			Questionnaire aimed to check the FI-STAR Applications service monitoring requirements (responce time, availability,..)			
4.4			Do you have an SLA evaluation need ? (YES means that you intend to offer your end-users Service Reports)	*???*		
4.5			If the answer to 4.4 is YES, please specify per use-case-scenario application / use-case the performance categories (response time, availability, load) and security categories (service access, data access) to be included in such service reports	*?*		
4.6			Do you intend to offer to your custumers incentives for changing their SLA ? (YES means that you intend to optimise the performance of your applications by peak shaving mechanisms)	*?*		
4.7			Do you intend to offer to your custumers incentives for avoiding a penalty that would result from an SLA breach ? (YES means that you intend to manage the performance of your applications by pro-active service management mechanisms)	*?*		
4.8			If you have other monitoring needs please specify them (e.g. parameters related to the end-user Quality of Experience (QoE))			
5	FI-STAR Applications Administration Services					
	FI-STAR Applications Administrator	Change and Release Management Services				
			Questionnaire aimed to check the FI-STAR Applications change & release management requirements			
5.1			How do you plan to manage the releases and changes of your FI-STAR Applications Services ?	alpha, beta testing in a demo system, release		
5.2			How do you intend to deploy / roll-out your releases and changes ?	FI-Star appstore		
5.3			Do you need to adopt mechanisms to enable the distributed deployment of the software (i.e. the modules of the use-case-scenario applications)?	*?*		
5.4			Do you need to upload your own VM images?	*?*		
5.5			How do you prefer to upload your templates (SFTP, SCP...)	*?*		
5.6			Is the software to deploy in the VMs strictly dependent from the OS?	*?*		
5.6.1			If such software depends from a Linux OS, can you specify the distribution?	*see next sheet*		
5.6.2			If such software depends from a not Linux based OS, can you specify such OS?	*see next sheet*		
5.7			Which software would you need to find pre-installed on the VM templates as required by the software to deploy?	*see next sheet*		
5.8			Do you need to document the releases and inform your changes as a result of a compliance requirement ?	*?*		
5.9			Do you have a releases and changes management system ?	*?*		
5.10			If the anser to 5.4 is YES, please name the product			
	FI-STAR Applications Administrator	Configuration Services				
			Questionnaire aimed to check the FI-STAR Applications configuration management requirements			
5.11			What configuration items can you identify (application services, HW resources, Virtual resources, documentation, ...)	?		
5.12			What configuration data can you identify ? (attributes of the configuration items)	?		
5.13			Would you need VM images to customize with respect to already built VMs?	?	TBD	
	FI-STAR Applications Administrator	Test & Maintenance Services				
			Questionnaire aimed to checkFI-STAR Applications test and maintenance requirements			
5.14			What test-services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	dedicated test system with dedicated computers, disconnected from the productive system		
	FI-STAR Applications Administrator	Incident Management Services				
			Questionnaire aimed to check theFI-STAR Applications Incidents Management requirements			
5.15			What incident management services do you foresee for your FI-STAR Use-Case-Scenario Applications ?	reports to operating team members; in productive system automated actions (i.e. call of other surgeon, switching lights,..)		
5.16			Do you intend to build a KB for support in problem solving?	??		
6	FI-STAR Applications Emergency Services					
	FI-STAR Applications Emergency Manage	Emergency Management Services				
			Questionnaire aimed to check the FI-STAR Applicationsemergency management requirements			
6.1			How do you plan to manage an emergency situation affecting your FI-STAR Applications Services ?	Warning in the OR eventually automatic steps (call of more experienced surgeon)		

10.3.7 Drug Supply Manager (Leeds, UK)

	FI-STAR Applications Dimensions / Requirements Category / Description / Requirements Questionnaire / Interviewed Actor				Drug Supply Manager (Leeds, UK)	Clarifications
1	FI-STAR Applications Delivery Solution					
	FI-STAR Infrastructure Manager	CAPEX and OPEX Costs				
				Questionnaire aimed to check the need for an on-premise or for a hosting solution under the cost perspective		
1.1				Are you interested to achieve lower "CAPEX & OPEX costs" by outsourcing the provision and management of your FI-STAR Back-End infrastructure to an external commercial organisation (hoster) ?	*NO*	
1.2				If the answer to 1.1 is NO, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in your existing data cente ? (NO means the FI-STAR Back-end infrastructure will be deployed in a new on-premise data center)	*NO*	
1.3				If the answer to 1.2 is YES, is your internal organisation planning to deploy the FI-STAR Back-End infrastructure in a separate physical environment (YES means new CAPEX, NO means reuse of existing infrastructure resources)?		Answer to 1.2 was no
1.4				If the answer to 1.3 is NO, please describe the resources intended to be used for the deployment of your FI-STAR Back-End infrastructure		No answer required for 1.3
1.4.1				Computing resources (server machines)		
				Hardware	DELL Power Edge Server	
				Operating System	*LINUX, Cent OS*	
1.4.2				Storage System		
				Hardware	*SAN/NAS*	
				Data base System	*MySQL, 5.x, Hardoop*	
1.4.3				Network System		
				Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)	*WLAN*	*WLAN from CP50 to Pharmacy PC.* *The remaining devices are connected via RS232, USB 2.0, or Bluetooth 2.0*
				Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)	*TCP/IP, WLAN, WWAN*	*TCP/IP from Local Application Server to Medichem Private Cloud and from Local Application Server to PC.*
1.5				If the answer to 1.3 is YES, please describe the resources you intende to purchase		
1.5.1				Computing resources (server machines)		
				Hardware	*DeELL Power Edge Server*	
				Operating System	*LINUX, CENT OS*	
1.5.2				Storage System		
				Hardware	*SAN/NAS*	
				Data base System	*MYSQL 5.X*	
1.5.3				Network System		
				Front-end network (towards you rend-user domain , i.e. VPN concentrator / router (network transport service, bandwidth), firewall, front-end LAN after the VPN concentrator)	*TBD*	
				Back-End network (towards your legacy application services, i.e. firewall, back-end LAN, network transport service)	*TBD*	
				Questionnaire aimed to check the real need of a cloud solution under the resource utilisation perspective		
1.6				If the answer to 1.1 is NO, are you interested to achieve higer "resource utilisation" by adopting economies of scale in your FI-STAR Back-End infrastructure management, by means of a greater sharing of your infrastructure resources ?	*NO*	
	FI-STAR Infrastructure Manager	Scalability				
				Questionnaire aimed to check the real need of a cloud solution under the scalability perspective		
1.7				Are you interested to offer an almost instantly "scalable" FI-STAR Applications Delivery solution ?	*NO*	With the BETA version the feature DSM14 Drug Recall will be introduced whoch requires such instant scalability for the Local Application Server
	FI-STAR Infrastructure Manager	Performance				
				Questionnaire aimed to specify the performance requirements of the FI-STAR Applications services		
1.8		Response Time		What is the typical and maximum required Responce Time (Round Trip Time plus Processing Time) of your FI-STAR use-case-scenario applications / use cases requests ?	*1.6 seconds*	*The round trip from the Barcode Scanner to the DSM Viewer to the Drug Supply Manager to data Collection and Back to the DSM Viewer. The round trip from the CP50 to the Medichem Private Cloud back to the CP50. The round trip from CP50 to the Medichem Private Cloud to the Manufacturer Private Cloud back to the Medichem Private Cloud and CP50.* *These ar the most critical round trips.*
1.9		Availability		What is the required availability of your FI-STAR use-case-scenario applications ?		
1.9.1				down-time pro month	*5 Hours*	TBD Verified
1.9.2				mean time to repair	*2Hours*	TB Verified
1.10		Load		What are your parallel processing and load requirements ?		
1.10.1				Number of Simultaneous patient sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*<4000*	*21 simultaneous sessions per patient.* *50 patients, 10,000 dispensed Items, in the first three months. Hence total expected total simultaneous session to be <4000.*
1.10.2				Number of Simultaneous profesional users (GP, clinical specialist, pharmacist, call ctr .agent, ...) sessions / session rate / upload data volume pro session / download data volume pro session (aggregated from all your use-case-scenario applications / use cases)	*4*	
1.10.3				How many peak-load situations do you expect?	*TBD*	*In the current deployment scenario*
1.11				Do you intend to provide to your end-users Application Performance Reports? If YES, please specify the reporting time-interval	*YES*	Weekly reports in system stability and down time.
1.12				Do you intend to provide to your end-users Application Delivery Incident Reports? If YES, please specify the time after incident occurance	*YES*	Daily report of incidents.
	FI-STAR Infrastructure Manager	Resilience				
				Questionnaire aimed to check the real need of a cloud solution under the reliability perspective		
1.13				Are you interested to offer an high level of "resilience" of the hosted applications by reducing, as much as possible, single points of hardware failure and offering, in such a way, an higher uptime?	*YES*	
	FI-STAR Applications Service Billing	Pricing				
				Questionnaire aimed to check the real need of a cloud solution under the pricing perspective		
1.14				Do you intend to offer a pricing model based on a fee (or a flat rate) ?	*FEE*	This is yet to be decided, the pricing structure may be two fold of both subscription fee per site/solution deployed and flat for maintenance contracts.
1.15				Do you intend to offer a pricing model based on a pay-per-use pricing mechanism (enabling, such a way, a real consumption service based "billing") ?	*NO*	This could change depending on the outcome of 1.15.

2	FI-STAR Applications Security					
	FI-STAR Applications Security Manager	Access Security				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application services			
2.1			Which of your FI-STAR Use-Case-Scenario Application Services require a secured access?		*DSM5, DSM4, DSM6, DSM17*	
2.2			How many security zones do you foresee for your FI-STAR Infrastructure deployment? (please give detail about security perimeters in the FI-STAR Back-End and Front-End domains)		*8*	*Back End: Local Application Server, Medichem Private Cloud, Manufacturer Private Cloud, Manufacturer Production Line, Pharmacy DMZ for External Access Front End: Pharmacy PC and CP50, Manufacturer PC*
2.3			Which Certificate Types do you foresee (e.g. end-user certificates, signature certificates, encription certificates, gateway certificates,sensor certificates, FI-STAR Applications certificates, root certificates, certificattion authority,...) / Source of the certificates (FI-STAR Infrastructure or Internet) ?		*HTTP SSL Transport. AES 128 or 25.*	
2.4			Do you already have a Public Key Infrastructure (PKI) in place ?		*NO*	
2.5			If YES please give details (symetric / asymetric keys, Certificates, Certificate Authorities, ...); If NO please specify requirements on your new PKI			
2.6			Do you intend to provide to your end-users Application Access Security Incident Reports? If YES, please specify the time after incident occurance		*YES*	This is to ensure unauthorised access to any part of the solution is logged and reported on to detemrine best cours eof action for mitigating and risk to data breach.
	FI-STAR Applications Security Manager	Data Security				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for secured access to application data objects			
2.7			Which of your FI-STAR Use-Case-Scenario Application data objects require a secured access and which actors have (read / write) rights?		*Patient R Pharmacy Assistance R/W Pharmacist R/W Pharmacy Driver W/R Dispenser R/W*	
2.8			Do you intend to provide to your end-users Application-Data Access Incident Reports? If YES, please specify the time after incident occurance		*NO*	
	FI-STAR Applications Security Manager	Data Privacy				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for anonymisation / pseudonimisation of application data objects			
2.9			Which of your FI-STAR Use-Case-Scenario Application data objects require anonymisation / pseudonimisation of the end-user?		*DSM11, DSM5, DSM6, DSM9*	
	FI-STAR Applications Security Manager	Security Risks				
			Questionnaire aimed to check the FI-STAR Use-Case-Scenario Applications need for protection against cyber attacks			
2.10			Against which type of cyber atacks do you want to protect your FI-STAR Applications ?		*BruteForce, Sensitive Data Exposure, DoS, DDoS,*	
3	FI-STAR Applications Auditing Services					
	FI-STAR Infrastructure Manager	Auditing				
			Questionnaire aimed to check the need for providing auditing services related to the FI-STAR Use-Case-Scenario Applications Services			
3.1		Governance	Are you interested / obliged to offer the FI-STAR Applications end-users a service that enables them to see all accesses (including refused requests) to their data ?		*YES*	Patient Consent is required for hosting patient information, hence patient can request access thot heir information
3.2		Compliance	Are you obliged to offer to external auditors information regarding the FI-STAR applications provision and usage ? (please enumerate what kind of audit logs are you supposed to provide, e.g. service usage statistics, performance, security, ...)		*NO*	
4	FI-STAR Applications Monitoring Services					
	FI-STAR Infrastructure Manager	System Monitoring				
			Questionnaire aimed to check the system monitoring requirements (HW resources, Virtual resources, others)			
4.1			Do you need to monitor hardware performances?		*YES*	
4.2			If the answer to 4.1 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)		*YES*	
4.3			Do you need to monitor the VMs resources?		*NO*	VM have not been ruled oput but could be considered.
			If the answer to 4.3 is YES, what do you need to monitor in detail? (e.g. CPU usage, RAM consumption, Network bandwidth, Network Throughput / Data Volume, Network Latency, Processing Time)			
	FI-STAR Infrastructure Manager	Service Monitoring				
			Questionnaire aimed to check the FI-STAR Applications service monitoring requirements (responce time, avalilability...)			
4.4			Do you have an SLA evaluation need ? (YES means that you intend to offer your end-users Service Reports)		*YES*	
4.5			If the answer to 4.4 is YES, please specify per use-case-scenario application / use-case the performance categories (response time, availability, load) and security categories (service access, data access) to be included in such service reports		*DSM6, DSM9, DSM1, DSS, DSM4*	
4.6			Do you intend to offer to your custumers incentives for changing their SLA ? (YES means that you intend to optimise the performance of your applications by peak shaving mechanisms)		*NO*	
4.7			Do you intend to offer to your custumers incentives for avoiding a penalty that would result from an SLA breach ? (YES means that you intend to manage the performance of your applications by pro-active service management mechanisms)		*NO*	
4.8			If you have other monitoring needs please specify them (e.g. parameters related to the end-user Quality of Experience (QoE))		*YES*	Response time, errors, downtime, throughput
5	FI-STAR Applications Administration Services					
	FI-STAR Applications Administrator	Change and Release Management Services				
			Questionnaire aimed to check the FI-STAR Applications change & release management requirements			
5.1			How do you plan to manage the releases and changes of your FI-STAR Applications Services ?			Roadmap, release plan, release validation, release notes
5.2			How do you intend to deploy / roll-out your releases and changes ?			Adopting ITIL V3 method for deployment scenarios for change control for release
5.3			Do you need to adopt mechanisms to enable the distributed deployment of the software (i.e. the modules of the use-case-scenario applications)?		*YES*	
5.4			Do you need to upload your own VM images?		*NO*	
5.5			How do you prefer to upload your templates (SFTP, SCP...)		*FTP*	
5.6			Is the software to deploy in the VMs strictly dependent from the OS?		*NO*	VM Ware is not intended at this stage which could change, in which case there may be a VM versionf or each OS and Platform.
5.6.1			If such software depends from a Linux OS, can you specify the distribution?		*CENT OS*	
5.6.2			If such software depends from a not Linux based OS, can you specify such OS?		*TBD*	
5.7			Which software would you need to find pre-installed on the VM templates as required by the software to deploy?		*TBD*	
5.8			Do you need to document the releases and inform your changes as a result of a compliance requirement ?		*YES*	
5.9			Do you have a releases and changes management system ?		*NO*	
5.10			If the anser to 5.4 is YES, please name the product			
	FI-STAR Applications Administrator	Configuration Services				
			Questionnaire aimed to check the FI-STAR Applications configuration management requirements			
5.11			What configuration items can you identify (application services, HW resources, Virtual resources, documentation, ...)			CP50 Package Handler, PC DSM Viwer, Local Application Server Drug Supply Manager, Medichem Private Cloud Entity Respository, Manufacturer Private Cloud Entity Repository, Manufcaturer PC Product Line Manager.
5.12			What configuration data can you identify ? (attributes of the configuration items)			Barcode Label, Barcode, Legal Entity ID, Location, Package, Order Expectation, Prescription Information, Patient Information, Drug Information, package Status Update, Stock Status, Order Status, EAN, Delivery Status, Despatch Status, User Authentitcation.
5.13			Would you need VM images to customize with respect to already built VMs?		NO	
	FI-STAR Applications Administrator	Test & Maintenance Services				
			Questionnaire aimed to check theFI-STAR Applications test and maintenance requirements			
5.14			What test-services do you foresee for your FI-STAR Use-Case-Scenario Applications ?		Simulating Interface Stability,	
	FI-STAR Applications Administrator	Incident Management Services				
			Questionnaire aimed to check theFI-STAR Applications Incidents Management requirements			
5.15			What incident management services do you foresee for your FI-STAR Use-Case-Scenario Applications ?		NONE	Not for FI-STAR. Yes for productization.
5.16			Do you intend to build a KB for support in problem solving?		NO	Not for FI-STAR. Yes for productization.
6	FI-STAR Applications Emergency Services					
	FI-STAR Applications Emergency Manage	Emergency Management Services				
			Questionnaire aimed to check the FI-STAR Applicationsemergency management requirements			
6.1			How do you plan to manage an emergency situation affecting your FI-STAR Applications Services ?		YES	Through contingency planning, the Pharmacists intervention of drug dispensing will be critical if the application produces unexpected results. Manual procedures

10.4 Conclusions

The final requirements document will be the reference framework in order to allow, the platform work packages, to start the platforms (back-end/front-end) infrastructure specification. It must pointed out, at the same time, that several answers could be modified in the future by the use case teams, in order to better fulfil their needs. This will imply a tuning action of the infrastructure which will affect the set up phase for the release of the beta FI-STAR Platform.

11 Security Requirements

11.1 Introduction

The objective of this section is to detail the security requirements of each of the seven FI-STAR Use Cases. The process for assessing the security is described and then an assessment for each Use Case is made. Thereafter, requirements, foreseen problems and solutions are discussed.

11.2 Process

11.2.1 Overview

The security requirements were specified after considering the use case's deployment or runtime diagram as a system with components and interfaces. This system is then assessed in order to determine and identify:

- The security level requirements of each component and interface
- The ultimate objectives of security, privacy and quality assurance

Thereafter, the requirements for preserving or even increasing the security levels were drawn as detailed in this section.

11.2.2 Objectives

Although each Use Case is slightly different, the broad objectives of security in FI-STAR are:

1. Confidentiality: safeguard important information (private patient data, their meta-data etc) are not disclosed to third-parties
2. Integrity: ensure that important information is not maliciously or accidentally altered
3. Authentication: ensure systems remain confident about the real identities of their users/devices
4. Quality of data: ensure that any medical results are not drawn from erroneous data

To achieve these, the following are assessed:

1. Trust: which components of the system can be trusted and which need to be protected by security measures
2. Cascading relationships and the prevention of low-quality data "poisoning" an otherwise high-quality data repository
3. Appropriate security primitives to be used for ensuring the above requirements

11.2.3 Compliance statement

The process has taken into account the following:

- ISO270001
- ISO80001
- NIST Recommendation for Key Management (2007)
- Good security practices
- The context of the FI-STAR project (time constrains and scope)
- The context of every Use Case (constrains, scope, feasibility and usability requirements)

It must be stressed that the last two factors from the above push the security provision of many Use Cases beyond what would be considered "highly secure" by any definition. For this reason, an attempt is made to provide a level of "adequate" security that would also serve the constrains of FI-STAR and the Use Cases. In these cases, effort has been made to mitigate the risks in other ways, for example by flagging potentially low-quality results and an analysis is provided in this section.

11.2.4 Terminology

11.2.4.1 Names of components

Components in this section are referred to with the name used in the runtime or deployment diagrams of the Use Cases, with the runtime diagrams being preferred. Please refer to other sections of this deliverable for these diagrams.

11.2.4.2 Mandatory and optional requirements

When the word **must** is used to describe a requirement, it denotes that this is an absolute requirement, which has to be met with no objections. Other words like may, should, optional etc denote a requirement that is not mandatory. The rationale behind most of the requirements is not explained, however this information can become available upon request. The word **must** in this context will also be emphasised with bold letters.

11.2.4.3 Notes

It is also noteworthy that some standard components, e.g. the cryptographic primitives, and interfaces appear in many of the Use Cases. These are covered separately in the resepctive subsections.

11.3 Primitives for all Use Cases

The following cryptographic and security primitives, grouped by function, have been identified as suitable for all use cases.

11.3.1 For Symmetric Encryption

Encryption is important to ensure confidentiality of private data. Not all use cases need to use encryption, but those who do **must** use one of these ciphers, to ensure that FI-STAR is using a secure and mature encryption algorithm. Alternative ciphers with these characteristics exist and Use Cases are invited to submit their case for using a different one, which will be evaluated.

The following ciphers are suitable for Symmetric Encryption, which may be used to encrypt stored data in Generic Enablers and/or data in transit after appropriate key negotiation and authentication.

11.3.1.1 AES128

The 128-bit complexity of the AES Cipher is considered secure and is used extremely widely in electronic communications and data storage. It is also very fast and lightweight. For these reasons, it is the preferred cipher for the FI-STAR Use Cases.

11.3.1.2 AES256

The 256-bit complexity of the AES Cipher should be used in the cases that the security of the data needs to be preserved in a secure manner for very long periods of time, typically reaching beyond year 2031. This option is acceptable but not recommended.

11.3.2 For transportation

When transporting data through the internet, a secure data transportation mechanism is absolutely required and all use cases that do so **must** use one. This will protect from eavesdropping and alterations in critical data.

The recommended data transportation protocol for FI-STAR **must** be TLS, with x509 for session initiation and AES for subsequent communication. It **must** be used in all cases where data is transported through an insecure medium like the Internet. It is also recommended for use when transferring within a relatively secure domain, but this is not necessary.

For the cases that data transfer does not happen automatically, e.g. when a USB stick is used, then the requirements for data storing, as described in 11.3.1, shall apply.

11.3.3 For digital signatures / Message Authentication Codes

Digital signatures, or message authentication codes, protect data integrity and provide confidence about their origin, ensuring reliable results. Digital signatures will be used in transportation by TLS but it is recommended to the Use Cases to implement their own, independent and permanent, digital signature for the generated data themselves. These should be used as extensively as possible by the components generating and/or storing data.

Implementing this suggestion should be easy for most Use Cases, as the cryptosystems enabling it will be available for other security functionality (encryption, authentication etc). The following algorithms are recommended for digital signatures.

11.3.3.1 CBC-MAC

AES can be used in CBC-MAC mode to generate digital signatures, this is the recommended option.

11.3.3.2 SHA2

This is an alternative option in the case the above is not possible. Use Cases looking to use SHA2, need to be aware that it is less efficient that AES CBC-MAC.

11.3.3.3 Clarification for the Tromsö case

The Tromsö Use Case can use the two-factor authentication system ID-Porten for authentication purposes, despite that it uses the non-recommended algorithm SHA1 for digital signing purposes. This is due to (a) the above recommendation not being applicable to authentication and (b) the ID-Porten system being a seemingly secure two-factor authentication system. However, the Tromsö Use Case should use SHA2 for purposes other than authentication.

11.3.4 For Authentication

The following mechanisms are recommended for authentication purposes.

11.3.4.1 Password over TLS

Passwords can be used of a secure TLS connection provided that:

- The password complies with the rules
- The password is never stored or transferred in plaintext anywhere in the system
    - A hashed-version of the password is used instead
    - The SHA2-512 hash function should be used to hash the password
    - The hash should be salted with 128 random bits
        - These need to be generated securely (further advise is available upon request)
        - These do not need to be securely stored/protected

11.3.4.2 Kerberos

This is an alternative authentication method for the Use Cases that with to implement it.

11.3.4.3 Password rules

Some Use Cases have local password rules, which they may follow. However, care needs to be taken to avoid the ill-advised practice of password rules that result in passwords that humans find difficult to remember – as this may result in less security and usability problems. The following password rules are recommended:

- Passwords consisting of actual words:
  - 16 characters long
  - Consisting of at least three distinct words (or more)
- Passwords consisting of seemingly random characters
  - At least 10 characters long
  - No requirement for specific mix of numbers or letters etc
- Not including the username or any other of the user's details (e.g. date of birth)

11.3.4.3.1 Notes

- With SHA-512 and a 128-bits salt, no password can be longer than 48 characters
- Salts can be stored along with the password hashes and do not need to be specially protected
- Physical password management should also be considered, e.g. it is a liability to send the passwords via post mail to the users

11.3.4.4 Clarification for the Tromsö case

The Tromsö Use Case can use the two-factor authentication system ID-Porten as it is.

11.3.5 For Pseudonymisation

A recommendation for pseudonymisation strategy is to be advised in the future.

11.4 Terminology determining and describing the security level

As explained, each Use Case will be treated as a system with components and interfaces, of which both need to be assessed for security provision. To understand the meaning of the components assessment results, which are presented in tables, we need to understand the used terminology.

11.4.1 Domain

Domains are conceptually or physically separated areas governed by different levels of security provision. Security, compliance, regulations, agreements or just general understanding of a domain's security may determine the security level of the domains. The domains are described in the **Domain** column.

11.4.2 Components & Subcomponents

The components are virtual or physical parts of a system, which may include subcomponents. These are identified in the column **(sub)component**, often in a descriptive manner incorporating many similar or related components.

11.4.3 Security levels

The following table describes the characteristics that will determine the security level of each component, in relation to the context of the Use Case.

Level	May be awarded to	Mark
Very high	The ultimate subject to be protected via security measures, which if compromised would jeopardise the **whole system** anyway.	Local rules
Very high	Any of the recommended cryptographic primitives.	Mathematically secure
High	A component designed to be secure, residing within a domain under the control of the Use Case or FI-STAR.	FI-STAR component

High	A component designed to be secure, residing within a domain controlled by a health or other government service.	Secure domain
High	A device trusted to produce reliable measurements due to its physical design, which cannot be easily tampered with via software means.	Secure device
Medium	A component designed to be secure and within FI-STAR's control, but residing in a domain that may affect it's reliability.	Unprotected domain
Low	A component whose security is not controlled by FI-STAR in any way but it is committed to producing reliable results in a best-effort fashion.	Third-party domain
Very low	A component which not committed to producing reliable results or not designed to be secure	Insecure

Components assessed to be of Medium or lower relative security level will be discussed further and will likely be given specific security requirements. The level will appear in the **Relative Security**. The mark will be given in the **Protected by & Remarks** column.

11.4.4 Other descriptive means

11.4.5 Protected by & Remarks

The Protected by & Remarks column contains an explanation about the security level and any other relevant information, including designations.

11.4.6 Designations

11.4.6.1 Baseline

Components designed as **Baseline** denote the highest level of provided security, exluding mathematically secured levels. This ultimate level of protection defines the metric to evaluate other components against. For each use case, this component will be first listed in the table of Security Level by Component and designated with the flag **Baseline**. This flag will appear in the **Protected by & Remarks** column of the tables.

11.4.6.2 Important

In many Use Cases, the Baseline cannot be equalled in the rest of the System. For assistance in understanding other important information that needs to be protected, the flag **Important** will be used to designate non-Baseline components that:

1. Generate or process data crucial to a Use Case
2. Are deemed worthy of relatively Medium or lower security level
3. Generates private data that should not be disclosed or altered

This flag will appear in the **Protected by & Remarks** column of the tables.

11.5 Standard components and functionality

11.5.1 Security of the FI-STAR App Store

The security of this component will always assumed to be High and will not be discussed in every Use Case independently. Requirements for this component are to be determined.

11.5.2 Security of Internet communications

All internet-based communication is assumed mathematically secure, provided that it adheres to the cryptographic primitives requirements discussed in 11.3.2.

11.5.3 Treatment Participant PC

Use Cases that use PC Computers as a component are liable to a great vulnerability from viruses, key loggers, Trojan horses and other malicious software. To mitigate this liability, the FI-STAR controlled subcomponent on the PC Computer should check the following:

- Whether the computer has anti-virus software enabled
- Whether all installed browsers are of the latest version
- The computer's firewall is enabled
- If Java is installed, is of the latest version
- If flash is installed, is of the latest version

If any of these checks fail, the component should **not** work until the problem is rectified. If that is not possible, given the constrains of the Use Case, another course of action needs to be determined.

In addition, data stored in the device may be encrypted and signed with a frequently changing in-memory only password managed by the Diabetes Share Proxy Server, without user intervention. The feasibility of this may be determined later.

11.5.3.1 Smartphones domain

Smartphone vulnerabilities are a potential risk, yet it is unlikely that an adversary would target smartphones in order to acquire medical observations. Although the "sandboxed" design of their Operating Systems does not allow any checking of their security, it does offer a relatively higher security than PC Computers.

Regardless, the following is a mandatory security requirement for these components; the FI-STAR component residing in a Smartphone should check whether the OS has been tampered with via Jailbreak (for iOS) or rooting (for Android and FirefoxOS). If the component detects tampering two things should happen:

- The patient should be wanted that privacy cannot be guaranteed because of the tampering
- The attending doctors and carers should also be informed in order to
    - Not trust any data originating from this device
    - Assist the patient to improve their device security and/or check whether the patient has ignored the message

Optionally, the component may refuse to work or flag the data as low-security in a manner the other components will understand and display.

In addition, the following suggestion, whose feasibility will be determined later, is made; data stored in the device may be encrypted and signed with a frequently changing in-memory only password managed by the Diabetes Share Proxy Server, without user intervention.

Finally, Use Cases may wish to consider authorising devices independently of the user's password, in a manner that ensures only qualified devices are used. Further advice on this is available upon request.

11.5.4 Quality of manually entered data

In terms of the quality of manually entered data, a set of rules may be devised to detect potential erroneous input. The feasibility of such activity needs to be determined, but a potential rule set may be taken into account

- The normal ranges of a medical attribute in healthy people
- The historical values of an attribute for this person

The frequency of potentially erroneous input from this person

11.6 Bilbao Use Case

The main security concerns of this Use Case are:

- The acceptance of manual data entry by patients poses a human factor risk
- The involvement of a PC-Based computer maintained by a patient who is likely to not be technologically attuned

On the other hand, the context of the Use Case has to allow for both liabilities in order to make it feasible and meaningful. In addition, the Use Case targets patients with mental diseases and aims to improve their quality of life, rather than predict and diagnose immediate life threatening situations.

For this reason, the focus of this assessment will be on protecting data from disclosure to third parties, rather than ensuring the quality of data and results.

11.6.1 Components and their relative security

The following table describes the characteristics that will determine the security level of each component, in relation to the context of the Use Case. The table merges both the runtime diagrams for this Use Case.

Domain	**(sub)component**	**Relative security**	**Protected by & Remarks**
OSAKIDETZA Secure Domain (OSAKIDETZA)	OSAREAN	Very High	Local Rules **Baseline**
OSAKIDETZA	All other subcomponents and interfaces	Very High	Local rules
3rd Party Certification Entity	Identifications	High	Secure domain
OSAKIDETZA DMZ	All subcomponents and interfaces	High	FI-STAR Component(s)
Treatment Participant PC	PC Device Integration	Medium	Unprotected Domain **Important**
Devices	SmartCard reader Activity Monitor Smart Scale Pulse Oximeter	High	Secure Device
Smartphone Apps	Android BPTM App FirefoxOS BPTM App iOS BPTM App	Medium	Unprotected domain **Important**

11.6.2 Further discussion

11.6.2.1 Notes

The use case uses the following standard components and functionality:

- PC computers
- Smartphones

- Manual entry of data

Please see the respective discussion on section 11.5 about these.

11.7 Bologna Use Case

The main security concerns of this Use Case are:

- The acceptance of manual data entry by patients poses a human factor risk
- The involvement of a PC-Based computer maintained by a patient who is likely not be technologically attuned

However, the Use Case is aware of this problem and current planning is to not substitute normal treatment with any information generated through this system.

11.7.1 Components and their relative security

The following table describes the characteristics that will determine the security level of each component, in relation to the context of the Use Case.

Domain	**(sub)component**	**Relative security**	**Protected by & Remarks**
SOLE System Regional Node (SOLE)	FSE Server: all subcomponents and interfaces	Very High	Local Rules **Baseline**
SOLE	All other subcomponents and interfaces	High	FI-STAR Component(s)
Medical Personnel PC	PC: FI-STAR Platform: all subcomponents and interfaces	Medium	Unprotected Domain **Important**
Smartphone App	Smartphone: FI-STAR Platform: all subcomponents and interfaces	Medium	Unprotected Domain **Important**
Devices	Pulsioxymeter (Pulse Oximeter) Spirometer	High	Secure Device

11.7.2 Further discussion

11.7.2.1 Notes

The use case uses the following standard components and functionality:

- PC computers
- Smartphones
- Manual entry of data

Please see the respective discussion on section 11.5 about these.

11.8 Bucharest Use Case

The main security concern of this Use Case is the use of a relatively Low security Smartphone for assisting in the data generation and transportation. This liability can be appropriately managed with a FI-STAR component adhering to the advice on 11.5.3.1.

11.8.1 Components and their relative security

The following table describes the characteristics that will determine the security level of each component, in relation to the context of the Use Case.

Domain	(sub)component	Relative security	Protected by & Remarks
Hospital Secure Domain (HSD)	CRP Share System	Very High	Local Rules **Baseline**
HSD	All components and interfaces	Very High	Local Rules
Smartphone Apps	CRP Doctor's App CRP Patient App Sensor Integration	Medium	Unprotected Domain **Important**
Devices	Pulse Oximetry Meter Blood Pressure Meter EGG Meter Heart Rate Meter	High	Secure Device

11.8.2 Further discussion

11.8.2.1 Smartphone Apps

This Use Case relies on a single vulnerable component: an Android Smartphone. Care can and should be taken to ensure the reliability and security of this component, by following the requirements of 11.5.3.1.

11.9 Krakow Use Case

The main security concern of this Use Case is the use of a relatively Low security Smartphone for assisting in the data generation and transportation. This liability can be appropriately managed with a FI-STAR component adhering to the advice on 11.5.3.1.

11.9.1 Components and their relative security

The following table describes the characteristics that will determine the security level of each component, in relation to the context of the Use Case.

Domain	(sub)component	Relative security	Protected by & Remarks
JP2 Hospital	InfoMedica System	Very High	Local Rules **Baseline**
HSD	All other subcomponents and internal interfaces	Very High	Local rules
Devices	Pulseoximeter Blood pressure monitor Video Camers (other sensors)	High	Secure Device Note: other sensors presumed the same

Devices	Patient's router *	Very High	Mathematically Secure **Important**
Smartphone App	TeleCare Patient App GEs	Medium	Unprotected Domain **Important**
Public Cloud	Google Play	Low	Third-Party domain **Important**

* This device should be protected by the requirements for Internet communication, see 11.3.2.

11.9.2 Further discussion

11.9.2.1 Smartphone Apps

This Use Case relies on a single vulnerable component: an Android Smartphone. Care can and should be taken to ensure the reliability and security of this component, by following the requirements of 11.5.3.1.

11.9.2.2 Separation of data from context

This Use Case has expressed an interest in separating medical data from identification vectors like the Patient's Name etc. Although a very interesting concept, further work needs to be done to determine the feasibility of it as well as requirements before it may work securely.

11.10 Leeds Use Case, Munich Use Case

11.10.1 Leeds Use Case

Review of this use case is scheduled for later.

11.10.2 Munich Use Case

This use case demonstrates the least security problems. The Use Case is enclosed in a secure hospital domain, which would be rated Very High in terms of security provision, as it is protected by local rules. In these cases, any security focus should be into ensuring compliance with these rules, yet again this is outwith the objective of this project. For this reason, there are not further comments on the security of this Use Case.

11.11 Tromsö Use Case

This use case is the most exposed in terms of data integrity due to the fact that third-party and cloud-based services are used to generate and/or store data. On the other hand, the context of the Use Case prevents potentially insecure data from affecting patient safety.

11.11.1 Components and their relative security

The following table describes the characteristics that will determine the security level of each component, in relation to the context of the Use Case.

Domain	**(sub)component**	**Relative security**	**Protected by & Remarks**
Hospital Secure Domain (HSD)	DIPS	Very High	Local Rules **Baseline**
HSD	All other subcomponents	Very High	Local rules

	and internal interfaces		
DMZ Insecure Domain	All subcomponents	High	FI-STAR component(s)
Public Cloud	Physical Activity Cloud: FitBit Physical Activity Cloud: RunKeeper Google Play Node iTunes App Store	Low	Third-party domain(s) **Important**
Smartphone FI-STAR Apps	DeSA App Sensor Integration	Medium	Unprotected domain **Important**
Smartphone Other Apps	FitBit Physical Activity App RunKeeper Physical Activity App VC Client App	Low	Third-party domain **Important**
Patient devices	Blood Glucose Meter Activ ID Entity Authentication Device	High	Secure device
ID Porten	All subcomponents	High	Secure domain
Norwegian Health Network	VC Server	High	Secure domain

11.11.2 Further discussion

11.11.2.1 Public cloud

This Use Case uses FitBit and RunKeeper and their respective public clouds as data sources. These clouds are not within the control of FI-STAR and therefore the security of data (Observations) originating from these clouds shall be deemed relatively Low.

However, the Use Case has planned to flag the quality of this data and any results where this data has contributed in producing in a way appropriate to illustrate the Low security and therefore quality.

11.11.2.2 Smartphones – DeSA App & Sensor Integration

The security of data (Observations) originating from this component is very important for this Use Case yet the components reside in a domain that is not controlled by FI-STAR (the Patient's Smartphone). Smartphone vulnerabilities are a potential risk, yet it is unlikely that an adversary would target smartphones in order to acquire medical observations. In addition, the advice on 11.5.3.1 should be followed.

11.11.2.3 Smartphones – Other Apps

These components are assessed as Low security and they adhere to the same limitations as the ones residing in the public cloud. However, the use case may wish to consider investigating ways of protecting data generated by these components, for example:

- Cross examination against data from more secure components like the DeSA App
- Cross-examination by humans and especially the doctors seeing the patients

11.12 Evaluation

This section underlines the security requirements of the FI-STAR project, based on the described assessment of each Use Case. Further work is required to ensure these requirements are met and therefore that each Use Case is in compliance with this document. The following should take place on each phase of the project. Further advice or clarifications can be obtained upon request and at any of the phases.

11.12.1 Design phase

In the design phase the Use Case teams shall agree to the requirements underlined here and/or object and undertake a review. Once the requirements and any objections are discussed, then an updated requirements document shall be produced, which will be used in the implementation and testing phase. This document should include a detailed analysis of each component and it's security features.

Crucial points to agree upon are:

1. Domains indeed offer the level of security described in this section
2. Security Levels are representative of what was expected so far
3. That all mandatory requirements are feasible and meaningful
4. Which of the optional requirements will be implemented

11.12.2 Implementation phase

During implementation, the Use Case teams need to ensure that the requirements are met and seek advice when unforeseen problems occur. This is especially true if problems arise that would prevent the use case from implementing mandatory requirements.

It is advised that the security features of each component and interface are tested independently for correct operation during the implementation in a unit-testing manner.

11.12.3 Testing phase

The Use Case teams should produce a report where they can show that all security features of components have been met. A party external to the team should audit the implementation (code, components, use of Generic Enablers) to validate and confirm that the requirements have been met correctly and that security is working as expected.

Use Cases that work with live private information may consider a full security review, by giving man-in-the-middle level of access to a party external to the team, who will attempt to "break" the system while it is being tested with real data.

11.13 Conclusion

This section described how each of the FI-STAR Use Cases can be assessed from a security point of view and thereafter what security requirements shall apply for each component of the systems. The mandatory and optional requirements were selected to reflect the pragmatic constrains of the real world, the project and usability.

If this section is understood and followed correctly by the FI-STAR consortium, and if the human users of the Use Cases are given an understanding of the involved risks, the project is set to prove that blended security solutions can be applied in the most sensitive information and lead to a string of important benefits that greatly overwhelm the mitigated security risks.

12 Preview on Legislation and Privacy Requirements

This section maps existing legal requirements and provides a preliminary high-level overview of existing legislation in Europe that need to be taken into account in the design and development of the FI-STAR platform and the FI-STAR use cases.The specific legal requirements for the use cases will be included in D1.3 'Preliminary general requirements report' and D1.4 'General Requirements Report'.

Although there have been continuous efforts towards European harmonization, typically, legal requirements regarding health care products and services differ from country to country. The specific national requirements pertaining to individual use cases are wide-ranging and require in-depth knowledge of each specific legal system; they cannot be mapped in the context of this deliverable.[8] In this report, we will focus on a high-level analysis of legal requirements agreed among European memberstates as integral part of the European legal framework overseen and administered by the European Union ("EU"). Although details may vary in national jurisdictions, these EU regulations contain the main elements of legal requirements, and the overview of the domains discussed in this report can be used as a guideline for a more detailed national analysis for each use case.

In the frame of the FI-STAR project, the following areas will be examined and analysed in order to elicit legal requirements:

- requirements of data protection
- data security requirements
- patient rights
- product safety requirements, in particularly hardware and software qualified as medical devices
- requirements associated with liability
- EU internal market requirements.

While this deliverable provides a high-level overview of European law, developers of modular medical architectures also need to consider whether non-European law applies, in case the architectures are intended to be used or exported outside of the EU, not necessarily within the context of the FI-STAR project but possibly at the commercialization stage. The legal picture then becomes much more complex and fragmented, as many different legal regimes will apply.[9] However, global regulation is beyond the scope of this deliverable. The authors want to point out that e-health law and policy risks becoming entrenched in local, national visions which affects the development and spread of e-health applications in the global community, including developing countries. Development of modular medical architectures should therefore also be embraced as an opportunity by regulators to join forces and come up with supranational solutions to the regulatory challenges of e-health systems.[10]

12.1 EU data protection framework and requirements

A common element in use-case trials for modular medical architectures is that they collect and process personal data of individuals, who in some cases are also patients. It is imperative that

[8] FI-STAR partners should be aware that the national requirements for their specific context must be taken into account and complied with. For mapping and assessing national legal requirements, the partners should seek specific advice from their internal legal teams and local legal and ethical boards.

[9] see J.D. Blum, "The role of law in global e-health: a tool for development and equity in a digitally divided world", St. Louis U.L.J., vol. 46, pp. 85-110, 2002 for discussion.

[10] M. Mars and R.E. Scott, "Global E-Health Policy: A Work in Progress", Health Affairs, vol. 29, pp. 239-245, 2010.

these use-case trials obey the European rules on the protection of personal data, with special attention for the special requirements that relate to health and medical data.[11]

The Data Protection Directive[12] lays down rules for the processing of personal data and recognizes specific rights of individuals on their personal data, while ensuring that such data can move freely within the internal EU market. When data can be linked directly or indirectly to an individual (the so-called data subject) they qualify as personal data. Only data, which are truly anonymous are excluded from the rules.[13] In January 2012, the European Commission presented its proposals for the reform of the data protection legal framework of the European Union, proposing the replacement of the Data Protection Directive with a Regulation, which was the outcome of consultation and debates of three intense years.[14]

12.1.1 General principles of data protection

The Directive contains general principles for processing personal data.[15] These principles include

- fairness
- data quality (data should be correct and up-to-date)
- purpose specification and usage limitation (data may only be processed for previously specified purposes)
- processing based on a legitimate ground (processing must be based on user consent, a contract, a legal obligation, or vital interest of the data subject)

Informed consent will almost always be the legal basis for processing personal data in use-case trials and practices, but special attention must be paid to the processing of health and medical data: the processing of health and medical data, in fact, is in principle prohibited, unless special grounds apply (see Article 8 Data Protection Directive).[16]

Of special importance for medical architectures is the principle that the design of data-processing systems should aim at processing either no personal data at all or as few as possible (data avoidance/data minimisation).[17] The Data Protection Directive also addresses the issue of data security, imposing a statutory obligation on data controllers to ensure that personal data are processed in a secure environment.

In the following sub-sections, we will briefly discuss these requirements, paying particular attention to those requirements that should be taken into account up-front at the start of each use case. A more detailed description will be provided in the General Requirements Report.

[11] J. Dumortier and C. Goemans, “Privacy protection and identity management”, in Security and Privacy in Advanced Networking Technologies, B. Blažič and W. Schneider, Eds. IOS Press, 2004, p. 193

[12] Directive 1995/46/EC , Official Journal 1995, L281/31.

[13] C. Kuner, European Data Protection Law – Corporate Compliance and Regulation, Oxford: Oxford University Press, 2008, p. 51.

[14] European Commission, Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) COM(2012) 11 final – 2012/0011 (COD), 25.01.2012, commonly known as ‘draft Data Protection Regulation’.

[15] I. Walden, “Data Protection”, in Computer Law, C. Reed and J. Angel, Eds., 5th edition. Oxford: Oxford University Press, 2003, p. 432.

[16] Luca Compagna, Paul El Khoury, Alžbeta Krausová, Fabio Massacci, Nicola Zannone, “How to integrate legal requirements into a requirements engineering methodology for the development of security and privacy patterns”, Artif. Intell. Law, vol. 17, pp. 1–30, 2009.

[17] B. Holznagel and M. Sonntag, “A Case Study: The JANUS Project”, in Digital Anonymity and the Law – Tensions and Dimensions, C. Nicoll et al, Eds. The Hague: TMC Asser Press, 2003.

12.1.1.1 The controller as bearer of compliance obligations and liability for data protection violations

Data protection law distinguishes between two principal actors (besides data subjects): the data controller and the data processor. This distinction is of great importance as the data controller (and not the data processor) is the party who carries the obligations described in the Data Protection Directive and hence the party responsible for defining the details of the data processing.

A **data controller** is a person or entity who determines the purposes and means of the processing of personal data (Article 2(d)). The Directive lists three other kinds of actors who can potentially be involved: a data processor (Article 2(e)), third parties (Article 2(g)), and a recipient of data (Article 2(f)). A data processor is a person or entity who, on behalf of the controller, executes data processing.

Use-case trials raise significant challenges in identifying who are the responsible entities, in order to assign accountability obligations, since usually many actors are involved. Especially when several devices or Generic or Usage Specific Enablers are combined in a use-case and personal data are transferred in a way that the data leave the control of one party to become the responsibility of another the identification of the responsible parties becomes difficult.[18]

The Article 29 Working Party[19] has adopted an opinion on the concepts of controller and processor where it clarified the two concepts and their relationship.[20] The opinion addressed issues such as the unravelling of the definition of controller and processor, and acknowledged the possibility of existence of multiple (co-) controllers and their joint and individual liability.

The distinction between the controller and the processor should be applied *pragmatically*. That is, when deciding which actor determines goals and means of processing, one should not only look at formal contractual and statutory (criminal, civil, and administrative law) arrangements determining the actors' powers and responsibilities to determine the purposes of data processing, but rather allocate responsibility where the factual influence lies. This pragmatic approach has two important implications: first, an actor without lawful competence to process data, e.g. an employee or (formally) a processor acting **outside** an assignment of a (formal) controller should be regarded as a controller himself and be held responsible in the scope of data protection. Second, there may be multiple co-controllers with regard to one data processing operation. Simultaneously, this pragmatic approach does not mean that the processor cannot have any discretion in determining the (organisational and technical) aspects of data processing. The criterion to determine whether a particular actor qualifies as a processor or a controller is whether he processed data without the formal controller's assignment. In case the answer is no, the actor qualifies as a processor. The evaluation of the distribution of roles between the involved actors should be conducted on a case-by-case basis.[21]

Relationships between a controller and a processor are governed by a contract (Article 17(3)). By means of this contract, the controller must ensure that the processor implements adequate security measures to prevent data security breaches. This contract is only binding on its parties, and, therefore, gives no rights to the data subject.[22] In the case of a data protection violation, the

[18] H. Löhr, A.-R. Sadeghi, and M. Winandy, "Securing the e-health cloud," in Proceedings of the 1st ACM International Health Informatics Symposium, ser. IHI '10, 2010, p. 223.

[19] Under Article 29 of the Data Protection Directive, a Working Party on the Protection of Individuals with regard to the Processing of Personal Data is established, made up of the Data Protection Commissioners from the Member States together with a representative of the European Commission. The Working Party is independent and acts in an advisory capacity. The Working Party seeks to harmonize the application of data protection rules throughout the EU, and publishes authoritative (but not formally binding) opinions and recommendations on various data protection topics.

[20] Article 29 Working Party, Opinion 1/2010 on the concepts of controller and processor (WP 169)

[21] WP 169, section III.1.a), b) of the Opinion.

[22] It is of course possible that the parties to a contract include a third party beneficiary clause into their agreement which will give data subjects data protection rights also against the data processor. However, inclusion of such a provision into

controller is liable to the data subject for any damages suffered as a result, unless the controller proves that he is not responsible for the events giving rise to the violation (Article 23).[23] One of the few exceptions is the confidentiality of the processing requirement of Article 16 of the Directive, which provides that '*any person* acting under the authority of the controller or of the processor,' including the processor himself who has access to personal data, must not process them except on instructions from the controller, unless he is required to do so by law.

12.1.1.2 Legitimate ground

Article 7 of the Data Protection Directive requires that the processing of personal data is legitimated on a specific legal ground, which must be one (or more) of the following:

a) unambiguous consent by the data subject;
b) performance of a contract;
c) compliance with a legal obligation;
d) necessity to protect vital interests of the data subject;
e) necessity for a public-interest task of the controller;
f) a preponderant legitimate interest of the controller that outweighs the data subject's interest.[24]

It is important that data controllers carefully consider which legal grounds is best suited for the purposes of their data processing. For FI-STAR use cases, however, it should be noted that for sensitive personal data, which include health data, stricter requirements apply as to the legal ground, under Article 8 of the Directive (see section 1.1.2 below).

12.1.1.3 Purpose specification and use limitation principles

Article 6(1)(b) of the Directive requires that 'personal data shall be collected for specified, lawful and/or legitimate purposes and not subsequently processed in ways that are incompatible with those purposes'. This combination of purpose specification and use limitation is commonly referred to as the 'purpose limitation' principle. The purpose limitation should be understood as a limit on how the data controllers can use personal data.[25] Under Article 6(1)(b) of the Directive, personal data must be collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. The underlying idea is not to let one-time legitimization of a

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a data processing contract remains dependant on the discretion and negotiating powers of the parties. At the moment, use of such provisions is encouraged in the cross-border data transfers, e.g. in the Standard Contractual Clauses for Data Transfers to third countries (most recent Commission Decision of 5 February 2010 on standard contractual clauses for the transfer of personal data to processors established in third countries under Directive 95/46/EC of the European Parliament and of the Council (notified under document C(2010) 593)).

[23] Note that some national data protection laws make an exception and provide for the processor's liability, jointly or severally with the controller (e.g. Dutch Data Protection Act).

[24] Under Article 7 of the Directive, data processing is lawful when one of the following requirements are met: 'Member States shall provide that personal data may be processed only if:

(a) the data subject has unambiguously given his consent; or

(b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract; or

(c) processing is necessary for compliance with a legal obligation to which the controller is subject; or

(d) processing is necessary in order to protect the vital interests of the data subject; or

(e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data are disclosed; or

(f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject which require protection under Article 1 (1).'

[25] WP 203, p. 11

single instance of data processing under Article 7, which stipulates the legitimates grounds for data processing, to provide a blank check for further unlimited uses of these data. Such further uses can be for instance data sharing and open data initiatives regarding public sector data,[26] keeping collected data longer than authorised in case some need for it presents itself later, etc.

The purpose limitation principle has two elements: purpose specification and limitation of further processing to uses that are compatible with the originally specified purpose.[27] Pursuant to the principle of *purpose specification*, the personal data should be only collected for 'specified, explicit and legitimate purposes.' These purposes are 'raison d'être of the processing operations.'[28] If personal data is processed further, the new purpose must be specified.[29] It is important for each use case that the purpose(s) of processing personal data are formulated as specifically as possible; the purpose specification need not be very detailed, but it should avoid too abstract or vague notions such as 'supporting the provision of healthcare to patients', and instead aim to use concrete formulations. For example the purpose for the processing of personal data for the Operation Room Monitor use case that will be carried out in Munich can be the correct assignment of patient to measurement data.

The compatibility principle prohibits further processing 'incompatible' with the original purposes of collection. Member States assess the compatibility of further use differently: some approach compatibility strictly, involving formal comparison of the initially given (often in writing) purpose of collection with the purposes of use. Others allow a degree of flexibility and apply a more accommodating approach. It involves a comparison of the two purposes; the context in which the data have been collected and the reasonable expectations of the data subject as to the further use; the nature of the data and the impact the further processing would have on the data subject; as well as the measures taken by the controller to ensure fair processing and protection of the individual from any undue impact.[30] Thus, although the assessment has to take place on a case-by-case basis, in principle the initial purpose of processing can change, as long as the purpose of collection explicitly or implicitly includes the new purpose,[31] or even when the purpose changes significantly, but appropriate safeguards are provided.[32]

12.1.1.4 Principle of data subject's control: data subject's rights

A key element of the data protection framework is to allow data subjects to influence the way in which data about them are processed. Recital 38 of the Directive explains that data processing is only fair (which is a requirement under article 6(1)) when the data subject is 'in a position to learn' about the data processing operation and is given full and accurate information about the facts and circumstances of the collection of his personal data. The principle of user control is visible in the consent of the data subject being an important legitimating ground for data processing, but also in a number of equally important conditions that foster individual participation and control in the form of information rights throughout the data processing process.

Under the principle of individual control and pursuant to Articles 12 and 14 of the Data Protection Directive, the controllers – use case deployers, app developers and other data controllers in charge of eHealth systems - must enable data subjects – patients, employees, etc. – to

[26] for the purpose specification assessment of the EU open data initiatives see Article 29 Working Party. 2013. Opinion 06/2013 on open data and public sector information ('PSI') reuse, adopted on 5 June 2013, 1021/00/EN WP 207

[27] WP 203, p. 11

[28] WP 203, pp. 11-12

[29] WP 203, p. 12

[30] WP 203, pp. 25-26

[31] WP 203, pp. 22-23

[32] Such as freely given and informed consent for using privately taken photos on a commercial website for promotional purposes, see Example 7, WP 203, p. 60.

- exercise rights of access
- rectification
- erasure
- and the right to object to data processing or block personal data that is incomplete, inaccurate or processed unlawfully.

Information rights are key to the exercise of control. Article 29 Working Party in its "on apps on smart devices"[33] recommends that, in smart environments "apps must clearly and visibly inform their users about the existence of these access and correction mechanisms" which should be "simple but secure online access tools", available preferably "within each app, or by offering a link to an online feature."[34] The Article 29 Working Party emphasizes that these tools are especially important if case sensitive data is processed (e.g. health data) and have to be accompanied by verification mechanisms that, however, should not lead to an additional, excessive collection of personal data.[35]

In case an automated decision is taken on the basis of the compiled data (e.g. concerning patient's condition fit or not fit for further treatment), the data subject – patient or user, etc. – needs to be informed about the logic behind those decisions.[36]

When data processing is based on consent – which is most likely to be the case on the experimentation stage of FI-STAR – the users should be provided with the possibility to withdraw their consent in a simple and not burdensome manner. A data subject may withdraw consent for data processing in a number of different ways and for a number of different reasons. Preferably the option of consent withdrawal should be available through the above mentioned easily accessible tools. It implies, among others, that it must be possible to un-install apps and thereby remove all personal data, also from the servers of the data controller(s).

12.1.1.5 Relevant other requirements

Apart from this other requirements in the Data Protection Directive also need to be taken into account in the development of FI-STAR applications:

- **notification** (article 18). The data controller must notify the Data Protection Authority of the processing operation and of the purpose(s) that this process serves. Some exemptions or simplified notification procedures may apply in national implementations of the Directive;
- **lawful** processing (article 6(1)). Data processing is lawful when it is in compliance with the requirements imposed on it by law, including but not limited to all requirements set by data-protection law;
- **fair** processing (article 6(1)). This includes the principle of proportionality: while processing data, the controller is expected to balance his interests and those of the data subject in order to avoid unnecessary, unreasonable, or excessive intrusions on data subjects' interests;[37]
- data **quality** (article 6(1)). Personal data should be valid, relevant and complete with respect to the purposes of processing.[38] Data must be 'accurate and, where necessary, kept up to date',[39] data obtained must be 'adequate, relevant and not excessive in relation

[33] Opinion 02/2013 on apps on smart devices adopted on 27 February 2013, WP 202

[34] WP 202, p. 25

[35] Ibid.

[36] WP 202, p. 25

[37] See, e.g. Lee A. Bygrave & Dag Wiese Schartum, 'Consent, Proportionality and Collective Power', in Reinventing Data Protection?, ed. Serge Gutwirth, Paul de Hert & Yves Poullet (Brussels: Springer, 2009), p. 163.

[38] Bygrave, Data Protection Law: Approaching Its Rationale, Logic and Limits, p. 62.

[39] Ibid.

to the purposes for which they are collected and/or further processed' (Article 6(1)(c)). '[E]very reasonable step must be taken' to ensure the quality of data (Article 6(1)(d));

- **deletion** of data after use (article 6(1)). Data can be processed only as long as it is necessary for the purposes for which the data were collected or for which they are further processed. As soon as the purpose has been fulfilled, the data should be deleted or (irreversibly) anonymised;
- **transfers to third countries** (articles 25 and 26). When health or other personal data is transferred outside of the European Economic Area (EEA),[40] a special regime applies. The recipient country must have an adequate level of data protection, or else the data controller must ensure adequate safeguards, which can be provided "appropriate contractual clauses" or so-called "Binding Corporate Rules" ('BCRs'). Certain derogations may apply according to article 26(1). As the FI-STAR project does not foresee a possibility that collected health data are transferred outside of the EEA, we do not discuss these requirements further.

12.1.1.6 Requirements specific to processing of health data

Processing of health data - classified as a special ('sensitive') category of data - is in principle forbidden, and is only allowed under a number of exceptions named in Article 8 of the Data Protection Directive. These exceptions must be interpreted narrowly.[41] The main relevant exceptions are explicit consent of the data subject (Article 8(2)) and processing in the context of a treatment relationship (Article 8(3)). Member states can also provide additional exemptions in national law for reasons of substantial public interest (article 8(4)).[42] The first two are of direct relevance for eHealth solutions and will be examined below.

Further detailed analysis of each use case is needed to determine under which heading – consent or context of a treatment relationship – health data is to be processed.

12.1.1.7 Explicit consent (Article 8(2)(a))

The Data Protection Directive allows for processing of health data where the data subject gives his 'explicit consent'.[43] Generally, consent is valid only when it is "freely given, specific and informed indication of the data subject's wishes.[44] Explicit consent is a qualified form of consent.

Freely given

The Article 29 Working Party explains that consent is 'free' when it comes as a result of a "voluntary decision, by an individual in possession of all of his faculties, taken in the absence of coercion of any kind, be it social, financial, psychological or other. Any consent given under the threat of non-treatment or lower quality treatment in a medical situation cannot be considered as 'free'."[45] Of special importance is the view of the Working Party that – in a medical context – where data is processed as a "necessary and unavoidable consequence of the medical situation", it is

[40] EEA includes all EU member states (except Croatia, whose accession to the EEA is not yet finalised as of 1 September 2013) and Norway, Liechtenstein and Iceland.

[41] Article 29 Working Party. 2012. Working Document 01/2012 on epSOS, adopted on 25 January 2012 (WP 189), p. 6

[42] Article 29 Working Party. 2007. Working Document on the processing of personal data relating to health in electronic health records (EHR), adopted on 2007 (WP 131)

[43] Note that Article 8(2)(a) of the Directive allows the laws of the Member State to implement this provision in a way that the prohibition to process health data may not be lifted by the data subject's giving his consent. Additional advice based on national implementation of the Directive is required.

[44] Article 2(h) Data Protection Directive.

[45] WP 131, p. 8

misleading to legitimise this processing through consent. **Consent to undergo a certain medical treatment does not equate "consent" necessary for processing health data.**[46]

Free consent also means that the data subject can withdraw the consent without detriment.[47]

Specific

Consent is 'specific' when it relates to a well-defined, particular situation. Consequently, a 'general agreement' to the processing of medical data, including future possible transfers to health professionals involved in treatment does not constitute consent in the terms of Article 2 (h) of the Directive.[48]

Informed consent

The data subject should give consent based on an understanding of the processing event(s) and their possible implications, as well as of the consequences of refusing consent. Information rights of the data subject play a key role in ensuring informed consent.[49]

Explicit

This is an additional criterion to the general requirements of consent under Article 7 of the Data Protection Directive, specific of sensitive data. Consent under Article 8(2) must be explicit (it therefore excludes 'opt-out solutions'). Consent in particular must explicitly relate to the sensitive nature of health data and demonstrate that the data subject is aware that he / she renounces the special protection (ban on processing) of health data.[50]

The requirement of explicit consent must be respected regardless the practical difficulties connected to obtaining it. In any case, the controller must be able to demonstrate that the consent is valid.[51]

In order to receive a full impression of the requirement of explicit consent one has to refer to the national legislation of the Member States. Article 8 (2)(a) allows the Member States to implement the Directive in a way that not even express consent can lift the general prohibition to process health data. Moreover, the form in which such explicit consent must be given varies from Member State to Member State. In some states such consent must be written whilst in others there is no such a requirement.[52]

Form

Although Article 29 Working Party advises that written form of the explicit consent is not required, some Member States do include it in their national laws.[53] The discrepancies in the national laws and resulting difficulties of implementation of the European-wide eHealth solutions may be

[46] WP 131, p. 8

[47] Article 29 Working Party. 2001. Opinion 8/2001 on the processing of personal data in the employment context" (WP 84), section 10.

[48] WP 131, p. 9

[49] WP 131, p. 9

[50] WP 131, p. 9

[51] WP 131, p. 9

[52] Paul Quinn, Ann-Katrin Habbig, Eugenio Mantovani and Paul De Hert. 2013. "The Data Protection and Medical Device Frameworks - Obstacles to the Deployment of mHealth across Europe?" in European Journal of Health Law 20 (2013) 185-204 (P. Quinn et al), p. 200

[53] P. Quinn et al. 200

resolved by reference to the eSignatures Directive,[54] which requires Member States to recognize the legally binding nature of electronic signatures.[55]

12.1.1.8 Context of treatment relationship (Article 8(3))

Article 8(3) of the Data Protection Directive allows for an exception from the general prohibition to process health data if *'processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.'*

Medical professionals often use this provision to process individual medical data once a treatment relationship has been established with that individual.[56]

For this exception to be applicable, three elements are necessary:

- **Purpose**. Processing of health data under Article 8(3) is only permitted for the specific purpose of providing health-related services of a preventive, diagnostic, therapeutic or after-care nature and for the purpose of the management of these healthcare services, such as invoicing, accounting or statistics.[57] Outside of the scope of Article 8(3) are instances of further processing not required for the direct provision of such services: medical research, the reimbursement of costs by health insurance, the pursuit of pecuniary claims, and some other processing operations in the areas of public health and social protection (e.g. ensuring quality and cost-effectiveness of the schemes for settling claims for benefits and health care services). These are covered by Article 8 (4) (public interest). If health data is to be used for other purposes, explicit consent must be obtained.
- **Necessity.** The processing of health data under Article 8(3) must be "required" for the purposes mentioned. This means that the use of health data for the stated purposes must be fully justified. In the context of electronic health records, Article 29 Working Party explains that the mere "usefulness" of processing such personal data would not be sufficient.[58]
- **Professional secrecy**. Processing of health data under Article 8 (3) may only be performed by medical or other staff subject to professional (medical) secrecy or an equivalent obligation to secrecy.

Article 29 Working Party emphasizes that the use of health information collected in the course of a treatment relationship under Article 8(3) is only allowed within the limits of the treatment contract, "the direct bilateral relationship between a patient and the health care professional/health care institution consulted by the patient."[59] This health data cannot be passed on to any third parties, including other health care professionals, unless the patient has given his explicit consent or such an exception is foreseen by law.[60]

Obligation of professional secrecy

[54] Directive 1999/ 93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures OJ L 13, 19.1.2000, p. 12–20

[55] Eugenio Mantovani and Paul Quinn. 2013. "mHealth and data protection – the letter and the spirit of consent legal requirements" in International Review of Law, Computers & Technology, published online on 1 July 2013, p. 10

[56] P. Quinn et al. 198

[57] WP 131, p. 10

[58] WP 131, p. 10

[59] WP 131, p. 11

[60] WP 131, p. 11

The medical professionals and other staff processing health data under Article 8(3) have to be under the special obligation of professional secrecy. Such an obligation must be either established in the national law of the Member States, or by national competent professional bodies with the power to adopt binding rules on the profession, containing effective sanctions. Non-medical staff involved in health data processing must be made subject to equivalent binding rules of confidentiality.[61]

In addition, the Article 29 Working Party points out that the electronic health records may render the obligation of medical confidentiality in its current state "no longer be fully applicable."[62] The same concern may apply to the eHealth solutions, as one of the purposes of electronic health records and eHealth in general is to open access to medical data for treatment to the professionals who have not been involved to the previous treatment relationship, e.g. medical professionals in another country or another institution.

Narrow interpretation of the exception

As Article 8 (3) of the Directive is an exemption from the general prohibition to process sensitive data, this exemption must be interpreted in a restrictive way.[63]

In the context of the electronic patient records, Article 29 Working Party points out that even if all the requirements are met, such electronic health record systems "create a new risk scenario, which calls for new, additional safeguards as counterbalance."[64] The same is true in case of the modular eHealth solutions, such as the ones developed by FI-STAR. *First*, such systems involve additional actors in the healthcare relationships (App developers, App stores, OS- and device manufacturers). Thereby they shift the traditional boundaries of the individual patient's direct relationship with a healthcare professional or institution. *Second*, eHealth solutions introduce new ways of collecting and using medical data of patients, introducing new data vulnerabilities related to risks of destruction, unauthorized access or data use for purposes other than treatment.

12.1.2 Data security

12.1.2.1 Data security obligations

The principle of data security expresses itself in the obligations of the data controller to take both organizational and technical measures[65] in order to ensure the adequate protection of personal data from any kind of unauthorised processing, including its destruction, alteration, disclosure and loss, both at the stage of designing data processing processes and during the processing itself (e.g. Recital 46 of the Data Protection Directive).

The Directive establishes an *objective standard of quality* of security measures. The measures must be in proportion to the risks involved in the data processing and 'the state of art and the cost of their implementation' (Article 17(1)). In the context of FI-STAR it means that especially close attention should be paid to the security measures, as the project deals with a special category of personal data, i.e. health data, which entail higher risks for the data subject in case of a security breach.

A controller also has an obligation to ensure – by way of a contract or other legal act (Article 17(3)) – that not only the controller but also data processors acting on his behalf provide such 'sufficient

[61] WP 131, p. 11

[62] WP 131, p. 11

[63] WP 131, p. 11

[64] WP 131, p. 11

[65] As explained by Article 29 Working Party in Opinion 02/2013 on apps on smart devices adopted on 27 February 2013 ('WP 202')

guarantees in respect of the technical security measures and organisational security measures governing the processing to be carried out' (Article 17(4)).

In the context of FI-STAR it is of special importance that Recital 46, which deals with the interpretation of Article 17 security obligations, is read as requiring that security measures cannot simply be added, but should already be incorporated when designing the processing system and the processing itself, a principle known as *privacy-by-design*.[66]

Importantly for the FI-STAR context, in case of multi-layered structures, such as mobile (health) Apps, security measures have to be taken by all actors involved: App developers, App store, operation system- and device manufacturers and third parties when they collect ad processed personal data for their purposes.[67]

The Article 29 Working Party advises that compliance with the security obligations requires 'an ongoing assessment of both existing and future data protection risks.'[68] In addition, effective mitigating measures have to be employed including data minimisation.[69]

12.1.2.2 Security requirements related to mandatory data security breach notifications

Currently, there is no general obligation to inform users in case a data security breach has occurred. Only the so-called ePrivacy Directive[70] imposes, in article 4, an obligation on providers of publicly available electronic communications services to proactively inform users. Whether eHealth or mHealth providers fall within the scope of this Directive is context-dependent and cannot be discussed here; this issue will be elaborated further in the General Requirements Report.

However, mandatory data security breach notification is likely to be introduced more widely in the near future. Some European countries, including Austria, Germany and Norway, have already introduced general mandatory data breach notification in their national law,[71] and other countries are discussing such regulations. Moreover, the Article 29 Working Party suggests that all the participants of the mobile health solutions market should be "mindful of the requirements set forth in the ePrivacy directive [as] it is expected that the obligation will be extended to all data controllers (and data processors) by way of the future Data Protection Regulation as per the Commission's proposals (COM 2012/0011/COD)."[72] In a similar vein, ENISA has published recommendations on technical implementation guidelines of Article 4 of the ePrivacy Directive,[73] which it intends to be of wider relevance for all data breach contexts in view of the upcoming General Data Protection Regulation.[74] Therefore, although the General Data Protection Regulation is still under consideration, it is recommended that data controllers anticipate the forthcoming changes and create both adequate security policies for preventing security breaches from happening, which is of

[66] Robinson, et al., 'Review of the European Data Protection Directive: Technical Report Prepared for the Information Commissioner's Office', p. 9.

[67] WP 202, p. 18

[68] WP 202, p. 18

[69] Ibid.

[70] Directive 2002/58 of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31/07/2002 P. 0037 - 0047) ('ePrivacy directive').

[71] Patrick Kierkegaard. 2011. 'Electronic health record: Wiring Europe's healthcare', in Computer Law and Security Review, 27. p. 512

[72] WP 202, p. 20

[73] Available online at http://www.enisa.europa.eu/activities/identity-and-trust/risks-and-data-breaches/dbn

[74] Ibid.

special importance to avoid liability in the form of heavy pecuniary penalties,[75] and appropriate notification procedures in case security breaches do occur.

12.1.2.3 Security measures for mobile solutions

Many public and private parties (operation system- and device manufacturers) have published guidelines regarding security in general and security of mobile apps in particular.[76] We focus here on mobile security requirements from the data protection field. The Article 29 Working Party has made recommendations for security measures relevant for multilayered platforms, such as the ones developed by the FI-STAR project, in its Opinion 02/2013 on apps on smart devices adopted on 27 February 2013.[77]

12.1.2.3.1 App developers

The Article 29 Working Party recommends the following security measures for App developers:

- Various data storage models have to be assessed on the matter of their security advantages and disadvantages. Storing and processing data *on the device* has an advantage of the greatest user control, e.g. allows deletion of data in case of withdrawal of consent. Storing data using *a client-server architecture* with the data transferred or copied to the service provider's systems has an advantage of easier data recovery resulting, e.g. from the loss or theft of a device. Combination of these methods is also possible.
- App developers should have clear policies on the creation and distribution of software where security issues are dealt with.
- A security-friendly environment should be implemented, including tools to prevent malicious apps from spreading, where each app can be easily installed and uninstalled.
- The lines and complexity of code should be minimized, checks have to be implemented to exclude unintentional data transfer or other data risks. All inputs should be validated to prevent buffer overflow or injection attacks.
- Adequate security patch management strategies have to be used, including regular, independent system security audits.
- App design should include the implementation of the 'least privilege by default' principle (where apps are enabled to access only the data they really need for functionality).
- It is recommended to encourage users (e.g. by warnings and reminders) to make use of virtuous user practices: updating their apps to the latest versions, avoiding use of the same passwords across different services.
- App developers, already on the stage of App development, must take measures to protect data in transit and during storage, in order to prevent unauthorised access.
- Mobile apps should run in specific locations within the memory of the devices (sandboxes - security mechanisms to separate running programs), in order to reduce the consequences of malware/malicious apps.
- In close collaboration with the OS manufacturer and/or app store, app developers must use available mechanisms that allow users to see what data are being processed by which apps, and to selectively enable and disable permissions. The use of hidden functionalities should not be allowed.
- Regarding methods of user identification, Article 29 Working Party advises not to use of persistent (device-specific) identifiers but, instead, low entropy app-specific or temporary device identifiers to avoid tracking users over time.

[75] WP 202, p. 20

[76] ENISA "Smartphone Secure Development Guideline": http://www.enisa.europa.eu/activities/Resilience-and-CIIP/critical-applications/smartphone-security-1/smartphone-secure-development-guidelines.

[77] WP 202

- Privacy-friendly authentication should be employed, especially, the management of user-ids and passwords. Passwords must be stored encrypted and securely, as a keyed cryptographic hash value. Article 29 Working Party suggests making a test (entropy check) available to users on the robustness of chosen passwords to encourage better passwords. It is generally recommended and specifically advised for access to sensitive data and access to paid-for resources, to use re-authentication, e.g. by means of multiple factors and different channels (e.g. access code sent by SMS) and/or the use of authentication data linked to the end user (rather than to the device); when selecting session identifiers, unpredictable strings should be used, also in combination with contextual information (date and time, IP address or geo-location data).
- After the delivery of a working version of an App to the market, app developers must develop fixes or patches for security flaws and provide them the users (via App stores and other actors or themselves).[78]

12.1.2.3.2 App stores

- App stores as an important intermediary between end users and app developers has to take appropriate security measures as well:
- include effective checks (including data protection checks) on apps before admitting them to the marketplace.
- provide information on the actually performed checks, e.g. types of data protection compliance checks they use. In order to accommodate a large number of apps that an App store receives daily, the process of checks may be facilitated by automatic analysis tools and implementing information exchange channels between security experts and software professionals, as well as procedures and policies to deal with already reported issues.
- Once admitted to the app store, apps should be subjected to a 'public reputation mechanism,' where they are rated by users on the basis of their functionalities and privacy and security mechanisms.
- A method to remotely uninstall malicious or insecure apps often employed by App stores should be based on information and user consent. Otherwise, it may depriving users of control of their data. Users should be able to report security problems and on the effectiveness of any remote removal procedure via feedback channels.[79]

12.1.2.3.3 OS and device manufacturers

Although FI-STAR does not involve Operation system- (OS) and device manufacturers, bringing health Apps on the market will require their participation. Therefore, this Deliverable considers (although briefly) the security measures to be taken on their part. Article 29 Working Party suggests:

- strong and well known encryption algorithms; support of appropriate key lengths.
- strong and secure authentication mechanisms to be made available for app developers (e.g. certificates signed by trusted certification authorities to verify the authorisation of a remote resource). In practice this is often poorly implemented.[80]
- management of access to and processing of personal data by apps through API built- in classes with proper checks and safeguards.
- methods of access to personal data should include granular consent requests. Access to personal data by means of low-level functions or other means that can undermine controls and safeguards incorporated into APIs should be limited or excluded.

[78] WP 202, pp. 18-20

[79] WP 202, pp. 20-21

[80] WP 202, p. 21

- clear audit trails into the devices allowing end users can insight into which apps have been accessing data on their devices.
- timely response to security vulnerabilities so that end users are not unnecessarily exposed to security flaws. End users should be given upfront information about the length of time they might expect regular security updates. The users should be informed as soon as possible if a security issue requires an update.[81]

12.1.2.3.4 Third parties

Third parties (such as advertisement companies and analytics providers) collecting and processing personal data for their own purposes should take same security measures, including secure transmission and encrypted storage of unique device and app user identifiers and other personal data.[82]

12.2 Patients' rights requirements

Health law is largely shaped at the national level. It is therefore useful to emphasise again that FI-STAR participants should seek local advice on the relevant provisions in their national legislation. However, EU law harmonizes some elements of patients' rights.

12.2.1 Clinical trials

First, the Directive 2001/20/EC regulates clinical trials, to protect human rights and the dignity of human beings with regard to biology and medicine.[83] It refers to the Helsinki Declaration, illustrating the link between ethical principles for medical research involving human subjects and good practices in clinical trials on medicinal products for human use as regulated by the Directive. In 2012, a proposal was presented to replace the Clinical Trials Directive with a Regulation.[84] Modular medical architectures that require clinical trials for testing will have to take into account the Directive and the proposed Regulation.

12.2.2 Patients' rights in cross-border healthcare

Second, where the FI-STAR project involves instances of cross-border healthcare, the EU requirements on cross-border healthcare apply, in particular, Directive 2011/24/EU.[85]

Cross-border healthcare means *healthcare*, i.e. health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices - provided or prescribed in a EU Member State other than the patient's Member State.[86] Therefore, the Patients' Rights Directive is particularly relevant for implementations of modular architectures that allow cross-border treatment, such as telemonitoring or telecare applications.

A service, e.g. a FI-STAR use case, is only considered a health service if it is provided by a *health professional*. A health professional is a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a

[81] WP 202, p. 21

[82] WP 202, p. 21

[83] 2001/20/EC (Clinical Trials Directive), Official Journal 2001, L121/34; F. Lemaire and an ESICM Task Force, "A European Directive for clinical research", Journal of Intensive Care Medicine, vol. 29, pp. 1818 ff, 2003.

[84] Proposal for a Regulation on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, COM(2012) 369 final, 17.7.2012.

[85] Directive 2011/24/EU (Patients' Rights Directive), Official Journal 2011, L88/45.

[86] Art. 3 Patients' Rights Directive

regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the member State of treatment.[87] Art. 3(h) defines a patient as a person who seeks to receive or receives healthcare.

The Directive stipulates that in cross-border healthcare, the laws apply of the (foreign) country of treatment,[88] while the (domestic) patient's country must reimburse costs according to its insurance system and, if necessary, provide follow-up care.[89] In telemedicine applications, the country of treatment is the country where the provider is established.[90]

The *Member State of Treatment*, i.e. the Member State where treatment is provided, has an obligation to ensure that the healthcare providers comply with the following obligations:

Concerning healthcare providers'[91] obligations, they have to provide:[92]

- the relevant information to help individual patients make informed choices on treatment options, their availability, their quality and safety;
- information on price;
- information on the registration status, insurance cover and other means of personnel or collective protection with regard to professional liability.

Concerning patients' rights Member States of Treatment must ensure that:[93]

- there are transparent complaints procedures and mechanisms available for patients that allow to seek remedies if any harm occurs as a result treatment;
- adequate professional liability insurance exists;
- an individual's fundamental right to privacy is respected, with the protection of personal data as discussed above.

Patients' Member State must ensure that:[94]

- Before or during cross-border healthcare, patients must have remote access to (or carry a copy of) their medical records, and afterwards, to ensure continuity of care, they are entitled to a written or electronic medical record of the treatment.
- National contact points must provide patients seeking cross-border healthcare with relevant information about providers, patient rights, complaint procedures, and legal remedies in the country of treatment.

The Directive contains detailed rules on the reimbursement of costs, authorization systems, and administration procedures.

Cross-border healthcare services also have to meet quality and safety standards laid down by the Member State of treatment, and Union legislation on safety standards (see further section 1.3).[95]

In line with recommendations to integrate law with governance,[96] the Directive also stimulates cooperation in healthcare through 'new governance' mechanisms, such as self-regulation and

[87] Art. 3 Patients' Rights Directive

[88] Art. 4(1) Patients' Rights Directive

[89] Art. 5 Patients' Rights Directive

[90] Art. 3(d) Patients' Rights Directive

[91] Art. 3(g) Patients' Rights Directive defines a healthcare provider as "any natural or legal person or any other entity legally providing healthcare on the territory of a Member State."

[92] Art. 4(2) Patients' Rights Directive

[93] Art. 4(2) Patients' Rights Directive

[94] Art. 5 Patients' Rights Directive

[95] Art. 4 Patients' Rights Directive

setting up various networks. An eHealth network is to draft guidelines on data to be included in patient summaries that can be shared between health professionals across borders. This network should also help develop common identification measures to foster cross-border data transfers.

12.2.3 Other specific legislation

Depending on the application, other specific legislation may apply. For example, one of the FI-STAR use-cases involves 2D bar-coding to offer real-time reverse supply chain modeling of pharmaceuticals. In this case, the European Commission guidelines on good distribution practice of medicinal products for human use must be taken into account. The guidelines aim at establishing adequate controls to ensure the quality and the integrity of medicinal products. The Guidelines have recently been revised and will enter into force in September 2013.[97]

12.3 Safety requirements and the regulation of medical devices

Directive 2001/95/EC[98] contains general safety requirements for all products – also in the context of providing a service – brought on the market for consumers or likely to be used by consumers. The Directive's requirements apply to products when specific legislation is insufficient or absent. Most hardware and software developed for FI-STAR will likely be subject to the specific EU rules on safety of medical devices; for products or services that do not qualify as medical devices, the general product safety requirements of Directive 2001/95/EC will apply:

Only safe products can be brought to the European market.[99] Safety of products is determined based one of the three criteria:

1. by their conformity with the provisions of national law of a Member State on territory of which they are marketed and / or
2. voluntary national standards transposing European standards, or,
3. in some cases, taking into account
   a) *voluntary national standards transposing relevant European standards;*
   b) *the standards laid down by the Member State where the product is marketed;*
   c) *Commission recommendations setting guidelines on product safety assessment;*
   d) *product safety codes of good practice*
   e) *the state of the art and technology;*
   f) *reasonable consumer expectations concerning safety (Article 3). The Directive establishes procedures for developing the European safety standards (Article 4).*

Both producers and distributors have obligations under the Directive in Article 6:

- Producers are obliged to place only safe products on the market (Article 3(1));
- Producers have to provide consumers with information allowing them to assess risks inherent in a product and take measures of precaution to avoid such risks;
- Distributors have an obligation to act in due care to help ensure compliance with safety requirements, in particular, not to distribute unsafe products, participate in safety monitoring, etc.;

[96] T. Hervey and G. Trubek, "Freedom to Provide Health Care Services within the EU: An Opportunity for a Transformative Directive", Columbia Journal of European Law, vol. 13, pp. 624ff, 2007.

[97] Guidelines of 7 March 2013 on Good Distribution Practice of Medicinal Products for Human Use, Official Journal 2013, C68/1, 08.03.2013.

[98] Directive 2001/95/EC of the European Parliament and the Council of 3 December 2001 on general product safety, Official Journal 11 l11/4, 15.1.2002 (The Product Safety Directive)

[99] Article 3(1) of the Product Safety Directive

- Both producers and distributors must inform competent national authorities immediately of an unsafe product that came on the market, when it comes to their knowledge, and cooperate with the national authorities on the actions to avoid the risks.

Several eHealth solutions developed as a result of FI-STAR may fall under the definition of a medical device and therefore subject to the European Medical Device Framework ('MDF'). A medical device is an instrument, apparatus, appliance, software, material or other article, intended to be used for diagnostic and/or therapeutic purposes which does not function through pharmacological, immunological or metabolic means. General software, including Generic Enablers, used in e-health is not a medical device, but software manufactured or specifically adapted for medical purposes will likely qualify as a medical device.[100]

The goal of the European Medical Device Framework is to ensure safety of medical devices brought on the European market, and their free movement in this market.

The MDF is at present composed of three different directives:

- Council Directive 90/385/EEC on active implantable medical devices (AIMDD),
- Council Directive 93/42/EEC on medical devices (MDD), and
- Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (IVDD).

These three Directives will be replaced by a Regulation on medical devices and a Regulation on in vitro diagnostic medical devices. As these are only in the stage of a proposal, the following analysis will only cover the instruments currently in force.

FI-STAR use cases do not deal with implantable or in vitro diagnostics technology. The general MDD is of direct relevance for FI-STAR technology.

12.3.1 Regulatory regime under the Medical Device Directive

All FI-STAR technology, including software,[101] that meets the definition of a medical device, must comply with the requirements of the Council Directive 93/42/EEC on medical devices (MDD).[102] It should be borne in mind that the national legislation will often have additional or more refined requirements for medical devices (e.g. on reporting safety incidents, quality standards etc.).

12.3.1.1 Scope and general principle

The MDD regime applies to medical devices and their accessories. The accessories to medical devices are treated as medical devices in their own right.[103]

The Directive defines a medical device as *'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings'* for the purpose of, among others,

- *'diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*

[101] Article 1(2) Directive 93/42/EEC on medical devices (MDD).

[102] OJ L 169, 12.7.1993, p. 1; amended by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998; Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000; Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001; Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003; Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007.

[103] Article 1(1) MDD

- *investigation, replacement or modification of the anatomy or of a physiological process […],*

'and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.'[104]

The 'intended purpose' refers to *'the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.'*[105]

Consequently, both hard- and software developed as a result of FI-STAR, as well as other generic software and devices used in combination with FI-STAR technology, will fall under the definition of a medical device, as long as they are **intended by a manufacturer to fulfil one of the above purposes.**

The producers of lifestyle eHealth solutions may avoid the additional regulatory burden by excluding explicitly the above-listed purposes as intended purposes of use. (They should make sure, however, that they then comply with the general Product Safety Directive.)

The MDD harmonises basic safety requirements to medical devices across the Member States, both brought on the European market and intended for clinical investigation. Its general principle is that medical devices may be placed on the European market[106] and/or put into service[107] only if they comply with the quality requirements of MDD, 'when duly supplied and properly installed, maintained and used in accordance with their intended purpose.'[108] Member States cannot disrupt free circulation of such devices within the internal market, as long as they are bearing the CE mark under Article 17 MDD, signifying that the device has gone through the procedure of conformity assessment.[109]

Such devices after the conformity assessment can still be taken off the market by the Member States (under the **'safeguard clause'** of Article 8 MDD), if -even though correctly installed, maintained and used for their intended purpose- medical devices 'may compromise the health and/or safety of patients, users or, where applicable, other persons.'[110] In order to implement the 'safeguard clause', the Member States establish a system of reporting the incidents of any defects or malfunctions, if they may lead or may have led to a death or a serious deterioration in the health of a patient, user, or any other person, or systematic recalls for the same reasons of the device at hand or a similar device by the manufacturer. Such reporting systems may envisage obligations of medical practitioners or medical institutions to report. All such incidents should be centrally recorded and assessed.

12.3.1.2 Essential requirements

The devices must meet the 'essential requirements' of safety set out in Annex I of MDD, taking account of the intended purpose and functions of the devices concerned.[111] Below follows an incomplete overview of the devices' functions and purposes and related requirements. For

[104] Article 1(2) of MDD

[105] Article 1(2)(g) of MDD

[106] meaning 'the first [made] available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished' (Article 1(2)(h) MDD).

[107] meaning 'made available to the final user as being ready for use on the Community market for the first time for its intended purpose' (Article 1(2)(i) MDD).

[108] Article 2 of MDD

[109] Article 4 of MDD

[110] Article 8 MDD

[111] Article 3 of MDD

requirements specific to particular devices and / or their elements use cases should consult the MDD Annex.

Among others, if the device is intended for use in combination with other devices or equipment, the whole combination must be safe and not impair the specified performances of the devices.[112] In the case of modular eHealth solutions, this means being tested in combination with all modular components. Mobile apps need to be tested in combination with each smart-phone that it is intended to be used with. This will create difficulties with obtaining a CE mark for software designed to operate on a wide range of devices.[113] To simplify the assessment procedure, the intended use of the smartphone in question should not exclude running eHealth apps. An eHealth app manufacturer may also choose to obtain a CE marking for its software in combination with a particular smartphone or other mobile device.

Devices with a measuring function (such as in the diabetes use case) must be designed and manufactured providing sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.[114]

There are special requirements for the information to be provided by the manufacturer, labelling, and devices in combination with an energy source.[115]

The compliance with the essential requirements is *presumed* with regard to devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards.[116]

12.3.1.3 Assessment of compliance, CE marking

In order to obtain CE marking that permits free circulation in the European market, the manufacturer has to follow a number of documentary procedures under Article 11 conducted to demonstrate that the essential requirements have been respected.[117] These procedures vary in intensity according to the type of the device and are described in the Annexes to the Directive.

The assessment of compliance with the quality requirements is performed by the national authorities of the Member States. Approval by one of these bodies results in the device to be permitted circulation in all Member States.[118]

Of special relevance for FI-STAR modular solutions is a provision concerning systems or combinations of devices. When a device is to be brought on the market as a system or in combination with another device, used within their intended purpose, and all of the devices bare a CE mark, no Article 11 procedures are required, and a declaration under Article 12 suffices, where a natural or legal person who brings the system on the market states that:

a) he has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions; and

[112] s. 9.1. Annex I of MDD

[113] P. Quinn et al. 193

[114] s. 10.1. Annex I of MDD

[115] see Annex I of MDD for a full list of essential requirements

[116] Article 5(1) MDD; Such harmonized standards include 'the monographs of the European Pharmacopoeia notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, the references of which have been published in the Official Journal of the European Communities.' (Article 5(2) MDD)

[117] Article 11 of MDD

[118] P. Quinn et al. 191

b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
c) the whole activity is subjected to appropriate methods of internal control and inspection.'

In all other cases, e.g. where some devices in the system do not bear a CE marking or where the combination of devices is not compatible in view of their original intended use, Article 11 procedures apply.

A special procedure of assessment is established for the devices intended for clinical investigations (Article 15).

All medical devices except for custom-made or intended for clinical investigations, meeting the essential requirements under Article 3 must bear the CE marking of conformity when they are placed on the market.[119]

12.4 Liability-related requirements

Directive 2011/24/EU provides that in cross-border healthcare, the country of treatment must ensure that systems of professional liability insurance are in place.[120] For domestic healthcare, national liability regimes apply, which can differ significantly in relation to medical treatment; it has been recommended that rules on compensation for damages be harmonized in the EU.[121] In one respect, liability is already harmonized, namely in product liability.[122] Producers are held liable for damages caused by defective products that do not provide the safety that can be expected of the product.[123] This underlines the importance for implementations of medical architectures to comply with general standards and requirements.

For modular architectures, liability provides complex challenges because they involve multiple actors. For example, in telemonitoring applications, the responsibility of patients themselves to comply with the monitoring schemes should be factored in in liability distribution.[124] Developers and providers of eHealth applications are recommended to make a risk assessment of liability risks in the framework of their national liability regime.

12.5 Internal market regulation

We have already listed some regulations aimed at the free movement of persons and services in the EU internal market. Many other regulations may also apply, depending on the type of application being developed.

Some implementations may constitute information society services, i.e., services normally provided for remuneration, at a distance, by electronic means at the individual request of a recipient. This can apply, e.g., to services allowing patients to electronically ask advice of physicians or to online medicine purchases.[125] The E-Commerce Directive (2000/31/EC) imposes obligations on service providers to provide various kinds of information to users, including registration and applicable professional rules for regulated (including the medical) professions. Commercial communications

[119] Article 17 MDD; the devices do not bare CE mark at trade fairs, exhibitions, demonstrations, etc.

[120] Art. 4 Patients' Rights Directive

[121] S. Callens, "The EU legal framework on e-health", in Health Systems Governance in Europe, E. Mossialos, G. Permanand, R. Baeten and T. Hervey, Eds. Cambridge etc.: Cambridge UP, 2010, pp. 561-588.

[122] Council Directive 85/374/EEC on liability for defective products, Official Journal 1985, L210/29.

[123] S. Callens, "The EU legal framework on e-health", in Health Systems Governance in Europe, E. Mossialos, G. Permanand, R. Baeten and T. Hervey, Eds. Cambridge etc.: Cambridge UP, 2010, pp. 561-588.

[124] A.H. Vedder and P. Vantsiouri, "Building trust in E-Health Services", unpublished.

[125] S. Callens, "The EU legal framework on e-health", in Health Systems Governance in Europe, E. Mossialos, G. Permanand, R. Baeten and T. Hervey, Eds. Cambridge etc.: Cambridge UP, 2010, pp. 561-588.

should be allowed for providers in regulated professions, subject to professional rules such as professional secrecy.[126] Alternatively, if implementations constitute electronic communication services, i.e., if they provide a service for users with a telecommunications functionality (without the provider exercising editorial control over conveyed signals), there are various obligations concerning universal access, user rights, and data protection.[127]

Another area of internal market regulation is competition (or antitrust) law. Countries are autonomous in organizing public health care, and EU competition law does not apply if health systems are based on solidarity, but countries that introduce some market organization in their public health system will have to take competition rules into account.[128] This affects, for example, pricing schemes for pharmaceuticals, medical devices, and related services, and also has implications for procurement procedures. It requires a very case-specific analysis to determine to what extent these rules apply.[129]

Similarly, the regulation of the free movement of people and services within the internal market might apply to (modular-based) medical architectures, in which (combinations of) the provider, the service, or the recipient can move between countries.[130]

12.6 Brief summary

In their designs the partners developing FI-STAR eHealth solutions should take into account:

A. Where personal data of patients, medical personnel and other employees is involved, data protection requirements should be met. Specifically:

   A.1. Responsibilities with regard to lawful processing of personal data should be clearly allocated, identifying which actor involved in a FI-STAR eHealth solution is a data controller and hence chiefly responsible for compliance with the data protection requirements.

   A.2. Any operation with personal data should be undertaken only when and insofar as there is a legitimate ground established by law. When health data is involved, explicit consent and context of a treatment relationship will most likely provide such a ground. Importantly, **consent to undergo a certain medical treatment does not constitute "consent" necessary for processing health data**. Processing is within the context of a treatment relationship when it is executed by medical professionals or other stuff subject to confidentiality obligations, and may not include medical professionals at another institution.

   A.3. Appropriate legal ground should be considered for each individual FI-STAR use case.

   A.4. Data protection rights of a patient or an employee whose data is processed should be respected:

      A.4.1. They should be in a position to learn about data processing operations.

      A.4.2. They should be enabled to withdraw their consent to data processing.

[126] Directive 2000/31/EC (Directive on electronic commerce), Official Journal 2000, L178/1.

[127] Directive 2009/136, amending Directives 2002/22/EC and 2002/58/EC, Official Journal 2009, L108/41.

[128] T. Prosser, "EU competition law and public services", in Health Systems Governance in Europe, E. Mossialos, G. Permanand, R. Baeten and T. Hervey, Eds. Cambridge etc.: Cambridge UP, 2010, pp. 315-336.

[129] J. Lear, E. Mossialos and B. Karl, "EU competition law and health policy", in Health Systems Governance in Europe, E. Mossialos, G. Permanand, R. Baeten and T. Hervey, Eds. Cambridge etc.: Cambridge UP, 2010, pp. 337-378.

[130] We refer to E. Mossialos, G. Permanand, R. Baeten and T. Hervey, Eds., Health Systems Governance in Europe, Cambridge etc.: Cambridge UP, 2010, Chapters 10-12. And T. Hervey and G. Trubek, "Freedom to Provide Health Care Services within the EU: An Opportunity for a Transformative Directive", Columbia Journal of European Law, vol. 13, pp. 624ff, 2007 for discussions of these legal norms

A.4.3. They should be enabled to access, rectify, erase and object to data processing or block personal data that is incomplete, inaccurate or processed unlawfully.

A.4.4. In smart eHealth environments this should be done via easily accessible tools, including an option to uninstall an e Health solution.

A.5. The data controller, both on the stage of design and once a FI-STAR solution is deployed, has to ensure that organizational and technical measures to ensure security of personal data are taken by manufacturers of devices and operation system, App developers and App stores, as well as hospitals and other institutions involved. Some actors involved may be under the obligation to inform competent national authorities and data subjects in case of a data security breach.

A.6. Sensitive nature of health data involved requires especially strict security measures: identity verification, authentication, encryption, etc.

B. FI-STAR eHealth solutions should be tested and deployed in a manner respectful of the patients' rights in the context of clinical trials, cross-border healthcare, and according to other specific legislation that may be relevant for individual use cases.

C. Most hardware and software developed for FI-STAR will likely be subject to the EU rules on safety of medical devices; for products or services that do not qualify as medical devices, the general product safety requirements will apply. Both regimes involve certification and standardization schemes that need to be analyzed for each use case.

D. Other legal requirements may be of relevance: e.g. telecommunications law, competition law, law of public procurement, and so on, depending on the context of individual use cases.

13 Preview of Standardisation and Certification requirements for FI-STAR

13.1 Introduction

Standardization and certification are issues not sufficiently addressed under FI-PPP so far. For FI-STAR and other projects to create sustainable value chains and become self-sufficient certification is important. FI-STAR is conducting a scoping exercise into certification in order to identify what elements would be needed to develop a certification process for the project. There are also relevant existing standards such as ISO 80001 and the ISO 27000 family, which needs to be specifically considered for the eHealth domain. The deliverable D1.2 will give more details on which relevant standards need to be considered under FI-STAR and which standards could be of relevance to a future certification process.

Looking at standardisation and certification, we need not only to look at individual component but the interaction between components as well as the global infrastructure in which the component is interaction. Therefore requirements will come from:

- quality of the component
- ability to be interfaced into the platform and interact within the defined architecture
- Ability to interoperate and data exchanged understood (i.e. semantic)

With the development of the ICT in Health in many medical specialties as well as in public health and patient access to his medical information, eHealth standards become the key for the success of the deployment of these technologies. This is why the European Commission set up the digital agenda for Europe and action plan 2012-2020 in eHealth. The purpose of the agenda is to consolidate the actions that have been initiated in the previous action plan started in 2004. Four objectives were defined and the objective 2 is to “address issues currently impeding eHealth interoperability” by achieving wider interoperability in eHealth services. The need of a eHealth European Interoperability Framework was one of the listed covering technical and semantic levels among the four levels of interoperability that were also targeted.

Before reaching this major step, the EU Commission “has issued a mandate to the European Standardizations organisations CEN, CENELEC and ETSI to develop a coordinated work program for standardization in health informatics” called Mandate M/403. The background was already well established and the following schema synthetizes all the aspects of the standardisation taken into account regulation, organisational and functional, technical and semantic layers.

Therefore the work will not to repeat all the analysis but more to limit what could be the value of standardisation for FI-STAR.

13.2 Background and Related Work

Certification is a well-defined but complex process. A certification program is a quality mark to guarantee that the products or systems are conformant to requirements or specifications that the owner of the certification scheme (authority or consortium) provides. The level of trust linked to the certification program is closely related to the level of recognition of the third party in charge of the certification (the third party is generally a certified laboratory or an audit entity). The level of recognition of the requirements and specifications are also part of the trust. When these requirements are originated from operational and robust standards already implemented, the level of trust is better.

The eHealth sector is relatively young. This implies that successful deployment of wide and large systems, where thousands of patients and several types of health organisations are involved, requires standards. The epSOS project (www.epsos.eu) uses IHE profiles and related standards. This demonstrates the relevance of existing standards for exchanging medical data across Europe.

A testing platform, test criteria, testing tools, and a validation process was the first step for a quality assurance process.

In the United States, the Meaningful Use program has the goal of promoting the spread of electronic health record to improve health care. The ONC (Office of the National Coordinator for Health IT) identifies standards and certification criteria (http://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2).

In Europe, some countries develop national certification of the EHR: These countries include Belgium, Ireland, France, and Slovenia.

Certification in eHealth for conformity to some eHealth standards (ie ISO 80001, ISO 27000) is well established and a lot of activities were developed in Europe within the EIF (European Interoperability Framework). FI-STAR is in contact with the eHealth thematic network called Antilope which in particular ensure a follow up of the HITCH project (Healthcare Interoperability Testing and Conformance Harmonisation http://www.hitch-project.eu) on interoperability and certification.

A lot of the focus of the certification is to ensure interoperability. For that a lot of works was done to identify profiles and develop tool to ensure conformity to the profiles.

Figure 117: Different categories of standards

13.3 FI-STAR Standardization and Certification Objectives

We define that the Standardisation should support a limited but important set of objectives corresponding to layers identified in the figure below, from lower to upper layers:

1. Support integration into FI-PPP platform (FI-STAR products can use any components and services which provide requested GEs)
2. Support Interoperability (information can be exchanged)
3. Support Semantic interoperability (information can be understood)
4. Support eHealth quality specific (what is provided for eHealth is compliant with eHealth requirements)
5. Support potential certification

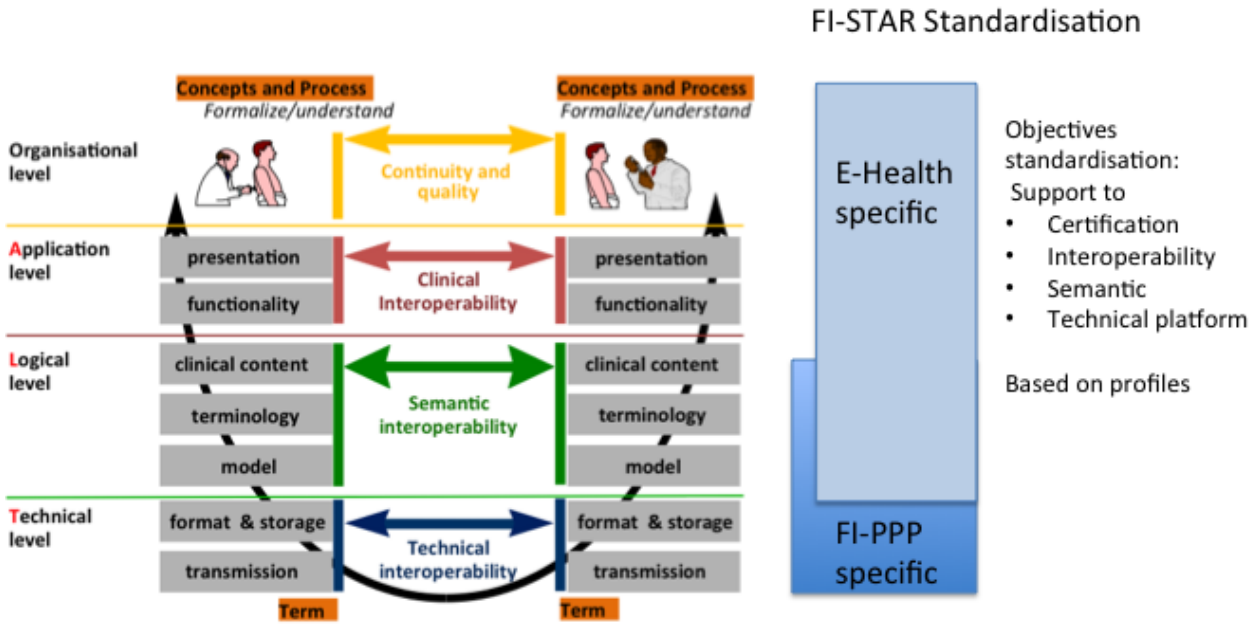


Figure 118: Different layers of Interoperability impacting standards and certification

The D1.2 deliverables will detail further the standards which can be important for each of the objectives.

An important part of FI-STAR support to standardisation and certification in particular for eHealth will be to identify FI-STAR profiles where we could already best practices and existing standards and tools

While we will look at eHeath specifics standards and certification matters, reusing some existing methods and tools, FI-STAR is part of the FI-PPP programme were there is no real conformity-to-specifications programme which could feed some certification programme

13.4 Standardization and Certification Approach

In absence of such important tests, methods and tools, FI-STAR will have an important focus more on ensuring conformity to FI-PPP specifications.

In summary, Certification will support:

- Conformity to FI-PPP core assets: Generic Enablers GEs, Specific Enablers SEs
- Quality Control (Quality Indicators QI, Key Performance Indicators KPI)
- eHealth specific (eg eHeath software or system if applicable)
- FI-STAR specific (requirements from FI-STAR which don't fall into other categories such as specific group of features or a complete Use Case)

Within the project but also within the FI-PPP programme, there is some wish to be ready for certification. The precise scope of certification will depend on stake holders which should decide to set up a certification programme. FI-STAR will suggest some certification scheme but will mainly provide all the certification elements so that it will be easy to implement a certification programme

After discussion, we came to the identification of 3 categories of certification items which will be combined to provide an overall FI-STAR certification. To get a certificate a FI-STAR component[131] must:

[131] We defined here component as a FI-STAR significant delivery which can be a complete Use Case,, part of , a technical key module such as the cloud platforms , A GE instance , etc

1. Comply with Quality Indicators. This will be measured by specific defined processes which can be a mixed of FI_STAR manual processes and developed tools. Quality indicators might comprise:
    a. Indicators on users satisfaction (e.g. Mean Opinion Score)
    b. Technical indicators (e.g. performance, end2end)
    c. Quality of the software (e.g. SW quality)
2. Comply with eHealth requirements when applicable: this will be done by requirement potential third party certification when applicable (e.g. ISO 80001) and/or comply with existing eHealth profiles testing.
3. Comply with platform requirements: This will check conformity to GEs and SEs and therefore verify "plugability" and exchangeability of FI-STAR components to work with any solutions offering the requested GEs. Check on conformity to GEs and/or SEs will be done using:
    a. Available GEs conformity tests and tools. FI-STAR will develop such solutions for some ones.
    b. V&V tests and methods using test beds such as OIL (Open Innovation lab) when formal tests and tools are not available.

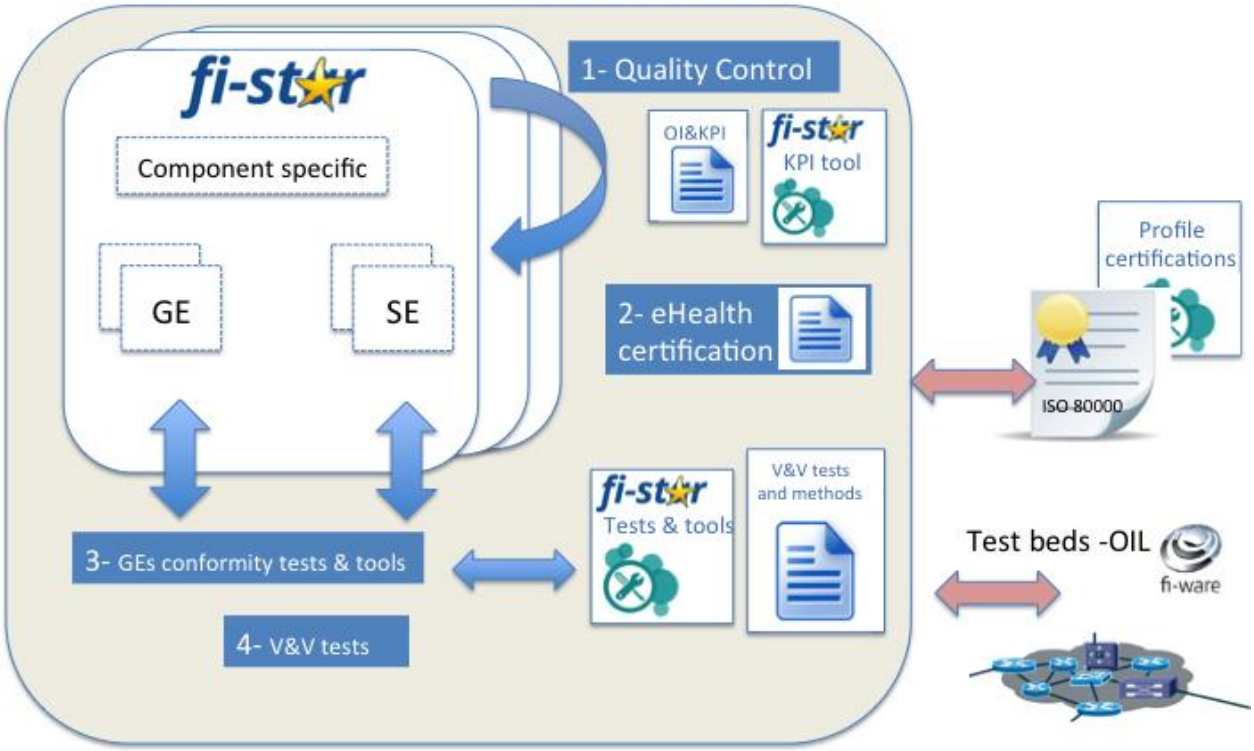


Figure 119: Overall Certification process with the different areas of conformity, process and tools to be used

The Use Cases scenarios will identify the important standards and certification requirements which ensure that the FI-STAR services will be provided with high quality and which will use GEs from any providers, thus securing investment done in the development as well as ensuring long term sustainability

13.5 Summary and Conclusions

This document has outlined that standards and key specifications (FI-PPP GEs) are essential to ensure interoperability and exchangeability thereby meaning that FI-STAR services based on GEs can use any GE provider and therefore preventing "vendor" lock-in.

The analysis however confirms that standards and specifications are not enough if there is no conformity to standards tests and tools, which is currently not available.

As far as eHealth are is concerned, FI-STAR will aim to identify common feature which can match eHealth profiles and for which there are available certification tests and tools available within the EU eHealth community thanks to key liaison established with EU eHealth themantic network project Antilope

As far FI-PPP programme is concerned, FI-STAR will therefore contribute to validate further key specifications of the programme as well as contribute to develop conformity to specifications tests and tools using best practice. This FI-STAR approach in standardisation and certification is essential to secure investment and ensure long term sustaibaniblity not only in the eHealth area where the project can stimulate further development and innovation but for the whole programme by the project contribution to validation of specifications and to a global certification programme. Such programme can provide the confidence in the various solutions promoted as well as ensuring necessary interoperability that any solutions using GEs can work with any provider, any where.

SECTION III – Application and Platform Architecture (Architecture Report)

The following chapters give previews of application and platform architecture. For exemplifying the application architecture, the most representative use case scenario has been chosen: the Diabetes Share System. The FI-STAR platform architecture describes how FI-STAR technology intends to support the development of FI-STAR applications and solutions. The last of the three chapters describes current state and next steps of GE selection and usage.

Chapter 14: Application Architecture – Diabetes Share System Example

Chapter 15: FI-STAR Platform Architecture

Chapter 16: Selection and Usage of Generic Enablers GE

14 Application Architecture – Diabetes Share System Example

14.1 Introduction

The objective of the application architectures, managed by work package 4, is to define the FI-STAR application development framework that will allow for conformant and coherent application design across all experimentation sites as well as towards the FI-STAR Service Provider and Service Consumer Edge Cloud Platform. The application architecture document specifies the components and structures of the target application deployments for each use case scenario and across experimentation sites. The definitions are verified against the system level use cases defined in the vision documents and the data flows specified in the deployment scenarios of the respective use case scenario.

The FI-STAR application development framework definition is a joint activity of all involved partners in this WP with the aim of a consolidated application planning, development and optimized end user experience. Joint workshops are used to define the application architectures based on following inputs:

- The solution features and use cases and the deployment scenarios specified by the respective use case scenario in work package 1.
- Domain knowledge that pertains to the design, construction, and evaluation of the kinds of applications that are being specified.
- Knowledge of FI-WARE and XIFI technology and of the design patterns for effective use of these technologies.

The resulting specifications are documented with state-of-art notation. UML component diagrams were used for denoting components and dependencies. UML sequence diagrams are intended to be used for describing how components and applications interact to realize a solution-level use case.

This document gives a preview of the deliverables intended by work package 4. It indicates how an application architecture is functionally specified. The presented example, the application architectures for the Diabetes Share System of the Experimentation site in Tromsö Norway, is representative for most of the use case scenarios that are included in the FI-STAR project currently. Further specification work is planned for refining the example in parallel to prototype implementation and verification work and for applying the approach on the remaining use case scenarios. This work has been launched as part of the work package 4 activities.

The resulting application architectures will be used as guidelines and constraints for application development and for planning of component-level and integration tests. A consolidation of the application architectures will be used to align the FI-STAR Service Provider and Consumer Edge Cloud Platform from WP2 and WP3 with the needs of the applications. That consolidation will also be used to understand the potential for Generic Enabler support through commonalities and variability identified at the functional/component level (e.g. access to shared sensor technologies, main user interface characteristics, access to the FI-STAR Service Consumer Edge Cloud Platform etc.).

14.2 Diabetes Share System (DSS) architecture

The Diabetes Share System (DSS) is positioned on the boundary between professional e-health environments and public consumer wellbeing cloud environments. It is designed to provide:

- **Diabetes patients** with services that can improve their day-to-day handling of the condition as well as their general wellbeing through:
    - DeStress Assistant mobile application for iOS smartphone,
    - Diabetes Diary mobile application for Android smartphone,

- **Doctors and nurses** with services that can improve in-clinic treatment of the Diabetes patient based on additional information related to patient's health and wellbeing.

The architecture of the DSS system is represented in Figure 120. It consists of client side (left hand side) and server side (right hand side).

On the client side, the diabetes patients use two different Diabetes mobile kits:

- Diabetes mobile kit for iOS:
  - DeStress Assistant (DeSA) mobile application for iOS-based smartphones (DeSA iOS App), and
  - Audiojack glucometer,
  - Fitbit activity tracker;
- Diabetes mobile kit for Android:
  - Diabetes Diary (DD) mobile application for Android-based smartphones (DD Android App), and
  - Bluetooth glucometer,
  - Runkeeper activity tracker.

The DeSA iOS application and the DD Android application offer services to collect, visualize and share observations related to patients' health and wellbeing, useful hints, community ranking observation, and videoconference consultations with doctors and nurses.

In addition, doctors and nurses use an EHR client application for PC to access the observations the patients have shared and to access videoconference consultations.

The server side consists of a consumer cloud environment and hospital environment.

The consumer cloud environment comprises two public consumer clouds:

- Runkeeper public cloud that provides the DD Android App with patient's activity data collected with a Runkeeper mobile app and connected services, and
- Fitbit public cloud that provides the DeSA iOS App with patient's activity data collected with a Fitbit pedometer.

In addition, the consumer cloud environment comprises a Diabetes Share Community (DSC) Server. DSC Server offers the patients a Diabetes community ranking service based on data collected from the DD Android App and the DeSA iOS App.

The server-side hospital environment consists of:

- Diabetes Share Proxy (DSP) Server, positioned in DMZ Hospital Unsecure Zone that connects the Secure Hospital Zone with DeSA iOS App and Diabetes Diary Android App in the outside world,
- Diabetes Share System (DSSy) Server in the Secure Hospital Zone, exposing an API for connections from an existent EHR system in production use at University Hospital of North Norway (UNN) in Tromsø and
- Norwegian Health Network, and Electronic Health Record System in production use at UNN.

In the following chapters, the architecture of the system is explained in more detail and the identified components are specified in terms of functional building blocks.

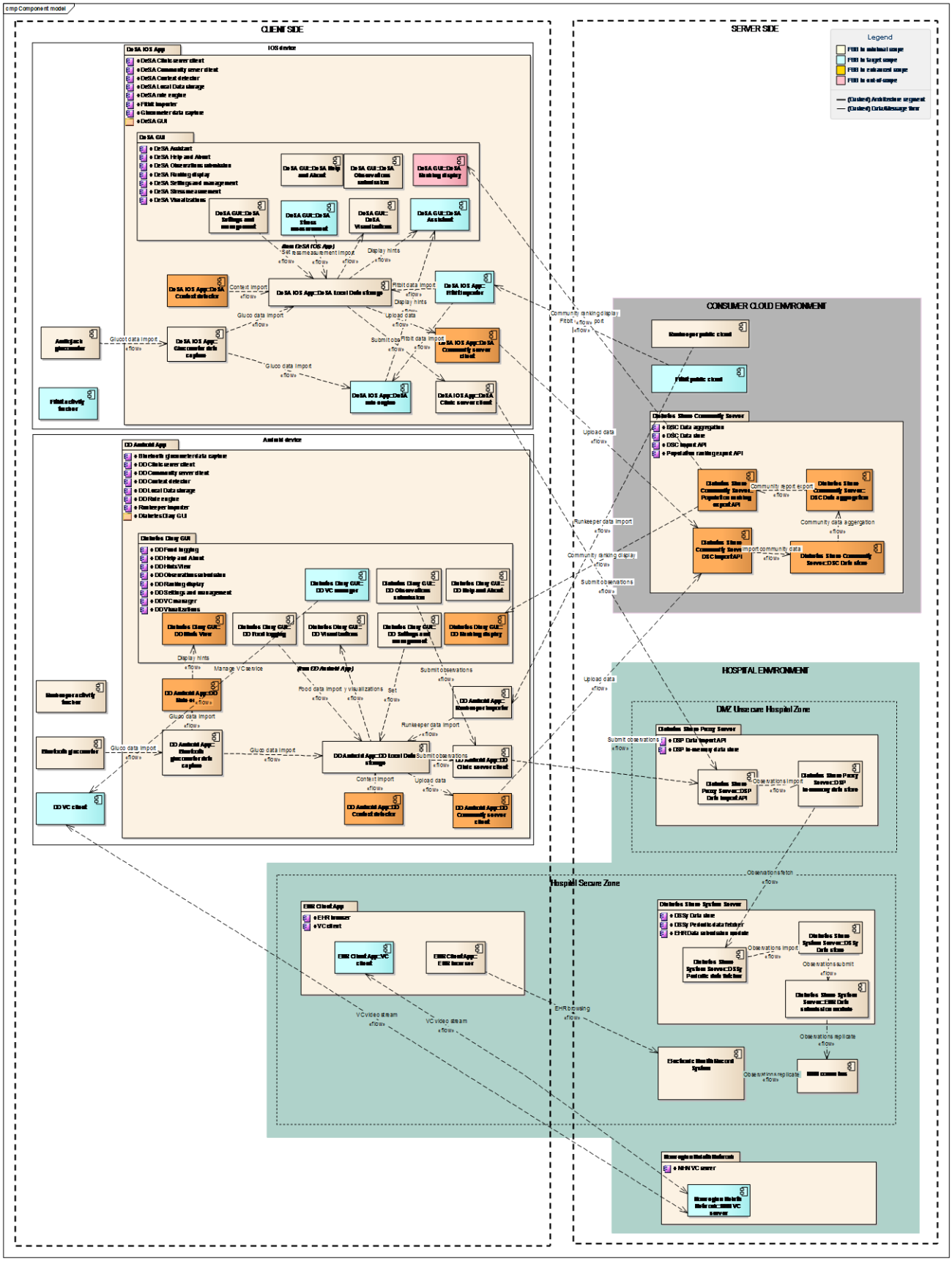


Figure 120: Diabetes Share System (DSS) Architecture.

14.2.1 Client side

On the client side, there will be two different mobile smartphone applications for patients, the Diabetes Diary Android Application and the DeSA iOS Application. Upon completed development and testing, the applications will be submitted into the App Store and FI-STAR Application Store, respectively.

In addition, there will be two types of glucometers, the Bluetooth glucometer that will be used together with the Diabetes Diary Android App, and the Audiojack glucometer that will be used together with the DeSA iOS App, and two types of activity trackers, the Runkeeper activity tracker that will be used together with the Diabetes Diary Android App and the Fitbit activity tracker that will be used together with the DeSA iOS App.

Finally, an existent EHR client application for PC will be available to doctors and nurses.

14.2.1.1 iOS smartphone components

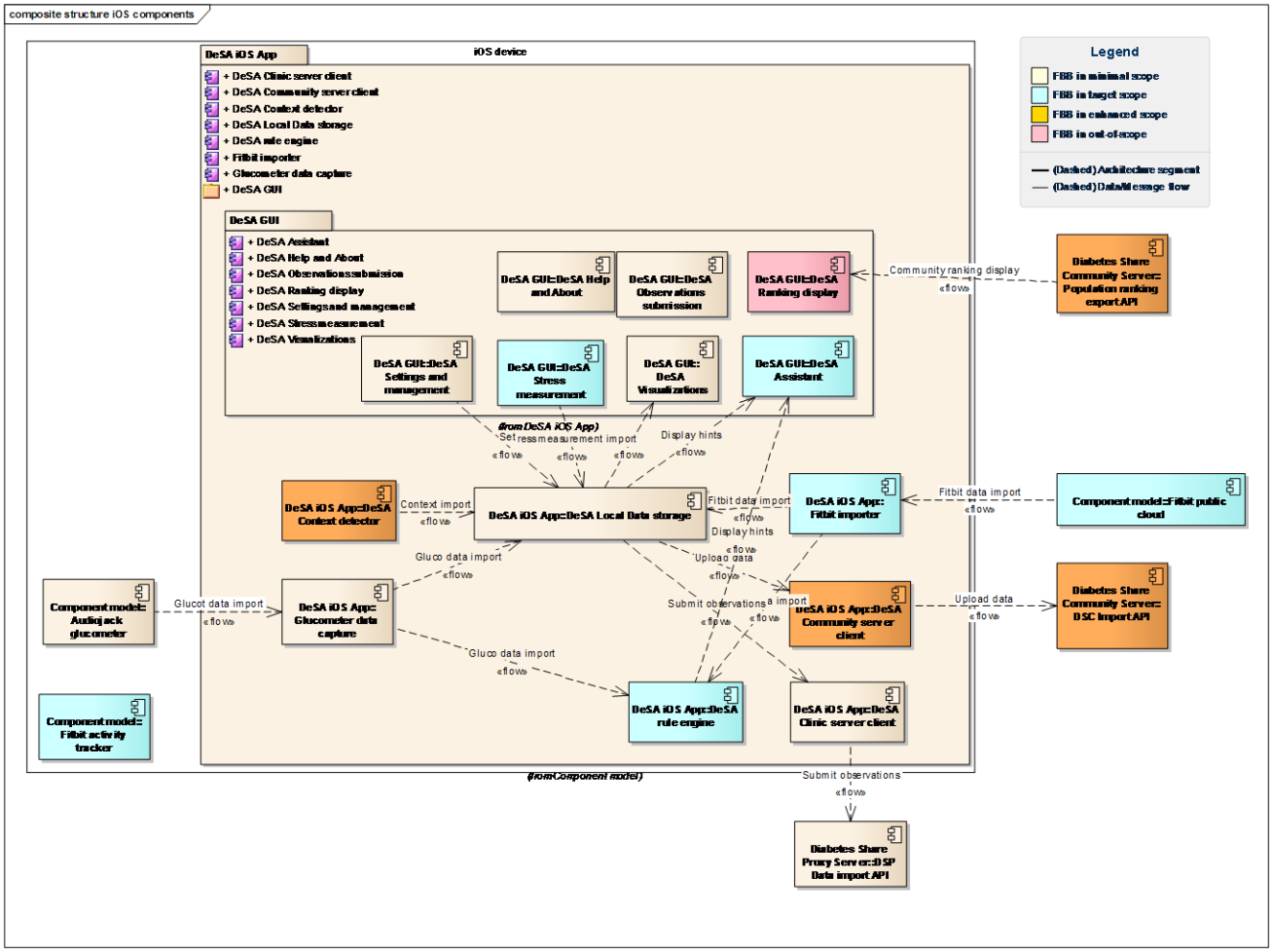


Figure 121: Client side – iOS smartphone components.

14.2.1.1.1 DeStress Assistant (DeSA) iOS Application

DeSA is a mobile application for iOS-based smartphones. It provides self-help services for diabetes patients in order to ease monitoring and management of their lifestyle in the context of their general wellbeing, stress exposure and diabetes condition.

It consists of the following main functional building blocks (FBB):

- Data storage:
  - Local data storage (FBB.N.11),

- Data processing:
  - DeSA Rule engine (FBB.N.8),
- APIs:
  - Fitbit importer (FBB.N.10),
  - Glucometer data capture (FBB.N.12),
  - Community server client (FBB.N.14),
  - Clinic server client (FBB.N.13),
- GUIs
  - DeSA GUI with
    - DeSA Stress measurement view (FBB.N.2),
    - DeSa Visualizations (FBB.N.1),
    - DeSA Assistant (FBB.N.3),
    - Settings and management (FBB.N.6),
    - Ranking display (FBB.N.5),
    - Report submission (FBB.N.4),
    - Help and About (FBB.N.7),
- Other:
  - DeSA Context detector (FBB.N.9).

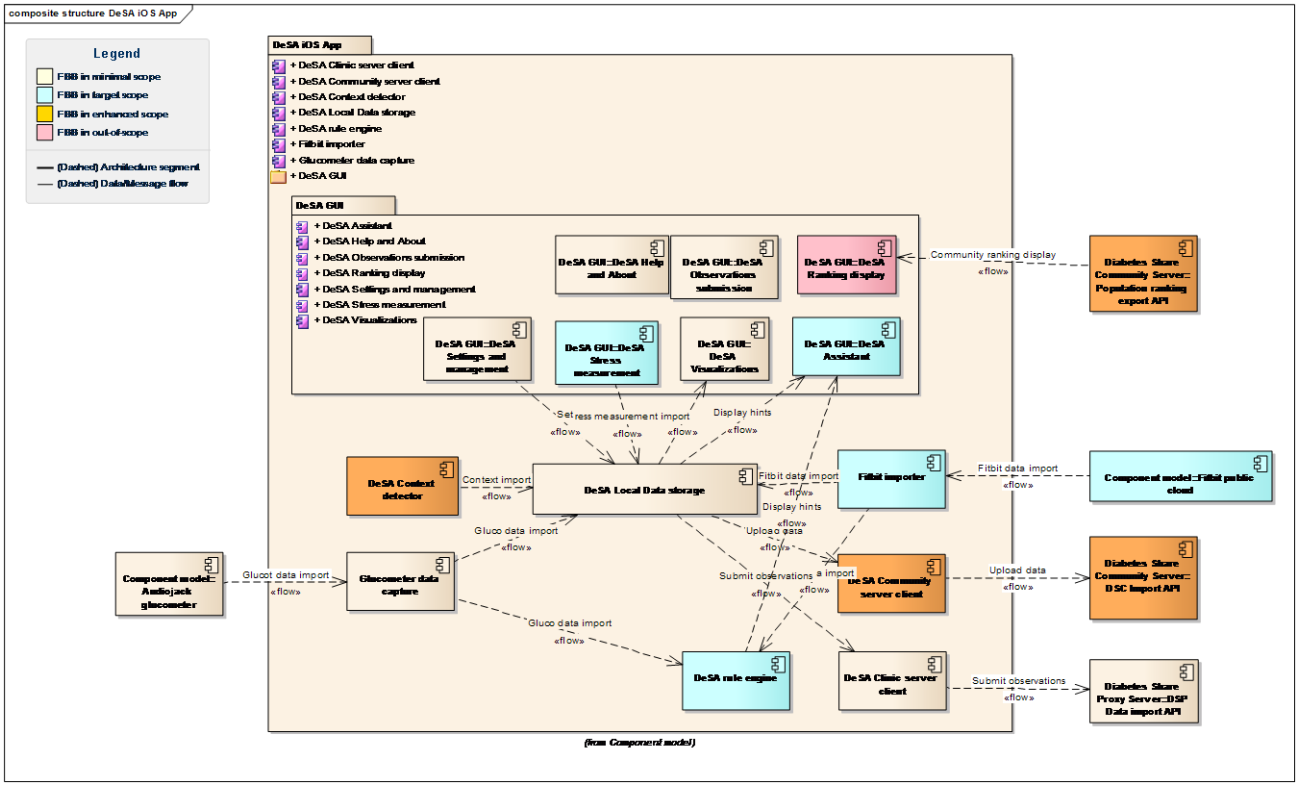


Figure 122: Client side – DeSA functional architecture.

The application will allow gathering of the following data:

- blood glucose level, measured with Audiojack glucometer and imported into the application via Glucometer data capture (FBB.N.12),
- Fitbit activity and sleep data, imported from Fitbit cloud via Fitbit importer (FBB.N.10),
- perceived stress levels through DeSA Assistant (FBB.N.3),
- local context detected based on smartphone sensors (FBB.N.9).

The services will be exposed to the diabetes patient through the DeSA GUI, which will provide the following basic stress and diabetes management functionalities:

- basic and advanced visualization of all captured data (FBB.N.1),
- manual stress self-reporting (FBB.N.3),
- display of useful tips that can help in management of patient's general wellbeing (FBB.N.3),
- community ranking display (FBB.N.5), and
- submission of observations (FBB.N.4).

In addition, Settings and management (FBB.N.6) and Help and About (FBB.N.7) will be enabled.

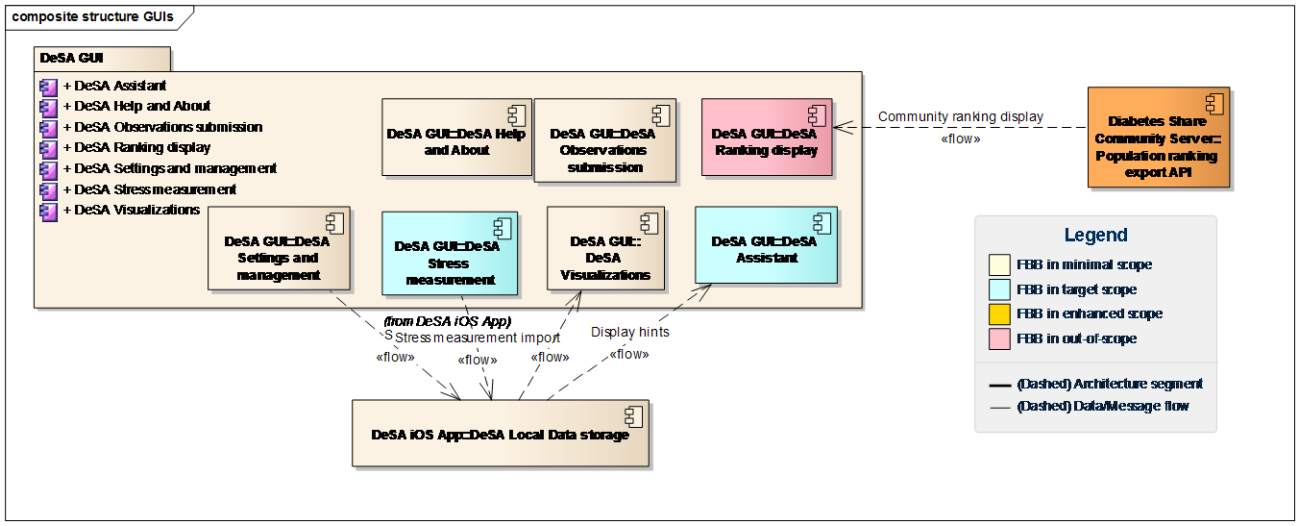


Figure 123: Client side – DeSA GUI functionalities.

All data will be stored locally on the smartphone (FBB.N.11). DeSA rule engine (FBB.N.8) will perform data processing to recognize certain thresholds, patterns or other significant markers, based on which tips for wellbeing management will be generated and displayed in DeSA Assistant (FBB.N.3). The results of data processing will be stored in the DeSA Local data storage (FBB.N.11).

In addition, selected wellbeing-related data will be uploaded to the Diabetes Share Community Server for community data analysis and visualizations. The transmission of data will be completed via the Community server client (FBB.N.14).

Also, the user will be able to trigger submission of the observations (FBB.N.4), which will result in uploading of the locally stored data to the Diabetes Share Proxy Server. The transmission of data will be completed via the Clinic server client (FBB.N.13).

Further details of individual FBB elements are available further in the document.

14.2.1.1.2 Audiojack glucometer

The Audiojack glucometer (FBB.N.37) is a Consumer Of The Shelf (COTS) device that will be used to capture blood glucose level. The measurement will be transmitted to the DeSA iOS App via Glucometer data capture (FBB.N.12).

14.2.1.1.3 Fitbit activity tracker

Fitbit activity tracker (FBB.N.38) is a Consumer Of The Shelf (COTS) device that will be used to capture activity and sleep pattern data. The measurements captured with the device are transmitted directly into the Fitbit cloud independently from the DSS system. The measurements will be collected in the DeSA iOS App by accessing Fitbit public cloud (FBB.N.36) through Fitbit importer (FBB.N.10).

14.2.1.2 Android smartphone components

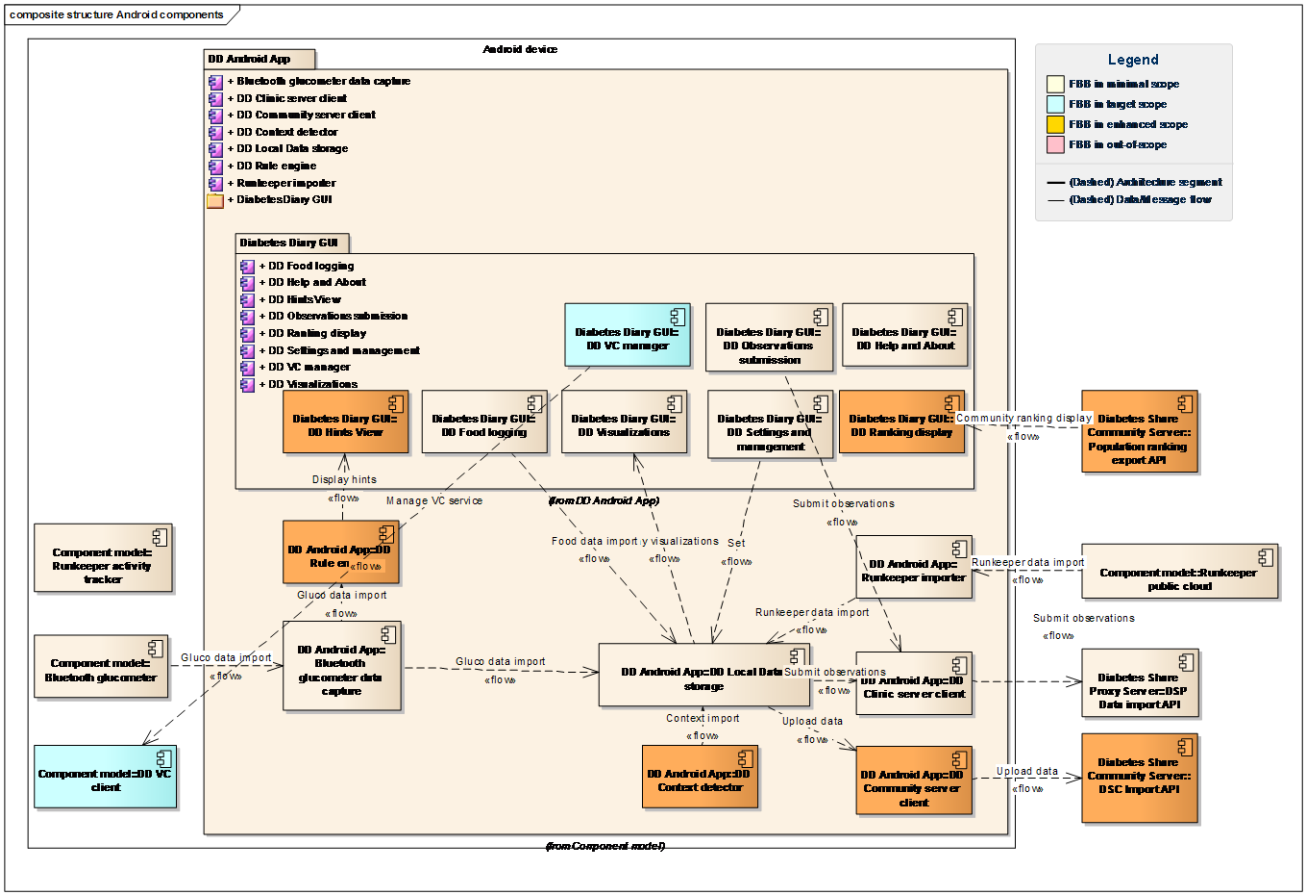


Figure 124: Client side – Android smartphone components.

14.2.1.2.1 Diabetes Diary (DD) Android Application

DD is a mobile application for Android-based smartphones. It will provide self-help services for diabetes patients in order to ease monitoring of goals for a healthier life.

It consists of the following main functional building blocks (FBB):

- Data storage:
  - Local data storage (FBB.N.26),
- Data processing:
  - DD Rule engine (FBB.N.22),
- APIs:
  - Runkeeper importer (FBB.N.25),
  - Bluetooth glucometer data capture (FBB.N.24),
  - Community server client (FBB.N.27),
  - Clinic server client (FBB.N.28),
- GUIs
  - Diabetes Diary GUI with
    - Observations logging (FBB.N.16),
    - DD Visualizations (FBB.N.17),
    - Hints View (FBB.N.15),
    - Ranking (FBB.N.19),
    - Settings and management (FBB.N.18),
    - Report submission (FBB.N.20),
    - Help and About (FBB.N.21);
    - DD VC manager (FBB.N.31);

- Communication:
  - DD VC client (FBB.N.29),
- Other:
  - DD Context detector (FBB.N.23).

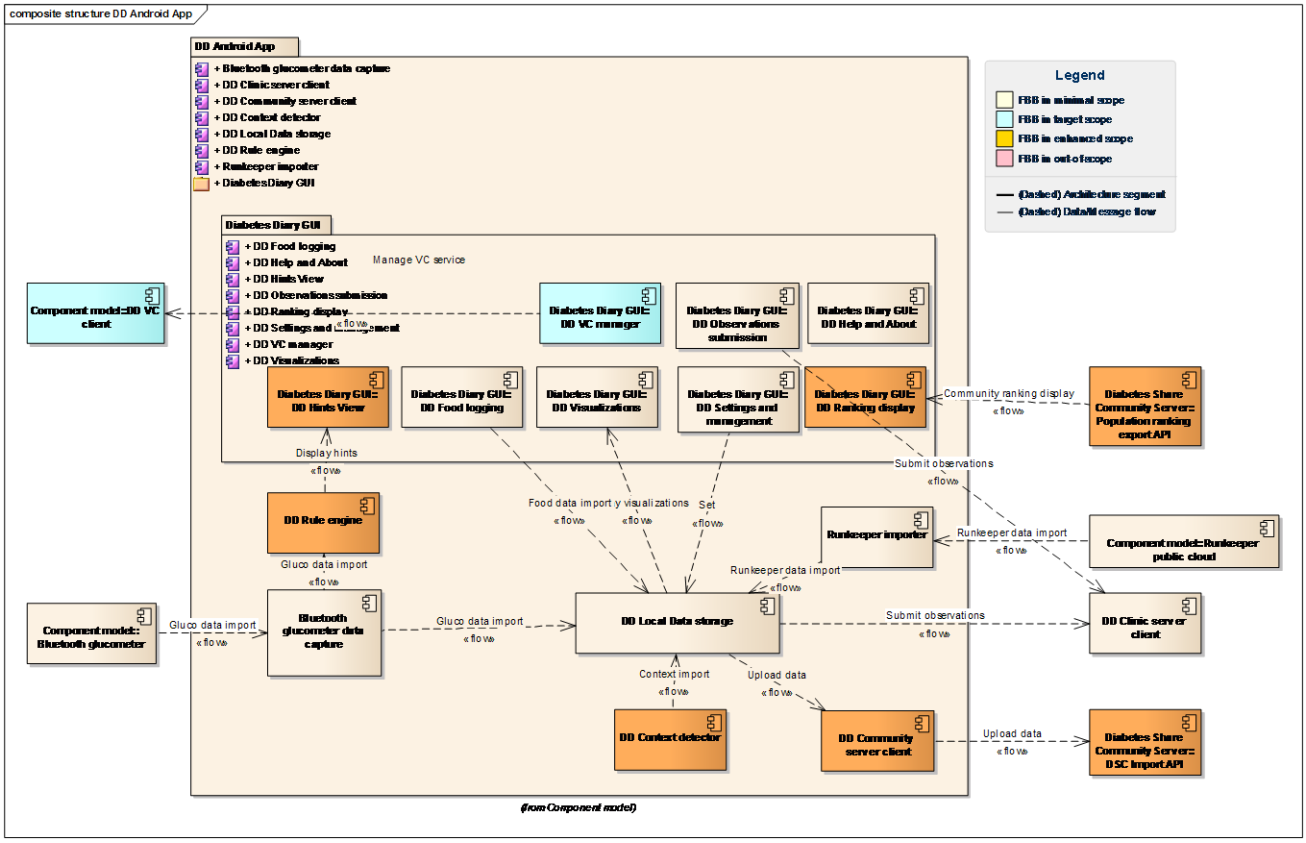


Figure 125: Client side – DD functional architecture.

The application will allow gathering of the following data:

- blood glucose level, measured with Bluetooth glucometer and imported into the application via Bluetooth glucometer data capture (FBB.N.24),
- Runkeeper activity data, imported from Runkeeper cloud via Runkeeper importer (FBB.N.25),
- Reported carbohydrate intake and insulin administration using Observations logging (FBB.N.16),
- Locally detected context using smartphone sensors (FBB.N.23).

The DD Runkeeper physical activity app (FBB.N.30) will track physical activity through the Android smartphone's internal accelerometer and/or GPS. This data is submitted by the app to the Runkeeper cloud making it accessible for download by the Runkeeper importer (FBB.N.25)

The services will be exposed to the diabetes patient through the Diabetes Diary GUI, which will provide the following diabetes management functionalities:

- basic and advanced visualization of all captured data (FBB.N.17),
- manual observations logging (FBB.N.16), and
- display of useful hints that can help in management of patient's diabetes condition (FBB.N.15),
- overview of community ranking (FBB.N.19),
- submission of observations (FBB.N.20) into the hospital environment.

In addition, the GUI will offer videoconference service using DD VC manager (FBB.N.31) by connecting to the DD VC client (FBB.N.29).

Also, Settings and management (FBB.N.18) and Help and About (FBB.N.21) will be enabled.

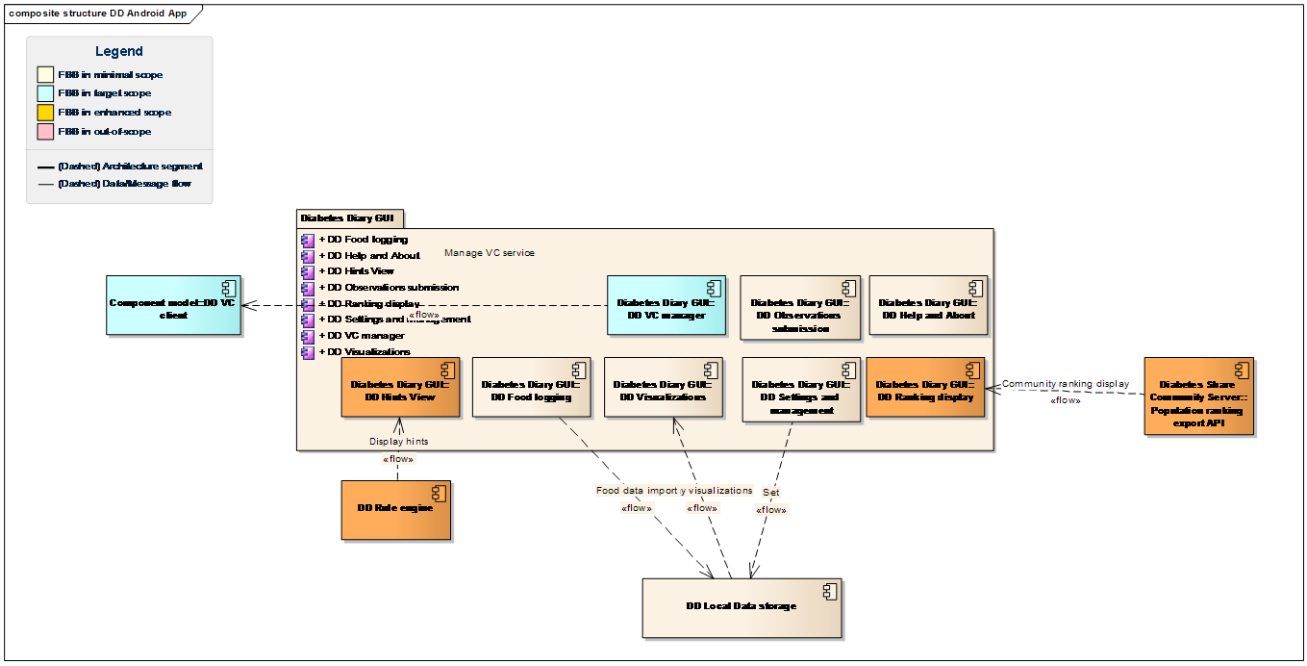


Figure 126: Client side – Diabetes Diary GUI functionalities.

All data will be stored locally on the smartphone (FBB.N.26). DD rule engine (FBB.N.22) will perform data processing to recognize certain thresholds, patterns or other significant markers, based on which tips for diabetes management will be generated.

In addition, selected wellbeing-related data will be uploaded to the Diabetes Share Community Server for community data analysis and visualizations. The transmission of data will be completed via the Community server client (FBB.N.27).

Also, the user will be able to trigger submission of the observations (FBB.N.20), which will result in uploading of the locally stored data to the Diabetes Share Proxy Server. The transmission of data will be completed via the Clinic server client (FBB.N.28).

Finally, videoconference consultation service will be available using a DD VC client (FBB.N.29).

Further details of individual FBB elements are available further in the document.

14.2.1.2.2 Bluetooth glucometer

The Bluetooth glucometer (FBB.N.32) is a Consumer Of The Shelf (COTS) device that will be used to capture blood glucose level. The measurement will be transmitted to the Diabetes Diary Android App via Bluetooth glucometer data capture (FBB.N.24).

14.2.1.2.3 Runkeeper activity tracker

Runkeeper activity tracker (FBB.N.37) is a standalone Android application that will be used to capture activity data. The measurements captured with the application are transmitted directly into the Runkeeper cloud independently from the DSS system. The measurements will be collected in the DD Android App by accessing Runkeeper public (FBB.N.33) cloud through Runkeeper importer (FBB.N.25).

14.2.1.3 EHR client application for PC

The EHR browser (FBB.N.32) is a desktop application running on Windows. The clinician uses this functionality to access the EHR system.

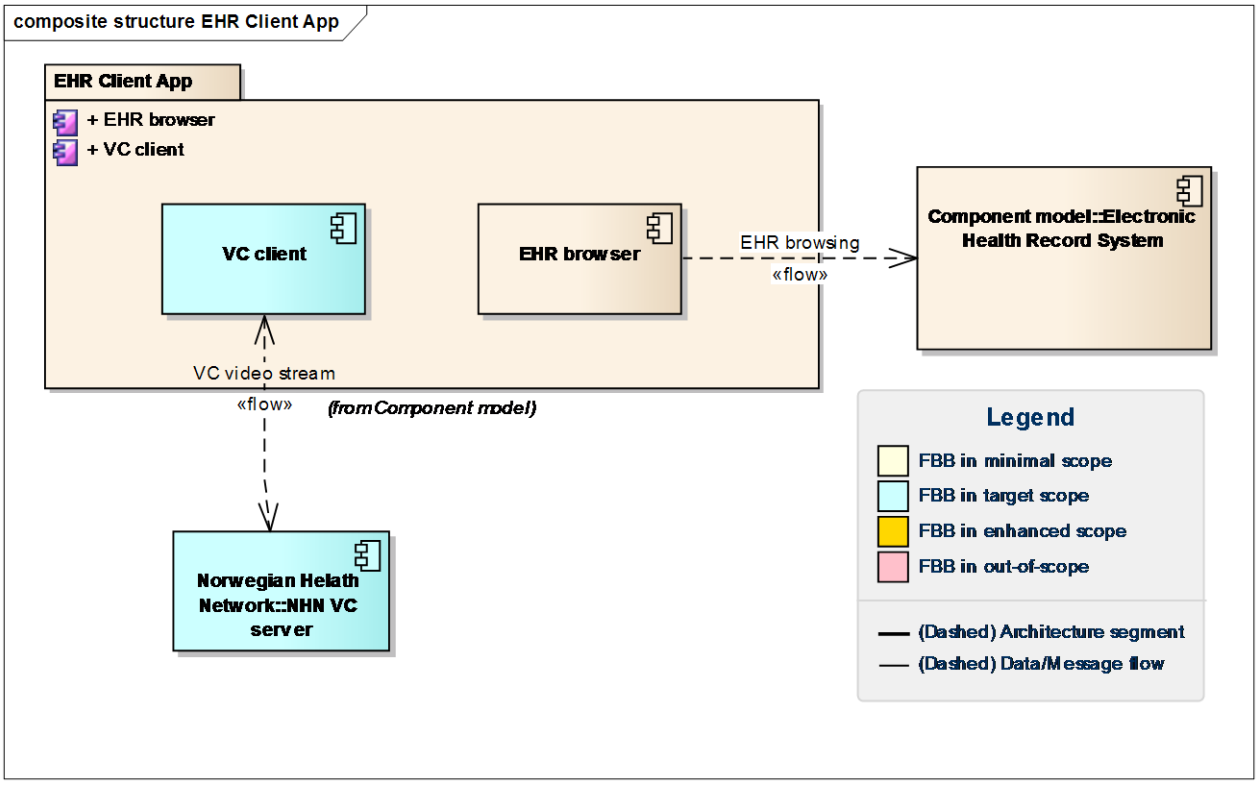


Figure 127: Client side – EHR client application architecture.

14.2.1.4 DD VC client

The VC Client (FBB.N.29) is a desktop client for placing video conferencing calls hosted by the Cisco Jabber Telepresence server (NHN VC Server).

14.2.2 Server side

14.2.2.1 Diabetes Share Proxy (DSP) Server

The Diabetes Share Proxy Server will be inside DMZ Insecure Domain. Its main role will be to interconnect DeSA iOS App and Diabetes Diary Android App outside the hospital environment with the Diabetes Share System Server.

The DSS Server consists of the following main functional building blocks (FBB):

- Data storage:
  - In-memory (ephemeral) data store (FBB.N.38),
- APIs:
  - Data import API (FBB.N.39).

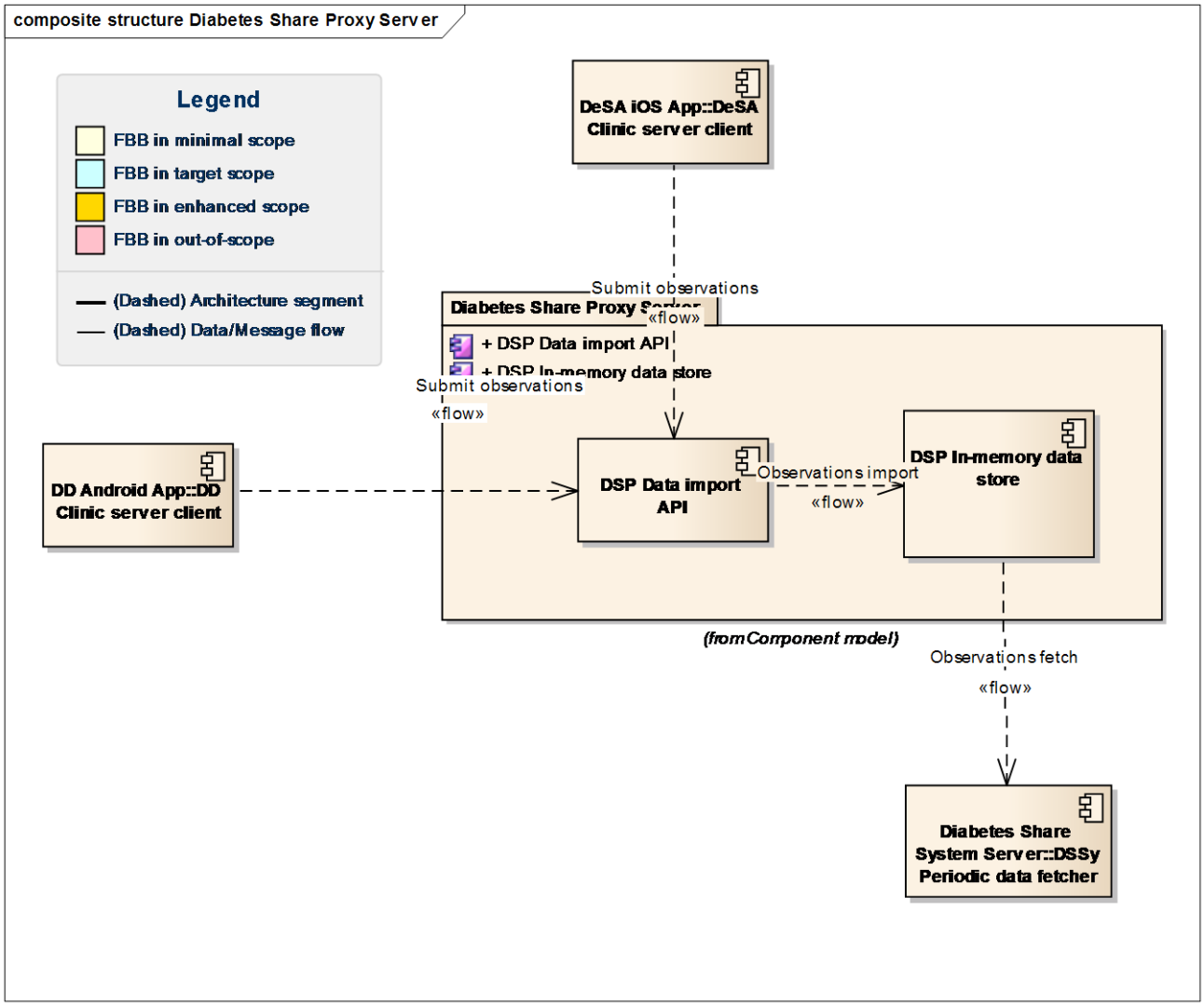


Figure 128: Server side – Diabetes Share Proxy Server functional architecture.

The Diabetes Share Proxy Server will import the submitted wellbeing and diabetes observations through the Data import API (FBB.N.39) and will store it in the In-memory (ephemeral) data store (FBB.N.38). It will allow periodic fetching of the collected observation from the periodic data fetcher (FBB.N.40) of the Diabetes Share System Server. Once the observations are fetched, the data is deleted from the memory.

14.2.2.2 Diabetes Share System (DSSy) Server

The Diabetes Share System Server will be deployed inside Hospital Secure Domain. Its main role will be to fetch and store data from the Diabetes Share Proxy Server and to submit data into the existent EHR system in production use at UNN in Tromsø.

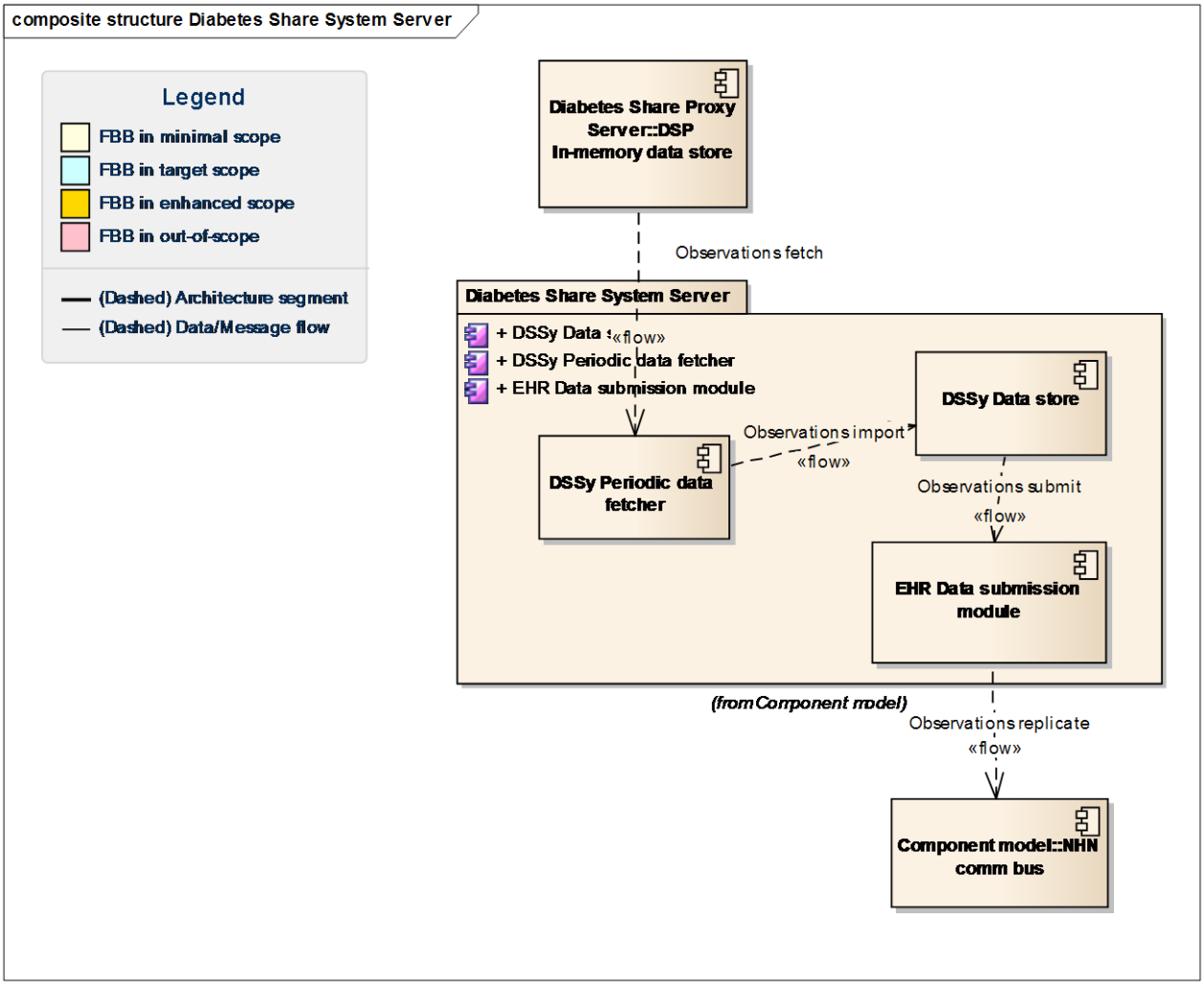


Figure 129: Server side – Diabetes Share System Server functional architecture.

The Diabetes Share System Server consists of the following main functional building blocks (FBB):

- Data storage:
  - Data store (FBB.N.41),
- APIs:
  - Periodic data fetcher (FBB.N.40),
  - EHR Data submission module (FBB.N.42).

The Periodic data fetcher (FBB.N.40) will periodically fetch observations from the In-memory (ephemeral) data store (FBB.N.38) and store them permanently in the Data store (FBB.N.41).

The Diabetes Share System Server will allow for replication of stored data in the Electronic Health Record System. Data will be transmitted from the EHR Data submission module (FBB.N.42) via the Norwegian Health Network comm bus (FBB.N.47) on request.

14.2.2.3 Diabetes Share Community (DSC) Server

The Diabetes Share Community Server will be deployed outside hospital environment. Its main role will be to collect community-related data from the DeSa iOS App and the Diabetes Diary Android App and provide information about population ranking.

The Diabetes Share Community Server consists of the following main functional building blocks (FBB):

- Data storage:

- Data store (FBB.N.44),
- Data processing:
  - Data aggregation (FBB.N.45),
- APIs:
  - Diabetes share community Import API (FBB.N.43),
  - Population ranking export API (FBB.N.46).

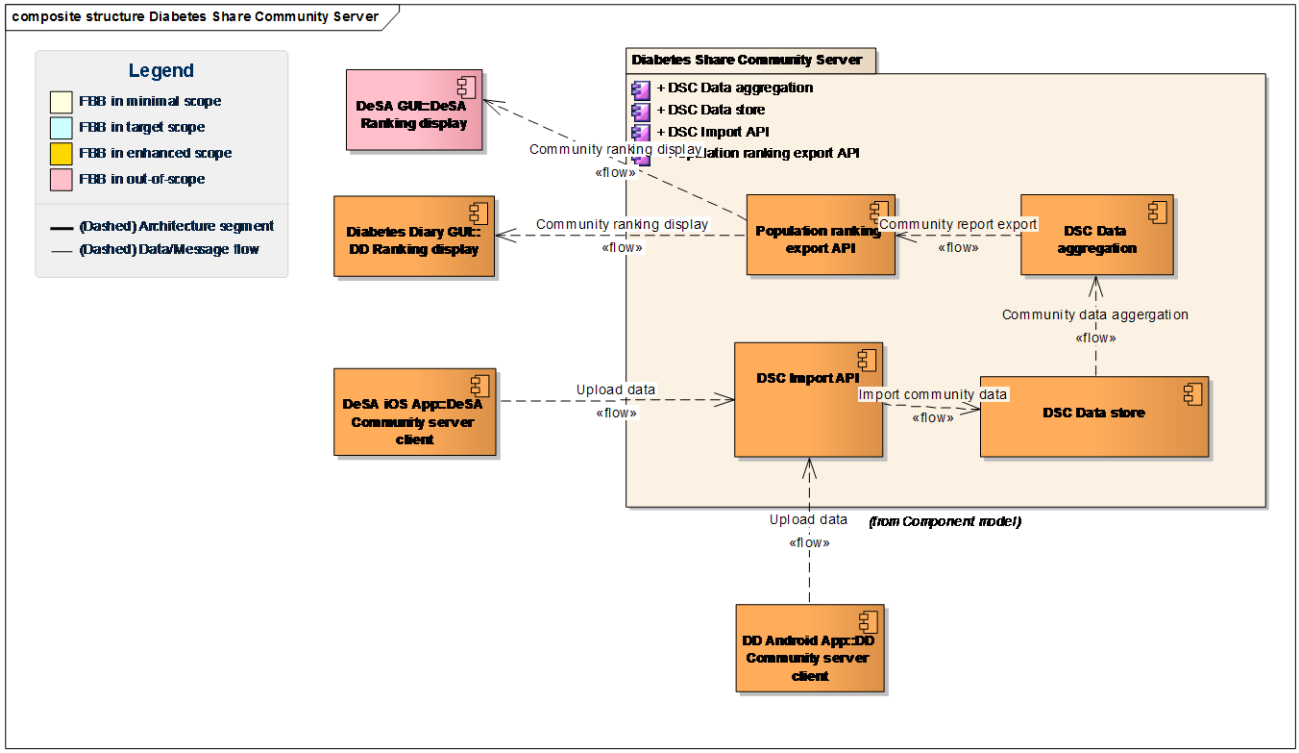


Figure 130: Server side – Diabetes Share Community Server functional architecture.

The Diabetes share community Import API will receive the submitted diabetes and wellbeing observations from the applications via the Community server client (FBB.N.14, FBB.N.27), and will store them centrally in the Data store (FBB.N.44). Data aggregation (FBB.N.45) will aggregate the received observations and provide visualizations of community rankings in the Ranking (FBB.N.19) and Ranking display (FBB.N.5) via the Population ranking export API (FBB.N.46).

14.2.2.4 Norwegian Health Network

The Norwegian Health Network is an existent infrastructure that connects IT infrastructures of medical institutions in Norway. The existent EHR system in production use at Helsenord hospital in Tromsø is connected through this network.

One available functional building block is of importance for Diabetes Share Solution, that is, NHN VC server (FBB.N.48), which is a Cisco Jabber Telepresence-based videoconferencing server.

14.2.2.5 NHN communication bus

NHN comm bus (FBB.N.49) serves as the main communication bus allowing connection to the existent EHR system in production use at UNN in Tromsø with other systems.

14.2.2.6 Electronic Health Record System

The Electronic Health Record System is an existent EHR system in production use at UNN in Tromsø.

14.2.2.7 Runkeeper public cloud

Runkeeper public cloud is an online social network of users that share progress, goals, training programs and mapped routes.

14.2.2.8 Fitbit public cloud

Fitbit public cloud is an online social network that offers users the ability to log their food, activities, weight, blood pressure, heart rate, and glucose levels to track over time. Users also have the ability to set daily and weekly goals for themselves for steps, calories burned and consumed, and distance walked.

14.3 List of Functional Building Blocks (FBB)

Table 17: Diabetes Share System – FBB to GE/SE/App modules mapping.

Funct. BB ID	Funct. BB Name	Section	Owner	Scope	Supported in[1]		Implemen-ted[2]	Tes-ted[3]
					APP	PLAT-FORM		
FBB.N.1	DeSA Visualizations	DeSA	UL	Minimal	X			Pass [REF]
FBB.N.2	DeSA Stress measurement	DeSA	UL	Target	X	[REF GE/SE]	YES	Fail [REF]
FBB.N.3	DeSA Assistant	DeSA	UL	Target				
FBB.N.4	DeSA Observations submission	DeSA	UL	Minimal				
FBB.N.5	DeSA Ranking display	DeSA	UL	Out-of-scope				
FBB.N.6	DeSA Settings and management	DeSA	UL	Minimal				
FBB.N.7	DeSA Help and About	DeSA	UL	Minimal				
FBB.N.8	DeSA Rule engine	DeSA	UL	Target				
FBB.N.9	DeSA Context detector	DeSA	UL	Extended				
FBB.N.10	Fitbit importer	DeSA	UL	Target				
FBB.N.11	DeSA Local data storage	DeSA	UL	Minimal				
FBB.N.12	Glucometer data capture	DeSA	UL	Minimal				
FBB.N.13	DeSA Clinic server client	DeSA	UL	Minimal				
FBB.N.14	DeSA Community server client	DeSA	UL	Extended				
FBB.N.15	DD Hints view	DD	UNN	Extended				
FBB.N.16	DD Observations logging	DD	UNN	Minimal				
FBB.N.17	DD Visualizations	DD	UNN	Minimal				

FBB.N.18	DD Settings and management	DD	UNN	Minimal				
FBB.N.19	DD Ranking display	DD	UNN	Extended				
FBB.N.20	DD Observations submission	DD	UNN	Minimal				
FBB.N.21	DD Help and About	DD	UNN	Minimal				
FBB.N.22	DD Rule engine	DD	UNN	Extended				
FBB.N.23	DD Context detector	DD	UNN	Extended				
FBB.N.24	Bluetooth glucometer data capture	DD	UNN	Minimal				
FBB.N.25	Runkeeper importer	DD	UNN	Minimal				
FBB.N.26	DD Local data storage	DD	UNN	Minimal				
FBB.N.27	DD Community server client	DD	UNN	Extended				
FBB.N.28	DD Clinic server client	DD	UNN	Minimal				
FBB.N.29	DD VC client	DD	UNN	Target				
FBB.N.30	DD Runkeeper physical activity app	DD	UNN	Minimal				
FBB.N.31	DD VC manager	DD	UNN	Target				
FBB.N.32	EHR browser	DD	UNN	Minimal				
FBB.N.33	VC client	DD	UNN	Target				
FBB.N.34	Bluetooth glucometer	DD	UNN	Minimal				
FBB.N.35	Runkeeper public cloud	DD	UNN	Minimal				
FBB.N.36	Fitbit public cloud	DeSA	UL	Target				
FBB.N.37	Audiojack glucometer	DeSA	UL	Minimal				
FBB.N.38	Fitbit activity tracker	DeSA	UL	Target				
FBB.N.39	Runkeeper activity tracker	DD	UNN	Minimal				
FBB.N.40	DSP In-memory data store	DSP	UNN	Minimal				
FBB.N.41	DSP Data import API	DSP	UNN	Minimal				
FBB.N.42	DSSy Periodic data fetcher	DSSy	UNN	Minimal				
FBB.N.43	DSSy Data store	DSSy	UNN	Minimal				
FBB.N.44	EHR Data submission module	DSSy	UNN	Minimal				
FBB.N.45	DSC Import API	DSC	UL	Extended				
FBB.N.46	DSC Data store	DSC	UL	Extended				

FBB.N.47	DSC Data aggregation	DSC	UL	Extended				
FBB.N.48	Population ranking export API	DSC	UL	Extended				
FBB.N.49	NHN comm bus	DSSy	UNN	Minimal				
FBB.N.50	NHN VC server	DSSy	UNN	Target				
FBB.N.51	Electronic Health Record System	DSSy	UNN	Minimal				
FBB.N.52	Runkeeper public cloud	Public cloud	UNN	Minimal				
FBB.N.53	Fitbit public cloud	Public cloud	UL	Target				

15 FI-STAR Platform Architecture

15.1 Introduction

The goal of this section is to define the FI-STAR Platform Architecture that will consists of FI-STAR applications-support-services that implement and offer “reusable business logic functionality”. This encapsulates applications-neutral functionality:

- To achieve low granularity in order to satisfy all FI-STAR use-case-scenarios
- To achieve high granularity in order to support future eHealth applications

This will developed in the view of FI-STAR architectural constraints that are describes as:

- Light-weight applications that supported by a rich-capability platform
- Robust security and privacy functionality that is complied by the e-health regulatory conformance
- Optimal usage of network resources that bring the data close to the use case site (that includes the Edge deployment of platform and application services)
- Virtualization of resources (such as cloud-based service delivery)

15.2 Overview

FI-STAR will provide mainly two assets:

- The extensible FI-STAR Platform which will support:
- The FI-STAR Reference Architecture (RA)[132] which eases the design development of FI-STAR Applications as well as FI-STAR Platform Services:
    - The design of the FI-START Platform itself
    - The design of FI-STAR Platform Service components
    - The design of FI-STAR Applications

In order to design a FI-STAR-compliant architecture and leverage the FI-STAR platform, it is important to understand that the FI-STAR Reference Architecture is, itself, an implementation of the FI-WARE reference architecture. Thus, any architectures derived from FI-STAR is compliant with FI-WARE. The FI-STAR Reference Architecture addresses the following requirements:

a) Ultra-light FI-STAR application services using generic services provided by the FI-STAR platform services
b) The FI-STAR application service providers ensure sensitive data-protection and data-governance (access to sensitive data) and regulatory reporting and auditing compliance to the ethical-legal regulations
c) The FI-STAR application service providers will monitor key parameters in order to manage their Service Level Agreements (SLAs)
d) The FI-STAR platform services providers will monitor key parameters in order to manage the QoS, availability and security of their platform services
e) The FI-STAR platform services will be implemented by making extensive use of the FI-WARE Generic Enablers (GEs)
f) The FI-STAR services (application and platform) will be deployed in the same nodes that will store the service-specific data (software to data paradigm)
g) The FI-STAR services will be delivered using Cloud technology and will be deployed as near as possible to the end-user access network (Edge Cloud)

[132] In the FI-WARE project the adjective “reference” is not used while technically it can be defined so according to the definition provided in Qin, Z., Xing, J., and Zheng, X., Software Architecture, Springer, 2008

h) Before deployment and distribution, the FI-STAR services (applications and platform) will be subject to a FI-STAR certification programme supported by the FI-STAR certification services

The overarching concept of FI-STAR is the user centricity. The FI-STAR platform design also adopts this approach and isbased on the requirements elicited from all stakeholder and user categories involved in the FI-STAR experimentation-sites / use-case-scenarios in order to solve specific problems of the eHealth domain and make value propositions to the end-user. As such, FI-STAR is a technology-pull project aiming at social-technology alignment (not a technology-push project).

Figure 131 shows the overview of the FI-STAR Platform Architecture, including its relation with the FI-WARE architecture. It is important to note though that, from the point of view of the end-user, no knowledge of the FI-WARE architecture or Generic Enablers is required.

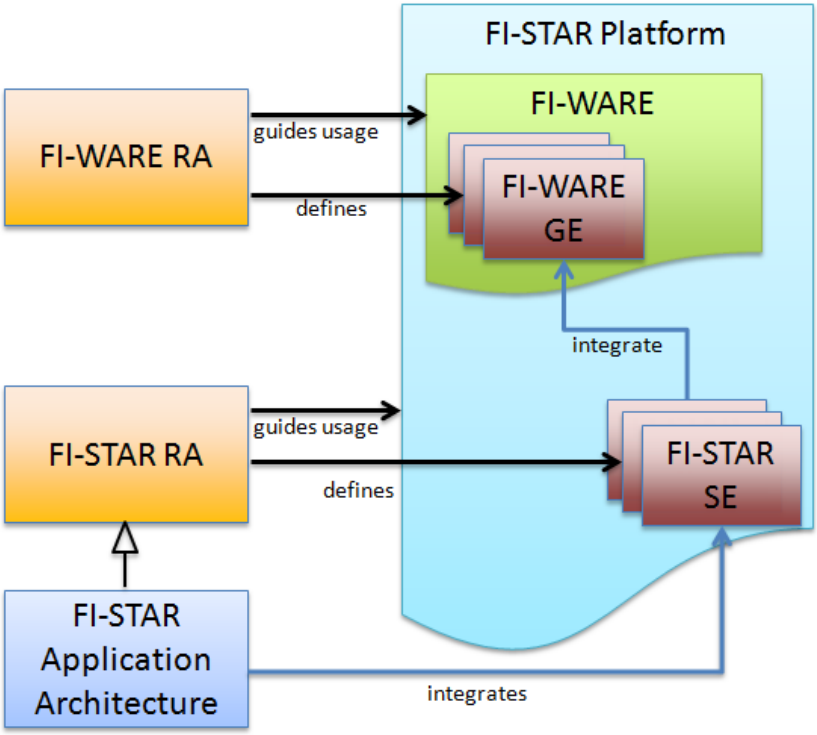


Figure 131: Overview of the FI-STAR Platform Architecture, including relation with the FI-WARE archiecture

15.3 FI-STAR Reference Architecture

In order to design the FI-STAR Platform Architecture, FI-STAR started out by designing the FI-STAR RA. This was done by identifying commonalities in application requirements and features across FI-STAR Use Cases.

The high level commonalities were used to identify reusable architectural components, i.e. FI-STAR Platform components called FI-STAR Specific Enablers (SEs). These aim of these components is their reuse across all FI-STAR Use Cases and potentially in many eHealth applications.

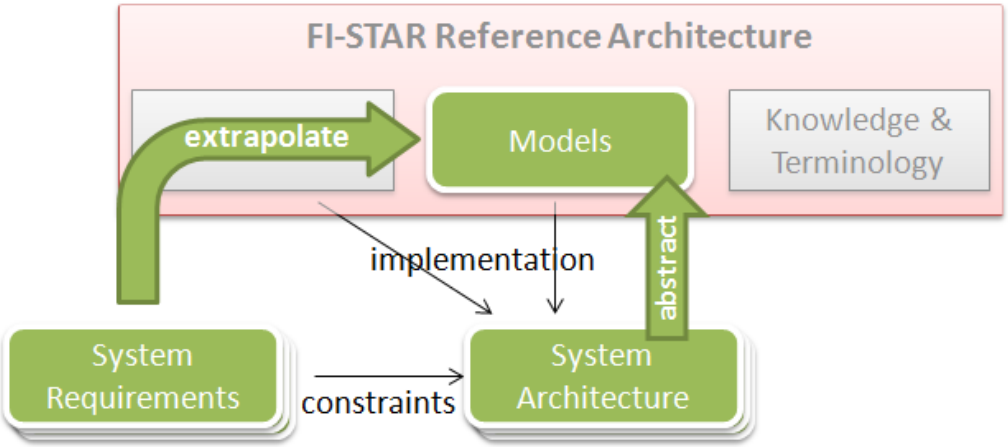


Figure 132: The process of designing the Fi-STAR Reference Architecture

On the other hand, the specification of the SEs has been included in the FI-STAR RA as architectural template for these components and they will be used in the models that are included in the FI-STAR RA. These models have been based on the abstraction of architectural commonalities from the FI-STAR Use Cases. Finally, guidelines (and best practices) for designing all components will be provided

A reference architecture, by definition, models the abstract architectural elements common to all the (successful) solutions in a given domain, identifying invariant architectural aspects or patterns and abstracting from specific technological aspects. A reference architecture also includes a terminology that can be used to discuss architectural aspects and guidelines for the implementation of the reference architecture into a concrete architecture.

By leveraging a reference architecture in the architecture design process, cost and time for discussing about the design of basic functions or components is saved, thus reducing time-to-market, allowing focus on more relevant aspects and generally increasing the competitiveness of the design process.

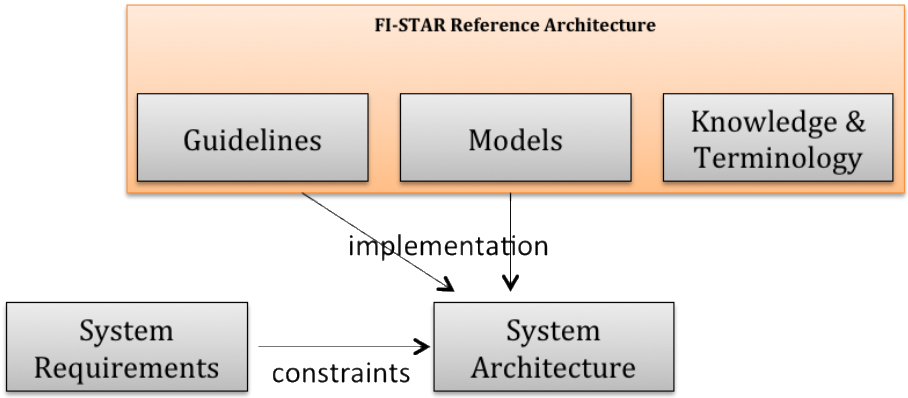


Figure 133: Overview of the implementation of the FI-STAR RA into a concrete architecture

From a FI-STAR-users point of view, in order to take advantage of the FI-STAR Platform, some key steps of the architecture design process must leverage the FI-STAR Reference Architecture and take into account FI-STAR-specific changes. These steps can regard all the Views that could be used to analyse the application to be designed.

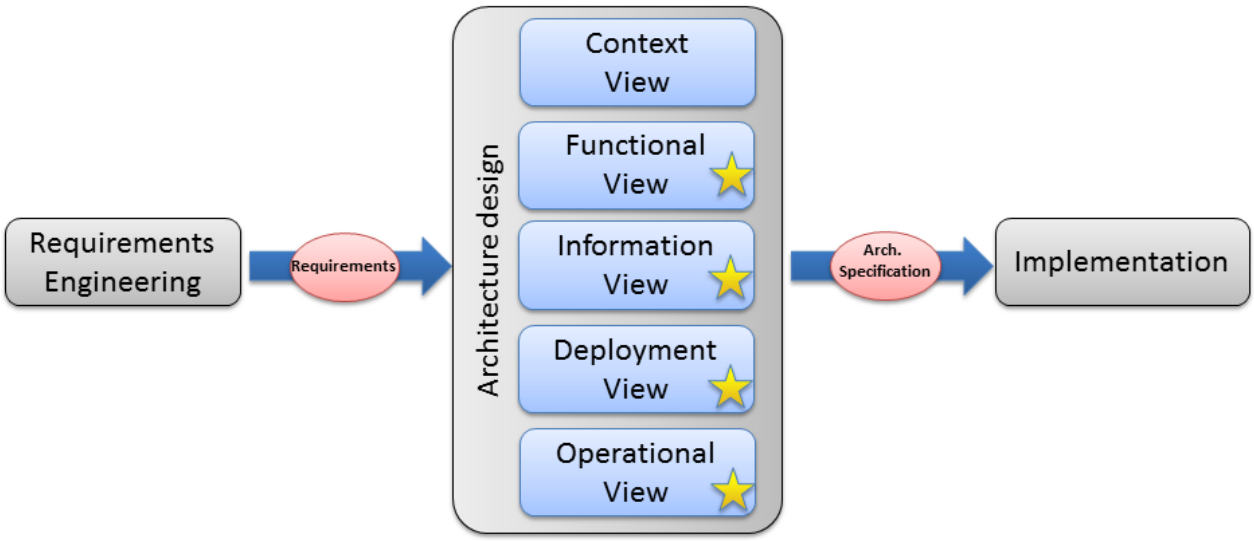


Figure 134: Some architectural views that could be affected (marked with a star) when using the FI-STAR RA in the design process of FI-STAR Platform Services or FI-STAR Applications. The same views may be affected on the abstraction level of the requirements as well as technology may offer interesting, but previously little understood opportunities.

In particular, models such as (but not limited to) the Functional Model, the Information Model (Data and Service Model), Deployment Model and the Security Model can be adjusted in order to take advantage of the features offered by the FI-STAR platform.

15.4 The FI-STAR Platform Architecture

This section demonstrates the FI-STAR platform architecture. The FI-STAR Platform consists of the following architecture design decisions:

a) Security Framework: This includes three different dimensions as follows:
   a. Dimension 1 - ISO 7498-2:Security Services (user), Security Mechanisms (security services, e.g. digital signature), Security Objects (on which the security mechanisms act upon for example cryptographic keys)
   b. Dimension 2 - Rights System: Role-based (data processing) and Identity-based (data authority)
   c. Dimension 3 – Technology Specific Patterns: Security mechanisms for different Communication Patterns (machine to machine (off-line), M2Service (on-line), Webservice (actor anonymization)

b) Distributed processing: FI-STAR is implemented as a distributed system. It consists of a number of loosely coupled services that do not use common data storage and thus communicate over messages among. Primary systems, Connector Service, Broker Service and Business Services are coordinating the Data Writing in their own contexts. Context defines linking of the Unit of work with its Work Steps, Messages and the Resources.

c) Component Model: FI-STAR includes a set of key components that are organized in the Application Architecture, Security Architecture, Common Platform Services and these are associated with Administration, Monitoring and platform services as shown in Figure 135.

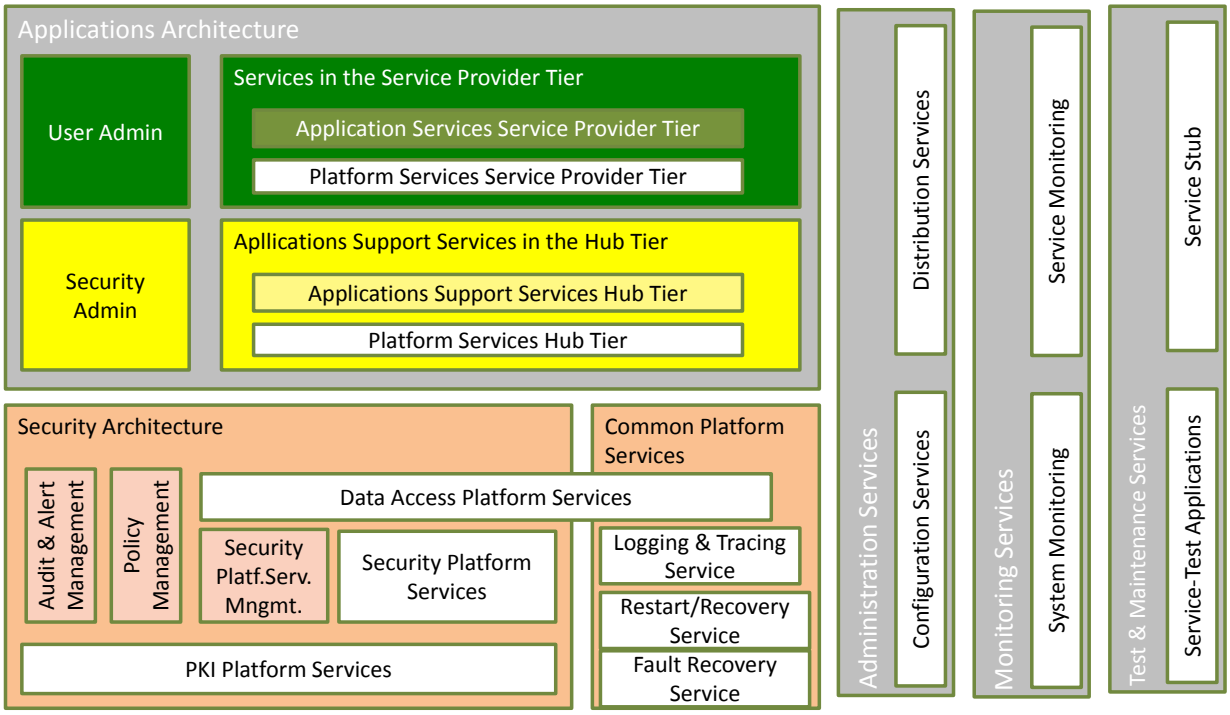


Figure 135: The Architecture design Component Model

d) FI-STAR Applications Support services called FI-STAR Specific Enablers (SEs) that will be implemented by making extensive use of FI-WARE GEs shown in Figure 136. The FI-STAR SEs are identified and specified by undertaking an analysis of all 7 use-case-scenario applications and by "abstracting" from these a set of services that support all 7 use-case-scenarios-applications. The FI-STAR Application Services together with the FI-STAR Platform Services and the physical computing, storage, networking, sensor resources and card-terminals they are deployed on build the FI-STAR Infrastructure. After having implemented the FI-STAR Platform, the application developers participating to the FI-STAR Open Call will be concerned only with the development of the GUI and of the business logic needed to orchestrate and configure the FI-STAR platform-services. This has a positive effect on the development costs and time for new applications.

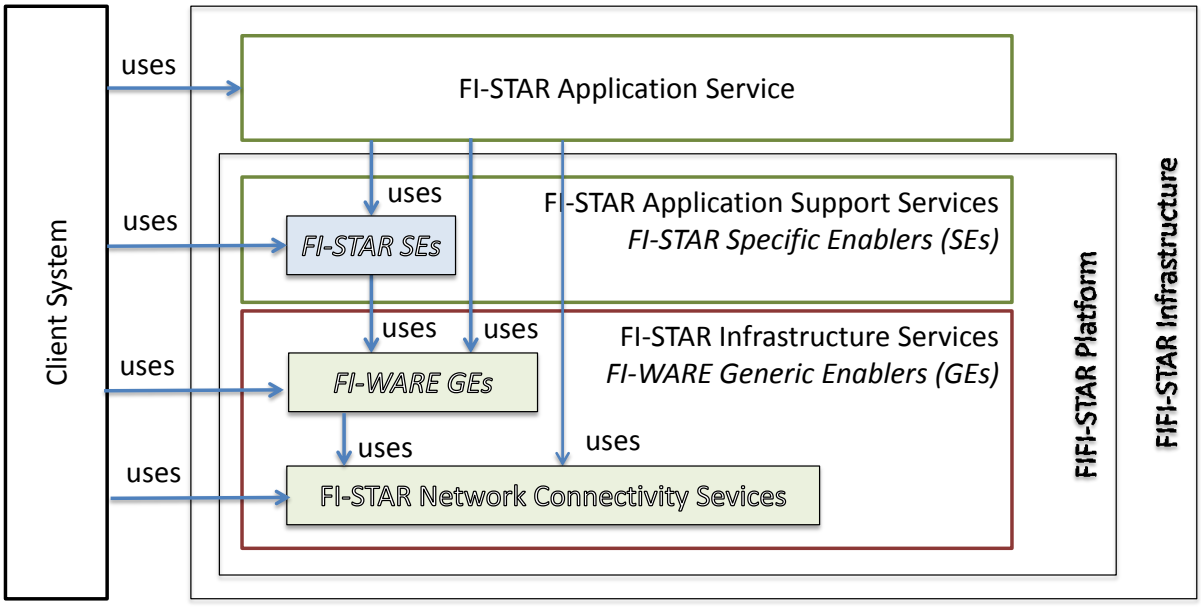


Figure 136: FI-STAR Applications Support services category view (FI-STAR Specific Enablers)

The next list demonstrates the application support services categories:

- Client system is a logical representation for local systems, that interact as clients with the FI-STAR Infrastructure but they are not seen as part of the FI-STAR Infrastructure (e.g. a hospital information system, a GP system, E-Mail-Clients). With this denotation we summarise both hardware and software components.
- FI-STAR Application Service lies under responsibility of the FI-STAR Application belongs to the FI-STAR Infrastructure and uses the FI-STAR SEs, FI-WARE GEs and FI-STAR Network Connectivity services of the FI-STAR Platform.
- FI-STAR Application Module is a decentralised part of the FI-STAR Application inside the FI-STAR Infrastructure with a secure connection to the FI-STAR Platform that uses the Interface- and Workflow definitions of the FI-STAR Platform. A FI-STAR Application can be deployed on a fixed or mobile product type.

The Client system, FI-STAR Application Service, FI-STAR Application Service Module and FI-STAR Platform Services are the FI-STAR technical roles. Besides these we identify also so-called FI-STAR operational roles:

- FI-STAR Application Service Provider is the provider of a FI-STAR Application Service in the FI-STAR Infrastructure
- FI-STAR Platform Service Provider is the provider of a FI-STAR Platform Service in the FI-STAR Platform
- FI-STAR Administrator is a professional involved in the building and operation of the FI-STAR Infrastructure and of the available primary front-end systems (e.g. a hospital information system, a GP system , a pharmacist system) and of the available back-end systems (legacy systems like e.g. EHR)

We distinguish between:

- Administrator of an organisation of the health sector, and
- Administrator of a FI-STAR Platform Service
- FI-STAR Card Issuer is the issuer of the cards used by the patients and healthcare professionals to access the FI-STAR Application Services and by the FI-STAR Applications to store and retrieve specific application data.
- FI-STAR Manufacturer is responsible for the development of product types of the FI-STAR Infrastructure

Finally, we identify the following FI-STAR business roles:

- FI-STAR Insured is a natural person (e.g. patient, family member) who received a FI-STAR Card or another means of access to FI-STAR Application Services from the FI-STAR Service Insurer.
- FI-STAR Healthcare Provider is a natural person who belongs to the circle of healthcare-service provider persons (e.g. GP, clinician, psychotherapist, nurse, pharmacist) and provides his professional services to the FI-STAR Insured
- FI-STAR Service Insurer is a health-insurance organisation who pays for the services provided by the FI-STAR Healthcare Provider

Based on the requirements available from T1.1 (described in the Tromso use case) we can foresee the partitioning of the FI-STAR Infrastructure in 4 logical architecture Zones / Tiers - Each zone is related to different deployment and security requirements (see Figure 137)

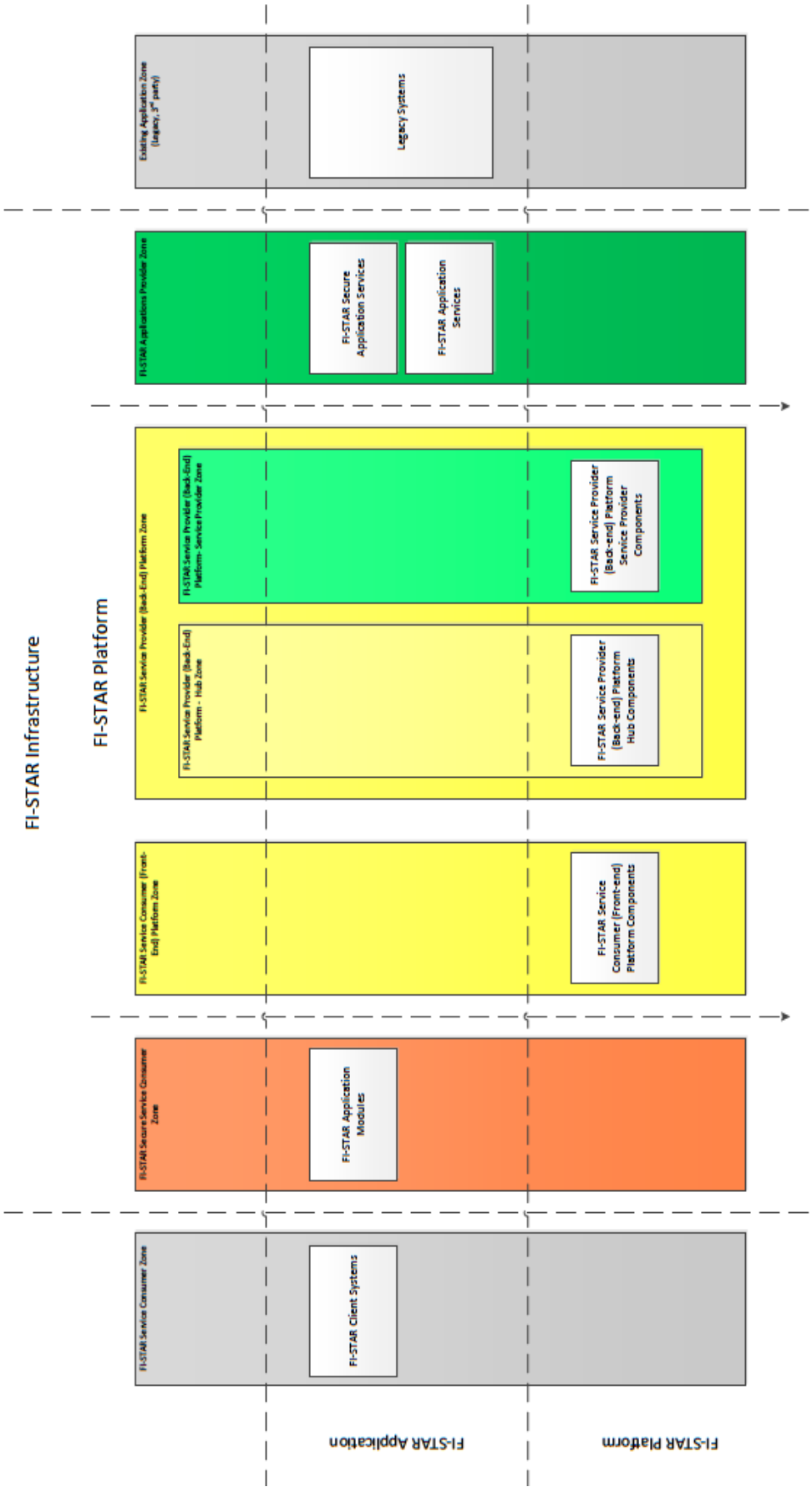


Figure 137: FI-STAR Logical Architecture Zones / Tiers

Based on the requirements available from T1.1 we can foresee the implementation of the SOA Intermediary Interaction Style – The FI-STAR Service Provider (Back-End) Platform Hub Zone. The The FI-STAR Service Provider (Back-End) Platform Hub Zone provides the following advantages:

- Localisation and Technology Transparency for both Service Consumer and Service Provider
- Anchor point for Privacy Services (Anonymisation or Pseudonymisation) for the Service Consumer towards the Service Provider
- Central Anchor points for SOA Services like Management, Security, Integration, Discovery and in the future Orchestration and Transformation
- Central Anchor points for Service Monitoring
- Anchor point for security Perimeter borders.
- Decoupling of Service Providers and Service Consumers, and hence decoupling from the changes in implementations
- Implementation of the Request / Response Communication pattern for intermediary communication
- Publish / Subscribe and Store / Forward considered too if required

Based on the use-case-scenario provided by T1.1 we can vision also a first set of relevant FI-STAR Specific Enablers that will be part of the FI-STAR Service Provider (Back-End) Platform (see Figure 138). In detail, the architecture follows a consumer to provider platform by separating front-end and back-end features.

- The back-end offers the standard core operations for service management and hosting (e.g. cloud hosting, event processing and management, mediation and data services, messaging, storage etc.).
- The front-end is the human user along with the Internet of Things (IoT) devices and accessibility interfaces (e.g. sensors and GUI). The network service provider relies on both front-end and back-end using appropriate software enablers to achieve communication and inter-operation. The deployment strategy planned to be adaptive and flexible as the use case scenarios will configure the back-end space according to their eligibility requirements.

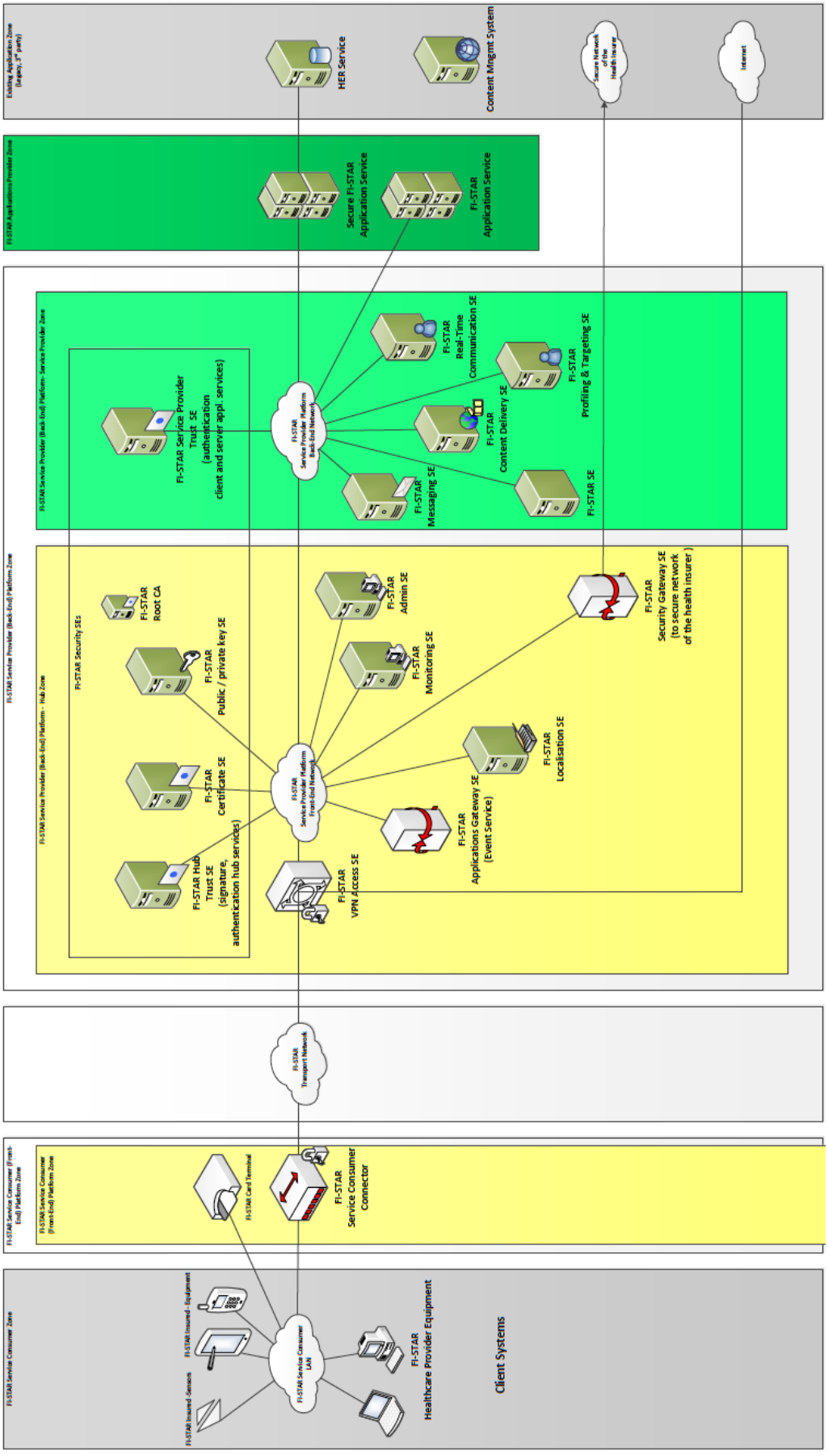


Figure 138: FI-STAR Infrastructure

The architectural constraints of the use case follows the FI-STAR architecture ecosystem based on a) the FI-WARE roadmap and b) the use case visions and descriptions from the visionary documents. The FI-STAR architecture will be generic and adaptive and will include Generic Enablers (GEs) and Specific Enablers (SEs) to integrate the operative environment. The APIs will be able to communicate based on an event-driven front-back-end approach with use case scenario application services and 3rd party legacy system. These are organized in various zones as demonstrated in Figure 138. The FI-STAR event-driven architecture includes the following zones.

- FI-STAR Service Consumer Zone: The service consumer network/devices
- FI-STAR Service Consumer Platform (Front-end) Zone: The connectivity mediator among consumer and provider.
- FI-STAR Transport Network: The physical network to the Back-end
- FI-STAR Service Provider (Back-end) Zone: This includes
    - FI-STAR Service Provider (Back-end) Platform-Hub Zone: Including authentication, security, localization, monitoring, administration, event service management, application gateway and VPN access services.
    - FI-STAR Service Provider (Back-end) Platform Zone: Including trust management, messaging, content delivery, communication and profiling services.
- FI-STAR Application Provider Zone: The Application services.
- Existing Application Zone: The Legacy system and services.

At last, the architecture of the Use Case follows the components of Figure 139. The Service Consumer Tier links to the Hub tier through a gateway. The Hub tier drives connectivity to the hub tier central that offers the key services. The provider adapter is the link to the service provider tier that includes the UC services, SEs and GEs. The legacy system is considered as an extension of the Use case services.

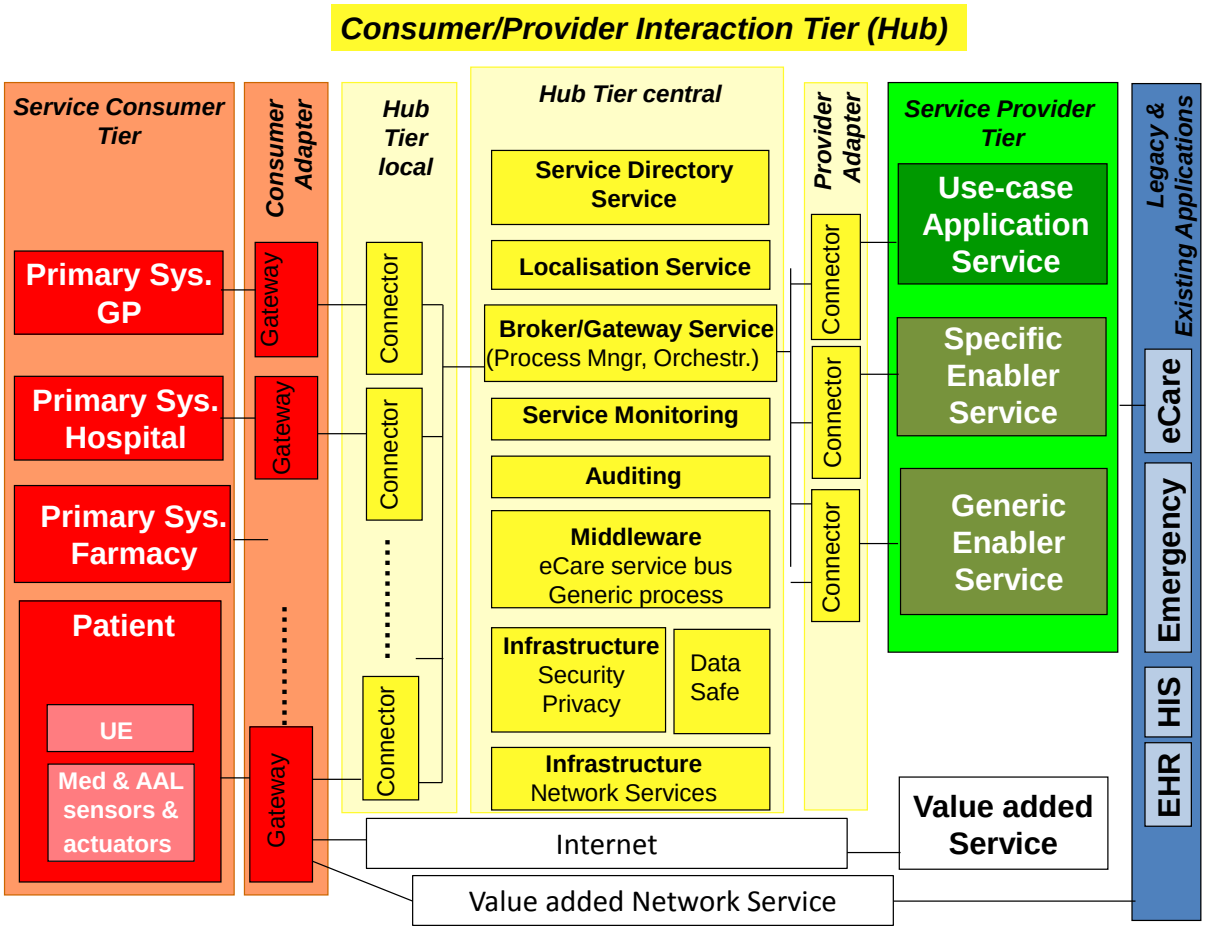


Figure 139: FI-STAR Use case Infrastructure

16 Selection and Usage of Generic Enablers GE

One of the key issues of the usability and dissemination of Generic Enablers is the standardization of the selection process. It is the declared objective of FI-STAR to use and validate FI-WARE Generic Enabler wherever possible, hence one of the tasks under D 1.1 was the establishment of recommendations towards the selection process of Generic Enablers (GEs) in FI-STAR use-case scenarios.

16.1 Progress and Plans

However, there have been problems with the specification and the availability of FI-WARE GEs, which have not been concluded yet. A high level description of GEs is available on the FI-WARE WIKI pages. These descriptions only support a very high level decision making process as detailed selection criteria based on specific technical requirements are not available in most cases. On the other hand there are generic high-level specifications available, which cannot be regarded as hard deterministic criteria.

By September 2013 only a few simplistic Generic Enablers have been made available to the public. There was no way to examine a sufficient number of relevant GEs in order to establish a structured approach towards differentiation and selection.

At the Campus Party Event in London in September 2013 a developer platform was introduced which will allow experts and developers to experiment with Generic Enablers and learn more about their capabilities and features. It remains to be seen what conclusions can be taken from this over the next months.

As part of deliverable D 1.1 projects have formulated their needs and demands and their functional and non-functional requirements. However, this alone is not sufficient to choose GEs or to establish any algorithm to serve as a blueprint for a selection process. Once more information will be available on the Generic Enabler FI-STAR will revisit the issue and hopefully will make rapid progress. Ideally Generic Enablers would be made available for download and experimentation but currently no dates for such a release have been announced.

SECTION IV – Completion of Project Scope

The FI-STAR open call has the objective of completing the FI-STAR project scope. The following chapter describes the technical requirements, eligibility requirements, and evaluation criteria for stated in the open call.

Chapter 17: Open Call Requirements

17 Open Call Requirements

17.1 Objectives of the open call

FI-STAR has dedicated an amount of its budget to invite local solution providers and system integrators to get involved in the project and deliver innovative technology for the benefit of its experimentation sites and the FI-PPP programme as a whole.

The objective of FI-STAR with this open call is to proactively prepare for Phase III of the FI-PPP programme[133] by soliciting additional partners to undertake specific tasks for increasing the value of the FI-STAR platform. The objectives fall into three categories:

1. Strengthen the technology basis of the FI-STAR platform by adding functionality that is currently not foreseen but which will provide significant added value to the existing experimentation sites and use case scenarios of FI-STAR[134].
2. To attract developers to deliver innovative applications or value added services, among others for the existing experimentation nodes, using the FI-STAR platform including the generic enablers and specific enablers that comprise this platform.
3. To strengthen the reach to the stakeholders of the sector by additional dissemination mechanisms

17.1.1 Technical requirements

Several areas have been identified as areas for providing added value for the FI-STAR platform and community and are organised according to the above categories

17.1.1.1 Category 1: Strengthen the technology basis

The following list presents services and functionalities that have been identified as being highly desirable to complete the service offering of the FI-STAR project in particular for the target sector of health care and in more generally the context of phase III of the FI-PPP programme in general.

The list below is not presenting a particular order or priority. Furthermore the list should not be considered exhaustive. Proposals that are strengthening the technology basis of FI-STAR in other, well presented, ways are equally welcome.

Minimum 3 proposals will be accepted in this category

Marketplace and deployment tool

For the purpose of discovering offered services and applications, as well as for automated deployment of FI-STAR platform services, a marketplace functionality with associated tools should be provided:

- Implementation of a marketplace component that offers catalogue and discovery functionality for software components
- Implementation of brokerage services and associated tools to browse, identify and provision the most suitable software components based on selection criteria for offered software components
- Implementation of minimal client-side functionality that is able to execute provisioning requests from the marketplace component
- Support the orchestration of multiple deployments on several clients with scalable properties

[133] http://cordis.europa.eu/fp7/ict/netinnovation/docs/wp2011-13.pdf

[134] https://www.fi-star.eu/use-cases.html

- Optionally, support version management of offered software components in the marketplace

Geo-fencing specific enabler

A geofencing enabler will allow the implementation of location-aware services and applications. The health sector knows many privacy, data management, good tracking, and patient monitoring services that critically depend on health sector specific location-awareness implementations.

This level of location-awareness will be provided by the geofencing specific enabler to be developed.

- Definition of health sector specific requirements on location-awareness
- Development of a geofencing enabler for typical health environments as hospitals
- Evaluation and demonstration of the enabler by integration in FI-STAR services

Reminder services for patients

Reminder services and devices for patients are necessary in several scenarios, like following the medication prescription instructions, do their physical exercise, follow special treatment schedules, etc. Such devices and service can be connected to health care stakeholder organisations that can monitor the treatment and progress of high risk patients remotely. Such devices should be minimally invasive and easy to use, yet interface with the FI-STAR platform backend services in a seamless way. Related concrete topics are:

- embedded architectures for remote user information management
- use-cases for smart appliances supporting remote monitoring over the Internet
- cloud services for appliances management

Real-time processing of patient data

In order to enable proactive reaction on health related problems a solution should be provided that can operate on patient data that are sensed and processed in real-time. The solution should potentially be supported by domain ontology and semantic technologies that allow fast mapping of events and ensure interoperability.

Among others, the capabilities that should be developed could be used to build early warning and decision making tools to automate the decision making process in health care, wellness and ambient assisted living.

17.1.1.2 Category 2: Innovative applications and value added services

The following list provides examples of applications and value added services that could complement the service offering of the FI-STAR project in particular for the target sector of health care and more generally in the context of phase III of the FI-PPP programme in general.

The list below is not presenting a particular order or priority. Furthermore the list should not be considered exhaustive. Proposals that are presenting additional value added services using the FI-STAR platform and the FI-PPP generic enablers are equally welcome.

Maximum 3 proposals will be accepted in this category

Work-flow engine for accounting purposes

For accounting purposes and other standardized processes involving actors being distributed over a number of remote locations, a web-based Workflow Application with the following core features should be provided:

- Definition and execution of workflows
- Development environment for the rapid implementation of the particular workflow tasks
- Self-explaining user interface for the execution of the work flow tasks even by unskilled end users

- Administrator user interface for monitoring the workflow states, starting, ending and resetting of the workflow instances as well as assigning workflow tasks to particular users and user groups
- History keeping of user actions and data capturing for auditing purposes
- Utilization of the FI-STAR cloud infrastructure to the maximum extend

Pseudonymization of users

Pseudonymization is a method by which the user adopts a new fake identity provided by a trusted and secure component. This identity is called pseudonym and includes all features and credentials needed by the existing Identity Management generic enabler. A pseudonymization specific enabler should:

- Preserve context coherence without allowing third parties to trace back the association to the user himself
- Preserve the non-repudiation security requirement allowing authorized parties to resolve the association between the pseudonym and the real identity.
- Implement secure logging and monitoring of all access to personal data.

Emotion recognition

Design and implement an emotion recognition solution that allows the collection of evidence concerning the emotional state of the patient. Optionally the solution should provide a prototype for system reactions (treatment purposes), for example based on neuro-feedback concepts.

Motion processing

Design and implement a solution that enables the utilisation of motion recognition devices for medical purposes in a generic manner. Non-exhaustive examples include support for end-user devices like the Microsoft Kinect or motion sensors and accelerometers in modern Android based smartphones, or the M7 co-processor in recent Apple iPhone smartphones.

GS1 Enabler

Design and implement a specific enabler to simplify the management of barcodes and radio frequency (RF) based identifiers supporting ad hoc interoperability with devices including Android, Windows and IOS based devices. While consideration of the GS1 standard is mandatory due to its use in health care in some European countries, for example the UK, proposers might consider additional existing standards for barcodes and RF based identifiers. The newly created enabler should not only be restricted to linear barcodes but should in particular enable the recognition of 2D barcodes and should endorse work done by the European Commission and the European Pharmaceutical Industry with a view towards serialization of pharmaceuticals and medical consumables.

Electronic Health Record (EHR) connector

Electronic Health Records (EHRs) are in widespread use today. Since several years several vendors are implementing personal and electronic health record systems. The continuous trend towards multi-institutional health networks may also pave the way for standards-based interfaces for accessing and managing EHRs. In the context of FI-STAR a solution should be provided that seamlessly connects to systems that store such records in standards based formats, and makes them available as a service of the FI-STAR platform adhering to the FI-PPP Generic and Specific enabler concepts. The work should cover insertion and retrieval of EHR conforming to legal requirements in Europe and enabling innovative business models for new stakeholders. Any solution should endorse the work so far completed under the epSOS project (www.epsos.eu). The focus hereby would be the use of the prospective specific enabler in order to integrate summary records created on the basis of epSOS rules into EHRs of organisations which have not yet subscribed to epSOS and which would otherwise not be able to integrate the epSOS records seamlessly.

17.1.1.3 Category 3: Strengthen the reach to stakeholders

Maximum 1 proposal will be accepted in this category

Dissemination – extension of TV/broadcast presence

For the purpose of increasing the dissemination potential of the project, this call is seeking a broadcast partner to disseminate FI-STAR generated content to television audiences.

The dissemination work in the project creates new content covering use cases, applications, cloud, data and internet technologies, creating the basis to gather and create content for TV audiences.

The objectives of the tasks of the additional participant are:

- To pilot and transmit a television programme about the FI-STAR and the Future Internet programme of innovative healthcare solutions for the elderly. Such a programme shall address the EU-wide issue of medical care for the aging population across Europe.
- Along with a TV pilot the broadcaster should be interested in a parallel, integrated Future Internet platform to enable further viewers and user participation.
- To pilot such a TV concept with a view to develop an integrated TV / multiplatform series based on future digital healthcare solutions.

FI-STAR partners include experienced TV and multiplatform producers and can provide content and concepts according to broadcast standards. The additional partner (broadcaster) will work very closely with the respective team in the project.

As the FI-STAR embraces many EU communities the call is addressed preferably to EU broadcasters.

17.2 Eligibility Requirements and Evaluation Criteria

The proposal must be submitted by an organisation that is an established legal entity and which can join forces with up to one further organisation to form a consortium of two organisations. The proposing organisations must be eligible for participation in the EC Framework Programme 7 (FP7). Information about eligibility criteria for participation and further information can be found at http://ec.europa.eu/research/participants/portal. Proposing organisations must be entities not part of the existing project consortium.

The proposal must state precise costs for the execution of the proposed work in terms of personnel and other costs following the financial rules for EC FP7 projects (http://ec.europa.eu/research/participants/portal). The maximum EC contribution for individual proposals is set at 180,000 € per proposal.

Following the selection of the proposals that should join the project, an updated resource and project plan will be developed through negotiations between the proposing organisations, the project coordinator the project Board, and in consent with the EC Project Officer. Successful negotiations with additional partners (maximum 2 partners per proposal) will lead to an amendment to the project Grant Agreement.

In the context of this call, proposals that are driven by industry or are defined in close collaboration with industry are preferred. It is necessary that the proposals present a detailed expect business impact of their work in the context of the FI-STAR project and the FI-PPP programme.

The additional beneficiaries will receive an EU contribution in accordance with the standard FP7 payment rules: covering 50 or 75% of eligible costs, depending on the type of organisation, and considering direct and indirect costs.

17.2.1 Category 1 and 2

Proposals falling in category 1 (Strengthen the technology basis) and category 2 (Innovative applications and value added services) have to demonstrate technological expertise, scientific novelty and quality. The proposed work must be undertaken using to the maximum extent possible

to services of the FI-STAR platform that are based on the FI-WARE Generic Enablers. Only in exceptional and well justified cases the use of other technologies is acceptable. If such a case arises, the proposal must present a detailed integration plan with the FI-PPP technology. The proposers are expected to pursue an appropriate level of knowledge dissemination (e.g. in international publications and FI-PPP related events) and potentially contribute to the planning of such activities by the consortium and the FI-PPP programme.

The proposals will be evaluated by independent experts, who will be briefed by the consortium about the selection criteria. Selection criteria will include:

- industrial relevance,
- degree of innovation,
- scientific excellence,
- fulfilment of one or more technical requirements,
- qualifications of the organisations performing the work,
- expected impact for the FI-STAR project,
- commitment to the long term vision of the FI-PPP programme,
- consideration of socio-economic and other relevant non-technical aspects

17.2.2 Category 3

Proposals falling in category 3 (Strengthen the reach to stakeholders) have to present an innovative concept and expertise to perform the proposed work and achieve the objective of a wide reach to the FI-STAR stakeholders. Proposals in this category are exempted from the requirements to use the FI-STAR platform and the FI-WARE Generic Enablers. The proposers are expected to support knowledge dissemination (e.g. in FI-PPP related events) and potentially contribute to the planning of such activities by the consortium and the FI-PPP programme.

The proposals falling in category 3 (Strengthen the reach to stakeholders) will be evaluated by independent experts, who will be briefed by the consortium about the selection criteria. Selection criteria for category 3 proposals will include:

- fulfilment of the technical requirements,
- degree of innovation of dissemination concept,
- potential reach to stakeholders,
- qualifications of the organisations performing the work,
- expected impact for the FI-STAR project,
- commitment to the long term vision of the FI-PPP programme,
- consideration of socio-economic and other relevant non-technical aspects

Detailed information about the open call and its aspects can be retrieved online at http://www.fi-star.eu/open-call/ including:

- Call announcement
- General Information and Requirements
- Guide for applicants
- Frequently asked questions

SECTION V – Roll-Out of FI-STAR Technology

The following chapters describe current status and plan for roll-out of FI-STAR technology. These include the stakeholder board and the open community. Excluded are the digital dissemination activities, which are reported as part of WP8 deliverables.

Chapter 18: Stakeholder Board

Chapter 19: Open Community

18 Stakeholder Board

A stakeholder is any group or individual who can affect, or is affected by, the achievement of a corporation's purpose. The group will meet 6-8 times during the project.

FI-STAR will be forming a stakeholder board:

- To maximize the chances to achieve the aims and objectives and to anticipate any changing external conditions, which are relevant to the project's purpose.
- It is assumed that the interests of stakeholders and the interests of FI-STAR project partners are joint and that to create value, one must focus on how value gets created for each and every stakeholder.
- Impact maximisation is achieved if needs and requirements of stakeholders are known and value for stakeholder can be created.

Stakeholder representatives are experienced professionals who can oversee relevant markets and can comment on recent developments and future trends. The stakeholder board is an informal body and individual members are expected to communicate openly and freely. They will not be held responsible or liable for any input they give or comments they make in their capacity as stakeholder representatives. Stakeholder board members are free to give their own personal opinions, which may differ from the views of the organizations they represent. The comments made in stakeholder board meetings will be treated as confidential.

19 Open Community

19.1 Introduction

WP 7 Community Building has the objective to build and support the community of stakeholders external to the FISTAR project. The community is an important asset to the requirement specification process serving multiple purposes.

- The community of solution providers are the ultimate consumer of the FISTAR technology developed by the project. Access to the solution providers is thus essential to ensure dissemination and adoption of the technology.
- The community of solution providers and solutions they provide to the market today and in the future must ultimately be supported by the technology developed by the FISTAR project for the solution providers to adopt the FISTAR technology. Consequently, the solution providers are a key source of validation current and future requirements.
- The solution providers' clients – the health care providers - are the ultimate source of demand for the solution and products of the solution providers. The demand for services based on the FISTAR technology thus ultimately rests on motivating the demand for these services at the health care providers. The requirements are thus ultimately set by the challenges the solutions need to solve at the health care providers.

The Future Internet program is aimed to develop and diffuse a new European information technology infrastructure to strategies industries in Europe. In this context, the FISTAR project addresses the health care industry.

19.2 The Open Community

The successful delivery of the FISTAR project depends on the building and engagement of key stakeholders in the European health industry. As health care spans across the entire European society, the stakeholders are many and diverse, spanning from public organizations across industry to citizens. However, at the core of the future transactions on the future internet technology infrastructure stands the markets that will ultimately consume and deliver the health care solutions making use of the generic (GE) and specific (SE) enablers. In the end, the successful commercialization and market uptake of the technologies is the key parameter determining their success and long-term sustainability. Consequently, the key stakeholders in focus of the FISTAR community building activities are these two stakeholders groups: the health care providers and the solution providers.

The health care providers are public and private organizations providing health care to citizens. These organizations are e.g. hospitals, clinics or tertiary caregivers, typically organized under regional authorities, hospital chains, national insurance companies or other large-scale procurement organizations. Their delivery processes can ultimately benefit from the future internet technologies to become for efficient, effective or deliver new services.

The solution providers are private companies of different sizes developing and delivering services, products, infrastructure or technologies to e.g. hospitals or clinic, which are procured by e.g. regional authorities through reimbursement schemes, tenders and / or framework contracts. Solution providers are often either medical device companies or information technology companies developing combinations of technology, devices, software and services.

The basic premise for building a community of professional organizations and ensuring that attention and participation is a high priority item is to ensure that the community solves concrete needs for the participating stakeholders. This involves among other activities creating tangible incentives for the stakeholders to allocate resources such as time, attention, know-how, resources and information to the community. Consequently, the community building process is based on real and identified incentives for the target stakeholders groups.

Studies of the European medical device sector[135] concluded that health care providers in Europe are looking for technology-based solutions to provide better services, provide existing services more efficient, reduce costs, and free up critical resources to accommodate for changes in the costs and provision of health care services in Europe. Secondly, health care providers are looking for ways to efficiently obtain knowledge about and access available solutions, to understand how they can plan short- and long-term technology investments to incorporate the benefits of such solutions. Thirdly, health care providers are looking for ways in which their knowledge of their specific challenges and needs can meet the innovativeness and ingenuity of solution providers to jointly develop new solutions that provide for specific challenges currently not catered for in the market.

Studies of solution providers[136] to the health care sector and other sectors with demand coming from public procurement show that solution providers are looking for opportunities to ultimately sell their solutions to the health care providers. However, the sales processes are often expensive and often for small- and medium-size enterprises market by limited information about the market, especially which health care providers are actively looking for solutions to challenges provided by the exact solution provider. Secondly, the solution providers are looking for opportunities to showcase or pilot their solutions to be able to validate their business case with the health care providers, with the purpose of overcoming barriers such as perceived risk, insecurity about impact, and lack of knowledge of the true benefits of the individual solutions. Thirdly, solution providers are looking for ways to interact with the actual health care providers to obtain knowledge about concrete needs that go into refining existing solutions to make them more marketable or to set the direction for future technology and product development.

19.3 Community Building

To ensure that the FISTAR project has access to a substantial community of health care providers and solution providers, the community building is based on targeting these exact incentives. The process is thus designed around engaging with health care providers to identify their current challenges and have solution providers propose solutions to those challenges through an open call process. The health care providers subsequently evaluate the proposed solutions and commits to pilot at least of the solutions to evaluate its impact under real world conditions with each party in the piloting phase carrying their own costs. The incentive for the health care organization is the prospect of getting a real solution for a real, high priority problem. The incentive for the solution provider is the attention and subsequent sales prospect.

The WP7 community building workpackage delivers a community of health care providers and solution providers, and creates incentives on the two main stakeholder groups own premises to ensure they are actively engaging in the community. The FISTAR project can subsequently tap into this community for purposes of dissemination, research, validation of results and other key activities relevant for the project as a whole. The key instrument to maintain the engagement and motivation of the community is to design and conduct the activities on the stakeholders' terms.

To achieve this, the process suggested for community building is based on the model for call for solutions, pioneered by Living Labs Global. This model has managed to connect health care providers with solutions from solutions providers across national borders and in this process build up a significant, active and sustainable community. The model is ultimately designed around helping public authorities identify and define key challenges in their community, in a form that solution providers from Europe and across the world can respond to. The solution providers can potentially achieving commercial value by solving these challenges, but must first provide that the solution work through a real-life pilot in the community. Through an open submission and

[135] Innovation Financing in the European Medical Device Sector, Interlace-Invent (2007)

[136] Connected Cities, Royal College of Art (2010)

evaluation process, the solutions which are allowed to pilot are selected. After a successful pilot, the solution can subsequently be tendered for in an open tender.

The example of York (below) shows how a public authority with procurement power and responsibility for health care service can manage to identify and select a solution to target a specific challenge in the community pertaining to reducing health inequality[137].

Example of a health challenge from York, United Kingdom.

Potential solutions for this specific challenge where nominated and included several innovative approaches to solving this problem such as solutions for children and adults with special needs, teenage pregnancy education, outdoor public classrooms, and services in the area of sexual health. The final solution selected by the city was found outside of the national borders[138].

Common for these solution are that the chances of them connecting with the specific place of and time of demand – in this case the needs of the City of York to solve this problem – were very small. However, through the call for solutions process the health authorities of the city had the opportunity to make their challenges public. Subsequently, the community building organization – in this case Living Labs Global – assisted in mapping out the complete supply chain and suggesting potential solution from solution providers across Europe and across the globe.

Beyond solving the immediate problems in the City of York, the process has several additional benefits for the health care community.

- Research has shown communities often have similar problems[139]. With the solution being implemented in York, other health authorities can monitor the progress of the solution and choose to implement the same solution if the impact on society and health is as expected.
- The solution providers through this process often obtains a first major client, enabling them to grow their organization, possible obtain investments and consequently take their solution global to benefit of society and the economy.
- Solution providers in similar fields obtain knowledge about each other which creates mutual learning, competition, innovation and thus better solutions in the future. This will benefit society as new and better solution become available.

[137] http://llga.org/call.php?idCall=42

[138] http://llga.org/solution.php?idS=62

[139] http://agilecities.org/category/agile-cities-survey/

- With the solutions being made visible on online portals, through the call for solutions' dissemination process, and through the award events and visioning workshops, health authorities get access to a repository of knowledge and systematic market intelligence that few of them today have access to. This inspires them to consider where existing problems in their local community might have a solution available somewhere in the world, to the benefit of society and the economy.

The design of the community building process is thus devised to achieve the key aims of the community development workpackage

- As close as we can get within the scope of the project / budget to a complete mapping of the European Health IT Sector
- Create a community of relevant organisations across all European member states.
- Make a community available for organisation-to-organisation interaction and collaboration
- Make a community available for high impact dissemination – a community that is listening and consuming information
- Create an efficient tool for other workpackages to reach out to relevant organisations on a need basis
- Allow tracking of success on the dimensions of engagement, reach, and dissemination
- Create a the basis for leveraging state-of-the-art technologies for FISTAR's communication, dissemination, interaction and collaboration dimensions
- Create community-based incentives for organisations to involve themselves and keep being involved in the project
- Create the basis the extending and expanding the project's results, by – in time – growing the community beyond the originals scope of the project

Furthermore, the community building process is designed to create tangible and measurable results for the FISTAR project:

- Identification and engagement of 100-500 health care providers.
- Identification and engagement of 500-1000 solution providers across Europe.
- Definition of at least 5 challenges to concrete problems of important to specific health care providers in the delivery of health care in Europe that can be piloted and solved by solution providers
- Delivery of an evaluation process in which solution providers are selected by the specific health care providers with an invitation to pilot their solution
- Creation of an online community where health care and solution providers can bridge demand and supply of health care services using future internet technologies
- Completion of networking event in Munich 2014, as part of the FI-PPP program, where health care providers and solution providers can meet face-to-face and develop opportunities on solving future challenges in the European health sector using future internet technologies
- Initiation of the piloting processes succeeding the challenges and evaluation process

19.3.1 Challenges

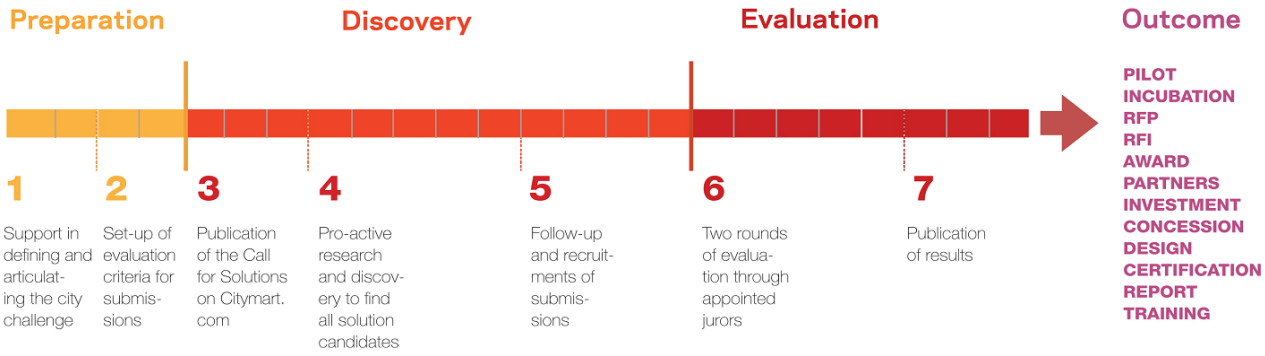
The health care providers might engage for different reasons. To ensure the interest of the maximum number of organizations, three types of engagement are initially planned.

Pilot Commitment is the main form of engagement. Here, the organization is committed to launch a call for solutions to a specific challenge, evaluate incoming challenges and commit to selecting at least one solution to pilot.

Call for interest is a second form of engagement. Here the organization launches a call for interested companies to submit solution to a challenge, the organization is committed to evaluate the incoming solutions and provide feedback, including potentially a winner. But the organization is not committed to piloting the solution.

Becoming a follower is a third form of engagement, in which the organization officially states its interest in the solutions to one or more of the published challenges of other organizations.

19.4 Open Community Development Plan



19.4.1 Calendar

Key phases	Timeline
Identification and outreach to health care providers	October 2013 – January 2014
Challenge Definition	December 2013 - February 2014
Identification and outreach to solution providers	November 2013 - April 2014
Submission and evaluation processes	December 2013 - June 2014
Networking event in Munich	September 2013
Follow-up on pilots	September 2014 – April 2015

19.5 Call for Proposals Process

The Call for Proposals process consists of the following steps.

19.5.1 Defining the problems and outcomes

Living Labs Global supports the health care providers in articulating their needs and desired outcomes to define and validate their challenge, based on our team's experience in delivering 75+ challenges.

19.5.2 Set-up of evaluation criteria for submissions

Living Labs Global develops the evaluation processes together with the health care providers including incorporating the health care provider's own evaluation models and criteria, or incorporate the health care provider's preferred standards.

19.5.3 Publication of the Call for Solutions

Call for Solutions are published on the microsite, and we notify our ready community of solution providers. Further, Living Labs Global promotes the Call extensively through social media channels and the FISTAR dissemination channels.

19.5.4 Pro-active research and discovery

The research team identifies all the relevant solutions available in the global marketplace. All findings are documented and shared with the health care provider in real-time, so that the health care provider, their stakeholders and citizens can participate.

19.5.5 Follow-up and recruitment of submissions

The research team proactively contacts all relevant solution providers, explains the challenge and conditions, and supports companies throughout the submission so that the health care provider can have a catalogue of relevant and committed solutions.

19.5.6 Evaluation through appointed Jurors

Living Labs Global provides the health care provider with the necessary tools, support and guidance for the evaluation process carried out by their appointed experts and stakeholders.

19.5.7 Publication of results

Winners are announced accordingly to the health care provider's desired outcomes and information becomes public on Living Labs Global and through the FISTAR media channels.

19.6 Integration with WP1.1

The community building workpackage is developed with the aim of the FISTAR project technical deliverables and results to be dissemination to a broader audience of health care providers, solution providers and other stakeholder groups.

The workpackage thus have several integration points with the efforts of workpackage 1, especially task 1.1.

19.6.1 Engagement of a developer community

The community is expected to number at least 1,000 solution providers from Europe defined as e.g. application developers, medical device companies, entrepreneurs, start-ups, app developers, software companies, specialised consulting companies, universities, NGOs, associations, research centers, as well as international organisations. This community will provide a fairly representative share of European application development companies, which is exactly the target group for the FI-PPP technologies.

The engagement of the community and the potential uptake will thus be the early sign of the success of the FI-PPP and FI-STAR strategy. The companies and organisations will be exposed to the deliverables of the project, and start investigating the potential for using the technology to provider more efficient, effective and innovation services to the market.

19.6.2 Validation of key functionality with the future market

Through the engagement of health care providers, and prioritized mapping of challenges the community building process outlines both the current and future demand for functionality beyond the use-cases of the FISTAR project. This process will both validate the existing technology roadmap and outline what they market expects from the project and associated activities in the longer term.

Secondly, with the exposure of the solution from across Europe, health care providers will furthermore be inspired to consider additional solution to both identified and yet unidentified challenges. This stimulates a continuing learning process

19.6.3 Input to the current state-of-the-art of the requirements

The interest from the developer community will provide for possibilities to get feedback on the current state-of-the-art of the requirements. This including comparing the requirements developed

on the existing selection of use-cases with more general requirements from other applications and solutions successfully running the market as well as potential future solution and development projects.

The input from this process can subsequently form part of future releases and technology decisions, allowing WP1.1 to get closer to the ideal specifications for ensure broad and long-term uptake of the technologies in the application provisioning of the market.

19.6.4 Addition of new use-cases and variations of existing use cases

The input from application developers will furthermore provide a significant repository of new use-cases that can be used to expand the scope as well as validate the existing requirements vis-à-vis a representative portion of the solution running in the market. With at least 1,000 solution providers expected, the repository will be significant and is expected to be dynamically updated as a result of the community activities.

As this repository will be searchable and mineable it will provide additional qualities to the maturity and comprehensiveness of the final scope and the final requirements to be produced by WP1.1. The solution providers in the community can furthermore by approached on a one-by-one basis to further explore specific solutions for additional information, inclusion of innovative features or other way of enhancing the value of the technical specifications.

19.6.5 Input to the longer-term technology road-map of the FISTAR components (hereunder especially specific enablers)

The community interest and the mapping of priorities in the health care providers, provide considerable intelligence about the market and both current and future demand situation. This intelligence can thus be used as input to the technology roadmap in the project as well as in the longer-term after the project has ended.

By having a large prioritized sample of problems and challenges in demand by the health care providers, additional intelligence can be created in terms of estimates of aggregated demand, business cases across different countries, and estimation of the combined expected uptake of certain potential functionalities. This will help in prioritized technology development on the basis of commercial attractiveness, and thus subsequent attractiveness to the application development companies. This will in turn ensure the attractiveness of the results from the overall project.

19.6.6 Opening of the market

With the successful piloting and implementation of solutions to concrete problems at the health care providers, and the subsequent measuring of impact, health care providers would ideally being to prioritize technology-enabled solutions to their problems. This will in time, open up the market for solution based on future internet technology, such as those developed by the FISTAR project. In turn, this will stoke demand and thus interest from the development community in the technology and other assets by the FISTAR project.

SECTION VI – Annexes

The following annexes are peer-reviewed papers that cover materials reported in this deliverable D1.1 and have been accepted at important scientific conferences. Due to the public nature of this report and the current non-public state of the publications, only references are given here.

- C. Thuemmler, S. Fricker, O. Mival, D. Benyon, W. Buchanan, A. Paulin, et al., "Norms and Standards in Modular Medical Architectures," accepted at the IEEE HealthCom 2013, Lisbon, Portugal, 2013.
- T. Pfeifer and S. Covaci, "Active Protection of Patient Data by Reverse Cloud Approach," accepted at the IEEE HealthCom 2013, Lisbon, Portugal, 2013.
- S. Covaci, T. Pfeifer, A. Schneider, and T. Jell, "Aktiver Schutz von Patientendaten in mobilen e-Health Clouds," accepted at the 18. ITG/VDE Fachtagung Mobilkommunikation (Mobilkomtagung), Osnabrück, Germany, 2013.
- Thuemmler, J. Mueller, S. Covaci, T. Magedanz, S. de Panfilis, T. Jell, et al., "Applying the Software-to-Data Paradigm in Next Generation E-Health Hybrid Clouds," accepted at the 10th International Conference on Information Technology: New Generations (ITNG'13), Las Vegas, NV, USA, 2013.

