HoliDes

Holistic Human Factors **Des**ign of Adaptive Cooperative Human-Machine Systems

Requirements & Specification & first Modelling for the Health AdCoS and HF-RTP Requirements Definition Update (Feedback)

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1 Introduction

This document describes the results of a first attempt to model the AdCoS using the HF-RTP and methodology with pre-existing tools and provides feedback to WP1-5.

The resulting requirements and specifications will further be used in task 6.3 for developing models of the AdCoS, and task 6.4 for providing the implementations.

The present document is broken down in different sections,

1. It is identified the tools provided from WP2 and applied in Healthcare Domain AdCoS.
2. Each AdCos is deeply defined through tools, requirements update and system architecture.
3. Finally, the most interesting section aiming at providing feedback to WP1-5 and conclusions in order to server as a reference outside the domain.

It should be stressed the fact that, feedback and conclusions are focused on Human Efficiency Evaluator Tool, due to the fact that it has been commonly used in the Healthcare Domain.

2 Tools and Services applied from the HF-RTP

After a thorough analysis of the Tools provided from WP2, the table below shows a definitive list of selected tools within Healthcare Domain AdCoS.

Tool name	Tool type	Tool provider	AdCoS
PED	Task Model and Specification	OFFIS	3D Acquisition?
Human Efficiency Evaluator (HEE)	Software	OFFIS	3D Acquisition Querying_openEHR_data Internal_analysis_and_reporting

Table 1: Selected tools within Healthcare Domain AdCoS.

This information is taken from deliverable D1.3 [1], the corresponding AdCoS has been added into a new column. Tools not suitable for the healthcare domain have been removed from the table in order to make it clearer, more understandable and efficient.

Notice that from a several number of tools the use of the HEE tool has been the most commonly used in the Healthcare Domain; 3D Acquisition, Querying openEHR data and Internal analysis and reporting AdCoS.

3 Modelling the use cases

3.1 Use case overview

The use cases in WP6 are derived from an overall scenario, which describes the flow of a patient through the hospital.

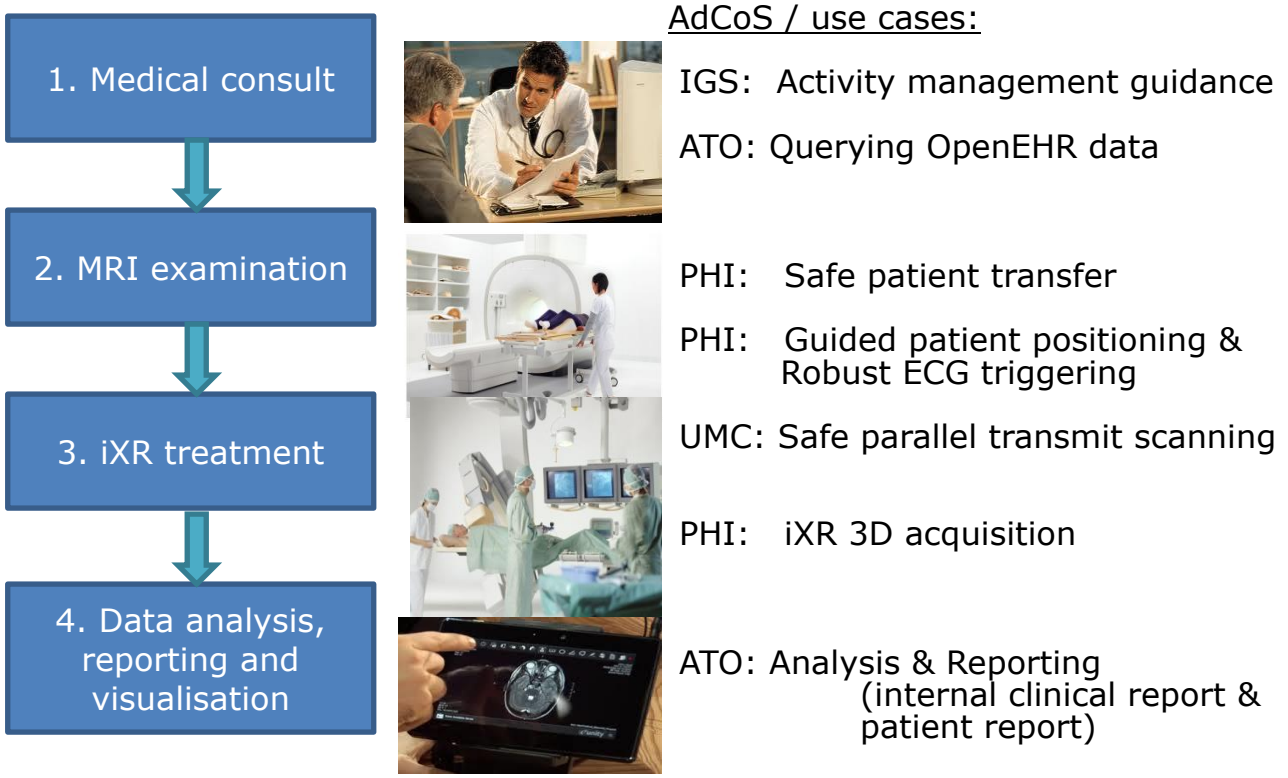

Figure 1: Overall WP6 scenario with AdCoS, use cases and responsible partners.

3.2 WP6_HEA_CON_UC01_Operator_task_schedule_and_guidance

Leader: Integrasys

3.2.1 Operational definition of the AdCoS

One of the problems older adults and newcomers face at work is the adaptation to a changeable working environment, which comes from many factors: new computer and machine interfaces, new devices, new procedures and workflow, new business line and markets, etc. An incorrect introduction of changes in the working environment can cause an improper assimilation of concepts, and it could cause demotivation and low productivity, especially in older employees. Furthermore, it can lead to user errors, which can put patients at risk.

On the other hand, workflow technology has expanded substantially into the industry over the last year. Companies are embracing this technology as a means to improve operational efficiency, achieve safety goals, and positively influence the quality of their services.

The workflow for operators in medical environment (nurses, physicians…) comprises very complex procedures with many factors that influence the execution of tasks, such unexpected events that make difficult to accomplish a pre-organized plan. Informal process at hospital is very common. For instance, short disruptions of daily task of nurses are usual in Hospital. When the number of small interruptions outweighs the amount of planned work done in a given hour, that impact is felt in slower progress, lower job satisfaction, and potentially lower quality of care. . Although in some cases the procedure are known (for instance the protocol for a surgery, the patient admissions…), in many other cases we depends on medical expertise and empirical experience.

The intention of our AdCoS system is to ease the development of workflow solution for hospital focused on the following aspect:

- Help to proper staff assignment to tasks
- To provide real time instructions – trigger alarms – reminders and check points

- To optimize the workflow and cooperation with rest of operators.
- To provide feedback to the platform for further refinement

As a consequence, this AdCos contributes to the optimization of Hospital resources and patient satisfaction.

Given the broad scope of workflow, we will focus on a subset of casuistic: Our application focused on a **prototype implementation** of a dynamic workflow system that helps to care personnel to carry out their daily tasks.

However **the testing and deployment is one of the main problems in the development of this system, since experimenting in real scenarios is a complicated task in health systems**. Early testing of system designs is important to reduce the risk of undesirable development. Provided by tools in HoliDes; Pre-testing applications with tools for critical environment. These tools will be used for functional pre-evaluation (to assess the correct functioning), to help to validate and improve the algorithms, and to assess the usability.

The main objective is to pre-validate a dynamic workflow system for hospital environment. The main players are:

- **The instructors**: the users that create the instructions and monitor the employee to guide the operators in their task.
- **The operators**: the employees themselves who benefit from the tools. In our case the employees are mainly nurses.

The technical infrastructure foreseen is composed by:

- Server infrastructure: Where the information is stored and workflow is created.
- Mobile platforms: Tablet, smartphone, smartwatch
- Communication network: To ease the monitoring and exchange of information

Goals in Holides

Our intention is to implement a simulation tool that helps us to pre-validate the implementation of an AdCos System, before the full implementation on real hospital is carried out.

The basic functionalities are:

- To help to assign/re-assign tasks to operators
- To give context-aware instructions to operators.
- Different user interfaces are foreseen: Tablet, smartphone, smart-watch.

The high level objectives are:

- To improve the efficiency of activity management in Hospital
- To ensure the usability of the system: satisfaction of operators, instructors and patient
- To accomplish strict requirement of hospitals procedure in terms of patient safety.

3.2.2 HMI for the AdCoS

In Holides, we mainly focus on operators. For this reason we aim to propose a simulation tool that allows to automatically inject stimulus (inputs) and in conjunction with mobile operators, assesses the usability of the solution.

The operators are hospital staff (nurses, physicians, operators…) equipped with a mobile handheld (tablet or smartphone) and optionally with a smart-watch. The interfaces of the mobile application with the operator are represented in the following diagram:

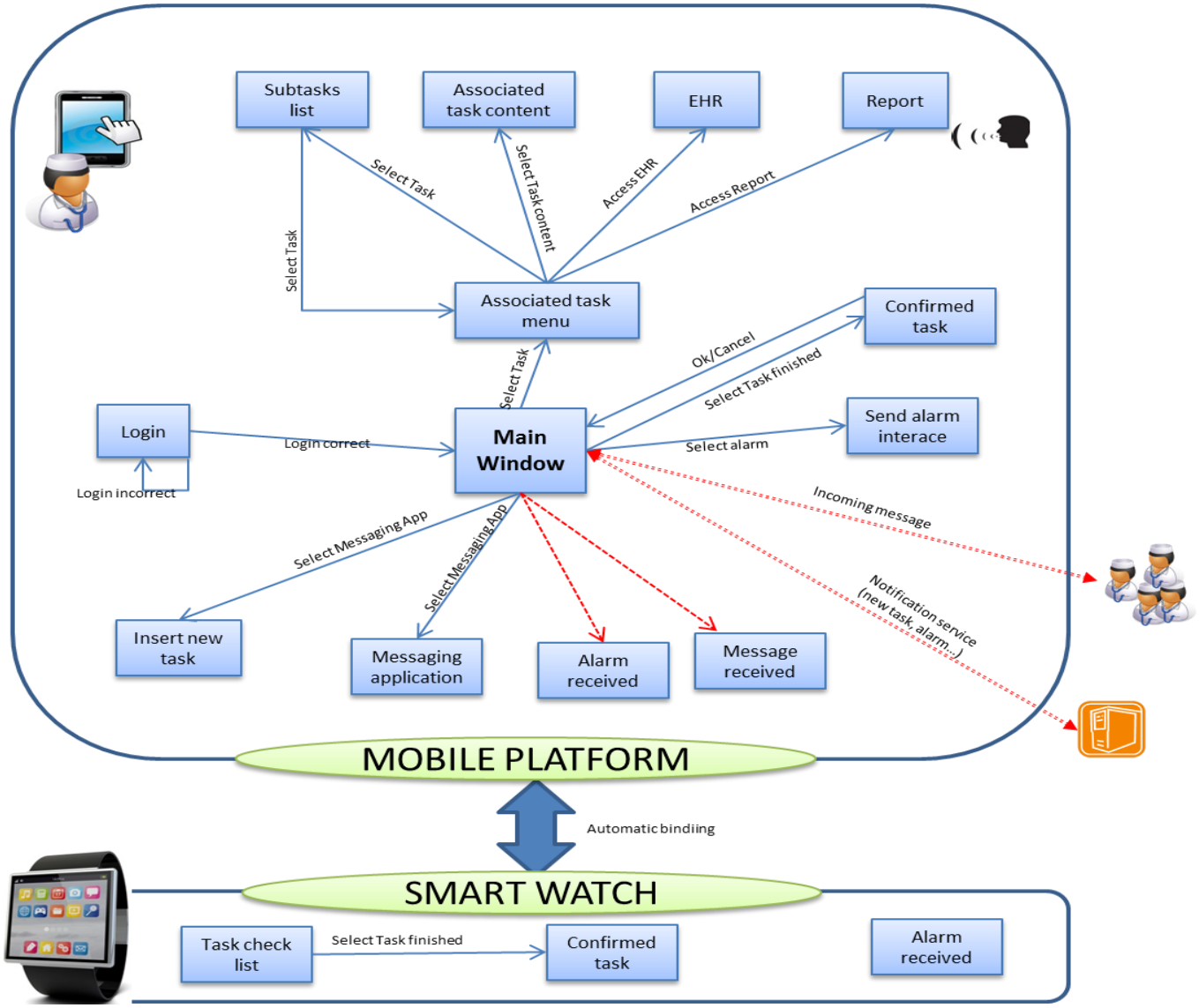

Figure 2: The interfaces of the mobile application with the operator.

Figure 3 represents the different functionalities which are mapped in user interfaces. Blue solid lines represent user inputs, while red dashed lines represent actions triggered by external entities (a notification from the server, an incoming message, etc.).

Next are described the different modules:

LOGIN SCREEN

Graphical interface:

Figure 3: Mockup of *Login* screen .

Basic functionality:

- It offers the access to the application based on authentication by credential
- User introduce user and password and click "OK"
- If credentials are correct, the user will be forwarded to main window. Otherwise, the user will be prompted to another try.

Communication with external infrastructure:

- Credentials are verify against user database
- System is aware about user status (logged)
- Binding with smartwatch is done if available
- If available, real time user positioning is also published into database

Previous requirement

- Previously, user has to be registered in database correctly

MAIN WINDOW SCREEN

Graphical interface:

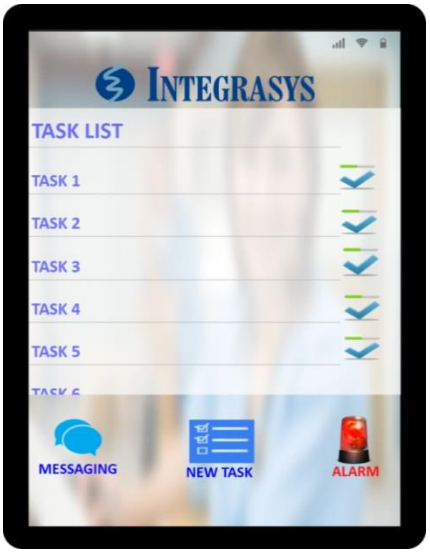

Figure 4: Mockup of *Main Window* screen.

Basic functionality: It allow user to visualize their assigned tasks, in a scrollable list. It gives access to complementary functional module of the application**.**

Continuously, can receive notification from server (new task, alarm) or from other operators (alarm or message)

- On touch on tasks will show the *associated task menu*. This will offer one of the following options, that will allow to:
  - Get subtasks associated to tasks: It can be used as a checklist
  - Associated task content: The associated content of a task would offer additional information related to the task. For instance, the task "take radiography" may have associated multimedia content about the equipment handling. This functionality is especially useful when new equipment is deployed, for new users, and for elderly operators.
  - Electronic Health Record (EHR): If performing task is associated to a patient, with this menu fast access to the EHR is allowed. This functionality is optional
  - Report: Access to reporting templates that will allow 'on the fly' report of the current task. This functionality is optional

- Each task is complemented with a clickable icon to indicate the status of the task: started/suspended/completed. Selecting this icon will open the "*confirmed task*" screen.
- From *Main Window* would be also possible to open the "*Send an alarm*" interface, it will notify to coordinator about specific event/issues.
- From *Main Window* would be also possible to open the "*Messaging application*" that will facilitate internal communication with other operators.
- Given the highly dynamic environment in hospital, from *Main Window* would be also possible to open the interface for *"Insert new task".* This functionality will allow the operator to insert new tasks
- If it receives a server notification, the operator will be notified accordingly. Two types:
  - Alarm received: It will open the "*Alarm received*" interface
  - If it is a new task, it will be added to the task list and the operator will be notified by using the "*Alarm received*" interface

Communication with external infrastructure:

- Tasks are retrieved from database
- System is aware about user status and tasks which is selected by user
- The task list is sent to the smartwatch
- If available, real time user positioning is also published into database

Previous requirements

- User is registered and logged in the system
- Previously, tasks and its associated content are assigned to operators in the database.
- Mobile application bound to smartphone

ASSOCIATED TASK MENU SCREEN

Graphical interface:

Figure 5: Mockup of *Associated Task Menu* screen.

Basic functionality: When a task of the *Main Window* is selected, this frame is launched to select among one of the functionalities by "touching" one of the following options:

- *Get subtasks associated to tasks*
- *Associated task content:*
- *EHR*
- *Report*

This interface will only display the available actions for the corresponding task. For instance, if a task is not associated to a patient, *EHR* option will not be presented. If the task does not have associated content, *Associated task content*, will not be displayed.

Communication with external infrastructure:

- Notification service is always running in background.
- Server communication is needed to display the associated options for the selected task
- If available, real time user positioning is also published into database

Previous requirements

- User is registered and logged in the system
- Previously, tasks and its associated content are assigned to operators in the database.
- Associated content to the task is in the database

SUBTASK LIST SCREEN

Graphical interface:

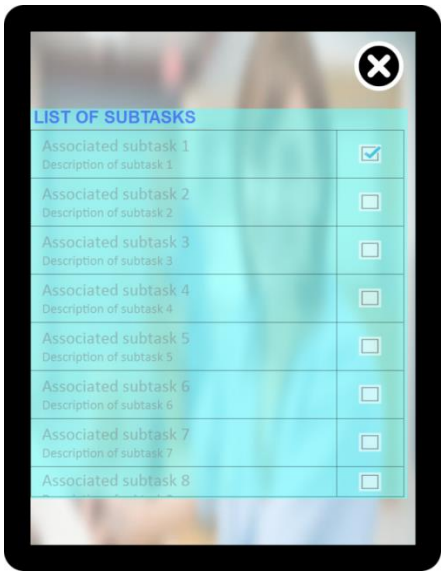

Figure 6: Mockup of *Subtask List* screen.

Basic functionality: When a task is selected, the sub-steps to guide the execution of such task can be visualized. It also can be used as a checklist tool. It also allows to indicate the status of the subtasks.

Communication with external infrastructure:

- The list of subtasks are retrieved from the server
- Notification, messaging service is always running in background.
- If available, real time user positioning is also published into database

Previous requirements

- User is registered and logged in the system
- Task has associated subtasks.

CONFIRMED TASKS SCREEN

Graphical interface:

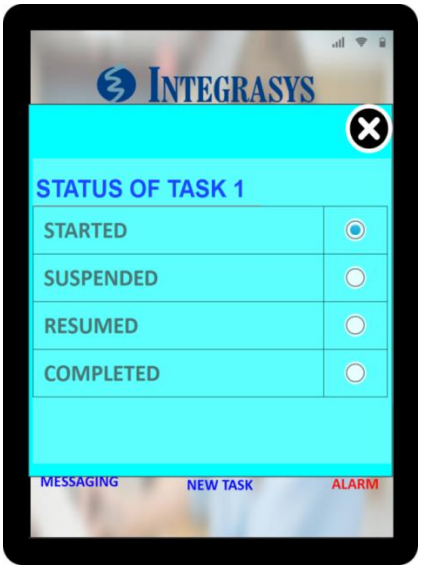

Figure 7: Mockup of *Confirmed Task* screen.

Basic functionality: It is accessed through the icon associated to the tasks, and it offers an interface to inform that a task is started, suspended, resumed or completed. When the task status is selected, the server will updated accordingly, and the application will go back to *Main Window.* This information is valuable for knowing the current status of work, and for future analysis and optimizations of workflow.

Communication with external infrastructure:

- The status selected by the operator will be saved in the server. Other information, as timestamp, position will enrich the register
- If available, real time user positioning is also published into database

Previous requirements

- User is registered and logged in the system
- User is assigned to tasks
- Task are assigned to operators

SEND ALARM SCREEN

Graphical interface:

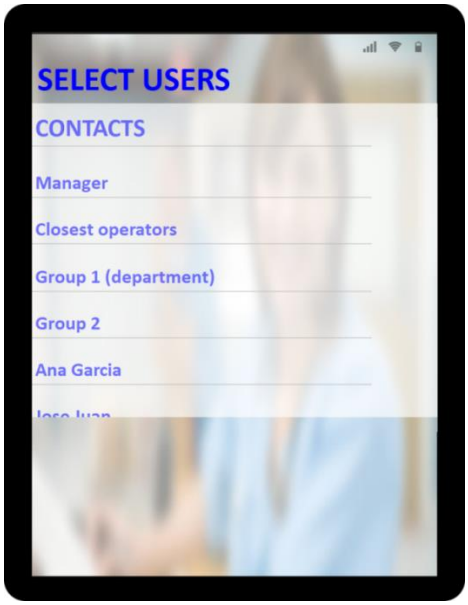

Figure 8: Mockup of *Send Alarm* screen.

Basic functionality: The operator is able to send an alarm to:

- Instructor/managers
- All the team
- Operator in the nearby
- Individual colleagues

The alarm could be enhanced with a text/voice message. Unlike the messaging application, this functionality should only be use in emergency situations, when support is needed.

Communication with external infrastructure:

- Alarm will be saved in the server and distributed to targeted users
- If available, real time user positioning is also published into database

Previous requirements

- Prioritization of this message with respect to other ones
- User is registered and logged in the system

MESSAGING APPLICATION

Graphical interface: The interface has to be defined

Basic functionality: It's a secure messaging application that helps medical staff to coordinate care and collaborate on cases and efficiently manage communication over the continuum of care. It would allow to connect to other colleagues, asking for support or providing information. The application would support text/voice/images. Users are retrieved from the database. It allows individual and group communication. With respect to others wide-spread messaging tools (as Whatsapp), this application will ease the separation of professional and personal communication

Communication with external infrastructure:

- Users are retrieved from database
- Content of messages are saved in database
- Messages are distributed from the server to targeted users

Previous requirements

- User is registered and logged in the system

INSERT NEW TASKS SCREEN

Graphical interface:

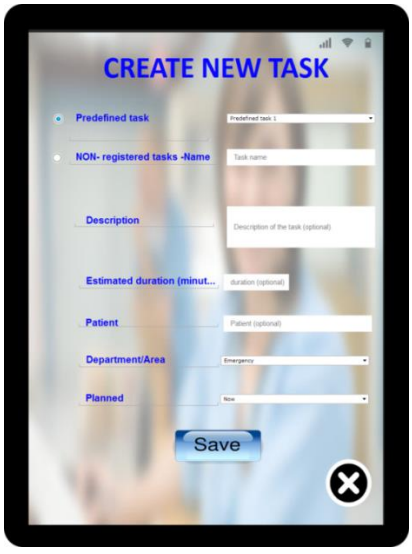

Figure 9: Mockup of *Insert New Task* screen.

Basic functionality: Given the high dynamicity of hospital environment, the user would be able to add its new tasks, and add it to the task list (displayed in the main window) in the correct position. This functionality will be flexible enough. They can select from a predefined list of tasks, or insert a new task, which are not registered previously in the database. The only mandatory field will be the task description. More information can be optionally added, as patient, position of execution, task classification, estimated execution time, owner of the task (who order it), etc.

Communication with external infrastructure:

- Predefined tasks are retrieved from the database
- New task is stored in the server
- Manager/coordinator/instructor are informed of this new task
- If available, real time user positioning is also published into database

Previous requirements

- User is registered and logged in the system

ALARM RECEIVED SCREEN

Graphical interface:

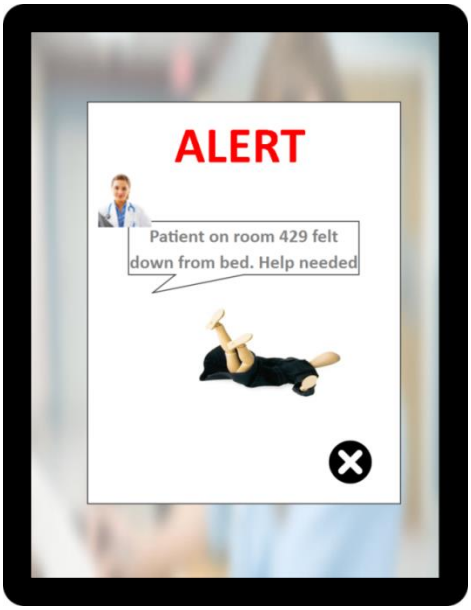

Figure 10: Mockup of *Alarm Received* screen.

Basic functionality: This interface is triggered by an alarm sent from other colleagues. The basic information is the position of the operators that generates the alarm, and the text/voice message. The alarm will emit a sound and vibration on mobile handheld. The operator will be able to indicate whether he is available to assist the alarm, and in the same interface also is shown the numbers of colleagues that already confirm that can help.

Communication with external infrastructure:

- The alarm is distributed from the server, which means that this interface is automatically trigger by a message coming from server
- Related content of the alarm is retrieved from server.
- Feedback from user is also received in the server, stored and distributed

Previous requirements

- Other user available online
- User is registered and logged in the system

MESSAGE RECEIVED

Graphical interface: This interface is similar to *Alarm received* interface

Basic functionality: When a message is received from other colleagues, the *Messaging application* will notify it (with vibration, no sound), and offer to operator access to display the message (the *messaging application* will be used)

Communication with external infrastructure:

- Messages are distributed by server.
- Related content of the message is retrieved from server.
- Feedback from user is also received in the server, stored and distributed

Previous requirements

- User is registered and logged in the system

SMARTWATCH APPLICATION

The medical staff will be also equipped with a smart watch that will support them in hands-free operations, and will offer an alternative for interact with the system.

When operator logs into the system, the mobile and smartwatch will be automatically bound. Smart-watch is not connected directly to the server. The information is transferred through it linked mobile platform.

Basically, three functionalities are offered:

- Task check list: it offers a scrollable view of assigned task and its corresponding subtask. It can be used also as a check-list to perform the activity in a confident way
- Confirmed task: It is accessed through the icon associated to the tasks, and it offers an interface to inform that a task is started, suspended, resumed or completed.
- Alarm received: It is an alternative way to receive alarm notifications.

3.2.3 Tools applied from HF-RTP

The development process

As explained above, the objective of this use case in Holides is to pre-validate the development before the deployment in a real scenario. For this reason we aim to propose a simulation tool that allow to automatically inject input/stimulus (inputs) and in conjunction with mobile operators, to assess the usability of the solution.

To implement such system we assume the following design workflow (orange box represents those boxes where Holides tools are used):

Figure 11: Operator task schedule and guidance design workflow.

- Requirement gathering: No special tool is required, although a tool that allows for management and traceability through the development cycle would be useful.
    - Open source tool preferred, such as RMF for Eclipse
    - A list of requirements was provided in D6.2.
- Requirements analysis: this is a previous step to the design and model
- Design: It mainly consists in the model of tasks, contextual information and functionality. Given the heterogeneity of information sources, we need a modelling profile that allow to cover all type of information
    - Enterprise Architect is preferred
    - Graphical interface to ease the generation and comprehension of model.
    - Based on UML (at least 2.0 specification supported)
    - To facilitate the export to standard text format which may be imported by other tools. XMI format is desired.
    - In this point Holides task model is a good candidate
- Modelling user interfaces: Mockups and interaction among them. This is already defined in this document.
- Prototype development: Implementation of the solution in a prototype basis. Modules to be implemented are mainly related with user application and interfaces. The implementation will include the scenario engine that helps to simulate the environment where the application would be deployed
- Testing and validation: The testing is based on high fidelity simulation environment, where we are able to create scenarios that are automatically executed although they allow manual inputs to stimulate the system.

Applied Tools from Holides

At this stage of this use case we have not performed an intensive usage nor thoroughly analysed tools provided by HoliDes:

- RTMAPS: We decided to use this tool as a "context management" module and "simulation engine" by allowing to add inputs/stimulus to the system, synchronizing, implemented the decision algorithms and distributing it.
    - Positive aspects: The tools offer facilities to automatically execute both real time inputs and predefined scenarios (saved in a file), and logs the output for further analysis. It is also possible to implement decision algorithms as a module with RTMAPS platform. Its modular and flexible architecture allows to communicate with external and distributed platforms (as mobile devices) so it enables that simulated outputs feed real or prototype applications on mobile devices. The output of RTMAP will feed the prototype application implemented in previous stage.
    - Desired features: RTMAPS is more focused on real time monitoring, which is not a requirement for this use case. The development of customized modules for our application is a time-consuming task, although later benefits are expected. We also consider that the effort to learn how to develop new modules will be high.
- Human Efficient Evaluator: The HEE could be applied to compare the task performance of the current design with the context-based guidance adaptations for different user profiles.
    - Positive aspects: It is based on cognitive model, which seems to be appropriate for our use case. It would be used to assess the usability of interfaces and extract conclusions. Interesting specific targets of the performance analysis could be an inspection of the

user interface navigation options of the mobile device, to figure out how they affect the overall task performance.

  - Desired features: For the use with the HEE, currently the best way to identify the tasks is for a linear workflow, without alternative branches or loops. Alternative branches can be modelled as separate versions of the workflow. We emphasize that different workflows need to be created for parallel tasks. The tools do not cover human error.

- Task modelling and analysis tools: Propose a model based in Task model by W3C. Although not intensively tested, it covers most of our requirements, such as:
    - Formal language, UML compliance
    - Order Independence Choice: The task can be performed in any order
    - Concurrency: The tasks are concurrent and can exchange information among them
    - Suspend and Resume: A task can interrupt and exchange information with others
    - Disabling/enabling: Task can be disabled/enabled when other tasks start.
    - There are tools like magic draw that ease the application of such model with intuitive graphical interfaces

All previous characteristics are desirable for this use case. However, a more intensive usage of the model and tools are needed for a thoroughly analysis.

- GreatSPN: Petri Net is a good candidate for task modelling. Basic Petri nets (usually referred to as place-transition nets) were used to create models for clinical guidelines. They are easy to learn and the diagrams are easy to understand. Petri nets are based on graph theory, and thus

can be defined mathematically. The simplest Petri net modeling tools have some level of simulation capability, which really helps in verifying that the model captures what was expected. However Basic Petri nets cannot model every aspect of clinical processes. For example, they do not handle time, rules, data, or complex control-flow sequences well. Fortunately GreatSPN is based on *Generalized Stochastic Petri Nets and their colored extension: Stochastic Well-formed Nets*. GreatSPN approach also allows for performance analysis and resource allocation optimization. However, GreatSPN as tool is more focused on modelling and simulation and it is not ready for real-time interaction with the rest infrastructure. So many developments are needed to be used as scenario and simulation engine. Moreover GreatSPN does not still have implemented all features of Colored Petri Nets, which makes inconvenient for use it in this use case.

3.2.4 Requirements Update

With analysed tools we plan to cover the followings requirements:

ID		Description	
WP6_[IGS]_HEA_REQ1_v0.1	operator profile	The system shall allow to model user profile.	The actors has different roles, and there are restrictions when assigning tasks to operators depending on the roles
WP6_[IGS]_HEA_REQ3_v0.1	modelling work and tasks profile	The system shall be able to represent activities that are performed by operators. It includes estimated, execution times, periodicity, staff involved, prerequisites…	Task modelling and work flow is central part of our simulation. It is needed to assess performance and improve resource allocation
WP6_[IGS]_HEA_REQ6_v0.1	Standard notations used for modelling	The notations used for modelling shall be based on standards language, as XML or UML	The usage of standard notations will ease the integration and interoperability among

			different tools.
WP6_[IGS]_HEA_REQ7_v0.1	Data gathering	Holides platform shall ease tools data monitoring in distributed environment. Interoperability among heterogeneous data and device in foreseen.	The simulator has to be feed by the contextual information and works . RTMAPs ease the acquisition of such tasks.
WP6_[IGS]_HEA_REQ8_v0.1	Data logging	The system shall ease data logging functionality, including information coming from distributed source	For further analysis, all events during simulation has to be logged. RTMAP offer facilities for this purpose
WP6_[IGS]_HEA_REQ9_v0.1	usability testing	The platform shall ease methods and tools to measure the usability of application	HEE is a candidate to test the usability of the application, although it does not cover all needs of our use case. Questionnaire is another technique to assess the user satisfaction.
WP6_[IGS]_HEA_REQ12_v0.1	Response time	The platform shall offer methods and tools to measure the response time of the system in several functions	It is part of the usability testing, and that both RTMAP and HEE would help to assess it.
WP6_[IGS]_HEA_REQ13_v0.1	Automated trials execution	The system shall ease the model and execution of trial for assessment of correct functioning and non-functioning of the platform	This requirement encloses the main objective of this use case in Holides. The simulator should allow automatic scenario execution and the communication with prototype applications in mobile devices

Table 2: Operator task schedule and guidance requirements.

3.2.5 System architecture

The system architecture is reflected in the following diagram:

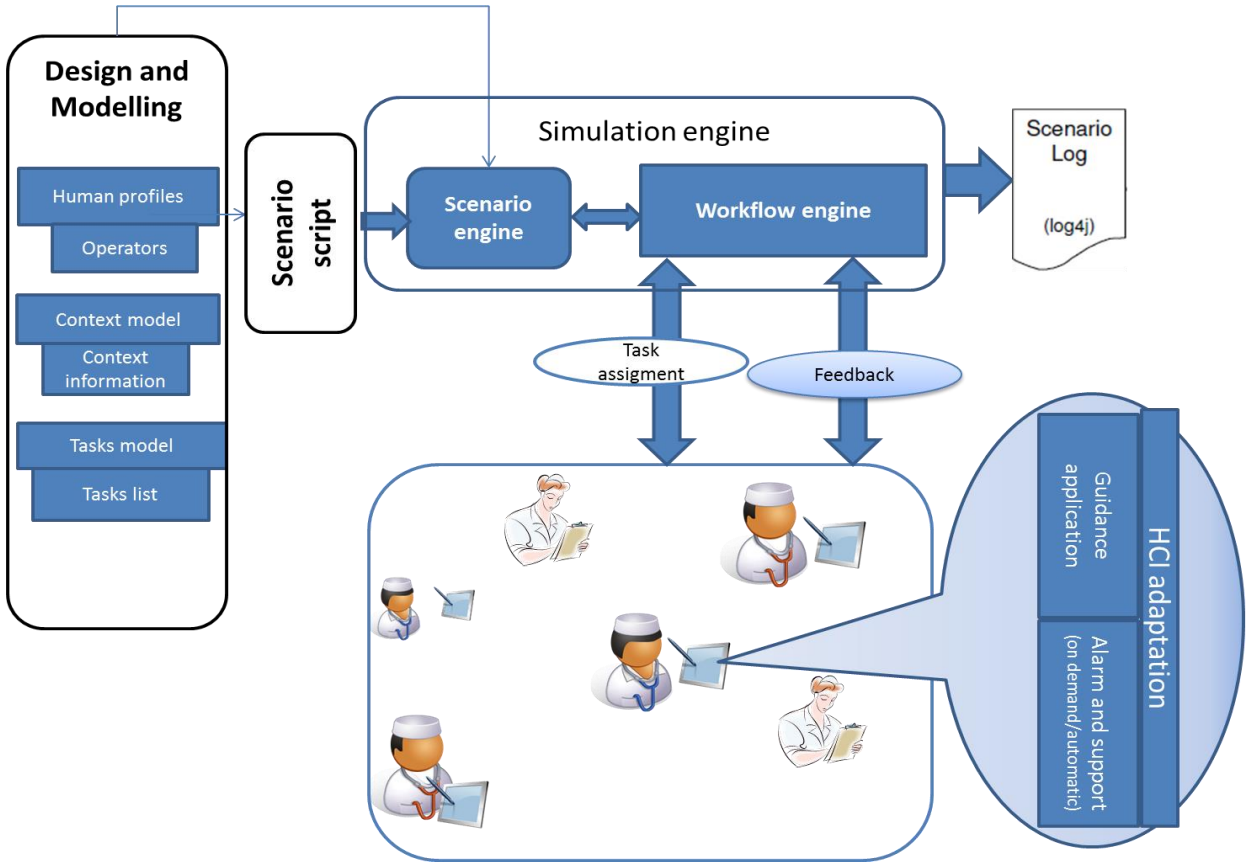

Figure 12: General architecture of *task assignment and guidance* use case.

In the previous illustration we can see the main modules of our implementation.

The scenario script will contain all the information that will be automatically executed. This will contain a script with instructions, such as set of task, time when they are launched, available operators and other contextual information. The semantic and information of such script is based on the model of the application. As explained in previous sections, we plan to use task model from WP2 or Petri net based model.

The scenario script will feed the simulation engine, which is in charge of processing the instructions, decision making and interacting with real device that implements the prototype mobile application. Moreover, the workflow engine will be able to process inputs from real users, process it and provide the output accordingly. The scenario engine also logs all the results of simulation for further analysis, these data could be reuse as return of experience to increase the accuracy of the decision process. It is important to emphasize the feedback from users. This module will help to continuously improve (1) the experience of the user and (2) quality of the platform, by providing feedback of the guidance process. For this purpose, quality metrics should be defined (for instance time elapsed to perform a specific task, number of request for help…). RTMAP is a good candidate to implement the simulation engine.

Finally, the scenario engine interacts with the mobile operators through the mobile and smartwatch devices. The functionality of these applications has been explained in section *3.1.2 HMI for the AdCoS.*

Characteristics of mobile applications

- The employee will be automatically prompted by the platform with instructions to accomplish his tasks, and he can also receive the messages
- The tool will monitor the user and activity state to guide him in the most appropriate way. The parameters are assessed through real time monitoring of the user.
- In a cooperative and distributed environment, the tool will consider information from other employees, in such a way that collaborative work is also possible. It will ease the human support – older employees can help younger ones, and vice versa.
- The devices that interact with the employee will range from fixed computer platforms (PC and laptop), mobile platform (mainly smartphone), to small gadgets (smart watches). It depends of the type of work and task performed.
- The instruction messages sent to the employees/instruction receivers will be enriched with various multimedia and interaction techniques such as text, speech, sound, videos, vibro-tactile feedback, etc.
- Inherent interfaces adaptation will also implemented according the user profile and environmental conditions: Adjust speaker volume, size of the text, brightness, content.

Adaptivity of the AdCoS

Two types of adaptivity are foreseen:

- Task reallocation to operators.
- Automatically prompting/provide instruction to operators
- To ease cooperation of operators, by adapting their workflow
- Automatic provision of feedback to the system for future improvement.
- User interfaces adaptation:
    - select between graphical interfaces, voice interface (if hands-free mode is needed)
    - Mobile to smartwatch task delegation.
    - Adjust volume of speaker to environmental conditions (noise or quiet environment)

3.3 WP6_HEA_CON_UC02_Querying_openEHR_data

Leader: ATOS

Notice that, in order to make it more clear, understandable and efficient, two use cases have been merged into one; (1) "Querying EHR Data" and (2) "Patient access to data"; The patient access is now treated in "Querying EHR Data" use case with slightly different functionalities and more restricted access than doctor role.

Therefore, the objective of this Use Case is (1) to provide effective access and modify all patient related data in EHR (Electronic Health Record) by any (authorized) physician at any location for fast and full documented medical support and (2) to provide effective remote access for the patient to his or her clinical data; health data and information related to the care. In addition, the patient is allowed to modify some data like demographic, habits or personal details in order to keep his or her information as updated as possible.

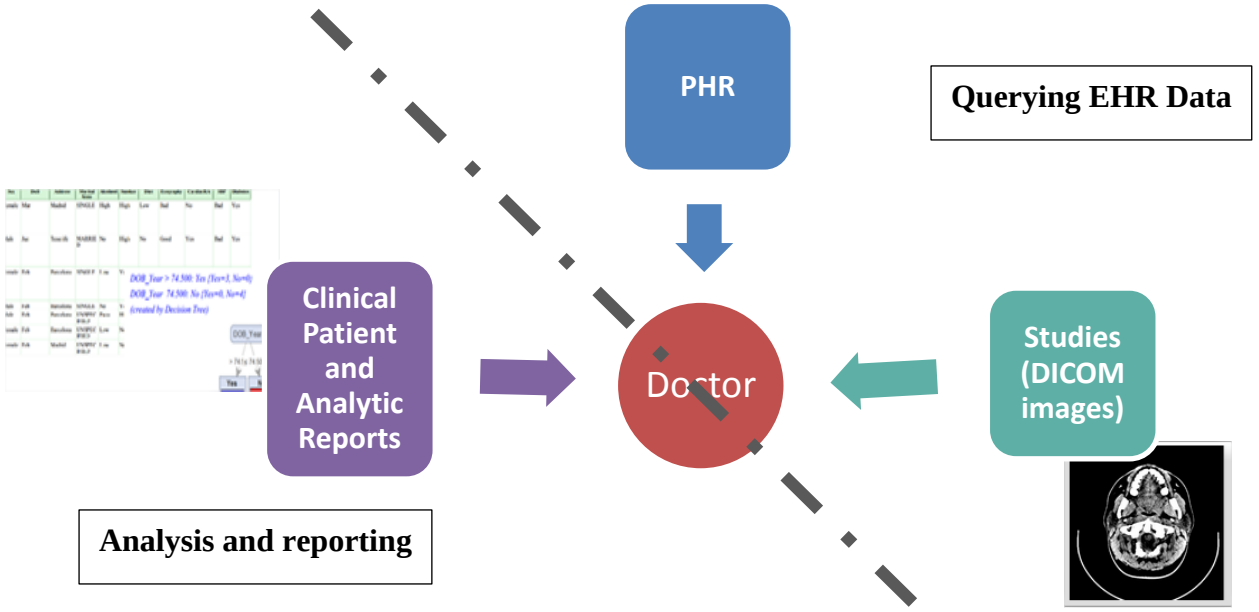

Figure 13: Different sources and relationship between two AdCoS.

3.3.1 Operational definition of the AdCoS

A problem statement for the AdCoS – what problem is the AdCoS intended to solve?

There are several issues; (1) security, (2) Heterogeneous data structure and (3) speed.

1. Security issues:

    a. The system can only be accessed by authorized physician using their credentials (at least user and password).
    b. The system MUST have a logout option and session time out.
    c. Other security mechanisms must be studied due to the sensitive information treated.
    d. The system must use secure protocols (e.g. https and encrypted mechanisms).

2. Heterogeneous data structure: Currently, the systems are usually not interconnected and have different nomenclature, data types, etc., giving interoperability problems. yourEHRM uses standards that enable medical information exchange (HL7, ISO 11073/IEEE 1073, CEN 13606, openEHR family of standards).

3. Speed and efficiency: Because it works with DICOM images (Digital Imaging and Communications in Medicine), which tend to be very unmanageable, we have to find a way to make this process as fast as possible.

What is the "controlled entity" of the use case?

To join DICOM images with patient´s EHR Querying openEHR data AdCoS will use WADO (Web Access to DICOM Persistent Objects) [2]. WADO will connect to the PACs (as an image server) and take the information from yourEHRM middleware (openEHR/EN13606 compliant).

The patient data will be collected on demand; it means that, the system will not collect all patient data from the very beginning (clinical data, prescriptions, reports…); instead, the data will be collected as the user wishes to consult them by clicking on different sections. This behaviour improves speed and efficiency.

What are the goals that the AdCoS should achieve for the operator when performing a clinical task?

The main goal is to implement a system which accesses and binds information from different systems by focusing in patient's clinical data (clinical reports, profile, etc.). The system will display those data in an intuitive and easy way for patients.

As patients may access the system from wherever outside the hospital (Web development), this information needs to be safely accessible anytime anywhere.

This system allows avoiding:
- Extra physical supports (Patient clinical report, CD, DVD…).
- Unnecessary patient timeouts and visits to the hospital.
- Dedicated administrative personnel just for data collection.

What are the situations that the AdCoS should ensure are avoided?

Due to the sensitive nature of the data, the system has to ensure, at any time and without a doubt, security and privacy of it. These data must be protected with the highest level of security.

3.3.2 Human-Machine Interaction for the AdCoS

Which input/output channels and devices are available to carry the communication between the operator and the AdCoS?

The technical infrastructure is composed by:

- Server infrastructure: Where the information is stored and standardized.
- Mobile platforms: PC or Tablet.
- Communication network: To access to the system.

Will the AdCoS employ innovative or unconventional user interaction (for instance gestures, voice interaction, etc.)?

User friendly interfaces are key feature for the success of the solution. For this purpose we foresee:

- User friendly interfaces
- Speed and efficiency on different devices
- Easier usage of the information
- Clinical information displayed in an integrated, easy and strong time representation of the patient health data.

3.3.3 Requirements Update

It is important to describe priority assigned to the requirement:

- ✓ High: Essential to have.
- ✓ Medium: Important to have.
- ✓ Low: Nice to have.

We have split requirements in different sections:

Security: Due the data nature, sensitive information must be treated with the highest security level.

ID	REQ Description	Priority
WP6_REQ1	The system MUST log all access to database, for example through a log file.	High
WP6_REQ2	The system MUST be aligned with national and international legislations and regulations in areas such as privacy.	High
WP6_REQ3	Patient data MUST be handled and kept confidential.	High
WP6_REQ4	The system MUST be aligned with national and international legislations and regulations in areas such as privacy.	High
WP6_REQ5	User and password to access is mandatory to unequivocally identify a user.	High
WP6_REQ6	Only strong password is permitted (eight characters or more, the greater the variety of characters the better) and it must be periodically changed (at least each six month).	High
WP6_REQ7	A digital signature certificate may be considered.	High
WP6_REQ8	A second password may be considered (through a provided email account).	High
WP6_REQ9	Different user roles clearly defined and documented	High
	All connections need to be done via Hypertext Transfer Protocol Secure (HTTPS).	High
WP6_REQ10	Certificate to authenticate the client	High

Table 3: Security requirements.

Communication

ID	REQ Description	Priority
WP6_REQ11	The system MUST allow a remote consultation (out from hospital environment).	High

Table 4: Communication requirements.

Data/ image integration

ID	REQ Description	Priority
WP6_REQ12	The system SHOULD be able to combine data from different sources	High
WP6_REQ13	The system SHOULD present clinical information to the physician in an integrated way.	High
WP6_REQ14	The system MUST provide a DICOM viewer	High

Table 5: Data/image integration requirements.

Accessibility: Using digital technologies can be a problem not just for the visually impaired but a much wider section of the community. Hearing impairment, arthritis, and elders are just some of the conditions that can make browsing the Web hard for some people. By making this website accessible we provide greater opportunity for participation, especially from patient point of view.

Following W3C (World Wide Web Consortium) [3] guidelines and focusing on patient role, it is pretended to make Web content accessible to people with disabilities and more available to all users (doctors and health environment).

ID	REQ Description	Priority
WP6_REQ15	**Patient** accessibility, level AA conformance	High
WP6_REQ16	**Doctor** accessibility, level A conformance	Nice
WP6_REQ17	**Language** should be clear, easy to read, and appropriate for patients	High
WP6_REQ18	**The patient** must be able to modify the default language (English, Spanish,…).	Medium
WP6_REQ19	**Patient** who use screen readers should be able to access into the system and display all his/her clinical details	High
WP6_REQ20	Text font, size, and color should be readable: The **patient** with low vision will be allowed to easily change the text size, font type and color	High

Table 6: Accessibility requirements.

3.3.4 System architecture

This section details each element and component integrated in this AdCoS. A number of different views are used in order to represent different aspects of the system. It provides a general and exhaustive overview.

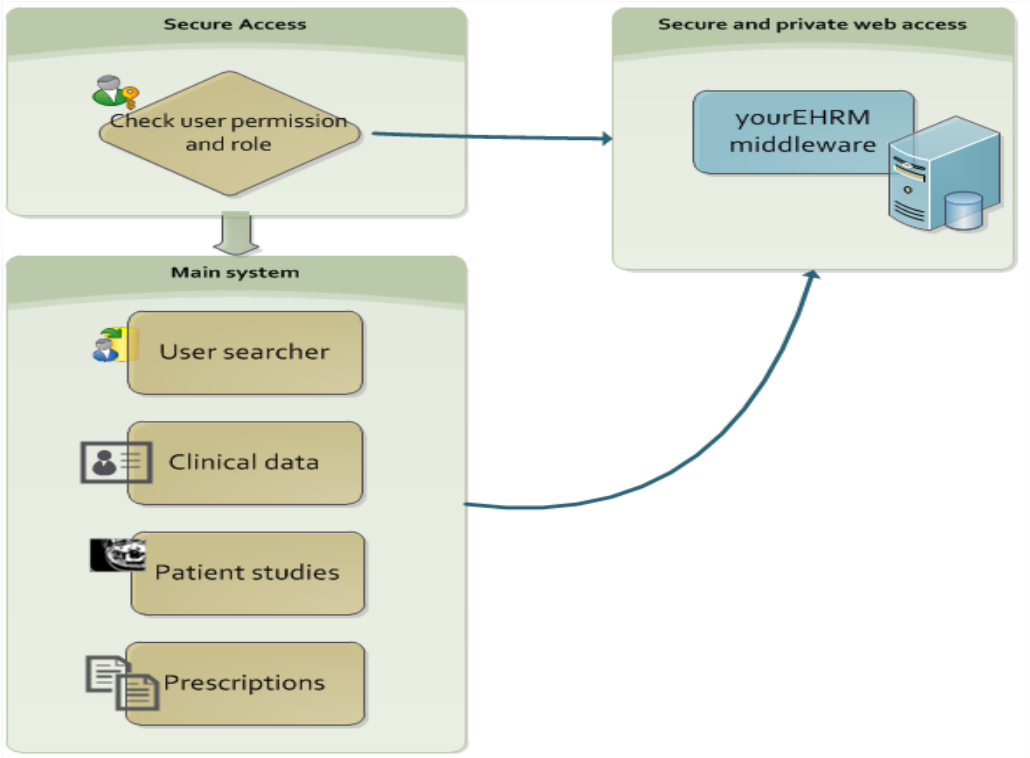

Figure 14: Querying openEHR data AdCoS Architecture.

This section starts with a general overview of the full system, describing roles and functionalities. Then, each subsystems is deeply analysed by using several UML diagrams, finally it is detailed a list of tools, standards and protocols to be used.

Roles and functionalities

Different roles have been defined. These roles allow us to restrict access; they are interrelated as shown in the following table:

	Secure Access	User Searcher	User Profile	Clinical data	Prescription	Studies
Doctor	✓	✓	☒	View and update	View and add	View and update
Nurse	✓	✓	☒	View and update	View	View
Admin	✓	✓	View and update	View	☒	☒
Patient	✓	☒	View and update	View and update	View and add dose taken	View

Table 7: Querying EHR Data use case and its functionalities by role.

A general diagram with roles and functionalities is displayed in Figure 15; this diagram contains functions, roles and relations between them in order to provide a clear understanding of the full process.

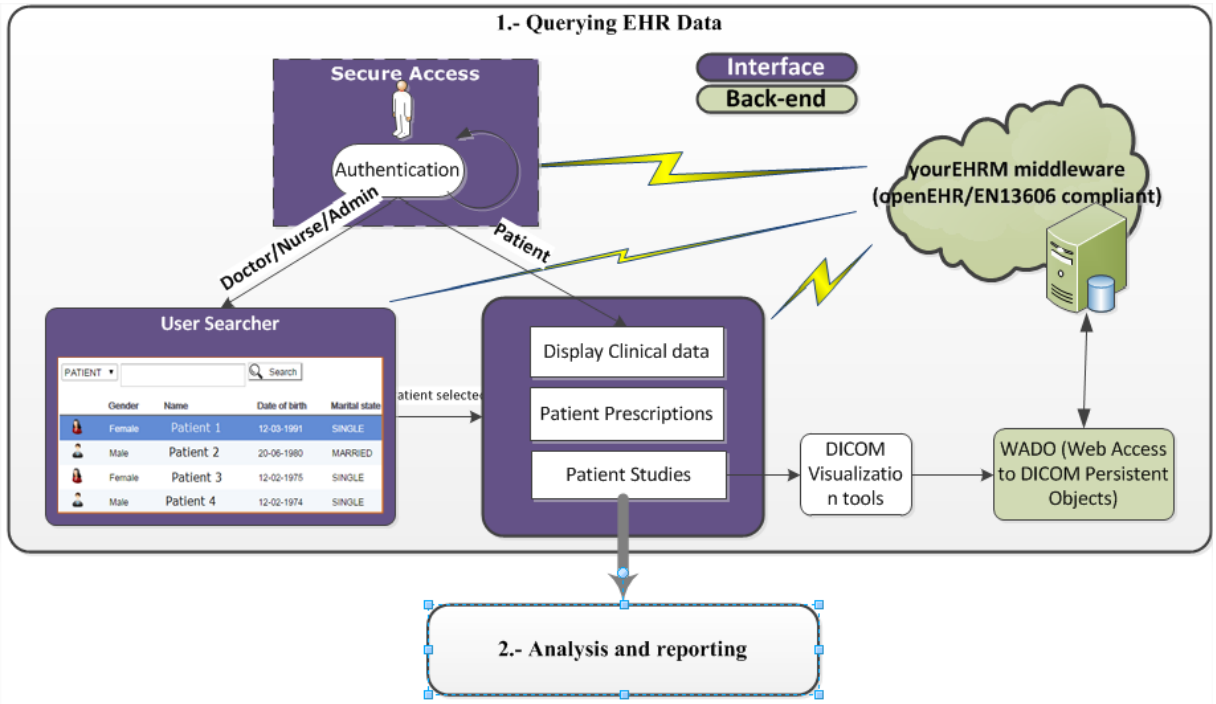

Figure 15: General diagram of Querying EHR Data AdCoS.

The diagram in Figure 15 shows:

- ✓ Database access is done through yourEHRM middleware.
- ✓ Any user needs to be correctly identified.
- ✓ User searcher can be used only by doctor, nurse or admin role.

Display clinical data, Prescriptions and Studies are not sequential steps; the authorized user (doctor, patient or nurse, see Table 7: Querying EHR Data use case and its functionalities by role.

- ✓) can access at any time.
- ✓ A DICOM viewer is needed in order to display medical images.
- ✓ DICOM objects are stored in repositories, such as PACS. The WADO standard is needed in order to access to DICOM repository by providing a simple mechanism for accessing DICOM persistent objects through HTTP/HTTPS, using the DICOM Unique Identifier (UID).
- ✓ This AdCoS is previous to Analysis and Reporting AdCoS (described in **Fehler! Verweisquelle konnte nicht gefunden werden.** section).

Now, each module is outlined, focusing on most critical part:

- ✓ Secure Access,
- ✓ Display Clinical Date,
- ✓ Patient studies and
- ✓ Display Patient prescriptions

Secure Access

While the user is not properly identified, the access to the system is not allowed, as we see on the following UML diagram:

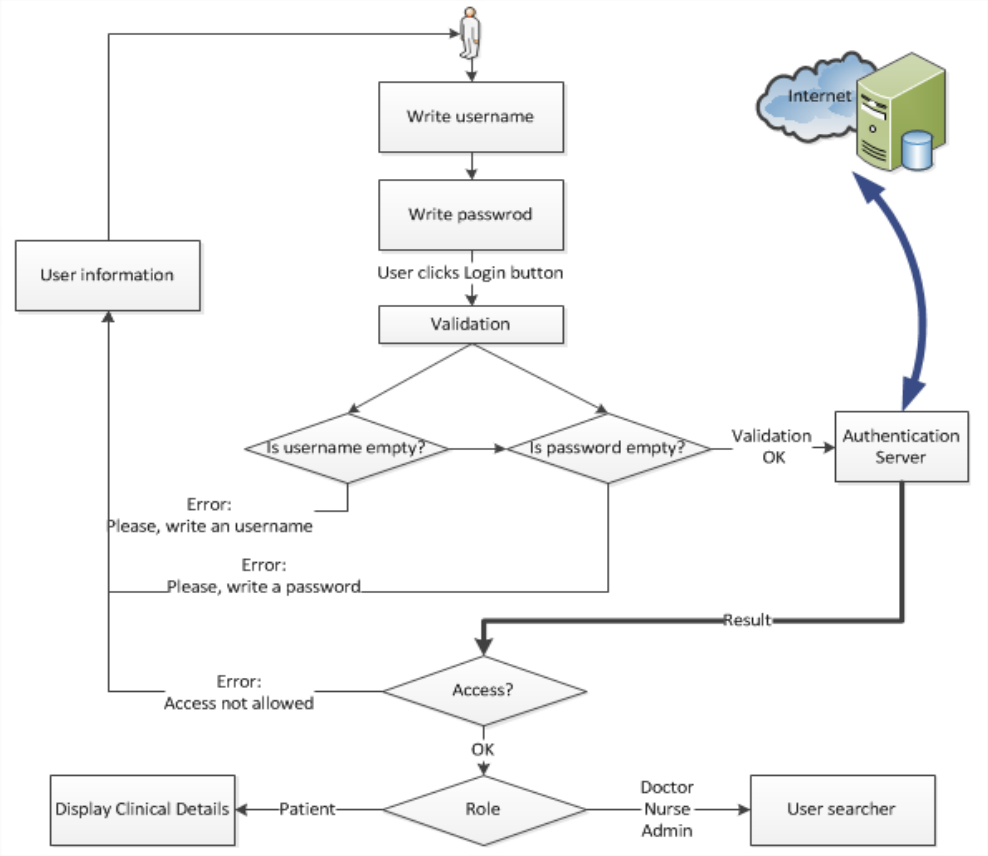

Figure 16: Diagram of use case "Secure access".

The inputs into this module are user username and password and the outputs are user details and role.

Display Clinical data

Once (1) the doctor selects a patient to work with or (2) a Patient is logged into the system, it displays all patient (selected/logged) clinical details.

Doctors and patients are allowed to update any information on it.

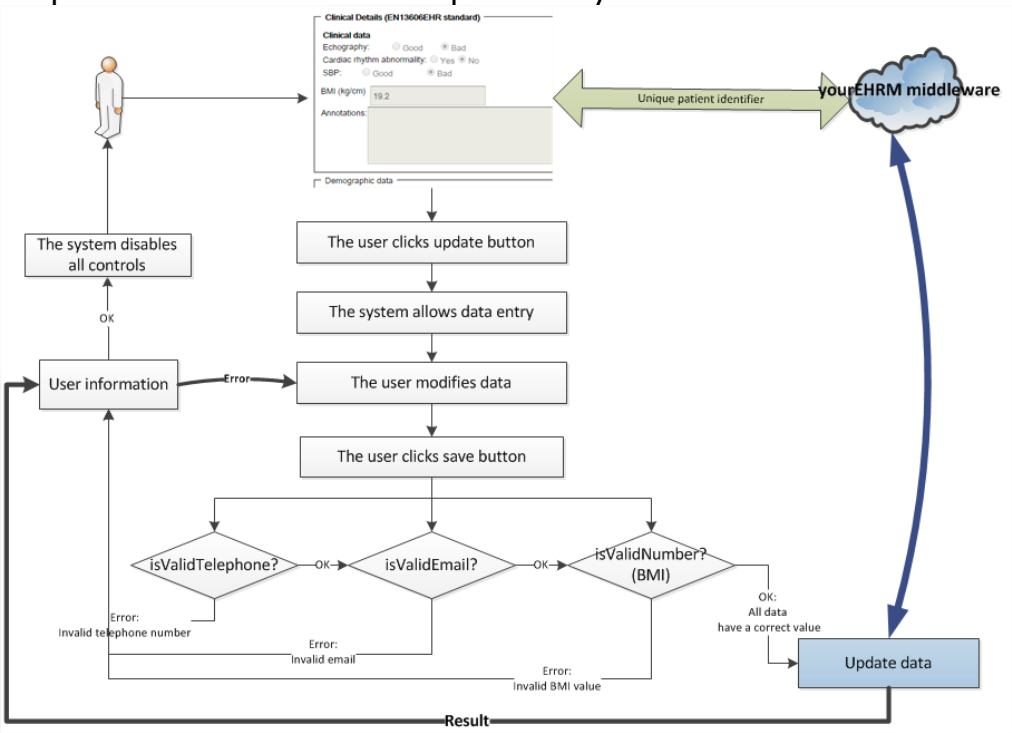

Figure 17: Diagram of use case "Display clinical data"

The input into this module is patient unique identifier, obtained from secure access (patient) or user searcher (doctor, nurse), and, after yourEHRM consultation, the system displays all patient clinical details.

Display Patient studies

The user (doctor, nurse or patient) is allowed to access to patient studies (DICOM images).

As a reminder, a specific patient´s study contains series of related DICOM images, each of them with certain information associated (name, date, type, etc.).
It provides a GUI which is capable to deploy these studies, apply filters, zoom the image, scroll through the whole series, etc.

It is also possible to create a preview image (png). These images can be attached to any clinical patient report (see WP6_HEA_DAT_UC01_internal_analysis_and_reporting).

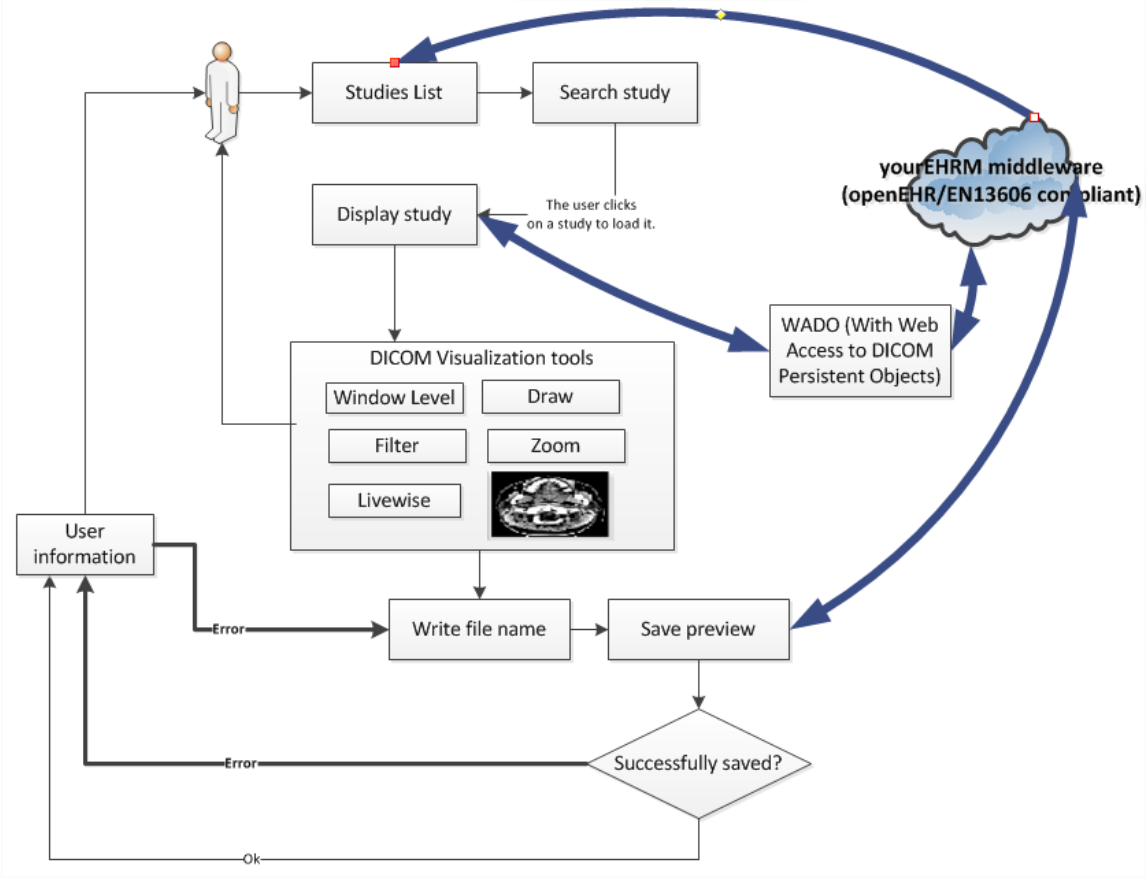

Figure 18: Diagram of use case "Patients studies (DCM images) display".

First, the user can see a list of all available studies, each of them with name, date and a preview (png image).

Figure 19: Graphical user interface of "Study list searcher".

Secondly, the full study is displayed in the central part of the screen and a tool bar with it. This tool bar controls various functions, filters, zoom, draw circles or lines, etc.

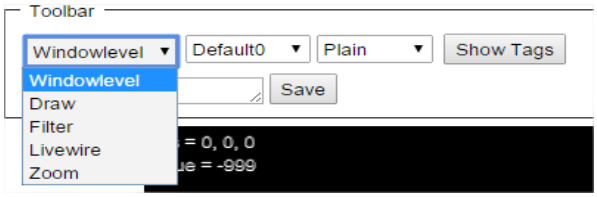

Figure 20: Graphical user interface of "Dicom toolbar".

Finally, a png image can be made with the displayed study, a print screen from the study. This image can be included in any patient clinical report (see WP6_HEA_DAT_UC01_internal_analysis_and_reporting section).

Figure 21: Graphical user interface of "Save image (png format)".

Display Patient prescriptions

In this section we are allowed to display patient prescriptions. The plan of care consists of name, beginning and end date, frequency, dose, units and also information on which doctor made the prescription.

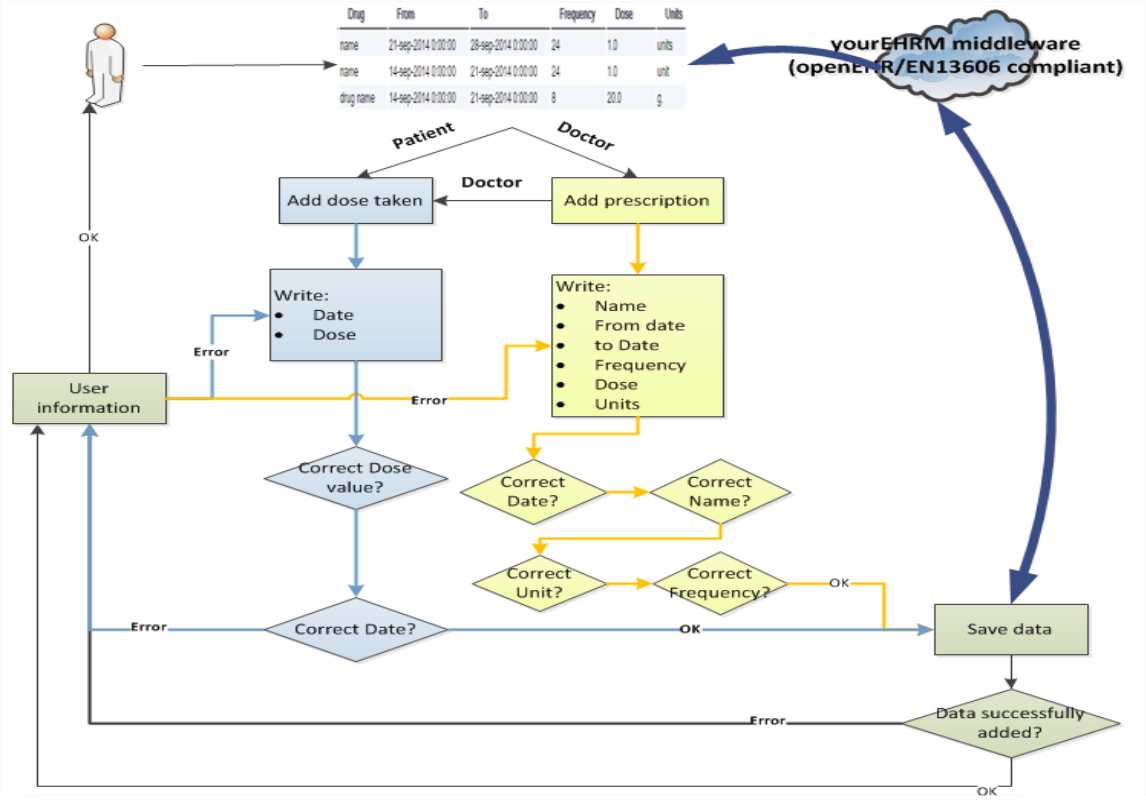

Figure 22: Diagram of use case "Patient´s prescription".

A qualified practitioner is allowed to add a prescription (yellow) to a selected patient and the patient is allowed to add his/her dose taken (date and time – blue).

Tools standards and protocols

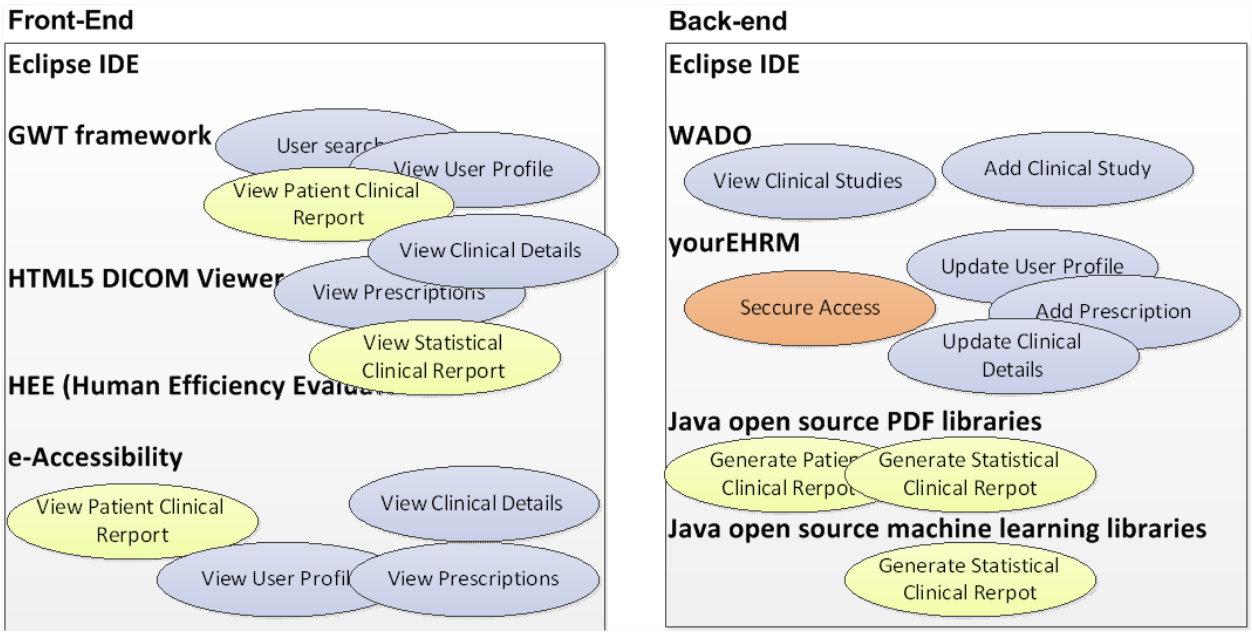

Figure 23: Relations between tools and use cases.

- **Eclipse IDE:** Eclipse is an integrated development environment (IDE) and it is used to develop the software application in Java. The main reasons why Eclipse is used are; (1) The Eclipse Public License (EPL) is an Open Source software license and (2) Its plugin architecture and its extensibility.

- **GWT framework:** Google Web Toolkit is an open source set of tools that allows web developers to create and maintain complex JavaScript front-end applications in Java. It will be used to build all GUIs.

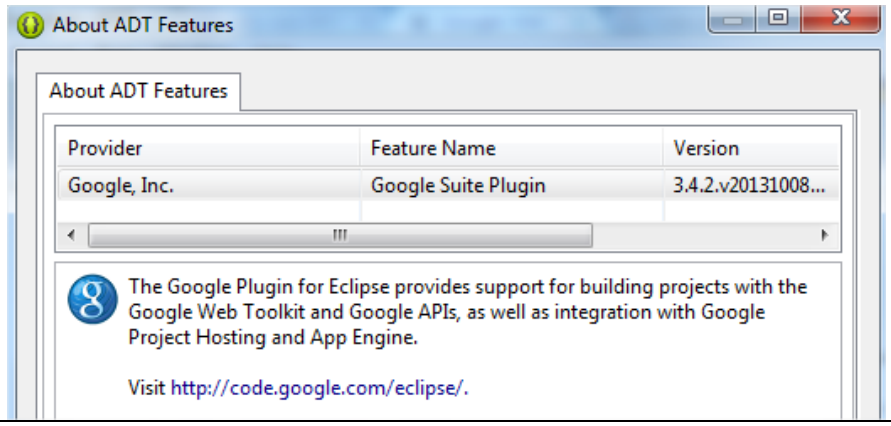

Figure 24: GWT plugin details.

- **DICOM:** Digital Imaging and Communication in Medicine is a standard for handling, storing, printing, and transmitting information in medical imaging.

- **HTML5 DICOM Viewer**: In order to display clinical images, this resource is absolutely required. It must be able to display a set of clinical images and apply filters, zoom, etc…, necessary tools into hospital environment. It will be used in studies use case.

- **WADO standard:** The WADO standard specifies a Web-based service for accessing and presenting DICOM persistent objects, such as images and medical imaging reports. WADO is intended for distribution of results and images to healthcare professionals. It will be used in studies use case in order to access to a patient study using the DICOM Unique Identifier (UID).

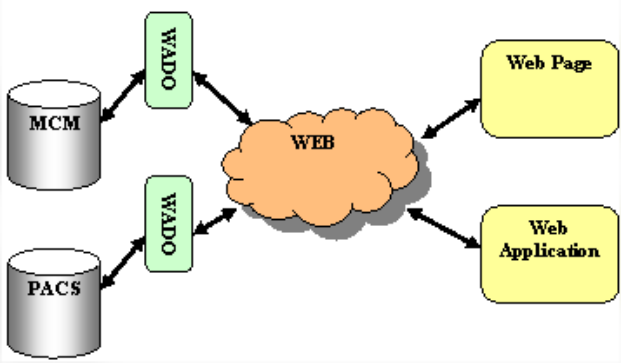

Figure 25: WADO diagram.

With WADO you can reach DICOM information from anywhere over the Web (http://www.research.ibm.com/haifa/projects/software/wado/).

- **yourEHRM middleware:** yourEHRM uses standards that enable medical information exchange (HL7, ISO 11073/IEEE 1073, CEN 13606, openEHR family of standards). It is mainly used to get clinical patient information and update it.

- **Java Coding Style Standards:** Code convention is important in order to improve the readability, usability and maintainability of the software. Code

conventions allow engineers to understand new code more quickly and thoroughly. It will be used throughout all software life cycle. The code convention covers filenames, file organization, indentation, comments, declarations, statements, white space, naming conventions, programming practices and includes a code example.

- **E-Accessibility tools:** It is essential that the Web be accessible (GUI) in order to provide equal access and equal opportunity to patients with diverse abilities. W3C's Web Accessibility Initiative (WAI) has published Web Content Accessibility Guidelines (WCAG). Any Section related to Patient MUST have Level AA conformance. It will be used throughout all software life cycle.

3.4 WP6_HEA_MRI_UC02_safe_patient_transfer

Leader: Philips

3.4.1 Operational definition of the AdCoS

The AdCoS is the system that enabled the design and validation of the Safe Patient Transfer System, also called the MRI Trolley.
This Trolley needs to be safe and easy to use for a broad range of operators and patients.
Anthropometric data:
MR operators with different stature will work with MR patient transportation and different patient sizes needs to be supported:
Patient weight: 0 – 250 kg.
Patient height: 0 – 2.20 m

The MRI Trolley is used to transport an immobile patient to and from the MRI scanner. The patient typically arrives in a non-MR compliant bed or wheel chair at the MRI facility. Outside the examination room the patient is put on the MRI table top, which is on the trolley. The operator wheels the trolley + patient into the examination room, and places this over the patient support, which is in lowered

position. If the patient support is lifted the tabletop with patient will be automatically put on top, ready to be shifted inside the MRI scanner.

User Needs

The high level user is:

Enable fast patient preparation, easy and safe patient transport, and comfort for immobile patients and flexibility in emergency situations

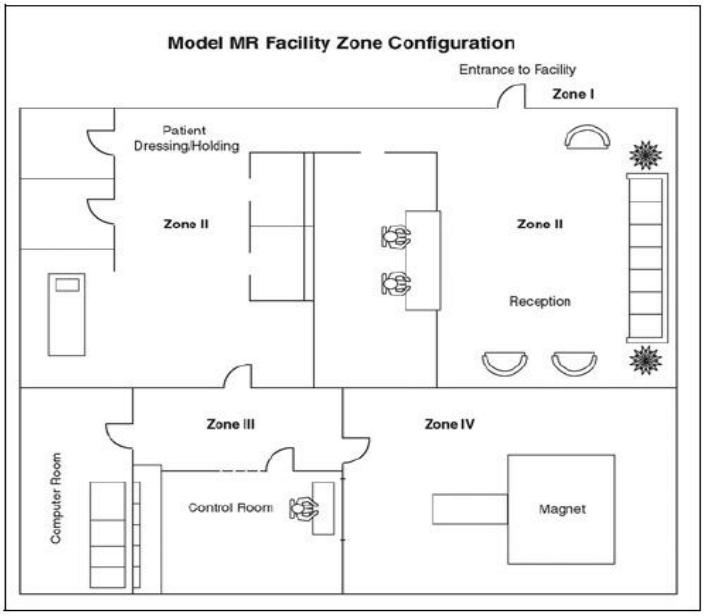

Figure 26: Safe patient transfer

The Figure 26 shows:

- Left below: Picture of the MRI Trolley;
- Left above: Patient on trolley is wheeled to the MRI system.
- Right: typically lay-out of the radiology department.

The AdCoS needs to be able to model the variety of applications, operators, patients and physical properties of the radiology department.

3.4.2 Human-Machine Interaction for the AdCoS

The MRI Trolley is a completely manually controlled device with clearly defined interfaces with:

- The MRI table top, which is placed on top of the trolley
- The Patient support (the static part in front of the magnet, that carries the table top when the patient is shifted into the magnet)

Human interfaces are:

- Handles to move the trolley
- Brakes
- Rotation blockers to enable straight or curved movement
- Bracket to prevent patient from falling off the trolley
- Fixation to the MRI table top
- Warning stickers to prevent finger pinching and mounting the wrong table top

For the AdCoS, so the Safe Patient Transport Design System, the HMI is:

Input/output channel:

Input:

- Mechanical design
- Use cases (including description of actors)

Output:

- Identification of usability issues

3.4.3 Tools applied from HF-RTP

Currently applied design tooling:

- Requirement management: HP Application Lifecycle Management
- Documentation archive: Agile
- Mechanical design tooling: ProEngineer

Currently applied analysis & feedback tooling:

- Usability analysis tooling: questionnaires, interviews, observations
- Internal defect tracking (during development): ClearQuest

- External defect tracking (after release): TrackWise

The Safe Patient Transport Design System shall be able to simulate the use of the proposed design in all relevant clinical situations, applications, patient and operator characteristics and radiology department lay-out and way of working. Also emergency situations need to be covered.

It shall be possible to assess both safety and ease of use.

Required Methods, Techniques, Tooling support:

1. **to simulate functional aspects** of the trolley and related components for the full range of specified users, patients and applications
2. to allows **fast iteration to rapidly validate various concepts** interactively
3. to **automatically validate a series of concepts**, resulting in a summary with pro's and con's for the various options
4. to **smoothly interface with applied mechanical design tools** (Pro-E) for product validation

From the list of available methods, tools and techniques in the HF-RTP the following preliminary selection is made. This is intended as the first estimate, based on available descriptions of the tools; the actually applicability of the MTT for this AdCoS needs to be explored in the next phases of the project.

Step of the tool-chain	Tools and techniques to be explored
Requirements definition and tracking	No support required
Modelling of tasks, agents, UI and interaction	Potential for the required MTT support 1 and 2: • OFFIS: Human Efficiency Evaluator. • CVT: Pro-SiVEC.
HMI	No design tools with HMI available
Implementation and integration	No tools available for required MTT support 4.
Simulation and evaluation of user related aspects	Potential for MTT support 3: • HFC: Task analysis; Human Factors and Safety regulations and guidelines for metrics; • HFC: Tests for Cognitive Task Models.

Table 8: Phases of the project.

3.4.4 Requirements Update

Currently optimization of the design of the trolley is very labor intensive and requires design, creation, and validation of various prototypes, including workflow tests and ergonomic reviews. No tooling is applied. There is low coverage of all cases, patient- and operator groups and applications.

The cost per prototype is € 20k; labor cost, including user validation is > € 200k.
MTT Requirements:

- Modeling: SW tool to study the functional aspects of the proposed design of the trolley in a series of use cases, including different clinical cases, number, position and sizes of operators and patient characteristics.
- Evaluation: Methods and tooling (e.g. including questionnaires) to systematically access the user related aspects of the actual trolley in clinical tests.
    - The method needs to be:
        - Reproducible
        - Cover the full range of tests to assure product safety in all clinical cases
    - Systematically storage of tests and results shall be provided. It shall be possible be reuse the tests and results later, e.g. for the next version of the product.

3.4.5 System architecture

The MRI Trolley is a separate component with clearly defined interfaces with:
- The MRI table top, which is placed on top of the trolley
- The Patient support (the static part in front of the magnet, that carries the table top when the patient is shifted into the magnet)

The AdCoS, so the tool to design and validate the MRI trolley, needs to interface with mechanical design tooling: ProEngineer.

3.5 WP6_HEA_MRI_UC01_guided_patient_positioning

Leader: Philips

3.5.1 Operational definition of the AdCoS

The AdCoS is the system that provided guidance to the operators during preparing and positioning patient for MRI examinations.

Figure 27: Pictures of several actions during patient positioning

Correct positioning of the patient for the MRI examination and using the right coils and other devices are important to get good diagnostic quality images, but also important to avoid safety issues. Currently the operator is trained for this. The on-line guidance system intends to improve usability and to reduce risks, also in case of novice, less experienced users.

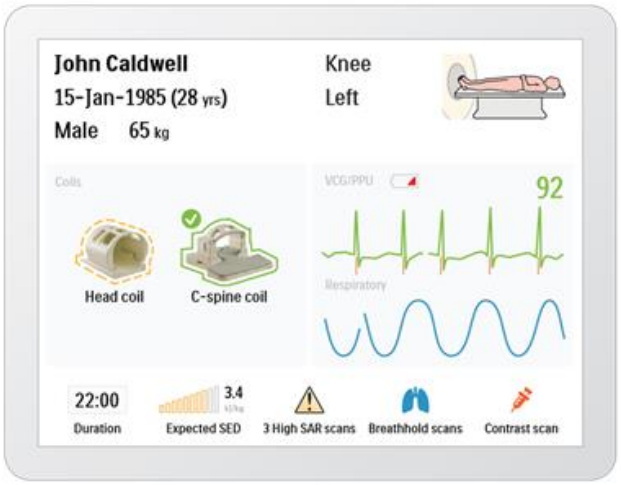

Figure 28: Example of the gantry display.

Adaptivity:
The Guided Patient Positioning System shall provide on-line guidance and actual information during positioning of the patient. It needs to use the input data, as listed above. From the patient characteristics and MRI examination procedure the system can derive the instructions to the operator, which needs to be updated on-line based on detectable actions by the operator.

The system shall provide clear and timely feedback to the operator on the status of relevant connected accessories, and help the operator in making corrections if necessary.

The system shall support multiple users, since patient positioning might be performed by more than one operator. Also other medical staff might be present, e.g. the anaesthesiologist.

The system could use historical data, e.g. derived from the systems log-file, to predict the flow of actions and optimize guidance.

Cooperation:
The Guided Patient Positioning System will always show the current status, and therefore updates if the situation changes that are detectable by the system: like

the connection of coils, availability of physiology signals and changes on patient attributes or examination by the operator.

The system provides a UI to the operator to obtain more detailed information.

If necessary the system generates warnings based on detected patient behaviour.

3.5.2 Human-Machine Interaction for the AdCoS

Operator control:
The touch screen UI on the Gantry Display allows the operator to access various levels of information (e.g. more detailed instructions for novice users, more details of received physiology signals)

Input:
The Guided Patient Positioning System has access to the following on-line information:

- Current patient (name, age, weight, etc.)
- Special patient characteristics (pregnancy, implants, etc.)
- Clinical request
- MRI examination procedure
- Connected coils
- Connected accessories
- Signals received from accessories, if applicable (e.g. ECG signal)
- Environment conditions (temperature, humidity, etc.)
- System settings (e.g. setting of headset volume, ventilator, light)

Output:
The Gantry Display, positioned at the front of the magnet at a fixed location, provides information and instructions for the operators. Additionally sound can be used to provide feedback to the operator.

Operator's background:
MR operators have been more extensively trained and educated in the broader aspects of MR safety issues, including, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing

gradients. Optionally MR operators have been further trained in MRI through an accredited program. On top of this, MR operators typically receive device specific training, which is also the case for operators using Philips equipment. Philips offers a device specific training by a Philips Clinical Education Specialist.
Nevertheless, operators may switch between modalities (MRI, CT, X-ray) and between MRI systems of different vendors. The number of available operators is reducing at several regions, so the work needs to be done by less staff and the education and experience level will vary.

Operator actions during patient positioning:
Connection of coils and accessories:

- RF coils: For optimal image quality the right RF receive coils need to be connected and positioned
- ECG electrodes: in case the scan needs to be synchronized with patient's heart rate ECG electrodes need to be attached to the chest and the ECG detector needs to be connected
- Respiratory sensor: in case the scans needs to be synchronized on the breathing of the patient a respiratory sensor needs to be attached to the patient chest
- Audio: Apply ear plugs and headset to prevent hearing damage, to allow communication with the patient and to provide music to the patient during the examination; Adjust audio volume
- Provide nurse call balloon to the patient to allow to signal or alarm the operator, and instruct the patient how to use this
- Comfort and Immobilization: In order to prevent movements of the patient during scanning pillows and straps may be used to prevent motion and to arrange a comfortable position
  Adjust patient ventilation and light settings, if necessary
- Patient instructions: Instruct the patient on do's and do not during the examination
- Scan plane: determine the centre of the anatomy to be scanned and shift the patient into the system to the preferred location

Safety risks to be reduced by the Guided Patient Positioning System:
During positioning of the patient, it is very important to be aware of all safety related aspects:

- RF heating:
  - Avoid loops of body parts (e.g. calves of the legs too close together, hand-in-hand position)

  - Avoid arms positioned too close to the side of the bore
  - no loops in conductive wires of coils and accessories (like VCG leads)
- Ventilation:
  - Provide adequate ventilation and do not cover the patient too much
- Peripheral nerve stimulation:
  - Explain the patient that he might encounter peripheral nerve stimulation due to fast switching of magnetic field gradients
- Acoustic noise:
  - Provide adequate hearing protection (for adults in-ear plugs and headset)
  - Adjust intercom volume on headset for voice instructions to the patient
- Table movement:
  - Prevent pinching of patient parts (e.g. fingers)
  - Prevent clamping of clothing / blankets
  - Avoid pinching / clamping of leads (e.g. of ECG) / wires (e.g. of coils) / tubes e.g. of nurse call and respiratory sensor)
- Nurse call:
  - Provide the nurse call to the patient and explain that this needs to be pressed once to get attention and twice to generate an alarm

3.5.3 Tools applied from HF-RTP

The design process, including validation of intermediate and final solutions, is hardly supported by tooling. It is therefore very likely that some tooling in the HF-RTP can be applied and leads to a more structural and repeatable design process.

Required MTT Support:

1. **to model and simulate functional aspects** patient positioning for the full range of specified users, patients and applications
2. **to systematically validate a series of concepts**, resulting in a summary with pro's and con's for the various options

From the list of available methods, tools and techniques in the HF-RTP the following preliminary selection is made. This is intended as the first estimate, based on available descriptions of the tools; the actually applicability of the MTT for this AdCoS needs to be explored in the next phases of the project.

Step of the tool-chain	Tools and techniques to be explored
Requirements definition and tracking	No support required
Modelling of tasks, agents, UI and interaction	Potential for MTT support 1: • OFFIS: Human Efficiency Evaluator. • EAD-FR: HGRAPH / Analysis of operator, patient and nominal interaction (based on patient characteristics and type of examination). Assess current operation and provide dynamic guidance according to the context • Anywi: Modelling of AdCoS data from a means-ends perspective
HMI	Potential for MTT support 1: • Anywi: HMI framework development
Implementation and integration	No support required
Simulation and evaluation of user related aspects	Potential for MTT support 2: • HFC: Task analysis; Human Factors and Safety regulations and guidelines for metrics; • HFC: Tests for Cognitive Task Models. • ERG: Dikablis (Head-mounted eye tracking system) • RE:LAB: Empirical validation methods in simulators • SNV: Empirical analysis and validation methods of cognitive and communicative processes in automotive and control room domain

Table 9: Next phases of the project.

3.5.4 Requirements Update

MTT Requirements:

- Modeling: SW tool to study the functional aspects of the proposed design in a series of use cases, including different clinical cases, position and sizes of operators and patient characteristics.
- Evaluation: Methods and tooling (e.g. including questionnaires) to systematically access the user related aspects of the actual trolley in clinical tests.
    - The method needs to be:
        - Reproducible
        - Cover the full range of tests to assure product safety in all clinical cases
    - Systematically storage of tests and results shall be provided. It shall be possible be reuse the tests and results later, e.g. for the next version of the product.

3.5.5 System architecture

The Guided Patient Positioning System is integrated in the Philips MRI systems

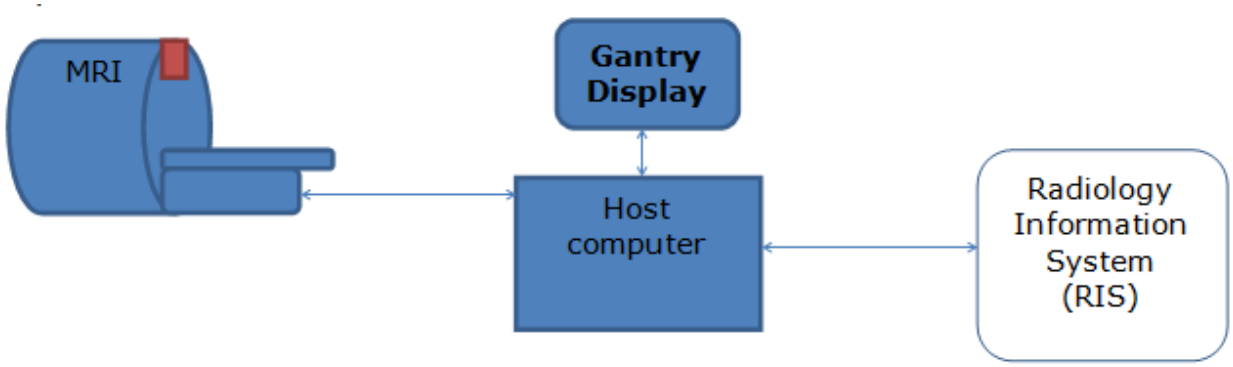

Figure 29: Simple diagram showing the connections of the Gantry display with the MRI system. Note that the display is physically on the front of the MRI magnet (indicated in red). The display is a touch screen, which allows operator control. No other sensors or cameras are part of the current system.

3.6 WP6_HEA_MRI_UC02b_robust_ECG_triggering

Leader: Philips

3.6.1 Operational definition of the AdCoS

The AdCoS is a system for real time acquisition of physiology signals from the patient to derive trigger signals required during MRI scanning.
Acquired signals:

- VCG (Vector Electro Cardiogram, via sensors on the chest)
- PPU (Peripheral Pulse Unit, typically via a finger clip)
- Respiratory (via sensor on the chest)

The system analyses the signals, determines calibration setting for the trigger detection algorithm, display the trigger signals and provide triggers to the MR system during scanning for real-time synchronization. The system also displays the signals, allowing the operator to judge the quality, and all data are logged for off-line analysis.

Many MRI scans require synchronization on the cardiac motion, either to minimize motion artefacts due to the motion of the heart itself or the pulsatile blood flow.
Two methods are available:

- VCG (Vector-ECG) signals, derived from electrodes on the patient's chest
- PPU, peripheral pulse unit, which measures the oxygen level in the fingertip.

The VCG signals are accurately linked to the cardiac motion and are needed if images are taken close to or of the heart. In that case trigger pulses are derived from the signal, either to directly synchronize the scans or to administer the timing together with the MR data collection, used to retrospectively align the MR data with the ECG signal. The signals are processed real-time, allowing a maximum delay between actual occurrence of the cardiac R-top and the trigger signal of 25 ms.

Detection of the ECG signal during MR scanning is complicated because of the following effects:

- The ECG signal is distorted because blood flow in the presence of a strong magnetic field creates significant potential differences, which interferes with the normal ECG signal
- Fast gradient switching induces additional potential differences in the body, which can be easily much larger than the normal ECG signal

Filters are available to deal with these issues. However, positioning of the electrodes in relation to the physiology of the patient and respiratory motion are still important sources for distortion.

Figure 30: Placement of the ECG electrodes

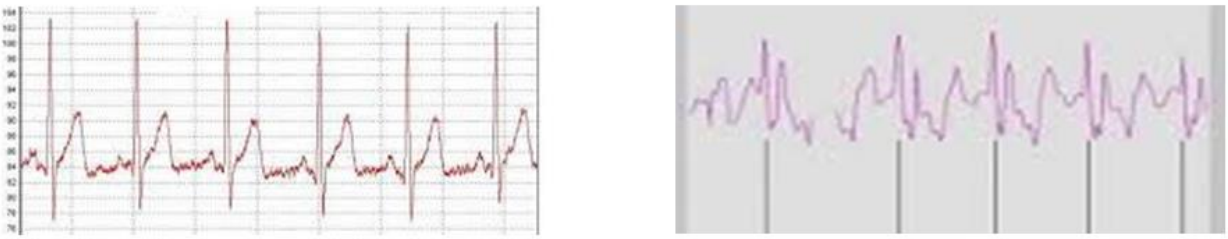

Figure 31: Left: Clean ECG signal outside the magnet, right distorted ECG signal in the magnet due to MHD effect in combination with blood flow.

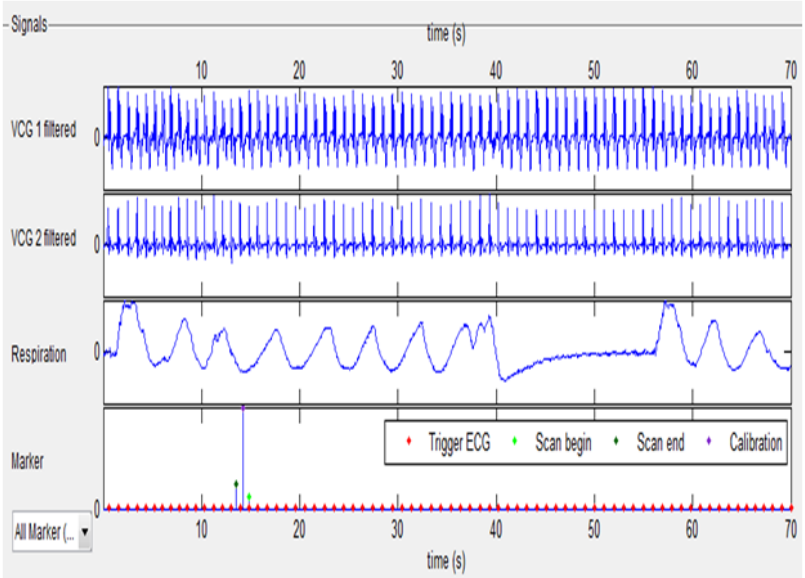

Figure 32: Example physiology display.

Figure 32 shows from top to bottom: two ECG traces, one respiratory trace, and the red trace with trigger signals. Note that this was a breathhold scan, as can be seen from the respiratory signal.

Adaptivity:
The Robust ECG Triggering System shall make sure that reliable trigger signals are derived from the ECG signal during MRI scanning. It therefore needs to adapt to the variety of possible input signals and provide adequate signal processing.
Also adequate on-line guidance and actual information needs to be provided to the operator, both during positioning of the patient and during scanning.
From the received physiology signals, the patient characteristics and MRI examination procedure the system can derive the instructions to the operator, which needs to be updated on-line. E.g. in case of strongly varying signals the patient probably moved during scan, in case of low signals there is an issue with the electrode attachment or wiring.

The system shall provide clear and timely feedback to the operator on the status, and provide clear instructions to the operator to make corrections if necessary.

The system shall support multiple users, since patient positioning might be performed by more than one operator. Also other medical staff might be present, e.g. the anaesthesiologist.

The system could use historical data, e.g. derived from the systems log-file, to predict the flow of actions and optimize guidance.

Cooperation:
The Robust ECG Triggering System will always show the current status, and therefore updates if the situation is changes.

The system provides a UI to the operator to obtain more detailed information.

If necessary the system generates warnings based on detected patient behaviour.

3.6.2 Human-Machine Interaction for the AdCoS

Input/output channels (see also previous paragraph):

Input:
- all data and settings available at the MRI system
- operator control via the UI touch screen

Output:
- images, text, graphics on the display
- sound

3.6.3 Tools applied from HF-RTP

The design process, including validation of intermediate and final solutions, is hardly supported by tooling. It is therefore very likely that some tooling in the HF-RTP can be applied and can lead to a more structural and repeatable design process.

Required MTT Support:

1. **Improved operator guidance** based on analysis of acquired data during patient positioning and scanning.

2. **Off-line data analysis** to identify patterns in the acquired signals trying to relate this to the success or failure of successful triggering, and to patient characteristics (like weight).
3. **Simulation environment** to study the generation of trigger signals derived from all available input data (ECG signals, PPU signal, respiratory signal, patient characteristics, etc.)
4. **Real time data analysis and system control**, including adequate feedback to the operator, based on all available input signals (ECG, PPU, respiratory, scan status, …)

From the list of available methods, tools and techniques in the HF-RTP the following preliminary selection is made. This is intended as the first estimate, based on available descriptions of the tools; the actually applicability of the MTT for this AdCoS needs to be explored in the next phases of the project.

Step of the tool-chain	Tools and techniques to be explored
Requirements definition and tracking	No support required
Modelling of tasks, agents, UI and interaction	Potential for MTT support 1 and 4: • OFFIS: Human Efficiency Evaluator. • Anywi: Modelling of AdCoS data from a means-ends perspective
HMI	Potential for MTT support 1 and 4: • Anywi: HMI framework development
Implementation and integration	No support required
Simulation and evaluation of user related aspects	Potential for MTT support 1: • HFC: Task analysis • HFC: Tests for Cognitive Task Models. • SNV: Empirical analysis and validation methods of cognitive and communicative processes in automotive and control room domain Potential for MTT support 2 and 3: • UTO: data analysis

Table 10: Next phases of the project.

3.6.4 Requirements Update

MTT Requirements:

- Modeling: SW tool to study the functional aspects of the proposed design in a series of use cases, including different clinical cases, position and sizes of operators and patient characteristics.
- Evaluation: Methods and tooling (e.g. including questionnaires) to systematically access the user related aspects of the actual trolley in clinical tests.
    - The method needs to be:
        - Reproducible
        - Cover the full range of tests to assure product safety in all clinical cases
    - Systematically storage of tests and results shall be provided. It shall be possible be reuse the tests and results later, e.g. for the next version of the product.

3.6.5 System architecture

The Guided Patient Positioning System is integrated in the Philips MRI systems

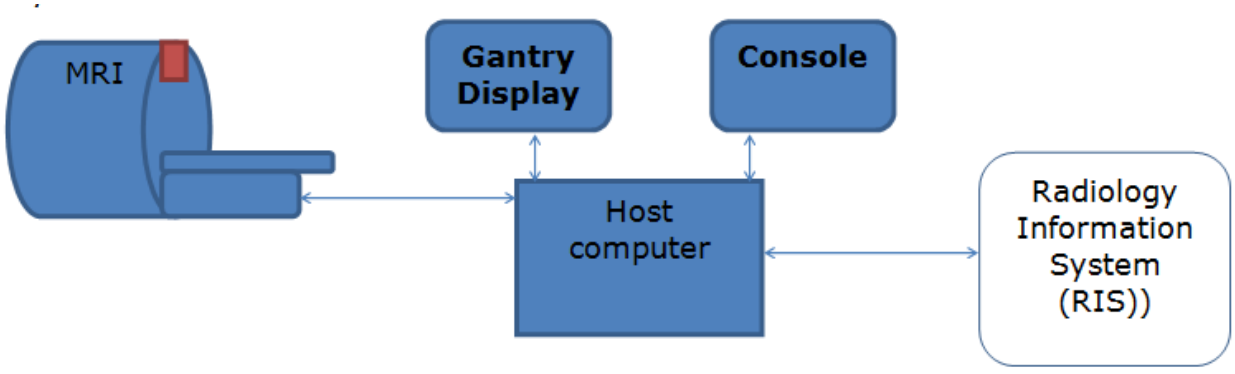

Figure 33: Simple diagram showing the connections of Console and the Gantry display with the MRI system.

Note that the display is physically on the front of the MRI magnet (indicated in red). The physiology traces can be displayed on both the Gantry Display and on the Console.

3.7 WP6_HEA_MRI_UC03_safe_parallel_transmit_scanning

Leader: UMCU

3.7.1 Operational definition of the AdCoS

To optimize the MR image quality for certain anatomical regions, a so-called phased antenna array is used in 7T head imaging.
A set of (e.g. 8) RF amplifiers each connected to a coil element (antenna) provides the transmit field to generate MR signal. Each channel is independently modulated: optimal phase, frequency and amplitude modulation should lead to the required excitation of part of the patient, e.g. homogeneous (same signal from all parts of the brain), or spatially focused (e.g. only signal from the spinal cord).

However, this temporal modulation of the RF signals alters also the spatial interference of the concomitant electric fields resulting potentially in unsafe RF induced tissue heating (microwave heating effect) at certain body location.

The electric fields and heating cannot be detected directly with MRI and their spatial patterns are highly patient specific due to the complex electromagnetic interaction of RF signals with the human body. The RF power absorption can only be determined by means of electromagnetic simulations employing dielectric models of the scanned subject.

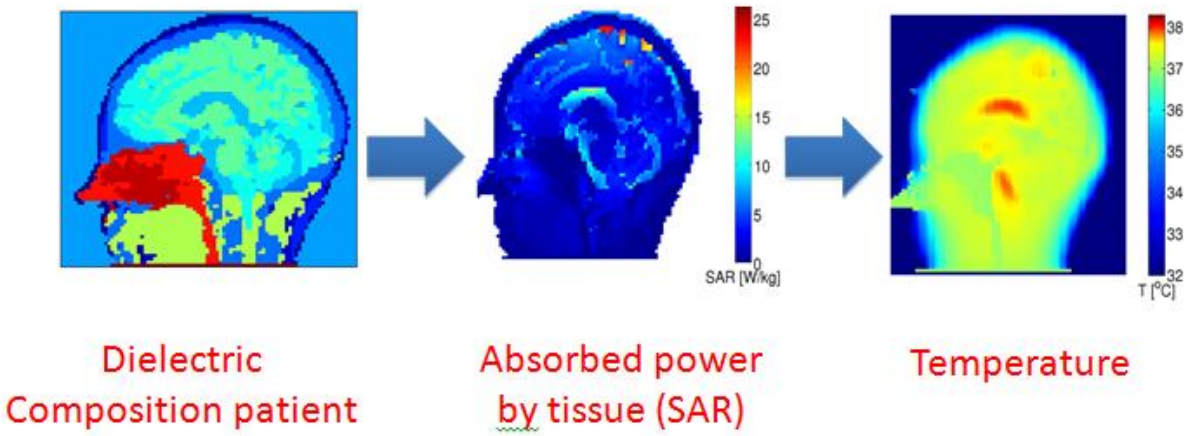

Figure 34: Relation between various calculated maps of field in the patient.

The AdCoS consists of the following parts:

- Tool to calculate the dielectric composition of the patient
- Tool to calculate the local absorption of RF energy in the patient
- Tool to calculate the local temperature change in the patient
- Mechanism to adjust the RF transmit system based on calculated temperature map, taking safety limits into account
- UI elements to communicate the status and required actions to the operator
- Control elements to run-time monitor the status of all elements in the RF transmit chain
- Mechanism to generate an interlock followed by a scan abort if any malfunction is encountered

The AdCoS makes use of the general capabilities of the MRI system to calibrate average RF power and to scan a series of scans and real-time generate images.

Adaptivity:

The Safe Parallel Scanning System has the challenge to automatically adapt the RF power and phase settings for all transmit channels to:

1. Reach optimal image quality
2. Guarantee patient safety

Input before scan:

- Scan definition (scan technique, required field of view, required signal suppression / selective excitation)
- Patient characteristics (e.g. weight, age, maximum allowed RF power, presence of implants, clinical request / expected pathology)
- System calibration settings
- Historical data (from log-files)

Input from pre-scans and preparation phases:

- Anatomical structure
- Course RF power settings (amplitude and phase per channel)
- Course RF field distribution

From dedicated pre-scans:

- Dielectric composition of the patient
- Map of locally absorbed RF power

- Map of predicted temperature change in the patient during scan

Real-time, during Scan:
- Power monitoring status
- Reflexed power per channel
- Pick-up coil signals per channel
- Patient's physiology signals (respiratory motion, heart rate)

The system shall automatically adapt RF power and phase settings and provide clear and timely feedback to the operator on the status, provide clear dialogues if intervention of the operator is required and help the operator in making corrections if necessary.

The system could use historical data, e.g. derived from the systems log-file, to predict the flow of actions and optimize guidance.

Cooperation:
The Safe Parallel Scanning System is a sub-system of the MRI system and shared resources and control with other sub-systems.

It will always show the current status, and therefore updates if the situation is changes.

The system provides a UI to the operator to present the actual status, provides options to obtain more detailed information and presents clear dialogues if intervention of the operator is required.

If necessary the system generates warnings based on receive RF signals and on detected patient behaviour.

3.7.2 Human-Machine Interaction for the AdCoS

Input/output channels (see also previous paragraph):

Input:
- all data and settings available at the MRI system
- operator control via the console

Output:

- images, text, pop-ups, dialogues, graphics on the console
- sound

3.7.3 Tools applied from HF-RTP

The design process, including validation of intermediate and final solutions, is hardly supported by tooling. It is therefore very likely that some tooling in the HF-RTP can be applied and can lead to a more structural and repeatable design process.

Required MTT Support:

1. **Modelling of physiology and human heating,** connecting measurements and theory.
2. **Analysis of operator actions and use patterns** to access the effectiveness of safety related user interaction
3. **Modelling of the AdCoS** to have a clear overview of the system and the user interaction

From the list of available methods, tools and techniques in the HF-RTP the following preliminary selection is made. This is intended as the first estimate, based on available descriptions of the tools; the actually applicability of the MTT for this AdCoS needs to be explored in the next phases of the project.

Step of the tool-chain	Tools and techniques used
Requirements definition and tracking	Potential for MTT support 1: • UTO: greatSPN: physiology & human heating modelling & analysis
Modelling of tasks, agents, UI and interaction	Potential for MTT support 3: • SNV & TEC: Analysis of system and operator actions from log files • Anywi: Modelling of AdCoS data from a means-ends perspective •
HMI	Potential for MTT support 3: • Anywi: presentation of data in UI
Implementation and integration	No support required

Simulation and evaluation of user related aspects	No support required

Table 11: Next phases of the project.

3.7.4 Requirements Update

MTT Requirements:

- Modeling:
  - SW tool to model and analyze physiology & human heating in order to justify / validate the modelling as provided by the AdCoS
  - SW tool to study the functional aspects of the proposed design in a series of use cases, including different clinical cases, position and sizes of operators and patient characteristics.
- HMI:
  - Design strategy for presentation of data in the UI

3.7.5 System architecture

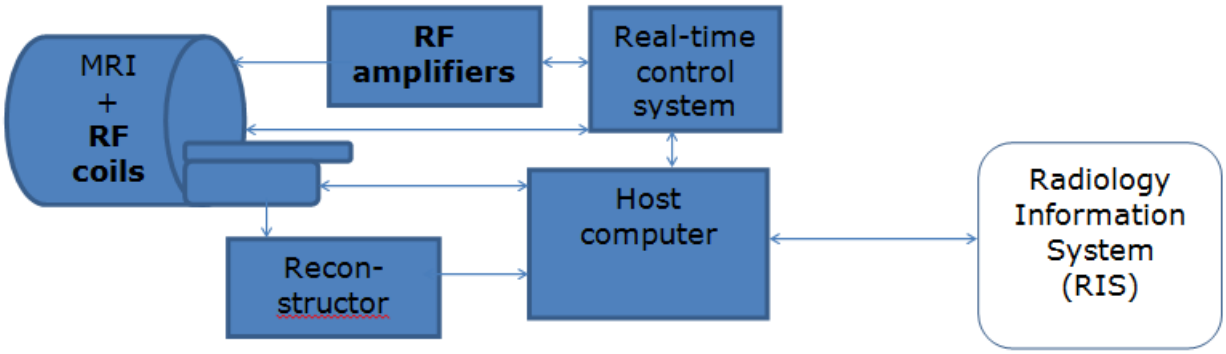

Figure 35: Simple diagram showing parallel transmit scanning system.

3.8 WP6_HEA_iXR_UC01_3D_acquisition

Leader: Philips

3.8.1 Operational definition of the AdCoS

An angiography x-ray system is used to visualize anatomy, catheters and other instruments during minimally invasive procedures like coronary stenting in the heart or aneurysm repairs in the brain. The X-ray images used to be only 2D, but advances in technology now also allow to make a 3D scan to better visualize the anatomy and use this 3D volume as planning and 'navigation' tool for the intervention.

Acquiring and working with the 3D data can be very complicated for many users. The tools require repetitive training and a lot of know-how, which is not always available in the hospital. Furthermore staff rotation and variability in their task division (roles) is high, so users are not likely to become expert users before the end of their rotation.

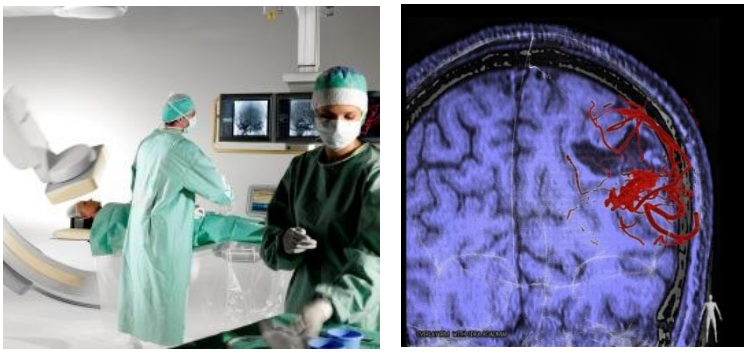

Figure 36: X-ray system acquires 3D volume to visualize the vessels (see red). In this example is then overlaid on a MRI scan that the patient had earlier (see purple).

Therefore in current practice it is a challenge to design optimal user interfaces and product behaviour for the variance in user roles/skills and ways of working in minimally invasive procedures. Inability of the product to adapt to specific user roles/skills and workflows result in sub-optimal workflow support and usability. This leads to low adoption rate of valuable clinical tools like 3D acquisition. With help of good design our objective is to make users become more confident and efficient in acquiring and using 3D data. An example of adaptability is to play

with level of user guidance, target information to the right users concerned with the related task and remember repetitive actions/preferences. The system can automatically adapt the display based on recorded history.

As a consequence we define the 3D Acquisition AdCos as a variable system of acting agents that consists of user agents and the product agent. Variability is in the roles of different users, order in which they perform tasks, skills they have, the way they are organized to work with 3D acquisitions and feedback provided by the product agent based on detected events.

3.8.2 Human-Machine Interaction for the AdCoS

In the 3D Acquisition AdCos multiple steps and multiple HMI components are identified. The workflow below lists all general steps for an interventional procedure in which 3D data is used:

Before procedure

1. Make pre-scan, CT or MR to be able to re-use in interventional suite
2. Make data available to be accessed in interventional suite: PACS, USB, CD/DVD

During procedure

3. Select patient for acquisition (from XtraVision)
4. Select relevant data for import
5. Import relevant data for interventional tools
6. Pre-processing of imported data
7. Prepare patient and surrounding equipment
8. Prepare system for 3D acquisition
9. Perform 3D acquisition scan
10. Register CT/MR data with 3D scan
11. Perform treatment (use live image guidance to guide the procedure)
12. Additional scan for navigation or assessment (optional)

After procedure

13. Remove patient
14. Create snapshots or movies to export or archive
15. Reporting - Create report of the procedure
16. Reporting of materials used (for billing)

Figure 37: General steps for an interventional procedure in which 3D data.

For the AdCos we are only interested in steps 7, 8 and 9. These steps and their specific HMI issues are described below.

Step 7: Prepare patient and surrounding equipment

Preparing patient and surrounding equipment – In this step the patient is put in the right posture (e.g. hands behind head). All tubes, lines and drips are fixed to the table in such a way that the c-arm does not collide with them when it makes its rotation around the patient for the 3D scan. The injector that automatically injects contrast agent into the patient is also prepared and programmed. Then staff makes sure the desired 3D application that reconstructs the acquired 3D data is visible on the monitors.

What the AdCos is supposed to do:

- Detect how user is performing and interpret system events
- Provide appropriate instructions to the right actor (user)
- Check if preparation is complete and done well

Figure 38: Step 7; Prepare patient and surrounding equipment.

Step 8: Prepare system for 3D acquisition

Prepare system for 3D acquisition – In this step the c-arc is moved in the right position and the table is adjusted. The goal is to get the patient anatomy that is to be imaged in the center of the c-arm trajectory. Low dose x-ray in a frontal and lateral view is used to check the position of the anatomy while adjusting table height and position. Next staff selects the desired imaging protocol to make the 3D scan.

What the AdCos is supposed to do:

- Detect how user is performing and interpret system events
- Provide the right instructions to the right actor (user)
- Check if preparation is complete and done well

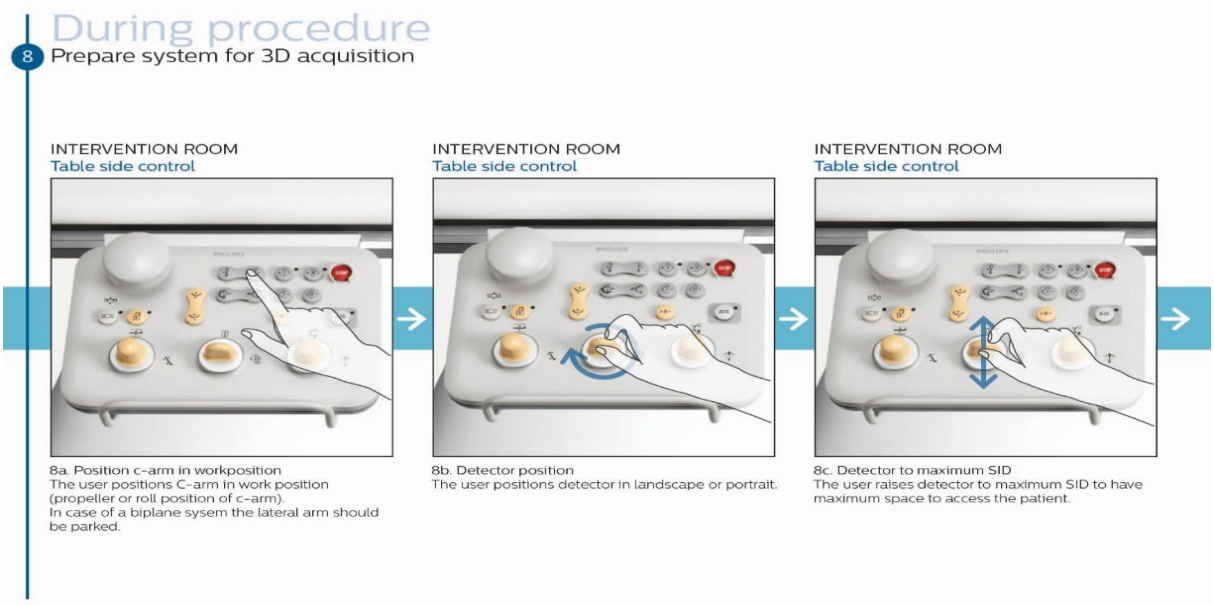

Figure 39: Step 8: Prepare system for 3D acquisition, table side control.

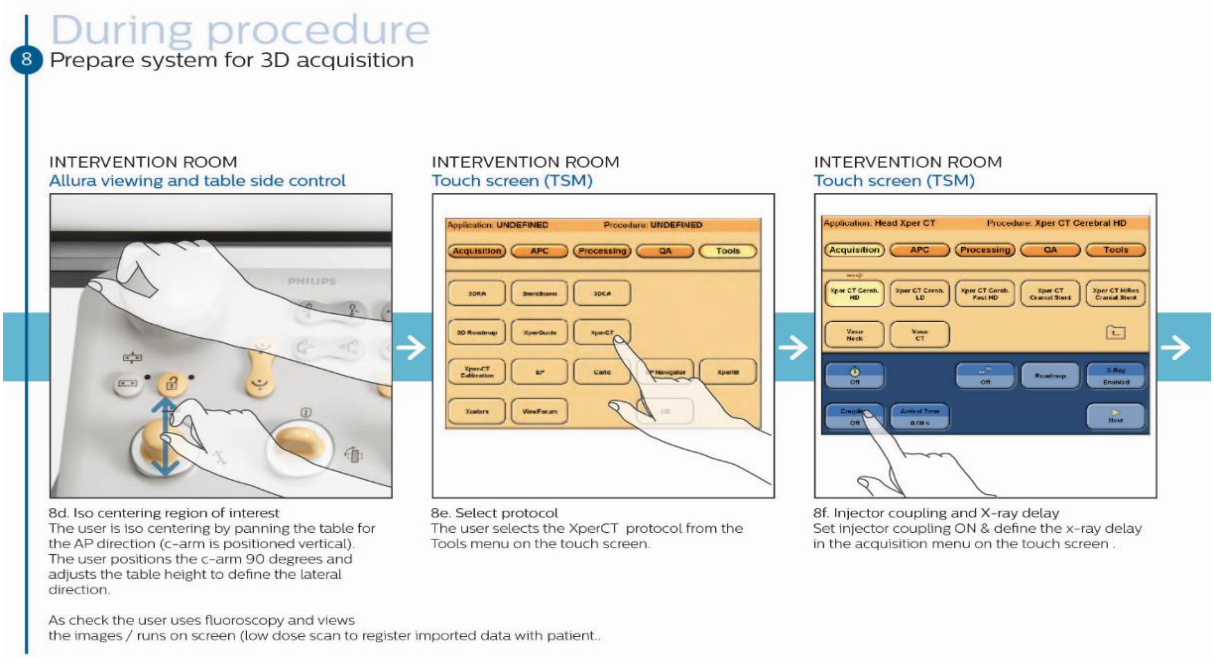

Figure 40: Step 8: Prepare system for 3D acquisition, Intervention room.

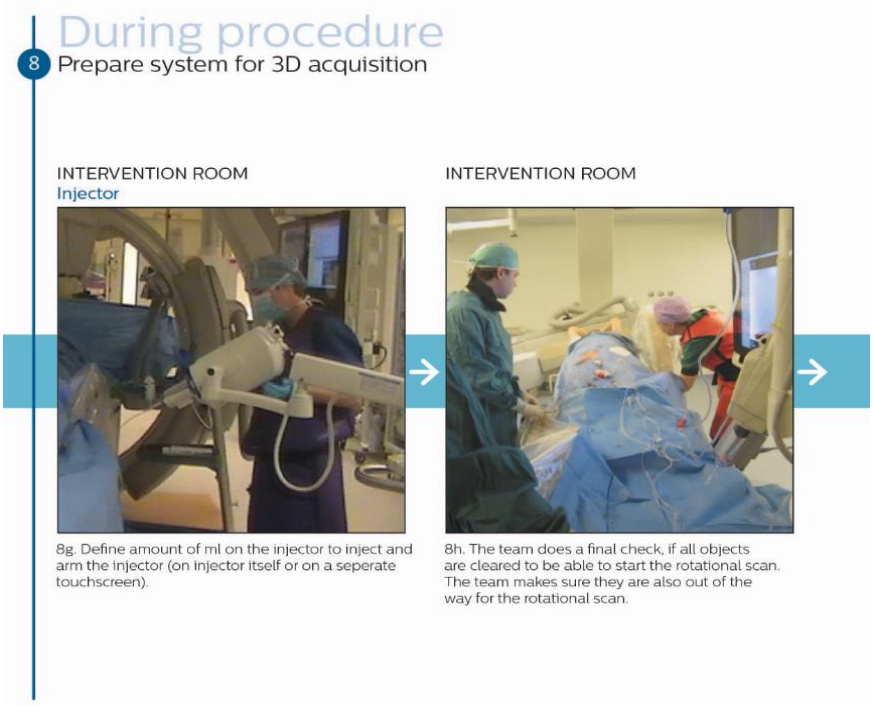

Figure 41: Step 8: Prepare system for 3D acquisition, Intervention room.

Step 9: Perform 3D acquisition scan

Perform 3D acquisition scan – In this step staff begins by performing a test round to see if the c-arm does not collide with the patient or equipment when making the 3D scan. The c-arm is equipped with sensors that detect potential collisions and stop movement. If that happens staff needs to remove the obstacle before they can continue. When the test round is successfully completed the system is ready for the actual 3D scan.

What the AdCos is supposed to do:

- Detect how user is performing and interpret system events
- Provide the right instructions to the right actor (user)

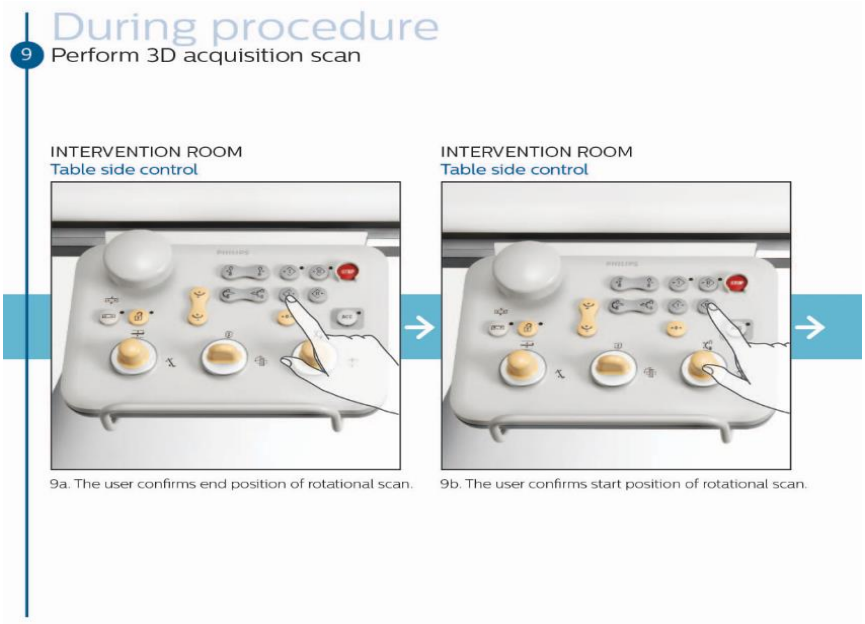

Figure 42: Step 9: Perform 3D acquisition scan, table side control.

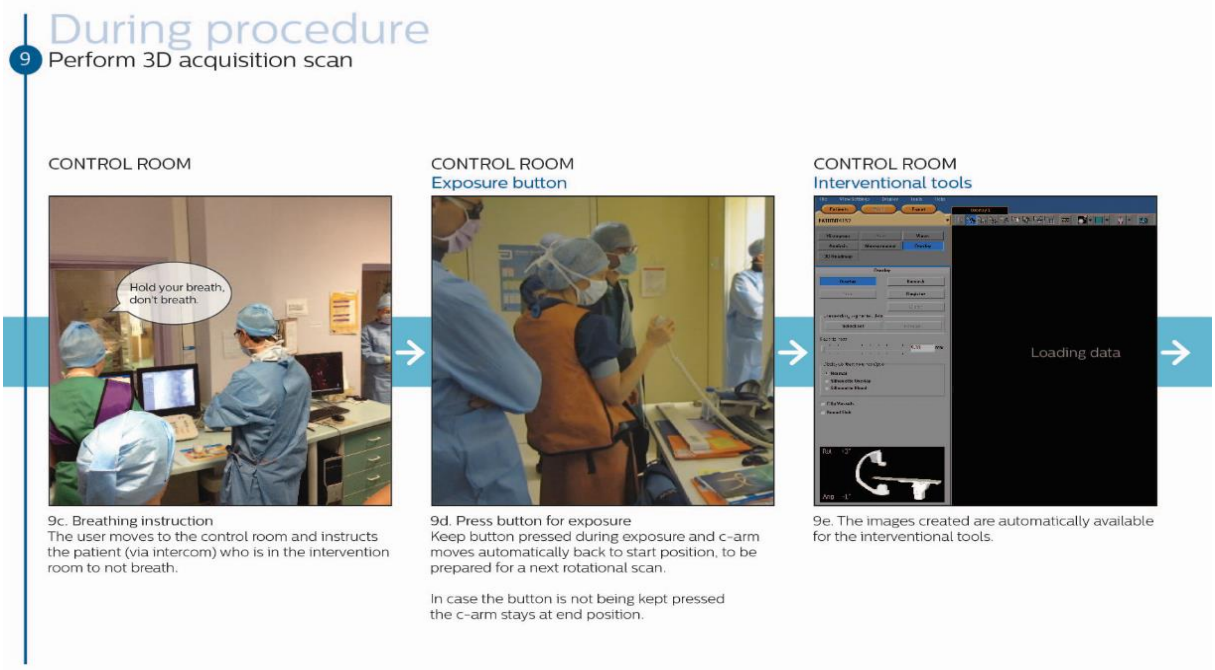

Figure 43: Step 9: Perform 3D acquisition scan, control room.

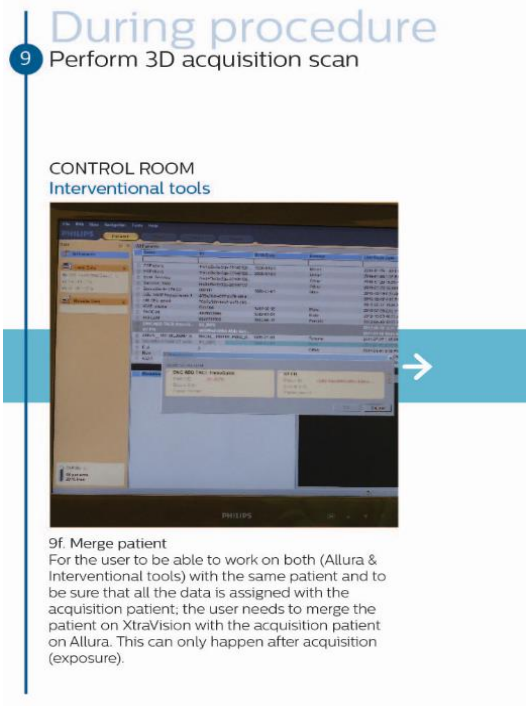

Figure 44: Step 9: Perform 3D acquisition scan, interventional tools.

3.8.3 Tools applied from HF-RTP

Within the state of the art development process of the 3D Acquisition AdCos several tooling is used. For the design phase Agile and Clearcase are used. For the analysis and feedback phase log-file analysis is done with RADAR and for usability analysis, questionnaires and observations are used. These tools do not reside in the HF-RTP.

HF-RTP tools: Human Efficiency Evaluator (HEE)

To improve the HMI and get earlier feedback on usability aspects of the new HMI, PHILIPS will use the Human Efficiency Evaluator (HEE) from OFFIS. See Figure 45 for a screenshot of the HEE-tool showing the system and UI components. With this tool we will analyse our state of the art workflow and compare this against early concepts of a new HMI.

As a first step PHILIPS has made a detailed task analysis in which the workflow that is described in section Human-Machine Interaction for the AdCoS has been decomposed into smaller tasks. This hierarchy of tasks is shown in Figure 45, Figure 46 and Figure 47.

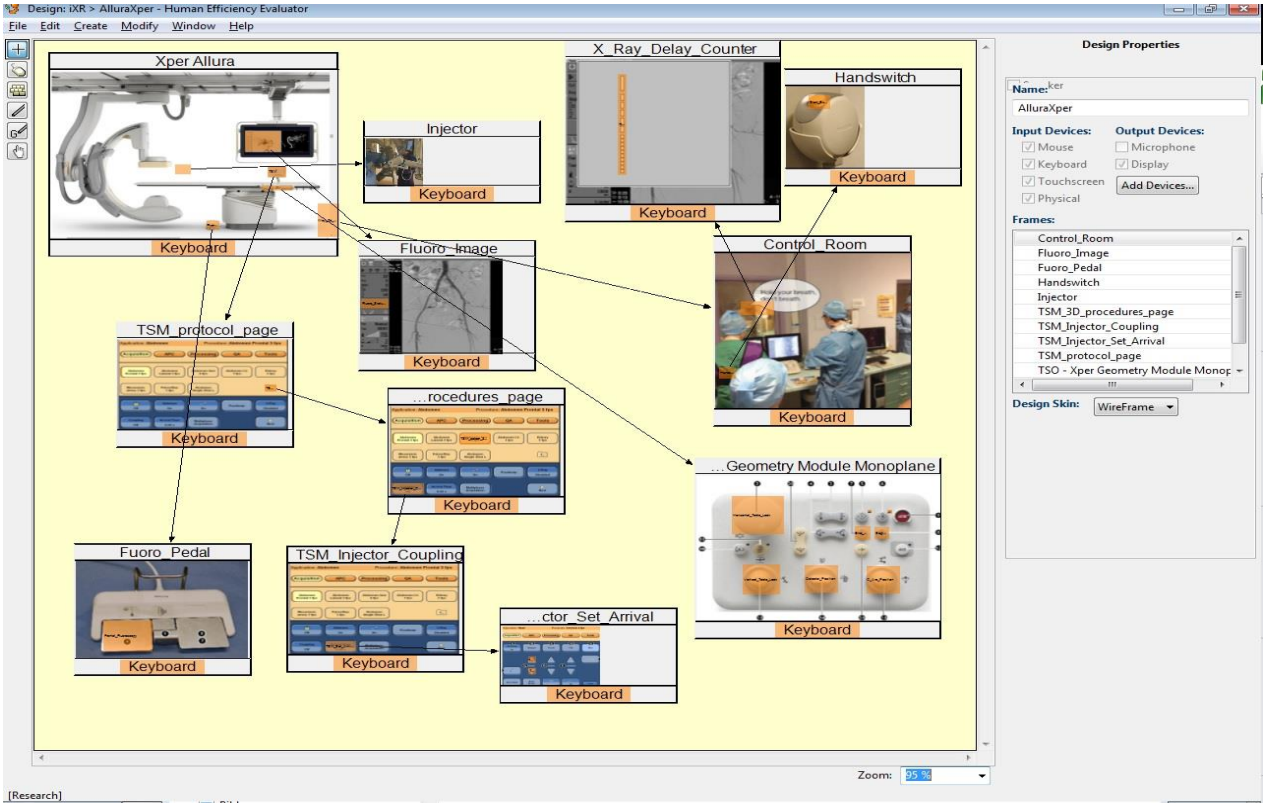

Figure 45: Screenshot from the HEE tool, depicting the 3D Acquisition AdCos and the relevant UI components.

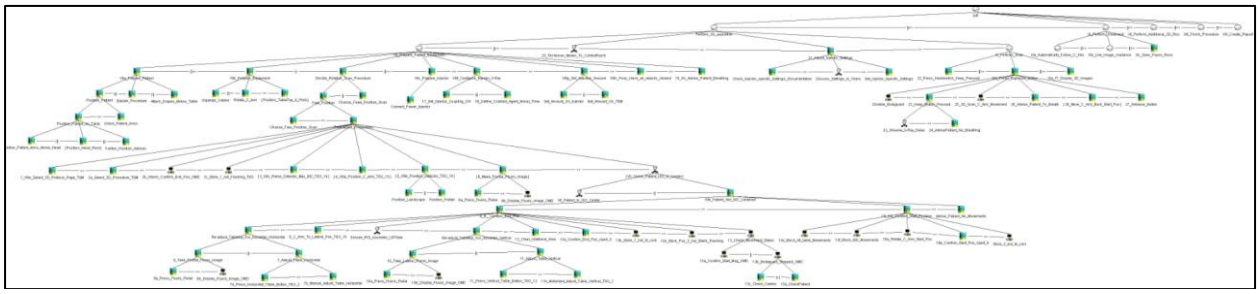

Figure 46: Decomposition of the 3D Acquisition workflow.

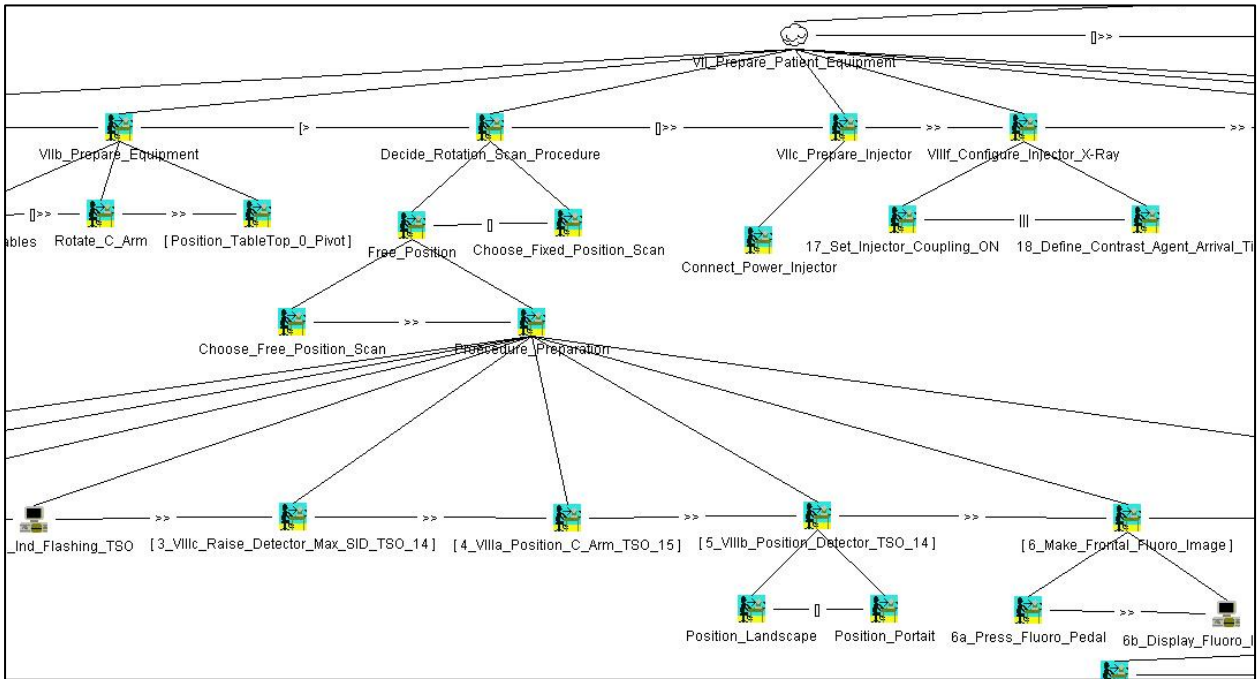

Figure 47: Detailed snapshot of the workflow, showing the hierarchy in tasks.

3.8.4 Requirements Update

In the initial stage of the project the following generic requirements for tooling have been defined for the 3D Acquisition AdCos.

ID	Name	Definition	Rationale
WP6_HEA_iXR_UC01_3D_acquisition_REQ1	AdCos behavior modeling	Tooling to model variability in behavior of the user agents and product agent in the AdCos	For our use case we need to understand the differetn user profiles and their impact on behavior of the AdCos in acquiring 3D x-ray scans. We also need to understand how the product plays a role in this AdCos so we can use that to model its behavior.
WP6_HEA_iXR_UC01_3D_acquisition_REQ2	AdCos opportunity identification	Tooling to help identify opportunities for adaptive behavior of product agent	When the Adcos behavior is modelled we can use that to identify opportunities to improve the AdCos, focusing on the role of the product agent as a cooperative player in the clinical team.
WP6_HEA_iXR_UC01_3D_acquisition_REQ3	AdCos iterative design	Tooling to guide the iterative design process of the adaptive product agent in the AdCos	In this phase we model behavior of the product agent for identified opportunities. We need toold and methods to model and design the behavior in the AdCos.
WP6_HEA_iXR_UC01_3D_acquisition_REQ4	AdCos testing	Tooling to test the effect of the designed product agent on the AdCos	When we have designed and modelled the bahevior of the product agent we want simulate it in the AdCos to see what the impact on the workflow and user agents is.
WP6_HEA_iXR_UC01_3D_acquisition_REQ5	AdCos sensing	Techniques for sensing context as input for adaptive behavior of the product agent in the AdCos (e.g. video camera input, user agent input, event timestamps)	In de concept phase we need to learn about available sensing and modelling techniques to equip our product agent so it can show bahavior based on what is senses or logs from its environment.

Table 12: 3D Acquisition Requirements

In addition to the abovementioned requirements and specifically to *AdCos_iterative_design* the following requirements are added:

- The tooling should be able to capture the steps of the 3D acquisition work flow
- The tooling should be able to model how a user interacts with the system

- The tooling should be able to compare the performance of 2 HMIs

3.8.5 System architecture

The 3D acquisition tool is integrated in the Philips Angiography system. A table side control is present with which the acquisition of images is controlled. The C-arm system generates 2D images of the patient. These images are sent to the 2D computer where real-time image processing is applied to improve the Image Quality and these images are shown on one or more 2D monitors.

The 2D images are also sent to the 3D computer. Here the images are processed and combined into a 3D volume rendering of the patient's anatomy. The 3D volume is shown on the 3D monitor.

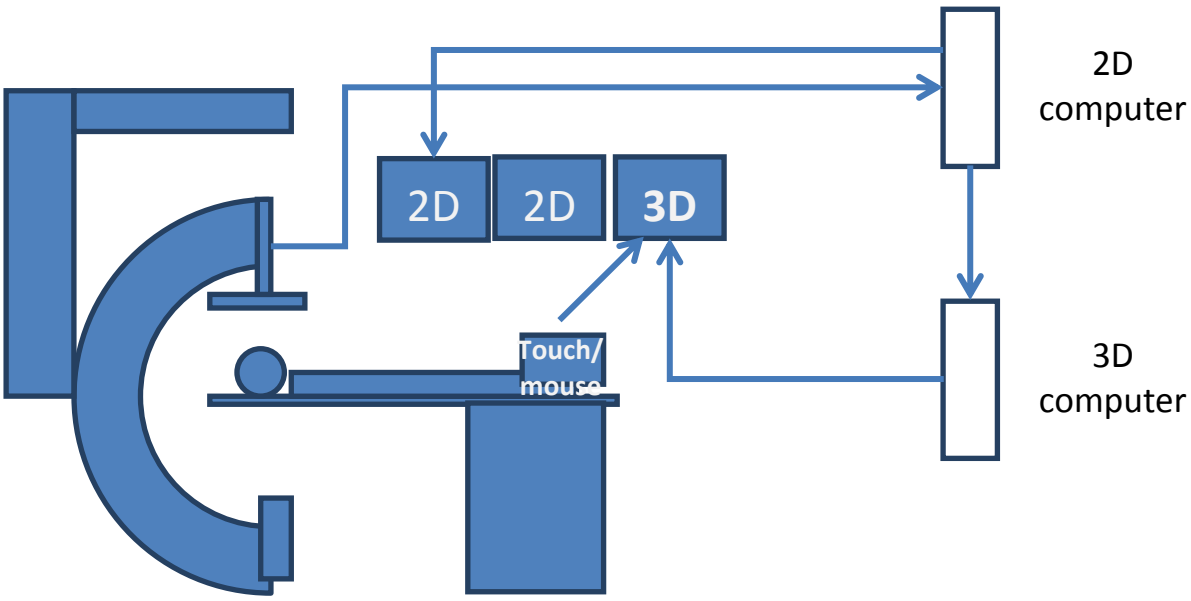

Figure 48: 3D Acquisition architecture.

3.9 WP6_HEA_DAT_UC01_internal_analysis_and_reporting

Leader: ATOS

The objective of this AdCoS is (1) to access the patient data for statistical analysis of pathologies and (2) to generate clinical reports based on data coming from heterogeneous and fragmented healthcare information systems.

3.9.1 Operational definition of the AdCoS

There are mainly two issues; (1) security and (2) Heterogeneous data structure.

Referring to security, it ranges from personal details access to clinical report stored, including transmission and treatment once the report is generated and downloaded.

In reference to heterogeneous data source, it is a transversal issue described in WP6_HEA_CON_UC02_Querying_openEHR_data.

The main effort is focused on the server side:

1. Heterogeneous data source.
2. Security issues:
   a. The system can only be accessed by authorized physicians using their credentials (at least user and password).
   b. The system MUST have a logout option and session time out.
   c. Other security mechanisms must be studied due to the sensitive information treated.
   d. The system must use secure protocols (e.g. https)
3. Predictive Analytics Tools.

What is the "controlled entity" of the use case?

From the physician point of view (or medical environment), this is a very simple workflow in which a user only follows very specific steps to get a smart clinical report.

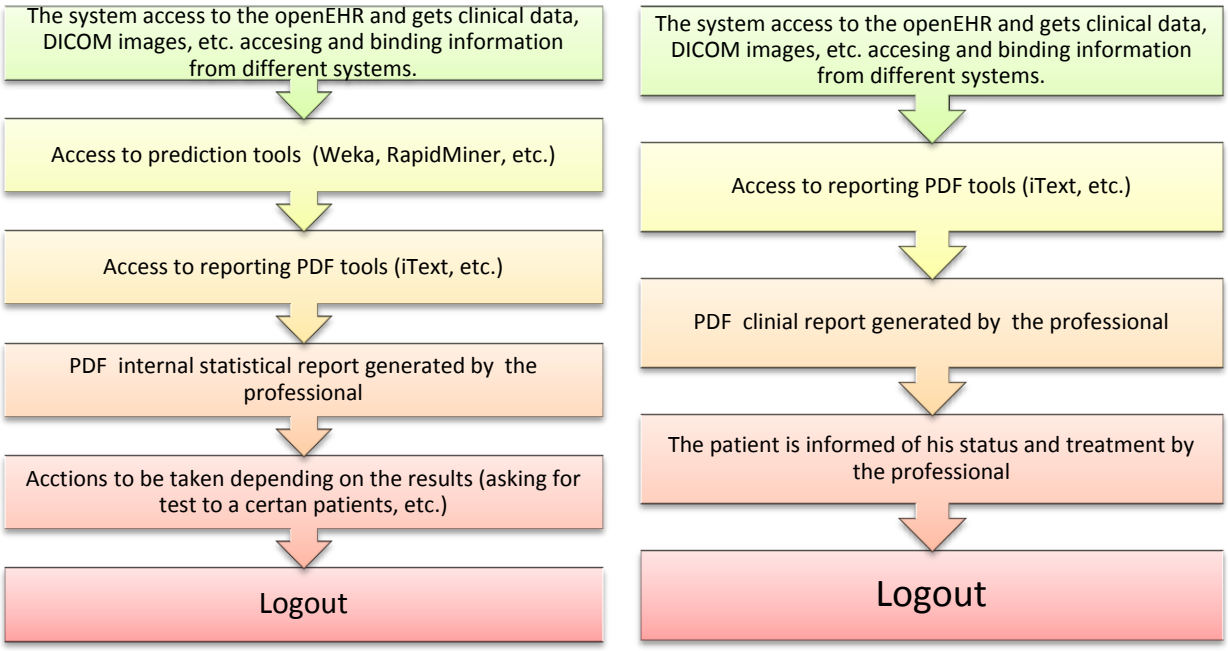

Figure 49: Internal Statistical Report (left) and Patient clinical Report (right).

What are the goals that the AdCoS should achieve for the operator when performing a clinical task?

The main goal is to implement a system which provides two different clinical reports (PDF format):

1. **Internal clinical report**: This report allows analysing possible causes that has brought a certain patient to the hospital by comparing and analysing data with other patients in order to avoid possible future illness. The professional selects a group of patients with similar diseases and generates an internal report with risks factors and predictions. This report is internal to the hospital and includes risk analysis, predictions, etc.

2. **Patient report:** Besides the predictive report for the doctor the tool would permit to generate simple reports for the patients just to provide a general overview of his/her health status. This custom report pretends to avoid additional CDs or paper reports given to the patient nowadays. This report

includes clinical patient data. MRI, Lab Tests, prescriptions, etc. Any EHR data that the professional considered desirable.

What are the situations that the AdCoS should ensure are avoided?

Due to the sensitive nature of the data, the system has to ensure security and privacy of data access. These data must be protected with the highest level of security.

3.9.2 Human-Machine Interaction for the AdCoS

Which input/output channels and devices are available to carry the communication between the operator and the AdCoS?

The technical infrastructure is composed by:

- Server infrastructure: Where the information is stored and standardized.
- Mobile platforms: PC or Tablet.
- Communication network: To access to the system.

Will the AdCoS employ innovative or unconventional user interaction (for instance gestures, voice interaction, etc.)?

User friendly interfaces are key feature for the success of the solution. For this purpose we foreseen:

- User friendly interfaces
- Speed and efficiency on different devices
- Easier usage of the information
- Clinical information displayed in an integrated way.

3.9.3 Requirements Update

It is important to describe priority assigned to the requirement:

- ✓ High: Essential to have.
- ✓ Medium: Important to have.

- ✓ Low: Nice to have.

We have split requirements in different sections:

Security: Due the data nature, sensitive information must be treated with the highest security level.

Security requirements from Querying openEHR data AdCoS are also included in this section.

ID	REQ Description	Priority
WP6_REQ21	Any generated Report (PDF) MUST be protected with a password.	High
WP6_REQ22	Any generated Report (PDF) MUST be downloaded and saved encrypted.	High
WP6_REQ23	Any generated report cannot be modified once generated	High

Table 13: Security requirements of Internal analysis and reporting AdCoS.

Data/ image integration

ID	REQ Description	Priority
WP6_REQ24	The report SHOULD present clinical information in an integrated way.	High

Table 14: Data/ image integration requirements of Internal analysis and reporting AdCoS.

Customization

ID	REQ Description	Priority
WP6_REQ25	The doctor MUST write a descriptive report name.	High
WP6_REQ26	The doctor user may add annotations appended to the report.	High
WP6_REQ27	The doctor can include Prescriptions detail to the patient report.	High
WP6_REQ28	The doctor can include dicom preview image to the patient report (see Figure 21: Graphical	High

	user interface of "Save image (png format)".)	
WP6_REQ29	The doctor can include Clinical data to the patient report.	High
WP6_REQ30	The doctor can include Personal details (full name, age, marital state,…) to the patient report.	High
WP6_REQ31	The doctor can include Demographic details (language, contact details,…) to the patient report.	High

Table 15: Customization requirements of Internal analysis and reporting AdCoS.

3.9.4 System architecture

In this section are detailed each of the elements and high-level components integrated in this AdCoS. A number of different views are used in order to represent different aspects of the system. It provides a general and exhaustive overview.

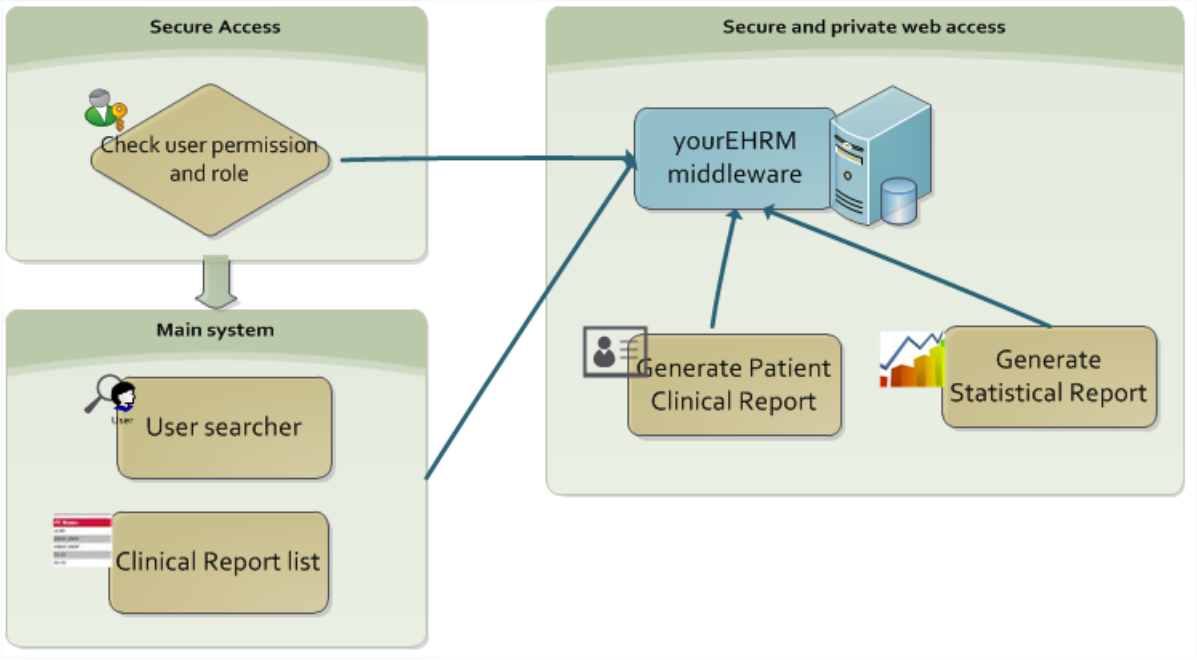

Figure 50: Internal analysis and reporting AdCoS Architecture.

This section starts with a general overview of the full system, describing roles and functionalities. Then, each subsystems is deeply analysed and a class diagram included. Finally, a list of tools, standards and protocols to be used is detailed.

Roles and functionalities

Four different roles have been defined. They are interrelated as shown in Table 16 and Figure 51:

	Generate Patient clinical report	Generate Statistical report	Clinical reports list
Doctor	✓	✓	✓
Nurse	☒	☒	✓
Admin	☒	☒	☒
Patient	☒	☒	✓

Table 16: Analysis and reporting use case and its functionalities by role.

Below is displayed a general diagram. We assume that the user has been correctly identified.

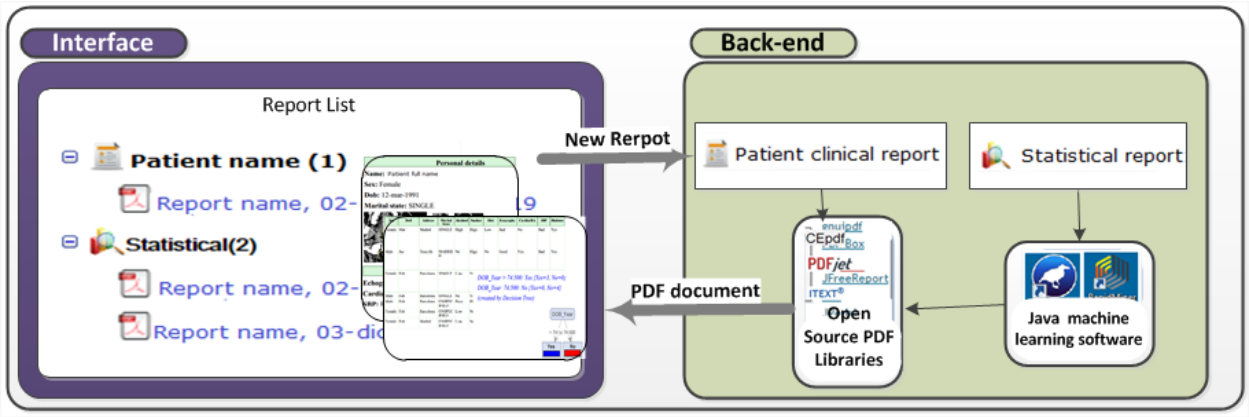

Figure 51: General diagram of Analysis and reporting AdCoS.

As already above:

- ✓ Java open source machine learning libraries will be used to generate internal clinical reports.
- ✓ Java open source PDF libraries will be used to generate PDF report.
- ✓ Only a doctor is allowed to generate a report.

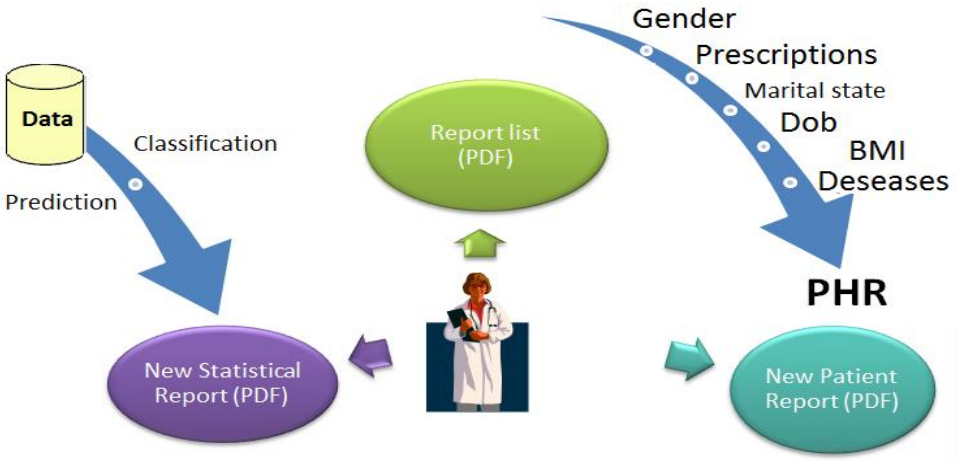

Figure 52: Analysis and reporting AdCoS, doctor functionalities.

An overview of doctor functionalities is shown in **Fehler! Verweisquelle konnte nicht gefunden werden.** and its different sources:

1. Clinical data provides by the patient (PHR –Patient Health Records) to generate patient reports and
2. Comparing data between patients themselves to generate Clinical reports.

UML diagram in **Figure 53** gives details of the process:

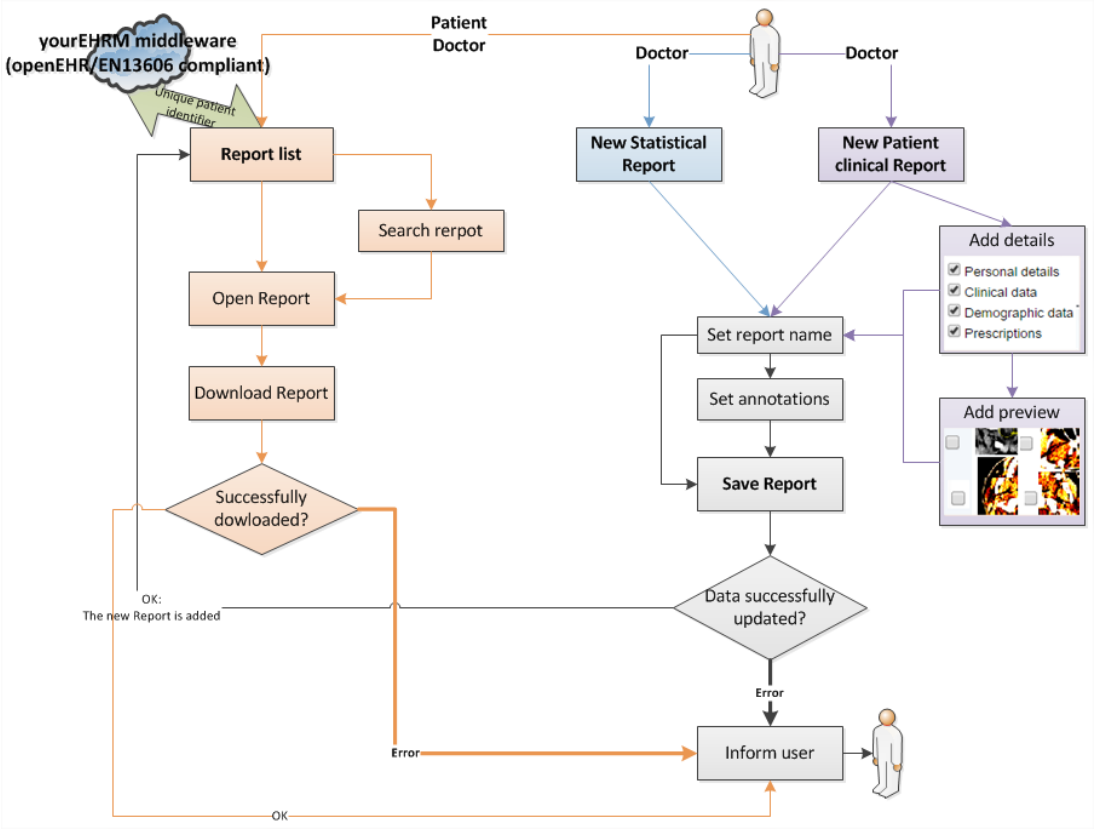

Figure 53: UML Diagram of use case "Analysis and reporting".

As we know, this use case allows doctors to generate two different reports; (1) Clinical patient report (in blue), and (2) Statistical reports (in violet), both have one previous step in common, Clinical report list (in orange).

Report list

The system shows a report list available in two sections:

1. **Patient selected clinical reports:** it displays all generated reports to the selected patient.

2. **Statistical report**: only applicable for Doctor and it shows all statistical reports previously generated by the logged doctor.

All available reports (clinical or statistical) are shown in the same format; report name and date of creation and each of them is a clickable link to its PDF file.

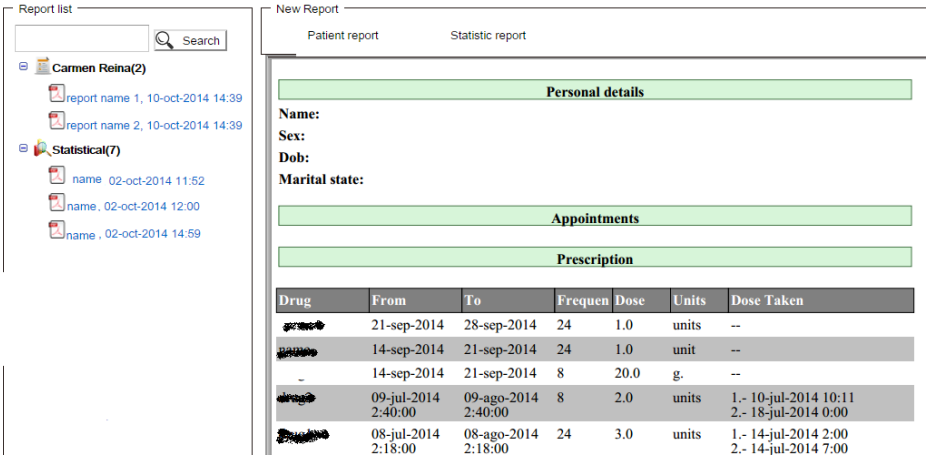

Figure 54: Graphical user interface of "Report List".

Generate Patient Clinical report

A doctor is allowed to create a new report by clicking on "Patient report". A dialog box is displayed in order to allow the physician to set report name, notes and patient's details.

We emphasize the possibility to add previously saved images (see Patient studies section).

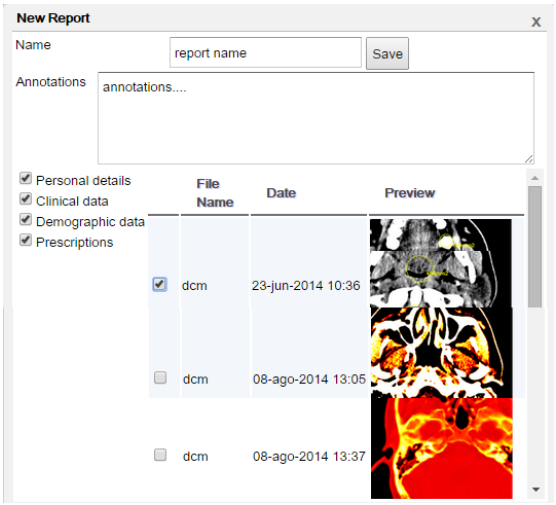

Figure 55: Graphical user interface of "New patient clinical report".

This report is generated taken details from PHR (Patient Health Record).

Generate Statistical report

A doctor is allowed to create a new report by clicking on "Statistical report". A dialog box is displayed in order to allow the physician to set report name and notes.

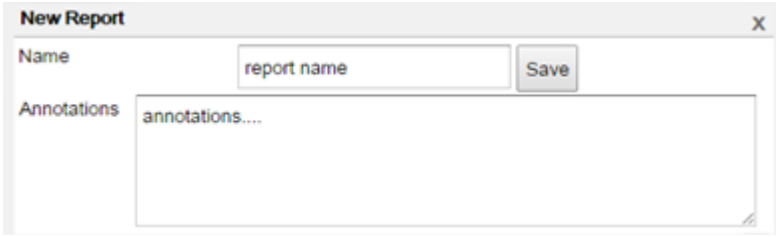

Figure 56: Graphical user interface of "New Statistical clinical report".

This report belongs to hospital environment. This report is generated by applying the model (previously) obtained with data mining techniques.

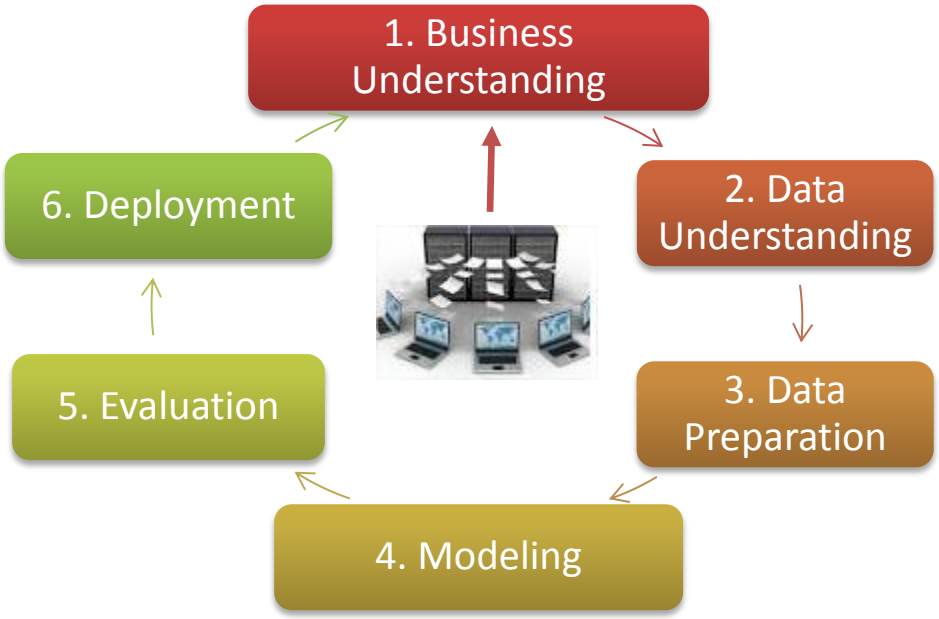

Figure 57: Data mining process steps or phases.

Notice that data mining process needs large data set.
The system will be trained with fake data and only when the relevant real data will be available the final modelling phase is completed.

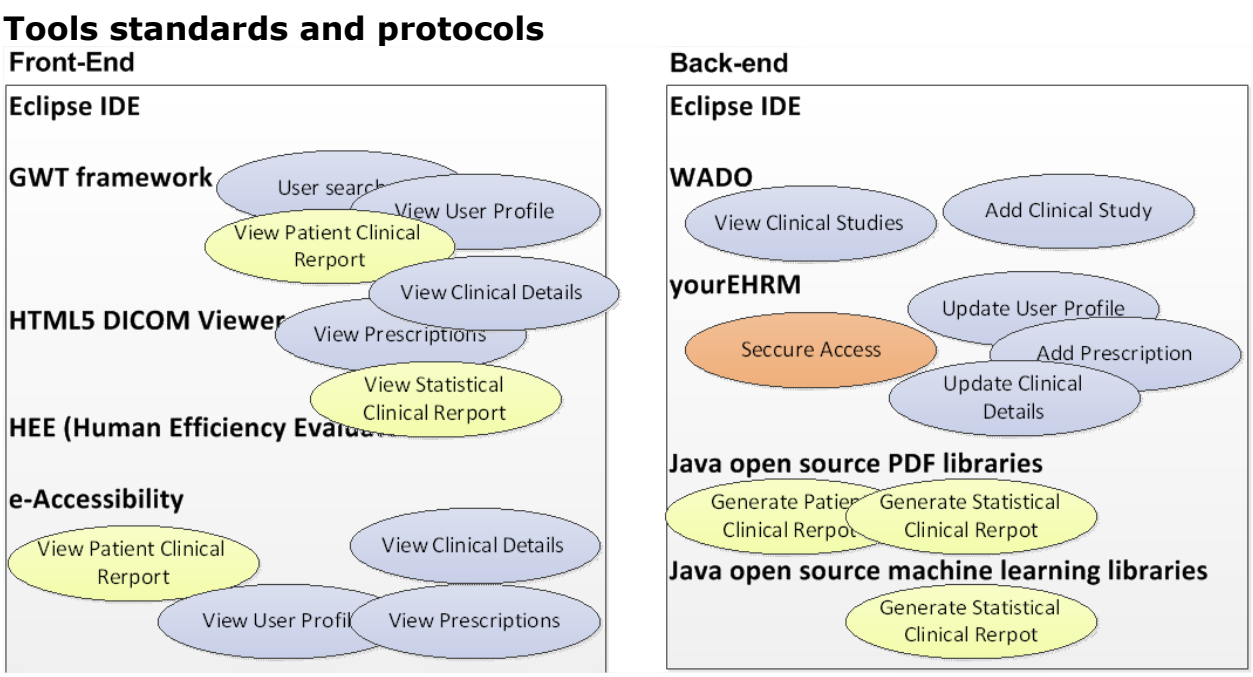

Figure 58: Relations between tools and use cases

- **Eclipse IDE:** Eclipse is an integrated development environment (IDE) and it is used to develop the software application in Java. The main reasons why Eclipse is used are; (1) The Eclipse Public License (EPL) is an Open Source software license and (2) Its plugin architecture and its extensibility.

- **GWT framework:** Google Web Toolkit is an open source set of tools that allows web developers to create and maintain complex JavaScript front-end applications in Java. It will be used to build all GUI.

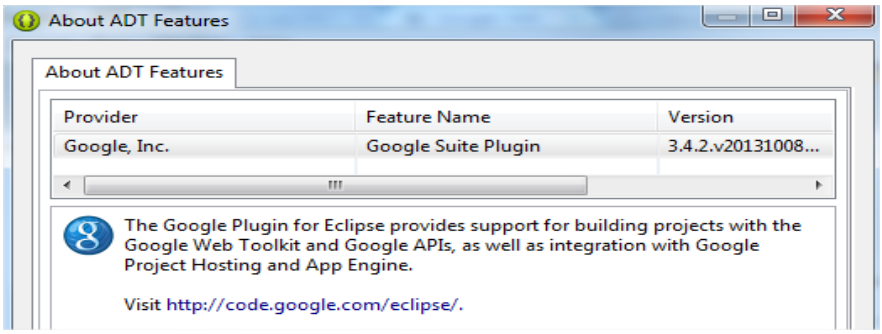

Figure 59: GWT plugin details

- **yourEHRM middleware:** yourEHRM uses standards that enable medical information exchange (HL7, ISO 11073/IEEE 1073, CEN 13606, openEHR family of standards). It is mainly used to get clinical patient information.

- **Java Coding Style Standards**: Code convention is important in order to improve the readability, usability and maintainability of the software. Code conventions allow engineers to understand new code more quickly and thoroughly. It will be used throughout all software life cycle. The code convention covers filenames, file organization, indentation, comments, declarations, statements, white space, naming conventions, programming practices and includes a code example.

- **E-Accessibility tools:** It is essential that the Web be accessible (GUI) in order to provide equal access and equal opportunity to patients with diverse abilities. W3C's Web Accessibility Initiative (WAI) has published Web Content Accessibility Guidelines (WCAG). Only report list section MUST have Level AA conformance.

- **Java open source PDF libraries**: It is necessary to generate a PDF document in Analysis and reporting AdCoS.

- **Java open source machine learning libraries:** It is necessary to generate a model from our collated data and apply it in order to generate our Analytic report in Analysis and reporting AdCoS. This report is generated by applying the model (previously) obtained with data mining techniques.

4 Feedback WP1-5

3D Acquisition

For the 3D Acquisition AdCos, Philips is investigating an improved HMI to make it easier for the hospital staff to perform a complex part of the clinical interventional procedure. In support of the design process of the new HMI, the Human Efficiency Evaluator (HEE) will be used for early testing of new UI concepts. In a first step we have a made a detailed task analysis in which the elementary workflow steps are described. The task analysis description was input for the HEE in which the complete workflow now has been modelled.

Apart from providing input to the HEE, doing the task analysis and decomposing tasks into atomic tasks, already gave some insights into possible workflow improvements. Furthermore, in a few bilateral calls we were able to define a template that supports the task analysis and at the same time matches the input format for the HEE.

At this stage of the project (Jan 2015) it is too early to give definitive feedback about the modelling results (which will be included in next deliverables). First the current HMI needs to be simulated to get some task performance figures. Secondly, the new HMI needs to be modelled and simulated in the same way as the existing HMI. Only then a comparison between the existing and the new HMI can be made.

Operator task schedule and guidance

For the use case WP6_HEA_CON_UC01_Operator_task_schedule_and_guidance, there is not a very intensive usage of methods and tools provided by Holides, so partial assessment is done.
We analysed RTMAPS: this tool is considered as a candidate tool to be used as the simulator engine. It offers the following interesting characteristics:
- Reusability of developed modules to implement different simulation scenarios
- It simplifies the communication with real distributed devices, which makes it a good candidate for simulations with real users.
- It allows to record and replay predefined scenarios. Customization and parametrization is well-supported with this tool. It helps to handle among use-cases.
- Modular and flexible architecture that allow to plug any type of sensor and implement any kind of processing (or decision making algorithms) modules based on different inputs
- Asynchronous data acquisition, time stamp facilities, data synchronization, multithreading, data fusion are other features which are useful for the simulation engine proposed in our use case

However, after first hand-on experience with the tool we also find the following drawbacks: RTMAPS is more focused on real time monitoring and data acquisition from sensors, which is not a requirement for this use case. The development of customized modules for our application is a time-consuming task, although later benefits are expected. We also consider that learning curve is high to develop

new modules, especially to implement tasks as inputs. It is not clear how predefined tasks and operator profiles can be included the simulator.
The other tool we also partially analysed is the Human Efficient Evaluator (HEE). The concept and foundations are adequate for the evaluation of the interface usability in our use case. As drawback, the tool allows to model only linear workflows (each branch has to be modelled as separate workflow), which makes the application to our use case, or to model human errors difficult.

With respect to the modelling approaches, we consider that the task model offered by WP2, based on W3C, is a good candidate to be used, but more empirical work is needed to provide feedback. Another candidate is GreatSPN, but as modelling and simulation tool is not ready for real-time interaction with the rest infrastructure, and many developments need to be used as scenario and simulation engine. Moreover GreatSPN does not still have implemented all features of Colored Petri Nets, which is an inconvenient to use it in this use case.

Querying openEHR data and Internal analysis and reporting AdCoS

The Human Efficiency Evaluator from OFFIS has been identified as a tool that can help analyse workflows – or parts of larger workflows – for most of the AdCos´s in healthcare domain. The approach carried out can be described as comprised of the steps outlined below.

1. Describe the workflow
2. Focus the most critical part of the workflow
3. Mock up the UI
4. Identify the tasks
5. Create a table with the task sequence
6. Preliminary conclusions

The most critical part of the whole workflow identified in Querying openEHR data AdCoS has been "Display patient Studies", due to, this Graphical User Interface (GUI) has several tools and options.

The most complicated issue found has been that it is not a linear sequence of tasks, even if there is a logical sequence, the user may use any alternative path

at any moment. Seems to be more useful to analyse the whole GUI and not go through atomic tasks.

5 Conclusions

3D Acquisition

An overview of the 3D Acquisition AdCos and a detailed description of the HMI have been made. The use of the HEE tool in the development process and some first results has been described. The HEE tool needs some adaptations to make it also usable for healthcare applications, the outlook is that it will give valuable insights to compare and improve the HMI.

Operator task schedule and guidance

For the use case WP6_HEA_CON_UC01_Operator_task_schedule_and_guidance, we describe the functionality and mock-up of the user interfaces. We propose a solution, based on a simulation engine that interacts with the prototype mobile applications handled by real distributed end users. With this approach, our objective is to pre-validate a prototype development, before we tackle the real development for the deployment in the Hospital. Although all results of WP1 - WP5 has been considered, we finally focus on four methodology and tools, which have been partially analysed to be used in different stage of the development cycle. They are the (i) task modelling approach provided in WP2, (ii) RTMAPS from Interpora, (iii) Human Efficiency Evaluator from OFFIS, and (iv)GreatSPN from Polytechnic of Torino. In this document we provide feedback to such tools, with emphasis in those aspects that will ease the usage in our use case. For next step, we will perform a more detail analysis and model of this use case.

6 Glossary

Abbreviation	Meaning
HMI	Human Machine Interaction
EHR	Electronic Health Record
DICOM	Digital Imaging and Communications in Medicine
WADO	Web Access to DICOM Persistent Objects
PACs	Picture Archiving and Communication System
HTTPS	Hypertext Transfer Protocol Secure
WAI	W3C's Web Accessibility Initiative
WCAG	Web Content Accessibility Guidelines

7 References

[1] D1.3 HF-RTP Vs0.5 incl. Methodology and Requirements Analysis Update.
D6.1 Requirements Definition for the HF-RTP, Methodology and Techniques and Tools from a Health Perspective.
D6.2 Tailored HF-RTP and Methodology Vs0.5 for the Health Domain.

[2] Web Access to DICOM Persistent Objects, The WADO standard specifies a Web-based service for accessing and presenting DICOM persistent objects, such as images and medical imaging reports. http://www.research.ibm.com/haifa/projects/software/wado/

[3] The World Wide Web Consortium (W3C) is an international community where Member organizations and the public work together to develop Web standards. http://www.w3.org/Consortium