First evaluation workshops round

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PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission)	
CO	Confidential, only for members of the consortium (including the Commission)	

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ABSTRACT:

The ACGT project experience and the first annual review were really fruitful in terms of "lesson learned"; they highlighted the importance of usability and to run usability evaluation as soon as tools become available. In this frame, establishing an iterative evaluation process is extremely important for two main reasons:

1. Feedback reports list issues and suggest possible improvements, modifications, and additional functionalities to be implemented by developers.
2. Users will benefit a new and improved tool version and they will continue in the learning process

An evaluation workshop has been held to bring together the groups implementing tools and services with the testing groups to hold usability evaluation sessions and discuss found issues.

In this deliverable we provide a comprehensive overview of key demonstration results based on the correct assessment of the user requirements and by demonstrating solutions that address practical end user problems.

KEYWORD LIST: Evaluation, end-user scenarios, data access

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[2] **R**=Report, **P**=Prototype, **D**=Demonstrator, **O**=Other

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Contents

Executive Summary

D15.2 is mainly reporting on usability evaluation activities (ObTiMA external usability tests) that took place during the third semester of the project.

The context scenarios describe various end-user requirements under the form of various activities that the p-medicine platform planned to support. The scenarios derive from interviews of two healthcare operators (a clinician and a nurse).

In projects like p-medicine, in which clinicians, data managers, bioinformaticians, biologists, data miners and patients are or will be provided of tools for clinical decision support (CDS), usability plays a central role along with security through an interactive role with the entire infrastructure architecture toward self-sustainability of the infrastructure, as shown in **Figure 1**.

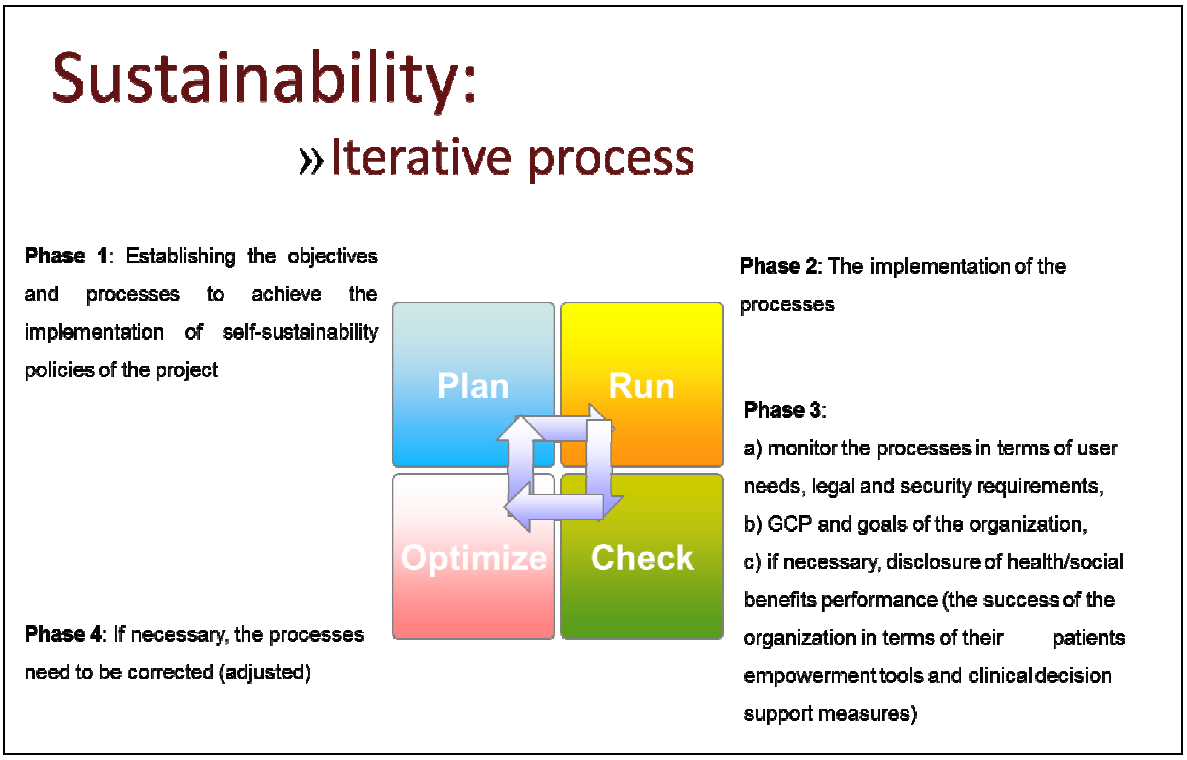


Figure 1. p-medicine self-sustainability management iterative process (adapted from ISO 14001, environmental management standard).

Introduction

p-medicine is putting clinicians in the driver's seat, especially by improving personalized medicine [3, 4], having particular attention on the clinician and patient empowerment and by planning and applying clinically relevant scenarios formulated to reach the goals from the introduction.

1 Quality assurance in p-medicine

Quality assurance in p-medicine can be described as a continuous dialogue between users, developers, security managers and data miners (see **Figure 2**). We can summarize this process in seven main points:

1. P-medicine follows quality assurance in all its components, being those human resources, tools or concepts.
2. P-medicine's plan is to be a self-sustained infrastructure from the economical and also from the knowledge and social point of view
3. Interaction, documentation, security, legal-ethical framework, good clinical practice (GCP) and patients empowerment are 6 fundamental aspects that lead p-medicine development
4. P-medicine is efficient: no duplication, efficient use of the resources
5. At least one of the p-medicine's tools, ObTiMA, has been planned to become an example of GCP compliant tool
6. Users' needs and requirements have been defined (WP2) and are going to be applied during the development phase
7. WP15 is dedicated to Quality Assurance, Evaluation criteria established, evaluation process started (ObTiMA, HDOT, Bioinfo Workflow)

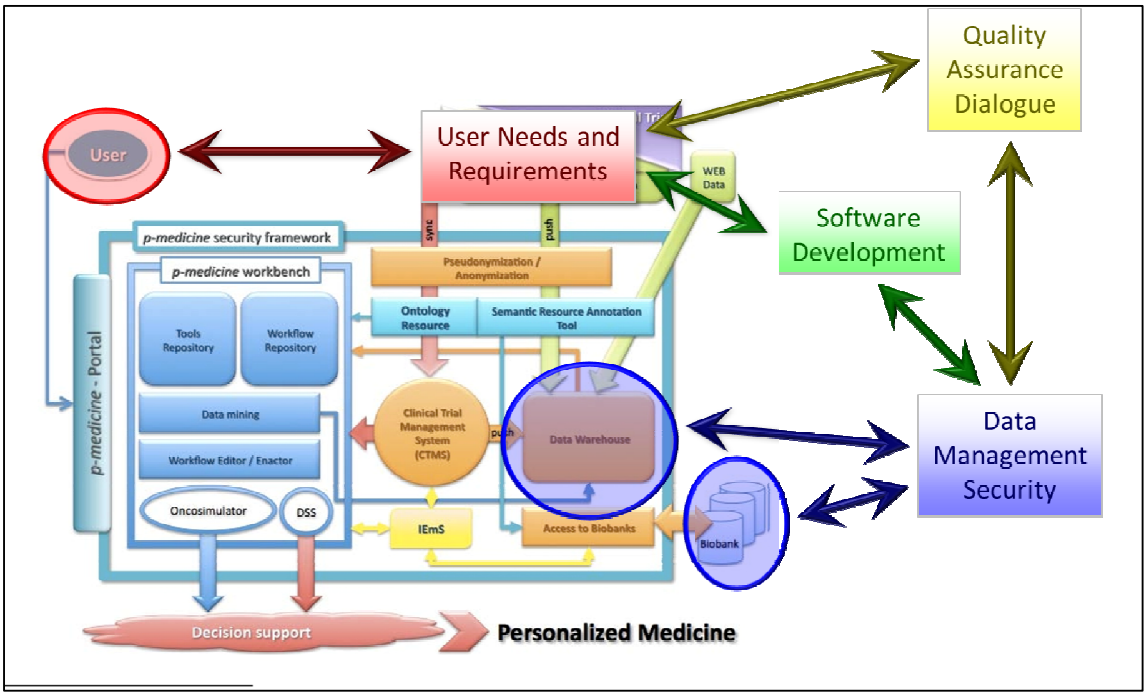


Figure 2. Quality assurance dialogue in the p-medicine infrastructure.

2 *Usability*

The ISO norms explain also how to take into account the user needs and requirements by evaluating the stated and implied needs, due to the fact that the users do not always reflect the real user needs because:

1. A user is often not aware of his real needs
2. Needs may change after they are stated
3. Different users may have different operating environments
4. It may be impossible to consult all the possible types of users

User needs and requirements have been identified in WP2 (D2.2). They provide the basis for the development of the p-medicine environment used by the various user groups (bioinformaticians, biostatisticians, data managers, clinicians and patients).

The five context scenarios derived from the interviews, illustrate the special tasks with the whole context of use of the various end users. These tasks have to be taken into consideration with the usability standards ISO 9241 - part 11, 110 and 12 when developing the user interface with a common portal for all end users.

The user's task can be listed in a short summary. These summaries should be read carefully by the different developer groups concerning the work flow environment, the clinical and VPH tools. For a better understanding of the user's task it is necessary to read the whole context scenario of an end user of the special user group in the deliverable D2.2 Chapter 4 and D2.2 Appendix 2 Context Scenarios.

3 *ObTiMA first usability test*

The p-medicine portal has been created during the first year of life of the project and a first demonstration has been performed during the first review process in Brussels (03/05/2012) and it contained an instance to ObTiMA. The document D8.1.2 is entirely dedicated to the subject.

Some portal characteristics:

- Name of the tool/service : p-medicine portal
- Institution(s): FHG-IBMT, FORTH, USAAR, CUSTODIX, UCL
- Contact person: Fatima Schera, fatima.schera@ibmt.fraunhofer.de
- Short description: Web portal based on the open source Liferay portal framework .Tools and Services of p-medicine should be integrated into the portal as portlets or should be linked in the GUI of the portal.
- Potential users: clinicians, clinical trial leader, researchers, scientific community (mathematician, physicist, informatics, …), patients and their relatives, data managers (clinicians, nurses, documentalists) , technical support (portal and data base administrators, developers), representatives from legal and ethical committees, auditors
- Reference: http://www.liferay.com

We focused mainly on the ObTiMA usability test due to its properties and availability:

- It is in process to be transformed from a *research prototype* into a *stable application*
- The development is going on for long period with well-established processes and tools
- Modularity: first we start to test whether ObTiMA works on a smaller scale then it will be deployed it on larger scale (i.e. for the whole system), **Figure 3**.

Figure 3. ObTiMA's modularity scenario. Modularity is intended as "inside" and "outside": composed of various modules and can itself become a module (e.g. portlet), as foundation the core system is a module associated to specialized modules developed separately. This architecture has several advantages like: clearer separation of concerns and higher robustness and fault tolerance.

Evaluation of the first prototype of the ontology-based trial management application ObTiMA

1 Introduction

To reduce high implementation costs we started very early with the evaluation process in the development process of p-medicine. The first usability test with the ontology-based trial management application ObTiMA took place in June 2012 to get ergonomic qualitative and reusable software tools for a heterogeneous user group.

Also from the first project review (held in Brussels on May 2012), one of the key points of the European Commission's evaluation report was that the usability focus must be on the health-care users acceptance of the developed (or under development) tools.

The citation "Design is not just what it looks like and feels like. Design is how it works" (Steve Jobs, 2003) shows that it is most important to know the user needs and requirements within its whole context of use to develop software in a way the user is able to conduct his/her task in an efficient, effective and satisfied manner [5].

Following this principle, we started considering the special user requirements and user needs in the first project's stage: we interviewed the prospective user groups of the medical tool ObTiMA, the outcomes of these interviews resulted in context scenarios which are described in [2]. These interviews are important for the usability engineers and the software developers to get a common understanding of the user's tasks [1]. It is a challenge to combine requirements and the context of use during the prototyping period to assure that the needs of the various, especially clinicians, biostatisticians and informaticians, end-users are satisfied.

We would like to stress the principle that usability should not only be reduced to simplicity. It is more important that the usability engineers and the developers understand the user needs with the whole context of use and that only a successful interface supports the user to achieve his/her aims. To reach these requirements the interface has to be developed in a way that the end-user has no understanding problems and he/she is supported by a very good navigation, so that he/she knows at any time where he/she is and how to go back step by step. All these characteristics are specified in the seven dialogue principles of part 110 of ISO 9241 [1, 6] and should be considered during the whole development stage. This phase should be an iterative process in which many prototypes are presented for evaluation of the extensions and the improvements made. Detecting usage problems can give reason to improve the software in a very early development stage in order to avoid expensive costs. The usability engineer acts as an independent agent between the end-users and the software developers stimulating the dialogue and the feedback process during the whole development period.

2 *ObTiMA*

ObTiMA is an ontology-based clinical trial management system that should fill the requirements from various end-users such as clinicians, biostatisticians and informaticians.

We here summarize some ObTiMA characteristics:

- Name of the tool/service : ObTiMA – Ontology-based Trial Management Application
- Institution(s) : USAAR, FhG-IBMT
- Contact person: Holger Stenzhorn (holger.stenzhorn@uks.eu)
- Short description
    - Type: standalone, web application
    - Input data: people enter manually data for a trial or (for retrospective data) they will be able to import them via CDISC
    - Output data: export of collected clinical trial data via CDISC that can be used to store (long-time) the data tools and the type of interaction: (see output data)
    - Potential users: bioinformaticians, researchers, clinicians, patients
- Reference : http://obtima.org

Fundamental evaluation criteria have been described for a successful interactive interface design (D2.1 ch. 9.3.7). These aspects have been tested in a real life situation by end-users and use scenario forms (D2.1 ch. 9.3.8) have been filled as evaluation report (first evaluation of ObTiMA was performed in June 2012). It covered the **data entry of prospective clinical trial data** (D2.2, ch.11.1.2) described in the ObTiMA scenarios. Data capture, speed and accuracy of data input, simplicity and clarity of use have been tested by recording the interactions between end-users and the application tool. The user group was the **"healthcare providers"** embodied by a clinician and a nurse.

The two external volunteers (a clinician and a study nurse) had to enter into the system a virtual patient's data[4] (**appendix A**) for the nephroblastoma therapy optimization trial SIOP 2001/GPOH. They both used ObTiMA for the first time without receiving any introduction to the tool. The user-system interactions were recorded in a form (**appendix B**) in order to identify problems or weaknesses of the system that should be improved in later versions of the software.

[4] The entered data are fictional

3 *Results of the Use Scenario of the first prototype of ObTiMA*

The evaluation was very fruitful as it uncovered several aspects of the ObTiMA tool that did not fulfil the fundamental criteria required by the end-users (D2.1 ch. 9.3.7). The whole evaluation results in a use scenario (s. below). It describes the user-system interaction with the aim to identify problems related to the interaction to denote norm conformity and to discover a critical incident as well as weaknesses of the system [1]. The use scenario is based on the evaluation of the context scenario in which the minimal functions and requirements of the system were derived from the users' implied needs.

During the whole test the usability engineer and two developers were involved as a participatory observer. The volunteers got a real task to enter patient data for the therapy optimization trial SIOP 2001 / GPOH. The external volunteers have seen the interface of ObTiMA before but they had no experience with the tool. It was the first time they conducted a task with it. When using the system periodically the initial usage problems can be "masked" because the user learned how to avoid these problems but this is not the aim of qualitative usable software.

The prospective users got a paper form with virtual patients' data to be entered into an existing trial into the application ObTiMA (the form is written in German and the filled fields include only virtual patient data, shown in Appendix A, **Figure A1**)[5]. The volunteers, a clinician and a study nurse got no introduction on how to work with the tool.

The user should be able to conduct his/her task at this development stage with the first prototype. It is not essential to have the whole functionality of the application in the first prototype, it should give the users a first impression of the user interface and have some of the planned functions implemented allowing the end-user to perform the evaluation test.

The usability engineer recorded only the direct interaction between the user and the application excluding the general behaviour except the *"thinking aloud"* method. It is of most importance to talk about all the interaction aspects, the emotions and the actions performed. This method shows the usability engineer where problems occur and what has to be improved.

Before the usability test started the volunteers were instructed that only the interaction with the tool was going to be recorded. The written scenario has also to be validated by the user himself before the usability engineer sends them to the developers. Both of them agreed with the protocols and the developers received the results which are described below.

[5] The entered data are fictional

4 First test: the clinician

The user received a username and a password from the developer to login on ObTiMA's website. Then she starts with the assigned task entering patients' data for the therapy optimization trial SIOP 2001 / GPOH (Appendix A)[6].

Tasks

This task was divided into several subtasks in the use scenario shown below:

1. Log in to ObTiMA
2. Enter patient personal data
3. Save the entered personal data.
4. Add CRF to fictional patient "Peter Maier".
5. Fill out the CRF for patient "Peter Maier" with data for a metastasis operation.
6. Data input to surgeon
7. Data input to surgery
8. Start the session once more to enter the information for the surgery

Use scenario of the clinician is visually described by screenshots shown in Appendix B

[6] The entered data are fictional

Use Scenario – User Clinician (Nasi)

Visually described by screenshots in appendix B

Task decomposed into subtasks	Step	User action and comment	Reaction of the dialogue system (ObTiMA - first prototype)	Usage requirement, observed problems
Key task: To work with the Ontology-based Trial Management Application ObTiMA (first prototype). The task to enter patient data for the therapy optimization trial SIOP 2001 / GPOH is divided into several subtasks.			**Initial situation:** The online page of ObTiMA is seen in the browser.	**Usage requirement:** To enter patient data in an efficient, effective and satisfied way. (ISO 9241.11) The user should be supported by the system when conducted her task.

Subtask 1: Log in to ObTiMA	1.	The user enters her user name with password and clicks on enter.	The system shows the "Welcome page of ObTiMA" with the speech bubble: "Please select a task from the main menu!" There are two tabs in the horizontal menu bar, the tab "Trials" and the tab "Patients". (Figure B1)	Login was successful.
Subtask 2: Enter patient personal data	2.	The user clicks on the menu tab "Trials" which shows the sub tab "List Trials". She clicks on "List trials".	One trial, the Nephroblastom study is shown with fields, acronym, name and status. (Figure B2)	
	3.	She clicks on the Nephroblastom study. Comment: *"This is not the task I will conduct with the system."*	A new window is opened with three tabs, "Overview", "CRFs" and "Treatment Plan". (Figure B3)	
	4.	She clicks on the tab "Patients".	A new window is opened with patient details sorted in three columns, "Patient Details", "Patient Address Patient Contact Details" and "Patient Organization Details". One field in column "Patient Details" is filled out with a number for the pseudonym of the patient. (Figure B4)	

	5.	The user enters the first and last name of the patient. Then she enters the birthplace and country where she has the possibility to choose between lists of different countries. Then she enters the date of birth and the gender, too.	All entered expressions are shown on the window.	The fields for the first and last name are mandatory fields, marked by a star (*). The patient name is a virtual name that concerns all other data, too. The virtual names guarantee the protection of data privacy.
Subtask 3: Save the entered personal data.	6. 7. 8.	After she had entered all data completely she wants to save the data. Then she clicks on the button "Save" Comment: *"The background and foreground colours give not the best contrast to see important information directly."* She marks the organization "UKS" and clicks once more on the "Save" button.	All entered data are presented directly on the window for patient details. **Critical Incident:** An error message occurs. *"There is an input missing at one data field!"* With a refresh of the window the patient data gets new tabs, "Patient Data", "CRFs" and "Treatment Plan". (Figure B5)	The user didn't recognize the sentence in the third column "Please select one or more organizations!" marked by a speech bubble. It should be highlighted or emphasized in a way that the user doesn't oversee this important information. (ISO 9241 – 110 Suitability for the task) (ISO 9241 – 12 Presentation of information) A refresh of the window is executed. It is not directly clear for the user whether the entered data are correctly saved. (ISO 9241 – 110 Self-descriptiveness)

Subtask 4: Add CRF to patient "Peter Maier". The user wants to document a metastases surgery for patient "Peter Maier"	9.	The user clicks on the tab "CRFs".	A new window comes up with a mark " No CRFs added for this patient" (Figure B6)	
	10.	She clicks on the button "Add CRFs"	A new window is shown with a speech bubble "Please select one or more CRFs to assign to patient" and one CRF with name "Metastases" for selection. (Figure B7) The "Metastases" CRF is shown as selected.	
	11. 12.	She selects the Metastases CRF for patient "Peter Maier". She clicks on the button "assign Selected CRFs to Patient". Comment: *"My first impression is that there are not enough variables for documentation."*	A new window of the CRF template "Metastases" is presented with two items for surgeon and surgery. The item "surgeon" is selected as default. (Figure B8) It is the form for surgeon.	The user doesn't recognize the selected item for surgeon in the template. Recommendation: A better highlight of the selected item. (ISO 9241 – 12 Presentation of Information) The user expects the complete input for surgeon and surgery. Her first view was to see the variables for surgeon, but that was not what she intent to do. The user was irritated in the first moment. (ISO 9241 -110 Conformity with user expectations)
	13.	Then she clicks on the item surgery. Comment: *"Here is the template with the variables I expect."*	The CRF template is presented with the selection of item surgery and its corresponding variables. (Figure B9)	The user supposes that it was the first one she selected and nothing happened but when she clicked a second time on the Assign selected ... button there are two Metastases forms suddenly. A mistake by the system? The user gets no reaction from the system when clicking the first time on the "Assign Selected CRFs to Patient" button. (ISO 9241 – 110 Dialogue principles)
	14.	She clicks on the button "Assign Selected CRFs to Patient" once more.	A new window occurs with two CRFs. (Figure B10)	

		Comment: *"It is no problem to have two CRFs, because considering the following case: if a patient will have several metastases surgeries, then you will have to use this CRF more than one time, e.g. liver and lung metastases surgery"*		
Subtask 5: Fill out the CRF for patient "Peter Maier" with data for a metastasis operation. Data input to surgeon	15. 16. 17.	She clicks on the first Metastases CRF to enter the data for the surgeon. The user enters the data in form of marking the corresponding variables and filling out the fields. After adding the data the user clicks on the button "Save".	The window occurs with selection for surgeon and the responsible variables. The entered data is shown in the window. A refresh of the window is executed. The window shows new possibilities to edit the entered data on the right. The surgeon and all data are marked with a red dot. (Figure B11)	The colour red is not usually considered as well done. It associates rather as something is missing or something failed. Recommendation: Legend for the different colours.
Data input to surgery	18.	Now the user would like to enter the information for the surgery. She clicks on the item "surgery". Comment: "*Why does it not work?"*	**Critical incident:** Nothing happens!	The user considers the additional functionality of the single variables. Her entered information was correct and she would like to go to the surgery to enter the corresponding data. The user is irritated and does not know what to do. She would like to enter the data for surgery and she doesn't know how to come to this form. Missing action guided information for the user. (ISO 9241 – 110 Suitability for the task, Self-descriptiveness) Hint from the developer: Only one click on the item works. With double click the system runs in dead end. Mistake by the system! The user has to login once more. No efficient working for clinicians.
	19.	The user has to stop the session.		

Subtask 6: Start the session once more to enter the information for the surgery	20.	The user logs in once more.	The welcome page of ObTiMA is shown in the browser.	The user is logged in and is wondering if all entered data from the session before is saved and can be used in the following session. Response by the system is missing.
	21.	She clicks on the tab "Patient" and then on "List Patients".	The patient list occurs.	The user is happy to find all entered data.
	22.	She clicks on "CRFs".	The two Metastases are shown.	She persuades by herself that all entered information in the session before has been saved by the system correctly. The user should not think about saved or not saved.
	23.	She opens the CRF "Metastases" with one click.	The window shows selected item surgeon with the entered information.	Now she learned that only with one click on "Surgery" the corresponding page will be opened.
	24.	Then she clicks on the item "Surgery".	The corresponding window appears with the variables for surgery. (Figure B12)	This should be improved by the designer. Because it is not intuitive.
	25.	The user enters the patient data for surgery into the form.	All entered data are shown on the window. **Critical Incident:**	The user gets no response from the system whether the save action has been executed. There is only a refresh and the same happens as in the situation of saving the surgeon data.
	26.	She saves the information with a click on the button "Save". The user is thinking if all entered data are saved by the system.	There is no visible reaction by the system. On the right side of the window red dots are presented.	The user doesn't recognize these red dots firstly. The user is not really satisfied because there is no red dot in front of the item surgery. She adds some more information and saved once more but without a visible reaction of the system.
		The session is stopped.		

Occurred problems

The occurred problems during the clinician's interaction with ObTiMA are listed in the following:

- mandatory fields should be marked better
- not expecting actions
- highlighting or emphasizing information
- better contrast of background to foreground colour
- marker for indication of status – consistency
- missing legends
- usual colours for green, red ... user has another understanding
- missing reaction from the system, only refresh of the system is not the expected reaction
- expecting complete input for surgeon and surgery together to get a better overview
- action and reaction of the system not visible for the user – doing action once more and then double output
- missing action guided information – unable to enter input for surgery
- double clicking on a button → mistake by the system; only one click is possible - user has to login once more, not efficient
- changes after save are not intuitive for the user, user need explanation
- not completely satisfied because she could not save the rest of information to surgery

5 Second test: the study nurse.

The nurse received the same task (Appendix A) as the clinician. It was her first contact with ObTiMA.

Tasks

The task to enter patient data for the therapy optimization trial SIOP 2001 / GPOH is divided into several subtasks in the use scenario shown below.

1. Log in to ObTiMA
2. Enter patient personal data[7]
3. Save the entered personal data.
4. Add CRF to patient "Peter Maier-Landruth".
5. Fill out the CRF for patient "Peter Maier-Landruth" with data for a metastasis operation.
6. Data input to surgeon
7. Data input to surgery
8. Delete one of the two surgery forms

Use scenario of the study nurse with screenshots is reported in Appendix C.

[7] The entered data are fictional

Use Scenario – User Han (Study Nurse)

Visually described by screenshots in appendix C

Task decomposed into subtasks	Step	User action and comment	Reaction of the dialogue system (ObTiMA - first prototype)	Usage requirement, observed problems
Key task: To work with the Ontology-based Trial Management Application ObTiMA (first prototype). The task to enter patient data for the therapy optimization trial SIOP 2001 / GPOH is divided into several subtasks.			**Initial situation:** The online page of ObTiMA is seen in the browser.	**Usage requirement:** To enter patient data in an efficient, effective and satisfied way. (ISO 9241-11) The user should be supported by the system when conducted her task.
Subtask 1: Log in to ObTiMA	1.	The user enters her user name with password and clicks on enter.	The system shows the "Welcome page of ObTiMA" with the speech bubble: "Please select a task from the main menu!" There	After some faulty insertion of the name the login was successful.

			are two tabs “Trials” and “Patients” in the horizontal menu bar. (Figure C1)	The system gives the user the hint for repeating the login.
Subtask 2: Enter patient personal data	2.	The user is looking where to enter patient data. She clicks on tab “Patients” and then on the sub tab “Add Patients”.	One trial, the Nephroblastom study is shown with the two fields, “Trial Acronym” and ”Trial Name”. (Figure C2)	The user clicks on the tab “Trials” first, because she doesn’t know where the patient data can be entered.
	3.	She selects the Nephroblastom study. Comment: *“I have to insert a patient.”*	A new window is opened with patient details sorted in three columns, “Patient Details”, “Patient Address Patient Contact Details” and ”Patient Organization Details”. One field in column “Patient Details” is filled out with a number for the pseudonym of the patient. (Figure C3)	
	4.	The user enters the first and last name of the patient. Then she tries to enter the date of birth but she doesn’t know in which format it is written. She enters the gender. That are all data she got from the patient.	All entered expressions are shown on the window directly. (Figure C4)	The fields for the first and last name are mandatory fields, marked by a star (*). For this test the patient name is a virtual name that concerns all other input data, too. The virtual names guarantee the protection of data privacy. The user doesn’t recognize the sign for calendar on the right side of the field for date of birth. She does not know in which format date of birth may be entered. Recommendation: Highlighting the calendar when entering the date of birth. (ISO 9241 – 110 Suitability for the task)

Subtask 3: Save the entered personal data.	5.	She clicks on the button "Save". Comment: *"What is missing? The system doesn't tell me what is missing."*	**Critical Incident:** An error message occurs. *"There is an input missing at one data field!"* (Figure C5)	After she had entered all known data she wants to save the data. The user doesn't recognize the sentence in the third column "Please select one or more organizations!" marked by a speech bubble. It should be highlighted in a way that the user doesn't oversee this important information. (ISO 9241 – 110 Suitability for the task)
	6.	The user fills out other optional fields with input now. She clicks many times on the "Save" button in expecting that it is the missing input.	The same error message occurs.	The system should tell the user in the error message which input is missing. (ISO 9241 -110 Error tolerance) The user does not know which field has to be filled out. She is irritated. (ISO 9241 – 110 Suitability for the task, Conformity with user expectations)
	7.	She marks the organization "UKS" after one hint of the developer and clicks once more on the "Save" button. Comment: *"Now I can enter a CRF."*	With a refresh of the window the patient data gets new tabs, "Patient Data", "CRFs" and "Treatment Plan".	A refresh of the window is executed. It is not directly clear for the user whether the entered data are correctly saved. (ISO 9241 – 110 Suitability for the task, Self-descriptiveness)
Subtask 4: Add CRF to patient "Peter Maier-Landruth".	8.	The user clicks on the tab "CRFs". Comment: *"There are no CRFs created."*	A new window comes up with a mark " No CRFs added for this patient" (Figure C6) A new window is shown with a speech bubble "Please select one or more CRFs to assign to patient" and one CRF with name	

	9.	She clicks on the button "Add CRFs"	"Metastases" for selection. (Figure C7)	
	10.	She selects the CRF Metastases CRF and clicks on the button "Assign Selected CRFs to Patient".	The "Metastases" CRF is shown as selected and the window changes the items "CRF" and "Description".	The user wants to create this CRF for patient Peter Maier-Landruth. The new window is not what the user expects. She has the feeling that the CRF is not created. She is irritated and at the moment she does not know what to do next.
	11.	Then she clicks once more on the "Add CRFs" button		The system didn't show the user that the first save of "Metastases" has been executed. The interaction with the system was not correct.
	12.	She marks "Metastases" once more and clicks on the button "Add CRFs" a second time. Comment: *"I will have to delete the second CRF afterwards."*	**Critical Incident:** The same action as before. Two CRFs with the same name "Metastases" are shown.	The user is confused that the CRFs are created two times. The user supposes that it was the first one she selected and nothing happened but when she clicked a second time on the Assign selected ... button there are two Metastases forms suddenly. A mistake by the system? The user gets no reaction from the system when clicking the first time on the button "Assign Selected CRFs to Patient". In the first moment the user does not realize what to do next. She could not recognize if the entered data have been saved completely. There was no action guided information and no response from the system. (ISO 9241 – 110 dialogue principles)
Subtask 5: Fill out the CRF for patient "Peter Maier-Landruth" with data for a metastasis operation.	13.	She clicks on the first CRF "Metastases"	A new window of the CRF template "Metastases" is presented with two items one for surgeon and one for surgery. The item "surgeon" is selected as default. (Figure C8) The fields for surgeon are shown in the window.	

Data input to surgeon	14.	She clicks on the item "surgeon" and enters the data for surgeon into the form.	A refresh of the window occurs with red dots for surgeon and all input variables as well as editing tools.	Another problem for the user is the language. She proposes to have a translation in German for the English expressions.
	15.	After entering the data for surgeon she clicks on the button "Save".	The fields for surgery are visible on the window for entering data. (Figure C9)	The mouse documentation should also be in German to understand the meaning of the different signs on the right side. The user does not know if the save action has been executed or if she has to enter missing data. The response from the system is missing. (ISO 9241 – 110 Dialogue principles)
Data input to surgery	16.	She clicks on the item "surgery"		The user is not satisfied. She gets no answer from the system.
	17.	The user enters the responsible data for surgery into the form.		She would prefer to get the filled out form in a printed version on paper.
	18.	She clicks on the button "Save".	All entered data are visible on the form for surgery. The system shows the red dots for surgery and all other variables with the additional editing tools.	The user doesn't recognize the red dots and she cannot interpret them.
		Comment: *"These were all data. I'm not sure if the data is complete."*		On the other side for the red dots there are no legends. The user needs an explanation to understand the different colours.
Subtask 6: Delete one of the two surgery forms	19.	The user wants to delete the second created surgery form. She clicks on the tab CRFs.	The window with the two surgery forms is presented. (Figure C10)	The user doesn't realize the different coloured dots of the two surgery forms. Recommendation: Legends for the colours to explain the difference.
	20.	Then she tries to click on the second surgery form, but it doesn't work. We stopped the session-	No reaction of the system!	The user has not the possibility to select the second "Metastases" form. She is thinking and waiting for a reaction of the system.

Occurred problems

The occurred problems during study nurse's interaction with ObTiMA are listed below:

- in which format to enter date of birth should be clear for the user
- error message should help the user for clarification
- reactions of the system are not clear for the user
- language should be consistent, German or English, for German users all should be in German, also the mouse documentation
- for the save action the user should get a response from the system
- for controlling the entered data a print button is essential
- coloured dots should be explained by a legend
- double clicking on a button → system's mistake
- delete one incorrect input is impossible, should be explained
- not completely satisfied because she could not click on surgery for entering data

6 Recommendations regarding the dialogue principles ISO 9241-110

Both prospective users received the same task. The occurred problems were very similar regarding their interaction with the tool, so that we evaluate them together.

Suitability for the task means that the system shall support the user in conducting his/her special kind of activity in an effective and efficient way. The program should be a helpful tool not making the user's work harder or more complicated.

After login and seeing the homepage of ObTiMA it was not intuitively clear for the user which tab has to be selected to proceed and enter patient data efficiently. Some hints from the software would be useful. We want to stress that the prospective users got no introduction or training of the tool ObTiMA. The nurse encountered problems in identifying in which format to enter the date of birth of the patient. She oversaw the calendar sign that could help her not to think about this input. Hint from the software to use the calendar.

Problems occurred when saving the entered patient data[8]. The users oversaw the not very good emphasized speech bubble in the third column. The background and foreground colors give not the best contrast to see important information directly. Considering the self-descriptiveness it is essential that all necessary information has to be obviously got into user's focus.

[8] The entered data are fictional

Considering [7] the user should be enabled to convey the content of the website quickly and accurately. In any case it should be clear what has to be entered.

When a save action is executed by the tool it is not directly clear for the user whether the entered data are correctly saved or not. The user does not see the short refresh of the screen and waits for a reaction. The dialogue should present the user with relevant information related to the fulfilled action. Therefore she enters the data twice and both data are saved without the knowledge of the user. The user is irritated and does not understand the result of two input data.

Regarding conformity with user expectations it is necessary to get immediate and suitable feedback on user actions appropriate to user expectations. Users who are not familiar with the English language should get an explanation of the unknown expressions. On the other side the language should be consistent, German, English or any native language. For the corresponding users all should be in their native language, also the mouse documentation. Recommendation could be to switch to the used language before starting the session.

To enter data input to surgery and surgeon the user expected a complete input of both entries to get a better overview. The user didn't recognize the selected item "surgeon" which was selected as default. A recommendation could be of better highlight selected items.

It is unusual for the user to mark well done actions as red dots. The user associates a red dot rather as something is missing or something failed. A recommendation could be a legend for the different colours. The user needs more action guided information to move from "surgeon" to "surgery". With double clicking on the item surgery the system runs into dead end. The user has to login once more. She learned not to click twice on a button. This should be improved by the designer because it is not intuitive. The user should not think about save or not save. It must be visible in every situation that the entered information is correctly saved. Response by the software should be clear and comprehensible.

Another problem concerning the error tolerance was to delete one incorrect input. It was impossible to remove one entered incorrect input. This should be explained by the designer and give the user a useful and comprehensible message to continue her work. The interactive system should support the user to detect input data error and to avoid them. It should also prevent that any user action guide to undefined system states or break-offs.

Error messages should support the user to continue his/her work without any loss of time and effort of correction. A print button would be an essential feature for controlling the entered data.

Both users were not really completely satisfied because they could not save the rest of information to "surgery".

In conclusion, the test was very fruitful for both sides: the user and the developers. The users have shown the developers how they are working and what they expect when executing their task in an efficient, effective and satisfied way. All detected problems should be improved for the next prototype in line with the quality assurance principles as described in D15.1 [8].

Data Access and Security

Several tools are under development to assure secure data access (please see D3.4 for a complete report on the p-medicine security architecture) among them:

1 ObTiMA Trial Biomaterial Manager

- Contact Person: Stephan Kiefer, stephan.kiefer@ibmt.fraunhofer.de, Gabriele Weiler, gabriele.weiler@ibmt.fraunhofer.de
- Short description: The trial biomaterial manager will be a component of the web based trial management system ObTiMA to enable management of biomaterial data in clinical trials and sharing selected biomaterial data. The trial biomaterial manager will provide an import service that enables users to import excel files with existing biomaterial data. Biobank data can be uploaded to p-BioSPRE (upload services provided). The trial biomaterial manager/ObTiMA integrates push services that are able to push selected biomaterial data into the data warehouse.
- Potential users: clinicians, biobank owners

2 CATS

- Name of the tool/service : CATS
- Institution(s) : Custodix
- Contact person : Elias Neri, elias.neri@custodix.com
- Short description: CATS is a service-based de-identification solution. CATS supports anonymisation of different types of data (XML, DICOM, Text, Database, ...) in a generic and extendable way.
- Potential users: data providers and data managers.

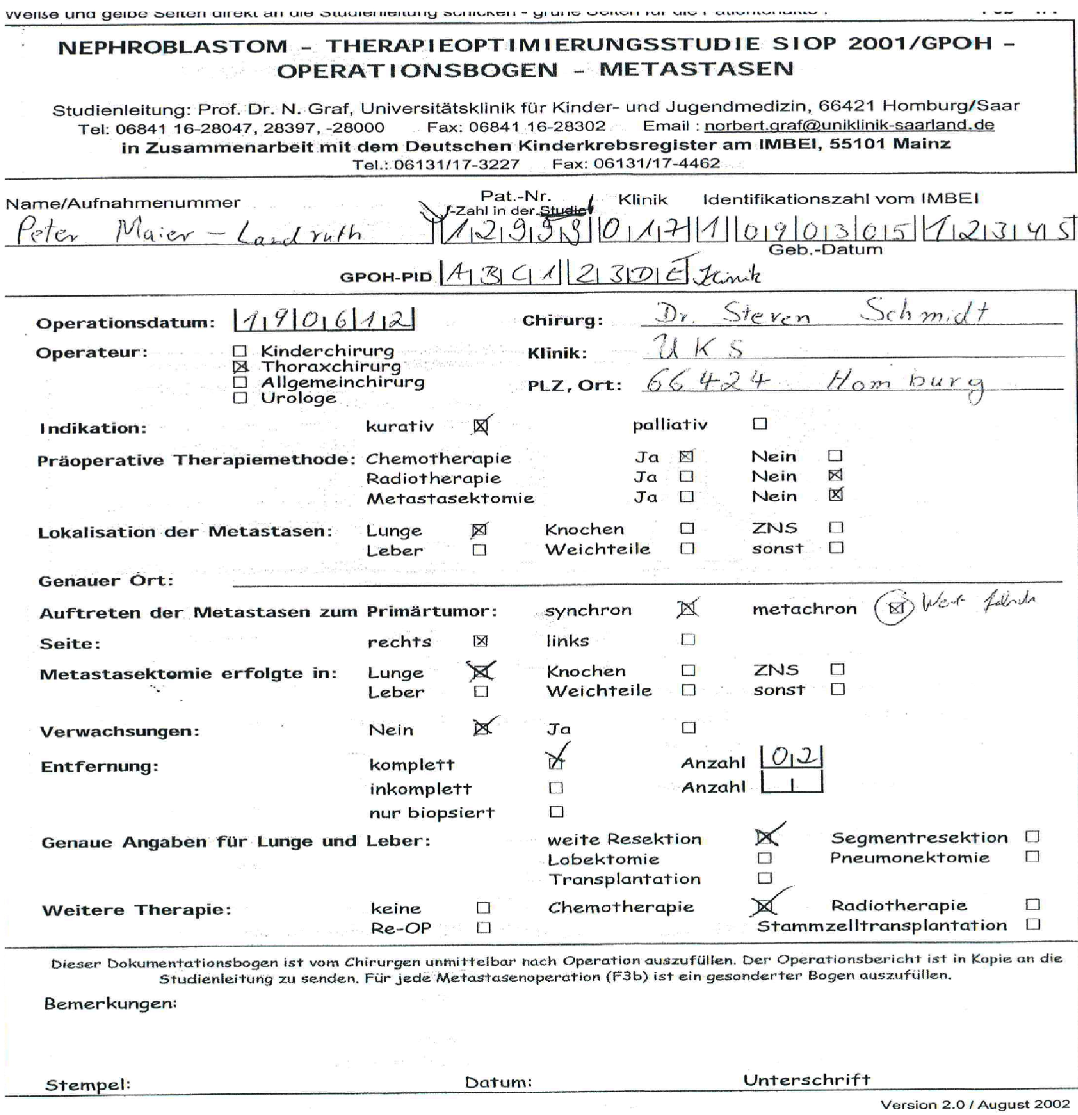
3 PIMS

- Name of the tool/service : PIMS
- Institution(s) : Custodix
- Contact person : Elias Neri, elias.neri@custodix.com
- Short description: PIMS combines a Master Patient Index (MPI) service with functionality for securely managing patient identities (and biological material) in clinical research environments.
- Potential users: data providers and data managers.
- Reference : PDF flyer (available on request)

Appendix A

1 *Task of the users, clinician and nurse study*

The clinician and the study nurse have to enter the patient data available on a paper form into ObTiMA[9].



NEPHROBLASTOM – THERAPIEOPTIMIERUNGSSTUDIE SIOP 2001/GPOH – OPERATIONSBOGEN – METASTASEN

Studienleitung: Prof. Dr. N. Graf, Universitätsklinik für Kinder- und Jugendmedizin, 66421 Homburg/Saar
Tel: 06841 16-28047, 28397, -28000 Fax: 06841 16-28302 Email : norbert.graf@uniklinik-saarland.de
in Zusammenarbeit mit dem Deutschen Kinderkrebsregister am IMBEI, 55101 Mainz
Tel.: 06131/17-3227 Fax: 06131/17-4462

Name/Aufnahmenummer: Peter Maier – Landruth
Pat.-Nr. / Zahl in der Studie: 1295 / 8
Klinik: 0174
Identifikationszahl vom IMBEI: 1 0903 05
Geb.-Datum: 71234
GPOH-PID: 43C1 23DE

Operationsdatum: 19 06 12
Chirurg: Dr. Steven Schmidt
Operateur: ☐ Kinderchirurg ☒ Thoraxchirurg ☐ Allgemeinchirurg ☐ Urologe
Klinik: UKS
PLZ, Ort: 66424 Homburg

Indikation: kurativ ☒ palliativ ☐
Präoperative Therapiemethode: Chemotherapie Ja ☒ Nein ☐; Radiotherapie Ja ☐ Nein ☒; Metastasektomie Ja ☐ Nein ☒
Lokalisation der Metastasen: Lunge ☒ Knochen ☐ ZNS ☐; Leber ☐ Weichteile ☐ sonst ☐
Genauer Ort:
Auftreten der Metastasen zum Primärtumor: synchron ☒ metachron ☐
Seite: rechts ☒ links ☐
Metastasektomie erfolgte in: Lunge ☒ Knochen ☐ ZNS ☐; Leber ☐ Weichteile ☐ sonst ☐
Verwachsungen: Nein ☒ Ja ☐
Entfernung: komplett ☒ Anzahl 02; inkomplett ☐ Anzahl; nur biopsiert ☐
Genaue Angaben für Lunge und Leber: weite Resektion ☒ Segmentresektion ☐; Lobektomie ☐ Pneumonektomie ☐; Transplantation ☐
Weitere Therapie: keine ☐ Re-OP ☐ Chemotherapie ☒ Radiotherapie ☐ Stammzelltransplantation ☐

Dieser Dokumentationsbogen ist vom Chirurgen unmittelbar nach Operation auszufüllen. Der Operationsbericht ist in Kopie an die Studienleitung zu senden. Für jede Metastasenoperation (F3b) ist ein gesonderter Bogen auszufüllen.

Bemerkungen:

Stempel: Datum: Unterschrift

Version 2.0 / August 2002

Figure A1. Paper form containing fictional patient's data.

[9] The entered data are fictional

Appendix B

1 Use Scenario – Clinician

Screenshots for the use scenario – Clinician[10]

Figure B1. Welcome

Figure B2. Trial – Nephroblastoma

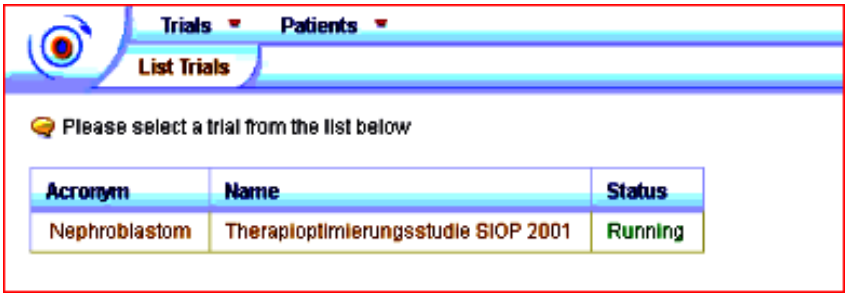


Figure B3. Trial – Nephroblastoma Details

[10] The entered data are fictional

Figure B4. Empty Patient CRF

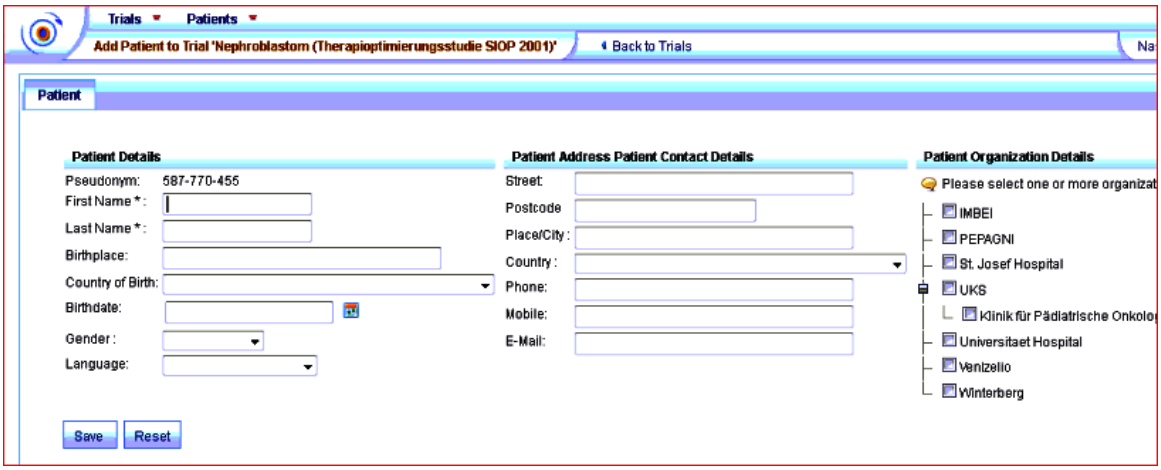


Figure B5. Entered patient data

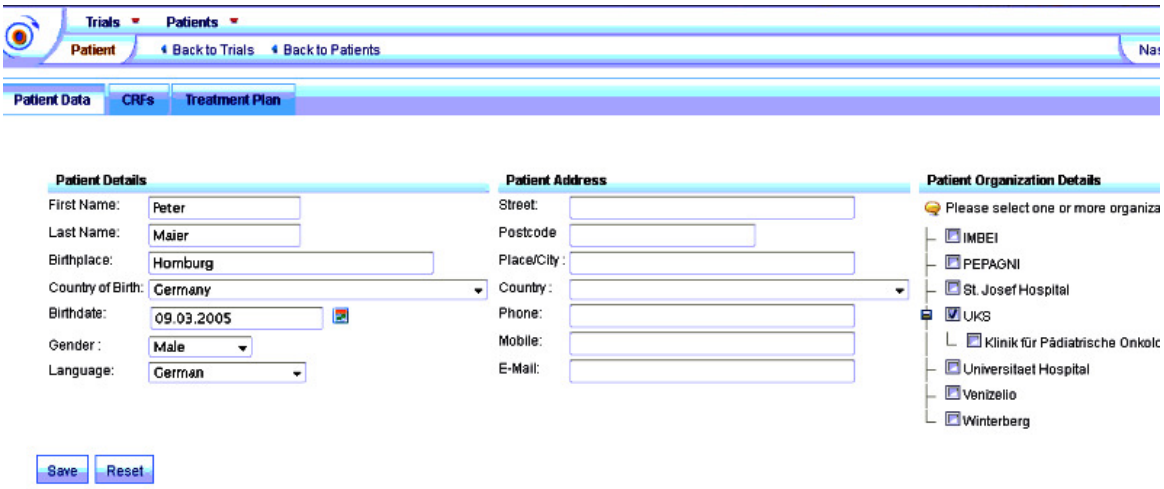


Figure B6. No CRFs added for patient "Peter Maier"

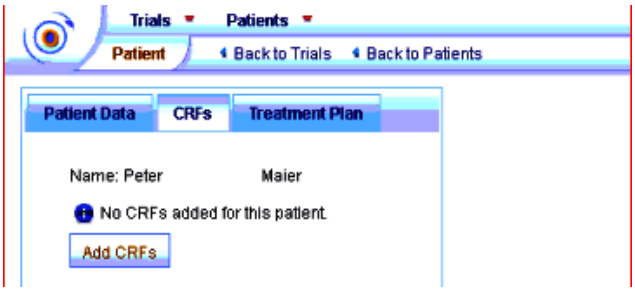


Figure B7. CRF-Metastases

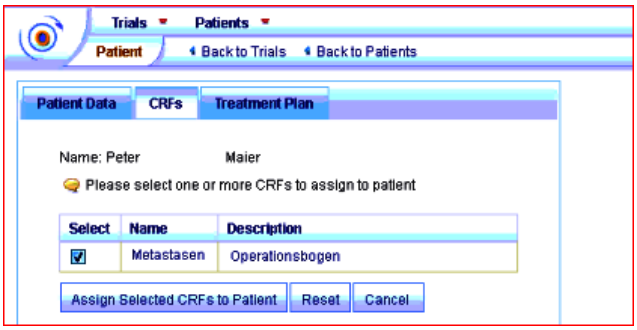


Figure B8. CRF template for surgeon

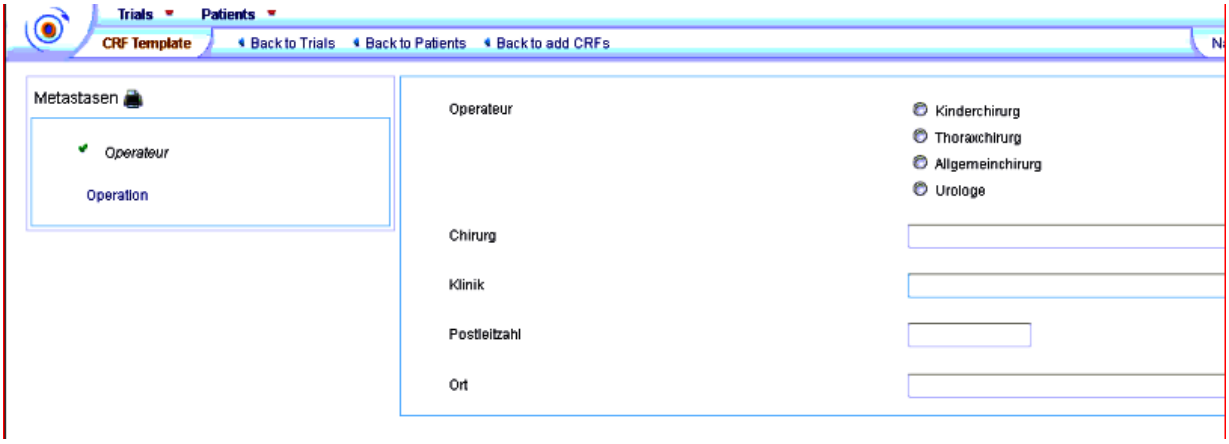


Figure B9. CRF template for surgery

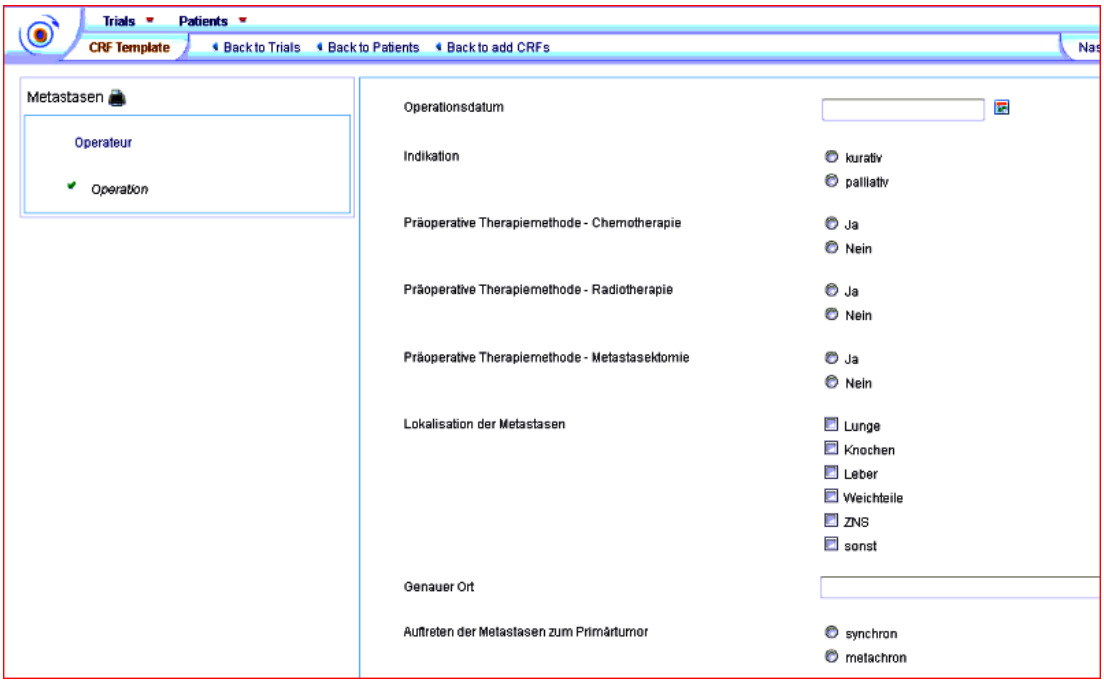


Figure B10. Two created Metastases

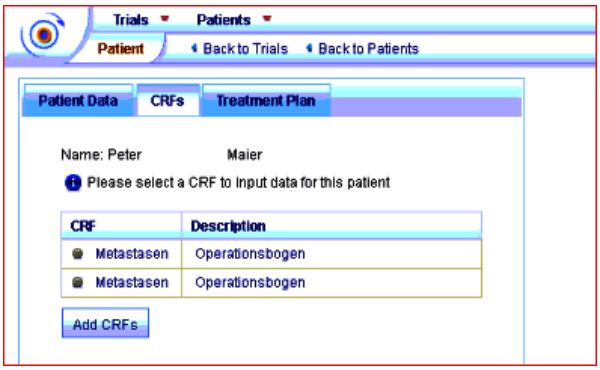


Figure B11. CRF for surgeon with added information

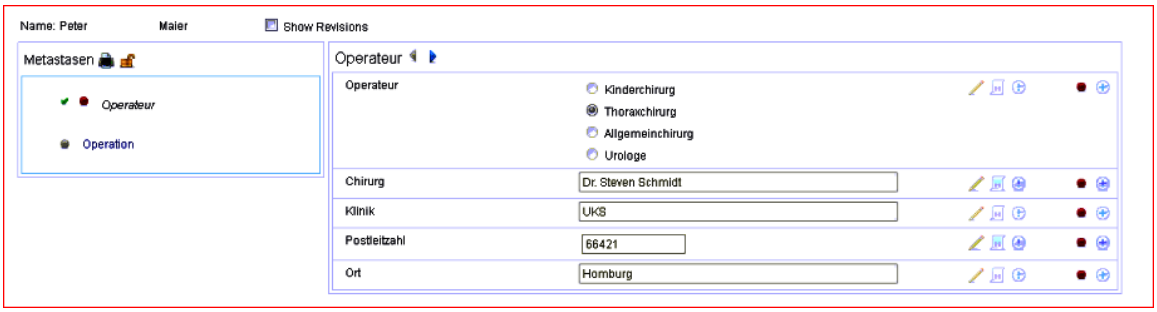
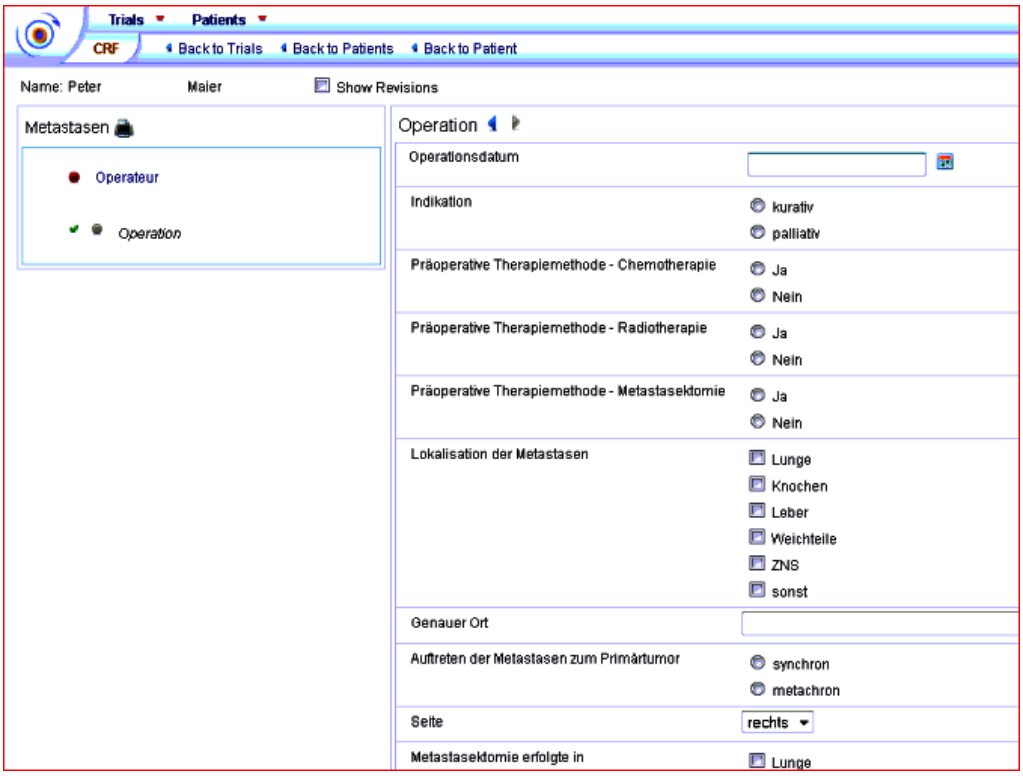


Figure B12. Empty CRF for operation



Appendix C

1 Use Scenario – Study Nurse

Screenshots for the use scenario – Study nurse[11]

Figure C1. Welcome

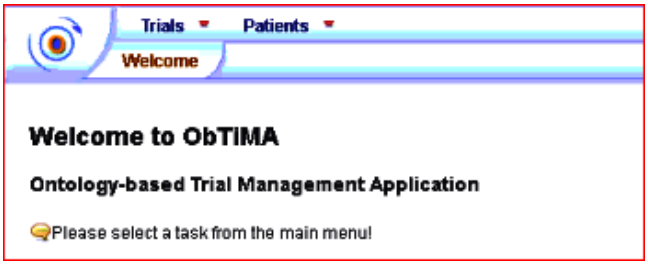
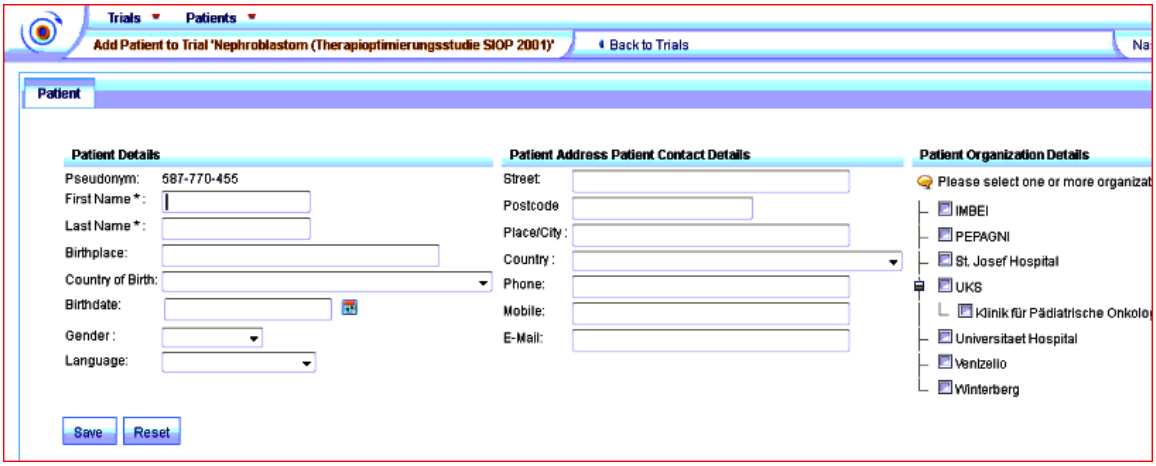


Figure C2. Trial – Nephroblastoma

Figure C3. Empty Patient CRF



[11] The entered data are fictional

Figure C4. Entered patient data

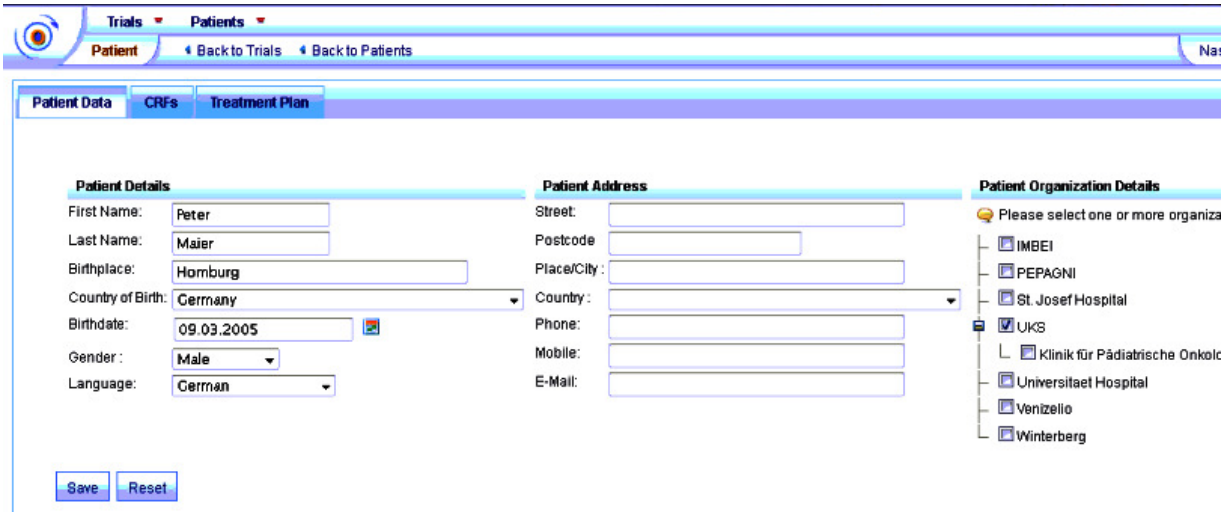


Figure C5. Error Message when saving the input data

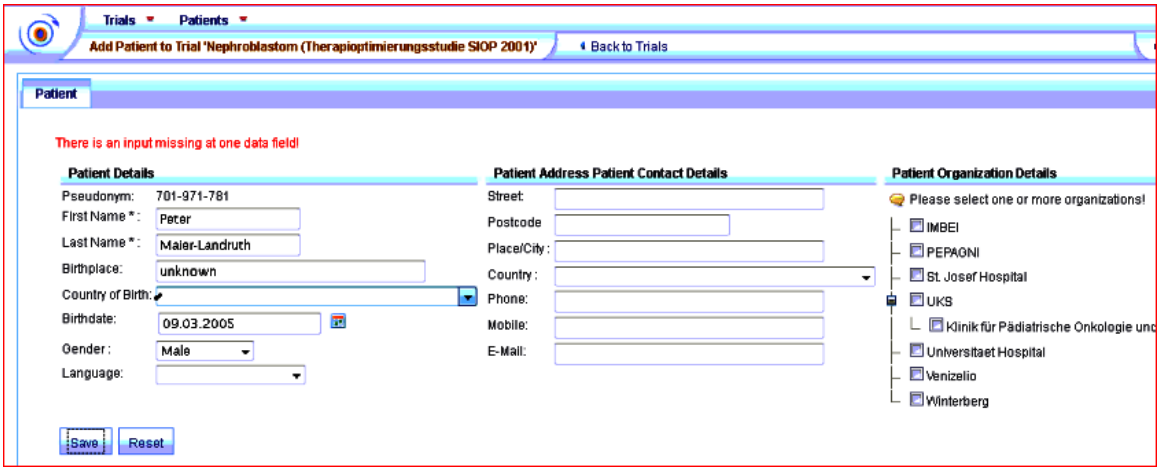


Figure C6. No CRFs added for patient "Peter Maier"

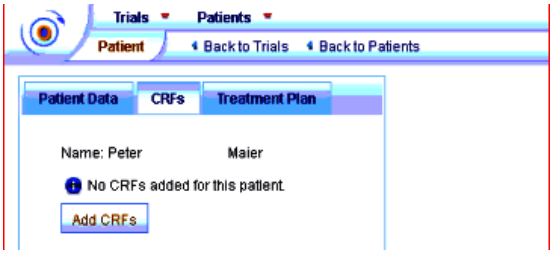


Figure C7. CRF-Metastases

Figure C8. CRF template for surgeon

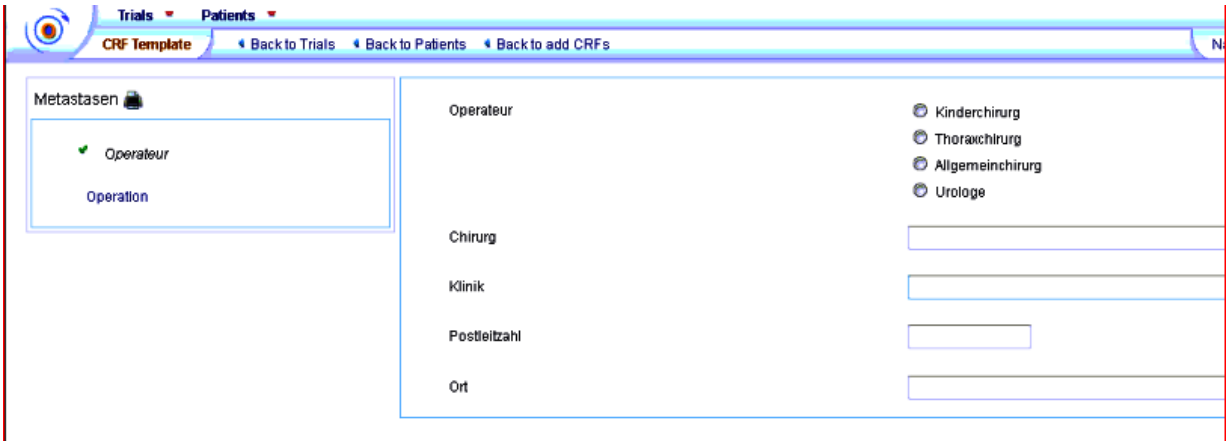


Figure C9. CRF template for surgery

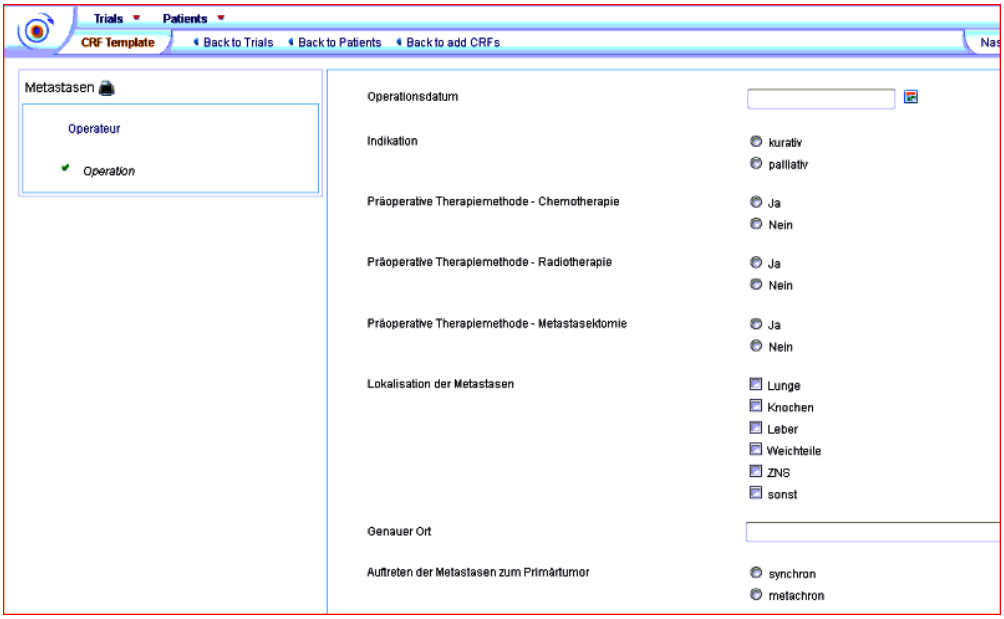
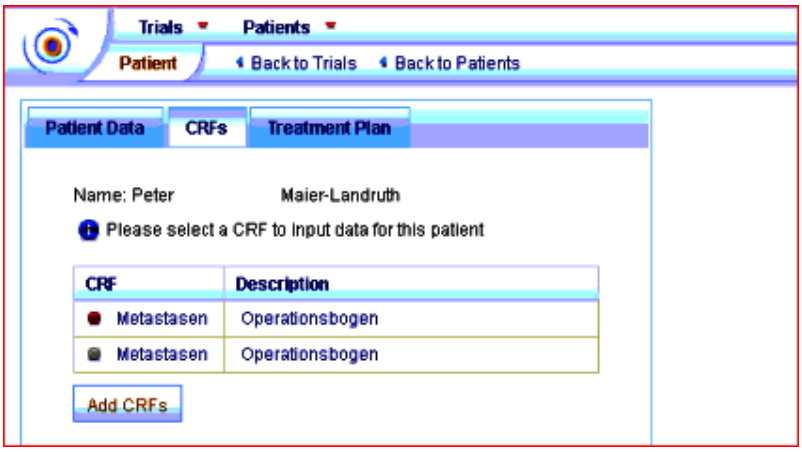


Figure C10. Two created Metastases



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[1] D2.01 – State of the art review of the p-medicine environment

[2] D2.02 – Definition on scenarios and use cases and report on scenario based user needs and requirements

[3] Hood L, Friend SH. (2011) Predictive, personalized, preventive, participatory (P4) cancer medicine. Nat Rev Clin Oncol. 8(3):184-7. PMID: 21364692

[4] Gorini A, Pravettoni G. (2011) P5 medicine: a plus for a personalized approach to oncology.

Nat Rev Clin Oncol. 8(7):444. doi: 10.1038/nrclinonc.2010.227-c1. PMID: 21629214

[5] ISO 9241 Ergonomics of human-system interaction – part 11: Guidance on usability

[6] ISO 9241 – part 110: Dialogue principles

[7] ISO 9241 – part 12: Presentation of information

[8] D15.1 – Evaluation criteria and verification procedures

Glossary

Symbol	**Definition**
CDS	Clinical decision support
GCP	Good clinical practice
CRF	Case report form

12

[12] This page is intended to be blank