ACGT Context Scenario (Clinician)

Context of Use	Dialogue Principle	Software Requirements
Introduction Alexander is a qualified physician and clinical researcher. He works as resident in the paediatric haematology and oncology department of a university hospital. He participates in the ACGT project – Advancing Clinico Genomic Trials on Cancer – in his capacity as researcher and physician in WP2 "User's needs and requirements" as assistant of the WP 2 leader Prof. Dr. Norbert Graf. His interests are paediatrics, oncology, biomolecular research and clinical trials, focusing particularly on nephroblastoma and brain tumours. His tasks as a physician essentially include: • performing routine examinations and documenting and treating patients in accordance with ethical and legal guidelines and with the principles of GCP (Good Clinical Practice) • documenting patients' histories as well as current and previous diseases of the patients (patients' history: social, family, business, vaccination etc.) in the HIS (Hospital Information System) and, for oncology cases, completing CRFs and handling specimen and images to be sent to the institutes prescribed in the corresponding protocol	Suitability for the task Suitability for the task	A clinical trial management system will be implemented to support the clinician/physician in performing his job, preparing clinical patient trials, reporting and processing the patient's data in an effective and efficient way. Query and analyze databases used in the patient trials in a standardized way and share these data to other corresponding research institutions and hospitals. Furthermore, the system should allow for the combination of clinical and research data in compliance with the ethical and legal directives in order to achieve an improved and more individualized treatment. Store all relevant patient data, the entire patient history in a structured way so that it is easy to recover the data. Store patient data into the system with all diagnostic procedures.

• admitting patients (especially children) and performing routine diagnostic procedures (minimally invasive procedures and basic imaging such as ultrasound, for example) • sending and, in part, supporting patients during diagnostic check-ups or special diagnostic procedures (X-ray, MRI, etc.) • "managing" the patient in an interdisciplinary team that is needed for the individual situation of the patient • initiating and collecting relevant data delivered by the examinations for diagnosis and documentation of all proceedings and events of the patient (Treatment in paediatric oncology is always the result of discussions in a team as well as interdisciplinary management and, in nearly all the cases, is directly linked to the procedures described in a trial protocol) • selecting the best clinical trial (based on cancer type and characteristics) for treatment with regard to exclusion, inclusion and stratification criteria for admission to a specific trial. • managing the follow-up of the patients, e.g. defining the off-clinic procedures in physician letters to peripheral physicians • providing advice on further proceedings and supportive treatment during and after therapy • visiting lectures and workshops to ensure that his knowledge is always state of the art and in line with GCP	Suitability for the task Suitability for the task Suitability for the task Controllability	All personalized data of the patient must be stored in a secure way and be accessible only for the treating physicians. Support the clinician in the treatment and interdisciplinary management of paediatric oncology and in describing the procedures in a trial protocol. In order to find out relevant information for diagnosis the system should support a search button or field. The discussions concerning paediatric oncology in a team as well as interdisciplinary management must run into the trial protocol. Support the clinician in selecting the best clinical trial (based on cancer type and characteristics) for treatment regarding exclusion, inclusion and stratification criteria for the acceptance into a trial A form should be offered in the system in which defined information from the CRFs are already included and automatically entered when the corresponding CRF is edited (e.g. administered drugs, diagnosis of imaging studies, etc.). That allows the physician to safe time, when writing physician letters.

and to improve his qualifications • attending daily ward rounds and reporting to in these rounds (in team discussions, at the patient, general hospital reports,..) • correspondence and request for advice from the trial centre of the corresponding trial in unclear situations His tasks related to clinical trials essentially include:		
• designing, running and implementing new scenarios for clinico-genomic trials within the ACGT project	Suitability for the task	The system should support designing, running and implementing of clinico-genomic scenarios.
• making sure that the scenarios are in line with the ethical and legal guidelines, especially the European directive…(the director of the trial has to ensure that each amendment is approved in writing by the ethical committee)	Suitability for the task	It should be ensured that the scenarios are in compliance with the ethical and legal guidelines and proved by the ethical committee.
• collecting and managing the probes and clinical data received from the participating centres	Suitability for the task Controllability	Later on in the process, the probes and all clinical data should be collected and managed in an easy and comfortable way.
• anonymize / pseudonymize the probes / specimen / sera / images before they are sent to the laboratory for further processing. This has been performed manually up to now and turns out to be a very time-consuming task. Work in ACGT:		Data, probes, specimen, sera or images which are sent to others (laboratories) must be anonymized / pseudonymized. The user needs a tool for handling this encryption automatically.
The tasks in the ACGT project are related to WP 2 and the WPs that are related to end users.	Suitability for the task	

These are mainly technical work packages for end user evaluation (WP 3, 5, 13), in silico oncology (WP 8), clinical trials (WP12) dissemination (WP 15) and exploitation (WP 16), ontologies (WP 7) and within the legal and ethical framework of WP 10 and 11. This is why the work on the ward is constricted at the moment and Alexander only attends the lectures, workshops and daily ward rounds. The work of WP 2 shall mainly provide the clinical view and state-of-the-art reviews, evaluation and support of the tools and software developed in the project, and all questions related to the users' needs and requirements. The clinical trials in Germany are organized within the German Society of Paediatric Haematology and Oncology. Once a new patient is diagnosed with cancer, the patient data are written on paper (registry form) and sent to the German Childhood Cancer Registry (GCCR) in Mainz. Once the patient is enrolled, the clinical data are sent to the trial offices in charge of the corresponding trials. The treatment is defined in the trial protocols and the trial office collects all relevant clinical data of the patient. One trial can include different types of cancer. Within a trial, the treatment itself depends on the risk stratification and on the characteristics of the cancer. These stratification criteria were found out by research and prior studies and are specific for each trial. Stratification criteria may include, for example, the response of a tumour towards treatment or the molecular or histological findings. During individual treatment, the patient can be stratified more than once. For example, the patient is stratified in accordance with the tumour localization or metastatic disease. After	Suitability for the task Suitability for the task Suitability for the task Suitability for the task Suitability for the task Controllability	Patient enrolment must be supported by the system. Direct input after / during the interview with the patient must be conducted in an easy and understandable way. All data have to be saved in a structured and clear way. There must be a possibility to send the data to the different institutions after encrypting and dependent on the rights the addressee has to be de-encrypted. At first the patient data has sent to the trial offices of the corresponding trials. All treatment data is saved in Case report forms (CRF) which are linked to the trial protocol which is supported by the system and collected by the trial office. These trial protocols are written in case report forms (CRF) and sent to various trial offices. The system must distinguish between different stratification criteria and lead the physician to the right treatment arm once the patient is stratified. This should be done automatically.. Patients can be stratified more than once. A patient's trial protocol must include all stratification events. There should be a clear and well-structured description of the different risk factors and the corresponding stratification parameters, in case further analysis are needed to stratify a patient, the corresponding institutes (if needed for further

preoperative treatment, the patient is once more stratified regarding e.g. volume, response (% of regression) and histological findings. In another trial, the patient is stratified based on the number of blasts found in the bone marrow puncture, the molecular findings and response of tumour towards high-dose Cortisone therapy (second bone marrow puncture and number of blasts at a predefined date).		analysis e.g. genetic characterisations) should be listed.
		There must be a secure possibility to send the trial protocol to other institutes.
The treatment of patients in paediatric cancer trials occurs in accordance with trial protocol.	Suitability for the task	The reference centres must also be informed in order to provide second diagnoses based on histology and imaging analysis and to ensure a correct diagnosis.
Which types of data must be reported and when they have to be reported is defined in the protocol. The protocol is sent to the relevant trial office or reference institutes in form of Case Report Forms (CRFs).	Controllability	If he has an advisory function, the physician at the reference centre or study office is also allowed to see the personalized patient data
Reference centres provide second diagnosis on histology and imaging analysis to ensure the correct diagnosis or to provide further analysis.	Suitability for the task Controllability	In all other cases all personalized patient data should be anonymized / pseudononymized when sent to other institutions.
The physicians at the reference centres and the trial office obtain the status of a physician in charge of the patient because they are directly embedded in an advising functionality towards the patient. The status of a physician in charge of the patient enables them to the patient's personal and clinical data.	Suitability for the task	The system must ensure the anonymization / pseudonymization of the probes / specimen / sera / images of a patient that are sent to the laboratory for further processing.
		The trial registration should be executed in an understandable and efficient way.
It is not allowed to any other person to see these data. Moreover, the trial chairman of a given trial is (usually) a specialist in the special type of cancer involved and may be asked for advice in case of unclear situations or procedures occurring during the treatment. Furthermore the trail chairman has an excellent overview, based on his experience, of events that may occur and can give advice.		All kind of data that have to be reported in a protocol are sent to the corresponding trial office or reference institute in form of CRFs.
	Suitability for the task	
This ensures a high level of quality and the best possible treatment		When it comes to admitting a patient

for every patient enrolled in the trial. The trial office is also responsible for the randomization of the patient if a randomization is in the trial protocol and if informed consent has been given by the patient/ by the patient's parents. Specimen and probes as well as imaging studies are sent to the reference centres by the peripheral hospital. Today this is mainly done in form of hardcopies and CD/ DVD. The reporting of CRF and related activities are written down on paper and sent by mail or fax. These activities are supported only in part by the use of electronic data processing systems. In the nephroblastoma trial a RDE system is used.	Suitability for the task Suitability for the task Controllability	diagnosed with cancer, the system should support the clinician / physician in an easy and comfortable way. He must have the possibility to enter all relevant data of the patient in an efficient way. It must be possible at any time to add missing information to the patient's data. The chairman himself can validate the data of a patient and disable the editing functionality. By doing so, a subsequent manipulation of patient's data is disabled. The treating physician is the only person authorized to access the personalized data. All others are not allowed to see or read the data.
Assumptions Alexander is a qualified physician and has the required knowledge in the field of oncology. His work is an individual activity embedded in a team of oncologic physicians at the ward. According to ACGT criteria and the scenarios, this is an individual activity. (Single task). When admitting patients in case of a cancer diagnosis and treatment he needs to know the different trials that are actually available and open and which are taken into consideration for the individual patient. In Germany these trials for the treatment of cancer in childhood is well-structured and clearly defined in the GPOH. He is experienced in finding the most efficient and effective trial for the patient. Each patient must be informed about the different procedures and tasks of the treatment after he has been informed about the disease itself and the risks and the benefits of the different treatments.	Suitability for the task	The system must show the different trials that can be selected by the clinician. There should be a full description of the trials for reference if anything is unclear. The different trials should be presented in an efficient way so that the clinician finds out the most efficient and effective trial for his patient. Before the treatment can be started, the system must check if the informed consent

Given the sensitivity of diagnosis, this task is performed by the heads of the ward and most experienced physicians. He has to provide the different opportunities for the treatment and the decision is given in written form by the patient (for patients under 18 years suffering from childhood cancer in Germany, it is given by the parents). Treatment can only be given after the patient/the parents of the patient have signed the informed consent. This consent can be withdrawn any time during the treatment. The patient has to be informed about all necessary procedures, and each procedure (e.g. blood transfusion, diagnostic procedure, etc.) requires an informed consent to be signed as long as it is not covered by a consent that was signed before. The clinical data are collected at the local hospital information system (HIS) and sent to the corresponding trial centre after having been written down in CRFs where the data are stored in an external trial database. Again, the data have to be entered manually. The personal data may be seen only by the physician in charge of the patient and the physicians in the reference institutes. The trial office is allowed to see these data as well because it has a special advisory function for the patient. The trial assistant has to retrieve all missing data that were not provided by the attending physician. The data are collected in case report forms that are defined in the trial protocol. The specimen and probes for further examinations have to be sent to the corresponding centres.	Suitability for the task Suitability for the task Controllability Suitability for the task Suitability for the task	was signed.. The information about the further proceedings will be shown only after the confirmation of the physician that the informed consent is signed If the consent for treatment was signed all necessary information about treatment and the procedure should be saved in the patient data in CRF at the local hospital and sent to the corresponding trial centre in an anonymized or pseudonymized form. The data are stored in an external trial database. This should happen automatically. The physician in charge of the patient and the physicians in the reference institutes and study office (depending on their roles and rights) are the only individuals allowed to see the personal data. The trial office is also allowed to see these data because it has a special advisory function for the patient. If there is any data missing the trial assistant should be supported by the system in completing all the data obtained from the attending physician. There must be a checklist made available by

It is important that the complete patient data be available. Otherwise, it is necessary to ask colleagues or, to retrieve missing patient data during the next examination (either a routine examination or an examination for defining diagnostic procedures).	Suitability for the task	the system to complete the patient data and to mark the important data. These should be saved in the database.
Currently, all data are only recorded in an archive or in a database with restricted access because the personal data are linked to the clinical data.	Suitability for the task	All relevant patient data should be accessed by the treating physician while only non-personalized data should be seen by others.
In case of further analysis of data the manual anonymization of data and the different terminologies create considerable problems and obstacles. Usually, the trial centre is the only entity that is able to conduct detailed statistical analyses of the patient's clinical data. Epidemiological statistics can be done by the GCCR (German Childhood Cancer Registry) because all tumours in childhood have to be reported to the centre.	Suitability for the task	It is necessary for statistical purposes to make the data available in an anonymized way. That allows every statistician to perform queries without the trial centre. Usually the trial centre is the only one who can run statistical analysis.
Alexander is a member of the ACGT project which involves the development of a powerful grid infrastructure for clinicians, molecular biologists and statisticians and the creation of tools and software to achieve a more individualized cancer treatment and to enable the various specialists to use the data without the described obstacles in a way that complies with the ethical and legal directives.	Suitability for the task	The system should provide the physician with an efficient and effective way of achieving a more individual treatment on cancer taking into account the ethical and legal directives for his patient.
Within the ACGT project, Alexander's function is to support the other partners by providing the clinical point of view, the processes in the medical world and usability and functionality criteria for newly developed software and tools from the end user's perspective. He assists Prof. Dr. Norbert Graf who is a specialist in the fields of clinical trials, paediatric oncology and computer applications and systems in medicine.	Suitability for the task	In ACGT physicians support in advising other partners with the clinical point of view and processes in medical world.

Furthermore, he is in charge of one of the scenarios developed for ACGT, namely the Antigen scenario, reporting as SAE/ SUSAR, etc., which is embedded in the SIOP 2001/ GPOH trial. The advisor of Alexander in all the issues related to the scenarios is Prof. Dr. Norbert Graf, the chairman of the SIOP 2001/ GPOH and clinical director of Department of Paediatric Haematology and Oncology of Saarland University Hospital.		
Routine activities Alexander's daily work (which is currently restricted as a result of the ACGT project activities) is done on the ward of the Department of Paediatric Haematology and Oncology of a university hospital. The prime task that he has to perform in his capacity of treating physician is to obtain and record all relevant data of the patient during a first interview. These patient data contain the social data (such as age, gender, parents/ family members' prior diseases, etc.) and the personal data and history as well as a complete physiological examination and the history of the present disease. The basic questions and examination are followed by planning the most likely suspected differential diagnoses, discussions with the other physicians and the diagnostic procedures for finding out the proper diagnosis in the most efficient way. If there is secured diagnosis of a haematological or oncological disease the appropriate trial is selected. The criteria for inclusion, exclusion and individual kind of treatment are described in the trial protocols and in all organizational procedures (report of CRF, diagnostic procedures and time schedules, etc. …). The supportive treatment and modification of the cancer treatment depend on the actual symptoms and on the health status of the patient.	Suitability for the task Controllability Suitability for the task Controllability Suitability for the task Controllability Self-descriptiveness	To admit a patient diagnosed with cancer, the system should support the clinician / physician in an easy and comfortable way. He must have an efficient possibility to enter all relevant patient data. It must be possible at any time to add missing information to the patient's data. The treating doctor is the only individual having access to the personalized data. All other persons are not allowed to see or read the data. The system should support the physician in looking for relevant information about diagnostics. The system should offer the clinician the corresponding trials to get the best treatment. All existing trials must be shown by the system in a well-structured and understandable way so that the physician can choose the right trial

The routine activities at the ward include: - conduct daily examination and necessary basic diagnostic procedures for the patient - provide support to the patient and answer questions - document the daily general condition of the patient, particularities and decisions on further treatment based on the general condition and examination results of the patient (e.g. decision to administer antibiotic therapy in case of an infection) - plan and document of the treatment - attend (if possible) the relevant diagnostic procedures - make sure that the patient receives ALL necessary information before he patient gives his informed consents - ensure that no procedure is initiated without the patient's consent - report the findings and particularities to the corresponding trial office and reference centres - send specimen and images to the corresponding institutes (some centres have specialized personnel resources such as documentation nurses, for example) for the purpose oi reference or additional research (e.g. bio-molecular research for further characterization) - make sure that the patient has adequate medical support outside the hospital and during the follow-up process - …… Apart from the ward rounds, only part of Alexander's daily activities during the ACGT project are performed on the ward. Currently, his daily work is to collect the data and samples for the antigen scenario, to collect the clinical data using the trial database and support Prof. Dr. Norbert Graf in all the issues relating to the WP 2 tasks.	Suitability for the task Controllability Controllability Controllability	if there is a final diagnosis. The trial protocol provides effective and self-descriptive information about the criteria for inclusion, exclusion and for the particular kind of treatment. All daily general conditions of the patient, particularities and further treatment decision should be documented and supported by the system. The system should support the planning and documentation of the treatment and provide a visualisation of the treatment scheme for each single patient. . The system should make sure that the patient informed consent is signed by the patient and saved before the treatment starts. The checklist of the patient data must be completed. Later on in the process, it has to ensure that all relevant patient data, specimen and images be submitted to the corresponding trial office and reference centres in a secure way. The system should warn the physician if data are missing / what can mean that he missed / or forgot or was not aware of a step / task in therapy.

All patient data must be complete. Otherwise, data completeness can only be achieved by asking colleagues and possibly by arranging new appointments with the patient. Data completeness is the absolute prerequisite for defining the best possible therapy. The requested data and case reporting forms are described in the trial protocol. The data must be complete in order for the patient to be able to be stratified.	Suitability for the task	The stratification of the patient can only start if the patient data that are needed for the stratification are complete. The different stratifications must be supported and displayed to the user in a clear and understandable way.
The data of the patients of the SIOP 2001/ GPOH are collected by the trial assistant of the study. The data are sent by the participating centres via postal mail, fax or via remote data entry (RDE system).	Controllability	
The software used for the trial was developed by software engineers of the hospital in close collaboration with Prof. Graf. If sent by postal mail or fax, however, the data have to be entered manually.	Suitability for the task	All collected data should be entered into the system in an efficient and effective way and sent the internet using the predefined CRF templates (defined and designed by the chairman) in an encrypted form.
The communication between the centres normally occurs via mail or fax or by phone. The specimen and probes are sent by postal mail. This can be done in a more efficient way if there would be the possibility to have an own Email system or Consultation functionality in the software itself where participants can easily share and send data.	Suitability for the task	. The communication between the centres should occur via Email system on the platform while the specimen and probes are also transmitted electronically in a secure way. Communications and Consultations (like Phone, Fax, letter etc…) should be possible as well and documented in the system after.
The data of the patients have to be anonymized / pseudonymized manually before they can be forwarded to the laboratories. Images are sent by postal mail in the form of hardcopies or DVDs/ CDs. In order for these images to be stored centrally, the imaging studies must be uploaded to the trial database manually. In case of further research, the imaging files (DICOM format) have to be	Controllability	All patient data have to be anonymized / pseudonymized by the system before being sent to the laboratories.

anonymized/ pseudonymized manually. All these activities are very time-consuming, and the transfer of data, probes and images also takes too much time. For SAEs and SUSARs, there is a strict timeframe for reporting these events which is prescribed by law. In case of special events during treatment, rare disease for which there is no trial protocol (especially dedicated to this disease) available or experimental individual therapies, it is necessary to search online libraries (e.g. pubmed. Medline etc…) for case report studies or prior trials in order to find an appropriate treatment strategy. Another problem that makes it difficult to perform further research and cross-trial research is the non-uniformity of the nomenclatures and the multi-lingual descriptions using different classifications. The data can be compared only if words have the same meaning. Comparison and transfer of data are also inhibited by the ethical and legal directives because the participating centres need the combined clinical and research data, and the effort to provide these data in a legal way is not reasonable for these centres. The amount of available data has increased enormously during recent years. It is nearly impossible for the individual physician or researcher to retrieve relevant information or correlate data in an affordable way. There is a high risk of ignoring important relations in the existing studies. What is needed to ensure an optimum yield of existing data is end user friendliness (especially end user friendly interfaces) to support the physician in dealing with the unmanageable amount of data.	Suitability for the task Suitability for the task Suitability for the task Suitability for the task	Images should be saved in a corresponding form (e.g. DICOM files) and also anonymized / pseudonymized before being sent to other trial centres. The system should support the user in searching for adequate treatment strategies or prior trials in situations where no trial protocols are available for rare diseases. The use of different nomenclatures and classification systems using the same word with different intentions is a gap for data comparability. The data is only comparable if each single item has exactly the same meaning for everyone involved. Support the ethical and legal directives for comparison and transfer of data, as the participating centres need the combined clinical and research data, and the effort to provide these data in a legal way is not reasonable for these centres. The amount of available data should be organized in an efficient way so that important data are well-structured and can easily be found by the clinician / physician.

Special features during the working process ACGT has been developed in order to obtain an electronic assistance to support the clinician in executing his job, in preparing clinical patient trials, reporting and processing the patient's data in an effective and efficient way and in sharing these data. Another objective is to provide the possibility of combining of clinical and research data in compliance with the ethical and legal directives in order to achieve an improved and more individualized treatment.	Suitability for the task	Furthermore, the system should provide the possibility to combine the clinical and research data in compliance with the ethical and legal directives in order to achieve an improved and more individualized treatment.
The tools to achieve this objective should support them in their daily work by offering services, by sharing anonymized or pseudonymised data in an automatic and secure way and by processing data in clinical trials more quickly and in compliance with the European directives. In Alexander's view, the following aspects should be taken into account when developing a software system in order to support the tasks described above:	Suitability for the task	The tools to achieve this objective should support the clinicians in performing their daily work by offering services, by sharing anonymized or pseudonymized data in an automatic and secure way and by processing data in clinical trials more quickly and in compliance with the European directives.
Alexander needs a tool into which patient data can be entered by the corresponding physician so that it can also be seen by others. The personalized data can only be displayed by the physicians in charge of the patient. What is needed to ensure compliance with the legal and ethical directives and to protect the patient's data is an efficient and user-friendly roles and rights management to read, enter, edit and validate the patient's data.	Suitability for the task	The following should be taken into account: the entered patient data should also seen by others while the personalized data can only be seen and accessed by the physician in charge of the patient. What is needed to ensure the conformity with the legal and ethical directives and to protect the patient data are efficient and user-friendly roles and rights management to read, enter, edit and validate patient data.
The reference centres, for example, are authorized to enter the data and see the personal data of a patient because, in this special case, the reference centre has the role of a treating physician. The centre is not able, however, to edit other data than those of patients for which it is responsible. The roles and rights can only be assigned by the trial chairman because it is him who is responsible	Suitability for the task Controllability	If the reference centres, as is the case here, for example, assume the role of a treating physician they are allowed to enter the data

for the trial. These data are entered into a CRF – Case Report Form - which is supported by the system and validated by the trial chairman. The functionalities needed for designing such a trial must be answered by a trial chairman. The local physician receives the trial protocol including all relevant information relating to the trial (defined in a master protocol for ACGT and available at the BSCW server in Deliverable D 2.2). This is very important. The usability and functionality of the system should support end user friendly visualization and management of the trial protocol. Ideally, the trial protocol is directly linked to the other functionalities, especially the CRFs. The software should include all previously registered studies which are described by the patient data including their full treatment. In particular, side effects, Severe Adverse Events (SAE) and Suspected unexpected Severe adverse reactions of medications and therapy should be listed depending on the therapy. Alexander wants to be able to enter data efficiently and to inform his patients quickly later on. For further analysis, the system must be protected to ensure that patient data be encrypted. Drawing conclusions as to the personal data of the patient is prohibited for all other individuals except the physicians in charge of the patient. There should be an easy and fast way to store, send, process and comment imaging data. Imaging data require lots of storage space, and data transfer is usually time-consuming with the currently used systems. What is needed to enable additional research and to make the data available for others is an efficient encryption and de-encryption	Suitability for the task Suitability for the task Suitability for the task Suitability for the task	and see the personal data of a patient. The roles and rights can only be assigned by the trial director because it is him who is responsible for the entire trial. The functionalities needed for designing such a trial must be answered by a trial director. The system should support the trial protocol for the local physician including all the relevant information relating to the trial. The system should support end user friendly visualization and management of the trial protocol. Ideally, the trial protocol is directly linked to the other functionalities, especially the CRFs. The software should include all previously registered studies which are described by the patient data including their full treatment. In particular, side effects of medications should be listed depending on the therapy. Physicians want to be able to enter data efficiently and to inform his patients quickly later on. There should be an easy and fast way to store, send, process and comment imaging data. What is needed to enable additional research and to make the data available for others is an efficient encryption and de-encryption system that should be executed automatically by the system. It should allow the user to transfer and store the data in an anonymized way while

system that allows the user to transfer and store the data in an anonymized way while enabling him to see the complete (personal and imaging) data on his screen.	Suitability for the task	enabling him to see the complete (personal and imaging data) on his screen.
The same is needed for the transfer of specimen and probes. The system should provide an automatic pseudonymization tool (such as printable barcodes, for example) to pseudonymize the patients' specimen. The re-identification should be done automatically by the system. With this solution, the laboratory employees receive all necessary data without receiving any personal patient data while the physician in charge of the patient can easily receive the combined data of the patient and the results of the laboratory analysis.	Suitability for the task Self-descriptiveness	The encryption is also needed for the transfer of specimen and probes. It should provide an automatic pseudonymization tool (such as printable barcodes for example) that pseudonymizes the patient specimen. The re-identification should be done automatically by the system. The laboratories should receive all necessary data but no personal data of the patient. After the laboratory did the analysis, the clinician gets back all combined data and all results.
For additional research or statistical analysis the results of the analysis should be available for the scientific community in an anonymized way.	Suitability for the task	For additional research or statistical analysis the results of the analysis should be available for the scientific community in an anonymized way.
In order to guarantee the security of personal data and the availability of data and thus to allow for successful and useful research, the data of the patient should be combined in some way in order to enable the researcher to retrieve further information about that special case of the patient – WITHOUT any possibility for third parties to re-identify the patient.	Suitability for the task Controllability	The security of personalized data must be guaranteed for successful and useful research. There should be a possibility to combine the data to allow the researcher to retrieve further information about that special case of the patient – without any possibility for third parties to re-identify the patient.
Uniformity of data can be achieved by establishing an international master ontology on cancer that defines every single item that can be defined in a trial. This means that not only the disease itself but also treatment, drugs, examination procedures, biological terms, genetic classifications etc. have to be implemented. Without such an ontology, there will be no end user friendly possibility to compare the trial data.	Suitability for the task	Uniformity of data can be achieved by establishing an international master ontology on cancer that defines every single item that can be defined in a trial. This means that not only the disease, but also treatment, drugs, examination procedures, biological terms,
For turning the data and findings obtained from biomolecular		

research into an available and usable resource for physicians, the results have to be presented in a way that the end user (who is the physician in this case) can easily understand.	Self-descriptiveness	genetic classifications etc. must be implemented.
Another requirement is trusted and evaluated tools to support the physician in "working" with the biomolecular, genetic, etc… findings. This is important for visualization systems for imaging studies as well as for research fields like silico oncology. The tools must support the physician in an easy, understandable and, ideally, in a self descriptive way,	Suitability for the task	The system should support such an ontology for comparing trial data in an usable and efficient way.
The major issues related to an end user-friendly trial management system were defined in the D 2.2. "User requirements for an ontology based clinical trial management system and for the trial builder" These requirements mainly include: - the overall concept - modularity of the system - user requirements - functionality of data management system - security, legal and ethical considerations - ontologies - basic datasets - trial-specific data - metadata - practical considerations The document also describes the specific requirements for a software module for trial design (Trial Builder), Case Report Forms (CRF Creator) and a data management concept including roles and right management.	Suitability for the task	Another requirement is trusted and evaluated tools to support the physician in "working" with the biomolecular, genetic, etc… findings. This is important for visualization systems for imaging studies as well as for research fields like silico oncology. The database should contain all relevant data of the patient and the corresponding trial. In the case the patient received prior therapy the corresponding CRFs should be available if the trial was already software supported.

The document can be found at: https://bscw.ercim.org/bscw/bscw.cgi/d328140/ACGT_D2.2_USAAR_final.pdf A lot of time is spent on literature research and web-based related search engines. The information that physicians retrieve from the different search machines requires a lot of analytical work and reading, and it is nearly impossible to relate the findings described in the journals and papers without running the risk of ignoring facts and relations that may be of high importance. Tools like BEA that enable the user to combine different elements and items on all levels (from genetics and pathways to drugs), to search the relevant web databases and to provide an end user friendly visualization of the correlations between the items are very useful when the goal is to avoid these risks and to allow the physician to discover relations more quickly that he might otherwise have ignored. The improvement and further development of such tools is important in order to turn the existing and published data into a usable resource for end users.	Suitability for the task Self-descriptiveness Suitability for the task	It should be possible to search databases for relevant literature using one search engines that can obtain all relevant databases and show the search results based on as many search parameters as requested. (e.g. BEA from Biovista) It is important to improve and enhance tools such as BEA in order to turn the existing and published data into a usable resource for end users.
Organizational conditions The physician at the ward needs a self-descriptive and easy to use interface, software support and database that allow him to easily enter and manage the patients registered in a trial. Furthermore, the software should work as a guideline that contains all relevant information regarding the trial and administrative tasks like sending reports (SAE, SUSAR), ask for consultation at reference centres and ask for advice from the trial office regarding the	Self-descriptiveness Suitability for the task	The physician at the ward needs a self-descriptive and easy to use interface, software support and database that allow him to easily enter and manage the patients registered in a trial. Furthermore, the software should work as a guideline that contains all relevant information regarding the trial and administrative tasks like

patient and treatment in the trial. The trial protocol should be easily available via the software as well as entering and editing the CRFs. The imaging studies and the tools that support the clinician should work very fast in respect to the large amount of data that are processed. The virtual organisation of ACGT in which the CTMS software is embedded should merge the different task the clinician has to handle on different web databases at one platform (e.g. R based analysis, statistics, literature research, querying a trial, etc.). The objective is to safe time and at the same time to optimise and individualize the treatment of the patient. The system needs a high level security system, because the data that are being processed are highly sensitive. The role and right system is only "one" mechanism to secure the personal data of the patient. An anonymization and pseudonymization tool must be accepted and trusted by end-users. Data observation committees and frequent reports to ethical and legal institutions are mandatory as well as the signed informed consent and the proven ethical committee. In the daily work the physician has to perform multiple tasks and especially administrative and logistical task take a lot of time. To safe time for the physician at the ward the system should perform standard workflows automatically. To achieve this, the system has to be tested in a usability-loop to secure its success and usability. Most important for clinical trials is the informed consent and the ethical and legal guidelines. To keep the physician up to date the system should provide proven informed consents (or templates for	Suitability for the task Suitability for the task Controllability Suitability for the task Suitability for the task Suitability for the task	sending reports (SAE, SUSAR), ask for consultation at reference centres and ask for advice from the trial office regarding the patient and treatment in the trial. The trial protocol should be easily available via the software as well as entering and editing the CRFs. The imaging studies and the tools that support the clinician should work very fast in respect to the large amount of data that are processed. The virtual organisation of ACGT in which the CTMS software is embedded should merge the different task the clinician has to handle on different web databases at one platform (e.g. R based analysis, statistics, literature research, querying a trial, etc.). The objective is to safe time and at the same time to optimise and individualize the treatment of the patient. The system needs a high level security system. The role and right system is only "one" mechanism to secure the personal data of the patient. An anonymization and pseudonymization tool must be accepted and trusted by end-users. To safe time for the physician in his daily work at the ward the system should perform standard workflows automatically. Therefore

it), the actual ethical and legal guidelines (e.g. The declaration of Helsinki in the latest version) and a data observation committee that takes care of the data processing and handling in the trial. The report to legal authorities is often difficult as not all participants of a trial know what to send to which place at which timepoint. The system should contain all relevant information and guide the physician in this task. Support by already provided templates and automatic reporting would be useful.	Suitability for the task Controllability	the system has to be tested in many usability steps to secure its success and especially its usability. To keep the physician up to date the system should provide proven informed consents (or templates for it), the actual ethical and legal guidelines. Not all participants of a trial know which report to legal authorities has to be sent to which place at which timepoint. The system should contain all relevant information and guide the physician in this task. Support by already provided templates and automatic reporting would be useful.
Other comments to critical incidents which already occurred It must be stressed that the work described in the context scenario can only be used exemplarily, as the scenario reflects the work at a university hospital. The work in peripheral hospitals is similar but can differ in parts. Nevertheless it shows the mechanism performed to secure a high class medicine for patients and high security level for patients enrolled in trials and the requirements for software that will enable physicians to run clinico-genomic trials. The work at the ward is very time consuming, especially the work with children with cancer. After all, the improvements in life quality and overall survival during the last years, achieved by a consequent enrolment of patients in the trials and research are impressive. To individualize the treatment for patients and make research results usable for the daily work, the clinicians and researcher,	Suitability for the task	The developed platform must support the user to individualize the treatment for patients and make research results usable for the daily work, the clinicians, researchers, statisticians and ethical, legal and administration persons need. To help the physician in his daily work the software should recognize that a "usual" physician is not aware of all parts that are

statisticians and ethical, legal and administration persons need a platform as developed in the ACGT project. The work of a physician becomes more and more an administrative challenge. It is nearly impossible for a "usual" physician to be aware of all parts that are needed to run a trial and to perform the tasks written in the trial protocol. The development of software that is designed in a close collaboration between end users and software developers can bridge the gap. In a later version even patients should be able to use this software with the role of a patient and the rights to see his individual data.	Suitability for the task	needed to run a trial and to perform the tasks written in the trial protocol. A usable interface should support the user in his daily work and with a close collaboration between end users and software developers the gap can be bridged. In a later version even patients should be able to use this software with the role of a patient and the rights to see his/her individual data.