ACGT Context Scenario (Chairman and Clinician)

Context of Use	Dialogue Principle	System Requirements
Introduction Prof. Graf. has been a paediatrician in a children's oncology clinic for more than 25 years. His tasks include supervising, managing and directing clinical trials which involve children across Europe with malignant tumours, especially with nephroblastoma. He is the trial chairman of the SIOP 2001/GPOH trial dealing with the treatment of children with nephroblastoma. He is interested in applying appropriate software to map, manage and utilize clinical trials for everyday use and to register patient data. The tasks of a trial chairman include: 1. administrative tasks and compliance with legal regulations 2. defining new trials or applying these trials 3. designing trials, i.e. graphically combining single events such as to create a trial design. 4. verifying and validate patient data during trials 5. providing (patient) data input into trials 6. management of patient data, analysis of the data,	Suitability for the task Suitability for the task Self-descriptiveness Controllability	The software should provide the possibility to map clinical trials and to manage and use them in the daily working process. Registration of patient data should be an easy and self-descriptive task. The system should support the trial chairman in performing his administrative tasks and in complying with the legal regulations. It should be easy and efficient to define new trials or to apply them. Later on, the system should help him to design trials and visualize them in graphical form. The verification of patient data in trials should be conducted in a comfortable

publication of trial results and providing advice to participating centres on any questions relating to the trial He may also act as a trial participant. In this case, only task no. 5 will apply. Previously, these trials were manually recorded on paper and stored in a library or database. In the future, however, these trials shall be developed using an appropriate platform and software to support Prof. Graf and all trial participants in their daily working process and to facilitate their work. They should have the possibility to enter data into the system during the daily working process through RDE (Remote Data Entry). The CRFs (Case Report Forms) needed for this purpose should be easily retrievable and editable for the clinician. Sending the completed CRFs to the trial centre should also be an easy task.	Suitability for the task Suitability for the task Suitability for the task Controllability Self-descriptiveness	way. Management and analysis of patient data and publication of trial results should be supported by the system in a comfortable and self-descriptive way. All clinical trials should be handled and stored by the system. All work handled manually should be supported by an appropriate platform in order to enable efficiency and ease of use in the daily working process for all trial participants. Entering data into the system should occur in an efficient and easy way. Managing a patient in a clinical trial should occur through RDE (Remote Data Entry). This includes entry of all data related to the administrative aspects (described in the trial protocol) for patients admitted to a trial. The CRFs should be easy to call and to use. They should display to the clinician which data he will need for the trial. Data entry should be as simple and efficient as possible.
Assumptions Prof. Graf has many years of experience in paediatric oncology		

and haematology and in the diagnosis and treatment of malignant tumours in children and adolescents. This has particularly included brain tumours and kidney tumours (nephroblastoma), and also blood coagulation disorders in young people. He has been a member of an IT working group developing software for children's oncology in Germany for 20 years. The disadvantage of this software has always been its low level of acceptance and the way it was used by the users. Prof. Graf has realized that it is useful to first figure out what you want and what you need and then to get into touch with the software developer, to have him do the programming work and, finally, to reflect on each step in the software. This will give him a clear understanding of what he needs for his work and what he doesn't need. The software is designed to reflect the clinical routines step by step. Based on his experience, he exactly knows what functionalities the developed software must deliver to meet the needs of a clinician. As the chairman and administrator, he is fully responsible for each trial that he created and he is in charge of. He is the only person entitled to assign and distribute the rights to the single trials. 95% of all the patients supervised by Prof. Graf are included in clinical trials.	Suitability for the task Controllability Suitability for the task	The system should reflect clinical routines step by step. The structure of the system should be self-descriptive and guide him through the system without time loss so that he can perform his work efficiently. The system should automatically recognize the role of the user. The administrator is the only person authorized to assign roles and rights for the individual trials. There must be a good information system and interdisciplinary cooperation with all other specialities, hospitals and institutions. Once pseudonymized, the available results should be sent to these institutions automatically. The encryption and decryption should be realized "on-the-fly". All required tools must be uniform in the sense that the clinician should not need

The care of patients occurs in interdisciplinary cooperation with all other specialities, hospitals and institutions. What is required are uniform tools. It should be avoided that the clinician stops to reflect on what he is doing and relies entirely on the software so that in case of a software failure, for example, he would not be able to treat his patients any more. Instead of making the clinician lose his clinical skills, the software should support him such as to enable him to perform his work in an efficient way, as if done manually. The clinician must be able to efficiently perform his task, no matter if the software is working properly or not.	Controllability	to think about the different types of handling. The software should not make the clinician lose his skills but rather support him in performing his work, enabling him to do his work in an efficient way, as if done manually. The clinician must be able to efficiently perform his task, no matter if the software is working properly or not.
Routine activities Prof. Graf has a double role. He is the trial chairman and, at the same time, may also be a trial participant in other trials. As an administrator (trial chairman), he arranges the trial, including all the content data such as graphical elements (templates = Case report form (CRF)), and also determines what rights and roles will be assigned and who will have access to the trial. In addition, he draws up the trial protocol specifying all the details of the trial. The treating physician is the only person who has access to the trial for which he himself has provided the patient-specific information. Drawing up the trial protocol should be an easy task based on templates in the system so that the physician will	Suitability for the task Controllability Self-descriptiveness Conformity with user expectations Suitability for the task	The software should automatically recognize the role of the user when he registers in the system and support the related functionalities. For the administrator, the system should arrange a trial with the entire content data such as graphical elements (templates). This should happen in a comfortable way. All relevant data relating to the patient are stored in the trial protocol. It must be easy to use and understand for any authorized user. The system should support the administrator in defining which rights and roles are assigned and who will have

not need to think and care about the actual state of the art regulations and standards. These tasks should be made available by the system automatically using a regularly updated master protocol. It is very important for Prof. Graf that this feature be supported by the software so that he will be able to work with it efficiently. When creating a trial, the clinician has to focus on questions such as "What will be the objectives of the trial?" "What should the trial be like?" "Which is the content of the trial?" "How will it be organized?". The software should offer him support for this functionality so that he gets a guideline in form of a master protocol and can access already existing or create CRFs. A graphical implementation of the trial would be useful. A trial contains all patient data which are necessary for the treatment process. In this trial, the treating physician gave a full description of the diagnosis of the patient (child). The treatment methods and the appropriate medication are listed as well. Side effects, Severe adverse events (SAEs) and Suspected unexpected severe adverse reactions (SUSARs) caused by the medications are listed by the treating physician. Prof. Graf as a trial participant would use the new software to help him perform his task efficiently and satisfactorily. The reporting should be done automatically. Until today, these data have been mainly noted on paper. Reporting is mainly done by postal, fax, mobile and, exceptional, RDE systems.	Controllability Conformity with user expectations Conformity with user expectations Self-descriptiveness Controllability Suitability for the task Conformity with user expectations	access to the trial. The treating physician is the only person who has access to the trial for which he himself has provided the patient-specific information. Drawing up the trial protocol should be an easy task based on templates in the system so that the physician will not need to think about his tasks as a trial chairman. These tasks should be made available by the system automatically. The software should support both the role of the administrator and the role of the clinician/ physician. It should automatically provide the user with the corresponding rights and roles. The system should offer the possibility to design trials graphically based on specific events. A graphical implementation of the trial would be useful. The trial protocol should be drawn up in a clear and understandable way to meet the requirements of the different user groups. The chairman would like the program to illustrate exactly what he needs for his trial without him needing to think about

The new system will be designed such as to support Prof. Graf in performing his administrative tasks and managing all of the data. Prof. Graf would like the program to visualize exactly what he needs for his trial without much reflection. The functions necessary for defining his trial are important and should be delivered in a concise and understandable form. Once he successfully defined a given trial, he defines who shall be entitled to have access to this trial, and in which form this access shall be granted. As a trial participant, he needs some functionality different from the functionality that he needs as an administrator. The software should recognize already during the registration process which role and which functions the physician will subsequently perform. The administrator can dedicate the role and rights for new users by choosing from a predefined list or manual modifications. Prof. Graf as a trial participant is interested to register patient data in a trial. These patient data include: - age - gender - affliction - earlier infections (previous medical history) - genetic disorders in the family - etc. The completeness of patient data is implicitly essential in order not to distort the assessment and evaluation of the data and to enable the right decisions for further treatments.	Conformity with user expectations Conformity with user expectations Error tolerance Suitability for the task Controllability Self–descriptiveness Conformity with user expectations	details. The functions required for defining his trial are important and should be available in a concise and understandable form. The rights and roles assigned for a specific trial by the administrator should also be defined in a clear and precise way. The software should recognize already during the registration process which role and which functions the physician will subsequently perform The registration of all patient data must be an easy and comfortable task for both the administrator and trial participant. All patient data must be provided in a consistent form so that it can be compared with other trials in other hospitals. To ensure completeness of patient data, a checklist must be available so that no important pieces of information will be forgotten and the right decisions for further treatments can be taken. Validation of data is essential and should be easily performed by the person who enters this data. The trial interface should always be the same so that the physician can quickly

Validation of data is essential and should be easily performed by the data manager. An important feature is the interface of the patient trial. Given the large number of trials, the interface should always be the same in order to enable the physician to find the desired trial quickly and to use the same procedure without needing to think about it. The software must deliver results to the physician in order to reduce his workload in the daily working process. Moreover, the software should be modular and extensible so that Prof. Graf can attach specific modules to the existing software, for example. He builds a clinical trial containing a module of a basic data set, as is the case in other trials. This module is saved in a CRF form that can also be used in other trials. Then there is a module, for example, which sends DICOM (Digital Imaging and COmmunications in Medicine) files or a file for imaging which is used for trial A as well as for trial B and also for trial C. Therefore, the software should be designed in a modular way so that Prof. Graf can select exactly what he needs in the current situation. When Prof. Graf is in a clinical trial he would like to be able to extract any data, e.g. a relevant treatment graph, and then set it on a "scratchboard," to import the questions from the statistic module and collect them on the "queryboard". Questions are created automatically and subsequently sent to	Suitability for the task Controllability Controllability Controllability Self-descriptiveness Controllability Conformity with user expectations Suitability for the task	locate and take the same procedure without any need to think about details. The system should provide the clinician with results for the compliance of his daily work. These results must be clear and understandable for him. The results should be presented in different ways. Moreover, the software should be modular and extensible. All trials should be consistent to enable comparison, better understanding and ease of use. A module which is used for trial A as well as for trial B and also for trial C, for example. The system should support the clinician in handling the different trials. The system should present the treatment graph on the scratchboard. It should support the physician to import the questions from the statisticians and collect them on the

the statisticians for analysis. The result is sent back to the physician who can visualize it in the form of a life table or a descriptive analysis, for example. He decides if he wants to get the visualization in such a form. The visualization tool may also be a "stand-alone" tool that may be used by the statisticians for other purposes as well. The clinician or physician can use this tool to see the results of his registered data and will have a broader information base. In the past, the clinician's only option was to admit data, which was of no use for him because he got all analysis results. For him as a non-statistician it is important to only collect the data and to get the results after the analysis that he is interested in. He wants to work using one workflow only. The results that he wants to see as a life table or as a frequency distribution that can be analysed using the R-analysis tool, or the result is delivered in the form of a bar chart or list. The system should support all different forms of result visualization.	Suitability for the task Suitability for the task Controllability Self-descriptiveness	"queryboard". Questions should be generated automatically generated and subsequently sent to the statisticians for analysis. The result is sent back to the physician who can visualize it in the form of a life table or a descriptive analysis. The visualization tool should be implemented also as a "stand-alone" tool that may be used by the statisticians for other purposes as well. For non-statisticians, it is important to collect only those data that they are interested in. They want to work using one workflow only. Therefore, the system should support all different forms of result visualization. The system should be self-descriptive and controllable.

Special features during the working process The local physician in charge of the patient registers all of his patient data gathered in a trial so that he can either display all his patient data as a whole or can make a selection. The trial chairman of a specific trial can map the trial on the system. The corresponding functionality is described in detail in D2.2. The software has several levels. The lowest level gives descriptions of events. This level can only be executed by an administrator. The next level delivers the definition of the trial. On the third level, the physician can register the data on the level of the individual patient. Each patient has its own workflow, i.e. the clinician will be guided through the trial by the branch of the patient. While the trial consists of several branches, the patient has only one branch. This is the branch that the clinician is guided through. On the third level, in the patient-specific view, the trial chairman, physician or trial doctor can also display the data of the individual patient by clicking on a specific event, for example. The empty CRF will be opened. He can register data, or the CRF has already been completed so that he can again inform himself about the data already admitted. What was the point with this patient? He knows with one click where the patient is and gets an graphical overview about the individual treatment regime for the patient. He can even generate a report that can be used as a doctor's letter specifying the entire therapy of the patient and including all data. This is helpful, as it saves the local doctor a lot of time.	Suitability for the task Controllability Self-descriptiveness Controllability Controllability Controllability	The local physician must have the possibility to display all his patient data as a whole or to make a selection. The trial chairman of a specific trial can map the trial on the system. He must be supported by the system to get an overview of the different existing trials. The different levels must be supported by the system in a self-descriptive way for the clinician as well as for the trial chairman so that they can perform their work in an efficiently and satisfactory manner. For each level, the user needs to know which are the important input data and how to enter them into the system. All available events must be supported and displayed to the physicians / clinicians who are interested in these events. This must be a process that is controllable and understandable for every user. It must be possible to generate a doctor's letter based on the entered data for the patient, specifying his or her particular therapy. Therefore a print button should be available. The patient data should be anonymized before being sent to the database.

It is at the highest level (4) that the data analysis is performed. The data are anonymized before being admitted into the database and before a trial will be chosen.	Suitability for the task	This anonymization should occur automatically and without the need for the physician to intervene manually or to perform any procedure.
The only person entitled to see the data is the person who registered the data, the chairman and persons with dedicated rights to see the data. Furthermore, the local doctor can only display data from his own clinic. In a given trial, all data collected for this trial were available to the trial chairman. The trial chairman instructs the system which participating hospitals and patients will be involved in the trial. When logging in into the system the physician is automatically assigned a specific role, whereas in another trial he may have a different role and other rights. Furthermore, the local doctor can only display data from his own clinic. In a given trial, all data collected for this trial were available to the trial chairman. The trial chairman is administrator only for those trials that are managed by himself.	Suitability for the task Controllability Controllability	The anonymized data can be found in a mirror database containing all the data of the trial database in an anonymized form. The system must make sure that data is read and edited only by the user who is responsible for the patient data. The local doctor can only display data from his own clinic. The trial chairman is the only person entitled to display the whole collection of data in a specific trial. The trial chairman instructs the system which participating hospitals and patients are involved in the trial. When logging in into the system, the physician is automatically assigned a specific role, whereas in another trial the same doctor may have a different role and as a consequence different rights. These facilities must be enabled by the system to perform clinical trials efficiently, effectively and safely.

Organizational conditions A doctor in a clinical trial wants to use the software to be guided through the trial. This has to happen intuitively and, if possible, self-descriptively. The clinical trial should offer a visualization of the results. (Deliverable D2.2) The software should enable all administrative tasks, such as automatic reporting of SAEs or SUSARs to the European database EMEA.	Controllability Self-descriptiveness Suitability for the task Suitability for the task	Going through a trial should be a self-descriptive process involving guided information for the clinician / physician and the trial chairman. The system should provide the possibility to visualize results, particularly for the statisticians. The software should enable all administrative tasks, such as automatic reporting of SAEs or SUSARs to the European database EMEA.
Other comments to critical incidents which already occurred In a later version, it should be possible that the patient work with the software, too. (workflow/branch)	Suitability for the task	In a later version, the system should be extendable so that the patient will be able to work with the software in an effective and satisfactory way.