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Evaluating the MACRO solution

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Abstract: This paper describes the evaluation approach of the MACRO project. This approach is based on earlier work in the European 3rd Framework Programme (AIM). We describe how user requirements and expectations play a role in the design of the various assessment studies in MACRO.

1. Introduction

Clinical research is facing major changes due to the need for a more effective and rapid evaluation of new therapeutic strategies and the need to perform clinical research within the framework of good clinical practice. Extensive and comprehensive research can only be accomplished through multidisciplinary, multinational efforts of research groups.

To support this whole research process, a clinical trial telematics system supporting the definition of studies (a formal description of the acts in a protocol and their validations, including a description of the data to be collected), remote data entry and communication will be developed by the MACRO (Multimedia Application for Clinical Research in Oncology) project. The expectation is that such a system will shorten the time to complete studies while simultaneously improving the quality of the collected data.
This paper describes mainly the evaluation approach of the MACRO solution.

2. What is MACRO

MACRO is a 3-year Research and Technology Development project funded by DG-XIII of the European Commission under the Health care sector of the Telematics Application Programme (contract HC 1030). The project team consists of the EORTC (European Organisation for Research and Treatment of Cancer) which is the co-ordinator of the project, industrial partners (ISL, PCR), and a usergroup.

2.1 What are the objectives of MACRO

MACRO will develop a unified system for remote entry of data into clinical studies. Oncology has been chosen as the initial application domain but it is envisioned that the results from MACRO will be exploited in the future in fields other than oncology. MACRO is intended to be used by research organisations, individual physicians and the pharmaceutical industry.

2.2 What are the products envisioned

The so called MACRO solution will provide the means to define a clinical trial including the data entry screens (electronic case report forms) and a way to distribute these study definitions over the network to the remote sites. At a remote site, MACRO will provide the means to enter data and validate data (e.g. dosages, biochemical data, dates and invalid ranges), to make queries and corrections to the collected data, to transmit the results to the central office, and to receive feedback. For the remote data entry two

solutions are foreseen: one using the WWW, the other as a stand-alone Windows® application. MACRO will define a standard for the exchange of clinical research data so that it will be possible to interface other systems with the products developed in the MACRO project. Furthermore, the system will support the clinicians in scheduling the tasks in the protocol of the trial as well as in scheduling the patient visits.

2.3 The development process

The MACRO solution will be firmly based on user requirements (URs) provided by various types of users that may interact with the system to ensure widespread acceptance of the outcome. The User Requirements phase feeds into the Technical Specifications which forms the basis of the Development. During subsequent assessment phases users will be exposed to the products. The results will be fed back to the developers to adapt the products to meet the URs and user wishes as much as possible.

3. Evaluation Methodology

To ensure that the developed software meets as good as possible the user requirements and expectations, a staged approach in the evaluation is proposed. This approach is largely based on work performed in the KAVAS-2 and ISAR projects and the ATIM accompanying measure of the 3rd framework program [1, 2, 3]. The selected approach can be considered as a constructive technology assessment approach in which the assessment process and the development process interact with each other to ensure a viable end product.

3.1 Mapping of terminology

The terminology as used in the KAVAS-2 and ISAR projects and in the ATIM-book differs from the terminology currently in use in the Telematics Application Programme (TAP) and its projects. The table below specifies how the various terms map onto each other. It seems that the terms used in KAVAS/ISAR are describing the aspects or scope of the assessments, while for TAP/MACRO the terms indicate a phase in the development and implementation process.

Table 1. Mapping of terminology used in KAVAS-ISAR and MACRO

KAVAS - ISAR	TAP - MACRO
Preliminary Exploration	User Requirements and Technical Specification
Validity	Development
Functionality	Verification
Impact	Demonstration

So the assessment of the *User Requirements and Technical Specification* should indicate whether they really express the user needs and user expectations regarding the product that is going to be developed.

After *development*, it is assessed whether a valid implementation of the URs and technical specification is achieved (is the system rightly implemented). Besides a technical assessment, users have to determine whether the system is *potentially* fit for usage in a clinical setting, a testing.

When the validity is established, the system is put into *verification* in a restricted setting during which it is assessed whether it functions according to the user's expectations (is the right system implemented), β testing)

Finally, when the system is used on a larger scale in *the demonstration phase*, one will assess the impact the system has on performing clinical trials.

4. User requirements and user expectations

The URs and the technical specifications describe the products that are to be developed and - to a certain extent - the user expectations. The URs were established by questionnaires and interviewing different direct user groups of the MACRO solution. During a joint session with all users in MACRO, a walk-through of the URs was made. The purpose of this meeting was to identify unclear or contradictory URs.

The URs for the MACRO solution largely specify which functions the system has to perform and to a lesser extent requirements about the usability, user friendliness and how it will integrate in the clinical working process. To secure that also the user expectations on what the MACRO solution will bring are taken into account, several (interested) users are being interviewed. The issues at stake during these discussions are not the functionalities of the MACRO solution, but the impact the MACRO solution may have on the clinical working process, the organisation (of the department), the economics of participation in a study and the social relations in a department. We are using the list proposed by Jørgensen as a guideline during these interviews [4].

These user expectations play a crucial role as they will to a large extent determine whether the users will use the MACRO solution in their working environment.

5. Evaluation approach at the end of development

Each industrial partner in the MACRO project that develops software performs its own quality management[1]. This implies that the quality of the product in terms of its correct implementation of the *technical specifications* is already documented before users are exposed to the product in a laboratory setting. During the laboratory test, at least some of the users involved in the UR specification, should assess the extent to which the *URs* are implemented and the extent to which the users expect to be able to use the product in their working environment.

5.1 Use of scenario

Rather than taking an approach based on the functions that the system supports, we will take a user/task oriented approach as this will be the most realistic way to assess the initial user acceptance of the system.

Our approach is that at least one representative of each relevant type of user (e.g. study designer, clinician, data manager) will exercise the system according to a given scenario. This scenario describes the tasks the user has to perform, e.g. make a study definition for the enclosed trial protocol, register a patient in a trial, enter the data of a patient's visit. In this scenario that tasks will be such that as many as possible URs are tested. Evaluation questions will be embedded in the scenario. This will support the recording of user comments and assessments while the scenario is executed. The scenario will be supplemented with error/bug/comment forms that will provide room for identification of problems and for writing comments.

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[1] One of the industrial partners has a ISO9000 certification, the other industrial partner is working according to the ISO9000 standards.

5.2 Usage of user requirements

To support the development of these scenarios each user requirement was analysed with respect to the role it could play in the design of the assessment study. The three major categories discerned are:

Scenario oriented. This type of UR specifies a task to be performed, e.g. modify an existing study definition.

Protocol oriented. This type of UR specifies criteria the trial protocol has to meet as to be able to test the UR. E.g. the protocol should define tests to validate the entered data.

Test case oriented. These URs describe situations that are related to the type of case to be entered in the system. For example, one of the cases should show adverse effects of the treatment such that the functionality of the system to propose dose changes can be tested.

Based on this analysis, a phase II and a phase III EORTC clinical trial protocol were selected for inclusion in the scenario. The phase II protocol aims to detect any anti-tumour activity of the new therapy while phase III measures efficacy relative to standard therapy. As cases have been already collected for these trials, these data can be used to guide the development of the test cases.

6. Evaluation approach for later phases

6.1 Verification and demonstration

The focus in the verification phase is on the usability of the products in a working environment. This entails, again, that various types of users should make an assessment of the tools, each with their own set of requirements in mind. For the verification, the tools should be used for real tasks; i.e., real clinical trials rather than some kind of artificial scenario. The objective of this phase is to show that the tools work in some chosen environments rather than in a large variety of environments, even though the latter is the final goal. A small number of interested user sites will be selected for this purpose. The various software components will be used in one or two clinical trials.

The last phase of the MACRO project intends to demonstrate the value of the MACRO solution in an objective way. Therefore, one should follow an evaluation design in which the impact of the products on the structure, process and outcome of clinical trials can be measured.

6.2 Success criteria

A number of specific success indicators have been identified that are considered to measure the impact the MACRO solutions may have in the long term on performing clinical trials. Being a member of the ACTION (Applications Cluster for Telematics in Oncology) cluster, MACRO followed the scheme as defined by the co-ordination project HORIZON. In the four project related categories, the following indicators have been defined:

Time	speed of design and implementation of trials
Resource	reduction of costs and effort of taking part in the trial
Quality	improvement in quality of data collected
Quantity/ Utilisation	increase in numbers of people entered into trials

6.3 Study design

The Randomised Controlled Trial is not feasible for the demonstration phase of MACRO due to limited resources and duration of the project. Therefore, a set-up in which the remote data entry solutions are evaluated by making measurements before and after the software is installed in three different user groups (WWW users, Window-solution users and the control group) seems to be most feasible.

The study should include measurements that will enable the determination of the circumstances under which the two solutions are most effective.

The design will incorporate measures tailored to the user expectations and the success indicators.

7. Discussion and Conclusion

To assure that a viable product is being developed, it is necessary that various potential user groups are continuously involved in the development and evaluation process.

MACRO has finalised the user requirements phase and is currently developing the various components of the MACRO solution. In parallel with these developments, the assessment plans are being detailed. Early 1997, the user acceptance test of the study definition server will take place.

During the analysis of the URs for information that could guide the development of the assessment plans, it became clear that a number of them were too vague or too general that they cannot be evaluated. An example is UR010: *The system will promote conformance to applicable regulatory requirements and Good Clinical Practice.* Such a UR requires much more detail before it can be assessed whether the system really promotes Good Clinical Practice. This analysis of URs with a focus on the evaluation can also be seen as a kind of assessment of the URs. From this analysis additional requirements may result. The requirements with respect to average response times can only be assessed when the system performs time-stamping and/or event logging, even when it is not a requirement for the final system from the users point of view.

Although the KAVAS evaluation methodology was initially developed for the assessment of decision support systems, the ISAR project showed that it could be modified to cope with system integration. In the MACRO project we map the KAVAS methodology on the product life cycle of a telematics applications. The future will show how usable the KAVAS methodology is for assessment of systems like the one developed in MACRO.

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