Exploring Complexity in Health: An Interdisciplinary Systems Approach
A. Hoerbst et al. (Eds.)

doi:10.3233/978-1-61499-678-1-292

Requirements on Clinical Trial Management Systems for Academic Site Management Organizations

Martin SCHÖBEL[a,1], Sebastian STÄUBERT[a,b], Matthias LÖBE[a], Kirsti MEINEL[b] and Alfred WINTER[a]
[a] *Institute for Medical Informatics, Statistics and Epidemiology, Leipzig University*
[b] *Center for Clinical Trials Leipzig (ZKSL), Leipzig University*

Abstract. As a part of the introduction of a Clinical Trial Management System (CTMS) for an Academic Site Management Organization (SMO) we had to determine the requirements such a system has to meet. By performing extensive Requirements Engineering, we aimed at raising the success of the future system and the user satisfaction. Investigations revealed the existence of TORE (Task and Object-oriented Requirements Engineering), a task-driven approach for determining requirements on user interface- and information-intensive systems. In this paper, we present an adoption of this method for our purposes, resulting in a reasonable list of requirements for CTMS acquisition.

Keywords. Secondary Use, clinical trials, site management, billing, CTMS

1. Introduction

The German Federal Ministry of Education and Research has founded eleven academic centers to foster non-commercial clinical trials and improve recruitment rates among patients [1]. Clinical trials are a very important part of clinical research to prove the medical efficacy of a new therapy or drug. Many hospitals in Germany are cooperating with so called Site Management Organizations (SMO), acting as scientific partners and service providers for physicians and scientists. The support in performing clinical trials typically includes trial design and preparation, project, data and safety management, clinical monitoring, patient recruitment and statistical analyses [2-4].

Due to the high number of clinical trials being conducted it is hard for a university hospital to keep track of which studies are performed in its departments, who is the sponsor, the local PI and so on. In case there is no system for managing clinical trials at all, study-related metadata and documents are very likely stored in folder structures. This solution bears the risk of being overloaded with documents and extensive searching for the documents of interest.

Whilst computer based management tools are already a natural part of the daily routine in the clinical environment, there is little spread of applications supporting the management of clinical trials. There are few commercial Clinical Trial Management

[1] Corresponding Author: Martin Schöbel, Institute for Medical Informatics, Statistics and Epidemiology, Härtelstraße 16-18, 04107 Leipzig; E-mail: martin.schoebel@imise.uni-leipzig.de

Systems (CTMS) supporting employees in SMOs, but investigations revealed hospitals are more likely to develop their own solution or try to use standard software [5]. That would reasonably suggest that each team of developers in hospitals have to determine the requirements on their system in advance because up to now there are no well documented requirements CTMS have to meet, as well as no precise definition what a CTMS is. Relating to the last point we are primarily focusing on functional requirements. Non-functional requirements, as for instance performance, portability and usability do not describe and define the purpose of a system.

When funding had begun in the year 2007, the Clinical Trial Center in Leipzig started activities to document and manage clinical trials electronically. At this point of time the supply of CTMS on the market was very low. This circumstances lead to the decision to develop a solution by ourselves. After development and introduction were finished, the CTMS was used several years. In the course of time, the requirements increased and the user satisfaction decreased. Due to reduced resources and growing claims, we decided to stop in-house development. Because four years had passed by, we did investigations on market again, discovering that now several solutions were available. Over time the users' needs had changed, wherefore requirements had to be determined anew.

2. Objectives

Our goal is to provide a reasonable list of requirements CTMS have to meet based on experiences and a formal analysis. That should serve as a basis for future developments of CTMS in Academic Site Management Organizations. Once determined the requirements will allow a general definition of the characteristics of a CTMS.

3. Method

As we planned to introduce the next generation of a CTMS in the Center for Clinical Trials in Leipzig we decided not to develop a system by ourselves again. Instead we were looking for an existing solution, academic, commercial or open-source. Before doing a market survey on existing products, we had to determine the requirements the CTMS has to meet. To assure success and satisfaction of our users, we concluded to perform an extensive requirements analysis.

There are several methods of Requirements Engineering (RE) for various areas of application, e.g. GRAnD [6], TORE [7] and KAOS [8]. While GRAnD (Goal-oriented Requirement Analysis for Data Warehouses) and KAOS (Knowledge Acquisition in autOmated Specification) are goal-oriented approaches on RE, TORE (Task- and Object-oriented Requirements Engineering) is a task-driven approach on requirements analysis for user interface and information-intensive systems [7, 9]. This is also true for a CTMS. Another point is that TORE focuses on tasks and needs and suggests involving users from the very beginning. Involving users in software development has been investigated in [10], with the result it increases system success and user satisfaction. Therefore, we decided to use TORE. This method was developed at the Fraunhofer Institute for Experimental Software Engineering in Kaiserslautern, Germany. As written by Adam et al., TORE "does not prescribe a concrete RE process; rather it guides and supports requirements engineers logically. In particular, TORE supports completeness as it

enables stakeholders to be aware of important decisions they have to make in order to avoid developers making these decisions unconsciously" [9]. Furthermore "in the TORE framework, the typical (and probably the most important) decisions (called 'decision points') to be made during a RE process are arranged on four different levels of abstraction." [9]

The very first step was to identify the tasks of employees in our Site Management Organization. For that purpose, we did several interviews with all users who would use the new the system. The first set of questions were related to the user's daily routine in documenting and managing clinical trials. Primarily we wanted to know: a) When is data documented? b) Which data is documented? c) Where is data documented? d) How is data documented? e) Who documents data?

All the answers on this questions gave us an insight and understanding of the activities of the users when it comes to documentation of clinical trials. Furthermore, we learned about data types and who is allowed to write and read which data. The next step was the analysis of documentation and management as it is. In another interview we had a demonstration of tools that were used to create study files with all their relevant information. Thereupon we immediately discussed to-be activities as an improvement of the as-is activities. As part of that, documenting the system responsibilities was the next step. They describe features the new system should provide to support the activities of all users. As suggested by TORE, we collected the system responsibilities according to the different roles of the users.

Due to the reason, TORE "does not prescribe a concrete RE process" [9] and we were not planning to develop a whole solution, we suggested to stop at this point. Further decisions to be made in the RE process according to TORE are related to structural and architectural issues. Because we decided to introduce an existing solution and were aware of a low supply of CTMS, functional requirements were most significant. Up to here we learned a lot about the users' activities and tasks. Furthermore, we experienced the different roles of the users that simultaneously lead to requirements on rights of the different roles.

4. Results

Several interviews and discussions resulted in a list of features a CTMS for our purposes should include. Being aware that it will be hard to find a solution that meets all the requirements, we extracted the most important functions and categorized them. Clearly, functional features the system should support are the most important aspects, but nonetheless financial, regulative and temporally aspects as well as the effort for maintenance must be taken into account.

As we did a market survey on existing solutions we came up with three categories. The first category included successful academic solutions by other clinical trial centers or university hospitals. The second category had the focus on commercial products and the third group included vendor specific solutions, like SAP. For the readers' interest, we took a look at commercial products like Allegro by Forte Research Systems, Microsofts Dynamics CRM and Clinical Conductor by Bio-Optronics. After thorough investigations and discussions, we had one favorite for each category. The first one is the *CTC-A Study Management Tool* (CTC-A), a successful academic solution by the Clinical Trial Center in Aachen. The second one is the commercial product *Clinical Conductor*

by Bio-Optronics. The last one is the *Ulm Trial Management System* (UTMS), a SAP-integrated system developed by the university hospital in Ulm.

In the following table, functional- and non-functional requirements on CTMS are presented. For exemplification, we show the three solutions and how they meet the determined requirements.

Table 1. Evaluation of three CTMS on basis of determined *functional* requirements. The following abbreviations were used to score the availability of a feature: n/a = no information, – – = missing, – = partially supported, + = almost completely supported, ++ = completely supported

Feature	Clinical Conductor	CTC-A	UTMS
Highest Priority			
Study Management	++	++	++
Department Management	++	++	++
Personal contact data	+	+	+
Cost calculation	++	++	– –
Visit- and procedure management	+	+	– –
Proband documentation	+	+	–
Right and role management	+	+	+
Higher Priority			
Document management	+	+	+
Contract management	+	+	+
Accounting and financial overview	++	++	+
High Priority			
Inclusion- and exclusion criteria	–	–	– –
Feasibilities	+	+	– –
Time tracking and effort documentation	– –	+	– –
Audit trail	n/a	+	n/a
∅	+	+	–

Taking a look at Table 1 reveals the differences in the set of provided functions of our three favorites. As was said, when making a decision about a CTMS to be introduced, financial, regulative and temporally aspects, as well as the effort for maintenance must be taken into account. But since we do not want to expose financial issues at this point, we only list regulative requirements in the following.

Table 2. Evaluation of three CTMS on basis of determined *non-functional* requirements. The following abbreviations were used to score the availability of a feature: – = not satisfying, + = satisfying

Requirement	Clinical Conductor	CTC-A	UTMS
Protection of patient data	–	+	+
Protection of research findings	–	+	+
Data security	+	+	+
Protection of account data	–	+	+

It should be noted that Clinical Conductor assures to cover the requirements listed in Table 2. But being a Cloud-based service resident outside the European Union, we had to rate the non-functional requirements negative, due to general data protection concerns.

After further discussions and considerations, we decided in the favor of the CTC-A Study Management Tool by the Clinical Trial Center in Aachen. Analyzing the matches of our requirements compared to the features provided by the solutions, Clinical Conductor and the CTC-A are highly promising. On the other hand, regulative aspects of Clinical Conductor are problematic, see Table 2.

When looking at the resources and the effort for maintenance the UTMS would have been an attractive solution. Nevertheless, financial aspects had a meaningful contribution to the decision, resulting in the decision for the CTC-A.

5. Conclusion

As we planned to introduce a CTMS in our facility, we had to determine the requirements in advance. Dealing with different methods of Requirements Engineering, we discovered TORE, a task-driven approach on requirements analysis for user interface and information-intensive systems. We decided to apply a task-driven method, because we aimed to raise the success of the system and the user satisfaction.

Guiding and supporting logically, the application of TORE worked well. Because we were not developing a solution, but rather only wanted to determine functions that should support our users, we stopped after we had finished the Task-Level and Domain-Level of the model provided by TORE.

When compiling requirements, we involved the users from the very beginning. We had a lot of conversations and discussions to understand the tasks and activities of every role, but the meetings were always oriented towards the decision types provided by TORE. The result is a reasonable list of functional requirements based on our analysis and experience. Furthermore, on the basis of this list we were able to make a decision about a CTMS to introduce in the SMO Leipzig.

References

[1] Bundesministerium für Bildung und Forschung (BMBF). Klinische Studienzentren: Bundesministerium für Bildung und Forschung (BMBF); 2006 [cited 2016 Mar 11]. Available from: URL: http://www.gesundheitsforschung-bmbf.de/de/4302.php.

[2] Luntz SP, Gorbauch T, Schröder B, Seibert-Grafe M. Aufgaben der Koordinierungszentren für Klinische Studien. Bundesgesundheitsbl. 2009; 52(4): 444 – 50.

[3] Luntz S, Schröder B. Planung und Organisation klinischer Studien mit Medizinprodukten. In: Gassner UM, editor. Klinische Bewertung von Medizinprodukten. Aachen: Shaker; 2009. p. 76–88 (Augsburger Schriften zum Arzneimittel- und Medizinprodukterecht; vol. 9).

[4] Ohmann C, Kuchinke W, Canham S, Lauritsen J, Salas N, Schade-Brittinger C et al. Standard requirements for GCP-compliant data management in multinational clinical trials. Trials 2011; 12:85.

[5] Schwanke J, Rienhoff O, Schulze TG, Nussbeck SY. Suitability of Customer Relationship Management Systems for the Management of Study Participants in Biomedical Research. Methods Inf. Med. 2013; 52(4):340 – 50

[6] Giorgini P, Rizzi S, Garzetti M. GRAnD: A goal-oriented approach to requirement analysis in data warehouses, Decision Support Systems, Volume 45, Issue 1, April 2008, Pages 4-21.

[7] Paech B, Koehler K. Task-Driven Requirements in Object-oriented Development. Fraunhofer Institute for Experimental Software Engineering, Kaiserslautern, Germany, 2009.

[8] Lapouchnian A. Goal-Oriented Requirements Engineering: An Overview of the Current Research. Depth Report, University of Toronto, 2005.

[9] Adam S, Riegel N, Doerr J. Tore. A framework for systematic requirements development in information systems. Requirements Engineering Magazine. Online journal 2014 [cited 2016 Feb 5]; (4). Available from: URL: http://re-magazine.ireb.org/issues/2014-4-steady-flight/tore/.

[10] Abelein U, Sharp H, Paech B. Does Involving Users in Software Development Really Influences System Success? IEEE Software, 2013; 30(6):17--23, Nov.-Dec.