Clinical Trial Management Systems: Business Success with Modern Solutions

A trend study by Pierre Audoin Consultants (PAC) – market analysis and strategy consulting specialists

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1. INTRODUCTION

Expiring patents, greater competition and price pressure along with high regulatory requirements through legislation describe the current situation in the pharmaceutical industry.

Pharmaceutical companies are confronted with the challenge of filling their R&D pipelines in order to bring new medicines and active ingredients to the market in short cycles. At the same time, it is necessary to optimize all processes – from development to production of new medicines – in order to reduce costs and risks.

Clinical trial management assumes a key role in the development of new products. This involves meeting the requirements for the successful approval of new medicines. Despite this key role, the processes in this area are often not clearly structured. A more efficient and particularly more transparent design of the process would not only reduce costs, but also minimize the risks that arise in the individual courses of the study projects, which are sometimes difficult to forecast.

Of central significance for the optimization of the process in clinical trial management are suitable software solutions customized to meet the needs of life science companies.

In this study PAC describes the challenges and also the software solutions currently in use in clinical trial management. The findings are based on interviews with experts, which PAC conducted on behalf of BSI Business Systems Integration AG, Switzerland between October and November 2011 with pharmaceutical companies and clinical research organizations (CROs) in Europe.

The trend analysis will show, in particular, which specific added value special software solutions, so-called Clinical Trial Management Systems (CTMS), can provide in clinical trial management. Finally, also listed are the success factors that must be met so that CTMS solutions also optimally support the processes in clinical trial management, not just in theory, but also in the real course of the study.
2. THE SIX GREATEST CHALLENGES IN CLINICAL TRIAL MANAGEMENT

Characteristic for clinical trial management is the multitude of factors that influence the individual project processes and which are often unpredictable.

“Experience shows that each study is different and that a study cannot really be planned. It is guaranteed to turn out differently than anticipated and usually at the point where it is not expected, and this applies from the beginning to the end of a study.”

Head of a clinical research facility in Germany

As mentioned above, it is essential for pharmaceutical companies to reduce the time-to-market for new medicines and active ingredients. Therefore, when it comes to clinical trial management, is it important to accelerate processes in order to shorten the time needed to complete a study? The answer is no. It became clear in the expert discussions conducted by PAC that the challenges in clinical study management lay in other areas.

The following six challenges crystallized in the course of the interviews:

1. Obtaining governmental approvals

This issue was one of the most often named challenges among those interviewed, but was described as an *entirely normal aggravation in everyday business*.
2. Selection and management of sites

- The search for suitable sites: both nationally and internationally
- Low motivation among the investigators – despite remuneration
- Poor quality of the work at the sites (e.g. deadlines are not met or problems with data entry)

3. Project management

“Whether the project runs well or poorly essentially depends on the competence of the project manager in charge. There are neither guidelines nor a sensible, formulated work organization. While everyone knows what he has to do, errors naturally continually occur or, in the heat of the battle, things are forgotten and then not taken care of.”

Head of project management for clinical studies at a clinical research facility

- Lacking tools for the systematic planning of the required project steps
- Lacking tools for better planning and documentation of the visits to the investigators
- An additional demand is to “have the proper resources at hand when they are needed.”

4. Project performance and project controlling

“One major challenge is that you have to be in the position to be able to give instant status information about a variety of projects that are being managed and conducted at the same time.”

IT Head at a clinical research facility in Germany

- Lacking transparency when it comes to the current status at any given time in the course of the project
- Lacking cost control during the project
- Lack of transparency about project risks: How can medical, organizational or commercial vulnerabilities be identified early on, such
as too few study participants at a location or an accumulation of adverse events or factors, which could lead to exceeding the budgeted costs?

5. Time management

Clinical Research Organizations (CROs), in particular, mentioned that fitting unforeseen delays into the overall scheduling of studies is among their greatest challenges. Particularly for complex and multinational studies for which stringent planning is indispensable, such as for a project in which hundreds of sites are involved, which should all be initiated as synchronistically as possible. For smaller national studies, time management is not quite as high a priority. For pharmaceutical companies time management is logically also a central component of project management. However, this topic was viewed as more important among the CROs, because in their role as service providers, they must be able to meet customer deadlines and generally can only send bills when set work steps have been completed.

6. Reporting

“Reporting is a huge topic for us. Not just because we need it for our internal budgetary control, but also because our sponsors want to be informed comprehensively and quickly. The problem is also that each study is different and each one has different reporting requirements, so that we have to come up with something new each time.”

IT Head at a clinical research facility
7. Management of data and documents

- Mainly applies to large and complex studies
- Management of various data formats, document types and versions
- Different data protection regulation requirements

Among the pharmaceutical companies, the emphasis of the challenges mentioned centered on reporting and project controlling. Among the clinical research organizations, the main challenges, regardless of whether they were large or small CROs, lie in the area of project management, as well as in reporting.
3. STATUS QUO: WHICH SOFTWARE SOLUTIONS ARE USED TODAY TO MEET THESE CHALLENGES?

Discussions with experts showed that the spectrum of software solutions currently being used in clinical study management is very broad. The following software solutions were named for the individual challenges in clinical study management:

1. Selection and management of sites

No particular software is generally used here. Contact data for sites and other services provided are managed on Excel lists or databases. The corresponding contracts and documents are managed in paper form or placed in server directories. The selection of suitable clinical trial centers generally depends on the experience and competence of the project manager in charge.

2. Project and time management

Particularly smaller CROs and pharmaceutical companies mentioned that they are entirely able to plan and manage study projects using Excel and Gantt charts. Resources, such as company employees or external service providers, are entered in Excel, and even the meeting of deadlines takes place in Excel or is followed using Gantt charts. Some interview partners from larger CROs said that while MS Project is available within the company for project planning, it is hardly used.

Among large pharmaceutical companies and CROs, both custom-developed software solutions and dedicated software solutions, i.e. clinical trial management systems (CTMS), are used. These generally support all processes, from planning to execution and completion of the study. No small company among the smaller CROs that provided information has used a CTMS yet.

Large CROs and pharmaceutical companies often use special systems for the planning, conducting and documentation of the visits to the investigators.
(monitor visits), particularly CTMS. Among smaller CROs, the planning of the monitor visits is often managed with the classic MS Office products (Excel, Word & Outlook). The documentation of the monitor visits is often made in Word and sometimes even on paper!

3. Project performance, project controlling and reporting

Status information (such as the number of patients entered or questionnaires completed), especially among smaller companies, is often requested over the telephone at the sites and then entered in Excel lists. The monitoring of deadlines and costs in smaller companies is usually managed in Excel.

Larger CROs or pharmaceutical companies sometimes also use Excel for this or have developed custom software solutions. But those companies which, in the discussion with experts, were revealed to place great importance upon a more comprehensive project controlling as well as detailed tracking or project performance, tend to use dedicated CTMS solutions for this.

4. Management of data and documents

For the management of patient data, pharmaceutical companies tend to use commercially available electronic data capture systems (EDC). However, there are also cases where CROs have developed their own EDC solutions and their sponsors are given appropriate access to them. Sometimes these EDC solutions are also upgraded with the trial management functionalities, i.e. with CTMS solutions.

In addition to the patient data, for the entering and management of which special legal requirements must also be applied, there are still other data or documents that are created in the course of studies and which must be managed, such as contracts with the sites, the investigators' CVs or clinical trial protocols. Larger CROs and pharmaceutical companies use document management solutions for this or also comprehensive CTMS. Smaller CROs, however, do not work with dedicated software solutions, but with individual storage rules on their servers, for example.
Summary

Many interviewees saw considerable optimization potential in regard to the specific requirements in clinical trial management and mentioned that certainly a process or two in clinical trial management could be better supported than is currently the case with Excel, project management software or self-developed software solutions.

However, among many of those interviewed, it was not quite clear which additional and concrete benefits modern CTMS solutions could offer. Also those companies that are already using CTMS solutions often do not realize the full potential of such systems. For example, CTMS solutions may be used for various areas, but not as a comprehensive tool for all areas of study planning and study conduct.

However, particularly smaller CROs said that the use of a special application for clinical trial management only makes sense as of certain company size. Midsized pharmaceutical companies, in particular, are also rather skeptical about new solutions.

“We work exclusively with Excel, Word and Access, which many other pharmaceutical companies our size do as well, by the way. In the pharmaceutical industry new things are often associated with great uncertainty. The preference here is for something that is proven.”

*Head of clinical studies at a midsized pharmaceutical company*

Therefore, the specific added value that comprehensive CTMS solutions can provide for clinical trial management will be listed in the following section.
4. ADDED VALUE OF CLINICAL TRIAL MANAGEMENT SYSTEMS (CTMS)

The use of software solutions that comprehensively support the planning and conducting of clinical studies is not yet very widespread. While large pharmaceutical companies and larger CROs by all means use clinical trial management systems in some areas, the use of CTMS solutions is still rare, especially among small to midsized companies.

Therefore, PAC lists the specific added value that CTMS solutions can provide in clinical trial management in the following. And that specifically in differentiation to Excel or pure project management and document management systems. The figure below illustrates the areas that a CTMS should cover from PAC’s perspective.

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**Fig. 1:** Issues that a clinical trial management system should cover
4.1. Trial planning and project management

Although many, particularly smaller CROs, mentioned in the expert interviews that by using Excel and Gantt charts they are entirely able to plan and manage projects, most of them did see improvement potential when it came to the specific requirements in project planning and project management in clinical trial management.

For example, a CTMS solution can also significantly support the corresponding processes in the preliminary phase to the conducting of clinical studies. These processes include the obtaining of governmental approvals (e.g. from BfArM\(^1\), PEI\(^2\), the Ethics Committee in Germany), the conception of trial designs, the creation and finalization of the clinical trial protocol, the planning of the study logistics and the deployment of the study team.

With the help of a CTMS the respective necessary work steps can be placed in a central system with corresponding tasks that must be completed by a set time and appropriately documented.

This makes it possible to minimize the risk within clinical trials, for example, that employees involve project staff in a project with different qualifications, or when project staff drop out because of illness or leaving the company. In this way, the project management can be “depersonalized”.

Documents that are created during the planning phase can also be stored transparently in a CTMS. In this way, users of CTMS solutions can quickly see which documents have been submitted for which studies and which authorities and when. This is an issue that was brought up repeatedly in the expert interviews. The entire communication during the course of a project, e.g. with the sites, laboratories (and sponsors) can also be centrally documented in a single system, eliminating the need for tedious research.

4.2. Monitoring and reporting

A CTMS can also potentially help to more efficiently plan monitor visits. Appointments can be initiated directly through the CTMS, in which both the contract information and also calendar functionalities are placed. For

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\(^1\) Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)
\(^2\) Paul-Ehrlich-Institut (PEI)
example, the visits can be planned according to the status progress or according to the open issues at the individual sites.

A CTMS can also more efficiently design the conducting of the monitor visits through the placing of individual interview guidelines, such as in the form of guided entry screens (keyword: process wizard), which a monitor can call up according to the type of visit (e.g. whether it is an initial visit or a monitor visit). This method ensures that no issues that are to be inquired about are forgotten.

In the same way, text modules can be stored that the monitor can compose and print out according to the arisen issue. At the same time, he can also plan follow-up appointments and tasks. A CTMS also supports multilingualism, which can be necessary for multinational projects. This means that interview guidelines and text modules for the following up of issues can be stored in multiple languages.

A detailed, timely documentation of the monitor visits in a central CTMS enables the trial management – in contrast to separate documentation in Word or Excel – to more quickly evaluate progress at the sites. For the monitors a CTMS makes it possible to document the source data verification (SDV) or the central entering of issue tracking so that the respective data can then be more easily evaluated and better monitored.

"Our monitors would certainly have a good tool in their hands with a CTMS, with which they could better document and trace their visits."

Owner of a clinical research institute

The supply of medicines can also be entered and managed in a CTMS. This means that it is not necessary to make entries in a separate tool and the supply can also be appropriately evaluated.

Particularly in the area of reporting, most of the experts interviewed saw potential for improvement. Depending on the complexity of the study, it is relatively time-consuming to put together status reports. Especially if the status report must be delivered ad hoc, and in the worst case, on a Friday evening.
A CTMS facilitates the **creation of status reports**, because the project progress can be documented in a central system at the individual sites according to defined work steps and milestones. **Easy and flexible configuration of reports**, at best without support from the IT department, enables the creation of status reports at the "press of a button". An essential advantage of CTMS solutions is that the data can be called up in **real time throughout the course of the study** – if the corresponding data has also been entered in a timely manner by the monitors.

Status reports with **individually set characteristic parameters** (e.g. the number of previously entered patients or the number of questionnaires previously returned) enable comprehensive performance controlling.

Furthermore, at the same time, **risks in the course of the project** can be better grasped, which without the professional support of a CTMS are not transparent. In this way, various risks can be defined through specific characteristic parameters. For example, medical risks, including an accumulation of adverse events, organizational risks, such as an insufficient number of patients in a clinical trial center, or commercial risks, such as the exceeding of the cost budget within a study.
4.3. Site and investigator management

Since the topic of “selecting suitable sites” was revealed to be an “annoying” issue in all the expert interviews, a CTMS represents a suitable tool particularly for this selection process, one that can generate added value. A CTMS makes it possible to select such service providers in a targeted market which have, for example, supplied impeccable data quality in past studies, have adhered to the agreed times for status reports or those for which a low number of "issues" were marked, etc.

The uppermost goal here is not to accelerate the selection process. Instead, it is a matter of improving the quality of the collaboration. In this way, sites can be motivated in a more targeted manner to work together on improvements through a transparent presentation of the statistics (e.g. the tracked progress data or the number of open issues).

The situation of monitors being “helpless” towards the investigators is also amended when they can present traceable and transparent statistics to the investigators.

The management of documents that are generated in the work with the sites can be placed centrally in a CTMS. A CTMS user can instantly call up and see which documents already exist from which sites (e.g. the investigators' CVs, financial disclosures or contracts with sites and laboratories) and need not obtain the corresponding document again.
5. INTERIM CONCLUSION: WHAT DO USERS EXPECT FROM A CLINICAL TRIAL MANAGEMENT SYSTEM (CTMS)?

For a CTMS to provide advantages for the processes in clinical study management, it must meet the various requirements of the respective stakeholders. Stakeholders are, for example, the trial management as well as the monitors, the IT head who must implement such a solution, and – especially for smaller companies – the executive board who must generally make the investment decisions.

During the interviews, PAC asked the experts which factors are important to them when choosing software solutions for clinical trial management, and presented the results in the following tag cloud.

Fig. 2: Requirements for a Clinical Trial Management System (CTMS)

Depending on the individual “maturity level” of the respective interviewee in regard to the topic of CTMS – some of those interviewed still had a very vague sense of what advantages a CTMS would provide – the requirements for a CTMS were quite different.

Accordingly, interviewees who had not yet been intensively involved with CTMS listed relatively general requirements, such as that it be "user-friendly" or "Web-based". But these are requirements that any good software tool must meet. These are what are known as “hygienic factors”. The requirements for project management and project planning were treated the
same way. Here too, standard software solutions like MS project and MS Excel can provide reasonable support for clinical trial management.

It comes as no surprise that the topics of project management and project planning were important to nearly all the experts interviewed. They were, after all, described right from the start as some of the central challenges in clinical trial management.

The requirements listed by those interviewees who were involved at greater depth with the topic of CTMS were interesting. In contrast to the first group, they listed essentially more differentiated and elaborate requirements for a CTMS, which clearly can no longer be met with Excel or project management software alone, but which, in the opinion of PAC, can only be met with authentic dedicated CTMS solutions: These included “multilingualism”, “a status overview cockpit” and the possibility of custom reporting options.
6. FIELDS OF APPLICATION AND SUCCESS FACTORS FOR CLINICAL TRIAL MANAGEMENT SYSTEMS (CTMS)

Summarized in the following are the circumstances in which the use of a CTMS is viewed as sensible and which factors can be decisive for success or failure.

When does it make sense to use a CTMS?

In the interviews the experts emphasized that when it comes to large and complex projects, the use of a CTMS can really deliver improvements. Added value is generated in the form of increased transparency, lower efficiency losses in the course of trials and the resulting time-savings – all factors that lower both costs and risks.

“Complex trials are like conducting a symphony orchestra. When it comes to large and complex projects with correspondingly complex data, where there are plenty of regulations to observe and where many different participants must be integrated, a CTMS solution makes perfect sense.”

Owner of a clinical research institute

However, the expert interviews also showed that considerable entry barriers exist for CTMS. Investments for the acquisition of dedicated solutions are rarely on the budget for smaller pharmaceutical companies and CROs.

“A dedicated CTMS only seems sensible to me when large, multinational studies are to be coordinated among many widespread trial centers. For smaller companies like ours, with more manageable projects, a CTMS seems rather over-dimensional.”

Manager of a clinical research institute

In summary, where the complexity of trials is high, when multiple trials are conducted simultaneously or in multiple countries, then a CTMS absolutely makes sense.
What are the success factors?

PAC views three essential success factors as decisive for the success or failure of CTMS projects:

1. Acceptance

The successful use of a CTMS solution mainly depends on its acceptance among all users. The following quote from the expert interviews underlines just how important acceptance is:

“While we do have a dedicated clinical trial management system in use, our on-site monitors often still document their visits in Word or even on paper and then later type them into the CTMS. The motivation to use the CTMS, not to mention perceiving the CTMS as a work alleviator, is correspondingly low.”

Head of data management at a large, international clinical research facility

“A technical way to increase user acceptance is to integrate all the systems that are relevant to clinical trial management. This prevents having to enter data multiple times, such as the data entry for the documentation of monitor visits, reporting and settlement with the sites. If a CTMS helps to reduce redundancies, then it significantly contributes to the acceptance and more efficient usage thereof.

A finding from the area of change management also shows that the early integration of the future users represents a very promising approach: Key users, for example, can support the selection process by defining functions that the system should offer. This can mean that even before the introduction of the application the benefits of using a CTMS can be analyzed together and any potential concerns alleviated.

“For the project management a CTMS offers the possibility to see whether a project is going well or poorly. However, for those conducting the study, a CTMS only means disadvantages, because it takes more work to enter all the data.”

Head of clinical operations at a clinical research facility
2. User-friendliness

Although the topic of user-friendliness is a fundamental requirement for the successful use of any software solution, nevertheless it must be emphasized that the cause for a rejecting attitude towards (existing) CTMS solutions can also lie in inflexible systems or user-unfriendly entry screens. Intuitively operable solutions not only ensure greater acceptance, but at the same time also require minimal training efforts and costs. A certain amount of training is still necessary to introduce the individual benefits of a CTMS to all users.

3. Choice of vendors

Last, but not least, the choice of vendor is crucial for the successful use of CTMS. Due to the specific process in clinical trial management and the constantly changing legal framework conditions, the software provider should have thorough industry know-how. This is indispensable for the functioning and further development of the solution and ensures the sustained cooperation between the software users and vendor. It can also be advantageous if the vendor has sufficient resources for consulting and system integration, either within its own organization or through certified partners.
7. **PAC'S SUMMARY AND OUTLOOK**

PAC is of the opinion that enormous potential exists within clinical trial management today to design the processes even more transparently and efficiently. Clinical trial management systems (CTMS) are of central importance in this regard.

In contrast to commonly used solutions such as Excel or project management software, study managers in particular receive comprehensive performance controlling functions and status overviews in real time through the use of CTMS solutions. Risks can be significantly reduced within project planning, such as in the area of cost and time management, as well as in the medical area. And monitors can essentially design their visits to the clinical trial documents more efficiently and also monitor them better by using CTMS.

There is no getting around the fact that the acquisition and operation of a professional CTMS require high initial investments. However, in PAC's view, these expenses should be viewed in a differentiated manner. If the investment exceeds the budget, it is helpful to make comprehensive return-on-investment calculations in order to attain complete transparency about the costs and benefits of a CTMS.

Particularly in smaller companies, a person in charge who has sufficient time to look into the purchasing of software is usually lacking, not to mention someone who can calculate potential gains in efficiency.

Against this background, i.e. high initial investments and lacking persons in charge of IT, Software as a Service concepts could also represent an interesting alternative.
The topic of CTMS will continue to grow in importance

Based on the findings from the interviews and market analyses, PAC assumes that the deployment and use of CTMS solutions will further increase. While the term CTMS and its specific meaning are not yet uniformly embedded in the minds of potential users, nevertheless the functionality of the software will continue to grow in importance.

It will still take some time before CTMS solutions penetrate pharmaceutical companies and CROs of all sizes. This gives the providers of CTMS the possibility to further improve their solutions, to introduce flexible service models, such as Software as a Service, and to advertise for greater acceptance. This study is hopefully an effective step in this direction.
8. ABOUT BSI BUSINESS SYSTEMS INTEGRATION AG

BSI Business Systems Integration AG is a producer of business software, including CRM, contact center and CTMS solutions. BSI’s clinical trial management system, BSI CTMS, contains all the function modules needed for the planning, conducting and measuring of clinical trials. The modules can be flexibly combined and make it possible to conduct local, regional and global studies. The data of investigators, monitors and other stakeholders can also be managed, the supply of medicines can be planned and the financial operating figures can also be monitored.

The Process Wizard guides the monitor visit process and the automatic, adjustable visit protocol (author, time, data entry type and modification) enhances efficiency and also ensures the reproducibility of trials. BSI CTMS can be used on all end devices, in a SaaS model or in a classic license model. An offline version makes it possible to also enter data directly at the source.

BSI is also the initiator of the Eclipse Scout open source project, an open, modern framework for service-oriented business applications. Around 170 employees, most of which are software developers, work in seven locations in Switzerland and Germany. Internationally active companies from all industries are among their customers.

For further information about BSI CTMS please visit www.bsiag.com/ctms.
CONTACT

Author:
Stefanie Naujoks
Analyst – Project Services & Manufacturing Markets
+49 (0)89 23 23 68-22
s.naujoks@pac-online.com

Published by:
Pierre Audoin Consultants (PAC) GmbH
Holzstrasse 26
D-80469 Munich

Tel: +49 (0) 89 232 368-0
Fax: +49 (0) 89 719 62-65
Email: info-germany@pac-online.com

ABOUT PIERRE AUDOIN CONSULTANTS

From strategy to execution, PAC delivers focused and objective responses to the growth challenges of Information and Communication Technology (ICT) players.

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PAC helps ICT vendors to optimize their strategies by providing quantitative and qualitative market analysis as well as operational and strategic consulting. We advise CIOs and financial investors in evaluating ICT vendors and solutions and support their investment decisions. Public institutions and organizations also rely on our key analyses to develop and shape their ICT policies.

For more information, please visit www.pac-online.com.

OUR LOCATIONS

PARIS
Pierre Audoin Consultants (PAC)
92, Avenue de Wagram,
75017 Paris, France
Tel: +33(0) 1 56 56 63 33
Fax: +33(0) 1 48 28 41 06
info-france@pac-online.com

MUNICH
Pierre Audoin Consultants (PAC)
Holzstrasse 26,
80469 Munich, Germany
Tel: +49(0) 89 23 23 68 0
Fax: +49(0) 89 719 62 65
info-germany@pac-online.com

BERLIN
Pierre Audoin Consultants (PAC)
Am Kupfergraben 6A,
10117 Berlin, Germany
Tel: +49(0) 30 28 52 96 0
Fax: +49(0) 30 28 52 96 29
info-germany@pac-online.com

LONDON
Pierre Audoin Consultants (PAC)
2nd Floor, 15 Bowling Green Lane,
London EC1R 0BD, UK
Tel: +44 (0) 207 251 2810
Fax: +44 (0) 207 490 7335
info-uk@pac-online.com

BUCHAREST
Pierre Audoin Consultants (PAC)
Louis Pasteur 40,
050536 Bucharest-5, Romania
Tel: +40 (0) 21 410 75 80
Fax: +40 (0) 21 410 75 81
info-romania@pac-online.com

NEW YORK
Pierre Audoin Consultants (PAC)
192 Lexington Avenue - Suite 1101,
New York, NY 10016, USA
Tel: +1(646) 277 7255
Fax: +1(646) 607 1716
info-us@pac-online.com

SAO PAULO
Pierre Audoin Consultants (PAC)
Rua Pedro de Toledo, 130, Office 61,
Vila Clementino,
Sao Paulo, 04039-030 Brazil
Tel.: +55 (11) 5539 0280
Fax: +55 (11) 5539 0280
info-latam@pac-online.com