Keeping Tabs

The life sciences industry has a vital interest in managing clinical studies efficiently and with as little risk as possible. Could clinical trial management systems be the solution?

Jan Klint
Nielsen at BSI

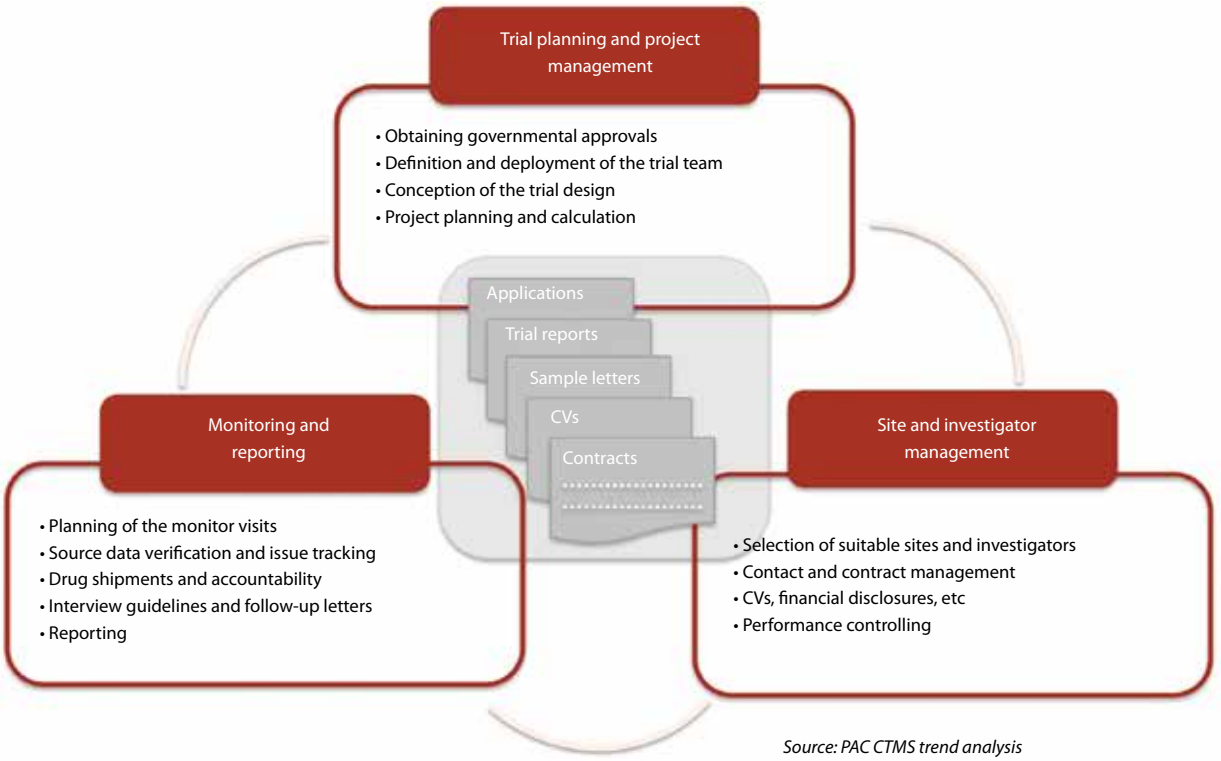
Expiring patents, greater competition and price pressure, together with high regulatory requirements through ever stringent legislation describe the current situation in the pharmaceutical industry.

According to the trend analysis 'Clinical trial management systems: Business success with modern solutions' by Pierre Audoin Consultants (PAC), pharma 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 optimise all processes – from development to the production of new medicines – to reduce both cost and risk. In the trend study, PAC points out the seven greatest hurdles in clinical trial management:

1. Obtaining governmental approvals
2. Selection and management of sites
3. Project management
4. Project performance and control
5. Time management
6. Reporting
7. Management of data and documents

Why CTMS?

PAC is not alone in the belief that there is enormous potential within clinical trial management today to design procedures even more transparently and efficiently, and that clinical trial management systems (CTMS) are of central importance in this regard. Current CTMS solutions cover



Source: PAC CTMS trend analysis

Figure 1: Issues that a CTMS should cover

Image: © PAC

the entire range of study planning and supervision – from monitoring and patient tracking, to document administration. They serve as central hubs by the integration of other important systems (like electronic data capture or electronic trial master file, for instance) within the eClinical IT landscape.

Many pharma companies are beginning to outsource the execution of their clinical trials to CROs. CROs have partially different needs for their CTMS compared to the pharma sponsors. Small- to medium-sized CROs especially wish to expand their CTMS in the near future to include HR management, business development, activity planning and tracking (such as offer generation and billing).

Efficiency Benefits

The introduction of CTMS is an important move towards digitalisation for any business. It is changing the heterogeneous system landscape and taking a significant step towards a paperless clinical trial management process. They are able to reduce the time and effort needed to maintain an overview of operational data on different levels. Through faster provision of information for a digital dashboard for trial managers, CTMS also facilitate early risk assessment and the decision-making process, while boosting efficiency across numerous operations.

In contrast to commonly used solutions – such as Excel or project management software – the use of CTMS provides study managers with comprehensive performance controlling functions and status overviews in real time, while project planning risks can be significantly lowered in terms of cost and time management. Furthermore, monitors can plan and schedule their visits according to clinical trial documents more efficiently, as well as control these more effectively by utilising CTMS.

There is no getting around the fact that the acquisition and operation of a professional CTMS requires initial investments. However, PAC believes that 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 to attain complete transparency about the costs and benefits offered by CTMS.

More and more providers offer CTMS on demand 'from the cloud'. This means that the CTMS is not hosted on-site on the IT infrastructure of the sponsor or the CRO, but is completely managed by the CTMS provider. The usage is normally a paid-per-user in a Software as a Service model. This can help to reduce the internal investments in IT infrastructure and operational personnel. Only a few years ago, the hosting of important clinical data in the cloud was unthinkable for many pharma sponsors – nowadays, eClinical software from the cloud is becoming more and more a commodity.

A Step Further

Instead of limited sponsor access, study progress will become more transparent with an online trials overview. It will also get easier to handle proposals, offers and invoices between sites, CROs and sponsors. There will be improvement in the tracking of the drug shipment process, from production by sponsors to supply and accountability, and on through to destruction. The specific main challenges described in the trend study by PAC – project management and reporting – are expected to significantly change for the better.

About the author

Jan Klint Nielsen is Senior Project Manager and CTMS Community Manager at BSI, and has been with the company since 2007. He has many years of experience as a project manager of large international projects, and as a department manager of major development and maintenance teams.

Email: janklint.nielsen@bsi-software.com