Clinical Researcher—June 2020 (Volume 34, Issue 6)

GOOD MANAGEMENT PRACTICE

How to Master the Clinical Trials Data Explosion

Lars Behrend, PhD; Michael Sigmund, DVM

According to an annual survey of the American software company Veeva, 81% of all professionals use spreadsheets during the start-up phase of clinical trials.{1}Therefore, it is hardly surprising that all of the survey respondents (100%) considered improvements in the processes between study sites, sponsors, and contract research organizations (CROs) to be necessary.

In clinical trials in particular, it is challenging to coordinate a number of teams and different disciplines in a time-critical working environment and with highest commitment to patient safety. Increasingly tough regulatory requirements and the advance of digitalization are producing more and more data that have to be documented, reviewed, and evaluated for trial leaders to make the best decisions. A clinical trial management system (CTMS) based on a low-code platform could be the solution, especially for medium-sized pharmaceutical, biotech, and medical device companies.

In multidisciplinary projects, the use of information technology (IT) systems based on separate applications inevitably produces data silos that are not practicable and that limit manageability. Moreover, in clinical trials, sponsors and CROs risk losing data and breaching data security requirements or Good Clinical Practice (GCP) standards by using spreadsheets and local data storage. High IT standards including central storage, regular backup, and user access management practices that are mandatory in a research field that involves handling patient data and has implications for people’s health.

Critical Decisions Require Consolidated Information

A project manager in charge of clinical trials has to handle a flood of information. Especially in an environment that is heavily dependent on outsourcing through many subcontractors, content is delivered in different formats, with variable degrees of complexity, and with different topicality. If information is not consolidated properly, drawing the right conclusions will be challenging. Unwanted developments could pass unnoticed and delay timelines as a consequence. Further, compliance and patient security may be at risk if lack of oversight results in wrong decisions or missing interventions.

A CTMS can assist project managers and teams in a clinical study alike by providing all relevant information in one location. These systems create a central workspace for all stakeholders and make information available to members of the project team. The functionalities usually comprise:

- Project management
- Budget planning
- Patient management and recruitment
- Document management
- Reporting system
- Risk management
- Project status
- Drug safety
- Regulatory submissions and requirements
- Investigational medicinal product (IMP) management

Ways of Implementing a CTMS

Once the decision has been made to implement a CTMS, different routes can be taken. In order to choose the right approach, parameters such as the size of the company, budget, internal IT competency, and existing IT structure—as well as the demand for functionality, reports, and flexibility—should be taken into account. In principle, there are three possible ways to implement a CTMS:

1. Using a **commercial, off-the-shelf system,** which is usually based on software as a service (SaaS). A growing number of CTMSs have been launched by software companies in recent years.
2. Developing a **proprietary system** on the basis of a low-code platform where pre-existing building blocks are used for programming customized features.
3. Building a completely **new software system** by having staff or vendors write the new source code according to your preferences.

Let's take a closer look at each of these options.

The Commercial, Off-the-Shelf System (COTS)

A COTS has a host of functionalities central to clinical trial management (e.g., assisting with keeping track, creating reports, and identifying time-critical paths). Key features include a customizable web page, sophisticated access control mechanisms, accessibility for new programmers, and the possibility to connect to other systems.

Most COTSs are based on SaaS, and are therefore easy to use and highly convenient. On the other hand, a COTS offers only limited flexibility when applications require customization in response to specific customer needs.

Clinical projects often differ in terms of geographic location, distribution of tasks between different stakeholders, or object of study (i.e., medical device or IMP). Limited adaptability could therefore be a disadvantage for the user. In addition, COTSs are cost-intensive and CROs may face problems transferring the costs to the sponsor of a study.

Programming on a Low-Code Platform

Programming a customized CTMS is usually not a feasible option for small to medium-sized companies. Indeed, developing a new system from scratch requires a dedicated team of programmers, substantial financial resources, and large outlays of time. Here, the development of a customized CTMS solution based on a low-code platform could provide an alternative.

Low-code platforms significantly reduce the development time needed, since even staff with relatively low levels of technical skills can access and use them, as the biggest proportion of programming is done automatically. The standardized toolkit used in these systems facilitates consistent quality and usability for programmers and users alike. Drag-and-drop elements can be applied into spaces on webpages and configured to satisfy all needs of the company and the customer.

Configuration on a low-code platform includes aspects such as appearance, visibility, and function. Data for these systems are usually stored securely in the background using modern, on-premise technologies or cloud solutions. Commonly used products for the background data model are Microsoft SQL Server, Oracle, or MySQL. These software products all handle data in a relational model optimized for a low-code approach. This provides the company with the best ratio between complexity, adaptability, and performance.

Development of New Software

If the decision has been made to build a CTMS based on a completely new software system, all functionalities (including the creation of a new user interface) have to be developed from scratch. Such a path is only economically meaningful if the company already has a strong IT background with a team of programmers and commercializes its CTMS products afterward.

The advantage of a CTMS based on a newly developed system is complete freedom of design and 100% flexibility in adapting the system to individual needs.

How a Low-Code Based CTMS Can Help to Increase Flexibility

The clinical research enterprise is characterized by highly diverse project settings. A CTMS has to meet a whole range of unique requirements that depend on the specific services being covered by a CRO company during a project, on country-specific technological and

regulatory differences in multinational trials, and on technological and managerial differences between the interacting teams and their IT systems. In such settings, a self-programmed solution which is quickly adaptable has outstanding advantages.

Two examples from the experience of the authors with low-code platforms show the flexibility of such solutions:

1) In only 10 days, a voting system for a trial steering committee was programmed, tested and implemented, allowing the committee members to vote on the eligibility of patients. A presentation with diagnostic images of each new patient is created by a diagnostic lab and loaded into the CTMS. This triggers an e-mail with a link to all committee members. The link guides them to the presentation, and each member can vote for or against the patient's eligibility. If the decisions of two members are in line, the system closes, allowing no further votes.
2) In only three weeks, a management system for an IMP was implemented and went live prior to the start of a multinational trial. The system allows trial managers to track available stock at sites and automatically triggers an order before sites run out of the IMP. Furthermore, IMP delivery, destruction, and potential temperature deviations are tracked by the system.

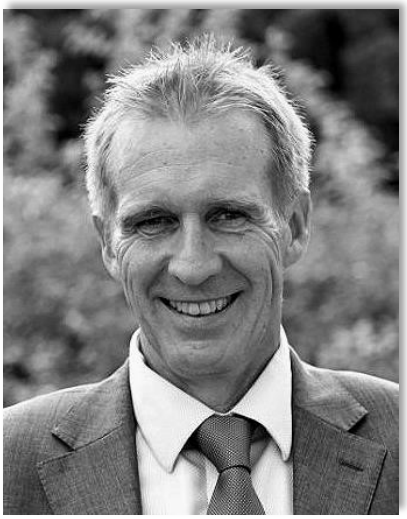
Conclusion

A CTMS based on a low-code platform allows trial leaders to create a very flexible IT workspace for managing the conduct of the trial. Such systems can be implemented with reasonable effort, thereby providing an interesting alternative to COTS solutions for mid-sized companies.

Reference

1. https://www.veeva.com/unified-clinical-operations-cro-report/

Lars Behrend, PhD, is Chief Operating Officer of SSS International Clinical Research GmbH (info@cro-sss.de) in Germany, which works with biotech, diagnostics, and pharmaceutical companies throughout Europe as a CRO. The company is based in Germering near Munich, with further locations in Poland and Romania. SSS is a member of the German Federal Association of Contract Research Organizations (BVMA) and an associated member of the European CRO Federation (EUCROF).



Michael Sigmund, DVM, is Chief Executive Officer of SSS International Clinical Research.