Clinical Trial Management System (CTMS) that meets the unique business needs of your research and development organization is a critical resource for tracking the vast number of details required for the successful development of a pharmaceutical product. Choosing the right CTMS from the large pool of available vendors, however, is fraught with challenges. You can avoid the common missteps many companies make during the selection process by adhering to certain best practices that Campbell Alliance has developed over the years while assisting dozens of organizations in implementing CTMS. These best practices were developed to help you clarify your clinical system strategy, structure your selection process, define your business needs, and successfully implement your new CTMS in your day-to-day workflow.

Defined Clinical Strategy

An organization’s clinical system philosophy will affect the selection and subsequent effectiveness of its systems across the development life cycle. With so many critical decisions needing to be made, it is important for an organization to create a strong vision that defines the business purpose for and interdependencies between each system. A clear clinical system strategy is the roadmap required to provide organizational direction, minimize functional redundancy, and optimize the systems.

Consider the example of a large pharmaceutical company that attempted to select clinical trial management, electronic data capture (EDC), and enterprise resource planning (ERP) systems through individual task forces. Although teams regularly shared selection updates, they rarely collaborated on the actual selection process, including deciding in which systems overlapping functionalities would reside and the methodology for integrating the systems. Meanwhile, the organizational leaders provided little guidance on expectations and failed to provide a long-term vision of how the systems would support clinical operations.

With the task forces left to develop individual strategies and no overarching steering committee to address questions or make cross-task-force decisions, the result was overlapping functionalities being examined across task teams. Without clear senior leadership support or vision, the teams struggled to define the strategic importance of the proposed system architecture and failed to clearly articulate the relationships between each system by the time the request for proposal (RFP) was developed.

Given the vast number of clinical systems with various levels of functionality, company leaders must develop a holistic overview of the organization’s clinical system strategy, including system interfaces, and understand which functionalities will be located in each system. R&D organizations also need to define primary vs. secondary data sources to clarify where data will be stored and how the data will be managed across systems. Finally, leaders need to determine the organization’s philosophy on utilizing a software-as-a-service (SaaS) solution vs. hosting the CTMS internally.

Clear Business Requirements

Once the strategy is in place, the evaluation process begins by establishing the business requirements for the new management system. If an organization selects a management system that does not fit its business requirements, the company runs the risk that the users will attempt to retrofit the CTMS to their needs through excessive customization or configuration. Too much customization, however, may compromise the quality of the system and risk diminishing the effectiveness and efficiency of the system. Additionally, organizations can greatly increase the initial cost and reoccurring maintenance requirements with excessive customizations. A system intended to improve the effective management of clinical trials can suddenly add to the work load if the
system does not address the nuances of the users’ business requirements.

While most organizations have a high-level understanding of their business needs, many do not properly understand the functional nuances required by each department prior to initiating an RFP. Without prioritized, detailed business requirements, an organization risks not having a clear understanding of exactly how a system can be used in day-to-day activities.

For example, the general business requirement of generating a report may appear to be sufficient detail for system selection, until one considers the complexity of gathering data from various sources, synthesizing each variable, and generating information at the desired detail level and in the format required. If these variables are not carefully considered when developing the business requirements, a simple report can suddenly be impossible for a CTMS to generate. Organizations run the risk of reverting back to Excel to create reports when they discover that they cannot generate data required to properly trigger payments, track milestones, and perform other critical CTMS functions.

The selection team needs to take the time to understand the unique business requirements for each department, listening not just to what they say, but also listening for “non-verbal” requirements. Native users may first need to be educated on system capabilities and utilization, including its purpose in the larger clinical system strategy. The team must also consider global requirements, such as language and currency requirements, and understand the vendor’s long-term system plan in order to ensure that anticipated changes to the platform will not alter the system’s value to the organization.

**Structured Selection Process**

Next, the R&D organization needs to establish a structured selection process for evaluating all of the CTMS options available. At a high-level, vendor selection can be divided into two sections: internal and external evaluation.

As part of the internal evaluation, the organization needs to generate an understanding of its unmet needs when it comes to managing its clinical trials. Daily tasks should be translated into business requirements for the new management system, as discussed in the previous section. These business requirements should then be divided into must-have and nice-to-have features. While many functionalities may seem like a must-have, companies must carefully select the features that will serve as points of differentiation between each system.

In addition to these requirements, the selection team needs to understand the resources required to support each system during CTMS implementation and utilization. For example, an organization with a lean internal IT function may need to inquire as to a CTMS vendor’s ability to perform ongoing technical assistance, such as Help Desk support or data storage. The size and geographic spread of a company may also require assistance across time zones or in multiple languages. During implementation, some organizations will require assistance to integrate systems and provide user training, while other organizations may be able to leverage current resources to adequately support some or all of these activities. Resource support decisions can significantly affect vendor selection and costs, emphasizing the need to have a clear system strategy and business requirements from the onset.

Once the RFP is developed, the focus shifts from internal preparations to external evaluation. A dedicated and unbiased vendor evaluation group needs to review the RFP responses and assess them based on fit to requirement. Assigning scores to RFP responses provides teams with a method of producing quantitative results to generate a more accurate presentation of the system’s fit. This group is also responsible for reviewing documentation supporting the vendors’ verbal promises, consulting with vendor references to gain first-hand experiences, and matching perceived benefits with actual capabilities. Vendor references are a critical method for hearing how the system operates in the real world. Finally, this group should also analyze the level of effort necessary to gain the results that the organization desires, including degree of customization and difficulty of system integration.

During the vendor demonstration process, the evaluation group should establish a test script for the vendors and force them to stick to it. Through the scripted demonstrations, the company will be able to do a side-by-side comparison of the key functionalities and choose the right system to meet its needs. If vendors are not held to a defined script during final vendor demonstrations, it will be impossible to perform a direct comparison. Additionally, without a script, companies may present functions that do not align with your organization’s requirements or that are unavailable in the current release of the product.

Importantly, the team should not allow emotions to overrule logic or select a system based on the brand name alone. A team should not select a system based on unnecessary “bells and whistles” or assume that it must select one vendor for all clinical systems. While no CTMS will perfectly meet all of your organization’s needs, the selection team should choose the system that best works for the organization and meets its critical business needs.

**Strong Implementation**

Once a decision has been made, it is time to put the new CTMS to work. One of the most common points of failure is the inability of an organization to properly deploy the system. Updated business processes, training, and pilot program(s) are required to support a new system. Without proper implementation planning and rollout, the company runs the risk of its R&D team becoming frustrated or even abandoning the system that it just carefully selected. The requirements for successful implementation can be broken down into eight categories.

**Steering/Guidance Committee**

As with the selection process itself, leadership is critical to the success of the
CTMS implementation process. A steering/guidance committee should be put in place to provide overall leadership and direction for the process, taking responsibility for compliance decisions and ensuring the required tasks are effectively executed on time and on budget. The committee can offer insight across corporate initiatives and remove obstacles for the successful adoption and use of the system.

**Process Modifications**

The only way to maximize the benefits of a CTMS investment is to update the way the company operates. Work process change, allowing for the full efficiencies of the system to be implemented, is critical for successful CTMS implementation. In fact, the work processes that impact CTMS should be redesigned before implementation. Then those new work processes can be used for the system configuration.

**Training and Compliance**

One of the responsibilities of the steering/guidance committee will be to make certain that a robust training plan is in place for implementation. R&D staff will need to be trained not only how to perform their job functions, but also on how to use the management system. Ongoing training will ensure that long-term compliance with new processes and workflows is maintained.

One common error that Campbell Alliance has seen is “implementation fatigue,” which occurs when a long implementation effort saps the enthusiasm for the system by the time the system is ready to be implemented. Since training is at the end of the process, that step ends up being conducted in an abbreviated fashion that, in turn, results in the entire organization failing to take full advantage of the new CTMS.

**Support Model**

Along with training, the committee will need to establish a support system for users, including help desk support and process support. The support infrastructure must provide consistent instructions to ensure compliance. If a SaaS management system has been chosen, much of the technical support will reside on the vendor side. If the CTMS resides on the company’s internal server, however, the support infrastructure and help desk will need to be manned internally or outsourced.

**System Integrations**

Data will need to feed in and out of a variety of different platforms, so the CTMS will need to integrate not only with other existing systems, but future systems as well. The committee will need to evaluate current and future integrations to provide a consistent method to effectively execute system integrations.

**Global Structure**

Within an organization, different countries may have different needs in terms of information tracking and regulatory filing. The committee must ensure that the system meets global requirements and establish feedback paths so that global users can easily provide input. Training will also need to be provided globally.

**Continuous Improvement**

Organizations rarely get implementation of a CTMS correct the first time. The system and system usage should be evaluated on a continuous basis to ensure ongoing improvement of the system. A pilot program may be in order to work out the bugs in the system with a small group of users before rolling the CTMS out to the entire organization.

**Communication**

Finally, communication is critical. The steering/guidance committee should develop a communication plan utilizing multiple methods of communication specific to the unique sub-groups within the user population.

**Conclusion**

A well-handled CTMS selection and implementation process is time consuming, but a poorly-handled CTMS selection and implementation process will be twice as time consuming and half as rewarding.

The best CTMS selection teams are formally assigned to the task, actively invested in managing it, and granted the time necessary to devote to the process. Given that a clinical trial management system is potentially a multi-million dollar investment, the effort to choose the best fit for your organization should not be given short shrift.

The key to successfully choosing and implementing a clinical trial management system is to be very clear on what you want from a system. Be able to articulate how your system fits into the larger strategy, otherwise you run the risk of duplicating functionality. Vendors should be held to a defined script during final vendor demonstrations, and the selection team should be sure to talk internally, talk to references, and talk to anyone else who can provide useful insights.

Most importantly, a system is only as good as how you use it. A new system will not automatically fix pre-existing business issues. You could have chosen the perfect system, you could have everything configured the right way, but if you do not take the time to implement it properly, the system is going to fail. By adhering to the best practices described above, however, your organization will stand a much better chance of avoiding the pitfalls that trip up other organizations in their attempt to bring on board a new clinical trial management system.

**About the author**

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