

Reduce the Time to Implement Your Clinical Trial Management System **WITH BIOCLINICA CTMS DIRECT**

A Bioclinica Case Study



Introduction

Because a Clinical Trial Management System (CTMS) defines and manages all the activities that make up the clinical trial process, it can be resource-intensive (finances, time and human) to implement. As a result, a CTMS is often considered out of reach for small to mid-sized companies. So these companies compromise with systems comprised primarily of manual processes using spreadsheets, half-built internal systems or less-than-ideal implementations, despite the recognized value of CTMS to centralize operational data and automate processes for better decisions, playing an integral role in the conduct of clinical trials. However, it is possible to achieve two-week implementation times when the eHealth Cloud and standardized, out-of-the-box configurations are used, as with Bioclinica CTMS Direct.

Bioclinica CTMS

Bioclinica CTMS is a fully developed CTMS designed to meet your specific organization and study needs. Unlike spreadsheets and/or manual processes, our CTMS is a powerful end-to-end clinical trial management solution that provides control, efficiency and quality data by including tools to plan, start up, conduct and manage your study. You can view and manage real-time operational performance from a centralized, web-based dashboard, wherever you are and at any time, saving you time, labor costs and operational expenses.

As with all full-featured CTMS systems, it can take six months or more to get from contract/kick-off to live production which adds to the overall configuration time. Because of the wide reach of CTMS to all facets of the study team, it is important to get system buy-in and acceptance from all team members to ensure that it is usable and useful. This can also be time-consuming, particularly because many of these team members maintain their primary role during CTMS development.

Despite the desire to take advantage of the full implementation of a CTMS, some companies are reluctant to commit to the time and financial requirements or simply don't have months to spend on implementation before study commencement.

FEATURES of Bioclinica CTMS

- 1 Centralized tracking of regulatory documents, missing documents and expiry dates
- 2 Easy detection of operational milestones that are falling outside the target range
- 3 Oversight of study budgets and invoice tracking
- 4 Offline capabilities to complete Monitoring Visit Reports (MVRs)
- 5 Management of document approval workflows
- 6 Ability to quickly respond to study management changes and needs, including tight start-up timelines
- 7 Ability to handle personnel and resourcing shifts as study volumes expand and shrink
- 8 World-class data security and safety
- 9 Training, documentation and validation
- 10 Sharing of results through standardized best-practice SharePoint reporting
- 11 Measurement of organizational metrics to provide continual process improvements

Bioclinica CTMS Direct

Bioclinica recognized this limitation of a traditional CTMS and developed a rapid start-up version of its CTMS – CTMS Direct – made possible by the eHealth Cloud. A two-week implementation is possible by using standardized, out-of-the-box configurations that were developed based on Bioclinica’s knowledge of industry best practices. As a result, Bioclinica CTMS Direct can be implemented rapidly while not compromising any of the full-featured functionality of its traditional CTMS.

The standardized configurations and reporting, covering approximately 90% of study requirements, streamline the initial implementation process. The remaining 10% of configurations are designed specifically for each study, requiring only a fraction of the time and cost for initial start up compared with full-scale CTMS deployments, making it ideal for smaller organizations, study-specific uses or tight timelines.

Reduce the Risk of Implementation

Bioclinica CTMS Direct is a unique, entry-level system that has a much lower up-front cost, representing a minimal investment without the need to commit to a much more expensive and time-intensive, full-scale solution. The system can be expanded later with additional configurations, which can be chosen based on budget and timing. This phased implementation often leads to more powerful discovery sessions and a better full-scale configuration because the users have a better understanding of their needs/wants for the system based on an approach of “now that you know what you didn’t know.” Custom configurations can be carried over to other studies using Bioclinica CTMS Direct, further streamlining the initial implementation.

Bioclinica CTMS Direct shortens most deployment timelines to only 2 weeks.

Bioclinica CTMS Direct	Configuration	Bioclinica CTMS
Standardized configuration based on best practices		Configuration tailored to customer specifications
Standardized configuration	SharePoint configuration	Configuration tailored to customer specifications
Included	Contact / institution migration	Included
Standardized integration module included	3rd-party integration	Unlimited custom integration
Standardized best-practice MVR	Monitoring Visit Report (MVR)	MVR configured to customer specifications
Hosted only	Hosting	Hosted or non-hosted
None	Function limitations	None
2 weeks	Deployment timeline	26 weeks

Bioclinica CTMS Direct in Action

FHI 360, a contract research organization (CRO), had an upcoming project involving two studies for which they needed a quick win. The company had previously not implemented or had only partially implemented a CTMS and also had an in-house system that did not tie in with their other systems, limiting the ability to use it in future projects. The FHI 360 teams worked closely with Bioclinica to implement CTMS Direct in a manner that worked perfectly for their project.

Both studies used the same out-of-the-box implementation model, and weekly meetings between Bioclinica and the study teams allowed for the system to be configured to the teams' needs, resulting in a system that was up and running faster than expected. However, because of additional time to fully validate and implement within their existing systems, the implementation was completed in approximately eight weeks. This was still viewed as a quick win, with demonstrable value in a short timeframe.

Users readily adopted the system, particularly because everyone remained engaged throughout the entire process. The phased implementation allowed the system to evolve over time, as the team, including different vendor teams, understood the product better. This and the integration of patient data helped make the system more relevant to study users. During the first implementation phase, the patient data were organized, which enabled the custom monitoring reports in the second implementation phase.

Based on the success of this implementation, Bioclinica CTMS Direct has been implemented for an additional study.

Conclusion

Bioclinica CTMS Direct is an effective CTMS option for any company looking for rapid implementation, especially given the ability for phased implementation of the entire system configuration. In addition, an entry-level system mitigates the risk of significant investment in implementing a system that does not meet the company's needs.

Learn more at bioclinica.com/ctmsdirect

LESSONS Learned

ORGANIZATIONAL CHARACTERISTICS & EXPECTATIONS

The adoption of Bioclinica CTMS Direct might differ by organization. User adoption and buy-in within the organization are required, and a comprehensive understanding from management and study team members of the level of effort needed to define requirements, become knowledgeable about the system, and engage in full-use adoption is helpful to set expectations.



VALIDATION

The testing and validation documentation from Bioclinica saved considerable time. However, some companies might choose to conduct further validation and User Acceptance Testing in addition to what Bioclinica provides; this could add time and resources to the process.



TRAINING & SUPPORT

Compared with a support person located at Bioclinica, having a fully trained, seasoned, on-site support person might help gain efficiencies. In addition, focused, structured training sessions help team members fully understand the system.

