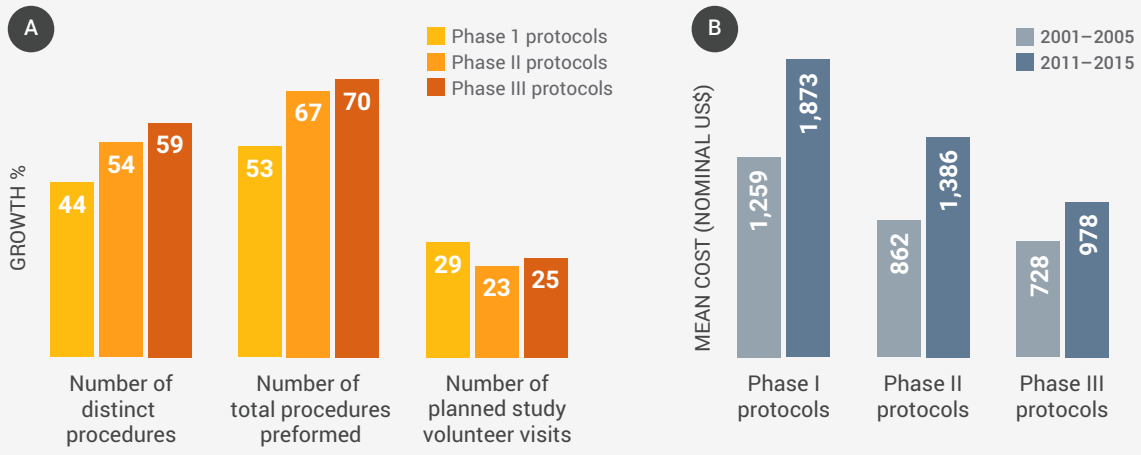
Modernizing the Hub of Clinical Operations

Streamlining Clinical Trials with a Modern and Connected CTMS

Increasing trial complexity and costs (Figure 1) demand flexible, modern solutions to support next-gen study designs and drive innovation in clinical operations. A modern and connected clinical trial management system (CTMS) brings together data, processes, and workflows in a single solution to help study teams easily execute today's trials with complex protocols, large amounts of data, and diverse global regulations.

FIGURE 1. TRENDS IN THE COMPLEXITY AND COSTS OF CLINICAL TRIALS



Source: Getz, K., Campo, R. Trends in clinical trial design complexity. Nat Rev Drug Discov 16, 307 (2017). https://doi.org/10.1038/nrd.2017.65

Legacy systems weren't built to cope with these requirements because the majority were developed to support outdated paper-driven and onsite processes. As many reach the end of their useful life, a new breed of digital clinical trial management system is transforming how studies are conducted.

Easily Optimize Your Trial Configuration

Adapting the CTMS to the needs of each trial no longer requires a disruptive software development cycle involving costly consultants and customization. Flexible cloud-based systems can be quickly configured and optimized for all types of trials – traditional, hybrid, virtual, digital – and therapeutic areas. Protocol amendments can be applied if requirements change mid-way through, and modern user interfaces ensure teams can intuitively navigate key business processes.

Increase Clinical Operations Efficiency

Unifying trial documents and operational data in a single system centralizes clinical processes, improves accuracy, and enables strategic planning.

For example, complete visibility into an upcoming planned site initiation visit enables study teams to:

- ➔ Prioritize contract development and reviews
- ➔ Collect essential documentation for investigational medicinal product release
- ➔ Ensure the monitor is prepared to conduct the study initiation visit

This can be done quickly and in the optimal sequence because team members can all access up-to-date operational data together with the latest version of the documents from the same source.

Historically, these processes require tedious and manual document management systems and data reconciliation, slowing or stalling the execution of essential actions. Additionally, combining essential information from study documents with the project management data in CTMS demands heavy administrative lift, especially when managing trials across multiple systems.

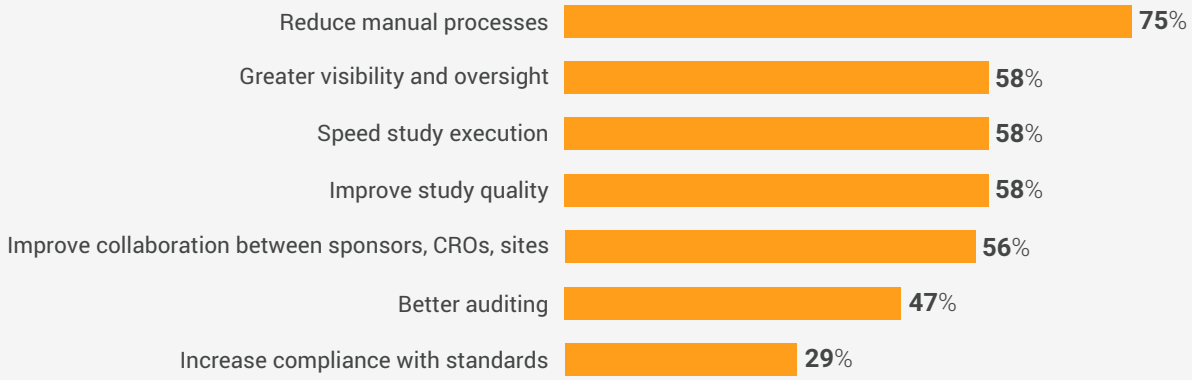
A CTMS application built on an industry platform with strong document and data management capabilities can provide a complete, accurate view of trial status, optimizing the efficiency of clinical operations.

Improve Collaboration with External Partners

The global rise in clinical trial outsourcing has made information sharing between all study stakeholders an industry-wide priority.[1] Sponsors and CROs are looking to reduce manual processes, improve visibility and oversight, and speed trials (Figure 2). Because so many critical trial processes are still managed with legacy systems and trackers, working together with external partners is still a top challenge. For example, CROs may send sponsors USB drives at the end of a study to share documents, and companies still manage patient informed consent manually, in person, and on paper.

[1] PharmaVoice, June 2015, Clinical Solutions: Clinical Services Market Poised For Growth

FIGURE 2: TOP DRIVERS TO STREAMLINE INFORMATION EXCHANGE WITH STUDY PARTNERS



Source: Veeva 2020 Unified Clinical Operations Survey Report

Applications that automate information flow enable sponsors and CROs to connect their clinical systems directly to streamline processes. The continued adoption of decentralized approaches in trials also improves information sharing across study stakeholders. Solutions like eConsent provide a complete digital experience, making it easier for patients to understand and provide informed consent, and for sponsors, CROs, and sites to exchange documents and data.

Transforming information exchange from manual and paper-based to digital and automated advances the industry toward better study collaboration.

A Unified and Connected Clinical Platform

Traditionally, a monitor might have to wait for hours while three or four systems updated before accessing a trip report. This is due to complex interdependencies and custom integrations between applications built on different platforms. Even vendors claiming to provide end-to-end suites may have purchased applications independently and then integrated them. This often results in a disjointed user experience and inefficiencies.

That's why clinical leaders are taking action to remove these integration bottlenecks and unify clinical systems. 83% say they already have, or plan to have, an initiative to bring together their clinical operations landscape.[2] This percentage is even higher for CROs, with 90% saying they plan to unify and streamline their systems and processes in the next 12 months.[3]

[2] Veeva 2020 Unified Clinical Operations Survey Report
[3] Veeva 2020 Unified Clinical Operations Survey: Annual CRO Report

A unified clinical operating environment that brings together data, processes, and workflows improves trial performance. Monitors and study teams can move seamlessly between a visit report in CTMS and the associated casebooks in EDC to perform source data verification (SDV) or review. Sponsors and CROs can create site candidate lists, leverage site performance data from EDC to target the best sites, and easily collect study feasibility input from investigators in a study start-up application. Milestones during study start-up and conduct are then aligned, and site information, document lists, and reports are shared and accessible for key stakeholders. This seamless flow automates trial activities, automatically files documents in eTMF, and ultimately speeds trial execution.

Modernizing Study Management for Greater Visibility and Speed in Trials

If the core infrastructure is outdated, inflexible, and hard to integrate, studies are much more complex to run. Positive change is underway as the industry modernizes its clinical trial management systems on a unified platform to effectively manage and optimize trials—and a modern CTMS provides the foundation for a patient-centric digital clinical trials strategy.

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