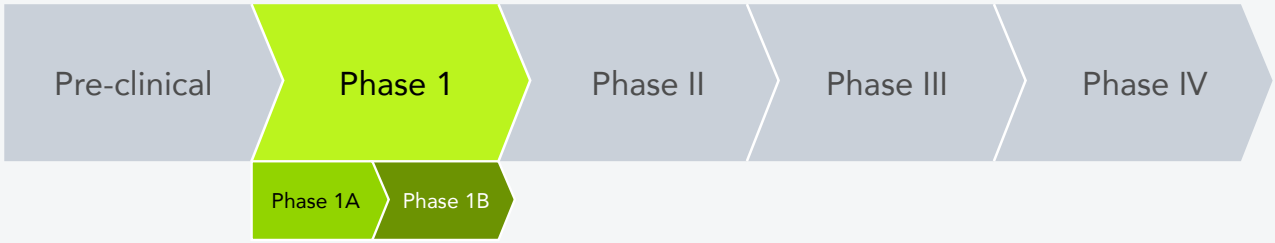
A Complete Technology Solution for Early Phase Trials

Solutions Overview

Managing a small, early phase study without a CTMS or related tools is possible, though doing so introduces additional difficulties, potential performance issues and reporting risks. For any team trying to capture study data in real-time and then extract the results in detailed reports, having a CTMS (and related tools such as eConsent, eSource and eReg) can make the process much easier.

When integrated to launch from one interface and share data between them, these tools enable decentralized workflows and real-time oversight. In addition, data from past studies can be leveraged for insights or negotiations for current or future studies. A comprehensive trial management solution builds a highly organized, multi-study database that can be accessed from any location.

Figure 1. Which Clinical Trial Phases are Considered Early Phase?



The ability to track the trial process in a participant-centric manner is key for smaller groups of participants. Above and beyond the ability to capture data, monitor processes, and generate reports, an integrated workflow provides full visibility to operations, financials, and compliance, providing a boost to quality of enrollment, data collection, and measurability of the safety of the drug or device.

The Ideal Early Phase Solution

The best technology tools for an early phase study will pay for themselves several times over by introducing less effort for teams, improved participant recruitment/safety/retention, and consistent compliance. The suite of interactive technologies that Advarra highly recommends for an early phase study includes the following:

Clinical Conductor™

Comprehensive, participant centric Clinical Trial Management System (CTMS)

eConsent™

Mobile friendly and 21 CFR Part 11 compliant electronic consenting system

eSource™

21 CFR Part 11 compliant electronic source data capture system

CCeReg™

21 CFR Part 11 compliant electronic regulatory document management system

Overview of Essential Tools for an Early Phase Trial Workflow

Clinical Conductor™

With participant safety the priority, the capability to track the trial process in a participant-centric manner is key. Beyond capturing data, monitoring processes, and generating reports, the social media integration for recruiting, status tracking, and automation of reminders provides a significant boost to enrollment quality, ideal for lower numbers of participants, easier data collection, and continuous measurability of drug or device safety. Clinical Conductor also offers optional CTMS embedded two-way texting, HIPAA compliant video sessions, and secure debit card payments that enhance decentralized workflows.

Clinical Conductor provides robust capabilities for all major aspects of trial management, with four especially useful for early phase trials:

Targeted Recruitment: Enhances recruitment quality, measures outreach efficacy, and increases participant retention with improved interaction.

Compliance Management: Tracks and reports required compliance data for funding or government auditors.

Project and Participant Management: Makes clinical trial planning, process management, and participant centricity seamless and easier.

Finance Management: Monitors status, flags issues, and reports the success or inefficiencies.

eConsent™

Comprehensive, 21 CFR Part 11 compliant electronic consenting system that keeps patients engaged throughout the consent process with interactive content, ensures their understanding of the study goals with knowledge assessments, is mobile friendly and improves the overall efficiency, quality, and compliance of the consenting process.

Participants stay engaged with easy, step by step, interactivity: Text, video, dictionaries, info-links, and multi-language support.

Helps ensure participant understanding with auto-assessments, progress tracking and analytics.

Improves quality, compliance, and reduces audit findings with consistent template-based process, enhanced participant experience, reduced errors and opt-out options.

Increases efficiency and ICF data quality by enabling standardized electronic consenting.

eSource™

Complete electronic source data system that enables workflows to capture source data in real-time, enhancing data quality, maintaining 21 CFR Part 11 compliance, enabling remote monitoring, and optimizing visit operations.

Captures digital data from any location, including offline for fast sync once online.

CIIC compliant source data collection with real-time reporting for quick corrective action.

All digital process eliminates cost and effort of paper source and record verification (SDV).

Realtime remote monitoring with tailored logins for monitors reduces frequency and duration of onsite monitoring visits.

CCeReg™

21 CFR Part 11 compliant electronic regulatory document management solution that helps ensure regulatory compliance, reduces the cost and inefficiency of paper binders, and provides workflow automation and reminders that help complete studies faster.

Speeds study completion with increased organization of electronic document and eBinders.

Enhances quality and compliance with automatic status, quality checks and eSignature reminders.

Increases efficiency while reducing staff workload with workflow automation.

Reduces costs associated with paper.

Seamless Early Phase Operations

Interoperability between Clinical Conductor, eConsent, eSource and CCeReg is key to smooth operations. The added flexibility, site tailored workflows, less duplication of efforts, and participant centricity is key for successful trials; also avoiding delays, ensuring finances are on track, and making reporting much easier.

Ready to talk about early phase technology solutions?

Contact CustomerRelationships@advarra.com to get started.

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