PHARMASEAL

How Engility™ CTMS supports Clinical Trial Management for Trial Governance

Protocol Design

Study teams can centralize protocol details in a structured manner along with high-level visit design, with the ability to export study data for direct registry upload to ClinicalTrials.gov.

Site Selection

With contact management, site, investigator and organizational assessments and in-built site contracting capabilities, study teams can benefit from building a knowledge base about sites and the investigators to support the site selection process.

Business Intelligence reporting provides visibility of past and current site performance for more informed decision making.

Site Initiation

Site Monitoring capabilities with the ability to manage structured templates that reduce the manual overhead of capturing data on site initiation.

Integrated Issue Management provides a collaborative central place to document issues and action items during the initiation process that can be tracked and reported on through business intelligence reporting.

Essential Document Tracking capabilities can be utilized for tracking key metadata which can be integrated directly with incumbent eTMF solutions.

Patient Recruitment

Utilize flexible APIs to integrate data from EDC, or utilize Subject Management capabilities to track ongoing patient recruitment progress. Business Intelligence provides visualizations on plan vs actual progress allowing study teams to focus on the countries and sites that require it.

Issue Management supports all functional workflows to capture, manage and resolve issues related to patient recruitment.

Study Conduct

From overall Study Management capabilities to track milestones and study progress, to flexible site monitoring capabilities supporting traditional and risk-based approaches.

Engility CTMS can support all key aspects of study conduct including site and investigator payments, essential document tracking and issue management at the country and study level.

Configurable security capabilities allow for flexible roles at study, country and site level while also supporting external parties having limited access to work within the same system.

Analysis and Reporting

Flexible business intelligence dashboards and out-of-box reporting that is built into Engility CTMS, and does not require you to work outside of the system.

Integrated into the product, deep-link from a report directly into the system to provide simple and intuitive workflows for drilling down into areas that require the highest focus. In-system dashboards provide views at all levels to provide study teams with immediate visibility, governance and oversight.

Study Closeout

Track and manage closeout activities through overall Study Management and Site Monitoring capabilities.

Study teams can effectively manage the closeout process and ensure that all remaining actions are complete in order to prepare for submissions to regulatory authorities.