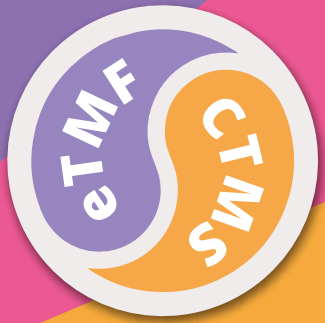
PHARMASEAL

Engility®
Trial Management

An intelligent and elegant unified clinical trial management platform



Engility® Trial Management Supports Centralised, Hybrid and Decentralised Clinical Trials

Engility Trial Management is a modern enterprise cloud-based platform developed for global clinical operations teams within Biopharmaceutical, Medical Device and Clinical Research Organisations.

Engility supports effortless control of clinical trials with automation of good clinical trial practice (GCP). This unifies clinical operating processes and associated eTMF document management, increasing control, oversight and productivity.

Key features of Engility Trial Management:

- Modern cloud-based SaaS platform
- Affordable for single and multiple trial volumes
- Support for different trial types (Centralised, Hybrid, DCT)
- Rapid implementation using advanced configuration and automation templates
- Intuitive user interface increases adoption across all user groups
- Seamlessly integrate with EDC and other eClincial systems using PHARMASEAL standard adaptors reducing the cost of integration
- Powerful business intelligence supports flexible reporting and delivery of actionable information for all stakeholders

Benefits for Biopharmaceutical Organizations

- Maintain trial oversight, for internal and outsourced clinical trials
- Affordable enterprise technology reduces total cost of ownership
- Simplified access control promotes system sharing and partner collaboration
- Retain data assets and trial conduct experience with flexible sourcing models

> “Above and beyond customer service. The system is innovative and very user-friendly to navigate. The capability of building custom reports and analytics was very attractive. The payments functionality will be a huge resource saver across multiple departments.”
>
> **DCT Company**

Benefits for Medical Device Companies

- Flexible and cost effective for medical device clinical evaluations
- Manage sponsor and investigator-initiated research
- Oversight and control of Medical Device Regulation (MDR) initiatives
- Management and insights for ongoing real-world evidence and observational research

> “The benefits are it helps streamline the consistency, communication and optimises efficiency. Without a doubt it will give us more efficient ways of working.”
>
> **Medical Device Company**

Benefits for CRO’s

- Flexible configuration for different sponsor requirements
- Flexible to manage different trial types
- Collaborate with sponsors improving transparency and control
- Improve productivity and quality with data driven workflows

> “It was the total package, it was adaptable. The PHARMASEAL Team has been super responsive on trying to help us get things moving in a more operational way.”
>
> **US CRO**

How Engility® Empowers Unified Trial Management

Study Planning

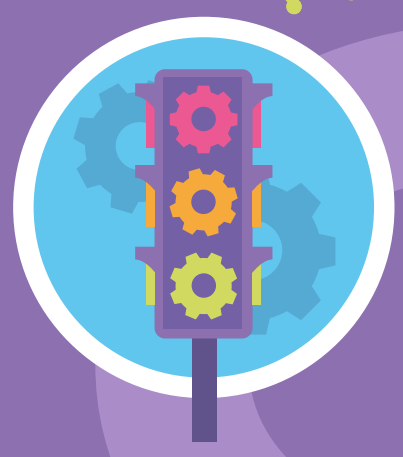
Study teams can centralize the protocol in a structured representation with high-level visit design which can then be exported to **ClinicalTrials.gov** registry via an XML upload. Searchable protocol information provides a valuable repository to improve future protocol designs. Protocol information can also be synchronized with other eClinical systems such as EDC when integrating data.

Site Selection

With global contact management, site, investigator and organizational assessments and in-built site contract management, study teams can benefit from building a knowledge base about sites and the investigators to support the site selection process. Leverage historical site performance, utilizing performance metrics and dashboards to improve future site and investigator selection. Strengthen intimacy with sites by leveraging global contact management database.

Site Initiation

Utilize site monitoring capabilities with the ability to manage structured templates that reduce the manual overhead of capturing data on site initiation processes. Integrated Issue Management provides a collaborative central place to document issues and action items during the study. Data driven monitoring reduces data duplication by key monitoring processes increasing CRA efficiency by reducing document authoring and associated eTMF operations.

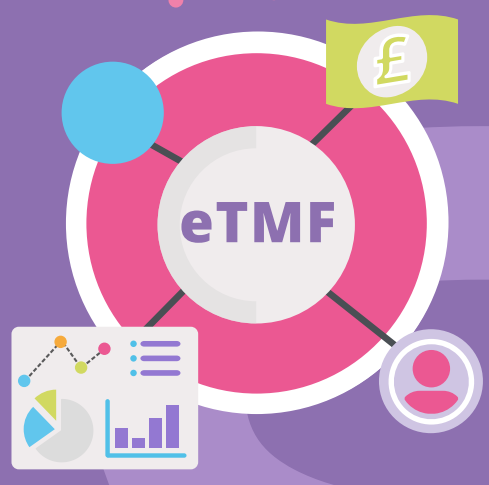


Patient Recruitment

Monitor and track patient enrolment entered directly in Engility or utilize EDC integration to synchronize patient tracking, reducing data duplication. Establish site and patient targets, and track actual vs budget in real time. `Rich interactive dashboards allow for proactive interventions to be targeted to countries and sites that are under-performing. Coordinate and trigger site payments based on specific patient events and site procedures that are completed.

Study Conduct

The integral eTMF is automatically updated with global contact information expediting associated document collection. Manage study milestones at study, country and site level. Support flexible monitoring models, which can be adjusted based on risk driven monitoring intervals. Integrate with other eClinical systems using reducing data duplication and increasing transparency. Leverage powerful in-built reporting and BI and create unlimited additional reports and dashboards. Track expenditure using financial payments and simplify sunshine reporting requirements. The Engility platform can be shared between Sponsors and CROs further strengthening collaboration and partnerships.



Study Closeout

Take control of all study closeout activities including remaining payments (holdbacks), TMF completion and final monitoring and issue management. Support long term archiving of TMF data with TMF exports via XML exchange mechanism standard (EMS). Leverage experience of previous closed studies to help improve the planning of future studies. Support quality and regulatory obligations in conducting trials in accordance with GCP and MDR.

Analysis and Reporting

Integrated system dashboards display data at study, country and site as you navigate throughout the system. Utilize powerful business intelligence for reports and dashboards for all stakeholders with the ability to schedule reports for automated delivery to recipients. Extend reporting with self service BI allowing companies to create additional reports. Extract reports in multiple office formats for offline use in company reports and presentations.

PHARMASEAL

Bring Joy to Your Clinical Operations Teams with Engility®

Engility is suitable for companies of all sizes. Whether your need is for single or multiple trials, we have flexible licensing models tailored to your unique study and organizational needs.

PHARMASEAL partners with other eClinical vendors to simplify the ways multiple systems integrate data. We bring best-of-breed technologies together to transform clinical trial processes.

We are passionate about working with our customers. With rapid implementation, excellent customer support and consulting on all aspects of usage and validation, we want you to feel empowered to influence our product direction and strategy.

Let's talk . . .

CONTACT US

PHARMASEAL

cdisc Proud Member

GDPR COMPLIANT

HIPAA Compliant

ICH GCP Compliant

FDA 21 CFR part 11 Compliant

Annex 11 COMPLIANT