Life & Health

The Clinical Trials Knowledge Program

MEASURABLE IMPROVEMENTS IN CLINICAL TRIAL PERFORMANCE

Meeting the Challenge

The challenge for all sponsors of clinical trials is accelerating time to market. Meeting that complex challenge is easily derailed by the inability of employees, contractors and site personnel to understand and execute their responsibilities.

Effectively managing a sponsor's clinical trial network requires a cohesive approach that links workforce knowledge and performance with business objectives. UL EduNeering has pioneered that results-oriented approach, developing the services and solutions that minimize study errors and costly delays through ComplianceWire®.

A Proven Solution

The ComplianceWire Clinical program equips sponsors with a practical global management system throughout the clinical trial process. The program delivers objective documentation that each team member understands specific study requirements. Equally important, ComplianceWire creates and maintains an automated, centralized repository that confirms the distribution and receipt of study documents, providing a Part 11-compliant e-signature and audit trail.

Through its cohesive approach, UL's proven knowledge solution transforms the clinical trial's typical "islands" of information – sponsor, Institutional Review Board (IRB), investigator site and Contract Research Organization (CRO) – into a seamless system that extends from site selection through study initiation, conduct and completion.

Coupled with the knowledge assessment program, ComplianceWire enables sponsors to improve team performance and quality, ensure regulatory compliance and reduce risk and liability.

Site Selection

ComplianceWire Clinical arms sponsors with an efficient means to screen potential sites, whether at the start of a study or as new investigator sites are enrolled. The unique Site Selection program enables distribution of the protocol synopsis along with an online application to identify site and subject quality. Analysis of the collected online data promotes cost-effective prequalification of sites prior to scheduled onsite visits.

Study Initiation

ComplianceWire confronts the more than 63% of clinical trial delays attributed to the failure of site investigation teams to understand and follow established protocol. A unique study initiation program gives sponsors objective assurance that their investigator team understands the protocol and other mandatory obligations – before subjects are enrolled – through two key components:

- **Pre-Investigator Meeting:** To optimize meeting productivity, the protocol and an objective assessment are distributed before the investigator meeting. Analysis of the assessments enables the sponsor to identify knowledge gaps and tailor investigator meetings to clarify these gaps.
- **Investigator Meeting**: Objective knowledge assessments employ interactive technology that highlights critical trial elements and evaluates participants' responses in real time. Based on these assessments, sponsors can develop targeted, cost-effective remediation plans that may include prioritized site monitoring visits and online delivery of UL's role-based clinical curriculum.

Study Conduct

An automated document distribution and communication system ensures timely, consistent and documented distribution and comprehension of study information. As new sites are enrolled or the study experiences key personnel turnover, study initiation materials and study documents are distributed for review and assessment.

Study Completion

ComplianceWire maintains an indisputable, validated audit trail of all documents distributed to trial participants. The correlation of data with key performance metrics, such as the number of protocol deviations or violations, enables sponsors to identify the quality and productivity of each site. Sponsors also can leverage archived knowledge assets, such as assessments, for use in later study phases or trials.

Clinical Team Education and Certification

UL provides a comprehensive library of online courses designed to ensure continuing clinical team education and certification. Co-developed by the US Food and Drug Administration (FDA) and our Clinical Global Advisory Board, the role-based (CRA, CRC, Investigator) curriculum incorporates FDA, European Union (EU) and International Conference on Harmonisation (ICH) regulations for drug, biologic and device industries.

Based on the sponsor's policies, this curriculum establishes site personnel's documented competency of GCP/ICH regulations and offers the option of continuing education credits.

UL EduNeering's Expertise

UL EduNeering's expertise is underscored by our clients and our partnerships with the US FDA and leading clinical organizations.

- We have an established reputation for innovation and service for more than 25 years. Today, we serve more than 75 Pharmaceutical, Biotech and Medical Device companies, including six of the top 10 Pharmaceutical companies in the world.
- Our unique partnership with the US FDA centers on a first-of-its-kind Cooperative Research and Development Agreement (CRADA). Under that agreement, UL provides the ComplianceWire Platform that ensures and documents consistent understanding by more than 50,000 FDA, state and local inspectors and investigators. Over 80,000 web-based activities, including online courses co-developed by the US FDA and UL, have been completed by FDA personnel. UL's ComplianceWire Platform and online courses enable new investigators to demonstrate proficiency in three months rather than the 6 -12 months required for the previous system.

UL has alliances with such organizations as the Association of Clinical Research Professionals (ACRP) and the Academy of Pharmaceutical Physicians and Investigators (APPI). Under these relationships, UL provides online education and certification programs offered by the organizations to their global membership.