Life & Health

Clinical Training Management

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LEARNING AND COMPLIANCE FOR CLINICAL RESEARCH

Helping to Fuel the Growth of CROs and Service Providers

According to clinical researcher CenterWatch, the FDA and global regulatory agencies have taken a much more aggressive approach to overseeing clinical investigations. These agencies expect sponsors, Contract Research Organizations (CROs) and related service providers to take a quality systems-based approach to Good Clinical Practice (GCP) compliance.

For this reason, CROs and clinical service providers have been strategically focused on implementing programs to address these objectives:

- Expand the Quality Assurance unit to support new areas such as R&D, commercialization, post-marketing, etc.
- Reduce the risk of noncompliance.
- Improve sponsor and regulatory audit preparedness.
- Accelerate staff training.
- Improve employee performance.
- Demonstrate to new clients a commitment to the highest standards of ethical and quality-focused activities.
- Improve operational efficiencies.

Our Solution: Used by the FDA and Clinical Organizations

UL EduNeering's solution for the clinical industry has helped leading CROs and service providers to demonstrate a commitment to quality and compliance.

Our web-based solution includes the following:

- An award-winning Learning Management System (LMS) that's used by the FDA and more than 250 Life Science companies, and designed to meet 21 CFR Part 11 and Annex 11 requirements for electronic recordkeeping.
- A highly secure, web-hosted solution that's easy to deploy, reduces IT hardware and data center costs, and supports training to non-employees.
- An online clinical and GCP Library that covers FDA and ICH regulations, and is designed forboth employees and site personnel.
- Additional tools, learning content development services to help clients deliver custom courses, manage protocol delivery to site personnel, conduct online risk assessments and more.

Web-Based Quality-Focused Solution that Helps You Manage:

- Electronic Training Records
- Employee Training
- Site and Third Party Training
- Protocol Training
- Risk Assessments
- Audit Inquiries

Why Leading CROs and Service Providers Are Using This Solution:

- Automate training recordkeeping
- Demonstrate effective quality and compliance programs during sponsor and regulatory agency audits
- Communicate with dispersed employees and clinical sites
- Identify site personnel for targeted training assignments
- Capture critical forms (acknowledgements, assessments, etc.)

CASE STUDY: Using Training as a Market Differentiator

BACKGROUND: A leading imaging assessment services firm began using ComplianceWire© in 2008 to strip the complexity from compliance and quality learning programs and attract new clients.

The firm launched an employee role-based certification program and streamlined delivery of document training to employees and third parties. Quality managers can demonstrate employee qualifications through real-time audit reports that are generated for about 25 sponsor and regulatory audits annually.

RESULTS: The company reports that the state of compliance has risen to 95% from 60% since ComplianceWire was deployed. The client has been able to reduce the training administrative effort and demonstrate the firm's commitment to quality and compliance, which has helped the firm increase marketshare.

IMPROVE EMPLOYEE PERFORMANCE

Same Learning Management System Selected by the FDA

ComplianceWire is a four-time Brandon Hall award-winning LMS used by FDA-regulated companies of all sizes, from Fortune 500 to emerging companies.

Clients benefit from a unique relationship that UL has with the FDA. ComplianceWire is used by FDA inspectors through the Office of Regulatory Affairs University. To date, more than 50,000 inspectors have been trained through ComplianceWire. We also deliver value to clients based on our alliances with DIA, AdvaMed, Duke Clinical Research Institute, and EduQuest.

Our GCP and Clinical Role-Based Training Library

UL's global curriculum for clinical and regulatory professionals is comprised of courses that cover underlying concepts and specific, advanced information. The courses are designed for those in clinical development, clinical operations, project team leadership and regulatory affairs.

The global curriculum includes courses describing FDA regulations, European Union (EU) directives, and ICH guidance. Several courses have been approved for Continuing Education (CE) and/or Continuing Medical Education (CME) credits for professional licensure.

Courses cover key GCP topics, the roles of CRAs and CRCs, informed consent and protection of human subjects.

Engage Employees While Reducing Risks

Our global curriculum for clinical and regulatory ComplianceWire has helped clients meet these key performance indicators:

1. Facilitate a paperless role-based training program.
2. Help employees grasp the FDA's sponsor/monitor inspection process.
3. Deliver accurate audit reports to sponsors.
4. Elevate control document training beyond basic "Read and Understand" requirements.
5. Integrate employee qualifications with the Clinical Trial Management System (CTMS) and other eClinical Applications.

ACCELERATE CLINICAL SITE TRAINING

Transfer Knowledge to Investigator Sites

As more and more trials are conducted globally, studies show that clinical trial delays can be attributed to the failure of site investigation teams to understand and follow established protocol.

Meeting these complex challenges can be easily derailed by the inability of employees, contractors and site personnel to understand and execute their responsibilities. Training is getting harder and harder to conduct as dispersed sites and training budget constraints continue to compound the problem.

ComplianceWire can solve these challenges, minimizing study errors and costly delays in time to market by making it easy to deliver and track critical documents to global sites via the web.

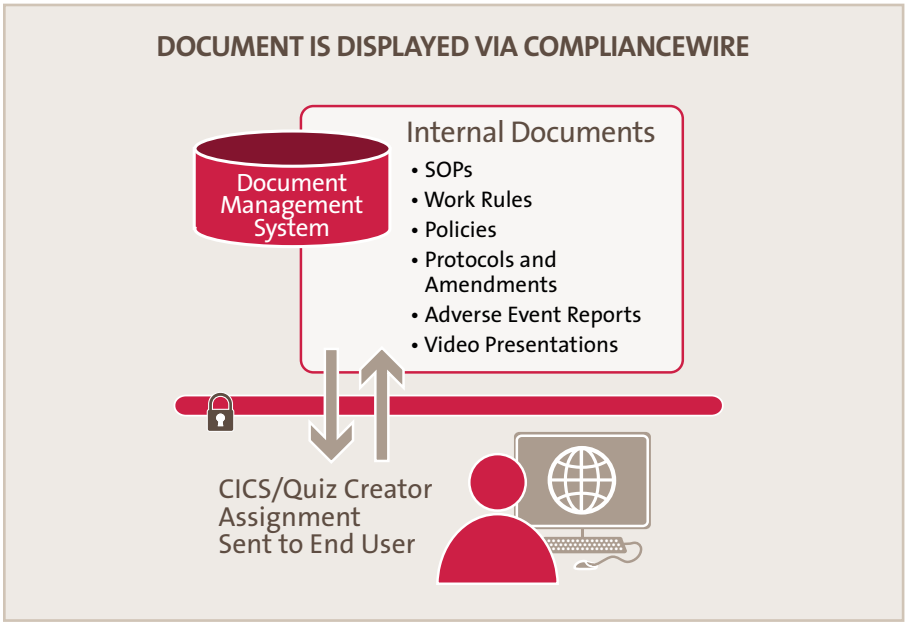
Assign GCP and Study-Specific Training with Full Audit Trail

With ComplianceWire, you can electronically deliver a single protocol, translated in up to 33 languages, to all of your participating global clinical sites.

This "one item, many languages" approach is just one of the many ways that ComplianceWire streamlines the delivery and tracking of GCP training and study-specific materials.

Our Critical Information Control System© (CICS) tool, available in ComplianceWire, enables you to target site personnel with protocols and amendments in a read-only format.

You can attach an online quiz that measures retention. The learner must complete the quiz and then electronically sign, thus assuring knowledge transfer while also capturing the completion for audit reporting purposes.



THE CREATE PROGRAM, POWERED BY DUKE CLINICAL RESEARCH INSTITUTE:

CREATe
Duke Clinical Research Institute

Our alliance with Duke Clinical Research Institute (DCRI) has resulted in the CREATe program, in which sponsors and CROs can share DCRI clinical research best practices to site personnel in a convenient web-based format.

Courses focus on the fundamentals of safe and effective clinical trial conduct, as well as day-to-day activities for conducting safe and efficient trials.

Site personnel receive a portable certificate of completion, which is applicable across companies and trials, providing valuable credentials that can lead to new opportunities while eliminating the need for retraining as the individual begins a new trial.

CASE STUDY: Reducing Costs While Improving Performance

BACKGROUND: A fast growth Pharmaceutical company began trials on several new indications and needed to develop an alternative approach to in-person investigator training meetings. In the past, each meeting cost thousands of dollars, required significant travel and time and resulted in inconsistent retention of critical knowledge among investigators and study coordinators.

Additionally, the company wanted to expand their recruitment of qualified, trained investigators outside the US. ComplianceWire was introduced to deliver study documents, administer GCP training and test on SOPs. Users were given the opportunity to "self-register" via UL's secure server, enabling rapid initiation of site personnel.

RESULTS: A 40% reduction in site initiation training costs was recognized, while proficiency on the study material was tracked and measured.

MEET STRINGENT DATA QUALITY REQUIREMENTS

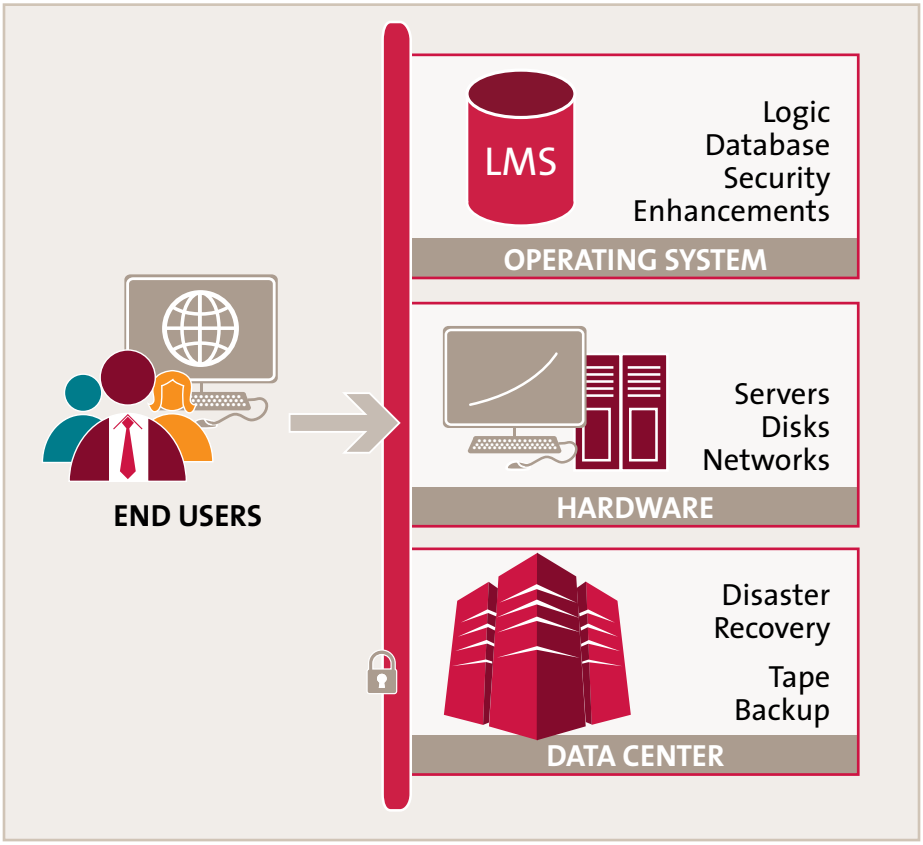
Leveraging One Platform to Train Sites, Contractors, etc.

Our engineering and IT personnel are responsible for designing and maintaining the computer hardware, software and security to meet the stringent validation requirements of FDA-regulated companies.

Our Quality Assurance team conducts the same validation activities that our client's team would perform if the software was installed within their data centers, thus reducing the time spent on validation effort.

Because our solution resides outside of an organization's firewall, your partners can receive training without compromising your organization's IT security policies.

In addition, we provide optional "Content Hosting Options" so you can upload your



RISK ASSESSMENT AND RISK

Combine Policy Distribution, Risk Assessment and Mitigation Planning

ComplianceWire provides tools that ensure that your clinical research site training programs are fully disclosed and documented, and that risk mitigation steps have been signed off on by project managers.

Using our SmartForms tool, you can apply business rules to your online risk assessments so that as an individual answers each question, the system assigns targeted training or alerts project managers based on the individual's specific answers.

For example, you can deliver assessments to clinical site personnel that will determine the type of training they need based on their job function.

Similarly, you can use SmartForms to identify "high-risk" learners, so that individuals on high-risk studies can be trained to recognize these areas and communicate them to investigators and monitors.

ComplianceWire provides dozens of reports and data query tools that let you configure standard reports to meet your workflow and monitoring activities.

Using these tools, you gain complete information and analysis of all compliance learning activity.

MEETING THE HIGHEST STANDARDS FOR DATA INTEGRITY

ComplianceWire captures each learner's electronic signature for every training activity, which is unimpeachable and secure, simplifying recordkeeping and administrative tasks.

Administrators gain a complete audit trail of all changes made to training items and user accounts, namely the field that was changed, the old value, the new value, the user who made the change and the date/time of the change.

CASE STUDY: Accelerating Site Initiation

BACKGROUND: A leading Human Therapeutics company for more than two decades, this Fortune 500 company is widely recognized for its commitment to innovation, patient safety and operational efficiency.

To accelerate site initiation across 60 clinical trials, the company implemented ComplianceWire to deliver study protocols and Electronic Data Capture (EDC) "How To" courses to study participants globally. Each course contained learning activities that measured proficiency and retention.

After learners qualified via the EDC training, they were granted access to the EDC system and given the ability to enroll patients, thus improving trial data integrity.

RESULTS: The time required for site initiation was cut from 6 weeks to 3 days, while accelerating subject enrollment and reducing training costs.

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

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